FTS-6

Central Monitoring System

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) cannot be held liable.

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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.

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Chapter 1 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 system.

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 The functions frequently used are marked with an asterisk*.

The system mainly consists of the work station and wireless transducers. It is intended to monitor FHR, TOCO and fetal movement.

1.1 Intended Use/Indications for Use

The FTS-6 Central Monitoring System (hereinafter called "FTS-6") is intended for the continuous and non-invasive monitoring of fetus for pregnant women during antepartum examination, labor and delivery. It provides real-time FHR, TOCO and fetal movement monitoring through wireless US transducers and TOCO transducers for several pregnant women at the same time.

It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labor and delivery rooms.

1.2 Features

The following table lists the measurements that FTS-6 supports.

Model / Measurement	FTS-6
FHR	√
TOCO	√
AFM	√
NOTE: √ = Standard × = Not Available	

For the Essential Performance of **FTS-6,** refer to Appendix1 in details.

1.3 Instruction for Safe Operation

- The system is designed to comply with the international safety requirements IEC/EN 60601-1 for medical electrical equipment. It is class I equipment.
- The system operates within specifications at ambient temperatures between +5℃ (+41℉) and +40℃ (+104 ℉). 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 system 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 protective degree against electric shock of the patient connections is:

Ultrasound (FHR) External TOCO	Type BF	

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

a) The effects of high frequency currents

b) The interference of electro surgery equipment

c) The effects of defibrillator

1.4 Ultrasound Safety Guide

◆ Fetal Use

The system is designed for continuous fetal heart rate monitoring during pregnancy and labor.

◆ Instructions for Use in Minimizing Patient Exposure

The acoustic output of the system is constant and internally controlled, and cannot be varied by the operator in the course of the examination. The duration of exposure is, however, fully under the control of the operator. Mastery of the examination techniques described in the User Manual will facilitate obtaining the maximum amount of diagnostic information with the minimum amount of exposure. The exercising of clinical judgment in the monitoring of low risk patients will avoid unnecessary insonation.

1.5 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

1 Installation of the system must be carried out by qualified personnel authorized by the manufacturer.
2 The system is provided for the use of qualified physicians or personnel professionally trained.
3 The system is not intended for use in intensive care units (ICU), operating rooms or for home use.
4 Do not switch on the system until all cables have been properly connected and verified.
5 **EXPLOSION HAZARD** - Do not use the system 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 system.
7 Multiple portable socket-outlets shall not be placed on the floor.
8 Additional multiple socket-outlet or extension cord can't be connected to the system.
9 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.
10 **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.
11 Do not touch accessible parts of non-medical electrical equipment and the patient simultaneously. Do not touch the signal input or output connector and the patient simultaneously.
12 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. Any non-medical equipment (such as the external printer) is not allowed to be used within the patient vicinity (1.5m/6ft.).
13 Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC 60601-1 approved to the system. The operation or use of non-approved equipment or accessories with the system is not tested or supported, and system operation and safety are not guaranteed.

WARNING

14 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.

15 Connecting any accessory (such as external printer) or other device to this monitoring system 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.

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

17 **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.

18 **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.

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

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

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

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

23 The system should be operated by the doctor or under the doctor’s instructions.

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

WARNING

25 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.

26 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.

27 Do not service or maintain the equipment or any accessory which is in use with the patient.

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

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

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

31 Please arrange a function test periodically for the system.

32 Do not move the system when it is powered on and do not soak it in any liquid.

33 If the transducer has been beaten or knocked, please check whether the cover is airproof or damaged. If you have any doubt, please contact the manufacturer or local agent.

34 Please check the transducer, cable and base station periodically. If the transducers are damaged, do not use them in water and repair them in time.

35 The battery in the wireless transducer should be replaced by the serviceman authorized by EDAN.

36 If the battery in the transducer is stored alone and not to be used for a long time, we recommend that the battery should be charged at least once every 6 months to prevent over-discharge.

37 If the system is not to be used for an extended period of time, batteries in the transducers are recommended to be charged periodically.

38 Charging points of the transducer should be kept clean and free of residual coupling gel or cleaning agent to avoid the possibility of unsuccessful charging.

39 No object is allowed on the trolley table lest they might fall and injure people.

40 Maximum load of the mouse tray and the container is both 3 kg. Do not put objects heavier than the maximum load.

41 Do not lean on the handle of the trolley while operating the system, otherwise the handle might be damaged.

42 Do not put any object on the mouse tray while moving the trolley.

43 Brakes on the trolley casters should be stepped down while using the system, lest it should move and accidentally crash into people and objects nearby.

WARNING

44 The brakes of 4 wheels should be stepped down while using the trolley to avoid crashing into the personnel and objects nearby in case of unexpected moving.

45 Height of the trolley must be adjusted by authorized professional service personnel. Be careful not to trap or pinch your fingers while adjusting the height.

46 PC software and operating system must be set up and maintained only by authorized professional service personnel. Do not change any settings.

47 Short-range radio devices are vulnerable to interference of strong electromagnetic sources nearby, such as microwave oven, devices with Bluetooth and WLAN (802.11b,g,n) and mobile phones, and be interrupted. Interruption may sustain for a while depending on the interference intensity and duration. Signal loss alarm messages will be displayed on the screen.

48 Frequency is essential to wireless devices. Please adhere to default frequency settings and do not change system settings. If interference occurs, please contact service personnel.

49 This device generates, uses and radiates RF energy. If it is not correctly installed or used according to accompanying documentation, it may interfere with radio communications around. Operating this system in residential areas may also cause interference to wireless transmissions. Operators must take measures to avoid it.

50 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 FTS-6, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

51 The EMISSIONS characteristics of FTS-6 make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) FTS-6 might not offer adequate protection to radio-frequency communication services. The user might need to take mitigation measures, such as relocating or re-orienting the equipment.

52 A potential hazard can exist if different ALARM PRESETS are used for the same or similar equipment in any single area. Please take notice of the alarm settings and messages of the current device in use to avoid accidents.

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 system in a location where the operator can easily access the disconnection device.
7 Do not sterilize the system 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 **Electromagnetic Interference**- Ensure that the environment in which the system 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 system may be interfered.
10 **Electromagnetic Interference**- Do not use mobile phones nearby in the process of monitoring.
11 Operation of the equipment below the minimum amplitude may cause inaccurate results.
12 **Electromagnetic Interference**-Fetal parameters, especially ultrasound, 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.
13 **Electromagnetic Interference**- The system should not be used adjacent to or stacked with other equipment, refer to section A3.4 Recommended Separation Distances.
14 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-endamplifiers 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.

CAUTION

15 The medical electrical equipment needs to be installed and put into service according to Appendix 3 EMC Information.

16 Portable and mobile RF communications equipment can affect medical electrical equipment. Refer to section A3.4 Recommended Separation Distances for details.

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

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

19 Waterproof degree of the wireless transducers is IPX8, but other parts of the system should be kept non-soaked and non-condensing. The system may be condensing during transportation in high humidity or low temperature.

20 The water temperature must not exceed +60 ºC (+140 ºF) when you wash the belt.

21 The use of accessories and cables other than those specified may result in increased electromagnetic emissions or decreased electromagnetic immunity of the system.

22 When the battery is charged, used or stored, keep it away from objects or materials with static electric charges.

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

24 The recommended charging temperature for the battery is between 0℃ ~ +40℃. Please do not exceed the temperature range.

25 Batteries have life cycles. If the time a transducer battery keeps working becomes much shorter than usual, the battery life is at an end. Please contact the manufacturer to replace the battery with a new one of the same specification as the one provided or recommended by the manufacturer.

26 Remove the battery in the transducer and store it at a cool and dry environment if the system is not to be used for a long time.

27 Please remove the battery out of the transducer at the end of its life.

28 Please read the user manual carefully when you install or remove the battery.

29 Setting alarm limits to extreme values may disable the alarm system. Default settings are recommended to use.

30 If the device in use is blacked out due to sudden power failure, only the monitoring data and alarm review messages in no more than a minute will not be saved. Settings are safe in storage.

31 Essential performance will not be degraded under standard-permitted electromagnetic interference.

CAUTION

32 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.

33 Use the standard all-in-one computer supplied by the manufacturer only. Restart the computer if it crashes.

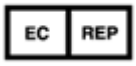
34 Keyboard and mouse are indispensable for inputting information. Please check them regularly.

35 When there are unknown bugs, the system will prompt messages to inform the user.

36 For better displaying and viewing effect, use recommended resolution or higher resolution.

1.6 Definitions and Symbols

FTS-6 Central Monitoring System		
1		Equipotentiality
2		Alternating Current (a.c.)
3		Warning (Background: Yellow; Symbol & outline: Black)
4		Caution
5		Operating instructions
6		Refer to User Manual (Background: Blue; Symbol: White)

7		Type BF applied part
8	IPX8	Protected against the effects of continuous immersion in water
9		CE marking
10		General symbol for recovery/recyclable
11		Authorized Representative in the European Community
12		Disposal method
13		Non-ionizing electromagnetic radiation
14		Serial Number
15		Caps Lock
16		Pushing prohibited (Background: White; Symbol: Black; Outline: Red)

NOTE:

The user manual is printed in black and white.

Chapter 2 Introducing the System

2.1 FTS-6 Configuration

FTS-6 mainly monitors fetuses and provides various kinds of fetal monitoring functions: FHR, TOCO (Tocotonometer), AFM (Automatic Fetal Movement) and so on. It supports single, twin and triple fetal monitoring.

FTS-6 can support 12 monitoring windows with flexible configuration. The maximum number of beds for single monitoring that FTS-6 can support is 8. 2 wireless ultrasonic probes and 1 wireless contractions pressure probe can constitute a twin fetal configuration. 3 wireless ultrasonic probes and 1 wireless contractions pressure probe can constitute a triple fetal configuration.

2.2 Overview

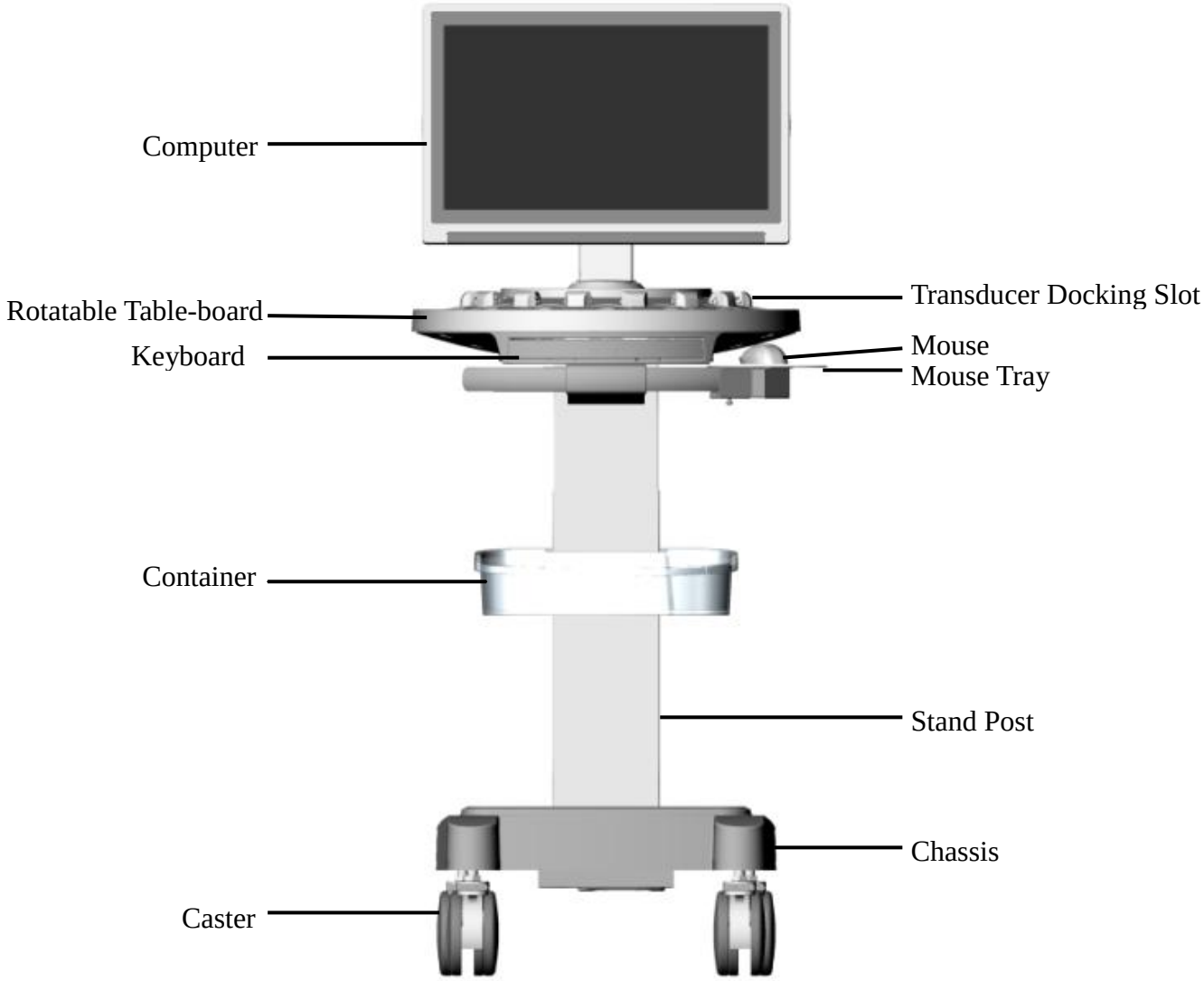


Figure 2-1 Overview of FTS-6 System (Front)

