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 152), 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 152).

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 152).

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 152).

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.

Runtime

The run time can be set from 10 to 60 minutes. See the Configuration Guide for details how to set the run time.

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.

10

Non-Stress Test Report

It is generally accepted that a non stress test (**NST**) allows you to assess fetal well-being. The monitor's NST report process uses fetal ultrasound (but not DECG) heart rate traces and the Maternal Toco trace to generate a printed report when criteria are met and it is an indication of the fetal well-being. The American term Non Stress Test (NST) is used for antepartum testing. The interpretation algorithm and rule set are equivalent to those implemented in OB TraceVue Revision G.xx or IntelliSpace Perinatal Revision H.xx and higher, and are based on the 2008 NICHD guidelines.

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 reassuring signs. 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 report.

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 (by color: inverse for "not started yet", white for "running", yellow for "stopped", green for "finished")

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.

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 considered as reassuring criteria.

NST Report Status Window

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 Variability - the current short term variability (STV) value.
- Decelerations - the number of FHR decelerations detected so far.
- FHR Availability - 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 against 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

Field	Field Content
Report Title, with FHR label and date	NST Report for FHR1 on 12 Oct. 2009
Product Information	Product DE53102345 G.01.70, OB A.04.24, Toco DE52401090, FHR1 DE00002345 A.05.26
Patient Information	Rogers, Alice **Age**: 27 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 (Range: 20-24 bpm)
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, v01" 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 Criteria

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 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.

Non-Reassuring Report

If the reassurance criteria are **not** met when the test has run for 90 minutes, or if you stop anytime during the 90 minute period, then the test is stopped, and a report is generated stating the reassurance 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.

10 Non-Stress Test Report

11

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 10).

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 165, "Monitoring Twin FHRs" on page 183, "Monitoring Triple FHRs" on page 191, and "Monitoring Maternal Heart / Pulse Rate" on page 221).

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):

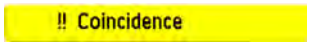
- Electrical impulses from the maternal heart can be transmitted to the fetal monitor through a recently deceased fetus via the spiral scalp electrode, appearing to be a fetal signal source.

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)	✓	✓	✓	✓	
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

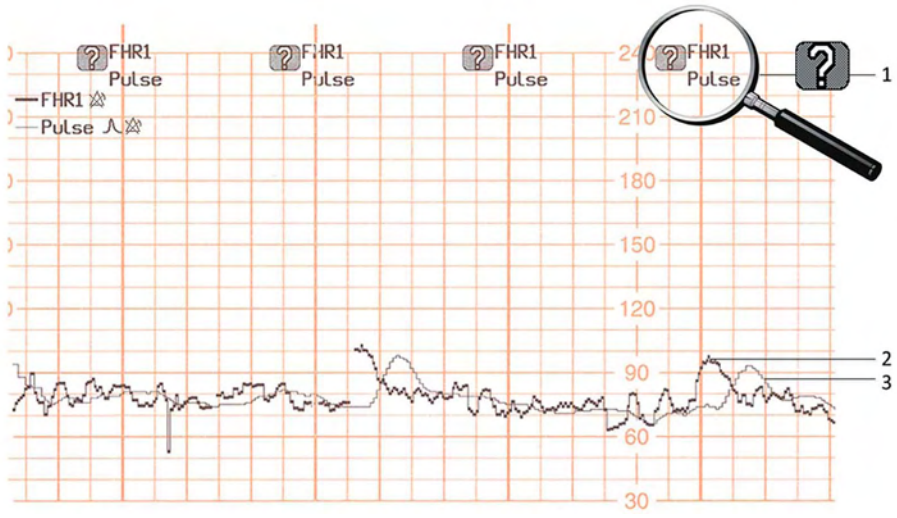
2 Coincidence question mark above **FHR1**

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

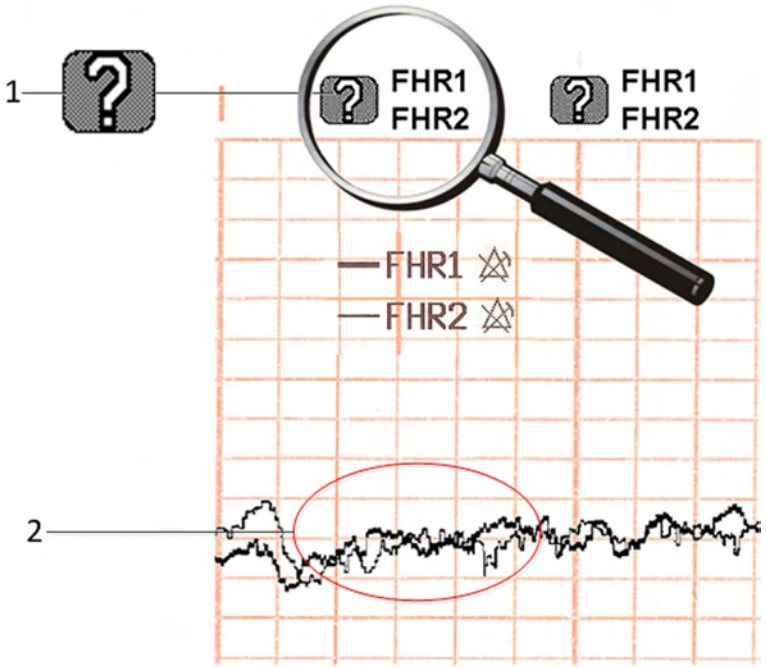
When both **FHR1** and **FHR2** are being monitored, and the measured values are very similar or the same, the coincidence question mark is displayed on the monitor's screen above both of the corresponding numerics (in this case **FHR1** and **FHR2**).

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.

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 10 and "Cross-Channel Verification (CCV)" on page 159).

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:

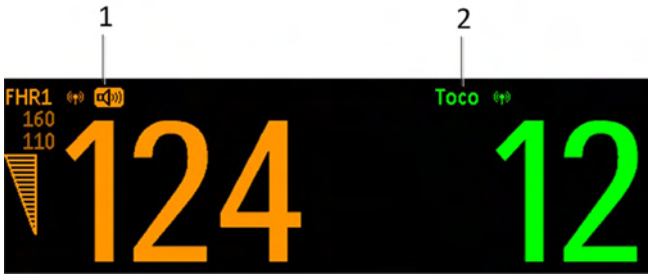
Refer to "Cableless Status Indication" on page 95 for general rules regarding the use of cableless transducers from an Avalon CL or Avalon CTS Cableless Fetal Transducer system.

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 Movement Off**) if the mother is walking. See also "Fetal Movement Profile" on page 170.
- 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 wireless symbol appears next to the measurement label, indicating that the measurement is being made by a cableless transducer.



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.
- 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 Movement Off**) 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.

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. Do not mistake a doubled or elevated maternal HR for FHR.

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).

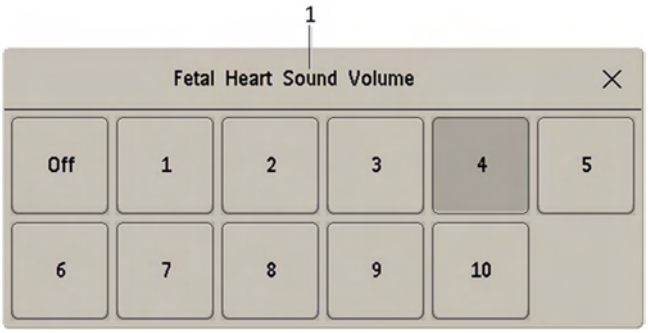
2 Press **Select Audio**. It may take a few seconds for the audio source symbol to appear.

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 171), it is triggered automatically whenever:

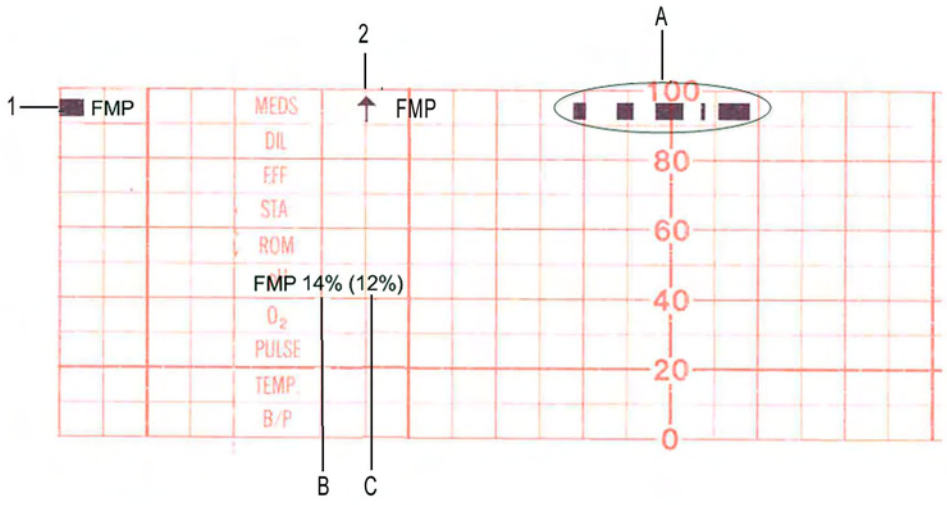
- You connect an ultrasound transducer.
- A patient is discharged.

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 60. 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.

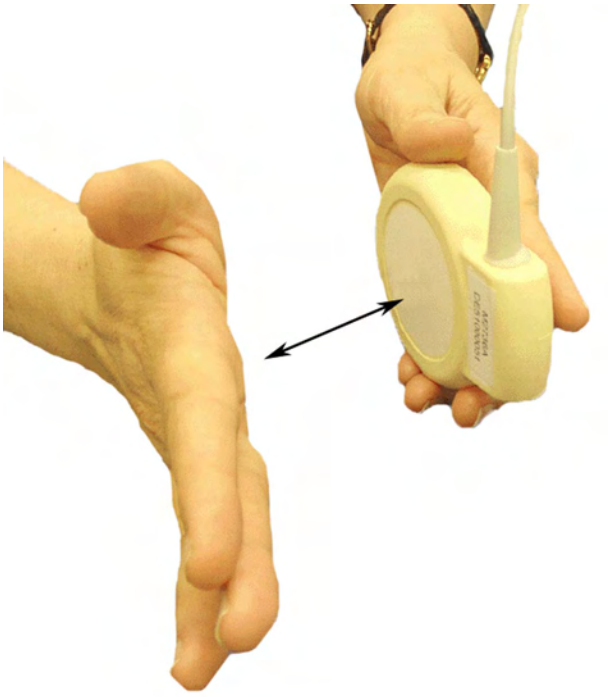
Troubleshooting

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 129.
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, especially during the second stage of labor, or when the maternal pulse is elevated over 100 bpm. 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 183 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

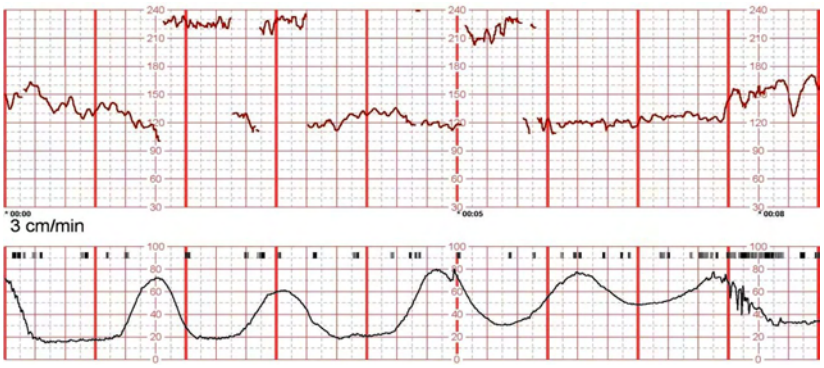
The signal quality on the Avalon fetal monitor is indicated by a triangle on the touchscreen that is displayed in one of three ways:

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).

