F15 Series

Fetal & Maternal Monitor

User Manual

CE 0123

EDAN

About this Manual

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Statement

This manual will help you understand the operation and maintenance of the product better. It is reminded that the product shall be used strictly complying with this manual. User's operation failing to comply with this manual may result in malfunction or accident for which EDAN INSTRUMENTS, INC. (hereinafter called EDAN) can not be held liable.

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The user shall understand that nothing in this manual grants him, expressly or implicitly, any right or license to use any of the intellectual properties of EDAN.

EDAN holds the rights to modify, update, and ultimately explain this manual.

Responsibility of the Manufacturer

EDAN only considers itself responsible for any effect on safety, reliability and performance of the equipment if:

Assembly operations, extensions, re-adjustments, modifications or repairs are carried out by persons authorized by EDAN, and

The electrical installation of the relevant room complies with national standards, and

The instrument is used in accordance with the instructions for use.

Terms Used in this Manual

This guide is designed to give key concepts on safety precautions.

WARNING

A **WARNING** label advises against certain actions or situations that could result in personal injury or death.

CAUTION

A **CAUTION** label advises against actions or situations that could damage equipment, produce inaccurate data, or invalidate a procedure.

NOTE

A **NOTE** provides useful information regarding a function or a procedure.

Table of Content

Chapter1 Safety Guidance

CAUTION

Federal (U.S.) Law restricts this device to sale by or on the order of a physician.

NOTE:

1 **In order to ensure the operator and patient's safety, read through this chapter before using this monitor.**

2 **This user manual is written to cover the maximum configuration. Therefore, your model may not have some of the parameters and functions described, depending on what you have ordered.**

3 **Whenever a monitor's identifier appears on the title, paragraph or picture, it means that the information applies to that monitor only. Where the information applies to all models, no distinction is made.**

4 **The functions frequently used are marked with an asterisk *, for example *4.14 *Reviewing Alarms*.**

1.1 Intended Use/Indications for Use

F15 series are intended for real time monitoring of fetal physiological parameters, including noninvasive monitoring of single, twin or triple fetal heart rates (FHR), fetal movements (FM).

F15 series are also intended for real time monitoring of maternal physiological parameters, including uterine activity, maternal heart rate (MHR), maternal ECG (MECG), temperature (TEMP), oxygen saturation (SpO2), pulse rate (PR), and noninvasive blood pressure (NIBP).

F15 series are intended for invasive monitoring of direct ECG (DECG) and intrauterine pressure (IUP).

F15 series can be compatible with FTS-3 which is a wireless system intended for monitoring physiological parameters including fetal heart rates (FHR), fetal movements (FM), uterine activity.

F15 series are intended for monitoring in a bath (FTS-3 only) or shower (FTS-3, and F15 wireless transducers).

F15 series can display, store, and print patient information and parameters, provide alarms of fetal and maternal parameters, and transmit patient data and parameters to Central Monitoring System.

Monitoring FHR using ultrasound is recommended from the 24th week of gestation. FECG is only indicated for use on women who are at >36 completed weeks, with singleton pregnancies.

F15 series are intended to be used by trained health care professionals in clinical and hospital-type facilities, in private households and during transports in healthcare facilities.

1.2 Features

F15 series fetal and maternal monitors are divided to wired models and wireless models based on configurations and functions and there are total two models: Wired model F15 and wireless model F15 Air.

The following table lists the configuration of F15 series.

Model / Configuration	F15	F15 Air
US Transducer		
-FHR-Singleton	√	√
-FHR-Twins	√	√
-FHR-Triplets	●	●
-AFM	√	√
TOCO Transducer		
-TOCO	√	√
-MFM	●	●
-MECG	●	●
-HR	●	●
DECG Fetal&Maternal Module		
-DECG	●	●
-IUP	●	●
FECG Fetal&Maternal Module		
-eFHR-Single	—	●
-HR	—	●
-eTOCO(FECG)	—	●
-TOCO(pressure sensor)	—	●
-MFM	—	●
F15 Main Unit		
-NIBP	●	—
-SpO2	●	—
-PR	●	—
-TEMP	●	—
-MFM	●	—
FT20 Telemetry Transmitter		
-NIBP	—	●
-SpO2	—	●
-PR	—	●
FTS-3 Fetal Telemetry System		
-FHR-Singleton	●	●
-FHR-Twins	●	●
-TOCO	●	●
- AFM	●	●
Others		

-WI-FI	●	●
-Battery	√	√
NOTE: √ = Standard ● = Optional — = Not Available		

1.3 Instruction for Safe Operation

NOTE:

In this manual, Monitor refers to both F15 and F15 air, and is used where the information applies to both models.

- The monitor is designed to comply with the international safety requirements IEC/EN 60601-1 for medical electrical equipment. It is class I equipment.
- The monitor operates within specifications at ambient temperatures between 0ºC (+32 ºF) and +40 ºC (+104 ºF). Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5 cm) clearance around the instrument for proper air circulation.
- You must check that the equipment, cables and transducers do not have visible evidence of damage that may affect patient safety or monitoring capability before each use. If damage is evident, replacement is recommended before use.
- The monitor must be serviced only by authorized and qualified personnel. The manufacturer does not accept responsibility for safety compliance, reliability and performance if modifications or repairs are carried out by unauthorized personnel. Identical replacement parts must be used.
- The typical operator's position is in front of the monitor. Please position the device in a location where the operator can easily see the screen and access the operating controls.
- The protective degree against electric shock of the patient connections is:

Ultrasound (FHR1, FHR2, FHR3) External TOCO Fetal Movement Mark (FM) Intrauterine Pressure (IUP) Maternal Electrocardiography (MECG) Direct Electrocardiography(DECG) Fetal Electrocardiography (FECG)	Type CF	
Non-invasive Blood Pressure (NIBP) Arterial Oxygen Saturation (SpO_2) Temperature (TEMP)	Type CF, defibrillation-proof	

The monitor described in this user manual is not protected against:

a) The effects of high frequency currents

b) The interference of electrosurgery equipment

1.4 Safety Precautions

WARNING and **CAUTION** messages must be observed. To avoid the possibility of injury, observe the following precautions during the operation of the instrument

WARNING

For using safety:

1 **The monitor is provided for the use of qualified physicians or personnel professionally trained.**

2 **The monitor is not intended for use in intensive care units (ICU), operating rooms or for home use.**

3 **No modification of this monitor is allowed.**

4 **Do not switch on the monitor until all cables have been properly connected and verified.**

5 **EXPLOSION HAZARD - Do not use the monitor in the presence of flammable anesthetics or other materials.**

6 **SHOCK HAZARD - The power receptacle must be a three-wire grounded outlet. Never try to adapt the three-prong plug to fit a two-slot outlet. A hospital grade outlet is required. If the outlet has only two slots, make sure that it is replaced with a three-slot grounded outlet before attempting to operate the monitor.**

7 **The protective earth conductor is required for EMC purposes. It has no protective function against electric shock. Double and/or reinforced insulation protects this device against electric shock.**

8 **Multiple portable socket-outlets shall not be placed on the floor.**

9 **Additional multiple socket-outlet or extension cord can't be connected to the system.**

10 **The multiple portable socket-outlet provided with the system shall be only used for supplying power to equipment which is intended to form part of the system. If the electrical device that does not belong to the system plug in the socket, the total power may exceed the maximum load of the separating transformer and cause high temperature and fire. Enclosure leakage current within the system exceeds the standard limit, which may lead an electric risk.**

11 **SHOCK HAZARD - Do not attempt to connect or disconnect a power cord with wet hands. Make certain that your hands are clean and dry before touching a power cord.**

12 **SHOCK HAZARD-To avoid the risk of electric shock, this equipment must only be connected to a supply mains with protective earth.**

13 **Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously.**

14 **Do not touch the signal input or output connector and the patient simultaneously.**

15 **Accessory equipment connected to the analog and digital interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, consult our technical service department or your local distributor.**

WARNING

16 Connecting any accessory (such as external printer) or other device (such as the computer) to this monitor makes a medical system. In that case, additional safety measures should be taken during installation of the system, and the system shall provide:

a) Within the patient environment, a level of safety comparable to that provided by medical electrical equipment complying with IEC/EN 60601-1, and

b) Outside the patient environment, the level of safety appropriate for non-medical electrical equipment complying with other IEC or ISO safety standards.

17 Using accessories other than those specified by the manufacturer may result in increased electromagnetic emissions or decreased electromagnetic immunity of the device.

18 The device should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, the device should be observed to verify normal operation in the configuration in which it will be used.

19 All the accessories connected to system must be installed outside the patient vicinity, if they do not meet the requirement of IEC/EN 60601-1.

20 Do not exceed the maximum permitted load when using multiple portable socket-outlets to supply the system.

21 SHOCK HAZARD – Do not connect non-medical electrical equipment, which has been supplied as a part of the system, directly to the wall outlet when the non-medical equipment is intended to be supplied by a multiple portable socket-outlet with an isolation transformer. If multiple instruments are connected to a patient, the sum of the leakage currents may exceed the limits given in the IEC/EN 60601-1 and may pose a safety hazard. Consult your service personnel.

22 SHOCK HAZARD - Don't connect electrical equipment, which has not been supplied as a part of the system, to the multiple portable socket-outlet supplying the system.

23 Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC 60601-1 approved to the monitor. The operation or use of non-approved equipment or accessories with the monitor is not tested or supported, and monitor operation and safety are not guaranteed.

24 Do not apply this monitor and other ultrasonic equipment simultaneously on a same patient, in case of possible hazard caused by leakage current superposition. Do not apply this monitor simultaneously with other PATIENT-connected equipment, such as, a cardiac pacemaker or other electrical stimulators, on the same patient.

25 Do not place the TOCO transducer on the oedematous or fragile tissue; change the measuring sites after half an hour.

26 The monitor can only be used on one patient at a time.

27 SHOCK HAZARD - Do not remove the top panel cover during operation or while power is connected.

28 Equipment and devices that connect to the monitor should form an equipotential body to ensure effective grounding.

29 No modification of this equipment is allowed without authorization of the manufacturer. If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe operation.

30 Only connect accessories supplied or recommended by the manufacturer to the device.

31 The system should be operated by the doctor or under the doctor's instructions.

WARNING

32 Do not apply the monitor during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.

33 ECG cables may be damaged when connected to a patient during defibrillation. Check cables for functionality before using them again.

34 Only SpO2, NIBP and TEMP applied parts of the monitor are defibrillation-proof. When a defibrillator is applied, keep other accessories away from the patient. Otherwise it may result in damaging the monitor or harming the patient.

35 After defibrillation, the screen display recovers within 10 seconds if the correct electrodes are used and applied based on the manufacturers' instructions.

36 Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).

37 Make sure that the power is turned off and the power cord is disconnected from the AC socket before connecting or disconnecting equipment. Otherwise, the patient or operator may receive electrical shock or other injury.

38 Parts and accessories used must meet the requirements of the applicable IEC 601 series safety standards, and/or the system configuration must meet the requirements of the IEC 60601-1 medical electrical systems standard.

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

40 Do not use a damaged transducer or one with exposed electrical contacts.

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

42 Do not service or maintain the monitor or any accessory which is in use with the patient.

43 Assembly of the monitor and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.

44 The disposable ECG electrode cannot be reused and cannot be used in case of package damage.

45 The instrument is precise; especially the touch screen is fragile. Therefore, for fear of instrument damage, do not operate the instrument violently, and avoid falling and impacting during usage.

For proper monitoring:

46 Alarms must be set up according to different situations of patients. Make sure that audio sounds can be activated when an alarm occurs.

47 Do not perform NIBP measurements on patients with sickle-cell disease or under any condition where the skin is damaged or expected to be damaged.

48 Clinical decision making based on the output of the device is left to the discretion of the provider.

49 Do not put the sensor on extremities with arterial catheter or venous syringe.

50 Do not apply the cuff to a limb that has an intravenous infusion or catheter in place. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.

WARNING

51 The disposable accessories are intended to be used only once. Dispose of them properly after use and do not reuse them.

52 The spiral electrode and IUP catheter are disposable and should not be reused.

53 The IUPC is neither intended nor approved for measuring intrauterine pressure extraovularly; attempting to do so may lead to maternal discomfort or injury.

54 FTS-3 transducers have priority over F15 series US Transducers, DECG Fetal & Maternal Module, TOCO transducer and FECG Fetal&Maternal Module. When FTS-3 transducers get on line, F15 series US Transducers, DECG Fetal & Maternal Module, TOCO transducer and FECG Fetal&Maternal Module will be disabled.

For using the Battery:

55 Before using the rechargeable lithium-ion battery (hereinafter called lithium battery), be sure to read the user manual and safety precautions thoroughly.

56 The lithium battery can only be used for this device.

57 The lithium battery can only be charged in this device.

58 Do not reverse the lithium battery polarity.

59 Do not connect the positive (+) and negative (-) terminals with metal objects such as lead wire, which can result in short circuits.

60 The cycle life of the lithium battery is 300 times. The service life of the lithium battery may shorten if it is used inappropriately. It is recommended to replace the lithium battery after 300 charge-discharge cycles, or it may cause safety risks such as heat and liquid leakage, and risks such as failure or decline of performance.

61 Do not heat or throw the lithium battery into a fire.

62 Do not immerse, throw or wet the lithium battery in water, beverages or other liquids.

63 Do not use or leave lithium battery at high temperature (charging>35℃, discharging>60℃, such as in direct sunlight or in a very hot car), otherwise it may cause overheat, fire, malfunction to the lithium battery, shorten the service life of the lithium battery, or damage the lithium battery.

64 Do not place the lithium battery near microwave equipment or other cooking devices. If the lithium battery is heated or subjected to strong electromagnetic radiation, liquid leakage, heat, smoke, fire, etc. may occur.

65 Do not hit with a hammer, step on or throw or drop to cause strong shock.

66 Do not weld the lithium battery directly.

67 Do not use a lithium battery of other specifications.

68 Do not use a lithium battery with serious scratch or deformation.

69 Keep lithium batteries out of the reach of children.

70 Power off the device, remove and stop using the lithium battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charge, or storage, or it may cause safety accidents such as heat, smoke, and fire.

71 Do not touch a leaking lithium battery. If the liquid leaked from the lithium battery gets into eyes, do not rub the eyes. Wash them well with clean water and see a doctor immediately.

WARNING

72 When the device is running on lithium battery power, do not replace the lithium battery during operation of the device.

73 High internal temperature may also cause the lithium battery unable to be charged. Keep the device at room temperature and move it away from heat sources or out of direct sunlight. The lithium battery will resume charging when the temperature is within range again.

74 Lithium batteries should be charged, used and stored in places far away from static electricity.

75 Only rechargeable button cell supplied or recommended by EDAN can be used. The rechargeable button should be replaced by serviceman authorized by EDAN if needed.

76 Do not replace the lithium battery in the transducer by yourself. If you need to replace the lithium battery, please contact EDAN or qualified service professionals authorized by EDAN for replacement.

77 If any serious incident that has occurred in relation to the device, user and/or patient should report to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

CAUTION

1 The device is designed for continuous operation. Avoid liquid splashing on the device.

2 Refer servicing to qualified personnel.

3 Keep the environment clean. Avoid vibration. Keep it far from corrosive medicine, dust area, high-temperature and humid environment.

4 When installing the unit into a cabinet, allow for adequate ventilation, accessibility for servicing, and room for adequate visualization and operation.

5 Do not operate the unit if it is damp or wet because of condensation or spills. Avoid using the equipment immediately after moving it from a cold environment to a warm, humid location.

6 The appliance coupler or mains plug is used as isolation means from supply mains. Position the monitor in a location where the operator can easily access the disconnection device.

7 Do not sterilize the monitor or any accessory with autoclave or gas.

8 Switch off the system power before cleaning. Cleaning consists of removing all dust from the exterior surface of the equipment with a soft brush or cloth.

9 Only the sensor and cable of US/TOCO transducers are watertight. Pay attention not let any liquid enter the transducer plug.

10 The materials with which the patient or any other person can come into contact conform to the standard of EN ISO 10993-1.

CAUTION

11 Electromagnetic Interference - Ensure that the environment in which the monitor is installed is not subject to any source of strong electromagnetic interference, such as CT, radio transmitters, mobile phone base stations, etc. Even though other devices are in accordance with national standard radiation requirements, the monitor may be interfered.

12 Electromagnetic Interference - Do not use mobile phones nearby in the process of monitoring.

13 Electromagnetic Interference - 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.

14 Electromagnetic Interference - The monitor should not be used adjacent to or stacked with other equipment, refer to section A7.4 Recommended Separation Distances.

15 Electromagnetic interference is not unique to this system but is 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.

16 The medical electrical equipment needs to be installed and put into service according to Appendix 7 EMC Information.

17 Portable and mobile RF communications equipment can affect medical electrical equipment, refer to section A7.4 Recommended Separation Distances.

18 Sterility cannot be guaranteed if package of the fetal spiral electrode is broken or opened.

19 The fetal spiral electrode has been sterilized by gamma radiation. Do not re-sterilize.

20 The device and reusable accessories could be sent back to the manufacturer for recycling or proper disposal after their useful lives.

21 The recommended battery charging temperature ranges from 0°C (32 ºF) to 35°C (95 ºF).

22 If the terminals of the battery become dirty, wipe with a dry cloth before using the battery.

23 The device and accessories are to be disposed of according to local regulations after their useful lives. Alternatively, they can be returned to the dealer or the manufacturer for recycling or proper disposal. Batteries are hazardous waste. Do NOT dispose them together with house-hold garbage. At the end of their life hand the batteries over to the applicable collection points for the recycling of waste batteries. For more detailed information about recycling of this product or battery, please contact your local Civic Office, or the shop where you purchased the product.

1.5 Safety Information

1.5.1 Protecting Personal Information

Protecting personal health information is a major component of security strategy. To protect the personal information and ensure the proper device performance, the user should take necessary precautions in accordance with local laws and regulations and institution's policies. EDAN recommends health care organizations or medical institutions to implement a comprehensive and multifaceted strategy to protect the information and systems from internal and external security threats.

To ensure the patients' safety and protect their personal health information, the user should implement practices or measures that include:

1. Physical safeguards - physical safety measures to ensure that unauthorized personnel do not have access to the monitor.
2. Operational safeguards - safety measures during operation.
3. Administrative safeguards - safety measures in management.
4. Technical safeguards - safety measures in technical field.

CAUTION

1 The operation of the monitor is restricted to authorized personnel only. Assign only staff with a specific role the right to use the monitor.

2 Ensure that all device components maintaining personal information (other than removable media) are physically secure.

3 Ensure that the monitor is connected only to the device authorized/approved by EDAN. Users should operate all EDAN deployed and supported monitors within EDAN authorized specifications, including EDAN approved software, software configuration, security configuration, etc.

4 Protect all the passwords to prevent unauthorized changes. Only the manufacturer's service personnel are allowed to modify the Factory Maintain settings.

5 Anti-virus measures such as USB device virus scanning should be carried out prior to using USB flash drive.

6 Firewalls and/or other security devices should be in place between the medical system and any externally accessible systems. It's recommended to use Windows defender firewall or any other firewall that can defend against DoS and DDoS attacks, and keep it up to date on computer installed with MFM-CNS, MFM-CNS Lite.

7 DoS and DDoS protection of the router or switch must be turned on for defensing against attacks.

8 When the monitor is returned for maintenance, disposed of, or removed from the medical institution for other reasons, it is necessary to ensure that all patient data are removed from the monitor (Refer to Section *File Management*).

9 To avoid the transmitted data being modified maliciously and (or) stolen, enable the network encryption of the monitor. After that, the device connected to MFM-CNS, MFM-CNS Lite and the transmitted data will be encrypted, ensuring the safety of data transmission.

CAUTION

10 **Protect patients' sensitive information while using the monitor in public places. For information and data displayed on the monitor and saved in the monitor, please pay attention to personal information protection.**

11 **When setting up the network environment: 1) Please enable the MAC address filtering function when using the wireless router. Only device whose MAC address meets requirement can use wireless network and add the MAC address of the monitor to the list of rules. 2) Suggest to build a VLAN. Assign the switch port, LAN port used by monitor and central station to the same VLAN, separated with other VLAN.**

12 **The upgrade of the monitor can only be carried out by persons authorized by the manufacturer.**

NOTE:

Log files generated by the monitor are used for system troubleshooting and do not contain protected medical data.

1.5.2 Security

For more security operations, please enter Main **Menu** > **System**, input user maintain password > **Security configuration**. In this window:

- Set the on or off of **Password Activation**. If **Password Activation** is set to **On**, after the device is restarted, the user shall modify the user maintenance password to enter the operation interface on password input interface; If Password Activation is set to **Off**, the user can enter the operation interface without modifying the password.

Note:

Please modify the user maintenance password according the prompt. The default initial user maintenance password is 9999.

- Choose the **Login Timing** time. If the user has not operated the monitor within the chosen time, the user shall input the user maintenance password in the pop-up window when operating the monitor again. If the user chooses **Infinite**, he will not be required to input the user maintenance password.
- Click **Password Revision** to enter the interface of modifying user maintenance password, please modify the password according to the prompt. For security's sake, please modify the password regularly. It is recommended that the password is composed of letters and numbers.
- Click **Restore Password** to restore the user maintenance password to initial user maintenance password.

Note:

Only the personnel of manufacturer can restore the user maintenance password. If the user forgets the original user maintenance password, please contact the personnel of manufacturer to restore the password.

- Choose the time of **Dynamic Password Period**. The system updates the Maintenance Password Credential of manufacturer according to the chosen time.

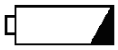
Note:

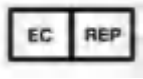
If the device needs manufacturer's maintenance, the user shall inform the personnel of manufacturer of the password credential in the password input interface according to which the personnel of manufacturer can acquire the maintenance authority of manufacturer.

- Set the on or off of **Authority Control**. When the **Authority Control** is set to **On**, it can resist against virus attack.
- Set the on or off of **Firewall**. When the **Firewall** is set to **On**, it can resist against network attack.
- Set the on or off of **Network Encryption**. When the **Network Encryption** is set to **On**, it can identify the accessed MFM-CNS, MFM-CNS Lite and encrypt the data transmitted from MFM-CNS, MFM-CNS Lite so as to ensure the security of data transmission.
- Set the on or off of **Saving Encryption**. When the **Saving Encryption** is set to **On**, it can encrypt the data exported to USB drive so as to ensure the security of exported data.

1.6 Definitions and Symbols

F15 Series Fetal & Maternal Monitor		
1		Fetal monitoring socket, ultrasound transducers, TOCO transducer and DECG Fetal&Maternal Module can be connected to it(Type CF applied part)
2		Socket for Remote Event Marker (Type CF applied part)
3		Socket for Fetal Stimulator (Type CF applied part)
4		Socket for ECG cable (Type CF applied part)
5	 TEMP	Socket for TEMP Transducer (Type CF applied part)
6	 NIBP	Socket for NIBP Cuff (Type CF applied part)
7	 SpO_2 (EDAN)	Socket for SpO_2 Transducer (Type CF applied part)
8	 SPO_2(Nellcor)	Socket for SpO_2 Transducer (Type CF applied part)
9		DB9 interface

10		RJ45 Interface
11		Battery check
12		Alternating Current
13		Direct Current
14		Stand-by
15		Power Supply switch
16		Warning (Background: Yellow; Symbol & outline: Black)
17		Caution
18		Operating instructions
19		Refer to User Manual (Background: Blue; Symbol: White)
20		TYPE CF APPLIED PART
21		DEFIBRILLATION-PROOF TYPE CF APPLIED PART
22	IP68	Dust-tight and protected against the effects of continuous immersion in water
23	IPX2	Protected against vertically falling water drops when enclosure tilted up to 15°
24		CE marking
25		General symbol for recovery/recyclable

26	P/N	Part Number
27		Date Of Manufacture
28		Manufacturer
29		AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY
30		Disposal method
31		Non-ionizing electromagnetic radiation
32		USB Port
33		Ethernet Port
34	SN	Serial Number
35	REF	Catalogue number
36	Rx Only	Federal (U.S.) Law restricts this device to sale by or on the order of a physician
37		MR Unsafe – keep away from magnetic resonance imaging (MRI) equipment
38		This way up
39		Fragile, handle with care
40		Keep dry

41		STACKING LIMIT BY NUMBER
42		HANDLE WITH CARE
43		DO NOT STEP ON

NOTE:
The user manual is printed in black and white.

Chapter2 Installation

WARNING

The system installation should be operated by serviceman authorized by the manufacturer.

2.1 Opening the Package and Checking

Visually examine the package prior to unpacking. If any signs of mishandling or damage are detected, contact the carrier to claim for damage.

Open the package; take out the monitor and accessories carefully. Keep the package for possible future transportation or storage. Check the components according to the packing list.

Check for any mechanical damage.

Check all the cables and accessories.

If there is any problem, contact us or your local distributor immediately.

2.2 Installing Battery

If your monitor has been configured with the rechargeable lithium-ion battery, follow these steps to install the battery:

WARNING

1 Switch off the monitor and unplug it before installing or removing the battery.

2 Make sure the battery has been installed before using the monitor.

(1) Battery Installation

a) Carefully place the monitor upside down on a flat surface covered with cloth or other type of protecting pad.

b) Remove the screws of the battery compartment using a cross-head screw driver. Remove the battery compartment cover.

c) Take the battery out from package, with the label side facing up.

d) Put the battery and the cables into the battery compartment and insert the cable connector into the socket.

e) Shut the battery compartment cover and fix the screws.

(2) Battery Removal

Fold the LCD display completely flat before turning the monitor upside down. Remove the battery in reverse order.

NOTE:

1 **If a rechargeable battery is outfitted, charge it fully each time after using the device to ensure the electric power is enough.**

2 **After the device is transported or stored for a long time, charge the battery fully before use. Connecting to power supply will charge the battery no matter if the monitor is powered on.**

3 **Do not pull the battery cables, or the battery may become damaged.**

2.2.1 Patient Transfer Within the Hospital

The battery in the monitor provides the opportunity of transferring a patient within the hospital without interruption in monitoring.

1 Unplug the power cable from the monitor, now the monitor is operating on battery power.
2 Transfer the patient with the monitor (on a trolley) to the new location.
3 Reconnect the power cable to the monitor.

2.3 Installing Monitor

The monitor can be placed on a flat surface, or be installed on a wall or a trolley. The service engineer should install the monitor properly.

CAUTION

If you choose to install the monitor on the wall, it is the user's responsibility to ensure their integrity and solidity evaluated by a registered, professional structural or mechanical engineer and compliance with all local regulations. The manufacturer will not be responsible for the failure and loss of any improper installation.

2.4 Loading Recorder paper

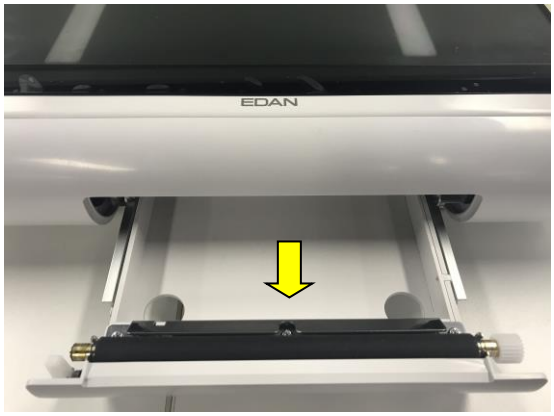
WARNING

1 **Only use the recorder paper provided by the manufacturer, otherwise the recorder may be damaged. This kind of damage is not covered by warranty.**

2 **Configured with different hardware, the monitor is compatible with both GE and Philips recorder paper. However, only one type of paper is configured with the monitor in the shipment. If you want to use the other type of paper, contact the manufacturer for service first, otherwise trace excursion or paper jam may occur.**
3 **Please check whether the recorder paper is correctly loaded.**
4 **Do not pull on the paper to advance it, as this can cause misalignment of the paper. Always tear off the paper along the perforation.**

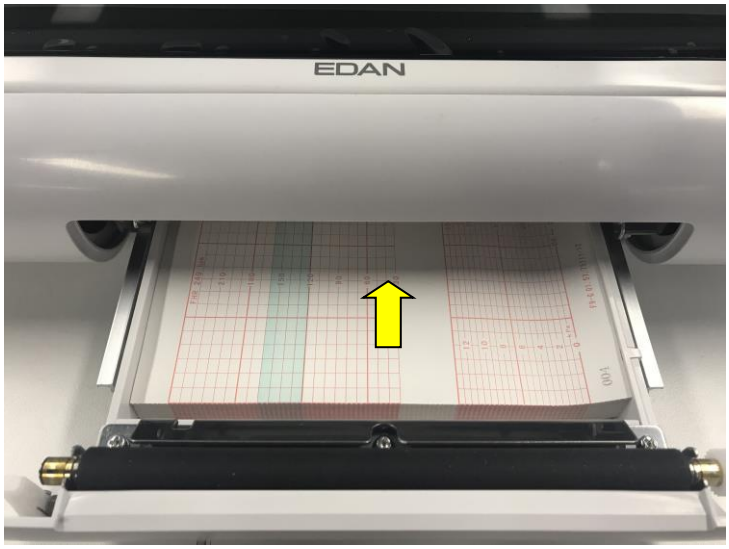
If the monitor is used for the first time or when the paper runs out, you should load paper.

1) Pull the handle of the paper drawer and slide the drawer out carefully.

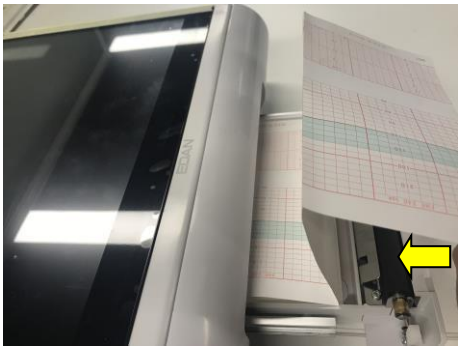
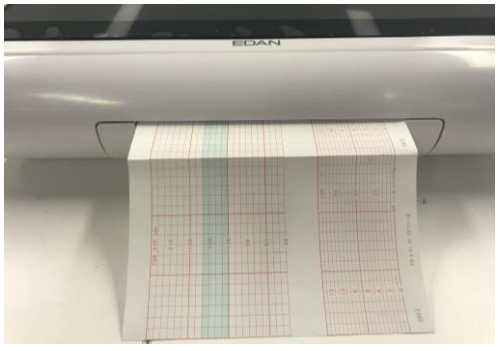
2) Take out the Z-fold thermosensitive paper and remove the wrapper.

3) Place the pack in the drawer, with the pane facing up and the FHR trace area on the left.



4) Unfold two sheets from the top of the pack and pull the end of the paper out of the drawer (make sure the pack in the drawer remains flat).

5) Slide the drawer in until it “clicks” closed.

NOTE:

1 **Be careful when inserting paper. Avoid damaging the thermosensitive print head.**

2 **Make sure the paper is evenly loaded in the drawer. Otherwise the data will be inaccurate or paper jam will happen.**

3 **Only use the paper the manufacturer approved to avoid poor printing quality, deflection, paper jam or failure to recover traces.**

4 **Keep the drawer closed unless when loading paper or servicing.**

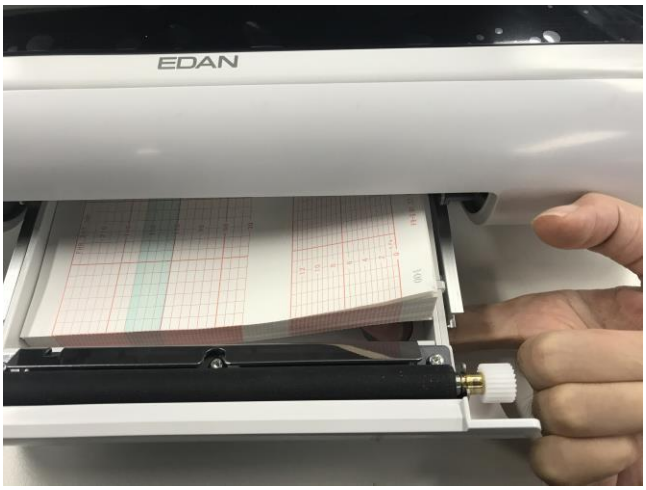
Removing Paper Jam

When the recorder does not function or sound properly, open the drawer to check for a paper jam. Remove the paper jam in this way:

Cut the recorder paper from the paper drawer edge.

Through the hole on the bottom panel of the paper drawer, push the recorder paper up with one finger. Remove the paper.

Reload paper and then close the drawer.



2.5 Connecting Power Cable

Make sure the AC power supply of the monitor complies with the following specification: 100V-240V~, 50Hz/60Hz.

Apply the power cable provided with the monitor. Plug one end of the power cable to the power socket of the monitor. Connect the other end to a three-slot power output special for hospital usage.

WARNING

If the protective grounding (protective earth) system is doubtful, the power of the monitor must be supplied by internal power supply only.

NOTE:

1 **Make sure the monitor and the power outlet are placed at a place where it is easy to connect and disconnect the power cord.**

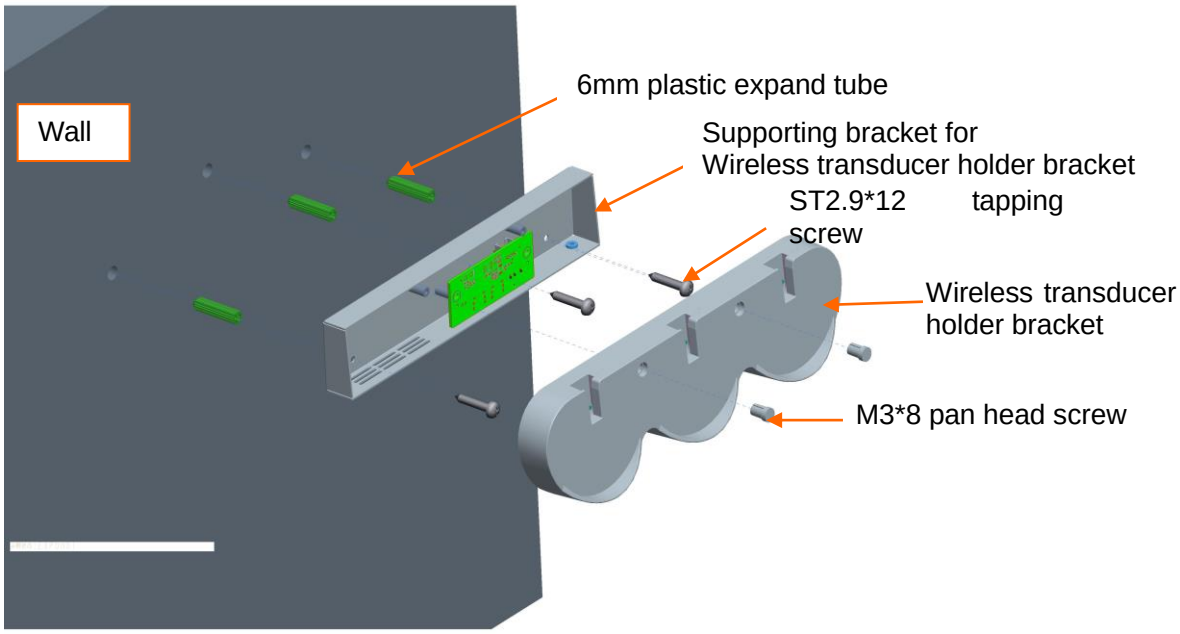
2 **When the supply mains is interrupted, the device switches to internal power supply and operates normally if the battery is installed. If the battery is not installed, the monitor shuts down and resumes the previous settings at the subsequent operation.**

3 **If the system is powered off and then turned on, the alarm setup will resume to the setup which is set before the power-off.**

2.6 Installing Transducer Holder Bracket

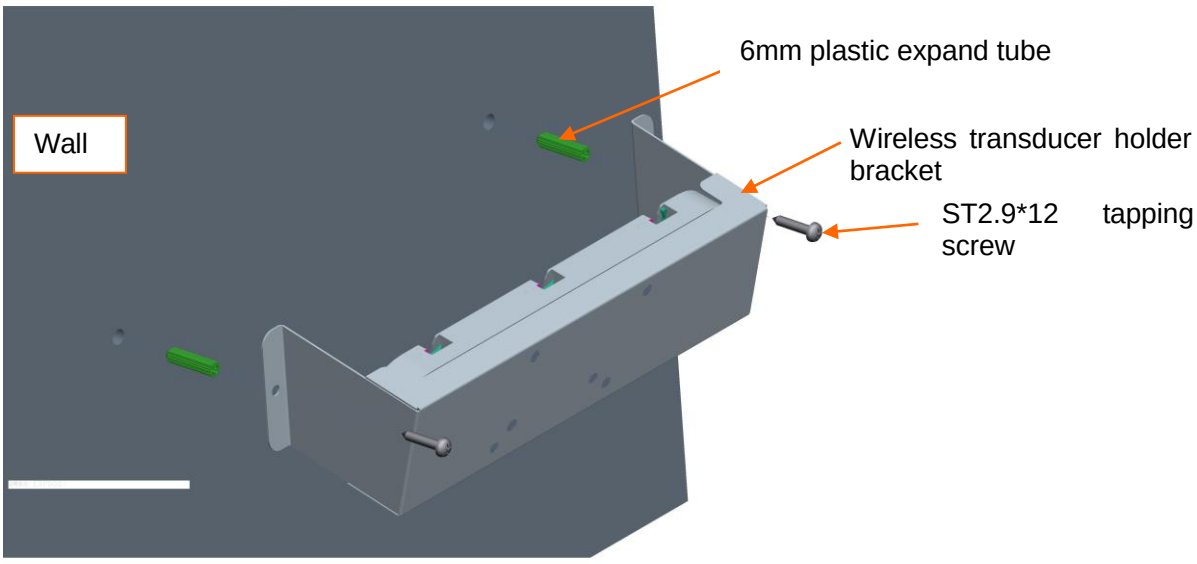
You can choose to install the transducer holder bracket on the wall or on the trolley.
Please refer to *MT-811 Trolley (For medical use) Assembling Instruction* for method to install it on the trolley.
The method to install it on the wall is as below.
Method to install wireless transducer holder bracket (Plan A):

1. Mark the location of mounting holes of wireless transducer holder bracket on the wall and then use a Φ6 drill to punch the wall.
2. Knock three 6mm plastic expand tubes into the punched holes.
3. Fix the wireless transducer holder bracket on the wall with three ST2.9*12 tapping screws.
4. Fix the wireless transducer holder bracket on the supporting bracket with two M3*8 pan head screws, and then fill two silicon plugs in the mounting holes of wireless transducer holder bracket.



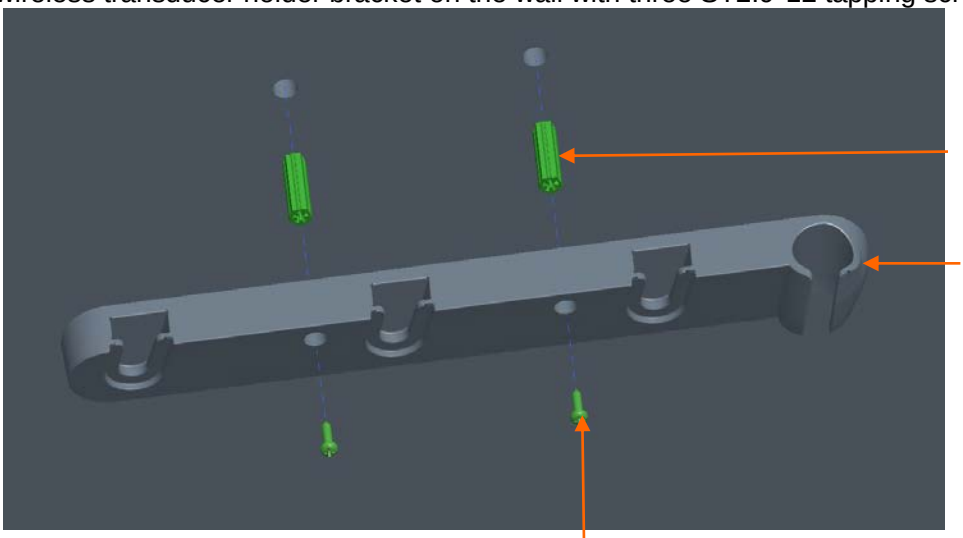
Method to install wireless transducer holder bracket (Plan B):

1. Mark the location of mounting holes of wireless transducer holder bracket on the wall and then use a Φ6 drill to punch the wall.
2. Knock three6mm plastic expand tubes into the punched holes.
3. Fix the wireless transducer holder bracket on the wall with three ST2.9*12 tapping screws.



Method to install wired transducer holder bracket:

1. Mark the location of mounting holes of wireless transducer holder bracket on the wall and then use a Φ8 drill to punch the wall.
2. Knock two 6mm plastic expand tubes into the punched holes.
3. Fix the wireless transducer holder bracket on the wall with three ST2.9*12 tapping screws.



Chapter3 Basic Operation

NOTE:

The pictures and interfaces in this manual are for reference only.

3.1 Overview

Figure 3-1 Appearance

1	Alarm Indicator
2	Display Screen
3	Charge, AC, Power Indicator
4	Sockets
5	Paper Drawer
6	Transducer

3.1.1 Left Panel

F15:

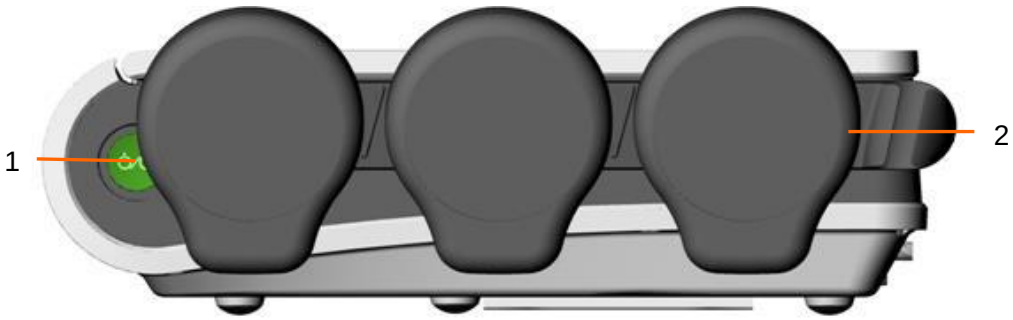
F15Air:

Figure 3-2 Left Panel

1	Sockets for Transducers and Cables: enables the parameter measurement.

3.1.2 Right Panel

F15:



F15Air:

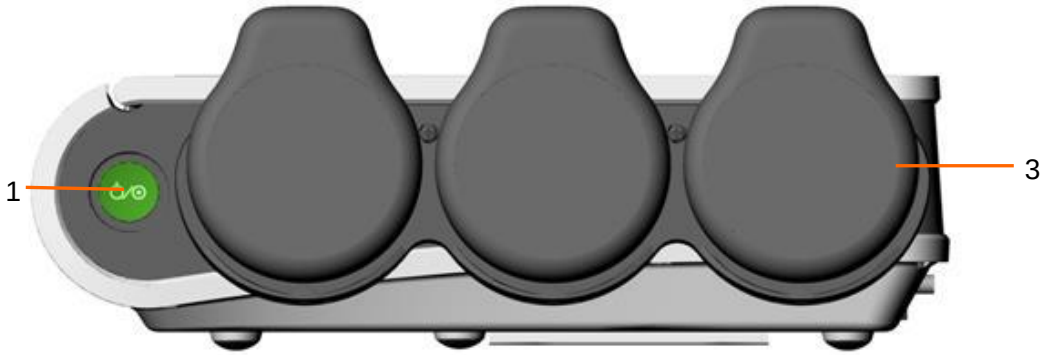


Figure 3-3 Right Panel

1	Power Switch
2	Transducer Holder
3	Transducer Docking Slots-- used to dock and charge wireless transducers.

NOTE:

1. Please dock the wireless transducers per figure 3-3(F15 Air) or charging can't be completed.

2. The wired transducer hanger and wireless transducer charging dock can be hanged on wall or can be fixed on the trolley.

3.1.3 Rear Panel

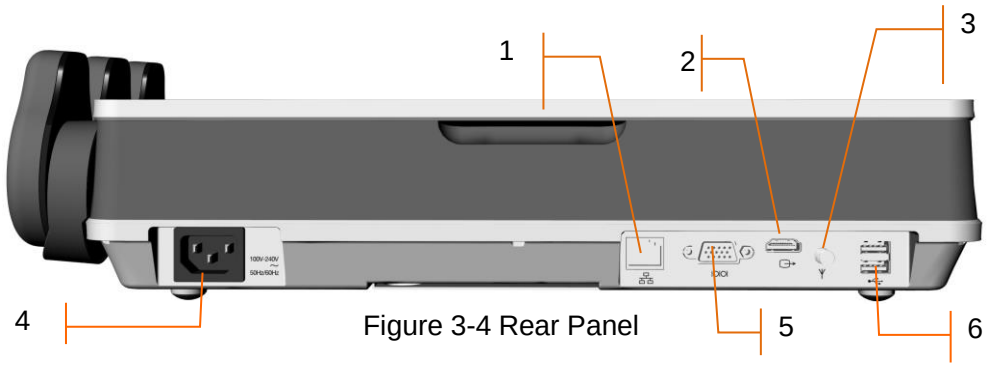


Figure 3-4 Rear Panel

1	RJ45 Socket: it connects the monitor to the central monitoring system (MFM-CNS, MFM-CNS Lite) through Ethernet, which enables MFM-CNS, MFM-CNS Lite to achieve bidirectional communication with the monitor.
2	HDMI Socket: it connects to an external display to project the display of the monitor, the output resolution is 1080P
3	Antenna: If the monitor has a built-in wireless module, an antenna will be configured. It is used to send signals of the bedside monitor to the obstetrical monitoring system.
4	Power Socket: for connecting AC power cable.
5	DB15: it connects the monitor to the central monitoring system (MFM-CNS, MFM-CNS Lite) through serial port, which enables MFM-CNS, MFM-CNS Lite to achieve bidirectional communication with the monitor.
6	USB Socket: supports USB 2.0 output. It connects approved USB devices, for example, USB flash disk.

3.1.4 Bottom Panel

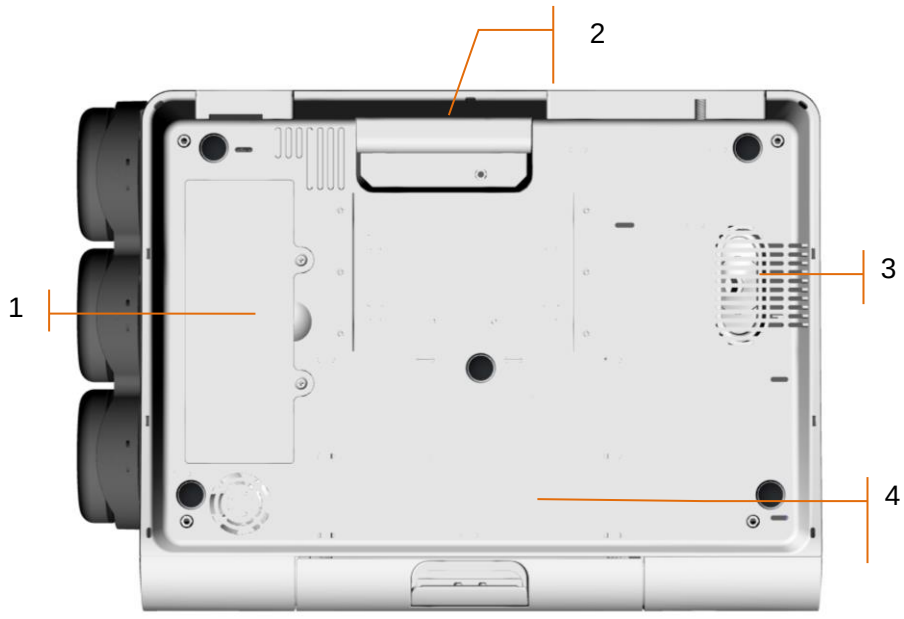


Figure 3-5 Bottom Panel

1	Battery Compartment
2	Handle
3	Loudspeaker
4	Label

3.1.5 Indicators

There are four indicators on the top of the screen and the front panel. From the top down they are: alarm indicator, CHARGE indicator, AC indicator and Power indicator. The table below lists their meanings:

Indicator		Status of Indicator	Meaning
	Alarm Indicator	Flash or light up in yellow or red according to alarm priority	An alarm is active.
		Off	No alarm is active.
	Charge Indicator	On	The battery is being charged.
		Flash	Battery low, please charge the battery in time.
		Off	No battery or the battery is fully charged.
	AC Indicator	On	The monitor is connected to AC power supply.
		Off	The monitor is not connected to AC power supply.
	Power Indicator	On	The monitor is powered on.
		Off	The monitor is powered off.

3.2 Transducers and Cables

The transducers and cables of wired model include: wired US transducers, wired TOCO transducer, wired DECG Fetal&Maternal Module, remote event marker, ECG cable, DECG cable, DECG-IUP integrated cable, fetal spiral electrode, IUP catheter, SpO_2 sensor, NIBP cuff and TEMP sensor.

The transducers and cables of wireless model include: wireless US transducers, wireless TOCO transducer, wireless FECG Fetal&Maternal Module, wireless DECG Fetal&Maternal Module, ECG cable, DECG cable, DECG-IUP integrated cable, fetal spiral electrode and IUP catheter.

You may not have all of these transducers and cables, depending on the monitor configuration purchased.