Figure 2-2 Overview of FTS-6 System (Back)

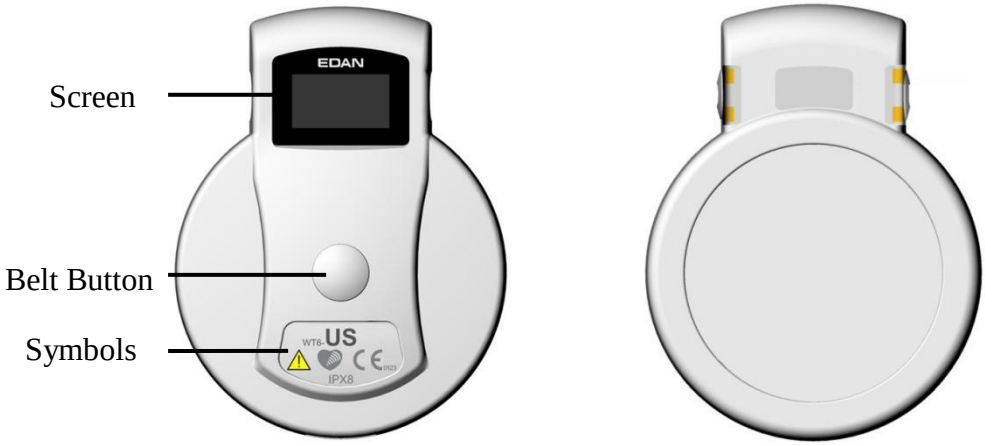


Figure 2-3 Front View and Back View of the Wireless US Transducer

Figure 2-4 Front View and Back View of the Wireless TOCO Transducer

2.3 Accessories

2.3.1 Belt

Figure 2-5 Belt

2.3.2 Mouse and Mouse Tray

A wireless mouse, together with a built-in keyboard, is equipped for the system. Before using the mouse, please insert the USB transceiver into the USB port of the equipped all-in-one computer, switch on the mouse and put the mouse on the tray.

There are two kinds of keyboards for option: standard keyboard and built-in keyboard. You can only choose one of them. The standard keyboard is used together with keyboard tray and wireless mouse, and the built-in keyboard is used together with mouse tray and wireless mouse.

The standard keyboard can be used directly after installation. The built-in keyboard is positioned inside the trolley. Press the key at middle of front side of keyboard to pop up the keyboard. After use, push the keyboard gently into the trolley to lock it.

The mouse tray can be installed either on the left or on the right side of the trolley. Ask the qualified service personnel to install it to your preference.

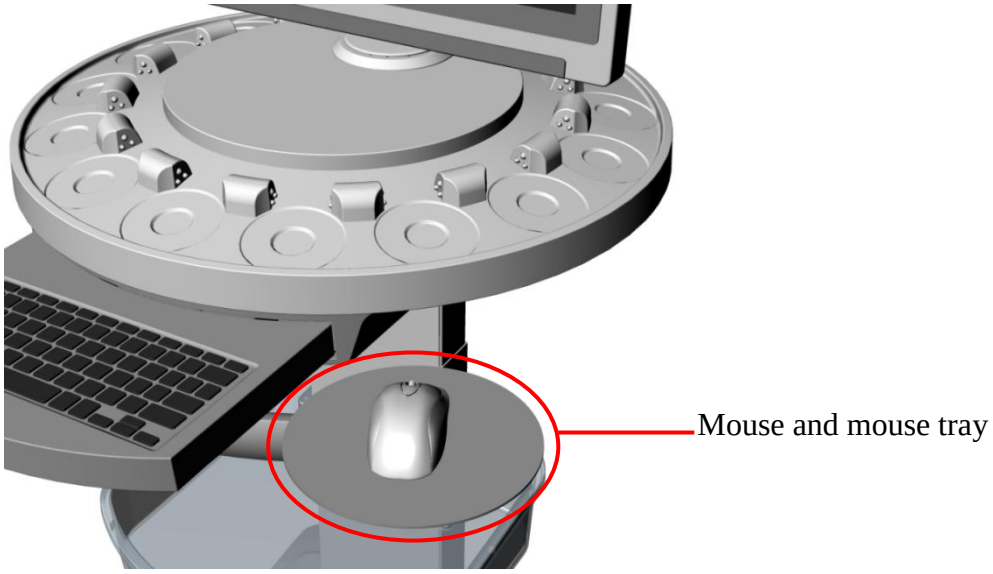


Figure 2-6 Mouse and Mouse Tray

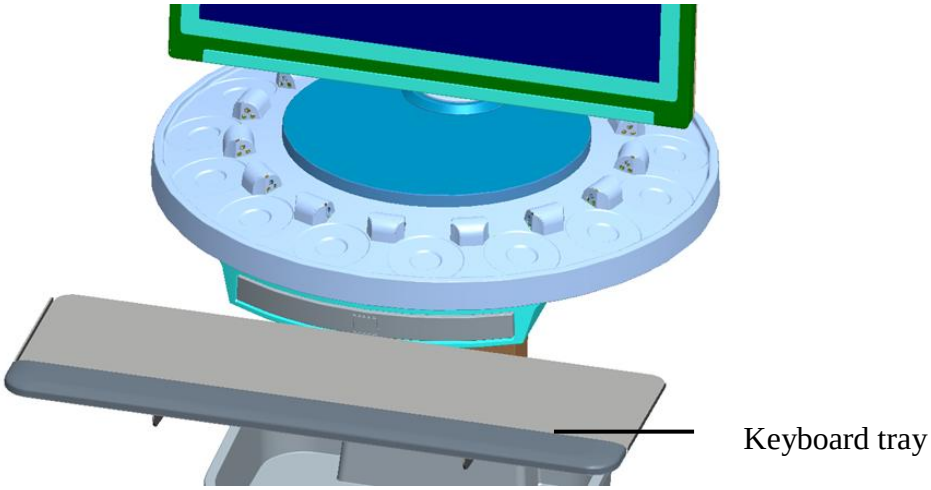


Figure 2-1 Keyboard Tray

The standard keyboard and mouse can be installed on keyboard tray.

The user can choose either keyboard tray or mouse tray according to his requirement.

WARNING

1 When installing the mouse tray, bolt it up first to stop it from shifting or falling.

2 The maximum load of the mouse tray is 3 kg. Do not put anything else other than the mouse. Besides, the mouse tray is small, be careful not to drop the mouse while using it on the mouse tray.

WARNING

3 Put the mouse into the container before moving the trolley. No object is allowed on the mouse tray during moving.

4 Put the mouse on the mouse tray in the container before moving the trolley. Do not put anything on the trolley during moving.

5 The maximum load of the keyboard tray is 3 kg. Do not put anything else other than the keyboard and mouse. Besides, the keyboard tray is small, be careful not to drop the keyboard and mouse while using them on the keyboard tray.

6 Put the mouse and keyboard on the keyboard tray in the container and remove the keyboard tray before moving the trolley. Do not install the keyboard tray during moving.

2.4 Peripheral Connections

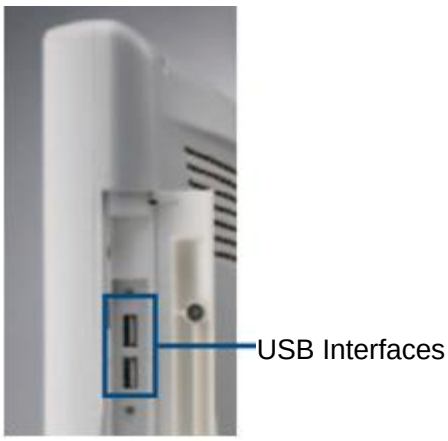


Figure 2-7 USB Interfaces on the Computer

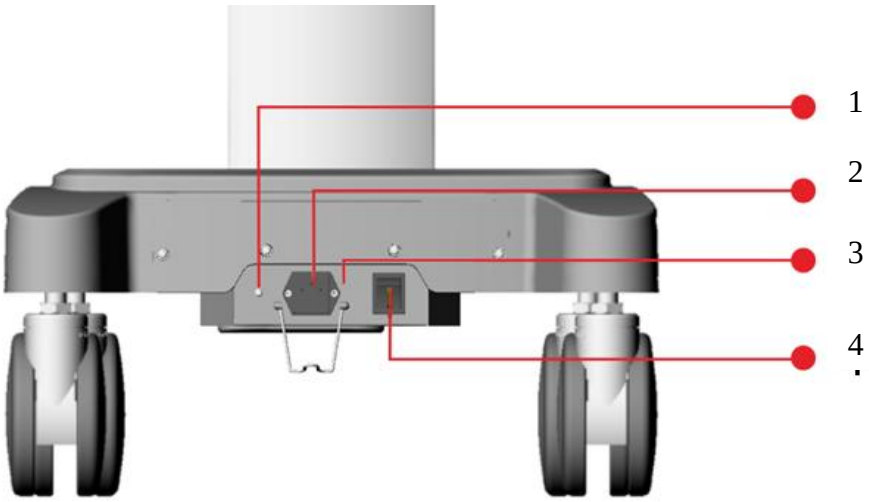


Figure 2-8 Interfaces on the Bottom of the Trolley

1. Equipotential EarthTerminal 2. Mains Power Interface
3. Power Cable Buckle 4. Power Switch

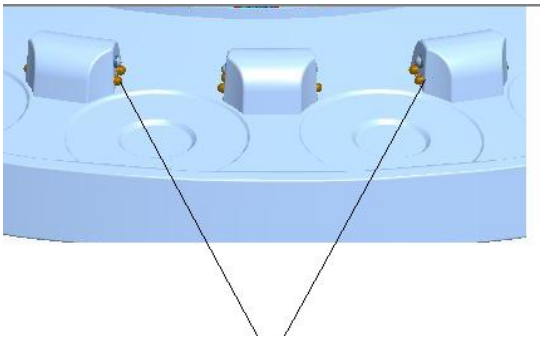


Figure 2-9 Transducer Charging Points

WARNING

The charging points are used for charging the transducers. DO NOT touch the charging points and the patient at the same time.

Chapter 3 Installation Guide

NOTE:

Installation must be carried out by qualified personnel authorized by the manufacturer.

3.1 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 packing box, and take out the transducer package, computer package, accessory package and the trolley carefully. Unpack the three packages and take out the components with care. Keep the package for possible future transportation or storage.

Place all the components in a position that is safe, stable and easy for observation, and check according to the accompanying 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.

Below are the exploded views of the four packages.

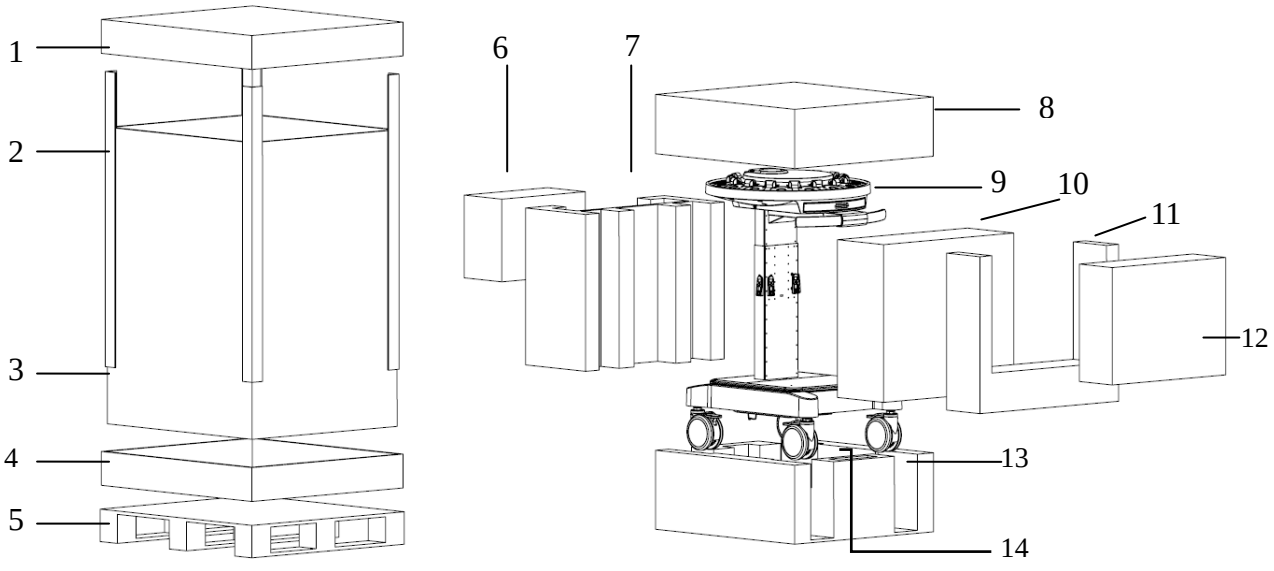


Figure 3-1Exploded View of the Packing Box

N0.	Item	N0.	Item
1	Top Cover	8	Packing foamy sponge (Top)
2	Paper angle bead	9	Trolley
3	Wingless box	10	Computer package
4	Bottom Cover	11	Packing foamy sponge (Front)
5	Wooden pallet	12	Accessory package
6	Transducer package	13	Packing foamy sponge (Bottom)
7	Packing foamy sponge (Back)	14	Mouse Tray