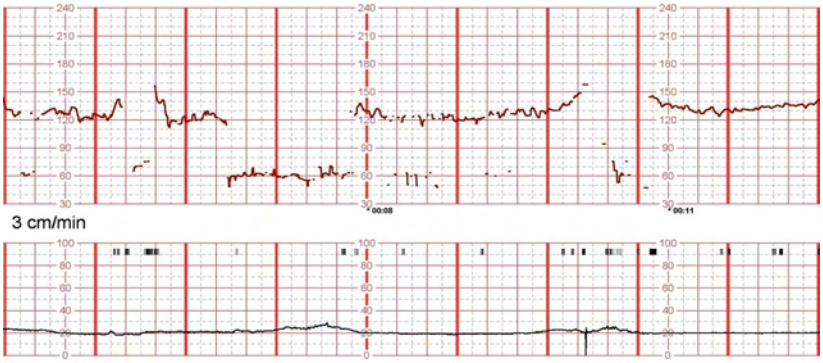
Examples of Artifacts

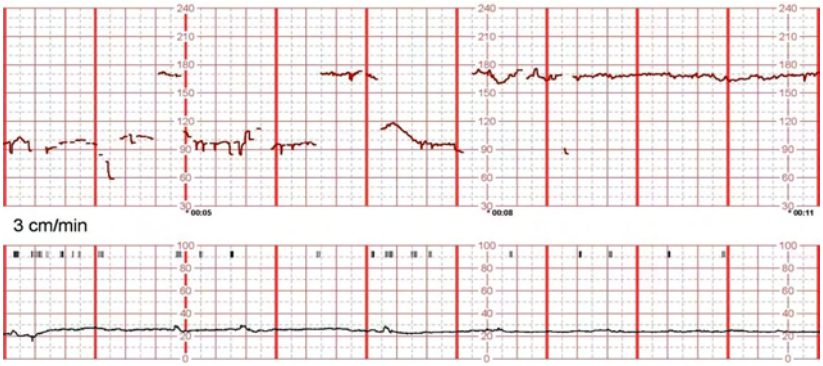
When monitoring the maternal ECG, a beat-to-beat maternal heart rate trace is printed alongside the FHR recorded trace. When monitoring the maternal SpO_2 derived pulse rate, a filtered and averaged heart rate trace is printed.

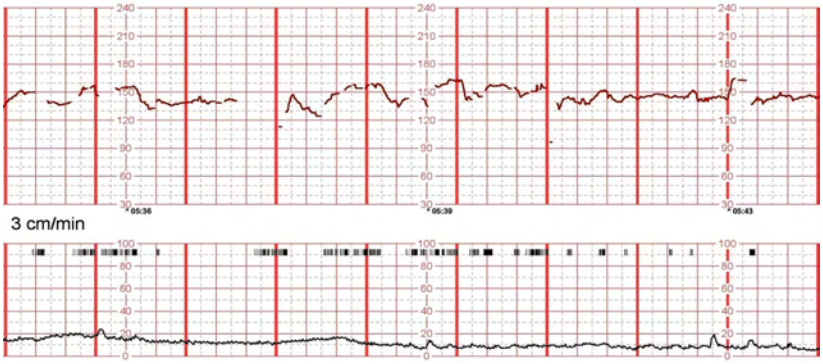
Following are recorded trace examples of complaints received regarding inaccurate output from the Avalon monitors. Scaling is 3 cm/min and 30 bpm/cm.

Double-Counting	
	
Baseline Rate	120
Baseline Variability	Moderate
Accelerations	Present
Decelerations	Not apparent

Double-Counting	
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
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

Noisy/Erratic Signal and Dropout	
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

Klapholz, Henry M, MD; Schifrin, Barry S. MD; Myrick, Richard RS

Obstetrics & Gynecology, September 1974, Volume 44, Issue 3

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12 Monitoring FHR and FMP Using Ultrasound

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 10 and "Cross-Channel Verification (CCV)" on page 159.

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

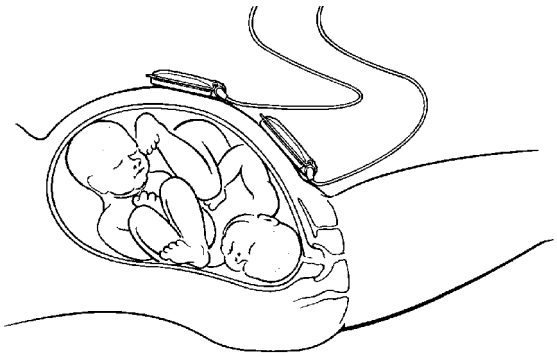
FM40/FM50

- 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 169).

- 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 167.

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 165. 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.

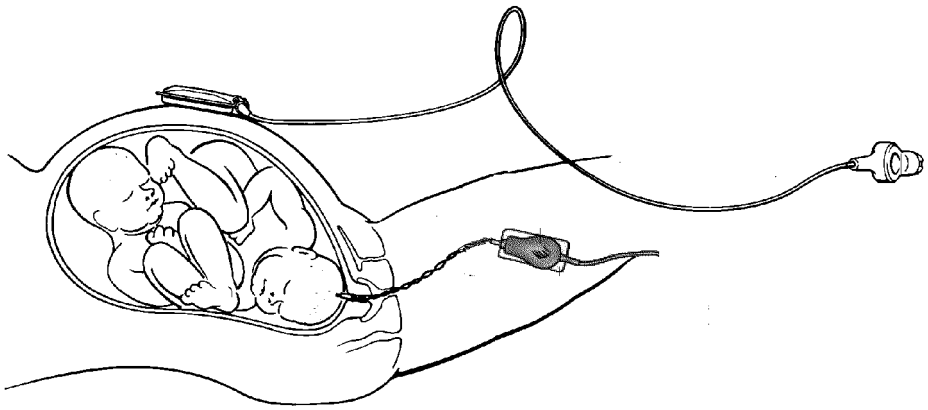


Example of the screen showing ultrasound monitoring of twin FHRs:

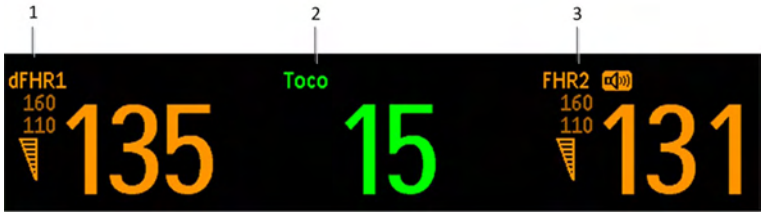
1 FHR 1
2 Toco parameter
3 FHR 2

Monitoring Twins Internally

FM30/50 Monitor one twin using the procedures described in "Monitoring FHR and FMP Using Ultrasound" on page 165. 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 186.

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.

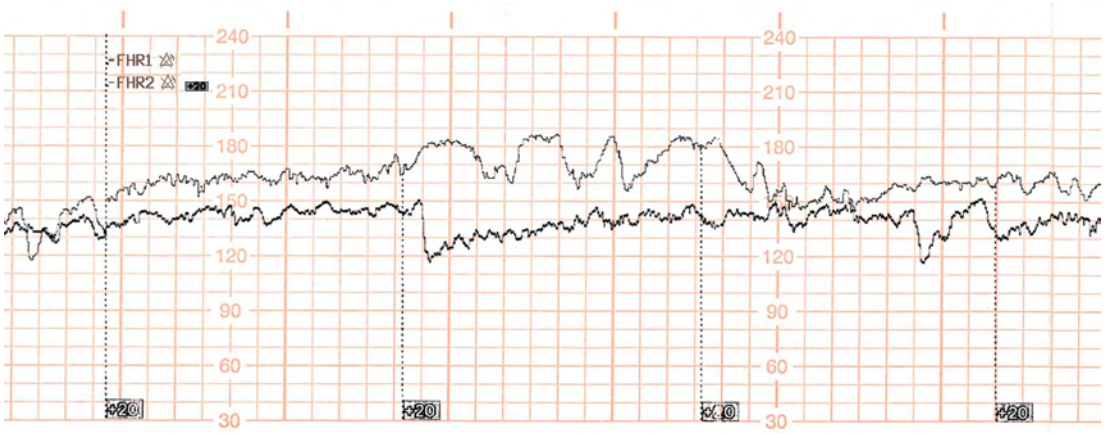
"Standard" Separation Order

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.

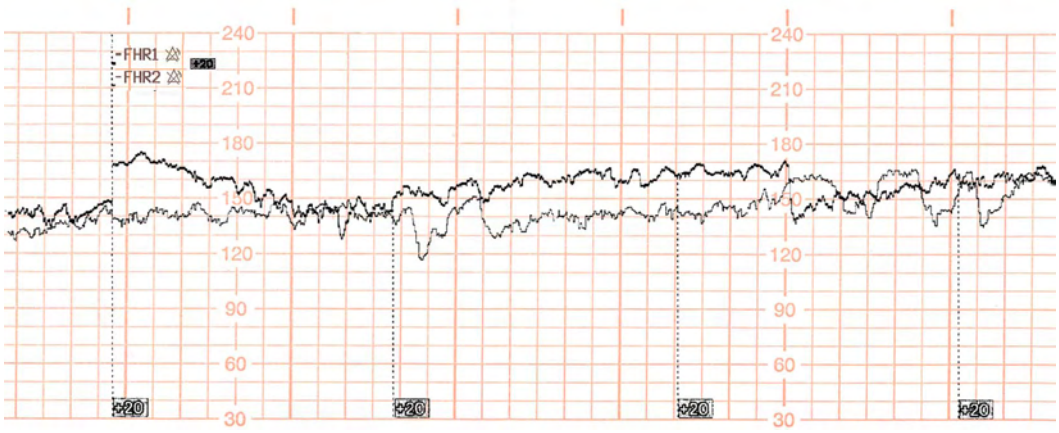
"Classic" Separation Order

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**:

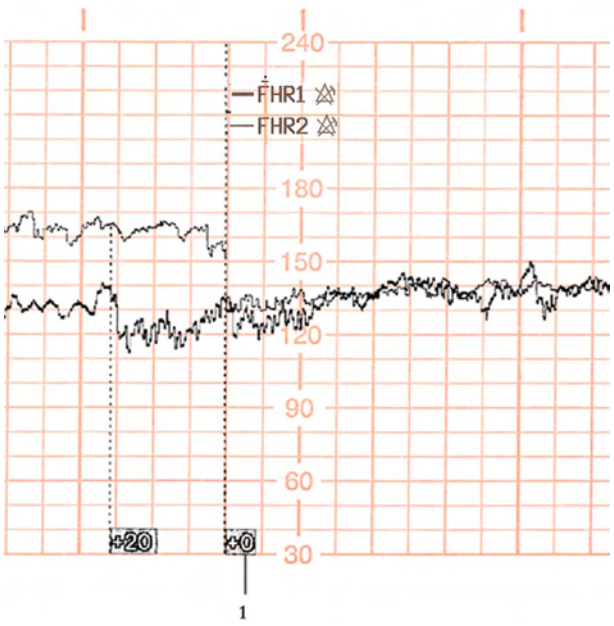
The following trace shows trace separation switched on.



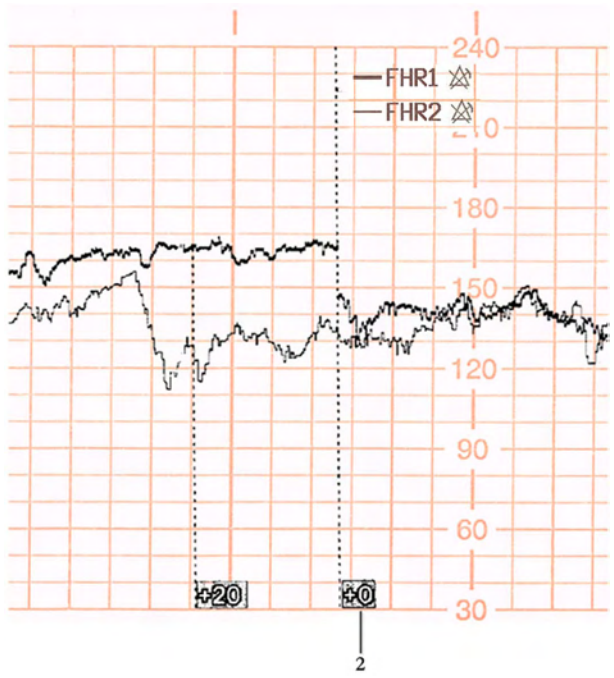
Only the FHR1 trace is shifted. The numerical FHR value displayed on the monitor remains unchanged. Subtract 20 from the recorded trace for FHR1 to obtain the true FHR1 value. For example, if the recorded trace shows 160, then the true FHR is 140.

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 165. 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 164.

For more information, see "Additional Information" on page 173.

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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 10 and "Cross-Channel Verification (CCV)" on page 159.

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 169).

- 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 167.

Monitoring Triplets

To monitor triple FHRs, you need three ultrasound transducers. Follow the procedures described in "Monitoring FHR and FMP Using Ultrasound" on page 165 and in "Monitoring Twin FHRs" on page 183. 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 186.

"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.

