Instructions for Use

Avalon Fetal Monitor

FM20/30, FM40/50, Avalon CL

Release L.3 with Software Revision L.3x.xx

Patient Monitoring

PHILIPS

Contents

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Introduction

Who this Book is For

This book is for trained healthcare professionals using the Avalon FM20, FM30, FM40, and FM50 fetal/maternal monitors, and the Avalon CL Transducer System. It describes how to set up and use the monitor and transducers. Familiarize yourself with all instructions including warnings and cautions before starting to monitor patients. Read and keep the Instructions for Use that come with any accessories, as these contain important information about application, care, and cleaning that is not repeated in this book.

If you have received this Instruction for Use because your fetal monitor has been upgraded to a newer software version L.3, be aware that the standards compliance information contained in the Instructions for Use for L.3 does not apply to your fetal monitor. Refer to your original Instructions for Use for standards compliance information.

You should be:

- Trained in the use of fetal heart rate (FHR) monitors.
- Trained in the interpretation of FHR traces.
- Familiar with using medical devices and with standard fetal monitoring procedures.

For information on how to configure and service the monitor, see the Configuration Guide and the Service Guides, or contact your authorized service provider.

Your monitor may not have all of the features and options described in this guide. The exact appearance of the monitor may differ slightly from that shown in the illustrations.

This guide may contain descriptions of functionality and features that are not implemented in the equipment currently shipped to Japan and/or of products that are not currently sold in Japan due to limitations and restrictions under the applicable local laws and regulations in Japan. Please contact your local sales representative and/or Philips Customer Support for details.

In this guide:

- A **warning** alerts you to a potential serious outcome, adverse event, or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.

  Always use clinical judgment to decide whether the benefit of using the device/the measurement in a specific situation outweighs the risk.
- A **caution** alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in:
  - minor or moderate personal injury,
  - damage to the product or other property,
  - possibly in a remote risk of more serious injury.
- A **contraindication** describes a situation, such as patient population, medical reason, or clinical condition, in which a device may not be used because the risk of use clearly outweighs any possible benefit.

- **Monitor** refers to the entire fetal/maternal monitor. **Display** refers to the physical display unit. **Screen** refers to everything you see on the monitor's display, such as measurements, alarms, patient data, and so forth.

NOTE

Any serious incident that has occurred in relation to this device should be reported to Philips and the competent authority of the member state in which the user and/or patient is established. In this context, "member state" refers to European Economic Area (EEA) countries including Switzerland and Turkey.

FM30

- Whenever a monitor's identifier appears to the left of a heading or paragraph, it means that the information applies to that monitor only. Where the information applies to all models, no distinction is made.

Avalon CL
Avalon CTS

Whenever one of these identifiers appear to the left of a heading or paragraph, it means that the information applies to that cableless transducer system. Where the information applies to both systems, no distinction is made.

For installation instructions and technical description, see the corresponding Service Guide of the fetal monitors.

Confirm Fetal Life Before Using the Monitor

Fetal monitoring technology available today is *not always* able to differentiate a fetal heart rate (FHR) signal source from a maternal heart rate (HR) source in *all* situations. Therefore, you should confirm fetal life *by independent means* before starting to use the fetal monitor, for example, by palpation of fetal movement or auscultation of fetal heart sounds using a fetoscope, stethoscope, or Pinard stethoscope. If you cannot hear the fetal heart sounds, and you cannot confirm fetal movement by palpation, confirm fetal life using obstetric ultrasonography. Continue to confirm that the fetus is the signal source for the FHR during monitoring.

Be aware that:

- a maternal HR trace can exhibit features that are very similar to those of an FHR trace, even including accelerations and decelerations. Do not rely solely on trace pattern features to identify a fetal source.
- Fetal Movement Profile (FMP) annotations on a fetal trace *alone* may not always indicate that the fetus is alive. The body of a deceased fetus can move and cause the monitor to annotate fetal body movements.

Here are some examples where the maternal HR can be misidentified as the FHR.

When using an ultrasound transducer:

- It is possible to pick up maternal signal sources, such as the aorta or other large vessels.
- Misidentification may occur when the maternal HR is higher than normal (especially when it is over 100 bpm).

When using a fetal scalp electrode:

- Electrical impulses from the maternal heart can sometimes be transmitted to the fetal monitor through a recently deceased fetus via the spiral scalp electrode cable, appearing to be a fetal signal source.
- The recorded maternal HR (and any artifact) can be misinterpreted as an FHR (especially when it is over 100 bpm).

When Fetal Movement Profile (FMP) is enabled:

FMP annotations in the absence of fetal life may be a result of:

- Movement of the deceased fetus during or following maternal movement.
- Movement of the deceased fetus during or following manual palpation of fetal movement (especially if the pressure applied is too forceful).
- Movement of the ultrasound transducer.

- The ultrasound transducer detecting a maternal movement source, such as the mother coughing.

See also "Monitoring FHR and FMP Using Ultrasound" on page 169 and "Monitoring FHR Using DECG" on page 199.

To reduce the possibility of mistaking the maternal HR for an FHR, it is recommended that you monitor both maternal and fetal heart rates. The monitor's cross-channel verification (CCV) feature can help by automatically detecting when a maternal HR coincides with an FHR. For further details, see "Cross-Channel Verification (CCV)" on page 163.

Introducing the Avalon Family of Fetal Monitors

The Avalon family of fetal monitors consists of the Avalon FM20, FM30, FM40, and FM50. While the FM20/FM30 and the FM40/FM50 have different form factors, the method of operation is very similar for all monitors. The Avalon fetal monitors also share transducers, accessories, software, and are compatible with the Avalon CL, and Avalon CTS Fetal Transducer Systems.

Intended Use

The Philips Avalon FM20 (M2702A), FM30 (M2703A), FM40 (M2704A), and FM50 (M2705A) fetal/maternal monitors are intended for:

- noninvasive monitoring of fetal heart rates and movements.
- noninvasive monitoring of maternal heart rates, maternal pulse rates, uterine activity, maternal noninvasive blood pressure, maternal oxygen saturation, and maternal temperature.
- invasive monitoring of direct fetal heart rate, intrauterine pressure, and for displaying and recording of fetal and maternal electrocardiogram (ECG) (FM30 and FM50 only).
- displaying, storing, and recording patient data and parameter values, and for generating alarms from fetal and maternal parameters.
- transmitting patient data and parameter values to a patient information and surveillance system.
- use by trained healthcare professionals.
- use in antepartum testing areas, in labor and delivery rooms, and during postpartum recovery in the hospital environment. They are not intended for use in intensive care units or operating rooms.
- monitoring in a bath or shower (Avalon CL cableless transducers Toco^{+} MP, Ultrasound, and ECG/IUP only).
- transport situations in healthcare facilities, for healthcare facilities outside hospitals, such as doctors' offices, and for use in private households (FM20 and FM30 only).

WARNING

- Check the mother's pulse periodically during monitoring and compare this with the FHR signal. Beware of mistaking a "doubled" maternal heart rate for FHR.
- Always confirm fetal life before using the monitor. If a fetus is dead, there is a risk that the maternal heart rate is monitored and misinterpreted as the fetal heart rate.
- The simultaneous monitoring of maternal heart rate (preferably, the maternal ECG) and the fetal rate is encouraged.
- Whenever possible make use of the cross-channel verification (CCV) feature. See "Cross-Channel Verification (CCV)" on page 163

WARNING

The fetal/maternal monitors are not intended for:

- use during defibrillation, electro-surgery, or magnetic resonance imaging (MRI).
- Electrocardiography (ECG) measurements on patients connected to electrical stimulator or with cardiac pacemakers.
- use of the invasive measurements IUP and fetal DECG, use of the patient module (M2738A) and use of the Avalon CL system in domestic establishments, and those connected directly to the public low-voltage supply network that supplies buildings used for domestic purposes.
- measuring the maternal temperature using the tympanic thermometer (866149) in private households.

WARNING

No modification of the fetal monitors, transducers, and the Avalon CL base station is allowed.

CAUTION

U.S. federal law restricts this device to sale by, or on the order of, a physician.

All users must read the Instructions for Use before working with the fetal monitor. Disregarding the contents of the Instructions for Use is considered abnormal use.

Indications for Use

Avalon Fetal/Maternal Monitor FM20

Indicated for use by trained health care professionals whenever there is a need for monitoring the physiological parameters uterine activity, heart rate, oxygen saturation, noninvasive blood pressure, pulse rate, and temperature of pregnant women, and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities.

Avalon Fetal/Maternal Monitor FM30

Indicated for use by trained health care professionals whenever there is a need for monitoring the physiological parameters uterine activity, heart rate, electrocardiography (ECG), oxygen saturation, noninvasive blood pressure, and pulse rate, and temperature of pregnant women, and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms, in antepartum testing areas, in private households and during transports in healthcare facilities.

Avalon Fetal/Maternal Monitor FM40

Indicated for use by trained health care professionals whenever there is a need for monitoring the physiological parameters uterine activity, heart rate, oxygen saturation, noninvasive blood pressure, and pulse rate, and temperature of pregnant women, and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Avalon Fetal/Maternal Monitor FM50

Indicated for use by trained health care professionals whenever there is a need for monitoring the physiological parameters uterine activity, heart rate, electrocardiography (ECG), oxygen saturation, noninvasive blood pressure, and pulse rate, and temperature of pregnant women, and the fetal heart rates of single fetuses, twins, and triplets in labor and delivery rooms and in antepartum testing areas.

Contraindications

A contraindication describes a situation, such as patient population, medical reason, or clinical condition, in which a device may not be used because the risk of use clearly outweighs any possible benefit.

- The fetal/maternal monitors are not intended for electrocardiography (ECG) measurements on patients connected to electrical stimulator or with cardiac pacemakers.
- Do not use the Avalon CL Wide Range Pod with patients for whom a momentary loss of vital sign monitoring is not acceptable.
- Do not use the CL Fetal & Maternal Pod and electrode patch for monitoring if the patient carries multiple fetuses.
- The Non-Stress Test Report (NST Report) functionality is not intended for intrapartum use.
- IUP Catheter: Do not catheterize if placenta previa is diagnosed, or if uterine bleeding from an undetermined source is present.

Safety Information

In this guide:

- A warning alerts you to a potential serious outcome, adverse event or safety hazard. Failure to observe a warning may result in death or serious injury to the user or patient.
- A caution alerts you to where special care is necessary for the safe and effective use of the product. Failure to observe a caution may result in minor or moderate personal injury or damage to the product or other property, and possibly in a remote risk of more serious injury.
- A contraindication describes a situation, such as patient population, medical reason, or clinical condition, in which a device may not be used because the risk of use clearly outweighs any possible benefit.

Electrical Hazards

WARNING

Electrical shock hazard: Do not open the monitor housing. Refer all servicing to qualified service personnel.

- Always use the supplied power cord with the earthed mains plug to connect to an earthed AC mains socket. Never adapt the mains plug from the fetal monitor to fit an unearthed AC mains socket.
- Do not use AC mains extension cords or multiple portable socket-outlets.
- **FM20/FM30 only:** The protective earth conductor is required for EMC purposes. It has no protective function against electric shock. Double and/or reinforced insulation protects this device against electric shock.
- Do not connect any devices that are not supported as part of a system.
- Any non-medical device placed and operated in the patient's vicinity must be powered with an approved isolation transformer that ensures mechanical fixing of the power cords, and covering of any unused power outlets.

- The fetal/maternal monitor is NOT intended for use during defibrillation, electro-surgery, or MRI. Remove all transducers, sensors, and accessories before performing electro-surgery, defibrillation, or MRI, otherwise harm to the patient or the user can result.
- Do not touch the charging contacts for the cableless transducers at the Avalon CL base station while you are touching the patient.

Leakage currents: If several items of equipment used to monitor a patient are interconnected, the resulting leakage current may exceed allowable limits.

Radio Frequency Interference

WARNING

- Short range radio connections are subject to interruption due to interference from other radio sources in the vicinity, including microwaves, bluetooth devices, WLAN devices (802.11b,g,n), and cordless phones. Depending on the strength and duration of the interference, the interruption may occur for an extended period. A loss of connection, due to moving out-of-range, interference, or for other reasons, is indicated with a **No Host Monitoring** INOP (here the host is the fetal monitor) on the IntelliVue CL NBP or CL SpO_2 Pods, or a **No Host Monitoring**, or **cl NBP Disconnect**, or **cl SpO_2 Disconnect** INOP at the fetal monitor. Correct channel configuration is important, refer to the Service Guides and the Configuration Guide for details.
- To avoid magnetic interference affecting the mode of the pacemaker, ensure that the Avalon CL base station does not come into close contact with implanted pacemakers.
- This equipment generates, uses, and radiates radio-frequency energy, and if it is not installed and used in accordance with its accompanying documentation, may cause interference to radio communications. Operation of this equipment in a residential area may cause interference, in which case the users must take whatever measures may be required to correct the interference.
- Do not use cordless/mobile phones or any other portable RF communication system within the patient vicinity, or within a 1.0 m radius of any part of the fetal monitoring system.
- For paced patients: The radiated SRR power of the CL SpO_2, CL NBP Pods, CL F&M Pod, and the CL Wide Range Pod, and other sources of radio-frequency energy, when used in very close proximity of a pacemaker, might be sufficient to interfere with pacemaker performance. Due to shielding effects of the body, internal pacemakers are somewhat less vulnerable than external pacemakers. However, caution should be exercised when monitoring paced patients.
- In order to minimize the possibility of interference, avoid positioning and wearing the Cableless Measurement Devices in very close proximity to a pacemaker. Consult the pacemaker manufacturer for information on the RF susceptibility of their products.

WARNING

The Avalon CL Wide Range Pod uses a WLAN connection to extend the operating range of CL transducers and CL Pods. The Avalon CL Wide Range Pod sends real-time patient data to the fetal monitor. The fetal monitor displays real-time patient data, provides alarms, data storage, and clinical decision support applications. The data is also transmitted to a connected obstetrical surveillance system. Using a WLAN connection may lead to network drop-outs resulting in the data loss of monitored vital signs. Do not use the Avalon CL Wide Range Pod with patients for whom a momentary loss of vital sign monitoring is not acceptable.

In case of frequent or prolonged network drop-outs (indicated by "Disconnect" INOPs at the fetal monitor and at the CL transducers or CL Pods):

- revert to the use of CL devices without the CL Wide Range Pod,
- restrict the patient to a reduced range around the Avalon CL base station,
- and inform your service personnel.

Use Environment

WARNING

Explosion Hazard:

- Do not use in the presence of flammable anesthetics, such as a flammable anesthetic mixture with air, oxygen, nitrous oxide, or in oxygen rich environment. Use of the devices in such an environment may present an explosion hazard.
- Use only Philips batteries part number M4605A with the FM20 or FM30 with battery option. Use of a different battery may present a risk of fire or explosion.

Environmental Specifications:

- The performance specifications for the monitors, measurements, and accessories apply only for use within the temperature, humidity, and altitude ranges specified in "Environmental Specifications" on page 287.

Liquid Ingress:

- Do not operate the monitor if it is wet. If you spill liquid on the monitor, contact your service personnel, or Philips service engineer.
- Never immerse the fetal monitor or the CL base station in liquid. You must protect them against water sprays or splashes. Place the fetal monitor and the CL base station where there is no chance of contact with, or falling into water or other liquids.
- Do not perform underwater monitoring (for example, in a bath or shower) using wired transducers.
- The CL Fetal & Maternal Pod is not intended for underwater monitoring. The contacts between the CL Fetal & Maternal Pod and the electrode patch have to be kept dry at all times. The CL Fetal & Maternal Pod mounted on the electrode patch, can be worn underneath a shower, as long as the CL Fetal & Maternal Pod stays mounted. Radio transmissions in the shower may be compromised.

Heat Exposure:

- Do not dry equipment using heating devices such as heaters, ovens (including microwave ovens), hair dryers, and heating lamps.
- Do not put equipment or accessories in autoclave (for sterilization).

Positioning Equipment:

- The device should not be used adjacent to, or stacked with, other equipment unless otherwise specified.

Prohibited Environments:

- The monitors and their transducers, Pods, and accessories are not intended for use in an MRI environment or in an oxygen-enriched environment (for example, hyperbaric chambers).

,Alarms

WARNING

- Do not rely exclusively on the audible alarm system for fetal monitoring. Adjustment of alarm volume to a low level or off during monitoring may result in a dangerous situation. Remember that the most reliable method of fetal monitoring combines close personal surveillance with correct operation of monitoring equipment.
- Alarm systems of the monitor and those of any connected obstetrical information and surveillance system are interdependent and not synchronized. Therefore audible alarms should not be relied upon for remote monitoring.
- In **INOP only** mode, no fetal/maternal patient alarms are enabled or indicated.

Accessories

WARNING

Philips' approval: Use only Philips-approved accessories. Using non-Philips-approved accessories may compromise device functionality and system performance, and cause a potential hazard.

Reuse: Never reuse disposable transducers, sensors, accessories, and so forth, that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance, and cause a potential hazard.

Electromagnetic compatibility: The use of accessories, transducers, and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

Damage: Do not use a damaged sensor or one with exposed electrical contacts.

Cables and tubing: When connecting devices for acquiring measurements, always position cables and NBP tubing carefully to avoid entanglement or potential strangulation.

Security Information

Protecting Personal Information

Protecting personal health information is a primary component of a security strategy. Each facility using the monitors must provide the protective means necessary to safeguard personal information consistent with country laws and regulations, and consistent with the facility's policies for managing this information. Protection can only be realized if you implement a comprehensive, multi-layered strategy (including policies, processes, and technologies) to protect information and systems from external and internal threats.

As per its intended use, the patient monitor operates in the patient vicinity and contains personal and sensitive patient data. This also includes the trace print-outs at the monitor.

The monitor also includes controls to allow you to adapt the monitor to the patient's care model.

To ensure the patient's safety and protect their personal health information, you need a security concept that includes:

- **Physical security access measures** - access to the monitor **must** be limited to authorized users. It is essential that you consider physical security measures to ensure that unauthorized users cannot gain access.
- **Operational security measures** - for example, ensuring that patients are discharged after monitoring in order to remove their data from the monitor.
- **Procedural security measures** - for example, assigning only staff with a specific role the right to use the monitors.

In addition, any security concept must consider the requirements of local country laws and regulations.

Always consider data security aspects of the network topology and configuration when connecting patient monitors to shared networks. Your medical facility is responsible for the security of the network, where sensitive patient data from the monitor may be transferred.

When a monitor is returned for repair, disposed of, or removed from your medical facility for other reasons, always ensure that all patient data is removed from the monitor by ending monitoring for the last patient (see "Discharging a Patient" on page 146). Also select **Erase All** in the **Stored Data Recording** menu, to erase all stored data.

NOTE

Log files generated by the monitors and measurement modules are used for system troubleshooting and do not contain protected health data.

About HIPAA Rules

If applicable, your facility's security strategy should include the standards set forth in the Health Insurance Portability and Accountability Act of 1996 (HIPAA), introduced by the United States Department of Health and Human Services. You should consider both the security and the privacy rules and the HITECH Act when designing policies and procedures. For more information, please visit:
http://www.hhs.gov/ocr/privacy/

About the EU Directives

If applicable, your facility's security strategy should include the practices set forth in the Directive on the protection of individuals with regard to the processing of personal data and on the free movement of such data (Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016). In addition, your facility should also take into account any additional, more stringent standards put forward by any individual EU countries; that is, Germany, France, and so on.

Philips Product Security Policy Statement

Additional security and privacy information can be found on the Philips product security web site at:
http://www.usa.philips.com/healthcare/about/customer-support/product-security

Manufacturer Disclosure Statement for Medical Device Security – MDS2

You can view the Manufacturer Disclosure Statements for Medical Device Security (MDS^2) for specific devices at:
http://www.usa.philips.com/healthcare/about/customer-support/product-security

Cyber Security Requirements and Controls

The Avalon fetal monitors cannot be connected to portable media such as USB drives or CDs. Cyber security threats therefore result mainly from network connectivity and may impact safe and secure operation of your network or any devices attached to this network.

As part of your security concept, you are responsible for establishing controls to protect your network and any networked devices, including the Avalon fetal monitors, against such cyber security threats.

Network Cyber Security Measures

Only connect the Avalon fetal monitors to networks that are explicitly intended for that purpose. The fetal monitor is intended to be used for monitoring of, and to generate alarms for, multiple physiological signals of patients. If you connect the fetal monitor to a network, it is therefore highly recommended that you deploy measures for protecting the network against cyber security threats. This includes the deployment of firewalls to limit remote access and antivirus protection of standard computer systems.

Network Security Requirements for Connectivity to Philips Systems

You must follow the network configuration instructions of the specific Philips system product. The IntelliVue Network Specification provides detailed network configuration requirements associated with the safe and secure operation of Avalon devices within your hospital network for the purpose of patient monitoring. The IntelliVue Network Specification ensures the configuration and operation of a logical isolated network (LAN or VLAN) for Avalon devices by the configuration of network infrastructure devices (switches, routers, etc.). The document also defines the interconnection of the isolated network with other hospital networks using firewalls as well as the use of antivirus software for computer platforms based on standard operating systems.

Compliance to the IntelliVue Network Specifications is verified by Philips in cooperation with the customer prior to go-live.

Network Security Requirements for Connectivity to other Systems

To ensure safe and secure operation of networked data collection applications involving Avalon fetal monitors, you must implement network traffic isolation by using dedicated physical or logical networks (isolated VLANs). Network traffic separation can be achieved by configuration of network infrastructure devices (switches, routers and firewalls) as outlined in the IntelliVue Network Specification. Only devices required by the specific system application should share this dedicated network. To prevent malware from affecting network performance or device operation, always ensure that all networked devices with standard operating systems have virus protection installed and kept up to date.

For managing risks in clinical network deployments, Philips recommends that you apply a formal process such as the IEC 80001 series of standards to address safety, effectiveness, and data and system security.

Security Software Updates

All software for the Avalon fetal monitors is completely built and integrated by Philips. There are no separate user-updatable software components from other manufacturers.

Philips authorized software updates for the Avalon fetal monitors, including any potential cyber security updates, are communicated via the Field Change Order Process which is a component of the Philips Quality System. Field Change Orders are published and available on InCenter at:
http://incenter.medical.philips.com/.
The procedure on how to install software updates is described within this Field Change Order.

If you have questions about InCenter access, please contact your local sales representative or service personnel.

Overview of System Components

New Generation Avalon Transducers

The new generation of Avalon transducers has the same functionality and usability aspects as the previous Avalon transducers, but they have the look and feel of the cableless transducers. Availability of the new generation Avalon transducers for all countries and territories depends on the local Regulatory market clearance.

The Avalon CL system consists of the Avalon CL base station, the Avalon CL transducers, the Avalon CL Fetal & Maternal Pod, the CL Wide Range Pod, and the IntelliVue CL Pods. The IntelliVue CL Pods are only used for maternal measurements within the Avalon CL solution. The following tables provide an overview of all the devices.

Wired Monitoring

Avalon monitors	FM20/FM30	FM40/FM50
	 M2702A and M2703A	 M2704A and M2705A

Wired transducers	US transducer  867246	Toco+ MP transducer  867245
	ECG/IUP transducer  867247	Toco+ transducer  867249
	Toco MP transducer  867248	

Cableless Monitoring

Avalon monitors	FM20/FM30  M2702A and M2703A	FM40/FM50  M2704A and M2705A
Avalon CL base station	base station  866074	

<table>
<tr><td rowspan="2">Cableless transducers</td><td>CL US transducer
 

866076</td><td>CL Toco+ MP transducer
 

866075</td></tr>
<tr><td>CL ECG/IUP transducer
 

866077</td><td></td></tr>
<tr><td rowspan="2">Avalon CL Pods</td><td>CL Fetal & Maternal Pod
 
866488</td><td>CL Wide Range Pod
 

866487</td></tr>
<tr><td>IntelliVue CL NBP Pod
 
865216</td><td>IntelliVue CL SpO_2 Pod
 

865215</td></tr>
</table>

Previous Generation Transducers

The previous generation of transducers has been discontinued in some countries and these transducers do no longer carry the CE mark. However, they are still supported and compatible with the fetal monitors.

Wired Transducers	Part Number
Avalon Toco Transducer	M2734A
Avalon Toco MP Transducer for Toco and Maternal Pulse	M2734B
Avalon Toco^{+} Transducer for Toco, DECG, MECG or IUP monitoring	M2735A
Avalon US Transducer	M2736A/M2736AA
ECG/IUP Patient Module (for DECG, MECG or IUP)	M2738A

2

What's New

This section lists the most important new features and improvements to the fetal monitors and their user interface introduced with Release L.3 and J.3.

You may not have all of these features, depending on the fetal monitor configuration purchased.

What's New in Release L.3

Avalon CL Fetal & Maternal Pod

The Avalon CL Fetal & Maternal Pod is an extension of the Avalon CL solution. The Avalon CL Fetal & Maternal Pod is used together with a single use patch with five abdominal electrodes. Prior to use, the Avalon CL Fetal & Maternal Pod is charged and assigned at the Avalon CL base station. The Avalon CL Fetal & Maternal Pod is used for women who are at >36 completed weeks, in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. This solution provides especially benefits to patients with high body mass index (BMI), although it can be used for all patients.

The Avalon CL Fetal & Maternal Pod includes the following features:

- The Avalon CL Fetal & Maternal Pod measures fetal heart rate (**aFHR**), maternal heart rate (**aHR**), and uterine activity (**aToco**) from electrical signals.
- The **cl F&M Electrode Status** window at the monitor gives an overview of the current electrode contact status, when the CL Fetal & Maternal Pod is placed on the electrode patch and the electrodes are applied to the patient's abdominal skin. The window can be opened by selecting the new SmartKey **cl F&M Status**, or selecting the corresponding function in the main setup menu.
- The Avalon CL Fetal & Maternal Pod and the CL Wide Range Pod are assigned at the CL base station in the same easy way as the IntelliVue CL Pods.
- The functions **Find** and **Call Patient** also work with the Avalon CL Fetal & Maternal Pod, CL Wide Range Pod, the CL NBP Pod, and the CL SpO_2 Pod.

See "Avalon CL Fetal & Maternal Pod" on page 25, "CL Fetal & Maternal Patch" on page 88, "Applying the CL Fetal & Maternal Patch and Pod" on page 97, and "CL Pod Assignment" on page 95.

NOTE

The Avalon CL Fetal & Maternal Pod and Patch are not available for U.S., other FDA regulated territories, and Canada.

Avalon CL Wide Range Pod

The Avalon CL Wide Range Pod is an extension of the Avalon CL solution. The Avalon CL Wide Range Pod extends the signal range of the cableless measurements. It transmits the cableless measurement signals via the hospital WLAN/WiFi to the fetal monitors. Wearing the CL Wide Range Pod, the patient can walk freely within the hospital's WLAN/WiFi range during monitoring. Prior to use, the Avalon CL Wide Range Pod is charged and assigned at the Avalon CL base station.

- A new WLAN symbol is printed on the trace to indicate the use of an assigned and active Avalon CL Wide Range Pod.

- During monitoring with an active Avalon CL Wide Range Pod, the sound from the fetal heart rate is replaced by an artificial QRS sound (when the patient is monitored with a CL US transducer or CL F&M Pod).

See "CL Wide Range Pod" on page 88.

New Generation Avalon Transducers

The new generation of Avalon transducers has the same functionality and usability aspects as the previous Avalon transducers, but they have the look and feel of the cableless transducers. Availability of the new generation Avalon transducers for all countries and territories depends on the local Regulatory market clearance.

Toco $^{+}$ MP Transducer (867245)

The new wired Toco^{+} MP transducer requires the Avalon Fetal Monitor software L.3x.xx.

NST Trace Interpretation according to Dawes/Redman

The NST trace interpretation according to Dawes/Redman is a method to assist the assessment of the fetal well-being. The algorithm based on the Dawes/Redman criteria for normality uses the parameters fetal heart rate, gestational age, fetal movement, accelerations and decelerations, and long term variability and short term variability to generate a report.

Not available for U.S. and FDA regulated territories.

Support of XDS Remote Display

The fetal monitor software supports the IntelliVue XDS Remote Display functionality only in combination with IntelliSpace Perinatal revision K or higher. From IntelliSpace Perinatal, you can access all screen-operable functions of the LAN connected fetal monitor. These functions include for example, starting and stopping physiological measurements, changing measurement modes, changing alarm limits, and silencing alarms.

New Alarm Behavior of CL Battery Empty INOP

The CL <xxx> Battery Empty INOP issued by the CL devices and the fetal monitor has a new alarm behavior:

- At the fetal monitor, it is issued now with a cyan INOP alarm and tone.
- At CL devices (CL transducers and CL Pods), it is issued now with a tone corresponding to a yellow alarm.

See "Patient Alarms and INOPs" on page 127.

New Alarm Mode Default

The new default configuration for the **Alarm Mode** is **All**. See the Avalon Fetal Monitor Configuration Guide for information on how to change the **Alarm Mode** setting.

Using CL Pods with FM20/30 #E25

The CL Pods can now also be used with a battery operated FM20 or FM30 (option #E25). All CL Pods can be assigned and activated. The CL F&M Pod can also be charged.

See "Using Batteries" on page 108.

Entering Notes - Type a Note

In the menu **Enter Note**, it is now possible to enter a note manually, instead of selecting one of the pre-configured notes. To enter a note, select the new menu item **Type a note**. A window with a touch keypad opens. The typed note can be up to 30 characters long.

See "Typing Notes" on page 70.

What's New in Release J.3

Avalon CL Transducer System

The Avalon CL Transducer System provides cableless monitoring with the Avalon FM20/FM30 and FM40/FM50 with the same functionality and performance as the wired measurement devices (e.g. twin and triplets monitoring). The Avalon CL Transducer System has a straight-forward handling and operating concept. The CL transducers are assigned by simply docking them at the CL base station, no further configuration is necessary.

The Avalon CL Transducer System includes the following features:

- Cableless monitoring of twins and triplets (see "Monitoring Twin FHRs" on page 185 and "Monitoring Triple FHRs" on page 191)
- Cableless maternal measurement Pods CL SpO_2 and CL NBP (see "IntelliVue CL Pods" on page 89)
- Maternal pulse from a CL Toco$^+$ MP (Smart Pulse) transducer (see "Monitoring Maternal Heart / Pulse Rate" on page 219)
- A cableless ECG/IUP transducer measuring IUP or fetal/maternal ECG (see "Monitoring MECG Wave" on page 222 and "Monitoring FHR Using DECG" on page 199)
- Watertight cableless transducers that can be used to monitor in water (see "Underwater Monitoring" on page 105)
- Patient call that pages an ambulating mother with an audible signal emitted by the worn CL transducers (see "Calling Patients" on page 96)
- Out-of-range audible signal emitted by the worn CL transducers to inform an ambulating mother that she has reached the limit of the active signal area-of-reach (see "Standard Radio Range of CL Transducers" on page 84)
- A transducer finder LED on all CL transducers to help identify the assigned transducer (see "Cableless Transducer LED Indication" on page 82)

Support For Use of Maternal Cableless Measurement Devices

The IntelliVue CL measurement Pods are patient-worn, battery-powered measurement devices for SpO_2 and NBP. The devices provide measurement values on the built-in display and communicate them to the fetal monitor using the wireless short range radio (SRR) interface of the Avalon CL base station (see "IntelliVue CL Pods" on page 89).

Maternal Temperature Measurement

To measure maternal temperature, the new optional tympanic thermometer (866149) is available for the Avalon fetal monitors (see "Monitoring Maternal Temperature" on page 245). The measurement data is:

- documented and printed out at the local recorder, and transmitted to the obstetrical information and surveillance system.
- displayed as a numeric on the screen.

Manually Entered Maternal Temperature Measurements

Manually measured temperatures can be entered at the fetal monitor. They are displayed as a numeric on screen, and are printed out on the recorder trace (see "Monitoring Maternal Temperature" on page 245).

SpO2 Recordings and Transmissions

SpO_2 annotation on local recorder

You can now configure the interval for printing the SpO_2 numeric values on the recorder trace. With the new configuration setting **Record on Trace**, you can set the interval to 1 or 5 minutes.

SpO_2 transmission to an obstetrical information and surveillance system

You can now configure the interval for transmitting the SpO_2 numeric values to an obstetrical information and surveillance system. With the new configuration setting **Send to OB Sys**, you can set the interval to 1 or 5 minutes.

New Design for the User Interface

The user interface for the fetal monitors has been redesigned to bring the presented information into the foreground, letting the structural elements such as keys and frames retreat into the background. Additionally special regard was given to making the "look and feel" similar to that of standard software products (see "Operating and Navigating" on page 39).

New SmartKeys

- The **Start ECG** SmartKey and menu item is renamed to **Record ECG**.
- With the **Call Patient** SmartKey, you can now page patients who are ambulating wearing Avalon CL transducers.
- With the **Tele Info** SmartKey, you can call up the **Tele Info** window on the fetal monitor display. In the **Tele Info** window, you can control and view the status of the cableless transducers from the connected Avalon CL base station.
- With the **Enter Temp** SmartKey, a pop-up window opens showing a numeric pad for entering manually measured maternal temperature values.
- With the **NBP Modes** SmartKey, you can access the NBP Mode selection and setup, and can directly start and stop a measurement.
- With the **QuickAdmit** SmartKey, you can quick admit a patient to the monitor.

All new SmartKeys are optional, and have to be configured in Configuration Mode for use (see "SmartKeys" on page 42).

Coincidence INOP Tone

When the cross-channel verification detects that the signal of the maternal heart rate coincides with the fetal heart rate, the **Coincidence** INOP is now issued with a tone at the fetal monitor. The **Coincidence** INOP tone has a configurable delay (see "Cross-Channel Verification (CCV)" on page 163).

Increased Internal Back-up Memory

The internal back-up memory is now able to store traces and data from at least the last 3.5 hours with the software revision J.3, and minimum 7 hours with the new mainboard hardware revision A 00.18 (see "Manually Recording Stored Data" on page 254 and "Recovering Data" on page 253).

Dual System Interface Support

If the fetal monitor is connected via a LAN connection to OB TraceVue/IntelliSpace Perinatal, the RS232 interface can be used independently to connect e.g. an EMR system on read-only basis. The system connected to the RS232 interface in this case cannot alter any data (such as ADT data, or the date and time setting), or interfere with functions of the monitor, but is able to read output data. The obstetrical information and surveillance system connected via LAN has priority.

USB Interface

An optional USB interface allows the use of bar code readers and input devices such as a keyboard, or mouse (see "Getting to Know Your Avalon FM20/FM30"/"Bottom" on page 35 and "Getting to Know Your Avalon FM40/FM50"/"Rear" on page 36).

Flexible Nurse Call Interface

An optional Flexible Nurse Call interface allows the connection of a nurse call device to the fetal monitors (see "Getting to Know Your Avalon FM20/FM30"/"Bottom" on page 35 and "Getting to Know Your Avalon FM40/FM50"/"Rear" on page 36).

DHCP Support

The DHCP support offers an alternative to BOOTP. DHCP (Dynamic Host Configuration Protocol) enables the fetal monitors to request an IP address (internet protocol address) from the connected network (OB TraceVue/IntelliSpace Perinatal) automatically.

Data Export Support

You can now export measurement values from the monitor to other devices via the LAN interface, or with the optional MIB RS232 interface (see "Getting to Know Your Avalon FM20/FM30"/"Bottom" on page 35 and "Getting to Know Your Avalon FM40/FM50"/"Rear" on page 36). Compatibility with third-party obstetrical information and surveillance systems has not been verified. Users should ensure that all required functionality is verified with any third-party system prior to clinical use.

NBP Configurable Measurement Sequence

Up to four measurement cycles can be set up which will run consecutively. For each cycle, you can set the number of measurements and the interval between them. By setting the last cycle to run continuously, you can have regular measurements continue after the sequence has run (see "Enabling Sequence Mode and Setting Up the Sequence" on page 235).

Alarms Enhancements

In addition to the standard cyan INOPs, some INOPs can now be configured as red or yellow INOPs to provide a severity indication (**ECG Leads Off**, **Cuff Overpress**, **Cuff NotDeflated**, **Battery Empty**, **No Pulse**) (see "Alarms" on page 115).

Alarm Reminder

In Configuration Mode, you can set now an **Alarm Reminder**. The **Alarm Reminder** emits an audible reminder of alarm conditions that remain active after the alarm is acknowledged. This reminder may take the form of a repetition of the alarm tone for a limited time, or an unlimited repetition of the alarm tone (this is the same as a new alarm). The interval between silencing the alarm and sounding the reminder tone can be set to one, two, or three minutes (see "Alarm Reminder" on page 119).

Auto Free

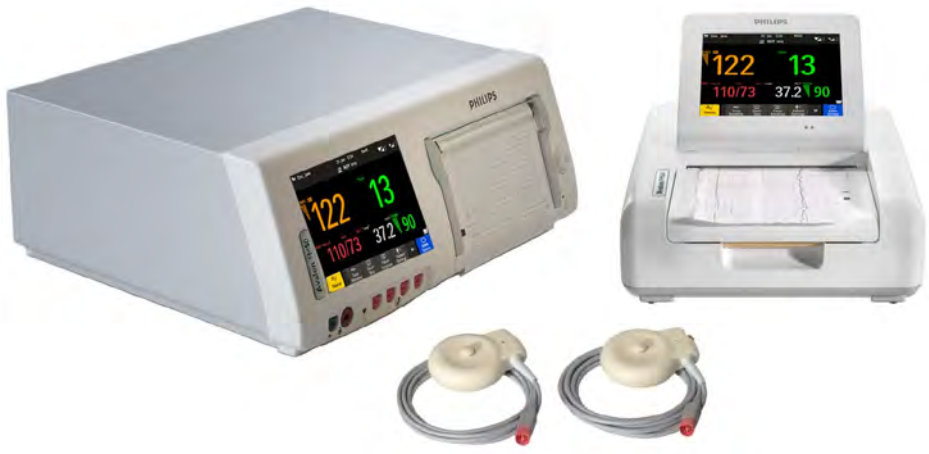
In Configuration Mode, you can now set an **Auto Free** setting which discharges a patient automatically when the fetal monitor has been powered off, or is in Standby mode for a set time. Only the demographic patient data is deleted, the trace data is not affected.

2 What's New

3

Basic Operation

This chapter gives you an overview of the monitor and its functions. It tells you how to perform tasks that are common to all measurements (such as entering data, switching on a measurement, changing some monitor settings, and setting up the recorder). The alarms section gives an overview of alarms. The remaining sections tell you how to perform individual measurements, and how to care for and maintain the equipment.



Supported Measurements

Different measurements for the same physiological parameter may have a different appearance on the trace, due to: variability (HR), averaging, delay, amplitude, or artifacts. Before interpreting the trace, regard the fetal monitor setup and transducers used.

The following **Fetal** measurements are supported:

Measurements	FM20	FM30	FM40	FM50
Fetal Heart Rate (FHR) via US (including Twins)	Standard	Standard	Standard	Standard
Triple FHR via US	Optional	Optional	Optional	Optional
dFHR via Direct ECG (DECG)	-	Standard	-	Standard
aFHR via CL F&M Pod	Optional	Optional	Optional	Optional
Toco	Standard	Standard	Standard	Standard
aToco via CL F&M Pod	Optional	Optional	Optional	Optional
Intrauterine Pressure (IUP)	-	Standard	-	Standard

The following **Maternal** measurements are supported:

Measurements	FM20	FM30	FM40	FM50
Maternal Heart Rate (HR) via Maternal ECG Electrodes	Standard	Standard	Standard	Standard
Maternal ECG (MECG wave)	-	Standard	-	Standard
aHR via CL F&M Pod	Optional	Optional	Optional	Optional
Maternal Pulse from Toco	Standard	Standard	Standard	Standard
Noninvasive Blood Pressure with Pulse Rate	Optional	Optional	Optional	Optional
Pulse Oximetry (Maternal SpO_2) with Pulse Rate	Optional	Optional	Optional	Optional
Maternal Temperature	Optional	Optional	Optional	Optional

Avalon FM20 and FM30

This section outlines the capabilities of your monitor.

Avalon FM20

The Avalon FM20 fetal/maternal monitor provides a solution for external fetal monitoring applications, and optional noninvasive maternal vital signs.

You can monitor fetal heart rates (FHRs) externally using ultrasound, uterine activity and maternal pulse using an external Toco transducer, and the maternal heart rate (HR) with maternal ECG electrodes, and optionally, noninvasive blood pressure and maternal oxygen saturation (SpO_2).

Measurements are displayed on a 6.5 inch color display as numerics. The display is a touchscreen, and you operate the monitor using this touchscreen interface. The integrated recorder documents fetal and maternal measurements as well as the user-defined annotations.

You can connect the monitor to an OB TraceVue/IntelliSpace Perinatal system via the RS232 connection, or over a LAN connection (with OB TraceVue Revision E.00.00 and later, or IntelliSpace Perinatal Revision H.0 and later).

Avalon FM30

The Avalon FM30 fetal/maternal monitor offers a solution for both external and internal fetal monitoring applications, and optional noninvasive maternal vital signs.

The Avalon FM30 shares all the features and capabilities of the Avalon FM20. In addition, you can monitor one FHR internally with a direct fetal electrocardiogram (DECG), uterine activity internally using an intrauterine pressure (IUP) catheter together with a Toco^{+} transducer or patient module.

The Avalon FM30 carries the **IP** label, indicating that it is capable of intrapartum monitoring.

FM20/30 with Battery Option #E25 Only

The battery option for the FM20/30 provides support for the in-transport monitoring of all measurements when disconnected from a power supply. Existing data storage is automatically uploaded to OB TraceVue or IntelliSpace Perinatal after reconnecting it to the system. Trace printing during transport is also possible.

Avalon FM40 and FM50

This section outlines the capabilities of your monitor.

Avalon FM40

The Avalon FM40 fetal/maternal monitor provides a solution for external fetal monitoring applications, and noninvasive maternal vital signs.

You can monitor fetal heart rates (FHRs) externally using ultrasound, uterine activity using an external Toco transducer, and the maternal heart rate (HR) via maternal ECG electrodes, and noninvasive blood pressure and maternal oxygen saturation (SpO_2).

Measurements are displayed on a 6.5 inch color display as numerics. The display is a touchscreen, and you operate the monitor using this touchscreen interface. The integrated recorder documents fetal and maternal measurements as well as the user-defined annotations.

You can connect the monitor to an OB TraceVue/IntelliSpace Perinatal system with the RS232 connection, or over a LAN connection (with OB TraceVue Revision E.00.00 and later, or IntelliSpace Perinatal Revision H.0 and later).

Avalon FM50

The Avalon FM50 fetal/maternal monitor offers a solution for both external and internal fetal monitoring applications, and noninvasive maternal vital signs.

The Avalon FM50 shares all the features and capabilities of the Avalon FM40. In addition, you can monitor one FHR internally with a direct fetal electrocardiogram (DECG), and uterine activity internally using an intrauterine pressure (IUP) catheter together with a Toco^{+} transducer or patient module.

The Avalon FM50 carries the **IP** label, indicating that it is capable of intrapartum monitoring.

IP

Getting to Know Your Avalon FM20/FM30

Overview

1 Touchscreen display (tilt and fold)
2 Power LED
3 Paper drawer
4 Paper drawer release
5 Connectors

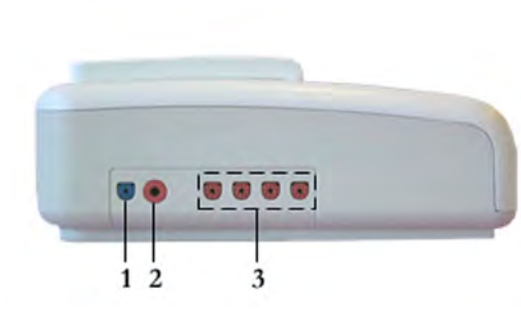
Right Side

1 On/Off switch
2 Power connector

with Battery Option

1 On/Standby button with power LED
2 MSL connector for external power supply

Left Side



1 SpO_2 socket (optional)

2 Noninvasive Blood Pressure socket (optional)

3 Fetal sensor sockets

Each of the fetal sensor sockets accepts any fetal transducer, one Avalon CL or one Avalon CTS Cableless Fetal Transducer System base station, or an event marker.

Bottom

There are five optional interfaces available for the Avalon FM20/30 monitor:

- LAN/RS232 system interface
- Dual PS/2 interface
- Dual MIB/RS232 interface
- Flexible Nurse Call interface
- USB ports interface

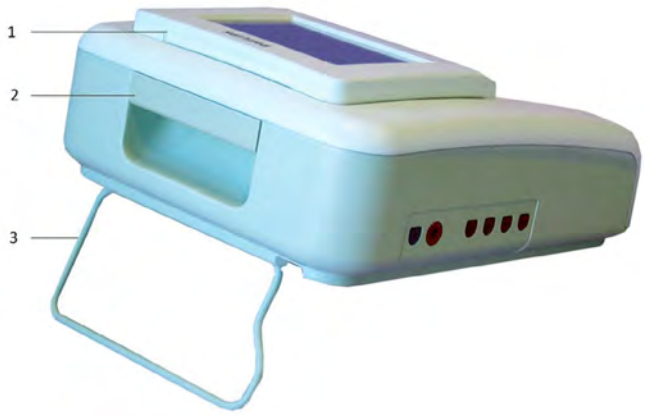
You can use two of the five optional interfaces at the same time.

1 LAN/RS232 system interface

2 Dual PS/2 system interface

Optional Interfaces	Description
	Flexible nurse call interface card
	Quad. USB ports
	Dual MIB/RS232

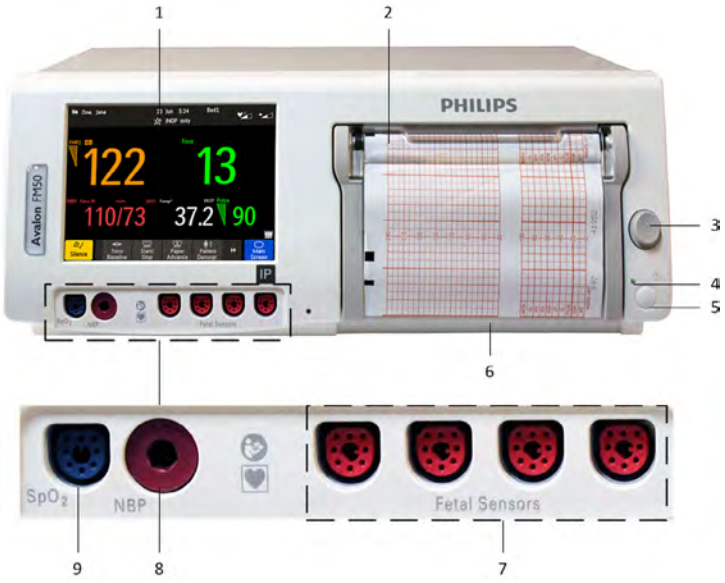
Rear



1 Display release
2 Carrying handle
3 Built-in stand

Getting to Know Your Avalon FM40/FM50

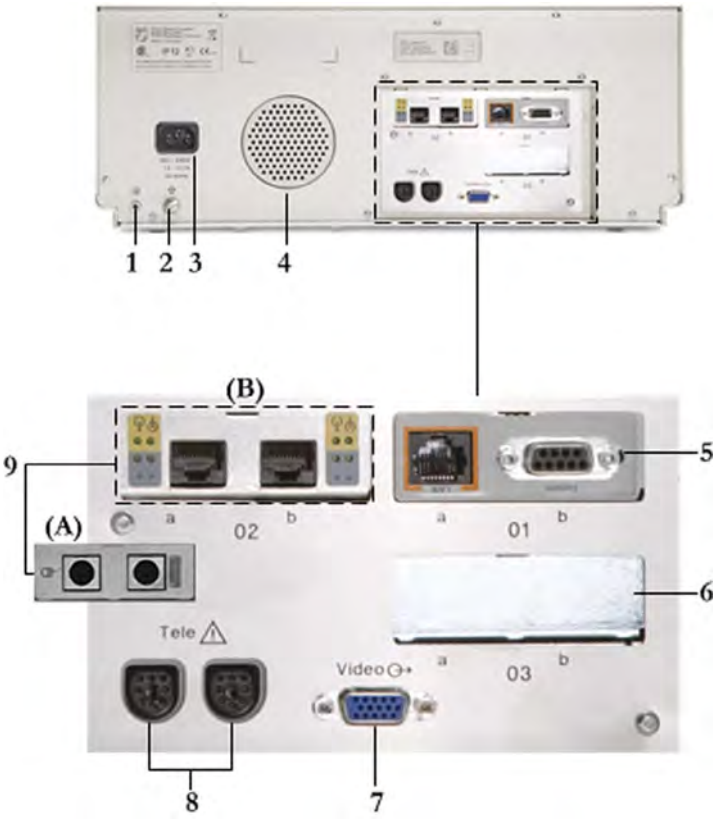
Front



1 Touchscreen color display
2 Transparent paper guide with tear-off edge
3 Paper eject button
4 Power LED
5 On/Standby button
6 Recorder paper table
7 Fetal sensor sockets
8 Noninvasive blood pressure socket (optional)
9 SpO_2 socket (optional)

Connect any fetal sensor or patient module at the fetal sensor sockets, including an Avalon CL or an Avalon CTS via interface cable (with red connector).

Rear



1 Reserved for future use: protective earth intended for use in system installations

2 Equipotential grounding point

3 Power cord connector

4 Loudspeaker

5 Slot 01 for optional LAN/RS232 system interface (for connection to an obstetrical information and surveillance system)

6 Slot 03 reserved for future use

7 Video output (VGA)

8 Telemetry interface

9 Slot 02 for optional interfaces: *Either* dual PS/2 system interface (**A**) for mouse and keyboard connection *Or* MIB interface (**B**) for external touchscreen connection, or the optional interfaces for the flexible nurse call or USB ports

Two Avalon CL base stations, or one Avalon CTS can be also connected to the Telemetry interface sockets using the interface cable (with black connector).

Additional Optional Interfaces

Optional Interfaces	Description
	Flexible nurse call interface card
	Quad. USB ports
	Dual MIB/RS232 interface

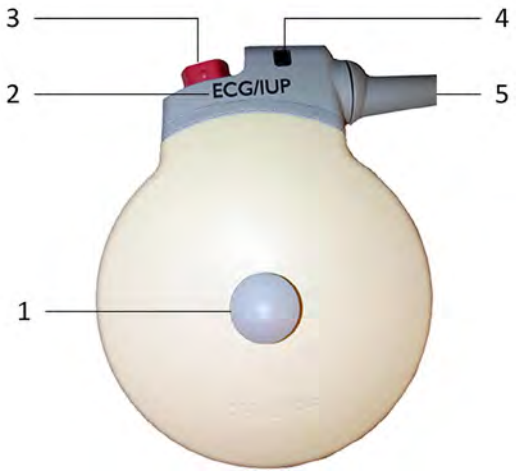
Connecting the Monitor to AC Mains

WARNING

- Always use the supplied power cord with the earthed mains plug to connect to an earthed AC mains socket. Never adapt the mains plug from the fetal monitor to fit an unearthed AC mains socket.
- Check that the line frequency is correctly configured in the **Global Settings** menu.
- **FM20/FM30 only:** The protective earth conductor is required for EMC purposes. It has no protective function against electric shock. Double and/or reinforced insulation protects this device against electric shock.
- Do not use AC mains extension cords or multiple portable socket-outlets.

Always ensure that the monitor is positioned so that the AC mains plug is easily accessible, to allow disconnection of the monitor from the AC mains.

Wired Transducers



1 Belt button

2 Label of transducer type

3 Connector - for connecting ECG/IUP adapter cables for the Toco^{+} transducer (867249), Toco^{+} MP transducer (867245), and the ECG/IUP transducer (867247)

4 Transducer finder LED - lights up to help identify the assigned transducer

5 Cable - connects to any of the four fetal sensor sockets on the monitor

Operating and Navigating

Your monitor has a touchscreen. Everything you need to operate the monitor, except the on and off switch, is contained on its screen. Most screen elements are interactive. Screen elements include measurement numerics, screen keys, information fields, status indicators, alarms fields, and menus. It is possible to view and operate the screen of a LAN connected fetal monitor with the IntelliSpace Perinatal K.00.1x or higher using the IntelliVue XDS Solution.

Operator Position

The typical operator's position is in front of the monitor.

FM40/50 If an optional external touch display is connected to the monitor, you can operate the monitor using the external touch display.

1 Monitor information line

2 Measurement area

3 Key area

CAUTION

The screen contains sensitive personal data. For information how to protect personal information, see "Protecting Personal Information" on page 19.

Screen Elements

Monitor Information Line

1 LAN connection status indicator only. RS232 system connection is not indicated. The locomotive icon indicates if the fetal monitor is connected to OB TraceVue/IntelliSpace Perinatal, via a LAN cable or not.

2 Patient identification

3 Date and time

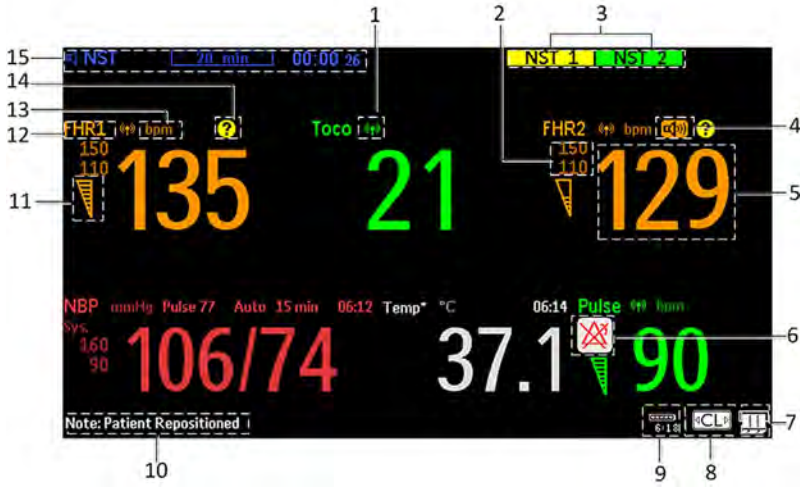
4 Bed label (when connected to a Philips OB TraceVue/IntelliSpace Perinatal system)

5 Fetal heart sound volume adjust/indicator

6 Alarm volume adjust/indicator

7 INOP and alarm status area - shows active alarm messages

Measurement Area



1 Antenna symbol (indicates a cableless measurement from a connected Avalon CL or Avalon CTS system)

2 Configurable alarm limits

3 NST test

4 Audio source symbol

5 Measurement numeric

6 Alarms off symbol

7 Fetal trace recorder - status indicator

8 Avalon CL or Avalon CTS system - status indicator

9 Battery status indicator

10 Status line - shows status and prompt messages

11 Signal quality indicator: good, acceptable, poor

12 Fetal heart rate measurement label

13 Measurement unit (configurable)

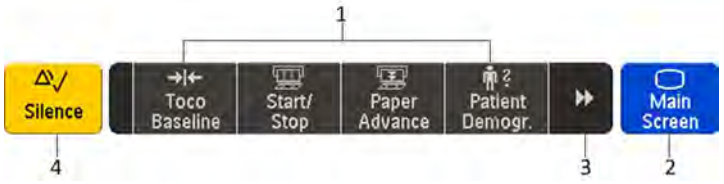
14 Coincidence symbol (see "Cross-Channel Verification (CCV)" on page 163)

15 NST timer, if configured (default is Off)

Screen Details

Icon	Description
	The antenna symbol indicates a cableless measurement (Avalon CL or Avalon CTS).
	Indicates a short range radio measurement (CL Pods).
	Signal quality indicator: **1** Good **2** Acceptable **3** Poor
	Fetal trace recorder - status indicator Fetal recorder is on
	Fetal recorder is off (when **Paper Save Mode** is off)
	Fetal recorder is off (when **Paper Save Mode** is on)
	There is a user-solvable recorder error (paper out, paper jam, wrong paper scale set)
	Fetal recorder is defective: call service
	When an Avalon CL or Avalon CTS system is connected to the monitor, a **CL** symbol is shown. It changes with the states of the connected cableless device see "Cableless Status Indication" on page 91.

Key Area



1 SmartKeys - these can vary according to your monitor's configuration

2 **Main Screen** - closes all open menus and windows and returns to main screen

3 Scroll to display more SmartKeys

4 **Silence** - acknowledges all active alarms by switching off audible alarm indicators

Keys

The monitor has three different types of keys.

Permanent Keys

A permanent key is a graphical key that remains permanently on the screen, giving you fast access to functions.

Key	Name	Function
	Silence	Acknowledges all active alarms by switching off audible alarm indicators.
	Main Screen	Closes all open menus and windows and returns to the main screen.

SmartKeys

SmartKeys are configurable graphical keys, located at the bottom of the main screen. They give you fast access to functions. The selection of SmartKeys available on your monitor depends on your monitor configuration, and on the options purchased.

SmartKey	Name	Function
	FRStart/Stop	Turns the trace recorder on or off
	Start Rec	Turns the trace recorder on
	Stop Rec	Turns the trace recorder off
	Paper Advance	Advances the paper automatically to the next fold
	Set Marker	Marks an event
	Enter Notes	Enters notes
	Record ECG	Starts printing the MECG, DECG, or both waves, when both are available
	Stored Rec	Prints trace data from the monitor's memory
	NST Report	Initiates an NST trace interpretation and obtains a Non-stress test (NST) report

SmartKey	Name	Function
	**Sound Vol. Up**	Increases the fetal heart rate volume
	**Sound Vol. Down**	Decreases the fetal heart rate volume
	**Toco/IUP Bsl**	Resets Toco baseline
	**Tele Info**	Calls up the **Tele Info** window
	**Call Patient**	Pages the patient. Only enabled, if at least one CL transducer or CL Pod is active
	**cl F&M Status**	Calls up the **cl F&M Electrode Status** window
	**Pause Alarms**	Pauses alarm indicators. Pause duration depends on monitor configuration. If the pause duration is infinite, this key is labeled **Alarms Off** Select again to immediately re-enable alarm indicators
	**Defaults**	Loads User Default
	**Main Setup**	Enters main setup menu
	**Strt/Stp NBP**	Starts/stops manual noninvasive blood pressure measurement Starts auto series Stops current automatic measurement within series
	**Start NBP**	Starts manual noninvasive blood pressure measurement Starts auto series
	**Stop NBP**	Stops manual noninvasive blood pressure measurement Stops current automatic measurement within series
	**Stop All NBP**	Stops all noninvasive blood pressure measurements
	**Repeat NBP**	Sets the time interval between two noninvasive blood pressure measurements
	**NBP Modes**	Access NBP mode selection and setup, with direct start/stop function
	**Enter Temp**	Allows the manual input of the patient's temperature
	**Zero IUP**	Resets the display and trace to 0. If you do not zero the IUP measurement properly, the pressure trace may exceed the paper scaling.
	**Timer**	Enters NST timer window
	**Standby**	Switches to Standby screen, suspends monitoring. All numerics and waves disappear from the display. All settings and patient data information are retained
	**Patient Demogr.**	Enters the patient identification menu to admit/discharge
	**QuickAdmit**	Quick admits the patient for monitoring
	Blank Key	Blank key, can be used as divider between a group of keys

Pop-Up Keys

Pop-up keys are context-sensitive graphical keys that appear automatically on the monitor screen when required. For example, the **Confirm** pop-up key appears when you need to confirm a change.

Using the Touchscreen

Select screen elements by pressing them directly on the monitor's screen.

Disabling Touchscreen Operation

1 To temporarily disable the touchscreen operation of the monitor, press and hold the **Main Screen** permanent key for about three seconds. A red padlock will blink on the **Main Screen** permanent key.

2 Press and hold the **Main Screen** permanent key again for about three seconds to re-enable the touchscreen operation.

Operating Modes

When you switch on the monitor, it starts up in Monitoring Mode. To change to a different mode:

1 Select the **Main Setup** menu.

2 Select **Operating Modes** and select a mode.

Your monitor has four operating modes. Some are passcode protected.

Mode	Description	Password Protected
Monitoring Mode	The Monitoring Mode is the normal operating mode to monitor patients. You can change elements such as alarm limits. When you discharge the patient, these elements return to their default values. You cannot select or change grayed out items. These items are for your information only. To change these items, switch to the Configuration Mode.	no
Demo Mode	The Demo Mode is used for demonstration and training purposes. Do not change into Demo Mode during monitoring. When transducers are connected to the monitor and the recorder is on, a demo trace is recorded. But the demo trace is not transmitted when the fetal monitor is connected via RS232 to an information and surveillance system such as OB TraceVue/IntelliSpace Perinatal.	yes
Configuration Mode	The Configuration Mode is for personnel trained in configuration tasks. You can change and store the default values and patient profiles permanently in the Configuration Mode. These tasks are described in the Configuration Guide. During installation, the fetal monitor is configured for use in your environment. This configuration defines the default settings you work with when you switch on the fetal monitor.	yes
Service Mode	The Service Mode is for trained and authorized service personnel only.	yes

A field displayed at the fetal monitor screen indicates if the monitor is in Demonstration Mode, Configuration Mode, or Service Mode. To change to a different mode, select this field.

Automatic Screen Layouts

Your monitor's preconfigured screen layouts define how measurement information is arranged on the screen. The monitor automatically applies the correct screen layout for the measurements you are monitoring. No user action is required.

Connecting or disconnecting transducers, or activating or deactivating a cableless measurement, results in an automatic adjustment of the screen layout. When a measurement is off, its numerics are removed from the monitor's screen. The monitor stops acquiring data and generating alarms for this measurement. If you disconnect a transducer while it is performing a measurement, the monitor issues a disconnect INOP (and in the case of SpO_2, replaces the measurement numeric with a question mark).

Using the XDS Remote Display

Using the IntelliVue XDS Solution it is possible to view and operate the screen of a connected fetal monitor in the IntelliSpace Perinatal application. XDS must be installed on the same PC as the IntelliSpace Perinatal application. XDS must be connected to the same Local Area Network (LAN) as the monitor. Depending on the configuration you can view or operate the monitor from the external display.

Use the remote display to access the following functions at the connected fetal monitor:

- Change measurement and alarm limits
- Start and stop physiological measurements
- Start and stop the recorder
- Check the status of the Avalon CL transducers and Pods
- Page the patient (in combination with CL transducers and CL Pods)
- Change the operation mode of the fetal monitor
- Configure the fetal monitor
- Switch the fetal monitor to Standby mode

For more details, including limitations and restrictions, refer to the IntelliSpace Perinatal Instruction for Use and the IntelliVue XDS Software Instructions for Use.

Settings

This section describes the various settings available on the monitor.

Active Settings

What the monitor displays, and the way it operates, is controlled by its settings. They determine sound volume settings, recorder settings, high and low alarm limits and so forth.

The “active settings” are the current settings the monitor uses, including any adjustments made by the last user. Active settings are not permanent, but are retained after a loss of mains power.

There are also two preconfigured default settings:

- User Default
- Factory Default

User Default

The **User Defaults** are a complete configuration stored in the monitor's long-term memory. You can store the active settings, modified to your preference, in the **User Defaults** (in Configuration Mode).

In Monitoring Mode, you can load the **User Defaults** settings to return to your preferred settings:

1 Select the **Defaults** SmartKey.

2 Select **Confirm** in the dialog box to load the **User Defaults**.

Factory Default

The **Factory Defaults** is a complete configuration predefined at the factory. You cannot modify it. In Configuration Mode, you can load the **Factory Defaults** as the active settings.

CAUTION

This resets all settings to factory defined values, but be aware that some values will differ from those with which the fetal monitor was originally shipped from the factory (recorder speed and paper scale type will need to be corrected, for instance). After loading the **Factory Defaults**, check the settings, and if necessary, change them to the settings you normally use.

You can use the **Factory Defaults** as the basis for producing your **User Defaults**. See the Configuration Guide for details.

Global Settings

General monitor configuration settings are stored in the **Global Settings**. These include settings for line frequency, QRS type, and whether the monitor is automatically reset to the **User Defaults** after a power interruption of more than one minute. You can change the **Global Settings** in Configuration Mode.

Changing Measurement Settings

Each measurement has a setup menu in which you can adjust all of its settings. You can enter a setup menu:

1 with the measurement numeric - select the measurement numeric on the screen to enter its setup menu. For example, to enter the **Setup FHR1** menu, select the **FHR1** (fetal heart rate 1) numeric.

2 with the **Main Setup** SmartKey - if you want to set up a measurement when the measurement is switched off, use the **Main Setup** SmartKey and select **Measurements**. Then select the measurement name from the pop-up list. With this SmartKey you can access any setup menu in the monitor.

This guide always describes the entry method using the measurement's setup menu. You can use the method you prefer.

Changing Monitor Settings

To change monitor settings such as brightness, or touch tone volume:

1 Enter the **Main Setup** menu.

2 Select the setting you want to change, or select **User Interface** to enter a sub menu where you can change user interface settings.

Adjusting the Screen Brightness

1 Enter the **Main Setup** menu.

2 Select **User Interface**.

3 Select **Brightness**.

4 Select the appropriate setting for the screen brightness. 10 is the brightest, 1 is the least bright. **Optimum** is suitable for most situations.

Adjusting Audio Volume

Here you can adjust the audio volume for **Alarm Volume**, **QRS Volume**, and **Timer Volume**. To adjust an audio volume:

1 Enter the **Main Setup** menu.

2 Select **User Interface**.

3 Select **Audio Volumes**, then select one of the volume types, and select an audio level. 10 is the loudest and 1 is the quietest. Selecting zero switches the volume off.

Setting the Date and Time

The current date and time is displayed in its own element in the information line of the monitor screen.

1 Select the date and time screen element from the monitor's information line to enter the **Date, Time** menu.

2 Select, in turn, the **Year**, **Month**, **Day**, **Hour** (in 24 hour format), and **Minute**, as necessary.

3 Select **Store Date, Time** to change the date and time.

WARNING

Do not change the date and time setting, if the fetal monitor is connected to a Philips OB TraceVue/ IntelliSpace Perinatal system. The monitor uses the OB TraceVue/IntelliSpace Perinatal system date and time, including daylight saving time changes. As long as the fetal monitor is connected to the OB TraceVue/IntelliSpace Perinatal system via the LAN-setup (locomotive symbol displayed on the monitor's screen), the option to change the date and time settings at the fetal monitor are disabled, this is not valid for RS232 connections, or the connection to other systems.

When disconnected from AC power, the monitor retains the date and time setting for at least 48 hours (typical: >72 hours). If the monitor is off longer than that, and the operating system detects that the date and time settings are invalid, the monitor initiates a "cold" start and sets the date to 1 Jan 1997 and the time to 00:00.

Checking Your Monitor Revision

1 Select **Main Setup**, **Revisions** to open the **Monitor Revision** menu.

2 From the **Monitor Revision** menu, select the monitor component for which you need revision information.

Preparing to Monitor

Confirm fetal life before you begin fetal monitoring. Familiarize yourself with the basic operation principles before you start to monitor.

CAUTION

Check the fetal monitors housing for damage before you start to monitor as part of your safety precautions.

After you switch on the monitor:

1 Check that you have the correct patient cables and transducers plugged in for the measurement you want to monitor.

2 If you use an Avalon CL or Avalon CTS system, check if the cableless transducers are ready and charged (apparent by either a lit up green or yellow LED indicator).

3 Admit your patient to the monitor (see "Admitting a Patient" on page 145).

4 Check that the alarm limits, alarm and fetal heart rate volumes, patient category, and so forth, are appropriate for your patient. Change the settings if necessary.

5 Refer to the appropriate measurement section for details of how to perform the measurements you require.

6 Start recording.

There is no special emergency access for the Avalon Fetal monitors. For all clinical use cases according the Intended Use, the monitors are taken into operation by connecting them to AC mains and by switching them on.

Switching On: FM20/FM30

1 Connect the monitor to AC mains and switch the monitor on.

- The green power-on LED lights up.
- The monitor performs a self-test as it starts up. **Self-test: OK**, the serial number, and revisions for the software and firmware are printed on the fetal trace paper (if recorder **Auto Start** is configured to **On**).
- The monitor display comes on.
- There is a start-up tone from the loudspeaker.

Battery Option

- If this option has been chosen, the green power-on LED on both the external power supply and the battery LED indicator will light up.

Switching On: FM40/FM50

1 Connect the monitor to AC mains.

– The green LED lights up.

2 Press the On/Standby switch.

– The monitor performs a self-test as it starts up. **Self-test: OK**, the serial number, and revisions for the software and firmware are printed on the fetal trace paper (if recorder **Auto Start** is configured to **On**).

– The monitor display comes on.

– There is a start-up tone from the loudspeaker.

Adjusting the Display Angle (FM20/FM30)

You can tilt the display on the FM20 and FM30 to one of five different positions, or you can fold it completely down. The tilt/fold mechanism works on a one-way ratchet system. You hear a click as each of the five positions is reached. The screen can be folded back down only after tilting the display forwards as far as it will go.

To tilt the display from the folded position:

1 Unlock the display by releasing the catch.

2 Lift the display forward. You will hear a click as the first position engages. If you want to tilt the display further, lift the display further forward until you reach the desired angle.

3 To fold the display, pull the display forwards as far as it will go.

4 Then push the display all the way back until it **clicks** shut.

If your monitor is wall-mounted, the display should be folded flat.

Fastening Belts and Transducers

You can use more than one belt if, for example, you are monitoring uterine activity and FHR simultaneously. There are two basic ways to fasten belts and transducers:

- Belts with button fixings.
- Velcro belts together with the butterfly belt clip.