3.2.1 Transducers

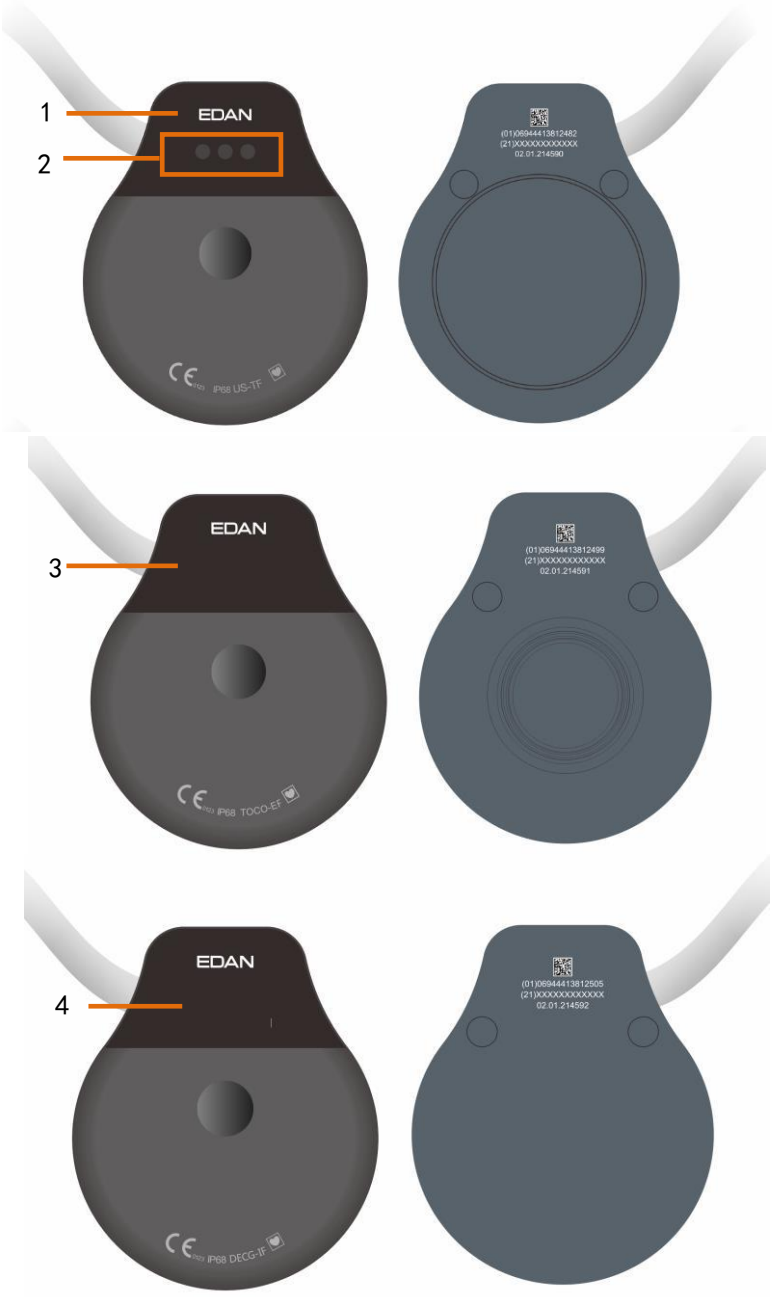


Figure 3-6 Wired Transducers

1. Wired US Transducer
2. Wired US Transducer Indicators
3. Wired TOCO Transducer
4. Wired DECG Fetal&Maternal Module

Note:

The indicators on the wired US transducer are intended to distinguish US transducer 1/2/3. When plugging in the wired US transducer, the three indicators will light up shortly for one time so users can perform self-check. After the self-check, the transducer enters normal working mode. The first indicator lights up, it indicates the US transducer is US1; the first and second indicators light up, it indicates the US transducer is US2; the three indicators light up, it indicates the US transducer is US3.

Figure 3-7 Wireless Transducers

5. Wireless TOCO Transducer 6. Wireless US Transducer 7. Wireless DECG Fetal&Maternal Module

CAUTION

Degree of protection against harmful ingress of water of the US transducer, TOCO transducer and Fetal&Maternal Module is IPX68. They can be continuously immersed in water to a depth of 1.1 meter for 24 hours and remain safe, but they are not allowed to be immersed in organic solvent, such as ethanol.

Figure 3-8 ECG Electrode Sleeve

The ECG electrode sleeve is used together with TOCO transducer for MHR monitoring.

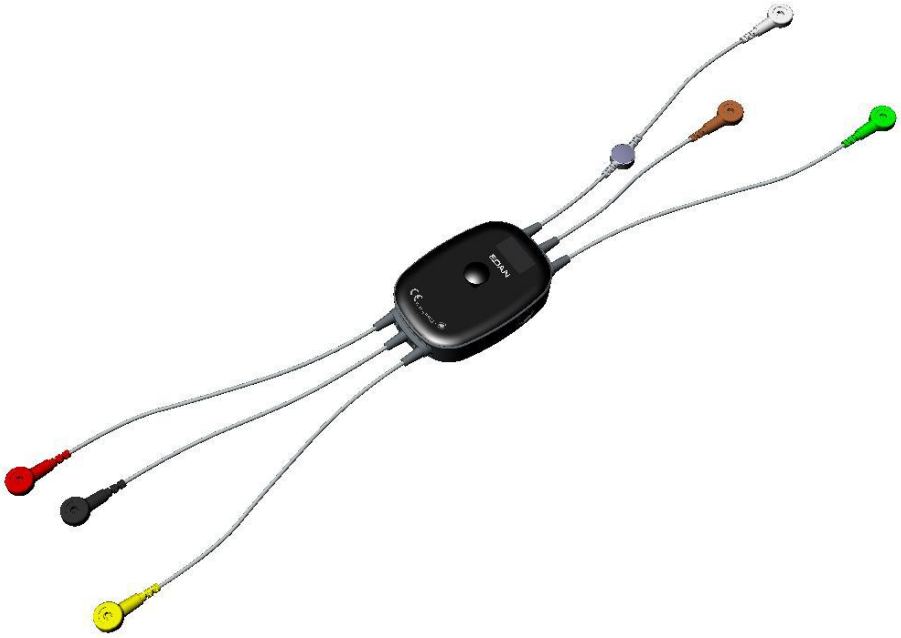


Figure 3-9 Wireless FECG Fetal&Maternal Module and ECG Leads

The FECG cable is configured with remote event marker. Press the remote event marker button when feeling fetal movement.

Figure 3-10 Front View and Back View of the Wireless FECG Fetal&Maternal Module

Figure 3-11 ECG Leads Socket

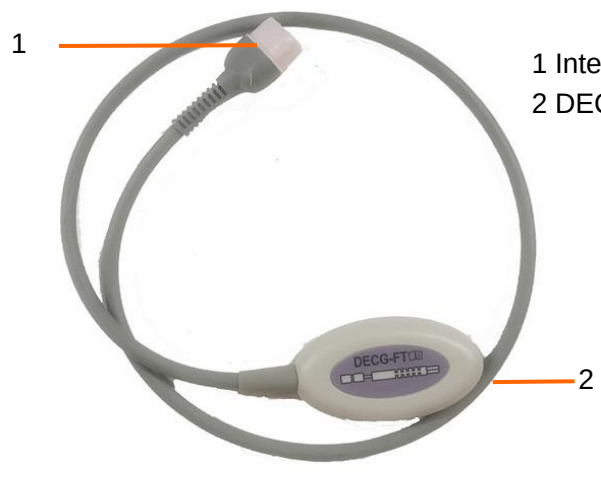
The wireless FECG Fetal&Maternal Module is used with ECG leads and monitor eFHR, HR and uterine activity through FECG techonology, uterine activity can also be monitored through the pressure sensor.

3.2.2 Remote Event Marker(Optional for F15 Only)

The remote event marker is a hand-held device operated by pregnant woman herself. Press the button on the remote event marker when feeling fetal movement.

Figure 3-12 Remote Event Marker

3.2.3 DECG Cable



1 Interface to DECG-IUP integrated cable
2 DECG cable plug

Figure 3-13 DECG Cable

3.2.4 DECG-IUP Integrated Cable

1 Interface to IUP catheter
2 Interface to TOCO transducer
3 Interface to DECG cable

Figure 3-14 DECG-IUP Integrated Cable

3.2.5 Fetal Spiral Electrode

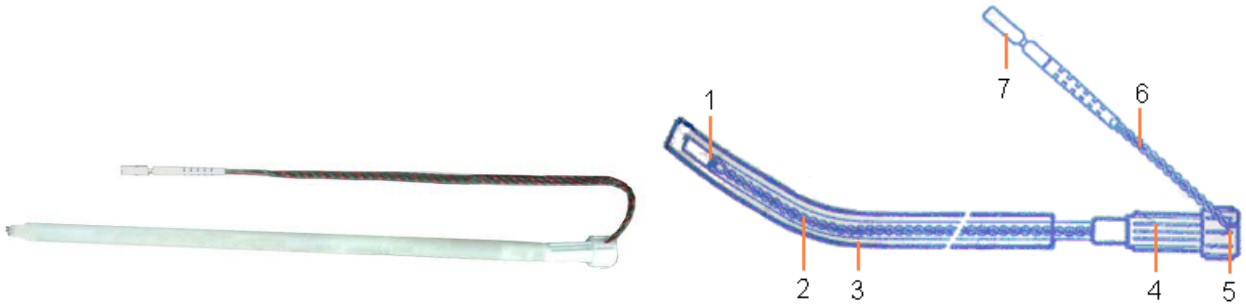
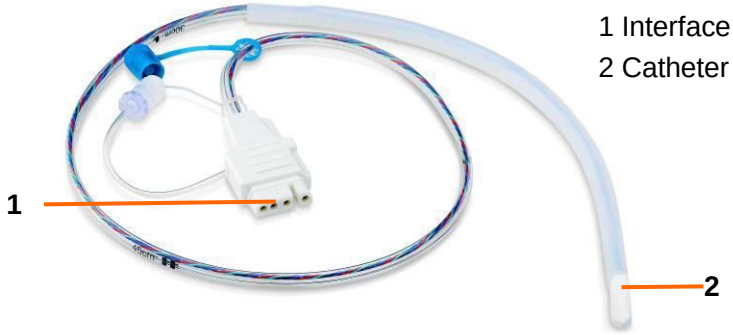


Figure 3-15 Fetal Spiral Electrode

1	Reference Electrode	2	Drive Tube	3	Guide Tube	4	Drive Handle
5	Handle Notch	6	Electrode Wire	7	Safety Cap		

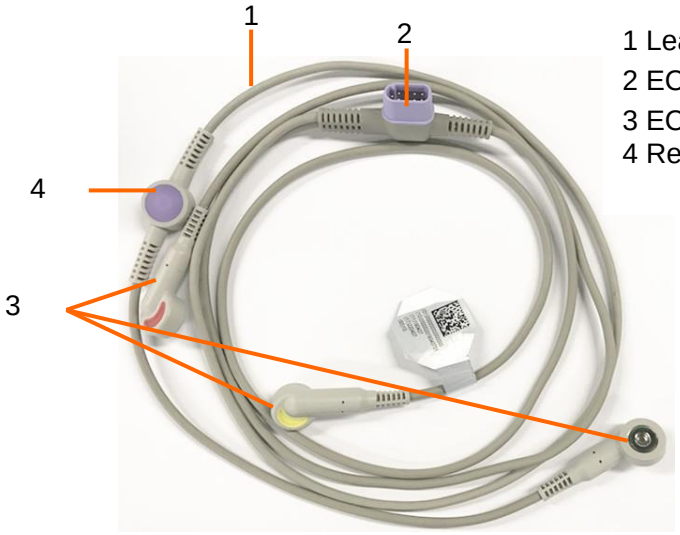
3.2.6 IUP Catheter



1 Interface to DECG-IUP integrated cable
2 Catheter

Figure 3-16 IUP Catheter

3.2.7 ECG Cable



1 Lead Wire
2 ECG Connector
3 ECG Fastener
4 Remote Event Marker

Figure 3-17 ECG Cable

The ECG cable is configured with remote event marker. Press the remote event marker button when feeling fetal movement.

3.2.8 SpO_2 Sensor

1 SpO_2 Connector
2 SpO_2 Sensor

Figure 3-18 SpO_2 Sensor

3.2.9 NIBP Cuff

1 NIBP Cuff
2 Inflation Tube Connector
3 Cuff Extension Tube

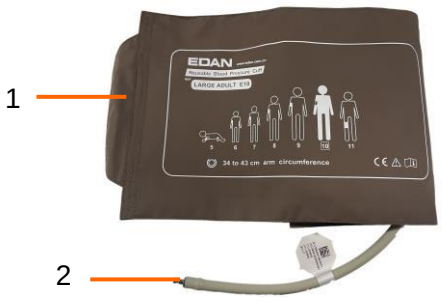


Figure 3-19 NIBP Cuff

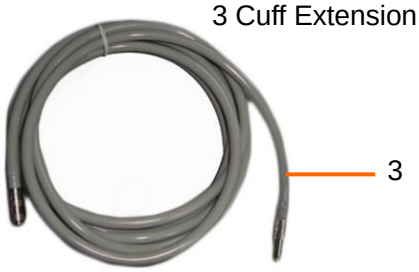


Figure 3-20 Cuff Extension Tube

3.2.10 TEMP Sensor

1 TEMP Connector
2 TEMP Sensor

Figure 3-21 TEMP Transducer

3.3 FT20 Telemetry Transmitter

Figure 3-22 FT20 Telemetry Transmitter

Figure 3-23 Socket of FT20 Telemetry Transmitter

The FT20 Telemetry Transmitter supports wireless measurement of maternal NIBP and SpO2.

3.3.1 Charging FT20 Telemetry Transmitter

There are two methods to charge the FT20 Telemetry Transmitter:

1. Put the FT20 Telemetry Transmitter in the docking slot, for details please refer to *3.4.1 Charging Wireless Transducer.*
2. Charge the FT20 Telemetry Transmitter with the power cable.

3.3.2 Displaying of FT20 Telemetry Transmitter

No.	Description	
1	Wireless Signal Strength Indicator	The wireless signal strength has four degrees:
2	Device Number	When the module connects to the monitor successfully, a number will appear in the center of the screen, which represents the device no. , e.g.: 3
3	Battery Indicator	The battery level has five degrees:
4	Module Connection Status	When the module connects to the monitor successfully, an icon appears at the top right corner of the screen; when the module fails to connect to the monitor, an icon appears at the top right corner of the screen
5	Measurement Numeric	When only SpO2 is measured, the measurement numeric is shown as the picture on the left, when NIBP is measured, the measurement numeric is shown as the picture on the right

3.3.3 Power Key

Press and hold the power key for at least 2 seconds to switch on/off the monitor; double click the power key to enable/disable NIBP measurement.

3.4 Wireless Transducer

3.4.1 Charging Wireless Transducer

CAUTION

1 **When the monitor indicates the power of wireless transducer is low, please change the wireless transducer in time, or the wireless transducer will be switched off automatically and monitoring will be interrupted.**
2 **After docking the transducer into the docking slot for charging, please check if the transducer is well placed and whether it is charging.**
3 **Please wait for 2 minutes to use the transducers after charging.**
4 **The transducer can be used only if the wireless transducer signal is shown as in position on the monitor.**
5 **The temperature of transducer will be increased by no more than 20 ℃ when in charge.**

Rechargeable lithium-ion batteries are installed inside the transducers.

In the process of monitoring, please pay attention to the battery level of the transducers. Battery level is indicated by the battery icon on the top right corner. They are shown as below:

 Full battery

 Sufficient battery

 Inadequate battery

 Low battery, please charge immediately

 The battery is almost depleted and needs to recharge immediately.

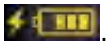
Place a wireless transducer in the docking slot when the monitor is connected to AC power, the docking slot will give out a “Di” sound and the indicator on it will turn green, at the same time, a charging icon  and a battery level icon will be displayed on the screen of the transducer. It indicates that the transducer is docked in the docking slot properly and being charged.

Place a wireless transducer in the docking slot when the monitor is not connected to AC power while powered by battery, the docking slot will give out a “Di” sound and the indicator on it will turn green, at the same time, only a battery level icon will be displayed on the screen of the transducer. It indicates that the transducer is docked in the docking slot properly but cannot be charged.

Before you charge the transducer, please clean the transducer with a dry cloth to make sure they are free of water and residual gel.

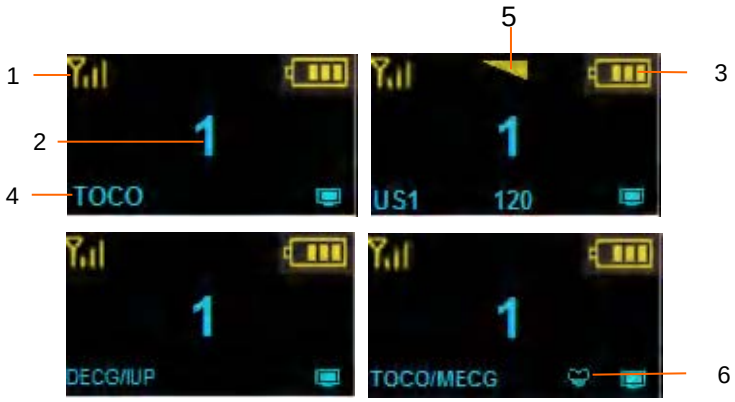
3.4.2 Displaying of Wireless Transducer

When the wireless transducer is being charged in the docking slot:

In the process of charging, a charging icon  displays beside the battery level icon, e.g.:  .

When the charging is finished, the transducer screen turns to blank.

When the wireless transducer is taken out from the docking slot, it will power on automatically and the display is as below:



No.	Description	
1	Wireless Signal Strength Indicator	The wireless signal strength has four degrees:
2	Device Number	When the transducer connects to the monitor successfully, a number will appear in the center of the screen, which represents the device no. , e.g.: 1
3	Battery Indicator	The battery level has five degrees:
4	Transducer Type	For US transducer, US1, US2 and US3 will appear at the bottom left corner of the screen according to the sequence of transducer being taken out. For TOCO transducer, TOCO will appear at the bottom left corner of the screen when ECG cable or electrode sleeve is not connected, and when ECG cable or electrode sleeve is connected, TOCO/MECG will appear.
5	US Fetal Heart Signal Quality Indicator	US fetal heart signal quality has three levels:
6	ECG signal strength of TOCO Transducer	When ECG cable is connected to TOCO transducer, the ECG signal strength icon will appear at the bottom of the screen and it has three degrees:
7	ECG signal strength of FECG Fetal&Maternal Module	FECG signal quality icon(left) and MECG signal quality icon(right) appear in the middle on the top of the screen and there are three degrees:
8	Status of ECG leads of FECG Fetal&Maternal Module	The status of ECG leads is represented by two rows of four letters. The first letter in the first row represents the status of top ECG leads, and the following three letters represent the status of right leg driven, C4 lead and F lead. The first letter in the second row represents the status of bottom ECG leads, and the following three letters represent the status of R, N and L lead. V represents successful connection and X represents failed connection.
9	Transducer Connection Status	When the transducer connects to the monitor successfully, an icon appears at the bottom right corner of the screen; when the transducer fails to connect to the monitor, an icon appears at the bottom right corner of the screen

3.4.3 Close Wireless Transducer

1 Click the measurement numerics fields on the screen and enter its setup menu;

2 Select **Close Probe**;

3 Select **OK** and the transducer will be closed.

NOTE:

1. **Fix the wireless transducers tightly to ensure that they will not shift during movement.**
2. **It is recommended that the transducer should be placed when the patient stands for better monitoring.**
3. **Instruct the patient to move in the prescriptive area and distance for obtaining better signal.**
4. **Please apply coupling gel to the US transducer before use and move the transducer to get the desired fetal heart and belt it to the belly.**
5. **Excessive coupling gel may slide the transducer.**

3.4.4 Monitor the Ambulatory Patient

For ambulatory patients, you can take out the transducer from the docking slot and fix the transducer on the location where the best fetal heart signal is received.

Please pay attention to the following during the monitoring.

- Ensure the transducer is tied up well.
- Record the effective FHR.
- The patient should not walk in strong tramps.
- The patient should move in the prescriptive area, hold the US transducer slightly in case of sliding.
- The patient should be under monitoring when the wireless signal is good.

When the patient moves during monitoring, the interference may occur. The artificial interference may influence the signal transmission quality. It will cause drop out or other interference if the transducer works in the changing environment. Some kind of the artificial interference can be anticipated and others can be discovered by observing the signal.

Some artificial interference may be caused by certain place. You can leave the place such as the elevator or the window in iron for the place with signal reception.

The FHR may not be detected clearly when the patient moves in virtue of artificial interference. During cableless monitoring, the occasional US /TOCO /DECG&IUP dropouts are inevitable.

The manufacturer has no control over the RF environment in the places where the monitor is used. If interference exists at operating frequencies, the monitor performance will be affected. You can change the working channel or move the monitor away from the interference to solve the problem.

Caution

1 **The patient's steps may interfere with the monitoring of fetal heartbeats. It is suggested that the patient walks as less as possible.**

2 **Movement may interfere with the monitoring and computing of FHR. Please try to avoid them.**

3.5 Operating and Navigating

3.5.1 Screen Elements

Everything you need to operate the monitor is contained on its screen. Almost all the elements on the screen is interactive. Screen elements include information fields, waveforms/menu fields, measurement numerics, status fields, and screen keys.

Figure 3-24 Main Interface

Information Fields

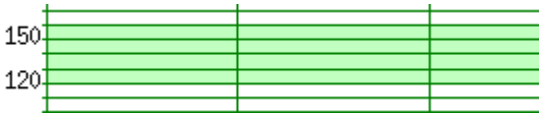
The information fields locate on the top of the screen. When an alarm is active, the message will be displayed here. Patient alarms will be displayed on the left and technical alarms in the center.

Waveforms/menu Fields

The waveforms/menu fields occupy most space of the screen. During monitoring or reviewing, it displays traces; during setting, it displays setup menus.

The background pane bar supports two standards: 30 ~ 240 (American standard) and 50 ~ 210 (International standard).

The green band in between the fetal heart rate panes indicates the preset alarm range (the top edge is not higher than 180 and the bottom edge is not lower than 100). It makes it easy to observe if the FHR exceeds the normal range. So you can easily tell if the fetal heart rate is too low or too high.

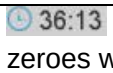
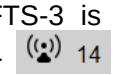
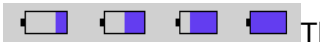


Measurement Numerics Fields

The measurement numeric are displayed on the monitor in real time. For more details, please refer to *3.6.2 Monitoring Numerics.*

Status Fields

No.	Description	
1	Power indicator	AC power supplied; no AC power supplied
2	Battery indicator	The battery is working correctly. The green portion represents the remaining charge. The battery power is low and needs to be charged. There is alarm information on the screen.

		 The battery is almost depleted and needs to recharge immediately  No battery is loaded  Battery malfunction or battery charging stops due to its high temperature  The battery is being charged.
3	Network connection indicator and device no.	 the monitor is online, i.e. the monitor is connected to internet;  the monitor is offline, i.e. the monitor is not connected to internet or not well connected
4	Audio alarm indicator	 the audible alarm is switched on;  the current audible alarm is switched off infinitely;  the current audible alarm is switched off temporarily. The silence duration is configurable to 1min(default), 2min, 3min, or infinite.  the audible alarm reset is switched on (when the audible alarm is configured to alarm reset.).
5	Recorder status indicator	 the recorder is in the process of printing,  no printing is going on
6	Print speed	 The speed of the printing, eg., 3 represents 3 cm/min
7	Print remaining time	 The remaining time of the printing
8	Monitoring timer	 It indicates the duration of the current monitoring, and zeroes when the **START** key is pressed.
9	Status indicator for wireless transducer (for F15 Air only)	The three icons from left to right indicate the status of the three docking slots from inside to outside.  It indicates there's no wireless transducer in the docking slot It indicates the wireless transducer is being charged (when the monitor is connected to the AC power supply)  It indicates the wireless transducer is fully charged It indicates the wireless transducer is in the docking slot but is not charged by the monitor (the monitor is not connected to the AC power supply)
10	FTS-3 system working channel indicator	When FTS-3 is power on and connected to the monitor, the indicator  will be displayed, the number represents the channel number.
11	FTS-3 Base Station Battery indicator of	 The battery power is low and needs to be charged. There is alarm information on the screen.  The battery is almost depleted and needs to recharge immediately  The battery is being charged.

Key Fields

The key filed locates at bottom of the screen, giving you fast access to functions.

(1)*START 

Function: Start monitoring

Press this key to start monitoring (on the main interface).

(2)SILENCE 

Function: Silence/reset

Press this key to disable the current auditory alarm manifestation, and re-enable the monitor's response to new abnormal patient condition.

(3)Alarm Reset 

Function: Alarm reset

When the Alarm Setup→Audible Alarm is set as alarm reset, silence reset is performable. When the audible alarm is set as alarm reset, press the key to perform silence function, then press the key to recover audible alarm.

Even though silence function is performed to shield the audio, the system still could break the silence status and recover the normal work of audio system if new alarm is generated.

(4)AUTO ZERO 

Function: TOCO/IUP zero

Adjust the external TOCO contractions trace/numeric to preset baseline value (external monitoring contractions) or the IUP trace/numeric to reference point 0 (internal monitoring contractions).

(5)MARK 

Function: Record an event.

Press this key to make an event mark or open the smart note list.

(6)PRINT 

Function: Start/stop printing

Press this key to toggle between starting and stopping printing.

(7)*CHANNEL 

Function: Switch the channels

The monitor has three separate channels (channel 1, channel 2 and channel 3). The default fetal heart sound comes from channel 1. When two transducers are connected to the monitor, press this key to switch the sound to channel 2; press it again to switch the sound back to channel 1; when three transducers are connected to the monitor, press the key to switch to channel 2, press it again to switch the sound to channel 3, press it again to switch the sound back to channel 1.

(8)NIBP 

Function: Start or stop a NIBP measurement

Press this key to inflate the cuff and start a NIBP measurement. During the measuring process, press this key to cancel the measurement and deflate the cuff.

(9)BRIGHTNESS 

Function: Adjust the brightness of the screen

Press this key and the up/down key will be displayed. Press the up/down key to increase or decrease gradually the brightness. 9 is the brightest, 0 is the least bright.

(10)PAUSE 

Function: Pause/Continue monitoring

Press the PAUSE key on monitoring status, the curves of MECG, and SpO2 stop tracing; Press the PAUSE key again, the curves restart tracing.

(11)PAT. TRANS. (F15 Air only) 

Function: Admitting and discharging

Firstly, Press this key on the original monitor and select discharging to discharge all the transducers bound to the monitor. Secondly, press this key and select admitting, input the device no. of the original monitor, and wait until all the transducers bound to the original monitor are admitted automatically. Patient transfer can be realized without removing the bound transducers from the body.

Note: If patient transfer is failed, take the transducer off the patient and put it back the dock, then match it and reuse it.

(12)PAPER ADV. 

Function: Advances the paper automatically

When printing stops, press this to advance the paper, making sure the paper has a perforation outside the drawer and is easy to be torn off. Press this key and the paper will advance 8 cm automatically (PHILIPS paper) or 7 cm (GE paper).

(13)SWITCH (Monitor configured with maternal parameters only) 

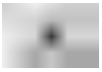
Function: Switch display mode

Press this key to switch display mode among maternal-fetal mode, fetal mode and maternal mode in order.

(14)MAT.INFO 

Function: Input and revise maternal information

Press this key to input and revise maternal information.

(15)MAIN MENU 

Function: Setup menu

Press this key to enter the setup menu of the monitor.

(16)PROBE OFF 

When a transducer unplugged alarm, US/DECG/ECG signal weak alarm or DECG/ECG/IUP leads off alarm or CTG alarm is active, select this key to confirm the alarm and it will be turned off audibly and visually, but it still exists in the alarm review.

NOTE:

If the key sound is enabled, the monitor gives a normal key sound when the operation is valid, and gives a sharp "Di" sound when the operation is invalid.

CAUTION

This monitor is a normal medical device. Please avoid violent operations such as continuously pressing the keys.

3.5.2 Main Menu

Setup menus are provided to change the monitor configurations and monitoring settings. Press the main menu key [redacted] on the main interface to open the main menu.

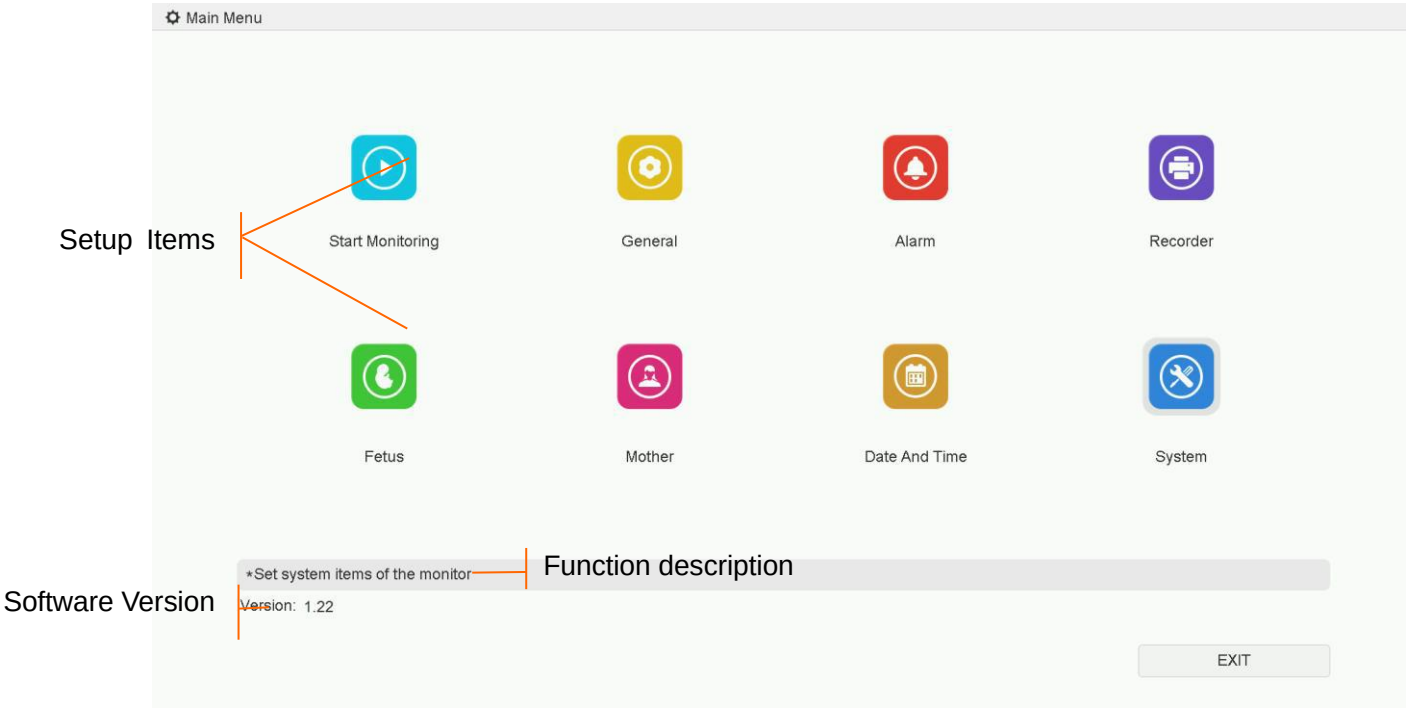


Figure 3-25 Setup Menu

In the setup main menu, you have access to all the items other than **System**. You can select **EXIT** to exit from this menu.

The items in this main menu all have submenu(s). To confirm the setting changes in the submenus, you need to select **OK** to exit. If you don't want to store the new settings, select **Cancel**. If no operation is performed in 30 seconds, the menu will return to the upper directory. The change will not be stored.

Once you select **OK** to confirm the setting changes, the new settings will be stored in the monitor's long-term memory. If the monitor is switched on again after being switched off or a power loss, it will restore the new settings. The setting does not take effect if the system exits automatically or is shut down before **OK** is selected.

For your reference, when the cursor is located at an item in this menu, the monitor provides a brief function description of this item in a pane with blue frame under the items. For example, the cursor is located at "System" in the illustration above. Correspondingly, its function description "Set system items of the monitor" is issued in the below frame pane.

3.5.3 Quick Setup

You can click the waveforms fields and measurement numerics fields on the screen to adjust the settings of waveforms and measurement numerics. For example, to enter the FHR1 setup menu, select the FHR1 (fetal heart rate 1) numeric.

You can also adjust the settings though the main menu key [redacted]. This user manual describes the entry method through the main menu.

3.6 Monitoring Interface

3.6.1 Interface Display

3.6.1.1 *Switch Display Mode

The monitor has three display modes: maternal-fetal mode (figure 3-26), fetal mode (figure 3-27) and maternal mode (figure 3-28).

To change the display mode, select the display mode switch on the main interface. The display mode will switch among the three modes.

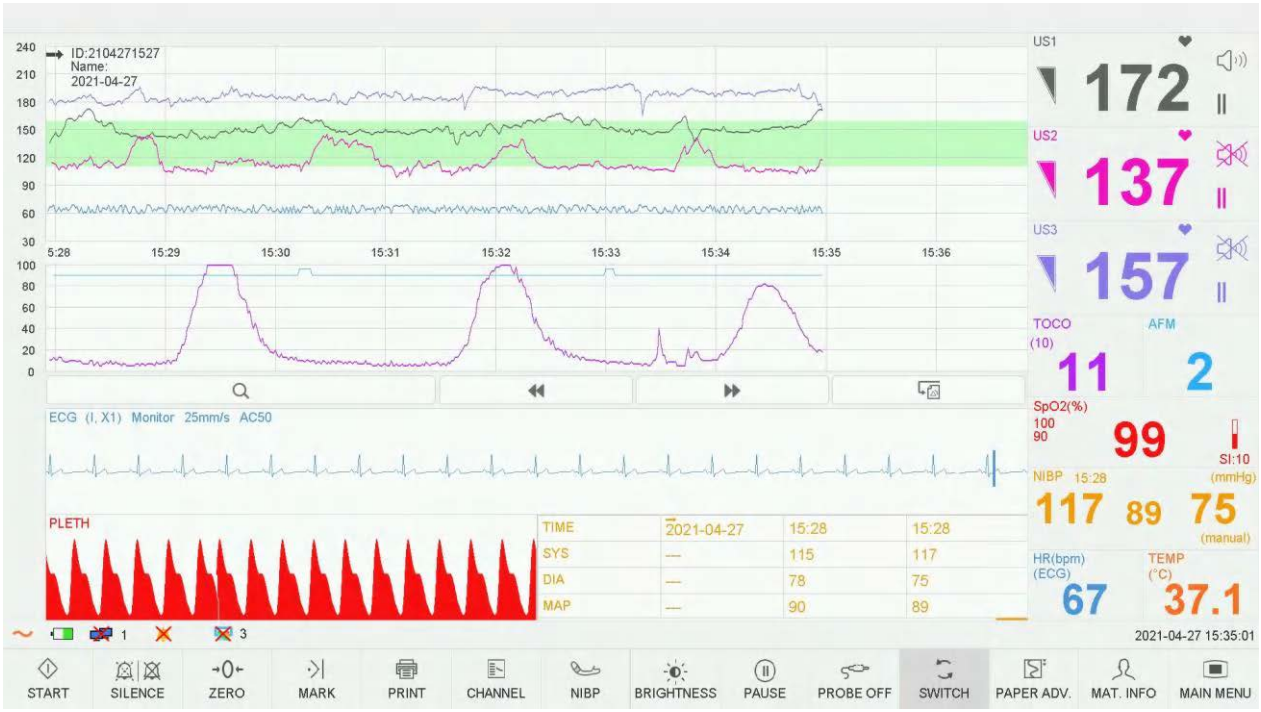


Figure 3-26 Maternal-Fetal mode

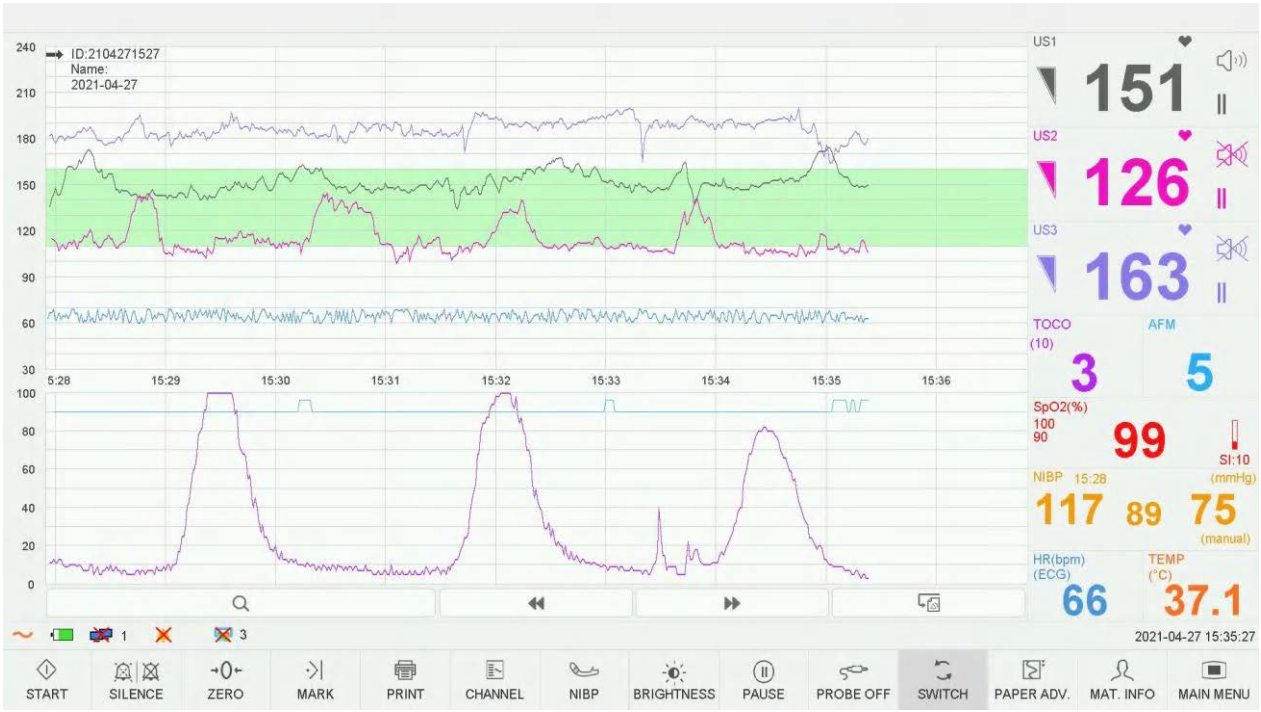


Figure 3-27 Fetal Mode

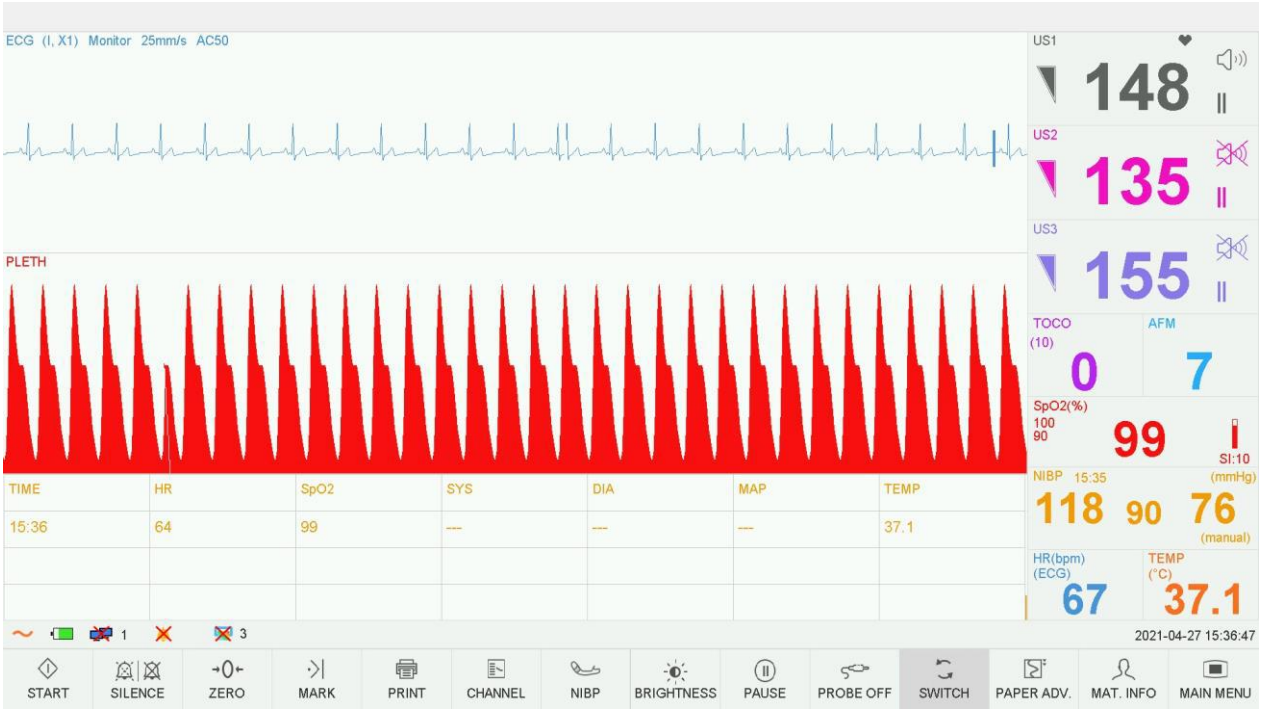
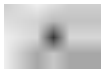


Figure 3-28 Maternal Mode

3.6.1.2 *Background Color Switch

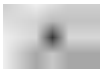
The screen background color has two choices: black and grey (default).

To change the screen color,

1 Select the main menu key  on the main interface.
2 Select **General > Screen Color**.
3 Select the required color.
4 Select **OK**.

3.6.1.3 Changing Numeric Window Position (Suitable for AP/IP Configuration Models)

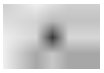
The numeric window can be located either on the right of the traces or on top of them. To change its position,

1 Select the main menu key  on the main interface.
2 Select **General > Numeric Window**.
3 Select **Top** or **Right** (default).
4 Select **OK**.

3.6.1.4 Changing Time Scale

The fetal monitoring traces share the same time scale. This scale is either in real time format or relative time format. Real time is the time of the monitor. Relative time records the elapsed time for the current monitoring.

To change this time format:

1 Select the main menu key  on the main interface.

2 Select **Date And Time > Time Scale**.

3 Select **Real Time** (default) or **Relative Time**.

4 Select **OK**.

NOTE:

The real time contains only the hour and minute, but no second. As a result, the time scale may correspond to the 0 ~ 59th second of the system time. Do not mistake the time scale for the exact time.

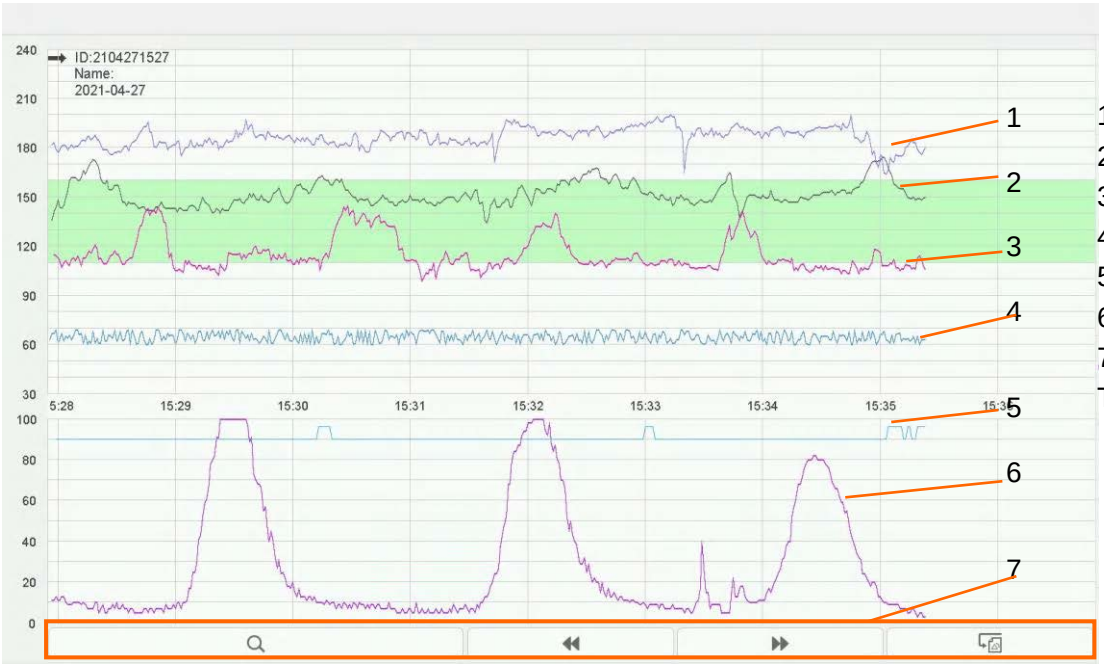
3.6.2 Monitoring Numerics

3.6.2.1 Fetal Monitoring

WARNING

1 Due to the LCD size, resolution and system settings, the traces displayed on the screen may look different from the recorder printout. The printout should prevail when making diagnoses.

2 If the data is doubtful, clinicians should make diagnoses based on the real condition.



1 FHR1Trace
2 FHR2 Trace
3 FHR3 Trace
4 HR Trace
5 AFM Trace
6 TOCO Trace
7 Trace Control Tools

Figure 3-29 Fetal Monitoring Traces

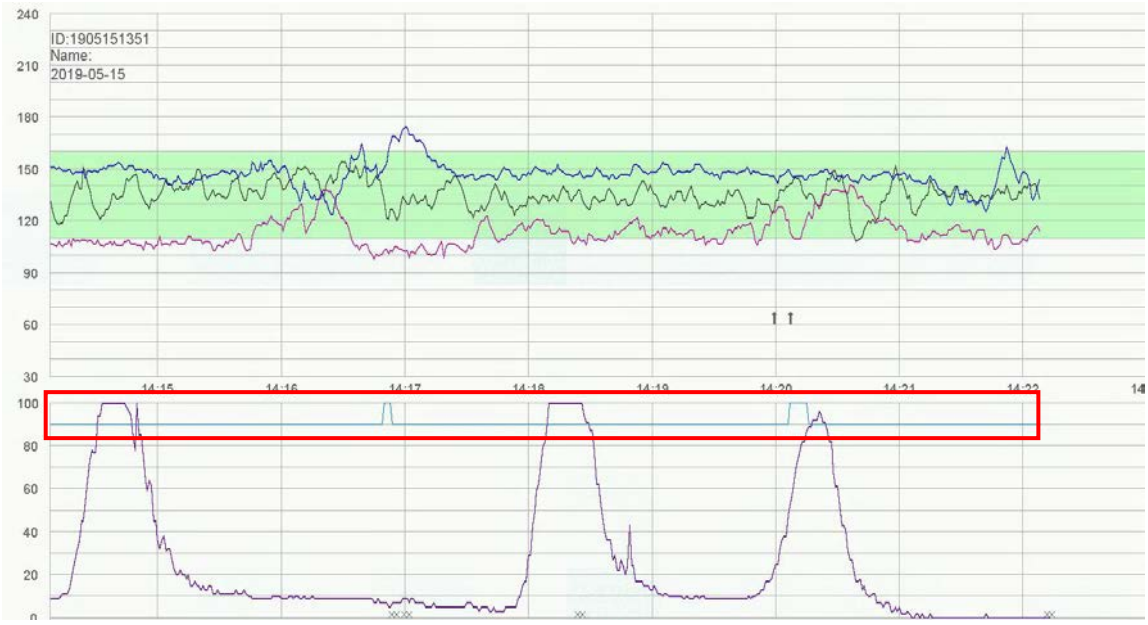
During monitoring or reviewing, the trace window displays six traces: FHR1 trace, FHR2 trace (dual configuration), FHR3 trace (triple configuration), HR trace, AFM trace and TOCO trace.

FHR1/FHR2/FHR3 trace

The y-axis of the trace indicates the numerics of FHR. The range is 30 bpm ~ 240 bpm (American standard) or 50 bpm ~ 210 bpm (International standard).

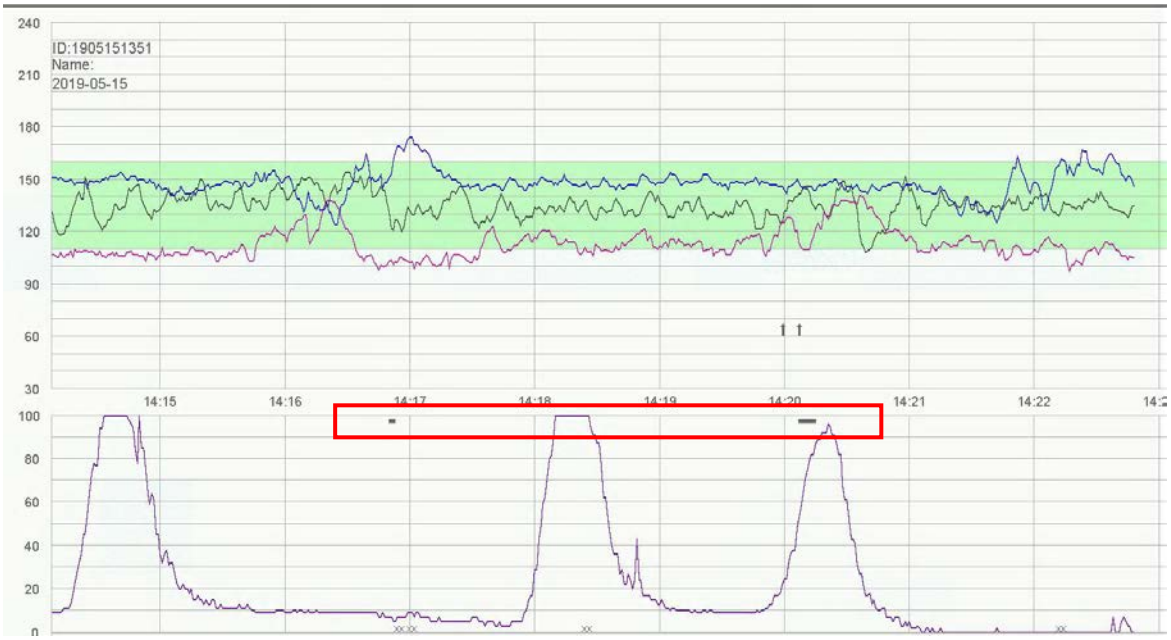
AFM trace

The x-axis of each wave indicates the duration of a detected fetal movement.



AFM black mark

The x-axis of each wave indicates the duration of a detected fetal movement.



NOTE:

AFM trace is only for reference. Please take the MFM marks as criterion.

TOCO trace

The y-axis indicates the numeric of TOCO. The range is 0 ~ 100.

Besides, some other symbols appear among the traces:

1	➞:This symbol indicates the new monitoring starts.
2	⬆: This symbol indicates a manual fetal movement, and it appears after the patient presses the FM marker when she feels a fetal movement.
3	⬇:This symbol indicates the **MARK** key is pressed to record an event, such as the patient turning around, taking injection.
4	→0←:This symbol indicates the monitor is zeroed by pressing **AUTO ZERO** key.