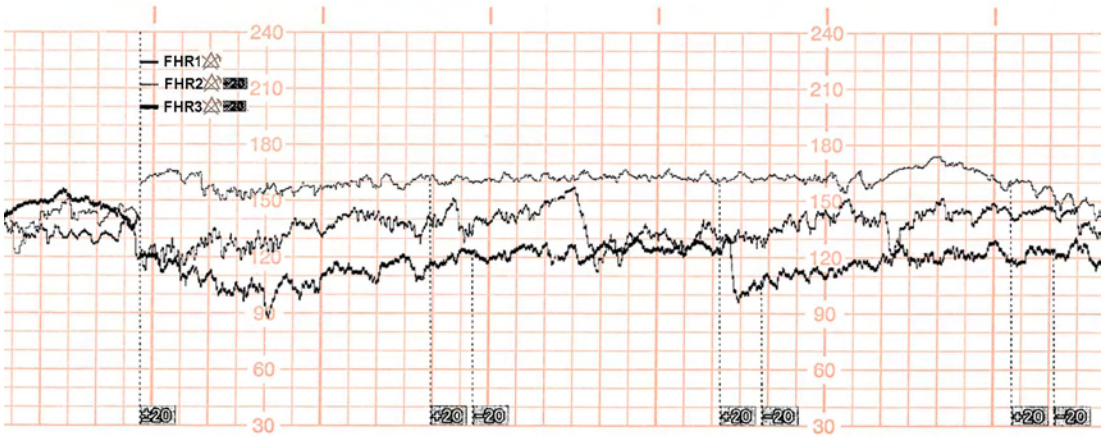
The recorder prints a dotted line labeled **+20** across the FHR scale, to identify the trace for FHR2.

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.

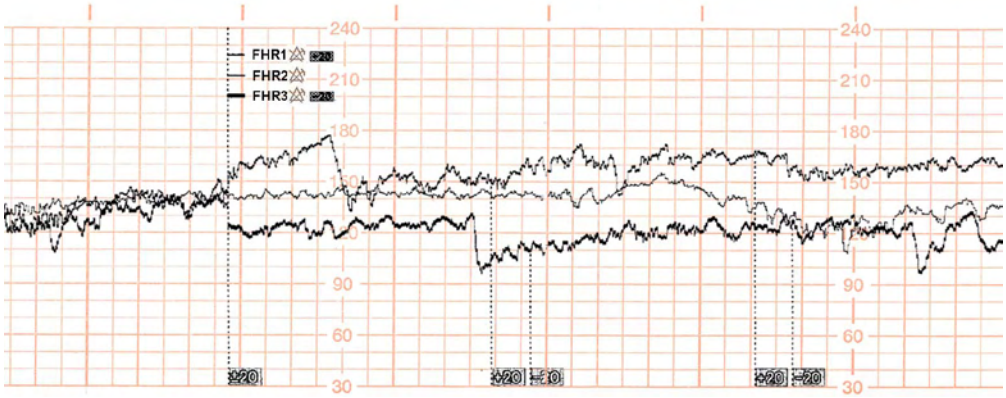
The recorder prints a dotted line labeled **+20** across the FHR scale, to identify the trace for FHR1.

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.

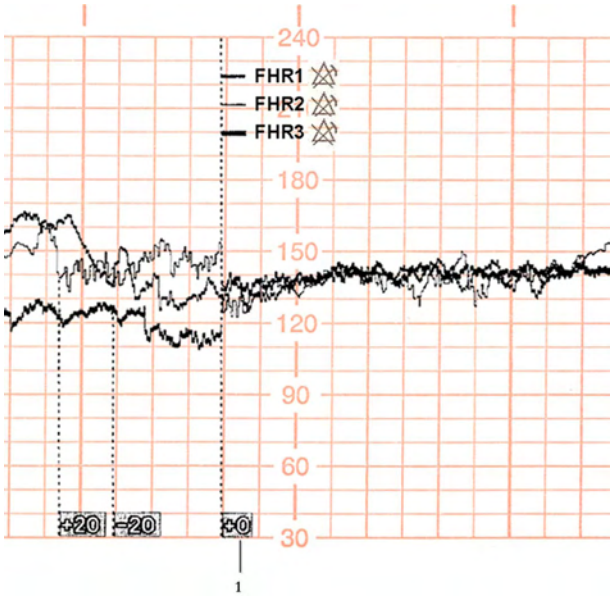
2 See "Switching Trace Separation On and Off" on page 186 for details of how to switch trace separation on or off.

When Trace Separation is On

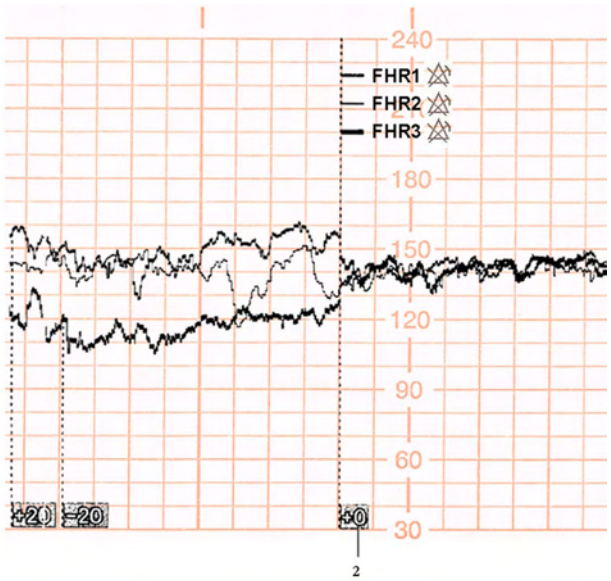
When trace separation is turned on, the recorder prints a dotted line labeled with the three FHRs at the top, and **±20** at the bottom. Examples of the two methods (**Standard**, **Classic**) for determining the trace separation order are provided here.

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 165.

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 164

For more information, see "Additional Information" on page 173.

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 117).

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 221). 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 10 and "Cross-Channel Verification (CCV)" on page 159.

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

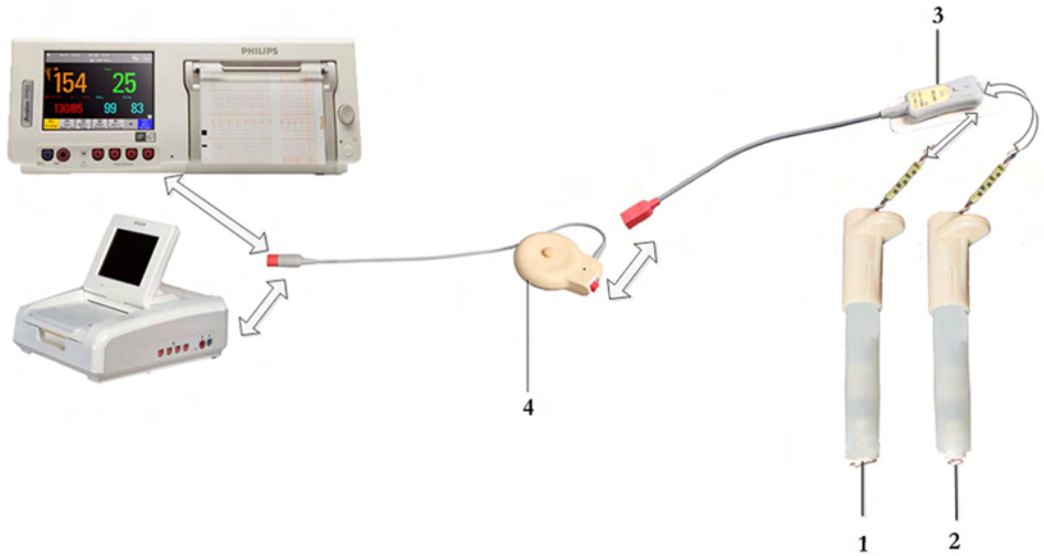
You can measure fetal DECG using the equipment combinations shown in the following figures.

WARNING

Never attempt to connect the fetal scalp electrode to anything other than the correct DECG adapter cable.

DECG with Toco$^+$

The figure below shows the complete connection chain from the fetal scalp electrode to the fetal monitor using the Toco$^+$ transducer.



1 Fetal Scalp Electrode, single spiral (989803137631)

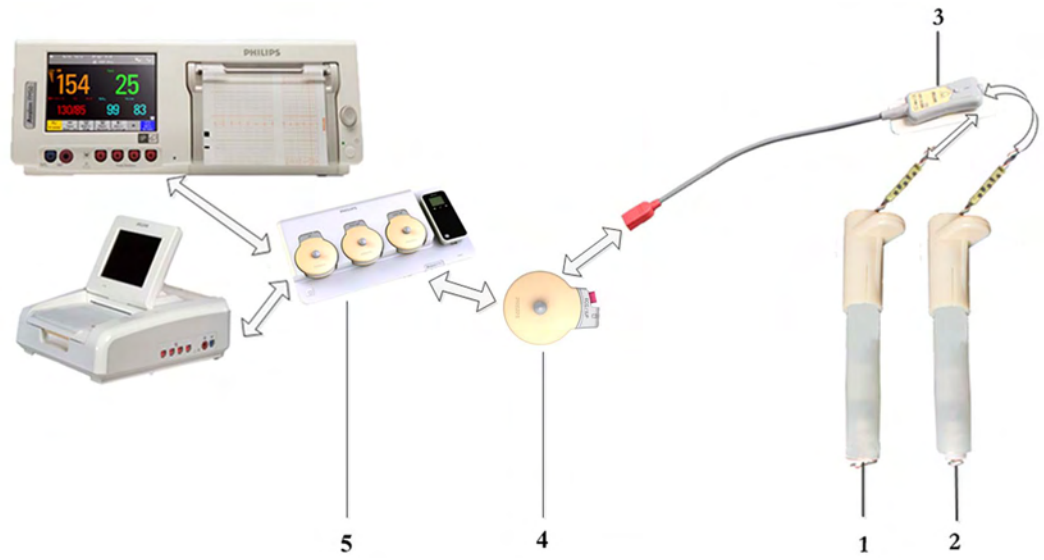
2 Fetal Scalp Electrode, double spiral, Europe only, not for USA (989803137641)

3 DECG Adapter Cable (9898 031 37651) with Pre-gelled Attachment Electrode (989803139771)

4 Toco+ transducer (M2735A)

DECG with CL Toco+MP or CL ECG/IUP

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 USA (989803137641)

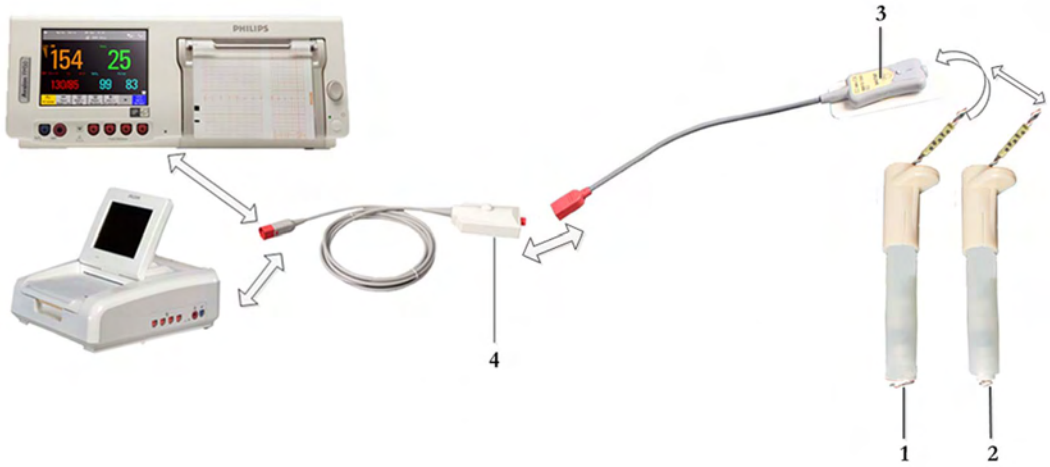
3 DECG Adapter Cable (9898 031 37651) with Pre-gelled Attachment Electrode (989803139771)

4 CL Toco+ MP (866075) or CL ECG/IUP transducer (866077)

5 Avalon CL base station (866074)

DECG with Patient Module

The figure below shows the equivalent chain using the patient module.



1 Fetal Scalp Electrode, single spiral, (989803137631)

2 Fetal Scalp Electrode, double spiral, Europe only, not for USA (989803137641)

3 DECG Adapter Cable (9898 031 37651) with Pre-gelled Attachment Electrode (989803139771)

4 Patient Module (M2738A)

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 Toco$^+$ transducer, CL Toco$^+$ MP, the CL ECG/IUP 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$^+$ transducer, CL Toco$^+$ MP, the 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.