What You Need

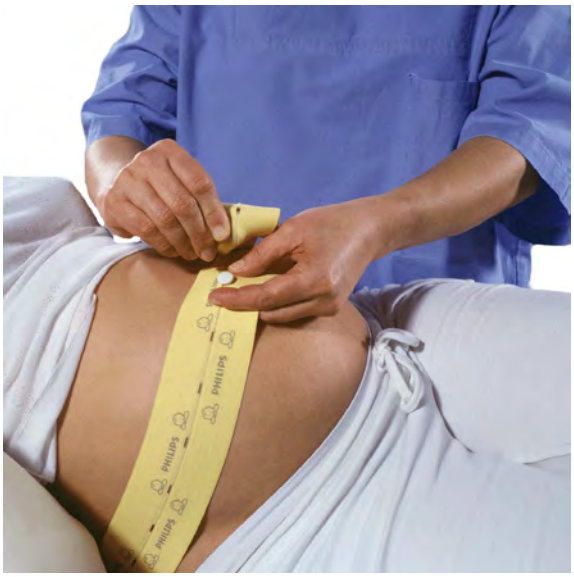
- Ultrasound transducer
- Toco$^+$ MP or CL Toco$^+$ MP transducer
- Ultrasound gel
- Transducer belt (and optional butterfly belt clip, if applicable)

Using Belts with Button Fixings

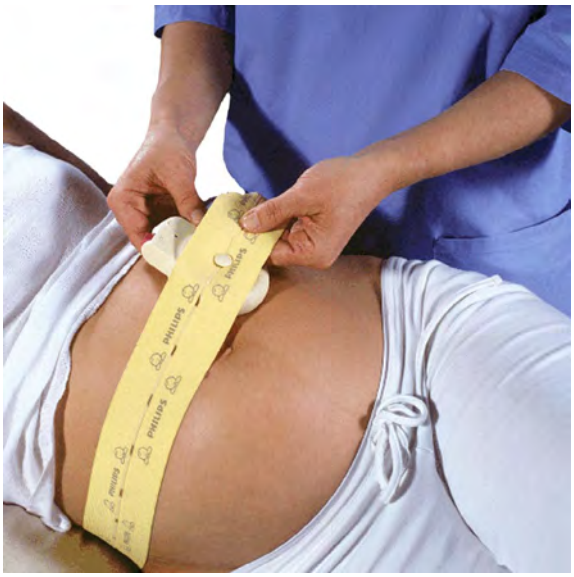
1 Place the transducer belt across the bed, so that the fixing button will face away from the mother when it is fastened.

2 Lie the patient on the bed and arrange the belt around her until it is tight but still comfortable.

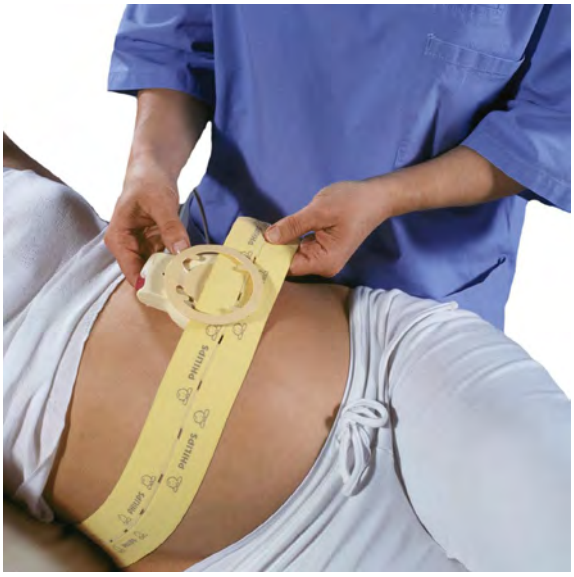
3 Fasten the belt by pushing the fixing button through the overlapping section of the belt. Ensure that the fixing button and the loose ends of the belt are at the patient's side.



4 When you have positioned a transducer satisfactorily, you can attach it to the belt by pushing the belt button on the transducer through one of the holes in the belt.

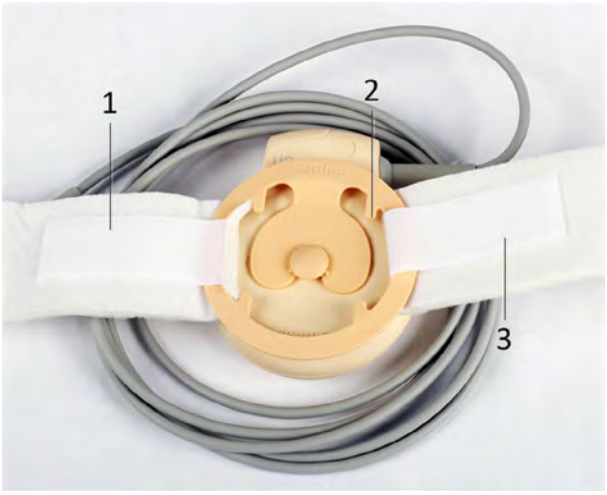


5 Alternatively, attach the butterfly belt clip to the transducer belt button and use this to attach the transducer to the belt. The clip allows you to slide the transducer for easy repositioning.



Using Belt with Velcro Fixings

Insert one end of the belt between the belt guides on one side of the butterfly belt clip, and secure with the velcro fixing. Insert the other end of the belt between the belt guides on the other side of the butterfly belt clip, adjust for the correct tension, then secure with the velcro fixing.



1 Velcro fixing
2 Belt guides
3 Velcro fixing

WARNING

When connecting devices for acquiring measurements, always position cables and NBP tubing carefully to avoid entanglement or potential strangulation.

Repositioning Transducers

A patient possibly wears transducers for long periods without interruption. In rare cases, skin irritations may occur if a transducer is attached to one location for a longer period. To ensure there are no adverse effects on the patient's skin, inspect the transducer application site at least every three hours. If the skin quality changes, move the transducer to another site.

NOTE

At elevated ambient temperatures, the housing temperature of all fetal transducers (M2734A/B, M2735A, M2736A/AA, M2738A, 867245, 867246, 867247, 867248, 867249) may exceed 41°C on the skin. Especially after prolonged application on the same application site, consider inspection of the transducer application site.

The ultrasound transducer is often repositioned to follow the fetal heart as part of the normal monitoring process, but this is not so for the Toco transducer. Therefore, remember to check its application site (between contractions) at least every three hours.

To reduce the risk of skin irritations, do not allow a cleaning or disinfecting agent to remain on the transducer. Follow all instructions that accompany the specific cleaning and disinfecting agents you are using. Remove agent residues with a cloth dampened in water before applying a transducer to a patient.

See "Care and Cleaning" on page 257 for further information, and a list of approved agents.

Connecting a Transducer to the Monitor

1 SpO_2 socket

2 Noninvasive blood pressure socket

3 Fetal sensor sockets

You can plug a fetal transducer, an ECG/IUP patient module, an Avalon CL or Avalon CTS Cableless Fetal Transducer System interface cable (red connector), or an external event marker into any of the four fetal sensor sockets marked by the fetal symbol, or "Fetal Sensors" (depending on geography).

For measuring maternal SpO_2, connect the sensor to the socket marked with the SpO_2 symbol or "SpO_2" (depending on geography).

For maternal noninvasive blood pressure, connect the cuff to the socket marked with the NBP symbol or "NBP" (depending on geography).

For the FM20 and FM30, you can connect an Avalon CL or Avalon CTS Cableless Fetal Transducer system interface cable (red connector) to one of the fetal sensor sockets at the left side of the monitor.

For the FM40 and FM50, you can connect an Avalon CL or Avalon CTS Cableless Fetal Transducer System interface cable (black connector) to one of the two dedicated black sockets marked "Tele" at the rear of the monitor, as an alternative to using one of the fetal sensor sockets (red connector) at the front.

1 Interface cable to Avalon CL and Avalon CTS Cableless Fetal Transducer System.

2 Connect the black connector to one of the two black sockets (marked "Tele") on the rear of the monitor.

What You See on the Monitor

When you connect a transducer or sensor, the measurement numeric appears on the screen.

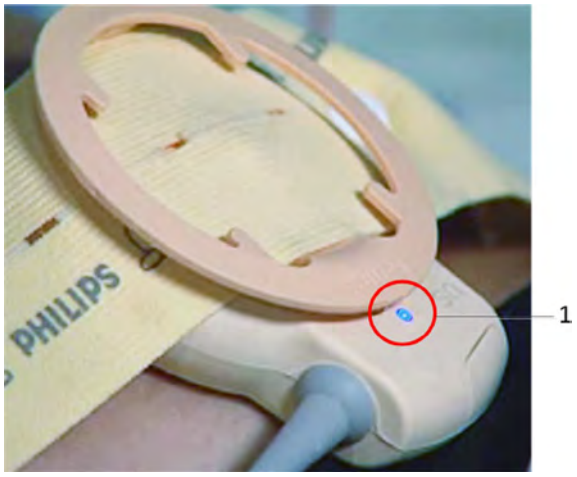
FM20/FM30

FM40/FM50

Fetal heart rate measurements are labeled in the order in which you plug in the transducers for those measurements. It does not matter which fetal sensor socket you use, as the monitor allocates a channel automatically. For instance, when monitoring triplets, the first transducer you connect is automatically allocated a channel, and the measurement is labeled **FHR1**, the second **FHR2**, and the third **FHR3**. See also chapters "Monitoring Twin FHRs" on page 185 and "Monitoring Triple FHRs" on page 191.

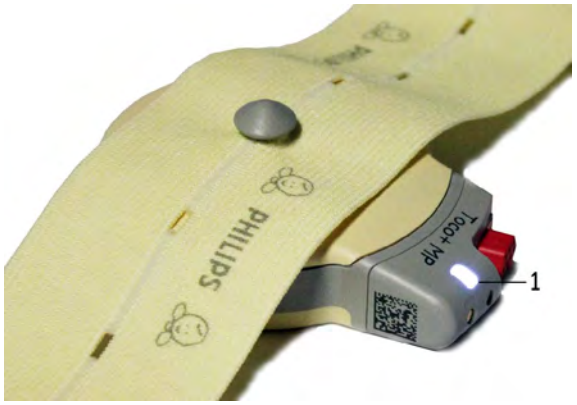
When you touch a measurement numeric on the screen, the setup menu for that measurement opens. The fetal sensor socket to which the transducer for this measurement is connected is identified by the transducer position indicator in the setup menu header.

The blue finder LED on a wired fetal transducer lights up when you touch the measurement on the screen, allowing you to identify the corresponding transducer.



1 finder LED

The white finder LED on a cableless fetal transducer lights up when you touch the measurement on the screen, allowing you to identify the corresponding transducer.



1 finder LED cableless transducer

The recorder prints an annotation showing the date, time, recorder speed, and Monitoring Mode. It repeats this every 10 minutes.

Start Recording

Checking/Setting Paper Scale

You can check the paper **Scale Type** (**US** for U.S., or **Internat'l** for other geographies) in the **Fetal Recorder** menu. In Monitoring Mode, you can see these settings (grayed out), but you cannot change them. They can be changed in Configuration Mode, see the Configuration Guide.

NOTE

Check if the scale type of the paper and the settings in the fetal monitor match.

Paper Guide FM40/FM50

The recorder in the FM40 and FM50 features a transparent paper guide which:

- facilitates correct alignment of the paper, both during loading and while the recorder is running. See "Loading Paper FM40/FM50" on page 65.
- incorporates a tear-off edge, which not only allows you to tear off the trace paper where you like (not necessarily at a fold), but also helps to avoid paper misalignment while doing so (see "Tearing Off the Paper" on page 62).
- is removable (see "Removing the Paper Guide: FM40/FM50" on page 268).

Switching the Recorder On and Off

In addition to the normal recording of real-time traces, you will sometimes see a trace recovery printout from the monitor's internal backup memory at high speed when the recorder is started. For details, see "Recovering Traces on Paper" on page 253.

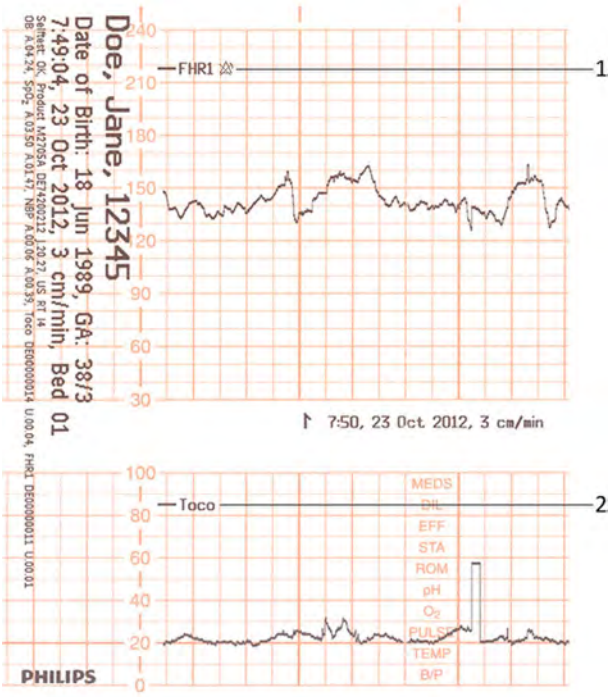
For an explanation of the various symbols that can appear on the trace recording, see "Recorder Specifications" on page 310.

To switch the recorder on, select in **Main Setup** the menu item **Fetal Recorder**, or press one of the SmartKeys: **Start/ Stop** or **Start Recordng**.

The "recorder on" status indicator is displayed in the bottom right-hand corner of the screen when you switch on the recorder.

The paper advances quickly for 2 cm and then returns to the set speed. Whenever the recorder is switched on, a trace header is printed vertically on the trace paper, containing the following:

- **Self-test: OK**: confirmation that the monitor's self-test completed successfully, and that it is ready to use
- the software revision and firmware revision
- the serial number
- the time
- the date
- patient first name, last name, lifetime ID (with the configured label), encounter ID (with the configured label), date of birth, gestational age, and patient bed label
- the recorder speed



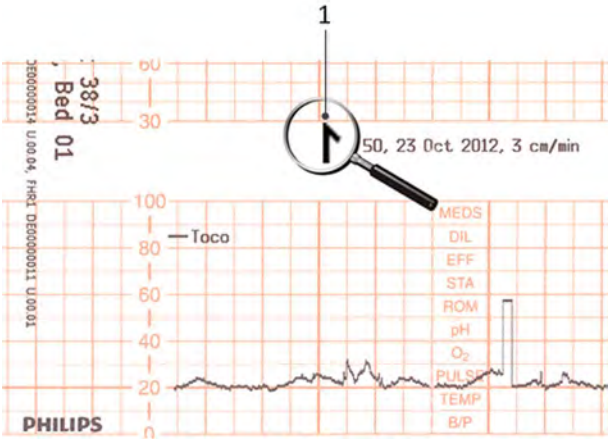
1 Fetal heart rate label

2 Uterine activity label

The current parameter setup information (if any transducers are connected to the monitor) are printed. Whenever a transducer's mode is changed, the following are printed:

- the time
- the date
- trace identification symbols
- the recorder speed

The monitor prints the time, date, recorder speed, and current parameter setup information in the trace header when first switched on, in a periodic time stamp every ten minutes after, and if the monitoring modes change. The time stamp begins with the symbol shown below. The data is reprinted in the header if the time and date are locally adjusted, or if an obstetrical information and surveillance system is connected that readjusts the time and date automatically.



1 The time stamp is printed every ten minutes and every time the measurement parameter setup is changed.

The trace records maternal parameters also. When measuring noninvasive blood pressure, the annotation is made at the end of the measurement. If the noninvasive blood pressure measurement repetition time is short, the noninvasive blood pressure numeric may not always be printed.

The recording of notes (see "Entering Notes" on page 69) or time/date information may be interrupted by connecting, or unplugging a transducer, or by a change in measurement-related setting (for example, artifact suppression, Toco sensitivity, or alarm settings).

A new patient admission or a change to the paper scale setting stops all annotations, and prompts a new vertical trace header to be printed.

To switch off the recorder:

1 *Either* select **Start/Stop** from the **Fetal Recorder** menu.

2 *Or* press one of the SmartKeys (depending on configuration): fetal recorder **Start/ Stop** or **Stop Recordng**.

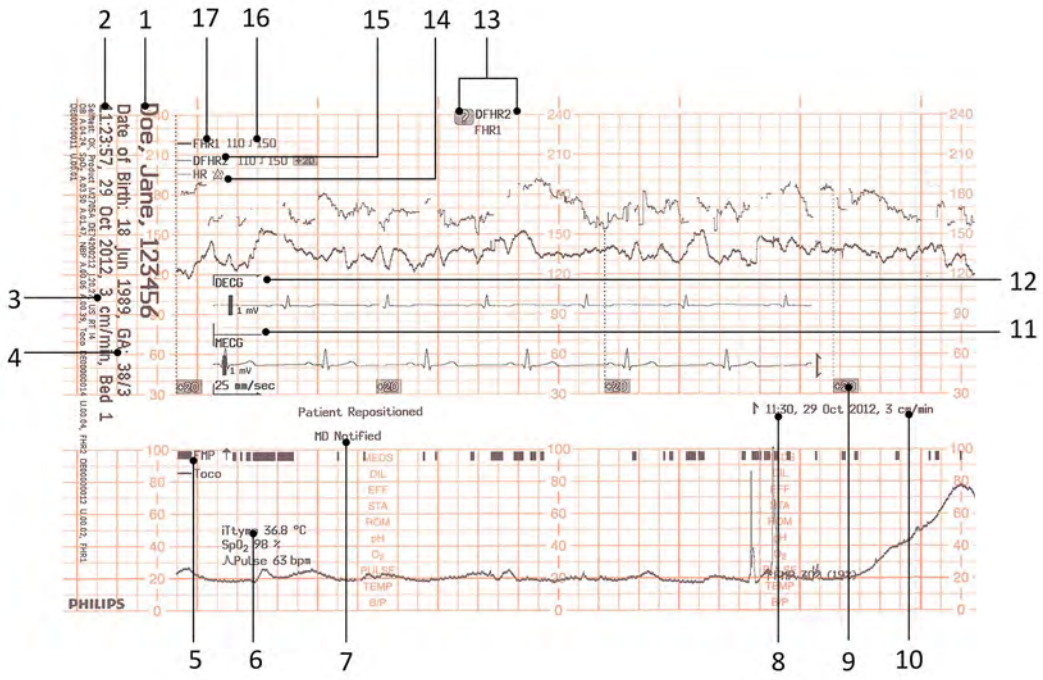
If your recorder is configured with **Confirmed Stop** on (a Configuration Mode setting), you will need to confirm that you want to stop the recorder, before it will stop.

When the recorder is off, the "recorder off" status indicator is displayed in the bottom right-hand corner of the screen: When the **Paper Save Mode** is set to **Off** the paper symbol shows an **x** mark, and when **Paper Save Mode** is **On** the icon shows a paper trace icon.

Recording Elements

A variety of information can appear on the recorder trace. Here is a sample trace with some of the most common elements and their meaning. Each trace header contains the last name and first name, the patient ID, patient date of birth, the current date and time, patient's bed label, and the gestational age of the pregnancy.

Trace example obtained from wired transducers



1 Last name, first name, lifetime ID (with the configured label), encounter ID (with the configured label), date of birth

2 Current date and time

3 Recorder speed

4 Gestational age and patient bed label

5 FMP - Fetal Movement Profile

6 Other measurements for the patient such as temperature, arterial oxygen saturation, and pulse

7 Entered notes such as patient repositioned, or MD notified, or others

8 Time stamp

9 Trace separation

10 Recorder speed

11 Maternal ECG

12 Direct ECG

13 Coincidence of heart rate detected

14 HR with Alarms Off symbol

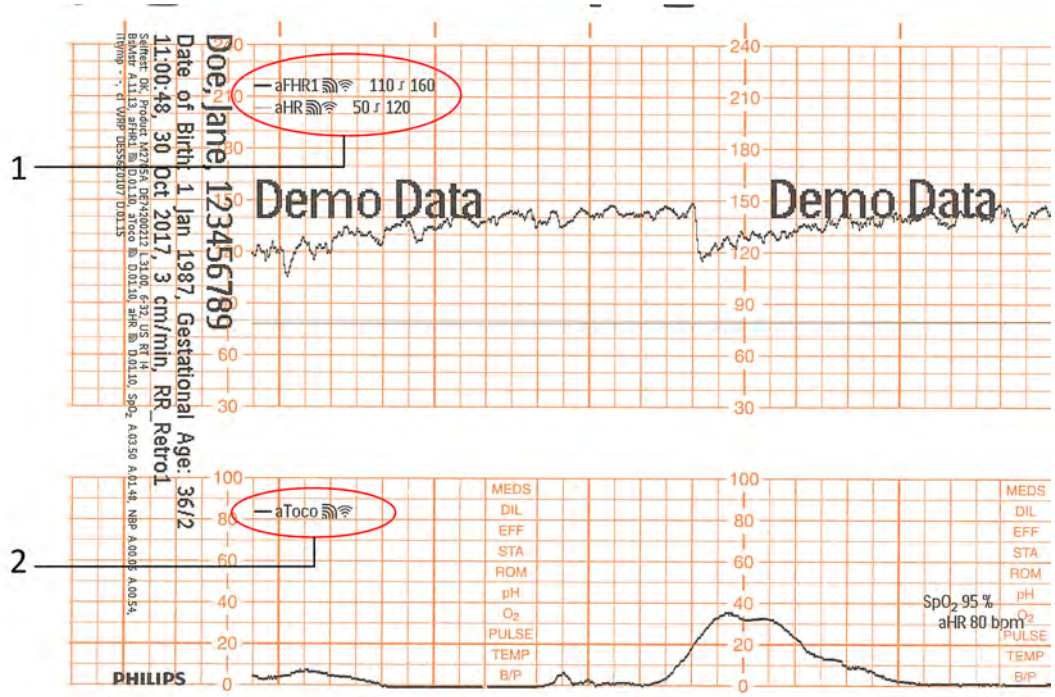
15 dFHR2 (second fetal heart rate from DECG)

16 Alarm Limits

17 FHR1 (first fetal heart rate)

Trace example obtained from the Avalon CL Fetal & Maternal Pod and Patch and CL Wide Range Pod

If the CL Wide Range Pod transfers the data of a CL Pod or a CL transducer via WLAN to the fetal monitor, it is indicated by an additional WLAN symbol next to the parameter label.



1 Fetal and maternal heart rate from the Avalon CL Fetal & Maternal Pod and Patch transferred over the CL Wide Range Pod.

2 aToco measurement from the Avalon CL Fetal & Maternal Pod and Patch transferred over the CL Wide Range Pod.

For a complete list of recording symbols, see "Recorder Symbols" on page 321.

CAUTION

The trace contains sensitive personal data. For information how to protect personal information, see "Protecting Personal Information" on page 19.

Choosing Recorder Speed

You can choose a recorder speed of 1, 2, or 3 centimeters per minute (cm/min). The default setting is 3 cm/min.

The ACOG technical bulletin on FHR monitoring states that "*accurate pattern recognition is difficult if not impossible at 1 cm/min and that 1 cm/min is only recommended for more economic screening. When FHR abnormalities arise, the faster recorder speeds will enhance FHR pattern recognition*".

Additionally, because a change in recorder speed results in a change in the appearance of an FHR trace, you are advised to ensure ALL monitors in your institution are set to the same speed.

To set the recorder speed (in Configuration Mode), see the Configuration Guide.

Advancing the Paper

You can advance the paper automatically to the next fold by pressing the **Paper Advance** SmartKey at any time except during a stored data recording. This is also possible using the **Fetal Recorder** menu.

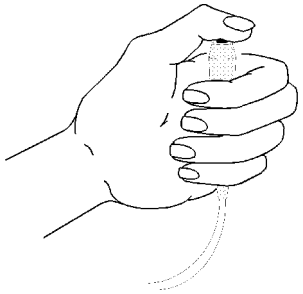
Marking an Event

You can record significant events on the trace paper (for example, when pain medication is administered or when the mother changes position). The mother can use the remote event marker to mark events herself. You connect the remote event marker to any free fetal sensor socket.

To mark an event on the trace paper, you can:

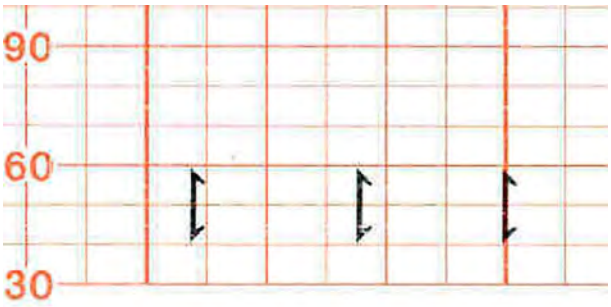
1 Either select the **Set Marker** SmartKey.

2 Or press the button on the optional remote event marker (989803143411). The remote event marker is connected to the monitor via any fetal transducer socket.



A small arrow is printed on the heart rate scale on the trace paper.

This reflects exactly when the marker button was first pressed; keeping the button pressed has no influence on the annotation.



Tearing Off the Paper

CAUTION

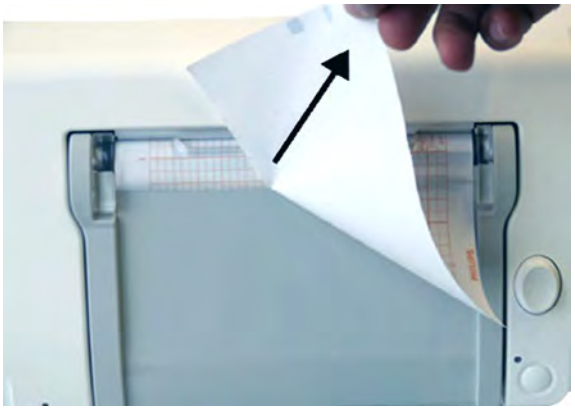
Never pull on the paper to advance it, as this can cause misalignment of the paper. Always tear off the paper along the perforation.

FM40/FM50 The recorder's paper guide incorporates a tear-off edge, allowing you to tear off the trace paper cleanly where you like (not necessarily at a fold). When you are **not** using the paper guide, always tear off the paper along the perforation.

To tear off the trace paper after monitoring **using the paper guide**:

1 If the recorder is running (the "recorder on" status indicator is displayed), turn off the recorder by selecting the fetal recorder **Start/ Stop** SmartKey or the **Stop Recordng** SmartKey.

2 Tear off the paper as shown in the picture. To ensure a clean tear, always tear in an upwards motion, as indicated by the arrows. You can start tearing from the left or right, (right-handed user shown). You may want to use both hands to guarantee that the paper is not misaligned during the tear off.



3 If you wish to tear off the paper at a fold, select the **Paper Advance** SmartKey, wait for the paper to stop, then tear it off.

FM20/FM30 The FM20/FM30 does not have a paper guide. The procedure is the same as described for the FM40/FM50 with the exception that you should advance the paper to a perforation.

If you wish to tear off the paper at a perforation, select the **Paper Advance** SmartKey, wait for the paper to stop, then tear it off.

Paper-Out Indication

Each pack of paper has 150 pages. The monitor issues a paper-out warning in the status line at the bottom of the screen, when there are five pages to go. If you switch on the recorder or press the **Paper Advance** key when there are fewer than five pages remaining, it may take two pages before the alarm is activated. Load a new pack in time.

If the recorder runs out of paper, an audible paper-out alarm is sounded, if so configured. See "Loading Paper FM40/FM50" on page 65, and "Loading Paper FM20/FM30" on page 63 to learn how to reload paper.

Fetal traces continue to be recorded into the monitor's backup memory, and can be retrieved and printed completely if new paper is loaded within one hour, when the **Bridge Paperout** setting is enabled in Configuration Mode. See "Recovering Traces on Paper" on page 253 for further information.

Loading Paper FM20/FM30

CAUTION

Using recorder paper that is not approved by Philips can result in accelerated paper fading and can damage the thermal line printhead. This type of damage is not covered by warranty.

FM20/FM30 To load a pack of paper:

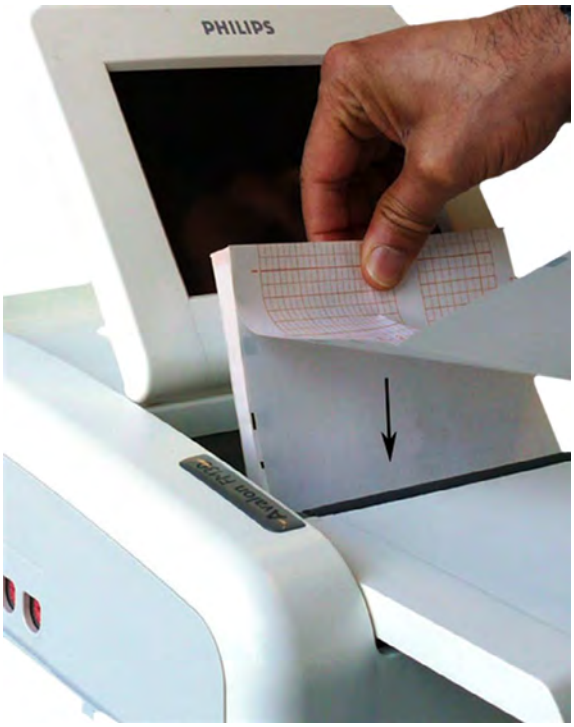
1 If the recorder is on, press the recorder **Start/ Stop** SmartKey or the **Stop Recordng** SmartKey to turn it off before loading a new pack of paper.

2 Press the paper table release to unlock the paper drawer and then pull the table forward to open it fully.

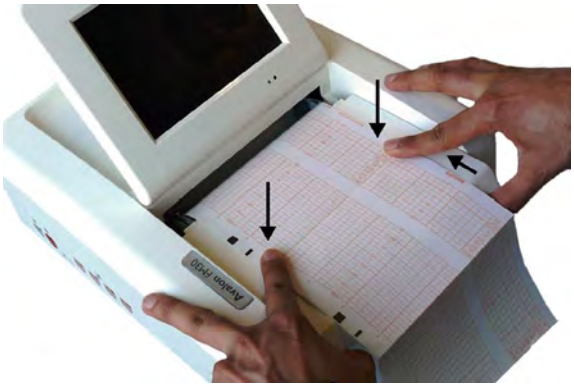
3 Lift out any remaining paper from the tray.

4 Prepare to place the new pack of paper in the tray with the bottom side down. The bottom side is indicated by the word STOP printed on the final page of the new pack.

5 Unfold the top page of the pack and position the uterine activity scale on the right.



6 Slide the pack into the tray.



7 Push the paper drawer back until it "clicks" closed.

8 Press the recorder **Start/ Stop** SmartKey or the **Start Recordng** SmartKey to switch on the recorder.

Annotations of trace information are printed on the trace paper (see "Switching the Recorder On and Off" on page 56 for details).

Loading Paper FM40/FM50

CAUTION

Using recorder paper that is not approved by Philips can result in accelerated paper fading and can damage the thermal line printhead. This type of damage is not covered by warranty.

FM40/FM50 To load a pack of paper:

1 If the recorder is on, press the **Start/ Stop Rec** SmartKey or the **Stop Recordng** SmartKey to turn it off before loading a new pack of paper.

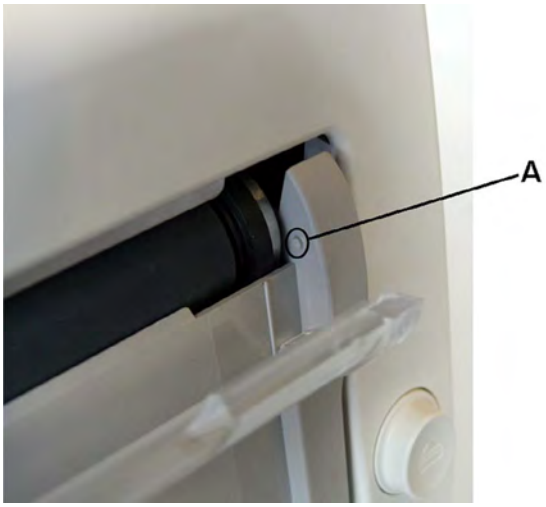
2 Press the paper eject button to open the paper drawer.

3 Lift out any remaining paper from the tray.

4 Press and hold the paper eject button to partially eject the paper, thus making it easier to remove.

5 Hinge the transparent paper guide forward. It is held in the closed position by a small protrusion on each side of the holder.

A - Protrusion holds paper guide in closed position.

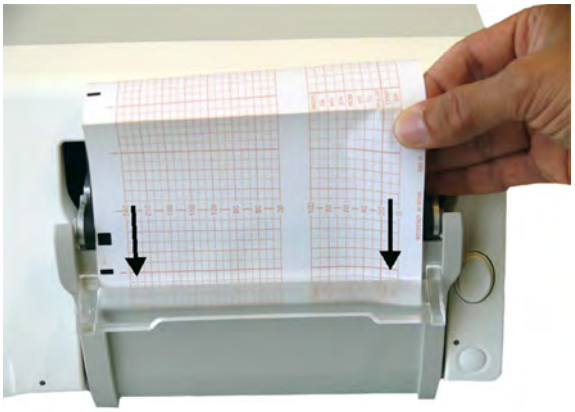


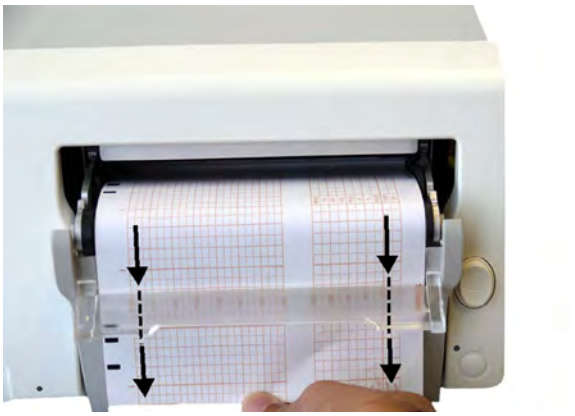
6 Prepare to place the new pack of paper in the tray with the bottom side down. The bottom side is indicated by the word STOP printed on the final page of the new pack.

7 Unfold the top page of the pack and position the uterine activity scale on the right.

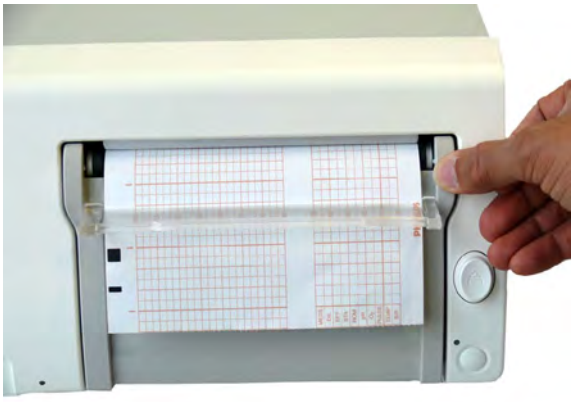
8 Slide the pack into the tray.

9 Feed the paper evenly through the paper guide. Do not close the paper guide yet.

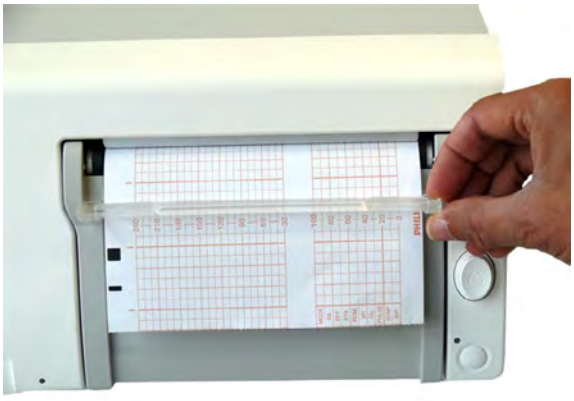


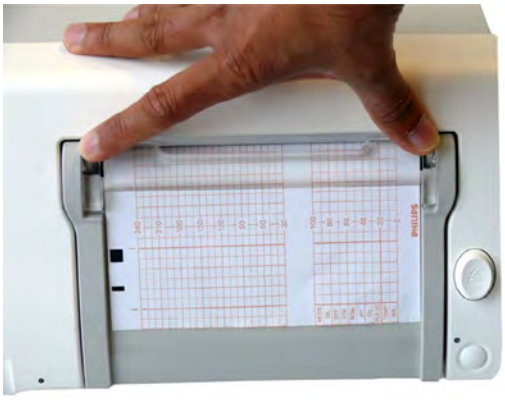


10 Close the paper drawer.



11 Now close the paper guide.





12 Press the recorder **Start/ Stop** SmartKey or the **Start Recordng** SmartKey to switch on the recorder.

Annotations of trace information are printed on the trace paper (see "Switching the Recorder On and Off" on page 56 for details).

Entering Notes

Your monitor has a set of 15 factory pre-configured notes (see below). It is possible to edit these notes in Configuration Mode (see the Configuration Guide). The maximum length of one single note is 30 characters.

To enter a note:

1 Select the **Enter Notes** SmartKey to open the **Enter Note** menu.

2 Scroll if necessary, then select the note you wish to enter. A confirmation dialog box opens:

3 Select **Confirm** to enter the note. The note is then shown in the status line of the display, and is annotated on the fetal trace if the fetal recorder is on.

4 By default, notes are printed lengthwise in the direction of the trace, in the space between the FHR grid and the uterine activity grid. If you prefer, you can configure the recorder to print across the trace. You can change this in Configuration Mode.

The following are the pre-configured notes from which to choose:

1 **Patient Repositioned**

2 **Vaginal Examination**

3 **MD Notified**

4 **Sitting**

5 **On Back**

6 **Left Lateral**

7 **Ambulating**

8 **Tocolytic Given**

9 **Membranes Ruptured**

10 **Amniotomy**

11 **Amniotic Fluid Clear**

12 **Amniotic Fluid Not Clear**

13 **Oxytocin**

14 **Urinary Catheter**

15 **Micro Blood Analysis**

Up to two notes can be printed directly, and the monitor can temporarily store up to a further two notes, and these are printed after the first two have been printed. Any further notes are discarded. For example, if you enter six notes in quick succession, the first two notes you entered are printed right away, the next two are stored in memory and then printed when the first two have been printed, and the last two are discarded.

If the printing of two notes happens to coincide with the regular printing of the time stamp that takes place once every ten minutes, the time stamp is delayed until the notes have finished printing.

Typing Notes

Other than the pre-configured notes selectable in the **Enter Note** menu, a note can be typed in manually.

To type a note:

1 Select the **Enter Notes** SmartKey to open the **Enter Note** menu.

2 Select **Type a note** and a window with a touch keypad opens.

3 Type the note and select **Enter**. The typed note can be up to 30 characters long. The note is shown in the status line of the display, and is annotated on the fetal trace if the fetal recorder is on.

NOTE

The typed note remains in the window until it is deleted by using the backspace/clear key of the keyboard.

Signal Quality

During monitoring, if the fetal heart rate signal quality fluctuates, and becomes poor, it does not necessarily mean that the transducer needs repositioning. The fluctuation may be caused by fetal movement. Allow time for the signal to stabilize before deciding whether to reposition the transducer (ultrasound), or apply a new electrode (ECG). For the best trace quality, the signal quality indicator should be full, indicating good signal quality, even though it may be possible to make traces at a lower signal quality level.

After Monitoring

Wired and cableless transducers

1 Discharge the patient.

2 Remove the transducer from the patient and, using a soft tissue, remove any gel from it. Then clean the transducers.

3 Dock CL transducers to the base station so they can recharge.

4 Tear off the paper at the fold. To avoid misalignment of the recorder mechanism, NEVER pull on the paper to advance it, or try to tear it other than at a fold (unless using the paper guide with the FM40/FM50).

5 Switch off the monitor.

NOTE

If an Avalon CL base station is connected to your FM20/30 monitor, do not turn off the monitor if you need to recharge the batteries of the CL transducers. They can only be recharged if the FM20/30 monitor is on. If an Avalon CL base station is connected to an FM40/50 at the Telemetry ports in the rear, the batteries of the CL transducers can be recharged while the monitor is not switched on. If you disconnect a base station from a fetal monitor when the CL transducers are not fully charged, the base station starts beeping. If you want to still disconnect it, confirm your choice by pressing the Standby key of the base station, and the beeping stops.

Switching the Monitor to the Standby Screen

To switch the monitor to the Standby screen:

Either

1 Select the **Monitor Standby** SmartKey.

Or

1 Enter the **Main Setup** menu using the SmartKey.

2 Select **Monitor Standby**.

3 Pressing any key or selecting any field on the screen will resume monitoring.

Disconnecting from Power

FM20/30

To disconnect the monitor from AC power, switch the monitor off using the On/Off switch located on the right side of the device, or unplug the power cord from the AC mains socket.

FM20/FM30 with Battery Option and FM40/FM50

The On/Standby button does not disconnect the monitor from the AC power source. To disconnect, unplug the power cord from the AC mains socket. Note that if the power cord is unplugged from the AC mains socket before the monitor is put into Standby, a beeper is activated. The beeper warns you if the monitor is accidentally disconnected from AC mains.

External Power Supply for the Avalon CL Base Station

To disconnect, unplug the power supply from the AC mains socket. Note that if the power supply is unplugged from the AC mains socket before all CL devices are fully charged, a beep is issued. To confirm the disconnection from power, and to silence the beep, press the On/Standby button of the CL base station.

Power On/Power Off Behavior

The general rules determining the behavior of the fetal monitors when connected to, or disconnected from power are as follows:

- A fetal monitor that was switched on prior to a temporary power loss, switches on again when power is restored.
- A fetal monitor that was switched off prior to a temporary power loss, remains off when power is restored.
- When AC mains power is lost, a battery powered monitor (FM20/30) continues to run without interruption on battery power.

Monitoring After a Power Failure

- A fetal monitor that was switched on prior to a temporary power loss, switches on again when power is restored.
- A fetal monitor that was switched off prior to a temporary power loss, remains off when power is restored.
- If the fetal monitor is without power for less than one minute, monitoring will resume with all active settings unchanged.

- If the fetal monitor is without power for more than one minute, the behavior depends on your configuration.
  - If **Automat. Default** is set to **Yes**, the default profile will be loaded when power is restored.
  - If **Automat. Default** is set to **No**, all active settings are retained, if power is restored within 48 hours. The **Automat. Default** setting is made in Configuration Mode.

Troubleshooting

Problem	Possible Causes	Solutions
Light or no trace	Wrong paper	Use recommended paper
	Dirty printhead	Clean printhead, see "Cleaning the Print Head" on page 272
	FM20/30 only: Paper misaligned due to drawer not being correctly shut	Shut the drawer fully, pushing evenly with both hands
End of paper noted when pack not finished	Bad paper feed or wrong paper	Check paper feed and use recommended paper
Check Paper INOP is displayed	INOP messages always indicate equipment problems	See "Patient Alarms and INOPs" on page 127
FetRec Equip Malf INOP is displayed		
Paper End INOP is displayed		
Wrong Paper Scale INOP is displayed		

4

Cableless Monitoring

Avalon CL Transducer System

The Avalon CL Fetal Transducer System lets you monitor the patient continuously with cableless transducers during the antepartum period, labor, and delivery.

You can monitor the fetal heart rate (FHR):

- Noninvasively, using the CL Ultrasound transducers
- Noninvasively, using the CL F&M Pod
- Invasively, using the CL ECG/IUP transducer or CL Toco^{+} MP transducer with a fetal scalp electrode

You can monitor the uterine activity:

- Noninvasively, using the CL Toco^{+} MP transducer
- Noninvasively, using the CL F&M Pod
- Invasively, using the CL ECG/IUP transducer or CL Toco^{+} MP with an IUP catheter

NOTE

The Avalon CL Fetal & Maternal Pod and Patch are not available for the U.S., other FDA regulated territories, and Canada.

The fetal and maternal parameters are measured and transmitted via radio frequency from the CL transducers and CL Pods to the CL base station, eliminating the need for patient cables. With the Avalon CL Transducer System, you can monitor a single fetus, twins, and triplets.

The Avalon fetal monitor (FM20-FM50) connected to the CL base station displays and records the parameters. All the CL transducers and the CL F&M Pod are watertight. The IntelliVue CL Pods should not be immersed in water. You can continuously monitor patients in a bath or shower using the CL Toco^{+} MP and the CL Ultrasound transducers, the CL F&M Pod should not be used during a bath.

Basics of Cableless Systems

Avalon CL Transducer System	Avalon CTS Transducer System
	

Assigning Cableless Devices

The cableless devices of the Avalon CL are assigned by simply docking them at the base station connected to the patient's fetal monitor. See the Avalon CTS Instructions for Use for the assignment of the CTS transducers.

Activating Cableless Devices

The CL devices of the Avalon CL are activated by picking them up from the base station. If the CL devices are activated, a corresponding symbol is displayed on the fetal monitor screen next to the numeric of the measurement. See the Avalon CTS Instructions for Use for the activation of the CTS transducers.

Deactivating Cableless Devices

The CL devices of the Avalon CL are deactivated by redocking them at a base station. To deactivate all cableless devices at once, press the Standby key of the Avalon CL base station. See the Avalon CTS Instructions for Use for the deactivation of the CTS transducers.

Unassigning Cableless Devices

The CL devices of the Avalon CL are unassigned by manually removing them in the corresponding setup menu from the group of assigned cableless devices, or by unassigning them directly in the **Tele Info** window. See the Avalon CTS Instructions for Use for the unassignment of the CTS transducers.

Twins and Triplets Support

Twins and Triplets	Singletons only
Avalon CL Transducer System and CL transducers	Avalon CTS System
	Avalon CL Transducer System with CL Fetal & Maternal Pod

Configuration of Cableless Systems

You have to configure the radio channels of the Avalon CL and Avalon CTS transducer system for communication to work, and not to interfere with any other telemetry devices.

The configuration of a connected Avalon CL system is done in Configuration Mode or Service Mode of the fetal monitor. Service Mode functions can be used to identify channel assignment conflicts in the hospital environment. The configuration should be carried out by authorized and qualified service personnel, either by the hospital's biomedical department, or by Philips Support.

For a detailed description of the configuration see the Avalon CL Service Guide and the Fetal Monitor Configuration Guide. For details regarding the configuration of a connected Avalon CTS system see the Avalon CTS Service Guide.

Fetal Movement Profile

When using an Avalon CL or Avalon CTS you should be aware that monitoring FMP is not recommended when the mother is likely to move, and you should disable Fetal Movement Profile (FMP) on the fetal monitor (**Fetal Movement Off**) if the mother is walking. Maternal movements are likely to create artifact in the FMP output. See also "Switching FMP On and Off" on page 175, the sections "Cableless Monitoring - Important Considerations" on page 171, and "Fetal Movement Profile" on page 173.

Getting to Know Your Avalon CL

Front

1 Transducer docking slots

2 On/Standby button with LED

3 Device label

4 LED for optional cableless Pods

5 Docking slot for cableless Pods

WARNING

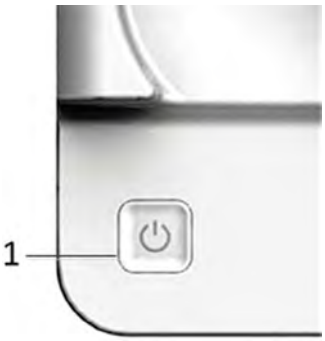
- To avoid magnetic interference affecting the mode of the pacemaker, ensure that the Avalon CL base station does not come into close contact with implanted pacemakers.
- This equipment generates, uses, and radiates radio-frequency energy, and if it is not installed and used in accordance with its accompanying documentation, may cause interference to radio communications. Operation of this equipment in a residential area may cause interference, in which case you must take whatever measures may be required to correct the interference.

Docking Slots for Cableless Transducers

The Avalon CL base station has three docking slots to hold the CL transducers. The transducers are charged while docked. The base station has a built-in radio interface with an integrated antenna to communicate with the transducers.

On/Standby Button

Pressing the On/Standby button switches the Avalon CL base station between the two modes On and Standby.



1 On/Standby button

If you switch the base station to **On**, the LED button lights up green. The base station is ready for use. When the transducers are picked up from their docking slot, the base station sets up the radio communication to the CL transducer automatically. Wired transducers connected to the fetal monitor are disabled, and the antenna symbol for the CL transducer is displayed on the screen of the fetal monitor.

NOTE

The wired event marker is supported when cableless transducers are active.

If you switch the base station to **Standby**, the LED button turns off. The base station is now in Standby mode. No radio communication occurs, any existing radio communication is stopped.

If the LED of the On/Standby button turns red, it indicates a technical problem has occurred that needs your attention. Check your monitor for a possible related INOP message.

Docking Slot for Cableless Measurement Pods

The Avalon CL base station has one docking slot to hold a CL F&M Pod or an IntelliVue CL Pod. The CL Pod is charged while docked. The LED under the docking slot indicates the battery status of the CL Pod. The base station has a built-in short range radio interface with an integrated antenna to communicate with the CL Pod.

1 Docking slot for CL Pods

WARNING

Short range radio connections are subject to interruption due to interference from other radio sources in the vicinity, including microwaves, bluetooth devices, WLAN devices (802.11b,g,n), and cordless phones. Depending on the strength and duration of the interference, the interruption may occur for an extended period. A loss of connection, due to moving out-of-range, interference, or for other reasons, is indicated with a **No Host Monitoring** INOP (here the host is the fetal monitor) on the NBP or SpO_2 Pods, or a **cl NBP Disconnect** or **cl SpO₂ Disconnect** INOP at the fetal monitor. Correct channel configuration is important, see the Configuration Guide for details.

Audio Signal CL Base Station

The Avalon CL base station has two audio signals:

- If the base station issues a descending tone sequence, the attempt to set up radio communication to a CL transducer or CL Pod has failed.
- The base station issues a permanent beeping tone if it is disconnected from a fetal monitor, or if the FM20 or FM30 monitor is switched off, and the base station has transducers or a Pod currently docked that need to be recharged.

Alarming is only available at the Avalon Fetal Monitor, not at the Cableless Measurement Devices, see the Instructions of Use for the IntelliVue Cableless Measurements.

Rear and Bottom

1 Name plate

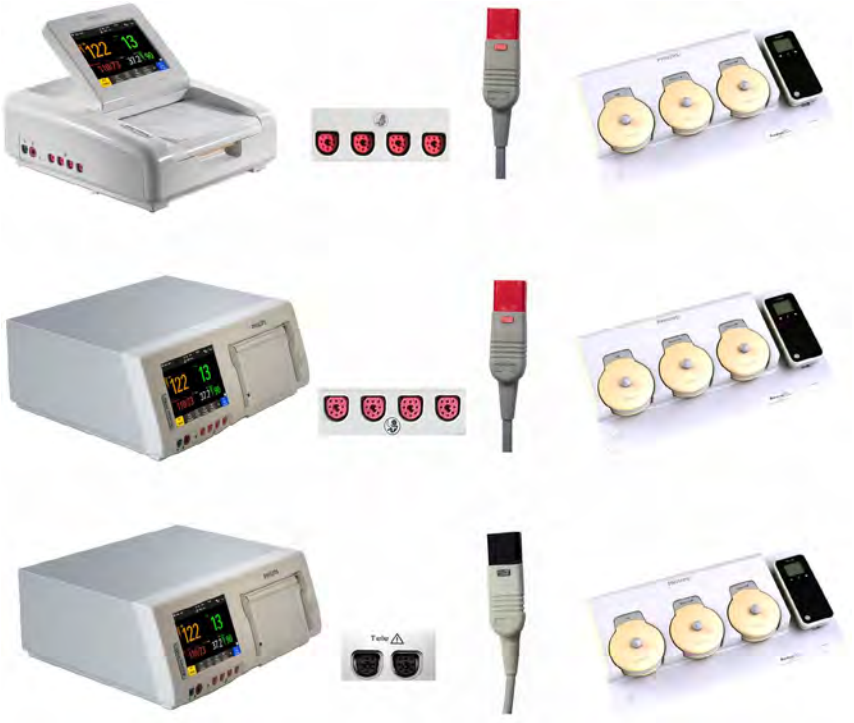
1 Manufacturer label

2 Cable reel

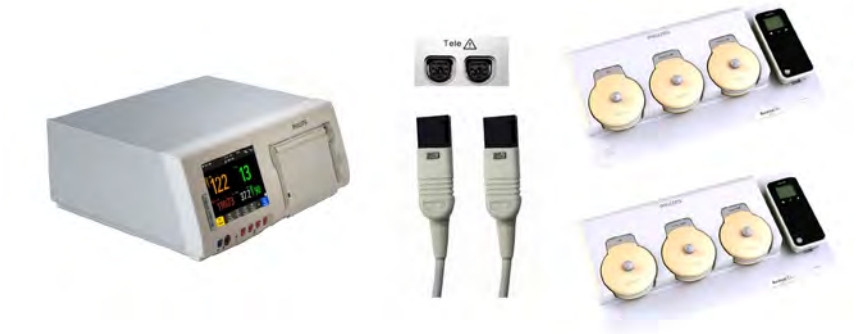
Connection Options

The fetal monitors FM20/FM30 and FM40/FM50 are compatible with the Avalon CL and Avalon CTS Transducer Systems. Regard the following points for cableless monitoring:

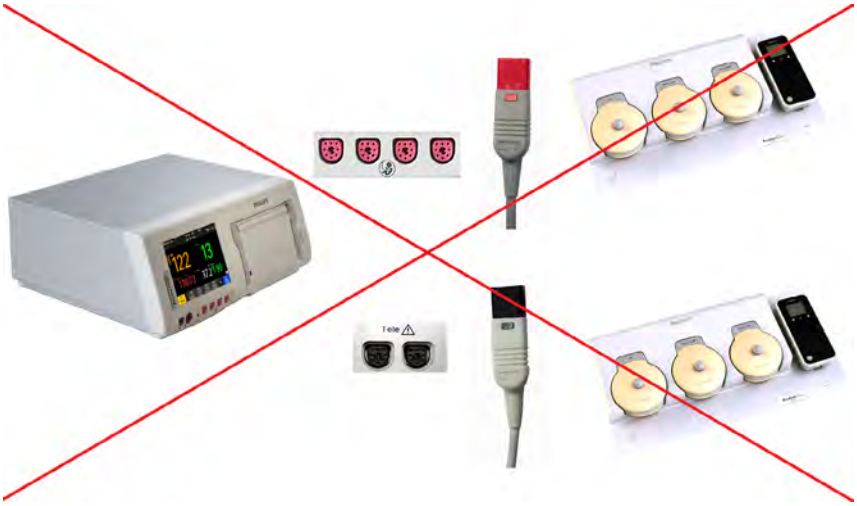
- You can connect one Avalon CL base station with a red connector to an FM20/FM30 or an FM40/FM50 (fetal socket), or one Avalon CL base station with a black connector to an FM40/FM50 (telemetry socket).



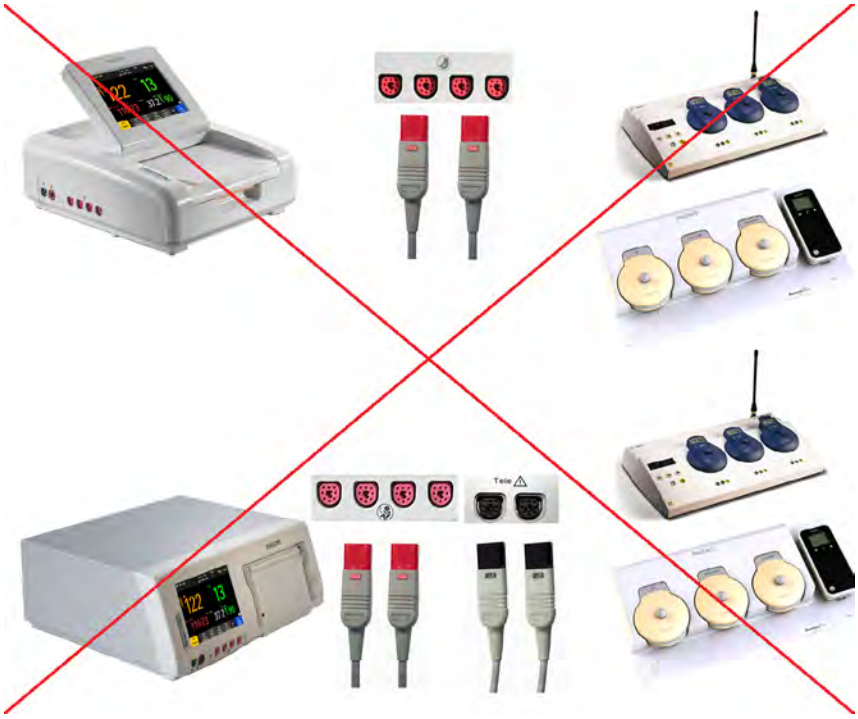
- You can connect two Avalon CL base stations with black connectors to an FM40/FM50 (telemetry sockets)



- You **cannot** connect two Avalon CL base stations to an FM40/FM50, if one Avalon CL base station has a red connector, and the other Avalon CL base station has a black connector.



- You **cannot** connect an Avalon CTS and an Avalon CL at the same time to the same fetal monitor.



- Monitoring a multiple pregnancy using cableless transducers is supported by the Avalon CL system only.
- Using a mixture of wired and cableless fetal transducers is not supported. You can use *either* wired *or* cableless fetal transducers.

NOTE

The wired event marker is supported when cableless transducers are active.

Connecting Two CL Base Stations to an FM40/50 Monitor

Two base stations can be connected to an FM40/50 fetal monitor at the rear black telemetry ports. At both base stations CL transducers and CL Pods can be assigned, activated, and redocked for charging. The base stations work as one extended system together. Pressing the Standby key of either base station, puts both base stations in Standby mode. The **Tele Info** window shows both base stations in operation.

External Power Supply (Option K60)

In combination with the optional external AC power supply an Avalon CL base station serves only as a charging station for Avalon CL transducers and IntelliVue CL Pods, and all radio communications are disabled. The On/Standby button of the base station lights up white in this operation mode. The charging indication of the LEDs of the docked CL transducers and the IntelliVue CL Pods remain the same as described in the sections "Cableless Transducer LED Indication" on page 82 and "Battery Status LED for CL Pods" on page 90.

When a transducer is picked up from the base station after charging, it needs to be activated for monitoring by docking it on a CL base station connected to the patient's fetal monitor.

Cableless Transducers

The cableless Avalon CL transducers have a built-in radio interface with an on-board, integrated antenna. The fetal monitor connected to the Avalon CL base station can control the transducer using radio communication. The CL transducer transmits measured values, alarms, and status information to the fetal monitor.

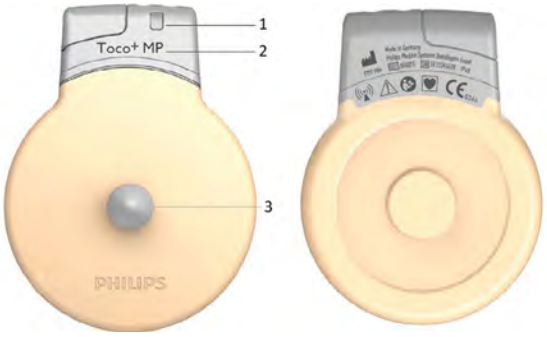
The CL transducers are assigned by simply docking them at the Avalon CL base station. If they are picked up from their docking slot at the base station, they are automatically activated.

CAUTION

To ensure the correct assignment of CL transducers to the fetal monitor in use, always dock them at the base station connected to that fetal monitor before use. This is particularly important when you add an additional CL transducer that was previously docked at another base station.

NOTE

Avoid dropping the transducers.



1. Transducer finder LED - lights up on the transducer providing the measurement source.
2. CL Toco^{+} MP transducers (capable of providing the maternal pulse measurement)
3. Belt button

CL Ultrasound transducer

CL ECG/IUP transducer

Connector Cap for the CL Toco+ MP Transducer

The CL Toco^{+} MP transducer is delivered with a connector cap covering the MECG/DECG/IUP connector. The connector cap is designed to cover the connector, not to protect it from water. (The connector itself is water-proof and may be immersed in water).

Cableless Transducer LED Indication

The cableless transducers have a multi-color LED that indicates the status of the transducer with specific colors. This LED remains visible when the transducer is correctly attached to the transducer belt (Philips standard belt).

1 LED

LED Status	Meaning
White	The LED lights up to identify the transducer among other transducers, and to easily verify the correct transducer assignment (transducer finder). The transducer finder LED is controlled by the fetal monitor. Press the numerics to identify the corresponding transducer. The LED also lights up when the mother is paged with the **Call Patient** SmartKey.
White one short blink	The LED shortly lights up to indicate that the transducer successfully opened a radio communication with the base station and that it is ready to use.
Green	The LED lights up green when the transducer is fully charged and docked at the base station.
Yellow	The LED lights up yellow when the transducer is charging and docked at the base station.
Red	The LED flashes red when the transducer is out of battery and has to be recharged. When a docked transducer performs an update, the LED will blink fast red for about 1 minute. In this case, do not remove the transducer until the LED lights up green or yellow again.
Cyan	The LED lights up cyan to indicate a technical problem that needs your attention. Check your fetal monitor for a related INOP.

Audio Signal CL Transducers

The Avalon CL transducers have three audio signals:

- If an ascending tone sequence is played three times, the transducer was triggered by the fetal monitor to page the patient wearing it, or to locate a not docked transducer.
- If the CL transducer's battery is empty, the transducer issues three beeps in intervals.
- An INOP tone indicates that the transducer has detected a technical problem (INOP). Check your fetal monitor for a related INOP message.

Standard Radio Range of CL Transducers

The CL transducers have an operating range around the base station of at least 100 m/300 ft in the line of sight. Obstructions such as walls, metal doors, elevators, and other environment structures can lead to signal loss. The CL symbol indicator and the **Tele Info** window on the monitor's display (see "Screen Elements" on page 40 and "Tele Info Window" on page 90) provide information on the status of the signal strength.

When a patient is approaching the end of range, the US sound is replaced by an artificial QRS sound (like DECG), and the DECG and MECG waves are no longer displayed on the monitor.

Out of Range

If the patient walks out-of-range, the CL transducer LED lights up cyan and every 16 seconds a two-tone audio signal is emitted. At the monitor the INOP e.g. **cl US Disconnect** is issued. Inform the patient to return to the CL base station, when a CL transducer starts beeping.

Radiated Transmission Power

The Avalon CL transducers provide all the benefits and flexibility of cableless operation, but do so with an effective radiated transmission power significantly less than that of a typical remote controlled child's toy or mobile phone.

Extended Range Radio

Using the optional CL Wide Range Pod extends the radio range of the CL transducers and the CL Pods to the local WLAN infrastructure. If the CL Wide Range Pod is active, the US sound is replaced by an artificial QRS sound (like DECG), and the DECG and MECG waves are no longer displayed on the fetal monitor. Numerics, alarms, and traces are shown at the fetal monitor as usual. See also "CL Wide Range Pod" on page 88.

WARNING

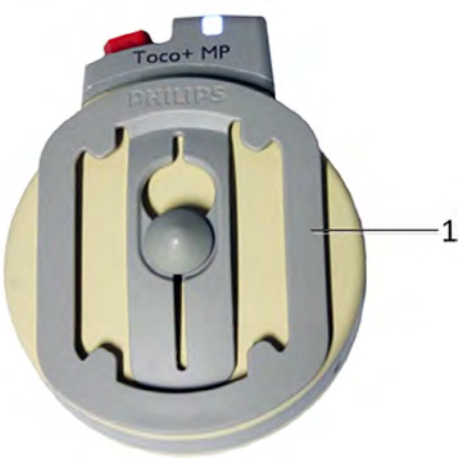
The Avalon CL Wide Range Pod uses a WLAN connection to extend the operating range of CL transducers and CL Pods. The Avalon CL Wide Range Pod sends real-time patient data to the fetal monitor. The fetal monitor displays real-time patient data, provides alarms, data storage, and clinical decision support applications. The data is also transmitted to a connected obstetrical surveillance system. Using a WLAN connection may lead to network drop-outs resulting in the data loss of monitored vital signs. Do not use the Avalon CL Wide Range Pod with patients for whom a momentary loss of vital sign monitoring is not acceptable.

In case of frequent or prolonged network drop-outs (indicated by "Disconnect" INOPs at the fetal monitor and at the CL transducers or CL Pods):

- revert to the use of CL devices without the CL Wide Range Pod,
- restrict the patient to a reduced range around the Avalon CL base station,
- and inform your service personnel.

Using CL Transducers with a Belt Clip

The Avalon CL transducers can also be used with an optional belt clip to be ordered separately (989803184851).



1 Avalon CL belt clip

CL Pods

CL Fetal & Maternal Pod

The CL F&M Pod transmits measurement values for FHR, Toco, and maternal HR to the Avalon CL base station and the connected fetal monitor using short range radio (SRR).

The CL F&M Pod is assigned by docking it at the Avalon CL base station. Before monitoring, the CL F&M Pod is mounted on a single-use electrode patch, the CL Fetal & Maternal Patch, and held in place by integrated magnets. When the CL F&M Pod is active, the wired transducers connected to the fetal monitor are disabled, except the wired event marker is still supported.

CL F&M Pod

CL F&M patch

WARNING

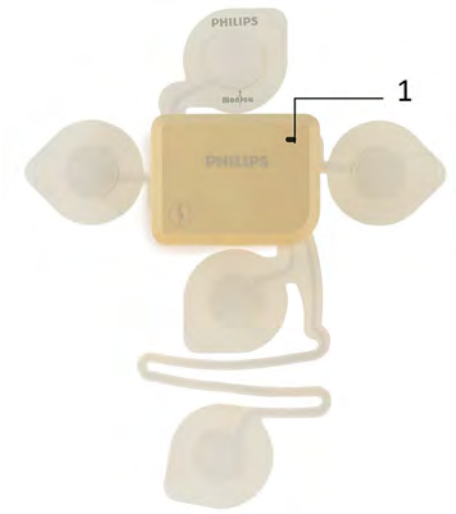
The CL Fetal & Maternal Pod has been validated with a gestational age of >36 completed weeks with patients in labor. The Avalon CL Fetal & Maternal Pod is used for women who are in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen. If the measurement signals are not good or in any way suspicious, use other means of monitoring (CL transducers or wired transducers).

NOTE

The Avalon CL Fetal & Maternal Pod and Patch are not available for the U.S., other FDA regulated territories, and Canada.

CL Fetal & Maternal Pod LED Indication

The CL F&M Pod has a multi-color LED that indicates the status of the CL F&M Pod with specific colors.



1 LED

LED Status	Meaning
White	The LED lights up to identify the CL Pod, and to easily verify the correct assignment (finder). The finder LED is controlled by the fetal monitor. Select the numerics to identify the corresponding CL Pod. The LED also lights up when the mother is paged with the **Call Patient** SmartKey.
White, one short blink	The LED briefly lights up to indicate that the CL Pod successfully opened a radio communication with the base station and that it is ready to use.
Green	The LED lights up green when the CL Pod is fully charged and docked at the base station.
Yellow	The LED lights up yellow when the CL Pod is charging and docked at the base station.
Red	The LED flashes red when the CL Pod's battery is empty, and has to be recharged.
Cyan	The LED lights up cyan to indicate a technical problem that needs your attention. Check your fetal monitor for a related INOP.

Audio Signal CL Fetal & Maternal Pod

The Avalon CL F&M Pod has three audio signals:

- If an ascending tone sequence is played three times, the CL F&M Pod was triggered by the fetal monitor to page the patient wearing it, or to locate a not docked CL F&M Pod.
- If three beeps are issued at intervals, the CL F&M Pod's battery is empty.
- An INOP tone indicates that the CL F&M Pod has detected a technical problem (INOP). Check your fetal monitor for a related INOP message.

CL Fetal & Maternal Patch

The single-use disposable adhesive electrode patch holds the CL F&M Pod at the intended application site on the abdomen of the patient. The electrode patch has five adhesive electrodes. The CL F&M Pod is held in place during monitoring with magnetic contacts, and a connector. The electrode patch and the CL F&M Pod can only be used together and within the Avalon Cableless Transducer System solution for monitoring.

CAUTION

The electrode patch is single-patient use only, do not reuse the electrode patch on another patient to avoid possible cross-infection.

CL Wide Range Pod

The Avalon CL Wide Range Pod is a battery-powered auxiliary network device that converts the SRR and OB radio technology of Avalon CL transducers and the CL Pods into WLAN technology. This allows data from the measurement devices to be transmitted to a fetal monitor while the patient is ambulating.

The Avalon CL Wide Range Pod is a mobile device which can be worn by the patient or by an attending caregiver. The display on the CL Wide Range Pod shows only technical data that may be useful for troubleshooting system problems. The Avalon CL Wide Range Pod is assigned by docking it at the Avalon CL base station. See also "Understanding the Display" on page 101.

CL Wide Range Pod

Working with IntelliSpace Perinatal

When the fetal monitor is connected via LAN to IntelliSpace Perinatal K.00.1x or higher, the CL Wide Range Pod's current WLAN connection status and location is displayed with an icon in the Patient Panel of the application.

IntelliVue CL Pods

The two IntelliVue CL Pods provide measurement values for SpO_2 and NBP on the built-in display, and communicate them to the fetal monitor using short range radio (SRR). They are controlled with SRR from the Avalon CL base station and the connected fetal monitor.

The maternal measurement pods are assigned by docking them at the Avalon CL base station.

CL NBP Pod

CL SpO_2 Pod

The CL SpO_2 Pod and the CL NBP Pod have a display and three keys for basic operation e.g. to assign the device to a patient:

1 Integrated display

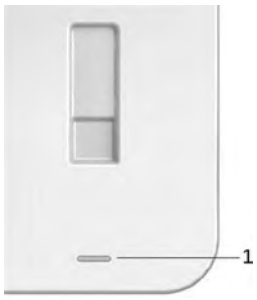
2 Hardkeys

3 Measurement identifier

For further details, see the IntelliVue Cableless Measurements Instructions for Use.

Battery Status LED for CL Pods

The CL Pods do not have their own battery status LED, but a small battery gauge on their display. On the Avalon CL base station, the battery status LED for the CL Pods is located directly under the docking slot.



1 Battery status LED for CL Pods

The battery status LED shows five different states:

Status	Meaning
Green	The docked CL Pod is fully charged.
Yellow	The docked CL Pod is charging.
Yellow blinking	The communication is established with the docked CL Pod.
Cyan	Indicates that the docked CL Pod or the charging slot has a technical problem that needs your attention. Check your fetal monitor for a related INOP message.
Off	The battery status LED is off, when no CL Pod is docked.