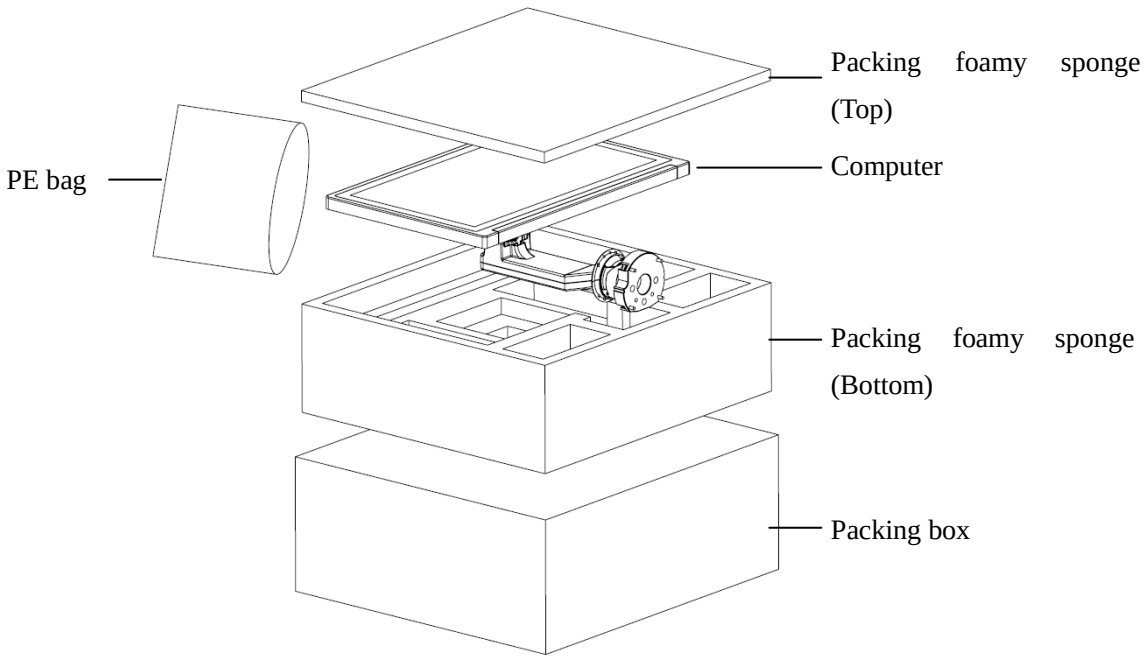


Figure 3-2 Computer Package

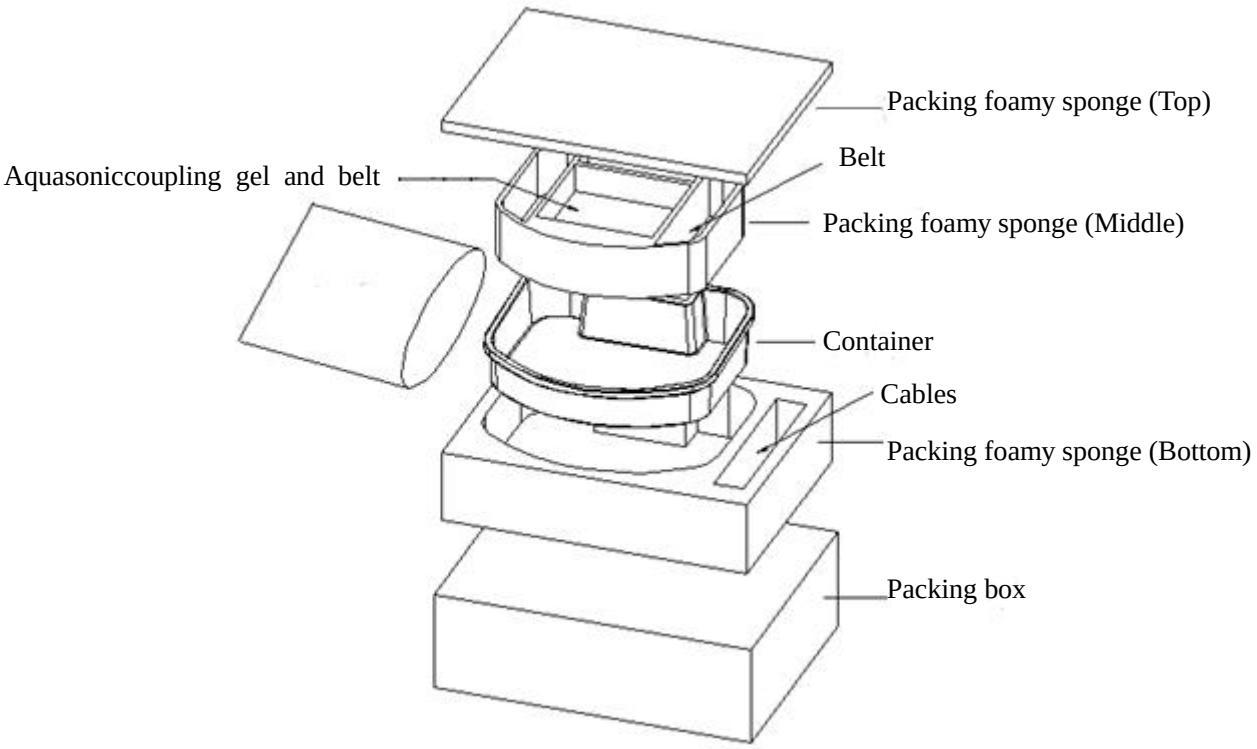


Figure 3-3 Accessory Package

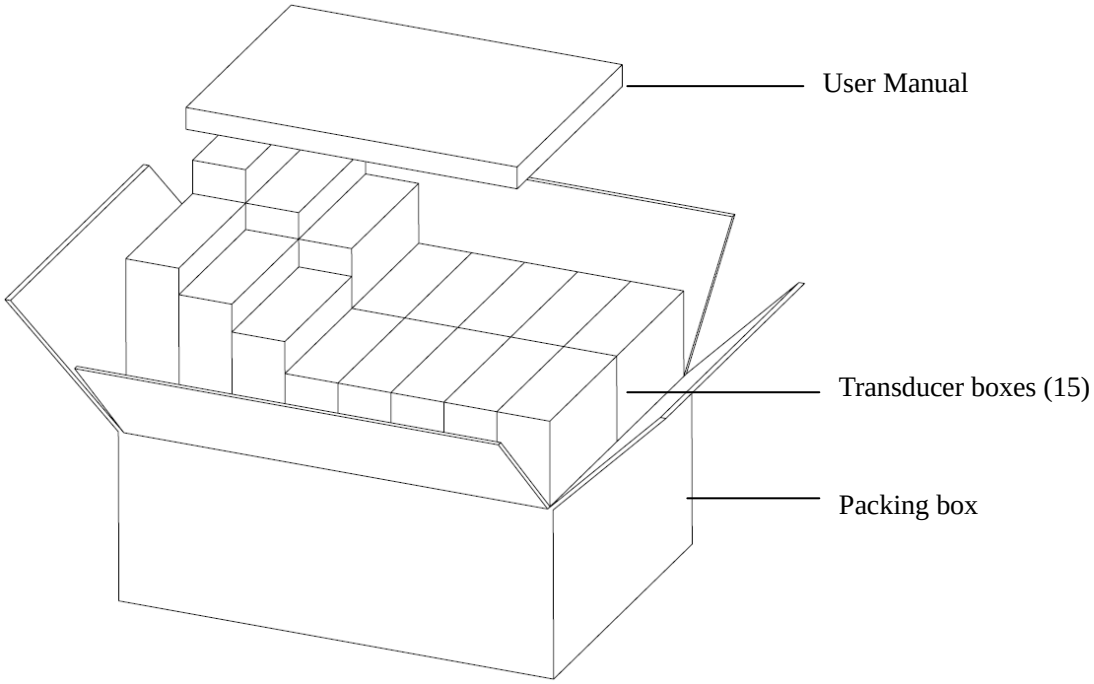


Figure 3-4 Transducer Package

3.2 Installing FTS-6

NOTE:

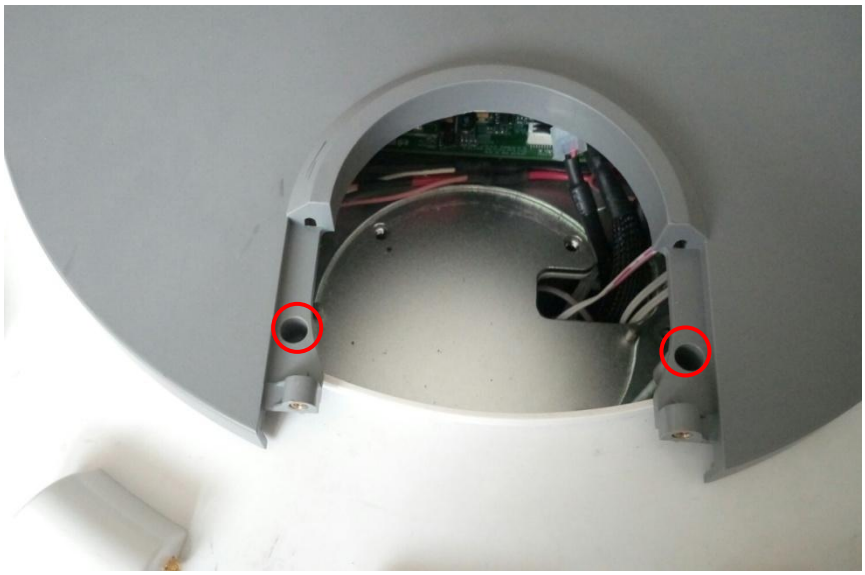
Installation must be carried out by qualified personnel authorized by the manufacturer.

Please follow the steps to install FTS-6:

a) Place the trolley gently on a flat, clean and open area. Use a cross screwdriver to remove the two screws shown in the figure below.

Figure 3-5

b) Remove the decoration cover and the 2 internal screws as well.



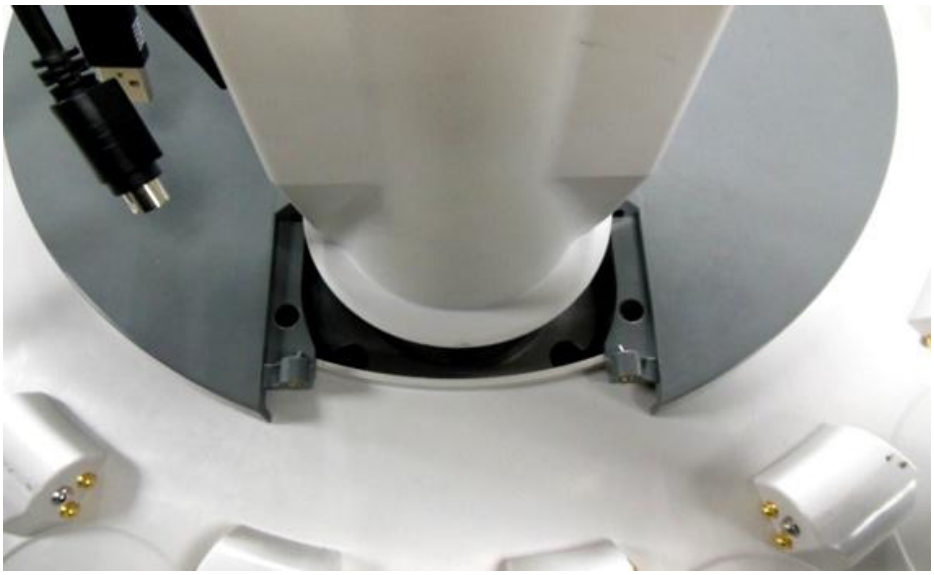


Figure 3-6

c) Remove the top cover and install the computer module. Connect the 6 wires and the Wi-Fi aerial accordingly to the positions shown below.