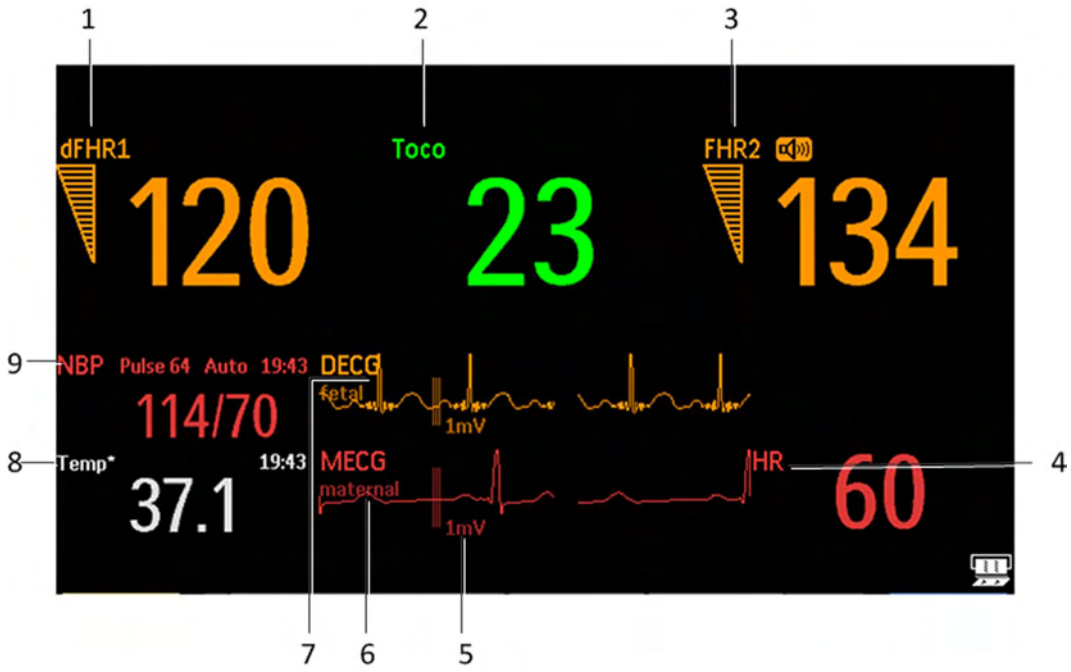
Monitoring DECG

To simultaneously measure DECG and MECG, you need the CL ECG/IUP transducer or the patient module for DECG, and a Toco+, CL Toco$^+$ MP, or CL ECG/IUP transducer for MECG (see "Monitoring Maternal Heart / Pulse Rate" on page 221). Alternatively, you can monitor the maternal pulse rate via pulse oximetry (see "Pulse Rate from SpO2" on page 228). 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 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 10 and "Cross-Channel Verification (CCV)" on page 159.

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 231.

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 129.
dFHR1 Leads Off **dFHR2 Leads Off** **dFHR3 Leads Off** Numeric is displayed with a -?-; INOP tone See also "Patient Alarms and INOPs" on page 129. 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 129.
dFHR1 Unplugged **dFHR2 Unplugged** **dFHR3 Unplugged**	No connection	See "Patient Alarms and INOPs" on page 129.

Testing DECG Mode

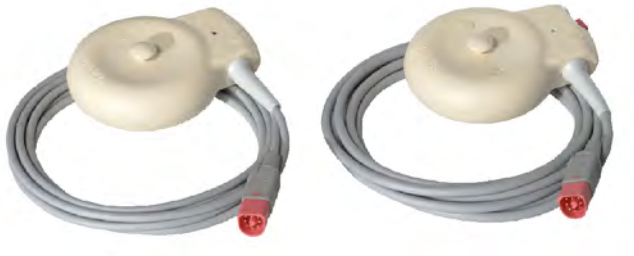
See the monitor's Service Guide.

Monitoring Uterine Activity Externally

You can measure uterine activity externally using a Toco transducer. You can also use a Toco+, 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+ transducer

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.

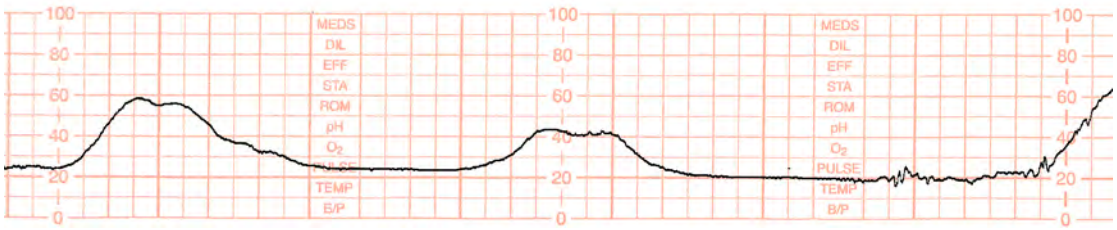
1 Fasten the abdominal transducer belt around the patient.

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 that 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 sensitivity.
Toco Equip Malf is displayed.		See "Patient Alarms and INOPs" on page 129.
Toco Unplugged is displayed.		See "Patient Alarms and INOPs" on page 129.
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.

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.

You can test all Toco transducers, including the cableless ones, as described above.

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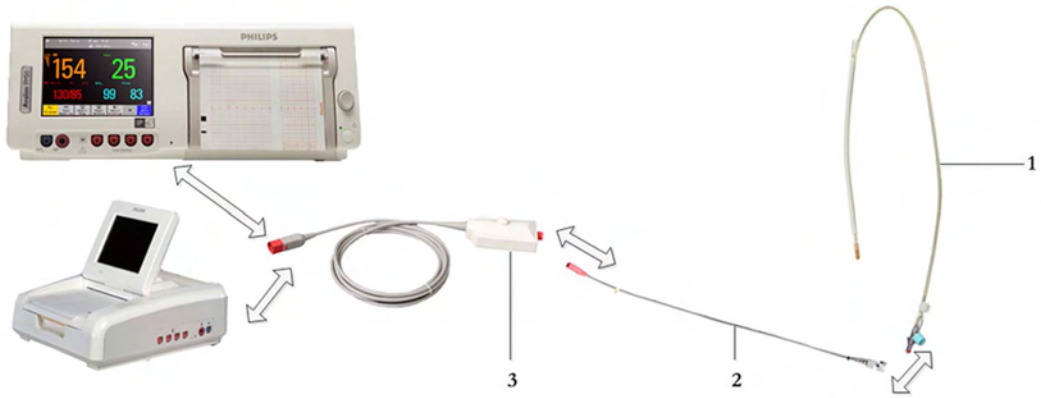
Monitoring Uterine Activity Internally

FM30/50 You can monitor intrauterine pressure (IUP) using an intrauterine catheter together with a patient module, Toco^{+}, or the CL ECG/IUP or CL Toco^{+} MP transducer, after rupture of the membranes and the cervix is sufficiently dilated.

What You Need

IUP with Patient Module

The figure below shows the complete connection chain from the IUP catheter to the fetal monitor using the patient module:



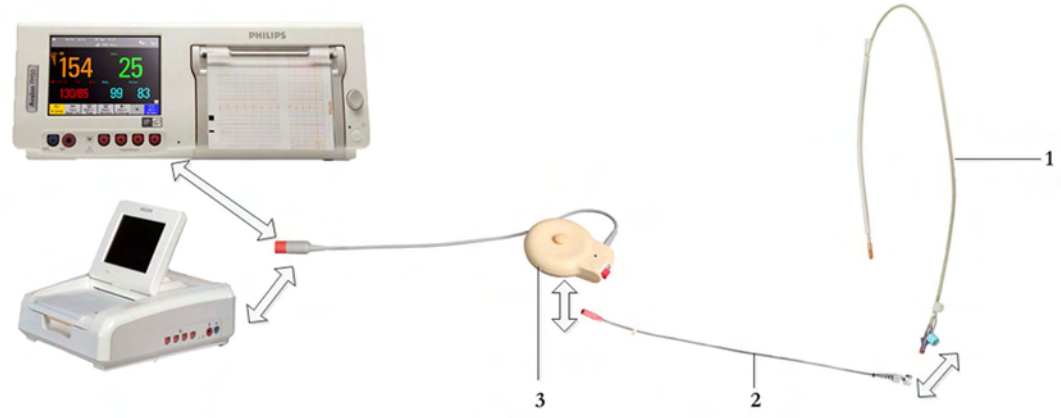
1 Disposable Koala IUP Catheter (M1333A)

2 Reusable Koala IUP Adapter Cable (9898 031 43931)

3 Patient Module (M2738A)

IUP with Toco+

The figure below shows the complete connection chain from the IUP catheter to the fetal monitor using the Toco+ transducer:



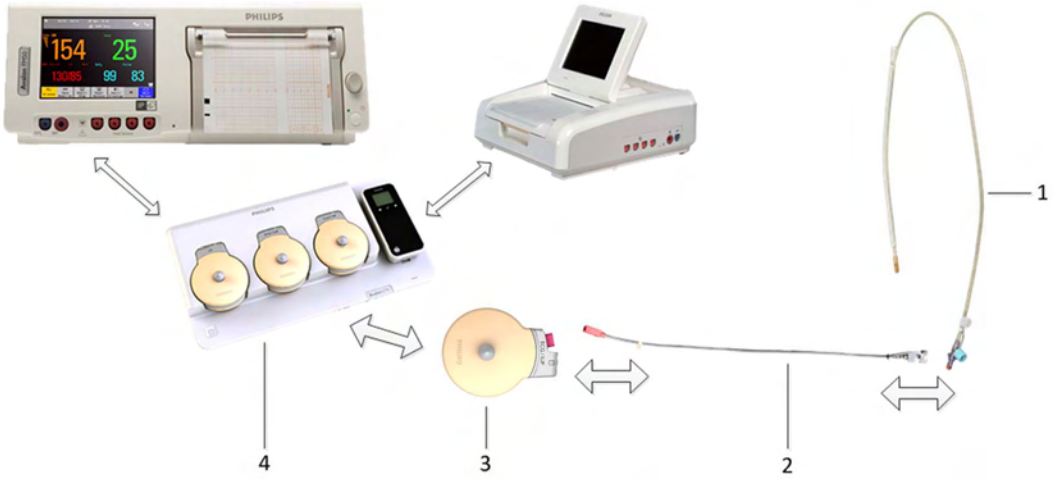
1 Disposable Koala IUP Catheter (M1333A)

2 Reusable Koala IUP Adapter Cable (9898 031 43931)

3 Toco^{+} transducer (M2735A)

IUP with CL ECG/IUP

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 or CL Toco^{+} MP transducer (866077)

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 129.	
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.

CAUTION

Use the CL F&M Pod and electrode patch with singleton pregnancies only. The measurements have been validated with a gestational age of >36 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.

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 intrauterine contraction-like artifacts.

Maternal movement

When 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

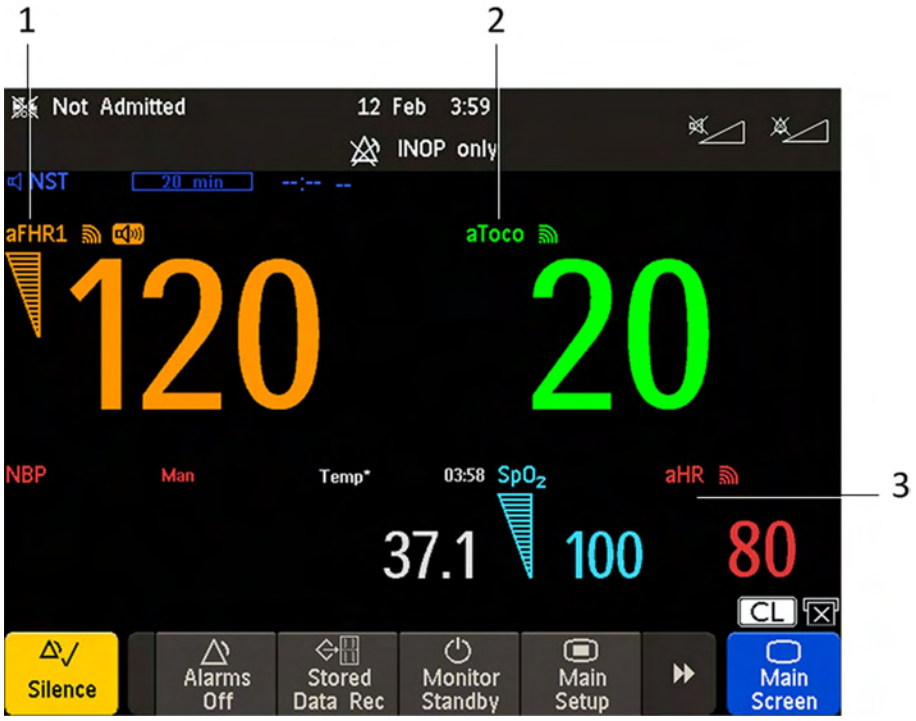
- For monitoring with the CL F&M Pod, see "Avalon CL Fetal & Maternal Pod" on page 21 and "CL Fetal & Maternal Electrode Patch" on page 91.
- For assigning the CL F&M Pod, see "CL Pod Assignment" on page 99.
- For applying the electrode patch and the CL F&M Pod, see "Applying the CL Fetal & Maternal Patch and Pod" on page 100.