Audio and Visual Signals CL Pods

The CL Pods have audio and visual signals:

- If a CL Pod's battery is empty, the CL Pod issues three beeps at intervals.
- If an ascending tone sequence is played three times and the backlight of the display lights up, the CL Pods were triggered by the fetal monitor to page the patient wearing them, or to locate a not docked CL Pod.

Telemetry

Tele Info Window

The **Tele Info** window of the fetal monitors allows you to manage the Avalon CL or CTS system. Below is an exemplary view of the **Tele Info** window. Your window may differ depending on the status of the connected system.

To open the **Tele Info** window, you can:

1. Configure a **Tele Info** SmartKey to open the window,
2. select the **CL** symbol on the main screen, or
3. select the **Main Setup** and then **Tele Info**.

1 CL transducer symbol assigned with the parameter labels

2 Cableless measurement symbol and equipment ID

3 Base station symbol with docking indication (the white slot indicates a charging transducer)

4 Key **Remove**

5 Key **Find**

6 Key **Battery Report** (in Service Mode)

7 **CL** symbol

8 Remaining battery time

9 Out of battery symbol

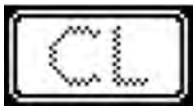
10 Indication of radio signal quality

Cableless Status Indication

When the monitor recognizes a connected Avalon CL or Avalon CTS interface cable (red or black connector), it confirms the recognition with the following status indicators displayed in the lower right-hand corner of the screen:

Avalon CL

Indicator	Description
	A base station is connected to the monitor, but the base station is in Standby mode.
	A base station is connected to the monitor, but the base station is in Standby mode. The CL Wide Range Pod is activated and trying to connect to the monitor.
	A base station is connected to the monitor, but the base station is in Standby mode. The CL Wide Range Pod is activated and connected to the monitor.

Indicator	Description
	A base station is connected to the monitor but no cableless transducers and no cableless Pods are currently active. All are still docked at the base station, or the base station holds no transducers.
	A base station is connected to the monitor but no cableless transducers and no cableless Pods (except the CL Wide Range Pod) are currently active. All are still docked at the base station, or the base station holds no transducers. The CL Wide Range Pod is activated and trying to connect to the monitor.
	A base station is connected to the monitor but no cableless transducers and no cableless Pods (except the CL Wide Range Pod) are currently active. All are still docked at the base station, or the base station holds no transducers. The CL Wide Range Pod is activated and connected to the monitor.
	A base station is connected to the monitor, it is on, and minimum one assigned cableless transducer or cableless Pod is active.
	A base station is connected to the monitor, it is on, and minimum one assigned cableless transducer or cableless Pod is active. The CL Wide Range Pod is activated and trying to connect to the monitor.
	A base station is connected to the monitor, it is on, and minimum one assigned cableless transducer or cableless Pod is active. The CL Wide Range Pod is activated and connected to the monitor.
	A CL transducer has moved away from the base station and is approaching the limit of the area of reach (min. 100 m/300 ft in line of sight). The US sound is replaced by an artificial QRS sound (like DECG). The DECG and MECG waves are no longer displayed.
	A CL transducer has moved away from the base station and is approaching the limit of the area of reach (min. 100 m/300 ft in line of sight). The CL Wide Range Pod is activated and trying to connect to the monitor.

NOTE

A CL transducer is considered still active, even if it has an INOP condition (e.g. **cl US Disconnect**), until it is either deactivated by docking it at the base station, or until it is manually removed from the **Tele Info** window.

Avalon CTS

Indicator	Description
	Avalon CTS interface cable is connected to the monitor, but the Avalon CTS base station is not connected to the interface cable, or it is disconnected from AC mains, or is in Standby mode.

Indicator	Description
	Avalon CTS interface cable is connected to the monitor, Avalon CTS base station is connected, powered on, and cableless transducers are ready to use, but no cableless transducers are currently active (all are still docked at the base station).
	Avalon CTS interface cable is connected to the monitor, Avalon CTS base station is connected, powered on, and at least one cableless transducer is active and assigned.

Pop-up Keys

Pop-Up key	Function
Remove	Selecting the **Remove** key deactivates and unassigns the selected active transducer or CL Pod and removes it from the list. This key is disabled if no active device is selected.
Find	Selecting the **Find** key pages the selected active CL transducer or CL Pod. This key is disabled if no active device is selected, or if the selected device is currently out of range.

Messages

The fetal monitor issues messages to certain user interactions. For example, if the CL SpO_2 Pod is picked up from the base station to activate it, the monitor displays the message **cl SpO_2 Added** and the equipment label of the CL Pod.

Use Priority When Combining Cableless and Wired Measurements

CL Transducers versus wired transducers

CL transducers have priority over wired transducers. If an Avalon CL or Avalon CTS base station is connected to the fetal monitor, and both wired and CL transducers are connected to the monitor, all the wired transducers are disabled whenever one CL transducer is active. A wired connected event marker remains active. To switch back to using wired transducers, switch the base station to Standby mode, or redock all CL transducers at the base station, and continue monitoring with the wired transducers.

CL NBP and CL SpO_2 versus fetal monitor built-in NBP and SpO_2 measurements

CL NBP and CL SpO_2 have priority over the built-in NBP and SpO_2 measurements. If a CL NBP or CL SpO_2 Pod is activated, the corresponding built-in measurement of the fetal monitor is deactivated. To switch back to the built-in measurements, switch the base station to Standby mode, or redock the CL Pods at the base station.

CL F&M Pod versus wired transducers

The CL F&M Pod has priority over wired transducers. If a CL F&M Pod is active, all the wired transducers are disabled. To switch back to using wired transducers, switch the base station to Standby mode, or redock the CL F&M Pod at the base station.

About RF Signal Quality

If you cannot get sufficient ultrasound signal quality using the Avalon CTS base station, try repositioning the transducers, or switch to wired transducers.

Using an Avalon CL base station you should get a better signal by reducing the distance between the CL transducer and the base station.

Signal transmission can be disturbed if:

- the patient is out of range of the receiving area.
- there is interference from another, possibly stronger, RF signal (a broadcasting station, for instance).
- the patient is near material that absorbs electromagnetic waves (for example, metal-reinforced concrete, elevator doors) or the base station is in an enclosed metal rack.

CL Transducer Assignment

The CL transducers are assigned by simply docking them at the Avalon CL base station connected to the patient's fetal monitor.

Since twins and triplets can be monitored with the Avalon CL base station, it can be delivered with up to six CL transducers: one CL Toco$^+$ MP, three CL US, and two CL ECG/IUP transducers. Up to four CL transducer can be assigned at one time to the Avalon CL base station. Four assigned CL transducers enable monitoring combinations such as 1 CL Toco$^+$ MP transducer + 3 CL US transducers for monitoring triplets externally, or 1 CL Toco$^+$ MP transducer + 2 CL US transducer + 1 CL ECG/IUP transducer for monitoring twins.

Three CL transducers can be docked and charged at the Avalon CL base station at a time. If a fourth transducer should be assigned to the Avalon CL base station:

1 Remove first the three docked CL transducers from the base station and place them on the patient.

2 Then dock the remaining fourth transducer at the base station and wait until the LED of the fourth transducer signals that it has communication with the base station.

3 Place the fourth CL transducer on the patient and check on the fetal monitor in the **Tele Info** window if the base station and the monitor have communication with all four transducers, and if their numerics are displayed on the screen of the fetal monitor.

CL Transducer Unassignment

The cableless transducer needs to be unassigned:

- before being used with another base station on another patient
- to allow cleaning before docking it back onto the base station (e.g. to replace it with a fully charged transducer of the same type)

There are three methods to do this:

1 Open the setup menu of the measurement e.g. **FHR1** by selecting the numeric on the screen.

2 Select **Remove** from the open setup menu.

3 A confirmation window opens with the prompt **Please Confirm** and **Device will be removed**.

4 Select the **Confirm** pop-up key. A message confirms **cl US has been removed**.

or

1 Open the **Tele Info** window.

2 Select the symbol of the cableless transducer you want to unassign, and select **Remove** from the pop-up menu.

3 A confirmation window opens with the prompt **Please Confirm** and **Device will be removed**.

4 Select **Confirm** the pop-up key. A message confirms **cl US has been removed**.

or

1 Redock the CL transducer at the base station.

2 Switch the base station to stand-by.

3 Remove the CL transducer; it is now unassigned.

NOTE

When a CL transducer is unassigned, all the measurements from this transducer are no longer monitored.

For example, if you unassign a CL Toco^{+} MP transducer, the Toco measurement, maternal Pulse, and, if in use, the MECG/DECG/IUP measurement are no longer monitored.

CL Pod Assignment

The CL Pods are assigned by simply docking them at the Avalon CL base station connected to the patient's fetal monitor.

CL Pod Unassignment

The CL Pods have to be unassigned:

- before assigning them to another base station or to another patient
- to allow cleaning, before docking them back onto the base station

There are three methods to do this:

1 Open the setup menu of the measurement e.g. by selecting the numeric on the screen (not available for the CL Wide Range Pod).

2 Select **Remove** from the open setup menu.

3 A confirmation window opens with the prompt **Confirm** and **Device will be removed**.

4 Select the **Confirm** pop-up key. A message confirms **<cl Measurement> has been removed**.

or

1 Open the **Tele Info** window.

2 Select the symbol of the CL Pod, and select **Remove** from the pop-up menu.

3 A confirmation window opens with the prompt **Confirm** and **Device will be removed**.

4 Select the **Confirm** pop-up key. A message confirms **<cl Measurement> has been removed**.

or

1 Redock the CL Pod at the base station.

2 Switch the base station to Standby.

3 Remove the CL Pod; it is now unassigned.
To unassign a IntelliVue CL Pod using its user interface, see the Cableless Measurement Instructions for Use.

NOTE

If you unassign a CL Pod, all the measurements from it are no longer monitored, or are monitored by a connected lesser prioritized sensor.

Replacing a CL Pod with an empty battery

To replace CL Pod with an empty battery, assign and activate a new CL Pod of the same type at the CL base station. The CL Pod with the empty battery is unassigned automatically from the CL base station, and replaced by the newly activated CL Pod.

Calling Patients

To call a patient currently not near the fetal monitor and base station, select the SmartKey **Call Patient** at the fetal monitor. The base station will then select one transducer, or one of the CL Pods, if one is assigned and active, to emit the tone sequence to notify the patient. Inform the ambulating patient, if the cableless device is issuing any beeping sounds, to return to the room with the fetal monitor.

Preparing to Monitor Cablelessly

When monitoring cablelessly with the FM20/30/40/50 monitors, most of the same procedures apply as described in "Preparing to Monitor" on page 48. Additions and deviations applying to cableless devices and existing procedures are described here.

WARNING

The Avalon CL Wide Range Pod uses a WLAN connection to extend the operating range of CL transducers and CL Pods. The Avalon CL Wide Range Pod sends real-time patient data to the fetal monitor. The fetal monitor displays real-time patient data, provides alarms, data storage, and clinical decision support applications. The data is also transmitted to a connected obstetrical surveillance system. Using a WLAN connection may lead to network drop-outs resulting in the data loss of monitored vital signs. Do not use the Avalon CL Wide Range Pod with patients for whom a momentary loss of vital sign monitoring is not acceptable.

In case of frequent or prolonged network drop-outs (indicated by "Disconnect" INOPs at the fetal monitor and at the CL transducers or CL Pods):

- revert to the use of CL devices without the CL Wide Range Pod,
- restrict the patient to a reduced range around the Avalon CL base station,
- and inform your service personnel.

CL Transducers

1. To monitor cablelessly with the CL transducers, assign them at the base station as described in "CL Transducer Assignment" on page 94.
2. Place the CL transducers and the belt on the patient as described in "Fastening Belts and Transducers" on page 50.
3. Check the measurements on the monitor, and if necessary, move the CL transducers until you have a good signal for all measurements.

IntelliVue CL Pods

1. To monitor cablelessly with the IntelliVue CL Pods, assign them at the base station as described in "CL Pod Assignment" on page 95.
2. Put the CL Pods in their cradles and place them on the patient as described in the IntelliVue Cableless Measurements Instructions for Use.

Applying the CL Fetal & Maternal Patch and Pod

WARNING

Do not use the CL Fetal & Maternal Pod and electrode patch for monitoring if:

- The skin on the abdomen of the patient has established erythema, lesions, infection, inflammation, or any kind of injuries at the applications site
- The patient has a history of skin irritation, allergies, or hypersensitivity to adhesives
- The patient carries multiple fetuses
- The gestational age is less than 36 completed weeks. The measurement method is also only validated with patients in labor.

CAUTION

During handling, avoid close contact of the CL Fetal & Maternal Pod or the electrode patch to an implanted pacemaker or defibrillator.

NOTE

The Avalon CL Fetal & Maternal Pod and Patch are not available for the U.S., other FDA regulated territories, and Canada.

At the Mother's Side

1. Have a new single-use electrode patch ready, and make sure that the pouch is still intact. Check the expiration date that is printed on the pouch.
2. Clean the application area on the abdomen of the patient. Use mild soap to wash any cream, oil, or gel from the abdomen. Make sure to thoroughly wipe the area dry afterwards, ideally using paper towels.
3. Take the electrode patch from its pouch.
4. Study the electrode patch Instructions for Use showing the correct placement of the electrode patch on the abdomen of the patient.
5. Remove the cover from the adhesive area under the central area of the patch. (Do not remove the cover from any of the five surrounding electrodes yet).
6. Verify the correct orientation of the patch. The "Philips/Monica" printed top electrode must point to the patient's chest.
7. Place the central adhesive area of the patch over the patient's umbilicus as shown in the patch Instructions for Use. Then press it down.

   For patients with a displaced umbilicus:

   Where the umbilicus has been displaced downwards, position the center of the patch along the midline, where it intersects the horizontal line passing over the iliac crests. Alternatively, estimate the mid-point between the fundus and symphysis pubis.

   For very obese patients or patients with a large panniculus:

   An alternative strategy is to position the patch along the midline such that the edge of the top electrode is placed 10-12 cm (4-5 in) below the fundus.
8. Lift up one of the four electrodes. Identify the small area of the skin where you will place the center of the electrode.

9 Use one piece of abrasive ECG skin preparation paper to prepare the patient's skin. Make three horizontal and three vertical strokes with the skin preparation paper. Focus the strokes on the small area of the skin where the conductive center of the electrode will be placed. Make deliberate but gentle strokes, lifting the finger after each stroke.

CAUTION

Do not use too much pressure with the abrasive skin preparation paper to avoid skin injury.

incorrect

correct

10 Remove the protective cover from the electrode. Place the electrode on the prepared skin. Press it down firmly, but avoid pressing the central gel area of electrode.

CAUTION

Avoid placing electrodes over: umbilicus, piercings, scars, thick stretch marks, open skin, moles, and very dark linea nigra if possible.

11 Repeat the steps for the skin preparation and electrode placement for the other three electrodes.

12 For the last remaining electrode attached to the long flexible cable, identify the small area of skin to prepare, so that the center of this reference electrode will be positioned on the midline, approximately 6 cm (2.4 in) above the rim of the symphysis pubis.

For patients with a displaced umbilicus, very obese patients, or patients with a large panniculus:

Place the electrode on top of the panniculus approximating to the point 6 cm (2.4 in) vertically from the symphysis pubis. If during monitoring the aFHR signal quality is poor, reposition the electrode lower down on the abdomen to maximize the FHR signal, and consider placing the electrode under the panniculus just below the turn.

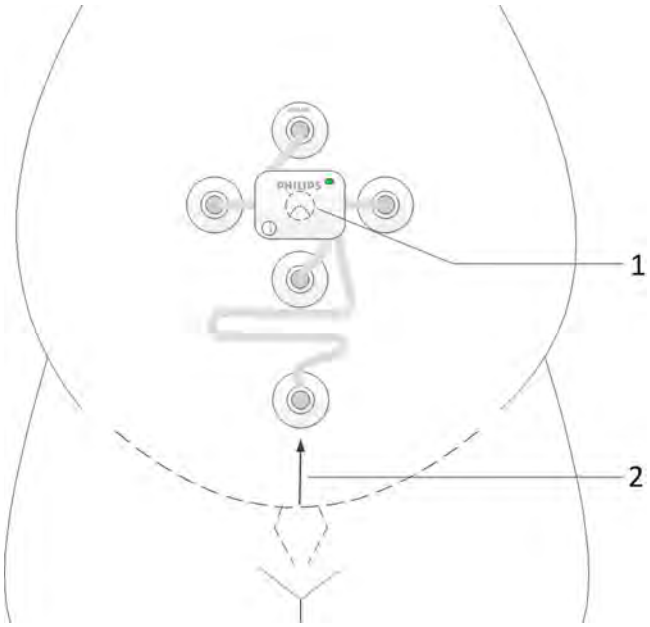
13 Prepare the skin like for the first four electrodes.

14 Remove the protective cover from the electrode. Then place the electrode on the prepared skin and press it down firmly, but avoid pressing the central gel area of electrode.

15 Assign a CL F&M Pod at the base station as described in "CL Pod Assignment" on page 95.

16 Place the CL F&M Pod on the electrode patch.

17 After you have placed the CL F&M Pod on the patch, allow the measurement some time to get to stable parameter value readings and leave the patient 10 to 15 minutes in bed before ambulating.



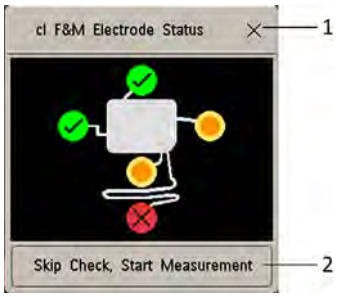
1 CL F&M Pod and electrode patch centered on the umbilicus

2 Placement of electrode 6 cm (2.4 in) above the rim of the symphysis pubis

At the Monitor

After you have placed the CL F&M Pod on the electrode patch, the **cl F&M Electrode Status** window opens at the monitor.

In the **cl F&M Electrode Status** window, the electrodes and their skin contact status are shown. The skin contact status indicates, whether the skin preparation at each electrode site was successful.

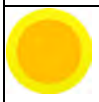
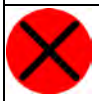


1 **cl F&M Electrode Status**

2 **Skip Check, Start Measurement**

There are three methods to reopen a closed **cl F&M Electrode Status** window. Select:

- The **clF&M Status** SmartKey (configurable)
- **cl F&M Status** in the setup menu of one of the CL F&M parameters (for example, **Setup aFHR1**)
- **cl F&M Status** from the **Main Setup** menu

Electrode Status	Description	What to Do
	The skin contact status is good.	When a good skin contact status is indicated for all five electrodes, the **cl F&M Electrode Status** window closes, and the measurement starts automatically.
	The skin contact is limited.	Further skin preparation may be required: **1** Carefully remove the electrode from the skin. **2** Dry the skin. **3** Repeat the skin preparation procedure. **4** If the contact status cannot be improved, you can choose to skip the electrode status check by selecting the **Skip Check, Start Measurement** button in the **cl F&M Electrode Status** window. Measurement accuracy should not be affected, but fetal heart rate detection may be less sensitive.
	The skin contact is insufficient.	The electrode is not applied to the skin, or further skin preparation is required: **1** Carefully remove the electrode from the skin. **2** Dry the skin. **3** Repeat the skin preparation procedure. **4** It is not recommended to skip the electrode status check, if bad skin contact quality is persistently indicated for one or more electrodes.
	Electrode status is unknown.	This status may be shown temporarily, or in case of a patch malfunction, combined with an INOP message.

NOTE

If you have to repeat the skin preparation, or fix a loose electrode, ensure that enough wet gel remains in the conductive middle of the electrode during the reapplication of the electrode. Add additional fixation (any type of medical grade tape) to the pad in case the adhesive is compromised.

- Allow the skin some minutes to absorb the gel before repeating the skin preparation.
- If you cannot get a good measurement signal quality, use an alternative monitoring method.
- The electrode patch can remain applied for up to 48 hours. Remove the electrode patch, if there are signs of skin irritation.
- If you have to replace an electrode patch:
  - Gently remove the electrode patch from the abdomen of the patient.
  - Wipe the abdomen dry thoroughly.
  - Apply a new patch over exactly the same location. In this case, no further skin preparation is required.
- Monitoring with the CL F&M Pod and electrode patch can continue when the patient takes a shower. However, ensure that the CL F&M Pod remains on the electrode patch all the time, to keep the contacts of the electrode patch dry. The achievable maximum wireless operating range may be compromised when monitoring under a shower.
- The CL Fetal & Maternal Pod is not intended for underwater monitoring, for example in a bathtub.

WARNING

Do not reuse a patch on another patient due to the risk of cross contamination.

After Monitoring

1. After monitoring is done, remove the CL F&M Pod from the electrode patch.
2. Clean and disinfect the CL F&M Pod, see "Care and Cleaning" on page 257.
3. Dock the CL F&M Pod back at the base station.
4. Gently remove the electrode patch and the electrodes from the abdomen of the patient.
5. Dispose of the electrode patch.
6. Remove the residuals of the adhesive from the patient's skin.

Working with the CL Wide Range Pod

The CL Wide Range Pod extends the signal range for the cableless measurement devices worn by the ambulating patient.

Understanding the Display

When the CL WRP Pod is active, the display shows the following screen elements:

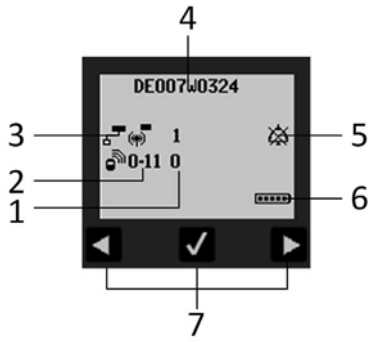
- Equipment label
- Network and WLAN connectivity status
- Channel configured
- Number of connected CL Pods
- Alarm status
- Battery status

When the CL WRP is inactive, the display only shows:

- Equipment label
- Time
- Network and WLAN connectivity status
- Battery status

When the CL WRP Pod is charging on the CL base station, the display only shows:

- Equipment label
- Network and WLAN connectivity status
- Battery status



1 Number of connected CL Pods
2 Channel configured
3 Network status and connectivity
4 Equipment label
5 Alarm status
6 Battery status
7 Hardkeys

Assigning and Activating the CL WRP Pod

Assign the CL Wide Range Pod at the base station as described in "CL Pod Assignment" on page 95.

To activate a CL WRP Pod, place it on the CL base station. When a CL WRP Pod is not activated, the backlight of the display is automatically switched off and the low-activity screen is displayed. The CL WRP has three hardkeys.

The three hardkeys have an additional function when a key is pressed for a couple of seconds:


Opens the network menu.


Opens the SmartKeys menu.


Returns to the Main Screen. Pressing the hardkey while on the Main Screen, locks the hardkeys and a lock symbol appears on the screen above the battery symbol. Press it again to unlock the keys and the lock symbol disappears.

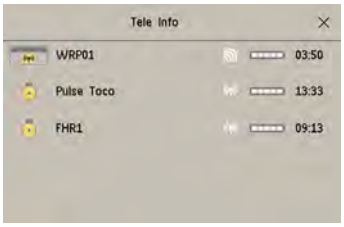
As soon as the CL WRP Pod is picked up from the CL base station, it connects itself over WLAN and LAN with the fetal monitor. With the connection established, the CL WRP Pod takes over from the base station, and sends the signals from the cableless devices to the monitor. While the CL WRP Pod is active, cableless devices can still be assigned or unassigned at the base station dynamically to the patient. It does not matter in which sequence the cableless devices or the CL WRP Pod are activated.

At the fetal monitor

The connection status of the CL WRP Pod is shown on the monitor, see "Cableless Status Indication" on page 91.

The telemetry icon indicates that the CL WRP Pod is active and connected to the fetal monitor.

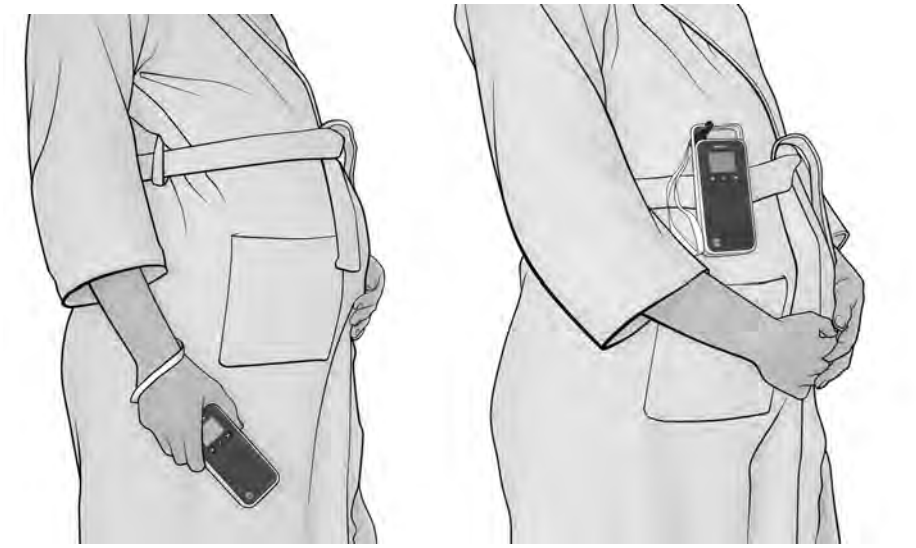
The **Tele Info** shows the active CL WRP Pod.



Redocking the CL WRP Pod at the CL base station hands the signal transfer from the CL WRP Pod back to the CL base station.

Handing the CL WRP Pod to the Patient

Hand the CL Wide Range Pod to the patient to carry with her, or optionally wearing it using the Mobile CL Transmitter Cradle (989803168881) or Telemetry Pouch with window (989803137831). The CL Wide Range Pod should be worn with its rear side facing the body.



CL Wide Range Pod carried in hand, or CL Wide Range Pod worn with the belt clip (supporting loop and belt clip part of the optional Mobile CL Transmitter Cradle).

Battery Lifetime Management

The lifetime of a Lithium Ion battery depends on the frequency and duration of use.

CL Transducers

Battery replacement is recommended after 500 charge-discharge cycles, or if the battery is older than 4 years whatever is reached first. If the battery of a cableless transducer has aged and an exchange of the battery is highly recommended, a prompt message is displayed at the fetal monitor for ca. 60 seconds. The prompt is repeated whenever the **Tele Info** window is opened until the battery is replaced. The CL transducer battery allows for 10 hours of continuous operation.

Depending on the transducer type the following messages are displayed:

cl US battery has aged. Replacement strongly recommended
cl Toco battery has aged. Replacement strongly recommended
cl ECG/IUP batt has aged. Replacement strongly recommended

If you are getting this message, contact your service personnel so they can replace the CL transducer's battery.

CL F&M Pod

Pod replacement is recommended after 500 charge-discharge cycles, or if the battery is older than 4 years whatever is reached first. If the battery of a CL F&M Pod has aged and an exchange of the Pod is highly recommended, a prompt message is displayed at the fetal monitor for ca. 60 seconds. The prompt is repeated whenever the **Tele Info** window is opened. The CL F&M battery allows for 16 hours of continuous operation.

The following message is displayed:

cl F&M battery has aged. Replacement strongly recommended

If you are getting this message, contact your service personnel so they can replace the CL F&M Pod.

CL Wide Range Pod

Battery replacement is recommended after 500 charge-discharge cycles, or if the battery is older than 4 years whatever is reached first. If the battery of a CL Wide Range Pod has aged and an exchange of the battery is highly recommended, a prompt message is displayed at the fetal monitor for ca. 60 seconds. The prompt is repeated whenever the **Tele Info** window is opened until the battery is replaced. The CL Wide Range Pod battery allows for 4 hours of continuous operation

The following message is displayed:

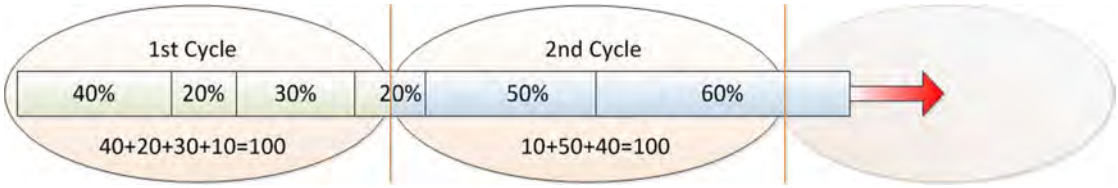
cl WRP battery has aged. Replacement strongly recommended

CL NBP and CL SpO_2 Pods

For battery charge-discharge cycles specification of the IntelliVue CL Pods (NBP and SpO_2), refer to the Service Guide of the Cableless Measurements.

Charge Cycle

The age of a lithium ion battery begins at the date of manufacture. The lithium batteries are designed for frequent recharging. A complete charging cycle is only reached and counted, when all recharging periods equal a 100% charge.



The date of manufacture and number of charge-discharge cycles can be printed out in a battery report.

Patient Transport Within the Hospital

During transport, the patient wearing the CL transducers can be transferred from one fetal monitor to another fetal monitor.

1. To stop monitoring, discharge the patient at the fetal monitor. Do not switch the CL base station to Standby.
   Note: If you switch the CL base station to Standby after the discharge, the CL transducers only hold the assignment to the CL base station for **1 minute**.
2. Disconnect the CL base station from the fetal monitor.
3. The CL transducers hold the assignment to the CL base station for **30 minutes**. Transport the patient wearing the CL transducers with the disconnected CL base station to another fetal monitor.
4. Connect the CL base station to the other fetal monitor. The fetal monitors need to have the same software revisions, and the correct time and date settings.
5. Manually admit the patient to the fetal monitor, unless the patient is transferred to the new fetal monitor with the OB TraceVue/IntelliSpace Perinatal system.
6. Resume monitoring. Once the base station and the transducer are connected and assigned to the new monitor, the previous monitor can be switched off or to Standby.

Underwater Monitoring

Only the battery-operated CL transducers of the Avalon CL and Avalon CTS systems can be used to monitor under water. You can use them to monitor patients in a bathtub or shower. This does not apply to the IntelliVue CL SpO_2, CL NBP, and the CL Wide Range Pod, do not immerse the CL Pods into water.

The CL F&M Pod can be worn within the shower, if the Pod is securely placed on the electrode patch, so that the contacts cannot get wet. Radio transmission range of the CL F&M Pod may be reduced under a shower.

Cableless transmission distances are shorter when monitoring under water. A metal bathtub is likely to further reduce the operating range.

WARNING

Never immerse the base station in liquid. You must protect it against water sprays or splashes. Place the base station where there is no chance of contact with water, or falling into water or other liquids.

CAUTION

Avoid the use of pulsating water jets in the bath or shower while monitoring, as these can be misinterpreted as an incorrect (or totally artificial) heart rate.

Toco Baseline drift: When using transducers under warm water, the temperature increase causes a significant baseline change due to internal pressure increase. The depth under water at which the Toco transducer is used also has an effect on the Toco baseline, as the water pressure increases with depth. After immersion, allow one to two minutes for the pressure to stabilize, then adjust the Toco baseline (between contractions), and check it frequently.

When using the transducers underwater, the radio transmission range is reduced, and signal loss may occur.

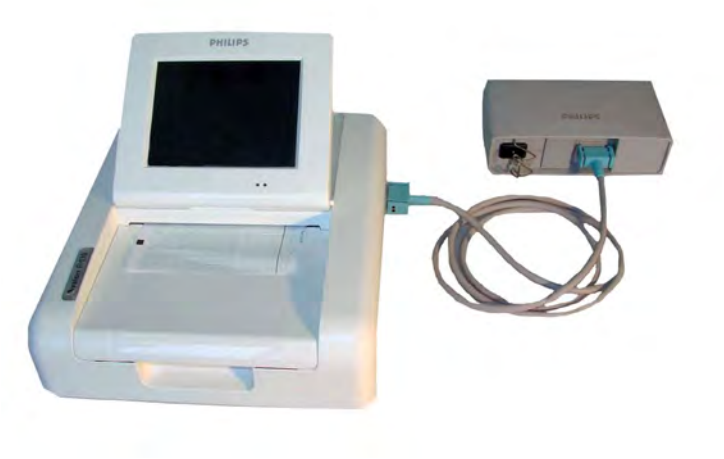
Water-proof belts like M1562B are recommended for the cableless transducers when monitoring in water.

5

FM20/30 Battery Option

You can switch between battery-powered and mains-powered (AC) operation without interrupting monitoring.

The monitor is connected to the AC mains power via the external power supply.

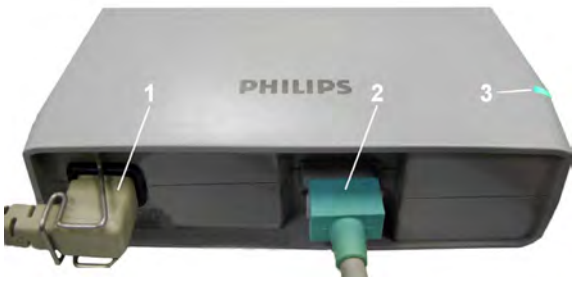


NOTE

The battery option is not available for the FM40/FM50.

External Power Supply M8023A

The external power supply M8023A (option #E25) allows you to operate the fetal monitor from an AC (alternating current) power source of 100 V to 240 V (±10%) and 50/60 Hz (±5%). If this option is used, then the M8023A (option #E25) power supply is included for FM20/30.



1 AC power cord, connected to AC mains socket

2 Measurement Link (MSL) cable, supplies the power to the monitor for operation and for battery charging

3 Power-on LED, the green light is on when the external power supply is connected to the AC mains

WARNING

- Always use the supplied power cord with the earthed mains plug to connect the external power supply M8023A (option #E25) to an earthed AC mains socket. Never adapt the mains plug from the power supply to fit an unearthed AC mains socket.
- Do not use AC mains extension cords or multiple portable socket-outlets. If a multiple portable socket-outlet without an approved isolation transformer is used, the interruption of its protective earthing may result in enclosure leakage currents equal to the sum of the individual earth leakage currents, so exceeding allowable limits.
- Do not connect any devices that are not supported as part of a system.
- Any non-medical device placed and operated in the patient's vicinity must be powered with an approved isolation transformer that ensures mechanical fixing of the power cords and covering of any unused power outlets.

Using Batteries

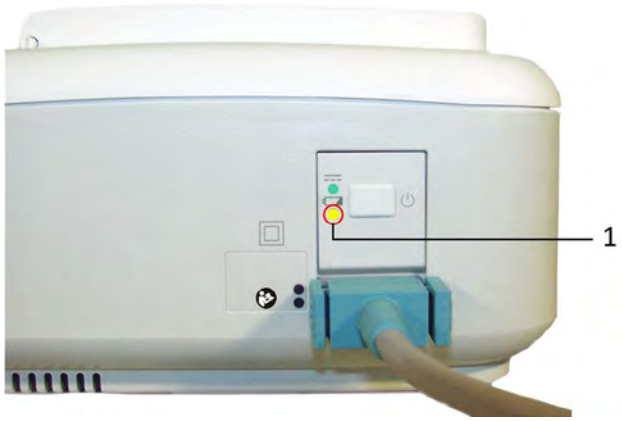
The Lithium Ion batteries used in your monitor store a large amount of energy in a small package. This allows reliable battery-operated monitoring, but also requires care in use and handling of the batteries. Follow the instructions in this chapter and see the Service Guide for further details.

Battery Power Indicators

The battery LED and battery status information on the main screen, in combination with INOP messages and prompts, help you keep track of the battery power status. The indicators always show the remaining capacity in relation to the battery's actual maximum capacity, which may lessen as the battery ages. You can see the actual capacity in the **Battery Status** window.

Battery LED

The possible battery LED status on the right side of the monitor is described in the table below.



1 Battery LED

Battery LED Colors	If the monitor is connected to mains power, this means	If the monitor is running on battery power, this means
Green	Battery power is >90%	
Yellow	Battery charging (battery power <90%)	
Red, flashing		Less than 10 minutes power remaining
Red, flashes intermittently	Battery or charger malfunction	Battery malfunction

Battery Status on the Main Screen

Battery status information is permanently displayed on all screens. It shows the status of the battery, with the battery power remaining, with an estimate of the monitoring time this represents.

Battery power gauge: This shows the remaining battery power. It is divided into sections, each representing 20% of the total power. If three sections are filled, as in this example, this indicates that 60% battery power remains. If no data is available from the battery, a question mark is shown in the gauge.

Monitoring Time Available: Below the battery power gauge a time is displayed. This is the estimated monitoring time available with the current battery power. Note that this time fluctuates depending on the system load (the display brightness, the recorder configuration, and how many measurements you carry out).

Battery malfunction symbols: Normal battery function is indicated by the battery power gauge, together with the remaining operating time, on the main screen. You are informed of problems or changes in the status of the battery by the battery status/malfunction indicator. This consists of a blank battery gauge containing a "**!**" symbol. If the symbol is red, this indicates a critical situation. You can check the specific cause of the problem by looking at the symbol(s) displayed in the **Battery Status** window.

Battery Status Indicator		Battery Malfunction Indicator	
	Alternates with the battery gauge on the main screen. Check in the **Battery Status** window to see which status symbol is displayed to identify the cause.		The red exclamation mark flashes. Critical battery situation or malfunction. Check in the **Battery Status** window to see which malfunction indicator is displayed, or refer to the INOP, to identify the cause.

Battery Status Window

1 To access the **Battery Status** window and its associated pop-up keys, select the battery status information on the screen, or select **Main Setup**, **Battery**.

- **Capacity**, **remaining** tells you how much power is left in the battery.
- **Capacity**, **fullCharge** tells you how much power the battery can hold when fully charged.
- **TimeToEmpty** tells you approximately how long you can continue to use the monitor without an AC connection. The time span fluctuates depending on the system load (the display brightness and how many measurements you carry out), and the remaining capacity of the battery.
- **TimeToFull** is shown in place of **TimeToEmpty** if the monitor is connected to a power supply, and tells you how much time is left until the battery is charged to 90%. If >10 hr is shown here, the battery may not charge completely when the monitor is in use.

Battery status/malfunction symbols: If a problem is detected with the battery, an INOP may be issued, and the following symbols are displayed in the **Battery Status** window, where they may be accompanied by a status message providing more details.

Symbols indicating critical situations are colored red.

Battery Status Symbols		Battery Malfunction Symbols	
	Battery is empty		(Red) incompatible battery
	Battery not charging as the temperature is above or below the specified range		(Red) battery malfunction
	Battery requires maintenance		(Red) battery has no power left
	Charging stopped to protect the battery		(Red) battery temperature too high
			(Red) battery is missing, insert battery

Checking Battery Charge

To check the charge status of a battery, refer to the battery power gauge on the screen, or open the **Battery Status** window.

When Battery Lifetime is Expired

When the battery is aged, either after 3 years from manufacturing date or after 500 charge-discharge cycles, it is recommended to replace the battery. To remind you of this, a message will appear in the **Battery Status** window. This message will only be displayed at the appropriate time when the date and time on the monitor is correct.

Optimizing Battery Performance

The performance of rechargeable batteries may deteriorate over time. Battery maintenance as recommended here can help to slow down this process.

Display Brightness Setting

1 In the **Main Setup** menu, select **User Interface**, **Brightness**, then **Optimum**. This selects a level of brightness suitable for most monitoring locations that uses less battery power than brighter settings.

2 Ensure that the current level of brightness is suitable for your monitoring location.

Charging the Battery

To charge the battery:

1 Connect the monitor to the external power supply (M8023A).

2 Charge the battery until it is full, the battery LED is green, and the battery power gauge is filled.

During high load of the monitor (usage of multiple measurements) the battery may not charge. To remedy this:

- reduce the load by removing measurements
- reduce the screen brightness or stop the recorder

Internal temperature conditions can also cause the battery to not charge. This is necessary to protect the battery from damage and does not indicate a malfunction. Keep the monitor at room temperature and move it away from heat sources or out of direct sunlight. The battery will resume charging when the temperature is within range again. The battery will charge more quickly if the monitor is switched off.

Conditioning the Battery

You must condition the battery when the "battery requires maintenance" symbol shows on the screen. Do not interrupt the charge or discharge cycle during conditioning.

CAUTION

Condition the battery with a monitor not currently in use. The monitor switches off automatically when there is no battery power left.

To condition the battery:

1 Charge the battery until it is completely full. Open the **Battery Status** window and check that the **Batt fully charged** message is displayed.

2 Disconnect the monitor from mains power, and let the monitor run until there is no battery power left and the monitor switches itself off.

3 Reconnect the monitor to mains power and charge the battery until it is full for use or charge to 50% for storage.

Battery Safety Information

WARNING

Use only Philips batteries part number M4605A. Use of a different battery may present a risk of fire or explosion.

Do not open batteries, or dispose of them in fire, or cause them to short circuit. They may ignite, explode, leak, or heat up, causing personal injury.

If battery leakage should occur, avoid contact with skin. Refer to qualified and authorized service personnel.

Dispose of used batteries promptly and in an environmentally responsible manner. Do not dispose of the battery in normal waste containers. Consult your hospital administrator to find out about local arrangements. Do not expose batteries to liquids.

Do not crush, drop, or puncture batteries - mechanical abuse can lead to internal damage and internal short circuits which may not be visible externally.

If a battery has been dropped or banged against a hard surface, whether damage is visible externally or not:

- discontinue use
- dispose of the battery in accordance with the disposal instructions above.

Keep batteries out of the reach of children.

CAUTION

Do not disassemble, heat above 100°C (212°F) or incinerate the batteries, to avoid the risk of fire and burns. Keep batteries out of the reach of children and in their original package until you are ready to use them.

If battery leakage should occur, use caution in removing the battery. Avoid contact with skin. Refer to qualified and authorized service personnel.

Do not install or use pre-damaged batteries.

Storing the Battery

WARNING

Remove the battery from the monitor when it is not used for a longer period of time, to avoid potential damage caused by battery leakage.

Batteries should be charged to a maximum of 50% for storage.

The battery will discharge over time if it is stored inside the monitor without AC power connection. The reported values for "remaining capacity" and "runtime" will become less accurate when the battery is stored in this way for a longer period of time (that is, several weeks).

Cableless Monitoring with FM20/30 Battery Option

The CL Pods can be used with the FM20/30 with battery option #E25. The CL Pods can be assigned and activated, but will not be charged. The only exception to this is the CL F&M Pod, which can also be charged.

The charging time of the CL transducers can take up to 6 hours if they are charged from an FM20/30 with battery option.

If you charge the CL transducers at an FM20/30 with battery option, be sure to remove all wired transducers from the fetal monitor. Leaving them connected to the fetal monitor can cause the CL transducers not to charge at all.

Patient Transport Within the Hospital

The FM20 and FM30 fetal monitor with battery option offer the possibility of continuous monitoring of a patient, while she is transported within the hospital.

1. Unplug the MSL connector at the fetal monitor. Or, in case an external power supply is mounted on a rollstand, unplug it from the AC Mains.
   The fetal monitor is now operating on battery power.
2. Move the patient with the fetal monitor (on a cart) to the new location.
3. Reconnect the MSL connector at the fetal monitor or the external power supply to the AC Mains.

5 FM20/30 Battery Option

6

Alarms

The alarm information here applies to all measurements. Measurement-specific alarm information is contained in the sections on individual measurements.

The fetal monitor has two different types of alarm: patient alarms and INOPs.

Patient Alarms

Patient alarms are red and yellow alarms. A red alarm indicates high priority, such as a potentially life threatening situation (for example, SpO_2 below the desaturation alarm limit). A yellow alarm indicates a lower priority alarm (for example, a fetal heart rate alarm limit violation).

INOPs

INOPs are technical alarms. They indicate that the monitor cannot measure and therefore not detect critical conditions reliably. If an INOP interrupts monitoring and alarm detection (for example, **MECG Leads Off**), the monitor places a question mark in place of the measurement numeric and sounds an audible tone. INOPs without this tone indicate that there may be a problem with the reliability of the data, but that monitoring is not interrupted.

INOPs are cyan by default. The following INOPs can also be configured as red or yellow INOPs to provide a severity indication:

- **ECG Leads Off**
- **Battery Empty** (FM20/30, CL devices)
- **Cuff Overpress**
- **Cuff NotDeflated**
- **No Pulse**

Alarm Delays

There is a delay between a physiological event at the measurement site and the corresponding alarm indication at the monitor. This delay has two components:

- **The general measurement delay time is the time between the occurrence of the physiological event and when this event is represented by the displayed numerical values**. This delay depends on the algorithmic processing and on the measurement dependent averaging time.
- **The time between the displayed numerical values exceeding an alarm limit and the alarm indication on the monitor**. This delay is the sum of the alarm delay configured for the specific measurement plus the system alarm delay. The system alarm delay is the processing time the system needs for any alarm on the monitor to be indicated after the measurement has triggered the alarm. See the performance specifications in "Specifications and Standards Compliance" on page 287 for the system alarm delay specification.

Multiple Alarms

If more than one alarm is active, the alarm messages are shown in the alarm status area in succession. An arrow symbol next to the alarm message informs you that more than one message is active.

The monitor sounds an audible indicator for the highest priority alarm. If more than one alarm condition is active in the same measurement, the monitor announces the most severe alarm condition first.

WARNING

Alarm systems of the monitor and those of any connected obstetrical information and surveillance system are interdependent and not synchronized. Therefore audible alarms should not be relied upon for remote monitoring.

Alarming is only available at the Avalon fetal monitor, not at the Cableless Measurement Devices, see the Instructions for Use for the IntelliVue Cableless Measurements.

If configured so, **SpO_2 No Pulse** will only be displayed in yellow or red (instead of cyan), when no other Pulse source is valid and is displayed instead of the Pulse from SpO_2.

Alarm Mode

You can configure the alarm mode for your fetal monitor. There are two possible modes:

- **All**: alarms and INOPs are enabled, with all audible and visual indicators active.
- **INOP only**: only INOPs are enabled, with audible and visual indication active.

WARNING

In **INOP only** mode, no fetal/maternal patient alarms are enabled or indicated.

The alarm status area for yellow and red alarms shows the **INOP only** indication in conjunction with the "Alarms Off" symbol. No individual measurement alarm limits or alarm off symbols are displayed. No fetal/maternal patient alarm settings are available in the setup menus.

Nurse Call Systems

If configured to do so, red, yellow, and cyan alarms are indicated on a nurse call system which is connected to the optional nurse call relay.

Visual Alarm Indicators

Alarm message: An alarm message appears in the alarm status area on the second line at the top of the screen indicating the source of the alarm. If more than one measurement is in an alarm condition, the message changes every two seconds, and has an arrow at the side. The background color of the alarm message matches the alarm priority: red for red alarms and red INOPs, yellow for yellow alarms and yellow INOPs, and cyan for INOPs. The asterisk symbols (*) beside the alarm message match the alarm priority: *** for red alarms, and ** for yellow alarms. INOPs are displayed without asterisks, but a red INOP has !!! three exclamation marks, and a yellow INOP has !! two exclamation marks before it.

Depending on how your monitor is configured, it may display alarm limit violation messages:

- in text form, for example **** FHR1 Low** or
- in numeric form, for example **** FHR1 94<110**, where the second number shows the currently set alarm limit, and the first number shows the value at which that alarm limit was violated by the widest margin.

Flashing numeric: The numeric of the measurement in alarm flashes.

Bright alarm limits: If the alarm was triggered by an alarm limit violation, the corresponding alarm limit on the monitor screen is shown more brightly.

Audible Alarm Indicators

The audible alarm indicators configured for your fetal monitor depend on which alarm standard applies in your hospital. Audible alarm indicator patterns are repeated until you acknowledge the alarm by switching it off or pausing it, or until the alarm condition ceases (if audible alarm indication is set to non-latching).

WARNING

Do not rely exclusively on the audible alarm system for fetal monitoring. Adjustment of alarm volume to a low level or off during monitoring may result in a dangerous situation. Remember that the most reliable method of fetal monitoring combines close personal surveillance with correct operation of monitoring equipment.

Alarm Tone Configuration

The audible alarm indicators of your monitor are configurable. In the monitor's Configuration Mode, you can:

- increase the alarm volume of unacknowledged alarms at regular intervals
- change the interval between alarm sounds (ISO/IEC Standard alarms only)
- change the base volume of the red and yellow alarm tones and the INOP tones
- change the alarm sound to suit the different alarm standards valid in different countries

Standard Philips Alarms

- Red alarms and red INOPs: a high pitched sound is repeated once a second.
- Two-star yellow alarms and yellow INOPs: a lower pitched sound is repeated every two seconds.
- One-star yellow alarms (short yellow alarms): the audible indicator is the same as for yellow alarms, but of shorter duration.
- Standard INOPs: an INOP tone is repeated every two seconds.

ISO/IEC Standard Audible Alarms

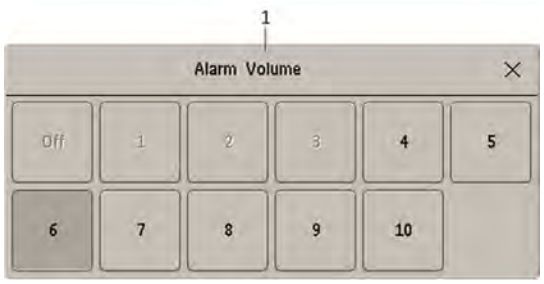
- Red alarms and red INOPs: a high pitched tone is repeated five times, followed by a configurable pause.
- Two-star yellow alarms and yellow INOPs: a lower pitched tone is repeated three times, followed by a configurable pause.
- One-star yellow alarms (short yellow alarms): the audible indicator is the same as for yellow alarms, but of shorter duration.
- Standard INOPs: a lower pitched tone is repeated twice, followed by a pause.

Changing the Alarm Tone Volume

The alarm volume symbol at the top right of the monitor screen gives you an indication of the current volume. To change the volume:

1 Select the volume symbol.

2 The volume scale pops up.



1 **Alarm Volume**

3 Select the required volume from the volume scale.
When the alarm volume is set to zero (**Off**), the alarm volume symbol shows this symbol:

If you switch the alarm volume off, you will not get any audible indication of alarm conditions.

Minimum Volume for Severe Yellow or Red INOPs

Severe yellow or red INOPs require action to ensure the well-being of the patient. Therefore the minimum volume for the INOP tone is set to at least alarm volume 8, irrespective of the current alarm volume setting. The INOP tone will sound even if the monitor alarm volume is set to zero.

The severe INOPs for which this applies are:

INOP	Factory Default	INOP tone
Battery Empty	cyan	severe (fetal monitor with battery option)
Battery Empty	cyan	severe (CL transducers and Pods)
Cuff Overpress	cyan	severe
Cuff NotDeflated	cyan	severe

Power Loss Tone

FM20/30 with Battery Option, FM40/50

When power is lost - no power is available from the AC power source or from the battery - a beeper will sound. The tone can be silenced by pressing the On/Standby button.

Acknowledging Alarms

To acknowledge all active alarms and INOPs, select the **Silence** key. This switches off the audible alarm indicators.

- A checkmark beside the alarm message indicates that the alarm has been acknowledged.
- If the condition that triggered the alarm is still present after the alarm has been acknowledged, the alarm message stays on the screen with a checkmark symbol beside it.
- If the alarm condition is no longer present, all alarm indicators stop and the alarm is reset.
- Switching off the alarms for the measurement in alarm, or switching off the measurement itself, also stops alarm indication.

Acknowledging Disconnect INOPs

Acknowledging an INOP that results from a disconnected transducer, switches off the associated measurement.

Alarm Reminder

If **Alarm Reminder** is configured on for your monitor, you will get an audible reminder of alarm conditions that remain active after you have acknowledged the alarm. This reminder may take the form of a repetition of the alarm tone for a limited time, or an unlimited repetition of the alarm tone (this is the same as a new alarm). **Alarm Reminder** is available only for yellow and red alarms and INOPs and not for standard cyan INOPs.

In Configuration Mode, you can set the interval between silencing the alarm and sounding the reminder tone to one, two, or three minutes.

Pausing or Switching Off Alarms

If you want to temporarily prevent alarms from sounding, for example while you are moving a patient, you can pause alarms. Depending on your fetal monitor configuration, alarms are paused for one, two, or three minutes, or infinitely.

To view the alarm pause setting chosen for your unit:

1 Select **Main Setup**, **Alarms**, **Alarm Settings**.

2 Check the **Alarms Off** setting.

This setting can be changed in Configuration Mode.

There are some settings made in Configuration Mode that can affect the availability of the pause alarms functionality.

- The **Pause Alarms**/**Alarms Off** SmartKey can be removed from the screen to avoid unintentional switching off of alarms. In this case you can only pause alarms or switch alarms off permanently in the **Alarms** menu, under **Main Setup**.
- The **Pause Alarms**/**Alarms Off** SmartKey can be configured to pause or switch off red and yellow alarms, yellow alarms only, or not to function at all. If it is configured not to function, you cannot pause alarms or switch alarms off permanently at all.

When the alarms off priority is set to **Yellow Only**, the **Pause Alarms**/**Alarms Off** key becomes the **Pause Yellow**/**Yellow Al. Off**.

To Pause All Alarms

If you have configured alarms to be paused for one, two, or three minutes, the SmartKey is labeled **Pause Alarms**.

Select the **Pause Alarms** SmartKey to pause all alarms.

Or

1 Select **Main Setup**.

2 Select **Alarms**.

3 Select **Pause Alarms**.

To Switch All Alarms Off

You can switch alarms off permanently if your monitor is configured to allow infinite alarms pause, and the SmartKey is labeled **Alarms Off**.

Select the **Alarms Off** SmartKey.

Or

1 Select **Main Setup**.

2 Select **Alarms**.

3 Select **Alarms Off**.

While Alarms are Paused or Off

When red alarms are paused or off:

In the alarm field, the monitor displays the message **Al. Paused x:yy** or **Alarms Off**, together with the alarms paused symbol or the alarms off symbol.

When yellow alarms are paused or off:

In the alarm field, the monitor displays the message **YellowPaused x:yy** or **Yellow Alarms Off**, together with the alarms paused symbol or the alarms off symbol.

For red and yellow alarms:

Alarms Paused

Alarms Off

- No alarms are sounded and no alarm messages are shown.
- INOP messages are shown but no INOP tones are sounded.

The only exceptions are the INOPs **Cuff NotDeflated**, **Cuff Overpress**, and **Battery Empty** from the FM20/30 monitor with battery option.

These INOPs switch all alarms back on again, so that an INOP tone can be sounded. You must remove the INOP condition first, before you can switch off or pause the alarms again.

Restarting Paused Alarms

To manually switch on alarm indication again after a pause, select the SmartKey **Pause Alarms** (or **Alarms Off**) again.

Alarm indication starts again automatically after the pause period expires. If the monitor is configured to stay paused infinitely, you must select **Alarms Off** again to restart alarm indication.

Extending the Alarm Pause Time

If your monitor has the function extended alarm pause enabled, you can extend the alarm pause time. Use this to prevent alarms being indicated, for example, while you are washing a patient or carrying out a procedure. Only extend the alarm pause time when you are sure that clinical personnel are available to monitor the patient's condition closely.

To extend the alarm pause time to five or 10 minutes:

1 Select one of the alarm fields. This calls up the **Alarm Messages** window.

2 Select either the pop-up key **PauseAl. 5 min** or the pop-up key **PauseAl. 10 min**. Each time you select one of these pop-up keys, the Alarm Pause Time is reset to five or 10 minutes.

To Switch Individual Measurement Alarms On or Off

This applies to **Alarm Mode All**.

1 Select the measurement numeric to enter its setup menu.

2 Select **Alarms** to switch between **On** and **Off**.

The alarms off symbol is shown beside the measurement numeric.

Alarm Limits

The alarm limits you set determine the conditions that trigger yellow and red limit alarms.

WARNING

Be aware that the monitors in your care area may each have different alarm settings, to suit different scenarios. Always check that the alarm settings are appropriate before you start monitoring.

Viewing Individual Alarm Limits (Alarm Mode "All" Only)

1 Alarm Limits

You can usually see the alarm limits set for each measurement next to the measurement numeric on the main screen.

If your monitor is not configured to show the alarm limits next to the numeric, you can see them in the related measurement setup menu. Select the measurement numeric to enter the menu and check the limits.

Changing Alarm Limits

To change individual measurement alarm limits using the measurement's setup menu:

1 In the measurement's setup menu, select the alarm limit you want to change. This calls up a list of available values for the alarm limit.

2 Select a value from the list to adjust the alarm limit.

CAUTION

Set the alarm limits to a meaningful value for the individual patient. Setting the alarm limits to a too high or too low value may render the alarm function useless.

Extreme Alarm Limits for Heart Rate and Maternal Pulse

The extreme rate alarms, Extreme Tachy and Extreme Brady, generated by the active alarm source, either HR or Pulse, are set in Configuration Mode by adding a set value (the Δ value) to the high and low alarm limits.

1 Extreme Brady Limit
2 Low Limit
3 High Limit
4 Extreme Tachy Limit
5 Δ Extreme Brady
6 Δ Extreme Tachy

You need to know which value has been configured for your monitor. Changing the high and low alarm limits automatically changes the extreme alarm limits within the allowed range.

To see the extreme rate alarms set for your monitor, in the **Setup ECG** menu, see the menu items **Δ ExtrTachy** and **Δ ExtrBrady**.

Reviewing Alarms

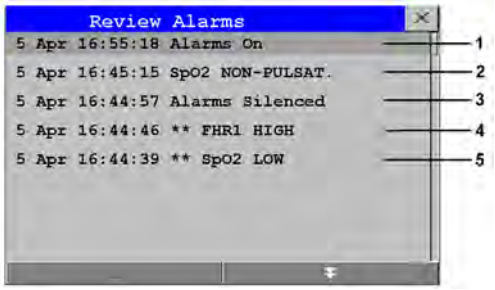
To review the currently active alarms and INOPs, select any of the alarm status areas on the fetal monitor screen. The **Alarm Messages** window pops up. All alarms and INOPs are erased from the monitor's alarm history when you discharge a patient, or if you leave the Demonstration Mode.

Alarm Messages Window

The **Alarm Messages** window shows all the currently active alarms and INOPs in chronological order, beginning at the top with the most recent. INOPs are shown on the left hand side, and alarms are shown on the right hand side. Any active red alarms are shown first, followed by yellow alarms. Acknowledged alarms or INOPs are shown with the checkmark symbol.

The **Alarm Messages** window pop-up keys appear when the window is opened. Selecting the **Review Alarms** pop-up key opens the **Review Alarms** window.

Review Alarms Window



1 **Alarms On**
2 **SpO_2 No Pulse**
3 **Alarms Silenced**
4 **** FHR1 High**
5 **** SpO_2 Low**

The **Review Alarms** window contains a list of up to 300 of the most recent alarms and INOPs with date and time information. If configured to do so, each alarm is shown with the alarm limit active when the alarm was triggered and the maximum value measured beyond this limit. The **Review Alarms** window also shows any changes made to the **Alarms On/Off** or **Alarms Silenced** status. Only the main alarms On/Off transitions are logged in the alarm history, and On/Off alarm transitions for individual measurements are not logged.

The information in the **Review Alarms** window is deleted when a patient is discharged.

The **Review Alarms** window pop-up keys appear when the window is opened. Selecting the **Active Alarms** pop-up key opens the **Alarm Messages** window.

Latching Alarms

The alarm latching setting for your monitor defines how the alarm indicators behave when you do not acknowledge them. When alarms are set to non-latching, their indicators end when the alarm condition ends. Switching alarm latching on means that visual and/or audible alarm indications are still displayed or announced by the monitor after the alarm condition ends. The indication lasts until you acknowledge the alarm.

Viewing the Alarm Latching Settings

To see the alarm latching setting for your monitor:

1 In the monitor's **Main Setup** menu, select **Alarms**.

2 Select **Alarm Settings**, and see the **Visual Latching** and **Audible Latching** settings.

This setting can be changed in Configuration Mode. You should be aware of the settings chosen for your unit. There are three possible choices each for visual and audible latching: **Red & Yellow**, **Red Only**, and **Off**. The audible latching configuration can never be configured to a higher level than that configured for the visual latching. In other words, the audible latching setting is always the same level, or lower, than the visual latching setting. For example, if visual latching is configured to **Red Only**, then audible latching can only be set to **Red Only** or **Off**. The following table shows the possible combinations for latching settings:

Possible Combinations for Alarm Latching Settings	
Visual Latching Setting	**Audible Latching Setting**
Red & Yellow	Red & Yellow
Red & Yellow	Red Only
Red & Yellow	Off
Red Only	Red Only
Red Only	Off
Off	Off

Alarm Latching Behavior

Alarm Condition		Red and Yellow Measurement Alarms		
Acknowledgment	**Presence**	**Non-latching alarms**	**Visual and audible latching**	**Visual latching, audible non-latching**
Alarm has not been acknowledged	Alarm condition still present	Alarm tone on Alarm message Flashing numerics	Alarm tone on Alarm message Flashing numerics	Alarm tone on Alarm message Flashing numerics
	Alarm condition no longer present	All audible and visual alarm indicators automatically stop	Alarm tone on Alarm message Flashing numerics	Audible alarm indicators automatically stop Alarm message Flashing numerics
Alarm has been acknowledged	Alarm condition still present	Alarm tone off Audible alarm reminder (if configured) Alarm message Flashing numerics	Alarm tone off Audible alarm reminder (if configured) Alarm message Flashing numerics	Alarm tone off Audible alarm reminder (if configured) Alarm message Flashing numerics
	Alarm condition no longer present	Audible and visual alarm indicators automatically stop	Audible and visual alarm indicators automatically stop	Audible and visual alarm indicators automatically stop

All INOPs except the “unplugged” INOPs are non-latching.

Testing Alarms

When you switch the fetal monitor on, a self test is started. You should hear a single tone. This indicates that the audible alarm indicators are functioning correctly. For further testing of individual measurement alarms, perform the measurement on yourself (for example SpO_2 or NBP) or use a simulator. Adjust alarm limits and check that appropriate alarm behavior is observed.

To test the functioning of visible and audible alarms, do the following:

1 Enable the alarm (**Alarm Mode** needs to be set to **All**, see the Configuration Guide).

2 Set the alarm limits.

3 Measure or simulate the parameter that is out of range, or signal loss.

4 Verify that the visible and audible alarms are working.

As an example, to test the FHR alarms:

1 Connect the US transducer to a fetal sensor socket.

2 Enable the FHR alarming (see “Turning Alarms On or Off” on page 197).

3 Set the high alarm limit and delay to 150 bpm and 60 seconds respectively, and the low alarm limit and delay to 110 bpm and 60 seconds respectively (see “Changing Alarm Limits” on page 197).

4 Generate a fetal heart rate of approximately 180 bpm (3 beats per second) for more than one minute.

5 Verify the functioning of the visible and audible alarms.

Alarm Behavior at Power On

If the monitor is switched off for longer than one minute and then switched on again, or after a loss of power lasting longer than one minute, the monitor can be configured to restore either the alarm settings from the monitor's **User Defaults**, or the most recently used alarm settings. When a patient is discharged, the **User Defaults** of the monitor are always restored independent of the setting. After any of these situations, ensure that the alarm settings are appropriate for your patient. If power is lost for less than one minute, the alarm settings prior to the power loss are restored.

- If **AlarmsOffAtStart** is enabled in Configuration Mode alarms will be initially paused or off the next time the monitor is switched on, depending on a set of related configuration settings, see the Configuration Guide.

6 Alarms

7

Patient Alarms and INOPs

This chapter lists alarms and technical alarms (INOPs) for the fetal monitors irrespective of their priority.

Alarm Messages

Fetal alarms are identified by either "FHR", "dFHR", or "aFHR". All other alarms without these identifiers refer to maternal parameters. Alarm messages can be configured with the **Enhanced** setting to give more information. These messages are shown additionally in the table below, with **xxx** for the measured value and **yyy** for the alarm limit concerned.

Alarm Message	From	Condition	Indication
**** aFHR1 High** **** aFHR2 High** **** aFHR3 High** **** aFHR1 xxx>yyy** **** aFHR2 xxx>yyy** **** aFHR3 xxx>yyy**	FHR (CL F&M Pod)	The fetal heart rate obtained from the CL F&M Pod has risen above the high alarm limit. xxx denotes the highest measured value, and yyy is the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm message, alarm tone.
**** aFHR1 Low** **** aFHR2 Low** **** aFHR3 Low** **** aFHR1 xxx<yyy** **** aFHR2 xxx<yyy** **** aFHR3 xxx<yyy**	FHR (CL F&M Pod)	The fetal heart rate obtained from the CL F&M Pod has fallen below the low alarm limit. xxx denotes the lowest measured value, and yyy is the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm message, alarm tone.
****aHR High** **** HR xxx>yyy**	HR (CL F&M Pod)	The maternal heart rate obtained from the CL F&M Pod has risen above the high alarm limit. xxx denotes the highest measured value, and yyy is the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm message, alarm tone.
****aHR Low** **** HR xxx<yyy**	HR (CL F&M Pod)	The maternal heart rate obtained from the CL F&M Pod has fallen below the low alarm limit. xxx denotes the lowest measured value, and yyy is the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm message, alarm tone.
***** Brady (Pulse)** ***** Brady/P xxx<yyy**	SpO_2	The heart rate from the Pulse signal has fallen below the bradycardia limit. xxx denotes the lowest measured value; yyy is the bradycardia limit.	Numeric flashes, red alarm message, alarm tone.

Alarm Message	From	Condition	Indication
*** Desat *** Desat xx < yy	SpO_2	The SpO_2 value has fallen below the desaturation alarm limit. xx denotes the lowest measured value, and yy is the desaturation limit.	Numeric flashes, red alarm message, alarm tone.
** dFHR1 High ** dFHR2 High ** dFHR3 High ** dFHR1 xxx>yyy ** dFHR2 xxx>yyy ** dFHR3 xxx>yyy	FHR (DECG)	The fetal heart rate obtained from DECG has risen above the high alarm limit. xxx denotes the highest measured value, and yyy is the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm message, alarm tone.
** dFHR1 Low ** dFHR2 Low ** dFHR3 Low ** dFHR1 xxx<yyy ** dFHR2 xxx<yyy ** dFHR3 xxx<yyy	FHR (DECG)	The fetal heart rate obtained from DECG has fallen below the low alarm limit. xxx denotes the lowest measured value, and yyy is the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm message, alarm tone.
*** Extreme Brady *** xBrady xxx<yyy	MECG	The maternal heart rate obtained from the maternal ECG has fallen below the extreme bradycardia limit. xxx denotes the lowest measured value, and yyy is the extreme bradycardia limit.	Numeric flashes, red alarm message, alarm tone.
*** Extreme Tachy *** xTachy xxx>yyy	MECG	The maternal heart rate obtained from the maternal ECG has risen above the extreme tachycardia limit. xxx denotes the highest measured value, and yyy is the extreme tachycardia limit.	Numeric flashes, red alarm message, alarm tone.
** FHR1 High ** FHR2 High ** FHR3 High ** FHR1 xxx>yyy ** FHR2 xxx>yyy ** FHR3 xxx>yyy	FHR (ultrasound)	The fetal heart rate obtained from ultrasound has risen above the high alarm limit. xxx denotes the highest measured value, and yyy is the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm message, alarm tone.
** FHR1 Low ** FHR2 Low ** FHR3 Low ** FHR1 xxx<yyy ** FHR2 xxx<yyy ** FHR3 xxx<yyy	FHR (ultrasound)	The fetal heart rate obtained from ultrasound has fallen below the low alarm limit. xxx denotes the lowest measured value, and yyy is the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm message, alarm tone.
** HR High ** HR xxx>yyy	MECG	The maternal heart rate obtained from the maternal ECG has risen above the high alarm limit. xxx denotes the highest measured value, and yyy is the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm message, alarm tone.

Alarm Message	From	Condition	Indication
**** HR Low** **** HR xxx<yyy**	MECG	The maternal heart rate obtained from the maternal ECG has fallen below the low alarm limit. xxx denotes the lowest measured value, and yyy is the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm message, alarm tone.
**** <iTemp Label> High**	iTemp	The temperature value has exceeded the high alarm limit.	Numeric flashes and high limit is highlighted, alarm tone.
**** <iTemp Label> Low**	iTemp	The temperature value has dropped below the alarm limit.	Numeric flashes and low limit is highlighted, alarm tone.
**** NBPs High** **** NBPd High** **** NBPm High**	Noninvasive blood pressure	The measured noninvasive blood pressure value is above the high alarm limits **s**, **d**, or **m** after the label indicates whether the systolic, diastolic, or mean pressure has crossed the limit.	Numeric flashes and high limit is highlighted, yellow alarm message, alarm tone.
**** NBPs Low** **** NBPd Low** **** NBPm Low**	Noninvasive blood pressure	The measured noninvasive blood pressure value is below the low alarm limits **s**, **d**, or **m** after the label indicates whether the systolic, diastolic, or mean pressure has crossed the limit.	Numeric flashes and low limit is highlighted, yellow alarm message, alarm tone.
**** Pulse High**	SpO_2	The pulse rate has exceeded the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm message, alarm tone.
**** Pulse Low**	SpO_2	The pulse rate has dropped below the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm message, alarm tone.
**** SpO_2 High**	SpO_2	The arterial oxygen saturation has exceeded the high alarm limit.	Numeric flashes and high limit is highlighted, yellow alarm message, alarm tone.
**** SpO_2 Low**	SpO_2	The arterial oxygen saturation has fallen below the low alarm limit.	Numeric flashes and low limit is highlighted, yellow alarm message, alarm tone.
***** Tachy (Pulse)** ***** Tachy/P xxx>yyy**	SpO_2	The heart rate from the Pulse signal has exceeded the tachycardia limit. xxx denotes the highest measured value, and yyy is the tachycardia limit.	Numeric flashes, red alarm message, alarm tone.