The fetal monitoring values in the numeric window include FHR1/DFHR value, FHR2 value,

FHR3 value, TOCO/IUP value and FM count:

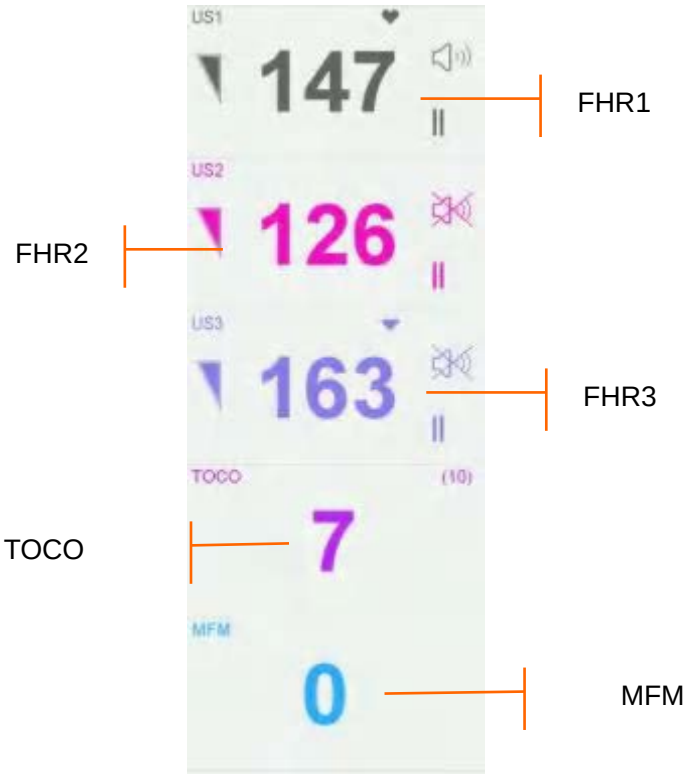
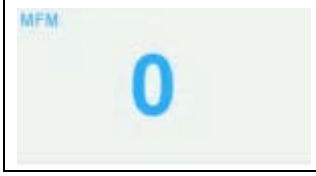


Figure 3-30 Fetal Monitoring Numerics

FHR1/DFHR  **FHR2**  **FHR3** 	 :FHR signal quality. When the quality is poor, it turns into   :FH refreshing rate 147:FHR1/DFHR measurement numeric. If the fetal monitoring socket is not connected with US1 transducer/DECG Fetal&Maternal Module, nothing displays here; if the US1 transducer/ DECG Fetal&Maternal Module is connected but no monitoring is going on or signal is lost or numeric is out of range, it displays ---. 126:FHR2 measurement numeric. If the fetal monitoring socket is not connected with US2 transducer, nothing displays here; if the US2 transducer is connected but no monitoring is going on or signal is lost or numeric is out of range, it displays ---. 136:FHR3 measurement numeric. If the fetal monitoring socket is not connected with US3 transducer, nothing displays here; if the US3 transducer is connected but no monitoring is going on or signal is lost or numeric is out of range, it displays ---.  :FH sound volume adjusting key  :FH sound volume indicator
TOCO/IUP	(10):UA baseline

	7:current UA measurement numeric
FM 	MFM/AFM: MFM source 0: FM count

When monitoring with wireless model, the wireless signal strength icon, and battery level icon of the wireless US transducers, wireless TOCO transducer and wireless DECG Fetal&Maternal Module are displayed in the numeric window. The wireless signal strength of wireless transducer has three degrees, 0 is the poorest signal strength (when the signal strength is 0, transducer wireless signal weak alarm is produced) and 3 is the best signal strength; the battery level of wireless transducer has 5 degrees, 0 is the lowest battery level and 4 is the highest battery level.

When F15 Fetal Monitor is connected to FTS-3 Fetal Telemetry System, and transducers are taken up from the base station, the signal strength icon and battery level icon of the US-T transducers and TOCO-T transducer or TOCO-E transducer are displayed in the numeric window.

3.6.2.2 Maternal Monitoring(F15)

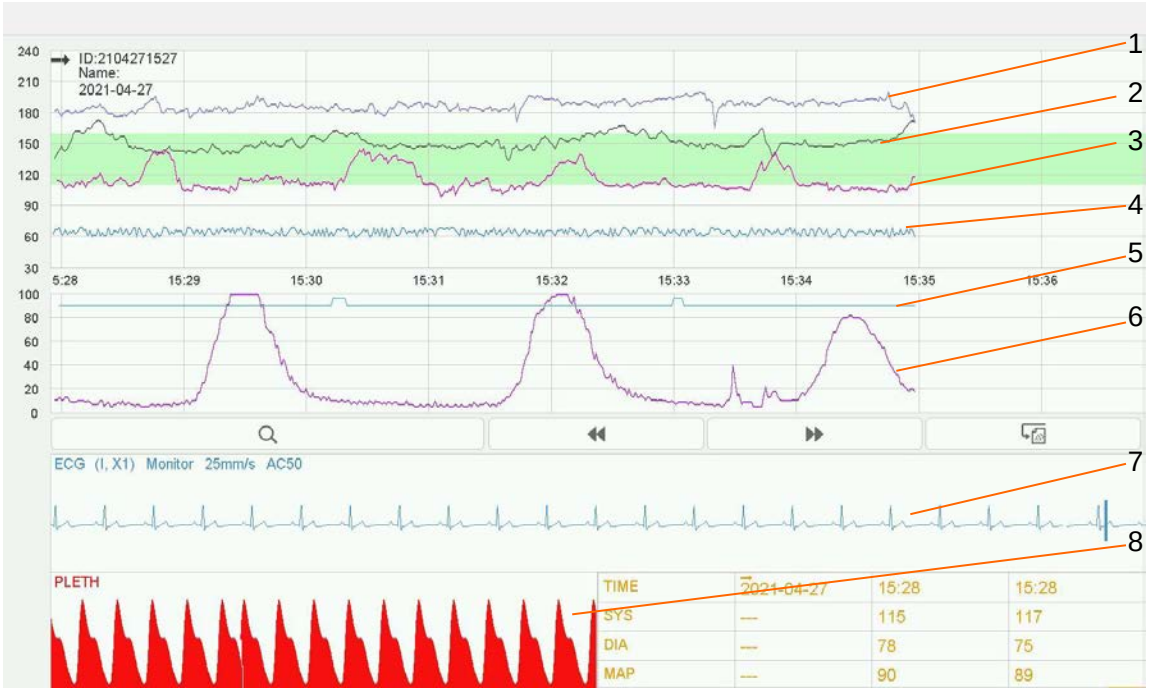


Figure 3-31 Maternal Monitoring Traces

1	FHR1 Trace	2	FHR2 Trace	3	FHR3 Trace	4	HR Trace
5	AFM Trace	6	TOCO Trace	7	ECG Trace	8	SpO_2 Waveform

Under maternal-fetal monitoring mode, the trace window displays at most nine traces. Compared with fetal monitoring mode, four maternal traces/waveform are added: MHR trace, ECG waveform and SpO_2 waveform.

The maternal vital sign list keeps records of the recent maternal vital signs and the measuring time. A start mark ➞ and the date appear when a new monitoring begins.

In maternal-fetal display mode, the list contains the time, SYS, DIA and MAP numerics of every measurement.

TIME	14:25	14:26	
SYS	112	114	
DIA	76	79	
MAP	88	90	

Figure 3-32 Maternal NIBP List

In maternal display mode, the list contains the time, HR, SpO_2, SYS, DIA, MAP, PR and TEMP numerics. The numerics are recorded every minute.

TIME	HR	SpO2	SYS	DIA	MAP	PR	TEMP
13:44	63	99	---	---	---	---	37.1
13:45	64	99	112	77	88	61	37.1
13:46	63	99	119	76	90	62	37.1

Figure 3-33 Maternal Vital Sign List

The numeric list can be reviewed: select the list, press the  symbol to review the previous lists.

Besides the fetal numerics, the numeric window of **F15** includes maternal vital signs: SpO_2, NIBP, HR and TEMP:

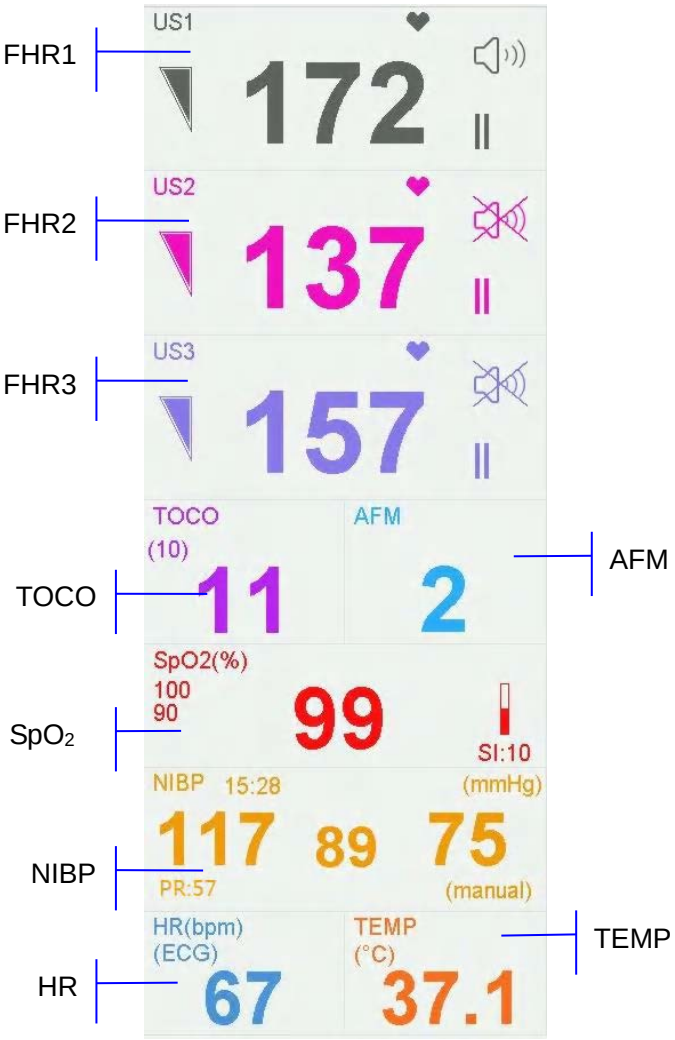


Figure 3-35 Maternal Monitoring Numerics

SpO_2 	99: Current SpO_2 measurement numeric.
	 : SpO_2 indicator. SI: Signal intensity.
NIBP 	14:23: Time when the NIBP measurement starts.
	mmHg: NIBP unit.
	From left to right, top to bottom in turn: current systolic pressure (117), mean artery pressure (89) and diastolic pressure (75) and PR (57).
	(manual): The current NIBP measurement mode is manual.

HR 	(ECG): The current HR comes from ECG.
	67: Current maternal heart rate measurement numeric.
TEMP 	(ºC): TEMP unit.

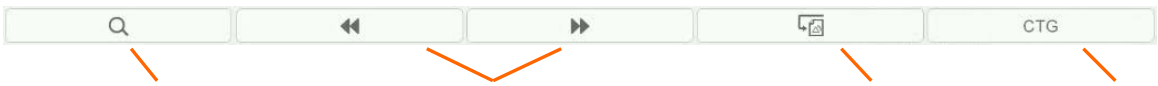
When F15 Fetal/Maternal Monitor is connected to FTS-3 Fetal Telemetry System, and transducers are taken up from the base station, the signal strength icon and battery level icon of the US-T transducers and TOCO-T transducer or TOCO-E transducer are displayed in the numeric window.

When monitoring with wireless model, the measurement numeric fields will display FHR1, FHR2, FHR3, TOCO, FM (manual or auto) and HR.

When FT20 Telemetry Transmitter is connected to the monitor, besides above parameters, NIBP and SpO2 will be displayed.

The wireless signal strength icon, and battery level icon of the wireless transducers and modules are displayed in the numeric window. The wireless signal strength of wireless transducer has three degrees, 0 is the poorest signal strength (when the signal strength is 0, wireless signal weak alarm is produced) and 3 is the best signal strength; the battery level of wireless transducer has 5 degrees, 0 is the lowest battery level and 4 is the highest battery level.

3.6.3 Trace Control Tools



1 2 3 4

Figure 3-35 Trace Control Tools

1	Searching Key	2	Backward key/Forward key
3	Alarm Reviewing Key	4	CTG Analyzing Key

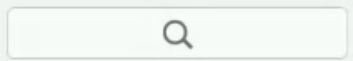
3.6.3.1 Data Saving

When the **START** key is pressed, the monitor saves data of the previous ID in a file, and then clears it from the main interface. The main interface only displays the new patient's data. During monitoring, the data is saved every 10 minutes. All data of the same patient is saved in a file (the maximum duration is 24 hours, the rest data is saved in another file.)

The files are stored in the monitor. When the data amount reaches the maximum capacity (500 files or 5000 hours), the monitor deletes the oldest file(s) automatically.

When the network version is ETHERNET 1.4 and above, if the central station disconnects with the fetal monitor in one minute, the monitoring data will be re-uploaded to the central station after re-connection, if the disconnection is over one minute, then the monitoring data can't be uploaded to the central station.

3.6.3.2 *Searching for a File

When the USB facility is disabled, the searching key  under the traces is used to search for a patient's data file saved in the monitor.

To search for a patient,

1 Select the searching key to open the file list. It contains six sets of most recent patients' ID, name and start time of monitoring. Select the required item, this file is loaded to the main interface immediately.

Figure 3-36 File List

If the required file is not in this list,

2 Select **MORE** to open the **Patient Searching** window.

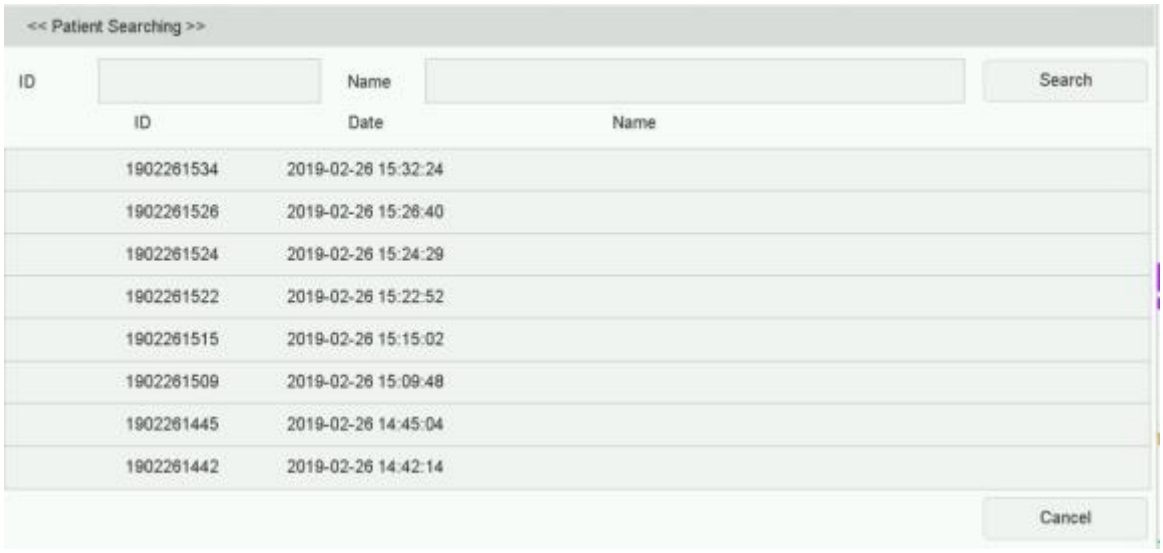


Figure 3-37 Patient Searching

3 Select **ID**, input the patient ID with the soft keyboard and select **Enter**.

4 Select **Name**, input the patient's name with the soft keyboard and select **Enter**.

NOTE:

You can input only a part of the patient ID or name. However, the more information you input, the more accurate result you will get.

5 Select **Search**. The files with the matched information are listed in the window.

6 Select the required item, and this file is loaded to the main interface immediately. You can review the traces backward or forward.

3.6.3.3 * File Management (Optional)

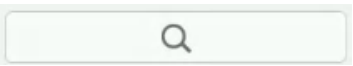
The USB facility of the monitor allows you to export the auto-saved files into a USB disk, and then you can save the files in a PC or open them in a data managing system.

Once the monitor is configured with the relevant hardware, the USB feature can be enabled or disabled by the service personnel of the manufacturer.

To Export files,

1 Make sure the USB feature is enabled. Stop printing and disconnect the network.

2 Plug the USB disk into the USB socket on rear panel of the monitor (figure 3-5). A message "Ready to use USB disk" in the message area indicates the proper insertion of the disk.

3 Select the file managing key  on the main interface to open the File Management interface, which records a list of up to 300 most recent monitoring records (patients' ID, name and date) and a few operation items.

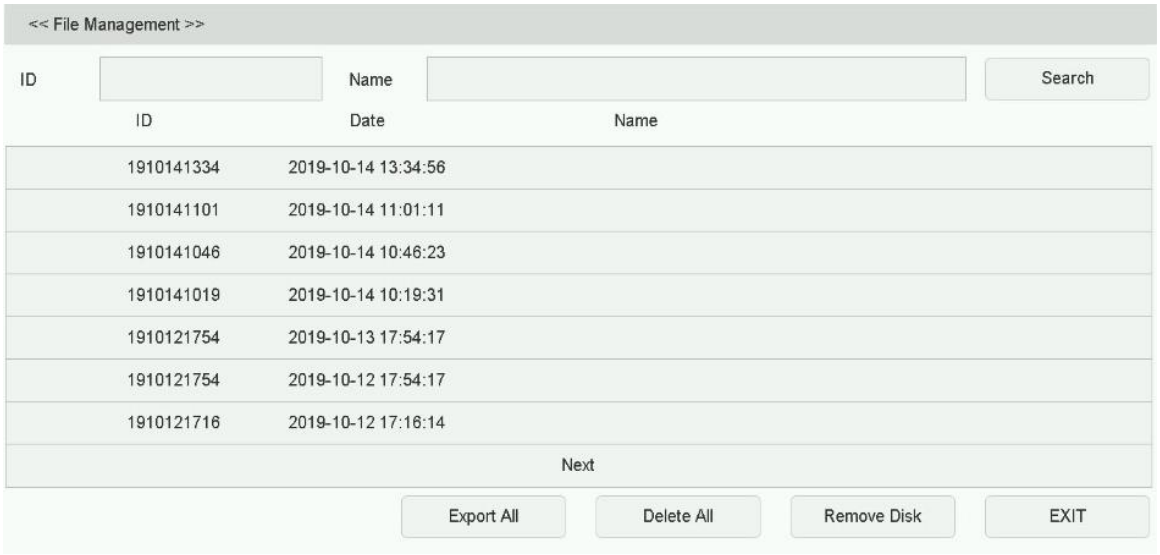


Figure 3-38 File Management

4 If the required record is not on the current page, select Next to view more records.

5 Move the cursor to select the required item, and then select Export in the pop-up item, and the monitor exports this record to the USB disk. Or you can select Export All to export all the records to the USB disk.

NOTE:

1 **The files cannot be exported if the printing and network connection are in process during real time monitoring.**

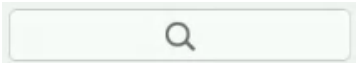
2 **To avoid impact on the real-time monitoring, the manufacturer advises against plugging in the USB disk and exporting the data in the process of monitoring.**

3 **The USB disk is not a tool for long-term data storage. You should save the exported files in a PC in time and clear the USB disk termly.**

4 **The monitor only supports those USB disks with FAT32 format. You are advised to use the USB disk provided by the manufacturer.**

In the **FetusData** folder of the USB disk, a sub-folder named after the export date and time is created when the export is performed. The exported records are saved in this sub-folder as .trc files, named after the monitor started date, time and ID, e.g. “20100120-124936-12345.trc”.

After the files are saved, you can delete them.

1 Select the file managing key  on the main interface to open the **File Management** interface.

2 Select Delete All > Yes. All the files in the monitor are deleted.

3 Select Exit.

NOTE:

1 **When the monitor is in the process of printing, the files cannot be deleted.**

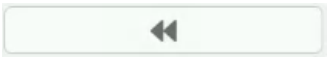
2 **File deleting should be performed with caution since the deleted files cannot be restored.**

3 **The monitor automatically erases the earliest files when the memory is full (the maximum capacity is 500 files or 5000 hours). You should export and save the files in time.**

4 **When there are more than 500 files or 5000 hours of monitoring data, it may take extended time for the monitor to load them. You should export the files in time and then delete them**

from the monitor.

3.6.3.4 *Reviewing

The reviewing keys  (backward key) and  (forward key) are used to review the traces. The word **REVIEW** is shown in the background when reviewing the traces.

Select the backward key to review the previous traces. The traces start to retreat. The amount of the progress symbol “<” on top of the traces indicates the retreating speed. Touch the  symbol to increase the speed until it reaches the maximum. Touch the  symbol to decrease the speed until it reaches the minimum. Touch any place of the trace window on the screen to pause.

Select the forward key to review the next traces. The traces start to advance. The amount of the progress symbol “>” on top of the traces indicates the advancing speed. Touch the  symbol to increase the speed until it reaches the maximum. Touch the  symbol to decrease the speed until it reaches the minimum. Touch any place of the trace window on the screen to pause.

When the reviewing is paused, the progress symbol turns to <--X%-->. If the **PRINT** key is pressed at this moment, the recorder will print the traces starting from the left edge of the screen at a high speed.

X% indicates the proportion of current traces positioned in the whole reviewable traces.

Touch any place out of the trace window on the screen to return to the real-time main interface. If no operation is performed in 10 seconds, the monitor switches to real-time interface automatically, unless the printing is in process.

When reviewing the traces, the monitor does not stop. The FH sound and numerics are all real time information of the current patient.

WARNING

The reviewing printout is provided for reference only. Please take the real-time printout as criterion when making diagnoses.

NOTE:

1 **The main interface only displays traces and patient information of one file. If you want to review another file you should search for the file and load it.**

2 **For a real-time monitoring patient, you can print all her traces, including SpO2 trace. However, when printing traces in a file, the SpO2 trace cannot be printed.**

3 **You must pause before printing starts. Printing in the process of playback might result in failure information on the paper.**

4 **After the reviewed data has been printed out, the recorder does not switch back to real-time printing automatically.**

3.6.3.5 *CTG Analysis

CTG analysis aims at a real-time trace, providing some reference data for the physicians. It only analyzes the real-time trace after it’s been printed for 10 minutes, and the longest duration is 60 minutes.

WARNING

1 **CTG analysis is used for the surveillance of pregnancies and not in delivery room of**

childbirth.

2 CTG analysis is just an analysis intended to assist the physicians in interpreting the waveforms. Conclusions should be drawn on the basis of the physicians' diagnosis.

3 This analysis describes the fetal heart rate, the tocography and the fetal movements. It's the responsibility of qualified medical staff to do the diagnostic interpretation of the waveform.

To enable CTG Analysis,

1 Select the main menu key  on the main interface.
2 Select **General > CTG Analysis**.
3 Select an analysis method: KREBS Analysis, Fischer Analysis, Improved Fischer Analysis, NST Report, NST Analysis, NST Three-level Classification Report or OFF.
4 Select **OK**.

A CTG analysis key 

appears on the main interface, indicating that CTG analysis is enabled.

NOTE:

1 CTG analyze starts after the real-time trace has been printed for 10 minutes.

2 The CTG analysis result is for reference only.

After the real-time trace is printed for 10 minutes, select the CTG analysis key 

on the main interface. The analysis result window opens.

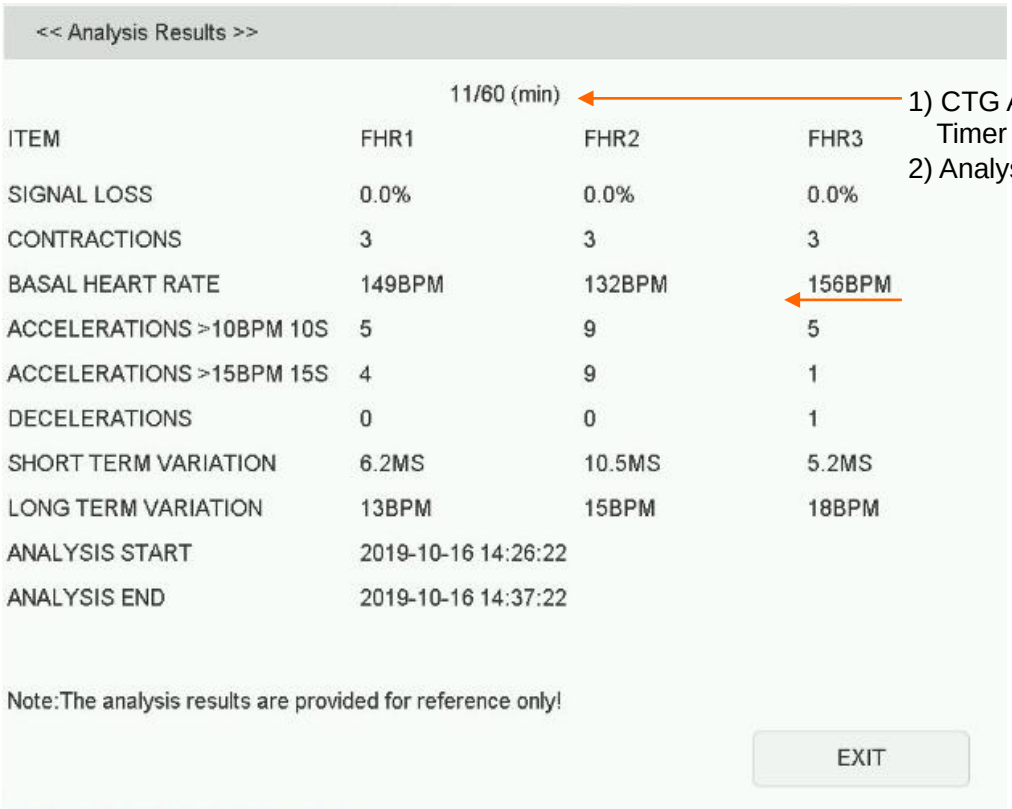


Figure 3-39 CTG Analysis Results

Refer to figure 3-41, the CTG analysis results on the screen include:

1) CTG Analysis Timer:

The CTG analysis timer starts when the recorder starts printing; it stops when the timer reaches 60 minutes (the timer turns into **>60**) and resets when the recorder stops printing.

2) CTG Analysis Results:

SIGNAL LOSS:	The proportion of the signal loss. If it is larger than 10%, analysis results cannot be acquired.
CONTRACTIONS:	The contraction time during analysis.
BASAL HEART RATE:	The average FHR in 10 minutes when it is not influenced by fetal movement or contractions.
ACCELERATIONS:	The acceleration time, including the acceleration with amplitude larger than 10bpm and lasts more than 10 seconds, and the acceleration with amplitude larger than 15bpm and lasts more than 15 seconds.
DECELERATIONS:	The deceleration time.
SHORT TERM VARIATION:	The short-term variation analysis result.
LONG TERM VARIATION:	The long-term variation analysis result.
ANALYSIS START:	The start time of the analysis.
ANALYSIS END:	The finishing time of the analysis.

During 10 to 60-minute of the timer, the monitor gives CTG analysis results every minute.

At the end of the printing, the recorder prints the CTG analysis results of this moment on the recorder paper.

Be aware that CTG analysis result is a calculation output. It can be used as a reference to assist medical personnel in making correct diagnosis, instead of replacing it.

NOTE:

Do not disconnect the ultrasound transducer(s) before the printing stops, otherwise the analysis results will not be printed.

3.6.3.6 *Marking a Note

When there is a significant event, you can press the **MARK** key on the main interface to add a note. An event mark ↓ will appear on both the main interface and the recorder paper.

However, an event mark cannot clearly indicate an event. **Smart Notes** provides a list of annotation for the events, including events that relate to drugs, positions, membranes, procedures, antenatal, reasons and others.

To enable or disable **Smart Notes**,

1 Select the main menu key  on the main interface.

2 Select **General > Smart Notes**.

3 Select **ON** or **OFF** (default).

Once **Smart Notes** is enabled, press the **MARK** key on the main interface to open the smart note list, choose an event catalog and then choose an annotation from the list.

The annotation of this event will be printed in the top area of recorder paper during real-time printing.

You can change the smart note content in the smart note list by performing the following steps:

1 Select the main menu key  on the main interface.

2 Select **General**.

3 Select the smart note editing key  .

4 Select a catalog.

5 Select a note.

6 Use the soft keyboard to edit the note content.

7 Select **Enter**.

8 Select **OK**.

3.7 Introduction of FTS-3 Fetal Telemetry System

F15 is compatible with FTS-3 Fetal Telemetry System which is intended for monitoring in a bath or shower. For introduction of FTS-3, Please refer to the user manual of FTS-3 Fetal Telemetry System.

Chapter4 Alarms

WARNING

A potential hazard can exist if different alarm presets are used for the same or similar equipment in any single area.

4.1 Alarm Classification

The monitor has two types of alarm: patient alarm and technical alarm.

Patient alarms indicate the situation of vital sign exceeding its configured limit. Audible alarms and visual alarms can be disabled excluding ASYSTOLE alarm. The adjustable alarm limits determine the conditions that trigger the alarm.

Technical alarms indicate that the monitor cannot measure and therefore cannot detect critical patient conditions reliably. They cannot be disabled.

In terms of severity, the alarms are divided into three priorities: high, medium and low. High priority alarm indicates the condition where the patient is endangered; it is a severe warning, labeled with the symbol ***; Medium priority alarm is a moderate warning, labeled with the symbol **; low priority alarm is a general warning.

The high priority alarms have highest priority, and the medium priority alarms take the second place. If more than one type of alarm is active at the same time, the monitor sounds an audible indicator for the higher priority alarms.

The alarm priorities are preset, and you cannot change them.

4.2 Alarm Delay

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

1 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 time and on the measurement dependent averaging time. (For example, the FHR algorithmic processing time is no more than 30s)

2 The time between the displayed numerical values exceeding 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 delay time. The general system delay time is less than 4s.

4.3 Audible Alarm

If the audible alarm is not disabled, the alarm indicator displays  . When an alarm is active, the monitor gives out a sound. (The sound pressure range is 45dB ~ 85dB.)

High priority alarm: a “Do” tone is repeated five times, and then pauses for 3seconds.

Medium priority alarm: a “Do” tone is repeated three times, and then pauses for 4seconds.

Low priority alarm: a “Do” tone is issued, and then pauses for 20 seconds.

Press the **SILENCE** key, the current audible alarm toggles between on and off (temporarily or infinitely, you can change the setting).

If the current audible alarm is temporarily disabled, the alarm indicator displays  , with a remaining time on the right. The audible alarm is enabled again when the time is out, or when the **SILENCE** key is pressed.

If the current audible alarm is infinitely disabled, the alarm indicator displays  , which is flashing

in the manner of lighting for one second and pausing for one second. The audible alarm is enabled again only when the **SILENCE** key is pressed.

If Alarm Reset is enabled (see *4.9 Pausing or Resetting the Alarm*), and you press the **SILENCE** key to disable an audible alarm, the alarm indicator will display  , which is flashing in the manner of lighting for one second and pausing for one second. When other alarms present, the monitor will enable the audible alarm again automatically.

During the silence period, the alarm messages are displayed and the alarm indicator lights up as usual. You can press the **SILENCE** key again to enable the audible alarm.

WARNING

1 **If the patient safety may be endangered, do not switch off the audible alarm infinitely.**

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

3 **When the sound pressure of audible alarm is equivalent to the ambient noise, it may be difficult for the operator to distinguish the audible alarm.**

NOTE:

After you enable the audible alarm again, whether the alarm sound still exists depends on whether the alarm persists.

4.4 Visual Alarm

When an alarm is active,

- The alarm indicator lights up:

Alarm Category	Indicator Color	Flashing Frequency	Duty Cycle
High priority alarm	red	1.4Hz to 2.8Hz	20% to 60% on
Medium priority alarm	yellow	0.4Hz to 0.8Hz	20% to 60% on
Low priority alarm	yellow	Constant (on)	100% on

- The alarm message appears in the message window of the main interface, with patient alarms on the left and technical alarms in the middle.

- The numeric of the measurement flashes in grey with a frequency of 2Hz.

When more than one alarm of the same priority is active, the alarm messages appear in the same area in succession.

When more than one alarm of different priorities are active, only the alarms of the highest priority are displayed in the message window.

The patient alarm messages are displayed either:

in text form, for example “** FHR2 LOW”; or

in numeric form, for example “** FHR2 115 < 120”; ** indicates this is a medium priority alarm event; the first number is the current measurement result; the second number is the preset alarm limit.

The technical alarm messages are displayed in text form, for example “**Battery Low”.

WARNING

Setting alarm limits to extreme values may cause the alarm system to become ineffective. It is

recommended to use the default settings.

4.5 Choosing the Alarm Display Form

You can change the patient alarm display form,

4 Select the main menu key  on the main interface.
5 Select **Alarm**. On the displayed **Password** box, enter user password, and then select **Enter**.
6 Select **Message Form**.
7 Select **Text** (default) or **Numeric**.
8 Select **OK**.

4.6 Changing the Alarm Volume

You can change the alarm volume,

1 Select the main menu key  on the main interface.
2 Select **Alarm**. On the displayed **Password** box, enter user password, and then select **Enter**.
3 Select **Alarm Volume**.
4 Select **Low** (default), **Medium** or **High**.
5 Select **OK**.

4.7 *Choosing Alarm Silence Duration

You can change the alarm silence duration,

1 Select the main menu key  on the main interface.
2 Select **Alarm**. On the displayed **Password** box, enter user password, and then select **Enter**.
3 Select **Silence Duration**.
4 Select **Infinite**, **1 min** (default), **2 min**, or **3 min**.
5 Select **OK**.

4.8 Choosing Signal Loss Delay

When the fetal signal or MECG signal is lost and this condition continues for a certain time, the monitor issues a technical alarm. This time (signal loss delay) is adjustable. To change the signal loss delay,

1 Select the main menu key  on the main interface.
2 Select **Alarm**. On the displayed **Password** box, enter user password, and then select **Enter**.
3 Select **Signal Loss Delay**.
4 Select **0** (default) ~ **300** seconds.
5 Select **OK**.

4.9 Pausing or Resetting the Alarm

You can enable the function of pausing or resetting audible alarms.

1 Select the main menu key  on the main interface.
2 Select **Alarm**. On the displayed **Password** box, enter user password, and then select **Enter**.
3 Select **Audio Alarm**.

4 Select **Alarm Pause** (default) or **Alarm Reset**.

If **Alarm Pause** is selected: When the monitor gives out alarm sound and you press the **SILENCE** key, the alarm indicator displays  , and the alarm sound is muted.

If **Alarm Reset** is selected: When the monitor gives out alarm sound and you press the **SILENCE** key, the alarm indicator displays  , and the alarm sound is muted. When other alarms present, the monitor will enable the audible alarm again automatically.

5 Select **OK**.

4.10 To Switch Individual Measurement Alarms On or Off

1 Select the main menu key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter user password, and then select **Enter**.

3 Select a measurement parameter and the corresponding alarm setup menu pops up.

4 Select **ON** (default) or **OFF**.

5 Select **OK**.

6 If the alarm is switched off, an alarm switched-off symbol  will appear in the numeric window; if the alarm is switched on, the symbol will disappear.

WARNING

Do not switch the alarm off for the condition where the patient's safety maybe endangered.

4.11 Changing the Alarm Limits

The alarm limits you set determine the conditions that trigger the alarm.

1 Select the main menu key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter user password, then select **Enter**.

3 Select a measurement parameter and the corresponding alarm setup menu pops up.

4 Select a value from **High Alarm Limit**.

5 Select a value from **Low Alarm Limit**.

6 Select **OK**.

4.12 Switching Transducer Unplugged On or Off

You can switch "Transducer Unplugged" on or off:

1 Select the main menu key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter user password, and then select **Enter**.

3 Select **Transducer unplugged** on the alarm settings interface.

4 Select **ON** or **OFF** (default).

5 Select **OK**.

4.13 Switching CTG Alarm On or Off

You can switch “CTG Alarm” on or off:

1 Select the main menu key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter user password, and then select **Enter**.

3 Select **CTG Alarm** on the alarm settings interface.

4 Select **ON** or **OFF** (default).

5 Select **OK**.

4.14 *Reviewing Alarms

An alarm reviewing menu not only can record the immediate alarm messages with date and time information, but also record the historically physiological alarm, signal overlap alarm and US1, US2 and US3 signal weak alarm, US1, US2 and US3 wireless signal weak alarm, TOCO wireless signal weak alarm and DECG wireless signal weak alarm messages with date and time information.

The monitor can display a maximum of 100 immediate alarm messages. When the storage is full, it will delete the earliest alarm message automatically to store the new one.

The monitor can display a maximum of 1000 historically physiological alarm,signal overlap alarm, and US1, US2 and US3 signal weak alarm, US1, US2 and US3 wireless signal weak alarm, TOCO wireless signal weak alarm and DECG wireless signal weak alarm messages. When the total number exceeds 1000, the alarm messages cannot be stored.

Select the alarm reviewing key  to open this menu. When you review the traces with the word **REVIEW** shown in the background, the alarm reviewing menu displays historic alarm review. Otherwise, it displays the immediate alarm review.

Each page displays 10 alarm records. The page mark “1/6” informs you that there are 6 pages and the present one is page 1.

To review more records, select the alarm list and then press the up/down key to switch to the previous or next page.

Select **OK** to exit from this menu.

When the monitor is switched off, the power supply is cut off accidentally, or a new monitoring starts, the immediate alarm messages in **Review Alarms** window will be cleared.

NOTE:

You can select Main Menu > Alarm > Review Alarms to set up On (by default) or OFF. When the alarm review is enabled, the icon will appear on the main interface.

4.15 Alarm Treatment Measures

During monitoring, make sure there is at least one physician in the area where the alarm sound can be heard or the alarm messages can be seen, so necessary measures can be taken when an emergency occurs.

When the monitor gives out an alarm and catches your attention, you should:

- Check the patient's condition.
- Identify the cause of the alarm.
- Silence the alarm if necessary.
- Check if the alarm is terminated when the alarm condition is solved.

When the monitored parameter(s) come(s) back within the adjusted limits, or if the abnormal technical condition does not exist any longer, the monitor stops giving out the alarm.

If "Transducer Unplugged" is enabled (set to "ON"), and you press the probe off key  on the main interface to confirm any active transducer unplugged alarm: US1 UNPLUGGED, US2 UNPLUGGED, US3 UNPLUGGED, TOCO UNPLUGGED, DECG UNPLUGGED, SpO2 SENSOR OFF, TEMP UNPLUGGED, US1 Signal Weak, US2 Signal Weak, US3 Signal Weak, DECG Signal Weak, DECG LEADS OFF, IUP LEADS OFF, ECG LEADS OFF and ECG Signal Weak, FHR1/FHR2/FHR3 Low Variability, FHR1/FHR2/FHR3 Delayed Deceleration, FHR1/FHR2/FHR3 Sinusoidal Mode, FHR1/FHR2/FHR3 Tachycardia Without Variability, FHR1/FHR2/FHR3 Suspected Delay Deceleration during the monitoring process, the transducer unplugged alarm(s) will be turned off audibly and visually until any of them occurs again. But the transducer unplugged alarm(s) still exist(s) in the alarm review list.

4.16 Testing Alarms

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

1 Switch on the monitor.

2 Enable the alarm.

3 Set the alarm limits to a small range.

4 Stimulate a signal that is higher than the upper limit or lower than the lower limit. Or disconnect one of the plugs.

5 Verify if the visible and audible alarms are working properly.

4.17 Patient Alarm Defaults

Alarm Setting	**Options**	**Default**
High Priority		
ASYSTOLE	On (not adjustable)	On
Asystole Alarm Delay	0 seconds (not adjustable)	0 seconds
Asystole Alarm Priority	High (not adjustable)	High
Medium Priority		
FHR1/DFHR/FHR2/FHR3 Alarm	On, Off	On

FHR1/DFHR/FHR2/FHR3 Low Alarm Limit	60 bpm ~ 205 bpm, in increments of 5	110 bpm
FHR1/DFHR/FHR2/FHR3 High Alarm Limit	65 bpm ~ 210 bpm, in increments of 5	160 bpm
FHR1/DFHR/FHR2/FHR3 High Alarm Delay	0 ~ 300 second(s), in increments of 5	10 seconds
FHR1/DFHR/FHR2/FHR3 Low Alarm Delay	0 ~ 300 second(s), in increments of 5	10 seconds
FHR1/DFHR/FHR2/FHR3 Alarm Priority	Medium, not adjustable	Medium
HR Alarm	On, Off	On
HR Low Alarm Limit	28 bpm ~ 242 bpm, in increments of 1	50 bpm
HR High Alarm Limit	29 bpm ~ 243 bpm, in increments of 1	120 bpm
HR Alarm Delay	0 second, not adjustable	0 second
HR Alarm Priority	Medium, not adjustable	Medium
SpO_2 Alarm	On, Off	On
SpO_2 Low Alarm Limit	50% ~ 99%, in increments of 1	90%
SpO_2 High Alarm Limit	51% ~ 100%, in increments of 1	100%
SpO_2 Alarm Delay	0 second, not adjustable	0 second
SpO_2 Alarm Priority	Medium, not adjustable	Medium
SYS Alarm	On, Off	On
SYS Low Alarm Limit	40 mmHg ~ 269 mmHg, in increments of 1 (5.3 kPa ~ 35.9 kPa, in increments of 0.1)	90 mmHg (12.0 kPa)
SYS High Alarm Limit	41 mmHg ~ 270 mmHg, in increments of 1 (5.4 kPa ~ 36.0 kPa, in increments of 0.1)	160 mmHg (21.3 kPa)
SYS Alarm Delay	0 second, not adjustable	0 second
SYS Alarm Priority	Medium, not adjustable	Medium
DIA Alarm	On, Off	On
DIA Low Alarm Limit	10 mmHg ~ 214 mmHg, in increments of 1 (1.3 kPa ~ 28.6 kPa, in increments of 0.1)	50 mmHg (6.8 kPa)
DIA High Alarm Limit	11 mmHg ~ 215 mmHg, in increments of 1 (1.4 kPa ~28.7 kPa, in increments of 0.1)	90 mmHg (12.0 kPa)
DIA Alarm Delay	0 second, not adjustable	0 second
DIA Alarm Priority	Medium, not adjustable	Medium
MAP Alarm	On, Off	On
MAP Low Alarm Limit	20 mmHg ~ 234 mmHg, in increments of 1 (2.7 kPa ~31.2 kPa, in increments of 0.1)	60 mmHg (8.0 kPa)
MAP High Alarm Limit	21 mmHg ~ 235 mmHg, in increments of 1 (2.8 kPa ~31.3 kPa, in increments of 0.1)	110 mmHg (14.8 kPa)

MAP Alarm Delay	0 second, not adjustable	0 second
MAP Alarm Priority	Medium, not adjustable	Medium
TEMP Alarm	On, Off	On
TEMP Low Alarm Limit	0 ºC ~ +49.9 ºC, in increments of 0.1	+36.0 ºC
TEMP High Alarm Limit	+0.1 ºC ~ +50.0 ºC, in increments of 0.1	+39.0 ºC
TEMP Alarm Delay	0 second, not adjustable	0 second
TEMP Alarm Priority	Medium, not adjustable	Medium

NOTE:

The upper limit must be higher than the lower limit. When setting the upper limit, you do not have access to the options that are lower than the preset lower limit, and vice versa.

4.18 Alarm Messages

4.18.1 Fetal Monitoring Alarm Messages

During fetal monitoring, the monitor gives alarms for the situations that need the physicians to pay attention to. The alarm messages are listed below.

Patient Alarm Messages

Alarm Message	Cause	Countermeasure
Medium Priority		
**FHR1 HIGH or ** FHR1 xxx > yyy, **FHR2 HIGH or ** FHR2 xxx > yyy **FHR3 HIGH or ** FHR3 xxx > yyy **DFHR HIGH or **DFHR xxx > yyy **eFHR HIGH or **eFHR xxx > yyy	FHR1, FHR2, FHR3, DECG or FECG measuring result (xxx) is higher than the set upper limit (yyy) and the alarm delay time of the upper limit is out.	Check if the alarm limits are suitable; check the patient's condition.
**FHR1 LOW or ** FHR1 xxx < yyy, **FHR2 LOW or ** FHR2 xxx < yyy **FHR3 LOW or ** FHR3 xxx < yyy **DFHR LOW or **DFHR xxx < yyy **eFHR LOW or **eFHR xxx < yyy	FHR1, FHR2, FHR3, DECG or FECG measuring result (xxx) is lower than the set lower limit (yyy) and the alarm delay time of the lower limit is out.	

CTG Alarm(Medium Priority)		
**FHR1/FHR2/FHR3 Low Variability	There are 18 minutes of variability ≤ 2bpm within 21 min.	Check the patient's and fetus's current condition.
**FHR1/FHR2/FHR3 Delayed Deceleration	Delayed deceleration >0 within 9 min	Check the patient's and fetus's current condition.
**FHR1/FHR2/FHR3 Sinusoidal Mode	15 minutes of FHR is sinusoidal trace in the last 20 min	Check the patient's and fetus's current condition.
**FHR1/FHR2/FHR3 Tachycardia Without Variability	Tachycardia and there are 9 minutes of variability ≤2 bpm within 10 min.	Check the patient's and fetus's current condition.
**FHR1/FHR2/FHR3 Low Variability With Decelerations	There are 7 minutes of variability <2bpm within 10 min and the number of deceleration is>0	Check the patient's and fetus's current condition.
**FHR1/FHR2/FHR3 Recurrent Variable Decelerations With No Variability	There are more than 50% of the contactions are accompanied with variable decelerations within 20 min and the decelerations are ≤ 5bpm	Check the patient's and fetus's current condition.
**FHR1/FHR2/FHR3 Tachycardia With Decelerations	The duration of tachycardia is >6 min within 9 min and the number of decelerations within 10 min is >0	Check the patient's and fetus's current condition.
**FHR1/FHR2/FHR3 Bradycardid With No Variability	Bradycardid and there are more than 9 minutes of variability <=2bpm within 10 min	Check the patient's and fetus's current condition.
**FHR1/FHR2/FHR3 Recurrent Late Decelerations With No Variability	More than 50% of the uterine contractions are accompanied with late decelerations within 20min and the variability is <5bpm	Check the patient's and fetus's current condition.

CTG Alarm(Low Priority)		
FHR1/FHR2/FHR3 Suspected Delayed Deceleration	Delayed deceleration is detected when maternal and fetal heart rate are close, and the number of delayed decelerations is >0 within 9 min	Check the patient's and fetus's current condition.

Technical Alarm Messages

Alarm Message	Cause	Countermeasure
Medium Priority		
**Battery Low	The battery indicator of the monitor is  . The battery power is too low to support further work of the monitor.	Connect the monitor to AC power supply.
** Battery Failure	The battery is defective or damaged, and the effective status of the battery cannot be obtained.	Please contact the manufacturer for service
**The battery level is low(US1)	The battery indicator of wireless US transducer 1 is  .The battery power is too low to support further work of the transducer.	Charge the wireless US transducer 1 in the docking slot.
**The battery level is low(US2)	The battery indicator of wireless US transducer 2 is  . The battery power is too low to support further work of the transducer.	Charge the wireless US transducer 2 in the docking slot.
**The battery level is low(US3)	The battery indicator of wireless US transducer 3 is  . The battery power is too low to support further work of the transducer.	Charge the wireless US transducer 3 in the docking slot.
**The battery level is low(TOCO)	The battery indicator of wireless TOCO transducer is  . The battery power is too low to support further work of the transducer.	Charge the TOCO transducer in the docking slot.
**The battery level is low(DECG)	The battery indicator of wireless DECG Fetal&Maternal Module is  . The battery power is too low to support further work of the transducer.	Charge the DECG Fetal&Maternal Module in the docking slot.
**The battery level is low(FT20)	The battery indicator of FT20 Module is  . The battery power is too low to support further work of the module.	
**The battery level is low(FECG)	The battery indicator of FECG Fetal&Maternal Module is  . The battery power is too low to support further work of the	Charge the FECG Fetal&Maternal Module in the docking slot.

	transducer.	
Low Priority		
Check Paper	There is no paper in the paper drawer or the drawer is open.	Load paper and/ or close the drawer.
US1 UNPLUGGED or US2 UNPLUGGED or US3 UNPLUGGED	US transducer 1 or US transducer 2 or US transducer 3 is not well connected.	Check the connection of the transducer.
US1 Signal Weak or US2 Signal Weak or US3 Signal Weak	FHR1 or FHR2 or FHR3 signal is too weak for the system to analyze.	Check if the US transducer is aimed at the fetal heart; check if the alarm limits are suitable; check the patient's condition.
FETUS 302 MODULE MALF or Extend 302 MODULE MALF or FETUS 417 MODULE MALF	The fetus 302 module or extend 302 module or fetus 407 cannot communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
TOCO UNPLUGGED	TOCO transducer is not well connected.	Check the connection of both TOCO transducer and US transducer.
IUP LEADS OFF	DECG-IUP integrated cable is not well connected.	Check the connection of the DECG-IUP integrated cable.
DECG LEADS OFF	The spiral electrode or DECG cable is not well connected.	Check the connection of the spiral electrode or DECG cable.
DECG UNPLUGGED	The DECG Fetal&Maternal Module is not well connected.	Check the connection of DECG Fetal&Maternal Module.
FECG RLD Off	FECG electrodes (C1//N/F) are not well connected.	Check the connection of the FECG electrodes.
FECG LEADS OFF(TOP/BOTTOM/C4/F/R/N/L)	FECG leads (top/bottom/C4/F/R/N/L) are not well connected.	Check the connection of the FECG leads (top/bottom).
DECG Signal Weak	DECG signal is too weak for the system to analyze.	Check if the spiral electrode is well attached to the fetus; check the patient's condition.
US1 Wireless Signal Weak	Wireless FHR1 signal is too weak for the system to analyze.	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
US2 Wireless Signal Weak	Wireless FHR2 signal is too weak for the system to analyze.	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
US3 Wireless Signal Weak	Wireless FHR3 signal is too weak for the system to analyze.	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.