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 169.



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.

Problem	Possible Causes	Solutions
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 129.

19 Monitoring aFHR, aHR, and aToco

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 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 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

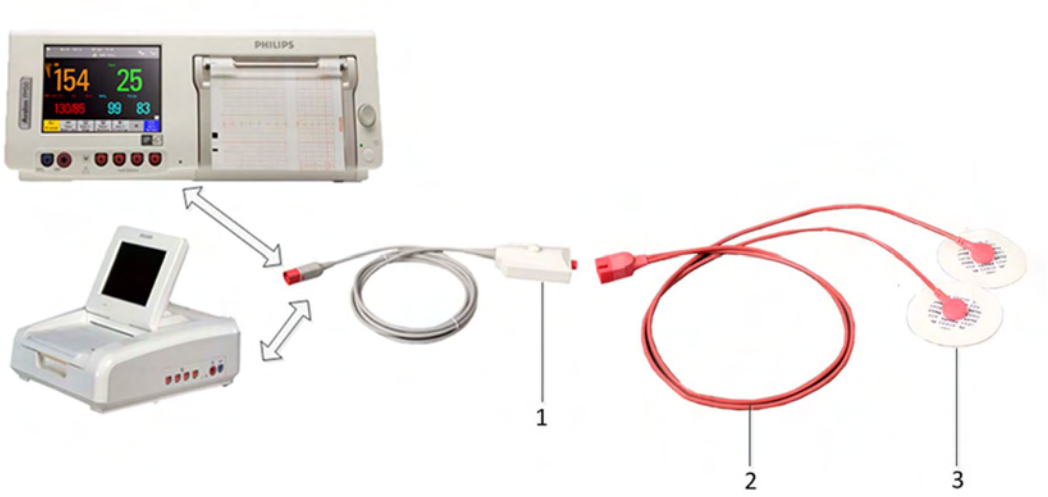
To reduce the possibility of mistaking the maternal HR for FHR, it is recommended that you monitor both maternal and fetal heart rates (see "Confirm Fetal Life Before Using the Monitor" on page 10 and "Cross-Channel Verification (CCV)" on page 159).

Maternal HR from MECG Electrodes

You can measure maternal HR using the equipment combinations shown in the following figures.

MECG with Patient Module

The figure below shows the complete connection chain from the foam electrodes applied to the patient to the fetal monitor using the patient module.



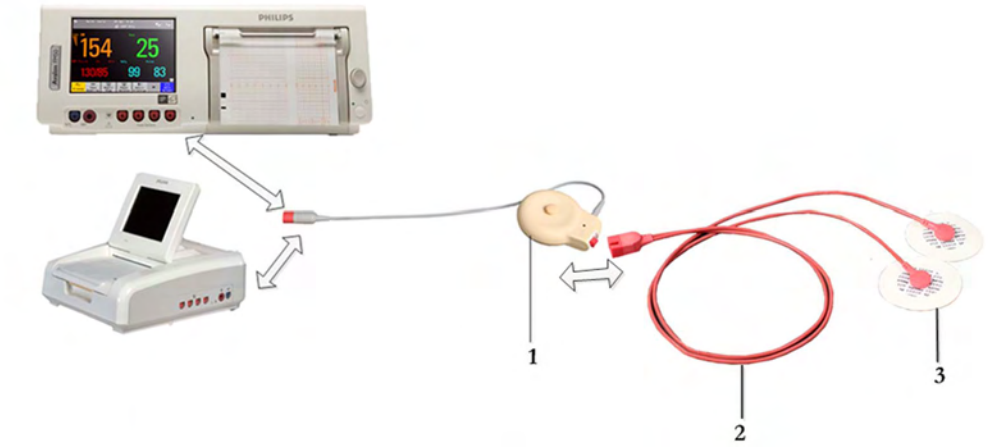
1 Patient Module (M2738A)

2 MECG Adapter Cable (M1363A)

3 Pre-gelled Foam Electrodes (40493A/B/C/D/E)

MECG with Toco+

The figure below shows the equivalent chain **using the Toco+ transducer**.



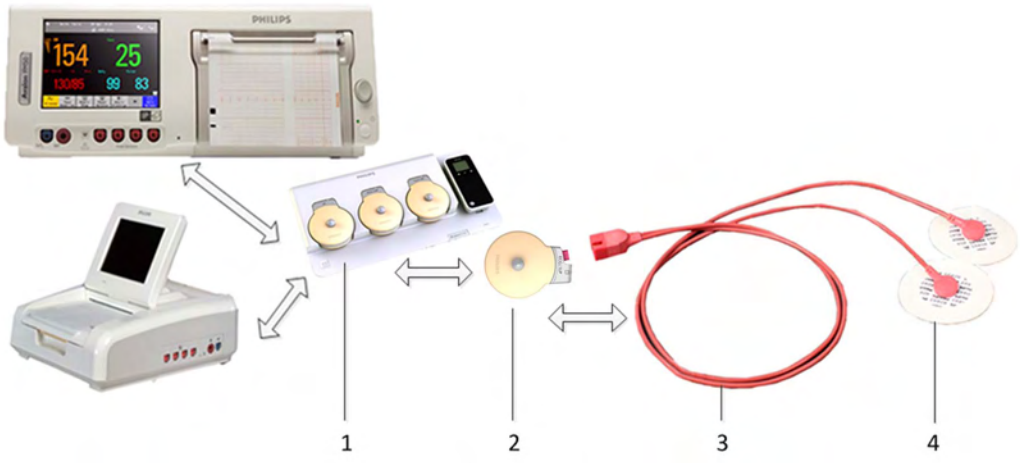
1 Toco+ Transducer (M2735A)

2 MECG Adapter Cable (M1363A)

3 Pre-gelled Foam Electrodes (40493A/B/C/D/E)

MECG with CL Toco+MP or CL ECG/IUP

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)

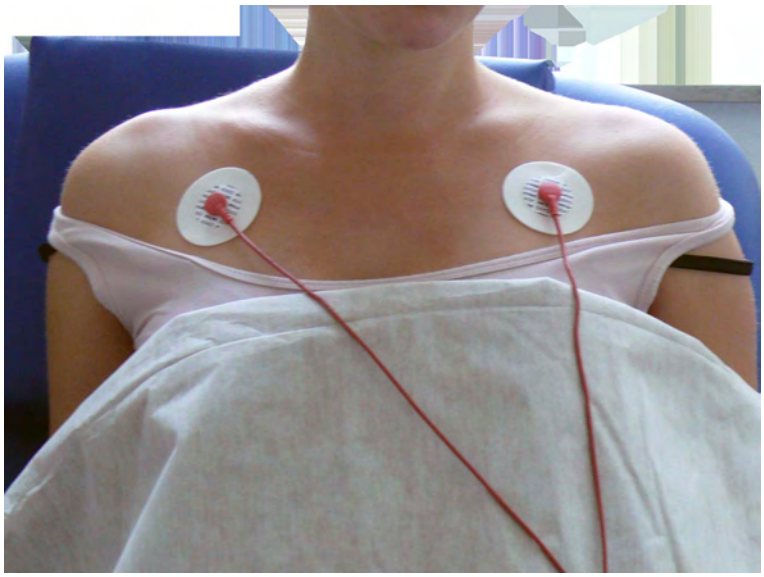
3 MECG Adapter Cable (M1363A)

4 Pre-gelled Foam Electrodes (40493A/B/C/D/E)

To simultaneously measure DECG and MECG, you can use a Toco+, a CL Toco+ MP, or a CL ECG/IUP transducer for MECG. For measuring DECG, you need a 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$^+$ 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$^+$ 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.

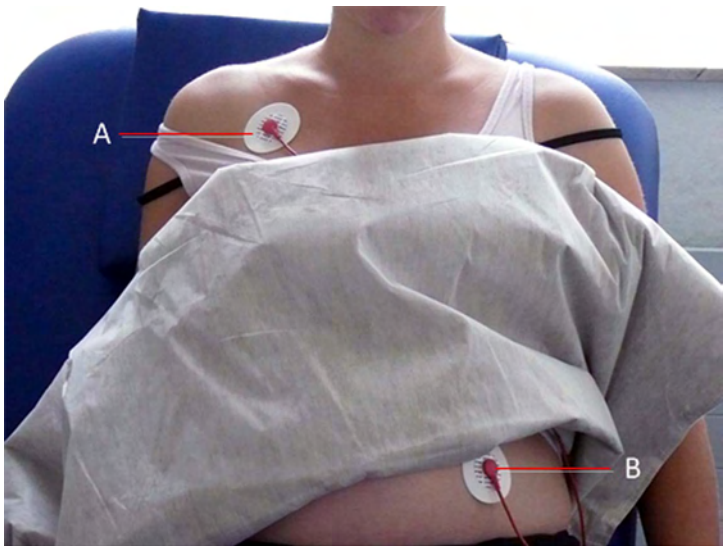
FM30/50 When measuring MECG with the Avalon FM30 or FM50, the MECG waveform, along with the heart rate numeric, is displayed on the screen when using a Toco$^+$, CL Toco$^+$ MP transducer, a patient module, or a CL ECG/IUP transducer. If a maternal ECG wave analysis is required, use a patient monitor.

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

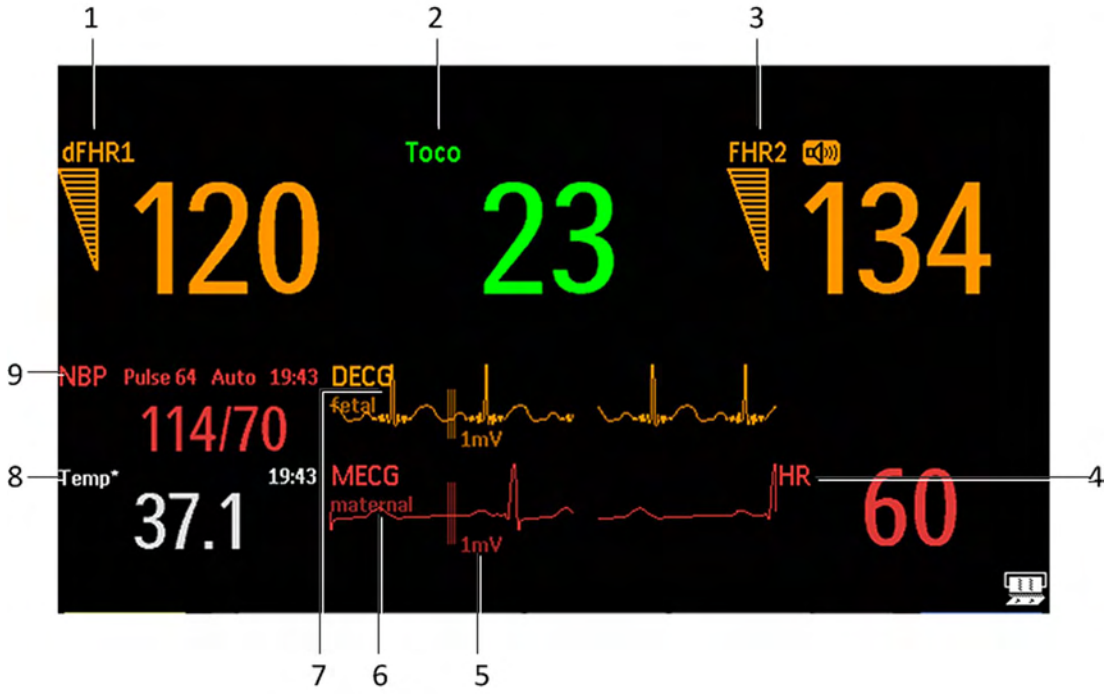
To obtain a satisfactory maternal ECG waveform, you must use the RA to LL (lead II) position of the standard 5-lead ECG.



1 Place the RA electrode (**A**) directly below the clavicle and near the right shoulder.

2 Place the LL electrode (**B**) 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 129	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 164
MECG Equip Malf displayed	Equipment malfunctions	See "Patient Alarms and INOPs" on page 129
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 231.

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

- No alarm is possible when Toco MP or CL Toco$^+$ MP transducer is the source of the pulse rate.
- No QRS tone is audible when Toco MP or 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

No alarm is possible when noninvasive blood pressure is the source of the pulse rate.