Technical Alarm Messages (INOPs)

Measurement INOPs

FHR INOPs: aFHR, dFHR, FHR

INOP Message	Indication	What to do
aFHR1 Signal Loss **aFHR2 Signal Loss** **aFHR3 Signal Loss**	Monitor: INOP tone Numeric is replaced by a -?- INOP tone if **Alarm Mode** is set to **All**. No tone if **Alarm Mode** is set to **INOP only**. CL F&M Pod: No LED indication, no INOP tone	The input signal quality is not sufficient to process the measurement. Reapply the electrodes of the electrode patch.
dFHR1 Equip Malf **dFHR2 Equip Malf** **dFHR3 Equip Malf**	Monitor: INOP tone	There is a problem with the DECG hardware. Contact your service personnel.
dFHR1 Leads Off **!! dFHR1 Leads Off** **!!! dFHR1 Leads Off** **dFHR2 Leads Off** **!! dFHR2 Leads Off** **!!! dFHR2 Leads Off** **dFHR3 Leads Off** **!! dFHR3 Leads Off** **!!! dFHR3 Leads Off**	Monitor: INOP tone (configurable cyan, yellow, red) Numeric is replaced by a -?-	One or more DECG lead is not attached. Make sure that all required leads are attached, and no electrodes have been displaced. Check all connections are sound, and that the leg plate attachment electrode is properly attached. If the INOP persists, try using another adapter cable, or leg plate attachment electrode. If the INOP persists, contact your service personnel.
dFHR1 Signal Loss **dFHR2 Signal Loss** **dFHR3 Signal Loss**	Monitor: INOP tone Numeric is replaced by a -?- INOP tone if **Alarm Mode** is set to **All**. No tone if **Alarm Mode** is set to **INOP only**.	The input signal quality is not sufficient to process the measurement. Reapply the fetal scalp electrode.
FHR1 Equip Malf **FHR2 Equip Malf** **FHR3 Equip Malf**	Monitor: INOP tone	There is a problem with the FHR hardware. Contact your service personnel.
FHR1 Signal Loss **FHR2 Signal Loss** **FHR3 Signal Loss**	Monitor: INOP tone Numeric is replaced by a -?- INOP tone if **Alarm Mode** is set to **All**. No tone if **Alarm Mode** is set to **INOP only**.	The input signal quality is not sufficient to process the measurement. Adjust the position of the transducer to obtain a better signal.

Maternal HR and Pulse INOPs: aHR, HR, Pulse

INOP Message	Indication	What to do
MECG Equip Malf	Monitor: INOP tone	There is a problem with the MECG hardware. Contact your service personnel.
MECG Leads Off **!! MECG Leads Off** **!!! MECG Leads Off**	Monitor: INOP tone (configurable cyan, yellow, red) Numeric is replaced by a -?-	One or more MECG leads are not attached. Ensure that all required leads are attached, and no electrodes have been displaced. Check if all connections are sound. If the INOP persists, try using another adapter cable. If the INOP still persists, contact your service personnel.

Toco and IUP INOPs

INOP Message	Indication	What to do
IUP Equip Malf	Monitor: INOP tone	There is a problem with the IUP hardware. Contact your service personnel.
Pulse(Toco) Malf	Monitor: INOP tone Toco MP Maternal Pulse Measurement	There is a problem with the Toco MP transducer hardware. Contact your service personnel.
Toco Equip Malf	Monitor: INOP tone	There is a problem with the Toco hardware. Contact your service personnel.

NBP INOPs

INOP Message	Indication	What to do
Cuff Not Deflated **!! Cuff Not Deflat** **!!! Cuff Not Deflat**	Monitor: INOP tone (configurable cyan, yellow, red) Numeric is replaced by a -?- During this INOP, alarms cannot be paused or switched off.	Remove the cuff from the patient. Make sure that the tubing is not kinked or twisted. Try restarting the measurement. You can silence the INOP, but the INOP message remains visible until the next measurement is started, or the **Stop All** SmartKey is selected.
NBP Check Cuff	Monitor: INOP tone Numeric is replaced by a -?-	Check if cuff is connected to the CL NBP Pod or the NBP connector at the fetal monitor and the cuff is applied to the patient; check tubing and cuff for leakage. Try restarting the measurement. If the INOP occurs repeatedly, contact your service personnel. You can silence this INOP, but the INOP message remains visible until the next measurement is started or the **Stop All** SmartKey is selected. This INOP is issued, when the maximum time for inflation is exceeded, or when there is a significant change in inflation time between two successive measurements in auto and sequence mode.

INOP Message	Indication	What to do
NBP Cuff Overpress **!! Cuff Overpress** **!!! Cuff Overpress**	Monitor: INOP tone (configurable cyan, yellow, red) Numeric is replaced by a -?- During this INOP, alarms cannot be paused or switched off.	The cuff pressure exceeds the overpressure safety limits. Remove the cuff from the patient. Ensure that the tubing is not kinked or twisted, and that the correct patient category is selected. Try restarting the measurement. You can silence this INOP, but the INOP message remains visible until the next measurement is started, or the **Stop All** SmartKey is selected.
NBP Equip Malf	Monitor: INOP tone Numeric is replaced by a -?-	Remove the cuff from the patient. The noninvasive blood pressure hardware is faulty. Contact your service personnel. You can silence this INOP, but the INOP message remains visible until the next measurement is started, or the **Stop All** SmartKey is selected.
NBP Interrupted	Monitor: INOP tone Numeric is replaced by a -?-	Check the tubing and cuff for leakages or kinks. Check that you are using the correct cuff size and placement, and that the correct patient category is selected. Try restarting the measurement. If the INOP occurs repeatedly, contact your service personnel. You can silence this INOP, but the INOP message remains visible until the next measurement is started, or the **Stop All** SmartKey is selected. This INOP arises when the measurement needed longer than the maximum time allowed for inflation, deflation, or the total measurement.
NBP Measure Failed	Monitor: INOP tone Numeric is replaced by a -?-	Check that you are using the correct cuff size and placement, and that the correct patient category is selected. Try restarting the measurement. You can silence this INOP, but the INOP message remains visible until the next measurement is started, or the **Stop All** SmartKey is selected. Check the condition and suitability of the patient for noninvasive blood pressure monitoring. Use another cuff to continue measuring.
NBP Neo Patient? (only with CL NBP Pod)	Monitor: INOP tone Numeric is replaced by -?- CL NBP Pod: Display message	The CL NBP Pod has detected a neonatal cuff. Replace the neonatal cuff by an adult cuff or if an adult cuff is used check the tube for kinks. If the INOP persists, contact your service personnel.

SpO2 INOPs

INOP Message	Indication	What to do
SpO_2 Equip Malf	Monitor: INOP tone	There is a problem with the SpO_2 hardware. Contact your service personnel.
SpO_2 Erratic	Monitor: INOP tone Numeric is replaced by a -?-	Check the sensor placement. Try another adapter cable and sensor. If the INOP persists, contact your service personnel.
SpO_2 Extd.Update	Monitor: No INOP tone Numeric is replaced by a -?-	The update period of displayed values is extended due to a noninvasive blood pressure measurement on the same limb, or an excessively noisy signal.

INOP Message	Indication	What to do
SpO_2 Interference	Monitor: INOP tone Numeric is replaced by a -?-	There is too much interference caused by a high level of ambient light, and/or electrical interference. Cover the sensor to minimize ambient light. If the INOP persists, ensure that the sensor cable is not damaged, or positioned too close to power cables.
SpO_2 Low Perf	Monitor: No INOP tone Numeric is displayed with a -?-	Accuracy may be compromised due to very low perfusion. Stimulate circulation at sensor site. If INOP persists, change the measurement site.
SpO_2 No Pulse **!! <SpO_2 Label> No Pulse** **!!! <SpO_2 Label> No Pulse**	Monitor: INOP tone (configurable cyan, yellow, red) Numeric is replaced by a -?-	Check the perfusion at measurement site. If necessary, stimulate circulation or change measurement site. If the INOP is due to noninvasive blood pressure measurement on the same limb, wait until the measurement is finished.
SpO_2 No Sensor	Monitor: INOP tone Numeric is replaced by a -?-	Ensure the SpO_2 sensor is connected. If the INOP persists, try another adapter cable and sensor. If you silence this INOP, the measurement will be switched off.
SpO_2 NoisySignal	Monitor: INOP tone Numeric is replaced by a -?-	Excessive patient movement or electrical interference is causing irregular pulse patterns. Try to reduce patient movement, or to relieve the cable strain on the sensor.
SpO_2 Poor Signal	Monitor: No INOP tone Numeric is displayed with a -?-	The signal condition of the SpO_2 measurement is poor and measurement accuracy may be compromised.
SpO_2 Pulse?	Monitor: INOP tone Numeric is replaced by a -?-	The detectable pulsations of the SpO_2 signal are outside the specified pulse rate range.
SpO_2 Searching	Monitor: No INOP tone Numeric unavailable	SpO_2 is analyzing the patient signal to derive Pulse, and SpO_2 values. Please wait until the search analysis is complete.
SpO_2 Sensor Malf	Monitor: INOP tone Numeric unavailable	The SpO_2 sensor or adapter cable is faulty. Try another adapter cable and sensor. If the INOP persists, contact your service personnel.
SpO_2 Sensor Off	Monitor: INOP tone Numeric unavailable	The SpO_2 sensor is not properly applied to the patient. Apply the sensor following the instructions supplied by the manufacturer.
SpO_2 Unkn.Sensor	Monitor: INOP tone Numeric is replaced by a -?-	The connected sensor or adapter cable is not supported by the SpO_2 measurement. Use only specified sensors and cables.
SpO_2 Upgrade	Monitor: No INOP tone Numeric unavailable	The SpO_2 measurement is currently in upgrade mode. Monitoring is not possible in this mode.

Tympanic Temperature INOPs

INOP Message	Indication	What to do
<iTemp Label> CalRequired	Monitor: INOP tone	The thermometer requires calibration. Contact your service personnel.
<iTemp Label> Malfunction	Monitor: INOP tone Numeric is replaced by a -?-	The thermometer or the interface board is defective. Check the thermometer on another monitor - if the same INOP occurs, replace the thermometer. If not, connect another thermometer to this monitor. If the problem persists, the interface board has a problem. Contact your service personnel.
<iTemp Label> Meas Failed	Monitor: INOP tone Numeric is replaced by a -?-	The ambient temperature is out of range. If the ambient temperature is within the valid range, check the thermometer. Try picking up a new probe cover. If the problem persists replace the thermometer and contact your service personnel.
<iTemp Label> Overrange	Monitor: INOP tone Numeric is replaced by a -?-	The measured temperature is out of range. If the temperature is within the valid range, check with another thermometer.

Measurement Applications INOPs

INOP Message	Indication	What to do
Coincidence **!! Coincidence**	Monitor: Yellow with INOP tone. (If the initial temporary reduction of severity is configured: Cyan without INOP tone). (See **Coincidence Tone** in **Alarm Settings** menu)	The fetal heart rate(s) and maternal heart rate/pulse persistently coincide with another. (see "Cross-Channel Verification (CCV)" on page 163). The INOP tone has a configurable delay. The default setting is an instant INOP tone.
NST:TimeElapsed	Monitor: INOP tone (Message and tone only if **Setup NST Timer**, **Notification** is set to **Alarm** in Configuration Mode).	The time has expired for the NST timer. Clearing the timer clears the INOP.

Device INOPs

Monitor INOPs

INOP Message	Indication	What to do
2nd Tele Incompat	Monitor: INOP tone	One of the connected base stations is not supported by the monitor. Check software revisions.
Bus Master Incomp	Monitor: INOP tone	The Bus Master board or firmware is incompatible and cannot be used with this monitor software revision. Contact your service personnel.
Bus Master Malfunc	Monitor: INOP tone	There is a problem with the monitor's hardware. Contact your service personnel.
Check Flex Texts	Monitor: INOP tone	If this INOP appears, check the monitor and patient settings before you resume monitoring. If the settings are unexpected, there may be a problem with the monitor software. Contact your service personnel.
Check Keyboard	Monitor: INOP tone	Perform a visual and functional check of the keyboard. Contact your service personnel.
Check Monitor Func	Monitor: INOP tone	A potential internal problem with the monitor has been detected. Contact your service personnel.
Check Monitor Temp	Monitor: INOP tone	The temperature inside the monitor is too high. Check that the monitor ventilation is not obstructed. If the situation continues, contact your service personnel.
Check Mouse	Monitor: INOP tone	Perform a visual and functional check of the mouse input device. Contact your service personnel.
Check OBR Config	Monitor: INOP tone	OBR (OB Radio) channel configuration is invalid or settings are not present. Check channel configuration and hardware option.
Check Settings	Monitor: INOP tone	If this INOP appears, check the monitor and patient settings before you resume monitoring. If the settings are unexpected, there may be a problem with the monitor software. Contact your service personnel.
Check TI Config	Monitor: INOP tone	If this INOP appears, the monitor can be used normally, except for the Trace Interpretation feature. Contact your service personnel.
Check Touchscreen	Monitor: No INOP tone	Perform a visual and functional check of the touch input device. Contact your service personnel.
Internal.Comm.Malf	Monitor: INOP tone	There is a problem with I2C Bus communication in the monitor. Contact your service personnel.
OBR Interference	Monitor: INOP tone	OBR (OB Radio) communication is disturbed by other devices (not necessarily other wireless measurements). Contact service personnel.
Rem. Display Malf.	Monitor: INOP tone	One of the Remote Display's input devices is not working correctly. Perform a visual and functional check. If the INOP persists contact your service personnel.
Settings Malfunct	Monitor: INOP tone	The monitor cannot use the predefined settings for monitoring. Contact your service personnel.

INOP Message	Indication	What to do
Speaker Malfunct	Monitor: INOP tone	Contact your service personnel to check the speaker and the connection to the speaker.
SRR Incompatible	Monitor: INOP tone	The connected SRR (Short Range Radio) board or firmware cannot be used with this base station's software revision. Contact your service personnel.
SRR Malfunction	Monitor: INOP tone	Malfunction in the SRR (Short Range Radio) module(s). If the INOP persists, contact your service personnel.
Tele Incompatible	Monitor: INOP tone	The base station is not supported by the monitor. Check software revisions.
Tele Malfunction	Monitor: INOP tone	Malfunction of the connected base station. If the INOP persists contact your service personnel.
Tele Unplugged	Monitor: INOP tone	The base station has been disconnected from the monitor, while one or more CL devices were active. This INOP is only issued, if the setting **Sensor Disconnct** is **No Auto Off**, or the **Alarm Mode** is set to **All**.
Unsupported LAN	Monitor: INOP tone	There is a problem with the communication to the network and central monitoring is currently not possible. Check the connection. If the INOP persists, switch off the monitor and contact your service personnel.
User I/F Malfunct	Monitor: INOP tone	Perform a visual and functional check of all the monitor input devices. Contact your service personnel.

FM20/FM30 Battery INOPs

INOP Message	Indication	What to do
Batt Empty **!! Batt Empty** **!!! Batt Empty**	Monitor: INOP tone (configurable cyan, yellow, red) Battery LED at the monitor flashes. During this INOP, alarms cannot be paused or switched off.	The estimated remaining battery-powered operating time is less than 10 minutes. Connect the monitor to AC immediately. If the condition persists and the monitor is not connected to mains power, this INOP is re-issued two minutes after you acknowledge it.
Batt Incompat	Monitor: INOP tone	The battery cannot be used with this monitor. Replace it with the correct battery.
Batt Low	Monitor: INOP tone	The estimated battery-powered operating time remaining is less than 20 minutes.
Batt Malfunction	Monitor: INOP tone Battery LED at the monitor flashes. During this INOP, alarms cannot be paused or switched off unless the monitor is connected to mains power.	The monitor cannot determine the battery status. If the INOP persists, replace the faulty battery. If the condition persists and the monitor is not connected to mains power, this INOP is reissued two minutes after you acknowledge it.
Batt Missing	Monitor: INOP tone	No battery found in FM20/30. Contact your service personnel.

INOP Message	Indication	What to do
Charger Malfunct	Monitor: INOP tone Battery LED at the monitor may flash.	There is a problem with the battery charger in the monitor. Connect the monitor to mains power and contact your service personnel.
Check Batt Temp	Monitor: INOP tone	The temperature of the battery is too high. Check that the monitor is not exposed to heat.

Recorder INOPs

INOP Message	Indication	What to do
Check Paper	Monitor: No INOP tone Recorder: printout	Check that there is no paper jam, that the print drawer is properly shut, that the paper is loaded with the grid facing upwards, and that the correct Philips paper is being used.
FetRec Chk Config	Monitor: INOP tone	**Recorder Speed** and/or **Scale Type** settings are set to **Unknown** and need to be set to the correct values in Configuration Mode before the recorder can be operated.
FetRec Equip Malf	Monitor: INOP tone	There is a problem with the fetal recorder hardware. Contact your service personnel.
Paper End	Monitor: INOP tone	The end of the paper pack is detected. Insert a new pack of paper.
Printhead Overheat	Monitor: INOP tone	The printhead is too hot. The recorder stops, the recorder **Start/ Stop** key is disabled, and remains so until the printhead cools down sufficiently. Wait for the printhead to cool down, then press the recorder **Start/ Stop** key or the **Silence** key to clear the INOP.
Wrong Paper Scale	Monitor: INOP tone Recorder: printout	The grid scale of the paper in the monitor does not match the grid scale configured in the monitor. Make sure that you use the correct paper and scale for your institution: pre-printed: 30-240 in US and Canada, 50-210 in other geographies.

Wired Transducer INOPs

INOP Message	Indication	What to do
dFHR1 Unplugged **dFHR2 Unplugged** **dFHR3 Unplugged**	Monitor: INOP tone Numeric is replaced by a -?-	Reconnect the DECG transducer to the monitor. Check if all connections are sound.
FHR1 Unplugged **FHR2 Unplugged** **FHR3 Unplugged**	Monitor: INOP tone	Reconnect the FHR transducer to the monitor. Check if all connections are sound.
IUP Unplugged	Monitor: INOP tone	Reconnect the IUP transducer to the monitor. Check if all connections are sound.

INOP Message	Indication	What to do
MECG Unplugged	Monitor: INOP tone Numeric is replaced by a -?-	Reconnect the MECG transducer to the monitor. Check if all connections are sound.
Toco Unplugged	Monitor: INOP tone	Reconnect the Toco transducer to the monitor. Check if all connections are sound.

Cableless Transducer INOPs

INOP Message	Indication	What to do
cl US Batt Empty !! cl US Batt Empty !!! cl US BattEmpty cl Toco Batt Empty !! clToco BattEmpty !!! clTocoBattEmpty cl ECG/IUP Empty !! cl ECG/IUP Empty !!! clECG/IUP Empty	Monitor: INOP tone (configurable cyan, yellow, red) CL transducer: LED flashes red, yellow INOP tone	The remaining monitoring time with this transducer is below 15 minutes. Charge battery.
cl US Batt Low cl Toco Batt Low cl ECG/IUP BattLow	Monitor: No INOP tone CL transducer: LED flashes red, no INOP tone	The remaining monitoring time with this transducer is below 30 minutes. Charge battery.
cl US Batt Malf cl Toco Batt Malf clECG/IUP BattMalf	Monitor: INOP tone CL transducer: Cyan LED, INOP tone	Malfunction of the battery system (charger circuit or battery) detected (e.g. persistent communication error, overvoltage, overcurrent, battery incompatible). Contact your service personnel.
cl US Check Temp cl Toco Chk Temp clECG/IUP Chk Temp	Monitor: INOP tone CL transducer: Cyan LED, INOP tone	The temperature of the transducer or its battery is critically high. If the transducer is docked on the base station, charging is interrupted. Check that the transducer is not covered and do not expose it to a heat source. Do not place the base station in a sunny window in a room without active air conditioning. The environment temperature to charge a transducer battery should not exceed 40°C/104°F. If the INOP persists, remove the transducer from patient and contact your service personnel.
cl US Disconnect cl Toco Disconnect cl ECG/IUP Disconn	Monitor: INOP tone CL transducer: Cyan LED, INOP tone	The cableless transducer has lost the connection to the monitor.
cl US Malfunction cl Toco Malf cl ECG/IUP Malf	Monitor: INOP tone Numeric is replaced by a -?- CL transducer: Cyan LED, INOP tone	Malfunction of the transducer. Contact your service personnel.

CL Fetal & Maternal Pod INOPs

The INOP indication describes the system behavior when the Pod is connected to the monitor.

INOP Message	Indication	What to do
cl F&M Batt Empty !! cl F&M BattEmpty !!! cl F&M BatEmpty	Monitor: INOP tone (configurable cyan, yellow, red) CL F&M Pod: LED flashes red, yellow INOP tone	The remaining monitoring time with the CL F&M Pod is below 15 minutes. Charge the battery.
cl F&M Batt Low	Monitor: No INOP tone CL F&M Pod: LED flashes red, no INOP tone	The remaining monitoring time with the CL F&M Pod is below 30 minutes. Charge the battery.
cl F&M Batt Malf	Monitor: INOP tone CL F&M Pod: Cyan LED, no INOP tone	Malfunction of the battery system (charger circuit or battery) detected (for example: persistent communication error, overvoltage, overcurrent, battery incompatible). Contact your service personnel.
cl F&M Batt Temp	Monitor: INOP tone CL F&M Pod: Cyan LED, no INOP tone	The temperature of the CL F&M Pod or its battery is critically high (in charging mode) or critically low (independent of battery mode). If the Pod is docked on the base station, charging is interrupted. Check that device is not covered. Do not expose device to heat sources. If INOP persists, remove the CL F&M Pod from patient. Contact your service personnel.
cl F&M Chk Electr.	Monitor: INOP tone; without tone, if no CL F&M Pod parameter shows -?- CL F&M Pod: No LED indication, no INOP tone	• Not all electrodes have sufficient skin contact: Prepare the skin at the application site further with the abrasive pad. • One or more leads between the measurement Pod and the electrode(s) is broken: Replace the electrode patch. • Contact problem between the CL F&M Pod and the electrode patch: Reconnect the CL F&M Pod. This INOP can only occur in Monitoring Mode after the initial electrode impedance check has occurred.
cl F&M ChkSettings	Monitor: INOP tone CL F&M Pod: Cyan LED, no INOP tone	The CL F&M Pod settings are incompatible or corrupted. Check the settings. Contact your service personnel.
cl F&M Disconnect	Monitor: INOP tone CL F&M Pod: Cyan LED, INOP tone	The CL F&M Pod has lost the connection to the monitor. Call the patient back to the monitor. If the CL F&M Pod has still no connection, remove it from the monitor, and reassign it. If it still does not have a connection, contact your service personnel.
cl F&M License Req	Monitor: INOP tone CL F&M Pod: No LED indication, no INOP tone	There is no valid license registered. Contact your service personnel.
cl F&M Malfunction	Monitor: INOP tone CL F&M Pod: No LED indication, no INOP tone	The CL F&M Pod malfunctions. Contact your service personnel.

INOP Message	Indication	What to do
cl F&M Patch Disc	Monitor: INOP tone CL F&M Pod: No LED indication, no INOP tone	The CL F&M Pod has been disconnected from the electrode patch during Monitoring Mode. Reconnect the CL F&M Pod.
cl F&M Patch Malf	Monitor: INOP tone CL F&M Pod: No LED indication, no INOP tone	The connected electrode patch cannot be identified. Either the electrode patch is malfunctioning, or the connection between the CL F&M Pod and the patch is defective.
cl F&M Remove	Monitor: INOP tone CL F&M Pod: Cyan LED, no INOP tone	The battery temperature is too high (above 60°C/140°F). Remove the CL F&M Pod immediately from the patient. Contact your service personnel.

CL Wide Range Pod INOPs

The INOP indication describes the system behavior when the Pod is connected to the monitor.

INOP Message	Indication	What to do
cl WRP Batt Empty !! cl WRP BattEmpty !!! cl WRP BatEmpty	Monitor: INOP tone (configurable cyan, yellow, red) CL Wide Range Pod: Display and yellow INOP tone	The remaining monitoring time with the CL Wide Range Pod is below 15 minutes. Charge the battery.
cl WRP Batt Low	Monitor: No INOP tone CL Wide Range Pod: Display only	The remaining monitoring time with the CL Wide Range Pod is below 30 minutes. Charge the battery.
cl WRP Batt Malf	Monitor: INOP tone CL Wide Range Pod: Display only	Malfunction of the battery system (charger circuit or battery) detected (for example: persistent communication error, overvoltage, overcurrent, battery incompatible). Contact your service personnel.
cl WRP Batt Temp	Monitor: INOP tone CL Wide Range Pod: Display only	The temperature of the CL Wide Range Pod or its battery is critically high (in charging mode) or critically low (independent of battery mode). If the Pod is docked on the base station, charging is interrupted. Check that device is not covered. Do not expose device to heat sources. If INOP persists, remove the CL Wide Range Pod from patient. Contact your service personnel.
cl WRP Chk Chrg IF	Monitor: INOP tone CL Wide Range Pod: Display only	Overvoltage or undervoltage detected at the charger interface. Clean contacts of charger interface at Cableless Measurement Device and charging station. If the INOP persists, contact your service personnel.
cl WRP ChkSettings	Monitor: INOP tone CL Wide Range Pod: Display only	The CL Wide Range Pod settings are incompatible or corrupted. Check the settings. Contact your service personnel.
cl WRP Disconnect	Monitor: INOP tone CL Wide Range Pod: No message, no tone	The CL Wide Range Pod has lost the WLAN/LAN connection for more than 10 seconds to the monitor.

INOP Message	Indication	What to do
cl WRP License Req	Monitor: INOP tone CL Wide Range Pod: Display only	There is no valid license registered. Contact your service personnel.
cl WRP Malfunction	Monitor: INOP tone CL Wide Range Pod: No message, no tone	The CL Wide Range Pod is malfunctioning. Contact your service personnel.
cl WRP Remove	Monitor: INOP tone CL Wide Range Pod: Display only	The battery temperature is too high (above 60°C/140°F). Remove the CL Wide Range Pod immediately from the patient. Contact your service personnel.

CL NBP Pod INOPs

The INOP indication describes the system behavior when the Pod is connected to the monitor. The INOP message on the CL device differs from the text on the monitor. For further information see IntelliVue CL Device Instruction for Use.

INOP Message	Indication	What to do
cl NBP Batt Empty !! cl NBP BattEmpty !!! cl NBP BatEmpty	Monitor: INOP tone (configurable cyan, yellow, red) CL NBP Pod: Display, yellow INOP tone	The remaining battery time of the CL NBP Pod is below 30 minutes. Charge the battery.
cl NBP Batt Low	Monitor: INOP tone CL NBP Pod: Display only	The remaining battery time of the CL NBP Pod is below 2 hours.
cl NBP Batt Malf	Monitor: INOP tone CL NBP Pod: Display only	There is a malfunction in the CL NBP Pod's battery system. Contact your service personnel.
cl NBP Batt Temp	Monitor: INOP tone CL NBP Pod: Display only	The temperature of the battery in the CL NBP Pod is critically high (in charging mode) or critically low (independent of battery mode). Check that the Pod is not covered or exposed to a heat source. If the INOP persists, remove the Pod from the patient, and contact your service personnel.
cl NBP Check Batt	Monitor: INOP tone CL NBP Pod: Display only	The battery in the CL NBP Pod is nearing the end of its useful life. Only 50 charge-discharge cycles remain. Contact your service personnel to replace the battery.
cl NBP Chk Chrg IF	Monitor: INOP tone CL NBP Pod: Display only	Overvoltage or undervoltage detected at the charger interface. Clean contacts of charger interface at Cableless Measurement Device and charging station. If the INOP persists, contact your service personnel.

INOP Message	Indication	What to do
cl NBP ChkSettings	Monitor: INOP tone CL NBP Pod: Display only	If this INOP appears and an INOP tone sounds, check the Cableless Measurement Device and patient settings before you resume making measurements. If the settings are unexpected, there may be a problem with the Cableless Measurement Device software. Contact your service personnel. If this INOP is acknowledged at the Cableless Measurement Device, it is cleared. If it is silenced remotely, only the tone is cleared.
cl NBP Disconnect	Monitor: INOP tone CL NBP Pod: Display message "No host monitoring", INOP tone	The CL NBP Pod has lost the SRR connection to the monitor.
cl NBP License Req	Monitor: INOP tone CL NBP Pod: Display only	The CL NBP Pod requires a valid software license for operating. Contact your service personnel.
cl NBP No Cradle	Monitor: INOP tone CL NBP Pod: Display only	The CL NBP Pod is not in the cradle. You can silence this INOP, but the INOP message remains visible until the CL NBP Pod is inserted into the cradle, and the next measurement is started, or the **Stop All** SmartKey is selected.
cl NBP Remove	Monitor: INOP tone CL NBP Pod: Display only	The temperature of the battery in the CL NBP Pod is too high. Remove the Cableless Measurement Device from the patient and contact service personnel.
cl NBP Serv Batt	Monitor: INOP tone CL NBP Pod: Display only	The battery in the CL NBP Pod has reached the end of its useful life. It can no longer be charged. Contact your service personnel to replace the battery.

CL SpO2 Pod INOPs

The INOP indication describes the system behavior when the Pod is connected to the monitor. The INOP message on the CL device differs from the text on the monitor. For further information see IntelliVue CL Device Instruction for Use.

INOP Message	Indication	What to do
cl SpO_2 Batt Empty !! cl SpO_2 BatEmpty !!! cl SpO_2 BtEmpty	Monitor: INOP tone (configurable cyan, yellow, red) CL SpO_2 Pod: Display, yellow INOP tone	The remaining battery time of the CL SpO_2 Pod is below 30 minutes. Charge the battery.
cl SpO_2 Batt Low	Monitor: INOP tone CL SpO_2 Pod: Display only	The remaining battery time of the CL SpO_2 Pod is below 2 hours.
cl SpO_2 Batt Malf	Monitor: INOP tone CL SpO_2 Pod: Display only	There is a malfunction in the CL SpO_2 Pod's battery system. Contact your service personnel.

INOP Message	Indication	What to do
cl SpO_2 Batt Temp	Monitor: INOP tone CL SpO_2 Pod: Display only	The temperature of the battery in the CL SpO_2 Pod is critically high (in charging mode) or critically low (independent of battery mode). Check that the Pod is not covered or exposed to a heat source. If the INOP persists, remove the CL Pod from the patient, and contact your service personnel.
cl SpO_2 Check Batt	Monitor: INOP tone CL SpO_2 Pod: Display only	The battery in the CL SpO_2 Pod is nearing the end of its useful life. Only 50 charge-discharge cycles remain. Contact your service personnel to replace the battery.
cl SpO_2 Chk ChrgIF	Monitor: INOP tone CL SpO_2 Pod: Display only	Overvoltage or undervoltage detected at the charger interface. Clean contacts of charger interface at Cableless Measurement Device and charging station. If the INOP persists, contact your service personnel.
cl SpO_2 Chk Sett	Monitor: INOP tone CL SpO_2 Pod: Display only	If this INOP appears and an INOP tone sounds, check the Cableless Measurement Device and patient settings before you resume making measurements. If the settings are unexpected, there may be a problem with the Cableless Measurement Device software. Contact your service personnel. If this INOP is acknowledged at the Cableless Measurement Device, it is cleared. If it is silenced remotely, only the tone is cleared.
cl SpO_2 Disconnect	Monitor: INOP tone CL SpO_2 Pod: Display message "No host monitoring", INOP tone	The CL SpO_2 Pod has lost the SRR connection to the monitor.
cl SpO_2 Remove	Monitor: INOP tone CL SpO_2 Pod: Display only	The temperature of the battery in the CL SpO_2 Pod is too high. Remove the CL SpO_2 Pod from the patient and contact service personnel.
cl SpO_2 Serv Batt	Monitor: INOP tone CL SpO_2 Pod: Display only	The battery in the CL SpO_2 Pod has reached the end of its useful life. It can no longer be charged. Contact your service personnel to replace the battery.
clSpO_2 License Req	Monitor: INOP tone CL SpO_2 Pod: Display only	The CL SpO_2 Pod requires a valid software license for operating. Contact your service personnel.

8

Admitting and Discharging

The fetal monitor can store basic patient demographic information used to identify patients.

Admit/Discharge on the Monitor

This section describes how you admit and discharge patients when using the monitor as a stand-alone device (that is, when not used with an obstetrical information and surveillance system such as OB TraceVue/IntelliSpace Perinatal).

Admitting a Patient

The fetal monitor displays physiological data as soon as a patient is connected. This lets you monitor a patient who is not yet admitted. It is however important to admit patients properly so that you can identify your patient on recordings.

Use the **Patient Demographics** window and its associated pop-up keys to admit and discharge patients.

To admit a patient:

1 Select the patient name field or select the **Patient Demogr.** SmartKey to open the **Patient Demographics** window.

2 Clear any previous patient data by selecting **Dischrge Patient** and then **Confirm**.
If you do not discharge the previous patient, you will not be able to distinguish data from the previous and current patients on the recording.

3 Select **Admit Patient**.

4 Enter the patient information: select each field and use the on-screen keyboard.
If a conventional keyboard is connected to the monitor, you can use this to enter patient information:

- **Last Name**: Enter the patient's last name (family name), for example **Doe**.
- **First Name**: Enter the patient's first name, for example **Jane**.
- **MRN**: Enter the patient's medical record number (MRN), for example **12345678**. Depending on your configuration this field may be labeled differently e.g. **Record ID**, **Lifetime ID**, **Account Number**, **Serial Number**, or **SSN**.
- **Gestational Age**: Enter the gestational age of the pregnancy. Enter one numeric for the week (0-50) and one numeric for the day (0-6).
- **Date of Birth**: Enter the patient's date of birth.

5 Select **Confirm**. The patient status changes to admitted. If the recorder is running, the recorder stops and immediately restarts to annotate the new patient data.

Quick Admitting a Patient

Use **Quick Admit** to quickly admit a patient using only a limited set of demographic data.

1 Select the **Quick Admit** SmartKey.

2 Enter the required data (ID fields or last name depending on configuration) with the keyboard or a barcode scanner.

3 Select **Enter**.

4 In the confirmation window, select **Confirm** to stop monitoring for the previous patient.

Complete the rest of the demographic details as soon as possible to fully identify the patient on the network, on the monitor, and on printed reports. To complete the details, open the **Patient Demographics** window and complete all required fields.

Editing Patient Information

To edit the patient information after a patient has been admitted, select the patient name field on the main screen of the fetal monitor to open the **Patient Demographics** window, and enter the required changes.

Discharging a Patient

You should always perform a discharge even if your previous patient was not admitted. A discharge:

- clears the information in the **Patient Demographics** window.
- resets all monitor settings to the settings defined in the **User Defaults**.
- advances the paper automatically if the recorder is running.
- stops the fetal recorder.

When a patient is discharged from the monitor, all patient demographic data is deleted (trace data is not affected).

Depending on your configuration, monitoring for a patient may end automatically when the fetal monitor has been powered off, or is in Standby mode for a set time.

To discharge a patient:

1 Select the patient name field to display the **Patient Demographics** window and associated pop-up keys.

2 Select the pop-up key for **Dischrge Patient**.

3 Select **Confirm** to discharge the patient.

CAUTION

In order to ensure that the settings are reset to **User Defaults** for a new patient, always discharge the previous patient from the fetal monitor.

NOTE

In order to ensure a continuous record, it is recommended to discharge the patient at the monitor before performing a new patient admission in OB TraceVue/IntelliSpace Perinatal.

New Patient Check

The fetal monitor can be configured to ask you in certain situations:

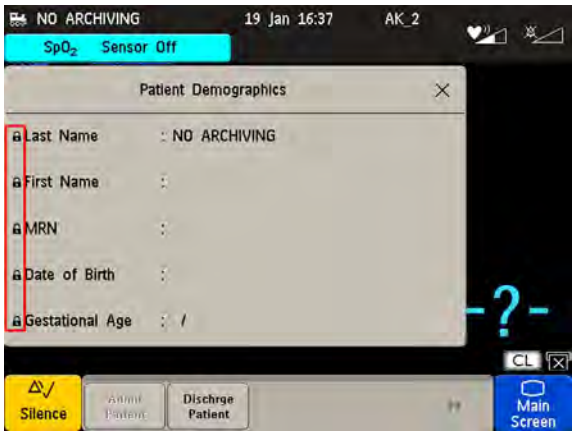
- after a specified power-off period
- after a specified Standby period

whether a new patient is now being monitored. The pop-up window is entitled **Is this a New Patient?**. The monitor offers a **Yes** key, to discharge the previous patient and begin monitoring a new patient, and a **No** key, to continue monitoring with the current patient data and settings.

The time periods for the two conditions can be configured independently.

OB TraceVue/IntelliSpace Perinatal

When the monitor is connected over a LAN connection to an OB TraceVue/IntelliSpace Perinatal system, the patient demographic data is controlled by the OB TraceVue/IntelliSpace Perinatal system. All patient and location-related data visible on the monitor is set, overwritten, or updated by the OB TraceVue/IntelliSpace Perinatal system. In the **Patient Demographics** window, a padlock symbol before the patient identification fields indicates the locked state. The locked state prevents the reuse of the monitor for another patient, until the current patient is discharged, and the monitor is freed through the OB TraceVue/IntelliSpace Perinatal system. Locked fields remain locked when system connectivity is lost, until the monitor is freed by discharging the patient. See the OB TraceVue/IntelliSpace Perinatal Instructions for Use for details.



Transferring a Patient

When you are transferring a patient from one bed to another, both the monitor from which you are transferring her and the monitor to which you are transferring her must be switched on and connected to the OB TraceVue/IntelliSpace Perinatal network during the patient transfer.

OB TraceVue/IntelliSpace Perinatal via RS232

In contrast to a LAN connection, when the monitor is connected to an OB TraceVue/IntelliSpace Perinatal system over an RS232 connection, the OB TraceVue/IntelliSpace Perinatal system does not have full control over the monitor's patient admission and discharge functions.

Depending on how OB TraceVue/IntelliSpace Perinatal is configured, *either* the **Last Name**, **First Name**, and the bed label, *or* just the bed label alone, are taken from the OB TraceVue/IntelliSpace Perinatal system. See the OB TraceVue/IntelliSpace Perinatal Instructions for Use for details.

9

Non-Stress Test Timer

The non-stress test (**NST**) timer shows the elapsed time for the non-stress test. The timer counts up to the time you set for the NST.

Setting NST Autostart/Autostop

You can set the recorder so that it starts automatically (**NST Autostart**) when the NST timer is started, and stops automatically (**NST Autostop**) when the NST is complete (when the set run time has elapsed). As default, **NST Autostart** is **On**, and **NST Autostop** is **Off**.

Viewing the NST Timer

You can configure the timer notification symbol, (the NST label), a progress bar and the elapsed time to be displayed in the top left-hand corner of the screen. By default, the NST timer is not displayed on the screen.

Alternatively, you can view the timer in the **Timers** window.

To open the **Timers** window:

Either

- Press the **Timer** SmartKey.

Or

- Access the NST pop-up keys (see "Accessing the NST Setup Pop-up Keys" on page 149), and press the **Timers** key.

Timer Expiry Notification

When the timer expires, the color changes from blue to green, you hear a single tone, and a message appears in the status line on the main screen.

The volume of the tone can be set in Configuration Mode.

Accessing the NST Setup Pop-up Keys

You control and set up the NST timer (for example, start, stop, or clear the timer, and set the run time) using a selection of pop-up keys that you access via any one of three possible routes:

- Via the **Timer** SmartKey (Route 1)
- Via the **Main Setup** SmartKey (Route 2)
- Via the NST display area at the top left-hand corner of the screen (Route 3). When you touch the NST display area, the NST pop-up keys become available at the bottom of the screen.

Via the Timer SmartKey (Route 1)

Press the **Timer** SmartKey. The **Timers** window opens, and the pop-up keys for controlling/setting up the NST timer appear (see "Pop-up Keys for NST Timer Setup" on page 150).

Via the Main Setup SmartKey (Route 2)

1 Enter the **Main Setup** menu using the SmartKey.

2 Select **NST** to enter the **Setup NST** menu. At the same time, the pop-up keys for setting up the NST timer appear (see "Pop-up Keys for NST Timer Setup" on page 150).

Via the NST Display Area (Route 3)

Select the NST display area at the top left-hand corner of the screen (when so configured). The pop-up keys for controlling/setting up the NST timer become available at the bottom of the screen (see "Pop-up Keys for NST Timer Setup" on page 150).

Pop-up Keys for NST Timer Setup

Pop-Up Keys	Selecting this pop-up key lets you:	Comments
Start	Start the timer.	
Stop	Stop the timer, allowing either restarting after a pause (**Start**) or clearing (**Clear** key).	
Setup NST	Enter the **Setup NST** menu. From here you can set the run time.	This pop-up key is not available with Route 2, as the **Setup NST** menu is already open.
Timer	Return to the **Timers** window.	This pop-up key is not available with Route 1, as the **Timers** window is already open.

Run Time

The run time can be set from 10 to 60 minutes. See the Configuration Guide for details how to set the run time.

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Non-Stress Test Report

A Non-Stress Test (**NST**) allows you to assess fetal well-being. The monitor's NST report functionality is intended for antepartum testing. It interprets the fetal heart rate trace (FHR from ultrasound, but not dFHR or aFHR) and the maternal Toco trace to generate a printed report of criteria met or not met. The interpretation algorithm and rule sets are equivalent to those implemented in OB TraceVue Revision G.xx or IntelliSpace Perinatal Revision H.xx and higher.

An NST report is a diagnostic aid, but it does not replace the clinician's judgment. The interpretation and the appropriate clinical response remain with the clinician.

A fetus normally produces characteristic heart rate patterns. Average baseline variability and acceleration of the FHR in response to fetal movement are considered normal. This test does not take into account any form of external fetal stimulation.

For every active ultrasound fetal heart rate measurement, one NST report can reside in the monitor's memory. The reports are cleared when you discharge a patient and when you start a new NST trace interpretation.

When the NST Report option is available and the **NST Report** feature is on, the NST status for all available ultrasound fetal heart rate measurements are displayed on the screen.

The minimum displayed information is:

- NST identification (by FHR number: 1, 2, 3)
- Current NST status

NST Status Transitions	
	Inverse for **Ready** to white for **Ongoing**
	White for **Ongoing** to green for **Finished at** *
	White for **Ongoing** to yellow for **Stopped at** *

*For date and time see the **NST Status** window or the printed report.

Depending on the report configuration, Non-Stress Tests can be calculated:

Based on NICHD Guideline for trace interpretation

The NST test using the NICHD algorithm has configurable parameters. It has a maximum run time of 90 minutes and no interdependent criteria. The interpretation algorithm and rule set are based on the 2008 NICHD guidelines.

Based on Dawes/Redman Guideline for trace interpretation

The trace interpretation according to Dawes/Redman 2002 is not available for U.S. and other FDA regulated territories. It has preconfigured parameters (range and limit), a maximum run time of 60 minutes, and interdependent input criteria.

Terminology FHR variability/FHR variation

NST according to the NICHD guideline uses the term **variability**. NST according to the Dawes/Redman trace interpretation uses the term **FHR variation**.

Setting Up an NST Report

To set up NST Report functionality:

1 Enter the **Main Setup** menu and select the **NST Report**.

2 Or select the **NST Report** SmartKey.

3 Press the **Setup** pop-up key.

4 Set your configuration options.

Select from:

- **NST Analysis**- choose from **On** or **Off**.

This switches the report feature on or off. This is linked to the NST timer. Both must be set to **On** for the NST report to function.

- **Report Recording** choose from:
  - **Manual** - press the **Record Report** pop-up key to trigger a manual request.
  - **After Recorder Stop** - report is recorded as soon as recorder becomes idle.
  - **Immediately** - if a realtime recording is running, the monitor pauses it. The recording is continued after the report has been recorded.

Criteria Not Met

If the criteria are not met when the test has finished, or if you stop anytime during the test period, a report is generated stating the criteria have not been met.

Nonreactive NST Test

If a nonreactive test occurs, and you then use acoustic stimulation, you must exercise caution in interpreting the resulting traces, as artificial stimulation is not taken into account when calculating test results.

Printing an NST Report

When an NST test is finished or has been stopped, an NST report is printed depending on the **Report Recording** configuration.

NST According to NICHD Trace Interpretation

NST Criteria NICHD

The patient is monitored for a user-definable period of time (10-60 minutes in steps of 5 minutes). The test is considered reassuring when the following criteria are met:

- The fetal heart rate is valid at least 90% (this is configurable) of the specified time span.
- The FHR features a user-defined minimum number of accelerations.
- The FHR features a user-defined maximum number of tolerated decelerations, and must not include severe or prolonged decelerations, which are never tolerated.
- There are no severe, prolonged, late, or variable decelerations. Does not include severe or prolonged decelerations, which are never tolerated.

- The average baseline fetal heart rate lies within the user-defined limits for low heart rate and high heart rate over the whole time span.
- The FHR exhibits a moderate variability (user-defined) for the specified time span.

An NST Report is generated when the reassuring criteria are met the first time in the current monitoring phase. When performing NST with twins or triplets, a separate NST Report is generated for each fetus.

After the reassurance criteria have been met, the clinician can print the NST Report and then turn the fetal monitor off, or may continue fetal monitoring and print the report at any time.

Reporting Parameters NICHD

Long Term Variability

Variability is generally understood to be fluctuations in the baseline FHR that are irregular in amplitude and frequency. The NICHD definitions classify variability as absent, minimal, moderate, and marked, based on the amplitude of the complexes related to baseline FHR variability.

Classification	Condition
Absent FHR variability	amplitude range undetectable (0–2 bpm)
Minimal FHR variability	amplitude range > undetectable and ≤5 bpm
Moderate FHR variability	6-25 bpm
Marked FHR variability	amplitude range >25 bpm

Sinusoidal Pattern

A sinusoidal pattern is a smooth, sine wave-like pattern of regular frequency and amplitude. The calculation to determine if the FHR trace exposes a sinusoidal pattern is done every 1 minute covering a time window of about 8.5 minutes. Wave-like patterns with less than 12 cycles per minute go into the calculation. However, the segment is only considered as being sinusoidal, when a cycle frequency of 3-5/min is detected.

Accelerations

An FHR acceleration is generally understood to be a visually apparent abrupt increase in the FHR from the baseline (from onset to peak less than 30 seconds). The detection of accelerations depends on the calculated gestational age. If the gestational age is not available, the system uses the limits for >32 weeks gestation.

Accelerations		
Criterion	Gestational age <32 weeks	Gestational age ≥32 weeks
Amplitude	≥10 bpm	≥15 bpm
Duration	≥10 seconds, <10 minutes	≥15 seconds, <10 minutes

The onset of acceleration to peak must be <30 seconds.

Decelerations

An FHR deceleration is generally understood to be a gradual or abrupt decrease in the FHR from the baseline. Decelerations are classified as late, early, variable, and prolonged.

Decelerations Types					
Criterion	Type				
	Late	Early	Variable	Prolonged	Other
Duration	≥15 seconds	≥15 seconds	≥15 seconds	>2 minutes, <10 minutes	≥15 seconds

Decelerations Types					
Associated contractions	Yes	Yes	n/a	n/a	n/a
Amplitude	≥15 bpm	≥15 bpm	≥15 bpm	≥15 bpm	≥15 bpm
Steep fall (onset to nadir <30 seconds)	No	No	Yes	n/a	n/a
Time from acme of contraction to nadir of deceleration	>10 seconds	≤10 seconds	n/a	n/a	n/a

Deceleration Severity Classification			
Criterion	Severe	Moderate	Mild
Amplitude	>60 bpm	>30 bpm, ≤60 bpm	≤30 bpm
Duration	>60 seconds	>30 seconds, ≤60 seconds	≤30 seconds

Average short term variability (STV) value is documented in [bpm] and [ms] if STV is configured as part of the NST Report. This parameter is not a criterion of the NICHD guideline.

NST Report Status Window NICHD

The **NST Report** window displays a detailed overview of the current NST status for any available ultrasound fetal heart rate measurement. You can see:

- **NST Status** - whether it is ready, ongoing, or the time and date at which it was stopped, or at which it was finished.
- **Elapsed Time** - the time that has elapsed since the NST began.
- **Accelerations** - the number of FHR accelerations detected so far.
- **Baseline** - the average baseline value.
- **Variability** - the average variability value.
- **Short Term Var.** - the current short term variability (STV) value (only displayed if it is configured).
- **Decelerations** - the number of FHR decelerations detected so far.
- **FHR Available** - current statistical FHR availability value.
- **Sinusoidal** - the current status of sinusoidal rhythm detection.

For criteria not yet met, a white arrow symbol marks the overall status on the top line, and also appears next to every criterion not yet met. A yellow symbol indicates detection of severe or prolonged decelerations.

The pop-up keys let you perform the following actions:

- **FHR1**, **FHR2**, **FHR3** - switch to the window showing the current NST status for the fetal heart rate.
- **Record Report** - print the NST Report on paper.
- **Record Trace** - record the trace episode that belongs to the current report. Depending on device usage, the trace recording might be incomplete.
- **Setup** - open the **Setup NST Report** window.

Example NST Report According to NICHD

Field	Field Content
Report Title, with FHR label and date	NST Report for FHR1 on 12 Oct. 2017
Product Information	Product DE53102345 G.01.70, OB A.04.24, Toco DE52401090, FHR1 DE00002345 A.05.26
Patient Information	Rogers, Alice Date of Birth: 30.5.1991 Age: 26 Gestational Age: Week 34, Day 5
Start time, end time, Elapsed time, configured runtime	Time: 11:34 – 12:06 Elapsed time: 32 min Run time: 20 min
Overall one-line NST result summary	NST Criteria*: not met
Title	Trace Interpretation Summary
Result Accelerations	Accelerations: 2 at: 11:59 12:02
Result: Contractions	Contractions: 3 at: 11:57 12:00 12:04
Result: Baseline and Variability	Baseline: 125 bpm (Range: 118-129 bpm) Variability: 23 bpm
Short Term Variability	0.9 bpm (3.8 msec)
Statistics: FHR availability	FHR available: 95%
Result: Decelerations	Decelerations: 1 at: 11:58 ↓ ↓ severe ↔ prolonged
Result: Sinusoidal Rhythm detected	Sinusoidal: No

Field	Field Content
Result: Decelerations before Reporting Period	Events before Reporting Period: Decelerations: 1 at: 11:38 ↓ ↓ severe ↔ prolonged This field is enabled if there were decelerations between the start of NST and the start of the reporting period.
Guideline/Criteria Information	(*) Interpretation criteria based on guideline "NICHD 2008, v<xx>" User-defined criteria for CTG tracing: • valid FHR for 90% of reporting period • baseline heart rate between 120 bpm and 160 bpm • at least 2 accelerations in 10 min • not more than 1 decelerations • moderate baseline variability (6-25 bpm) Additional criteria: • no severe or prolonged decelerations • no sinusoidal pattern in reporting period

NST According to Dawes/Redman Trace Interpretation

NOTE

Not available for USA and other FDA regulated territories.

WARNING

The Non-Stress Test Report (NST Report) functionality according to Dawes & Redman has not been validated for use for patients with a gestational age of less than 26 weeks.

NST Criteria According to Dawes/Redman

A trace is considered normal whenever the following criteria are met within the time range of 10-60 minutes:

- The recording must contain at least one episode of high variation.
- The short-term variation (STV) must be greater than 3.0 ms.
  - If STV is greater than 3.0 ms but less than 4.5 ms, the long-term variation (LTV) averaged across all episodes of high variation must be greater than the third percentile for the gestational age (GA).
- There must be no evidence of a high-frequency sinusoidal rhythm.
- There must be either:
  - at least one acceleration, **or**
  - a fetal movement rate of ≥20 per hour, **and** an LTV averaged across all episodes of high variation that is greater than the 10th percentile for the GA.
- There must be at least one fetal movement or three accelerations.
- Concerning decelerations:
  - If the recording time is less than 30 minutes, there must be no decelerations of more than 20 lost beats.
  - If the recording time is more than 30 minutes, there must be no more than one deceleration of 21-100 lost beats.
  - Independent of recording time, there must be no decelerations at all of more than 100 lost beats.
- If the recording time is less than 30 minutes, the basal heart rate must be in the range 116-160 bpm.
- The LTV must be within three standard deviations (SDs) of its estimated value. Alternatively, if it is not, all the following must apply:
  - the STV must be larger than 5.0 ms,
  - there must be an episode of high variation with ≥0.5 fetal movements per minute,
  - the basal heart rate must be ≥120 bpm,
  - the signal loss must be smaller than 30%.
- The final epoch of the recording:
  - must not be part of a deceleration if the recording time is less than 60 minutes,
  - can include a deceleration at 60 minutes, but this must not be larger than 20 lost beats.
- If the recording time is less than 60 minutes, there must be no suspected artifacts at the end of the recording.

NOTE

- STV is the short-term variation parameter used in the guideline based on the Dawes/Redman criteria*

- LTV is the long-term variation parameter used in the guideline based on the Dawes/Redman criteria*
- Fetal movements are maternally perceived fetal movements. To acquire these movements, a remote event marker (989803143411) is required, and the patient or a clinician is required to press the marker button whenever fetal movements are perceived.
- Lost beats in association with decelerations are the number of fetal heart beats missing due to the reduced FHR during the deceleration compared to the baseline. Example: If the baseline is 140 bpm, and there is a deceleration with a duration of 1 minute, and a decreased FHR of 100 bpm on average, the number of lost beats would be 140-100 = 40 beats.
- The NST analysis according to Dawes/Redman requires the entering of the gestational age. The Non-Stress Test Report (NST Report) functionality according to Dawes & Redman is not intended for use for patients with a gestational age of less than 26 weeks.

*James Pardey, Mary Moulden, Christopher Redman: A computer system for the numerical analysis of Non-Stress Tests, American journal of obstetrics and gynecology, vol 186 nr 5, 2002.

Reporting Parameters Dawes/Redman

Long Term Variation

Variation is generally understood to be fluctuations in the baseline FHR that are irregular in amplitude and frequency. The Dawes/Redman criteria classify the variation as low or high FHR variation. For each minute of the trace the maximum excursions of the FHR above and below the baseline are calculated. The sum of these two values is the minute range. The average of consecutive minute ranges is the mean range and is used to measure the long term variation.

Classification	Condition
Low FHR variation	When the minute range in at least 5 of 6 consecutive 1-minute intervals is less than, or equal to, a threshold defined by a pulse interval of 30 ms.
High FHR variation	When the minute range in at least 5 of 6 consecutive 1-minute intervals is greater than, or equal to, a threshold defined by a pulse interval of 32 ms, and the mean minute range over the entire episode is above the first centile in the distribution of mean minutes ranges for episodes of high variation in healthy fetuses at that gestational age.

Sinusoidal Pattern

A sinusoidal pattern is a smooth, sine wave-like pattern of regular frequency and amplitude. The calculation to determine if the FHR trace exposes a sinusoidal pattern is done every 1 minute covering a time window of about 20 minutes. When a cycle frequency of 2-5/min is detected, the segment is considered as being sinusoidal.

Short Term Variation

Short term variation (STV) is averaged in milliseconds based on the averaged epochs of 3.75 seconds (1/16 minute). The short term variation is calculated by discarding the minutes containing all or part of the decelerations and calculating the difference between the average pulse interval values for adjacent epochs. These pulse interval differences are then averaged over each minute, and the 1-minute averages are in turn averaged over the entire NST to give the short term variation in milliseconds.

Accelerations

An FHR acceleration is generally understood to be an increase in FHR above the baseline that lasts for longer than 15 seconds and has a maximum excursion above the baseline of greater than 10 beats per minute.

Accelerations	
Criterion	Definition
Amplitude	>10 bpm
Duration	>15 seconds, <10 minutes

Decelerations

A deceleration is defined as a decrease in FHR below the baseline that lasts for longer than 30 seconds and has a maximum excursion below the baseline of greater that 10 beats per minute. The size of a deceleration is measured by its area in lost beats. This measurement provides an estimate of the number of fetal heart beats that would have occurred, if there was no deceleration.

Decelerations		
Criterion	Definition	
Amplitude	>10 bpm	>20 bpm
Duration	>60 seconds, <10 minutes	>30 seconds, <10 minutes

The deceleration types are not defined in the Dawes/Redman guidelines, but are additional classifications of IntelliSpace Perinatal.

Decelerations Types					
Criterion	Type				
	Late	Early	Variable	Prolonged	Other
Duration	≥15 seconds	≥15 seconds	≥15 seconds	>2 minutes, <10 minutes	≥15 seconds
Associated contractions	Yes	Yes	n/a	n/a	n/a
Amplitude	≥15 bpm	≥15 bpm	≥15 bpm	≥15 bpm	≥15 bpm
Steep fall (onset to nadir <30 seconds)	No	No	Yes	n/a	n/a
Time from acme of contraction to nadir of deceleration	>10 seconds	≥10 seconds	n/a	n/a	n/a

Lost Beats

Lost beats are the number of fetal heartbeats missing caused by a deceleration compared to the normal baseline. Example: When an FHR drops from 120 bpm to 100 bpm for 1 minute, the number of lost beats would be (120 bpm-100 bpm) * 1 minute = 20 beats.

NST Report Status Window Dawes/Redman

The **NST Report** window displays a detailed overview of the current NST status for any available ultrasound fetal heart rate measurement. You can see:

- **NST Status** - whether it is ready, ongoing, or the time and date at which it was stopped, or at which it was finished.
- **Elapsed Time** - the time that has elapsed since the NST began.

- **Signal Loss** - the current percentage of fetal heart rate signal loss.
- **Baseline** - the current average baseline value.
- **Accelerations > 10 bpm** - the number of FHR accelerations detected so far greater than 10 beats per minute.
- **Accelerations > 15 bpm** - the number of FHR accelerations detected so far greater than 15 beats per minute.
- **Decelerations > 20 lost beats** - the number of FHR decelerations detected so far, greater than 20 lost beats (the number of fetal heartbeats missing caused by a deceleration compared to the normal baseline).
- **Contractions** - the number of contractions detected so far.
- **Short Term Var.** - the current short term variation (STV) value.
- **Long Term Var.** - the current long term variation (LTV) value.
- **High Variation** - When the minute range in at least 5 of 6 consecutive 1 minute intervals is greater than, or equal to, a threshold defined by a pulse interval of 32 ms, and the mean minute range over the entire episode is above the first centile in the distribution of mean minutes ranges for episodes of high variation in healthy fetuses at that gestational age.
- **Low Variation** - When the minute range in at least 5 of 6 consecutive 1 minute intervals is less than, or equal to, a threshold defined by a pulse interval of 30 ms.
- **Sinusoidal** - the current status of sinusoidal rhythm detection.
- **Fetal Movements** - the number of times fetal movement was detected and indicated by pressing the remote event marker button.

For criteria not yet met, a white arrow symbol marks the overall status on the top line, and also appears next to every criterion not yet met. A yellow symbol indicates that criteria are not met for example, if a sinusoidal pattern or a deceleration with more than 100 lost beats were detected.

The pop-up keys let you perform the following actions:

- **Record Report** - print the NST Report on paper.
- **Record Trace** - record the trace episode that belongs to the current report. Depending on device usage, the trace recording might be incomplete.
- **NST Details** - opens a detail window with detailed descriptions of the criteria.
- **FHR1**, **FHR2**, **FHR3** - switch to the window showing the current NST status for the fetal heart rate.
- **Setup** - open the **Setup NST Report** window.

Example NST Report According to Dawes/Redman

Field	Field Content
Report Title, with FHR label and date	NST Report for FHR1 on 3 Dec. 2017
Product Information	Product M2705A DE74200202 L.33.04 BsMstr A.11.12, Toco DE24800233 B.00.39, FHR1 DE32200649 B.00.39
Patient Information	Rogers, Alice Date of Birth: 30.05.1991 Age: 26 Gestational Age: Week 34, Day 5
Time Elapsed time	Time: 11:34 – 12:06 Elapsed time: 32 min
Overall one-line NST result summary:	NST Criteria*: not met • If the short term variation is <4.5 ms, the long term variation must be higher. • The short term variation must be >3.0 ms.
Title	Trace Interpretation Summary
Signal Loss	Signal Loss: 15%
Result: Baseline	Baseline: 125 bpm (Range: 118-129 bpm)
Result: Accelerations > 10 bpm	Accelerations: 3
Result: Accelerations >15 bpm	Accelerations: 1
Result: Decelerations >100 lost beats	Decelerations: 1 at 11:46
Result: Short Term Variation	Short Term Var.: 5 msec
Result: High Variation	High Variation: 0 min
Result: Low Variation	Low Variation: 0 min
Result: Sinusoidal Rhythm detected	Sinusoidal: No
Result: Fetal Movements	Fetal Movements: 0/hr
Maternally perceived fetal movements are indicated using the remote event marker	
Result: Accelerations	Accelerations: 3 at 11:59 12:02 12:05
Result: Decelerations at 4:15	Decelerations at 4:15 ⟷ >100 lost beats
Result: Contractions	Contractions: 3 at: 11:57 12:00 12:04
Guideline/Criteria Information	(*) Interpretation criteria based on guideline “Dawes/ Redman 2002 v<xx>”

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Cross-Channel Verification (CCV)

The cross-channel verification helps to reduce the possibility of misidentification of the maternal heart rate for the fetal heart rate. It does this by comparing the measured fetal heart rate to the maternal heart rate. If there are multiple fetal rates, they are also compared with each other and the maternal heart rate.

Misidentification of Heart Rates

FHR detection by the monitor may not always indicate that the fetus is alive. Confirm fetal life before monitoring, and continue to confirm that the fetus is the signal source for the recorded fetal heart rate (see "Confirm Fetal Life Before Using the Monitor" on page 12).

To reduce the possibility of mistaking the maternal HR or pulse for FHR, or FHR1 for FHR2 or FHR3, it is recommended that you monitor both maternal HR/pulse and the heart rates of all fetuses (see "Monitoring FHR and FMP Using Ultrasound" on page 169, "Monitoring Twin FHRs" on page 185, "Monitoring Triple FHRs" on page 191, and "Monitoring Maternal Heart / Pulse Rate" on page 219).

Here are some examples where the maternal HR can be misidentified as the FHR, or one FHR for another FHR (twins/triplets).

When using an ultrasound transducer:

- It is possible to pick up maternal signal sources, such as the maternal heart, aorta, or other large vessels. Especially if the recorded maternal HR, and any other artifact is over 100 bpm.
- It is possible to pick up the same fetal heart rate simultaneously with multiple transducers.

NOTE

When an ultrasound transducer is connected to the monitor, but not applied to the patient, the measurement may generate unexpected intermittent FHR readings.

When Fetal Movement Profile (FMP) is enabled:

The FMP annotations on a fetal trace **alone** may not always indicate that the fetus is alive. For example, FMP annotations in the absence of fetal life may be a result of:

- Movement of the deceased fetus during or following maternal movement.
- Movement of the deceased fetus during or following manual palpation of fetal position (especially if the pressure applied is too forceful).
- Movement of the ultrasound transducer.

When using a scalp electrode (DECG):

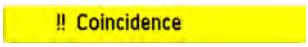
- Electrical impulses from the maternal heart can be transmitted to the fetal monitor through a recently deceased fetus via the spiral scalp electrode, appearing to be a fetal signal source.

Cross-Channel Verification Functionality

The cross-channel verification functionality (**CCV**) of the fetal monitors compares all monitored heart rates (maternal and fetal), and indicates automatically whether any two channels are picking up the same signal, or monitoring similar values.

If the fetal monitor detects that any channels have the same or similar values, the **Coincidence** INOP is issued with an **INOP tone** that can have a configurable delay. In addition, yellow question marks appear next to the numerics on the touchscreen that have the same or similar values. On the recording trace there is also a question mark from the point where recorded traces continuously overlap.

Visual Aids for CCV Detection



Coincidence INOP appears on the screen of the fetal monitor.

Question mark appears on the screen of the fetal monitor next to the numerics that show the same or similar values.

Question mark recorded on the trace from the point where two measured values coincide.

Overview of Cross-Channel Comparisons

Measurements from Transducers

Measurement	Transducer
FHR (US)	From Ultrasound or CL Ultrasound transducer
dFHR (DECG)	From a fetal scalp electrode
aFHR (abdom. ECG)	From the CL Fetal & Maternal Pod
Pulse (Toco)	From Toco$^+$ MP, or CL Toco$^+$ MP transducer
Pulse (SpO_2)	From SpO_2 or CL SpO_2 Pod
HR (MECG)	From MECG electrodes
aHR (abdom. ECG)	From the CL Fetal & Maternal Pod

Measurement Comparison Done by the Fetal Monitor for Cross-Channel Verification

	FHR1 (US)	FHR2 (US)	FHR3 (US)	dFHR (DECG)*	aFHR* (ECG)
FHR1 (US)		✓	✓	✓	✓
FHR2 (US)	✓		✓	✓	✓
FHR3 (US)	✓	✓		✓	✓
dFHR (DECG)*	✓	✓	✓		✓
aFHR (abdom. ECG)	✓	✓	✓	✓	

	FHR1 (US)	FHR2 (US)	FHR3 (US)	dFHR (DECG)*	aFHR* (ECG)
Pulse (Toco)	✓	✓	✓	✓	✓
Pulse (SpO_2)	✓	✓	✓	✓	✓
HR (MECG)	✓	✓	✓	✓	✓
aHR (abdom. ECG)	✓	✓	✓	✓	✓

* dFHR and aFHR always replace one of the fetal channels (1,2, or 3) and cannot be compared to the channel it replaces. If you monitor for example twins with two ultrasound transducers, you see the numerics FHR1 and FHR2 at the monitor. If you decide to replace the ultrasound transducer for FHR2 with a fetal scalp electrode, the dFHR numeric is then shown as dFHR2.

Coincidence Examples

Coincidence of Maternal Pulse and FHR

When the maternal pulse and FHR are being monitored, and the measured values are very similar or the same, the coincidence question mark is displayed on the monitor's screen above both of the corresponding numerics (in this case maternal pulse and FHR). Often the signal loss or coincidence happens because the fetal or maternal movement displaced the ultrasound transducer, and a repositioning of the transducer is necessary.

1 **Coincidence** INOP

2 Coincidence question mark above **FHR1**

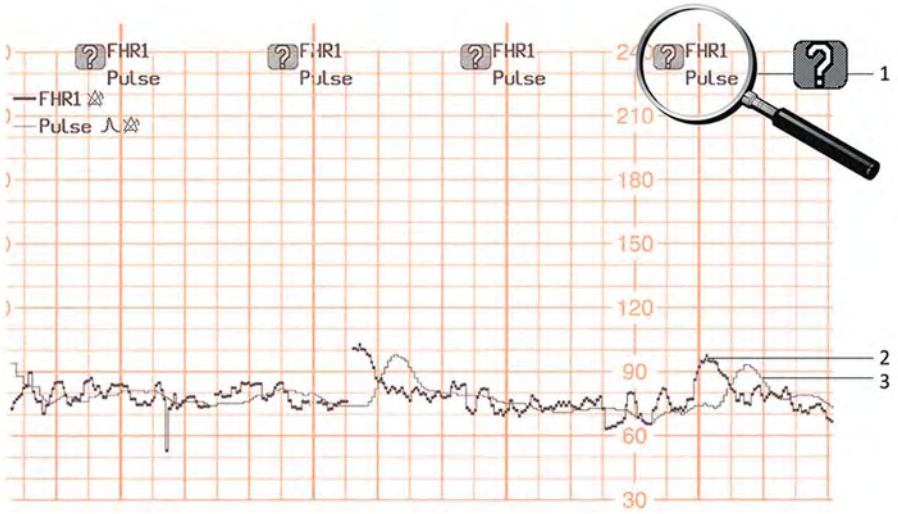
3 Coincidence question mark above pulse from Toco+ MP

Pulse Delay

SpO_2 pulse rate traces have an averaging calculation of approximately 10 seconds and an overall delay of approximately 12 seconds (depending on recorder speed). This differs from a non-averaged beat-to-beat MECG heart rate trace or an ultrasound heart rate trace calculation (having switched to the maternal HR)

with no significant delay. Note that Maternal Pulse from Toco has an averaging of 4 seconds and an overall delay of between 6 and 8 seconds.

The coincidence question mark is also printed on the trace paper next to the corresponding FHR and maternal pulse.



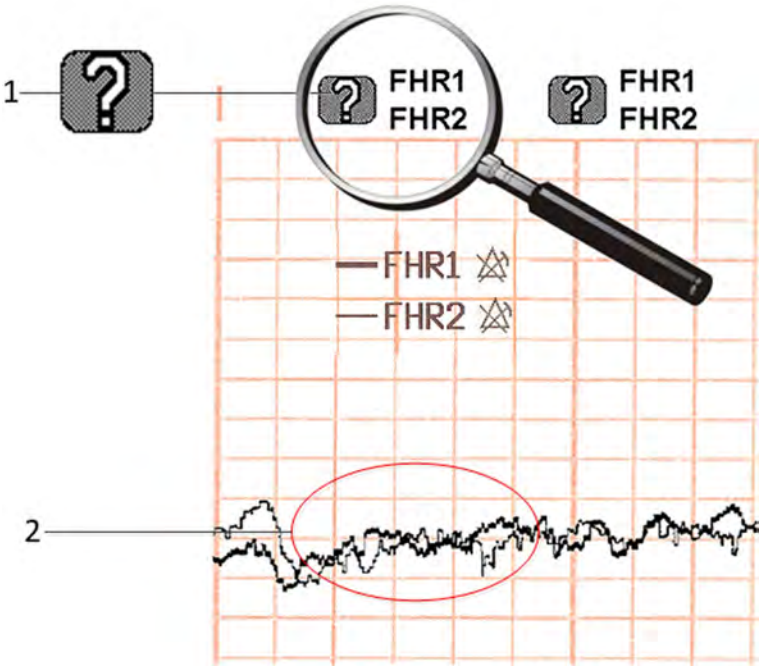
1. Printed coincidence question mark on trace
2. Fetal heart rate trace from Ultrasound
3. Maternal pulse trace from SpO_2

Coincidence of Twins/Triplets FHRs

When both **FHR1** and **FHR2** are being monitored, and the measured values are very similar or the same, the coincidence question mark is displayed on the monitor's screen above both of the corresponding numerics (in this case **FHR1** and **FHR2**).

1. **Coincidence** INOP
2. Coincidence question mark above **FHR1**
3. Coincidence question mark above **FHR2**

The coincidence question mark is also printed on the trace paper next to **FHR1** and **FHR2**.