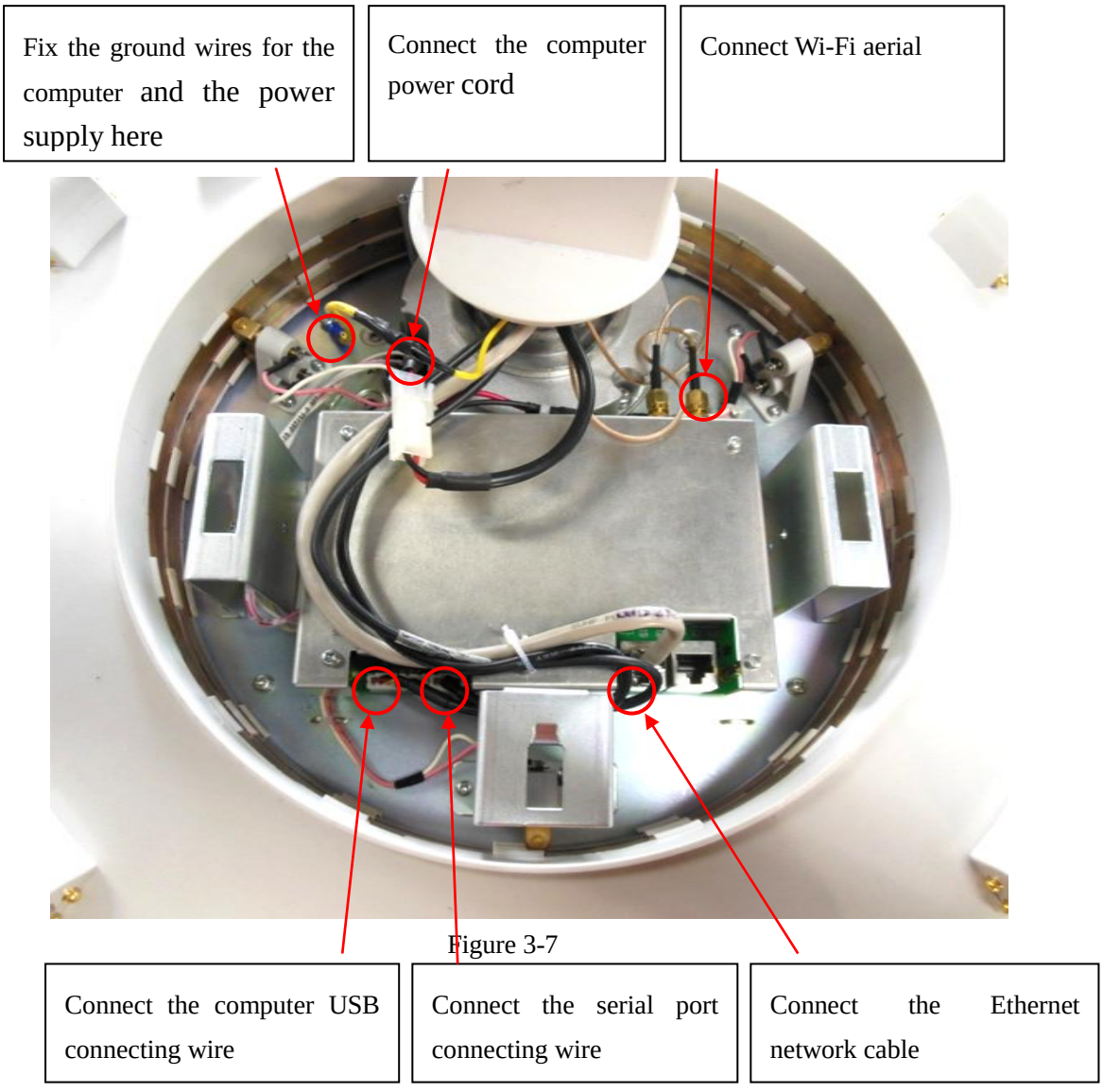


Figure 3-7

d) Install the top cover and secure it with the two M3×8 screws removed in step **b)**.Put the decoration cover back in position and fix it.

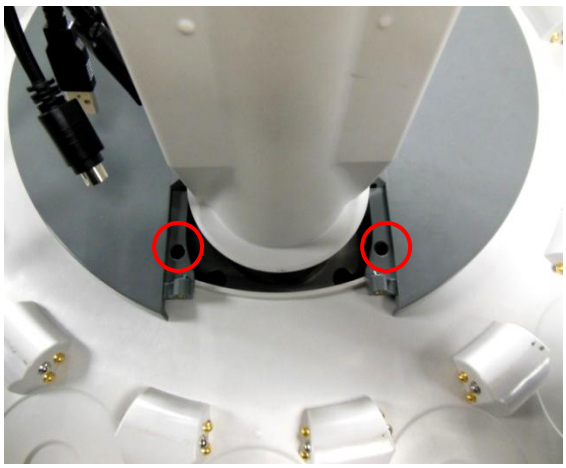


Figure 3-8

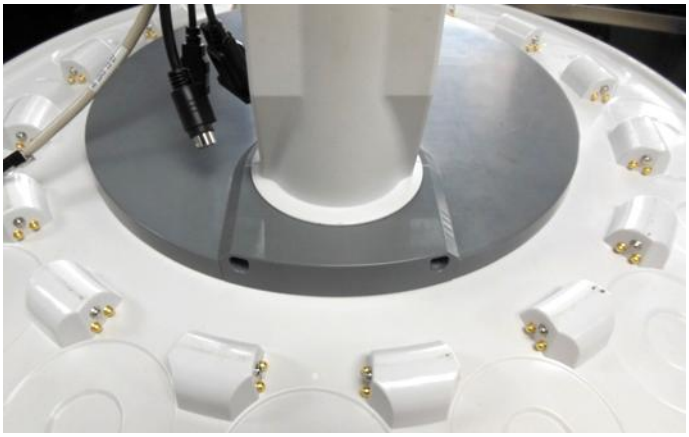


Figure 3-9

e) Install the mouse tray or keyboard tray (you can only choose one of them).

- Install mouse tray: take the mouse tray, solid jaw and screw (M5×15, 1 piece) from the package.

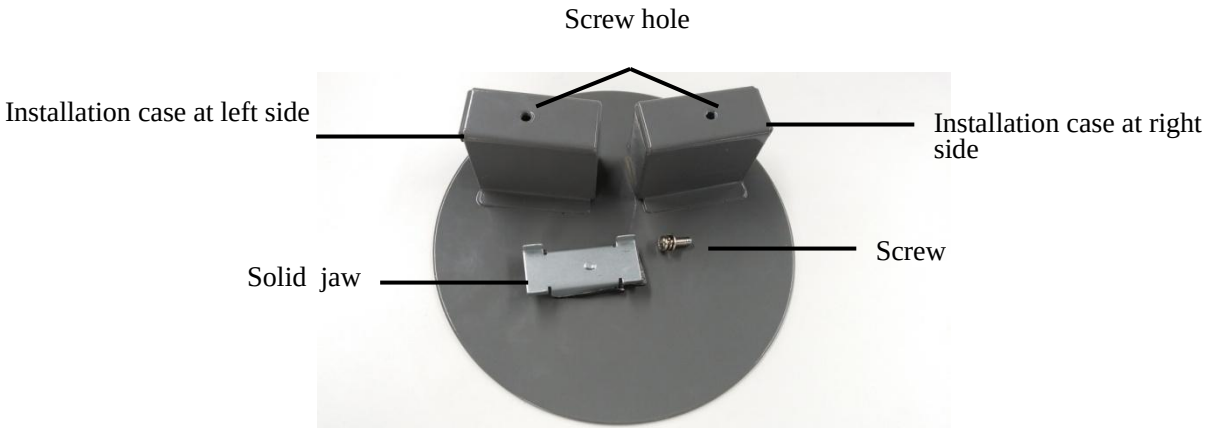


Figure 3-1

Firstly, confirm whether the mouse tray is installed at left side or at right side of trolley according to the user's requirement. If the mouse tray is installed at left side of trolley, the corresponding installation case and trolley handle are at left side. Otherwise the corresponding installation case and trolley handle are at right side.

Then, put the right side of mouse tray up, install the solid jaw at the bottom of installation case, then insert the installation case into trolley handle, finally, bolt the M5×15 screw up to the screw hole and screw it with screwdriver to fix the tray.

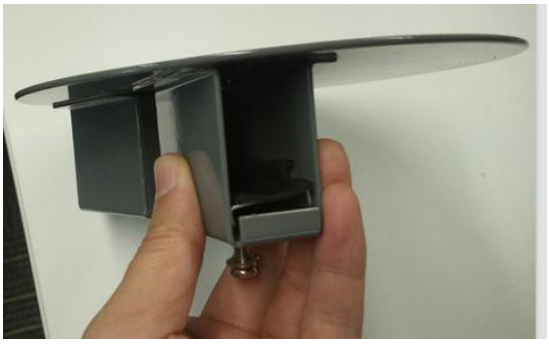


Figure 3-2

Figure 3-3

- Install keyboard tray: take the keyboard tray from package. The keyboard tray has two supports, with two screw holes in each one.

  Put the right side of keyboard tray up, clip two supports into the handle bracket of trolley, push downward the tray into the trolley, and then use 4 M4×10 screws to lock the tray supports. After installation, you can put keyboard and mouse on it.

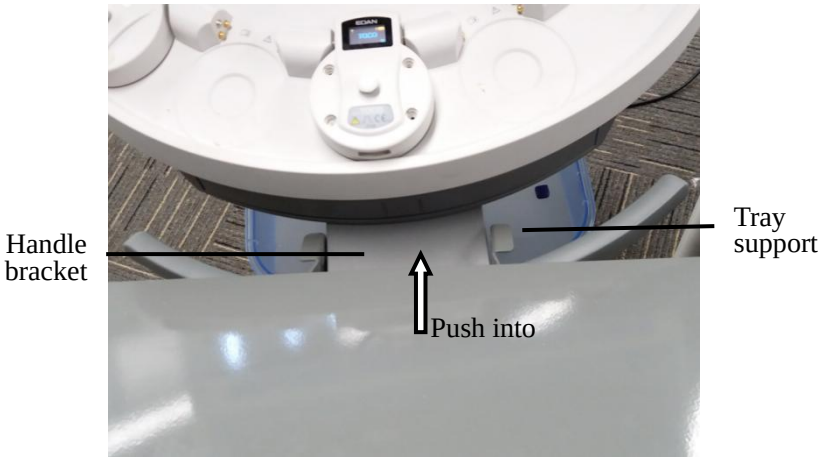


Figure 3-4

Figure 3-5

f) The installation is completed.

3.3 Installing and Uninstalling the FTS-6 Software

3.3.1 Preparation

3.3.1.1 Installing a Printer

To perform the printing function of the software, you need to install a printer prior tousing it. Printers of the HP LaserJet series are recommended.

3.3.1.2 Network Setup

Recommended IP address ranges are below:

- Computer: 192.168.1.110
- Wireless US Transducer: 192.168.1.151~192.168.1.165
- Wireless TOCO Transducers: 192.168.1.166~192.168.1.180
- Loudspeaker: 192.168.1.254
- FTS-6 COM port: 5522

NOTE:

1 Please make sure that the network adapter as well as the required driver has been installed in the computer prior to network setup, or you may not go on with the setup.

2 If multiple monitors are simultaneously connected to the software, please make sure all these monitors share the same server IP address but not the same bed No., or some monitors cannot be connected to the software.

3 IP address for each transducer should be unique.

4 When F series monitors are connected to the system, it’s recommended that their IP

addresses are set within this range: 192.168.1.2~192.168.1.99.

3.3.2 Installing the Software

WARNING

Close your anti-virus software before installing the FTS-6 software.

Follow the steps below to install the software on your computer:

a) Double-click the setup icon  in the FTS-6 file package.

b) Click **Install** to continue.

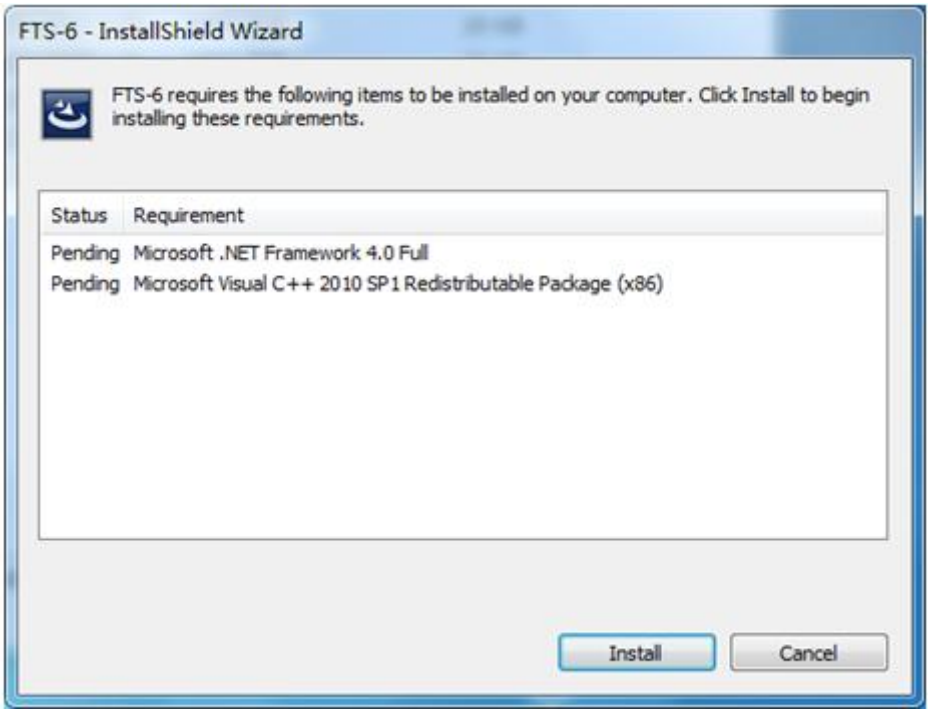


Figure 3-10 Items Required to be Installed

c) Click **Next**.