TOCO Wireless Signal Weak	The wireless signal of wireless TOCO is too weak for the system to analyze.	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
DECG Wireless Signal Weak	The wireless signal of wireless DECG transducer is too weak for the system to analyze.	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
FECG Wireless Signal Weak	The wireless signal of FECG Fetal&Maternal Module is too weak for the system to analyze.	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
Signals Overlap (FHR1, FHR2)	US transducer 1 and US transducer 2 are aimed at the same fetal heart; the signals overlap.	Adjust one of the US transducers until another fetal heart signal is detected.
Signals Overlap (FHR2, FHR3)	US transducer 2 and US transducer 3 are aimed at the same fetal heart; the signals overlap.	Adjust one of the US transducers until another fetal heart signal is detected.
Signals Overlap (FHR1, FHR3)	US transducer 1 and US transducer 3 are aimed at the same fetal heart; the signals overlap.	Adjust one of the US transducers until another fetal heart signal is detected.
Signals Overlap (FHR1, FHR2, FHR3)	US transducer 1, US transducer 2 and US transducer 3 are aimed at the same fetal heart; the signals overlap.	Adjust two of the US transducers until the rest two fetal heart signals are detected.
Signals Overlap (DFHR, FHR2)	US transducer 2 is aimed at the fetus that the spiral electrode is attached to; the signals overlap.	Adjust the US transducer until another fetal heart signal is detected.
Signals Overlap (DFHR, FHR3)	US transducer 3 is aimed at the fetus that the spiral electrode is attached to; the signals overlap.	Adjust the US transducer until another fetal heart signal is detected.
Signals Overlap (DFHR, FHR2, FHR3)	US transducer 2 and 3 are aimed at the fetus that the spiral electrode is attached to; the signals overlap.	Adjust the US transducers until the rest two fetal heart signals are detected.
Probe MALF (FHR1)	US transducer 1 is disconnected with the monitor	Connect US transducer 1 with the monitor
Probe MALF (FHR2)	US transducer 2 is disconnected with the monitor	Connect US transducer 2 with the monitor

Probe MALF (FHR3)	US transducer 3 is disconnected with the monitor	Connect US transducer 3 with the monitor
Probe MALF (DECG)	DECG&IUP transducer is disconnected with the monitor	Connect DECG&IUP transducer with the monitor
Probe MALF (TOCO)	TOCO transducer is disconnected with the monitor	Connect TOCO transducer with the monitor
Probe MALF (FECG)	FECG Fetal&Maternal Module is disconnected with the monitor	Connect FECG Fetal&Maternal Module with the monitor
Current network environment poor (US1)	The current network environment is poor and US transducer 1 has problem to connect with the monitor	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
Current network environment poor (US2)	The current network environment is poor and US transducer 2 has problem to connect with the monitor	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
Current network environment poor (US3)	The current network environment is poor and US transducer 3 has problem to connect with the monitor	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
Current network environment poor (TOCO)	The current network environment is poor and TOCO transducer has problem to connect with the monitor	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
Current network environment poor (DECG)	The current network environment is poor and DECG&IUP transducer has problem to connect with the monitor	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
Current network environment poor (FECG)	The current network environment is poor and FECG Fetal&Maternal Module has problem to connect with the monitor	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
Network is offline	The central station disconnects with the fetal monitor (ETHERNET network)	Examine the network connection between the central station and the fetal monitor

4.18.2 Maternal Monitoring Alarm Messages

Besides the fetal monitoring alarms, **F15** also gives alarms for the situations that occur during maternal monitoring. The alarm messages are listed below.

Patient Alarm Messages

Alarm Message	Cause	Countermeasure
High Priority		
***ASYSTOLE	No QRS wave is detected by TOCO&MECG transducer in 4 seconds or no QRS wave is detected by FECG Fetal&Maternal Module in 6 seconds	Check the patient's condition and take necessary measures.
Medium Priority		
**HR HIGH or **HR xxx > yyy	Maternal HR result (xxx) is higher than the upper limit (yyy).	Check if the alarm limits are suitable; check the patient's condition.
**HR LOW or **HR xxx < yyy	Maternal HR result (xxx) is lower than the lower limit (yyy).	
** SpO_2 HIGH or ** SpO_2 xxx > yyy	SpO_2 result (xxx) is higher than the upper limit (yyy).	
** SpO_2 LOW or ** SpO_2 xxx < yyy	SpO_2 result (xxx) is lower than the lower limit (yyy).	
**SYS HIGH or **SYS xxx > yyy	SYS result (xxx) is higher than the upper limit (yyy).	
**SYS LOW or **SYS xxx < yyy	SYS result (xxx) is lower than the lower limit (yyy).	
**DIA HIGH or **DIA xxx > yyy	DIA result (xxx) is higher than the upper limit (yyy).	
**DIA LOW or **DIA xxx < yyy	DIA result (xxx) is lower than the lower limit (yyy).	
**MAP HIGH or **MAP xxx > yyy	MAP result (xxx) is higher than the upper limit (yyy).	
**MAPLOW or **MAP xxx < yyy	MAP result (xxx) is lower than the lower limit (yyy).	
**TEMP HIGH or **TEMP xxx > yyy	TEMP result (xxx) is higher than the upper limit (yyy).	
**TEMP LOW or **TEMP xxx < yyy	TEMP result (xxx) is lower than the lower limit (yyy).	

Technical Alarm Messages

Alarm Message	Cause	Countermeasure
High Priority		
*** CPU Temp high	CPU temperature exceeds the safe limits	Check whether the fan of the monitor works normally, if no, please contact the manufacturer for service

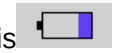
Low Priority		
Signals Overlap (FHR1, HR)	US transducer 1 has picked up the maternal heart signal; the signals overlap.	Reposition the US transducer 1 until the fetal heart signal is detected.
Signals Overlap (FHR2, HR)	US transducer 2 has picked up the maternal heart signal; the signals overlap.	Reposition the US transducer 2 until the fetal heart signal is detected.
Signals Overlap (FHR3, HR)	US transducer 3 has picked up the maternal heart signal; the signals overlap.	Reposition the US transducer 3 until the fetal heart signal is detected.
Signals Overlap (DFHR, HR)	The spiral electrode has picked up the maternal heart signal; the signals overlap.	Reposition the spiral electrode until the DFHR signal is detected.
Signals Overlap (FHR1, FHR2, HR)	US transducer 1 and US transducer 2 have picked up the maternal heart signal; the signals overlap.	Reposition the US transducers until the fetal heart signals are detected.
Signals Overlap (FHR2, FHR3, HR)	US transducer 2 and US transducer 3 have picked up the maternal heart signal; the signals overlap.	Reposition the US transducers until the fetal heart signals are detected.
Signals Overlap (FHR1, FHR3, HR)	US transducer 1 and US transducer 3 have picked up the maternal heart signal; the signals overlap.	Reposition the US transducers until the fetal heart signals are detected.
Signals Overlap (DFHR, FHR2, HR)	The spiral electrode and US transducer 2 have picked up the maternal heart signal; the signals overlap.	Reposition the spiral electrode and US transducer until the DFHR signal and fetal heart signal are detected.
Signals Overlap (DFHR, FHR3, HR)	The spiral electrode and US transducer 3 have picked up the maternal heart signal; the signals overlap.	Reposition the spiral electrode and US transducer until the DFHR signal and fetal heart signal are detected.
Signals Overlap (FHR1, FHR2, FHR3, HR)	US transducer 1, US transducer 2 and US transducer 3 have picked up the maternal heart signal; the signals overlap.	Reposition the US transducers until the fetal heart signals are detected.
Signals Overlap (DFHR, FHR2, FHR3, HR)	The spiral electrode, US transducer 2 and US transducer 3 have picked up the maternal heart signal; the signals overlap.	Reposition the spiral electrode and US transducers until the DFHR signal and fetal heart signals are detected.
Signals Overlap (eFHR, HR)	FECG Fetal&Maternal Module has picked up the maternal heart signal.	Relocate the electrodes until the fetal heart signal is detected.

FT20 MALF	FT20 is disconnected with the monitor	Restart the monitor and try again, contact the manufacturer if the connection still fails.
Current network environment poor(FT20)	The current network environment is poor and FT20 module has problem to connect with the monitor	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
FT20 Wireless Signal Weak	The wireless signal of FT20 module is too weak for the system to analyze.	Check whether the ambulating mother has reached the limit of the active signal area-of-reach and whether the network communication is fine.
ECG LEADS OFF	The ECG cable is not well connected to the transducer, or the leads of the ECG cable are not well attached to the patient.	Check the connection between the ECG cable and the monitor or the TOCO-E transducer. Check also the attachment of the ECG leads to the patient.
ECG SINGNAL EXCEEDS LIMIT	ECG signal exceeds the measurement limits.	Check the connection of the leads and the patient's condition.
Bad contact between the electrode sleeve and the skin	Bad contact between the electrode sleeve of TOCO transducer and the skin.	Adjust the transducer and make sure good contact between the electrodes and the skin.
ECG Signal Weak	The ECG signal is too weak that the system can't calculate HR correctly.	Check the attachment of the ECG leads to the patient.
HR EXCEEDS MEASUREMENT RANGE	The heart rate exceeds the measurement limits.	Check the connection of the ECG leads/SpO_2 transducer and the patient's condition.
NIBP EQUIP MALF	The NIBP board cannot communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
NIBP SYSTEM FAILURE	The NIBP module defective.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
NIBP Airway Pressure Abnormality	NIBP cannot be deflated, and the system pressure has remained unchanged	Measure again, if the fault persists, stop using the monitor for NIBP measurement, and contact the manufacturer for repair
NIBP CUFF LOOSE or OFF	The cuff is loose or not connected.	Wrap the cuff properly.
NIBP OVER PRESSURE	The pressure has exceeded the specified upper safety limit.	Measure again, if failure persists, stop using the monitor for NIBP measuring and contact the manufacturer for service.

NIBP CUFF TYPE ERROR	A different cuff other than the one supplied by the manufacturer is used.	Use the cuff supplied by the manufacturer.
NIBP LEAK	The cuff, hose and (or) connector are (is) damaged.	Check and replace the leaking part(s). Contact the manufacturer for service if required.
NIBP Signal Weak	Cuff is too loose or the patient pulse is too weak.	Use other methods to measure NIBP.
NIBP SIGNAL INTERFERED	Large signal noise or irregular pulse rate caused by excessive motions of the patient.	Keep the arm that is wrapped with the cuff still.
NIBP EXCEEDS MEASUREMENT RANGE	The blood pressure exceeds the measurement limits.	Check the connection of the cuff and the patient's condition.
NIBP TIME OUT	Measuring time has exceeded 120 seconds.	Start measuring again, or use other measuring methods.
SpO_2 LOW PERFUSION	The signal received by SpO_2 sensor is too weak, or the measurement part has low perfusion, and therefore the result may be inaccurate.	Check the patient's condition and reposition the SpO_2 sensor. Contact the manufacturer for service if the problem persists.
SpO_2 SENSOR OFF	SpO_2 sensor is not well connected.	Check the connection of SpO_2 sensor and finger placement.
SpO_2 EQUIP MALF	The SpO_2 board cannot communicate with the system successfully.	Restart the monitor and try again, contact the manufacturer if the connection still fails.
TEMP UNPLUGGED	TEMP transducer is not well connected.	Check the connection of TEMP transducer.
TEMP EXCEEDS MEASUREMENT RANGE	The temperature exceeds the measurement limits.	Check the connection of the TEMP transducer and the patient's condition.
TEMP Calibration Failed	Calibration of the TEMP transducer failed.	Restart the monitor and try again. Contact the manufacturer for service if the problem persists.
Flow abnormal	Abnormal network traffic has been detected. The data traffic exceeds the limit.	Disconnect the network to make the monitor work properly, and then contact the professionals authorized by manufacturer to check the network problem.

4.18.3 FTS-3 Technical Alarm Messages

When FTS-3 is connected to F15 series fetal/maternal monitor, the monitor gives technical alarms for the situations that need the physicians to pay attention to during wireless monitoring, the alarm messages are listed below.

Alarm Message	Cause	Countermeasure
Medium Priority		
** The battery level is low(US1)	The battery indicator is  . The battery power is too low to support further work of the transducer.	Please charge the US1 transducer immediately.
** The battery level is low(US2)	The battery indicator is  . The battery power is too low to support further work of the transducer.	Please charge the US2 transducer immediately.
** The battery level is low(TOCO)	The battery indicator is  . The battery power is too low to support further work of the wireless TOCO-T transducer or the wireless TOCO-E transducer.	Please charge the TOCO-T transducer or TOCO-E transducer immediately.
** The station battery level is low	The battery indicator is  . The battery power is too low to support further work of the base station.	Connect the base station to AC power supply.
Low Priority		
Wireless US1 Signal Weak	Wireless FHR1 signal is too weak.	Check if the patient moves out of the base station RF range, if the transducer is well connected to the base station.
Wireless US2 Signal Weak	Wireless FHR2 signal is too weak.	Check if the patient moves out of the base station RF range, if the transducer is well connected to the base station.
Wireless TOCO Signal Weak	The signal of the wireless TOCO-T transducer or wireless TOCO-E transducer is too weak.	Check if the patient moves out of the base station RF range, if the transducer is well connected to the base station.

4.18.4 Alarm Bilateral Control

When the network version is ETHERNET 1.4 and above, alarm bilateral control is supported. The alarm settings that fetal monitor and central station synchronize bilaterally include high/low alarm limit, alarm switch and alarm delay of physiological alarm settings: FHR high/low alarm limit, FHR alarm switch and FHR alarm delay settings, HR high/low alarm limit, HR alarm switch, SpO2 high/low alarm limit, SpO2 alarm switch, SYS high/low alarm limit, SYS alarm switch, DIA high/low alarm limit, DIA alarm switch, MAP high/low alarm limit, MAP alarm switch, TEMP high/low alarm limit, TEMP alarm switch.

When the fetal monitor gets on line, the central station will send above alarm settings to the fetal monitor for synchronization; the central station and the fetal monitor will send alarm settings to the other when alarm settings are revised on either of them after confirmation.

Chapter5 Printing

5.1 *Function Description

The built-in thermal recorder applied in the monitor supports both the American and international standard wide recorder paper. It prints synchronously monitoring traces: FHR1/DFHR/FHR2//FHR3/TOCO/ eFHR /AFM/HR/SpO_2 traces; trace marks: FHR1//DFHR/ FHR2/FHR3/eFHR/HR/SpO2; monitoring information: patient's ID, patient's name, date, time, speed(i.e. printing speed), FHR2 offset, FHR3 offset, HR, SpO_2, TEMP; SYS/DIA/MAP/PR; event marks: AUTO-zero symbol, MFM mark, event mark, fetal stimulation mark, alarm indicator, SOV indicator, US1, US2 and US3 signal weak alarm indicator, transducer wireless signal weak indicator.

The monitor supports some other functions listed below:

- **Auto start printing:** If the function is enabled, the recorder starts printing automatically when new monitoring starts (the **START** key is pressed). Otherwise you have to press the **PRINT** key to start printing.
- **Printing timer:** The printing timer determines the elapsed time for each print. This time is adjustable. Refer to *5.2.3 Changing the Print Timer*.
- **Remaining time indicating:** If the printing timer is set, a process indicator 

appears in the status window after printing starts, with the remaining time shown in it. When the time is up, the monitor gives three “Do” tones and flashes the indicator.
- **Fast printing:** The recorder prints the data saved in the monitor at a high speed (up to 18.5mm/s).
- **Data Caching:** When the paper drawer runs out of paper or when it is open, the recorder stops printing. The data from this time on (at most 60 minutes) will be temporarily saved in the internal memory. When new paper is loaded and/or the drawer is closed, the saved data will be printed out at a high speed. When the saved trace has been printed out, the recorder switches back to continue printing the current data at the normal speed automatically.

  NOTE:

  1 When the monitor is switched off, the data in the internal memory will be lost.

  2 If a printing timer is set, and the time is out when the paper runs out, the CTG analysis result may disaccord with the printout. Therefore, reload the paper in time to avoid paper shortage.
- **FHR2/FHR3 offset:** You can set the offset of the FHR2/FHR3 trace to separate the two FH traces on the screen and the recorder paper. Refer to *7.4.4 Changing FHR2 Offset and 7.5.4 Changing FHR3 Offset.*
- **Print self-check:** The recorder prints a baseline for self-checking when the monitor is switched on.
- **Paper advance:** When printing stops, press the paper advancing key  to advance the paper, making sure the paper has a perforation outside the drawer and is easy to be torn off.
- **Separation Printing:** If the function is enabled, the twins/triplets FHR traces in real time or saved in the monitor can be printed separately. During real time monitoring, the recorder will print the FHR trace at a normal speed and then quickly print traces of FHR2/FHR3, and in the end print the grading result.

  NOTE:

  The paper advancing key is invalid in the process of printing and paper advancing.

5.2 Printing Configuration

NOTE:

All the parameters should be well configured before printing starts. You cannot change the configuration in the process of printing.

5.2.1 Switching Auto Start Printing On or Off

You can switch auto start printing on or off:

1 Select the main menu key  on the main interface.
2 Select **Start Monitoring > PRINT**.
3 Select **ON** or **OFF** (default).
4 Select **OK**.

5.2.2 *Choosing the Paper Speed

You can choose a paper speed of 1 cm/min, 2cm/min or 3cm/min:

1 Select the main menu key  on the main interface.
2 Select **Recorder > Print Speed**.
3 Select **1 cm/min**, **2 cm/min** or **3 cm/min** (default).
4 Select **OK**.

NOTE:

Different paper speed setting causes different FHR trace appearance on the record paper. To avoid misinterpretation, we recommend you to set all monitors in your institution to the same paper speed.

5.2.3 *Changing the Print Timer

You can choose different time lengths for the print timer

1 Select the main menu key  on the main interface.
2 Select **Recorder > Timer**.
3 Set timer to **10 ~ 90** (minutes, the step is 5) or **Infinite** (default). For a fixed time, the recorder stops when the time is up. For **Infinite**, there is no time limit. Whatever the setting is, the recorder stops when this patient's traces come to the end or if the **PRINT** key is pressed in midway.
4 Select **OK**.

5.2.4 Switching Print Self-Check On or Off

You can choose to switch print self-check on or off:

1 Select the main menu key  on the main interface.
2 Select **Recorder** > **Print Self-Check**.
3 Select **ON** (default) or **OFF**.
4 Select **OK**.

5.2.5 Changing Printing End Volume

The monitor gives a tone when printing ends and this tone volume is adjustable.

1 Select the main menu key  on the main interface.
2 Select **Recorder > Print Ending Beep**.
3 Select **High, Low** (default) or **OFF**.
4 Select **OK**.

5.2.6 Changing Title Print Cycle

1 Select the main menu key  on the main interface.
2 Select **Recorder** > **Title Print Cycle**.
3 Select **10min** (Default)**, 20min, 30min, 60min**.
4 Select **OK**.

5.2.7 Switching Separation Printing On or Off

1 Select the main menu key  on the main interface.
2 Select **Recorder** > **Separation Printing**.
3 Select **ON** or **OFF**(default).
4 Select **OK**.

5.2.8 Switching Maternal Monitor Information On or Off

1 Select the main menu key  on the main interface.
2 Select **Recorder > Maternal Monitor Information**.
3 Select **ON** (default) or **OFF**.
4 Select **OK**.

Note:

When the **Maternal Monitor Information** switch is turned off, the HR trace, SpO2 trace switch will be turned on automatically. You can turn them off manually if needed.

5.3 Understanding Recorder Paper Printout

WARNING

1 If there is any discrepancy between the display and the printout, the printout should prevail.

2 If the data is doubtful, clinicians should make diagnoses based on the real condition.

Figure 5-1 is an example of the recorder paper with traces. Comparing it with the monitor screen, you can find this extra information on it:

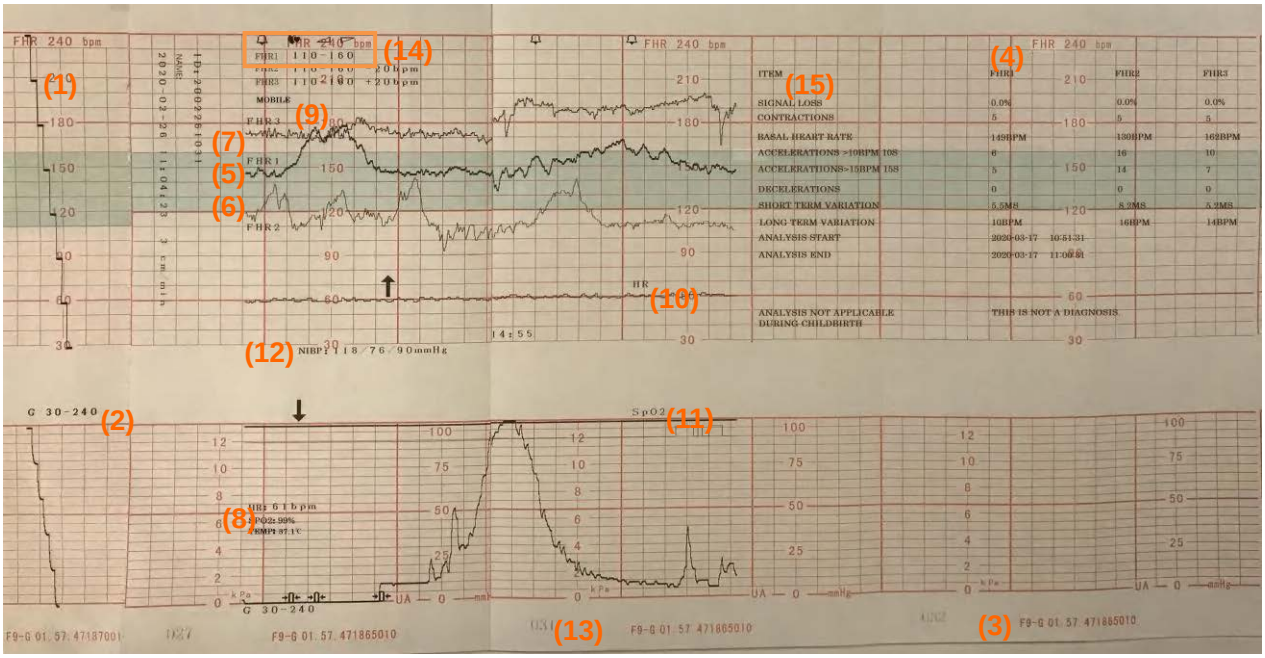


Figure 5-1 an example of recorder paper with traces

Item	Information	Description
1.	Self-Check Trace	The monitor prints a self-check trace after being switched on. It is used to check if the recorder paper is properly loaded.
2.	Paper Settings	The paper settings of the monitor. It consists of the paper type and paper style, e.g. “G 30-240”, indicating that the paper type is “F9-G”, and the paper style is International. It is printed out to check if the proper recorder paper is used.
3.	Paper Type	There are two types of paper: F9-G and F9-P.
4.	Paper Style	The FHR pane range indicates the paper style. American style: 30 ~ 240 International style: 50 ~ 210
5.	FHR1 Mark	The trace marked with “FHR1” is the FHR1 trace.
6.	FHR2 Mark	The trace marked with “FHR2” is the FHR2 trace.
7.	FHR3 Mark	The trace marked with “FHR3” is the FHR2 trace.
8.	Trace Information List	A list of current date, time, FHR2 offset, FHR3 offset, HR, SpO_2 and TEMP is printed at the start of the monitoring and every 10 minutes/20 minutes/30 minutes/ 60 minutes (optional) afterwards.
9.	Smart Note	The annotation of the event mark below.
10.	HR Mark	The trace marked with “HR” is the maternal HR trace.
11.	SpO_2 Mark	The trace marked with “SpO_2” is the maternal SpO_2 trace.
12.	NIBP	In the real-time printing mode, each NIBP measurement result is printed on the paper in the order of SYS/DIA/MAP/PR.

13.	Page Mark	Each recorder paper pack has 150 pages. When you notice the page mark comes to the end, remember to load new paper in time.
14.	Alarm Message	It indicates the physiological alarm symbol, signal overlap alarm symbol, US signal weak symbol, ECG signal weak symbol transducer wireless signal weak and FT20 wireless signal weak symbol.
15.	CTG Analysis Result	The CTG analysis results of FHR1, FHR2 and FHR3.

Chapter6 Pre-Monitoring Preparation

6.1 Switching On the Monitor

WARNING

1 **Check if all the metal parts are linked to the protective earth cord and the cord is in good condition before switching on the monitor.**

2 **If any sign of damage is detected, or the monitor displays some error messages, do not use it on any patient. Contact biomedical engineer in the hospital or our service engineer immediately.**

3 **Check all the functions to make sure that the monitor is in good condition.**

Press the **POWER** switch on the right panel to switch on the monitor. The power indicator lights up and a start-up music will be heard. You can operate the monitor after the main interface appears.

You can choose to switch the start-up music on or off,

1 Select the main menu key  on the main interface.

2 Select **General > Start-up Music**.

3 Select **ON** (default) or **OFF**.

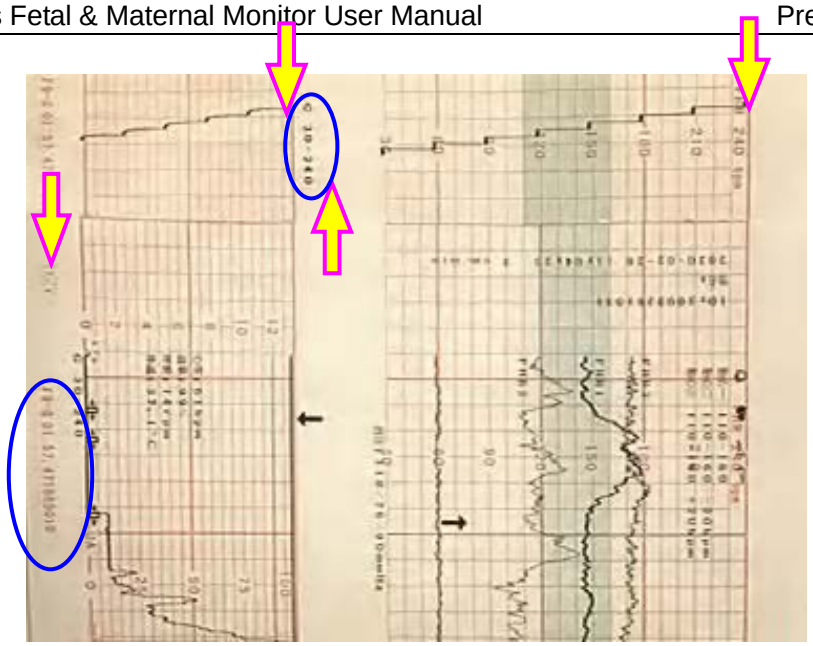
4 Select **OK**.

6.2 Checking the Recorder Paper

The monitor provides the print self-check function to check if the recorder paper is correctly loaded and set.

The recorder prints a baseline and paper settings after start-up (if **Print Self-Check** is **ON**).

Check if the paper settings match the paper being used (in the circled area below, **P** should correspond to **F9-P**, and **G** to **F9-G**), and then observe the starts and ends of the printed baselines (illustrated with the arrow). The starts and ends should be printed exactly on the edges of the pane if the recorder paper is correctly loaded and set. If they do not comply with the edges, reload paper or ask the service engineer to check the paper settings of the monitor.



If the monitor does not print the baseline, switch on the **Print Self-Check** function and then restart the monitor.

NOTE:

Make sure the paper is correctly loaded before the printing starts.

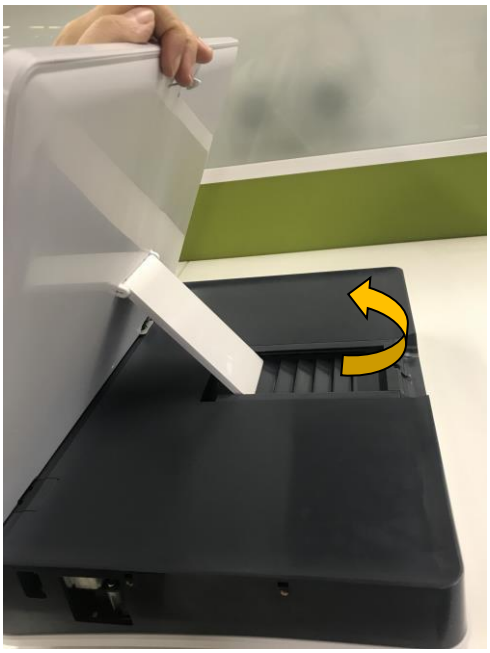
6.3 Adjusting the Screen Angle

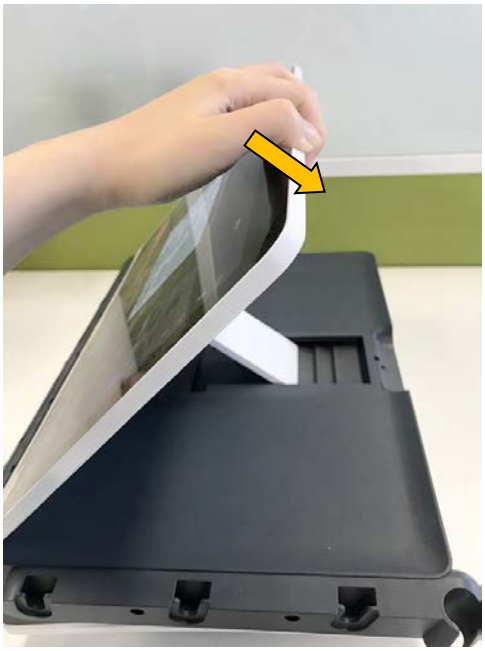
The angle between the screen and the top cover of the monitor is adjustable as needed, allowing it to be mounted on a wall or placed on a flat surface.

Adjustment method:

Push the hook on top of the screen left to spring it open. Pull the screen forward to let the screen stop at one of the three preset positions.

To bring the screen back to flat, pull it all the way forward and then push it back.





6.4 Setting Screen Brightness

You can adjust the brightness of the screen,

1 Select the brightness key on the main interface or
2 Select the main menu key on the main interface.
3 Select **General>Brightness**.
4 Select up/down key to set the brightness level.
5 Select **OK**.

6.5 Setting Date and Time

You can change the date and time of the monitor,

1 Select the main menu key on the main interface.
2 Select **Date And Time**.
3 Set the year, month, date, hour, minute and second. The first three numbers are used to set the year, month and date. Their orders vary with the preset Date Format below.
4 Select **Date Format** for the format of the date; there are three options: yyyy-mm-dd (default), mm/dd/yyyy and dd/mm/yyyy.
5 Select **OK**.

CAUTION

1 You should set date and time information in advance. After this information is changed, the monitor starts new monitoring with an auto ID. Therefore, we advise you to restart the monitor after changing date or time information, and do not perform this operation when monitoring is in process.

2 If date and time cannot be saved, it is probably the battery has reached the end of its

service life. Please contact the service personnel or your local distributor.

NOTE:

1 **The date and time remain in the monitor for at least two months after it is switched off. You do not have to set date and time each time before monitoring.**

2 **When the network version is ETHERNET 1.4 and above, if the fetal monitor gets on line or time is revised on the central station and the time difference between the fetal monitor and the central station is bigger than 1 minute, then the fetal monitor will synchronize time with the central station.**

6.6 Connecting Transducers

Check for visible damages of the transducers every time before connecting them to the monitor. Pay special attention to the cracks on the transducers and cables before immersing them into conductive fluid. If damage is found, replace them with good ones at once.

Wired Model: When plugging transducers into the monitor, pinch the afterbody of the transducer plug and put it into the corresponding socket. When disconnecting a transducer, pinch the afterbody of the transducer plug and pull it out slightly.

NOTE: Never try to disconnect the transducer by pulling the cable directly.

Wireless Model: After switching on the monitor, take up the wireless transducers from the docking slots. When the screen of the transducer displays device no. and icon  , it indicates that the transducer is connected to the monitor successfully and monitoring can be started.

6.7 Placing Accessories in the Holder

Wired Model: The accessory holder is on the right of the front panel. The first hole from the top is for the remote event marker, and the rest three are for the transducers.

To place a transducer into the holder, hold the transducer on the edge, and then place the buckle all the way into one of the holes on the holder. Make sure that the transducer cable is on the bottom.

To place the remote event marker, put the small end of the marker into the hole as far as it can go.

NOTE:

In the process of monitoring, the transducer that is placed in the holder may be affected and thereby produces interfering signals. Therefore, when monitoring a patient, it is recommended to remove or disconnect the transducer that is not in use.

6.8 Adjusting the Volume

The monitor automatically detects which channel the transducer is connected to. The corresponding volume adjustment key of this channel displays  , indicating the FH sound is coming out from this channel; while the other two display and , for example: 

. When all the three channels are connected, the FH sound comes out from Channel 1 by default. Press the **CHANNEL** key to switch the fetal heart sound to Channel 2; press the **CHANNEL** key again to switch the fetal heart sound to Channel 3.

Adjust the default monitoring volume:

The FH volume returns to a default level after the **START** key is pressed. This default level is adjustable. To change this level,

1 Select the main menu key  on the main interface.

2 Select **Start Monitoring > Volume**.

3 Select the volume from 0 ~ 9; the step is 1 and the default level is 3.

4 Select **OK**.

***Adjust the real-time monitoring volume:**

If the default volume level is not satisfying during monitoring, you can adjust the real-time volume of each channel.

1 Select the volume adjustment key  on the main interface.

2 Touch the  symbol for one step, the volume increases by one level, there are ten levels in all; the volume level indicator  increases by one at every two steps; touch the  symbol to decrease the volume.

3 Touch any other place on the screen to confirm the volume level.

***Adjust the key volume:**

1 Select the main menu key  on the main interface.

2 Select **General > Key Volume**.

3 Select **Low** (default), **High** or **OFF**.

4 Select **OK**.

Chapter7 Fetal Monitoring

WARNING

1 **The monitor is not intended for use in intensive care units (ICU), operating rooms or for home use.**

2 **Do not apply this monitor during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.**

3 **Always check if the alarm settings are appropriate for your patient before starting monitoring.**

7.1 Confirming Fetal Life

Fetal monitoring with ultrasound or DECG cannot differentiate a fetal heart rate signal source from a maternal heart rate source in all situations. These are some of the signal sources that might be taken as FHR signal source by mistake:

- High maternal heart rate signal.

- Maternal aorta or other large vessels signals.

- Electrical impulse from the maternal heart transmitted through a recently deceased fetus.

These are some of the signal sources that might be taken as fetal movement signal source by mistake:

-Movement of the ultrasound transducer.- Movement of the deceased fetus during or following manual palpation of fetal movement.

- Movement of the deceased fetus during or following maternal movement.

So you need to confirm fetal life by other means before starting to use the fetal monitor, such as using a fetoscope, stethoscope, Pinard stethoscope or obstetric ultrasonography.

7.2 FHR Monitoring FHR with Ultrasound

The ultrasound monitoring is a method to obtain FHR on maternal abdominal wall. Place a US transducer (Ultrasound transducer) on maternal abdomen. It transmits low energy ultrasound wave to the fetal heart, and receives the echo signal. Monitoring FHR using ultrasound is recommended from the 24th week of gestation.

WARNING

1 **Make sure you have confirmed the fetal life by other means before using this monitor for FHR monitoring.**

2 **When monitoring with wireless US transducer, make sure the transducer has connected to the monitor successfully, i.e. device no. and icon  are displayed on the screen of the transducer.**

3 **FHR should not be monitored until a clear fetal heart signal is detected.**

4 **If FHR reduces more than 10 bpm suddenly, or the beat of fetal heart sounds slower abruptly, please check if it is the MHR that is being monitored by the transducer. If so, relocate the transducer for the best fetal heart signal.**

5 **The sphere of activity for the fetus is much larger during mid-trimester of gestation (from 24th week to 28th week). When fetal heart moves away from the US transducer, please redetermine the fetal heart position and relocate the transducer.**

WARNING

6 Inspect patient skin before applying the transducer for monitoring. If the skin quality is poor, especially when the skin is damaged or irritated, please change a site to apply the transducer.

7 During long-time monitoring, please inspect the application site of the transducer at least every half an hour. If the skin quality changes, you should move the transducer to another site.

8 Do not mistake the maternal movement for fetal movement.

9 During ultrasound fetal monitoring, performing ultrasound imaging or Doppler flow measurements or monitoring together with ultrasound transducer of other manufacturer may cause false FHR readings, and the trace recording may deteriorate.

10 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.

11 The movement of the pregnant woman will influence the calculation of the HR.

CAUTION

1 It is recommended to start printing FHR trace after clear fetal heart signal is detected and FHR computing has stabilized.

2 If AFM is enabled, please fix the transducer with a belt, suggest to reduce maternal movement and walking, and do not pat the abdomen.

3 Using coupling gel not approved by EDAN may reduce signal quality and may damage the transducer. This type of damage is not covered by warranty.

7.2.1 Monitoring FHR with Ultrasound Transducer

Monitoring with F15

◆ Parts Required

a) Wired/wireless US transducer

b) Aquasonic coupling gel

c) Belt

◆ Monitoring Procedure

a) Placing Transducer Belt

Place the transducer belts across the bed, ensuring that the belt will be around the abdomen when it is fastened. Lay the patient on the bed.

Alternatively, the patient can take a sitting position. Arrange the belt around her abdomen.

b) Determining the Transducer Position

◆ Determine the fetal position using Leopold’s maneuvers.

◆ Search for the location of the fetal heart. The best fetal heart signal can be obtained through the fetal back.

◆ Place the transducer below the navel for head presentation and place the transducer above the navel for breech presentation.

◆ During parturition, the fetal heart moves downward as the labor progresses. It is recommended to move the transducer along with the fetus.

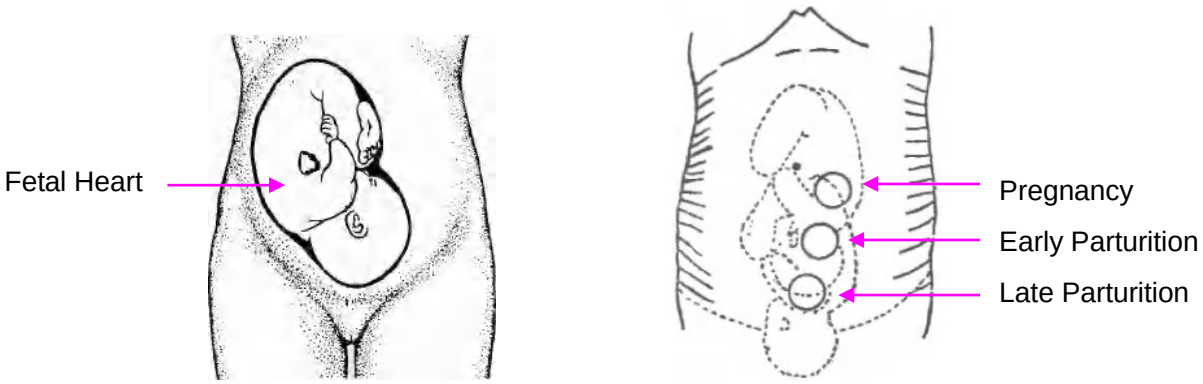


Figure 7-1 Positioning Ultrasound Transducer (single fetus)

c) Acquiring Fetal Heart Signal

Apply a certain amount of acoustic gel on the transducer and move the transducer slowly around the fetus site to even the gel. The best fetal heart signal can be obtained through the fetal back. Find at least 2 or 3 sites, and choose the one where the clearest, most sonorous and steady fetal heart sound is heard (adjust the volume to medium level and the fetal heart sound can still be heard clearly). When the transducer is connected correctly and communicated well, the fetal heart signal indicator is full. If the signal is poor, the signal indicator shows as it is and no FHR data are displayed. When you move the transducer on the abdomen, adjust the speaker volume so that it can be clearly heard.

d) Fixing the Transducer

For long-time FHR monitoring, please use a belt to fix the transducer in order to obtain stable fetal heart signal. When you find clearest and most steady fetal heart sound, wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt.

Make sure the belt fits the patient snugly but comfortably. Meanwhile, fetus heart beat sound is heard; the FHR trace and numeric are displayed. During long-time monitoring, the gel may dry out as the transducer moves around. Add more gel in time if it is inadequate.

e) Confirming that the Fetus is the Signal Source

There are possibilities that maternal heart rate signal is mistaken for FHR signal, so it is recommended to confirm that the fetus is the signal source continuously. To reduce the possibility of mistaking the maternal HR for an FHR, you can perform either of the following:

■ Measure the maternal heart rate with ECG or SpO2 synchronously. The monitor's SOV function can issue an alarm when the FHR signal source is likely to be from the maternal heart.

■ Feel the maternal pulse at the same time, such as feeling the arteria carotis and arteriae radialis and see whether the beating rhythm is the same as the sound rhythm from the loudspeaker.

If the maternal heart signal is misidentified as the fetal heart signal, repositioning of the transducer is needed.

NOTE:

1 Do not mistake the high maternal heart rate for fetal heart rate. It is recommended to monitor maternal heart rate at the same time to distinguish it from fetal heart rate.

2 The best quality records will only be obtained if the probe is placed in the optimum position. Positions with strong placental sounds or umbilical blood flow sound should be avoided.

3 If the fetus is in the cephalic presentation and the mother is supine, the clearest heart sound will normally be found on the midline below the umbilicus. During monitoring, the patient's prolonged lying in the supine position should be avoided owing to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more

comfortable.

4 **During long-time monitoring, the gel may dry out as the transducer moves around. Add more gel in time if it is inadequate.**

5 **When applied to the patient, the ultrasound transducer may warm slightly (less than 10℃ (18ºF) above ambient temperature). When NOT applied, the ultrasound transducer may warm slightly (less than 10℃ (18ºF) above ambient temperature).**

6 **When an ultrasound transducer is connected to the monitor, but not applied to the patient, the measurement may generate unexpected intermittent FHR readings.**

Monitoring with FTS-3

◆ Parts Required

a) US-T transducer

b) Aquasonic coupling gel

c) Belt

◆ Monitoring Procedure

a) Connect the FTS-3 system to the monitor and switch it on. Refer to user manual of FTS-3 Fetal Telemetry System.

b) Take up a US-T transducer and make sure it is successfully connected to the base station.

c) Monitor FHR following the procedures described above.

7.2.2 Changing the FHR Alarm Delay

You can change the FHR alarm delay. The alarm delay indicates how long the measured result continues exceeding its limit before the alarm is triggered.

1 Select the main menu key  on the main interface.

2 Select **Alarm**. On the displayed **Password** box, enter user password, then select **Enter**.

3 Select **FHR**.

4 Select a value from 0 ~ 300 second(s) for **High Alarm Delay.** (The step is 5, and the default value is 10 seconds.)

5 Select a value from 0 ~ 300 second(s) for **Low Alarm Delay.** (The step is 5, and the default value is 10 seconds.)

6 Select **OK**.

WARNING

The FHR alarm delay is adjustable between 0 and 300 seconds.

7.2.3 Testing US Transducers

To test a US transducer:

1 Switch on the monitor.

2 Connect the US transducer to the fetal monitor.

3 Hold the transducer with one hand, and gently touch the center of the transducer with the other hand in the frequency of 2 times per second.

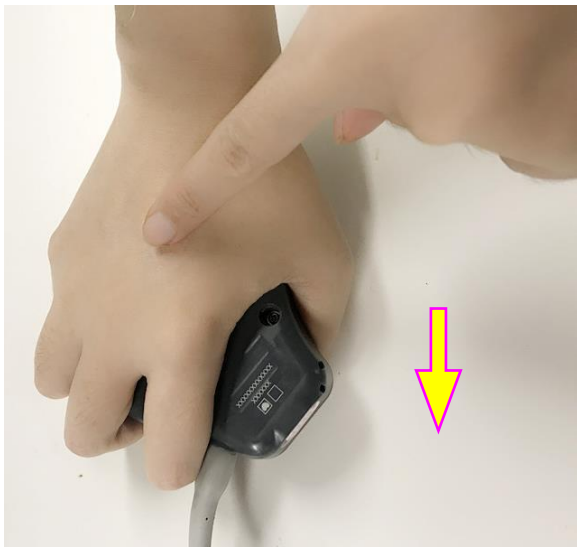


Figure 7-2 Testing a US Transducer

4 Check that the value on the display shows this change in FHR.

If a US transducer fails the test, repeat this test with another transducer. If the second one passes the test, defect of the first transducer is confirmed. Replace it with a good one. If the second transducer fails the test as well, contact the manufacturer for service.

7.3 Monitoring FHR with DECG

The fetal spiral electrode can be used when amniotic membranes are adequately ruptured and sufficient cervical dilatation is ensured. The fetal electrode tip is designed to penetrate the epidermis of the fetus; therefore, trauma, hemorrhage and/or infection can occur. The electrode should be used with strict adherence to aseptic technique.

The fetal spiral electrode should not be applied to the fetal face, fontanels or genitalia.

Do not apply the fetal spiral electrode when placenta previa is present; when the mother has visible genital herpes lesions or reports symptoms of prodromal lesions; when the mother is HIV sero-positive; when mother is a confirmed carrier of hemophilia and the fetus is affected or of unknown status; or when it is not possible to identify fetal presenting part where application is being considered. This method is not recommended when fetus is extremely premature, or in the presence of a maternal infection such as Hepatitis B, Group B hemolytic strep, syphilis or gonorrhea, unless a clear benefit to the fetus or mother can be established.

7.3.1 Preparing the Patient's Skin Prior to Placing Electrodes

The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- Shave hair from electrode sites, if necessary.
- Wash the sites thoroughly with soap and water. (Do not use ether or pure alcohol, which will increase skin impedance)
- Rub the skin briskly to increase capillary blood flow in the tissues.
- Remove skin scurf and grease.

7.3.2 Directions for Using Fetal Spiral Electrode

1 With the patient in the dorsal lithotomy position, perform a vaginal examination and clearly identify the fetal presenting part.

2 Remove the spiral electrode from the package; leave the electrode wires locked in the handle notch.

3 Gently bend the guide tube to the desired angle.

4 Hold the drive handle, ensure the spiral electrode is retracted about one inch (2.5 cm) from the distal end of the guide tube.

5 Place the guide tube firmly against the identified presenting part.

6 Maintain pressure against the fetal presenting part with guide and drive tubes. Rotate the drive tube by rotating the drive handle clockwise until gentle resistance is encountered. Resistance to further rotation and recoil of the drive handle indicates that the spiral electrode is well attached to the fetus.

7 Release the electrode wires from the handle notch and straighten them. Slide the drive and guide tubes off the electrode wires.

8 Insert the safety cap into DECG cable.

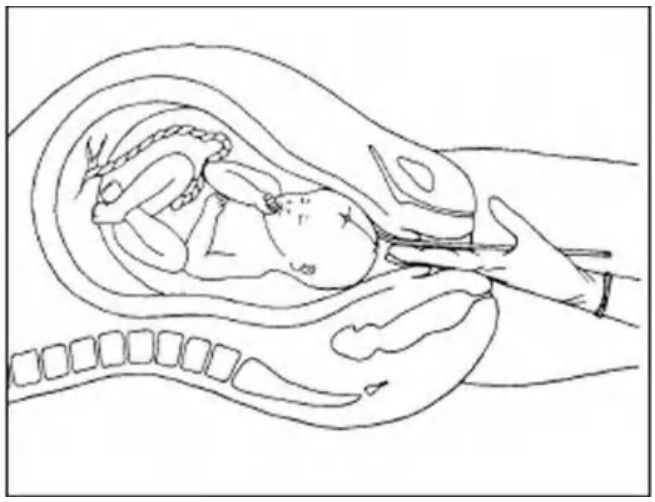


Figure 7-3 The Well-Attached Fetal Spiral Electrode

7.3.3 DECG Monitoring

Monitoring with F15:

◆ Parts Required

a) Fetal spiral electrode

b) DECG cable

c) DECG-IUP Integrated Cable

d) Wired/wireless DECG Fetal&Maternal Module

e) Disposable maternal attachment pad electrode

The following illustration shows how these parts should be connected:

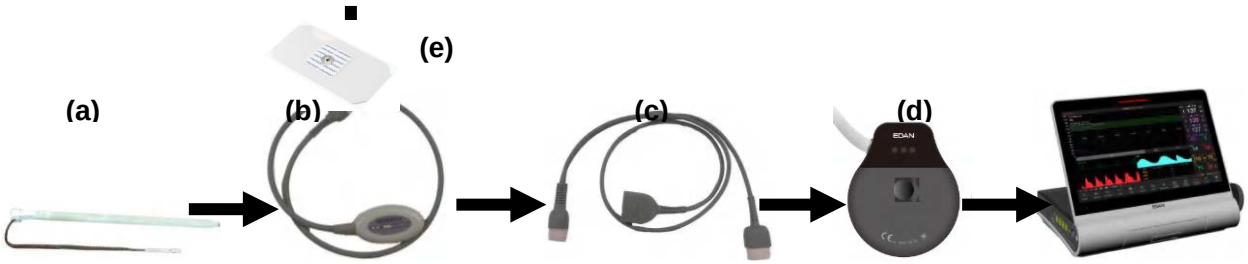


Figure 7-4 Connection for wired DECG Monitoring

Note:

The filter of AC power supply can be configured by selecting System>Factory Configuration>Line Frequency>50(default) or 60. Please select it according to the current AC frequency.

◆ Monitoring Procedure

a) Perform a vaginal examination to identify the fetal presenting part.

b) Prepare the patient's skin using the procedures described in section *7.3.2 Preparing the Patient's Skin Prior to Placing Electrodes.*

c) Attach the fetal spiral electrode to the fetal presenting part using the procedures described in section *7.3.3 Directions for Using Fetal Spiral Electrode*.

d) Fix an attachment pad electrode to DECG cable.

e) Remove the film on the back of the electrode and place the electrode on maternal thigh; press it firmly in place.

f) Connect the fetal spiral electrode to the DECG cable.

g) Connect the DECG cable to the DECG-IUP integrated cable.

h) Connect the DECG-IUP integrated cable to the DECG Fetal&Maternal Module.

i) Connect the DECG Fetal&Maternal Module to the fetal monitoring socket of the monitor.

WARNING

1 Do not plug the fetal spiral electrode wire into the power socket.

2 Never attempt to connect the fetal spiral electrode to anything other than the correct DECG cable.

3 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 Artifact Suppress 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.

CAUTION

Do not mistake the higher maternal heart rate for DECG.

NOTE:

1 **If there is any doubt as to the presence of a fetal heart signal with ECG, check with the US transducer on the patient's abdomen or with a separate diagnostic instrument. The presence of an audible heart sound at a rate distinct from that of the maternal pulse is unequivocal evidence of the fetal life.**

2 **After the electrode is well attached, allow a few minutes for the electrode and fetal tissue to become stabilized. It is essential that the ECG signal electrode is in good contact with the fetal presenting part.**

7.3.4 Changing DECG Beep Volume

When the DECG beep is enabled, the monitor gives a beep sound of DECG. The frequency of DECG beep corresponds to the fetal heart rate, but occasionally it may differ due to weak DECG signal.