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

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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

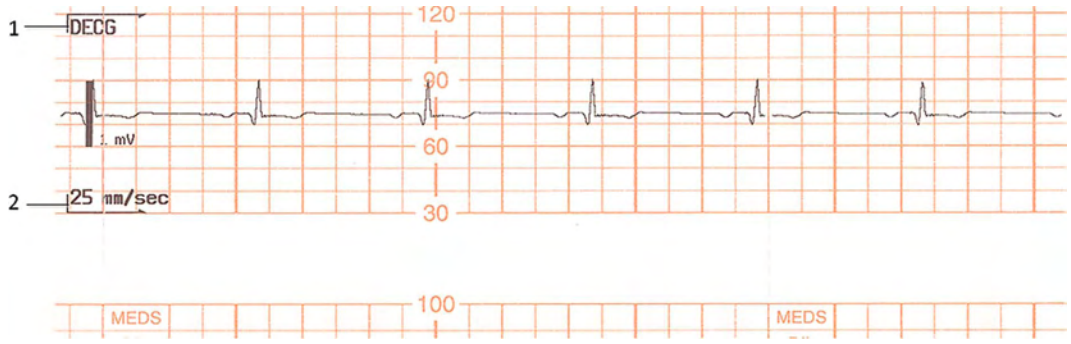
1 The fetal/maternal monitor is not a diagnostic ECG device. In particular, the display of fetal/maternal ECG is intended only for evaluating signal quality for fetal/maternal heart rate as derived from the ECG waveform.

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:

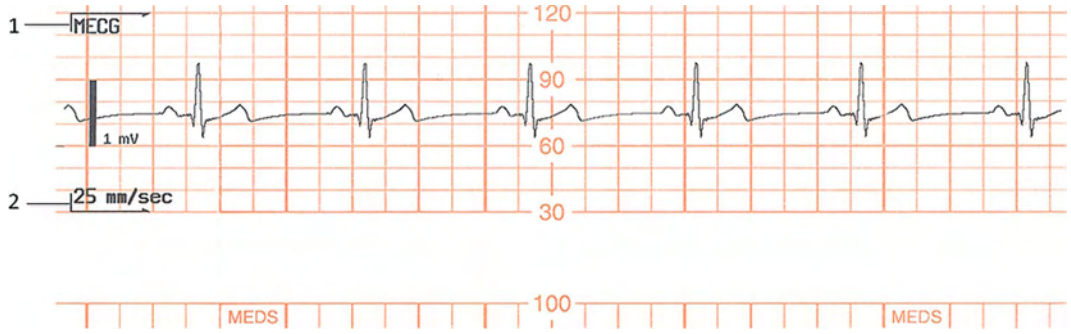
DECG waveform on its own



1 **DECG**

2 Recorder speed

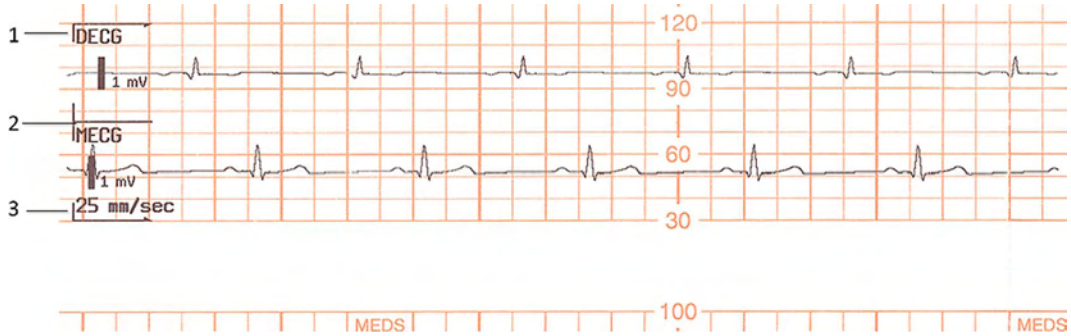
MECG waveform on its own



1 **MECG**

2 Recorder speed

DECG and MECG waveforms



1 **DECG**

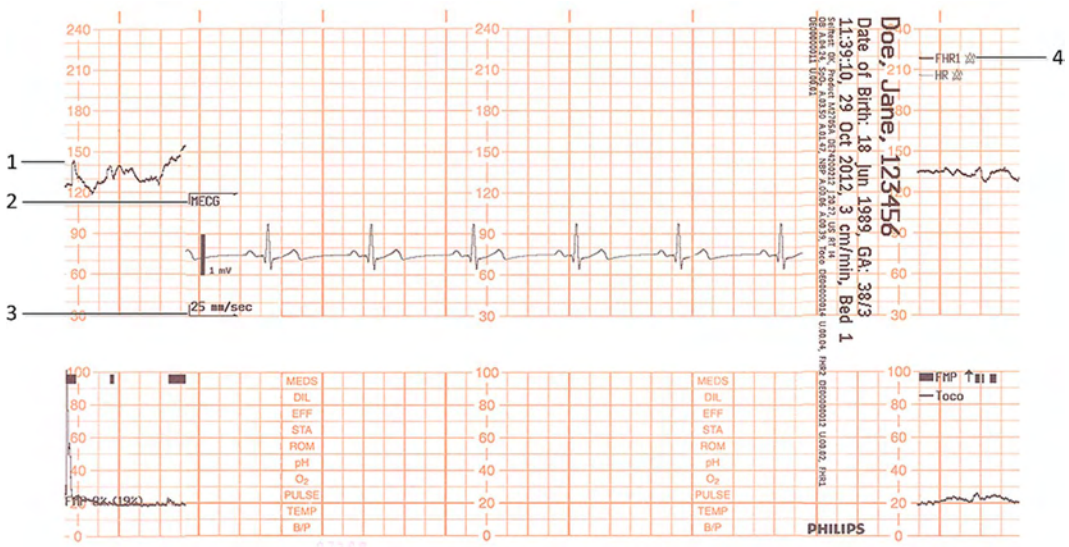
2 **MECG**

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

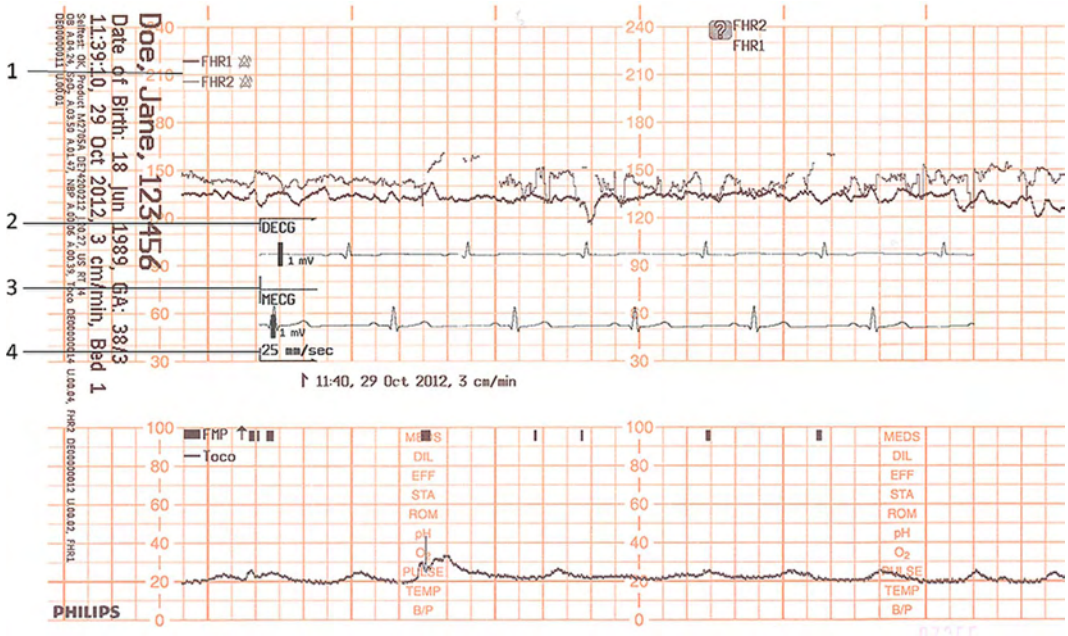
2 **MECG** header

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.

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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: Avoid applying the cuff on the side of the mastectomy, as the pressure increases the risk of lymphedema. For patients with a bilateral mastectomy, use clinical judgement to decide whether the the benefit of the measurement outweighs the risk.

Unattended Measurement: Use clinical judgement 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

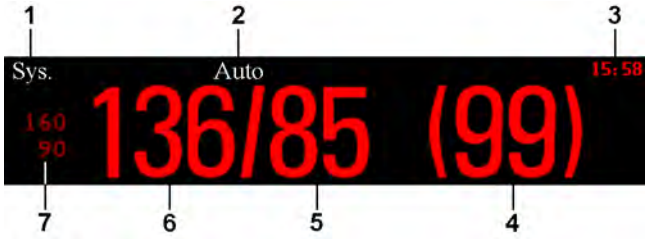
To make a measurement for use in the diagnosis of hypertension, follow the steps below:

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 source
2 Measurement Mode
3 Timestamp/Timer
4 Mean pressure
5 Diastolic
6 Systolic
7 Alarm limits

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
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

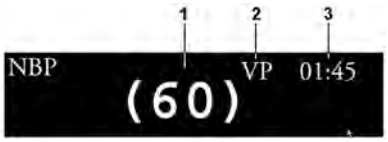
You can use the cuff to cause subdiastolic pressure. The cuff deflates automatically after a set time if you do not deflate it.

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 236
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 129.	
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 221 and "Cross-Channel Verification (CCV)" on page 159).

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 photodetector 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.

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.

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

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:

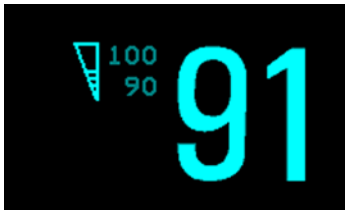
  Inspect the application site every two to three hours to ensure skin quality and correct optical alignment. Correct the sensor alignment if necessary. If the skin quality changes, move the sensor to another site. Change the application site at least every four hours.

- 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 (FAST SpO2 only)

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 117 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 228.

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 221).

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

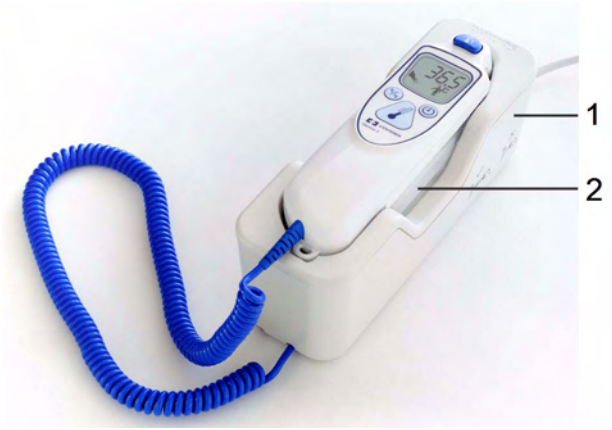
The tympanic thermometer (866149) measures the patient's temperature in the ear using infrared technology.

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).

Functional Keys	Description of Use
	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 261 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.

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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 221 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

26

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.

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.

27

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

- 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

Clean and disinfect the Avalon FM20, FM30, FM40, and FM50 fetal monitors and the transducers M2734A, M2734B, M2735A, M2736A, and M2738A (including ECG adapter cables) and the Avalon CL base station and the cableless transducers after each use. Clean equipment before disinfecting. For other accessories, see "Cleaning and Disinfecting Monitoring Accessories" on page 263.

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 263).

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.

Wash soiled reusable belts with soap and water. Water temperature must not exceed 60°C/140°F.

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	0.5% accelerated hydrogen peroxide
Oxivir® Tb Cleaner Disinfectant	spray	0.5% accelerated hydrogen peroxide
Oxivir® Tb Wipes	wipes	0.5% accelerated hydrogen peroxide
Carpe Diem™/MC Tb Ready-to-Use General Virucide, Bactericide, Tuberculocide, Fungicide, Sanitizer	spray	0.5% accelerated hydrogen peroxide
Carpe Diem™/MC Tb Wipes	wipes	0.5% accelerated hydrogen peroxide
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%

Cleaning and Disinfecting Monitoring Accessories

To clean, disinfect and sterilize reusable transducers, sensors, cables, leads, and so forth, refer to the instructions delivered with the accessory.

Do not allow a cleaning or disinfecting agent to leave residues on any of the equipment surfaces. Wipe residues off, after allowing the appropriate time to for the agent to work, with a cloth.

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.

Cleaning and Disinfecting CL Transducers and CL Pods

To clean, disinfect and sterilize reusable CL transducers and CL Pods refer to the instructions delivered with the accessory.

Do not allow a cleaning or disinfecting agent to leave residues on any of the equipment surfaces. Wipe residues off, after allowing the appropriate time to for the agent to work, with a cloth damp with water.

NOTE

Pay especially close attention to cleaning and wiping down the gold connection contacts.

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).

28

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 110.