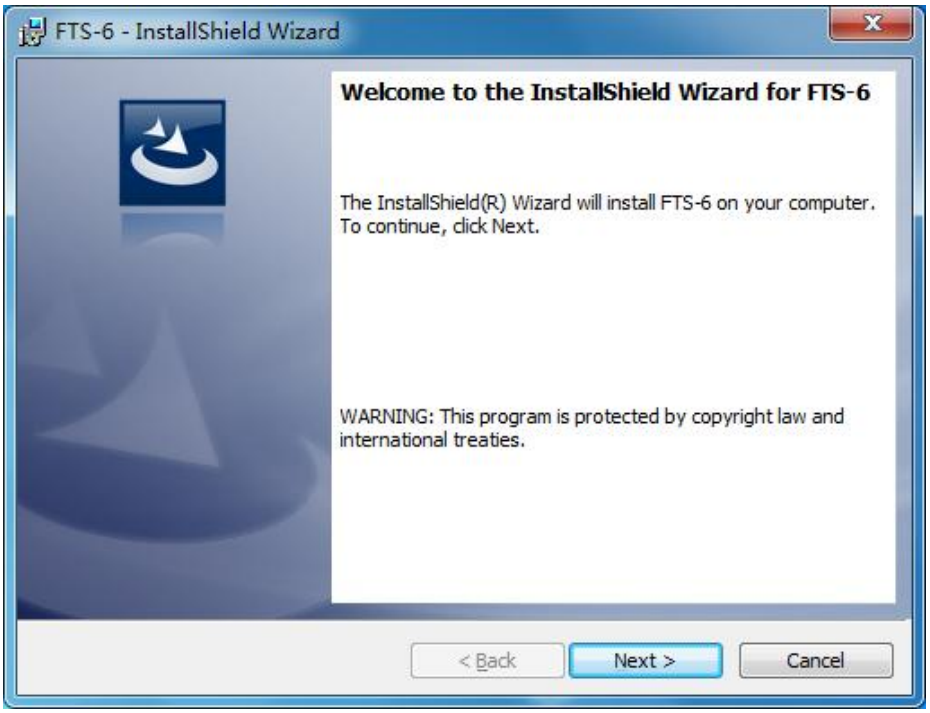


Figure 3-11 Welcome Interface

d) Select a language type and click **Next**.

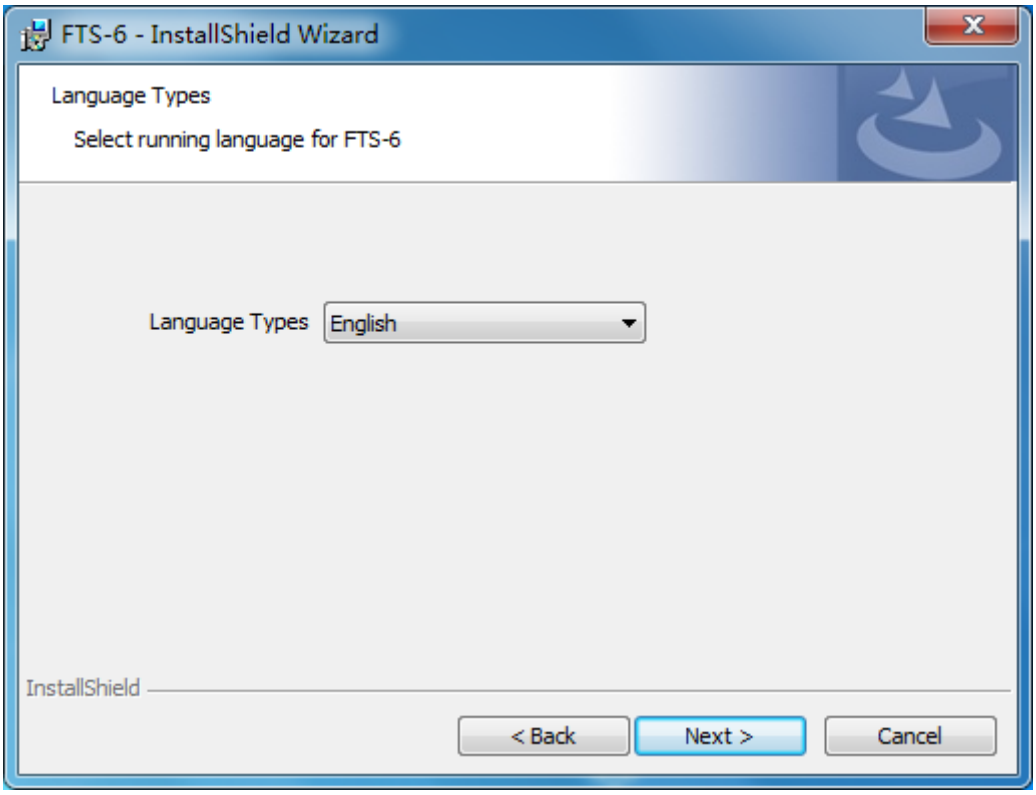


Figure 3-12 Selecting Language Types

e) The system loads the user name and organization of your computer automatically. Click **Next**.

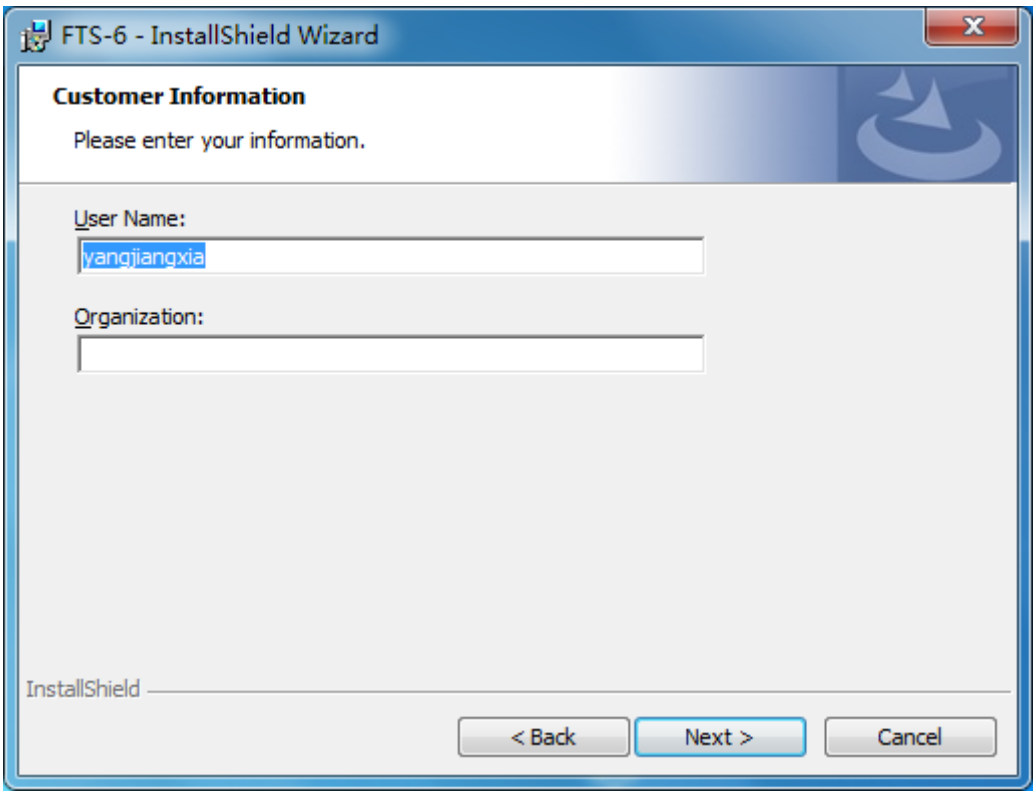


Figure 3-13Entering Customer Information

f) Select "Complete" and click **Next**.

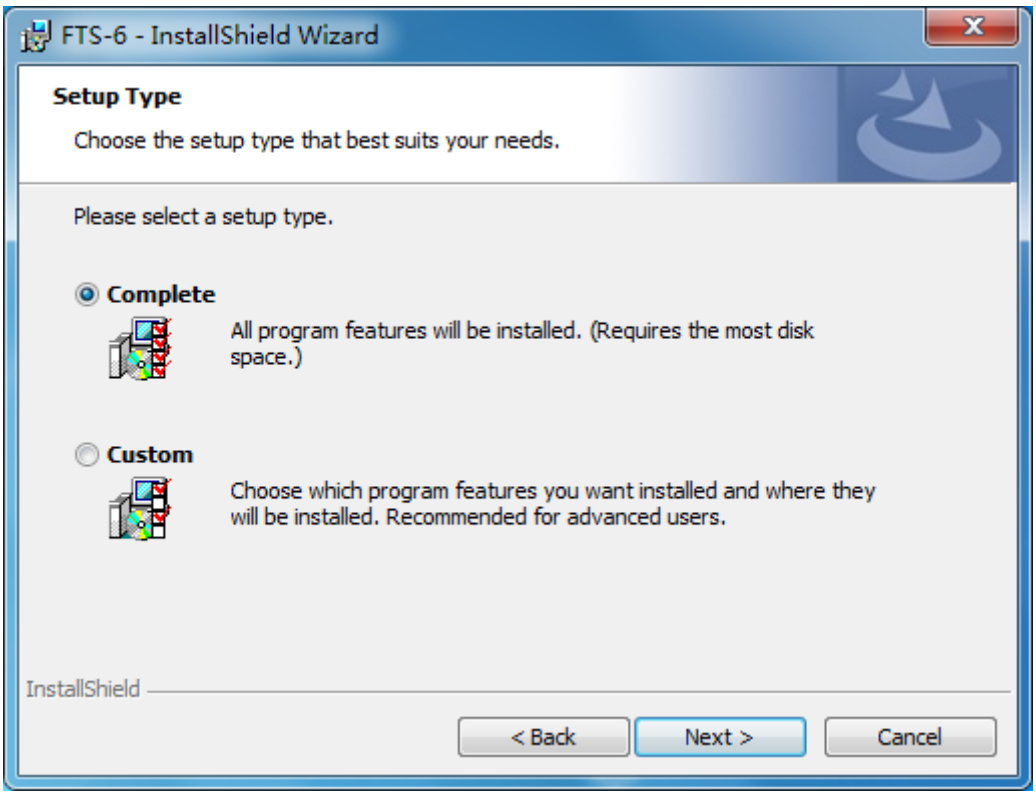


Figure 3-14 Selecting Setup Type

g) Click **Install**.

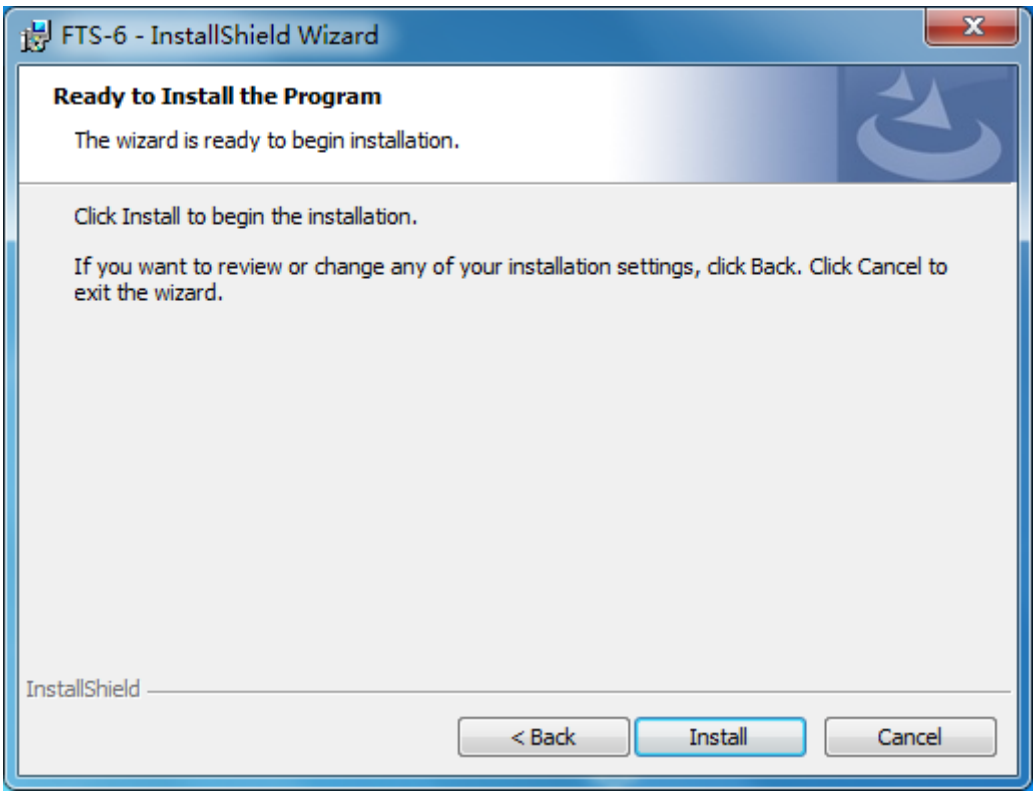


Figure 3-15 Ready to Install

h) The database is to be installed in D Drive by default. Click **Next** to continue. If you need to change the path, click **Browse** to select one and then click **Next**.