To change the DECG beep volume,

1 Select the main menu key  on the main interface.

2 Select **Fetus > DECG Beep**.

3 Select **0** (default) **~ 9**.

4 Select **OK**.

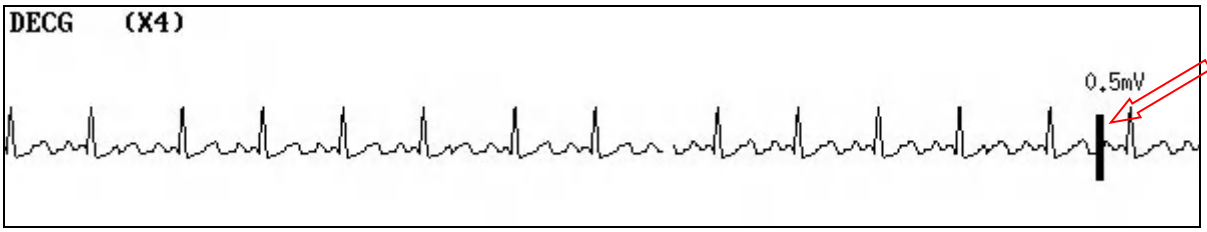
NOTE:

1 The DECG beep and HR beep share the same audio channel. Once the DECG beep is switched on, the HR beep is disabled (set to OFF) automatically.

2 Once the DECG/HR beep volume is changed, the sound switches to channel 1 automatically. Therefore, it is advised against changing DECG/HR beep volume in the monitoring process.

7.3.5 DECG Gain and Display

You can change the DECG gain by selecting from X1/2, X1, X2, X4 and X8 to adjust the DECG waveform size for better observation. The system displays a 0.5mV scale at the right side of the DECG waveform. The height of the 0.5mV bar is directly proportional to the waveform amplitude.



7.3.6 Switching the Artifact Suppression On or Off

When monitoring FHR with DECG, artifacts may occur due to bad connection of the spiral electrode, excessive motion of the mother, electromyographic interference etc.. The **Artifact Suppression** feature is designed to eliminate the interference. When artifact suppression is on, artifacts are suppressed and not recorded. When it is off, the artifacts are shown as well as the fetal heartbeats.

You can choose to switch the artifact suppression on or off.

1 Select the main menu key  on the main interface.

2 Select **Fetus > Artifact Suppression**.

3 Select **ON** (default) or **OFF**.

4 Select **OK**.

WARNING

When artifact suppression is on, fetal arrhythmia will also be suppressed. Therefore, if fetal arrhythmia is suspected, switch artifact suppression off.

7.3.7 Detaching the Fetal Spiral Electrode

To detach the fetal spiral electrode, rotate it counterclockwise until it is free from the fetal presenting part. Do not pull the electrode from the fetal skin forcefully.

Dispose of the used fetal spiral electrode in a proper way. Do not use it again.

7.4 Monitoring Twin FHRs

7.4.1 Monitoring Twins Externally

To monitor twin FHRs externally, you need to connect a US transducer to a fetal monitoring socket and the second US transducer to another fetal monitoring socket of the monitor. Follow the instructions described in Section *7.2 Monitoring FHR with Ultrasound* to acquire FHR signals for both channels. Press **CHANNEL** key to switch the FH sound from one channel to the other.

When the two US transducers are fixed, make sure FH sounds from both channels are clear, two FHR traces and two FHR numerics are displayed on the screen.

NOTE:

To ensure that both transducers stay at the optimum location, each transducer should be fixed with a separate belt.

7.4.2 Monitoring Internally

Alternatively, you can monitor a FH using ultrasound externally, and monitor the second FH using DECG internally.

Connect the US transducer to a fetal monitoring socket; connect the DECG Fetal&Maternal Module to another fetal monitoring socket.

Monitor one twin with a US transducer using the procedures described in Section *7.2 Monitoring FHR with Ultrasound*.

Monitor the other twin with a DECG cable using the procedures described in Section *7.3 Monitoring FHR with DECG*.

7.4.3 Signals Overlap Verification (SOV)

When monitoring twins, there are possibilities that one twin's FHR signal is mistaken for the other one's signal. The monitor provides signals overlap verification (SOV) function to reduce these possibilities.

In the process of monitoring, if the SOV detects signals overlapping, an alarm message "Signals Overlap (FHR1/DFHR, FHR2)" will appear on the screen to warn you. Checking the patient and reposition of transducers might be needed.

WARNING

1 **Though SOV alarm function helps to detect the overlap of FHR1/DFHR and FHR2 automatically, do not rely solely on it to judge the fetal heart signal overlap. As in the process of actual monitoring, the movement of transducer and fetus, detecting MHR by mistake, interference of fetal movement and maternal movement can cause fetal heart signal weak and loss, and magnified error of fetal heart calculation led by poor signal. In these situations, SOV alarm function can not totally identify the signal overlap, so user needs to observe FHR1/DFHR trace and FHR2 trace simultaneously to help the judgment and adjust the transducer to the optimal position in time.**

7.4.4 Changing FHR2 Offset

In order to distinguish FHR1 trace from FHR2 trace, FHR2 offset is provided to help you separate the two traces by an offset of -20 bpm or +20 bpm.

To change the FHR2 offset,

1 Select the main menu key  on the main interface.
2 Select **Recorder > FHR2 Offset**.
3 Select **-20 bpm** (default), **0 bpm** or **+20bpm**.
4 Select **OK**.

This preset FHR2 offset will be printed on the recorder paper every 10 minutes (Default)/20min/30min/60min (optional).

"FHR2: -20bpm": the FHR2 trace is 20bpm lower than it really is.

"FHR2: 0bpm": the FHR2 trace is in its real position.

"FHR2: 20bpm": the FHR2 trace is 20bpm higher than it really is.

7.5 Monitoring Triple FHRs

7.5.1 Monitoring Triplets Externally

To monitor triple FHRs externally, you need to connect three US transducers to fetal monitoring socket of the monitor. Follow the instructions described in Section *7.2 Monitoring FHR with Ultrasound* to acquire FHR signals for three channels. Press **CHANNEL** key to switch the FH sound from one channel to another.

When the three US transducers are fixed, make sure FH sounds from three channels are clear, three FHR traces and three FHR numerics are displayed on the screen.

NOTE:

To ensure that the transducers stay at the optimum location, each transducer should be fixed with a separate belt.

7.5.2 Monitoring Internally

Alternatively, you can monitor two FHs using ultrasound externally, and monitor the third FH using DECG internally.

Connect the two US transducers and DECG Fetal&Maternal Module to fetal monitoring sockets.

Monitor two of the triplets with two US transducers using the procedures described in Section *7.2 Monitoring FHR with Ultrasound*.

Monitor the last triplet with a DECG Fetal&Maternal Module using the procedures described in Section *7.3 Monitoring FHR with DECG*.

7.5.3 Signals Overlap Verification (SOV)

When monitoring triplets, there are possibilities that one of the triplets' FHR signal is mistaken for the rest two's signal. The monitor provides signals overlap verification (SOV) function to reduce these possibilities.

In the process of monitoring, if the SOV detects signals overlapping, an alarm message "Signals Overlap (FHR1/DFHR, FHR2)", "Signals Overlap (FHR2, FHR3)" and "Signals Overlap (FHR1/DFHR, FHR3)"will appear on the screen to warn you. Checking the patient and reposition of transducers might be needed.

WARNING

1 **Though SOV alarm function helps to detect the overlap of FHR1/DFHR and FHR2, FHR2 and FHR3, FHR1/DFHR and FHR3 automatically, do not rely solely on it to judge the fetal heart signal overlap. As in the process of actual monitoring, the movement of transducer and fetus, detecting MHR by mistake, interference of fetal movement and maternal movement can cause fetal heart signal weak and loss, and magnified error of fetal heart calculation led by poor signal. In these situations, SOV alarm function can not totally identify the signal overlap, so user needs to observe FHR1/DFHR trace and FHR2 trace, or FHR2 trace and FHR3 trace, or FHR1/DFHR trace and FHR3 trace simultaneously to help the judgment and adjust the transducer to the optimal position in time.**

7.5.4 Changing FHR3 Offset

In order to distinguish FHR1 trace from FHR2 and FHR3 trace, FHR3 offset is provided to help you separate the three traces by an offset of -20 bpm or +20 bpm.

To change the FHR3 offset,

1 Select the main menu key  on the main interface.

2 Select **Recorder > FHR3 Offset**.

3 Select **-20 bpm** (default), **0 bpm** or **+20bpm**.

4 Select **OK**.

This preset FHR2 offset will be printed on the recorder paper every 10 minutes (Default)/20min/30min/60min (optional).

"FHR3: -20bpm": the FHR2 trace is 20bpm lower than it really is.

"FHR3: 0bpm": the FHR2 trace is in its real position.

"FHR3: 20bpm": the FHR2 trace is 20bpm higher than it really is.

7.6 Monitoring Uterine Activity Externally

WARNING

1 Inspect patient skin before applying the transducer for monitoring. If the skin quality is poor, especially when the skin is damaged or irritated, please change a site to apply the transducer.

2 When monitoring with wireless TOCO transducer, make sure the transducer has connected to the monitor successfully, i.e. device no. and icon are displayed on the screen of the transducer.

3 During long-time monitoring, please inspect the application site (between contractions) of TOCO transducer at least every half an hour. If the skin quality changes, you should move the transducer to another site.

7.6.1 TOCO Monitoring

Monitoring with F15:

◆ Parts Required

a) Wired/Wireless TOCO transducer

b) Belt

◆ Monitoring Procedure

a) Placing Transducer Belt

Place the transducer belts across the bed, ensuring that the belt will be around the abdomen when it is fastened. Lay the patient on the bed.

Alternatively, the patient can take a sitting position. Arrange the belt around her abdomen.

b) Fixing the Transducer

Wipe any gel remaining on abdomen around the fundus area.

Place the TOCO transducer on the patient's abdomen, which is flat and approximately 3 cm away from the fundus, e.g. slightly above the umbilicus on the left or on the right. The position should be different for different purposes: place the transducer close to the fetal buttocks for NST, and place it on fetal back in delivery.

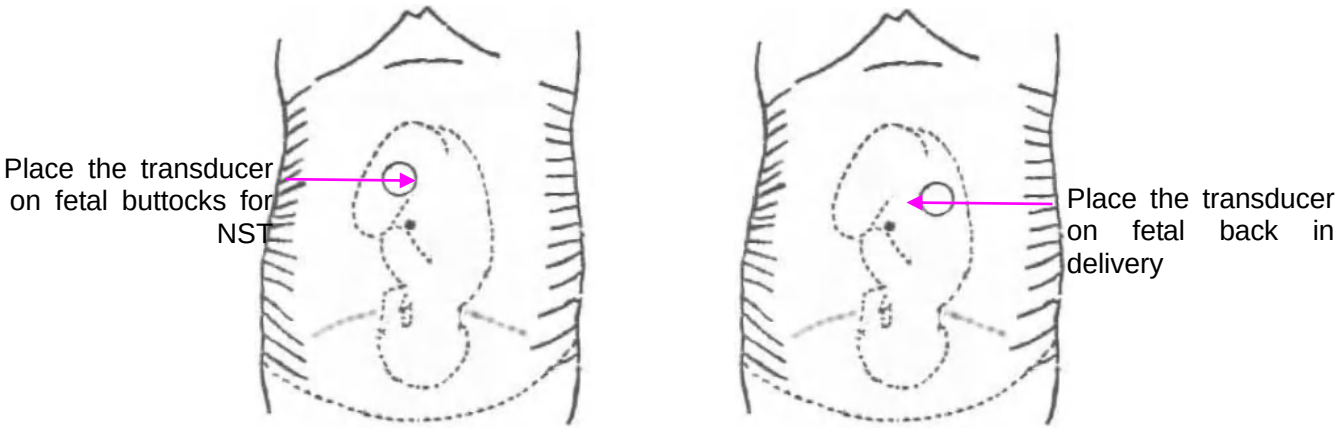


Figure 7-6 Positioning TOCO Transducer

Wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt. Make sure the belt fits the patient snugly but comfortably.

c) *Adjusting the Numeric to Zero

Press the **AUTO ZERO** key to adjust the numeric to the baseline. Make sure this is not done during a contraction.

Wipe off any gel presents on abdomen around this area.

NOTE:

1 Do not apply aquasonic coupling gel on a TOCO transducer or its contact area.

2 Check the function of the TOCO transducer by applying pressure on it to see if this is displayed on the screen.

Monitoring with FTS-3:

◆ Parts Required

a) TOCO-T transducer or TOCO-E transducer

b) Belt

◆ Monitoring Procedure

a) Connect the FTS-3 system to the monitor and switch it on. Refer to the user manual of *FTS-3 Fetal Telemetry System.*

b) Take up the TOCO-T transducer or the TOCO-E transducer. Make sure it is successfully connected to the base station.

c) Monitor TOCO following the procedures described above.

7.6.2 Changing the UA Baseline

You can change the UA baseline,

1 Select the main menu key  on the main interface.

2 Select **Fetus > UA Baseline**.

3 Select **5**, **10** (default), **15** or **20**.

4 Select **OK**.

NOTE:

If the monitor has been configured with IUP, the IUP baseline is 0 and it is not adjustable. The TOCO baseline is adjustable.

7.6.3 Testing TOCO Transducers

To test a TOCO transducer:

1 Switch on the monitor.

2 Connect the TOCO transducer to the fetal monitor.

3 Gently press the center of the transducer.

Figure 7-7 Testing a TOCO Transducer

4 Check that the value on the display shows this change in pressure.

If a TOCO transducer fails the test, repeat this test with another transducer. If the second one passes the test, defect of the first transducer is confirmed. Replace it with a good one. If the second transducer fails the test as well, contact the manufacturer for service.

7.7 Monitoring Uterine Activity Internally

7.7.1 Parts Required

a) Disposable intrauterine pressure catheter ACCU-TRACE™ IUPC (“IUPC” for short)

b) DECG-IUP Integrated Cable

c) Wired/wireless DECG Fetal&Maternal Module

The following illustration shows how these parts should be connected:

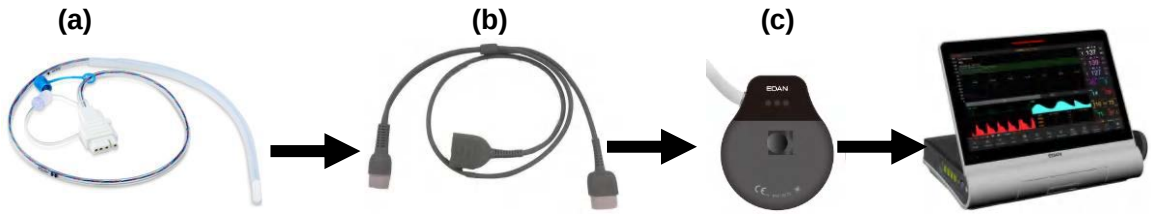


Figure 7-8 Connection for IUP Monitoring

7.7.2 Directions for Use of IUPC

Preparation

1) Gather supplies: ACCU-TRACE IUPC, DECG-IUP integrated cable, and amnioinfusion supplies if needed.

2) Open the sterile ACCU-TRACE IUPC package.

Insertion

NOTE:

This product is designed for use with the introducer.

3) Using aseptic technique, remove the catheter from the package.

4) Perform vaginal exam to ensure ruptured membranes and adequate dilation.

5) Advance the catheter tip to the cervical os along the examination hand, using the hand as a guide. Do not advance the introducer through the cervix.

6) Continue to gently advance the catheter tip through the cervical os and feed the catheter into the intra-amniotic cavity until the 45 cm mark is at the introitus. If the 45cm mark is not clearly visible, stop advancing when the ● symbol on the catheter meets the introducer.

NOTE:

For easier insertion, do not twist the catheter in the introducer.

7) The IUPC may be spontaneously filled with amniotic fluid. This can be seen in the clear lumen of the catheter. The filter cap will prevent the amniotic fluid from leaking.

8) Slide the introducer out of the vagina along the catheter. When the introducer is completely out of the vagina, slide thumb between catheter and introducer tab, which will begin to separate the introducer from the catheter.

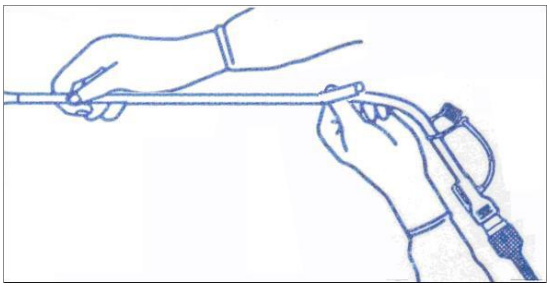


Figure 7-9 Separate the Introducer

9) Anchor the catheter in place with one hand, and pull the introducer straight back off the catheter.

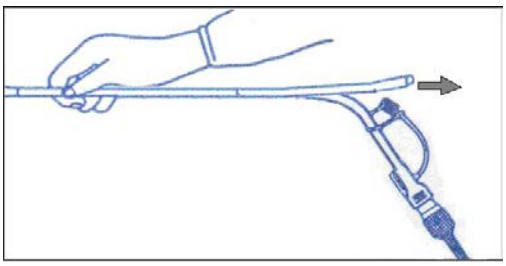


Figure 7-10 Remove the Introducer

10) Remove the liner from the adhesive pad, and then adhere the pad to the patient's skin. Secure the catheter by placing the catheter attachment strap to the adhesive pad.

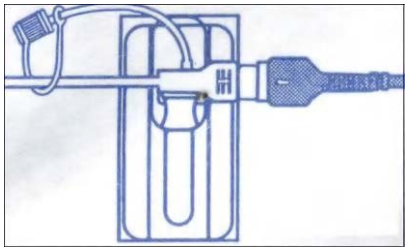


Figure 7-11 Secure the Adhesive Pad to Mother

Rezeroing the System during Monitoring

With the catheter connected to the DECG-IUP integrated cable, momentarily adjust the monitor to zero by pressing **AUTO ZERO** key.

WARNING

1 **Before insertion of IUPC, placental position should be confirmed, amniotic membranes are adequately ruptured and sufficient cervical dilatation is assured.**

2 **Try to insert the catheter opposite the placental site. Do not insert the introducer beyond the cervical OS. Use it with caution when uterine infection is present.**

3 **If resistance is met at any time during insertion, withdraw the catheter slightly and try at a different angle. Forced insertion may result in patient's discomfort or injury.**

4 **Do not catheterize if placenta previa is diagnosed, or if uterine bleeding from an undetermined source is present.**

CAUTION

1 **Since procedures vary according to hospital needs/preferences, it is the responsibility of the hospital staff to determine exact policies and procedures for both monitoring and amnioinfusion. The safe and effective use of the IUPC depends on the skill of the clinician who applies /uses it.**

2 **The IUPC has been sterilized by gamma radiation and is sterilized and non-pyrogenic unless package is broken or open. Do not re-sterilize it.**

NOTE:

Refer to the instruction on the package for more information about using the IUPC.

7.7.3 IUP Monitoring Procedure

1) Insert IUPC using the procedure described in section *7.7.2 Directions for Use of IUPC*.
2) Connect the IUPC to the DECG-IUP integrated cable.

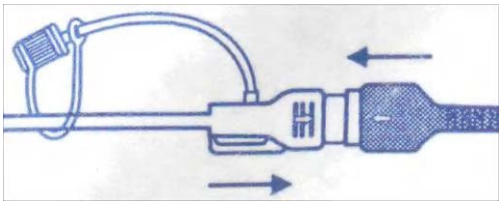


Figure 7-12 Connect Catheter to DECG-IUP Integrated Cable

3) Connect the DECG-IUP integrated cable to the DECG Fetal&Maternal Module.
4) Connect the DECG Fetal&Maternal Module to the fetal monitoring socket of the monitor.
5) Ask the mother to cough. A spike on the trace in response to the cough indicates proper positioning and function of the IUPC.
6) Wash timely during monitoring. A spike on the tracing will respond to the washing.

7.8 Monitoring Fetal Movement

7.8.1 Auto Fetal Movement (AFM) Monitoring

During fetal heart monitoring with ultrasound, the fetal movement signals are also detected. The fetal movement signals differ from the Doppler heart rate signals in that they have larger extent and lower frequency. The larger extent is because of the bigger scope of moving areas (e.g., the fetal arms or legs); lower frequency is because of the lower velocity of the fetal movements compared with those of the fetal heart.

Only US1 channel can perform AFM. But be aware that when monitoring twins or triplets, the movements detected by US1 may also be caused by the second or third fetus's movement.

The movement of the fetus will be detected and displayed in the form of a trace on the screen and the recorder paper.

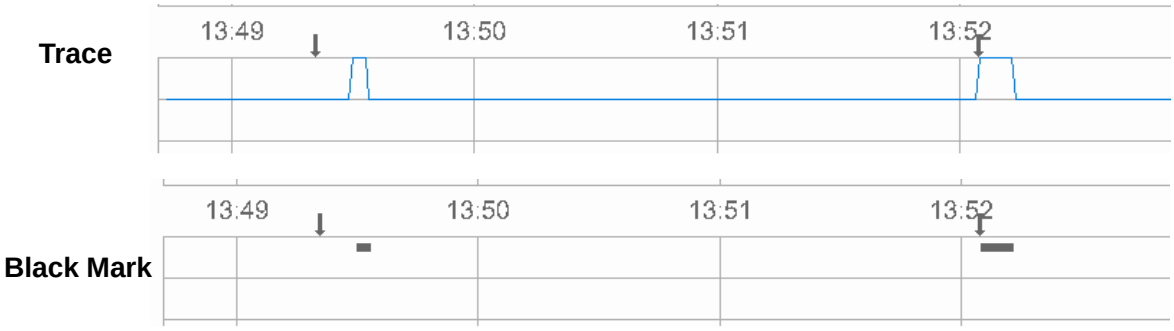
7.8.2 Enabling or Disabling AFM Monitoring

To enable or disable AFM monitoring,

1 Select the main menu key  on the main interface.
2 Select **Fetus > AFM**.
3 Select **ON** or **OFF** (default).
4 Select **OK**.

7.8.3 Choosing AFM Mode

When AFM monitoring is enabled, the AFM monitoring result is displayed either in the form of a trace or black marks. The x-axis of each wave or each black mark indicates the duration of a detected fetal movement.



To choose AFM mode,

1 Select the main menu key  on the main interface.
2 Select **Fetus > AFM Mode**.
3 Select **Trace** (default) or **Black Mark**.
4 Select **OK**.

7.8.4 Choosing FM Source

When AFM monitoring is enabled, the FM has two sources: AFM and MFM.

To choose the FM source,

1 Select the main menu key  on the main interface.
2 Select **Fetus > FM Source**.
3 Select **MFM** (default) or **AFM**.
4 Select **OK**.

7.8.5 Manual Fetal Movement (MFM) Monitoring

MFM result comes from the patient's feeling of fetal movement. The count will be displayed on the screen in MFM numeric area.

1) Insert the FM marker connector into the **MARK** socket on the monitor.
2) Let the patient hold the marker in hand; ask her to press the top key of it when a fetal movement is felt. Continuous movements in 5 seconds are considered to be one movement and only press the key once.

7.8.6 Changing MFM Volume

The monitor gives a sound when the FM marker key is pressed, and the volume is adjustable.

To change the MFM volume,

1 Select the main menu key  on the main interface.
2 Select **Fetus > MFM Volume**.
3 Select **Low** or **High** (default).
4 Select **OK**.

7.9 *Start Monitoring

After the **START** key is pressed, the monitor automatically zeroes the pressure, clears the FM count and starts monitoring.

If the Auto start printing is disabled, press the **PRINT** key to start printing.

7.10 *Inputting Maternal Information (Mat. Info)

7.10.1 Auto ID

After you press the **START** key, the system creates an auto-ID for the present patient. (if Mat. Info inputting is switched off.) The auto-ID consists of the date and time when the monitoring starts.

7.10.2 Changing Maternal Information

You can change the patient's information after the monitoring starts:

1 Select Mat. Info key  on the main interface.

Figure 7-13 Mat. Info Inputting Menu

2 Select **ID**.

Figure 7-14 Soft Keyboard

3 Select the required character for patient's ID on the soft keyboard.
4 Select **Enter**.
5 Select **Name**.
6 Select the required letter for patient's name on the soft keyboard.
7 Select **Enter**.
8 Select **OK**.

The monitoring does not stop when you change maternal information. After you select **OK** to exit, the

new ID takes place of the old one for this patient.

NOTE:

1 **Pressing the START key separates two patients. The monitor only displays the most recent ID for the same patient.**

2 **If printing starts automatically with the monitoring, the first ID printed on the recorder paper will be the auto-ID. The new ID will be printed 10 minutes/20 minutes/30 minutes/ 60 minutes (optional) later.**

3 **The ID and name are shown on the screen, the paper printout and the archive list.**

4 **For the non-English system, more letters are provided for inputting the name. Select the key on the bottom left corner to toggle between them.**

5 **When you change maternal information during monitoring, the monitoring doesn't stop but the trace printing will be interrupted.**

6 **When the network version is ETHERNET 1.4 and above, if ID is revised on either the fetal monitor or the central station after confirmation, they will synchronize ID with each other.**

7.10.3 ID Entry with a Scanner

You can enter patient's ID with a scanner.

1 Connect the scanner to the USB of the monitor. When you hear a "Di" tone, it means the scanner is identified.

2 Select Mat. Info key  on the main interface.

3 Scan the patient's barcode/QR code with the scanner and the patient's ID will be entered automatically.

NOTE: The scanner only supports entry of ID, but it doesn't support entry of patient's name.

7.10.4 Switching Mat. Info Inputting On or Off

The **Mat. Info inputting** function allows the menu to pop up automatically after the **START** key is pressed. After you input the mother's information and exit from the menu, the monitoring starts immediately.

To switch the **Mat. Info Inputting** on or off:

1 Select the main menu key  on the main interface.
Select **Start Monitoring > Mat. Info**.

2 Select **ON** or **OFF** (default).

3 Select OK.

Chapter8 Maternal Monitoring

WARNING

1 **Do not apply this monitor during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.**

2 **Always check if the alarm settings are appropriate for your patient before starting monitoring.**

3 **Check for any fault of the transducers before applying them to the patient.**

8.1 Maternal ECG Monitoring

8.1.1 Introduction

ECG monitoring produces a continuous wave form of the patient's cardiac electric activity to enable an accurate assessment of current physiological state. Only proper connection of ECG cables can ensure a satisfactory measurement.
A 20-second monitor stabilization period shall be allowed before testing. The monitor has Tall T-wave rejection capability.
The response time of heart rate meter to change in heart rate is less than 10s.
The minute heart rate display is updated at an interval of 1s.
The monitor computes heart rate by excluding the minimum and maximum values from the 12 most recent RR intervals and averaging the residual 10 RR intervals. If each of three consecutive RR intervals is greater than 1200ms, then the four most recent RR intervals are averaged to compute the MHR.
FTS-3 system computes heart rate by averaging the 12 most recent RR intervals.
The monitor or FTS-3 system does not have capability of detecting or rejecting pacemaker pulse, nor does it provide a pulse to synchronize a defibrillator discharge.
The monitor does not give alarm for tachycardia and cardiac arrhythmia.
The d.c. offset voltage tolerance of the monitor is from -500mV to +500mV. If the d.c. offset voltage of the detected ECG signal is out of this range, the monitor issues a high priority alarm: ECG SINGNAL EXCEEDS LIMIT.

WARNING

1 **When connecting the cables and electrodes, make sure no conductive part is in contact with the ground. Verify that all ECG electrodes, including neutral electrodes, are securely attached to the patient.**

2 **The electrodes should be made of the same metal materials.**

3 **ECG accessories are not suitable for DIRECT CARDIAC APPLICATION (Refer to IEC60601-1 for more information about the definition of DIRECT CARDIAC APPLICATION).**

CAUTION

1 **A different type of electrode may produce higher offset voltage. Therefore, only use the ECG leads supplied by the manufacturer when using the monitor for ECG monitoring.**
2 **Please use EDAN approved disposable electrodes with legal and valid medical device qualification.**

NOTE:

Interference from a non-grounded instrument near the patient and ESU interference can cause inaccuracy of the waveform.

A good ECG signal should be –

1) With normal QRS wave.
2) Tall and narrow with no notches.
3) With tall R-wave completely above the baseline.
4) With T-wave less than one-third of the R-wave height.
5) With P-wave much smaller than the T-wave.

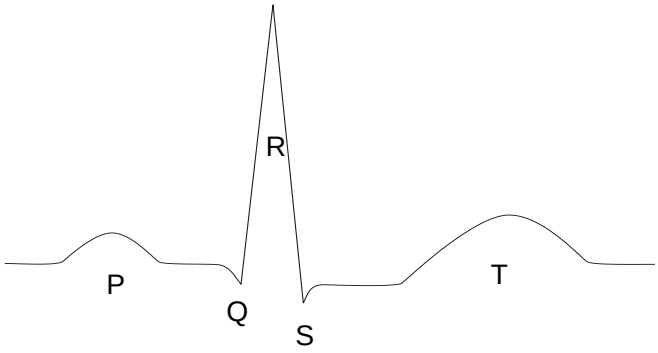


Figure 8-1 Standard ECG Waveform

8.1.2 How to Place 3-lead ECG Cables

The table below lists the names and position of 3-lead ECG cable in America and Europe.

AHA		IEC		Position
Name	**Color**	**Name**	**Color**	
RA	White	R	Red	Near the right shoulder, right below the clavicle
LA	Black	L	Yellow	Near the left shoulder, right below the clavicle
RL	Green	N	Black	On the right hypogastrium

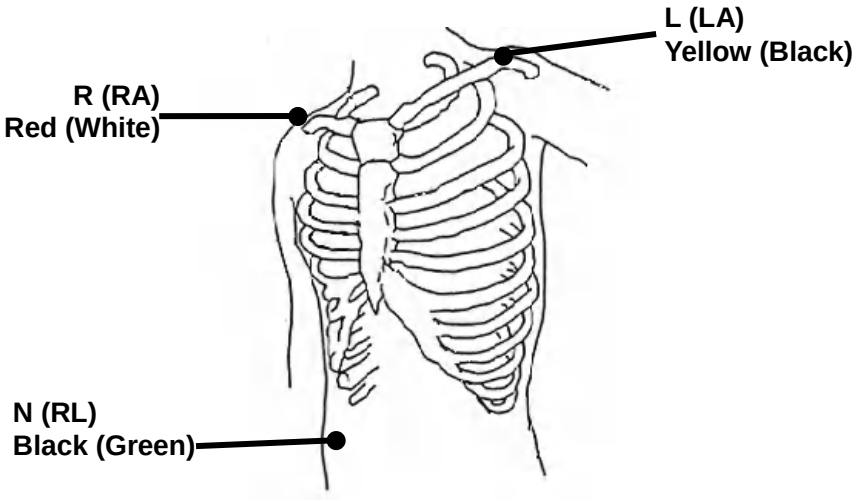


Figure 8-2 Placing 3-lead ECG Cable (obtain wave of I lead)

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

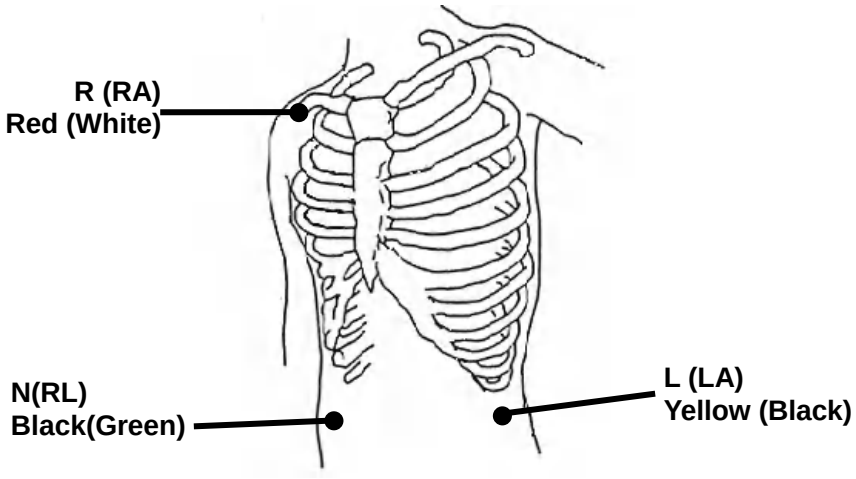


Figure 8-3 Placing 3-lead ECG Cable (obtain wave of II lead)

NOTE:

1 **To ensure patient's safety, all leads must be attached to the patient.**

2 **Check every half an hour if the skin is irritated from attachment of electrodes, if so, remove the electrodes immediately.**

3 **Recycle or dispose the used electrodes properly to protect the environment.**

8.1.3 ECG Monitoring

Monitoring with F15:

◆ Parts Required

a) ECG cable

b) Attachment pad electrodes

c) Wired/ wireless TOCO transducer

Note:

The filter of AC power supply can be configured by selecting **System>Factory Configuration>Line Frequency>50(default)** or **60**. Please select it according to the current AC frequency.

◆ Monitoring Procedure

a) Prepare the skin for ECG monitoring. Refer to section *7.3.2 Preparing the Patient's Skin Prior to Placing Electrodes*.

b) Connect the ECG cable to the wired/wireless TOCO transducer.

c) Connect attachment pad electrodes with an ECG cable.

d) Connect the wired/wireless TOCO transducer to the fetal monitoring socket.

e) Peel the protection membrane off the back of attachment pad electrodes and attach electrodes to the patient. Refer to section *8.1.2 How to Place 3-lead ECG Cables*.

WARNING

1 **The electrodes for wireless ECG cable should be placed on flat and smooth positions right in the middle of the first intercostals space. Please check the contact of the electrodes regularly.**

2 **When the pregnant woman is lying on the left or right side, please make sure the electrodes are well-placed.**

3 **When monitoring with FTS-3, there is no ECG waveform displayed in the ECG display area on the main interface of the monitor.**

NOTE:

1 **After the monitor is switched on, if electrodes are not well attached or fell off, alarm message "ECG LEADS OFF" will appear on the screen to draw your attention.**

2 **Vigorous exercise will interfere with MHR monitoring and computing. Please try to avoid it.**

8.1.4 Changing ECG Gain

You can change the ECG gain. The ECG gain affects overall numeric and scope of the ECG waveform.

1 Select the main menu key  on the main interface.
2 Select **Mother > Gain**.
3 Select **X1/4**, **X1/2**, **X1** (default), **X2** or **X4**.
'Auto' means the monitor adjusts the gain automatically. The system displays a 1mv scale at the left side of the ECG waveform. The height of 1mv bar is directly proportional to the waveform amplitude.
4 Select **OK**.

8.2 Maternal SpO_2 Monitoring

8.2.1 Introduction

The monitor provides continuous monitoring of functional arterial oxygen saturation (SpO_2) and pulse rate (PR) for pregnant women.

SpO_2 Plethysmogram measurement is employed to determine the oxygen saturation of hemoglobin in the arterial blood. If, for example, 97% hemoglobin molecules in the red blood cells of the arterial blood combine with oxygen, then the blood has a SpO_2 oxygen saturation of 97%. The SpO_2 numeric on the monitor will read 97% .The SpO_2 numeric shows the percentage of hemoglobin molecules which have combined with oxygen molecules to form oxyhemoglobin. The SpO_2/PLETH parameter can also provide a pulse rate signal and a plethysmogram wave.

SpO_2 Plethysmogram Measurement Principle:

Pulse oximetry is a continuous and noninvasive monitoring technique used to estimate the measurement of arterial oxygen saturation. It measures the amount of light penetrating the patient tissue and reaching the receiver. The reading, obtained through pulse oximetry, uses a light sensor containing two sources of light (red and infrared) that are absorbed by hemoglobin and transmitted through tissues to a photodetector.

The amount of light penetrated depends on multiple factors and most of them are constant. However, the arterial blood flow changes with time passing by as is pulsative. The arterial oxygen saturation can be obtained through testing the absorbed light during pulsation. Plethysmogram wave and pulse rate signal can be also provided during pulsation testing.

The sensor contains LEDs that emit red light at a wavelength of approximately 660 nm and infrared light at a wavelength of approximately 900 nm. Information about wavelength range can be especially useful to clinicians.

The F15 monitor is compatible with the SpO_2 transducers supplied by EDAN only. The SpO_2 transducer manufactured by EDAN can only be used with the F15 monitor. Compatibility should be checked prior to use. Otherwise the monitor performance can be degraded.

They have been tested and found to comply with the limits for medical device in IEC/EN60601-1-2 (International standard for EMC testing of Medical Electrical Equipment, second edition). These limits are designed to provide reasonable protection against harmful interference in typical medical installation.

WARNING

1 **Before monitoring, check whether the sensor cable is normal. If any sign of damage in the SpO_2 sensor is detected, do not use the sensor. Return it to the manufacturer for service.**

2 **Do not put the SpO_2 sensor on the extremities with arterial catheter or venous syringe.**

3 Do not perform SpO_2 measuring and NIBP measuring on the same arm at one time, because obstruction of blood flow during NIBP measuring may adversely affect the reading of SpO_2 numeric.

4 Prolonged and continuous monitoring may increase jeopardy of unexpected change of dermal condition such as abnormal sensitivity, rubescence, vesicle, repressive putrescence, and so on. It is especially important to check the sensor placement of neonate and patient of poor perfusion or immature dermogram by light collimation and proper attaching strictly according to changes of the skin.

5 The maximum application time of the SpO_2 sensor at a single site is 3 hours. Check per 2 ~ 3 hours the sensor placement and move it when the skin deteriorates. More frequent examinations may be required for different patients.

6 Setting the SpO_2 higher alarm limit to 100% is equivalent to switching off the alarm on higher limit. High oxygen levels may predispose a premature infant to retrolental fibroplasia. Therefore, the higher alarm limit for oxygen saturation must be carefully selected in accordance with commonly accepted clinical practices.

7 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.

8 Do not apply sensor too tightly as this results in venous pulsation which may severely obstruct circulation and lead to inaccurate measurements.

9 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.

CAUTION

Compatibility between the monitor and transducer should be verified before use to avoid injuring the patient or operator.

NOTE:

1 The device is calibrated to display functional oxygen saturation.

2 A functional tester cannot be used to assess the accuracy of the SpO_2 transducer or the monitor.

3 The monitor does not have specific SpO_2 calibration baselines.

4 SpO_2 waveform is not proportional to the pulse volume.

5 Injected dyes such as methylene blue or intravascular dyshemoglobins such as methemoglobin and carboxyhemoglobin may lead to inaccurate measurements.

6 SpO_2 measurement is not applicable during low perfusion and movement.

Measurement Limits -

In operation, the accuracy of oximetry readings can be affected by:

1) Magnetic resonance imaging (MRI) scanning. Induced current could potentially cause burns.
2) Excessive patient movement.
3) Low perfusion.
4) High-frequency electrical noise, including noise created by the host system, or noise from external sources, such as electrosurgical apparatus, which is admitted by the host system.
5) Intravascular dye injections.
6) Improper sensor application.

7) Sensor temperature. (Maintain the temperature between +28 ℃ (+82.4 °F) and +41 ℃ (+105.8 °F) for best operation)

8) Placement of the sensor, such as on an extremity that has a NIBP cuff, arterial catheter, or intravascular line.

9) Significant concentrations of dysfunctional hemoglobin, such as carboxyhemoglobin and methemoglobin.

10) External illumination more than 5,000 lumens/square meter (typical office lighting). (Cover the sensor site with opaque materials is recommended.)

11) Venous pulsations.

12) When the application site for the sensor is deeply pigmented or deeply colored, for example, with nail polish, artificial nails, dye, or pigmented cream.

13) Another SpO2 sensor in close proximity (e.g. when more than one SpO2 measurement is performed on the same patient). Always cover both sensors with opaque material to reduce cross-interference.

To use the sensor:

a) Select an appropriate sensor. Use the SpO_2 transducers approved by the manufacturer.

b) Apply the sensor as directed, and observe all warnings and cautions presented in the sensor user manual.

c) Clean and remove any substances, such as nail polish, from the application site.

d) Periodically check to ensure that the sensor remains properly positioned on the patient.

e) Cover the sensor site with opaque material.

8.2.2 Monitoring Procedure

1) Depending on the equipment you are using, insert the SpO_2 sensor plug into the SpO_2 socket on the monitor or the FT20 Telemetry Transmitter.

2) Place the forefinger, middle finger or third finger into the SpO_2 sensor.

NOTE:

1 The nail should cover the light but not too long.

2 The cable should be placed on the backside of the hand.

3 Avoid external light sources such as radiated rays or ultrared rays.

8.2.3 Enabling SpO_2 Trace Printing

The real-time SpO_2 measurement result is displayed in the parameter area of the main interface. You can choose to print them as a continuous trace on the recorder paper (refer to figure 5-1).

To enable or disable SpO_2 trace printing,

1 Select the main menu key  on the main interface.
2 Select **Recorder > SpO_2 Trace**.
3 Select **ON** or **OFF** (default).
4 Select **OK**.

8.2.4 Assessing the Validity of a SpO_2 Reading

You can check the quality of the pleth wave and the stability of the SpO_2 values to assess whether the sensor functions properly and whether the SpO_2 readings are valid. Always use these two indications simultaneously to assess the validity of a SpO_2 reading.

NOTE:

1 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. The volunteer population in the studies composed of local healthy men and women from age 19 to 37, with variations of skin pigmentations. The SpO_2 accuracy is as follows: ±2% for 90%-100% and ±4% for 70%-90%.

2 **The pulse rate accuracy is obtained by comparison to the pulse rate generated with an arterial oxygen simulator (also an electronic pulse simulator).**

3 **Generally, the quality of the SpO_2 pleth wave reflects the quality of the light signals obtained by the sensor. A wave of poor quality manifests a decline of the signal validity. On the other hand, the stability of the SpO_2 values also reflects the signal quality. Different from varying SpO_2 readings caused by physiological factors, unstable SpO_2 readings are resulted from the sensor's receiving signals with interference. The problems mentioned above may be caused by patient movement, wrong sensor placement or sensor malfunction. To obtain valid SpO_2 readings, try to limit patient movement, check the placement of the sensor, measure another site or replace the sensor.**

8.2.5 SI (Signal Intensity)*

*Only applicable to the EDAN module

The signal intensity (SI) shows perfusion in numeric, and it reflects the pulse intensity of the measurement site. The SI ranges from 0 to 10, with a larger value indicating the more intense signal. When the SI value reaches 10, the signal quality is optimal. If the SI value is less than 2, it indicates that the pulse at the current site is weak, and you should change the measurement site.

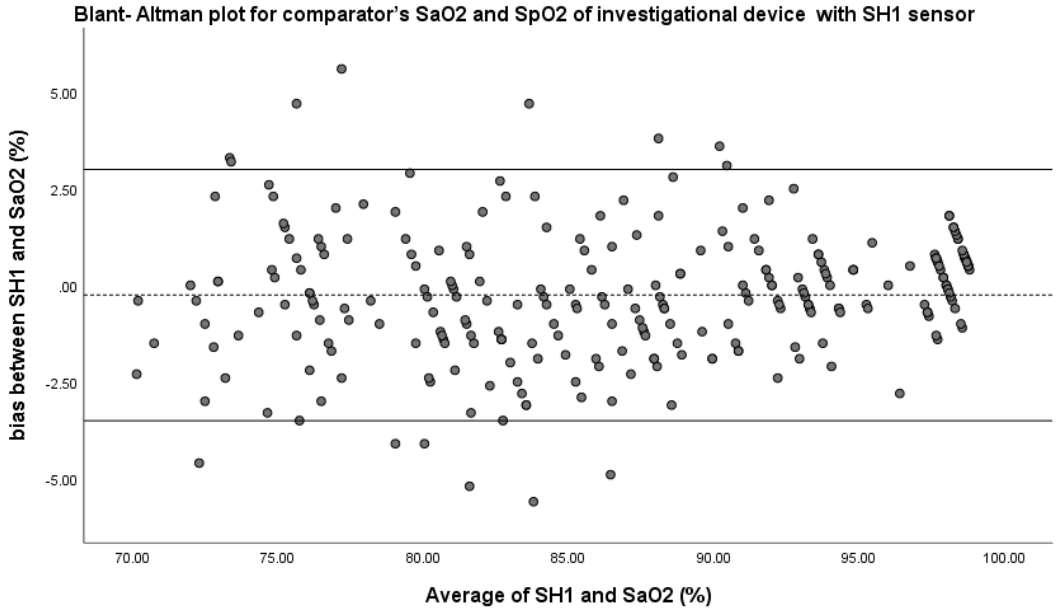
The SI value is displayed in the SpO_2 parameter area.

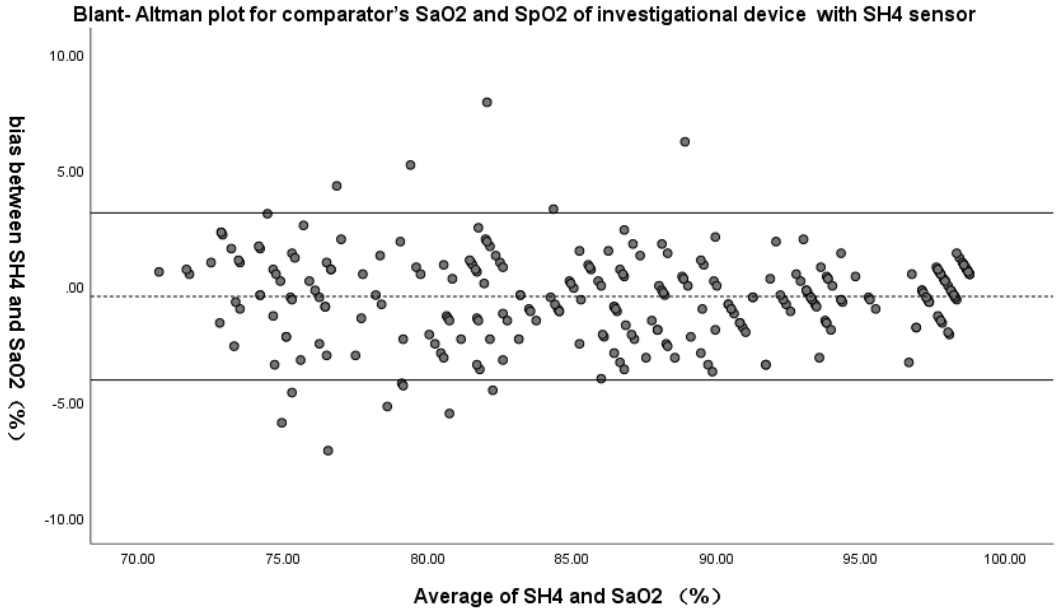
8.2.6 SpO_2 Relevant Data for Reference

1. The table below shows Arms values measured using with SH series sensors in a clinical study.

SaO_2 Range	Arms	
	With SH1	With SH4
90%-100%	1.01	1.29
80%-90%	2.01	2.17
70%-80%	2.01	2.29
70%-100%	1.68	1.89

2. The figures below show the Bland-Altman Plot of SaO_2 vs SpO_2 measured using SH series sensor. In the plots, the upper and lower dotted lines represent the upper and inferior limits of the 95% consistency, and the middle dotted line represents the average of the bias.





8.3 Maternal HR Monitoring

8.3.1 Introduction

Maternal heart rate (MHR) monitoring does not need an extra accessory. When you perform ECG or SpO_2 (Pulse) monitoring, the MHR result can be acquired at the same time.
When monitoring ECG and SpO_2 at the same time, you can choose the HR source. If only one of them is being performed, the source will automatically switch to the available one (the screen reading should prevail).

8.3.2 Choosing HR Source

You can change the HR source.

1 Select the main menu key  on the main interface.
2 Select **Mother > HR Source**.
3 Select **ECG** (default) or **Pulse** (during SpO_2 monitoring).
4 Select **OK**.

8.3.3 Monitor HR with Electrode Sleeve

◆ Principle Introduction

The HR monitoring is based on the obtaining of ECG signal on the abdomen. The three meal electrodes of MECG-R electrode sleeve correspond to lead L, N and R of the ECG leads. As the electrodes are near to each other and the obtained ECG signal amplitude is small and vulnerable to interference, it's necessary to make sure good contact between the electrodes and the skin so as to get a continuous and accurate monitoring result.

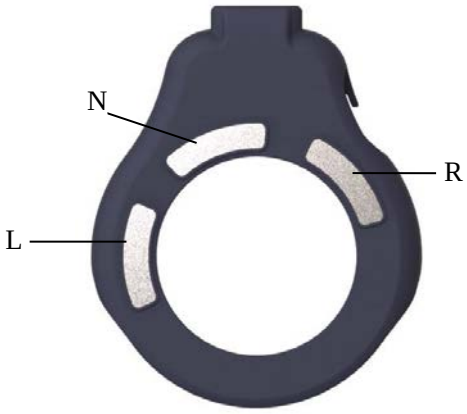


Figure 8-6 MECG-R Electrode Sleeve

◆ Required parts

1 Wired/wireless TOCO transducer 2 Electrode sleeve 3 belt

◆ Monitoring Procedures

1) Confirm that the electrode sleeve is properly installed

Insert the transducer into the electrode sleeve per below picture and ensure that the interface is in good contact. When the bottom of the wireless transducer screen displays TOCO/MECG, it indicates that it has been installed correctly. The wired transducer can be viewed through the top area of ECG waveform display area. When "ECG (X1)" is displayed, it indicates that it has been correctly installed.

Figure 8-7 Install the Electrode Sleeve

2) Determine the transducer position

Refer to the recommended position in TOCO Monitoring, and select the upper, flat area as much as possible, ensure good contact between the three metal electrodes. The skin is a poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- ◆ Wash the sites thoroughly with hospital alcohol, wet tissues and soap water. (Do not use ether or pure alcohol, which will increase skin impedance)
- ◆ Avoid using conductive substance that is easy to leave residual such as conductive paste to prepare the skin.

3) Obtain ECG signals

Place the transducer interface end up on the above selected position and set the monitor ECG gain to

X4. When a good signal is obtained, the ECG signal with regular rhythms will appear in the ECG waveform display area, and the wireless transducer signal quality icon will become full in 3~5s. If effective ECG signal is not obtained or the ECG signal is not obvious, the accuracy and stability of HR calculation will be influenced. When ECG signal is not good, you can rotate the transducer slightly in the left and right 90° range or change the placement position. The ECG signal can only be obtained when there's good contact between the three metal electrodes and the skin, or there will be phenomenon of bad contact or ECG leads off.