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

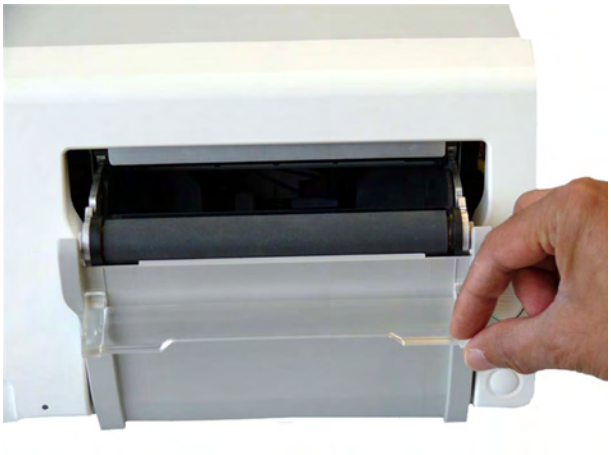
Removing the Paper Guide: FM40/FM50

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 61).

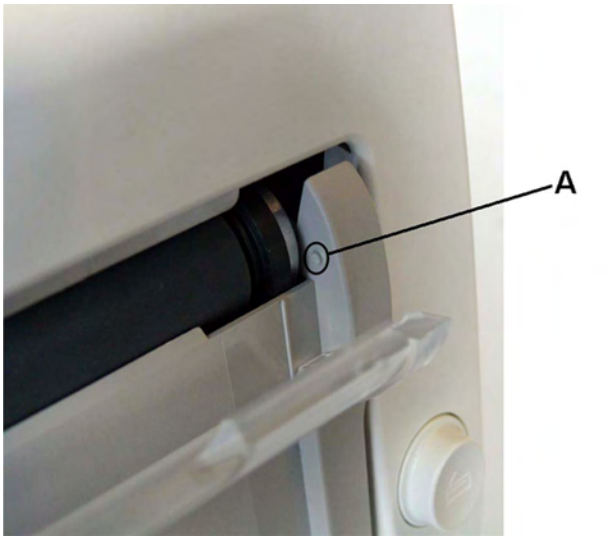
To remove the paper guide:

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

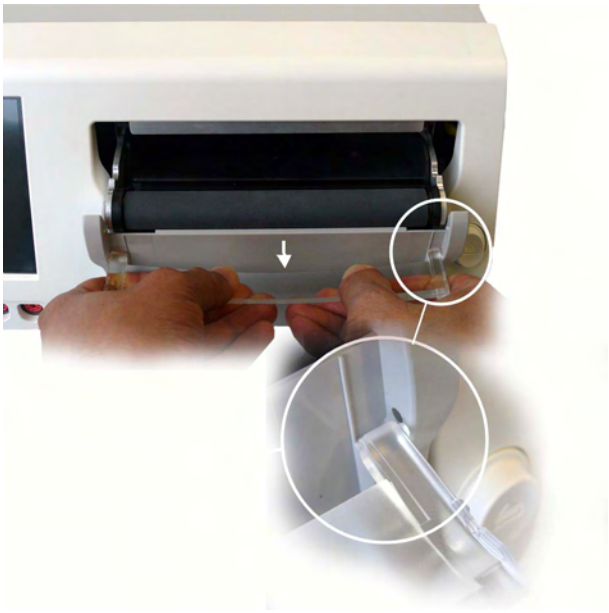
2 Hinge the transparent paper guide forward.



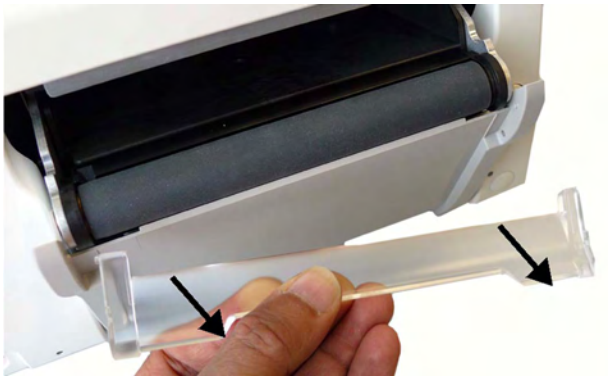
3 A protrusion (A) holds paper guide in closed position.

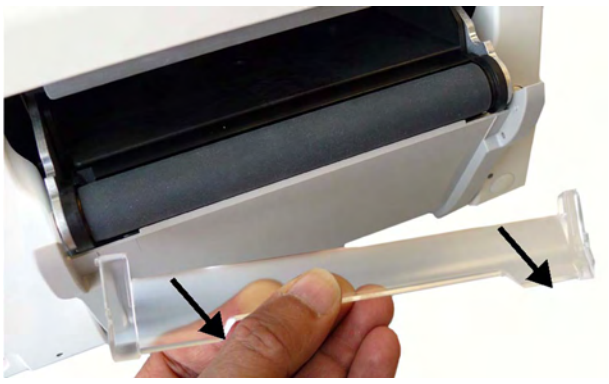


4 Release the paper guide from one side of the holder.



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 Philip's 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).

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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 latex-free, 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

Transducer	Part Number
Avalon Toco Transducer	M2734A
Avalon Toco^{+} Transducer for Toco, DECG, MECG, or IUP monitoring	M2735A
Avalon Toco MP Transducer for Toco and Maternal Pulse	M2734B
Avalon Ultrasound Transducer	M2736A
Avalon Ultrasound Transducer USA	M2736AA
ECG/IUP Patient Module (for DECG, MECG or IUP)	M2738A
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
Remote Event Marker	989803143411

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
	5 liter refill (with dispenser) for 40483A Shelf life: 24 months max.	40483B
Belt buttons (kit of 10) for wired transducers M273xA		M1569A
Belt Clips for wired Smart Transducers (kit of 6)		989803143401

Accessory	Description	Part Number
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
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
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:

Adult Multi Patient Reusable Comfort 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 4 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).

Adult EasyCare 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
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

Maternal Patient Category (color)	Limb Circumference	Part Number
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).

Adult Single Patient Soft 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
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 USA 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 with longer cable (3.0 m)	M1191BL
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 USA:

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

Description	Comments	Part Number
Adapter Cable for OxiCliq sensors	Available from Nellcor	OC-3
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
USA/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

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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)

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)

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).

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 and 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)

Avalon CL Fetal and Maternal Pod (866488)		
Altitude Range	Operating	-500-3000 m (-1640-9840 ft)
	Storage/Transportation	-500-13100 m (-1640-43000 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)

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)

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

Monitor Physical Specifications		M2702A/M2703A	M2704A/M2705A
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 129, "Standard Philips Alarms" on page 120, and "ISO/IEC Standard Audible Alarms" on page 120.
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

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)
Degree of Protection Against Electrical Shock		Type CF	
Transducer Identification		Optical Signal Element (Finder LED), not M2738A	

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)

Avalon CL Transducers (866075/866076/866077)	
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 89 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)
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
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

Short Range Radio Specifications	
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
Frequency Band	USA: 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 Avalon fetal monitors in combination with the specified wired transducers and sensors, and also with the cableless measurements (Avalon CL, Avalon CTS).

Under normal and single fault conditions either at least the performance/functionality listed in the tables below is provided, or failure to provide this performance/functionality is readily identifiable by the user (e.g. technical alarm, no waves and/or numeric values, complete failure of the monitor, readily identifiable distorted signals, etc.).

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).

Measurement	Essential Performance
ECG (Monitoring)	Measurement of the fetal and maternal heart rate over the specified measurement range and with an accuracy of ± 5 bpm.
	Alarming on heart rate limit violation within specified delay time.
Maternal Pulse from Toco (MP)	Measurement of the maternal pulse rate within the specified 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 and pulse rate within the specified accuracy/error limits.
	Alarming on oxygen saturation and pulse rate limit violation.
Temperature (tympanic)	Measurement of temperature within specified accuracy/error limits.
	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).
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.

The table above also represents the minimum performance when operating under non-transient electromagnetic phenomena according to IEC 60601-1-2:

- Radiated electromagnetic fields
- Conducted disturbances induced by RF fields
- Conducted disturbances induced by magnetic fields
- Voltage dips/voltage variations

The following table identifies minimum performance for 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, surges and electro surgery interference, the equipment will return to previous operation mode within 10 seconds (SpO_2 30 seconds) without loss of any stored data.
	After voltage interruptions the equipment returns to previous state without operator intervention and loss of 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
Buffered Memory	Hold Time	if powered by AC infinite 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 / 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
Display Update Rate		1 per second

Performance Specifications		
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.	
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
Sensitivity		1 unit = 2.5 g
Resolution	Display	1 unit
	Printer	1/4 unit
Measurement Range		400 units
Signal Range		0-127 units
Maximum Offset Range		-300 units
Baseline Setting		20 units

Performance Specifications		
Update Rate	Display	1 per second
	Printer	~4 per second
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
Resolution	1 bpm
Display Update Rate	1 per second
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
Signal Range		-99-127 mmHg or (-13.2-16.9 kPa)
Resolution	Display	1 mmHg
	Printer	1/4 mmHg
Sensitivity		5 µV/V/mmHg
Offset Compensation		+100- -200 mmHg
Accuracy (not including sensor accuracy)		±0.5% per 100 mmHg
Update Rate	Display	1 per second
	Printer	~4 per second
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 / 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
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 297).
	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

Maternal ECG Supplemental Information as required by IEC 60601-2-27		
Response Time of Heart Rate Meter to Change in Heart Rate	HR change from 80-120 bpm: 10 seconds HR change from 80-40 bpm: 14 seconds	
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
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
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

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

aToco	
Resolution	0-255 levels representing 100% of the full scale
Accuracy	±5%

Noninvasive Blood Pressure

Complies with IEC 80601-2-30:2009 / EN 80601-2-30:2010.

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 297).
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 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

SpO_2 Performance Specifications		
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	≤15mW
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	
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 80601-2-56:2009 / EN ISO 80601-2-56:2012.

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)

Performance Specifications		
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
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 297).

Physical Specifications

Thermometer	
Dimensions	190 mm x 43 mm x 55 mm (±3 mm)
Cable length	60 ±5 cm (spiral cable relaxed) 250 ±15 cm (spiral cable extended)
Weight (including cable)	180 ±10 g
Ingress protection classification	IP 21

Base Station	
Dimensions	205 mm x 65 mm x 75 mm (±3 mm)
Weight (excluding cable)	400 g ±10 g

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

Recorder Symbols	
Symbol	**Description**
	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 Pods
	Measurement from cableless devices connected with 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)

Recorder Symbols	
Symbol	**Description**
	Trace separation -20 bpm (in trace)
	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)

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 Boeblingen GmbH

Hewlett-Packard-Str. 2

71034 Boeblingen

Germany

Visit our website for local contact information at: www.healthcare.philips.com

Trademark Acknowledgment

Oxisensor^{TM} *II*, Oxi-Cliq^{TM}, and OxiMax^{TM} are trademarks of Tyco Healthcare Group LP, Nellcor Puritan Bennett Division.

Regulatory and Standards Compliance

The fetal monitors are in conformity with the requirements of the European Medical Devices Directive 93/42/EEC and bear the CE marking:

CE 0123

The fetal monitors are classified into Class IIb according to Annex IX rule 10.

The Avalon CL Transducer System is in conformity with the requirements of the European Radio Equipment and Telecommunications Terminal Equipment Directive 99/5/EC. 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 R&TTE 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 310 section of this manual.

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+AC:2013
- IEC 60601-1-6:2010 / EN 60601-1-6:2013
- IEC 60601-1-8:2006+A1:2012 / EN 60601-1-8:2007+AC:2013
- IEC 60601-2-49:2011 / EN 60601-2-49:2015
- ANSI/AAMI ES60601-1:2005+A1:2012+C1:2009+A2:2010
- CAN/CSA C22.2#60601-1-08
- JIS T 1303 2005
- AS/NZS 3200.1.0-1998

The possibility of hazards arising from hardware and software errors was minimized in compliance with ISO 14971:2012, IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC:2013.

Alarm sounds are compliant with Standard IEC 60601-1-8:2006+A1:2012 / EN 60601-1-8:2007+A1:2013+AC:2014.

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+AC:2013 (Edition 3) and related standards.

When your fetal monitor is compliant with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC: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 300 220-1:2012
- ETSI EN 300 220-2:2012
- ETSI EN 301 489-1:2011
- ETSI EN 301 489-3:2013
- FCC 47 CFR Part 95
- IC RSS-210 Issue 8
- ARIB STD-T108
- ETSI EN 300 328:2012
- ETSI EN 301 489-17:2012
- FCC 47 CFR Part 2 & 15
- AS/NSZ 4268
- ARIB STD-T66

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+AC: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+AC:2013. The whole installation, including devices outside of the patient vicinity, must comply with IEC 60601-1:2005+A1:2012 / EN 60601-1:2006+AC: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+AC: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, listed in the accessories section, comply with the following EMC standards:

- IEC 60601-1-2:2007 / EN 60601-1-2:2007+AC:2010

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.