1 Printed coincidence question mark on trace

2 **FHR1** and **FHR2** traces

Recommended Actions for Coincidence INOP

1. Confirm fetal life by palpation of fetal movement or auscultation of fetal heart sounds using a fetoscope, stethoscope, or Pinard stethoscope.
2. Manual determination of the maternal pulse and comparison with the fetal heart rate sound signals from the loudspeaker.
3. Reposition the transducer, or ensure that the fetal scalp electrode is placed correctly, until you receive a clear signal and the monitor is no longer issuing the **Coincidence** INOP.
4. In case of difficulties deriving a stable maternal pulse reading using the Toco$^+$ MP or CL Toco$^+$ MP transducer, use SpO_2 or the CL SpO_2 Pod instead. In case of similar problems with the pulse measurement from SpO_2, use MECG instead. Reasons to switch the method for deriving a maternal pulse or heart rate include: motion artifacts, arrhythmia, and individual differences in pulse signal quality on the abdominal skin (via Toco$^+$ MP).
5. If you cannot hear the fetal heart sounds, and you cannot confirm fetal movement by palpation, confirm fetal life using obstetric ultrasonography.

11 Cross-Channel Verification (CCV)

12

Monitoring FHR and FMP Using Ultrasound

To monitor a single FHR externally, you use an ultrasound transducer attached to a belt around the mother's abdomen. The ultrasound transducer directs a low-energy ultrasound beam towards the fetal heart and detects the reflected signal. Your monitor can also detect fetal movements and print the fetal movement profile (**FMP**) on the trace. Monitoring using ultrasound is recommended from the 25th week of gestation for non-stress testing or routine fetal monitoring.

WARNING

Performing ultrasound imaging or Doppler flow measurements together with ultrasound fetal monitoring may cause false FHR readings, and the trace recording may deteriorate.

Technical Description

Fetal monitors use the ultrasound Doppler method for externally monitoring the fetal heart rate. Using the Doppler method, the transducer (in transmitter mode) sends sound waves into the body which are then reflected by different tissues. These reflections (Doppler echoes) are picked up by the transducer (in listening mode). These Doppler echoes are amplified and sent to the monitor's speaker through which the fetal heart signal can be heard. In parallel the Doppler echoes are processed through an autocorrelation algorithm to determine the fetal heart rate (FHR). The FHR is displayed on the monitor's numeric display and on the recorded trace.

Properly representing the fetal heart rate using a device that derives heartbeats from motion is a formidable task and the limitations of the technology will be discussed shortly. Basic fetal cardiac physiology may contribute to difficulties in obtaining a reliable ultrasound signal.

A heart rate pattern of a fetus is capable of extraordinary variation, ranging from a stable pattern with minimal variation while the fetus is "asleep" to robust accelerations of 40-60 bpm above baseline rate over a few seconds, or exaggerated variability when the fetus is active. Decelerations of the rate 60-80 bpm below baseline may develop even more abruptly than the accelerations. Beat-to-beat arrhythmias may further exaggerate the amount of "variability" and can be seen at the bottom of variable decelerations, or in the presence of fetal breathing movements which also tend to lower the fetal heart rate. The recognition of these normal variations in fetal heart rate patterns will greatly assist in the separation of genuine fetal information from the artifact.

Limitations of the Technology

All tissues moving towards or away from the transducer generate Doppler echoes. Therefore, the resulting signal that is provided to the monitor's speaker, and for further fetal heart signal processing, can contain components of the beating fetal heart wall or valves, fetal movements, fetal breathing or hiccup, maternal movements such as breathing or position changes, and pulsating maternal arteries.

The fetal heart signal processing uses an autocorrelation algorithm to obtain periodic events such as heart beats. If the signal is erratic such as from a fetal arrhythmia, the ultrasound device may have trouble tracking the abrupt changes, and may misrepresent the true FHR pattern. Signals such as those from moving fetal limbs are usually very strong, thereby masking the fetal heart signal. During prolonged movements where the fetal heart signal is masked, the FHR appears blank on the numeric display and as a gap on the recorded trace. Fetal position changes, maternal position changes, or uterine contractions can move the fetal heart partly or fully out of the ultrasound beam resulting in signal loss, or even picking up Doppler echoes from pulsating maternal arteries. In these cases a maternal heart rate or sometimes even a rate resulting from the mixture of fetal and maternal signals may be displayed on the monitor's numeric display and on the recorded trace.

In contrast to the timely well-defined R-peak of an ECG signal obtained with a fetal scalp electrode, the ultrasound Doppler signal from a fetal heart consists of multiple components from atria (diastole), ventricles (systole), valves, and pulsating arteries. These components vary depending on fetal and transducer position and angle, and are further modulated by factors such as fetal or maternal breathing. These effects may produce what is called "artifact". Optimal transducer positioning therefore is key to minimizing these effects and thereby minimizing artifact.

Misidentification of Maternal HR as FHR

FHR detection by the monitor may not always indicate that the fetus is alive. Confirm fetal life before monitoring, and continue to confirm that the fetus is the signal source for the recorded heart rate (see "Confirm Fetal Life Before Using the Monitor" on page 12 and "Cross-Channel Verification (CCV)" on page 163).

What You Need

- Ultrasound transducer
- Toco^{+} MP or CL Toco^{+} MP transducer
- Ultrasound gel
- Transducer belt (and optional butterfly belt clip, if applicable)

Cableless Monitoring - Important Considerations

When using an Avalon CL or Avalon CTS Fetal Transducer system with your monitor, note the following:

Refer to "Cableless Status Indication" on page 91 for general rules regarding the use of cableless transducers from an Avalon CL or Avalon CTS Cableless Fetal Transducer system.

CAUTION

Never use ultrasound transducers connected to more than one fetal monitor on the same patient.

- When using an Avalon CL or Avalon CTS you should be aware that FMP is not recommended when the mother is likely to move, and you should disable Fetal Movement Profile (FMP) on the fetal monitor (**Fetal MovementOff**) if the mother is walking. See also "Fetal Movement Profile" on page 173.
- With the Avalon CL Transducer System, you can monitor twins and triplets with cableless transducers. The Avalon CTS System does not have this option.

The OBR symbol appears next to the measurement label, indicating that the measurement is being made by a cableless transducer with OB radio.

The SRR symbol appears next to the measurement label, indicating that the measurement is being made by a cableless Pod with short range radio.

1 FHR1

2 Toco parameter

WARNING

- During ambulant FHR monitoring, the chance of losing the signal or detecting the maternal heart rate is higher than during stationary monitoring. The frequency of the patient's walk may be detected, and mistaken for an FHR signal.
- Check the mother's pulse periodically during monitoring and compare this with the FHR signal. Beware of mistaking a "doubled" maternal heart rate for FHR. If a fetus is dead, there is a risk that the maternal heart rate is monitored and misinterpreted as the fetal heart rate. Therefore, the simultaneous monitoring of maternal heart rate (preferably, the maternal ECG) and the fetal heart rate is encouraged.
- Periodically compare the mother's pulse with the signal coming from the monitor's loudspeaker to ensure that you are monitoring fetal heart rate. Do not mistake a doubled or elevated maternal HR for FHR.
- Do not interpret maternal movements as fetal movements.
- Artifacts: FMP artifacts are generated during fetal heart rate searching by changing the transducer position, therefore the fetal monitors enable the FMP only after detecting a valid heart rate signal for several seconds. FMP is not recommended when the mother is likely to move, and you should disable Fetal Movement Profile (FMP) at the fetal monitor (**Fetal MovementOff**) if the mother is walking.

- Gaps in maternal heart rate detection can occur:
  - If the transducer is not correctly positioned.
  - Due to the pulsation of uterine blood vessels.
  - If the fetus moves.

Preparing to Monitor

Prepare for ultrasound monitoring using the list below. The standard procedures in use in your facility determine the sequence of actions.

1 Determine fetal position.

2 Fasten the belt around the patient.

3 Switch on the monitor and the recorder.

4 Connect the transducer to a free socket. The signal quality indicator for the heart rate initially displays an invalid signal.

5 Apply a thin layer of ultrasound gel to the underside of the transducer.

CAUTION

Using ultrasound gel not approved by Philips may reduce signal quality and may damage the transducer. This type of damage is not covered by warranty.

1 Place the transducer on the abdomen, if possible over the fetal back or below the level of the umbilicus in a full-term pregnancy of cephalic presentation, or above the level of the umbilicus in a full-term pregnancy of breech presentation. Work the transducer in a circular motion to ensure the gel layer makes good contact.

2 When the transducer is connected correctly and you receive a good signal, the signal quality indicator should be filled out. If an inadequate signal is produced, the signal quality indicator will indicate a poor signal, and no numeric will appear on the screen.

3 Adjust the audio volume of the monitor's loudspeaker to a clearly audible level, while moving the transducer over the abdomen. When you have a good signal, secure the transducer in position below the belt.

The ultrasound transducer may warm slightly (less than 1°C/1.8°F above ambient temperature) when applied to the patient. When not applied, the transducer can reach a maximum temperature of 44°C/112.2°F at an air temperature of 40°C/104°F.

Selecting Fetal Heart Sound

You can listen to the fetal heart sound from **one** ultrasound transducer at a time. When the fetal heart sound is selected for an FHR channel, you see the audio source symbol next to the FHR numeric label for that channel.

1 FHR1

2 Audio source symbol

To select the audio source for an FHR channel:

1 Enter the **Setup FHR1** menu for the channel you want to hear (FHR1 used as an example).

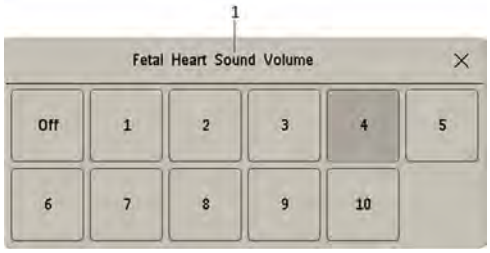
2 Press **Select Audio**. It may take a few seconds for the audio source symbol to appear.

Changing the Fetal Heart Sound Volume

The FHR volume symbol at the top right of the **Fetal Heart Sound Volume** window gives you an indication of the current volume. To change the volume:

1 Select the volume symbol. The volume scale pops up.

2 Select the required volume from the volume scale.



1 **Fetal Heart Sound Volume**

Fetal Movement Profile

The Fetal Movement Profile (FMP) parameter detects fetal movements with an ultrasound transducer connected to the monitor. Only the fetus monitored on the FHR1 channel is monitored for FMP.

Once you have enabled FMP (see "Switching FMP On and Off" on page 175), it is triggered automatically whenever:

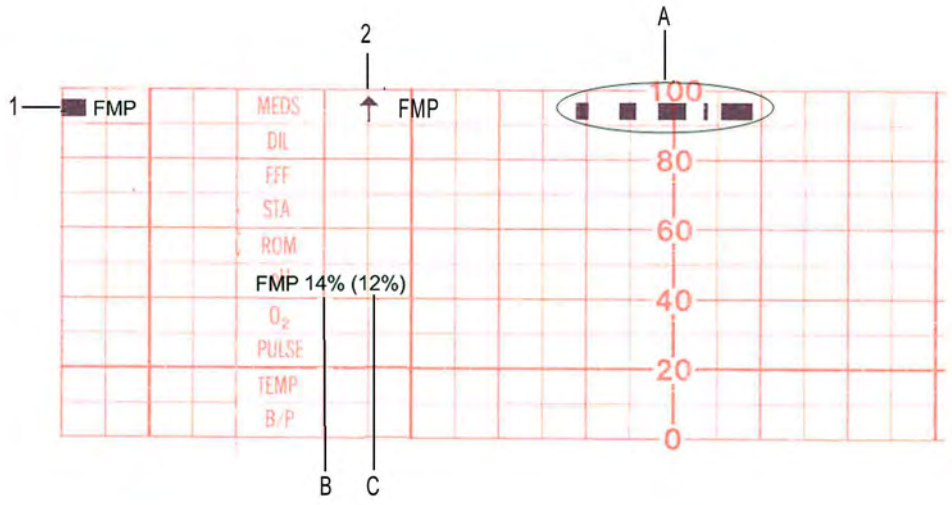
- You connect an ultrasound transducer.
- A patient is discharged.

When FMP is enabled, the ultrasound transducer detects most fetal body movements. Eye movements are not detected, and movement of the feet and hands may not be detected. Positioning or repositioning of the transducer is recorded as fetal movement. Maternal movement, excessive fetal breathing, or fetal hiccups may also be recorded as fetal movement (also in case of fetal demise or during the second stage of labor). You can mark these artifacts on the trace paper using either the remote event marker, or the event marker key as described in "Marking an Event" on page 61. FMP should be interpreted with care, or disabled when the patient is ambulating or during the second stage of labor. Ignore these movements when you interpret the FMP. When monitoring twins or triplets, only the fetus monitored on the FHR1 channel is monitored for movement, but be aware that movements recorded for FHR1 may also be caused by movement of the second or third fetus.

The fetal movement profile (FMP) appears as "activity blocks" along the top of the Toco scale, the length of each block showing the duration of the activity.

FMP Statistics

FMP statistics are printed every ten minutes.



1 FMP enabled

2 FMP started here

A Indication of current fetal movement

B The FMP statistics are presented as two percentage figures:

The first figure shows the percentage of detected fetal movements in the previous ten minutes.

C The second figure shows the percentage of detected fetal movements since the start of recording.

↑ To mark the start of the FMP statistic, FMP is printed on the paper with an arrow.

The FMP detection activates after about half a minute of steady heart rate signals (signal indicator half-full, or full) to minimize transducer positioning artifact. You will notice this deliberate delay:

- When a new patient is admitted. A patient discharge restarts the FMP statistics from zero.
- When you connect an ultrasound transducer.

Switching FMP On and Off

You can switch FMP on and off from any FHR channel. For example, to set it from the FHR1 channel:

1 Enter the **Setup FHR1** menu.

2 Select **Fetal Movement** to switch between **On** and **Off**.

3 Return to the main screen.

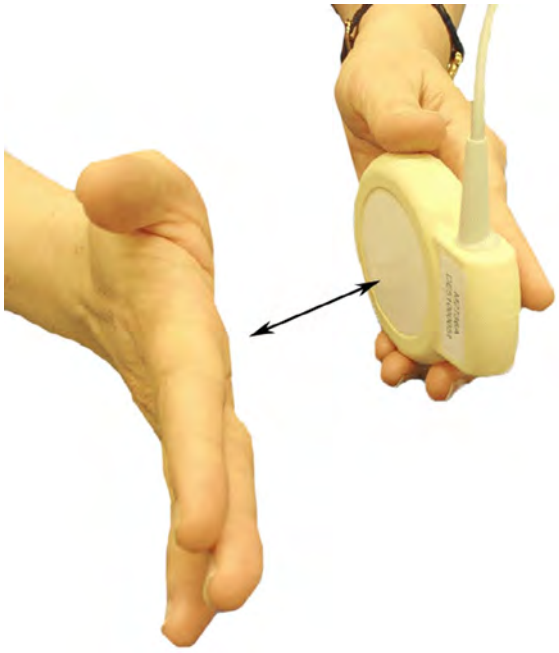
Troubleshooting

Problem	Possible Causes	Solutions
Erratic trace Erratic display	Fetal arrhythmia	Consider monitoring FHR using DECG after the rupture of membranes.
	Obese patient	
	Transducer position not optimal	Reposition transducer until signal quality indicator shows a good signal (at least half-full).
	Belt loose	Tighten belt
	Too much gel	Remove excess
	Very active fetus	-
	Insufficient gel	Use enough gel to ensure the transducer makes good contact with the mother's skin.
Signal quality indicator is continuously poor	Transducer position not optimal	Reposition transducer until signal quality indicator shows a good signal (at least half-full).
	FHR less than 50 bpm (and the FHR is audible)	If membranes are ruptured, using a fetal scalp electrode (FM30 and FM50 only) allows measurement of FHR down to 30 bpm.
Questionable FHR	Recording maternal HR by mistake	Reposition transducer Confirm fetal life
	Recording periodic signals when the transducer is not applied to the patient	Disconnect all NON-USED ultrasound transducers, as continuous, regular mechanical, or electromagnetic influences can result in an artificial trace.
	Recorded FHR appears to be suspiciously higher, or suspiciously lower, than real FHR. In very rare cases, half- or double-counting of the FHR can occur.	If you have reason to question the validity of the recorded FHR, always verify FHR by independent means (by auscultation, for example). Measure maternal pulse by independent means.
FHR not recorded	FHR is less than 50 bpm or over 240 bpm	If membranes are ruptured, using a fetal scalp electrode (FM30 and FM50 only) allows measurement of FHR down to 30 bpm.
		If FHR is outside of the specified range, verify FHR by independent means.
FHR1 Equip Malf or **FHR2 Equip Malf** or **FHR3 Equip Malf** INOP displayed.		See "Patient Alarms and INOPs" on page 127.
FHR1 Signal Loss or **FHR2 Signal Loss** or **FHR3 Signal Loss** INOP displayed.		
FHR1 Unplugged or **FHR2 Unplugged** or **FHR3 Unplugged** INOP displayed.		
If you suspect the transducer is malfunctioning		Test the transducer.

Testing Ultrasound Transducers

If any of the following tests fail, repeat the test using another transducer. If the second transducer passes the tests, confirming that the first transducer is defective, contact your service personnel.

If the second transducer also fails the tests, contact your service personnel.



To test an ultrasound transducer:

1. Switch on the monitor and the recorder.
2. Connect the transducer to the fetal monitor.
3. Select the fetal heart sound for this channel.
4. Increase the loudspeaker volume to an audible level.
5. Holding the transducer in one hand, move your other hand repeatedly towards and then away from the surface.
6. Check that a noise is heard from the loudspeaker.

You can test all ultrasound transducers, including the cableless ones, as described above.

Additional Information

Artifact in Fetal Heart Rate Measurement

How to detect it and reduce its occurrence using the Avalon Fetal Monitor

The ultrasound derived FHR measurement technique in Avalon fetal monitors, like all other ultrasound fetal monitors' FHR measurement techniques, has limitations that can lead to misrepresentation of the fetal heart rate pattern and potential misinterpretation of the fetal condition.

An incorrect interpretation of the trace may lead to either unnecessary interventions, or to failure to detect fetal distress, and the need for intervention. Thus, the on-going evaluation of the recorded trace requires regular confirmation that the trace represents the true FHR. Specific situations requiring such confirmation include the following:

- After starting a measurement or changing a transducer
- After maternal position changes, for example during pushing with contractions
- When the tracing shows abrupt changes in baseline rate, variability, or pattern (decelerations to accelerations) especially in the second stage of labor
- When the baseline maternal heart rate is within about 15 bpm of the FHR
- When you are unable to determine a baseline rate, and variability occurs between consecutive contractions

There are several ways to verify the source and/or accuracy of the recorded fetal heart rate pattern. These include:

Verification of the FHR with:

- An obstetric stethoscope
- Ultrasound imaging
- A fetal scalp electrode

Verification of the maternal heart rate:

- Using pulse oximetry - for a maternal heart rate pattern displayed simultaneously with the FHR (Cross-Channel Verification (CCV) feature)
- Using Maternal ECG - for a maternal heart rate pattern displayed simultaneously with the FHR (CCV feature)
- Manual determination of the maternal pulse

Whenever possible measure the maternal pulse rate to make use of the monitor's Cross-Channel Verification (CCV) feature. The Avalon fetal monitor provides a Toco$^+$ MP or CL Toco$^+$ MP transducer for maternal pulse detection and the creation of a maternal heart rate pattern plotted on the same recorder as the FHR pattern. In case of difficulties deriving a stable maternal pulse reading using the Toco$^+$ MP or CL Toco$^+$ MP transducer, use SpO_2 or MECG instead.

When either of these parameters is utilized, the monitor will automatically and continuously perform a CCV of the maternal heart rate pattern against the FHR pattern displayed on the monitor. If the patterns and rates are similar, the CCV provides an alarm that both rates are probably from the same source (i.e., they both represent the maternal heart rate pattern and the fetus is not being monitored). Repositioning the ultrasound transducer will usually correct this, but it may be necessary to apply a fetal scalp electrode. Advising the mother to temporarily cease pushing during contractions may help to more rapidly resolve any uncertainty in this situation.

Doubling: The autocorrelation algorithm can display a doubled fetal or maternal heart rate if the duration of diastole and systole are similar to each other, and if the heart rate is below 120 bpm. Doubling, usually brief, is accompanied by an abrupt switch of the trace to double the baseline value.

Halving: With fetal tachycardia (above 180 bpm) and some interference from breathing or maternal arteries the autocorrelation algorithm may only recognize every second beat resulting in a halved rate for a limited time. If the actual FHR is above the maximum limit of the monitor (240 bpm), the algorithm will also half-count. Halving is accompanied by an abrupt switch of the trace to exactly half the prior baseline value. This switch may simulate an FHR deceleration and be referred to by clinicians as a "false deceleration.

Switching to maternal heart rate (also referred to as "Maternal Insertion"): The fetal heart can move partly or fully out of the ultrasound beam and the autocorrelation algorithm may then pick up and display the maternal heart rate. Depending on the signal mix in the ultrasound signal, switching to the maternal heart rate may mimic several conditions with the potential for erroneous interpretation and response as follows:

- **The switch to the maternal heart rate may simulate an FHR deceleration** (i.e., a decrease of the fetal heart rate, and be referred to by clinicians as a "false deceleration").
- **The maternal heart rate may simulate a normal fetal heart rate pattern** (i.e., it may mask an FHR deceleration or fetal demise).

  Especially during pushing with contractions in the second stage of labor, the maternal heart rate may increase to the point where it may equal or exceed the fetal rate. Here the maternal trace may mimic a normal fetal trace while the fetus may be having decelerations or fetal demise has occurred. This change from fetal to maternal heart rate pattern may not be at all obvious unless CCV is used and represents the most dangerous pitfall of all the artifacts because fetal distress may go unrecognized.

- **The maternal heart rate may simulate an FHR acceleration**, which is an increase of the fetal heart rate.

  During expulsive efforts, the maternal heart rate normally accelerates and may be at or above the normal FHR range.

- **The FHR may display gradual appearing decelerations**. Generally, the "false decelerations" described above are abrupt. Rarely, combinations of "noisy/erratic signal" associated with changes in maternal and/or fetal rate or movement will produce more gradual appearing "false decelerations" but these are usually short-lived with an **abrupt** return to an obviously stable FHR baseline.

"Noisy/Erratic" signals: With mixed or weak signals the tracing may reveal very brief episodes of erratic recorded traces. These represent the autocorrelation algorithm finding brief sequences of apparent and persistent heartbeats amidst a mixed or weak signal. These erratic recorded traces are commonplace, especially in association with fetal or maternal movement. **During prolonged periods of such noisy/erratic signals, the fetus is not being adequately monitored.**

Drop out: With mixed or weak signals there may be no heart rate tracing at all. These episodes reflect that if the algorithm does not find an apparent and persistent heartbeat amidst a mixed or weak signal, it will not print a heart rate on the tracing. Brief episodes of drop out are commonplace, especially in association with fetal or maternal movement. **During prolonged periods of drop out, the fetus is not being adequately monitored.**

Multiple Fetuses

With multiple fetuses, the potential to experience these artifacts is increased. Positioning of the transducer is even more critical. Ultrasound scanning should be used to help with positioning of individual transducers. See also "Monitoring Twin FHRs" on page 185 and "Monitoring Triple FHRs" on page 191.

Obtaining a Good Heart Signal

To successfully position the ultrasound transducer, first determine the fetal position using palpation. Position the transducer over the strongest audible fetal heart sound from the monitor's speaker and **wait at least six seconds after each transducer adjustment** to verify a good signal quality displayed on the Signal Quality Indicator and a consistent FHR numeric display. Having determined the position that provides a strong fetal signal, fix the transducer on the abdomen with the belt.

If the quality of the signal or the appearance of the heart rate trace from the ultrasound transducer is questionable, the transducer should be repositioned as described above. Alternatively, the use of an ultrasound scanner will greatly facilitate the determination of the optimal site for the ultrasound heart rate transducer. Factors during the second stage of labor that may influence the quality of the FHR tracing obtained with ultrasound include:

- Uterine contractions
- Changing contour of the maternal abdomen
- Maternal body movement - positioning
- Maternal expulsive efforts - pushing
- Maternal tachycardia/accelerations with contractions
- Fetal decelerations, Fetal tachycardia
- Delayed return of the fetal heart rate from a deceleration
- Descent of the fetus in the birth canal
- Rotation of the fetus in the birth canal

In some cases during the second stage of labor, a good and reliable ultrasound FHR signal may not be obtainable, and the use of a fetal scalp electrode must be considered (fetal ECG).

Heart Rate Sound

The heart rate sound emitted by the device is a representation of movement that, in most cases, permits accurate auscultation of the FHR corresponding to the FHR displayed on the monitor and rate pattern depicted on the trace recording. On occasion, the user may hear an FHR that differs from the FHR display and the recorded trace. This may occur in situations where the fetal heart moves partly out of the transducer ultrasound beam. In these cases, the user may hear the FHR emitted from the monitor's speaker, even though another periodic signal (usually the maternal heart rate) has become stronger. The autocorrelation algorithm will display the stronger maternal heart rate, despite the persistence of a weaker fetal signal. These occurrences are usually very brief and, if persistent, can be addressed by repositioning the transducer.

Signal Quality Indicator

The signal quality on the Avalon fetal monitor is indicated by a triangle on the touchscreen that is displayed in one of three ways:

1 Completely filled triangle, indicating good signal quality (good/full).

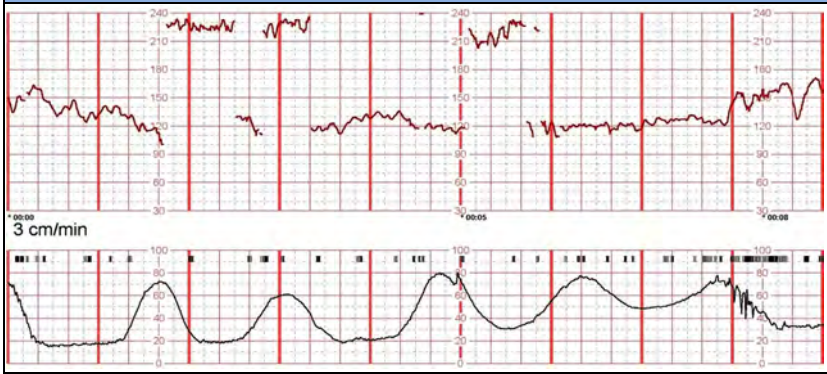
2 Half-filled triangle, indicating limited signal quality. This condition may indicate a weak or ambiguous signal. If this status persists, reposition the transducer (acceptable/medium).

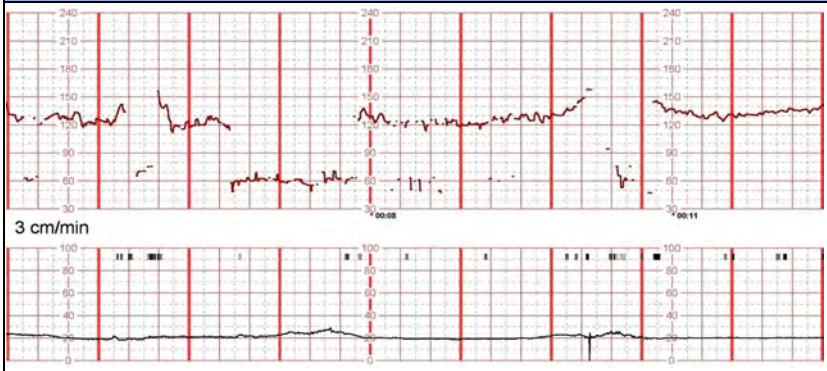
3 Empty triangle, indicating insufficient signal quality. No FHR is displayed on the monitor's numeric display or the recorded trace. If this status persists, reposition the transducer (poor/no signal).

Examples of Artifacts

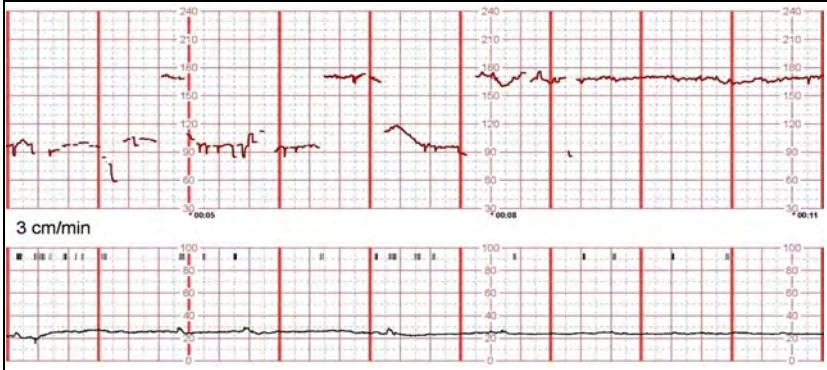
When monitoring the maternal ECG, a beat-to-beat maternal heart rate trace is printed alongside the FHR recorded trace. When monitoring the maternal SpO_2 derived pulse rate, a filtered and averaged heart rate trace is printed.

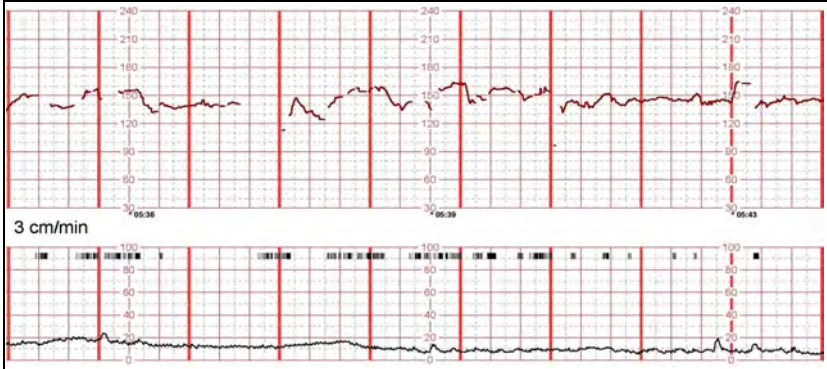
Following are recorded trace examples of complaints received regarding inaccurate output from the Avalon monitors. Scaling is 3 cm/min and 30 bpm/cm.

Double-Counting	
	
Baseline Rate	120
Baseline Variability	Moderate
Accelerations	Present
Decelerations	Not apparent
Contractions	Excessive, coupling, hypertonus
Artifact	Double-Counting
Comment	Reassuring tracing. The excessive uterine activity should prompt discontinuation of any oxytocic agent.
Remediation	The true fetal rate can be confirmed by auscultation or by fetal scalp electrode.

Half-Counting	
	
Baseline Rate	120
Baseline Variability	Moderate
Accelerations	Present
Decelerations	Not apparent

Half-Counting	
Contractions	Minimal
Artifact	Half-counting, noise, drop out
Comment	Reassuring tracing. The half-count at 4-5 minutes into the tracing may simulate a fetal deceleration, but the abruptness and the lack of any compensatory changes when the normal rate returns suggests that this is half-counting. Insertion of the maternal heart rate (see below) may produce a similar pattern. Note also very brief episodes of half-counting, maternal insertion, and signal dropout.
Remediation	Auscultation or the application of a direct scalp electrode, if feasible, will reveal the true fetal heart rate.

Maternal-Switching (Maternal Insertion)	
	
Baseline Rate	170 - Tachycardia
Baseline Variability	Moderate
Accelerations	Unable to determine
Decelerations	Absent
Contractions	Absent
Artifact	Maternal insertion, noise
Comment	The fetus has an elevated baseline rate of about 170 bpm with minimal to moderate variability. The ability to assess fetal status is limited because about half of the tracing displays the maternal heart rate.
Remediation	The application of a maternal transducer (ECG or pulse oximeter) will likely resolve any possible confusion with the tracing. Repositioning the transducer may produce a more reliable tracing. Consideration must also be given to applying a fetal scalp electrode.

Noisy/Erratic Signal and Dropout	
	
Baseline Rate	140
Baseline Variability	Moderate
Accelerations	Present
Decelerations	Absent
Contractions	Minimal
Artifact	Noisy signal, drop-out
Comment	Reassuring tracing. Note that there is episodic drop out of the signal with discontinuity of the fetal tracing.
Remediation	Either improving the position of the transducer or the application of a fetal scalp electrode will reduce the amount of artifact in the tracing.

Selection of Literature References on Artifacts

Mosby's Pocket Guide to Fetal Monitoring: A Multidisciplinary Approach (Nursing Pocket Guides) 8th Edition (May 2016).

Lisa A. Miller, David A. Miller, Rebecca L. Cypher

Elsevier Ltd, Oxford. 2017, ISBN 978-0-323-40157-9

Signal ambiguity resulting in unexpected outcome with external fetal heart rate monitoring

By Duncan R. Neilson Jr, MD; Roger K. Freeman, MD; Shelora Mangan, RNC, MSN, CNS

American Journal of Obstetrics & Gynecology, June 2008

Antepartal and Intrapartal Fetal Monitoring, 3rd Edition (2007)

By Michelle L. Murray, PhD, RNC

Springer Publishing Company, ISBN 0-8261-3262-6

Page 2, Table 2: **Limitations of Continuous EFM**

Item 15: "The US may detect maternal aortic wall movement and the maternal HR will be printed. A failure to recognize the lack of an FHR may delay appropriate management."

Page 38, "Solving Equipment Problems", Table 3: **The Ultrasound Transducer**

JOGC (Journal of Obstetrics and Gynecology Canada)

Volume 29, Number 9, September 2007

Chapter 2: **Intrapartum Surveillance**

Page S35: **"Methods of Electronic Fetal Monitoring"**

"… Among its disadvantages are the need for readjustment with maternal or fetal movements and the following: the transducer may record the maternal pulse, it may be difficult to obtain a clear tracing in obese women or those with polyhydramnios, artifact may be recorded, and there may be doubling or halving of the fetal heart rate when it is outside of the normal range."

Maternal or Fetal Heart Rate? Avoiding Intrapartum Misidentification

by Michelle L. Murray

JOGNN Clinical Issues, April 2003, 33, 93-104; 2004. DOI: 10.1177/0884217503261161

Figure 9 "The recording is of the MHR with occasional doubling."

Maternal Heart Rate Pattern – A Confounding Factor In Intrapartum Fetal Surveillance

Schifrin BS, Harwell R, Hamilton-Rubinstein T, Visser G:

Prenat Neonat Med 2001; 6:75-82

Fetal Monitoring in Practice, 2nd Edition 1998

By Donald Gibb, S. Arulkumaran

Butterworth-Heinemann, ISBN 0-7506-3432-2

Page 65, "False or erroneous baseline because of double counting of low baseline FHR"

Page 66, "Bradycardia: fetal or maternal"

Role of Maternal Artifact in Fetal Heart Rate Pattern Interpretation

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Obstetrics & Gynecology, September 1974, Volume 44, Issue 3

13

Monitoring Twin FHRs

The FHRs of twins are externally monitored using two ultrasound transducers. The Avalon CL Transducer system provides the option to monitor twins with cableless transducers. The Avalon CTS system and the CL F&M Pod do not have this option.

FM30/50 Twin FHRs are monitored throughout labor and delivery. After rupture of the membranes, you can monitor one twin externally using ultrasound, and the other internally using DECG.

Refer to the appropriate preceding chapters for contraindications, and more information about the available measurement methods.

FHR detection by the monitor does not always indicate that the fetuses are alive. Confirm fetal life before monitoring, and continue to confirm that the fetuses are the signal source for the recorded fetal heart rates. See "Confirm Fetal Life Before Using the Monitor" on page 12 and "Cross-Channel Verification (CCV)" on page 163.

Important Considerations

When monitoring:

- Ensure that you are recording two different fetal heart rates. The cross-channel verification feature alerts you if the two heart rates coincide (if both transducers are recording the same FHR). If this happens, check the trace and if necessary, reposition an ultrasound transducer to detect the second FHR correctly.
- Fetal heart rate measurements are labeled in the **order** in which you plug in the transducers for those measurements. It does not matter which fetal sensor socket you use, as the monitor allocates a channel automatically. For instance, the first transducer you connect is automatically allocated a channel, and the measurement is labeled **FHR1**, the second is labeled **FHR2**, and so on.

If you need to disconnect the transducers measuring the FHR temporarily, with the intention to continue monitoring after the temporary break (for example, if the mother needs to go to the bathroom), it is important that you reconnect the transducers in the same order as you originally connected them to make sure that the measurement labels remain consistent.

Upon discharge of the patient all connected transducers are reset from left to right. Example: Only one transducer is still connected to the monitor, it was labeled **FHR2** while monitoring the previous discharged patient; it is now reset to **FHR1**.

- The transducer finder LED lets you identify at a glance which transducer is monitoring which heart rate channel.
- The fetal sensor socket to which a transducer is connected is identified by the transducer position indicator in the setup menu header:

FM20/FM30

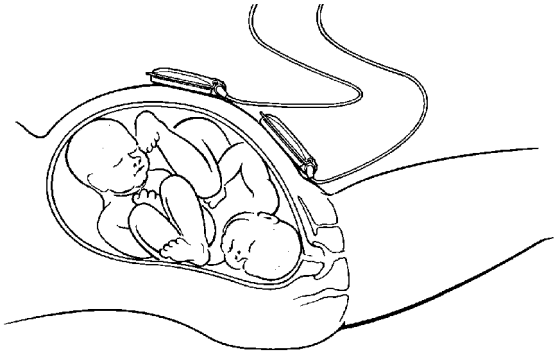
FM40/FM50

- The trace recorded for FHR1 is thicker (darker) than that recorded for FHR2. This ensures that the two heart rates are easily distinguishable. The thickness of the recorded trace can be changed in Configuration Mode.
- Remember that only one fetal heartbeat can be heard from the loudspeaker at a time.
- The audio source symbol shows you which fetus you are listening to. To hear the other fetal heartbeat, select the fetal heart rate sound for this channel (see "Selecting Fetal Heart Sound" on page 172).

- Monitor maternal pulse, especially during later stages of labor, to avoid mistaking maternal heart rate for FHR.
- Make sure that you are recording the best possible signals by referring to the signal quality indicators and repositioning the transducers if necessary.
- For the Avalon CL transducer system, see "Cableless Monitoring - Important Considerations" on page 171.

Monitoring Twins Externally

To monitor twin FHRs externally, you need two ultrasound transducers. Follow the procedures described in "Monitoring FHR and FMP Using Ultrasound" on page 169. The transducer finder LED lets you identify at a glance which transducer is monitoring which FHR channel, and lights when you select the FHR numeric field on the screen.



Example of the screen showing ultrasound monitoring of twin FHRs:

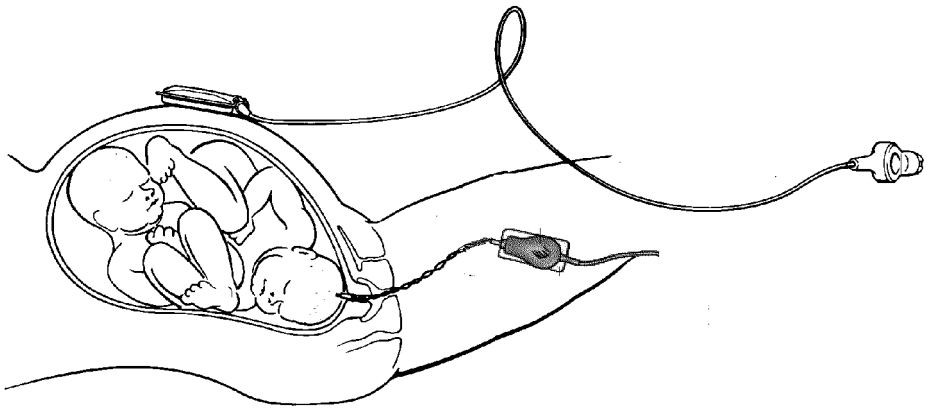
1 FHR 1

2 Toco parameter

3 FHR 2

Monitoring Twins Internally

FM30/50 Monitor one twin using the procedures described in "Monitoring FHR and FMP Using Ultrasound" on page 169. Monitor the second twin using the procedures described in "Monitoring FHR Using DECG" on page 199.



Example of a screen showing twin monitoring using a combination of US and DECG (the fetal heart rate monitored via DECG is labeled "**dFHR1**"/ "**dFHR2**" / "**dFHR3**" on the screen):

1 dFHR 1

2 Toco parameter

3 FHR 2

Separating FHR Traces

To help you to interpret traces with similar baselines, you can separate the baselines by an offset of 20 bpm by switching on trace separation. For details of the offset, see "Separation Order Type" on page 187.

Switching Trace Separation On and Off

Connect transducers to the monitor to measure FHR. Depending on the measurement method, you need *either* two ultrasound transducers *or*, for FM30/FM50, one ultrasound and one Toco^{+} transducer, or one CL ECG/IUP transducer (to monitor DECG):

1 Enter the **Main Setup** menu by pressing the **Main Setup**.

2 Select **Fetal Recorder**.

3 Select **Trace Separation** to switch between **On** and **Off**.

4 Exit the **Main Setup** menu.

Separation Order Type

In Configuration Mode, you can choose between two methods, **Standard** and **Classic**, for dealing with the trace offsets on the recording (the order in which they are separated) when **Trace Separation** is **On**.

- **Standard**: the FHR2 trace is shifted up by 20 bpm (it is recorded 20 bpm higher than it really is). No offset is ever applied to the FHR1 trace - it stays where it is (a third FHR would be shifted down by 20 bpm).
- **Classic**: the FHR1 trace is shifted up by 20 bpm when there is more than one FHR measurement. No offset is ever applied to the FHR2 trace - it stays where it is (a third FHR would be shifted down by 20 bpm).

When Trace Separation is On

When trace separation is turned on, the recorder prints a dotted line labeled with the two FHRs at the top, and **+20** at the bottom.

Examples of the two methods (**Standard**, **Classic**) for determining the trace separation order are provided here.

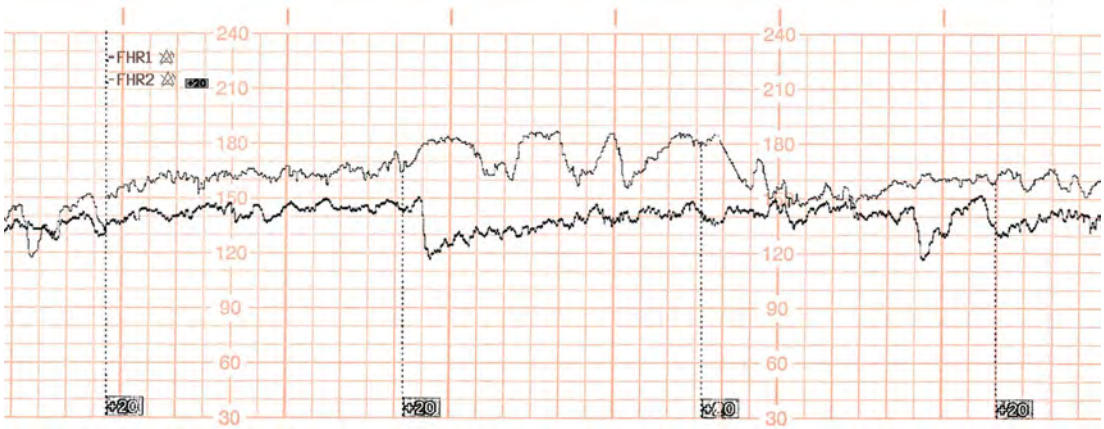
"Standard" Separation Order

To make differentiating the traces easier, the trace from the ultrasound transducer connected to the FHR2 channel is separated from that of FHR1 by 20 bpm. In other words, the trace for FHR2 is recorded 20 bpm higher than it really is. The trace for FHR1 is never shifted.

The recorder prints a dotted line labeled **+20** across the FHR scale, to identify the trace for FHR2. The FHR trace is labeled **+20** every 5 cm:

The label for FHR2 is annotated with a black filled **+20**:

The following trace shows trace separation switched on.



Only the FHR2 trace is offset. The numerical FHR value displayed on the monitor remains unchanged. Subtract 20 from the recorded trace for FHR2 to obtain the true FHR2 value. For example, if the recorded trace shows 160, then the true FHR is 140.

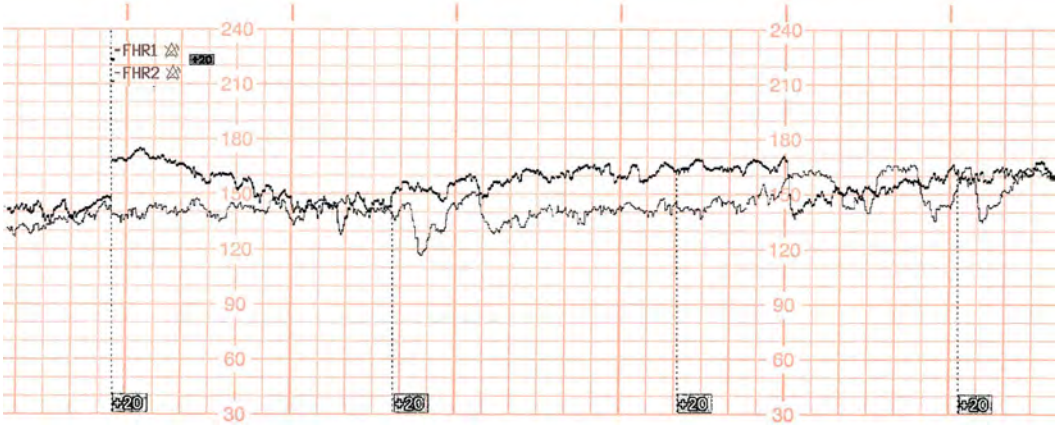
"Classic" Separation Order

To make differentiating the traces easier, the trace for FHR1 is offset by +20 bpm when FHR2 is present. The FHR2 trace is never shifted.

The recorder prints a dotted line labeled **+20** across the FHR scale, to identify the trace for FHR1. The FHR trace is labeled **+20** every 5 cm:

The label for FHR1 is annotated with a black filled **+20**:

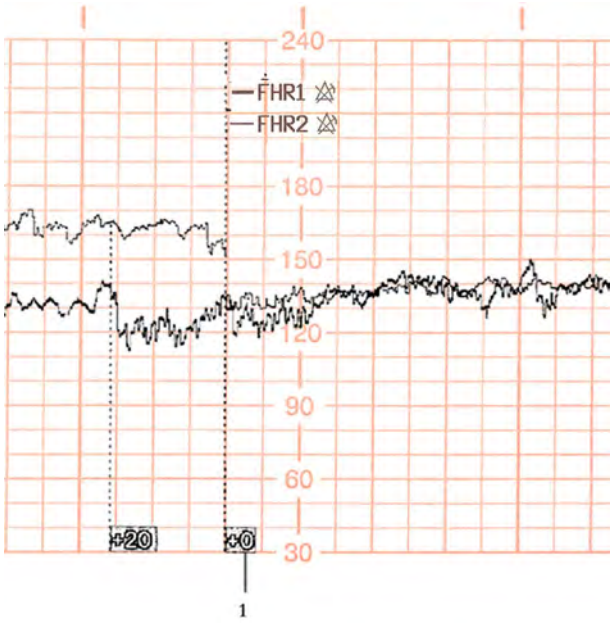
The following trace shows trace separation switched on.



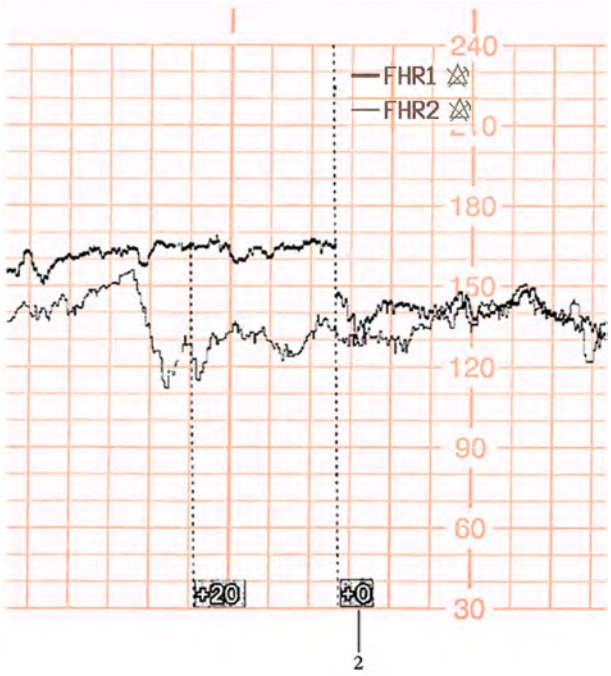
Only the FHR1 trace is shifted. The numerical FHR value displayed on the monitor remains unchanged. Subtract 20 from the recorded trace for FHR1 to obtain the true FHR1 value. For example, if the recorded trace shows 160, then the true FHR is 140.

When Trace Separation is Off

To indicate that trace separation is switched off, a dotted line labeled **+0** prints across the FHR scale.



1 **Standard** trace separation switched off here



2 **Classic** trace separation switched off here

Troubleshooting

Common problems that may occur when monitoring FHR using ultrasound are listed in "Monitoring FHR and FMP Using Ultrasound" on page 169. See also "Monitoring FHR Using DECG" on page 199 for common problems you might encounter when monitoring FHR directly.

The following problem may occur when monitoring twins.

Problem		Possible Cause	Solution
	The question mark is printed repeatedly, and appears on the screen and the INOP **Coincidence** is issued.	Both transducers are recording the same FHR, or one fetal transducer is recording the maternal HR.	Reposition an ultrasound transducer. See "Recommended Actions for Coincidence INOP" on page 167.

For more information, see "Additional Information" on page 176.

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Monitoring Triple FHRs

If your monitor is equipped with the triplets option, it carries the label:

You can monitor triple FHRs externally using three ultrasound transducers. With the Avalon CL Transducer system, you can monitor triplets with cableless transducers. The Avalon CTS system and the CL F&M Pod do not have this option.

Refer to the appropriate preceding chapters for contraindications, and more information about the available measurement methods.

FHR detection by the monitor may not always indicate that the fetuses are alive. Confirm fetal life before monitoring, and continue to confirm that the fetuses are the signal source for the recorded fetal heart rates. See "Confirm Fetal Life Before Using the Monitor" on page 12 and "Cross-Channel Verification (CCV)" on page 163.

Important Considerations

- The procedures and any contraindications that apply for twins monitoring also apply for monitoring triplets. In addition, when monitoring triplets: Be aware that monitoring three FHRs is inherently more difficult than monitoring single or twin FHRs. The nature of the application increases the likelihood that a fetal heart rate is monitored by more than one transducer.
- Ensure that you are recording three different fetal heart rates. Pay particular attention to any coincidence of heart rates detected by the monitor's cross-channel verification feature.
- Fetal heart rate measurements are labeled in the **order** in which you plug in the transducers for those measurements. It does not matter which fetal sensor socket you use, as the monitor allocates a channel automatically. For instance, the first transducer you connect is automatically allocated a channel, and the measurement is labeled **FHR1**, the second is labeled **FHR2**, and the third **FHR3**.

  If you need to disconnect the transducers measuring the FHR temporarily, with the intention to continue monitoring after the temporary break (for example, if the mother needs to go to the bathroom), it is important that you reconnect the transducers in the same order as you originally connected them to make sure that the measurement labels remain consistent.

  Upon discharge of the patient all connected transducers are reset from left to right. Example: Only one transducer is still connected to the monitor, it was labeled **FHR2** while monitoring the previous discharged patient; it is now reset to **FHR1**.
- The transducer finder LED lets you identify at a glance which transducer is monitoring which heart rate channel.
- The fetal sensor socket to which a transducer is connected, is identified by the transducer position indicator in the setup menu header:

FM20/FM30 **FM40/FM50**


- The trace recorded for the **FHR3** is thicker (darker) than that recorded for **FHR1**, which is thicker than that for **FHR2**. This ensures that the three heart rates are easily distinguishable. The thickness of the recorded trace can be changed in Configuration Mode.
- Remember that only one fetal heartbeat can be heard from the loudspeaker at a time. The audio source symbol shows you which fetus you are listening to. To hear the other fetal heartbeat, select the fetal heart rate sound for this channel (see "Selecting Fetal Heart Sound" on page 172).

- Monitor maternal pulse to avoid mistaking maternal heart rate for FHR.
- Ensure you are recording the best possible signals by referring to the signal quality indicators and repositioning the transducers if necessary.

For the Avalon CL transducer system, see "Cableless Monitoring - Important Considerations" on page 171.

Monitoring Triplets

To monitor triple FHRs, you need three ultrasound transducers. Follow the procedures described in "Monitoring FHR and FMP Using Ultrasound" on page 169 and in "Monitoring Twin FHRs" on page 185. The transducer finder LED lets you identify at a glance which transducer is monitoring which heart rate channel.

Separating FHR Traces

To help you to interpret traces with similar baselines, you can separate the baselines by an offset of 20 bpm by switching on trace separation. For details of the offset, see "Separation Order Type" on page 187.

"Standard" Separation Order

To make differentiating the traces easier, the trace for FHR2 is offset by **+20** bpm, and the trace for FHR3 is offset by **-20** bpm. In other words, the trace for FHR2 is recorded 20 bpm higher than it really is, while the trace for FHR3 is recorded 20 bpm lower than it really is. The trace for FHR1 is never shifted.

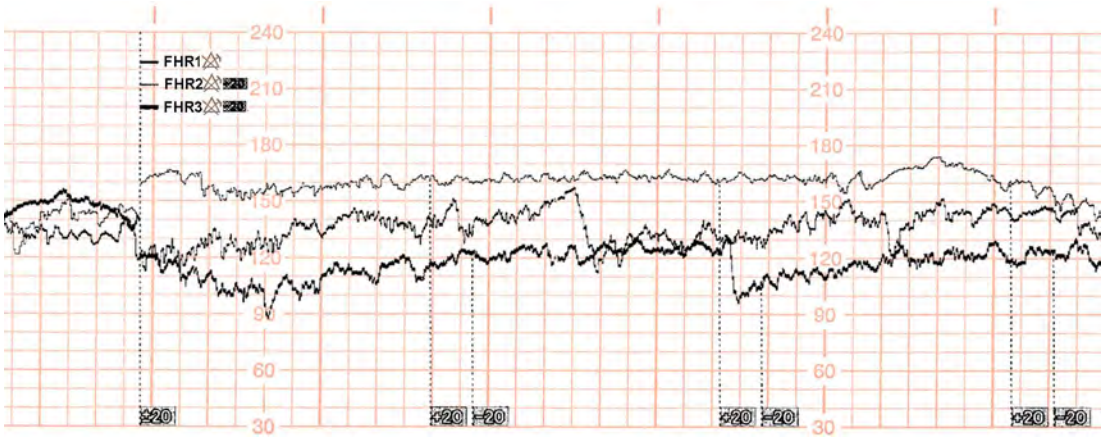
The recorder prints a dotted line labeled **+20** across the FHR scale, to identify the trace for FHR2.

The recorder prints a dotted line labeled **-20** across the FHR scale, to identify the trace for FHR3.

The FHR trace is labeled every 5 cm.

The label for FHR2 is annotated with **+20** and the FHR3 label is annotated with **-20**.

The following trace shows triplets with **Trace Separation** on, and using **Standard** separation order.



The traces for FHR2 and FHR3 are offset. The numerical FHR values displayed on the monitor remain unchanged. Subtract 20 from the recorded trace for FHR2 to obtain the true FHR2. For example, if the recorded trace shows 160 bpm, then the true FHR is 140 bpm. Similarly, add 20 to the recorded trace for FHR3 to obtain the true FHR3.

"Classic" Separation Order

To make differentiating the traces easier, the trace for FHR1 is offset by **+20** bpm when other FHR measurements are present, and the trace for FHR3 is offset by **-20** bpm. The FHR2 trace is never shifted. In other words, the FHR traces are always sorted in ascending order from top to bottom.

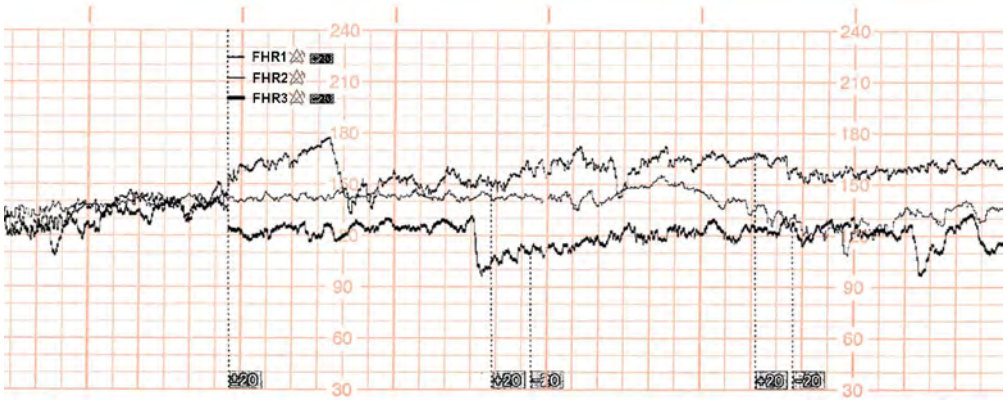
The recorder prints a dotted line labeled **+20** across the FHR scale, to identify the trace for FHR1.

The recorder prints a dotted line labeled **-20** across the FHR scale, to identify the trace for FHR3.

The FHR trace is labeled every 5 cm.

The label for FHR1 is annotated with **+20** and the FHR3 label is annotated with **-20**.

The following trace shows triplets with **Trace Separation** on, and using **Classic** separation order.



The traces for FHR1 and FHR3 are shifted. The numerical FHR values displayed on the monitor remain unchanged. Subtract 20 from the recorded trace for FHR1 to obtain the true FHR1. For example, if the recorded trace shows 160 bpm, then the true FHR is 140 bpm. Similarly, add 20 to the recorded trace for FHR3 to obtain the true FHR3.

Switching Trace Separation On and Off

1 Connect three ultrasound transducers to the monitor to measure FHR.

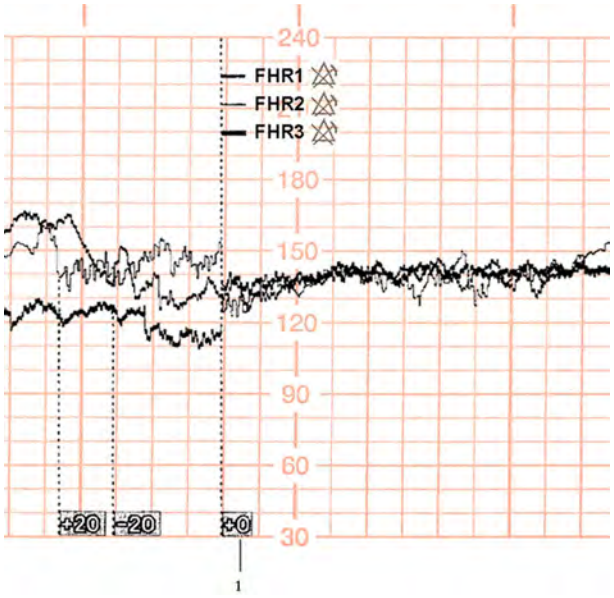
2 See "Switching Trace Separation On and Off" on page 187 for details of how to switch trace separation on or off.

When Trace Separation is On

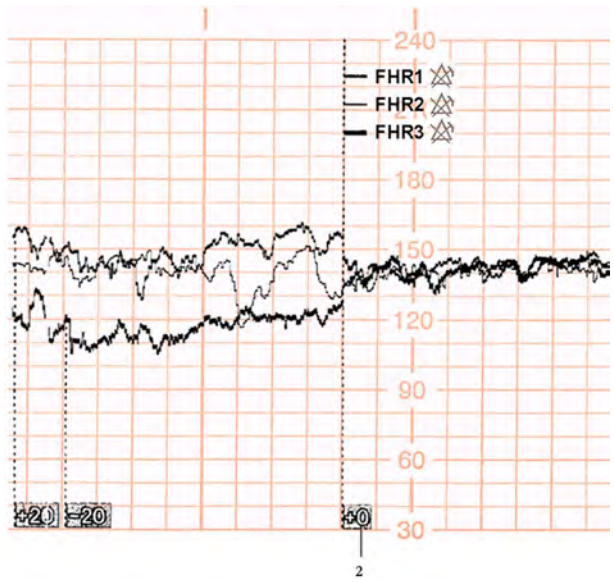
When trace separation is turned on, the recorder prints a dotted line labeled with the three FHRs at the top, and **±20** at the bottom. Examples of the two methods (**Standard**, **Classic**) for determining the trace separation order are provided here.

When Trace Separation is Off

To indicate that trace separation is switched off, a dotted line labeled **+0** prints across the FHR scale.



1 **Standard** trace separation switched off here



2 **Classic** trace separation switched off here

Troubleshooting

Common problems that may occur when monitoring FHR using ultrasound are listed in "Monitoring FHR and FMP Using Ultrasound" on page 169.

The following problem may occur when monitoring triplets.

Problem		Possible Cause	Solution
	The question mark is printed repeatedly, and appears on the screen and the INOP **Coincidence** is issued.	More than one transducer is recording the same FHR, or a fetal transducer records the same heart rate as the maternal HR.	Reposition one or more ultrasound transducer, as appropriate. See "Recommended Actions for Coincidence INOP" on page 167

For more information, see "Additional Information" on page 176.

15

Fetal Heart Rate Alarms

Fetal heart rate (FHR) alarms can give both audible and visual warning of a non-reassuring fetal condition. **Your monitor must be configured to Alarm Mode All to enable the FHR alarms** (see "Alarms" on page 115).

Changing Alarm Settings

When you do any of the following actions for any FHR measurement channel, this applies for all active FHR measurements, ultrasound, DECG, and aFHR:

- Turning FHR alarms on or off
- Changing alarm limits
- Changing alarm delays
- Changing signal loss delay

The monitor retains these settings, even when switched off. The alarm limits are printed on the trace every few pages if alarms are on.

Turning Alarms On or Off

1. Connect either an ultrasound or a DECG transducer to a free socket on the monitor, or use the CL F&M Pod.
2. Enter the setup menu for a connected FHR measurement.
3. Select **Alarms** to switch between **On** and **Off**.

Changing Alarm Limits

1. Connect either an ultrasound or a DECG transducer to a free socket on the monitor, or use the CL F&M Pod.
2. Enter the setup menu for a connected FHR measurement.
3. To change the high alarm limit, select **High Limit** and select the alarm limit from the pop-up list.
4. To change the low alarm limit, select **Low Limit** and select the alarm limit from the pop-up list.

Changing Alarm Delays

You can change the alarm delays if the **Alarm Mode** is set to **All**.

1. Connect either an ultrasound or a DECG transducer to a free socket on the monitor, or use the CL F&M Pod.
2. Enter the setup menu for a connected FHR measurement.
3. To change the high alarm limit delay time, select **High Delay** and select the delay time (in seconds) from the pop-up list.
4. To change the low alarm limit delay time in seconds, select **Low Delay** and select the delay time (in seconds) from the pop-up list.

Changing Signal Loss Delay

The signal loss delay is the configurable delay before a **Signal Loss** INOP is issued. You can change the delay:

1 Connect either an ultrasound or a DECG transducer to a free socket on the monitor, or use the CL F&M Pod.

2 Enter the setup menu for a connected FHR measurement.

3 Select **SignalLoss Delay** and select the signal loss INOP delay time (in seconds) from the pop-up list.

16

Monitoring FHR Using DECG

FM30/50 This chapter describes how to monitor a single fetal heart rate via direct ECG (DECG), using a spiral fetal scalp electrode in the intrapartum period.

Read and adhere to the instructions that accompany the fetal scalp electrode, the DECG adapter cable, and the attachment electrode. Pay attention to all the contraindications, warnings, and for the DECG adapter cable, the cleaning and disinfection procedures.

Before starting to monitor, first define the fetal position, and ensure that it is suitable for DECG monitoring.

Misidentification of Maternal HR as FHR

Confirm fetal life before monitoring, and continue to confirm that the fetus is the signal source for the FHR during monitoring. Here are two examples where the maternal HR can be misidentified as the FHR when using a fetal scalp electrode:

- Electrical impulses from the maternal heart can sometimes be transmitted to the fetal monitor through a recently deceased fetus via the spiral scalp electrode, appearing to be a fetal signal source.
- The recorded maternal HR, and any artifact, can be misinterpreted as an FHR especially when it is over 100 bpm.

To reduce the possibility of mistaking the maternal HR for FHR, monitor both maternal and fetal heart rates (see "Monitoring Maternal Heart / Pulse Rate" on page 219). The monitor's cross-channel verification (CCV) facility can help by automatically detecting when the same heart rate is being recorded by different transducers. See "Confirm Fetal Life Before Using the Monitor" on page 12 and "Cross-Channel Verification (CCV)" on page 163.

If the **Coincidence** INOP is issued at the fetal monitor if you are measuring FHR with DECG:

1. Confirm that the scalp electrode is placed correctly.
2. Confirm fetal life by palpation of fetal movement or auscultation of fetal heart sounds using a fetoscope, stethoscope, or Pinard stethoscope.
3. If you cannot hear the fetal heart sounds, and you cannot confirm fetal movement by palpation, confirm fetal life using obstetric ultrasonography.

4 In case of difficulties deriving a stable maternal pulse reading using the Toco+ MP or CL Toco+ MP transducer, use SpO_2 instead. In case of similar problems with the pulse measurement from SpO_2, use MECG instead. Reasons to switch the method for deriving a maternal pulse or heart rate include: motion artifacts, arrhythmia, and individual differences in pulse signal quality on the abdominal skin (via Toco+ MP).

What You Need

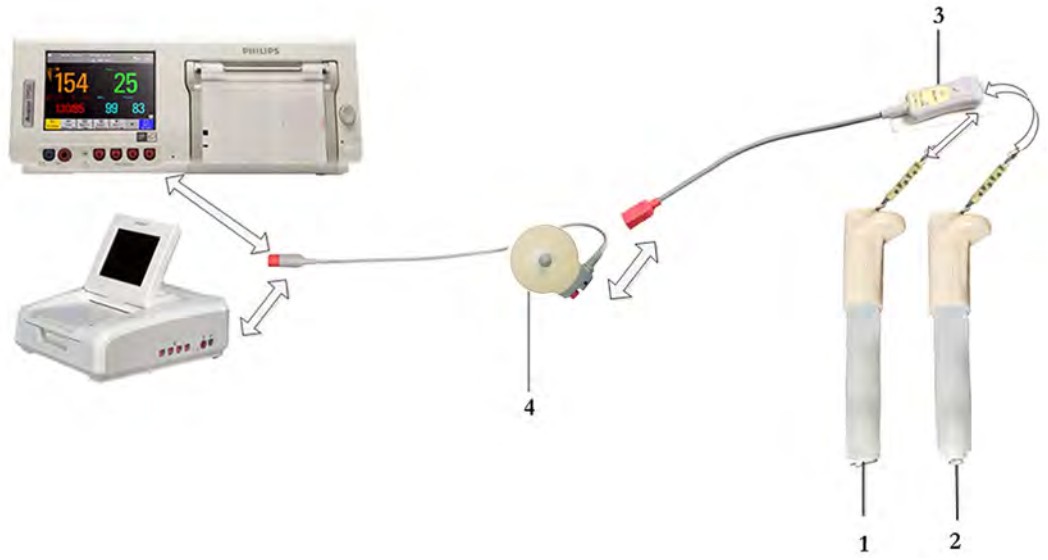
You can measure fetal DECG using the equipment combinations shown in the following figures.

WARNING

Never attempt to connect the fetal scalp electrode to anything other than the correct DECG adapter cable.

DECG with ECG/IUP Transducer (cable)

The figure below shows the chain using the ECG/IUP transducer.



1 Fetal Scalp Electrode, single spiral, (989803137631)

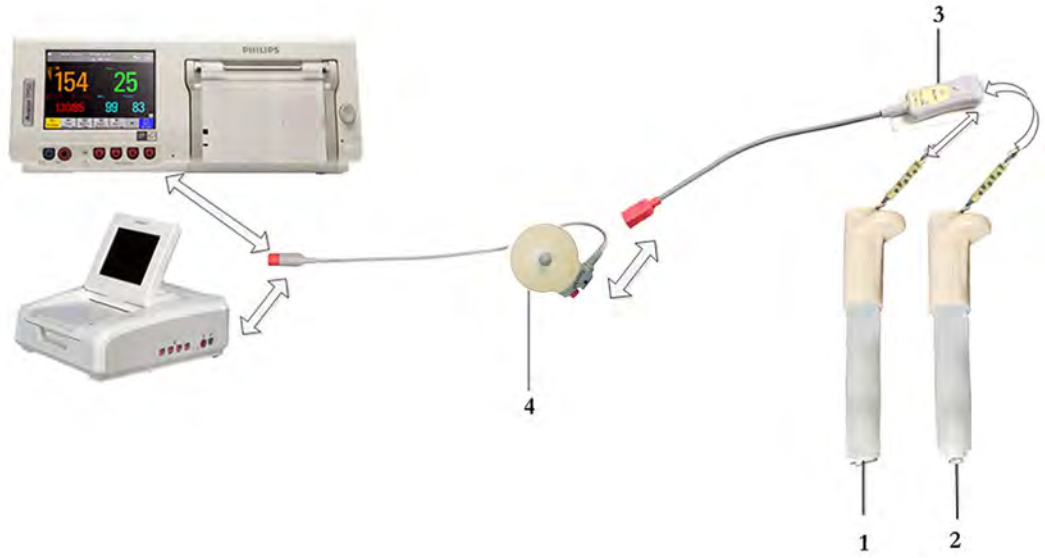
2 Fetal Scalp Electrode, double spiral, Europe only, not for U.S. (989803137641)

3 DECG Adapter Cable (9898 031 37651) with Pre-gelled Attachment Electrode (989803139771)

4 ECG/IUP (867247)

DECG with Toco+ or Toco+ MP (cable)

The figure below shows the complete connection chain from the fetal scalp electrode to the fetal monitor using the Toco+ MP transducer.