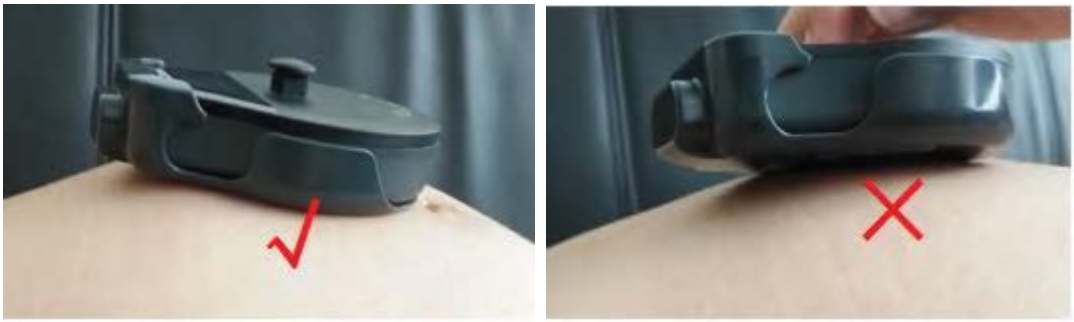


Figure 8-8 Placing the TOCO Transducer

4) Fix the transducer

During long-term monitoring process, contractions, fetal movements, pregnant women's movements and changes of abdomen profile are easy to cause the transducer to slide, and then the severe interference will cover the ECG signal and in the end cause wrong calculation of HR In order to reduce the interference caused by such situations, please ensure that the tightness of the belt is appropriate so that the transducer can be well fitted to the skin.

WARNING

1 **The reliability of the mother's ECG signal obtained by the MECG-R in the pregnant woman is significantly reduced when there's a large body movement or during the second stage of labor. In this case, it is recommended to adopt maternal ECG monitoring with wired leads or a SpO2 transducer to obtain maternal heart rate.**

2 **The electrode sleeve used to monitor maternal heart rate should be attached to the upper, flat area of abdomen as much as possible. Please check regularly if the metal electrode is in good contact with the skin.**

3 **When the pregnant woman is in lateral position, please pay attention to the lead-off alarm information and adjust the transducer position in time to ensure that the monitoring continues normally.**

4 **The purpose of using electrode sleeve is to obtain maternal HR. When the ultrasound transducer detects MHR by mistake, the monitor will issue signal overlap alarm (FHR HR), reminding user to re-confirm the detection of fetal heart rate.**

5 **The ECG waveform obtained by the electrode sleeve is not through standard leads. The ECG waveform is only a reference for ECG signal quality when user is obtaining HR and it can't be used for diagnosis.**

NOTE:

1 If the electrode is not in contact with the skin after starting up of the monitor or falls off during the monitoring process, the monitor will display "ECG LEADS OFF" alarm in the screen information area to draw the medical staff's attention; the time to reactivate alarm after the alarm is muted is determined by the set silence duration.

2 Strenuous exercise interferes with heart rate calculations, please try to avoid them.

3 Due to the individual differences in the quality of the ECG signal in the abdominal position, there are very few individuals who cannot obtain an effective ECG signal. In this case, please change other MHR monitoring methods.

8.3.4 Changing HR Beep Volume

When the HR beep is enabled, the monitor gives a beep sound of maternal heart. The frequency of HR beep corresponds to the maternal heart rate, but occasionally it may differ due to weak HR signal.

To change the HR beep volume,

1 Select the main menu key  on the main interface.
2 Select **Mother > HR Beep**.
3 Select **OFF** (default), **Low** or **High**.
4 Select **OK**.

NOTE:

1 The DECG beep and HR beep share the same audio channel. Once the HR beep is switched on, the DECG beep is disabled (set to OFF) automatically.

2 Once the DECG/HR beep volume is changed, the sound switches to channel 1 automatically. Therefore, it is advised against changing DECG/HR beep volume in the monitoring process.

8.3.5 Enabling HR Trace

The real-time MHR measurement result is displayed in the parameter area of the main interface. Also, you can choose to display and print those as a continuous trace on the recorder paper (refer to figure 5-1).

To enable or disable HR trace printing,

1 Select the main menu key  on the main interface.
2 Select **Recorder > HR Trace**.
3 Select **ON** or **OFF** (default).
4 Select **OK**.

8.3.6 Signals Overlap Verification

When monitoring maternal heart rate and fetal heart rate at the same time, there are possibilities that maternal HR signal is mistaken for FHR signal. The SOV function of the monitor can also reduce these possibilities.

In the process of monitoring, if the SOV detects signals overlapping, an alarm message “Signals Overlap (FHR1/FHR2/ FHR3/DFHR/eFHR, HR)” or “Signals Overlap (FHR1, FHR2, HR)” or “Signals Overlap (FHR1, FHR3, HR)” or “Signals Overlap (FHR2, FHR3, HR)” or “Signals Overlap (DFHR, FHR2, HR)” or “Signals Overlap (DFRH, FHR3, HR)” or “Signals Overlap (FRH1, FHR2, FHR3, HR)” or “Signals Overlap (DFHR, FHR2, FHR3, HR)” will appear on the screen to warn you. Checking the patient and reposition of transducers might be needed.

WARNING

- **Though SOV alarm function helps to detect the overlap of MHR and FHR automatically, do not rely solely on it to judge whether the mother is the signal source. As in the process of actual monitoring, the movement of transducer and fetus, detecting MHR by mistake, interference of fetal movement and maternal movement can cause fetal heart signal weak and loss, and magnified error of fetal heart calculation led by poor signal. In these situations, SOV alarm function can not totally identify the signal overlap, so user needs to observe MHR trace and FHR trace simultaneously to help the judgment and adjust the transducer to the optimal position in time.**

8.4 Maternal NIBP Monitoring

8.4.1 Introduction

The monitor measures blood pressure using the oscillometric method.

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 artery pressure), and then diminish.

There are two modes available: Manual and Auto. In manual mode, NIBP is measured once on each demand. In auto mode, NIBP is measured repeatedly after a preset time interval. This interval is adjustable. You can perform a manual measurement during an Auto measurement interval.

In both modes, systolic pressure (SYS), diastolic pressure (DIA), mean artery pressure (MAP) and pulse rate (PR) (optional) are measured and displayed.

The blood pressure measurements determined with this device comply with the American National Standard for Electronic or Automated Sphygmomanometers (ANSI/AAMI/ISO 81060-2:2013) in relation to mean error and standard deviation.

In clinical investigation method with a reference sphygmomanometer, the fifth Korotkoff sound was used to determine adult diastolic pressure, and the fourth Korotkoff sound was used to determine pediatric diastolic pressure.

WARNING

1 Check for any fault of the cuff before start monitoring.

2 Do not perform NIBP measurements on patients with sickle-cell disease or under any condition where the skin is damaged or expected to be damaged, such as on the arm on the side of a mastectomy.

3 Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitor on the same limb.

4 If liquid is splashed on or into the main unit inadvertently, or enters the conduit, stop using the monitor and contact the manufacturer for service immediately.

5 For a thrombasthemia patient, it is important to determine whether the measurement of blood pressure shall be done automatically. The determination should be based on clinical evaluation.

6 Do not apply the cuff to a limb that has an intravenous infusion or catheter in place frequently. This could cause tissue damage around the catheter when infusion is slowed or blocked during cuff inflation.

7 Do not apply the cuff to a limb where intravascular access or therapy, or an arterio-venous (A-V) shunt is present, otherwise, it may result in injury to the patient.

8 NIBP readings can be affected by the measurement site, the position of the patient, exercise, or the patient's physiologic conditions.

9 Continuous cuff pressure due to connection tubing kinking can block the blood flow, and may result in injury to the patient.

10 Make sure that the air conduit connecting the blood pressure cuff and the monitor is neither blocked nor tangled.

NOTE:

1 The monitor is intended to measure NIBP for adults only.

2 NIBP measurement can be affected by extremes of temperature, humidity and altitude.

3 Continuous use of the automatic measuring mode for short intervals may lead to the discomfort of the patient.

4 If a NIBP measurement is suspected, repeat the measurement. If you are still uncertain about the reading, use another method to measure the blood pressure.

Measurement Limitations -

To different patient conditions, the oscillometric measurement has certain limitations. The measurement is in search of regular arterial pressure pulse. In those circumstances where the patient's condition makes it difficult to detect, the measurement becomes unreliable and the measuring time increases. You should be aware that the following conditions could interfere with the measurement, making the measurement unreliable or longer to derive. In some cases, the patient's condition will make a measurement impossible.

1) Patient Movement

Measurements will be unreliable or may not be possible if the patient is moving, shivering or having convulsions. These motions may interfere with the detection of the arterial pressure pulses. In addition, the measurement time will be prolonged.

2) Cardiac Arrhythmia

Measurements will be unreliable and may not be possible if the patient's cardiac arrhythmia has caused an irregular heartbeat. The measuring time thus will be prolonged.

3) Heart-lung Machine

Measurements will not be possible if the patient is connected to a heart-lung machine.

4) Pressure Changes

Measurements will be unreliable and may not be possible if the patient's blood pressure is changing rapidly over the period of time during which the arterial pressure pulses are being analyzed to obtain the measurement.

5) Severe Shock

If the patient is in severe shock or hypothermia, measurements will be unreliable since reduced blood flow to the peripheries will cause reduced pulsation of the arteries.

6) Heart Rate Extremes

Measurements can not be done to a patient whose heart rate is lower than 40 bpm or higher than 240 bpm.

8.4.2 How to Apply NIBP Cuff

WARNING

Accuracy of NIBP measurement depends on using a cuff of the proper size. It is essential to measure the circumference of the limb and choose the proper cuff size. If you find something is wrong with the cuff size, please replace it immediately.

1) Select appropriate cuff for the patient.
The table below lists the reference size:

Type	Limb Perimeter	Cuff Size	Air Hose Length
Upper Arm (Adult 1)	27 cm ~ 35 cm	14.5 cm	3 m
Upper Arm (Adult 2)	34 cm ~ 43 cm	18 cm	

2) Squeeze the cuff to discharge the air.

3) Apply the cuff to the patient; make sure that the index line is placed in the appointed range and the symbol  is over the appropriate artery (Refer to figure 8-5). If the index line is not in the appointed range, please replace for a proper one. Ensure that the cuff is not wrapped too tightly around the limb. Excessive tightness may cause discoloration and eventual ischemia of the extremities.

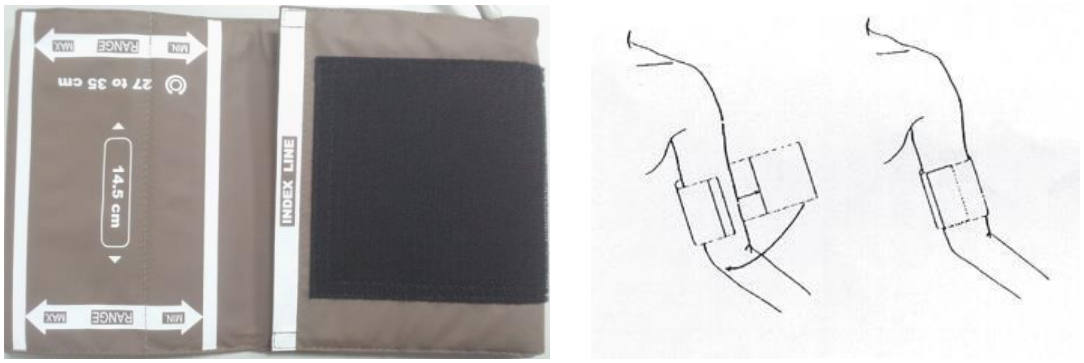


Figure 8-9 Applying the Cuff

8.4.3 Measurement Procedures

To obtain accurate measurements, the following operating steps need to be observed:

1. Ensure the patient position in normal use, including
   a) comfortably seated
   b) legs uncrossed
   c) feet flat on the floor
   d) back and arm supported
   e) middle of the cuff at the level of the right atrium of the heart
2. Relax as much as possible and do not talk during the measurement.
3. Wait for five minutes until the first reading is taken.

To start the measurement:
1) Depending on the equipment you are using, insert the cuff plug into NIBP socket on the monitor or the FT20 Telemetry Transmitter.

2) Apply the NIBP cuff to the patient's arm or leg following the instructions described in section *8.4.2 How to Apply NIBP Cuff*.

3) Connect the cuff to the air hose. The limb chosen for taking the measurement should be placed at the same level as the patient's heart.

Figure 8-10 Connection for NIBP measurement

8.4.4 *Auto Measurement

To perform an auto measurement,

1 Select the main menu key  on the main interface.
2 Select **Mother > Cycle**.
3 Select a time interval from 1, 2, 3, 4, 5, 10, 15, 30, 60, 90, 120, 180, 240 and 480 minutes.
4 Select **OK**.
5 Press **NIBP** key to start an Auto measurement.

NOTE:

The monitor checks uterine contract (UC) pressure when the NIBP key is pressed. If the UC is over 50, a prompt "Intense UC, can't measure NIBP now." is issued, and the monitor will check the UC every 30 seconds. The monitor will measure NIBP only when the UC is lower than 50, and it will then start timing for the Auto measurement.

To stop the current measurement,

Press the **NIBP** key anytime during the current measurement to stop it. Another measurement will start after the time interval.

WARNING

Prolonged NIBP measurements in automatic mode may be associated with purplish patches, ischemia and neurologic damage in the limb wearing the cuff. When monitoring a patient, examine the extremities of the limb frequently for normal color, warmth and sensitivity. If any abnormality is observed, stop the NIBP measurement.

8.4.5 *Manual Measurement

To perform a manual measurement,

1 Select the main menu key  on the main interface.
2 Select **Mother > Cycle**.
3 Select **Manual**.
4 Select **OK**.
5 Press **NIBP** key on the main interface to start a manual measurement.

To stop the manual measurement,

Press the **NIBP** key anytime during the measurement to stop it.

To perform a manual measurement during an auto measurement interval,

1 Press the **NIBP** key to start the manual measurement.

2 Press the **NIBP** key again anytime to stop it.

The monitor will restart timing for the Auto measurement and resume measuring after the time interval.

NOTE:

1 If you are in doubt about the accuracy of any reading(s), check the patient's vital signs by an alternative method before checking the functioning of the monitor.

2 The monitor checks uterine contract (UC) pressure when the NIBP key is pressed. If the UC is over 50, a prompt "Intense UC, can't measure NIBP now." is issued. Please wait and do not attempt to measure NIBP until the UC is lower than 50.

CAUTION

1 Do not squeeze the rubber tube on the cuff.

2 If liquid is inadvertently splashed on the equipment or its accessories, or may enter the conduit or inside the monitor, contact local service center.

8.4.6 Changing NIBP Unit

You can change the NIBP unit.

1 Select the main menu key  on the main interface.
2 Select **Mother > Unit** (NIBP Setup).
3 Select **mmHg** (default) or **kPa**.

4 Select **OK**.

Note:

When the network version is ETHERNET 1.4 and above,if the fetal monitor gets on line, the central station will control to make the NIBP unit of the fetal monitor in concert with that of the central station.

8.4.7 *Choosing NIBP Printing Mode

When the recorder is printing real-time fetal traces, the NIBP result is also recorded on the paper whenever NIBP measurement is performed. After the paper stops advancing, you can choose to keep recording NIBP results on the paper.

To enable or disable NIBP printing after paper advancing stops,

1 Select the main menu key  on the main interface.
2 Select **Recorder > NIBP**.
3 Select **ON** or **OFF** (default).
4 Select **OK**.

NOTE:

The NIBP measurement results during the period of paper lacking and fast printing after new paper is loaded will not be printed. Therefore, do not perform NIBP measurements during this period.

8.4.8 *Calibrating NIBP

NIBP is not user-calibrated. Cuff-pressure transducers must be verified and calibrated, if necessary, at least once every two years by a qualified service professional.

8.5 Maternal TEMP Monitoring

8.5.1 Monitoring Procedure

1) Insert the TEMP plug into the TEMP socket on the monitor.
2) Apply the sensor firmly underneath the patient's axilla. It takes 5 minutes for the temperature measurement to stabilize.

WARNING

1 Check if the TEMP sensor functions properly prior to use.

2 Do not apply the TEMP sensor to the mouth or the rectum.

CAUTION

Be cautious when taking and putting the TEMP sensor. Do not pull the cable too tight or it might cause mechanical damage.

The transient response time for the continuous TEMP sensor is not larger than 30s. The laboratory method used to test the response time is as follows:

1. Prepare two reference temperature sources. Set the temperature of the first temperature source to 25ºC (77ºF) and set the temperature of the second temperature source to 27ºC (80.6ºF).
2. Put the TEMP sensor to the first reference temperature source until the temperature reading reaches 25ºC (77ºF).
3. Move the TEMP sensor to the second reference temperature source. Note the time (t1) from the TEMP sensor being moved in to the temperature reading reaching 27ºC (80.6ºF).
4. Set the temperature of the second temprature source to 23℃ (73.4 ºF).
5. Put the TEMP sensor to the first temperature source again until the temperature reading reaches 25ºC (77ºF).
6. When the temperature reading is stable, move the TEMP sensor back to the second reference temperature source. Note the time (t2) from the TEMP sensor being moved in to the temperature reading falling to 23ºC (73.4 ºF).
7. The larger value of t1 and t2 is the response time.

Note:

The reference body site temperature is the same as the temperature of the measuring site.

8.5.2 Changing TEMP Unit

You can change the TEMP unit.

1 Select the main menu key  on the main interface.
2 Select **Mother > Unit** (TEMP Setup).
3 Select **ºC** (default) or **ºF**.
4 Select **OK**.

Note:
When the network version is ETHERNET 1.4 and above, if the fetal monitor gets on line, the central station will control to make the TEMP unit of the fetal monitor in concert with that of the central station.

Chapter9 Monitoring Mother and Fetus Using FECG

FECG is only indicated for use on women who are at >36 completed weeks, with singleton pregnancies.

9.1 Confirming Fetal Life

Fetal monitoring with FECG cannot differentiate FECG signal source from a MECG source or other interfering signal source in all situations. These are some of the signal sources that might be taken as FECG signal source by mistake:

- High amplitude MECG signal.
- Interfering signal generated by maternal tense muscles.
- Interfering signal generated by power frequency.
-Noise generated by maternal body.
-Interfering signal generated by maternal or fetal movement that leads to deflections from baseline.
- Electrical stimulation signal generated by analgesia during laboring.
- Interfering signal generated by movement of ECG leads or electrodes.

Besides, fetal monitoring with FECG cannot always capture the FECG signal as the FECG signal itself is very weak and it will be attenuated gradually after transmission through the fetal body, and amniotic fluid till the maternal abdomen and in the end cannot be detected by the device and FHR calculation cannot be performed.

Here are some examples where the FECG signal cannot be detected.

-Preterm gestation (i.e. ⩽ 36 completed weeks gestation).

-The fetal vernix caseosa is too thick to conduct the FECG signal.

The skin of locations where the electrodes will be placed is not prepared and the FECG signal is attenuated completely by grease or dead skin on the surface of the abdomen

So you need to confirm fetal life by other means before starting to use the monitor, such as using a fetoscope, stethoscope, Pinard stethoscope or obstetric ultrasonography. At the same time, when fetal monitoring with the device, if FHR cannot be detected for a long time, please change another monitoring method, such as ultrasound or DECG monitoring.

9.2 Start Monitoring

9.2.1 Introduction

FECG Fetal&Maternal Module not only monitors eFHR, HR and eTOCO by fetal ECG(FECG) technology, but also TOCO by pressure sensor technology. The ECG lead is configured with a remote event marker. Press the remote event marker button when feeling fetal movement.

WARNING

1 **The monitor is not a diagnostic ECG device. The ECG lead system of the monitor is not the standard one. The ECG waveform displayed is different from that of the standard ECG lead system, so it is not intended for diagnosis.**

2 **Make sure you have confirmed the fetal life by other means before using this monitor for FHR monitoring.**

3 **Fetal vernix caseosa can block the conduction of FECG signals. Optimal FECG signals may not be obtained from fetus in the vernix caseosa period. If the maternal-fetal heart rate cannot be detected for a long time, it's suggested to change the monitoring method to ultrasound or DECG monitoring.**

WARNING

4 If montoring TOCO with the pressure sensor, inspect patient skin before applying the transducer. If the skin quality is poor, especially when the skin is damaged or irritated, please change a site to apply the transducer.

5 In the process of labor, excessive movement of the pregnant woman will influence the calculation of the HR.

6 If you cannot get a good measurement signal quality, use an alternative monitoring method.

7 During long-time TOCO monitoring with the pressure sensor, please inspect the application site of the transducer at least every half an hour. If the skin quality changes, you should move the transducer to another site.

8 Do not monitor with FECG if :

a. The skin on the abdomen of the patient has established erythema, lesions, infection, inflammation, or any kind of injuries at the applications site

b. The patient has a history of skin irritation, allergies, or hypersensitivity to adhesives.

9 The FECG Fetal&Maternal Module detects fetal and maternal parameters based on ECG principle. The ECG signal is extremely sensitive to electromyography interference generated by tense muscles, or interference generated by maternal or fetal movement that leads to deflections from baseline. So when the pregnant woman pushes during contractions, moves when wearing the device or sits on the birth ball, the interference generated will cause the monitor unable to calculate the correct FHR/MHR.

10 During the second stage, the pregnant woman pushes with all her strength to deliver the fetus, and the muscles are in tense status for a long time. The EMG interference generated may cover the maternal/fetal ECG signals and in the end the correct FHR/MHR is unable to be calculated. So if FHR/MHR hasn't been detected for a long time during this stage, it's suggested to change the monitoring method to ultrasound for or DECG monitoring.

11 Doctor should examine carefully the monitoring data of the pregnant woman.

12 FECG Fetal&Maternal Module has priority over F15 Air US Transducers, DECG Fetal & Maternal Module and TOCO transducer. When FECG Fetal&Maternal Module gets on line, F15 Air US Transducers, DECG Fetal & Maternal Module and TOCO transducer will be disabled.

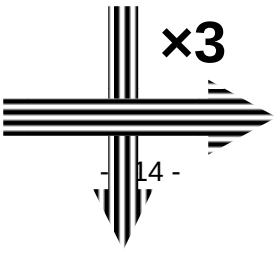
9.2.2 Parts Required

①FECG Fetal&Maternal Module and ECG leads ② Electrodes ③Skin prep tape

9.2.3 Skin Preparation

The skin is poor conductor of electricity; therefore preparation of the patient's skin is important to facilitate good electrode contact to skin.

- If the women has been using creams, or coupling gel, remove any residue with wet tissues and make sure the skin where electrodes will be placed is dry.
- Select area without any injury or any abnormality
- Avoid area with hair. Shave hair from electrode sites, if necessary.
- Using the skin prep tape and make three vertical and three horizontal strokes (making a cross shape) on the area where the electrode will be placed (remove the dead skin cells below the electrode foam gel pad). For most women 3 strokes in 2 directions should be sufficient.



×3

CAUTION

Please be gentle during skin preparation to avoid skin injury.

9.2.4 Electrode Placement

FECG adopts 6-lead cables. The table below lists the names and position of the ECG leads.

Name	Color	Position
C1	White	8-12 cm right of the umbilicus
C4	Brown	3cm over the umbilicus
F	Green	8cm below the left nipple
L	Yellow	20 to 45 degree to the umbilicus and 10-15cm away
N	Black	4-6 cm above the symphysis pubis
R	Red	20 to 45 degree to the umbilicus and 10-15cm away

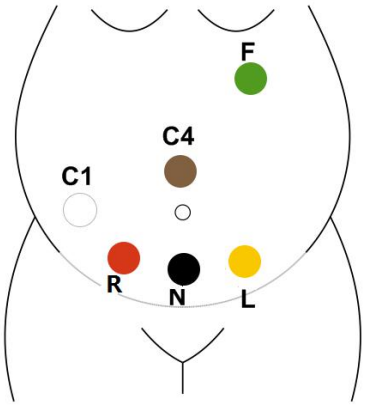


Figure 9-1 Electrode Positions

WARNING

1 **Make sure that all electrodes are connected to the patient correctly before operation.**
2 **Make sure that the conductive parts of electrodes and associated connectors, including neutral electrode, do not contact with earth or any other conducting objects.**
3 **Do not use any electrodes which are expired or already dry.**
4 **The electrodes should be finished before the specified time after opening the package.**
5 **Make sure the electrodes are firmly attached to the skin after placing the electrodes.**
6 **Examine the electrodes before each usage. If any problems, change the electrodes when needed.**
7 **For disposal of abandoned electrodes, please follow hospital requirements or local laws**

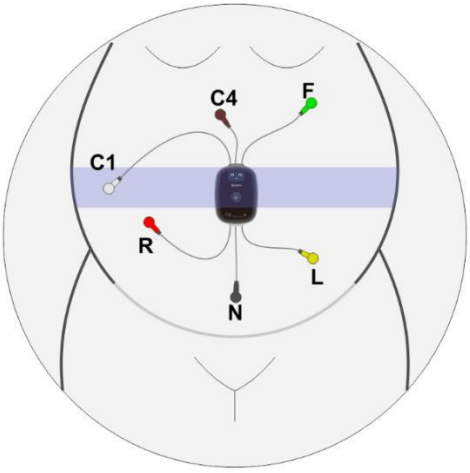
and regulations. Do not discard them randomly.

8 **Electrodes are for one-off use only as they may cause cross infection between different patients. Repeated use is forbidden!**

9 **Clean the ECG leads before monitoring.**

9.2.5 Connecting the ECG Leads to the Electrodes

Straighten out the leads and avoid tangling or bending. Connect the leads to the electrodes according to the color and make sure that the connection is tight.



WARNING

1 **Only the patient cable and other accessories supplied by the manufacturer can be used. Or else, the performance and safety cannot be guaranteed.**

2 **Monitoring can only be started when all the ECG leads are connected correctly and signal is normal.**

CAUTION

Please use EDAN approved disposable electrodes with legal and valid medical device qualification.

9.2.6 Placing the Transducer

When monitoring uterine activity by pressure sensor of the transducer, put the transducer on the patient's fundus, which is flat and solid.

When monitoring uterine activity by EMG signal, then no special requirement for the location of the transducer.

Wrap the abdomen with the belt over the transducer. Fix the transducer by pushing its buckle through the overlapping section of the belt. Make sure the belt fits the patient snugly but comfortably.

WARNING

When monitoring uterine activity by EMG signal,

1 **The monitor may display deflections from baseline that do not represent uterine contractions. These deflections from baseline may represent electrical activity in the myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract. When this occurs, the "false contraction" often does not attain the amplitude of true uterine contractions. If the waveform looks suspicious, another method of monitoring should be considered.**

2 **Sometimes low amplitude electrical activity insufficient to cause a contraction detected by a pressure sensor is displayed as a deflection above baseline on the waveform. These**

deflections from baseline may represent electrical activity in myometrium that is not sufficiently organized to cause the uterine smooth muscle to contract.

WARNING

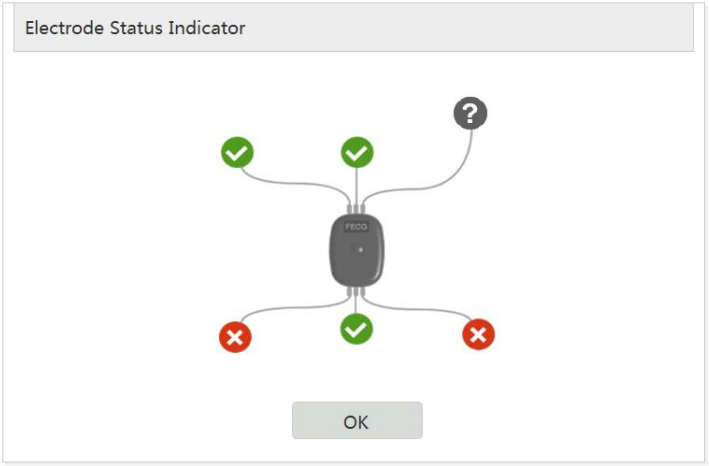
3 Interference that leads to deflections from baseline due to maternal and fetal movements may be mistaken as electrical activity in myometrium. When this occurs, a "false contraction" will be generated in the waveform of uterine contractions.

NOTE:

1. **Instruct the patient to move in the prescriptive area and distance for obtaining better signal.**
2. **During monitoring, the patient's prolonged lying in the supine position should be avoided owing to the possibility of supine hypotension. Sitting up or lateral positions are preferable and may be more comfortable.**
3. **Check the function of the pressure sensor on the transducer by applying pressure on it to see if this is displayed on the screen.**
4. **Temperature of the transducer may rise and be close to body temperature during charging, but this is normal phenomenon. Please inform the patient before monitoring.**
5. **If TOCO is zero and lasts for 30 seconds, the monitor will auto-zero TOCO.**

9.2.7 Electrode Checking

Click the FHR numeric in the measurement numeric fields and the electrode status window will pop up. The electrode status in the window correspond to the status of six electrodes of the transducer.  represents bad contract between the electrode and the skin or electrode off;  represents good contact between the electrode and the skin;  represents the skin impedance is too high and the signal is weak, and it is recommended to prepare the skin or check the connection of electrodes.



The status of the electrodes can also be checked on the screen of the transducer. See *Section 3.4.2* of the user manual.

9.2.8 Changing FECG Gain

1. Select the main menu key  on the main interface.
2. Select **Fetus > FECG Gain**.
3. Select **X1/2**, **X1** (default), **X2** or **X4**, **X8**, **X16**, **X32**, **X64**, **X128**.

4 ‘Select **OK**.

Suggest to select X32 at the beginning of the monitoring, and then adjust the gain according to the actual displayed waveform to reach the best effect.

9.2.9 Changing ECG Gain

You can change the ECG gain. The ECG gain affects overall numeric and scope of the ECG waveform.

1 Select the main menu key  on the main interface.
2 Select **Mother > Gain**.
3 Select **X1/4**, **X1/2**, **X1** (default), **X2** or **X4**.
4 ‘Select **OK**.

9.2.10 Changing FECG Beep Volume

To change the FECG beep volume,

1 Select the main menu key  on the main interface.
2 Select **Fetus > FECG Beep**.
3 Select **0** (default) **~ 9**.
4 Select **OK**.

9.2.11 Choosing TOCO Source

You can change the TOCO source.

1 Select the main menu key  on the main interface.
2 Select **Fetus > TOCO Source**.
3 Select **TOCO** (default) or e**TOCO**
4 Select **OK**.

9.2.12 Monitoring Interface

Figure 9-2 Fetal Monitoring Interface

Figure 9-3 Maternal Monitoring Interface

Chapter10 After Monitoring

10.1 Completing Monitoring

After monitoring,

1) Remove transducers or electrodes from the patient; wipe the remaining gel off the patient and the transducer with a clean soft cloth or tissue.
2) Press the **PRINT** key to stop printing, and press the paper advancing key to advance the paper.
3) Wait the paper to stop and then tear it off along the perforation.

NOTE:

After the fetus is delivered in the labor, the monitor may pick up signals of the umbilical cord or maternal abdominal aorta and display a trace/numeric. To avoid misinterpretation, it is recommended to remove the transducers from the patient and switch off the monitor immediately after the fetus is delivered.

10.2 Switching Off

1) Press and hold the **POWER** switch for at least 3 seconds to switch off the monitor.
2) Unplug the power cord.

CAUTION

Do not press the POWER switch continuously. Allow at least 10 seconds between switching the monitor on and off.

Chapter11 Maintenance and Cleaning

11.1 Maintenance

11.1.1 Maintaining Inspection

(1) Visual Inspection

Prior to using the monitor every time, do the following inspections:

- Check the monitor and accessories to see if there is any visible evidence of damage that may affect patient safety. Pay special attention to the cracks on the transducers and cables before immersing them into conductive fluid.
- Check all the outer cables, power socket and power cables.
- Check if the monitor functions properly.

If any damage is detected, stop using the monitor on the patient. Replace the damage part(s) or contact the manufacturer for service before reusing it.

(2) Routine Inspection

The overall check of the monitor and the accessories, including safety check and function check, should be performed by qualified personnel every 6 to 12 months, and each time after service.

The equipment should undergo periodic safety testing to ensure proper patient isolation from leakage currents. This should include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol.

(3) Mechanical Inspection

Make sure all exposed screws are tight.

Check the external cables for splits, cracks or signs of twisting.

Replace any cable that shows serious damage.

Pay particular attention to the supply socket.

WARNING

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.

CAUTION

Besides the maintenance requirements recommended in this manual, comply with local regulations on maintenance and measurement.

11.1.2 Maintenance of Monitor

Keep the exterior surface of the monitor clean, free of dust and dirt.

The gathering of dew on the screen may occur with abrupt temperature or humidity changes. A stable environment is recommended. Stop using the monitor and contact the service personnel immediately if accidental wetting occurs.

Scratching and damaging the screen should be avoided.

Operate the touch screen with special stylus pen or finger. Sharp edged or hard particles like ball pen or propelling pencil are prohibited. Keep the touch screen surface clean, and no adhesive should be applied. Avoid high voltage and static charge.

11.1.3 Maintenance of Wired and Wireless Transducers

WARNING

1 The transducers must be cleaned before docking after each use. Make sure that there is no

residual coupling gel.

2 The transducers are delicate and sensitive. Please handle them with care and try to avoid dropping on to the ground or any hard surfaces.

Although transducers are designed for durability, they should be handled with care. Rough handling could damage the cover, piezoelectric crystals and mechanical movement. Contacting the transducers with hard or sharp objects should be avoided. Do not excessively flex the cables.
The transducers must be thoroughly cleaned and disinfected at least once a month. When cleaning, please firstly use a lint-free cloth moistened with mild near neutral detergent, ethanol 75% solution or isopropanol 70% alcohol-based solution to clean the transducers. Then use a cotton cloth moistened with clear water to clean again. At last, use a dry, soft cloth to dry them.

In case of unsuccessful charge or poor contact, please use detergent with abrasive effect to rub the electrodes of the transducers in order to clear away the oxide of coupling gel.

Charge and discharge the wireless transducer battery every 3 months.

11.1.4 Storage of Recorder Paper

When storing recorder paper (including used paper with traces):

Do not store in plastic envelopes.

Do not leave exposed to direct sunlight or ultraviolet light.

Storage conditions outside these limits may distort the paper and adversely affect the accuracy of grid lines or make the trace unreadable.

11.1.5 Cleaning of Recorder

The recorder platen, thermal print head and paper sensing mechanism must be cleaned at least once a year or when needed (when traces become faint).

To do this:

1) Clean the recorder platen with a lint-free cloth dampened in soap/ water solution.

2) Wipe the thermal array using a cotton swab moistened with 70% Isopropyl alcohol-based solution.

3) Check that the paper sensing mechanism is free of dust.

WARNING

Switch off the monitor and remove the power cord prior to recorder cleaning.

11.1.6 Maintaining the Battery

The performance of rechargeable batteries may deteriorate over time. It is recommended to check and maintain the batteries regularly every 3 months.

1. Disconnect the patient from the device and stop all measurement.
2. Switch off the device, connect it to mains power, install the battery and fully charge it.
3. Disconnect the device from mains power, switch on the device and let the device run until there is no battery power left and the device shuts off.
4. Reconnect the device to mains power and charge the battery until it is full for use or charge to 40%~60% for storage.

NOTE:

1. Do not use the device on a patient during the battery maintenance.

2. Do not interrupt the battery maintenance process.

11.1.6.1 Checking Battery Performance

The performance of rechargeable batteries may deteriorate over time. If you suspect that the battery may have failed, check the battery performance.

Please refer to Step 1~Step 3 in Section 11.1.6, and record the running time of the battery, which reflects the battery performance. If the running time is obviously less than the specified time in the specification, the battery may have reached its service life or malfunctioned, please change the battery or contact the service personnel. If the running time meets the specification, then the battery can continue to be used normally.

11.1.6.2 Storing the Battery

Remove the lithium battery and store it at a cool and dry environment if the lithium battery or the device is not used for a long time. Charge the batteries to 40%-60% for storage. Check and maintain the batteries regularly every 3 months. For more information, please refer to Section 11.1.6.

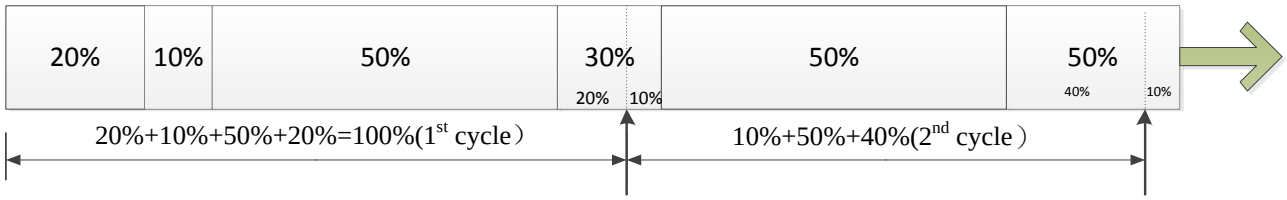
NOTE:

1. **When storing the battery, avoid contact between the battery interface and metal objects.**
2. **The service life of the battery will be shortened if it is stored under high temperature for a long time**
3. **Store the battery in a cool place can slow down the aging process. The ideal storage temperature is 15°C.**

For rechargeable button cell or lithium battery in wireless transducer, no need to remove it if the device is not used for a long time. Check and maintain the batteries regularly every 3 months. Charge the batteries to 40%-60% for storage.

11.1.6.3 Charge Cycle of the Battery

The battery is designed for frequent recharging. A complete charging cycle is only reached and counted, when all recharging periods equal a 100% charge (900 mAh equal 8 hours continued operation).



Battery replacement is recommended after 300 charge-discharge cycles.

11.2 Cleaning

If the device or accessory has been in contact with the patient, then cleaning and disinfection is required after every use. If there has been no patient contact and there is no visible contamination then daily cleaning and disinfection is appropriate.

The validated cleaning agents for cleaning the monitor and reusable accessories are:

1. Mild near neutral detergent
2. Ethanol (75%)

Cleaning agents should be applied and removed using a clean, soft, non-abrasive cloth or paper towel.

WARNING

1 Use only recommended cleaning substances and disinfectants listed in this manual. Others may cause damage (not covered by warranty), reduce product lifetime or cause safety hazards.

2 Inspect the monitor and reusable accessories after they are cleaned and disinfected.

11.2.1 Cleaning the Monitor

Regular cleaning of the monitor enclosure and the screen is strongly recommended.

WARNING

1 Unplug the monitor from the AC power source and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

2 If liquid is splashed on or into the main unit inadvertently, or enters the conduit, stop using the monitor and contact the manufacturer for service immediately.

3 Do not dry equipment using heating devices such as heaters, ovens (including microwave ovens), hair dryers, and heating lamps.

To surface-clean the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the entire exterior surface, including the screen, of the equipment using a soft cloth dampened with the cleaning solution thoroughly until no visible contaminants remain.
3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Dry the monitor in a ventilated and cool place.

CAUTION

1 Although the monitor are chemically resistant to most common hospital cleaners and non-caustic detergents, different cleaners are not recommended and may stain the monitor, such as disinfectant didecyl dimethyl ammonium bromide which contains quanternary ammonium salt.

2 Many cleansers must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the monitor.

3 Do not use strong solvent, for example, acetone.

4 Never use an abrasive such as steel wool or metal polish.

5 Do not allow any liquid to enter the product, and do not immerse any part of the monitor into any liquid.

6 Avoid pouring liquids on the monitor while cleaning.

7 Do not allow any remaining solution on the surface of the monitor.

NOTE:

1 The monitor surface can be cleaned with hospital-grade ethanol and dried in air or with crisp and clean cloth.

2 The manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

11.2.2 Cleaning the Reusable Accessories

11.2.2.1 Cleaning the Ultrasound Transducer

1. Disconnect the transducer from the monitor.
2. Wear sterile protective gloves to prevent infection.
3. Remove all residual foreign matters from the transducer using sterile cloth or paper towel immediately after examination. For the situation where a protective sheath is used, the protective sheath should be removed first and discarded.
4. Wipe the surface of transducer and cable with a sterile cloth dampened with the cleaning solution until no visible contaminants remain.
5. After cleaning, wipe off the cleaning solution with a new sterile cloth dampened with tap water until no visible cleaning agent remains.
6. Wipe off with a dry sterile cloth to remove residual moisture.
7. Leave the transducer to air dry.
8. If the transducer is not visually clean at the end of the cleaning steps, please repeat the cleaning steps through step 4 to step 7.
9. Inspect the transducer to ensure that there is no damage. The transducer should be disposed of properly when any damage is found.

CAUTION

1 The waterproof parts of the transducer are restricted to the main body and the cable. Do not immerse the plug into water during the process of monitoring or cleaning.

2 Be sure the temperature of cleaning solutions does not exceed +45 ºC (+113 ºF).

3 Only wipe the outer surface of accessories. Do not immerse them in any liquid.

4 Make sure no liquid enters the connector.

5 When you clean the TEMP transducer, take the head in one hand and clean with the soft cloth in the other hand.

6 After cleaning, no remaining cleanser is allowed on the surface.

11.2.2.2 Cleaning the NIBP Cuff

Cleaning the Cuff:

1. Take out the air bladder before cleaning.
2. Hand wash the cuff with the cleaning solution; clean the air bladder with a soft cloth dampened with the cleaning solution. until no visible contaminants remain
3. Rinse the cuff and after cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Wipe off residual moisture with a dry cloth.
5. Air dry the cuff thoroughly after cleaning.

Replacing the Air Bladder:

After cleaning, replace the air bladder into the cuff following the steps below:

1. Roll the bladder lengthwise and insert it into the cuff from the large opening at one end of the cuff.
2. Thread the hose from within the cuff and out through the small hole at the top of the cuff.

3. Adjust the bladder until it is in position.

CAUTION

1 Do not squeeze the rubber tube on the cuff.

2 Do not dry-clean the cuff.

3 Only clean the outer surface of the connectors, make sure no liquid goes into the connector.

4 When the reusable cuff is not connected with the monitor, or being cleaned, always place the cover on the rubber tube to avoid liquid permeation.

11.2.2.3 Cleaning the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
3. Wipe off residual moisture with a dry cloth.
4. Leave the cable assembly to air dry.

11.2.2.4 Cleaning the TOCO Transducer and SpO2 Sensor

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the cleaning solution until no visible contaminants remain.
3. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
4. Wipe off residual moisture with a dry cloth.
5. Leave the sensor to air dry.

11.2.2.5 Cleaning the TEMP Sensor

1. Wipe the patient contact area with a soft cloth dampened with the cleaning solution until no visible contaminants remain.
2. After cleaning, wipe off the cleaning solution with a fresh cloth or towel dampened with tap water until no visible cleaning agent remains.
3. Wipe off residual moisture with a dry cloth.
4. Leave the sensor/probe to air dry.

11.3 Disinfecting

Clean the monitor and reusable accessories before they are disinfected. The validated disinfectants for cleaning the monitor and reusable accessories are:

- Ethanol (75%)

11.3.1 Disinfecting the Monitor

To disinfect the monitor, follow these steps:

1. Switch off the monitor and disconnect it from the power line.
2. Wipe the display screen using a soft, clean cloth dampened with the disinfectant solution.
3. Wipe the exterior surface of the equipment using a soft cloth dampened with the disinfectant solution.
4. Wipe off the disinfectant solution with a dry cloth after disinfection if necessary.
5. Dry the monitor for at least 30 minutes in a ventilated and cool place.

CAUTION

1 Do not use any disinfectant containing additional active ingredients other than those listed, such as disinfectant didecyl dimethyl ammonium bromide which contains quanternary ammonium salt.

2 Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.

3 Do not immerse any part of the monitor or any accessory into liquid.

4 After disinfection, no remaining disinfectant is allowed on the surface.

5 Check if the monitor and accessories are in good condition. If any aging or damage is detected (e.g. the belt loses its elasticity), replace the damage part(s) or contact the manufacturer for service before reusing them.

6 Please do not light the TOCO transducer with ultraviolet light for a long time.

7 Disinfect the product as determined by your hospital's policy, to avoid long-term damage to the product.

8 Do not mix disinfecting solutions (such as bleach and ammonia) as hazardous gases may result.

NOTE:

The manufacturer has no responsibility for the effectiveness of controlling infectious disease using these chemical agents. Please contact infectious disease experts in your hospital for details.

11.3.2 Disinfecting of Reusable Accessories

11.3.2.1 Disinfecting the Ultrasound Transducer

1. Disconnect the transducer from the monitor.
2. Wear sterile protective gloves to prevent infection.
3. Clean and dry the transducer according to the methods in section *11.2.2.1 Cleaning of Ultrasound Transducer*.
4. Prepare the disinfectant solution (75% ethanol).
5. Spray the solution to the transducer interface or wipe it with a sterile cloth dampened with the disinfectant solution. Follow the disinfectant manufacturer's recommended contact time and mode.
6. Rinse the transducer according to the disinfectant instructions. Wipe the transducer with a dry sterile cloth or leave the transducer to air dry.

7. Inspect the transducer to ensure that there is no damage.

11.3.2.2 Disinfecting the NIBP Cuff

Disinfecting the Cuff:

1. Take out the air bladder before disinfection.
2. Wipe the cuff and the air bladder with a soft cloth dampened with the disinfectant solution.
3. Leave the cuff and air bladder to air dry for at least 30 minutes.

Replacing the Air Bladder:

After disinfection, replace the air bladder into the cuff. Refer to Section *11.2.2.2* for more information.

NOTE:

Prolonged use of disinfectant may cause discoloration of the cuff.

11.3.2.3 Disinfecting the ECG Cable Assembly

1. Wipe the cable assembly with a soft cloth dampened with the disinfectant solution. Wipe off the disinfectant solution with a dry cloth after disinfection.
2. Leave the cable assembly to air dry for at least 30 minutes.

11.3.2.4 Disinfecting the TOCO Transducer and SpO2 Sensor

1. Wipe the surfaces of the sensor and cable using a soft cloth dampened with the disinfection solution.
2. Wipe the patient contact area of the sensor with the cotton swab dampened with the disinfection solution.
3. Wipe off the disinfection solution with a dry cloth after disinfection.
4. Leave the sensor to air dry for at least 30 minutes.

11.3.2.5 Disinfecting the TEMP Sensor

1. Wipe the patient contact area with a soft cloth dampened with the disinfectant solution (ethanol or isopropanol).
2. Wipe off the disinfectant solution with a dry cloth after disinfection.
3. Leave the sensor to air dry.

11.3.3 Cleaning and Disinfecting Other Accessories

For cleaning and disinfecting other accessories, refer to the instructions delivered with the accessories. If the accessories are not accompanied by instructions, refer to this manual for the methods of cleaning and disinfecting the monitor.

11.4 Storage

1. Ensure the monitor and reusable accessories are cleaned, disinfected and completely dried before storage.
2. Store the monitor and reusable accessories in a dry environment free of dust.
3. Store the monitor and reusable accessories under the following conditions:

a) Atmospheric Temp.: -20 ºC～+55 ºC
b) Relative Humidity: 15%~95% (Non-condensing)
c) Atmospheric Pressure: 70kPa ~ 106kPa.

Chapter12 Warranty and Service

Warranty
EDAN warrants that EDAN's products meet the labeled specifications of the products and will be free from defects in materials and workmanship that occur within warranty period.

The warranty is void in cases of:

a) Damage caused by mishandling during shipping.
b) Subsequent damage caused by improper use or maintenance.
c) Damage caused by alteration or repair by anyone not authorized by EDAN.
d) Damage caused by accidents.
e) Replacement or removal of serial number label and manufacture label.

If a product covered by this warranty is determined to be defective because of defective materials, components, or workmanship, and the warranty claim is made within the warranty period, EDAN will, at its discretion, repair or replace the defective part(s) free of charge. EDAN will not provide a substitute product for use when the defective product is being repaired.

12.1 Contact information

If you have any question about maintenance, technical specifications or malfunctions of devices, contact your local distributor.

Alternatively, you can send an email to EDAN service department at: support@edan.com.cn.