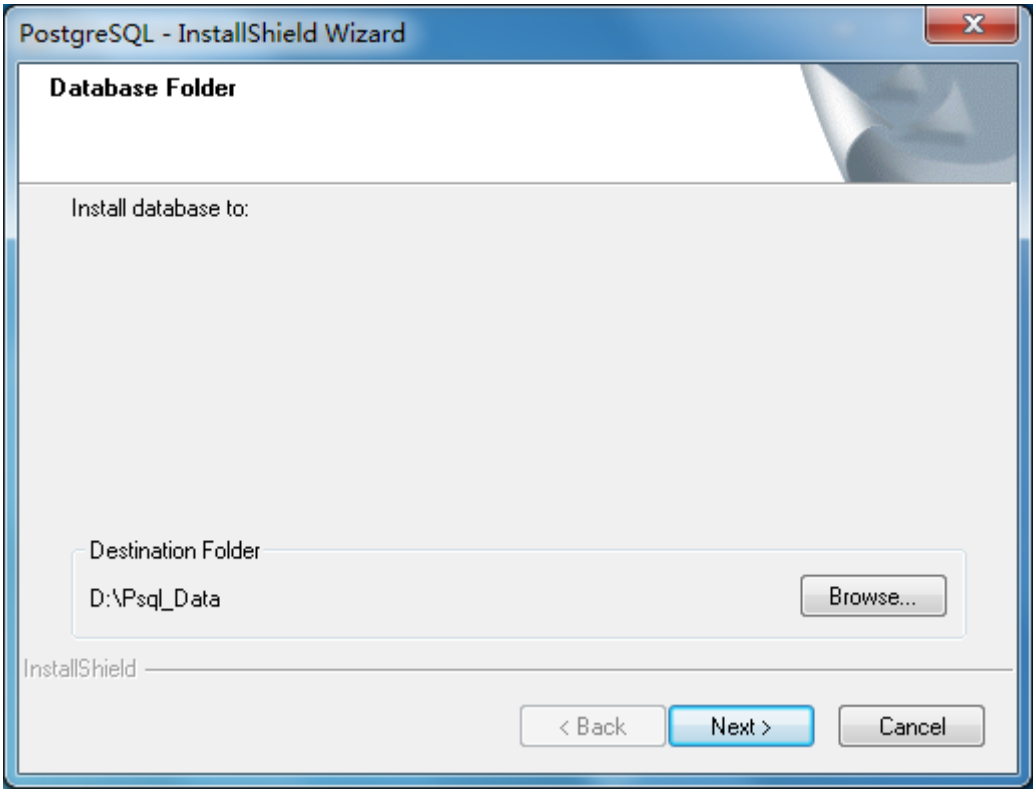


Figure 3-16 Selecting a Destination Folder for Database

i) Click **Finish** and the installation is completed.

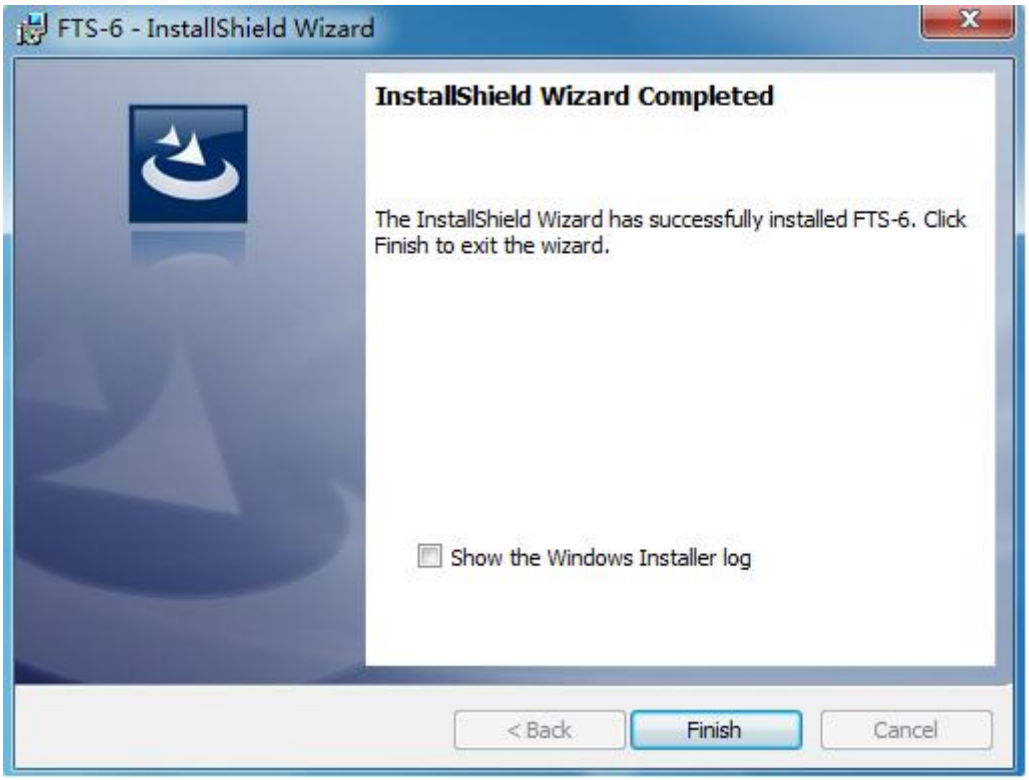


Figure 3-17 Installation Completed

NOTE:

If you cancel the installation during the installation process and install the software again later, you may fail to install it. You need to restart the computer first.

3.3.3 Uninstalling the Software

Choose **Computer**>**Uninstall or change a program** and select **FTS-6**in the list. Right-click **FTS-6** and click **Uninstall** to remove it.

NOTE:

Before you uninstall the software, please make sure if you need to back up the data.

3.3.3.1 Deleting Database and Data

If you need to delete the database and data of the software, go to the OS disk first. For example, if the OS is installed on C disk, you need to find C:\Program Files\psql. Double-click "remove_db.bat" and the database will be removed. Then, go to the directory where the database is installed. For example, if you have installed the database in D Drive, find D:\Psql_Data and delete the Psql Data folder.

3.3.3.2 Database Backup and Restoration

If malfunction in the software occurs due to causes such as hard disk damage resulting from abnormal power cut-off and so on, you have to reinstall the software. Prior to reinstallation, uninstall the earlier version first. When you uninstall an earlier version, you need to back up database. To back up the database, choose **Start** >**All Programs** >**FTS-6**>**DbBackup** on the computer.

After reinstallation, you need to restore the database. To restore the database, choose **Start** >**All Programs** >**FTS-6** >**DbRestore**.

If the OS is corrupted due to causes such as hard disk damage resulting from abnormal power cut-off and so on, you have to reinstall the OS and likewise the software.

NOTE:

1 You need to back up data regularly to avoid the loss of data caused by the damage of hard disks. You are recommended to back up data once a month by a removable hard disk.

2 The backup function is not enabled automatically after your computer is opened. You have to back up data manually following the steps above.

3 Before you restore the database, first ensure that the DCS is closed.

3.4 System Setup and Firmware Setup

Only super users (or service engineers) can conduct the system setup and firmware setup of the software. Two super users are offered for the software:

No.	Username	Password
1	administrator	8888
2	service	8888

The super users have the following rights that are not possessed by other users:

a) Set up the **Sending Config** item in the **General Setup** interface. This item must be set by super users in precedence so that other users can send reports by email on the **Print** interface.

b) Allow high users to visit the **System Setup** interface. If **Modify System Setup** is selected when a super user adds a high user or modifies a high user's information, then the high user will have access to the **System Setup** interface.

c) Conduct HL7 settings in the **System Setup** interface. Super users can tick **Receive Data from HIS** or **Send Data to HIS**, or set how to name files and when to export them.

Receive Data from HIS:

Reservation service falls into two types: HIS sends unsolicited data (initiatively sending data to FTS-6 through HL7 Protocol) or HL7 Gateway queries data (Requesting maternal information from

HIS through HL7 Protocol).

The reservation information acquired from HIS is displayed in the reservation list.

Send Data to HIS:

Send data during saving: Save monitoring data in a sub-window as a PDF report and send a message to HL7 Gateway. The message includes the patient's ID, name, and ID.

Send data during analysis: Save an analysis report in PDF format and send a message to HL7 Gateway. The message includes the patient's ID, name, and ID.

d) Restore the settings to Save as Default User Setup, Default User Setup, or Default Factory Setup in the **System Setup** interface.

e) Set FH algorithm to Thin variability or smooth.

f) Set transducers and loudspeakers:

1) Transducer Setup

After the software is started, put a wireless transducer on a transducer docking slot and open the **Firmware Setup** interface. Click **Query** to detect the transducer (US or TOCO, US1/US2/US3 for US while TOCO for TOCO) and initialize its configuration. Restart the software after the configuration is done.

Click **Delete** if you want to remove the transducer.

NOTE:

1 Transducer configuration can only be done through serial ports. Every transducer has a unique IP.

2 Every window can connect at most 3 US transducers and 1 TOCO transducer, and the transducer type of a window must be different.

WARNING

Please ensure all transducers share one connection mode, or an error may be caused.

2) Loudspeaker setup

To setup a loudspeaker, you need to:

a) Get all devices offline;

b) Click **Query** to see the number of audio devices, enter the IP and port No. of each audio device and click **OK**.

c) Configuration completed. All audio devices you set are ticked by default. You can play 1, 2, or 3 audio devices at a time according to your needs.

NOTE:

The IP of audio devices can be the same but the port must be different for port setting.

3） Online transducer management

Select a transducer and click **Search Transducer** to check if the transducer can sound. Click Refresh to display all online transducers.

Ports used by the software include:

- 80 (http service)
- All ports between4502 and 4530 (user data connection)
- All ports between 5510 and 5519(monitor data connection)
- Port 5556 (broadcase port of the DCS server)
- Port 5522 (port for wireless transducer communication)
- Port 51232 and 58232 (internal communication port of the DCS server

3.5 Connecting FTS-6 to AC Mains

- Make sure the AC power supply of the system complies with the following specification: 100V-240V~, 50Hz/60Hz.
- Apply the power cable provided with the system. Connect one end of the power cable to the power socket of the system and fasten the power cable buckle. Plug the other end into a three-slot power output special for hospital usage.
- The equipotential earth terminal is provided for the connection of a potential equalization conductor. Therefore, it is recommended to connect the earth terminal of the system and the power outlet with the earth wire, ensuring the system is grounded.

NOTE:

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

2 Make sure the power cord is fastened with the buckle to avoid accidental disconnection of power cord and thus interruption of power supply.

3.6 Equipotential Bonding

Connection of other devices to the system may endanger the patient’s safety and void the manufacturer’s warranty for the system. According to IEC/EN 60601-1 requirements, connections of peripheral equipment to the system must fulfill either of the following conditions:

a) The peripheral equipment itself is a medical device complying with IEC/EN 60601-1.

b) Non-medical peripheral equipment approved according to any other EN or IEC standard must take the following measures during installation:

- Connect the equipotential connector of the system to an independent protective earth terminal with a potential equalization conductor.
- The peripheral equipment is located at least 1.5 meters (1.8 meters in Canada and the U.S.A) outside the patient environment. A patient environment is defined as the area in which medical examination, monitoring, or treatment of the patient takes place.
- The peripheral equipment is connected to a main outlet outside the patient environment but still within the same room with the system.

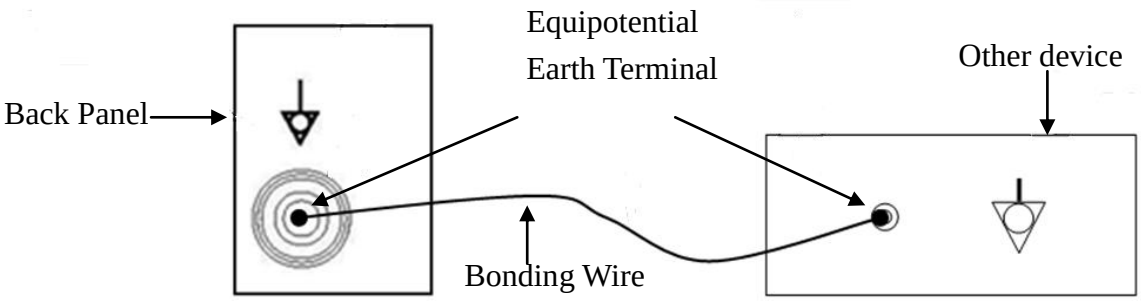


Figure 3-18 Equipotential Bonding

WARNING

1. Equipotential bonding: when the device is running with other instruments jointly, consideration should be given to equipotentiality.
2. Doctors and patients might be exposed to the hazardous and uncontrollable effects of compensating current caused by unbalanced equipotentiality between indoor medical device and touchable conducting parts. The safest solution is to build a unified equipotential network, to which the medical device is connected, using an angular plug.

3.7 Printer Installation

This system supports graph/text report printers.

To install a graph/text report printer:

1. Power off the main unit and the printer.
2. Connect the printer with the main unit by using a USB cable.
3. Power on the main unit and run the printer.

NOTE:

1. Please check the printer user manual for details about printer installation.
2. Multiple portable socket-outlet is not intended for the device, anybody, who connects it to

the signal input or output connector to configure a medical system, must make sure that it 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.

3. If you want to use a multiple portable socket-outlet to supply power to the whole FTS-6 system, you are suggested to calculate the system power consumption when building a FTS-6 system so as to match the system power consumption with the power sustained by a multiple portable socket-outlet.