1 Fetal Scalp Electrode, single spiral (989803137631)

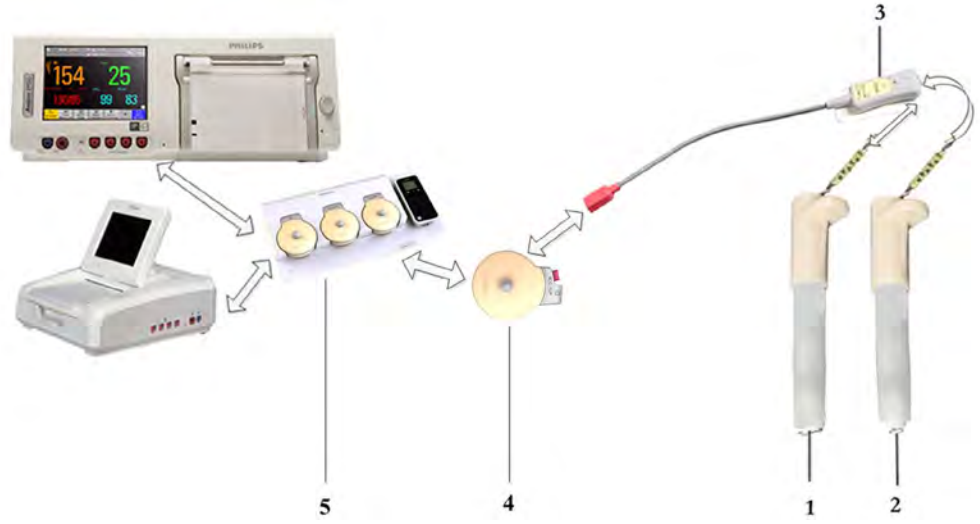
2 Fetal Scalp Electrode, double spiral, Europe only, not for U.S. (989803137641)

3 DECG Adapter Cable (9898 031 37651) with Pre-gelled Attachment Electrode (989803139771)

4 Toco+ transducer (M2735A), Toco+ transducer (867249), Toco+ MP (867245)

DECG with CL Toco+ MP or CL ECG/IUP Transducer (cableless)

The figure below shows the equivalent chain using the CL Toco+ MP or CL ECG/IUP transducer.



1 Fetal Scalp Electrode, single spiral (989803137631)

2 Fetal Scalp Electrode, double spiral, Europe only, not for U.S. (989803137641)

3 DECG Adapter Cable (9898 031 37651) with Pre-gelled Attachment Electrode (989803139771)

4 CL Toco+ MP (866075) or CL ECG/IUP (866077) transducer

5 Avalon CL base station (866074)

Making Connections

WARNING

Follow the instructions supplied with each of the monitoring accessories you are using.

Prepare for DECG monitoring using the list below. The standard procedures in use in your facility determine the sequence of actions.

1 If you change the Monitoring Mode from US to DECG, first disconnect the US transducer.

2 Depending on the equipment you are using, ensure that the transducer, or the patient module is connected to the fetal monitor.

3 Attach the fetal scalp electrode to the fetus, following the instructions supplied with the fetal scalp electrode.

4 Attach a pre-gelled attachment electrode to the DECG adapter cable, following the instructions supplied with the DECG adapter cable.

5 Fix the attachment electrode to the mother's thigh, following the instructions supplied with the attachment electrode.

Depending on the equipment you are using, connect the red connector plug on the DECG adapter cable to the red connector on the Toco+ MP or CL Toco+ MP transducer, or the ECG/IUP or CL ECG/IUP transducer, or the patient module.

6 Connect the fetal scalp electrode to the DECG adapter cable.

You are now ready to begin monitoring DECG.

WARNING

The fetal/maternal monitor is not a diagnostic ECG device. In particular, the display of fetal/maternal ECG is intended only for evaluating signal quality for fetal/maternal heart rate as derived from the ECG waveform.

When in doubt, it can be used to identify sources of compromised signal quality, such as noise or muscle artifacts. It can subsequently be used to verify the result of measures taken to resolve them (e.g. checking ECG cable connections or adapting the fetal **ArtifactSuppress** configuration).

The safety and effectiveness of the displayed fetal/maternal ECG waveform (i.e. P, QRS, and T segments) for evaluation of fetal/maternal cardiac status during labor have not been evaluated.

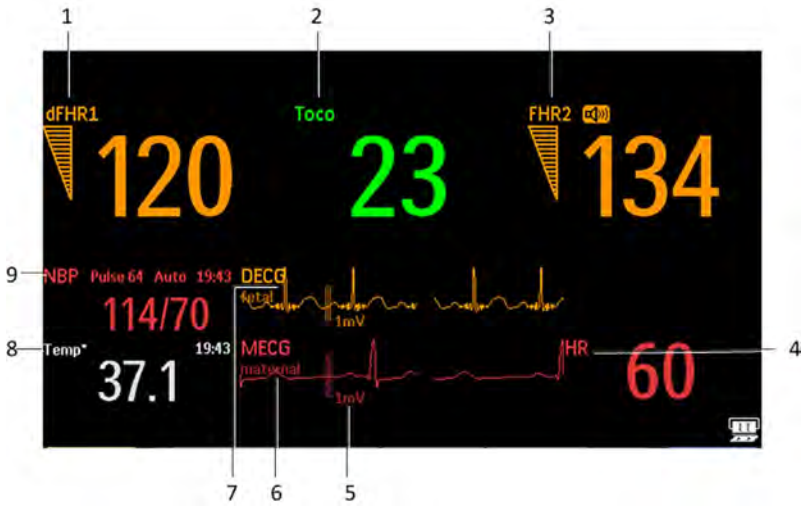
Monitoring DECG

To simultaneously measure DECG and MECG, you need the ECG/IUP or CL ECG/IUP transducer, or the patient module for DECG, and a Toco+, Toco+ MP, or CL Toco+ MP, or ECG/IUP, CL ECG/IUP transducer for MECG (see "Monitoring Maternal Heart / Pulse Rate" on page 219). Alternatively, you can monitor the maternal pulse rate via pulse oximetry (see "Pulse Rate from SpO2" on page 225). You can also monitor maternal pulse with the Toco+ MP or CL Toco+ MP transducer. In any case, where you would use a Toco+ or Toco MP transducer, you can also monitor with a Toco+ MP or CL Toco+ MP transducer.

1 Switch on the recorder.

2 The heart rate monitored via DECG is labeled **dFHR1** / **dFHR2** / **dFHR3** on the screen. If configured, the DECG wave is displayed automatically on the screen, labeled **DECG**, and **fetal**. If MECG is being monitored, both waves are displayed, with the DECG wave above the MECG wave. The MECG wave is labeled **MECG** and **maternal**.

3 Check the artifact suppression setting and change it if necessary (see "Suppressing Artifacts" on page 204).



1 Measurement label (dFHR1)

2 Measurement label (Toco)

3 Measurement label (FHR2)

4 Measurement label (HR)

5 1mV scale bar

6 MECG wave with maternal label

7 DECG wave with fetal label

8 Measurement label (Temp) maternal temperature

9 Measurement label NBP

NOTE

The 1mV scale bar for the DECG and MECG wave is not displayed on the screen if you monitor DECG or MECG with an Avalon CTS system. The Avalon CTS system does not provide a scaled ECG.

WARNING

Periodically compare the mother's pulse with the signal coming from the monitor's loudspeaker to ensure that you are monitoring fetal heart rate. If the maternal HR coincides with the FHR, do not misinterpret the maternal HR as the FHR (see also "Confirm Fetal Life Before Using the Monitor" on page 12 and "Cross-Channel Verification (CCV)" on page 163.

Suppressing Artifacts

When the monitor's artifact suppression is on, instantaneous heart rate changes of 28 bpm or more, however caused, are not recorded. Fetal arrhythmia will also be suppressed. **If you suspect fetal arrhythmia, switch artifact suppression off.** When artifact suppression is off, all recorded fetal heartbeats within the specified range are shown. The default setting is **On** (artifacts are suppressed).

To change the setting:

1 Enter the **Setup dFHR1** menu.

2 Select **ArtifactSuppress** to switch between artifact suppression **On** (artifacts are suppressed) and **Off** (no artifact suppression, use this setting if you suspect fetal arrhythmia).

When artifact suppression is off, **Artifact Suppression Off** is annotated on the trace recording.

Printing the Waveform

You can print the DECG wave onto the trace paper. Refer to "Printing the ECG Waveform" on page 227.

Troubleshooting

NOTE

In many cases you need to see the DECG wave to check if the signal quality is good enough to derive a valid fetal heart rate. In the dFHR setup menu, switch on the display of the DECG wave.

Problem	Possible Cause	Solutions
dFHR1 Equip Malf **dFHR2 Equip Malf** **dFHR3 Equip Malf**	Malfunctioning equipment	See "Patient Alarms and INOPs" on page 127.

Problem	Possible Cause	Solutions
dFHR1 Leads Off **dFHR2 Leads Off** **dFHR3 Leads Off** Numeric is displayed with a -?-; INOP tone See also "Patient Alarms and INOPs" on page 127. Erratic trace Erratic display	Fetal scalp electrode detached at connector	Reconnect the fetal scalp electrode If the wave is configured to be displayed on the monitor, you can observe if the ECG signal is clear, or if it shows interruptions and noise
	Poor or no contact between leg attachment electrode and mother	Check all connections Disconnect and reconnect the connector several times
	No contact between the DECG adapter cable and the leg attachment electrode No contact between the fetal scalp electrode connector and the DECG adapter cable	Check all connections Disconnect and reconnect the connector several times If problem persists, use a new fetal scalp electrode
	No ECG signal Poor contact between the reference electrode and the mother	Check for fetal demise Use a new fetal scalp electrode if necessary
Signal quality indicator continuously shows a poor signal	Fetal arrhythmia	Use a new fetal scalp electrode if necessary
dFHR1 Signal Loss **dFHR2 Signal Loss** **dFHR3 Signal Loss**	No signal	See "Patient Alarms and INOPs" on page 127.
dFHR1 Unplugged **dFHR2 Unplugged** **dFHR3 Unplugged**	No connection	See "Patient Alarms and INOPs" on page 127.

Testing DECG Mode

See the monitor's Service Guide.

17

Monitoring Uterine Activity Externally

You can measure uterine activity externally using a Toco transducer. You can use a Toco+, Toco MP, Toco+ MP, or a CL Toco+ MP transducer for the same purpose, although they also have more (ECG/IUP and Pulse) capabilities.

The external Toco transducer allows to monitor the frequency, duration, and relative strength of contractions, but not their absolute intensity. Amplitude and sensitivity depend on various factors such as the position of the transducer, the belt tension, and the size of the patient.

What You Need

Toco+, Toco MP, or Toco+ MP transducer (Toco MP and Toco+ MP additionally capable of providing the maternal pulse measurement)

CL Toco+ MP transducers (additionally capable of providing the maternal pulse measurement)

Abdominal belt (disposable shown)

External Toco Monitoring

Prepare for Toco monitoring using the list below. The standard procedures in use in your facility determine the sequence of actions.

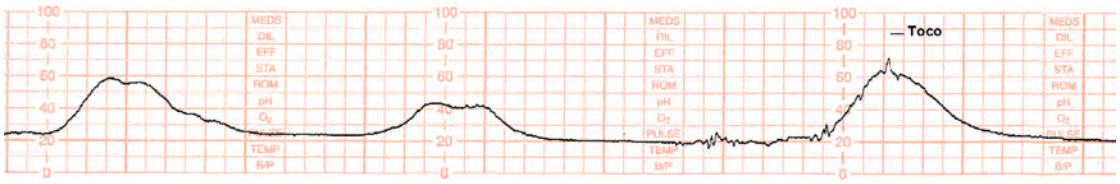
1 Fasten the abdominal transducer belt around the patient.

2 Connect the Toco transducer to a free socket on the monitor. The Toco baseline is automatically reset. The Toco display shows 20. "**Toco**", indicating external uterine measurement, is printed on the trace at intervals.

3 Place the transducer on the patient's fundus to ensure the optimum recording of uterine activity.

4 Reset the Toco baseline as necessary (see "Resetting the Toco Baseline" on page 208), but not during a contraction.

The following example trace shows two contractions.



Resetting the Toco Baseline

1 Press the **Toco Baseline** SmartKey. This resets the Toco baseline to 20 on the display and trace.

2 If the Toco value is negative for more than five seconds, the Toco baseline is automatically reset to 0 units.

Toco Sensitivity

If the Toco sensitivity is too high, and the Toco trace exceeds the paper scale, you can reduce the Toco sensitivity to 50%. The default setting is 100%.

To change the Toco sensitivity:

1 Enter the **Setup Toco** menu.

2 Select **Gain** to switch between **100%** and **50%**.

Troubleshooting

External Toco Monitoring		
Problem	**Possible Causes**	**Solutions**
Quality of the trace deteriorates or the Toco baseline varies	The belt is incorrectly fastened and is too slack or too tight, or the belt has lost its elasticity.	The belt must be tight enough to ensure good contact between the patient's skin and the entire surface of the transducer without causing discomfort. Ensure you are using the correct belt. Adjust it as necessary.
	Fetal movement	Check if the belt is correctly fastened and adjust it as necessary. Reposition the transducer and reset the Toco baseline if necessary.
	Maternal respiration superimposed on trace	Check if belt is not too loose.
	Maternal movement/change of position	Following maternal movement, reset Toco baseline
Toco sensitivity is too high (above 100 units) Toco trace is exceeding the paper scale	Physical transmission of pressure from the uterus to the sensor is much higher than the average value.	Check if the belt is too tightly fastened. Select 50% Toco **Gain**.
Toco sensitivity is too low. Contractions are not clearly visible on the trace.	Physical transmission of pressure from the uterus to the sensor is insufficient.	Check if the belt is too loose. Select 100% Toco **Gain**.
Toco Equip Malf is displayed.		See "Patient Alarms and INOPs" on page 127.
Toco Unplugged is displayed.		See "Patient Alarms and INOPs" on page 127.
If you suspect the signal from the transducer.		Test the Transducer (see "Testing Toco Transducers" on page 210 below).

Testing Toco Transducers

If any of the following tests fail, repeat the test using another transducer. If the second transducer passes the tests, confirming that the first transducer is defective, contact your service personnel.

If the second transducer also fails the tests, contact your service personnel.

You can test all Toco transducers, including the cableless ones. To test a Toco transducer:

1. Switch on the monitor and the recorder.
2. Connect the transducer to the fetal monitor.
3. Gently apply pressure to the pick-up button.
4. Check if after a few seconds the values on the display and paper show this change in pressure.

18

Monitoring Uterine Activity Internally

FM30/50 You can monitor intrauterine pressure (IUP) using an intrauterine catheter together with a patient module, Toco+, Toco+ MP, ECG/IUP, or the CL ECG/IUP or CL Toco+ MP transducer, after rupture of the membranes and the cervix is sufficiently dilated.

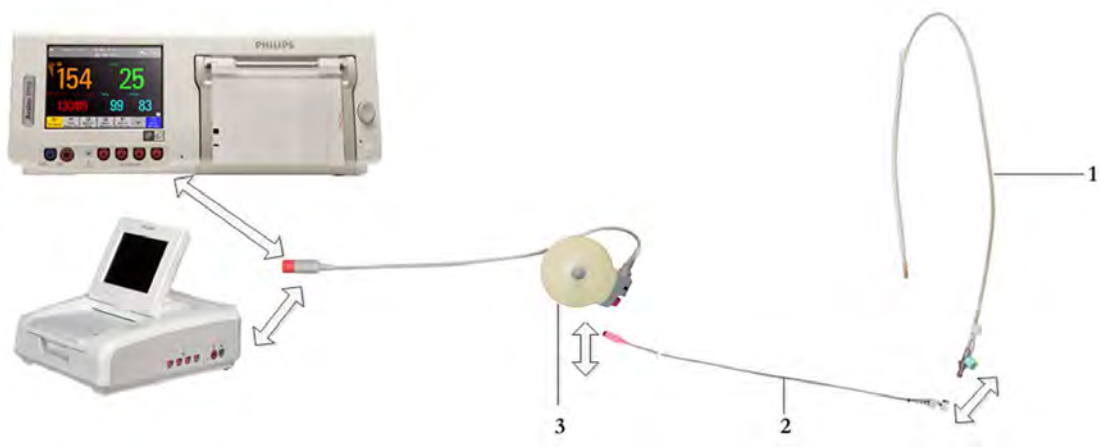
WARNING

IUP Catheter: Do not catheterize if placenta previa is diagnosed, or if uterine bleeding from an undetermined source is present.

What You Need

IUP with ECG/IUP Transducer (cable)

The figure below shows the complete connection chain from the IUP catheter to the fetal monitor using the ECG/IUP transducer:



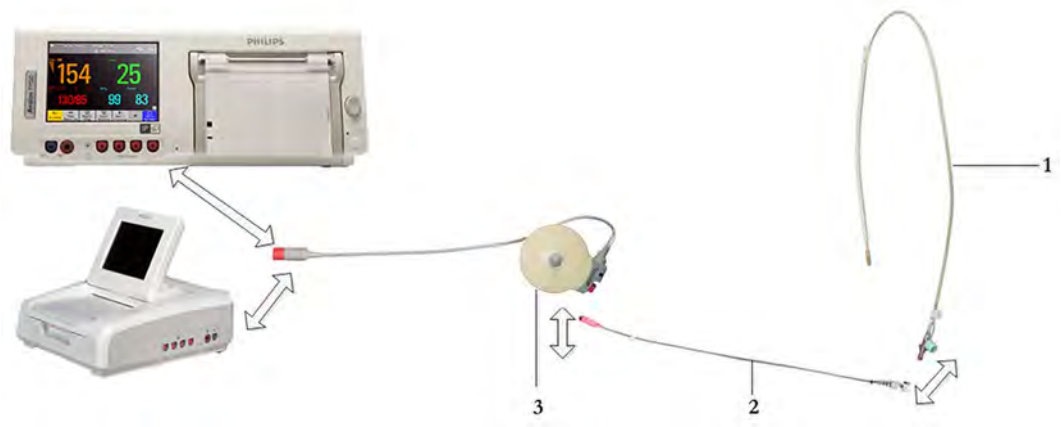
1 Disposable Koala IUP Catheter (M1333A)

2 Reusable Koala IUP Adapter Cable (9898 031 43931)

3 ECG/IUP transducer (867247)

IUP with Toco+ MP or Toco+ Transducer (cable)

The figure below shows the complete connection chain from the IUP catheter to the fetal monitor using the Toco+ MP transducer:



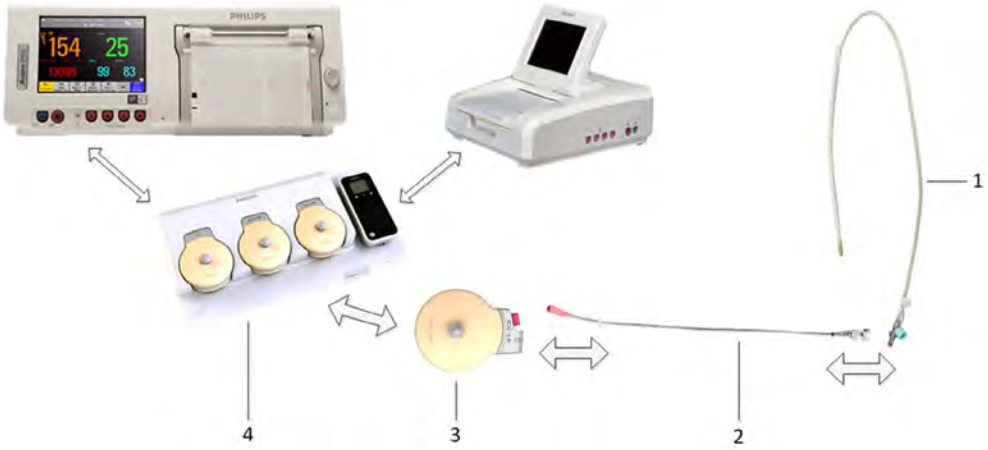
1 Disposable Koala IUP Catheter (M1333A)

2 Reusable Koala IUP Adapter Cable (9898 031 43931)

3 Toco+ MP (867245) or Toco+ (867249) transducer

IUP with CL ECG/IUP, or CL Toco+ MP Transducer (cableless)

The figure below shows the complete connection chain from the IUP catheter to the fetal monitor using the CL ECG/IUP transducer:



1 Disposable Koala IUP Catheter (M1333A)

2 Reusable Koala IUP Adapter Cable (9898 031 43931)

3 CL ECG/IUP transducer (866077), or CL Toco+ MP (866075) transducer

4 Avalon CL base station (866074)

Internal (IUP) Monitoring

Read the instructions that accompany the intrauterine catheter and the adapter cable before you start monitoring. Zero the IUP measurement when instructed.

WARNING

Do not catheterize if placenta previa is diagnosed, or if uterine bleeding from an undetermined source is present.

Prepare for IUP monitoring using the list below. The standard procedures in use in your facility determine the sequence of actions.

1. Perform a complete clinical evaluation.
2. Catheterize after membrane rupture. Insert the catheter according to its accompanying instructions.
3. Connect the catheter to the socket on the patient module.
4. Connect the patient module to a free socket on the monitor. The monitor is automatically zeroed. The IUP display shows 0. **IUP**, indicating internal measurement is printed at intervals on the trace.
5. Zero the IUP measurement (see "Zero The IUP Measurement" on page 213).
6. If you suspect the catheter is not responding appropriately, flush as directed in the catheter's Instructions for Use. A pressure spike appears on the trace if you flush after connecting the transducer to the monitor.

Zero The IUP Measurement

Zero the IUP measurement by selecting the **Zero IUP** SmartKey, or selecting **Zero IUP** in the **Setup IUP** menu. This resets the display and trace to 0. If you do not zero the monitor properly, the pressure trace may exceed the paper scaling.

Selecting the IUP Unit

You can select between mmHg (default) and kPa for the IUP unit.

1. Enter the **Setup IUP** menu.
2. Press **Unit** to switch between **mmHg** and **kPa**.

Troubleshooting

Internal (IUP) Monitoring

Problem	Possible Causes	Solutions
Only pressure peaks can be seen (baseline not visible).	Zero adjustment is incorrect.	Zero the IUP measurement.
No change in pressure during contraction.	Catheter tip not in contact with amniotic fluid or possible extra-ovular placement of the catheter.	Refer to catheter Instructions for Use.
Trace is a straight line.	Connection issue or cable or catheter defective.	• Unplug/replug catheter • Unplug/replug or exchange adapter cable • Try new catheter
Trace is superimposed with noise.	Possible extra-ovular placement of catheter.	Refer to catheter Instructions for Use.
IUP Equip Malf INOP is displayed.	See "Patient Alarms and INOPs" on page 127.	
IUP Unplugged INOP is displayed.		

19

Monitoring aFHR, aHR, and aToco

Introducing the abdominal Avalon CL Fetal & Maternal Pod Measurement

The Avalon CL Fetal & Maternal Pod (CL F&M Pod) noninvasively measures fetal heart rate (aFHR), maternal heart rate (aHR), and uterine activity (aToco). The CL F&M Pod is used together with a single-use electrode patch. The electrode patch has five adhesive electrodes. The CL F&M Pod and electrode patch are placed on the maternal abdomen. It picks up the fetal and maternal electrocardiography (ECG) signals, and the uterine electromyography (EMG) signals. The CL F&M Pod separates and processes the signals, and transmits aFHR, aHR, and aToco to the fetal monitor via the CL base station.

WARNING

Use the CL F&M Pod and electrode patch with singleton pregnancies only. The measurements have been validated with a gestational age of >36 completed weeks.

NOTE

- Fetal ECG and uterine EMG signals are very small. Therefore, skin preparation is required when applying the electrodes.
- Different measurements for the same physiological parameter may have a different appearance on the trace, due to variability (HR), averaging, delay, amplitude, or artifacts.

The beat-to-beat variability of aFHR may appear lower than FHR from ultrasound and lower than dFHR from DECG due to averaging. The accuracy of all FHR parameters is sufficient for diagnosis following commonly agreed guidelines.

NOTE

The Avalon CL Fetal & Maternal Pod and Patch are not available for U.S., other FDA regulated territories, and Canada.

Fetal Heart Rate aFHR

It is recommended to verify the presence of the fetal heart beat, for example with a stethoscope, before starting continuous monitoring with the CL F&M Pod.

CAUTION

If the aFHR signal quality indicator on the fetal monitor screen continuously indicates an insufficient signal quality (empty triangle), although the CL F&M electrode status is green, then an alternative method to monitor should be used.

Uterine Activity aToco

The CL F&M Pod measures the electrical activity of the uterus which is different to the mechanical measurements of a Toco transducer or an IUP catheter. Depending on the measurement method, the shape of a recorded contraction can look different. The uterine EMG signals can be interfered with by the electrical activity of other muscles, for example during maternal or fetal movements or position changes.

CAUTION

The aToco measurement does not represent the absolute intrauterine pressure. If aToco seems questionable, verify uterine activity by other means (maternal perception, manual palpation, or intrauterine pressure (IUP) measurement). For monitoring the real intrauterine pressure in mmHg or kPa, an IUP catheter is required.

CAUTION

The duration of the contraction measured by the CL F&M Pod can be shorter than the physical contractions. When you palpate the uterus, there is a delay between the manual detection of contraction, and when it is displayed at the monitor.

CAUTION

Maternal or fetal movements can cause electrical signals that may result in uterine contraction-like artifacts.

Maternal movement

Shortly after and during consistent maternal movement is detected:

- A question mark is displayed in front of the aToco numeric at the monitor (?aToco).
- The aToco trace is printed with a lighter intensity for the duration of the maternal movements, indicating that the signal may be compromised and not suitable for trace interpretation.

Uterine Activity Measurement Priority

When several uterine activity measurements are active, the priority given on the monitor display is:

- IUP (Intrauterine pressure from the connection with an IUP catheter)
- aToco (CL F&M Pod)
- Toco (CL Toco$^+$ MP transducer, Toco$^+$, or Toco$^+$ MP wired transducer)

aToco Sensitivity

Monitoring with the CL F&M Pod, the aToco sensitivity can be set to **High** or **Low** at any time. The **Low** sensitivity setting provides an additional suppression of artifacts, for example artifacts coming from maternal and fetal movements. The additional filtering delays the onset of recording the contraction on the trace and shows a reduced amplitude.

The default setting is **High** and recommended for active labor.

Setting the aToco Sensitivity

1 Select the **Setup aToco** menu.

2 Select the **Sensitivity** by toggling between **High** and **Low**.

What You Need

- For monitoring with the CL F&M Pod, see "Avalon CL Fetal & Maternal Pod" on page 25 and "CL Fetal & Maternal Patch" on page 88.
- For assigning the CL F&M Pod, see "CL Pod Assignment" on page 95.
- For applying the electrode patch and the CL F&M Pod, see "Applying the CL Fetal & Maternal Patch and Pod" on page 97.

At the Monitor

1 Switch on the recorder.

2 The fetal heart rate is labeled **aFHR1**, **aFHR2**, or **aFHR3** on the screen. The CL F&M Pod monitors only singletons, but if in addition to **aFHR** a CL US transducer and/or a scalp electrode (DECG) are used to monitor FHR, the aFHR numeric is labeled 1 to 3 depending on the sequence in which the other measurement methods are added.

3 aFHR and aHR have a QRS tone. The volume can be set in the measurement's setup menu, see "Selecting Fetal Heart Sound" on page 172.

1 Measurement label aFHR

2 Measurement label aToco

3 Measurement label aHR

Troubleshooting

Problem	Possible Causes	Solutions
Erratic trace Erratic display	Fetal arrhythmia	Consider monitoring FHR with alternative methods.
	Electrode contact not optimal	Reposition the electrode and repeat the skin preparation until the CL F&M Status shows that all electrodes have good contact.
	Obese patient	If a patient is obese, re-position the lower electrode on the midline 1-2 in/3-5 cm below the original placement, or on the underside of the panniculus just below the turn.
	Too much maternal or fetal movement	Ask the patient to sit or lie still until the signal improves. If the signal indication does not improve, consider monitoring with alternative methods.
Signal quality indicator is continuously poor	Electrode contact not optimal	Repeat the skin preparation until the CL F&M Status shows that all electrodes have good contact.
	Patient in unfavorable position	Make the patient more comfortable, if the abdominal muscles are relaxed it may improve the signal. For example, place a pillow to support the patient's back. If the signal indication does not improve, consider monitoring with alternative methods.
	Mobile abdomen	If the abdomen is mobile, or patient position has changed, use a rolled blanket/towel or pillow to support abdomen to keep the patch centered on the uterus. If the signal indication does not improve, consider monitoring with alternative methods.
aFHR not recorded or questionable	aFHR is less than 60 bpm or over 240 bpm, fetal demise, fetal arrhythmia, or the baby is born	Verify the FHR by independent means.

NOTE

For all signal loss, malfunction, or other alerts see "Patient Alarms and INOPs" on page 127.

20

Monitoring Maternal Heart / Pulse Rate

You can monitor the maternal heart/pulse rate using one of five sources:

- Maternal heart rate (HR) via MECG electrodes
- Maternal heart rate (aHR) via CL F&M Pod
- Maternal pulse rate from Toco MP, Toco$^+$ MP, or CL Toco$^+$ MP transducer (Pulse)
- Maternal pulse rate from SpO_2 (Pulse)
- Maternal pulse rate from NBP (Pulse)

Maternal heart/pulse rates derived from Toco MP, Toco$^+$ MP, or CL Toco$^+$ MP, SpO_2, aHR, and MECG are **continuous** measurements, and are compared against the FHR for cross-channel verification. Average pulse rate derived from noninvasive blood pressure is an **intermittent** measurement, and is therefore not used for cross-channel verification.

Priority for Maternal Heart / Pulse Rate

Priority	Maternal Heart / Pulse Rate Source	Alarming	Used for CCV	Provides QRS Tone
1	HR from MECG measurement	Yes	Yes	Yes
2	aHR from CL F&M Pod	Yes	Yes	Yes
3	Pulse from CL SpO_2 Pod measurement	Yes	Yes	No
4	Pulse from SpO_2 measurement	Yes	Yes	Yes
5	Pulse from Toco MP measurement cableless or cabled	No	Yes	No
6	Pulse from CL NBP Pod measurement	No	No	No
7	Pulse from NBP measurement	No	No	No

Only one maternal heart rate/pulse rate numeric is displayed and recorded at a time (see priority table). If higher-priority measurements are connected but temporarily not providing valid numerics, lower-priority numerics may be displayed and recorded instead.

Misidentification of Maternal HR for FHR

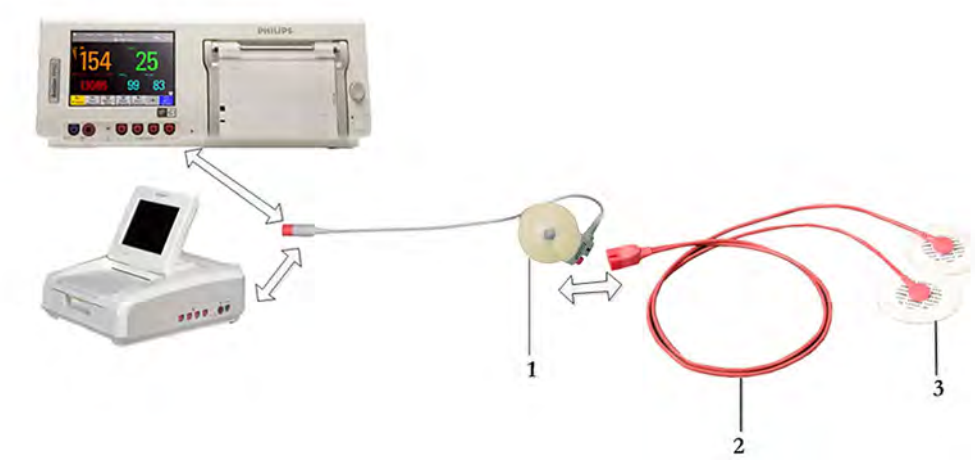
To reduce the possibility of mistaking the maternal HR for FHR, it is recommended that you monitor both maternal and fetal heart rates (see "Confirm Fetal Life Before Using the Monitor" on page 12 and "Cross-Channel Verification (CCV)" on page 163).

Maternal HR from MECG Electrodes

You can measure maternal HR using the equipment combinations shown in the following figures.

MECG with ECG/IUP Transducer (cable)

The figure below shows the complete connection chain from the foam electrodes applied to the patient to the fetal monitor using the ECG/IUP transducer.



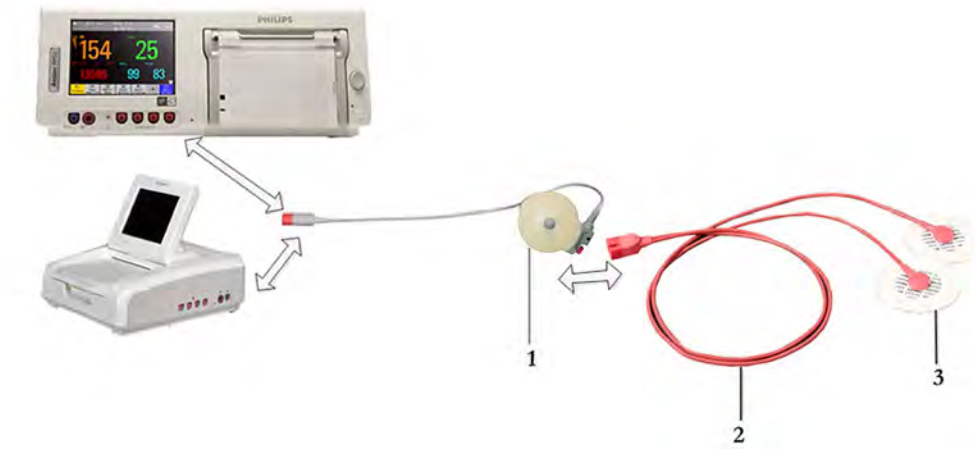
1 ECG/IUP (867247)

2 MECG Adapter Cable (M1363A)

3 Pre-gelled Foam Electrodes (40493A/B/C/D/E)

MECG with Toco$^+$ or Toco$^+$ MP (cable)

The figure below shows the equivalent chain using the Toco$^+$ MP transducer.



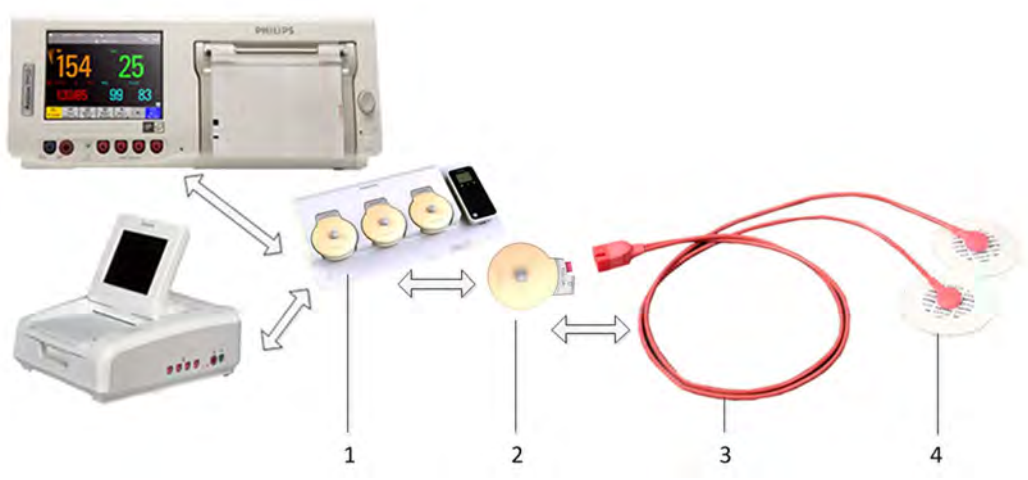
1 Toco$^+$ (M2735A), Toco$^+$ (867249), or Toco$^+$ MP (867245) transducer

2 MECG Adapter Cable (M1363A)

3 Pre-gelled Foam Electrodes (40493A/B/C/D/E)

MECG with CL Toco+ MP or CL ECG/IUP Transducer (cableless)

The figure below shows the equivalent chain using a CL Toco+ MP transducer or a CL ECG/IUP transducer.



1 Avalon CL base station (866074)

2 CL Toco+ MP (866075) or CL ECG/IUP transducer (866077)

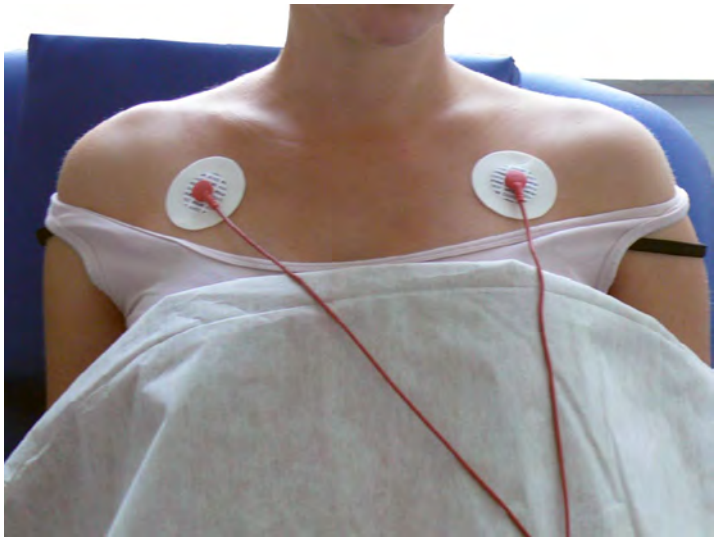
3 MECG Adapter Cable (M1363A)

4 Pre-gelled Foam Electrodes (40493A/B/C/D/E)

To simultaneously measure DECG and MECG, you need the ECG/IUP or CL ECG/IUP transducer, or the patient module for DECG, and a Toco+, Toco+ MP, or CL Toco+ MP, or ECG/IUP, CL ECG/IUP transducer for MECG. For measuring DECG, you need a Toco+, Toco+ MP, or CL Toco+ MP, or ECG/IUP, CL ECG/IUP transducer or a patient module (see also "Monitoring FHR Using DECG" on page 199).

Applying Electrodes

To derive the maternal HR (when you do not want to view the MECG waveform), you can place the electrodes just below the outer end of the clavicle near each shoulder.



1 MECG Electrodes

Making Connections

WARNING

Follow the instructions supplied with each of the monitoring accessories you are using.

Prepare for monitoring maternal HR using the list below. The standard procedures in use in your facility determine the sequence of actions.

1 Depending on the equipment you are using, ensure that *either* the Patient Module *or* the Toco$^+$, Toco$^+$ MP, or ECG/IUP transducer is connected to the fetal monitor. If you are using cableless monitoring, use the CL ECG/IUP or the CL Toco$^+$ MP transducer.

2 Connect a pre-gelled foam electrode to each of the two leads on the MECG adapter cable.

3 Apply the foam electrodes to the patient, following the instructions supplied with the foam electrodes.

4 Depending on the equipment you are using, connect the pink connector plug on the MECG adapter cable to the pink connector on *either* the Patient Module *or* the Toco$^+$, Toco$^+$ MP, or ECG/IUP transducer. If you are using cableless monitoring, connect the MECG Adapter cable to the connectors of the CL ECG/IUP or the CL Toco$^+$ MP transducer.

You are now ready to monitor maternal HR.

Monitoring Maternal HR

1 Switch on the recorder.

2 The maternal heart rate is labeled **HR** on the screen.

Monitoring MECG Wave

WARNING

The fetal/maternal monitor is not a diagnostic ECG device. In particular, the display of fetal/maternal ECG is intended only for evaluating signal quality for fetal/maternal heart rate as derived from the ECG waveform.

When in doubt, it can be used to identify sources of compromised signal quality, such as noise or muscle artifacts. It can subsequently be used to verify the result of measures taken to resolve them (e.g., checking ECG cable connections or adapting the fetal **ArtifactSuppress** configuration).

The safety and effectiveness of the displayed fetal/maternal ECG waveform (i.e., P, QRS, and T segments) for evaluation of fetal/maternal cardiac status during labor have not been evaluated.

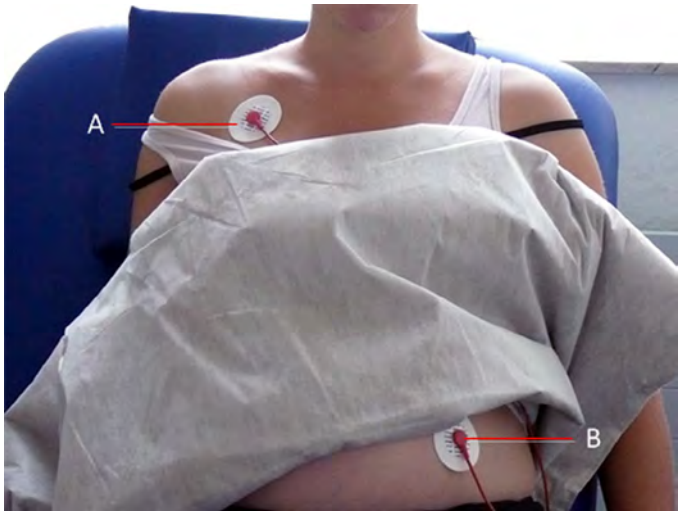
FM30/50 When measuring MECG with the Avalon FM30 or FM50, the MECG waveform, along with the heart rate numeric, is displayed on the screen when using a Toco$^+$, Toco$^+$ MP, or CL Toco$^+$ MP, or ECG/IUP, CL ECG/IUP transducer, or a patient module. If a maternal ECG wave analysis is required, use a patient monitor.

WARNING

The fetal/maternal monitor is NOT intended for use during defibrillation, electro-surgery, or MRI. Remove all transducers, sensors, and accessories before performing electro-surgery, defibrillation, or MRI, otherwise harm to the patient or the user can result.

Applying Electrodes

To obtain a satisfactory maternal ECG waveform, you must use the RA to LL (lead II) position of the standard 5-lead ECG.



1. Place one electrode directly below the clavicle and near the right shoulder.
2. Place the other electrode on the left lower abdomen.

Viewing the Waveform on the Screen

1. Measurement label dFHR1
2. Measurement label Toco
3. Measurement label FHR2
4. Measurement label HR
5. 1mV scale bar
6. MECG wave with maternal label
7. DECG wave with fetal label
8. Measurement label Temp maternal temperature
9. Measurement label NBP

NOTE

The 1mV scale bar for the DECG and MECG wave is not displayed on the screen if you monitor DECG or MECG with an Avalon CTS system. The Avalon CTS system does not provide a scaled ECG.

For the FM30/50, the **MECG** wave is displayed automatically on the screen, labeled **MECG**. If **DECG** is also being monitored (FM30/50), and the DECG Wave is configured to **On**, both waves are displayed, with the DECG Wave above the MECG wave. The DECG Wave is labeled **DECG**.

Troubleshooting

Problem	Possible Causes	Solutions
MECG Leads Off displayed. Numeric is displayed with a -?- for 10 seconds; INOP tone See also "Patient Alarms and INOPs" on page 127	One or more MECG leads is not attached.	Make sure that all required leads are attached If the wave is configured to be displayed on the monitor, you can observe if the ECG signal is clear, or if it shows interruptions and noise
	Bad electrical contact	Check positioning of the electrode, ensuring that none are displaced Check electrodes and replace if necessary
	Electrodes defective	
 prints repeatedly	The ultrasound transducer is measuring maternal pulse	Reposition the ultrasound transducer. See "Recommended Actions for Coincidence INOP" on page 167
MECG Equip Malf displayed	Equipment malfunctions	See "Patient Alarms and INOPs" on page 127
MECG Unplugged	Equipment not connected	

Printing the Waveform

You can print the MECG wave onto the trace paper. Refer to "Printing the ECG Waveform" on page 227.

Pulse Rate from Toco+ MP

The maternal pulse is taken from the Toco$^+$ MP or CL Toco$^+$ MP transducer when SpO_2 or MECG measurements are not used or have signal loss. When the pulse rate is very low, or strong arrhythmia is present, the pulse rate measured by the Toco$^+$ MP or CL Toco$^+$ MP transducer may differ from the heart rate calculated from MECG. If the mother is moving about, or began pressing during the second stage of labor, this can cause longer gaps in the recording of the maternal pulse signal. In this case, use the SpO_2 or MECG measurement to derive the maternal heart rate.

WARNING

- Physiological alarms (pulse low / pulse high) are not available if the maternal pulse is measured with either Toco$^+$ MP or CL Toco$^+$ MP.
- No QRS tone is audible when the Toco$^+$ MP or the CL Toco$^+$ MP transducer is the source of the pulse rate.
- The Toco$^+$ MP or CL Toco$^+$ MP transducer signal is significantly less reliable, if the patient is up and moving about, or is pushing during the second stage of labor.

NOTE

In rare cases, it is possible to pick up a fetal signal source. When a Toco$^+$ MP or CL Toco$^+$ MP transducer is connected to the monitor, but not applied to the patient, the measurement may generate unexpected intermittent pulse readings.

Pulse Rate from SpO2

If you are not monitoring maternal HR via MECG electrodes, but you are monitoring SpO_2, the maternal pulse rate is derived from the SpO_2 measurement. The pulse numeric is labeled **Pulse** on the screen.

WARNING

- No QRS tone is audible when the CL SpO_2 Pod is the source of the pulse rate.

Adjusting the Heart Rate / Pulse Alarm Limits

To adjust the pulse alarm limits for SpO_2:

1 In the **Setup SpO2** menu, select **Pulse (SpO2)**. This opens the **Setup Pulse (SpO2)** menu.

2 Ensure **Pulse (SpO2)** is **On**. Select **Pulse (SpO2)** to switch between **On** and **Off**.

3 Set the pulse alarm limit:

- Select **High Limit** then choose the upper alarm limit for tachycardia from the pop-up list.
- Select **Low Limit** then choose the lower alarm limit for bradycardia from the pop-up list.

To adjust the pulse alarm limits for MECG:

1 In the **Setup MECG** menu, select **MECG/Pulse Alarms**. This opens the **Setup Pulse (MECG)** menu.

2 Ensure **Pulse MECG** is **On**. Select **Pulse MECG** to switch between **On** and **Off**.

3 Set the pulse alarm limit.

- Select **High Limit** then choose the upper alarm limit for tachycardia from the pop-up list.
- Select **Low Limit** then choose the lower alarm limit for bradycardia from the pop-up list.

Average Pulse Rate from Noninvasive Blood Pressure

WARNING

Physiological alarms (pulse low / pulse high) are not available if the maternal pulse is measured with NBP.

When you are measuring noninvasive blood pressure, the monitor can also calculate the average pulse rate. This occurs in either manual or automatic mode, when neither MECG, SpO_2 nor pulse from Toco$^+$ MP or CL Toco$^+$ MP transducer are measured. The value is displayed on the screen, and printed on the trace. It is not the actual pulse value, but an average pulse rate, taken during the most recent noninvasive blood pressure measurement. The value is updated after each successive measurement. If you need a continuous measurement, you should monitor using MECG, SpO_2, or pulse from Toco$^+$ MP or CL Toco$^+$ MP transducer.

Testing MECG Mode

See the monitor's Service Guide.

20 Monitoring Maternal Heart / Pulse Rate

21

Printing the ECG Waveform

FM30/50 You can print the ECG wave onto the trace paper. If you are monitoring both DECG and MECG, both waves will be printed. The start of the wave recording is annotated above the wave with **MECG** for Maternal ECG, with **DECG** for Direct fetal ECG, and with **25 mm/sec** below the wave. When only MECG and/or DECG are measured without any real-time recording, the **25 mm/sec** recorder speed is printed in the trace header.

WARNING

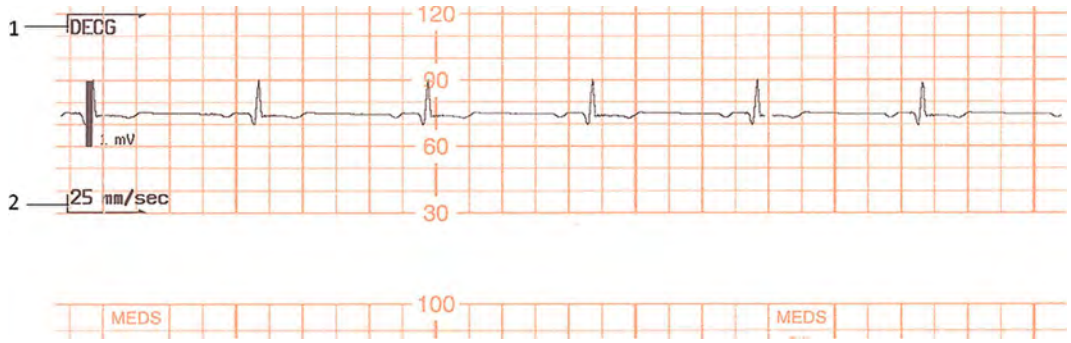
1 The fetal/maternal monitor is not a diagnostic ECG device. In particular, the display of fetal/maternal ECG is intended only for evaluating signal quality for fetal/maternal heart rate as derived from the ECG waveform.

When in doubt, it can be used to identify sources of compromised signal quality, such as noise or muscle artifacts. It can subsequently be used to verify the result of measures taken to resolve them (e.g., checking ECG cable connections or adapting the fetal **ArtifactSuppress** configuration).

The safety and effectiveness of the displayed fetal/maternal ECG waveform (i.e., P, QRS, and T segments) for evaluation of fetal/maternal cardiac status during labor have not been evaluated.

The ECG waveform is printed along the bottom of the heart rate grid, and the three different possibilities look like this:

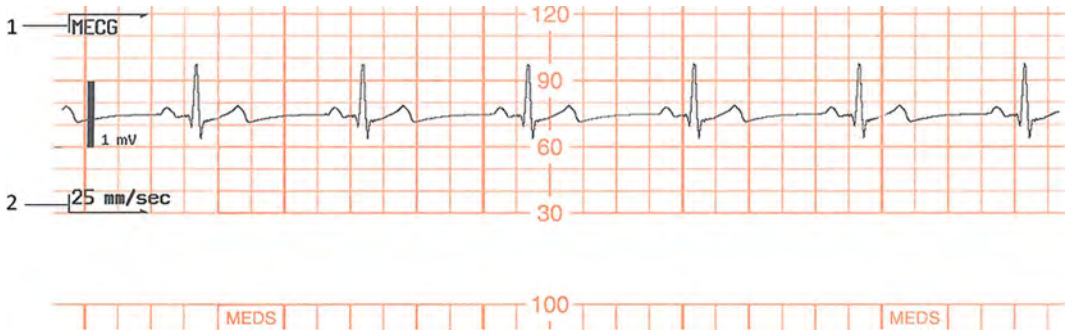
DECG waveform on its own



1 **DECG**

2 Recorder speed

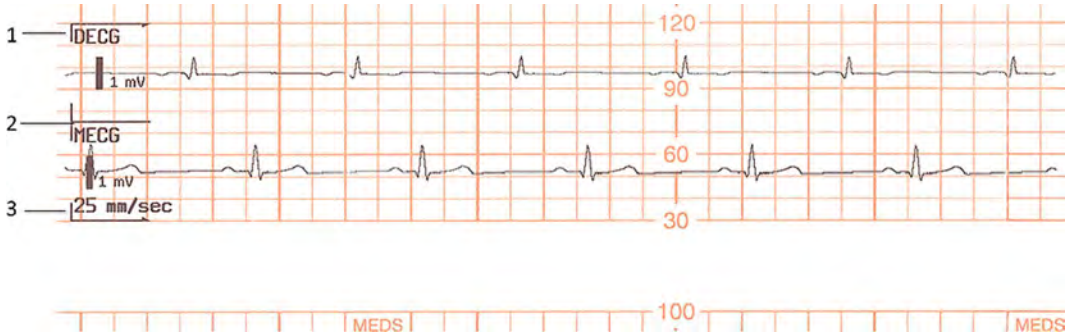
MECG waveform on its own



1 **MECG**

2 Recorder speed

DECG and MECG waveforms



1 **DECG**

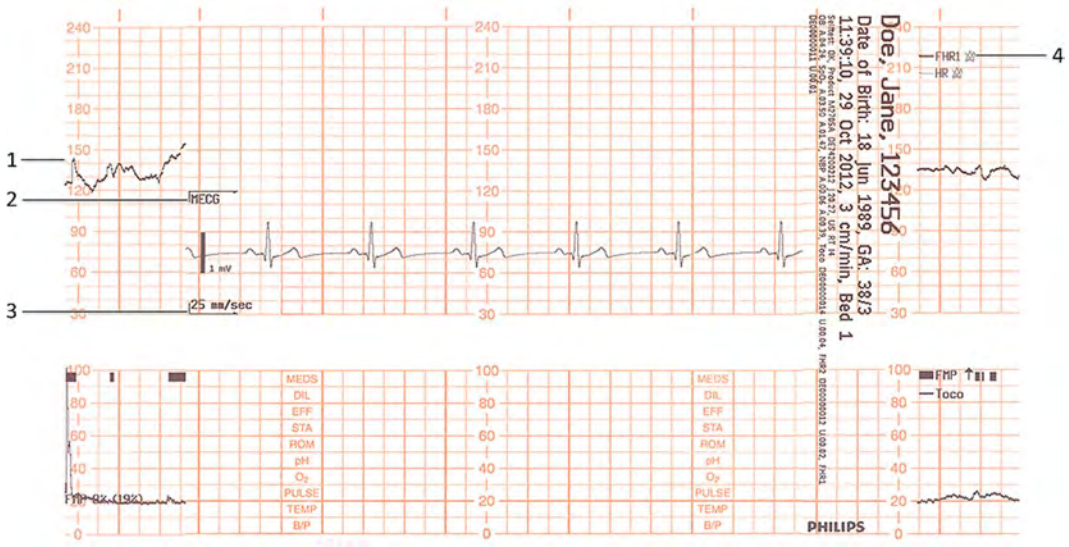
2 **MECG**

3 Recorder speed

When the recorder is on, there are two choices for printing the ECG wave:

- **Separate**: This recording mode gives you a six-second ECG strip on the fetal trace paper in fast printout mode. The real-time fetal trace recording is temporarily interrupted while the ECG strip prints. A new MECG header is printed to mark where the MECG wave starts, and a new trace header and FHR header mark when the fetal trace resumes.

The following trace shows the MECG waveform:



1 FHR1 trace interrupted

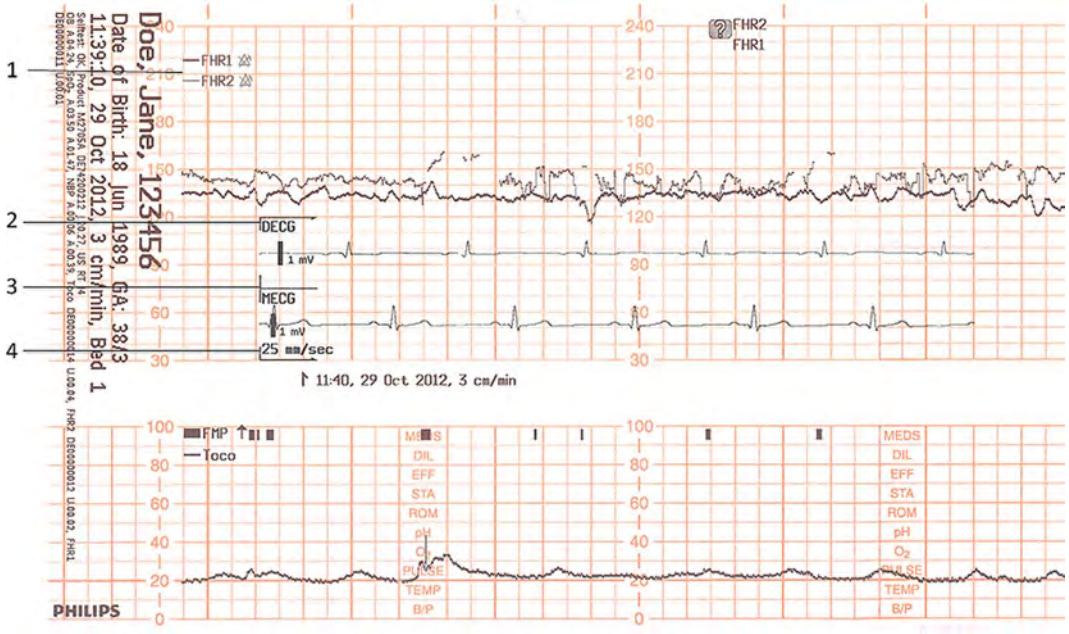
2 **MECG** header

3 Recorder speed

4 FHR1 trace resume

- **Overlap**: This recording mode gives you a delayed six-second snapshot of the maternal and/or direct fetal ECG for documentation on the fetal strip, but without interrupting the fetal trace. It takes 5 minutes to print this six-second snapshot at a recorder speed of 3 cm/min. It is documented as if it was recorded at 25 mm/s.

The following trace shows both the DECG and MECG waveforms:



1 FHR1 and FHR2

2 **DECG** header

3 **MECG** header

4 Recorder speed

To make your choice:

1 Enter the **Main Setup** menu.

2 Select **Fetal Recorder** to enter the **Fetal Recorder** menu.

3 Select **ECG Wave** to switch between **Separate** and **Overlap**.

To print the ECG wave(s):

1 Select the **Record ECG Wave** SmartKey (configurable) and the recording trace is started.

Or

1 Enter the **Main Setup** menu by selecting the SmartKey.

2 Select **Fetal Recorder** to enter the **Fetal Recorder** menu.

3 Select **Record ECG Wave** and the recording trace is started.

Or

1 Select the **ECG Wave**.

2 Select **Record ECG Wave** in the ECG wave menu and the recording trace is started.

22

Monitoring Noninvasive Blood Pressure

The noninvasive blood pressure measurement (NBP) is intended for use with maternal patients.

This monitor uses the oscillometric method for measuring NBP.

A physician must determine the clinical significance of the NBP information.

Introducing the Oscillometric Noninvasive Blood Pressure Measurement

Oscillometric devices measure the amplitude of pressure changes in the occluding cuff as the cuff deflates from above systolic pressure. The amplitude suddenly increases as the pulse breaks through the occlusion in the artery. As the cuff pressure decreases further, the pulsations increase in amplitude, reach a maximum (which approximates to the mean pressure), and then diminish.

Studies show that, especially in critical cases (arrhythmia, vasoconstriction, hypertension, shock), oscillometric devices are more accurate and consistent than devices using other noninvasive measuring techniques.

WARNING

Intravenous infusion: Do not use the NBP cuff on a limb with an intravenous infusion or arterial catheter in place. This could cause tissue damage around the catheter when the infusion is slowed or blocked during cuff inflation.

Skin Damage: Do not measure NBP in cases of sickle-cell disease or any condition where skin damage has occurred or is expected.

Existing Wounds: Do not apply the cuff over a wound as this can cause further injury.

Mastectomy or lymph node clearance: Avoid applying the cuff on the side of the mastectomy or lymph node clearance, as the pressure increases the risk of lymphedema. For patients with a bilateral mastectomy or lymph node clearance, use clinical judgment to decide whether the benefit of the measurement outweighs the risk.

Unattended Measurement: Use clinical judgment to decide whether to perform frequent unattended blood pressure measurements. Too frequent measurements can cause blood flow interference potentially resulting in injury to the patient. In cases of severe blood clotting disorders frequent measurements increase the risk of hematoma in the limb fitted with the cuff.

Temporary Loss of Function: The pressurization of the cuff can temporarily cause loss of function of monitoring equipment used simultaneously on the same limb.

Measurement Limitations

NBP readings can be affected by the position of the subject, their physiological condition, the measurement site, and physical exercise. Thus a physician must determine the clinical significance of the NBP information.

The measurement may be inaccurate or impossible:

- with excessive and continuous patient movement such as during contractions
- if a regular arterial pressure pulse is hard to detect
- with cardiac arrhythmias
- with rapid blood pressure changes
- with severe shock or hypothermia that reduces blood flow to the peripheries
- with obesity, where a thick layer of fat surrounding a limb dampens the oscillations coming from the artery
- on an edematous extremity

Measurement Methods

There are three measurement methods:

- **Manual** - measurement on demand. Results are displayed for up to one hour.
- **Auto** - continually repeated measurements (between one and 120 minute adjustable interval). You can make a manual measurement between two measurements in Auto Mode.
- **Sequence** - up to four measurement cycles which run consecutively, with a number of measurements and intervals between them configurable for each cycle.

Reference Method

The measurement reference method can be Auscultatory (manual cuff) or Invasive (intra-arterial). For further information, see the Application Note supplied on the monitor documentation DVD.

To check the current setting, select **Main Setup**, **Measurements**, **NBP**, and check whether the **Reference** setting is set to **Auscultatory** or **Invasive**. This setting can be changed in Configuration Mode.

Preparing to Measure Noninvasive Blood Pressure

If possible, avoid taking measurements during contractions, because the measurement may be unreliable, and may cause additional stress for the patient.

1 Connect the cuff to the air tubing.

2 Plug the air tubing into the red NBP connector. Avoid compression or restriction of pressure tubes. Air must pass unrestricted through the tubing.

WARNING

Kinked or otherwise restricted tubing can lead to a continuous cuff pressure, causing blood flow interference, and potentially resulting in injury to the patient.

3 Make sure that you are using a Philips-approved correct sized cuff, and that the bladder inside the cover is not folded or twisted.

A wrong cuff size, and a folded or twisted bladder, can cause inaccurate measurements. The width of the cuff should be in the range from 37% to 47% of the limb circumference. The inflatable part of the cuff should be long enough to encircle at least 80% of the limb.

4 Apply the cuff to a limb at the same level as the heart. If it is not, you must use the measurement correction formula to correct the measurement.
The marking on the cuff must match the artery location. Do not wrap the cuff too tightly around the limb. It may cause discoloration, and ischemia of the extremities.

WARNING

Inspect the application site regularly to ensure skin quality and inspect the extremity of the cuffed limb for normal color, warmth, and sensitivity. If the skin quality changes, or if the extremity circulation is being affected, move the cuff to another site, or stop the blood pressure measurements immediately. Check more frequently when making automatic measurements.

Correcting the Measurement if Limb is not at Heart Level

To correct the measurement if the limb is not at heart level, to the displayed value:

Add 0.75 mmHg (0.10 kPa) for each **centimeter** higher or	Deduct 0.75 mmHg (0.10 kPa) for each **centimeter** lower or
Add 1.9 mmHg (0.25 kPa) for each **inch** higher.	Deduct 1.9 mmHg (0.25 kPa) for each **inch** lower.

Recommendations For Measurements Used in Diagnosis of Hypertension

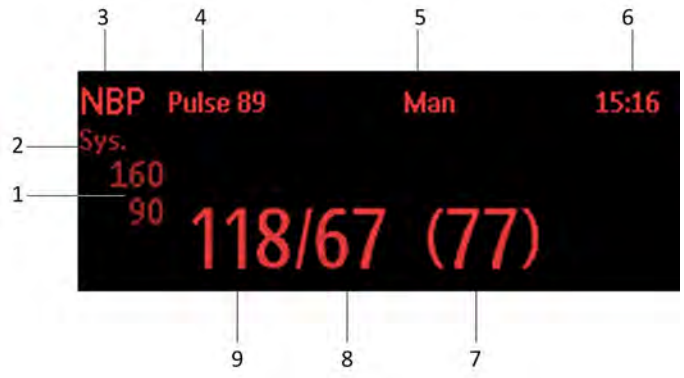
To make a measurement for use in the diagnosis of hypertension, follow the steps below:

1 Ensure the patient is comfortably seated, with their legs uncrossed, feet flat on the floor, and back and arm supported.

2 Ask the patient to relax and not talk before and during the measurement.

3 If possible, wait 5 minutes before making the first measurement.

Understanding the Numerics



1 Alarm limits
2 Alarm source
3 Measurement label
4 Pulse from NBP
5 Measurement mode
6 Timestamp/Timer
7 Mean pressure
8 Diastolic
9 Systolic

Depending on the numeric size, not all elements may be visible. Your monitor may be configured to display only the systolic and diastolic values. If configured to do so, the pulse from NBP is displayed with the NBP numeric.

Aging Numerics

The measured NBP value, together with the corresponding pulse rate, if this is switched on, are displayed for one hour. After that the values are regarded as invalid and are no longer displayed. During this time, measurement values may be grayed out, or disappear from the screen after a set time, if configured to do so. This avoids older numerics being misinterpreted as current data. The time can be set in Configuration Mode. In **Auto** Mode, the measurement values may disappear more quickly (to be replaced by new measurement values), if the repeat time is set to less than one hour.

Alarm Sources

If you have parallel alarm sources, the sources are displayed instead of the alarm limits.

NBP Measurement Timestamp

Depending on your configuration, the time shown beside the NBP numeric can be:

- the time of the most recent NBP measurement, also known as the "timestamp", or
- the time until the next measurement in an automatic series, displayed with a graphic representation of the remaining time, as shown here.

- The NBP timestamp will normally show the **completion** time of the NBP measurement.

NBP Measurement Start Time

In **Auto** or **Sequence** mode, the monitor is configured to synchronize the measurements in a measurement series to an "easy-to-document" time. For example, if you start the first measurement at 08:23, and the **Repeat Time** is set to **10 min**, the monitor automatically performs the next measurement at 8:30, then 8:40, and so on, unless it has been configured to **NotSynchron.**

During Measurements

The cuff pressure is displayed instead of the units and the repeat time. An early systolic value gives you a preliminary indication of the systolic blood pressure during measurement.

Starting and Stopping Measurements

Use the setup menu or the SmartKeys to start and stop measurements.

Action to be performed	Setup menu	SmartKeys
Start/Stop manual measurement Start Auto series Stop current automatic measurement	**Start/Stop**	**Start/ Stop**
Start manual measurement Start Auto series	-	**Start NBP**
Stop manual measurement Stop current automatic measurement	-	**Stop NBP**
Stop automatic, or manual measurement AND series	**Stop All NBP**	**Stop All**

Enabling Automatic Mode and Setting Repetition Time

1 In the **Setup NBP** menu, select **Mode**.

2 Switch between **Auto** and **Manual**, if necessary, to pick the measurement method.

3 If making an automatic measurement, select **Repeat Time**, or press the **Repeat Time** SmartKey and set the time interval between two measurements.

NOTE

Be aware that a combination of a recorder speed of less than 3 cm/min and a repetition time of less than five minutes can result in not all noninvasive blood pressure measurements being recorded on the fetal trace. For example, if the recorder speed is set to 1 cm/min and the repetition time is set to two minutes, due to the low speed setting, the recorder will only be able to record every other noninvasive blood pressure measurement. This affects only the local fetal trace recording, and all measurements are displayed as normal on the monitor's screen.

Enabling Sequence Mode and Setting Up the Sequence

1 In the **Setup NBP** menu, select **Mode** and select **Sequence** from the pop-up menu.

2 Select **Setup Sequence** to open the **Setup Sequence** window.
Up to four measurement cycles can be set up which run consecutively. For each cycle, you can set the number of measurements and the intervals between them. If you want to run fewer than four cycles in a sequence, you can set the number of measurements for one or more cycles to **Off**.

3 Select each sequence in turn, and select the number of measurements and the time interval between the measurements.

4 To have measurements continue after the sequence, set the number of measurements for your last cycle to **Continuous** and this cycle will run indefinitely.

CAUTION

Be aware that, if none of the cycles are set to **Continuous**, NBP monitoring will end after the last measurement of the cycle.

When the NBP measurement mode is set to **Sequence**, the repetition time for **Auto** Mode cannot be changed.

Choosing the Alarm Source

You can monitor for alarm conditions in systolic, diastolic, and mean pressure, either singly or in parallel. Only one alarm is given, with the priority of mean, systolic, diastolic.

Menu option	Pressure value monitored
Sys.	systolic
Dia.	diastolic
Mean	mean
Sys & Dia	systolic and diastolic in parallel
Dia & Mean	diastolic and mean in parallel

Menu option	Pressure value monitored
Sys & Mean	systolic and mean in parallel
Sys&Dia&Mean	all three pressures in parallel

If mean is not selected as alarm source (**Sys.**, **Dia.**, or **Sys & Dia** selected), but the fetal monitor can only derive a mean value, mean alarms will nevertheless be announced using the most recent mean alarm limits. Check that the mean alarm limits are appropriate for the patient, even when not using mean as the alarm source. When no value can be derived, an **NBP Measure Failed** INOP is displayed.

Assisting Venous Puncture

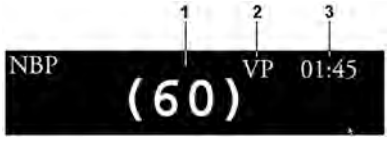
You can use the cuff to cause subdiastolic pressure. The cuff deflates automatically after a set time if you do not deflate it.

1 In the **Setup NBP** menu, select **VeniPuncture**.

2 Puncture vein and draw blood sample.

3 Reselect **VeniPuncture** to deflate the cuff.

During measurement, the display shows the inflation pressure of the cuff and the remaining time in venous puncture mode.



1 Cuff pressure

2 Venous puncture measurement mode

3 Time left in venous puncture mode

Calibrating NBP

NBP is not user-calibrated. NBP pressure transducers must be verified at least once every two years by a qualified service professional, and calibrated, if necessary. See the Service Guide for details.

Troubleshooting

Problem	Possible Causes	Solutions
Cuff will not inflate	Monitor is in Service or Configuration Mode	
	Technical defect	Call service
	Cuff tubing not connected	Connect cuff tubing
High or low values measured (against clinical expectations)	Contraction occurring	Wait until contraction has finished
	Patient talking before or during measurement	Allow patient to rest quietly, then try again after three to five minutes
	Incorrect cuff size or cuff not at heart level	Check cuff size, level, and position
	Noninvasive blood pressure reference method set incorrectly	Check the reference method configured (auscultation or intra-arterial) and correct if necessary in Configuration Mode
	Measurement limitations have not been taken into account	Check the list in "Measurement Limitations" on page 232

Problem	Possible Causes	Solutions
Displays zeros for systolic and diastolic values. Measurement automatically repeats	Severe vasoconstriction at cuff site	Move cuff to another limb, check for shock, or verify blood pressure using another method
	Erratic blood pressure fluctuations due to arrhythmias or rapid-acting drugs or contractions	Try again, if unsuccessful, verify blood pressure using another method Wait until contraction has finished
	Excessive patient movement or convulsions	Restrain movement or verify blood pressure using another method
NBP Cuff Overpress INOP is displayed	See "Patient Alarms and INOPs" on page 127.	
NBP Equip Malf INOP is displayed		
NBP Interrupted INOP is displayed		
NBP Measure Failed		

23

Monitoring SpO2

FM30/40/50 The pulse oximetry measurement (SpO_2) is intended for use with maternal patients.