Appendix 1 Product Specifications

A F15 Fetal/Maternal Monitor

A1.1 Environmental Specifications

The monitor may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

Working	Temperature	0 ºC ~ + 40 ºC (+32 ºF ~ +104 ºF)
	Relative Humidity	15% ~ 95% (non-condensing)
	Atmospheric Pressure	86 kPa ~ 106 kPa
Transport and Storage	Temperature	-20 ºC ~ +55 ºC (-4ºF ~ +131 ºF)
	Relative Humidity	15% ~ 95% (non-condensing)
	Atmospheric Pressure	70 kPa ~ 106 kPa

A1.2 Physical Specifications

Monitor		
Dimensions and Weight	Size (depth x width x height)	389 mm x 296 mm x 82.5 mm
	Weight	≤8.0 kg
Power Supply	Operating Voltage	100V-240V~
	Operating Frequency	50Hz/60Hz
	Input Power	1.2A-0.5A
	Battery	10.8VDC/5100mAh(±10%)
Wireless transducer holder bracket	Input Power	5V/3A
Standards Compliance	IEC 60601:2005+A1:2012, EN 60601-1:2006+A1:2013, IEC 60601-1-2:2014, EN 60601-1-2:2015, IEC 60601-1-8: 2012, EN 60601-1-8: 2007+A1: 2013 IEC/EN 60601-2-27, IEC/EN 60601-2-37, IEC/EN 60601-2-49, IEC 80601-2-30, ISO 80601-2-61, ISO 80601-2-56.	
Anti-electric Shock Type	Class I equipment with internal power supply	
Anti-electric Shock Degree	MECG,FHR1,FHR2,FHR3,TOCO,MARK,EXT.1, DECG, IUP, FECG	CF

	SpO2, NIBP , TEMP	CF (Defibrillating-proof)
Degree of Protection against Harmful Ingress of Water	Main Unit: IPX2, protected against vertically falling water drops when enclosure tilted up to 15° (provided recorder drawer is shut and the monitor is not mounted on the wall vertically) US-TF, US-TAF , US-SF , US-SAF, TOCO-EF, TOCO-EA, FECG-TA , DECG-IF , DECG-IA : IP68, dust-tight and protected against the effects of continuous emersion in water FT20 : IPX2	
Degree of Safety in Presence of Flammable Gases	Equipment not suitable for use in presence of flammable gases	
Disinfection/Sterilizing Method	Refer to this user manual for details	
EMC	CISPR11 Group 1 Class A	
Working System	Continuous operation equipment	
Display		
Screen Diagonal	15.6"	
Pixel	1920×1080 (Pixels)	
Signal Interface		
RS232 interface (DB15), RJ45 interface, HDMI interface, Antenna interface		
Ultrasound Transducer		
Dimension	91±3mm(L)×Φ76±3mm(W)×20±2 mm(H)	
Weight	◆Wireless transducer≤150g ◆Wired transducer≤150g (not including the wire)	
Cable Length	2.5m	
Shock Resistance	Withstands a 1.5 m drop at least 3 times to concrete surface with possible cosmetic damage only	
TOCO Transducer		
Dimension	91±3mm(L)×Φ76±3mm(W)×20±2 mm(H)	
Weight	◆Wireless transducer≤150g ◆Wired transducer≤150g (not including the wire)	
Cable Length	2.5m	
Shock Resistance	Withstands a 1.5 m drop at least 3 times to concrete surface with possible cosmetic damage only	
DECG Fetal&Maternal Module		
Dimension	91±3mm(L)×Φ76±3mm(W)×20±2 mm(H)	

Weight	◆Wireless transducer≤150g ◆Wired transducer≤150g (not including the wire)
Cable Length	2.5m
Shock Resistance	Withstands a 1.5 m drop at least 3 times to concrete surface with possible cosmetic damage only
FECG Fetal&Maternal Module	
Dimension	86±3mm(L)×61±3mm(W)×26±3mm(H)
Weight	< 150g (not including the wire)
Screen Size	0.96 inches
Screen Resolution	128×64 (Pixels)
FT20 Telemetry Transmitter	
Dimension	139mm(L)×68mm(W)×28mm(H)
Weight	<260g
Screen Size	0.96 inches
Shock Resistance	Withstands a 1.5 m drop at least 3 times to concrete surface with possible cosmetic damage only
Coupling Gel	
pH	
Acoustic Impedance	1.5x10^6 Pa.s/m ~1.8x10^{6}Pa.s/m (35°C/95ºF)

A1.3 Performance Specifications

FHR	Technique:	Ultrasound Pulse Doppler with autocorrelation
	*FHR Measurement Range	50 bpm ~ 240 bpm
	Resolution	1 bpm
	*Accuracy	±2 bpm
	FHR Ultrasound Signal Range	3.5uV Vpp~350 uV Vpp
	*Alarm	FHR Alarm
	Pulse Repetition Rate:	(2+10%)KHz
	Pulse Duration:	(92+10%) μs
	Ultrasound Frequency:	(1.0±10%) MHz
	Ultrasound Signal Range:	3.5uV Vpp~350 uV Vpp

	*Ultrasound Output	Isppa.3<190W/cm^2 Ispta.3<94mW/cm^2 Iob≤3.6 mW/cm^2 Isata≤.6 mW/cm^2 TI<1.0 MI<1.0
	*Temperature Rise	When applied to the patient, the ultrasound transducer may warm slightly (less than 10℃ (18ºF) above ambient temperature). When NOT applied, the ultrasound transducer may warm slightly (less than 10℃ (18ºF) above ambient temperature).
	p- <1 MPa	
	I_{spta} <100 mW/cm^2	
	Max Output Power <15mW	
	Effective Radiating Area (12 Crystals)	(942 ± 15%) mm^2
	Effective Radiating Area (7 Crystals)	(550 mm ±15%) mm^2
	Dielectric Strength	4000Vrms
TOCO	*TOCO Range	0~100
	*Non-linear Error	±10%
	Resolution	1%
	Baseline Drift due to Temperature Changes	1 unit/min/°C (free air)
		5 units/min/°C (underwater)
	Zero Mode	Automatic (TOCO value becomes zero or below lasting for 30 seconds)/ Manual
	Dielectric Strength	4000Vrms
DECG	*DFHR Measurement Range	30bpm ~ 240bpm
	Resolution	1bpm
	*Accuracy	±1bpm
	*Alarm	DFHR Alarm
	Input Impedance	> 10M (Differential, DC50/60Hz)
	Input Impedance	> 20M (Common Mode)
	CMRR	> 110dB
	Noise	< 30μVp-p
	Skin Voltage Tolerance	±500mV
	Fetal Input Voltage Current	20μVp-3mVp
IUP	*Pressure Range	0mmHg ~100mmHg (0.0 kPa~13.3 kPa)
	Resolution	1mmHg (0.1 kPa)

	*Accuracy	±3mmHg
MFM & AFM	*Display Range	0 ~ 999
	*FM Mode	Automatic/Manual
	*AFM Mode	Trace (default) or Black Mark
	AMF Technique	Pulsed Doppler ultrasound
MECG	*MHR Measurement Range	30bpm ~ 240bpm
	*MHR Measuring Accuracy	±2bpm
	Resolution	1 bpm
	MHR Alarm Limits	28bpm ~ 243bpm
	*Alarm	HR Alarm
	Anti-electric Shock Type	Type CF(complies with IEC 60601-2-27:2011 except clauses about defibrillation-proof)
	Input Signal Range	◆0.5mV~8mV (lead wire) ◆50uV~8mV (electrode sleeve)
	ECG Waveform	Manual control ECG waveform display
	ECG falls off	Detect automatically
	Patient Leakage Current (Limit)	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
	Patient Auxiliary Current (Limit)	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
	Differential Input Impedance	>2.5MΩ
	Display Sensitivity	2.5mm/mV (X1/4), 5mm/mV (X1/2), 10mm/mV (X1), 20mm/mV (X2), 40mm/mV (X4)
	Waveform Scan Speed	25mm/s
	Electrode Offset Potential Tolerance	±500mV
	Auxiliary Current (Leads off detection)	Active electrode: < 100 nA Reference electrode: < 900 nA
	Accuracy and Response to Irregular Rhythm	Not Supported
	Bandwidth(-3dB)	Diagnosis: 0.05 Hz to 120 Hz Monitor: 0.5 Hz to 40 Hz
	Response time to Change in MHR	MHR range: 80bpm ~ 120bpm Range: 7s ~ 11s (average:9s) MHR range: 80bpm ~ 40bpm Range : 8s ~ 12s (average: 10s)
	Tall T-wave Rejection	Exceeds ANSI/AAMI EC13-2002 Sect. 3.1.2.1 (C)

		maximum recommended 1.5mV T-Wave amplitude
SpO2	*Measurement Range (EDAN)	50% ~ 100%
	*Measurement Range(Nellcor)	50% ~ 100%
	Resolution	1 %
	*Measuring Accuracy (EDAN)	70% ~ 100% ± 2% 50 ~ 69% unspecified
	*Measuring Accuracy (Nellcor)	70% ~ 100% ± 3% 50 ~ 69% unspecified
	*Data update period (EDAN)	1s
	*Data update period (Nellcor)	2s
	PR Measurement	*Range: 30~240bpm
		Resolution: 1 bpm
		*Accuracy: ±2 bpm(EDAN) *Accuracy: ±3 bpm(Nellcor)
	SpO2 Alarm Limits	50% ~ 100%
	*Alarm	PR Alarm and SpO2 Alarm
	Wavelength	Red light: (660±3) nm
		Infrared light: (905±10) nm
		Emitted light energy: < 15 mW
	Information about the wave length range can be especially useful to clinicians (for instance, when photodynamic therapy is performed.)	
NIBP	*Measurement	Systolic Pressure, Diastolic Pressure, Mean pressure
	Method	Oscillometric Method
	*Measurement Range	Systolic Pressure: 40 mmHg ~ 270 mmHg (5.3 kPa~36.0 kPa) Diastolic Pressure: 10 mmHg ~ 215 mmHg (1.3 kPa~28.7 kPa) Mean pressure: 20 mmHg ~ 235 mmHg (2.8 kPa~31.3 kPa)
	Resolution	1 mmHg (0.1 kPa)
	*Measuring Accuracy	Max. average deviation ≤ ±5mmHg (≤ ±0.8 kPa) Max. standard deviation ≤ 8mmHg (≤1.2 kPa)
	Measuring Time (MAX)	120s
	Alarm Limits	Systolic Pressure: 40 mmHg ~ 270 mmHg (5.3 kPa~36.0 kPa) Diastolic Pressure: 10 mmHg ~ 215 mmHg (1.3 kPa~28.7 kPa) Mean Artery Pressure: 20 mmHg ~ 235 mmHg

		(2.7kPa~31.3 kPa)
	*Alarm	Systolic pressure, Diastolic pressure, Mean pressure Alarm
	Software Over Voltage Protection	(297 ± 3) mmHg [(39.6 ± 0.4) kPa]
	Hardware Over Voltage Protection	(320 ± 10) mmHg [(42.8±1.3) kPa]
	Unit	mmHg, kPa
	Measurement Methods	Auto, Manual
	PR Measurement	* Range:40bpm ~ 240bpm
		* Accuracy: ±3 bpm or 3.5%, whichever is greater
		Resolution: 1bpm
	*Limits of the error of the manometer	Over the temperature range of 10 °C to 40 °C and the relative humidity range of 15 % to 85 %(non-condensing), the maximum error for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to ± 3 mmHg (± 0,4 kPa) or 2 % of the reading, whichever is greater.
TEMP	Channel	1
	*Measurement Range	0°C ~ +50°C
	Resolution	0.1°C
	*Accuracy	At 25°C ~45°C, the measurement accuracy is 0.2°C. Other measuring range, the measurement accuracy is 0.3°C. The accuracy of this part consists of two parts, as follows: (1) Accuracy (without sensor error): ±0.1℃ (2) Sensor error: ±0.1°C at 25°C~45°C; ±0.2°C at other measurement ranges
	Unit	°C, ℉
	Refresh Time	1 ~ 2s
	Alarm Limits	0.0℃ ~ +50.0℃
	*Alarm	TEMP Alarm
	Position	Axilla
	Transient Response Time	≤30 s
	Measuring Mode	Direct Mode
FECG	eFHR	

	Resolution	1bpm
	* Accuracy	±1bpm
	* Measurement Range	30~240bpm
	Signal Range	5uV~3mV
	QRS Wave Width	30ms~60ms
	Differential Input Impedance	>2.5MΩ
	Electrode Offset Potential Tolerance	±500mV
	HR	
	*HR Measuring Accuracy	±1bpm
	TOCO	
	* Measurement Range	0% ~ 100%
	* Non-linear Error	±10%
	Baseline Drift due to Temperature Changes	1 unit/min/°C (free air) 5 units/min/°C (underwater)
	eTOCO	
	Measurement Range	0% ~ 100%
	Signal Range	0 ~ 500 μV
	Accuracy	±5%(unit:%)
	FM	
	* FM Mode	Manual
	* Display Range	0 ~ 999

NOTE:
The essential performance is marked with an asterisk *.

A1.4 Recorder Specifications

Paper	Z-fold, thermosensitive (compatible with GE and PHILIPS recorder papers)
Paper width	152mm (GE), 150mm (PHILIPS)
Effective printing width	110mm (American Standard) 120mm (International Standard)
FHR printout width	70mm (American Standard) 80mm (International Standard)

FHR scaling	30bpm/cm (American Standard) 20bpm/cm (International Standard)
TOCO printout width	40mm
TOCO scaling	25%/cm
Printing speed	
Standard Speed(Real-Time Traces)	1 cm/min, 2 cm/min, 3 cm/min
Fast Print Speed(Stored Traces)	Up to 15mm/sec
Accuracy of data	± 5% (X axis)
Accuracy of data	± 1% (Y axis)
Resolution	8 dots/mm
Record Information	FHR1/DFHR trace/mark, FHR2 trace/mark, FHR3 trace/mark, TOCO/IUP trace, AFM trace/black mark, fetal movement mark, event mark (and annotation), AUTO-zero symbol, alarm indicator, SOV alarm indicator, US signal weak alarm indicator, transducer wireless signal weak indicator, date, time, printing speed, ID, name, FHR2 Offset, FHR3 Offset, HR, SpO_2, SYS, DIA, MAP, PR, TEMP, CTG analysis results etc.

A1.5 Rechargeable Lithium-ion Battery

Monitor Battery:

Type	Rechargeable Lithium-ion Battery
Continual Working Time	⩾2 hours (use new fully charged battery, in environmental temperature 20~30℃, access fetal transducer, TOCO transducer, MECG lead wire, blood pressure sleeve, finger blood oxygen transducer and temperature transducer to simulate monitoring, and open the real-time print and automatic blood pressure measurement functions, with paper speed 1cm/min, and automatic blood pressure measurement interval 15 min.)
Necessary charge time from "out of power" to "fully charged"	⩽7 hours (stand by or power off status)
Necessary charge time from "out of power" to "90% charged"	⩽5 hours (stand by or power off status)
Nominal Capacity	5100 mAh(±10%)
Nominal Voltage	10.8V
Cycle Life	⩾300 times

Transducer Battery:

Type	Rechargeable Lithium-ion Battery
Continual Working Time	≥8 hours (new battery used in fully charged)
Necessary charge time from "out of power" to "fully charged"	≤5 hours (stand by or power off status)
Necessary charge time from "out of power" to "90% charged"	≤3.5 hours (stand by or power off status)
Charging mode	Wireless charging
Nominal Capacity	1600 mAh
Nominal Voltage	3.7 V
Cycle Life	≥300 times

FT20 Telemetry Transmitter Battery:

Type	Rechargeable Lithium-ion Battery
Continual Working Time	≥12 hours(new battery used in fully charged)
Necessary charge time from "out of power" to "fully charged"	Wireless charging:≤ 6h Wired charging:≤ 2.5h
Charging mode	Wireless charging Wired charging
Nominal Capacity	1600mAh
Number of Batteries	2
Nominal Voltage	3.7 V
Cycle Life	≥300 times

A1.6 WIFI Specifications

Technology	802.11 b/g/n
Frequency Range	2.4GHz ~ 2.4835GHz
RF Modulation Schemes	DBPSK/DQPSK/CCK/BPSK/QPSK/16QAM/64QAM
EIRP Transmission Power	<20dBm
Transmission Range (line of sight)	Visibility: >20m (indoor distance depends on the architecture structure and material)

A1.7 NFC Specifications

Working Frequency	13.56MHz

A1.8 Interface Specifications

A1.8.1 USB Interfaces

Number of USB Interfaces	Standard: 2
Drive Mode	HOST interface, USB 2.0 protocol
Power Supply	5 .3VDC±5%, 1500 mA Max.
Interface Type	USB A-type port

A1.8.2 Wired Network Interface

Specification	100-Base TX (IEEE802.3)
Interface Type	Standard RJ-45 network interface

A1.8.3 HDMI Interface

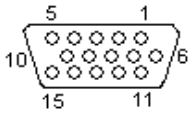
Number of HDMI Interface	1
Interface Type	HDMI

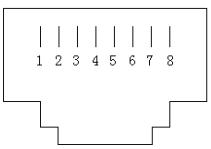
A1.8.5 DB15 Interface

Specification	RS-485 signal	pin4、pin6 to pin9
	RS-232 signal	pin2、pin3
	UART signal	Pin10、pin14、pin15
	FHR analog signal input	pin1、pin11
	Power signal	pin5、pin12
Interface Type	DB-15 female receptacle	

Appendix 2 Signal Input/ Output Connector

Accessory equipment connected to these interfaces must be certified according to the respective IEC/EN standards (e.g. IEC/EN 60950 for data processing equipment and IEC/EN 60601-1 for medical equipment). Furthermore all configurations shall comply with the valid version of the system standard IEC/EN 60601-1. Anybody who connects additional equipment to the signal input connector or signal output connector to configure a medical system must ensure that the system complies with the requirements of the valid version of the system standard IEC/EN 60601-1. If in doubt, contact our technical service department or your local distributor.

	Pin	Signal	Input/Output
DB15 Interface 	1	Reserved	/
	2	232_RXD_FROM_CNS_FB	Receive MFM-CNS, MFM-CNS Lite Serial Data
	3	232_TXD_TO_CNS_FB	Transmit to MFM-CNS, MFM-CNS Lite Serial Data
	4	485_EN_FB	RS485 Transmit Enable
	5	GND	Refer to 0V Electrical Level
	6	485_TA_FB	RS485 Signal Transmit
	7	485_TB_FB	RS485 Signal Transmit
	8	485_RA_FB	RS485 Signal Receive
	9	485_RB_FB	RS485 Signal Receive
	10	Reserved	/
	11	Reserved	/
	12	5V	Output Power
	13	Reserved	/
	14	Reserved	/
	15	Reserved	/

	Pin	Signal	Input/Output
RJ45 Interface 	1	TD+	Output
	2	TD-	Output
	3	RD+	Input
	4	Reserved	Reserved
	5	Reserved	Reserved
	6	RD-	Input
	7	Reserved	Reserved
	8	Reserved	Reserved

CAUTION

Only the PC or telemetry system recommended by the manufacturer can be connected to the signal input/output interface of the monitor. Other equipment is forbidden.

Appendix 3 Troubleshooting

A3.1 No Display

Phenomenon	Possible Cause	Solution
Power indicator is off.	Power cable is loose.	Tighten the power cable.
	The battery runs out of power.	Connect to AC power supply.

A3.2 No Touch Response

Phenomenon	Possible Cause	Solution
No touch response	There's water drop on the touch screen.	Clean the touch screen.
	Touch screen is faulted.	Restart the device.
	Touch screen is faulted.	Connect a USB keyboard for temporary use to operate the direction key + Enter key.
	Touch screen is faulted.	Contact the maintenance personnel of EDAN for maintenance

A3.3 Noise

Phenomenon	Possible Cause	Solution
Noise	Too high volume.	Turn down the volume.
	Interfered by mobile phone or other interfering source.	Keep the interfering source far away from the monitor.

A3.4 Recorder Error

Phenomenon	Possible Cause	Solution
Paper jam	Wrong loading paper or paper is dampened.	Load paper correctly and keep paper from moist.
Recorder does not work.	The recorder is not started.	Press the **PRINT** key.
	Run out of paper.	Load paper.
	The paper drawer is not locked.	Slide the paper drawer in until both latches are locked in position.

Incorrect time and date	Time incorrectly set	Reset time and date and note the difference between Daylight Saving Time and Winter Standard Time(See 6.5)
	Battery fault	The battery needs service. Call the service personnel.

A3.5 Trouble with Ultrasound FHR Monitoring

Phenomenon	Possible Cause	Solution
Inconstant trace / display	The patient is overweight.	Monitor FHR with DECG.
	Improper ultrasound transducer position.	Adjust the position of the transducer till the better signal is received.
	Loose belt.	Tighten the belt.
	Superfluous aquasonic coupling gel.	Wipe off superfluous aquasonic coupling gel.
	Frequent fetal movements.	Delay the monitoring.
	Maternal movement.	Request the patient to calm down and stay still.
	Inadequate aquasonic coupling gel.	Use recommended aquasonic coupling gel quantity.
Doubtful FHR	Record maternal heart rate wrongly.	Change the position of the ultrasound transducer.
	The transducer is not well placed in position, and the mixed noise has been recorded.	Adjust the position of the transducer.
Faint trace or no trace	Improper paper.	Use paper recommended by manufacturer
	The paper drawer is not locked.	Slide the paper drawer in until both latches are locked in position.
	Adjusting nuts of the print head are unbalanced.	Contact the manufacturer for service.

A3.6 Troubles with DECG Monitoring

Phenomenon	Possible Cause	Solution
Inconstant trend Inconstant display	No ECG signal	Use a new spiral electrode
	Bad contact of reference electrode and patient	Use a new spiral electrode

Inconstant trend	The DECG cable has not been fixed firmly	Fix an attachment pad at the DECG cable.

A3.7 Troubles with Contractions Monitoring (External)

Phenomenon	Possible Cause	Solution
Bad trace quality or fluctuant TOCO baseline	The belt is too tight or too loose.	Adjust the belt.
	The belt has no elasticity.	Renew the belt.
	Maternal movement.	Request the patient to calm down and stay still.
	Frequent fetal movements.	Delay the monitoring.
Too high TOCO sensitivity (higher than 100 unit)	The body pressure from uterus to TOCO transducer is far higher than the average numeric.	Insure favorable contact for patient skin with TOCO transducer. Change the position of TOCO transducer, if necessary.

A3.8 Troubles with Contractions Monitoring (Internal)

Phenomenon	Possible Cause	Solution
No trend	The intrauterine catheter is jammed	Wash with disinfector
No pressure change when uterine contraction	“Dry” environment or the tip of intrauterine catheter is placed extraovularly	Wash with disinfector or change the position of transducer
Only see the IUP peak but no baseline	Zero adjustment is wrong	Zero the system
The trend is a beeline	The connector failure.	Move or contact catheter. If trend no fluctuation, change intrauterine cable.

A3.9 Trouble with ECG Monitoring

Phenomenon	Possible Cause	Solution
Big ECG signal interference or thick baseline	Abnormal electrodes placing or electrodes invalidation.	Check the electrodes placing and the period of validity of electrodes.
	The cable connector is not well connected.	Check the connection of cable connector.
	Power socket has no standard ground wire.	Check if power socket has standard ground wire.

	The special ground wire connecting with monitor is not properly earthed.	Check if the special ground wire connecting with monitor is earthed.
Inconstant trace / display	Improper positions of ECG electrodes	Place the ECG electrodes per suggested positions.
	Poor contact between ECG electrodes and the skin	Change the ECG electrodes and attach them to the body

A 3.10Troubles with HR Monitoring with Electrode Sleeve

Phenomenon	Possible Cause	Solution
Weak ECG signal	The angle of the transducer is not appropriate	Rotate the transducer slightly in the left and right 90° range until a clear ECG signal is found
	The placement location is not optimal	Select the upper, flat area of the fundus as much as possible
	The belt is too loose or the signal of the patient herself is too weak	Adjust the belt and transducer, if no improvements are made, change another method of detection when ECG calculation is doubtful.
Big ECG signal interference or thick baseline	Bad contact between electrodes and skin	Ensure the three electrodes are in complete contact with the skin
	Dry or rough skin of the patient	Prepare the skin and remove skin scurf and grease with medical alcohol cotton or wet tissue. Avoid using conductive substance that is easy to make residual such as conductive paste in case of short circuit between electrodes.
	Patient sweats	Clean the skin regularly and keep it dry
	Patients' movements and changes of abdomen profile that lead to bad contact of electrodes	Suggest the patient to move less, and adjust the belt and transducer while changing position, and ensure electrodes are in contact
	The special ground wire connecting with monitor is not properly earthed.	Check if the special ground wire connecting with monitor is earthed.
	The power socket of the monitor, infusion pump that connects to the patient or electric delivery bed doesn't have standard ground wire	Check if power socket has standard ground wire.

A3.10 No NIBP and SpO2 Results

Phenomenon	Possible Cause	Solution
NIBP and SpO_2 have no results	The NIBP cuff is not properly wrapped to the position of patient's arm.	Check if the NIBP cuff is properly wrapped to the position of patient's arm.
	The NIBP can not be inflated.	Extend catheter, and check the connection.
	Hose connector plug is not connected well with the NIBP socket.	Check if the hose connector plug is connected well with the NIBP socket.
	SpO_2 transducer is not connected well with the SpO_2 socket.	Check if the SpO_2 transducer is connected well with the SpO_2 socket.
	Abnormal working condition.	Shut off the power, then switch it on again.

A3.11 Monitor Unable to be Charged

Phenomenon	Possible Cause	Solution
Monitor unable to be charged	The environmental temperature is high.	Check the fan of the monitor or shut down the monitor to cool it.

Appendix 4 Ultrasound Intensity and Safety

A4.1 Ultrasound in Medicine

The use of diagnostic ultrasound has proved to be a valuable tool in medical practice. Given its known benefits for non-invasive investigations and medical diagnosis, including investigation of the human fetus, the question of clinical safety with regards to ultrasound intensity arises.

There is no easy answer to the question of safety surrounding the use of diagnostic ultrasound equipment. Application of the ALARA (As Low As Reasonably Achievable) principle serves as a rule-of-thumb that will help you to get reasonable results with the lowest possible ultrasonic output.

The American Institute of Ultrasound in Medicine (AIUM) states that given its track record of over 25 years of use and no confirmed biological effects on patients or instrument operators, the benefits of the prudent use of diagnostic ultrasound clearly outweigh any risks.

A4.2 Ultrasound Safety and the ALARA Principle

Ultrasound waves dissipate energy in the form of heat and can therefore cause tissue warming. Although this effect is extremely low with Doppler, it is important to know how to control and limit patient exposure. Major governing bodies in ultrasound have issued statements to the effect that there are no known adverse effects from the use of diagnostic ultrasound, however, exposure levels should always be limited to As Low As Reasonably Achievable (the ALARA principle).

A4.3 Explanation of MI/TI

A4.3.1 MI (Mechanical Index)

Cavitations will be generated when ultrasound wave passes through and contacts tissues, resulting in instantaneous local overheating. This phenomenon is determined by acoustic pressure, spectrum, focus, transmission mode, and factors such as states and properties of the tissue and boundary. This mechanical bioeffect is a threshold phenomenon that occurs when a certain level of ultrasound output is exceeded. The threshold is related to the type of tissue. Although no confirmed adverse mechanical effects on patients or mammals caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported, the threshold for cavitation is still undetermined. Generally speaking, the higher the acoustic pressure, the greater the potential for mechanical bioeffects; the lower the acoustic frequency, the greater the potential for mechanical bioeffects.

The AIUM and NEMA formulate mechanical index (MI) in order to indicate the potential for mechanical effects. The MI is defined as the ratio of the peak-rarefactional acoustic pressure (should be calculated by tissue acoustic attenuation coefficient 0.3dB/cm/MHz) to the acoustic frequency.

$$MI = \frac{P_{r,\alpha}}{f_{awf} \times C_{MI}}$$

$$C_{MI} = 1 \text{ (MPa / MHz)}$$

A4.3.2 TI (Thermal Index)

Heating of tissues is caused by absorption of ultrasound when the ultrasound energy is applied. The temperature rise is determined by the acoustic intensity, exposed area and thermophysical properties of the tissue.

In order to indicate the potential for temperature rise caused by thermal effects, the AIUM and NEMA formulate thermal index (TI). It is defined as the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1ºC (1.8ºF).

According to different thermophysical properties of the tissue, TI is divided into three kinds: TIS, TIB and TIC.

TIS (Soft Tissue Thermal Index): It provides an estimate of potential temperature rise in soft or similar tissues.

TIB (Bone Thermal Index): It provides an estimate of potential temperature rise when the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.

TIC (Cranial Bone Thermal Index): It provides an estimate of potential temperature rise in the cranial bones or superficial bones.

A4.3.3 Measurement Uncertainty

The uncertainties in the measurements were predominantly systematic in origin; the random uncertainties were negligible in comparison. The overall systematic uncertainties were determined as follows.

1. Hydrophone Sensitivity

Based on the HNP-0400 hydrophone calibration certificate, the hydrophone measurement uncertainty for 1-15MHz is 1 dB, which is equivalent to an uncertainty of ±12.20% for intensity and ±6.10% for pressure. This uncertainty is used in PW measurement uncertainty assessment.

2. Digitizer

Based on the oscilloscope calibration certificate, the oscilloscope uncertainty is ±1.16% for intensity and ±0.58% for pressure.

3. Temperature

Based on the temperature variation of the water bath, the uncertainty is ±1.6% for intensity and ±0.8% for pressure.

4. Spatial Averaging

±10.2% for intensity, and ±6.1% for pressure.

5. Non-linear Distortion:

N/A. No effects of nonlinear propagation were observed.

Since all the above error sources are independent, they may be added on an RMS basis, giving a total uncertainty of ±26.62 percent for all intensity values reported, ±13.31 percent for all the pressure values and ±14.52 percent for the Mechanical Index.

A4.4 Prudent Use Statement

Although no confirmed bioeffects on patients caused by exposure from present diagnostic ultrasound equipment have ever been reported, the potential exists that such bioeffects may be identified in the future. Therefore, the ultrasound should be used prudently. High levels of acoustic output and long exposure time should be avoided while acquiring necessary clinical information.

A4.5 References for Acoustic Output and Safety

1. “Bioeffects and Safety of Diagnostic Ultrasound” issued by AIUM in 1993
2. “Medical Ultrasound Safety” issued by AIUM in 1994
3. "Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in 2019.
4. "Medical electrical equipment—Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment" issued by IEC in 2015.

A4.6 Transducer Acoustic Output Parameters List

A4.6.1 Test of Wired Transducer(F15)

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: US-TF
Nominal Frequency: 1.0MHz
Operating Mode: PW Mode

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.034	0.0034		0.12		N/A
Index component value			N/A	0.0034	N/A	0.12	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	0.034					
	P (mW)		16.43		16.43		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			5.30			
	z_b (cm)					5.30	
	z_{MI} (cm)	0.50					
	$z_{PII.\alpha}$ (cm)	0.50					
	f_{awf} (MHz)	1.00	1.00		1.00		N/A
Other Information	*prr* (Hz)	2000.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	0.056					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	9.97					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	10.32					
	$p_{r.}$ at z_{PII} (MPa)	0.035					
Operating control conditions	Focus(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Depth(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Frequency(MHz)	1.00	N/A	1.00	N/A	1.00	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Acoustic Output Reporting Table for Track 1(Non-autoscanning Mode)

Transducer Model: US-TF
Nominal Frequency: 1.0MHz
Operating Mode: PW Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.034	9.97	0.056
Associated Acoustic Parameter	$p_{r.3}$ (MPa)		0.034		
	P_o (mW)			16.43	16.43
	f_c (MHz)		1.00	1.00	1.00
	Z_{sp} (cm)		0.50	0.50	0.50
	Beam dimensions	x_{-6} (cm)		0.42	0.42
		y_{-6} (cm)		0.40	0.40
	PD (usec)		90.97		90.97

	PRF (Hz)		2000.00		2000.00
	EBD	Az. (cm)		Φ3.46	
		Ele. (cm)		Φ3.46	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		1.0		

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: US-SF
Nominal Frequency: 1.0MHz
Operating Mode: PW Mode

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.046	0.010		0.15		N/A
Index component value			N/A	0.010	N/A	0.15	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	0.046					
	P (mW)		16.14		16.14		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			4.10			
	z_b (cm)					4.10	
	z_{MI} (cm)	0.50					
	$z_{PII.\alpha}$ (cm)	0.50					
	f_{awf} (MHz)	1.00	1.00		1.00		N/A
Other Information	*prr* (Hz)	2000.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	0.11					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	20.14					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	20.84					
	$p_{r.}$ at z_{PII} (MPa)	0.047					
Operating control conditions	Focus(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Depth(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Frequency(MHz)	1.00	N/A	1.00	N/A	1.00	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Acoustic Output Reporting Table for Track 1(Non-autoscanning Mode)

Transducer Model: US-SF
Nominal Frequency: 1.0MHz
Operating Mode: PW Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.038	14.17	0.079
Associated Acoustic Parameter	$p_{r.3}$ (MPa)		0.038		
	P_o (mW)			14.09	14.09
	f_c (MHz)		1.00	1.00	1.00
	Z_{sp} (cm)		0.60	0.60	0.60
	Beam dimensions	x_{-6} (cm)		0.36	0.36
		y_{-6} (cm)		0.45	0.45

	PD (usec)		91.78		91.78
	PRF (Hz)		2000.00		2000.00
	EBD	Az. (cm)		Φ2.65	
		Ele. (cm)		Φ2.65	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		1.0		

A4.6.2 Test of Wireless Transducer(F15 Air)

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: US-TAF
Nominal Frequency: 1.0MHz
Operating Mode: PW Mode

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.045	0.0076		0.082		N/A
Index component value			N/A	0.0076	N/A	0.082	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	0.045					
	P (mW)		11.41		11.41		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			5.25			
	z_b (cm)					5.25	
	z_{MI} (cm)	0.50					
	$z_{PII.\alpha}$ (cm)	0.50					
	f_{awf} (MHz)	1.00	1.00		1.00		N/A
Other Information	*prr* (Hz)	2000.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	0.12					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	21.18					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	21.93					
	$p_{r.}$ at z_{PII} (MPa)	0.046					
Operating control conditions	Focus(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Depth(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Frequency(MHz)	1.00	N/A	1.00	N/A	1.00	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Acoustic Output Reporting Table for Track 1(Non-autoscanning Mode)

Transducer Model: US-TAF

Nominal Frequency: 1.0MHz
Operating Mode: PW Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.045	21.18	0.12
Associated Acoustic Parameter	$p_{r.3}$ (MPa)		0.045		
	P_o (mW)			11.41	11.41
	f_c (MHz)		1.00	1.00	1.00
	Z_{sp} (cm)		0.50	0.50	0.50
	Beam dimensions	x_{-6} (cm)		0.53	0.53
		y_{-6} (cm)		0.44	0.44
	PD (usec)		89.52		89.52
	PRF (Hz)		2000.00		2000.00
	EBD	Az. (cm)		Φ3.46	
		Ele. (cm)		Φ3.46	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		1.0		

Acoustic output reporting table
(IEC60601-2-37:2007+AMD1:2015, table 201.103)

Transducer Model: US-SAF
Nominal Frequency: 1.0MHz
Operating Mode: PW Mode

Index label		*MI*	*TIS*		*TIB*		*TIC*
			At surface	Below surface	At surface	Below surface	
Maximum index value		0.036	0.0071		0.11		N/A
Index component value			N/A	0.0071	N/A	0.11	
Acoustic Parameters	$p_{r.\alpha}$at z_{MI} (MPa)	0.036					
	P (mW)		11.38		11.38		N/A
	P_{1x1} (mW)		N/A		N/A		
	z_s (cm)			4.05			
	z_b (cm)					4.05	
	z_{MI} (cm)	0.50					
	$z_{PII.\alpha}$ (cm)	0.50					
	f_{awf} (MHz)	1.00	1.00		1.00		N/A
Other Information	*prr* (Hz)	2000.00					
	srr (Hz)	N/A					
	n_{pps}	N/A					
	$I_{pa.\alpha}$ at $z_{PII.\alpha}$ (W/cm^2)	0.075					
	$I_{spta.\alpha}$ at $z_{PII.\alpha}$ or $z_{SII.\alpha}$(mW/cm^2)	13.57					
	I_{spta} at z_{PII} or z_{SII} (mW/cm^2)	14.14					
	$p_{r.}$ at z_{PII} (MPa)	0.037					
Operating control conditions	Focus(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Depth(mm)	Fixed	N/A	Fixed	N/A	Fixed	N/A
	Frequency(MHz)	1.00	N/A	1.00	N/A	1.00	N/A
NOTE: N/A indicates that there is no corresponding intended use or no data reported.							

Acoustic Output Reporting Table for Track 1(Non-autoscanning Mode)

Transducer Model: US-SAF

Nominal Frequency: 1.0MHz
Operating Mode: PW Mode

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (W/cm^2)
Global Maximum Value			0.036	13.57	0.075
Associated Acoustic Parameter	$p_{r.3}$ (MPa)		0.036		
	P_o (mW)			11.38	11.38
	f_c (MHz)		1.00	1.00	1.00
	Z_{sp} (cm)		0.50	0.50	0.50
	Beam dimensions	x_{-6} (cm)		0.49	0.49
		y_{-6} (cm)		0.44	0.44
	PD (usec)		91.41		91.41
	PRF (Hz)		2000.00		2000.00
	EBD	Az. (cm)		Φ2.65	
		Ele. (cm)		Φ2.65	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		1.0		

A4.6.3 Standard Parameter Equal Contrast List

IEC60601-2-37 standard parameter equal contrast list	
IEC60601-2-37 parameter	**NOTE**
$p_{r.\alpha}$	Attenuated Peak-rare-factional Acoustic Pressure
p_r	Peak-rare-factional Acoustic Pressure
P	Output Power
z_s	Depth for Soft Tissue Thermal Index
$P_\alpha(Z_s)$	Attenuated Output Power
$I_{ta.\alpha}(Z_s)$	Attenuated Temporal-average Intensity
z_{bp}	Break-point Depth
z_b	Depth for Bone Thermal Index
$I_{pi.\alpha}$	Attenuated Pulse-intensity Integral
I_{pi}	Pulse-intensity Integral
$d_{eq}(Z_b)$	Equivalent Beam Diameter at the point of Z_{sp}
f_{awf}	Center Frequency, Acoustic Working Frequency
X	-12dB Output Beam Dimensions
Y	
t_d	Pulse Duration
prr	Pulse Repetition Frequency (Pulse Repetition Rate)
d_{eq}	Equivalent Beam Diameter
FL_x	Focal Length

FL_y	
$I_{pi.\alpha}$ at max *MI*	Attenuated Pulse-average Intensity at the point of Maximum MI
A_{aprt}	-12dB Output Beam Area
MI	Mechanical Index
TIS	Soft Tissue Thermal Index
TIB	Bone Thermal Index
TIC	Cranial-bone Thermal Index

parameter specified in TRACK1 of FDA Guidance	
TRACK1 parameter	**NOTE**
$p_{r.3}$	Derated Peak-rare-factional Acoustic Pressure
W_0	Output Power
z_{sp}	$z_{sp} = z_{B.3}$, Depth for Bone Thermal Index
f_c	Center Frequency, Acoustic
x_{-6}	-6dB Beamwidth
y_{-6}	
PD	Pulse Duration
PRF	Pulse Repetition Frequency
MI	Mechanical Index
$I_{SPTA.3}$	Derated Spatial-peak Temporal-average Intensity
$I_{SPPA.3}$	Derated Spatial-peak Pulse-average Intensity
Az.	Aperture X width Y Dimeter
Ele.	
EDS	Entrance Dimensions Of The Scan
EBD	Entrance Beam Dimensions

Appendix 5 Abbreviation

The abbreviations used in this manual and their full names are listed below:

Abbreviation	Full Name
AC	Alternative Current
AFM	Automatic Fetal Movement [Detection]
BPM	Beat(s) Per Minute
CTG	Cardiotocography
DC	Direct Current
DECG	Direct ECG
DFHR	Direct FHR
DIA	Diastolic Blood Pressure
ECG	Electrocardiogram
FECG	Fetal Electrocardiogram
FH	Fetal Heart
FHR	Fetal Heart Rate
FM	Fetal Movement
MHR	Maternal Heart Rate
ICU	Intensive Care Unit
ID	Identity
IUP	Intra-Uterine Pressure
IUPC	Intra-Uterine Pressure Catheter
LCD	Liquid Crystal Display
MAP	Mean Artery Blood Pressure
MECG	Maternal ECG
MFM	Manual Fetal Movement [Detection]
MRI	Magnetic Resonance Imaging
NIBP	Non-Invasive Blood Pressure
NST	Non Stress Test
PR	Pulse Rate
RF	Radio Frequency
SOV	Signals Overlap Verification
SpO_2	Pulse Oximetry

STV	Short-Term Variation
SYS	Systolic Blood Pressure
TEMP	Temperature
TOCO	Tocotonometer
UA	Uterine Activity [TOCO/IUP]
US	Ultrasound [Transducer]

Appendix 6 Ordering Information

Accessories (standard and optional configuration) supplied or approved by the manufacturer can be used with the monitors. See the following table for details.

Part Number	Product Name	Model	Specification
02.01.214589	Ultrasonic Transducer	US-SF	US-SF, 7 Ultrasound Crystals,1MHz
02.01.214590	Ultrasonic Transducer	US-TF	US-TF, 12 Ultrasound Crystals,1MHz
02.01.214591	TOCO Transducer	TOCO-EF	TOCO-EF, TOCO&MECG Transducer
02.01.214592	Fetal & Maternal Module	DECG-IF	DECG-IF, DECG&IUP Transducer
02.01.214593	Ultrasonic Transducer	US-SAF	US-SAF, 7 Ultrasound Crystals,1MHz,Wireless
02.01.214594	Ultrasonic Transducer	US-TAF	US-TAF, 12 Ultrasound Crystals,1MHz,Wireless
02.01.214595	TOCO Transducer	TOCO-EA	TOCO-EA, TOCO&MECG,Wireless
02.01.214596	Fetal & Maternal Module	DECG-IA	DECG-IA , DECG&IUP,Wireless
01.57.471939	ECG Cable	DECG-FT	DECG-FT with TYCO Fetal Spiral Electrode
01.57.471940	ECG Cable	DECG-FP	DECG-FP with Philips Fetal Spiral Electrode
01.57.471941	ECG Cable	DECG-FQ	DECG-FQ with Copeland(Quik) Fetal Spiral Electrode
01.57.471942	ECG Cable	DECG-I	DECG-I ,DECG-IUP Adapter, DECG&IUP Integrated Cable
01.57.472211	ECG Cable	DECG-IK	DECG-IK,DECG-IUP Adapter, DECG&IUP Integrated Cable
01.57.471943	ECG Cable	MECG-3AS	MECG-3AS,Snap Style,AHA Standard
01.57.472126	ECG Cable	FECG-3ISU	FECG-3ISU,Snap Style,IEC Standard,Upper Interface
01.57.472127	ECG Cable	FECG-3ISL	FECG-3ISL,Snap Style,IEC Standard,Lower Interface
01.57.471944	ECG Cable	MECG-3IS	MECG-3IS,Snap Style,IEC Standard
02.57.225104	ECG Electrode	MECG-R	MECG-R,Reusable ECG electrode sleeve, with wired probe
02.01.215347	Fetal & Maternal Module	FECG-TA	FECG,Wireless
02.01.215348	Telemetry Transmitter	FT20	NIBP&SpO2,Wireless
01.57.471405	SpO2 Extension Cable	/	0.65m, 7pin, reusable
01.57.078008	Ultrasound Gel	/	MIBO

01.57.078001	Ultrasound Gel	/	PARKER
01.57.471447	Belt	/	1400mm*58mm
02.01.210095	Remote Event Marker	02.01.210095	REM,2.6m
02.01.210120	SpO2 Sensor	SH1	DB9,SH1,adult, 1m, reusable
02.57.225039	SpO2 Sensor	SH1	D Type 7Pin,SH1,adult, 1m, reusable
02.01.210122	SpO2 Sensor	SH4	DB9,SH4,adult, 1m, reusable
01.15.030043	SpO2 Sensor	DS-100A	DS-100A,NELLCOR
01.57.471068	7-pin SpO2 adapter cable	SHEC3	SHEC3,2.0m
01.57.471069	Nellcor SpO2 Extension cable	DOC10	DOC10,3m,D type connector,Compatible with Nellcor OXI-Max SpO2 module and Nellcor sensor
01.59.473007	NIBP Tube	BPT2	NIBP Tube,3m
01.57.471908	NIBP Tube	BPT3	NIBP Tube,1m
01.57.471330	NIBP Cuff	Adult E9	NIBP Cuff ,E9, Adult,27-35cm, reusable
01.57.471907	NIBP Cuff	Adult E9	IM3S Connector, NIBP Cuff ,E9, Adult,27-35cm, reusable
01.57.471331	NIBP Cuff	Large adult E10	NIBP Cuff ,E10, Large adult,34-43cm, reusable
01.57.471396	NIBP Cuff	Thigh E11	NIBP Cuff ,E11, Thigh,42-54cm, reusable
01.57.471861	ECG Electrode	31499224	REF: 31499224 COVIDIEN Kendall 210 Foam Electrodes,Single Use
01.57.002146	ECG Electrode	50000095	REF:50000095 COVIDIEN Kendall Fetal Spiral Electrode Attachment Pad,Large,Single Use
01.57.02145	Fetal Spiral Electrode	31479549	REF:31479549 COVIDIEN Kendall Fetal Spiral Electrode,Single Helix
01.57.104153	Intrauterine Pressure Catheter	56300	REF:56300 COVIDIEN Kendall Intrauterine Pressure Catheter,Transducer Tipped,Dual Lumen
01.15.040225	Temperature Probe	01.15.040225	TAS03-10,Skin,adult,3.0m,reusablel
01.57.471865	Thermosensitive Paper	/	GE, AHA Standard, with green safe range
01.57.471857	Thermosensitive Paper	/	GE, IEC Standard
01.57.471867	Thermosensitive Paper	/	Phillips, AHA Standard

01.57.471868	Thermosensitive Paper	/	Phillips, IEC Standard
01.13.037122	Power Cord	/	AHA Standard
01.21.064381	Battery	ID996, Rechargeable Lithium-ion Battery ,	5100mAh
01.21.064414	Switching Power Adaptor	UES18LCP-050300SPA	5V/3A TYPE C
01.12.032797	UL AC PLUG	LCP-UL-A	LCP-UL-A Use with 01.21.064414 switch power adapter
02.01.216110	F15 wireless probe wall bracket assembly	/	/
02.01.216111	F15 Wired Probe wall bracket assembly	/	/
02.01.216112	F15 wireless probe trolley hanger assembly	/	/
02.01.216113	F15 cable probe trolley hanger assembly	/	/
01.13.037903	Type C USB cable	/	/
01.56.467039	FT20 String	/	/
83.62.461069	Trolley(For medical use)	MT-811	/
83.62.002271	Trolley(For medical use)	MT-803	/
83.62.460981	Trolley(For medical use)	MT-503	/
02.01.216110	Charger Stand	CS-15	Wall Mounting
02.01.216112	Charger Stand	CS-15	Trolley

CAUTION

Replacement of all above accessories can be performed by the operator. But only the accessories supplied or recommended by the manufacturer are allowed connected to the monitor.

Appendix 7 EMC Information

A7.1 Electromagnetic Emissions

Guidance and manufacture's declaration – electromagnetic emission		
The *F15 Series Fetal & Maternal Monitors* are intended for use in the electromagnetic environment specified below. The customer of the user of the *F15 Series Fetal & Maternal Monitors* should assure that it is used in such and environment.		
Emission test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	The *F15 Series Fetal & Maternal Monitors* use 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.
RF emission CISPR 11	Class A	The *F15 Series Fetal & Maternal Monitors* are suitable for use in all establishments, other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

A7.2 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The *F15 Series Fetal & Maternal Monitors* are intended for use in the electromagnetic environment specified below. The customer or the user of *F15 Series Fetal & Maternal Monitors* should assure that it is used in such an environment.			
Immunity test IEC 60601 test level	**Compliance level**	**Electromagnetic environment - guidance**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floor 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	± 2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	± 1 kV line(s) to line(s) ± 2 kV line(s) to ground	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % $U_{T;}$ 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	0 % $U_{T;}$ 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles) Single phase: at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the *F15 Series Fetal & Maternal Monitors* requires continued operation during power mains interruptions, it is recommended that the *F15 Series Fetal & Maternal Monitors* be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the a.c. mains voltage prior to application of the test level.			

Test Levels

RFID Specification	Frequency	Test level (RMS)	Result
ISO 14223	134.2 kHz	65 A/m	Complies
ISO/IEC 14443-3 (Type A)	13.56 MHz	7.5 A/m	Complies
ISO/IEC 14443-4 (Type B)	13.56 MHz	7.5 A/m	Complies
ISO/IEC 15693 (ISO 18000-3 Mode 1)	13.56 MHz	5 A/m	Complies
ISO 18000-3 Mode 3	13.56 MHz	12 A/m	Complies
ISO/IEC 18000-7	433 MHz	3 V/m	Complies
ISO/IEC 18000-63 Type C[a]	860-960 MHz	54 V/m	Complies
ISO/IEC 18000-4 Mode 1	2.45 GHz	54 V/m	Complies

NOTE:

Keep RFID readers away from the device.

A7.3 Electromagnetic Immunity

Guidance and manufacture's declaration – electromagnetic immunity			
The *F15 Series Fetal & Maternal Monitors* are intended for use in the electromagnetic environment specified below. The customer or the user of *F15 Series Express Fetal & Maternal Monitors* should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 6Vrmsc)in ISM bands between 0,15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz	3Vrms 6Vrmsc)in ISM bands between 0,15 MHz and 80 MHz 3 V/m 80 MHz to 2.7 GHz	Portable and mobile RF communications equipment should be used no closer to any part of the *F15 Series Fetal & Maternal Monitors* including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$ 150 kHz to 80 MHz $d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.7 GHz $d = 6\sqrt{P}/\mathrm{E}$ at RF wireless communications equipment bands (Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the monitor, including cables specified by the manufacturer). Where *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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a)] should be less than the compliance level in each frequency range.[b)] Interference may occur in the vicinity of equipment marked with the following symbol: 

NOTE 1: At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/wireless) 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 *F15 Series Fetal & Maternal Monitors* are used exceeds the applicable RF compliance level above, the *F15 Series Fetal & Maternal Monitors* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *F15 Series Fetal & Maternal Monitors*.

b) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

c) The ISM (industrial, scientific and medical) bands between 0.15 MHz and 80 MHz are 6.765 MHz to6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz. The amateur radio bands between 0.15 MHz and 80 MHz are 1.8 MHz to 2.0 MHz, 3.5 MHz to 4.0 MHz, 5.3 MHz to 5.4 MHz, 7 MHz to 7.3 MHz, 10.1 MHz to 10.15 MHz, 14 MHz to 14.2 MHz, 18.07 MHz to 18.17 MHz,21.0 MHz to 21.4 MHz, 24.89 MHz to 24.99 MHz, 28.0 MHz to 29.7 MHz and 50.0 MHz to 54.0 MHz.

Table-Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Brand [a] (MHz)	Service [a]	Modulation [b]	Maximum Power(W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation[b] 18Hz	1.8	0.3	27
450	430-470	GMRS 460, FRS 460	FM [C] ±5 kHz deviation 1kHz sine	2	0.3	28
710	704-787	LTE Brand 13, 17	Pulse modulation[b] 217 Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation[b] 18 Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation[b] 217 Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Brand 7	Pulse modulation[b] 217 Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation[b] 217 Hz	0.2	0.3	9
5500						
5785						
Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting						

antenna and the ME EQUIPMENT or ME SYSTEM maybe reduce to 1m. The 1 m test distance is permitted by IEC 61000-4-3.
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) As an alternative FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case

A7.4 Recommended Separation Distances

Recommended separation distances between

portable and mobile RF communications equipment and the

***F15 Series* Fetal & Maternal Monitors**

The *F15 Series Fetal & Maternal Monitors* are intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the *F15 Series Fetal & Maternal Monitors* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *F15 Series Fetal & Maternal Monitors* as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter (W)	**Separation distance according to frequency of transmitter (m)**		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2.7 GHz** $d = 2.3\sqrt{P}$
0.01	**0.12**	**0.12**	**0.23**
0.1	**0.38**	**0.38**	**0.73**
1	**1.2**	**1.2**	**2.3**
10	**3.8**	**3.8**	**7.3**
100	**12**	**12**	**23**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Appendix 8 Limitations of Ultrasonic Monitoring

A8.1 How Does Ultrasound Work

When the ultrasound waves strike an object, they bounce back and create an echo. If the object moves toward the sound source, the frequency of the echo increases. If the object moves away from the sound source, the frequency of the echo decreases. This is called “Doppler Effect”. In the 1960's, the ultrasonic technique was first applied to medical diagnostic imaging.

The ultrasound process involves placing a small device called a transducer, against the skin of the patient near the region of interest. The ultrasound transducer combines functions of emitting and receiving ultrasounds in one device. This transducer produces a stream of inaudible, high frequency sound waves which penetrate into the body and bounce off the organs inside. It detects sound waves as they bounce off or echo back from the internal structures and contours of the organs. The movement of the organs produces the Doppler Effect, and this movement can be measured and described by measuring the echo.