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.

Electromagnetic Emissions and Immunity

The EMC standards state that manufacturers of patient-coupled equipment must specify immunity levels for their systems. See Tables 1 to 4 for this detailed immunity information. See Table 5 for recommended minimum separation distances between portable and mobile communications equipment and the product.

Immunity is defined in the standard as the ability of a system to perform without degradation in the presence of an electromagnetic disturbance.

Caution should be exercised in comparing immunity levels between different devices. The criteria used for degradation are not always specified by the standard, and can therefore vary with the manufacturer.

In the table below, the term "device" refers to the Avalon FM20/30/40/50 fetal monitor together with its accessories. The table gives details of the electromagnetic emissions, and how these are classified, for the device, and the electromagnetic environments in which the device is specified to technically function.

Table 1 - Guidance and Manufacturer's Declaration: Electromagnetic Emissions

Emissions Test	Compliance	Avoiding Electromagnetic Interference
Radiofrequency (RF) emissions	Group 1	The device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations and flicker IEC 61000-3-3	complies	

Table 1 - Guidance and Manufacturer's Declaration: Electromagnetic Emissions		
Emissions Test	**Compliance**	**Avoiding Electromagnetic Interference**
RF emissions CISPR 11 For the Avalon FM20/30 fetal monitor with all accessories except the IUP/ECG patient module M2738A.	Class B	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes[1].
RF emissions CISPR 11 For the Avalon FM40/FM50 with all accessories. For the Avalon FM20/30 fetal monitor whenever used with the IUP/ECG patient module M2738A. For the Avalon CTS Interface Cable (M2731-60001/M2732-60001) whenever used with the Avalon CTS Cableless Fetal Transducer System. For the Avalon CL Base Station with cableless transducers whenever used with the fetal monitors.	Class A	The device is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage supply network that supplies buildings used for domestic purposes.

[1] Note that the device is not intended for home use.

Electromagnetic Immunity

The monitor is suitable for use in the specified electromagnetic environment. The user must ensure that it is used in the appropriate environment as described below.

Table 2 - Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/ output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial and/or hospital environment
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial and/or hospital environment

Table 2 - Guidance and Manufacturer's Declaration: Electromagnetic Immunity			
Immunity Test	**IEC 60601-1-2 Test Level**	**Compliance Level**	**Electromagnetic Environment Guidance**
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycles	<5% U_T (>95% dip in U_T) for 0.5 cycles	Mains power quality should be that of a typical commercial and/or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device is powered from an uninterruptible power supply.
	40% U_T (60% dip in U_T) for 5 cycles	40% U_T (60% dip in U_T) for 5 cycles	
	70% U_T (30% dip in U_T) for 25 cycles	70% U_T (30% dip in U_T) for 25 cycles	
	< 5% U_T (>95% dip in U_T) for 5 sec	< 5%U_T (>95% dip in U_T) for 5 sec	
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial and/or hospital environment
Key: U_T is the AC mains voltage prior to application of the test level.			

Radio Compliance Notice

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).

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).

Finding Recommended Separation Distances

In the following table, *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer, and *d* is the recommended separation distance in meters (m).

Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter.

Field strengths from fixed transmitters, such as land mobile radios, base stations for radio telephones (e.g. cellular, cordless), amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered.

Interference may occur in the vicinity of equipment marked with this symbol: 

Table 3 - Guidance and Manufacturer's Declaration: Electromagnetic Immunity		
Conducted RF Immunity Test EN/IEC 61000-4-6		
IEC 60601-1-2 Test Level over 150 kHz to 80 MHz	**Compliance Level**	**Electromagnetic Environment Guidance: Recommended Separation Distance (*d*) (in Meters, at Frequency Range Tested) for Ultrasound and ECG Measurements**
3.0 V_{RMS}	3.0 V_{RMS}	d = 1, 2√P
Key: *d* = Recommended separation distance in meters (m)		
P = maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer		
V1 = Tested compliance level (in Volts) for the Conducted RF Immunity test IEC 61000-4-6		
The device meets the compliance level of 3.0 V_{RMS} according to IEC 60601-1-2 over the specified test frequency range. Over the frequency range 150 kHz—80 MHz, the recommended separation distance in meters (d) is found by the following equation:		
$d = \left(\frac{3,5}{V1}\right)\sqrt{P}$	For a compliance level of 3.0 V_{RMS}:	d = 1, 2√P

Table 4 - Guidance and Manufacturer's Declaration: Electromagnetic Immunity		
Radiated RF Immunity Test EN/IEC 61000-4-3		
IEC 60601-1-2 Test Level over 80 MHz to 2.5 GHz	**Compliance Level**	**Electromagnetic Environment Guidance: Recommended Separation Distance (*d*) (in Meters, at Frequency Range Tested) for Ultrasound and ECG Measurements**
3.0 V/m	3.0 V/m	Over 80 MHz—800 MHz:d = 1, 2√P
		Over 800 MHz—2.5 GHz:d = 2, 3√P
Key: *d* = Recommended separation distance in meters (m)		
P = maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer		
E1 = Tested compliance level (in Volts/meter) for the Radiated RF Immunity test IEC 61000-4-3		
The device meets the compliance level of 3.0 V_{RMS} according to IEC 60601-1-2 over the specified test frequency range. Over the frequency range 80 MHz—800 MHz, the recommended separation distance in meters (d) is found by the following equation:		
$d = \left(\frac{3,5}{E1}\right)\sqrt{P}$	For a compliance level of 3.0 V_{RMS}:	d = 1, 2√P
Over the frequency range 800 MHz—2.5 GHz, the recommended separation distance in meters (*d*) is found by the following equation:		
$d = \left(\frac{7,0}{E1}\right)\sqrt{P}$	For a compliance level of 3.0 V_{RMS}:	d = 2, 3√P

Field strengths from fixed transmitters, such as base stations, or radio, (cellular, cordless) telephones, and land mobile radios, amateur radio, AM and FM radio broadcast, and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the

location in which the device is used exceeds the applicable RF compliance level above, it should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

If you require further information or assistance, please contact Philips Support.

Recommended Separation Distances from Other RF Equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Table 5 - Separation Distance (*d*) in Meters According to Frequency of Transmitter at IEC 60601-1-2 Test Compliance Level

Rated Maximum Output Power (*P*) of Transmitter (in Watts)	150 kHz to 80 MHz $d = \left(\frac{3,5}{V1}\right)\sqrt{P}$	80 MHz to 800 MHz $d = \left(\frac{3,5}{E1}\right)\sqrt{P}$	800 MHz to 2.5 GHz $d = \left(\frac{7,0}{E1}\right)\sqrt{P}$
0.01 W	d= 0.1 m	d= 0.1 m	d= 0.23 m
0.1 W	d= 0.4 m	d= 0.4 m	d= 0.7 m
1 W	d= 1.2 m	d= 1.2 m	d= 2.3 m
10 W	d= 3.8 m	d= 3.8 m	d= 7.3 m
100 W	d= 12.0 m	d= 12.0 m	d= 23.0 m

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 gasses, 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.

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.

Cardiac Pacemakers and Electrical Stimulators

WARNING

The fetal/maternal monitors are not intended for use for ECG measurements on patients connected to external electrical stimulator, or with cardiac pacemakers.

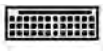
Fast Transients/Bursts

The equipment will return to the previous operating mode within 10 seconds without loss of any stored data.

Symbols on the System

These symbols can appear on the monitor and its associated equipment and packaging.

Symbol	Description
	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.
	This symbol indicates that you have to consult the Instructions for Use (this document).
	This symbol indicates that you should consult the Instructions for Use (this document).
	Power-On/Off Switch - FM20/FM30 without Battery Option
	Power-On/StandBy button - FM40/FM50 and FM20/30 with Battery Option
	Power-On LED
	Electrical Class II equipment, in which the protection against electric shock relies on double or reinforced insulation (FM20/FM30)
	Fetal Sensor Socket symbol
	SpO_2 Socket symbol

Symbol	Description
	Noninvasive Blood Pressure Socket symbol
	Type BF
	Symbol indicating the monitor has the triplets option
	Symbol indicating the monitor is capable of intrapartum monitoring
	Button to open paper drawer/paper eject. (FM40/FM50)
	Protective earth terminal (FM40/FM50)
	Equipotential grounding point (FM40/FM50)
Tele	Socket for connecting Avalon CTS interface cable M2732-60001 or Avalon CL interface cable (with black connector, FM40/FM50)
	Symbol indication for non-ionizing radiation
	Connection direction indicator FM20/FM30 with battery option
	Mouse connection indicator (optional)
	Keyboard connection indicator (optional)
	Serial/MIB connector (optional)
	USB interface (optional)
Video 	Analog interface indicator for connection to any analog video display (VGA resolution) FM40/FM50
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)

Symbol	Description
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)
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 31	Ingress Protection code according to IEC 60529 (protection against condensation only)
IP 21	Ingress Protection code according to IEC 60529 (protection against ingress of water when the water is dripping vertically)
	Type CF equipment, not defibrillation proof
	Indicates location of service number
	Indicates location of serial number
	Indicates location of catalog number
	Indicates location of the date of manufacture and/or name and address of manufacturer
	Identifies year and month of manufacture
	China RoHS
	Symbol indicating separate collection for waste electrical and electronic equipment
	EAC mark
	CSA US mark
FCC ID	Federal Communications Commission: FCC ID xxxx
CMIIT ID	Chinese Radio marking: CMIIT ID (China Ministry of Industry and Information Technology)
	CE marking accompanied by the Notified Body number 0123
	Industrial, Scientific, & Medical radio frequency band (Avalon CL frequency band used e.g. in the EU)

Symbol	Description
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

30 Specifications and Standards Compliance

31

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	Choice	Default
Alarm Mode	**INOP only, All**	**INOP only** (international) **All** (USA/CAN)
Alarm Volume	0..10	5
Alarms Off	**1 min, 2 min, 3 min, Infinite**	**2 min**
Alarm Text	**Standard/Enhanced**	**Standard**
Visual Latching	**Red & Yellow/Red Only/Off**	**Red & Yellow**
Audible Latching	**Red & Yellow/Red Only/Off**	**Red & Yellow**
Alarm Sounds	**Traditional/ISO**	**Traditional**
Alarm Low	0..10	4

Fetal / Maternal Defaults Settings (International)		
FHR, dFHR, aFHR	Alarms On/Off Default	**On**
	Default Color for FHR Numeric (for all FHR numerics)	**Orange**
Toco, aToco	Default color for Toco numeric	**Green**
IUP	Default IUP Scale Unit	**mmHg**
	Default color for IUP numeric	**Green**
HR, aHR Measurement	Default Color for MECG Numeric	**Red**

Fetal / Maternal Defaults Settings (US/CAN)		
FHR, **dFHR**, **aFHR**	Alarms On/Off Default	**On**
	Default Color for FHR Numeric: **FHR1**, **dFHR1**, **aFHR1** **FHR2**, **dFHR2**, **aFHR2** **FHR3**, **dFHR3**, **aFHR3**	 **Red** **Blue** **Green**
Toco, **aToco**	Default color for Toco numeric	**Green** (Toco) **Yellow** (aToco)
IUP	Default IUP Scale Unit	**mmHg**
	Default color for IUP numeric	**White**
HR, **aHR** Measurement	Default Color for MECG Numeric	**Red**

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** (USA/CAN)
NBP Sys/Dia only	**Yes** (International) **No** (USA/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**
NBP	**On**
Alarms	**On**
Color	**Red**
Reference	**Auscultatory**

CL NBP Default Settings

NBP Settings	Factory Defaults
Mode	Auto
Repeat Time	10 min
NBP	On
VP Pressure	60 mmHg
Reference	Auscultatory
Unit	mmHg
Done Tone	Off
Start Time	Synchronized
Aging Time	10 min
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
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
Repeat Time	15 min
Signal Quality	On
NBP Alarm Suppr.	On
Color	Cyan

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	Choice	Default
Recorder Speed	1, 2, or 3 cm/min	3 cm/min
Scale Type	US, Internat'l	US
Trace Style FHR1	Thin, Medium, Thick, Extra Thick	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, Overlap	Separate

Setting	Choice	Default
Notes Recording	Along, Across	**Along** (International) **Across** (USA/CAN)
Change Rec Speed	Monitoring, Config	Config
Auto Start	Off, On	Off
Confirmed Stop		Off
Bridge Paperout		On
Paper Save Mode		**Off** (International) **On** (USA/CAN)
NST Autostart		On
NST Autostop		Off
Trace Separation		Off
Separation Order	Standard, Classic	**Standard** (International) **Classic** (USA/CAN)
Intensity	4 (medium)	n/a
Cal. Offset	5	n/a

31 Default Settings Appendix

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