Philips pulse oximetry uses a motion-tolerant signal processing algorithm, based on Fourier Artifact Suppression Technology (FAST). It provides two measurements:

- Oxygen saturation of arterial blood (SpO_2) - percentage of oxygenated hemoglobin in relation to the sum of oxyhemoglobin and deoxyhemoglobin (functional arterial oxygen saturation).
- Pulse rate - detected arterial pulsations per minute. This is derived from the SpO_2 value, and is one of four sources of the maternal heart/pulse rate used for cross-channel verification (see "Monitoring Maternal Heart / Pulse Rate" on page 219 and "Cross-Channel Verification (CCV)" on page 163).

Selecting an SpO2 Sensor

See "Accessories and Supplies" on page 275 for a list of sensors, and the patient population and application sites for which they are appropriate.

Familiarize yourself with the Instructions for Use supplied with your sensor before using it.

CAUTION

Do not use OxiCliq disposable sensors in a high humidity environment, or in the presence of fluids, which may contaminate sensor and electrical connections causing unreliable or intermittent measurements. Do not use disposable sensors when there is a known allergic reaction to the adhesive.

Applying the Sensor

1. Follow the SpO_2 sensor's Instructions for Use, adhering to all warnings and cautions.
2. Remove colored nail polish from the application site.
3. Apply the sensor to the patient. The application site should match the sensor size so that the sensor can neither fall off, nor apply excessive pressure.
4. Check that the light emitter and the photo detector are directly opposite each other. All light from the emitter must pass through the patient's tissue.

WARNING

Compatibility: Use only the accessories that are specified for use with this fetal monitor, otherwise patient injury can result.

Proper Sensor Fit: If a sensor is too loose, it might compromise the optical alignment or fall off. If it is too tight, for example because the application site is too large or becomes too large due to edema, excessive pressure may be applied. This can result in venous congestion distal from the application site, leading to interstitial edema, hypoxemia, and tissue malnutrition. Skin irritations or lacerations may occur as a result of the sensor being attached to one location for too long. To avoid skin irritations and lacerations, periodically inspect the sensor application site and change the application site regularly.

Skin irritation, allergies or hypersensitivity: Do not use disposable sensors on patients with history of skin irritation, allergies or hypersensitivity to adhesives.

Venous Pulsation: Do not apply sensor too tightly as this results in venous pulsation which may severely obstruct circulation and lead to inaccurate measurements.

Ambient Temperature: At elevated ambient temperatures, be careful with measurement sites that are not well perfused, because this can cause severe burns after prolonged application. All listed sensors operate without risk of exceeding 41°C on the skin if the initial skin temperature does not exceed 35°C.

MRI Scanning: Do not use the pulse oximeter or oximetry sensors during magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns. The device may affect the MRI image, and the MRI unit may affect the accuracy of the oximetry measurements.

Damaged Sensors: Do not use damaged sensors/cables or sensors with exposed optical components.

Low Perfusion: With very low perfusion at the monitored site, the performance might be impaired and the SpO_2 readings may read lower than arterial oxygen saturation.

Conditions Affecting Performance: During hypotension, severe vasoconstriction, severe anemia, or hypothermia of the patient the performance may be impaired. Also in these conditions or when the patient is in cardiac arrest or in shock, it may not be possible to make measurements at all.

Extremities to Avoid: Avoid placing the sensor on extremities with an arterial catheter, an NBP cuff, or an intravascular venous infusion line.

Connecting SpO2 Cables

Connect the sensor cable to the color-coded socket on the monitor. If you are using a disposable sensor, plug the sensor into the adapter cable and connect this to the monitor. Connect reusable sensors directly to the monitor.

CAUTION

Do not use any extension cable with the long versions (> 2 m) of the Philips reusable sensors (e.g. M1191AL, M1191BL, M1191ANL or M1196A) with the long versions of adapter cables (e.g. M1943AL), and not with the Masimo adapter cables (e.g. LNOP MP12 or LNC MP10).

Extension cables: Do not use more than one extension cable (M1941A). Do not use an extension cable with Philips reusable sensors or adapter cables with part numbers ending in -L (indicates “long” cable version).

Electrical Interference: Position the sensor cable and connector away from power cables, to avoid electrical interference.

Measuring SpO2

During measurement, ensure that the application site:

- has a pulsatile flow, ideally with a signal quality indicator of at least medium.
- has not changed in its thickness (for example, due to edema), causing an improper fit of the sensor.

WARNING

- For fully conscious maternal patients, who have a normal function of perfusion and sensory perception at the measurement site:

  To ensure skin quality and correct optical alignment of the sensor, inspect the application site when the measurement results are suspicious, or when the patient complains about pressure at the application site, but at least every 24 hours. Correct the sensor alignment if necessary. Move the sensor to another site, if the skin quality changes.

- For all other patients:

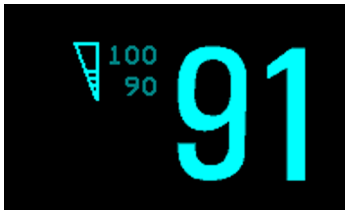
  Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. Correct the sensor alignment if necessary. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours.

- Injected dyes such as methylene blue, or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.
- Inaccurate measurements may result when the application site for the sensor is deeply pigmented or deeply colored, for example, with nail polish, artificial nails, dye, or pigmented cream.
- Interference can be caused by:
  - High levels of ambient light (including IR warmers), or strobe lights or flashing lights (such as fire alarm lamps). (Hint: cover application site with opaque material).
  - Another SpO_2 sensor in close proximity (e.g. when more than one SpO_2 measurement is performed on the same patient). Always cover both sensors with opaque material to reduce cross-interference.
  - Electromagnetic interference, especially when the signal quality indicator is below medium.
  - Excessive patient movement and vibration.

SpO2 Signal Quality Indicator

The SpO_2 numeric is displayed together with a signal quality indicator (if configured and enough space is available) which gives an indication of the reliability of the displayed values.

The level to which the triangle is filled shows the quality of the signal; the indicator below shows a medium signal quality. The signal quality is at a maximum when the triangle is completely filled.



Assessing a Suspicious SpO2 Reading

Traditionally, pulse rate from SpO_2 was compared with heart rate from ECG to confirm the validity of the SpO_2 reading. With newer algorithms, such as FAST-SpO_2, this is no longer a valid criteria because the correct calculation of SpO_2 is not directly linked to the correct detection of each pulse.

When the pulse rate is very low, or strong arrhythmia is present, the SpO_2 pulse rate may differ from the heart rate calculated from ECG, but this does not indicate an inaccurate SpO_2 value.

WARNING

With pulse oximetry, sensor movement, ambient light (especially strobe lights, or flashing lights), or electromagnetic interference can give unexpected intermittent readings when the sensor is not attached. Especially bandage-type sensor designs are sensitive to minimal sensor movement that might occur when the sensor is dangling.

Understanding SpO2 Alarms

This refers to SpO_2 specific alarms. See the "Alarms" on page 115 chapter for general alarm information. SpO_2 offers high and low limit alarms, and a high priority desat alarm. You cannot set the low alarm limit below the desat alarm limit.

CAUTION

If you measure SpO_2 on a limb that has an inflated noninvasive blood pressure cuff, a non-pulsatile SpO_2 INOP can occur. If the fetal monitor is configured to suppress this alarm, there may be a delay of up to 60 seconds in indicating a critical status, such as sudden pulse loss or hypoxia.

Alarm Delays

There is a delay between a physiological event at the measurement site and the corresponding alarm at the monitor. This delay has two components:

- The general system delay time is the time between the occurrence of the physiological event and when this event is represented by the displayed numerical values. This delay depends on the algorithmic processing and the averaging time.
- The time between the displayed numerical values crossing an alarm limit and the alarm indication on the monitor. This delay is the combination of the configured alarm delay time plus the general system alarm signal delay time.

Adjusting the SpO2 Alarm Limits

In the **Setup SpO_2** menu:

- Select **High Limit** then choose the upper alarm limit.
- Select **Low Limit** then choose the lower alarm limit.

Adjusting the Desat Limit Alarm

The Desat alarm is a high priority (red) alarm notifying you of potentially life threatening drops in oxygen saturation.

1 In the **Setup SpO₂** menu, select **Desat Limit**.

2 Adjust the limit.

Adjusting the Pulse Alarm Limits

See "Adjusting the Heart Rate / Pulse Alarm Limits" on page 225.

Setting Up Tone Modulation

If tone modulation is on, the QRS tone pitch lowers when the SpO_2 level drops. Remember, the QRS tone is derived from either heart rate (from MECG or the CL F&M Pod) or pulse (from built-in SpO_2) depending on which is currently displayed (see "Priority for Maternal Heart / Pulse Rate" on page 219).

NOTE

Pulse from CL SpO_2 and Toco MP does not provide a QRS tone.

Setting the QRS Volume

In the **Setup SpO₂** menu, select **QRS Volume** and set the appropriate QRS tone volume.

23 Monitoring SpO2

Monitoring Maternal Temperature

Measuring Tympanic Temperature

The tympanic thermometer (866149) measures the patient's temperature in the ear using infrared technology.

The result of this measurement can be automatically adjusted to correspond to a different body reference site. The result is displayed on the screen of the thermometer and transmitted to the monitor.

The thermometer is used with single-use probe covers for infection control during measurement.

WARNING

Do not use in the presence of flammable anesthetics, such as a flammable anesthetic mixture with air, oxygen, or nitrous oxide.

1 Base station

2 Thermometer

Place the thermometer into its base station, when it is not in use. The base station allows flexible mounting of the thermometer at the point of care. The base station is connected to the monitor's MIB/RS232 interface (optional) with a cable. It has storage space for up to 32 probe covers.

Thermometer Display and Controls

The tympanic thermometer has a liquid crystal display. The display shows the patient's temperature in numerics and guides you with symbols through the measurement process.

1. Eject key
2. Change unit key: °Celsius/°Fahrenheit
3. Start measurement key
4. Pulse timer key

Functional Keys	Description of Use
	Press the eject key to eject the probe cover. The eject key symbol is shown on the display when a measurement has been taken and transmitted.
	Press the change unit key after a measurement to switch between °C and °F (only affects the handheld device and not the monitor numerics).
	Press the start measurement key when you are ready to take a patient's temperature.
	The pulse timer key can be used to time vital signs you take manually. The pulse timer only functions after you have taken a temperature measurement. Press and hold the pulse timer key to enter timer mode. Press the pulse timer key again to start the timer. The thermometer will issue a one beep at 15 seconds, two beeps at 30 seconds, three beeps at 45 seconds, and four beeps at 60 seconds.

Status Screens

The thermometer performs an internal test at every start-up to verify that the system components are functioning properly. It measures the ambient temperature. During start-up and measurement, the thermometer screens communicate the current status.

Images	Description
	Ambient temperature above specified range
	Ambient temperature below specified range
System errors	
	**System error 12** - there is a problem with the settings. Contact your service personnel to have them check the settings and reset them, if necessary. If the display shows any other system error, then reset the thermometer by picking up a probe cover. If the system error does not clear, contact your service personnel.

Making a Temperature Measurement

WARNING

Inaccurate measurement results can be caused by:

- incorrect application of the thermometer
- anatomical variations in the ear
- build up of earwax in the ear
- excessive patient movement during the measurement
- absent, defective, or soiled probe covers
- probe covers other than the specified probe covers
- external environment temperature outside the range of 16ºC-33ºC (60.8ºF-91.4ºF)

1 Ensure that the base station is connected with the appropriate cable to the connector on the monitor.

2 Remove the thermometer from the base station.
The thermometer is latched to the base station to avoid an accidental fall when the base station is moved. To pick up the thermometer from the base station move it slightly up, and then lift it from the base station to release the latch.

3 Press the eject key on the thermometer to discard any probe that may have been left on the thermometer from a previous use.

4 Pick up a new probe cover from the container on the base station.

5 Inspect the probe cover to make sure that it is fully seated (no space between cover and tip base) and that there are no holes, tears, or wrinkles in the plastic film.

6 Place the thermometer with the probe in the ear canal, sealing the opening with the probe tip. For consistent results, ensure that the probe shaft is aligned with the ear canal.

7 Press and release the start-up key gently.

8 Wait until you hear the three beeps.

9 Remove the probe from the ear.
The temperature values are displayed both on the thermometer itself, and on the connected monitor.

10 Check that the correct temperature label for the measurement site is displayed: **iTrect**, **iToral**, **iTcore**, or **iTtymp**.

11 Press the eject key to eject the probe cover into a suitable waste receptacle.

12 Return the thermometer to the base station.

The thermometer switches to stand-by mode after 30 seconds when it is not used.

Possible INOPs

Images	Description
	Patient temperature above measurement range.
	Patient temperature below measurement range.

WARNING

- Never apply the probe to the patient when the thermometer is not connected to the base station.
- Always use a single-use probe cover to limit patient cross-contamination.
- Measurement errors or inaccurate readings may result when probe covers other than the specified probe covers are used (see "Tympanic Temperature Accessories" on page 285).
- Insert the probe slowly and carefully to avoid damage to the ear canal and the tympanic membrane.
- Inspect the probe cover for damage, holes, tears, or sharp edges to avoid injuring the skin.
- Always ensure that the used probe cover is removed before attaching a new probe cover.

CAUTION

- Do not immerse the probe in fluids, or drop fluids on the probe.
- Do not use a probe cover that has been dropped or is damaged.
- Do not autoclave. To prevent damage to the base station, thermometer and accessories, refer to the cleaning procedures in the "Care and Cleaning" on page 257 chapter.

WARNING

If you have dropped the base station or thermometer, or if the unit has been stored below -25°C or above 55°C, have service personnel test the unit for proper functions, and calibrate the unit before further use.

The **Value Lifetime** (length of time the entered value is shown on the screen) can be configured in Configuration Mode.

Body Reference Sites and Monitor Labels

The tympanic thermometer measures the patient's temperature in the ear. The thermometer can be configured to adjust the result of the measurement to correspond to a different body reference site. The measurement label displayed on the monitor corresponds to the body reference site that is configured. The following body reference sites are available:

Body Reference Site	Label on Monitor
Ear temperature (no adjustment)	**iTtymp**
Oral temperature	**iToral**
Core temperature	**iTcore**
Rectal temperature	**iTrect**

The body reference site can be selected in the Biomed mode of the tympanic thermometer. Refer to the Service Guide for more information.

The measured maternal temperature is only transmitted to a connected OB TraceVue/IntelliSpace Perinatal system, when the tympanic thermometer is configured to the **iTtymp** body reference site, and the **iTtymp** label is displayed on the fetal monitor screen, and printed on the trace.

Entering Temperature Manually

A temperature measurement can be entered manually.

1 Press the SmartKey **Enter Temp** (configurable)

or select the SmartKey **Main Setup**, then select **Measurements**, **Enter Temp**. A numeric pad opens.

2 Enter the temperature values.

3 Select the **Enter** key.

Interval

Use the **Interval** setting to define the time after which a manually entered temperature value becomes invalid (no value is then displayed).

NOTE

- A manually entered temperature has to be 25ºC or higher to be transmitted to a connected obstetrical information and surveillance system.
- As soon as the temperature value is entered, it is printed on the trace and transmitted to a connected obstetrical information and surveillance system.
- The time stamp of the temperature value on the display shows the time the user has opened the numeric pad and started to enter the temperature value.

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Paper Save Mode for Maternal Measurements

Your monitor's recorder features a Paper Save Mode, where maternal vital signs are recorded using less paper than during a normal trace recording.

When Paper Save Mode is enabled, and if the recorder is stopped, it will start automatically to print data from maternal measurements as they occur, and then stops again to save paper. You enable Paper Save Mode in Configuration Mode (default is off).

- A header is printed first before the measurements are recorded. A new header is also printed when there is a date change at midnight.
- Each NBP measurement is recorded. The time when the measurement **ended** is recorded.
- Each Temperature measurement is recorded. The time when the measurement **ended** is recorded.
- Other maternal parameters (SpO_2, maternal heart rate, or Pulse) are recorded every five minutes. The rules described in the section "Priority for Maternal Heart / Pulse Rate" on page 219 apply.
- Paper Save Mode recording stops if there are no valid maternal measurements for more than one hour, and a message will notify you that there are no active parameters. Paper Save Mode recording will restart automatically when another valid measurement is made.

Event	Paper Save Mode Reactivation
One of the maternal measurements (see above) is valid again.	yes
The recorder is turned off and on again or a report has been recorded (e.g. NST Report).	yes
The Paper Advance function is used.	yes
The Paper Save Mode setting is set off and on again.	yes
ADT information has changed (e.g. because patient information has been completed or updated).	no
The monitor is restarted (e.g. by switching it off and on again).	yes
The date has changed (e.g. at midnight).	no

25 Paper Save Mode for Maternal Measurements

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Recovering Data

The monitor stores trace data, including annotations, for a minimum of 3.5 hours with the software revision J.3 or higher, and for a minimum of 7 hours with the new mainboard hardware revision A 00.18, in its internal backup memory. This allows the monitor to recover trace data that would otherwise be lost under certain circumstances. In the event of the paper running out, this trace recovery data can be automatically retrieved and printed, or automatically transmitted to an OB TraceVue/IntelliSpace Perinatal system (LAN connection only), allowing continuity of data.

The fetal trace printed from the trace recovery data contains all data from the real-time trace.

Note that the data in the memory is cleared when a software upgrade is performed.

CAUTION

Only use Philips paper. Using paper other than Philips paper may result in the failure to recover traces.

Recovering Traces on Paper

The monitor is able to recover traces by printing them out at a high speed from the monitor's backup memory. If the monitor runs out of paper, or if the paper drawer is open, the exact time when this happens is stored in the backup memory. If the **Bridge Paperout** setting is set to **On** (default), when new paper is loaded and the recorder is started, a trace recovery printout of the data recovered from the backup memory is automatically printed out at high speed (up to 20 mm/s), starting from the time noted in the backup memory. This ensures that no data is lost. A minimum of one hour of trace recovery data is available for printing out from the backup memory. When the trace recovery printout has finished, the recorder automatically switches back to continue recording the current trace at the normal speed.

Note the following:

- If you press the fetal recorder **Start/ Stop** SmartKey during a trace recovery printout, the recording stops, and the next recording following a recorder restart will be a normal, real-time trace.

  

  After switching off the monitor, and then back on again, or following a power failure, the time of the last **Check Paper** INOP or paper-out detection is lost, and therefore any trace recovery data in the backup memory is no longer available to print. The next recording made following a restart of the recorder is a normal, real-time trace.
- The change back to a real-time recording from a trace recovery printout prompts the recording to restart. A new vertical trace header annotation consisting of the time, date, and recorder speed is printed, letting you see where the trace recovery printout ends, and where the real-time trace continues.

- There can be a gap of up to 30 seconds between the trace recovery printout, and the beginning of the real-time trace.
- With every time or date change, a question mark is displayed in front of the timestamp of the stored data recording.

Recovering Traces on an OB TraceVue/IntelliSpace Perinatal System

The trace recovery data stored in the monitor's backup memory can also be uploaded at high speed to an OB TraceVue/IntelliSpace Perinatal system connected over the LAN interface (OB TraceVue Revision E.00.00 or later, and IntelliSpace Perinatal H.0 or later).

When the OB TraceVue/IntelliSpace Perinatal system reconnects to the fetal monitor and detects that there is trace recovery data in the monitor's backup memory that has not yet been transmitted to the system, this data is transferred at high speed to the system. No user action is required.

The exact length of the recovered trace will vary depending on the amount of trace information, but it will cover **at least 3.5 hours** of trace data with the software revision J.3 or higher, and **7 hours** with the new mainboard hardware revision A 00.18, depending on the number of active parameters.

To recover traces on an OB TraceVue/IntelliSpace Perinatal system, the following applies:

- The trace data in the monitor's internal memory must relate to a specific patient in the OB TraceVue/IntelliSpace Perinatal system. In other words, there were no discharge events made on the monitor that would change the patient context.
- The patient must have an open episode. No data will be uploaded if the patient is not admitted to OB TraceVue/IntelliSpace Perinatal. For further details see the OB TraceVue/IntelliSpace Perinatal Instructions for Use.
- Current online trace data is held back until the fast upload is complete.

Manually Recording Stored Data

If the recorder is not running, you can choose to print trace data from the monitor's memory at any time. You can see a list of all stored traces, showing patient identification and trace period, in the **Stored Data Recording** window, from which you can choose one of the entries at a time.

CAUTION

Ensure that you admit each patient by name, including other patient identification information, and discharge the patient when you have finished monitoring, so that you can identify which trace period (entry in the patient list) refers to which patient.

Trace storage can be triggered by:

- Discharging a patient
- Powering on the monitor
- Entering Standby
- Entering Service Mode

Traces are not available for periods the monitor was switched off, in Service Mode, in Standby, or if the trace period was shorter than one minute.

The speed of the printout depends on the configured recorder speed and on the amount of trace data available. The fetal trace printed from the trace data contains all data from the real-time trace, with the exception of the maternal heart rate, the pulse numeric, and the ECG wave.

Information for scale type, trace separation, and recorder speed are not stored in the trace memory, but is applied when the stored recording starts. While the stored recording is printing, all functions are disabled, except that for stopping the recorder.

To start a stored data recording:

Either

1 Select the **Stored Data Rec** SmartKey.

2 Select **All** to print all stored trace data for the selected entry, or select one of the choices on the other pop-up keys to print only a specified portion of the entry (for example, **Last 15 min** for the last 15 minutes of trace data).

Or

1 Enter the **Main Setup** menu using the SmartKey.

2 Select **Fetal Recorder** to open the **Fetal Recorder** menu.

3 Select **Stored Data Rec** to open the **Stored Data Recording** window.

4 Select an entry for a patient.

5 Select **All** to print all stored trace data for the selected entry, or select one of the choices on the other pop-up keys to print only a specified portion of the entry (for example, **Last 15 min** for the last 15 minutes of trace data).

To delete all stored trace periods:

Either

1 Select the **Stored Data Rec** SmartKey.

2 Select the **Erase All** key to delete all stored trace periods listed.

3 Select the **Confirm** key.

Or

1 Enter the **Main Setup** menu using the SmartKey.

2 Select **Fetal Recorder** to open the **Fetal Recorder** menu.

3 Select **Stored Data Rec** to open the **Stored Data Recording** window.

4 Select the **Erase All** key to delete all stored trace periods listed.

5 Select the **Confirm** key.

The current patient's entry is at the top of the list. The oldest entry at the bottom of the list has no start time specified, as part of the data originally stored may have been over-written by the current patient's data.

It may be that you only see one entry (the current patient's data) in the **Stored Data Recording** window if that patient was monitored for a period long enough to erase any earlier entries.

If you make a stored data recording for an old entry (that is, not for the current patient), the recorder performs a fast trace printout of the stored data, advances the paper to the next paper fold, then stops.

If you make a stored data recording for the current patient, the recorder performs a fast trace printout of the stored data, and then reverts automatically to recording the real-time trace.

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Care and Cleaning

Use only the Philips-approved substances and methods listed in this chapter to clean or disinfect your equipment. Warranty does not cover damage caused by using unapproved substances or methods.

Philips makes no claims regarding the efficacy of the listed chemicals, or methods as a means for controlling infection. Consult your hospital's Infection Control Officer or Epidemiologist. For comprehensive details on cleaning agents and their efficacy refer to "Guideline for Disinfection and Sterilization in Healthcare Facilities" issued by the U.S. Department of Health and Human Services, Public Health Service, Centers for Disease Control, Atlanta, Georgia, 2008. See also any local policies that apply within your hospital, and country.

General Points

The transducers and patient modules are sensitive instruments. Handle them with care.

Keep your monitor, transducers, patient modules, cables, and accessories free of dust and dirt. After cleaning and disinfection, check the equipment carefully. Do not use if you see signs of deterioration or damage. If you need to return any equipment to Philips, **always** decontaminate it first before sending it back in appropriate packaging.

Observe the following general precautions:

- Always follow carefully and retain the instructions that accompany the specific cleaning and disinfecting substances you are using.
- Always dilute cleaning agents according to the manufacturer's instructions or use lowest possible concentration.
- Do not allow liquid to enter the case.
- Do not immerse the monitor in liquid. Protect it against water sprays or splashes.
- Do not pour liquid onto the system.
- Never use abrasive material (such as steel wool or silver polish).
- Never use bleach.

WARNING

If you spill liquid on the equipment, battery, or accessories, or they are accidentally immersed in liquid, contact your service personnel or Philips service engineer. Do not operate the equipment before it has been tested and approved for further use.

WARNING

- Do not operate the monitor if it is wet. If you spill liquid on the monitor, contact your service personnel or Philips service engineer.
- Do not perform underwater monitoring (for example, in a bath or shower) using wired transducers.

- Place the monitor where there is no chance of contact with, or falling into water or other liquid.
- Do not dry equipment using heating devices such as heaters, ovens (including microwave ovens), hair dryers, and heating lamps.
- Do not put equipment or accessories in autoclave (for sterilization).

Cleaning and Disinfecting the Monitor

Clean and disinfect the Avalon FM20, FM30, FM40, and FM50 fetal monitors and all wired and cableless transducers (including ECG adapter cables), the Avalon CL base station, and all fetal accessories that are not limited to single use after each use and before initial use. Clean equipment before disinfecting. For other accessories, see "Cleaning and Disinfecting Fetal Monitoring Accessories" on page 261.

Clean with a lint-free cloth, moistened with warm water (40°C/104°F maximum) and soap, a diluted non-caustic detergent, tenside, or phosphate-based cleaning agent. Do not use strong solvents such as acetone or trichloroethylene. After cleaning, disinfect using only the approved disinfecting agents listed (see "Recommended Disinfectants" on page 259).

CAUTION

Solutions: Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.

Hospital policy: Disinfect the product as determined by your hospital's policy, to avoid long-term damage to the product.

Local requirements: Observe local laws governing the use of disinfecting agents.

Touch display: To clean and disinfect the touch-enabled display, disable the touch operation by switching off the monitor during the cleaning procedure, or by selecting and holding the **Main Screen** key until the padlock symbol appears on it, indicating that touch operation is disabled. Select and hold again to re-enable touch operation.

WARNING

Skin contact: To reduce the risk of skin irritations, do not allow a cleaning or disinfecting agent to leave residues on any of the equipment surfaces - wipe it off with a cloth dampened with water, after allowing the appropriate time for the agent to work. Follow the safety instructions of the used cleaning or disinfection agent, especially regarding skin contact.

Take extra care when cleaning the screen of the monitor, because it is more sensitive to rough cleaning methods than the housing. Do not permit any liquid to enter the monitor case and avoid pouring it on the monitor while cleaning. Do not allow water or cleaning solution to enter the measurement connectors.

Wipe around and not over connector sockets, or those of the Toco^{+}, CL Toco^{+} MP transducer, ECG and IUP Patient Modules, CL ECG/IUP transducer and adapter cables.

Recommended Disinfectants

We recommend that you use one of the following disinfectants:

Product Name	Product Type	Ingredients
Isopropanol	liquid	Isopropanol 80%
Bacillol® AF	liquid, spray	100 g concentrate contains: Propan-1-ol 45.0 g Propan-2-ol 25.0 g Ethanol 4.7 g
Bacillol®25	liquid	Ethanol 100 mg/g Propan-2-ol (= 2-Propanol) 90 mg/g Propan-1-ol (= 1-Propanol) 60 mg/g
Meliseptol®	spray	50% 1-Propanol
Accel TB RTU	liquid	Accelerated hydrogen peroxide® 0.5%
Oxivir® Tb Cleaner Disinfectant	spray	Accelerated hydrogen peroxide® 0.5%
Oxivir® Tb Wipes	wipes	Accelerated hydrogen peroxide® 0.5%
Carpe Diem$^{TM/MC}$ Tb Ready-to-Use General Virucide, Bactericide, Tuberculocide, Fungicide, Sanitizer	spray	Accelerated hydrogen peroxide® 0.5%
Carpe Diem$^{TM/MC}$ Tb Wipes	wipes	Accelerated hydrogen peroxide® 0.5%
Super Sani-Cloth® Germicidal Disposable Wipes	wipes	Isopropanol 55% quaternary ammonium chlorides 0.5%
SANI-CLOTH® PLUS Germicidal Disposable Wipes	wipes	Isopropanol 15% quaternary ammonium chlorides 0.25%
SANI-CLOTH® HB Germicidal Germicidal Disposable Wipes	wipes	Isopropanol < 0.15% quaternary ammonium chlorides 0.14%

Preparation

Before cleaning and disinfecting, secure the following supplies:

- non-linting wipes
- cotton swabs with tapered mini tips
- the validated cleaner and disinfectant using the concentration recommended by the cleaner and disinfectant manufacturer, see "Recommended Disinfectants" on page 259.

Before cleaning and disinfecting the product:

1. Visually inspect the monitor for any visible damage or deterioration. Check for any tears, cracks, or bent connector pins.
2. Visually inspect the monitor for moderate to severe soiling.

Cleaning the Monitor

The cleaning procedure described below has been validated using an enzymatic solution. Before cleaning, visually inspect the monitor for moderate to severe soiling. If the monitor is severely soiled, use swabs to clear soil before cleaning.

To clean the monitor:

1 Prepare an enzymatic detergent solution (for example, Prolystica® Manual 2X Enzymatic Presoak and Cleaner, Cidezyme® or Enzol®) per the manufacturer's instructions.
Using non-linting wipe(s) saturated (but not dripping) with the prepared detergent solution, thoroughly wipe the exterior surfaces of the device for a minimum of one (1) minute and until visibly clean. Pay attention to surfaces such as seams and ridges.

NOTE

- Take extra care when cleaning the screen of the monitor because it is more sensitive to rough cleaning methods than the housing.
- If the drawer opens when cleaning the ejection button, close the drawer.
- FM20/30: Use cotton swab(s) with tapered mini tip(s) (Puritan P/N: 826-WC or equivalent) dampened in the prepared detergent solution to swab the difficult to clean surfaces of the on/off switch and handle.
- Do not permit any liquid to enter the monitor case and do not pour liquid onto the monitor while cleaning. Do not allow water or cleaning solution to enter the measurement connectors. Wipe around, not over, connector sockets.

CAUTION

To clean and disinfect the touch-enabled display, disable the touch operation by switching off the monitor during the cleaning procedure, or by selecting and holding the **Main Screen** key until the padlock symbol appears on it, indicating that touch operation is disabled. Select and hold again to re-enable touch operation

1 Remove the cleaner residue by wiping the device surfaces a minimum of one (1) time with non-linting wipe(s) saturated (but not dripping) with tap water.

2 Thoroughly dry the device using non-linting wipe(s).

3 Inspect the device in a well-lit area to ensure all surfaces are clean.

Disinfecting the Monitor

NOTE

The disinfection procedure described below has been tested and its efficacy validated using 70% Isopropanol Alcohol (IPA).

Clean equipment before disinfecting.

1 Thoroughly wipe all exterior surfaces of the device using non-linting wipe(s) saturated (but not dripping) with 70% Isopropanol Alcohol (IPA).

NOTE

Do not permit any liquid to enter the monitor case and do not pour liquid onto the monitor while cleaning. Do not allow water or disinfectant to enter the measurement connectors. Wipe around, not over, connector sockets.

CAUTION

To clean and disinfect the touch-enabled display, disable the touch operation by switching off the monitor during the cleaning procedure, or by selecting and holding the **Main Screen** key until the padlock symbol appears on it, indicating that touch operation is disabled. Select and hold again to re-enable touch operation

2 Allow all surfaces to remain visibly wet for a minimum of ten (10) minutes. If needed, use additional wipes to ensure the surfaces remain wet for the full duration.

3 Thoroughly dry the device using non-linting wipe(s).

Cleaning and Disinfecting Fetal Monitoring Accessories

The MECG cable and the Remote Event Marker consist of parts that can be cleaned and disinfected.

CAUTION

- Never submerge the products in any aqueous solution.
- Never sterilize cables.

Preparation

Before cleaning and disinfecting, secure the following supplies:

- non-linting wipes
- cotton swabs with tapered mini tips
- the validated cleaner and disinfectant using the concentration recommended by the cleaner and disinfectant manufacturer, see "Recommended Disinfectants" on page 259.

Before cleaning and disinfecting the product:

1 Visually inspect the MECG cable and the Remote Event Marker for any visible damage or deterioration. Check for any tears, cracks, or bent connector pins. Discard the product if damaged since there is a potential for incorrect readings.

2 Always replace the product when there is any visible damage to the product (such as, exposed wires or breaks).

3 Visually inspect the product for moderate to severe soiling. Products with moderate to severe soiling are not intended to be cleaned or disinfected. If this situation occurs, dispose of the product according to your institution's recommended disposal procedure for hospital waste. Refer to Disposal in the product's Instructions for Use for the additional information.

Validated Cleaner and Disinfectant

Philips has validated the following cleaner and disinfectant which were tested for efficacy and use on the MECG cable and Remote Event Marker. These agents were tested by Philips for both efficacy and prevention of damage to the Philips products being cleaned and disinfected:

Cleaner: Enzymatic detergent composition:

Product Ingredients	Percent
Alcohol, C9-11, ethoxylated surfactant	1-5
Glycerin	1-5
Citric Acid	1-5

Product Ingredients	Percent
N, N-Dimethyloctadecylamine oxide	1-2
Subtilisins (proteolytic enzymes)	0.1-1

Disinfectant: 70% Isopropanol Alcohol (Chemical Abstract Service #67-63-0)

Refer to the detergent manufacturer's label for proper concentration and water temperature requirements.

Material Compatibility with Disinfectants

The following disinfectants were tested for material compatibility during product development. The disinfectants listed below have not been tested for their efficacy as a means for inactivating and destroying microorganisms on these devices.

See "Recommended Disinfectants" on page 259

Do not use the following disinfectants because they will damage the product

Product Name	
Hexanios G+R	Surfanios Citron
Incidin® Plus	Virex® Tb RTU
Mikrobac® forte	

Cleaning the MECG Cable and the Remote Event Marker

Starting

- Position the connector end of the cable to ensure that no liquid can enter the inside of the connector during cleaning.
- The term 'saturate' in a step refers to a very wet condition, but not to the point where dripping occurs.
- If at any time during the procedure the non-linting wipes become visibly soiled, discard soiled wipes and use more clean wipes.
- Use cotton swabs during the procedure, as needed, to reach seams, grooves, and narrow spaces.

Cleaning

1. Saturate a non-linting wipe with the validated cleaner.
2. Saturate all surfaces of the product with the cleaner.
3. Saturate the surfaces of all accessories.
4. Allow surfaces to remain visibly wet for 3-5 minutes.
5. Dampen another non-linting wipe with cleaner.
6. Wipe the multi-pin connector and cable(s) until they are visibly clean. Be sure to clean all sides of the product. Do not allow liquid to come in contact with the inside of the connector.
7. MECG Adapter Cable only: Wipe the cable connectors.
8. Thoroughly clean all sides of the product.

Rinsing

1 Saturate a non-linting wipe with tap water.

2 Start at the multi-pin connector and wipe the connector and cable(s) at least one time.

3 Visually inspect the product and repeat steps 6 and 7, if needed. If any part is not visibly clean, use a cotton swab to clean between the grooves and narrow spaces.

4 Using clean wipes, dry all sides of the product.

5 Proceed with "Disinfecting the MECG Cable and the Remote Event Marker" on page 263

Disinfecting the MECG Cable and the Remote Event Marker

Starting

- Position the multi-pin connector to ensure that no liquid can enter the inside of the connector or come in contact with the electrical contacts.
- If at any time during the procedure non-linting wipes become visibly soiled, discard soiled wipes and use clean wipes.
- Use cotton swabs during the procedure, as needed, to disinfect and rinse seams, grooves, open areas, and narrow spaces.

Disinfecting

1 Saturate a non-linting wipe with the validated disinfectant.

2 Thoroughly saturate all surfaces of the product.

3 Allow surfaces to stay visibly wet for 10 minutes. Ensure that all seams, grooves, and narrow spaces are saturated.

Rinsing and completing final inspection

1 Saturate a non-linting wipe with tap water.

2 Start at the multi-pin connector and wipe to the end of the product.

3 Repeat step 2 two more times, using more wipes as needed.

4 Using clean wipes, dry the entire product.

5 Visually inspect the product to ensure all surfaces are clean and dry.

Washing Reusable Belts (M4601A, M4602A, M4603A, M1562B)

Reusable belts must be washed prior to patient use.

Reusable Belts (M4601A, M4602A, M4603A, M1562B)	
Washing cycles	30
Time per cycle	45 minutes
Washing recommendations	Wash soiled reusable belts with washing detergent and water. Water temperature must not exceed 60°C/140°F. Tumble dry.

Cleaning and Disinfecting the Tympanic Temperature Accessories

Probe and Thermometer Body

1 Wipe the thermometer body clean with a damp cloth. The water temperature should not exceed 55°C (130°F). Do not soak, rinse, or submerge the thermometer under water.
You may add a mild detergent to the water.

2 Clean the probe tip with a lint free swab. If the probe tip is soiled, clean it with a dampened swab.

3 After you have removed all foreign matter, clean the thermometer lens at the end of the probe tip with a lint free swab or lens wipe. The thermometer lens must be free from fingerprints and/or smudges for proper operation.

4 Thoroughly dry all surfaces before using the equipment.

CAUTION

Do not use cleaners and disinfectants such as Spray-Nine™, Phisohex™, Hibiclens™, or Vesta-Syde™ as they may result in damage to the thermometer case.

Occasional use of a 10:1 water and hypochlorite mixture or a damp isopropyl alcohol wipe or Cidex™ or ManuKlenz™ or VIROX™ or CaviWipes™ cleansing agents is acceptable, however, prolonged or repeated use of these chemicals may result in damage to the thermometer case and display area.

Use of a cloth or sponge is recommended for cleaning. Never use an abrasive pad or an abrasive cleaner on the thermometer.

The thermometer is non-sterile. Do not use ethylene oxide gas, heat, autoclave, or any other harsh method to sterilize this thermometer.

Cradle

To clean the cradle:

1 Prepare an enzymatic detergent solution (for example, Prolystica® Manual 2X Enzymatic Presoak and Cleaner, Cidezyme® or Enzol®) per the manufacturer's instructions.

Using non-linting wipe(s) saturated (but not dripping) with the prepared detergent solution, thoroughly wipe the exterior surfaces of the device for a minimum of one (1) minute and until visibly clean. Pay attention to surfaces such as seams and ridges.

2 If any portion of the device is not visibly clean after two (2) minutes using wipes, use cotton swab(s) with tapered mini tip(s) (Puritan P/N: 826-WC or equivalent) dampened in the prepared detergent solution and swab the difficult to clean surfaces. Pay attention to surfaces such as cavities and seams.

3 Remove the cleaner residue by wiping the device surfaces a minimum of one (1) time with non-linting wipe(s) saturated (but not dripping) with tap water.

4 Thoroughly dry the device using non-linting wipe(s).

5 Inspect the device in a well-lit area to ensure all surfaces are clean.

To disinfect the cradle:

NOTE

The disinfection procedure described below has been tested and its efficacy validated using 70% Isopropanol Alcohol (IPA).

Clean equipment before disinfecting.

1 Thoroughly wipe all exterior surfaces of the device using non-linting wipe(s) saturated (but not dripping) with 70% Isopropanol Alcohol (IPA).

2 Allow all surfaces to remain visibly wet for a minimum of ten (10) minutes. If needed, use additional wipes to ensure the surfaces remain wet for the full duration.

3 Thoroughly dry the device using non-linting wipe(s).

Sterilizing

Sterilization is not allowed for this monitor, related products, accessories, or supplies unless otherwise indicated in the Instructions for Use that accompany the accessories and supplies.

WARNING

Do not put device and accessories in autoclave (for sterilization).

27 Care and Cleaning

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Maintenance

WARNING

Schedule: Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

In case of problems: If you discover a problem with any of the equipment, contact your service personnel, Philips, or your authorized supplier.

Electric shock hazard: Do not open the monitor housing. Refer all servicing to qualified service personnel.

Inspecting the Equipment and Accessories

You should perform a visual inspection **before each use**, and in accordance with your hospital's policy. With the monitor switched off:

1. Examine unit exteriors for cleanliness and general physical condition. Make sure that the housings are not cracked or broken, that everything is present, that there are no spilled liquids that may have entered the housing, and that there are no signs of abuse.
2. Inspect all accessories (transducers, sensors and cables, and so forth). Do not use a damaged accessory.
3. Switch the monitor on, and make sure the display is bright enough. If the brightness is not adequate, contact your service personnel or your supplier.

Batteries Preventive Maintenance

For the FM20/30 with a battery option, see "Using Batteries" on page 108.

Inspecting the Cables and Cords

1. Examine all system cables, the power plug, and cord for damage. Make sure that the prongs of the plug do not move in the casing. If damaged, replace it with an appropriate power cord.
2. Inspect the cables, leads, and their strain reliefs for general condition. Make sure there are no breaks in the insulation. Make sure that the connectors are properly engaged at each end to prevent rotation or other strain.
3. Carry out performance assurance checks as described in the monitor's Service Guide.

Maintenance Task and Test Schedule

The following tasks are for Philips-qualified service professionals. All maintenance tasks and performance tests are documented in detail in the service documentation supplied on the monitor's documentation DVD.

Ensure that these tasks are carried out as indicated by the monitor's maintenance schedule, or as specified by local laws, whichever comes sooner. Contact a Philips-qualified service professional, if your monitor needs a safety or performance test. Clean and disinfect equipment to decontaminate it before testing or maintaining it.

Maintenance and Test Schedule	Frequency
Visual Inspection	Before each use.
Clean and disinfect the equipment	After each use.
Safety checks according to IEC 60601-1, and where applicable, to national standards	At least once every two years, or as specified by local laws. After any repairs where the power supply has been replaced (by an authorized service professional). If the monitor has been dropped, it must be repaired/ checked by an authorized service agent.
Performance assurance for all measurements	At least once every two years, or if you suspect the measurement values are incorrect.
Noninvasive blood pressure calibration	At least once every two years, or as specified by local laws.
Tympanic Thermometer Calibration	Once a year. If the unit is dropped or damaged, or if the unit was stored at less than -25ºC or above 55ºC, check it and calibrate it before further use.
Clean the thermal printhead	At each paper pack change, or every 500 m of paper run.

Recorder Maintenance

Removing the Paper Guide: FM40/FM50

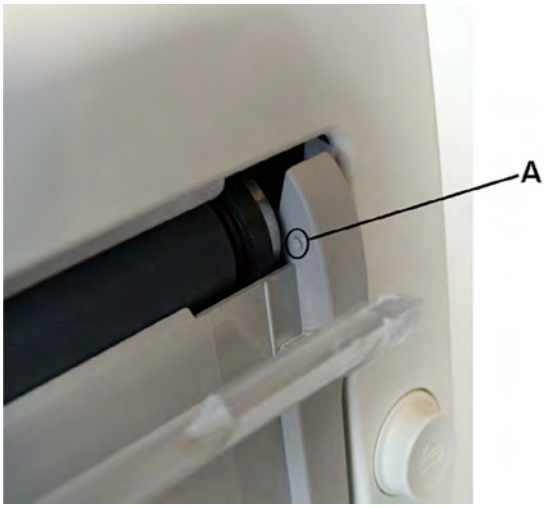
FM40/50 The paper guide is removable, and you can use the recorder without it. When **not** using the paper guide, ALWAYS tear off the paper along the perforation to avoid possible paper misalignment (see "Tearing Off the Paper" on page 62).

To remove the paper guide:

1 Press the paper eject button to open the paper drawer.

2 Hinge the transparent paper guide forward.

3 A protrusion (A) holds paper guide in closed position.



4 Release the paper guide from one side of the holder.

5 Then remove the paper guide.

6 Refitting is a reversal of the removal procedure.

Storing Recorder Paper

Recorder paper is not intended for long-term archival storage. Another medium should be considered if this is required.

Dyes contained in thermal papers tend to react with solvents and other chemical compounds that are being used in adhesives. If these compounds come into contact with the thermal print, the print may be destroyed over time. You can take the following precautionary measures to help avoid this effect:

- Store the paper in a cool, dry, and dark place.
- Do not store the paper at temperatures over 40°C (104°F).
- Do not store the paper where the relative humidity exceeds 60%.
- Avoid intensive light (UV light), as this may cause the paper to turn gray, or the thermal print to fade.

- Avoid storing the thermal paper in combination with the following conditions:
  - Papers that contain organic solvents. This includes papers with tributyl and/or dibutyl phosphates, for example recycled paper.
  - Carbon paper and carbonless copy paper.
  - Products containing polyvinyl chlorides, or other vinyl chlorides for example (but not exclusively) document holders, envelopes, letter files, divider sheets.
  - Detergents and solvents, such as alcohol, ketone, ester, and others, including cleaning and disinfecting agents.
  - Products containing solvent-based adhesives such as (but not exclusively) laminating film, transparent film, or labels sensitive to pressure.

To ensure long lasting legibility and durability of thermal printouts, store your documents separately in an air-conditioned place and use:

- only plasticizer-free envelopes or divider sheets for protection.
- laminating films and systems with water-based adhesives.

Using such protective envelopes cannot prevent the fading effect caused by other, external agents.

Cleaning the Print Head

To clean the recorder's thermal print-head:

1. Switch off the monitor.
2. Open the paper drawer, and remove the paper if necessary, to gain access to the thermal print head.
3. Gently clean the thermal print head with a cotton swab, or soft cloth soaked in isopropyl alcohol.

FM20/30

FM40/50

NOTE

If the print head is heavily coated with dust or dirt, contact your service personnel to clean it.

Returning Equipment for Repair

Before returning equipment for repair:

- disinfect and decontaminate the equipment appropriately.
- ensure that all patient data has been removed (i.e. that no patient is admitted).

Disposing of the Monitor

WARNING

To avoid contaminating or infecting personnel, the environment, or other equipment, make sure that you disinfect and decontaminate the monitor appropriately before disposing of it in accordance with your country's laws for equipment containing electrical and electronic parts. For disposal of parts and accessories such as thermometers, where not otherwise specified, follow local regulations regarding disposal of hospital waste.

You can disassemble the monitor and the transducers as described in the Service Guide. You will find detailed disposal information on the following web page:

http://www.healthcare.philips.com/main/about/Sustainability/Recycling/pm.wpd

Do not dispose of waste electrical and electronic equipment as unsorted municipal waste. Collect it separately, so that it can be safely and properly reused, treated, recycled, or recovered.

The Recycling Passports located on the Philips' web page contain information on the material content of the equipment, including potentially dangerous materials which must be removed before recycling (for example, batteries and parts containing mercury or magnesium).

28 Maintenance

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Accessories and Supplies

All accessories listed for the fetal monitor may not be available in all geographies. To order parts, accessories, and supplies, consult your local Philips representative for details. For customers in the United States, Australia, and Great Britain you can order at www.philips.com/healthcarestore. All accessories and supplies listed here are reusable, unless indicated otherwise.

WARNING

Reuse: Disposable accessories and supplies intended for single use, or single patient use only, are indicated as such on their packaging. Never reuse disposable accessories and supplies, such as transducers, sensors, electrodes, and so forth, that are intended for single use, or single patient use only.

Approved accessories: Use only Philips-approved accessories.

Packaging: Do not use a sterilized accessory if its packaging is damaged.

Protection against electric shocks: The transducers and accessories listed in this chapter are not defibrillator proof.

Electro-Surgery, Defibrillation and MRI: The fetal/maternal monitors are not intended for use during defibrillation, electro-surgery, or MRI. Remove all transducers, sensors, and accessories before performing electro-surgery, defibrillation, or MRI, otherwise harm can result.

Information on Latex

All Philips transducers and accessories are not manufactured with natural rubber latex, unless indicated otherwise in the following tables.

Avalon CL Base Station

CL Base Station	Part Number
Avalon CL Base Station can either be ordered with the option K30 (red connector), or K40 (black connector), or K60 (charging station)	866074

Transducers

New Generation Avalon Transducers

The new generation of Avalon transducers provides the same functionality as the previous generation of Avalon transducers. So wherever the previous generation of Avalon transducers were used to measure the fetal and maternal parameters, you can now use the new generation of Avalon transducers in the same way.The old and new generations of Avalon transducers correspond as follows:

Old Generation Avalon Transducers	New Generation Avalon Transducers
Avalon Toco MP Transducer (M2734B)	Toco MP Transducer (867248)
Toco$^+$ Transducer (M2735A)	Toco$^+$ Transducer (867249)
-	Toco$^+$ MP Transducer (867245) requires Avalon software revision L.3x.xx
Ultrasound Transducer (M2736A/AA)	Ultrasound Transducer (867246)
Patient Module ECG/ IUP (M2738A)	ECG/IUP Transducer (867247)
Remote Event Marker (989803143411)	-

CL Transducer and CL Pods	Part Number
Avalon CL Toco$^+$ MP Transducer for use with the Avalon CL base station	866075
Avalon CL Ultrasound Transducer for use with the Avalon CL base station	866076
Avalon CL ECG/IUP Transducer for use with the Avalon CL base station	866077
Avalon CL Fetal & Maternal Pod for use with the Avalon CL base station	866488
Avalon CL Wide Range Pod for use with the Avalon CL base station	866487
CL SpO_2 Pod for use with the Avalon CL base station	865215
CL NBP Pod for use with the Avalon CL base station	865216

Fetal Accessories

Accessory	Description	Part Number
Belt (reusable, gray, water resistant)	32 mm wide, 15 m roll	M4601A
	60 mm wide, 5 belts	M4602A
	60 mm wide, 15 m roll	M4603A
	50 mm wide, 5 belts	M1562B
Belt (disposable, yellow, water resistant)	60 mm wide, pack of 100	M2208A
Ultrasound gel	12 Bottles	40483A
Belt buttons (kit of 10) for wired transducers M273xA		M1569A
Belt Clips for wired Smart Transducers (kit of 6)		989803143401
Avalon CL Connector Caps	Connector Caps for Avalon CL Cableless Smart Transducers (kit of 10)	989803184841
Avalon CL Belt Clip	Belt Clip for Avalon CL Cableless Smart Transducers (kit of 10)	989803184851
Avalon CL Battery Replacement Kit		989803184861
Cable Management Kit		989803148841
Avalon CL Wide Range Battery Kit		989803196421
Kit of 20 Mobile CL Transmitter Cradles for use with 866487 Avalon CL Wide Range Pod		989803168881
Telemetry Pouch with window (case with 50 pouches) for use with 866487 Avalon CL Wide Range Pod		989803137831
Avalon CL Fetal & Maternal Patch (case with 10 each)		989803196341
ECG Skin Preparation Paper for use with the 989803196341 Avalon CL F&M patch	10 sheets, with 10 finger-tip sized skin prep pieces per sheet (100 preps per bag)	M4606A
DECG Accessories: Philips DECG Solution *(NOT compatible with QwikConnect Plus Solution accessories)*	DECG reusable leg plate adapter cable (with flushing port)	989803137651
	DECG leg attachment electrode for DECG leg plate adapter cable	989803139771
	DECG fetal scalp electrode: single spiral, worldwide availability	989803137631
	DECG fetal scalp electrode: double spiral, Europe only. Not for USA	989803137641
Disposable Koala IUP catheter		M1333A (obsolete)
Reusable Koala IUP adapter cable		989803143931

MECG Accessories

Accessory	Part Number
MECG reusable adapter cable	M1363A
Foam ECG electrodes, snap-fit, for MECG Adapter Cable (disposable)	40493D/E

Noninvasive Blood Pressure Accessories

The following accessories are approved for use with the fetal monitor:

Comfort Care 2-piece Reusable Cuffs

Maternal Patient Category	Limb Circumference	Part Number
Adult (Thigh)	42.0-54.0 cm	M1576A
Large Adult	34.0-43.0 cm	M1575A
Large Adult XL	34.0-43.0 cm	M1575XL
Adult	27.0-35.0 cm	M1574A
Adult XL	27.0-35.0 cm	M1574XL
Small Adult	20.5-28.0 cm	M1573A
Small Adult XL	20.5-28.0 cm	M1573XL
Cuff kit of 4 adult sizes		M1578A
Cuff kit of 3 adult XL sizes		M1579XL

The tubing required for all cuffs is M1598B (1.5 m) or M1599B (3.0 m).

Adult Multi Care Reusable Cuffs

Maternal Patient Category	Limb Circumference	Part Number
Adult (Thigh)	42.0-54.0 cm	989803183371
Large Adult	34.0-43.0 cm	989803183361
Adult	27.0-35.0 cm	989803183341
Adult X-Long	27.0-35.0 cm	989803183351
Small Adult	20.5-28.0 cm	989803183331

The tubing required for all cuffs is M1598B (1.5 m) or M1599B (3.0 m).

Easy Care 1-piece Reusable Cuffs

Maternal Patient Category (color)	Limb Circumference	Part Number
Adult Thigh (gray)	45.0-56.5 cm	M4559B
Adult Thigh (gray) pack of 5 cuffs	45.0-56.5 cm	M4559B5
Large Adult X-Long (burgundy)	35.5-46.0 cm	M4558B
Large Adult X-Long (burgundy) pack of 5 cuffs	35.5-46.0 cm	M4558B5

Maternal Patient Category (color)	Limb Circumference	Part Number
Large Adult (burgundy)	35.5-46.0 cm	M4557B
Large Adult (burgundy) pack of 5 cuffs	35.5-46.0 cm	M4557B5
Adult X-Long (navy blue)	27.5-36.5 cm	M4556B
Adult X-Long (navy blue) pack of 5 cuffs	27.5-36.5 cm	M4556B5
Adult (navy blue)	27.5-36.5 cm	M4555B
Adult (navy blue) pack of 5 cuffs	27.5-36.5 cm	M4555B5
Small Adult (royal blue)	20.5-28.5 cm	M4554B
Small Adult (royal blue) pack of 5 cuffs	20.5-28.5 cm	M4554B5
Cuff kits containing one small adult, one adult, one large adult and one thigh cuff		864288
Cuff kits containing one small adult, one adult, one adult X-long, one large adult, one large adult X-long and one thigh cuff		864291

The tubing required for all cuffs is M1598B (1.5 m) or M1599B (3.0 m).

Gentle Care Single Patient Use Cuffs

Maternal Patient Category	Limb Circumference	Part Number
Adult (Thigh)	45.0-56.5 cm	M4579B
Large Adult X-Long	35.5-46.0 cm	M4578B
Large Adult	35.5-46.0 cm	M4577B
Adult X-Long	27.5-36.5 cm	M4576B
Adult	27.5-36.5 cm	M4575B
Small Adult	20.5-28.5 cm	M4574B

The tubing required for all cuffs is M1598B (1.5 m) or M1599B (3.0 m).

Adult Single Care Cuffs

Maternal Patient Category	Limb Circumference	Part Number
Large Adult	35.0-45.0 cm	989803182321
Adult X-Long	27.5-36.0 cm	989803182311
Adult	27.5-36.0 cm	989803182301
Small Adult	20.5-28.5 cm	989803182291

The tubing required for all cuffs is M1598B (1.5 m) or M1599B (3.0 m).

Adult Value Care Cuffs

Maternal Patient Category	Limb Circumference	Part Number
Large Adult	34.0-43.0 cm	989803160861
Adult XL	27.0-35.0 cm	989803160851

Maternal Patient Category	Limb Circumference	Part Number
Adult	27.0-35.0 cm	989803160841
Small Adult	20.5-28.0 cm	989803160831

The tubing required for all cuffs is M1598B (1.5 m) or M1599B (3.0 m).

IntelliVue CL NBP Pod Accessories

Description	Limb Circumference Range	Contents	Part Number
Mobile CL Reusable Small Adult Cuff	21-27 cm	1 cuff	989803163171
Mobile CL Reusable Adult Cuff	26.0-34.5 cm	1 cuff	989803163191
Mobile CL Reusable Large Adult Cuff	33.5-45.0 cm	1 cuff	989803163211
Mobile CL Single-Patient Small Adult Cuff	21-27 cm	20 cuffs	989803163181
Mobile CL Single-Patient Adult Cuff	26.0-34.5 cm	20 cuffs	989803163201
Mobile CL Single-Patient Large Adult Cuff	33.5-45.0 cm	20 cuffs	989803163221
Mobile CL NBP Cradle Kit	-	20 cradles	989803163251
Mobile CL Extension Air Hose, 1.0 m	-	1 extension air hose	989803163131
Mobile CL NBP Battery Kit	-	1 Battery 1 disassembly tool 1 front housing	989803163261
Telemetry Pouch with window	-	50 pouches	989803137831
Telemetry Pouch with window	-	4 boxes of 50 pouches	989803140371
White Telemetry Pouch with Snaps	-	50 pouches	989803101971 (9300-0768-050)
White Telemetry Pouch with Snaps	-	4 boxes of 50 pouches	989803101981 (9300-0768-200)

SpO2 Accessories

Some Nellcor sensors contain natural rubber latex which may cause allergic reactions. See the Instructions for Use supplied with the sensors for more information. M1901B, M1903B, and M1904B are not available in U.S. from Philips. Purchase Nellcor OxiCliq sensors and adapter cables directly from Tyco Healthcare. Some sensors may not be available in all countries.

Do not use more than one extension cable with any sensors or adapter cables. Do not use an extension cable with Philips reusable sensors or adapter cables with part numbers ending in -L (indicates "**L**ong" version).

All listed sensors operate without risk of exceeding 41°C/105.8°F on the skin if ambient temperature is below 37°C/98.6°F.

Make sure that you use only the accessories that are specified for use with this device, otherwise patient injury can result.

Philips Reusable Sensors

Description	Part Number
Adult sensor (2.0 m cable), for patients over 50 kg. Any finger, except thumb.	M1191B
M1191A/B with longer cable (3.0 m)	M1191AL/BL
Small adult, pediatric sensor (1.5 m cable) for patients between 15 kg and 50 kg. Any finger except thumb. Use only on adult patients with FM30/40/50.	M1192A
Ear sensor (1.5 m cable) for patients more than 40 kg. Use only on adult patients with FM30/40/50.	M1194A
Adult clip sensor (3 m cable) for patients over 40 kg. Any finger except thumb.	M1196A
Adult clip sensor (2 m cable) for patients over 40 kg. Any finger except thumb.	M1196S

No adapter cable required.

Description	Part Number
Adult sensor (0.45 m cable), for patients over 50 kg. Any finger except thumb.	M1191T
Small adult, pediatric sensor (0.45 m cable) for patients between 15 kg and 50 kg. Any finger except thumb. Use only on adult patients with FM30/40/50.	M1192T
Adult clip sensor (0.9 m cable) for patients over 40 kg. Any finger except thumb.	M1196T

Requires M1943A (1.0 m) or M1943AL (3.0 m) adapter cable.

Description	Part Number
Special Edition (SE). Adult sensor (3 m cable), for patients over 50 kg. Any finger except thumb.	M1191ANL
Special Edition (SE). Small adult, pediatric sensor (1.5 m cable) for patients between 15 kg and 50 kg. Any finger except thumb. Use only on adult patients with FM30/40/50.	M1192AN
Special Edition (SE). Ear sensor (1.5 m cable) for patients more than 40 kg.	M1194AN

No adapter cable required. SE sensors work with FM30/40/50, as well as with OxiMax-compatible SpO_2 versions of other Philips monitors.

Philips Disposable Sensors

Not available in the U.S.:

Description	Part Number
Identical to OxiMax MAX-A	M1904B
Identical to OxiMax MAX-P	M1903B
Identical to OxiMax MAX-N	M1901B

Requires M1943A (1.0 m) or M1943AL (3.0 m) adapter cable

Available worldwide:

Description	Part Number
Adult/Pediatric finger sensor (0.45 m cable). Use only on adult patients with FM30/40/50.	M1131A
Adult/Pediatric finger sensor (0.9 m cable) for patients >40 kg. Any finger except thumb. Use only on adult patients with FM30/40/50.	M1133A
Adult/Pediatric finger sensor (0.9 m cable) for patients >40 kg. Any finger except thumb. Adhesive-free, use only on adult patients with FM30/40/50.	M1134A

Requires M1943A (1.0 m) or M1943AL (3.0 m) adapter cable

Nellcor Sensors

Nellcor sensors must be ordered from Nellcor/Covidien.

OxiMax Sensors

Description	Part Number
Adult finger sensor (patient size >30 kg)	OxiMax MAX-A
OxiMax MAX-A with long cable	OxiMax MAX-AL
Pediatric foot/hand sensor (patient size 10-50 kg). Use only on adult patients with FM30/40/50.	OxiMax MAX-P
Adult finger or neonatal foot/hand sensor (patient size >40 kg or <3 kg). Use only on adult patients with FM30/40/50.	OxiMax MAX-N

Require M1943A (1.0 m) or M1943AL (3.0 m) adapter cable.

Oxisensor II Sensors

Description	Part Number
Adult sensor (patient size >30 kg)	Oxisensor II D-25
Pediatric sensor (patient size 10-50 kg). Use only on adult patients with FM30/40/50.	Oxisensor II D-20
Neonatal/Adult sensor (patient size <3 kg or >40 kg). Use only on adult patients with FM30/40/50.	Oxisensor II N-25

Requires M1943A (1.0 m) or M1943AL (3.0 m) adapter cable.

OxiCliq Sensors

Description	Part Number
See OxiMax MAX-A	OxiCliq A
See OxiMax MAX-P. Use only on adult patients with FM30/40/50.	OxiCliq P
See OxiMax MAX-N. Use only on adult patients with FM30/40/50.	OxiCliq N

Requires M1943A (1.0 m) or M1943AL (3.0 m) adapter cable **together with** OC-3 adapter cable.

Masimo LNOP Reusable Sensors

Description	Product Number	Part Number
Adult Finger Sensor (>30 kg)	LNOP DC-I	989803140321
Pediatric Finger Sensor (10-50 kg). Use only on adult patients with FM30/40/50.	LNOP DC-IP	989803140331
Multi-Site Sensor (>1 kg). Use only on adult patients with FM30/40/50.	LNOP YI	n/a
Ear Sensor (>30 kg). Use only on adult patients with FM30/40/50.	LNOP TC-I	989803140341

For use with this sensor the adapter cable LNOP MP12 (M1020-61102) is needed.

Masimo LNCS Reusable Sensors

Description	Product Number	Part Number
Adult Finger Sensor (>30 kg)	LNCS DC-I	989803148281
Pediatric Finger Sensor (10-50 kg). Use only on adult patients with FM30/40/50.	LNCS DC-IP	989803148291
Ear Sensor (>30 kg). Use only on adult patients with FM30/40/50.	LNCS TC-I	989803148301

For use with this sensor the adapter cable LNC MP10 (989803148221) is needed.

Masimo LNOP Disposable Adhesive Sensors

Description	Product Number	Part Number
Adult Sensor (>30 kg)	LNOP Adt	989803140231
Adult Sensor (>30 kg)	LNOP Adtx	n/a
Pediatric Sensor (10-50 kg). Use only on adult patients with FM30/40/50.	LNOP Pdt	989803140261
Pediatric Sensor (10-50 kg). Use only on adult patients with FM30/40/50.	LNOP Pdtx	n/a
Neonatal (<3 kg) or Adult adhesive Sensor (>40 kg). Use only on adult patients with FM30/40/50.	LNOP Neo-L	989803140291

Appropriate LNOP/LNCS adapter cable required.

Masimo LNCS Disposable Adhesive Sensors

Description	Product Name	Part Number
Adult Sensor (>30 kg)	LNCS Adtx	989803148231
Pediatric Finger Sensor (10-50 kg). Use only on adult patients with FM30/40/50.	LNCS Pdtx	989803148241
Neonatal Foot Sensor (<3 kg) or Adult Finger Sensor (>40 kg). Use only on adult patients with FM30/40/50.	LNCS Neo-L	989803148271

Appropriate LNOP/LNCS adapter cable required.

IntelliVue CL SpO2 Pod Accessories

All listed sensors operate without risk of exceeding 41°C on the skin, if the initial skin temperature does not exceed 35°C.

Ensure that you use only the accessories that are specified for use with this device, otherwise patient injury can result.

Description	Contents	Part Number
Mobile CL 20 single patient SpO2 Sensors and Cradles for use on patients >10 kg	20 Single-Patient Mobile CL DSpO2-1A Sensors 20 Single-Patient Wristbands 20 Single-Patient Cradles pre-assembled	989803165941
Mobile CL 20 single patient SpO2 Sensors for use on patients >10 kg	20 Single-Patient Mobile CL DSpO2-1A Sensors	989803165921
Mobile CL reusable SpO2 sensor and Cradles for use on patients >15 kg	1 Reusable Mobile CL RSpO2-1A Sensor 20 Single-Patient Cradles with pre-attached Wristbands	989803165931[1]
Mobile CL 20 SpO2 Cradles (single patient)	20 Single-Patient Cradles with pre-attached Wristbands	989803165951
Mobile CL 50 SpO2 Wristbands (single patient)	50 Single-Patient Wristbands	989803165961
Mobile CL SpO2 Battery Kit	1 Battery 1 disassembly tool 1 front housing	989803168861

[1] May not be available in all geographies

Extension / Adapter Cables

Description	Comments	Part Number
Extension cable (2 m)	For use with Philips reusable sensors and adapter cables	M1941A
Adapter cable (1.1 m cable)	Adapter cable for Philips/Nellcor disposable sensors	M1943A
Adapter cable (3 m cable)		M1943AL
Adapter Cable for OxiCliq sensors	Available from Nellcor	OC-3

Description	Comments	Part Number
Masimo MP 12	LNOP MP Series Patient Cable (3.6 m) Adapter Cable for Masimo LNOP sensors	M1020-61100
LNC MP10	LNCS MP Series Patient Cable (3.0 m) Adapter Cable for Masimo LNCS sensors	989803148221

Tympanic Temperature Accessories

Description	Part Number
Temperature probe	989803180831
Disposable probe cover with CE marking (22 boxes each containing 96 covers)	989803179611
Disposable probe cover (22 boxes each containing 96 covers)	989803179381

Recorder Paper

Supplied in cases of 40 packs. Each pack has 150 numbered pages. Single use. Use the paper specified here.

Geography	FHR Scale	Grid Color	Scale Units	Highlighted 3 cm Lines?	Part Number
U.S./Canada/Asia	30-240	Red/Orange	mmHg	Yes	M1910A
Europe	50-210	Green	mmHg and kPa	No	M1911A
Japan	50-210	Green	mmHg	Yes	M1913A
Japan	50-210	Green*	mmHg	Yes	M1913J

*Bradycardia and tachycardia alarm ranges are shaded.

Batteries

Description	Comment	Part Number
Smart Battery 10.8 V, 6000 mAh, Lithium Ion	For Avalon FM20 or Avalon FM30 with battery option #E25	M4605A
Avalon CL Cableless Smart transducer Battery Replacement Kit	Consists of one Philips Lithium Ion Battery (Part No. 453564107871), a tool to open and close the cableless transducer for battery replacement and two replacement O-ring seals.	989803184861
Avalon CL Wide Range Battery Kit	For Avalon CL Wide Range Pod	989803196421

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Specifications and Standards Compliance

The monitors are intended to monitor a mother and her fetus(es), which from an electrical safety point of view, are one person.

Environmental Specifications

The monitor may not meet the given performance specifications, if stored and used outside the specified temperature and humidity ranges.

Avalon CL Base station 866074 with Option K30 and K40		
Temperature Range	Operating	0°C-45°C (32°F-113°F)
	Storage/Transportation	-20°C-60°C (-4°F-140°F)
Humidity Range	Operating	<95% relative humidity @ 45°C (113°F)
	Storage/Transportation	<90% relative humidity @ 60°C (140°F)
Altitude Range	Operating	-500-3000 m (-1640-9840 ft)
	Storage/Transportation	-500-13100 m (-1640-43000 ft)

Avalon CL Base station 866074 with Option K60		
Temperature Range	Operating	0°C-40°C (32°F-104°F)
	Storage/Transportation	-20°C-60°C (-4°F-140°F)
Humidity Range	Operating	<90% relative humidity @ 45°C (113°F)
	Storage/Transportation	<90% relative humidity @ 60°C (140°F)
Altitude Range	Operating	0-2000 m (0-6562 ft)
	Storage/Transportation	-500-13100 m (-1640-43000 ft)

Monitor (M2702A/M2703A/M2704A/M2705A); Interface Cable for Avalon CTS (M2731-60001 and M2732-60001)		
Temperature Range	Operating	Without battery option: 0°C-45°C (32°F-113°F)
		With battery option/charging: 0°C-35°C (32°F-95°F)
		With battery option/fully charged: 0°C-40°C (32°F-104°F)
	Storage/Transportation	-20°C-60°C (-4°F-140°F)
Humidity Range	Operating	<95% relative humidity @ 40°C (104°F)
	Storage/Transportation	<90% relative humidity @ 60°C (140°F)
Altitude Range	Operating	-500-3000 m (-1640-9840 ft)
	Storage/Transportation	-500-13100 m (-1640-43000 ft)

Previous Generation Transducers (M2734A/M2734B/M2735A/M2736A/M2738A)		
Temperature Range	Operating	0°C-40°C (32°F-104°F)
	Storage/Transportation	-20°C-60°C (-4°F-140°F)
Humidity Range	Operating	<95% relative humidity @ 40°C (104°F)
	Storage/Transportation	<90% relative humidity @ 60°C (140°F)
Altitude Range	Operating	-500-3000 m (-1640-9840 ft)
	Storage/Transportation	-500-13100 m (-1640-43000 ft)

New Generation Transducers (867245, 867246, 867247, 867248, 867249)		
Temperature Range	Operating	0°C-40°C (32°F-104°F)
	Storage/Transportation	-20°C-60°C (-4°F-140°F)
Humidity Range	Operating	<95% relative humidity @ 40°C (104°F)
	Storage/Transportation	<90% relative humidity @ 60°C (140°F)
Altitude Range	Operating	-500-3000 m (-1640-9840 ft)
	Storage/Transportation	-500-13100 m (-1640-43000 ft)

NOTE

Do not locate the M2738A ECG/IUP Module directly on the patient's skin when operated at an environmental temperature above 37°C (98.6°F). When operated at an environmental temperature of 40°C (104°F), the transducers can reach a temperature of 41-43°C (106-110°F).