In fetal monitoring, the ultrasound transducer produces a stream of sound waves which penetrate into the maternal abdomen and bounce off the fetal heart. Then the transducer receives the echoes and transfers them to the monitor, which turns the signal into fetal heart beating sound and fetal heart rate trace.

Therefore, placement of the transducer is critical to ultrasound fetal heart monitoring.

A8.2 Artifacts in Fetal Heart Monitoring

(1) How does artifact happen?

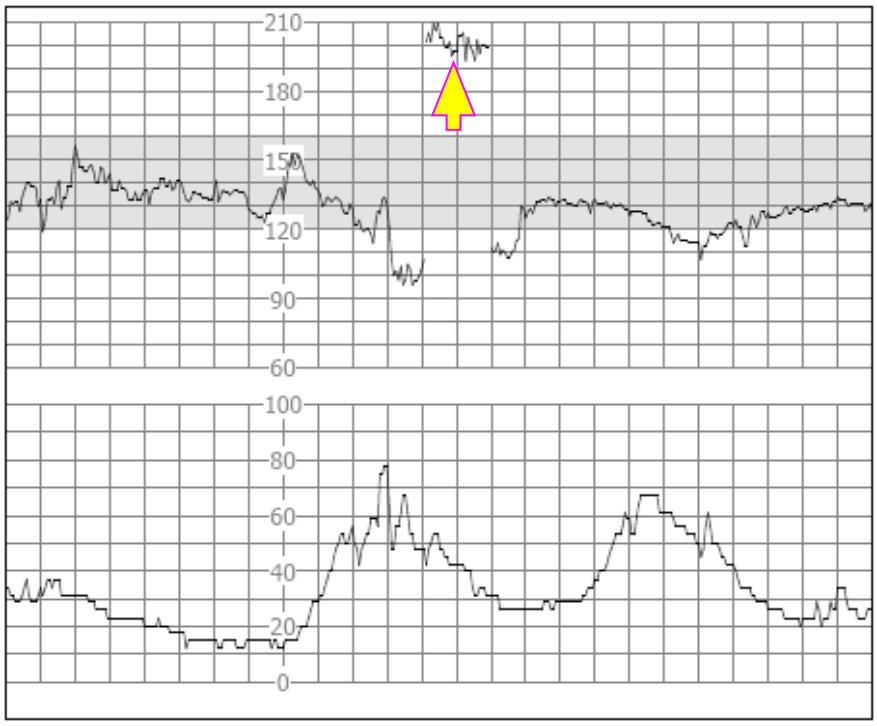
The transducer detects sound waves as they bounce off or echo back from the fetal heart. However, the sound waves bouncing off from maternal blood vessels may be detected by the transducer and then be processed by the monitor as well. As a result, artifacts may be produced.

The artifacts, if not correctly interpreted, may cause the physicians to perform unnecessary interventions, or to fail to detect the fetal distress and the need for interventions.

The most common artifacts are doubling, halving, erratic traces / drop out and switching to maternal heart rate.

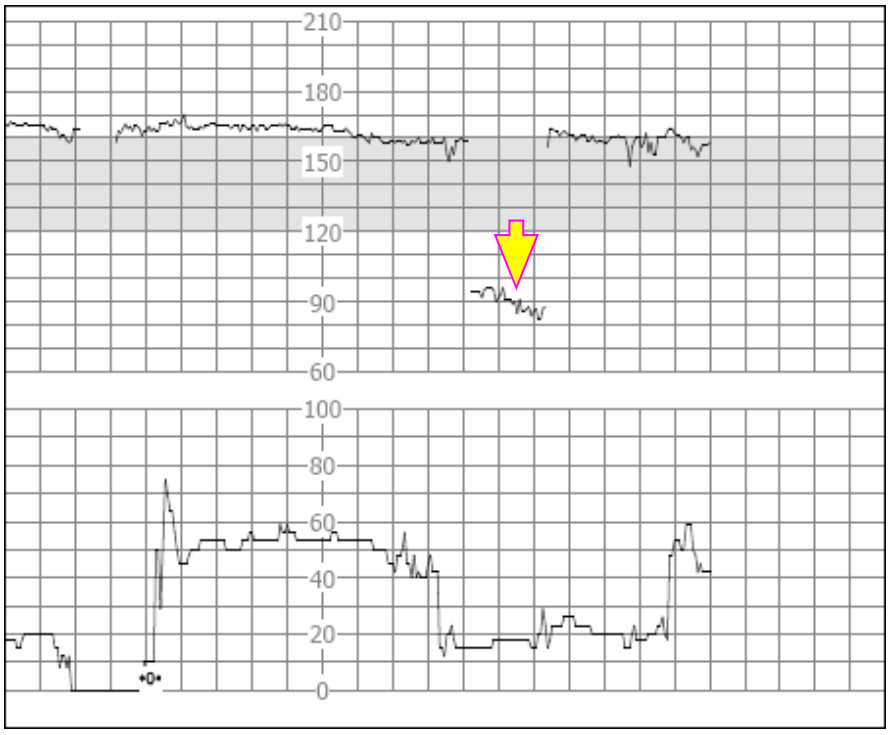
(2) Doubling:

When the FHR drops to 120 bpm or lower, the diastole and systole become far apart, thereby the monitor may mistake these two movements of a single heartbeat for two separate heartbeats. As a result, a heart rate trace that is double the actual heart rate is produced. This often happens during severe decelerations and bradycardia, representing an abrupt switch of the trace to double the actual heart rate.



(3) Halving:

When the FHR increases to 180 bpm or higher, it is possible for the monitor to mistake the two separate hearbeats for the diastole and systole of a single heartbeat. As a result, a heart rate trace that is half the actual heart rate is produced. This often happens during tachycardia, representing an abrupt switch of the trace to half the actual heart rate. The clinicians may interpret it as a “deceleration”.



However, the heart beat sound from the monitor speaker is still reliable even when doubling or halving is occurring.

Stethoscopy should be applied when sudden changes in baseline are detected.

If the amniotic membrane rupture and cervical dilatation are sufficient, consider using a spiral

electrode to obtain precise FHR with direct fetal ECG as the signal source.

(4) Erratic Traces / Drop out

When the fetal heart moves partially out of the ultrasound wave path, the transducer receives mixed or weak signals, and thereby the monitor presents erratic traces. When the fetal heart moves fully out of the path, inadequate consecutive and periodic signals are received, and no trace is represented.

Erratic traces and transitory episodes of drop out are common, especially when the fetus or/and mother move(s). If they exist for an extended period, it indicates that the transducer is not aimed at the fetus. Repositioning of the transducer is needed.

(5) Switching to maternal heart rate

When the fetal heart moves partly or fully out of the ultrasound beam, the transducer receives weak fetal heart signal and other strong signal (usually maternal heart signal). After the mixed signals are transferred to the monitor, as the fetal heart signal is too weak or lost, the maternal heart signal plays a leading role and the monitor picks up and displays the maternal heart rate.

When the maternal heart rate is relatively low, the switch to the maternal heart rate may simulate an FHR deceleration.

When the maternal heart rate is relatively high, the switch to the maternal heart rate may simulate a normal fetal heart rate pattern, which may cover FHR deceleration or fetal demise.

With twins or multiple fetuses, the potential to experience these artifacts is increased.

➢ **The following points shall be noticed in order to keep a good capture effect of ultrasound transducer for a long time:**

1. If the fetal heart sound is heard from loudspeaker, while the FHR traces in chaos, or not stable. This is because the transducer is placed at back of fetus, please adjust the position of transducer.
2. The FHR trace is not recorded well after fetal movement or change of mother's position. This is because the movement of the location of fetal heart which makes the ultrasound transducer deviated from the fetal heart.
3. The FHR trace is in chaos or interrupted during uterine contraction. This is because the fetus moves downward at that time. In order to avoid the situation, please fix the transducer at the position 1-2 cm lower than the transducer position when there are no contractions.
4. Apical abdomen may make fetal heart transducer move easily and difficult to record FHR trace, thus please fix the transducer in caution and adjust it in time.
5. Urine increase makes distention of bladder and then leads to deviation of ultrasound transducer from the fetal heart, thus please remind the patient to urinate.
6. Long time monitoring makes the couplant decrease, so that the ultrasound transducer cannot work normally, thus please supplement the couplant.
7. If the fetus is in occipitoposterior position due to fetal descent and rotation, and fetal back moves to the direction of maternal back, making monitoring become difficult. In this case please move the ultrasound transducer to the middle of abdomen below navel.
8. If the obvious fetal heart deceleration is heard, while the FHR trace display or record is not consistent with the sound, the sound from loudspeaker shall prevail, on the premise that the sound is indeed from the fetus, not mother by confirmation in other ways.
9. If the monitor alarms automatically, besides considering the fetus is in danger, the ultrasound transducer deviating from the optimum position should also be taken into consideration.

A8.3 Audio Output and Screen Reading

In most instances, the audio output from the monitor speaker corresponds to the readings presented on the monitor screen. But occasionally the fetal heart sound may differ from the trace and numeric.

When the fetal heart moves partially out of the ultrasound wave path, the transducer receives weaker FHR signal and other stronger signals (usually maternal heart/pulse rate). After the signals are transmitted to the monitor, the audio system and the video system of the monitor process the signals separately. On one hand, the audio circuit filters the low-frequency signals and gives audio output of

the high-frequency signals, so fetal heart sound is heard. On the other hand, the autocorrelation algorithm computes the stronger signal source and thereby the maternal heart/pulse rate is displayed. As a result, the audio output differs from the screen reading.
If this situation occurs, it can be dismissed by repositioning the transducer.

In a word, the abnormalities listed above (artifacts, sound and reading differences) are caused by the limitations of ultrasonic monitoring technique. Fortunately they rarely occur. But a good understanding of how to detect them and what countermeasures should be taken will help obtain better fetal monitoring effect.

We hope you find this information useful. If you have any questions about fetal monitoring, please contact our sales representatives and perinatal specialists.

Appendix 9 WI-FI Networking and Instructions

A9.1 General

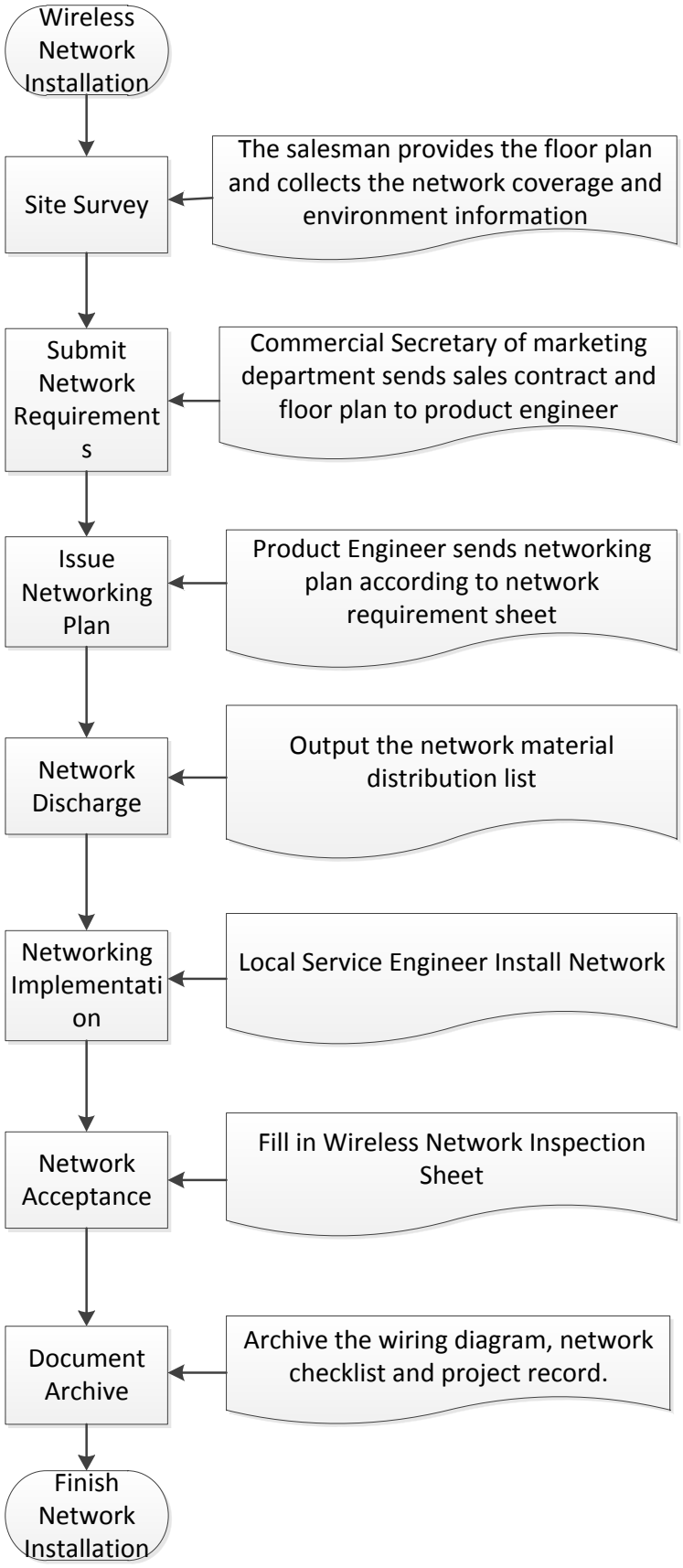
1. In order to standardize the implementation of the national network construction project of EDAN and unify the technical standards and requirements for construction work, this specification is specially formulated.
2. All equipment specifications and quality requirements of the construction shall comply with the provisions of this specification, design plan documents and contracts. Equipment that has not been qualified shall not be used in the construction of the project.
3. If the design plan or substitute materials need to be modified during the construction process, it must be approved by the design unit.
4. The main responsibility of the design unit is to design and plan the entire network, usually the customer service department takes the responsibility.
5. The wireless device must use the equipment recommended by EDAN, otherwise it may cause abnormal conditions such as frequent dropout of the monitor.

A9.2 Scope of Application

Product Name: Maternal / Fetal Monitor

Product model: F15, F15 Air

A9.3 Network Installation Process



A9.4 Site Survey and Network Requirements

Documents and tools to carry: related construction documents, tape measures, digital cameras,

laptops with WirelessMon or Android phones with inSSIDer software.

After arriving at the construction site, the sales or after-sales engineer immediately contact the relevant person in charge of the hospital to communicate and confirm the actual signal coverage, the placement of the monitor, the information on the number of co-frequency signal devices in the vicinity, and finally summarize the information to customer service engineer of domestic/international marketing for discharging. .

Survey the following items:

1) The overall building (room layout).

   -Building floor plan/size, room size

   - Take a picture of the fire evacuation plan of each floor of the hospital

   - The location and size of the ward's toilet should be indicated on the floor plan

   - load-bearing wall/beam, wall thickness, walkway corner

   - Decoration materials (metal, glass, brick, wood, etc.)

   - ceiling structure

   - room use and functional identification of each area

   The picture of above information is best taken on-site to the product engineer for reference.

   - Finally output the floor plan and wall thickness of the entire ward.

2) Signal coverage area

3) Placement of the central monitoring system, each F-series fetal monitor fixed location and its moving area.

4) The number of wireless networks in the coverage area.

5) Power supply conditions.

6) Number of devices and installation location.

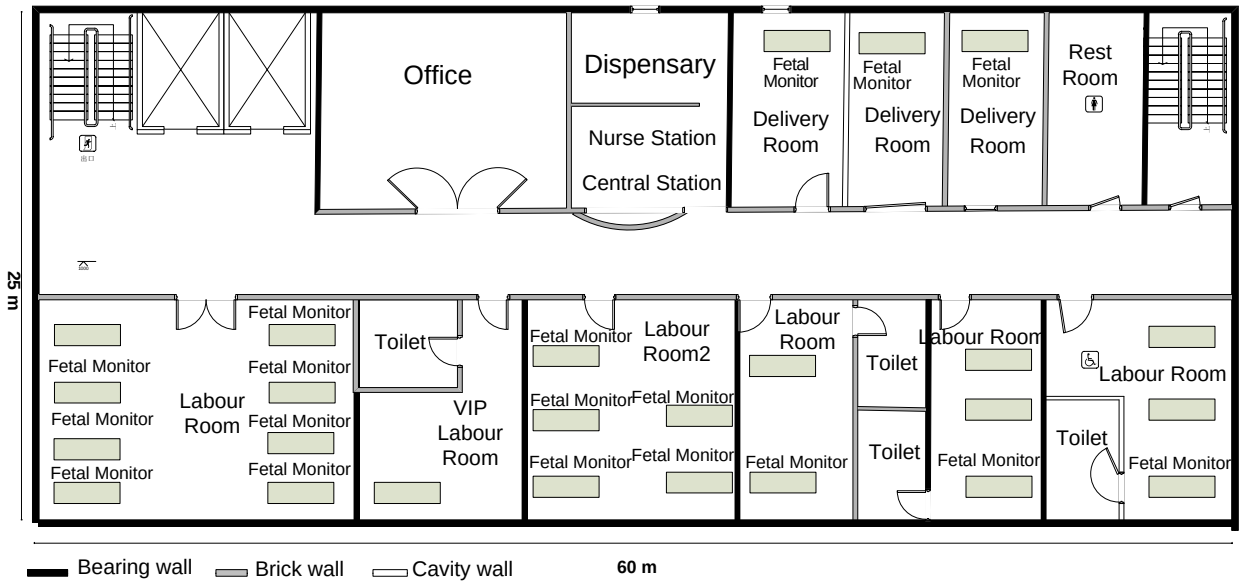
7) Contact information of users and agents.

Before the start of construction, negotiate the construction time limit and the issue of punching through the wall with the relevant person in charge of the hospital. Based on the above survey results, submit the network plan and network requirements table.

Network Plan

Network of XX Hospital

Note 1:
1. The wireless signal shall cover all marked labour rooms and delivery rooms.
2. The wall of inpatient ward is thick brick wall, the roof of corridor and rooms is the movable ceiling, with material gypsum, height 3 m from the ceiling to the ground.
3. The wall of delivery room is thick brick wall, with the door made of metal.
4. The toilet position is as shown in the figure.



A9.5 Network Design and Implementation

A9.5.1 Networking Scheme

F15 mainly involves networking between the bedside monitor and the central station; F15 Air not only involves networking between the bedside monitor and the central station, but also networking between the wireless transducer and monitor.

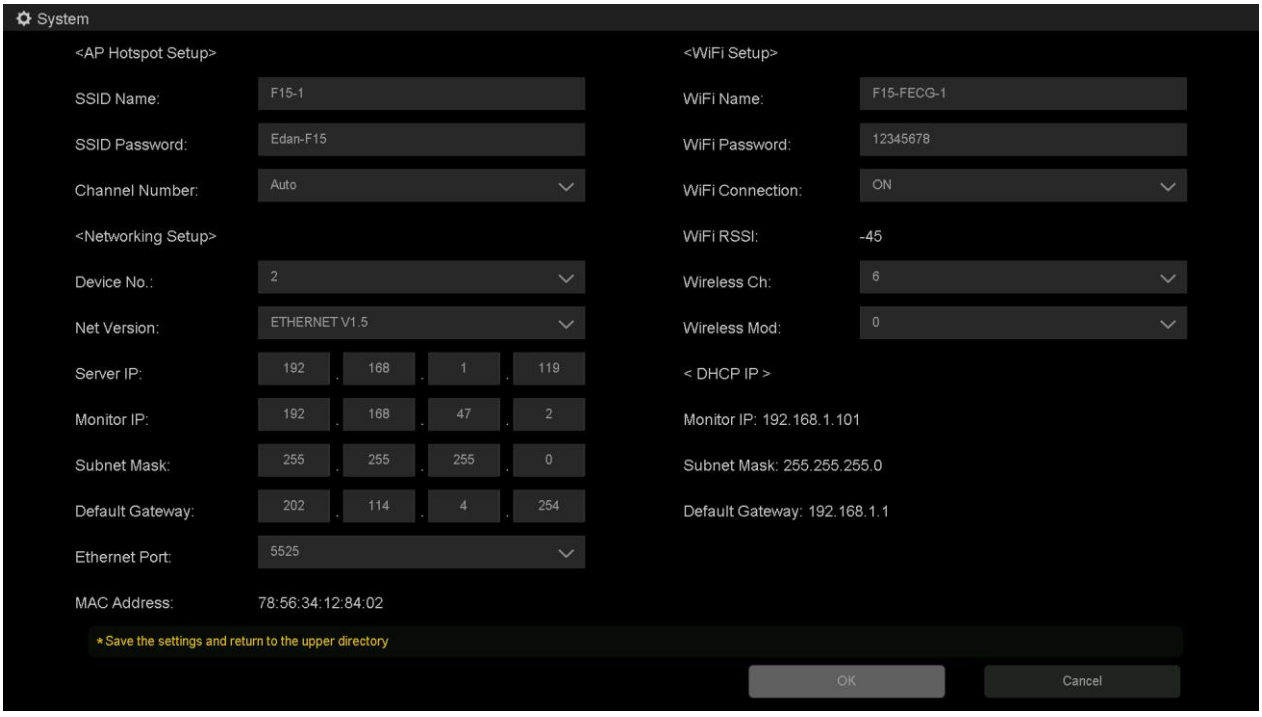
Wireless transducers and monitors have the following requirements for wireless coverage:

NO.	Item	Monitor Requirements	Description
1	Equipment compatibility	It is recommended to use the model recommended by EDAN	Recommended to meet
2	802.11 protocol	802.11 a/b/g/n requirements are met	Required to meet.
3	Spatial signal strength	≥-65dBm The signal coverage requirement of the AP connected to the monitor is the RSSI value felt by the monitor.	Required to meet.
4	Co-channel interference	≤ -20dB Measurement within the monitor's working channel	Required to meet.
5	Adjacent frequency interference	≤15dB Measurement around the monitor's working channel Recommended to meet, can improve the SNR of Wi-Fi	Required to meet.

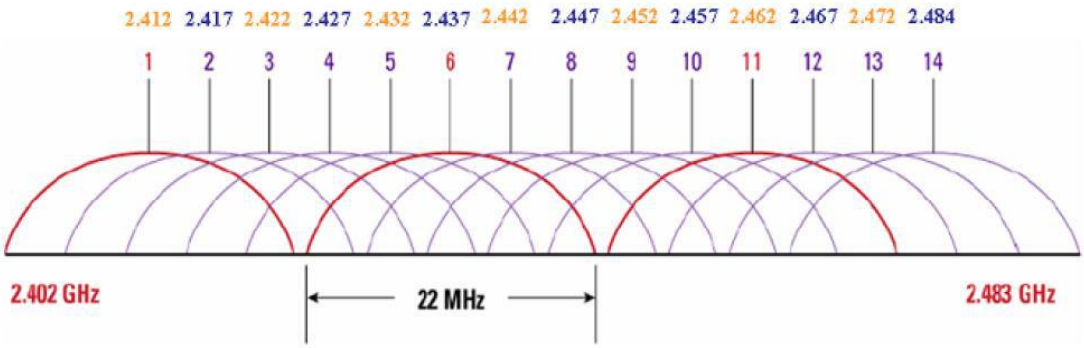
6	Other interference Bluetooth, zigbee, cordless phone, walkie-talkie, etc.	Bluetooth, zigbee, wireless phones, interphones need to be more than 20cm away from the monitor, microwave ovens and so on need to be more than 1m away. These devices will reduce the SNR of Wi-Fi	Required to meet.
7	Bandwidth	The average throughput requirement for a single monitor is 330 kbps, and a 50% throughput derating is recommended. For example, if there are 16 monitors that require 5.3 Mbps of bandwidth, the monitor needs to plan for at least 10 Mbps throughput.	Required to meet.
8	Ping Delay and Jitter	Ping the monitor from the central station, confirm the delay is less than 500ms, the jitter is less than 100ms It needs to be tested when other equipments in the hospital are running.	Required to meet.

Please pay attention that Edan recommends to use AP DLINK DAP2230 for Wi-Fi networking between monitor and central station, and the signal strength observed on the monitor end should be no less than -45dB.

The observation interface: Menu→System Setup→Networking Setup



Instruction:



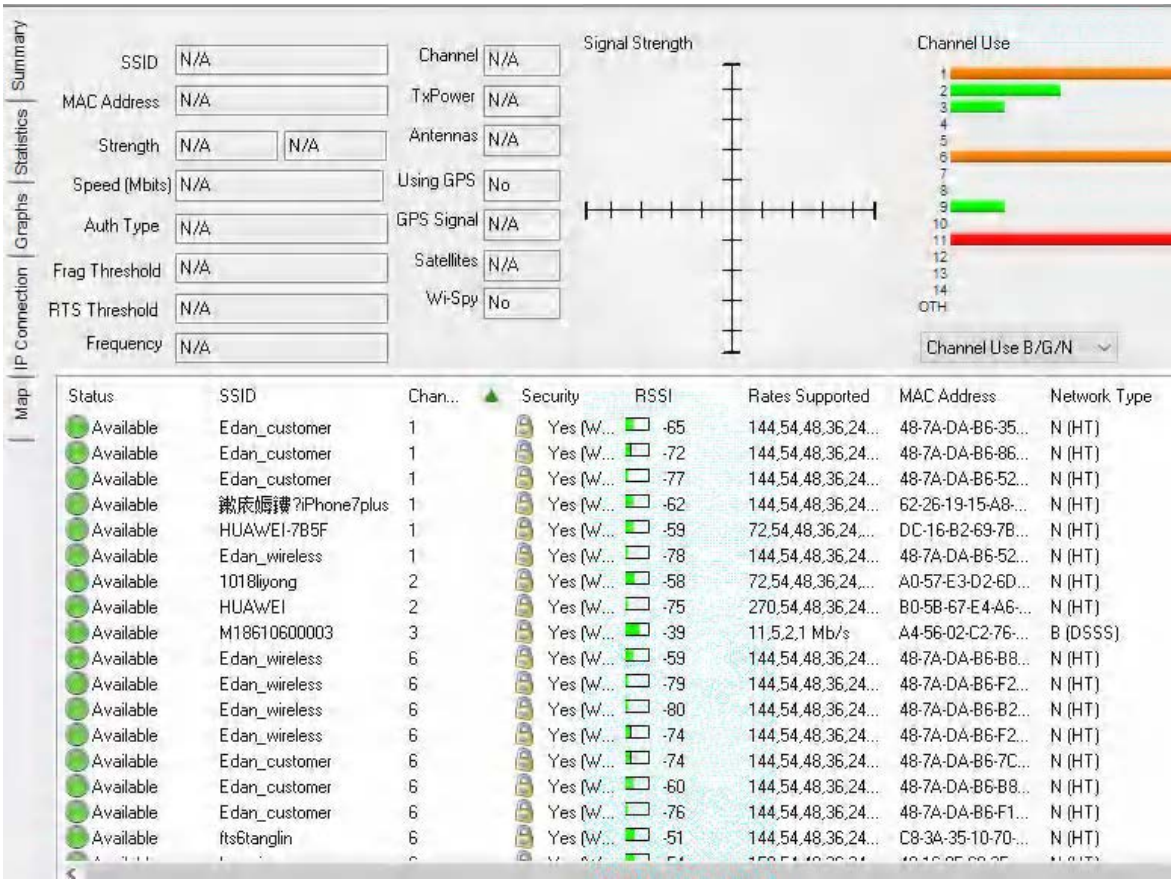
WiFi has a total of 14 channels, as shown in the figure above: IEEE 802.11b/g standard works in 2.4G frequency band, frequency range is 2.400-2.4835GHz. A total 83.5M bandwidth is divided into 14 sub-channels, and each sub-channel width is 22MHz. The center frequency of adjacent channels is 5MHz apart, and adjacent channels have overlapping frequencies. For example, channel 1 and channel 2, 3, 4, 5 have frequency overlap, only 3 channels (1, 6, 11) in the entire frequency band don't interfere with each other. According to the above figure, it can be seen very intuitively that the required co-channel frequency interference and adjacent frequency interference are defined. For example, AP works on channel 6, only APs of channel 1, 11, 12, 13, 14 do not interfere with the data transmission of F15, other channels more or less will interfere, especially channel 6 is same frequency, and it should be guaranteed that the co-channel interference on the channel must be less than -20dB, for other adjacent channels 2, 3, 4, 5, 7, 8, 9, 10, interference must be less than 15dB.

Wireless transducer network acceptance criteria:

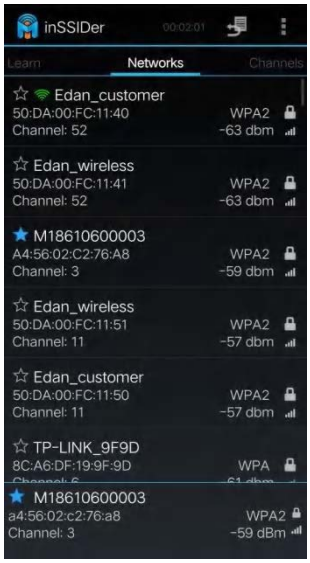
1. For the coverage of the wireless transducer and monitor, i.e., the range of use, the signal strength of the test point is required to be >-65dBm. The selection of the test point needs to cover signal strength test on the abdomen of the stimulated user (i.e.customer service engineer) during sitting, lateral position and lying, at the same time, the co-channel interference and adjacent frequency interference should be tested.
2. PING testing every monitor and transducer in the whole set of system, average delay and jitter should meet the requirements.

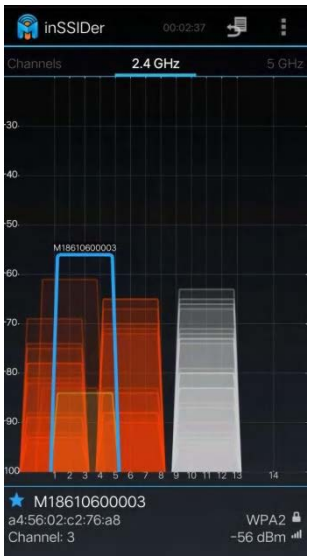
The sample test is as follows:

Step 1: Scan the signal strength of the AP in the environment:

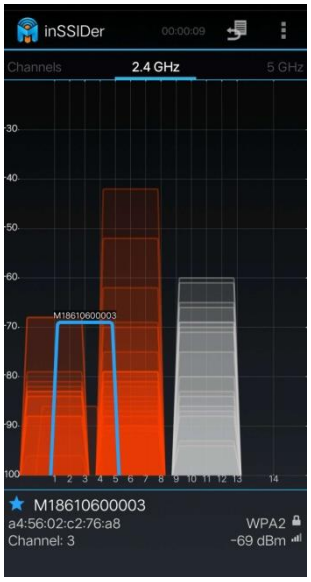


The above picture is a network scanned by a notebook. The AP is set to channel 3, so there is no AP on the channel, and the adjacent channel signal is also weak. It is not very intuitive to look at the WINDOWS software of the notebook. Using the software in the Android phone is as follows:





The selected channel 3 is relatively better in the available 1-13 channels. After the test, place the transducer far away and test the signal strength:



As shown in the above figure, channel 1 and 6 strongly interfere with the AP. In this case, the hospital needs to adjust the channel that interferes with the AP, remove or close the AP. Otherwise, dropouts will happen during data transmission.

Step 2: Use the PC host for PING test:

The transducer is on the monitor, and by connecting to the AP, the PING test is as follows:

C:\Users\Administrator>ping 192.168.1.166 –n 10

Ping 32-byte data from 192.168.1.166:

Response from 192.168.1.166: byte=32, time=44ms, TTL=128

Response from 192.168.1.166: byte=32, time=20ms, TTL=128

Response from 192.168.1.166: byte=32, time=19ms, TTL=128

Response from 192.168.1.166: byte=32, time=14ms, TTL=128

Response from 192.168.1.166: byte=32, time=11ms, TTL=128

Response from 192.168.1.166: byte=32, time=27ms, TTL=128

Response from 192.168.1.166: byte=32, time=44ms, TTL=128

Response from 192.168.1.166: byte=32, time=20ms, TTL=128

Response from 192.168.1.166: byte=32, time=18ms, TTL=128

Response from 192.168.1.166: byte=32, time=32ms, TTL=128

Ping statistical information of 192.168.1.166:

Data package: sent=10, received=10, lost=0 (0% lost),

Estimated time (in milliseconds) for round trip:

Shortest=11 ms, longest=44 ms, average=24 ms

Network delay = 44ms; meet the requirements;

Network jitter = max (44-11, 44-24) = max (33, 20) = 33ms; meet the requirements

Take the transducer to the position where the pregnant woman is doing the fetal monitoring. Pass the PING test as follows:

C:\Users\Administrator>ping 192.168.1.166 –n 10

Ping 32-byte data from 192.168.1.166:

Response from 192.168.1.166: byte=32, time=62ms, TTL=128

Response from 192.168.1.166: byte=32, time=29ms, TTL=128

Response from 192.168.1.166: byte=32, time=46ms, TTL=128

Response from 192.168.1.166: byte=32, time=39ms, TTL=128

Response from 192.168.1.166: byte=32, time=57ms, TTL=128

Response from 192.168.1.166: byte=32, time=14ms, TTL=128

Response from 192.168.1.166: byte=32, time=31ms, TTL=128

Response from 192.168.1.166: byte=32, time=28ms, TTL=128

Response from 192.168.1.166: byte=32, time=20ms, TTL=128

Response from 192.168.1.166: byte=32, time=39ms, TTL=128

Ping statistical information of 192.168.1.166:

Data package: sent=10, received=10, lost=0 (0% lost),

Estimated time (in milliseconds) for round trip:

Shortest=14 ms, longest=62 ms, average=36 ms

Network delay = 62ms; meets the requirements;

Network jitter = max (62-14, 62-36) = max (48, 26) = 48ms; meet the requirements;

Note that, in this environment, the AP's channel selection method is:

1. Channel 1, 6, 11 can not be selected unless you can communicate with the hospital to clear out a clean channel, otherwise the co-channel interference is too large to meet the requirements;
2. Compared with other channels, the signal strength of channel 6 and 11 is too high to meet the requirements, and only channel 2, 3, 4, and 5 can be selected. Channel 3 is the best choice at present;
3. When the customer service engineer scans the channel, not only the nearby AP signal intensity distribution around the monitor should be scanned, but also the AP signal strength near the location of all transducers should be tested. These places also have strong interference to wireless transmission;
4. For the interference of the wireless channel, it would be better to communicate with the customer clearly the reason for the disconnection is that the wireless resources are occupied, and the hospital needs to clear the AP, and otherwise there is a disconnection situation. Our software has the function of continuous transmission from disconnection to guarantee the data integrity, but short-lived data loss can occur, causing fetal heart sound interruptions and dropout alarms.

A9.5.2 Wireless Model Network Design

All wireless transducers are connected to the internal AP. The SSID, password and channel number can be set in the AP to ensure the accuracy of the network. The frequency resource of Wi-Fi determines that there are only 13 channel resources, and the channel bandwidth of the b mode is only 10 Mbps. The channel settings when multiple sets of machines are used at the same time must be paid attention to in order to avoid conflicts and interferences affecting the overall use.

When using multiple sets of monitors at the same time, you need to pay attention to channel distribution and bandwidth distribution:

For bandwidth distribution, according to the requirements of this paper, 16 similar monitors can be accommodated at most within a single channel in consideration of 50% of derating and ensure half of the bandwidth is idle.

For channel distribution, it is necessary to set more than 2 channels apart from channels whose

occupancy exceeds 50% to ensure that sufficient bandwidth can be used in the channel for the monitor so as to avoid frequent disconnection and interference.

Therefore, the following principles must be followed for channel settings for multiple sets of monitors:

1. For the same channel monitor, the physical distance is recommended to be kept above 20m to ensure mutual interference is minimized.
2. If the same channel number cannot be avoided within the range of 20m, it is necessary to control the number of monitor of which the same channel number should be no more than 16 units.
3. For monitors within 1m, the channel interval should be set above 2 channels. For example, if the channel of a monitor is set to 6, then the B monitor needs to be set to channel below 3 or above 9.
4. When using the transducer, ensure that the signal strength of the transducer is above 1 grid (the signal strength RSSI value is above -65dBm) and the signal strength is greater than the interference. For installation position of the monitor, test the signal quality in the range that the hospital wants to cover the monitors, and make sure the signal strength is above 1 grid.
5. At the same time, it is necessary to demand the hospital to ensure there are no Wi-Fi devices that occupy 50% of the channel for a long time in the surrounding environment.
6. For the network channel number of transducer AP, it should be set more than 3 channels' interval from the built-in Wi-Fi network card channel number to avoid mutual interference.

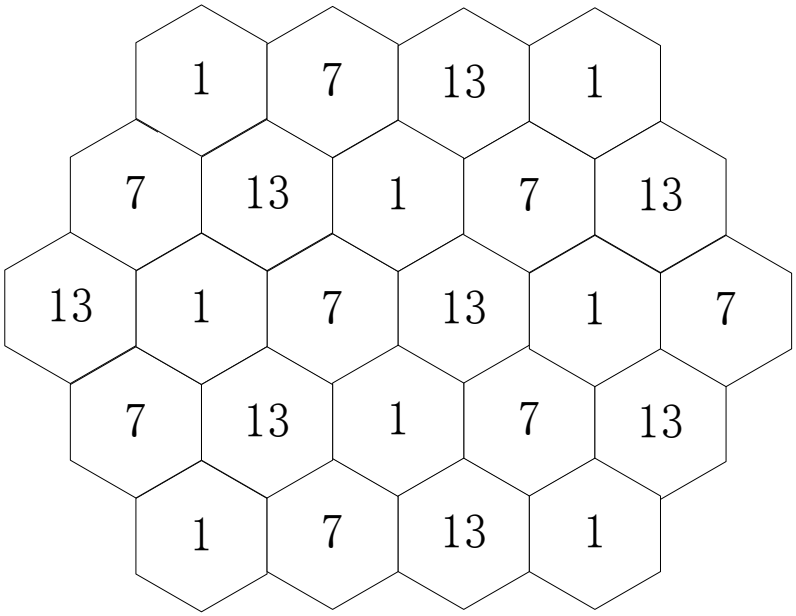
For the Wi-Fi network connected to the central station, it should be noted that the channel number should be 3 channels' interval from the AP built-in network, so there are two types of networking:

1 The Wi-Fi networking channel number between all the monitors and the central station can be set to channel 1, and the AP built-in network is set from channel 6 to ensure that the mutual interference between the two networks in the monitor is minimized. Similarly, the central station Wi-Fi networking can be set to channel 13 , and then the AP built-in network channel number can be set to channel 1~7 . For single monitor channel setup, refer to the previous paragraph, AP built-in network setup requirements.

For Wi-Fi hotspots, hotspots are placed at intervals. The coverage distance of hotspots is less than 20m. All hotspots are set to the same channel number to ensure that the interference between the Wi-Fi network of the central station and the monitor transducer AP network is minimized. The channels of Wi-Fi modules of all monitors connected to central stations are unified on one channel. The channel capacity is limited. The amount of data that a single monitor connecting to the central station is 12 kbps. The number of monitor that can be connected to a single AP is large, and there are no big communication conflicts.

This scheme is applicable to scenarios where there are many wireless models, central station network is not frequently used, and there are other Wi-Fi devices in the environment. Other devices that may interfere can be set near channel 10 to ensure mutual interference is minimized.

2 Considering the interference between the hotspots is the smallest for the Wi-Fi network of the central station, and the method of cellular network deployment can be adopted. The hotspots of the Wi-Fi network of the central station adopt the maximum channel spacing, and the interval is more than 6 with 1, 7, 13 next to each other, the interference of each hot spot can be minimized.



For transducer AP network, the monitor and the central station Wi-Fi hotspot should be 3 channels' interval from each other:

When channel 1 is selected for the built-in central station Wi-Fi, then for the monitor transducer AP network channel number, select channels above 4 and ensure that the channel interval in the monitor is more than 3 channels, and the channel can be set among channel 4~13;

Set the built-in central station network Wi-Fi to channel 7 and the transducer AP network to channel 1~3 and 11~13;

The channel number of the built-in central station network Wi-Fi is set to 13, and the transducer AP network is set at 1~9;

The network deployment scheme is applicable to a scenario where there are fewer wireless models, more wired models, and central station networking is frequently used. If there's public Wi-Fi network, large data transmission, and long-term occupation of network bandwidth, an interval of more than 3 channels is required.

Both of the above two networks need to follow the channel setup principle of multiple sets of monitors to ensure minimal interference between devices.

WARNING

1 In order to ensure the reliable operation of the wireless network of the monitor, the hospital needs to strictly follow the relevant requirements of this document for deployment, and continue to perform good network management during the operation after installation. Failure to follow this document may result in significant delays or even loss of data transmission, resulting in a corresponding clinical risk.

2 Avoid AP/wireless routers set by individuals. These devices will cause wireless interference, which will result in the data loss of the monitor/central station.

Network management is the responsibility of the hospital. After the installation, the network changes may cause the wireless performance of the monitor to deteriorate. The hospital needs to fully evaluate the network changes to avoid affecting the clinical use of the monitor.

✓ **Monitor network requirements**

The monitor transmits vital signs of the patient in real time, and the requirements for real-time and reliability are higher than those of the audio service. For network requirements, see the Wi-Fi network requirements table.

It is recommended to use EDAN-verified network equipment. This verification includes network architecture, device model, firmware version, and specific configuration. EDAN allows the use of higher-version network device firmware, but EDAN does not recommend the use of firmware versions

that are not officially released by device vendors.

Operation of the monitor may be risky if adopting network equipment of which compatibility is not certified by EDAN. In this case, EDAN recommends that the customer test run the monitor for at least 24 hours to confirm that there is no problem with the compatibility.

The following measures can be taken to confirm and guarantee wireless coverage requirements.

Air interface detection: Space environment confirmation for the wireless working frequency band is necessary. It is necessary to test and record the RSSI value and the co-channel interference condition (C/I) of the claimed coverage area. Space confirmation activities need to cover all declared areas, including elevators, remote corridors, etc. Air interface detection needs to be done while the network is normal and other wireless devices are in use. The client can implement air interface detection through third-party software tools such as airmagnet, wirelessmon, or other network acceptance tools recommended by EDAN. The coverage of the RSSI needs to be viewed from the monitor, so the airborne detection tool needs to be calibrated using the monitor's RSSI display. When doing the air interface detection, you need to enable the broadcast function for the SSID used EDAN.

Co-channel interference: The most obvious interference to Wi-Fi is co-channel interference. The signal strength closest to AP perceived by the wireless monitor must be at least 20 dB stronger than the signal strength of other APs in the same channel. Taking the 2.4G frequency band as an example, it is recommended to use a channel layout with 5 intervals to achieve Wi-Fi___33 coverage similar to cellular.

When considering the co-channel interference, it is necessary to take into account the inter-floor interference. It is necessary to avoid the occurrence of a pair of AP position corresponding to each other within a two-story building and working on the same channel.

✓ **Wireless Device Configuration Requirements**

Wireless device configuration is critical to the reliable operation of EDAN monitor. The following content should be paid special attention to:

Security settings

Try to use WPA2-PSK, WPA2-Enterprise authentication and encryption methods. If these authentication and encryption methods are not used, the monitor may not operate normally and patient information may be leaked. It is recommended to use WPA2-Enterprise and long password.

Throughput rate

The average throughput requirement for a single monitor is 330 kbps, and a 50% throughput derating is recommended. For example, if there are 16 monitors that require 5.3 Mbps of bandwidth, at least 10 Mbps throughput needs to be planned for the monitor. The service personnel should first check and verify the AP's wireless rate and bandwidth settings at the hospital site before installing the device.

If the monitor times out, it means that the waveform, parameters, patient information, working mode, etc. will lose data/function failure.

Cause 1: The recommended security authentication and encryption methods are not adopted, or authentication and encryption information is leaked, resulting in unauthorized Wi-Fi devices connected to the AP, thus consuming excessive communication bandwidth.

If the monitor issues network disconnection alarm, it means the waveform, parameters, patient information, working mode, etc. will lose data/function failure. The cause may be too many devices connected to the same AP or incorrect AP settings.

Users need to take measures to strictly control the acquisition method of Wi-Fi security settings in internal management to ensure that they are not obtained by unauthorized persons.

Cause 2: There is interference of the same frequency or adjacent frequency. Maybe because the channel setting of similar devices or devices with Wi-Fi function is the same or adjacent to that of the monitor. When their locations are close, it’s easy for them to interfere with each other.

A9.6 Continuous Transmission from Disconnection of Wireless Transducer

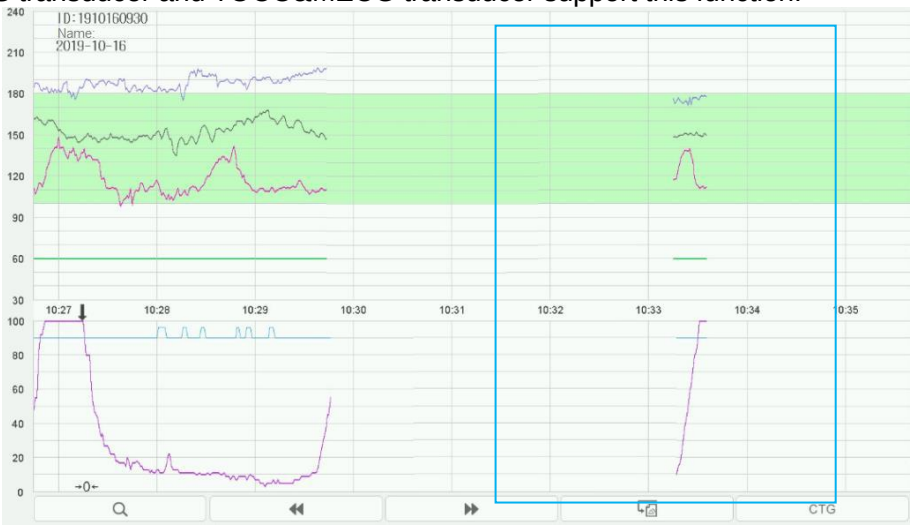
There might be WIFI disconnection between wireless transducer and the monitor in following situations:

- The distance between wireless transducer and monitor is too far;
- There are obstacles such as metal plates between wireless transducer and monitor, impacting the valid transmission of wireless signals;
- The device is subject to surrounding strong interference.

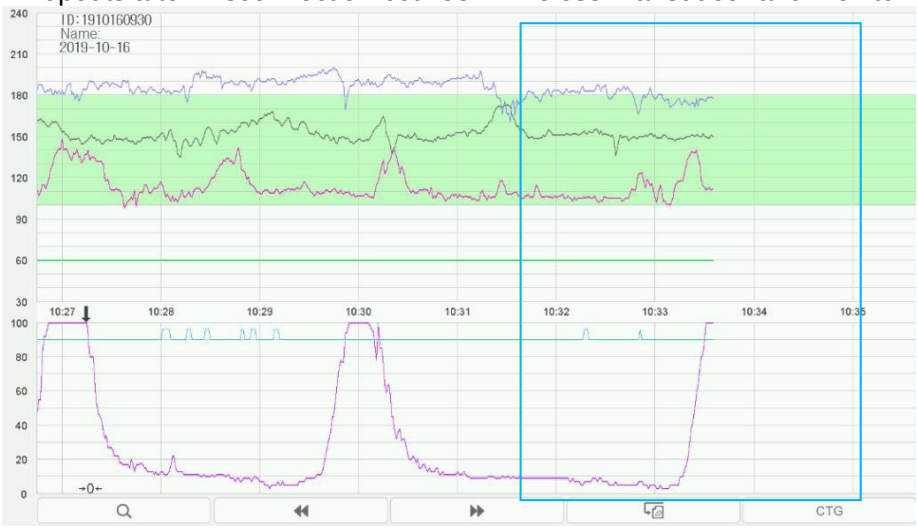
Aiming at the above situations, the function of continuous transmission from disconnection of wireless transducer is designed for the monitor, supporting continuous transmission of fetal monitoring data, including FHR1, FHR2, FHR3, TOCO, HR and AFM traces. The continuous transmitted parameter data is the valid data of patient. The design principle is saving the monitoring data in the transducer during disconnection first, then transmitting the valid data of patient to the monitor for display and saving when the wireless transducer is reconnected to the monitor. The following are the contrast diagrams before and after continuous transmission from disconnection:

Note:

1. The time for continuous transmission from disconnection is 15 minutes to the maximum.
2. This function can only supplement the lost traces due to wireless network, dropouts led by fetal heart signal weak cannot be supplemented through this function.
3. Only the US transducer and TOCO&MECG transducer support this function.



Dropouts after Disconnection between Wireless Transducer and Monitor



Monitoring Traces Supplement after Reconnection between Wireless Transducer and Monitor

A9.7 Connecting the Monitor to MFM-CNS/ MFM-CNS Lite

The monitor can be connected to the central monitoring system through the network:

1. The monitor sends patient information, real-time monitoring or measurement data to the central monitoring system.
2. The real-time monitoring information is displayed on the central monitoring system as the same to the monitor, and the central monitoring system can perform some bilateral control. For example: changing patient information, alarm settings, data and time and so forth.

For detailed information, please refer to *MFM-CNS Central Monitoring System User Manual* and *MFM-CNS Lite User Manual.*

Connecting Mode	**Other Requirements**	**Net Version**
F15 series connect to MFM-CNS via WIFI or network cable.	MFM-CNS version is V3.93 or higher	Ethernet V1.2 Ethernet V1.3 Ethernet V1.4
F15 series connect to MFM-CNS Lite via WIFI or network cable.	MFM-CNS Lite version is V 1.14 or higher	Ethernet V1.2 Ethernet V1.3 Ethernet V1.4

FCC STATEMENT :
This device complies with Part 15 of the FCC Rules. 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.
Warning: Changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
Reorient or relocate the receiving antenna. Increase the separation between the equipment and receiver. Connect the equipment into an outlet on a circuit different from that to which the receiver is connected. Consult the dealer or an experienced radio/TV technician for help.

FCC Radiation Exposure Statement:
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 20cm between the radiator & your body

P/N: 01.54.458308
MPN: 01.54.458308014

EDAN INSTRUMENTS, INC.
#15 Jinhui Road, Jinsha Community, Kengzi Sub-District
Pingshan District, 518122 Shenzhen, P.R.China
Email: info@edan.com.cn
TEL: +86-755-2689 8326 FAX: +86-755-2689 8330
Website: www.edan.com.cn

EC REPRESENTATIVE
Shanghai International Holding Corp. GmbH
Eiffestrasse 80, 20537 Hamburg Germany
TEL: +49-40-2513175
E-mail: shholding@hotmail.com