The system cannot automatically identify printers it does not support. You should install the printer driver.

3.8 Connecting to F Series Monitors

F series monitors can be connected to this system via Ethnet. But the operation must be carried out by qualified personnel authorized by the manufacturer.

Chapter 4 *Basic Functions and Operation

4.1 Binding Wireless Transducers to Sub-windows

Wireless transducers and sub-windows are bound in two ways: automatic binding and manual binding.

4.1.1 Automatic Binding

If a transducer is figured with automatic binding mode, you can select a sub-window for the transducer before monitoring, or the system will automatically allocate one for it. Transducer information and monitoring data will be displayed on the bound window. When the transducer is docked back, the binding will be terminated automatically.

In the automatic binding mode, each sub-window provides three monitoring modes: singleton, twins and triplets.

Below are the operation steps:

- Select a sub-window and take up a wireless transducer (US or TOCO) for singleton monitoring. If you are to monitor twins or triplets, configure the sub-window to "**Twins**" or "**Triplets**", and take up two or three wireless US transducers.
- Properly tie the transducer(s) to the patient.
- Start monitoring. Monitoring data will be displayed on the bound sub-window.

Note:

If you take up a wireless transducer without a bound sub-window, the system will automatically allocate one for it.

4.1.2 Manual Binding

If a transducer is figured with manual binding mode, the service engineers have already bound the transducer to a specific sub-window.

When the transducer is taken up from the docking slot, transducer information and monitoring data will be displayed on the bound sub-window. For instance, if transducer A is bound to the No.1 sub-window, its transducer information and monitoring data will always be displayed on the No.1 sub-window.

4.2 Preparing to Monitor a Patient

NOTE:

Familiarize yourself with the basic operation principles before you start to monitor.

4.2.1 Switching on the System

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 thesystem.

2 If any sign of damage is detected, or the system 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 system is in good condition.

- Connect the system to AC mains and press the power button on the back of the trolley.
- Switch on the computer by pressing the power button on its right side.
- The power button and the screen light up and the main interface will be displayed.
- The system is ready for monitoring.

4.2.2 Confirming Fetal Life

Fetal monitoring with ultrasound cannot always 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.
- Movement of the deceased fetus during or following maternal movement.

Therefore, you need to confirm fetal life by other means before starting to use the system, for example, by using a fetoscope, stethoscope, Pinard stethoscope or an obstetric ultrasonography.

4.3 Monitoring FHR Using 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 the24th week of gestation.

WARNING

1 Make sure you have confirmed the fetal life by other means before using this system for FHR monitoring.
2 FHR should not be monitored until a clear fetal heart signal is detected.
3 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.
4 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.
5 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.
6 The patient's steps may interfere with the monitoring of fetal heartbeats. It is suggested that the patient walks as less as possible.
7 Excessive motion or vigorous movement may interfere with the monitoring and computing of FHR. Please try to avoid them.

4.3.1 Monitoring Single FHR

4.3.1.1 Parts You Need

- ✓ Wireless US transducer
- ✓ Aquasonic coupling gel
- ✓ Belt

4.3.1.2 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 using a stethoscope or a fetoscope. 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.

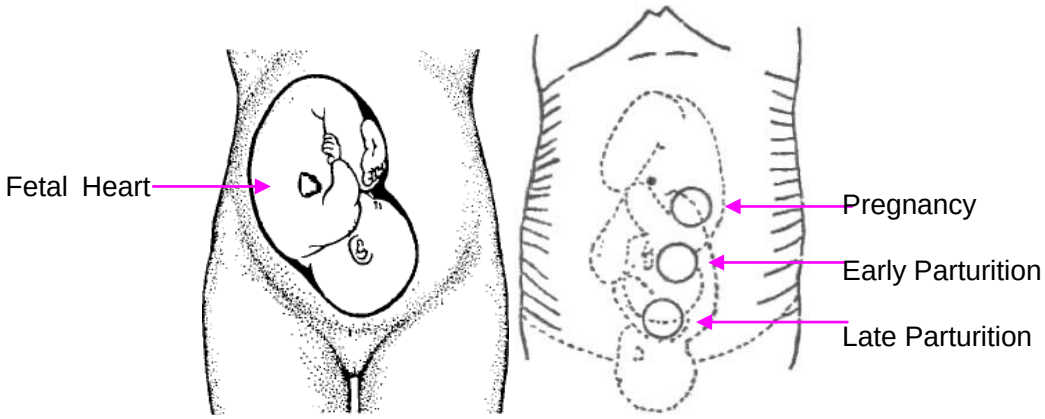


Figure 4-1 Positioning Ultrasound Transducer (single fetus)

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. 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

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

Ultrasound Doppler technology is utilized to observe the fetal heart rate externally when there are possibilities that maternal heart rate signal is mistaken for FHR signal. It is highly recommended to confirm that the fetus is the signal source continuously. You can perform the following operation:

- Feel the maternal pulse at the same time.

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

NOTE:

1 Fix the transducers tightly to ensure that they will not shift during movement.

2 For better monitoring, it is recommended to place the transducers when the patient is standing.

3 Instruct the patient to move in the prescriptive area and distance for obtaining better signal.

4 Do not mistake the high maternal heart rate for fetal heart rate. The fetal pulse can be distinguished from the maternal pulse by feeling the mother's pulse during the examination.

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

6 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.

7 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. TOCO transducers can be applied to the belly directly without coupling gel.

8 During long-time monitoring, the gel may dry out as the transducer moves around. Add more gel in time if it is inadequate. But be careful, because excessive coupling gel may slide the transducer.

9 When applied to the patient, the ultrasound transducer may warm slightly (less than 10°C (18ºF) above ambient temperature). When NOT applied, at the ambient temperature of 40°C (104ºF), the ultrasound transducer may reach the highest temperature of 50°C (122ºF).

10 When an ultrasound transducer is connected to the monitoring system, but not applied to the patient, the measurement may generate unexpected intermittent FHR readings.

4.3.2 Monitoring Twin FHRs

To monitor twin FHRs, the two US transducers must bind to the same sub-window. For monitoring procedures, please refer to *4.31.2 Monitoring Procedure*.

When acquiring the second FHR, do not shift the first US transducer. Make sure two FHR sounds are clearly heard, and two FHR traces and FHR values are displayed on the screen.

4.3.3 Monitoring Triple FHRs

To monitor triple FHRs, the three US transducers must bind to the same sub-window. For monitoring procedures, please refer to *4.31.2 Monitoring Procedure*.

When acquiring the third FHR, do not shift the first and the second US transducers. Make sure three FHR sounds are clearly heard, and three FHR traces and FHR values are displayed on the screen.

4.3.4 Signals Overlap Verification (SOV)

When monitoring twins or triplets, the monitored heart rate signals may overlap at any time and an FHR's signal may be mistaken for the other's or another one's signal. The system 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, FHR2)", "Signals Overlap (FHR1, FHR3)" or "Signals Overlap (FHR2, FHR3)" will appear on the screen to warn you. Check of the patient and reposition of transducers might be needed.

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

4.4.1 Parts You Need

- ✓ Wireless TOCO transducer
- ✓ Belt

4.4.2 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.

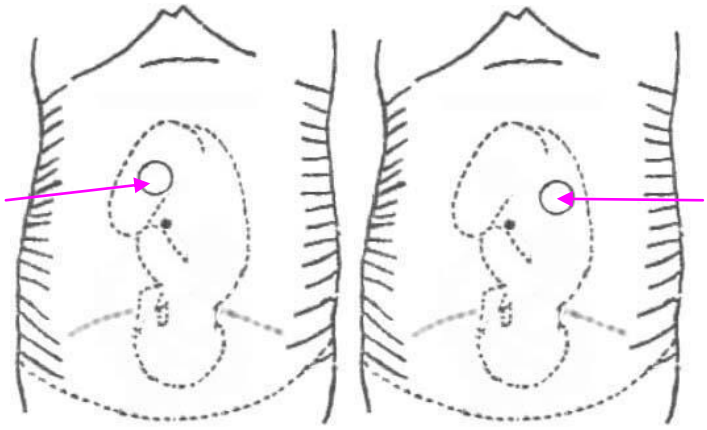
Alternatively, the patient can take a sitting position. Arrange the belt around her abdomen.

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.

Place the transducer on fetal buttocks for NST



Place the transducer on fetal back in delivery

Figure 4-2 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.

3 If TOCO is zero and lasts for 30 seconds, the system will auto-zero TOCO.

4 When applied to the patient, the TOCO transducer may warm slightly (less than 10°C (18ºF) above ambient temperature). When NOT applied, at the ambient temperature of 40°C (104ºF), the TOCO transducer may reach the highest temperature of 50°C (122ºF).

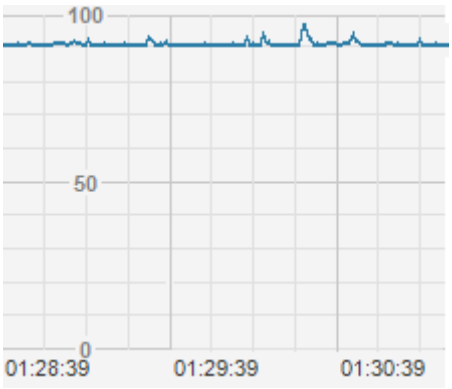
5 Temperature of the TOCO transducer may rise and be close to body temperature during charging, but this is normal phenomenon. Please inform the patient before monitoring.

4.5 Monitoring Auto Fetal Movement

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.

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

Trace



Black Mark

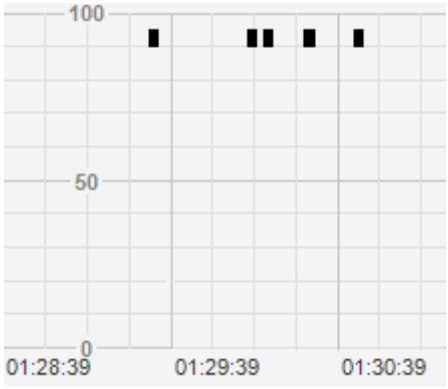


Figure 4-3 AFM Displaying

4.6 After Monitoring

At the end of monitoring, remove the transducers and belts from the patient. Wipe the remaining gel off the patient and the transducers with a clean soft cloth or tissue.

Then switch off the system and unplug the power cord.

WARNING

1 Remaining gel on the US transducer must be wiped clean after each use, or it may lead to unsuccessful charging of the transducer.

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.

CAUTION

Do not press the POWER switch continuously. Allow at least 10 seconds between switching the system on and off.

NOTE:

After the fetus is delivered, the system may pick up signals of the umbilical cord and display a trace/numeric. To avoid misinterpretation, it is recommended to remove the transducers from the patient and switch off the system immediately after the fetus is delivered.

4.7 Transducer Behavior

Additional information regarding transducer operation is given in this section.

4.7.1 Testing US Transducers

To test a wireless US transducer:

1 Switch on the system.

2 Connect the wireless US transducer to the system.

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.

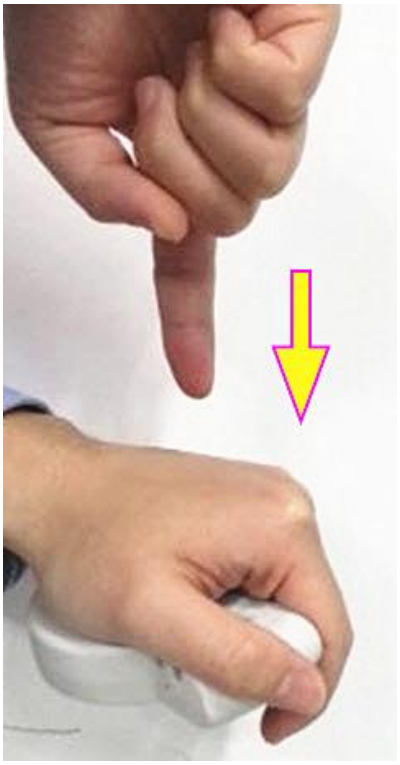


Figure 4-4 Testing a US Transducer

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.

4.7.2 Testing TOCO Transducers

To test a wireless TOCO transducer:

1 Switch on the system.

2 Connect the wireless TOCO transducer to the system.

3 Gently press the center of the transducer.

Figure 4-5 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.

4.7.3 Charging Transducers

Caution

1 When in indicates the power is low, please change for a new battery or charge the rechargeable battery in time, or the 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.

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

 Enough battery

 Sufficient battery

 Inadequate battery

 Low battery, please charge immediately; right now the message low battery will

be displayed at the message area.

 The battery is almost depleted and needs to recharge immediately.

Place a wireless transducer in the docking slot when the power box of the system is switched on, and it will charge automatically. But before you charge the transducer, please clean the transducer and the charging point with a dry cloth to make sure they are free of water and residual gel.

It takes about 3.5 hours to charge the battery. There are respective icons to indicate whether the transducer is charging or fully charged.

It is recommended to place the transducer in the docking slot when the transducer is not used for a long time.

4.7.4 Transducer Searching

Once taken up, a wireless transducer will be activated and becomes an online transducer. You can check all online transducers on the system. After activating new wireless transducers, click **Refresh** to refresh the online transducer list and you can see the newly activated transducers are listed.

If you want to search for a wireless transducer, choose it from the online transducer list and click **Search Transducer**, the transducer will buzz and you can locate it easily.