Remote Event Marker (989803143411)		
Temperature Range	Operating	0°C-55°C (32°F-131°F)
	Storage	-40°C-70°C (-40°F-158°F)
	Transportation	-40°C-70°C (-40°F-158°F))
Humidity Range	Operating	<95% relative humidity @ 40°C (104°F)
	Storage	<90% relative humidity @ 65°C (149°F)
	Transportation	<90% relative humidity @ 65°C (149°F)
Altitude Range	Operating	-500-3000 m (-1640-9840 ft) 1075hPa-700hPa
	Storage	-500-13100 m (-1640-43000 ft) 1075hPa-160hPa
	Transportation	-500-13100 m (-1640-43000 ft) 1075hPa-160hPa

Avalon CL Transducers (866075/866076/866077)		
Temperature Range	Operating	0°C-40°C (32°F-104°F)
	Charging	0°C-35°C (32°F-95°F)
	Storage/Transportation	-20°C-60°C (-4°F-140°F)
Humidity Range	Operating	<95% relative humidity @ 40°C (104°F)
	Storage/Transportation	<90% relative humidity @ 60°C (140°F)
Altitude Range	Operating	-500-3000 m (-1640-9840 ft)
	Storage/Transportation	-500-13100 m (-1640-43000 ft)

Avalon CL Fetal & Maternal Pod (866488)		
Temperature Range	Operating	10°C-40°C (50°F-104°F)
	Charging	10°C-35°C (50°F-95°F)
	Storage/Transportation	-20°C-60°C (-4°F-140°F)
Humidity Range	Operating	<95% relative humidity @ 40°C (104°F)
	Storage/Transportation	<90% relative humidity @ 60°C (140°F)
Altitude Range	Operating	-500-3000 m (-1640-9840 ft)
	Storage/Transportation	-500-13100 m (-1640-43000 ft)

Avalon CL Fetal & Maternal Patch (989803196341)		
Temperature Range	Operating	10°C-40°C (50°F-104°F)
	Storage/Transportation	10°C-30°C (50°F-86°F)
Humidity Range	Operating	<95% relative humidity
	Storage/Transportation	<90% relative humidity
Altitude Range	Operating	-500-3000 m (-1640-9840 ft)
	Storage/Transportation	-500-13100 m (-1650-43000 ft)

Avalon CL Wide Range Pod (866487)		
Temperature Range	Operating	0°C-40°C (32°F-104°F)
	Charging	0°C-35°C (32°F-95°F)
	Storage/Transportation	-20°C-60°C (-4°F-140°F)
Humidity Range	Operating	<95% relative humidity @ 40°C (104°F)
	Storage/Transportation	<90% relative humidity @ 60°C (140°F)
Altitude Range	Operating	-500-3000 m (-1640-9840 ft)
	Storage/Transportation	-500-4600 m (-1640-15092 ft)

MECG Adapter Cable (M1363A)		
Temperature Range	Operating	0°C-55°C (32°F-131°F)
	Storage	-40°C-70°C (-40°F-158°F)
	Transportation	-40°C-70°C (-40°F-158°F))
Humidity Range	Operating	<95% relative humidity @ 40°C (104°F)
	Storage	<90% relative humidity @ 65°C (149°F)
	Transportation	<90% relative humidity @ 65°C (149°F)
Altitude Range	Operating	-500-3000 m (-1640-9840 ft) 1075hPa-700hPa
	Storage	-500-13100 m (-1640-43000 ft) 1075hPa-160hPa
	Transportation	-500-13100 m (-1640-43000 ft) 1075hPa-160hPa

SpO_2 Sensors	
Operating Temperature Range	0°C-37°C (32°F-98.6°F)

Tympanic Temperature	
Operating Temperature Range	16ºC-33ºC (60.8ºF-91.4ºF)

Fetal Recorder Paper (M1910A, M1911A, M1913A, M1913J)		
Temperature Range	Operating	0°C-45°C (32°F-113°F)
	Storage	-20°C-40°C (-4°F-104°F)
	Transportation	-20°C-60°C (-40°F-140°F)
Humidity Range	Operating	<95% relative humidity @ 40°C (104°F)
	Storage	<70% relative humidity @ 40°C (104°F)
	Transportation	<90% relative humidity @ 60°C (140°F)
Altitude Range	Operating	-500-3000 m (-1640-9840 ft) 1075hPa-700hPa
	Storage	-500-13100 m (-1640-43000 ft) 1075hPa-160hPa
	Transportation	-500-13100 m (-1640-43000 ft) 1075hPa-160hPa

WARNING

Explosion Hazard: Do not use in the presence of flammable anesthetics, such as a flammable anesthetic mixture with air, oxygen, nitrous oxide, or in oxygen rich environment. Use of the devices in such an environment may present an explosion hazard.

Physical Specifications

Fetal Monitors

Monitor Physical Specifications		M2702A/M2703A	M2704A/M2705A
Power	Supply Voltages	100 VAC-240 VAC ±10%	
	Supply Frequency Range	50 Hz-60 Hz	
	Power Consumption (current)	0.7-0.4 A (M2702A/M2703A) 1.3-0.7 A (M8023A#E25)	1.3-0.7 A
Dimensions and Weight	Size (without options) mm/ (in): width x height x depth	286 x 134 x 335 mm (11.3 x 5.3 x 13.2 in)	425 x 174 x 365 mm (16.6 x 6.9 x 14.4 in)
	Weight	<5.1 kg (11.2 lbs)	<8.8 kg (19.5 lbs)
Degree of Protection Against Electrical Shock		Type CF	
Electrical Class		Class II equipment	Class I equipment
Electrical Power Source		External (AC) without battery option #E25 Internal (Lithium Ion battery) if with battery option #E25	External (AC)
Mode of Operation		Continuous operation	
Water Ingress Protection Code		IP X1 (provided recorder drawer is shut)	
Global Speed (DECG and MECG wave on the screen)		6.25 mm/sec, 12.5 mm/sec, 25 mm/sec, 50 mm/sec	
Startup Time	Time taken from switching on the monitor to seeing the first parameter labels	<30 seconds	

Fetal Monitor Sounds

Source	Description
Patient alarms and INOPs	See the sections on "Patient Alarms and INOPs" on page 127, "Standard Philips Alarms" on page 117, and "ISO/IEC Standard Audible Alarms" on page 117.
Ultrasound Doppler	Direct transmission of Doppler echoes to the speaker of the fetal monitor.
Pulse from SpO_2, MECG, DECG	QRS tone
SpO_2	Optional modulation of the QRS tone for changes in the SpO_2 level.
NST Timer	Tone for Timer expired.
Status/Prompt tone	Configurable volume tone sounded when status or prompt messages are issued by the fetal monitor.
Touch feed back tone	Anytime the user touches the display a low beep is issued in response.

Avalon CL Base Station

Avalon CL Base Station		
Dimension and Weight Size mm/(in)	W x H x D	349 x 74 x 183 mm (13.8 x 2.9 x 7.2 in)
	Weight	1 kg (2.3 lbs)
Electrical Class	When the base station is connected to the monitors M2702A/M2703A/M2704A/ M2705A it is a Class II equipment.	
Electrical Power Source	External (powered by fetal monitor)	
Mode of Operation	Continuous operation	
Interface cable connector type	Connector color	Red for FM20/30 left side or FM40/50 front fetal connector socket
		Black for FM40/50 rear telemetry connector socket
Interface cable length		1.5 m (4.11 ft)
Ingress Protection		IP 31

External Power Supply (Option K60 for the Avalon CL Base Station)	
Maximum Weight (with cable)	140 g (4.94 oz) (incl. cable, without country-dependent AC adapter)
Size (W x H x D)	52.0 x 39.5 x 85.0 mm (2.0 x 1.6 x 3.4 in)
Charging cable length	1.6 m (5.2 ft) (incl. power supply)
Supply Voltages	100 VAC-240 VAC
Supply Frequency Range	50 Hz/60 Hz
Power Consumption (current)	0.4-0.2A
Electrical Class	Class II
Electrical Power Source	AC Mains
Mode of Operation	Continuous
Water Ingress Protection Code	IP40

Wired Transducers

Previous Generation Avalon Transducers (M2734A/M2734B/M2735A/M2736A/M2738A)			
Shock Resistance		Withstands a 1 m drop to concrete surface with possible cosmetic damage only	
Water Ingress Protection Code	M2734A&B/35/36A	IP 68 (immersion up to 1 m water depth for 5 hours)	
	M2738A	IP 67 (immersion up to 0.5 m water depth for 30 minutes)	
Dimensions and Weight	M2734A&B/35/36A	Size (diameter)	83 mm (3.27 in)
		Weight (without cable)	0.2 kg (0.5 lb)
	M2738A	Maximum size mm/(in): width x height x depth	42 x 30 x 123 mm (1.7 x 1.2 x 4.8 in)
		Cable length	2.5 m
		Weight	0.2 kg (0.5 lb)

Previous Generation Avalon Transducers (M2734A/M2734B/M2735A/M2736A/M2738A)	
Degree of Protection Against Electrical Shock	Type CF
Transducer Identification	Optical Signal Element (Finder LED), not M2738A

New Generation Avalon Transducers (867245, 867246, 867247, 867248, 867249)		
Shock Resistance	Withstands a 1.5 m drop to concrete surface with possible cosmetic damage only	
Water Ingress Protection Code	IP 68 (immersion up to 1 m water depth for 5 hours)	
Dimensions and Weight	Size (diameter/height)	76 mm/37 mm (3 in/1.5 in)
	Cable length	2.5 m
	Weight	<0.2 kg (0.5 lb)
Degree of protection against electrical shock	Type CF	
Transducer Identification	Optical Signal Element (Finder LED)	

Avalon CL Transducers

Avalon CL Transducers (866075/866076/866077)			
Shock Resistance		Withstands a 1.5 m drop to concrete surface with possible cosmetic damage only.	
Water Ingress Protection Code		IP 68 (immersion up to 1 m water depth for 5 hours)	
Dimensions and Weight	Avalon CL Toco+ MP Transducer 866075	Size (diameter/height)	76 mm/37 mm (3 in/1.5 in)
		Weight	0.2 kg (0.5 lb)
	Avalon CL US Transducer 866076	Size (diameter/height)	76 mm/37 mm (3 in/1.5 in)
		Weight	0.2 kg (0.5 lb)
	Avalon CL ECG/IUP Transducer 866077	Size (diameter/height)	76 mm/37 mm (3 in/1.5 in)
		Weight	0.2 kg (0.5 lb)
Degree of Protection Against Electrical Shock		Type CF	
Transducer Identification		Optical Signal Element (Finder LED)	

Avalon CL Fetal & Maternal Pod

Avalon CL Fetal & Maternal Pod (866488)		
Shock Resistance	Withstands a 1.5 m drop to concrete surface with possible cosmetic damage only.	
Water Ingress Protection Code	IP 67 (immersion up to 1 m water depth for 30 minutes)	
Dimensions and Weight	W x H x D	63 x 20 x 49 mm (2.5 x 0.8 x 1.9 in)
	Weight	0.07 kg (0.15 lb)
Degree of Protection Against Electrical Shock	Type CF	
Pod Identification	Optical Signal Element (Finder LED)	

Avalon CL Wide Range Pod

Avalon CL Wide Range Pod (866487)		
Shock Resistance	Withstands a 1 m drop to concrete surface with possible cosmetic damage only.	
Water Ingress Protection Code	IP 32 (protection from dripping water)	
Dimensions and Weight	W x H x D	55 x 26.5 x 122 mm (2.1 x 1 x 4.8 in)
	Weight	0.14 kg (0.3 lb)

Interface Cable Avalon CTS

Interface Cable for Avalon CTS (M2731-60001 and M2732-60001)		
Shock Resistance	Withstands a 1 m drop to concrete surface with possible cosmetic damage only	
Water Ingress Protection Code	IP X1	
Dimensions and Weight	Maximum size mm/(in): width x height x depth	55 x 28 x 50 mm (2.2 x 1.1 x 2.0 in)
	Cable length	2.5 m
	Weight	0.2 kg (0.5 lb)

External Power Supply Option E25

M8023A (Option #E25) External Power Supply Weight and Dimensions	
Maximum Weight	0.6 kg (1.4 lb)
Size (W x H x D)	208 x 105 x 135 mm (8.2 x 4.1 x 5.3 in)

Interface Specifications

Fetal Monitors

Interface Specifications		
Network	Standard	100-Base-TX (IEEE 802.3 Clause 25)
	Connector	RJ45 (8 pin)
	Isolation	Basic isolation (reference voltage: 250 V; test voltage: 1500 V)

Interface Specifications		
MIB/RS232	Standard	IEEE 1073-3.2-2000
	Connectors	RJ45 (8 pin)
	Mode	Software-controllable BCC (RxD/TxD cross over) or DCC (RxD/TxD straight through)
	Power	5 V ±5%, 100 mA (max.)
	Isolation	Basic isolation (reference voltage: 250 V; test voltage: 1500 V)
USB Interface	Standard	USB 2.0 full-speed (embedded host)
	Connectors	USB series "Standard A" receptacle
	Power	Low power port 4.4V min; max. load for all ports together 500 mA
	Isolation	none
RS232 (Standard)	Connectors	RJ45 (8 pin)
	Power	none
	Isolation	Basic isolation (reference voltage: 250 V; test voltage: 1500 V)
RS232 (Independent display interface option)	Connectors	RJ45 (8 pin)
	Power	none
	Isolation	none
Flexible Nurse Call Relay[1]	Connectors	20 pin MDR (Mini D-Ribbon), active open and closed contacts
	Contact	≤100 mA, ≤24 V DC
	Isolation	Basic isolation (reference voltage: 250 V; test voltage: 1500 V)
	Delay	<[Configured Latency +0.5] sec

[1] The power loss indication functionality of the Nurse Call Relay board is not supported with fetal monitors.

Avalon CL Radio

Avalon CL Radio Interface Specifications		
Electronic Article Surveillance (EAS)		EAS tag inside the housing (58 kHz)
Short Range Radio Interface*	Type	Internal SRR interface
	Technology	IEEE 802.15.4
	Frequency Band	2.4 GHz ISM (2.400-2.483 GHz)
	Modulation Technique	DSSS (O-QPSK)
	Effective radiated power	max. 0 dBm (1 mW)
	Range	ca. 5 m without any physical obstructions as walls and doors

Avalon CL Radio Interface Specifications		
OBR (WMTS)*	Frequency Band	608-614 MHz
	Effective radiated power	<10 mW (base station) <1 mW (CL transducers)
	Range	min. 100 m/300 ft (in line of sight)
OBR (ISM)*	Frequency Band	433.05-434.79 MHz
	Effective radiated power	<10 mW (base station) <1 mW (CL transducers)
	Range	min. 100 m/300 ft (in line of sight)
OBR (T108)*	Frequency Band	920.6-923.4 MHz
	Effective radiated power	<40 mW (base station) <10 mW (CL transducers)
	Range	min. 100 m/300 ft (in line of sight)

*Wireless transmissions are encrypted for security.

CL Wide Range Pod Radio

OBR (OB Radio)		
OBR (WMTS)	Frequency Band	608-614 MHz
	Effective radiated power	<1 mW
	Range	5 m/16 ft
OBR (ISM)	Frequency Band	433.05-434.79 MHz
	Effective radiated power	<1 mW
	Range	5 m/16 ft
OBR (T108)	Frequency Band	920.6-923.4 MHz
	Effective radiated power	<5 mW
	Range	5 m/16 ft

Short Range Radio Specifications	
Type	Built-in interface with integrated antenna
Technology	IEEE 802.15.4
Frequency Band	2.4 GHz ISM (2.400-2.483 GHz) MBAN (2.360-2.400 GHz, for US / FCC regulated countries only)[1]
Modulation	DSSS (O-QPSK)
Bandwidth	5 MHz
Effective Radiated Power (ERP)	max. 0 dBm (1 mW)

WLAN Specifications	
Type	Internal wireless adapter
Technology	IEEE 802.11a/b/g/n

WLAN Specifications	
Frequency Band	U.S.: 2.400-2.483 GHz, 5.15-5.35 GHz, 5.725-5.825 GHz Europe: 2.400-2.483 GHz, 5.15-5.35 GHz, 5.47-5.725 GHz Japan: 2.400-2.483 GHz, 5.150-5.250 GHz, 5.25-5.35 GHz, 5.470-5.725 GHz China: 2.400-2.483 GHz, 5.725-5.85 GHz
Modulation Technique	802.11b/g DSSS (DBPSK, DQPSK, CCK) OFDM (BPSK, QPSK, 16-QAM, 64-QAM) 802.11a OFDM (BPSK, QPSK, 16-QAM, 64-QAM)
Effective Radiated Power (ERP)	2.400-2.483 GHz: max. 18 dBm (63 mW) 5.150-5.725 GHz: max. 19 dBm (79 mW) 5.745-5.825 GHz: max. 14 dBm (25 mW)

Performance Specifications

Essential Performance

This section defines the Essential Performance for FM20/30 and FM40/50 monitors, alone and in combination with the Avalon CL Solution. Under normal and single fault conditions and when operating under non-transient electromagnetic phenomena according to IEC 60601-1-2, either at least the performance listed in the following table is provided or failure to provide this performance is readily identifiable by the user. For example, identifiers are technical alarms, no waveforms and/or numeric values, complete failure of the monitor, readily identifiable distorted signals, and so on. The following are non-transient electromagnetic phenomena according to IEC 60601-1-2:

- Radiated radio frequency (RF) electromagnetic fields
- Conducted disturbances induced by RF fields
- Power frequency magnetic fields
- Voltage dips
- Proximity electromagnetic fields from RF wireless communication equipment

Measurement	Essential Performance
General	No interruption or cessation of current operating mode (e.g. no reboot, display OK). No spontaneous operation of controls (e.g. no activation of touchscreen without user interaction).
ECG (fetal and maternal heart rate monitoring): dFHR, HR	Measurement of heart rate within ±10% or ±5 bpm, whichever is greater.
	Alarming on heart rate limit violation within specified delay time.
Abdominal ECG: aFHR, aHR	No FHR/HR gaps greater than 30 s, no FHR/HR error >15 bpm for 15 s. No interruption of the transmission mode.
	Alarming on heart rate limit violation within specified delay time.

Measurement	Essential Performance
Maternal Pulse from Toco (MP)	Measurement of the maternal pulse rate within the specified accuracy limits. MP is susceptible to movement artifact potentially resulting in signal loss. It is not intended for continuous maternal HR monitoring. Limit alarms are not provided.
NBP	Measurement of noninvasive systolic, diastolic, and mean blood pressure and pulse rate within specified accuracy and error limits.
	Automatic cycling
	Alarming on limit violations of systolic, diastolic, and mean blood pressure, and pulse rate.
SpO_2	Measurement of oxygen saturation within $4\%_{RMS}$ over the range from 70 to 100% and pulse rate within $\pm 10\%_{RMS}$ or ± 5 bpm_{RMS} whichever is greater.
	Alarming on oxygen saturation and pulse rate limit violation.
Temperature (tympanic)	Measurement of temperature within ±0.3°C.
	Alarming on temperature limit violation.
Toco extern	Measurement of the external Toco ±5 units on display and recorder (with paper adjusted).
Toco intern (IUP)	Measurement of the internal Toco within specified accuracy limits on display and recorder (with paper adjusted).
Abdominal uterine EMG: aToco	No aToco gaps greater than 30 s, no aToco error larger than 20% of full scale for more than 30 s. No interruption of the transmissions mode.
Ultrasound	Measurement of the fetal heart rate ±5 bpm on display and recorder (with paper adjusted).
	Ultrasound energy within safe limits for continuous operation: p_ < 1 MPa, Iob < 20 mW/cm2, Ispta < 100 mW/cm2.

When operating under transient electromagnetic phenomena according to IEC 60601-1-2, either at least the performance listed in the following table is provided or failure to provide this performance is readily identifiable by the user. For example, identifiers are technical alarms, no waveforms and/or numeric values, complete failure of the monitor, readily identifiable distorted signals, and so on. The following are transient electromagnetic phenomena according to IEC 60601-1-2:

- Electrostatic Discharge (ESD)
- Electrical Fast Transients/Bursts
- Surges
- Voltage interruptions

Measurement	Essential Performance
All	After electrostatic discharge, fast transients/bursts, and surges, the equipment returns to previous operation mode within 30 seconds without operator intervention and wit$_h$out loss of any stored data.
	After voltage interruptions the equipment returns to previous operating mode without operator intervention and without loss of any stored data.

Fetal Monitors

Fetal Monitor Performance Specifications		
Alarm Signal	System alarm delay. The system alarm delay is the processing time the system needs for any alarm to be indicated on the fetal monitor, after the measurement has triggered the alarm.	less than 4 seconds
	Pause duration	1, 2, 3 minutes or infinite, depending on the configuration
	Extended alarm pause	5 to 10 minutes
	Sound pressure range	min. 0 dB(A) max. 45-85 dB(A)
Review Alarms	Information	all alarms/INOPs, main alarms on/off, alarm silence and time of occurrence
	Capacity	300 items
Real time Clock	Range	from: January 1, 1997, 00:00 to: December 31, 2080, 23:59
	Accuracy	better than ±1 min. per month
	Hold Time	infinite if powered by AC; otherwise at least 48 hours (typical: >72 hours)
Buffered Memory	Hold Time	infinite if powered by AC without power: at least 8 hours
	Contents	active settings, review alarms, stored trace data

Battery Specifications

Performance Specifications		
Avalon FM20/30 Battery Option #E25	Operating Time (with new, fully charged battery)	Basic monitoring configuration: >2 hours (Display Brightness: 70%, Recorder: "On" at 3 cm/min, NBP: Auto Mode at 15 min, 2 US Transducers, 1 Toco+ with MECG, 1 Patient Module with DECG)
	Charge Time	When monitor is off: approx. 6 hours When monitor is in use: more than 10 hours (depending on monitor configuration)

Performance Specification		
Avalon CL Transducer Battery	Operating time	With a new and fully charged battery min. 10 hours
	Charge time	From a "low battery" indication to a "fully charged" indication <3 hours
	Charge time with Avalon FM20/30 Battery Option #E25	From a "low battery" indication to a "fully charged" indication >6 hours

Performance Specification		
Avalon CL F&M Battery	Operating time	With a new and fully charged battery min. 16 hours
	Charge time	From a "low battery" indication to a "fully charged" indication <3 hours
	Charge time with Avalon FM20/30 Battery Option #E25	From a "low battery" indication to a "fully charged" indication >6 hours

Performance Specification		
Avalon CL Wide Range Pod Battery	Operating time	With a new and fully charged battery min. 4 hours
	Charge time	From a "low battery" indication to a "fully charged" indication <3 hours

Fetal / Maternal Specifications

Ultrasound

Complies with IEC 60601-2-37:2007+A1:2015/ EN 60601-2-37:2008

Performance Specifications		
Ultrasound		
Measurement Method		Ultrasound Pulse Doppler
Measurement Range	US	50-240 bpm
Resolution	Display	1 bpm
	Printer	1/4 bpm
Jitter @ 200 bpm		≤3 bpm
US Intensity (867246)	Average output power	P = (12.4 ± 0.4) mW
	Peak-negative acoustic pressure	p_- = (49.1 ± 5.2) kPa
	Output beam intensity (I_{ob}) (= spatial average - temporal average intensity)	I_{sata} = (2.77 ± 0.56) mW/cm^2
	Spatial-peak temporal average intensity	I_{spta} = (21.1 ± 5.1) mW/cm^2
	Effective radiating area @ -12 dB	A_{-12dB} = (4.47 ± 0.89) cm^2
	Thermal index (TI) and mechanical index (MI) are always below 1.0.	
US Intensity (M2736A/AA)	Average output power	P = (7.4 ± 0.4) mW
	Peak-negative acoustic pressure	p_- = (40.4 ± 4.3) kPa
	Output beam intensity (I_{ob}) (= spatial average - temporal average intensity)	I_{sata} = (2.38 ± 0.59) mW/cm^2
	Spatial-peak temporal average intensity	I_{spta} = (15.0 ± 3.2) mW/cm^2
	Effective radiating area @ -12 dB	(3.11 ± 0.74) cm^2
	Thermal index (TI) and mechanical index (MI) are always below 1.0.	

Performance Specifications		
US Intensity CL (866076)	Average output power	P = (12.4 ± 0.4) mW
	Peak-negative acoustic pressure	p_- = (49.1 ± 5.2) kPa
	Output beam intensity (I_{ob}) (= spatial average - temporal average intensity)	I_{sata} = (2.77 ± 0.56) mW/cm^2
	Spatial-peak temporal average intensity	I_{spta} = (21.1 ± 5.1) mW/cm^2
	Effective radiating area @ -12 dB	A_{-12dB} = (4.47 ± 0.89) cm^2
	Thermal index (TI) and mechanical index (MI) are always below 1.0.	
Signal Quality Indication	Poor Quality	empty
	Acceptable Quality	half-full
	Good Quality	full
Beat-to-Beat change (max.) for Ultrasound		28 bpm
US Frequency		1 MHz ± 100 Hz
US Signal range		3.5 µVpp-350 µVpp @ 200 Hz
US Burst	Repetition Rate	3.0 kHz
	Duration	≤100 µs
FMP Signal Range @ 33 Hz		200 µVpp-40 mVpp

Toco

Performance Specifications	
Toco	
Measurement Method	Strain Gauge Sensor Element
Resolution	1/4 unit
Sensitivity	1 unit = 2.5 g
Measurement Range	400 units
Signal Range	0-127 units
Maximum Offset Range	-300 units
Baseline Setting	20 units
Auto Offset Correction	3 seconds after connecting the transducer, the Toco value is set to 20 units
Auto Zero Adjust	Toco value is set to zero following a negative measurement value for 5 seconds

Performance Specifications	
Maternal Pulse from Toco	
Emitted Light Energy	≤15 mW
Wavelength Range	780-1100 nm
Range	40-240 bpm

Performance Specifications	
Resolution	1 bpm
Accuracy	± 2% or 1 bpm, whichever is greater
Update Rate	every 4 seconds

IUP

Performance Specifications	
IUP	
Measurement Method	Passive Resistive Strain Gauge Elements
Measurement Range	-100-+300 mmHg
Resolution	1/4 mmHg
Signal Range	-99-127 mmHg or (-13.2-16.9 kPa)
Sensitivity	5 µV/V/mmHg
Offset Compensation	+100- -200 mmHg
Accuracy (not including sensor accuracy)	±0.5% per 100 mmHg
Auto Offset Correction	3 seconds after connecting the transducer, the IUP value is set to 0 mmHg

ECG

Complies with IEC 60601-2-27:2011+AC:2012/ EN 60601-2-27:2014 except clauses listed below:

- 201.6.2, 201.8.5.5
- 201.12.1.101
- 202.6.2.101

Performance Specifications		
ECG		
Performance Specifications Type	DECG	Single Lead ECG (derived from Fetal Scalp Electrode)
	MECG	Single Lead ECG (derived from RA and LA electrodes)
Measurement Range		30-240 bpm
Resolution	Display	1 bpm (display update rate 1 per second)
	Recorder	1/4 bpm
Wave Speed (Global Speed)		6.25 mm/sec, 12.5 mm/sec, 25 mm/sec, 50 mm/sec
Accuracy		±1 bpm or 1%, whichever is greater (non-averaging)
Beat-to-Beat change (max.)		MECG: 28 bpm DECG: 28 bpm (with Artifact Suppression On)
Differential Input Impedance		>15MΩ
Electrode Offset Potential Tolerance		±400 mV
INOP Auxiliary Current (Leads Off Detection)		<100 µA

Performance Specifications		
Input Signal Range	DECG	20 µVpp-6 mVpp
	MECG	150 µVpp-6 mVpp
Dielectric Strength		1500 Vrms
Defibrillator Protection		None
ESU Protection		None
Paced pulse detection		None

WARNING

The fetal/maternal monitor is not a diagnostic ECG device. In particular, the display of fetal/maternal ECG is intended only for evaluating signal quality for fetal/maternal heart rate as derived from the ECG waveform.

When in doubt, it can be used to identify sources of compromised signal quality, such as noise or muscle artifacts. It can subsequently be used to verify the result of measures taken to resolve them (e.g., checking ECG cable connections or adapting the fetal **ArtifactSuppress** configuration).

The safety and effectiveness of the displayed fetal/maternal ECG waveform (i.e., P, QRS, and T segments) for evaluation of fetal/maternal cardiac status during labor have not been evaluated.

Fetal Heart Rate (Ultrasound/DECG) Alarm Specifications			
FHR Alarm Limits	Range	Bradycardia (low limit)	60-200 bpm adjustable in 10 bpm steps Default: 110 bpm
		Tachycardia (high limit)	70-210 bpm adjustable in 10 bpm steps Default: 170 bpm
FHR Alarm Delay	Range	Bradycardia (low limit) Delay	10-300 seconds in steps of 10 seconds + system alarm delay Default: 240 seconds
		Tachycardia (high limit) Delay	10-300 seconds in steps of 10 seconds + system alarm delay Default: 300 seconds
		Signal Loss Delay	10-30 seconds in steps of 10 seconds + system alarm delay

MECG Alarm Specifications	Range	Adjustment	Alarm Delay
MECG Alarm Limits	High Range: 31-240 bpm Default: 120 bpm	1 bpm steps (30-40 bpm) 5 bpm steps (40-240 bpm)	System alarm delay (see "Fetal Monitors" on page 299).
	Low Range: 30-235 bpm Default: 50 bpm		
Extreme Tachycardia	Difference to high limit: 0-50 bpm Default: 20 bpm	5 bpm steps	
	Clamping at: 150-240 bpm Default: 200 bpm	5 bpm steps	
Extreme Bradycardia	Difference to low limit: 0-50 bpm Default: 20 bpm	5 bpm steps	
	Clamping at: 30-100 bpm Default: 40 bpm	5 bpm steps	

Maternal ECG Supplemental Information as required by IEC 60601-2-27		
Heart Rate Averaging Method	The maternal heart rate is computed by averaging the 12 most recent R-R intervals. If each of three consecutive R-R intervals is greater than 1200 ms (i.e. rate less than 50 bpm), then the four most recent R-R intervals are averaged to compute the HR.	
Display Update Rate	2 seconds	
Ventricular tachycardia alarm for waveforms B1 and B2	No heart rate is detected for waveforms B1 and B2, resulting in ***** Extreme Brady** alarm	
Tall T-Wave Rejection Capability	M2735A	1.2 mV T-Wave amplitude
	M2738A	1.4 mV T-Wave amplitude
	CL Toco+ MP, CL ECG/IUP	1.2 mV T-Wave amplitude
	867245 867247 867249	1.2 mV T-Wave amplitude
Response Time of Heart Rate meter to Change in Heart Rate	M2735A, M2738A	HR change from 80-120 bpm Average: 12 seconds HR change from 80-40 bpm Average: 15 seconds
	CL Toco+ MP, CL ECG/IUP	HR change from 80-120 bpm Average: 10 seconds HR change from 80-40 bpm Average: 12 seconds
	867245 867247 867249	HR change from 80-120 bpm Average: 11 seconds HR change from 80-40 bpm Average: 13 seconds

Maternal ECG Supplemental Information as required by IEC 60601-2-27		
Heart Rate Meter Accuracy and Response to Irregular Rhythm	M2735A, M2738A	Ventricular bigeminy 40-60 bpm Slow alternating ventricular bigeminy 45 bpm Rapid alternating ventricular bigeminy 163 bpm Bidirectional systoles 63-73 bpm
	CL Toco+ MP, CL ECG/IUP	Ventricular bigeminy 40-60 bpm Slow alternating ventricular bigeminy 30 bpm Rapid alternating ventricular bigeminy 70-163 bpm Bidirectional systoles 63-73 bpm
	867245 867247 867249	Ventricular bigeminy 64-97 bpm Slow alternating ventricular bigeminy 93 bpm Rapid alternating ventricular bigeminy 92-138 bpm Bidirectional systoles 57-67 bpm

aFHR, aHR, aToco

aFHR		
Measurement Method		electrocardiography
Measurement Range		60-240 bpm
Resolution	Display	1 bpm
	Printer	1/4 bpm
Accuracy		±1 bpm

aHR		
Measurement Method		electrocardiography
Measurement Range		40-240 bpm
Resolution	Display	1 bpm
	Printer	1/4 bpm
Accuracy		±1 bpm

aToco	
Measurement Method	uterine electromyography
Measurement Range	0-500 µV
Signal Range	0-100 units
Accuracy	±5%

Noninvasive Blood Pressure

Complies with IEC 80601-2-30:2009 + A1:2013 / EN 80601-2-30:2010 + A12015.

Performance Specifications		
Measurement Ranges	Systolic	30-270 mmHg (4-36 kPa)
	Diastolic	10-245 mmHg (1.5-32 kPa)
	Mean	20-255 mmHg (2.5-34 kPa)
Accuracy [1]		Max. Std. Deviation: 8 mmHg (1.1 kPa) Max. Mean Error: ±5 mmHg (±0.7 kPa)
Pulse Rate	Range	40-300 bpm
	Accuracy (average over noninvasive blood pressure measurement cycle)	40-100 bpm: ±5 bpm
		101-200 bpm: ±5% of reading
		201-300 bpm: ±10% of reading
Measurement Time		Typical at HR >60 bpm Auto/manual: 30 seconds (adult) Maximum time: 180 seconds (adult)
Cuff Inflation Time		Typical for normal adult cuff: Less than 10 seconds
Initial Cuff Inflation Pressure		165 ±15 mmHg
Auto Mode Repetition Times		1, 2, 2.5, 3, 5, 10, 15, 20, 30, 45, 60, or 120 minutes
Venipuncture Mode Inflation		
Inflation Pressure		20-120 mmHg (3-16 kPa)
Automatic deflation after		170 seconds

*1: Clinical investigation with the auscultatory reference method

- The 5th Korotkoff sound (K5) was used to determine the diastolic reference pressures.
- The approximation MAP = (2*DIA + SYS) / 3 was used to calculate reference MAP (mean arterial pressure) values from the systolic and diastolic reference pressures.

Alarm Specifications	Range	Adjustment	Alarm Delay
Systolic	Adult: 30-270 mmHg (4-36 kPa)	10-30 mmHg: 2 mmHg (0.5 kPa) >30 mmHg: 5 mmHg (1 kPa)	System alarm delay (see "Fetal Monitors" on page 299).
Diastolic	Adult: 10-245 mmHg (1.5-32 kPa)		
Mean	Adult: 20-255 mmHg (2.5-34 kPa)		

Overpressure Settings	Adjustment
> 300 mmHg (40 kPa) > 2 sec	not user adjustable

SpO2

Complies with ISO 80601-2-61:2011 / EN ISO 80601-2-61:2011.

Measurement Validation: The SpO_2 accuracy has been validated in human studies against arterial blood sample reference measured with a CO-oximeter. Pulse oximeter measurements are statistically distributed, only about two-thirds of the measurements can be expected to fall within the specified accuracy compared to CO-oximeter measurements.

Display Update Period: Typical: 2 seconds, maximum: 30 seconds. Maximum with noninvasive blood pressure INOP suppression on: 60 seconds.

SpO_2 Performance Specifications		
SpO $_2$ The specified accuracy is the root-mean-square (RMS) difference between the measured values and the reference values	Range	0-100%
	Accuracy	**Philips Reusable Sensors:** M1191A/B, M1191AL/BL, M1191ANL, M1192A, M1192AN = 2% (70%-100%) M1191T, M1192T, M1194A, M1194AN, M1196A, M1196T = 3% (70%-100%) **Philips Disposable Sensors with M1943A(L):** M1131A, M1901B, M1903B, M1904B = 3% (70%-100%) M1133A, M1134A = ±2% (70%-100%) **Nellcor® Sensors with M1943A(L):** MAX-A, MAX-AL, MAX-P, MAX-N, D-25, D-20, N-25, OxiCliq A, P, N = 3% (70%-100%) **Masimo Reusable Sensors® with LNOP MP12 or LNC MP10:** LNOP DC-I, LNOP DC-IP, LNOP YI, LNCS DC-I, LNCS DC-IP: 2% (70%-100%) LNOP TC-I, LNCS TC-I: 3.5% (70%-100%) **Masimo Disposable Sensors® with LNOP MP12 or LNC MP10:** LNOP Adt, LNOP Adtx, LNOP Pdt, LNOP Pdtx, LNCS Adtx, LNCS Pdtx: 2% (70%-100%) LNOP Neo-L, LNCS Neo-L: 3% (70%-100%)
	Resolution	1%
Pulse	Range	30-300 bpm
	Accuracy	±2% or 1 bpm, whichever is greater
	Resolution	1 bpm
Sensors	Wavelength range	500-1000 nm Information about the wavelength range can be especially useful to clinicians (for instance, when photodynamic therapy is performed).
	Emitted Light Energy	≤15 mW
Pulse Oximeter Calibration Range		70%-100%

SpO_2 Alarm Specifications	**Range**	**Adjustment**	**Delay**
SpO $_2$	50-100%	1% steps	(0, 1, 2, 3, ... 30) + 4 seconds
Desat	50-Low alarm limit	1% steps	

SpO_2 Alarm Specifications	Range	Adjustment	Delay
Pulse	30-300 bpm	1 bpm steps (30-40 bpm) 5 bpm steps (40-300 bpm)	max. 14 seconds
Tachycardia	Difference to high limit 0-50 bpm	5 bpm steps	max. 14 seconds
	Clamping at 150-300 bpm	5 bpm steps	
Bradycardia	Difference to low limit 0-50 bpm	5 bpm steps	max. 14 seconds
	Clamping at 30-100 bpm	5 bpm steps	

Tympanic Temperature

Complies with:

- EN 12470-5 (Clinical thermometers - Part 5:2003: Performance of infra-red thermometers)
- ASTM E1965-98 (Infrared Thermometers for Intermittent Determination of Patient Temperature)

with minor exceptions as noted below.

The fetal monitor additionally complies with ISO 80601-2-56:2017 / EN ISO 80601-2-56:2017.

Performance Specifications		
Temperature Resolution		0.1°C or 0.1°F
Response Time		less than 2 seconds
Temperature Calibrated Accuracy Specifications (out of the Factory)		
Ambient Temperature	**Target Temperature**	**Accuracy**
25.0°C (77.0°F)	37.7°C-38.9°C (98.4°F-102.0°F)	±0.1°C (±0.2°F)
16.0°C-33.0°C (60.8°F-91.4°F)	33.0°C-42.0°C (91.4°F-107.6°F)	±0.2°C (±0.4°F)
Temperature Calibrated Accuracy Specifications (after recalibration using Genius 2 Checker/Calibrator)		
Ambient Temperature	**Target Temperature**	**Accuracy**
16.0°C-33.0°C (60.8°F-91.4°F)	36.0°C-39.0°C (96.8°F-102.2°F)	±0.2°C (±0.4°F)
16.0°C-33.0°C (60.8°F-91.4°F)	<36.0°C or >39.0°C (<96.8°F or >102.2°F)	±0.3°C (±0.5°F)
ASTM laboratory requirement for IR thermometers in the display range 37.0°C-39.0°C (98.0°F-102.0°F) is **±0.2°C (±0.4°F)**, whereas for mercury-in-glass and electronic thermometers, the requirement per ASTM standards E667-86 and E1112-86 is **±0.1°C (±0.2°F)**. Clinical accuracy characteristics and procedures are available from Covidien llc on request. To verify the accuracy, use a certified black body as specified in EN ISO 80601-2-56, Annex C, or use a Genius 2 Checker/Calibrator - available from Covidien llc under part number 303097. Clinical repeatability: meets section A.5 of EN ISO 80601-2-56(E) per Covidien llc technical report. Data is available from Covidien llc on request.		

Displayed Temperature Measurement Range		
Mode	**Range °C**	**Range °F**
Ear	33.0-42.0°C	91.4-107.6°F
Oral (ear + 0.6°C)	33.6-42.0°C	92.5-107.6°F

Displayed Temperature Measurement Range		
Mode	**Range °C**	**Range °F**
Core (ear + 1.04°C)	34.0-42.0°C	93.2-107.6°F
Rectal (ear + 1.16°C)	34.2-42.0°C	93.6-107.6°F
Caution: ASTM E1965-98 specifies 34.4°C-42.2°C (94°F-108°F)		

Ambient Temperature Range		
Mode	**Range °C**	**Range °F**
Operating 10%-95% RH, non-condensing	16.0-33.0°C	60.8-91.4°F
Storage up to 95% RH, non-condensing	-25.0-55.0°C	-13.0-131.0°F
Caution: EN ISO 80601-2-56 specifies 16.0°C-35.0°C (60.8°F-95.0°F), 10%-95% RH, non-condensing ASTM E1965-98 specifies 16.0°C-40.0°C (60.8°F-104.0°F), up to 95% RH, non-condensing Storing the thermometer outside the specified temperature/humidity range might adversely affect measurement accuracy. Check the calibration after storage in uncertain conditions.		

Tympanic Temperature Alarm Specifications	
Range	33.0°C-42.0°C (91.0°F-108.0°F)
Adjustment	0.5°C steps (33.0°C-35.0°C) 0.1°C steps (35.0°C-42.0°C) 1.0°F steps (91.0°F-95.0°F) 0.2°F steps (95.0°F-108.0°F)
Alarm delay	System alarm delay (see "Fetal Monitors" on page 299).

Physical Specifications

Thermometer	
Dimensions	187 x 44 x 71 mm (7.4 x 1.7 x 2.8 in)
Cable length	spiral cable relaxed: 600 mm (23.6 in) spiral cable extended: 2500 mm (98.4 in)
Weight (including cable)	0.2 kg (0.4 lbs)
Ingress protection classification	IP 21

Base Station	
Dimensions	205 x 65 x 78 mm (8.2 x 2.5 x 3.1 in)
Weight (excluding cable)	0.3 kg (0.7 lbs)

Recorder Specifications

Built-in Thermal Array Fetal Trace Recorder			
Mechanism	Thermal Array Recorder		
Paper & Printing	Type		Standard Z-fold paper
	Standard Speeds (real-time traces)		3 cm/min, 2 cm/min, 1 cm/min
	Fast Print Speed (stored traces)		Max. 20 mm/s Print speed is variable and depends on the print load
	ECG Wave Print Speed (not real-time)		Emulated 25 mm/s Print speed is variable and depends on the print load
	Paper Advance		20 mm/s
	Sensing		Optical Reflex Sensor for black page marks
Accuracy @ 3 cm/min, 2 cm/min, 1 cm/min	±5 mm/page		
Usable Print Width	128 mm		
Resolution	8 dots/mm (200 dpi)		
Time Delay to see trace on paper	<30s @ 1 cm/min		
Trace Separation Offset for FHR (Ultrasound and DECG)	Twin	Standard	FHR2 +20 bpm
		Classic	FHR1 +20 bpm in the presence of FHR2
	Triplet	Standard	FHR2 +20 bpm FHR3 -20 bpm
		Classic	FHR1 +20 bpm FHR3 -20 bpm in the presence of FHR2 and/or FHR3

External Displays: FM40/FM50 Only

External displays can be connected with a maximum cable run of 10 m. External displays must be approved for medical use (IEC 60601-1). The video output of the Avalon FM40/FM50 has VGA resolution.

Manufacturer's Information

You can write to **Philips** at this address:

Philips Medizin Systeme Böblingen GmbH
Hewlett-Packard-Str. 2
71034 Böblingen
Germany

Visit our website at: www.healthcare.philips.com

Australia Sponsor

Philips Electronics Australia Ltd
65 Epping Road
North Ryde, NSW Australia 2113

Importer for European Union

For all Philips branded products used with the Avalon Fetal Monitors, if not manufactured by Philips Medizin Systeme Böblingen GmbH, the Importer in the European Union is:

Trademark Acknowledgment

Oxisensor™ *II*, Oxi-Cliq™, and OxiMax™ are trademarks of Tyco Healthcare Group LP, Nellcor Puritan Bennett Division.

Regulatory and Standards Compliance

The fetal monitors and their current class IIa/b accessories are in conformity with the requirements of the European Medical Devices Directive 93/42/EEC and bear the CE marking:

CE 0123

The current class I accessories for fetal monitors are in conformity with the requirements of the European Medical Devices Directive 93/42/EEC and bear the CE marking:

CE

The Avalon CL Transducer System is in conformity with the requirements of the European Radio Equipment Directive 2014/53/EU. The Avalon CL base station used in this system is class 1 and the Avalon CL transducers of this system are class 1 under the scope of the RED Directive.

To obtain a copy of the original Declaration of Conformity, please contact Philips at the address given in the "Manufacturer's Information" on page 311 section of this manual.

The following products do not meet the requirements of the IEC 60601-1-2:2014 / EN 60601-1-2:2015. They are no longer presumed to comply with the corresponding essential requirements of the Medical Device Directive 93/42/EEC. Therefore shipped after December 31, 2018 they no longer carry the CE marking accordingly.

- Toco^{+}Transducer (M2735A)
- Toco MP Transducer (M2734B)
- Ultrasound Transducer (M2736A/AA)
- Patient Module (M2738A)

Safety and Performance

The fetal monitors comply with the following major international safety and performance standards:

- IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013
- IEC 60601-1-6:2010+A1:2013 / EN 60601-1-6:2010+A1:2015
- IEC 60601-1-8:2006+A1:2012 / EN 60601-1-8:2007+A1:2013
- IEC 60601-2-49:2011 / EN 60601-2-49:2015
- ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009/2012+A2:2010/2012
- CAN/CSA C22.2#60601-1-14
- JIS T 1303 2005

The possibility of hazards arising from hardware and software errors was minimized in compliance with ISO 14971:2007/EN ISO 14971:2012, and IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013.

Alarm sounds are compliant with standard IEC 60601-1-8:2006+A1:2012 / EN 60601-1-8:2007+A1:2013.

Compatibility

When your fetal monitor is compliant with IEC 60601-1:1988+A1:1991+A2:1995 / EN 60601-1:1990+A1:1993+A2:1995 (Edition 2) and related standards, it can still be used with the Avalon CL Transducer System and the software upgrade J.3 or higher, and all measurement accessories that are compliant with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013 (Edition 3) and related standards.

When your fetal monitor is compliant with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013 (Edition 3) and related standards, it can still be used with the Avalon CTS Transducer System, and all measurement accessories that are compliant with IEC 60601-1:1988+A1:1991+A2:1995 / EN 60601-1:1990+A1:1993+A2:1995 (Edition 2) and related standards.

Radio

The Avalon CL Transducer System complies with the following major international radio standards:

- ETSI EN 300 220-1:2017
- ETSI EN 300 220-2:2017
- ETSI EN 300 328:2016
- FCC 47 CFR Part 95
- FCC 47 CFR Part 2 & 15
- IC RSS-210 Issue 8
- ARIB STD-T108
- ARIB STD-T66
- AS/NSZ 4268

Safety Tests Fetal Monitor

All the safety tests and procedures required after an installation, or an exchange of system components are described in your monitor's Service Guide. These safety tests are derived from international standards, but may not be sufficient to meet local requirements.

WARNING

- Do not use additional AC mains extension cords or multiple portable socket-outlets. If a multiple portable socket-outlet is used, the resulting system must be compliant with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013.
- Do not connect any devices that are not supported as part of a system.
- Do not use a device in the patient vicinity if it does not comply with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013. The whole installation, including devices outside of the patient vicinity, must comply with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013. Any non-medical device, including a PC running an OB TraceVue/IntelliSpace Perinatal system, placed and operated in the patient's vicinity must be powered via a separating transformer (compliant with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+A1:2013) that ensures mechanical fixing of the power cords and covering of any unused power outlets.
- Do not use USB devices with own power supplies, unless an appropriate separation device is used, (either between USB interface and device or between device and power).

During the installation the fetal monitor is configured for your environment. This configuration defines your custom default settings you work with when you switch on your fetal monitor. See the fetal monitor's Service Guide and the Configuration Guide for details on how to configure your fetal monitor.

Electromagnetic Compatibility (EMC)

The device and its accessories, except the Avalon Fetal Toco^{+}Transducer (M2735A), Toco MP Transducer (M2734B), Ultrasound Transducer (M2736A/AA), the Patient Module (M2738A), the IntelliVue CL NBP Pod (865216), and the IntelliVue CL SpO_2 Pod (865215), listed in the accessories section, comply with the following EMC standards:

- IEC 60601-1-2:2014 / EN 60601-1-2:2015

Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment. You must operate your monitoring equipment according to the EMC information provided in this book. Before using the device, assess the electromagnetic compatibility of the device with surrounding equipment.

This ISM device complies with Canadian ICES-003:2012. Cet appareil ISM est conforme à la norme NMB-003 du Canada.

CAUTION

- **FM20/FM30 only:** Although this is an electrical Class II device, it has a protective earth conductor which is needed for EMC purposes.
- Always use the supplied power cord with the three-prong plug to connect the monitor to AC mains. Never adapt the three-prong plug from the power supply to fit a two-slot outlet.

WARNING

The use of accessories, transducers, and cables other than those specified, may result in increased electromagnetic emissions, or decreased electromagnetic immunity of the device.

WARNING

Do not use cordless/mobile phones, or any other portable RF communication system within the patient vicinity, or within a 1.0 m radius of any part of the fetal monitoring system.

WARNING

For paced patients: The radiated SRR power of the CL SpO_2 and CL NBP Maternal Cableless Measurement Devices, and other sources of radio-frequency energy, when used in very close proximity of a pacemaker, might be sufficient to interfere with pacemaker performance. Due to shielding effects of the body, internal pacemakers are somewhat less vulnerable than external pacemakers. However, caution should be exercised when monitoring paced patients.

In order to minimize the possibility of interference, avoid positioning and wearing the Cableless Measurement Devices in very close proximity to a pacemaker. Consult the pacemaker manufacturer for information on the RF susceptibility of their products.

CAUTION

High power radars are allocated as primary users (meaning they have priority) of the bands 5250-5350 MHz and 5650-5850 MHz and these radars could cause interference and/or damage to LE-LAN devices.

NOTE

Based on their emission characteristics, the Avalon FM40/FM50 and Avalon CL system are suitable for use in hospitals only (CISPR 11 class A). If they are used in a residential environment (for which CISPR 11 class B is usually required), these monitors might not offer adequate protection to radio frequency communication services. You might need to take mitigation measures, such as relocating or reorienting the equipment.

EMC Testing

CAUTION

Fetal parameters, especially ultrasound and ECG, are sensitive measurements involving small signals, and the monitoring equipment contains very sensitive high gain front-end amplifiers. Immunity levels for radiated RF electromagnetic fields and conducted disturbances induced by RF fields are subject to technological limitations. To ensure that external electromagnetic fields do not cause erroneous measurements, it is recommended to avoid the use of electrically radiating equipment in close proximity to these measurements.

Reducing Electromagnetic Interference

WARNING

The device should not be used adjacent to, or stacked with, other equipment unless otherwise specified.

The product and associated accessories can be susceptible to interference from continuous, repetitive, power line bursts, and other RF energy sources, even if the other equipment is compliant with EN 60601-1-2 emission requirements. Examples of other sources of RF interference are other medical electrical devices, cellular products, information technology equipment, and radio/television transmissions.

When electromagnetic interference (EMI) is encountered, for example, if you can hear spurious noises on the fetal monitor's loudspeaker, attempt to locate the source. Assess the following:

- Is the interference due to misplaced or poorly applied transducers? If so, re-apply transducers correctly according to directions in this book, or in the Instructions for Use accompanying the accessory.
- Is the interference intermittent or constant?
- Does the interference occur only in certain locations?
- Does the interference occur only when in close proximity to certain medical electrical equipment?

Once the source is located, there are a number of things that can be done to mitigate the problem:

1. Eliminating the source. Turn off or move possible sources of EMI to reduce their strength.
2. Attenuating the coupling. If the coupling path is through the patient leads, the interference may be reduced by moving and/or rearranging the leads. If the coupling is through the power cord, connecting the system to a different circuit may help.
3. Adding external attenuators. If EMI becomes an unusually difficult problem, external devices such as an isolation transformer or a transient suppressor may be of help. Your service provider can be of help in determining the need for external devices.

Where it has been established that electromagnetic interference is affecting physiological parameter measurement values, a physician, or a suitably qualified person authorized by a physician, should determine if it will negatively impact patient diagnosis or treatment.

System Characteristics

The phenomena discussed above are not unique to this system, but are characteristic of fetal patient monitoring equipment in use today. This performance is due to very sensitive high gain front end amplifiers required to process the small physiological signals from the patient. Among the various monitoring systems already in clinical use, interference from electromagnetic sources is rarely a problem.

Radio Compliance Notice

CAUTION

High power radars are allocated as primary users (meaning they have priority) of the bands 5250-5350 MHz and 5650-5850 MHz and these radars could cause interference and/or damage to LE-LAN devices.

Avalon CL with WMTS

Operation of this equipment requires the prior coordination with a frequency coordinator designated by the FCC for the Wireless Medical Telemetry Service.

This device complies with Part 15 of the FCC Rules and RSS-210 of Industry Canada. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation. Any changes or modifications to this equipment not expressly approved by Philips Medical Systems may cause harmful radio frequency interference and void your authority to operate this equipment.

Radio Information Canada

Installation of this telemetry device is permitted in hospitals and health care facilities only. This device shall not be operated in mobile vehicles (including ambulances and other vehicles associated with health care facilities). The installer/user of this device shall ensure that it is at least 80 km from the Dominion Radio Astrophysical Observatory (DRAO) near Penticton, British Columbia. The coordinates of DRAO are: latitude N 49E 19' 15", longitude W 119° 37' 12". For medical telemetry systems not meeting this 80 km separation (e.g. the Okanagan Valley, British Columbia) the installer/user must coordinate with, and obtain the written concurrence of, the Director of DRAO before the equipment can be installed or operated. The Director of DRAO may be contacted at 250-497-2300 (telephone) or 250-497-2355 (fax). (Alternatively, the Manager, Regulatory Standards, Industry Canada, may be contacted.)

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes: (1) l'appareil ne doit pas produire de brouillage, et (2) l'utilisateur de l'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

L'utilisation de cet appareil de télémesure est permise seulement dans les hôpitaux et établissements de soins de santé. Cet appareil ne doit pas être mis en marche dans des véhicules (y compris les ambulances et autres véhicules associés aux établissements de santé). La personne qui installe/utilise cet appareil doit s'assurer qu'il se trouve à au moins 80 km de l'Observatoire fédéral de radioastrophysique (OFR) de Penticton en Colombie-Britannique. Les coordonnées de l'OFR sont: latitude N 49° 19' 15», longitude O 119° 37 12 ". La personne qui installe/utilise un système de télémesure médicale ne pouvant respecter cette distance de 80 km (p. ex. dans la vallée de l'Okanagan (Colombie-Britannique), doit se concerter avec le directeur de l'OFR et obtenir de sa part une autorisation écrite avant que l'équipement ne puisse être installé ou mis en marche. Le directeur de l' OFR peut être contacté au 250-497-2300 (tél.) ou au 250-497-2355 (télécopieur). (Le Directeur des Norm es réglementaires d'Industrie Canada peut également être contacté).

CAUTION

High power radars are allocated as primary users (meaning they have priority) of the bands 5250-5350 MHz and 5650-5850 MHz and these radars could cause interference and/or damage to LE-LAN devices.

Avalon CL with T108

Japanese Radio Law and Japanese Telecommunications Business Law Compliance.

This device is granted pursuant to the Japanese Radio Law (電波法)
and the Japanese Telecommunications Business Law (電気通信事業法).

本製品は、電波法および電気通信事業法に基づき認可されています。

This device should not be modified (otherwise the granted designation number will become invalid).

Radio Frequency Radiation Exposure Information

The radiated output power of the Avalon CL Transducer System is far below the FCC radio frequency exposure limits.

CL Wide Range Pod

For body worn operation, this device has been tested and meets FCC RF exposure guidelines when used in the standard configuration with the rear side towards the body, without a gap. Alternatively, it can be used with any accessory that positions the front side of the device a minimum of 10 mm from the body. The accessory itself must not contain any metal parts. Use of other accessories may not ensure compliance with FCC RF exposure guidelines.

Nevertheless it is strongly recommended to operate the CL Wide Range Pod with the rear side towards the body to achieve best possible radio performance.

Environment

Before operation, make sure that the fetal monitor is free from condensation. This can form when equipment is moved from one building to another, and is exposed to moisture and differences in temperature.

Use the monitor in an environment which is reasonably free from vibration, dust, corrosive or explosive gases, extremes of temperature, humidity, and so forth. It operates within specifications at ambient temperatures between 0-+45°C (32°F-113°F). Ambient temperatures that exceed these limits can affect the accuracy of the system, and can damage the components and circuits.

Ambient temperature ranges for storage are -20°C-+60°C (-4°F-140°F) for the monitor, and -40°C-+60°C (-40°F-140°F) for transducers.

The transducers are watertight to a depth of 1.0 m for at least five hours (rated IP 68).

WARNING

- **Leakage currents:** If several items of equipment used to monitor a patient are interconnected, the resulting leakage current may exceed allowable limits.
- **ECG electrodes:** NEVER allow ECG electrodes to contact other electrical conductive parts, including earth.
- **Explosion Hazard:** Do not use in the presence of flammable anesthetics, such as a flammable anesthetic mixture with air, oxygen, nitrous oxide, or in oxygen rich environment. Use of the devices in such an environment may present an explosion hazard.

Monitoring After a Loss of Power

If the monitor is without power for **less** than one minute, monitoring will resume with all active settings unchanged. If the monitor is without power for **more** than one minute, the behavior depends on your configuration. If **Automat. Default** is set to **Yes**, the **User Defaults** will be loaded when power is restored. If **Automat. Default** is set to **No**, all active settings are retained, if power is restored within 48 hours. The **Automat. Default** setting is made in Configuration Mode.

FM20/30 with Battery Option, FM40/50

When power is lost - no power is available from the AC power source, or from the battery - a beeper will sound. The tone can be silenced by pressing the On/Standby button.

ESU, MRI, and Defibrillation

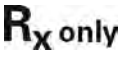
WARNING

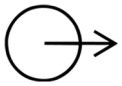
The fetal/maternal monitors are NOT intended for use during defibrillation, electro-surgery, or MRI. Remove all transducers, sensors, and accessories before performing electro-surgery, defibrillation, or MRI, otherwise harm to the patient or the user can result.

Symbols

Symbols on the System

These symbols can appear on the monitor and its associated equipment and packaging.

Symbols			
	This safety symbol indicates that you have to consult the Instructions for Use (this document), and particularly any warning messages. The symbol can be also printed out black and white.		Operating instructions should be considered when operating the device.
	This safety symbol indicates that you have to consult the Instructions for Use (this document), and particularly any warning messages. The symbol can be also printed out black and white.		Indicates that IfU is available in electronic form at www.philips.com/IFU
	This symbol indicates that you have to consult the Instructions for Use (this document).		Prescription use only
	Equipotential grounding point (FM40/FM50)		Protective earth terminal (FM40/FM50)
	Type CF equipment, not defibrillation proof		Electrical Class II equipment, in which the protection against electric shock relies on double or reinforced insulation (FM20/FM30)
	Type BF		It is unsafe to use the device in MR environments. The symbol can be also printed out black and white.

Symbols			
	Symbol indication for non-ionizing radiation		Temperature limitations
	Humidity limitations		Atmospheric pressure limitations
	Keep away from rain		Indicates the number of pieces in packaging
IP X1	Ingress Protection code according to IEC 60529. The monitors and interface cable for the Avalon CTS (M2731-60001/ M2732-60001) are rated IP X1 (protection against water dripping vertically only)	IP 21	Ingress Protection code according to IEC 60529 (protection against ingress of water when the water is dripping vertically)
IP 31	Ingress Protection code according to IEC 60529 (protection against condensation only)	IP 32	Ingress Protection code according to IEC 60529. The CL Wide Range Pod is rated IP 32 (protection against dripping water when the casing is inclined to 15° degree)
IP 67	Ingress Protection code according to IEC 60529. The IUP/ECG patient module (M2738A) is rated IP 67 (protection against dust, access to hazardous parts, and the effects of continuous immersion in water to a depth of 0.5 meter for 30 minutes)	IP 68	Ingress Protection code according to IEC 60529. All transducers (excluding M2738A) are rated IP 68 (protection against dust, access to hazardous parts, and the effects of continuous immersion in water to a depth of 1.0 meter for five hours)
	Power-On/Off Switch - FM20/FM30 without Battery Option		Power-On/StandBy button - FM40/FM50 and FM20/30 with Battery Option
	Power-On LED		Button to open paper drawer/paper eject. (FM40/FM50)
	Connection direction indicator FM20/ FM30 with battery option		Serial/MIB connector (optional)
	Socket for connecting Avalon CTS interface cable M2732-60001 or Avalon CL interface cable (with black connector, FM40/FM50)		USB interface (optional)
	Fetal sensor socket		SpO_2 socket
	Noninvasive Blood Pressure socket		Analog interface indicator for connection to any analog video display (VGA resolution) FM40/FM50
	The monitor has the triplets option		The monitor is capable of intrapartum monitoring

Symbols			
	Mouse connection indicator (optional)		Keyboard connection indicator (optional)
	Indicates location of the date of manufacture and/or name and address of manufacturer		Indicates the country and date of manufacture, for example DE stands for Germany.
	Indicates the environmental specifications for storage		Indicates the environmental specifications for transport
	Authorized representative in the European Community		Indicates location of serial number
	Indicates location of catalog number		Batch code
	Indicates the model number		Indicates the location of the UDI (Unique Device Identification). Identifier symbol with the GTIN (Global Trade Item Number).
	Medical Device Symbol		GS1 Data Matrix
	Indicates location of service number		Separate collection for waste electrical and electronic equipment
	Use by date		Do not reuse
 	Not manufactured with natural rubber latex		Not manufactured with di-(ethylhexyl)pthalate
	CE marking accompanied by the Notified Body number 0123		CSA US and Canadian mark
	EAC mark		China RoHS
	CE Marking (EU certification mark)		General symbol for recovery/recyclable
无汞	Mercury free		Please recycle waste batteries
	RCM compliance mark	FCC ID	Federal Communications Commission: FCC ID xxxx

Symbols			
CMIIT ID	Chinese Radio marking: CMIIT ID (China Ministry of Industry and Information Technology)	CAN ICES-1/ NMB-1	This ISM device complies with Canadian ICES-001. Cet appareil ISM est conforme à la norme NMB-001 du Canada.
ISM	Industrial, Scientific, & Medical radio frequency band (Avalon CL frequency band used e.g. in the EU)	T108	Association Of Radio Industries And Businesses T108 (Avalon CL frequency band used e.g. in Japan)
WMTS	Wireless Medical Telemetry Service (Avalon CL frequency band used e.g. in North America)	IC: 8888X-XXXXX8	IC-ID (Industry Canada ID) One IC-ID labeling for each built in radio: OBR, SRR
R 202-SMB025 R 202-SMB026		Japanese Radio marking: Radio mark + [R]-symbol + ID	
XXXX88XX8888X8		Taiwan Radio Label (NCC Logo) + ID	
KTL XX88888-8888		Korea radio mark: KC logo, KCC ID number, and Conformity assessment information	

Recorder Symbols

Recorder Symbols			
	Parameter is capable of alarming and alarms were enabled at the time of printing the annotation. The low limit is printed before the symbol, and the high limit after it.		Parameter is capable of alarming, but alarms were disabled at the time of printing the annotation. (Note: There is no alarm related annotation at all if a parameter does not have alarming capability.)
	FMP detection is on		Beginning of the date/time annotation
	Warning (INOP)		Measurement from a cableless transducer (printed next to measurement label)
	Measurement from a cableless measurement Pod		Measurement from cableless devices connected via WLAN (CL Wide Range Pod)
	Pulse from SpO_2		Pulse from Toco$^+$ MP
	Pulse from NBP		Trace separation +20 bpm (in label)
	Trace separation -20 bpm (in label)		Trace separation Off (in trace)
	Trace separation +20 bpm (in trace)		Trace separation -20 bpm (in trace)

Recorder Symbols			
	Trace separation +20 bpm and -20 bpm (in trace)		Coincidence of heart rates is detected
	Marker		Special wave, with different speed and scale (for example, fast printout of MECG wave on FM30)

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Default Settings Appendix

This appendix documents the most important default settings of your fetal monitor and the Avalon CL Base Station with the cableless transducers as they are delivered from the factory. For a comprehensive list and explanation of default settings see the Configuration Guide supplied with your fetal monitor. The monitor's default settings can be permanently changed in Configuration Mode.

Alarm and Measurement Default Settings

Alarm Defaults Settings

Alarm Settings	Default
Alarm Mode	All
Alarm Volume	5
Alarms Off	2 min
Alarm Text	Standard
Visual Latching	Red & Yellow
Audible Latching	Red & Yellow
Alarm Sounds	Traditional
Alarm Low	4

Fetal / Maternal Defaults Settings (International)	
Settings	**Default**
FHR, dFHR, aFHR	On
	Orange
High Limit	160 bpm
Low Limit	110 bpm
Alarms	On
Toco, aToco	Green
Sensitivity	High
IUP	mmHg
	Green
HR, aHR Measurement	Red
High Limit	120 bpm
Low Limit	50 bpm
MECG Alarms	On

Fetal / Maternal Defaults Settings (U.S./CAN)	
Settings	**Default**
FHR, dFHR, aFHR	On
	Red
	Blue
	Green
High Limit	160 bpm
Low Limit	110 bpm
Alarms	On
Toco, aToco	Green (Toco) Yellow (aToco)
Sensitivity	High
IUP	mmHg
	White
HR, aHR Measurement	Red
High Limit	120 bpm
Low Limit	50 bpm
MECG Alarms	On

Coincidence Default Settings

Coincidence Default Settings	
Coincidence Tone	immediately

NBP Default Settings

Factory Default Settings	
Mode	Manual
Repeat Time	15 min
Alarms from	Sys. (International) Sys&Dia&Mean (U.S./CAN)
NBP Sys/Dia only	Yes (International) No (U.S./CAN)
Low Limit	90/50 (60)
High Limit	160/90 (110)
VP Pressure	60 mmHg
Done Tone	Off
Veni Puncture	n/a
Start Time	Synchronized

Factory Default Settings	
NBP	On
Alarms	On
Color	Red
Reference	Auscultatory

CL NBP Default Settings

NBP Settings	Factory Defaults
Sys.High/Sys. Low	160/90
Dia.High/Dia. Low	90/50
MeanHigh/Mean Low	110/50
Alarms	On
Mode	Auto
Repeat Time	10 min
NBP	On
Pulse	On
VP Pressure	60 mmHg
Reference	Auscultatory
Unit	mmHg
Done Tone	Off
Start Time	Synchronized
Aging Time	10 min
AnnouncementTone	Off
Automatic Start	Off
Accelerated Msmt	Off
Color	Red

SpO2 Default Settings

SpO_2 Factory Default Settings	
Desat Limit	80
Low Limit	90
High Limit	100
Desat Delay	20 seconds
Low Alarm Delay	10 seconds
High Alarm Delay	10 seconds
Average	10 seconds
NBP Alarm Suppr.	On

SpO_2 Factory Default Settings	
Alarms	On
Color	Cyan

Pulse Default Settings	
Pulse (SpO_2)	On
High Limit	120 bpm
Low Limit	50 bpm
Δ ExtrBrady Bradycardia: Difference to Low Limit	20 bpm
Brady Clamp	40 bpm
Δ ExtrTachy Tachycardia: Difference to High Limit	20 bpm
Tachy Clamp	200 bpm

CL SpO2 Default Settings

SpO_2 Settings	Factory Defaults
Mode	Continuous
Repeat Time	15 min
Alarms	On
Pulse Volume	1
ToneMod.	Yes
Perfusion	On
Average	10 sec
NBP Alarm Suppr.	On
Aging Time	10 min
Color	Cyan
Average in Mon.	No
Signal Quality	On
Label	SpO_2

SpO2 Alarm Default Settings	Factory Defaults
DesatLim	80
Low Lim	90
High Lim	100
Desat Delay	20 sec
High Alarm Delay	10 sec
Low Alarm Delay	10 sec

Pulse Settings	Factory Defaults
Pulse	On
Alarms	On
High Lim	120
Low Lim	50
Δ Brady	20
Brady Clamp	40
Δ Tachy	20
Tachy Clamp	200

Tympanic Temperature Default Settings

pTemp Settings	Factory defaults
	Adult
Low Limit	36°C (96.8°F)
High Limit	39°C (102.2°F)
Unit	°C
Alarms	On
Color	White

Manually Entered Values Default Settings

Manual Entered Values	Default Settings
Label	Temp (fixed)
Unit	°C
Color	White
Interval	1 h
Msmnt	Off

Recorder Default Settings

Setting	Default
Recorder Speed	3 cm/min
Scale Type	US
Trace Style FHR1	Thick
Trace Style FHR2	Medium
Trace Style FHR3	Extra Thick
Trace Style Toco	Thick
Trace Style HR	Thin
Wave Style ECG	Thin
ECG Wave printing choice	Separate

Setting	Default
Notes Recording	**Along** (International) **Across** (U.S./CAN)
Change Rec Speed	**Config**
Auto Start	**Off**
Confirmed Stop	**Off**
Bridge Paperout	**On**
Paper Save Mode	**Off** (International) **On** (U.S./CAN)
NST Autostart	**On**
NST Autostop	**Off**
Trace Separation	**Off**
Separation Order	**Standard** (International) **Classic** (U.S./CAN)
Intensity	n/a
Cal. Offset	n/a

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