4.7.5 Relocation of Transducers

Transducers may be belted on the patient for a long time without stop. In rare cases, this may lead to irritations to the patient skin. To avoid skin irritations, please inspect the application site at least every three hours. If the skin quality changes, you should move the transducer to another site.

US transducers need to change application site frequently to track fetal heart. It is normal during a monitoring process. But TOCO transducers are different. Please periodically inspect the application site (between contractions) of TOCO transducer at least every three hours.

To reduce the risk of skin irritations, do not allow residual cleaning agent or disinfecting agent on the surface of transducers. Before using cleaning agent and/or disinfecting agent, refer to the cleaning and disinfecting sections in this user manual. Wipe the transducer surface with a cloth dampened with water before applying to the patient.

4.7.6 Transducer Displaying

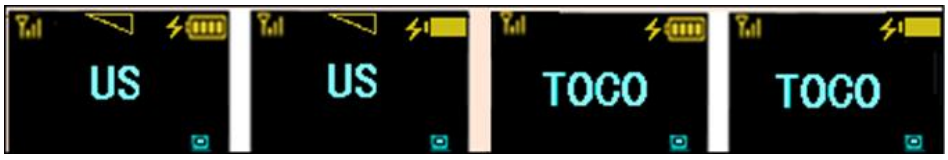
WARNING

1 Check if names appear on the US transducer and the TOCO transducer are of the same patient. Do not mix up the transducers of different patients.

2 Please ensure that the patient name displayed on the transducer is the same with that on its bound sub-window.

4.7.6.1 Displaying after Binding to Sub-windows

- Automatic Binding:



1 Transducer displays “0” when taken up.

2 Transducer displays the window number after automatic binding.

3 It also displays the patient’s name and transducer type (TOCO, US1/US2/US3).

- Manual Binding
-

Transducer displays the already configured window number and transducer type (TOCO, US1/US2/US3).

NOTE:

1 The transducer displays patient’s name in English and it displays 32 characters at most, including the blank spaces between words.

2 The transducer displays patient name and sub-window number alternately every 5 seconds

4.7.6.2 Other Displaying

- A transducer signal strength icon appears on the top left corner, and it has four degrees

- US signal level icon appears in the middle on the top of the screen
-  A battery level icon appears on the top right corner, and it has five degrees

- In the process of charging, a charging icon  displays beside the battery level icon

  e.g.: 

  When the transducer is fully charged, the icon changes to 

  If the transducer is not well connected to the charging point in the docking slot, or no battery is installed in the transducer, an error icon  will appear on the middle of the screen. In this occasion, no other icons will appear beside the error icon.

- ◆ After the wireless probe is well connected, the probe will receive the maternal names sent from work station. The probe supports Chinese and English display, if the work station sends English name, the wireless probe shows English name; if the work station sends Chinese name, it shows Chinese name.

  If the maternal name is Chinese, when the name is no more than 4 characters, the name can be shown completely. When the name is more than 4 characters, only the first three characters are shown, and the rest characters are replaced by "*";

  If the maternal name is English, at most 32 English characters can be shown (including the space between characters). The detailed English name is shown as per the format sent by the work station;

- ◆ The maternal name and window number are shown alternately, with alternation cycle of 5 seconds:

4.8 Changing Screen Brightness

WARNING

Please ask the authorized professionals to change screen brightness, lest traces and alarm messages might change and make it difficult to observe.

Screen brightness can be adjusted by the two brightness control buttons below the screen (see the figure below.)

Figure 4-6 Screen Brightness Control Buttons

Press the left button to lower brightness and the right one to increase brightness.

Chapter 5 *Software Operation

5.1 Login/Logout

5.1.1 Login

Double-click the software icon  on the desktop to enter the login interface as below.

Figure 5-1 Login Interface

Input your username and password, and then click **Login** to enter the software main interface. A "Do" tone for software audio test is repeated three times after you click **Login**, and you need to adjust the audio settings to ensure the sound can be clearly heard.

If you tick **Auto login**, you will not need to enter the password the next time you log in to the software.

CAUTION

Ensure that your sound equipment is active.

NOTE:

1 After you log in, you can press Ctrl+F2 to configure **Shield the operation software** (open by default and unchangeable) and **Shutdown after exit**.

2 Right-click the tool bar to select **Back to Windows** if you need to return to the operation software while the software is running.

5.1.2 Logout

After all monitoring is finished, please click **Close** on the tool bar and select **Yes** in the pop-up box to exit. The software will automatically load the un-archived data every time you restart the software.

NOTE:

1 After logging out, dock the wireless transducers back to the docking slots.

2 If you want to resume monitoring after logging out in the middle of a monitoring process, please dock the wireless transducers back to the docking slots first, and then take them up again.

5.2 Main Interface

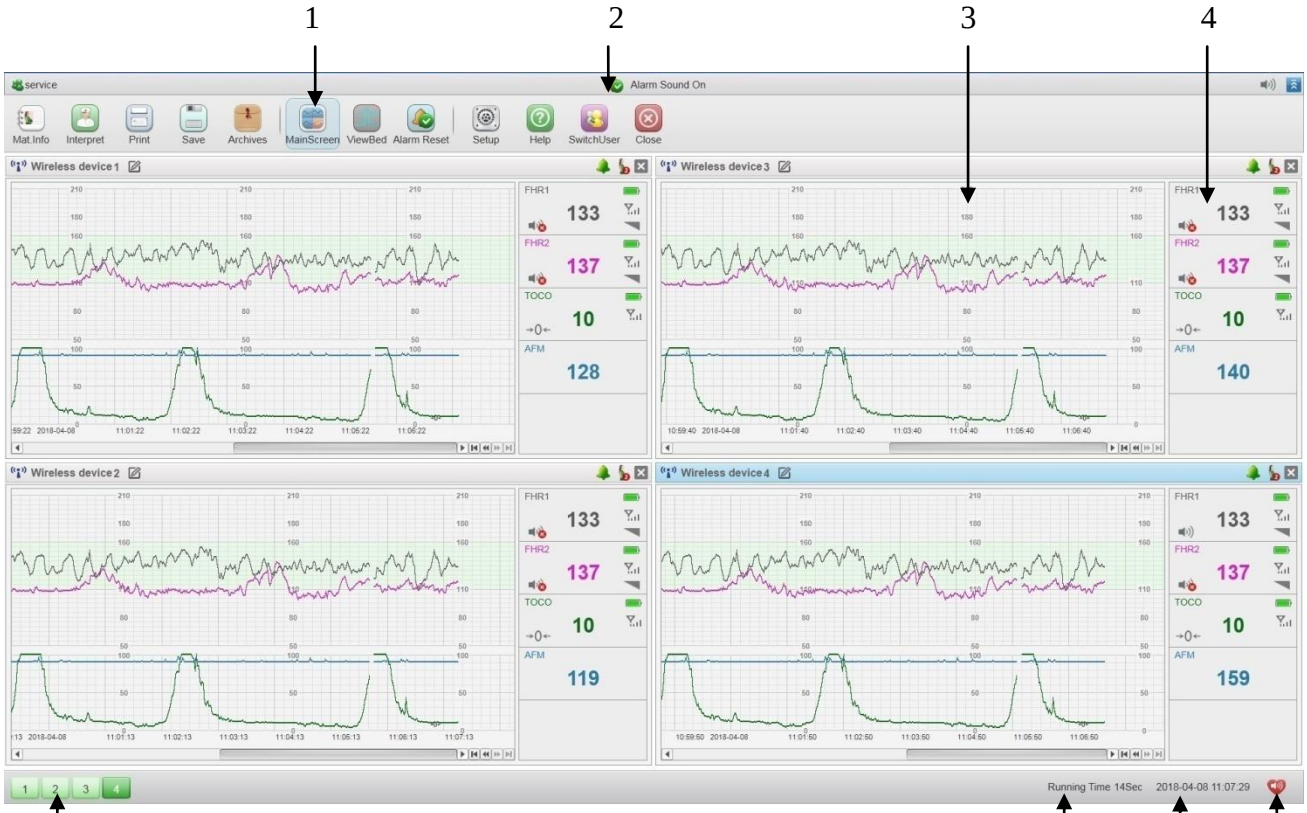


Figure 5-2Main Operation Interface

1 Tool Bar 2 Audio Alarm Indication 3 Monitoring Window

4 Numeric Area for Wireless Transducers 5 Device Light

6 Software Running Time 7 LocalTime8 Fetal Heart Sound Volume

NOTE:

1 The software can display at most 12sub-windows, including 8 sub-windows of data of wireless transducers and 4 sub-windows of data of monitors at most.

2 If sub-windows are less than 8, they will be displayed on one screen. If sub-windows are more than 8, the first screen will display 8 ones and the second screen will display the ones left. Wireless devices have the priority to appear on the first screen.

3 Only high/advanced users have the authority to add sub-windows for wireless transducers or monitors.

5.2.1 Toolbar

The location of the toolbar on the main interface can be adjusted by right-clicking the blank of the toolbar and selecting "Bottom display" or "Top display" . Click different buttons to do different operations. Refer to the following table for details.

Button	**Function**
Reserve	Establish the reservation list.
MainScreen	Return to the **Monitoring** window from the **ViewBed** window.
ViewBed	Maximize the current **Monitoring** window and enter the **ViewBed** window to observe the data and trends.
Mat.Info.	Open the **Mat.Info** window to input maternal information.
Analyze	Make an analysis on the fetal monitoring data.
Print	Preview and print reports.
Save	Save all monitoring data to the database.
Archives	Enter the **Archive** window to view, search or load monitoring records.
Silence	Set the audio alarm indication.
Setup	Enter the **Setup** window to change the settings.
Help	Get help information about the software operation.
SwitchUser	Log in as a new user after logout.
Chalkboard	Display the connection status of and maternal information on all the bedside monitors in a ward.
Close	Close the software.

Right-click the blank of the toolbar and the **Customize** button 

will show up. You can move any items in the **Available Function** list to the **Current Function** list. All items in the **Current Function** list are displayed in the toolbar.

Three separators are provided by the software. You can move a separator from the **Available**

Function list to the **Current Function** list or vice versa. Click  or  to change the position of the separator in the **Current Function** list. For example, if the separator is placed between the Silence and Setup button in the **Current Function** list, there will be a separator between the two buttons 

.

NOTE:

You can move any items in the **Current Function** list to the **Available Function** list except the following ones:

- MainScreen
- ViewBed
- Silence
- SwitchUser
- Close

5.2.2 Shortcut Keys

The workstation software supports shortcut keys so users can visit commonly used functions conveniently.

F1：Open Help interface

Ctrl+F2：Open System Function Configuration interface

Ctrl+1：Open Maternal Information interface

Ctrl+2： Open Analyze interface

Ctrl+3：Open Print Preview interface

Ctrl+4：Archive current data

Ctrl+5：Open History Data interface

Ctrl+6：Open MainScreen interface

Ctrl+7：Open ViewBed interface

5.2.3 Device Light

Device light stands for the status of a bedside monitor: gray for offline, green for online and yellow for an active alarm. A device light indicates the status of a monitoring window, for example, 

indicates that Device No.3 is online.

Besides, the device light can remind the user with different colors and flicker frequencies at an alarm.

Device Light	**Alarm Frequency**	**Alarm Level**
Yellow with 0.5Hz flicker frequency	Interval between two alarm sounds is 3 seconds	Medium
Yellow with no flicker	Interval between two alarm sounds is 16 seconds	Low

5.2.4 Local Time

Before you start monitoring, please ensure that the date and time on the main interface are correct.

5.2.5 Full Screen Display

Under the **MainScreen** or **ViewBed** mode, the tool bar will be hidden and the full-screen display will be started if you click the  button on the upper right of the screen. Then, the button will turn to  , a click on which will lead to the reappearance of the tool bar.

5.2.6 Close/Open a Sub-window

Under the **MainScreen** mode, click the close button on the upper right of a sub-window to close the sub-window. If you need to re-open the sub-window, click the sub-window's device light on the lower left of the main interface.

NOTE:

If there is only one sub-window, you cannot close it.

5.2.7 View Monitoring Data

Under the **MainScreen** or **ViewBed** mode, you can drag the curve and view data with a hand tool: right-click the window to select **Hand Tool** and the pointer turns to a hand. Also, you can select a certain length of curve to locate its trend in blue with a pointer tool: right-click the window to select

Pointer Tool and the hand switches back to a pointer. By default, the mouse appears as a pointer in the CTG area.

If the monitoring lasts for a long time and the CTG curve stretches over more than one screen, you can drag the scroll bar left or right or use the play back and review keys to view the previous data.

Figure 5-3 Scroll Control Keys

Icon	Description	Function
	Scroll Bar	Drag the scroll bar to jump to the required position.
	Home	Click **Home** or to jump to the start of the CTG;
	Backward	Click **Backward** or to view the previous CTG. Click in the trend display area to stop at the point where you need to review the trend.
	Forward	Click **Forward** or toview the later CTG. Click in the trend display area to stop at the point where you need to review the trend.
	End	Click **End** or to jump to the end of theCTG.

Alternatively, you can right-click in the curve area and select the keys in the pop-up menu

5.3 Monitoring Interface

5.3.1 Sub-window of the Wireless Transducers

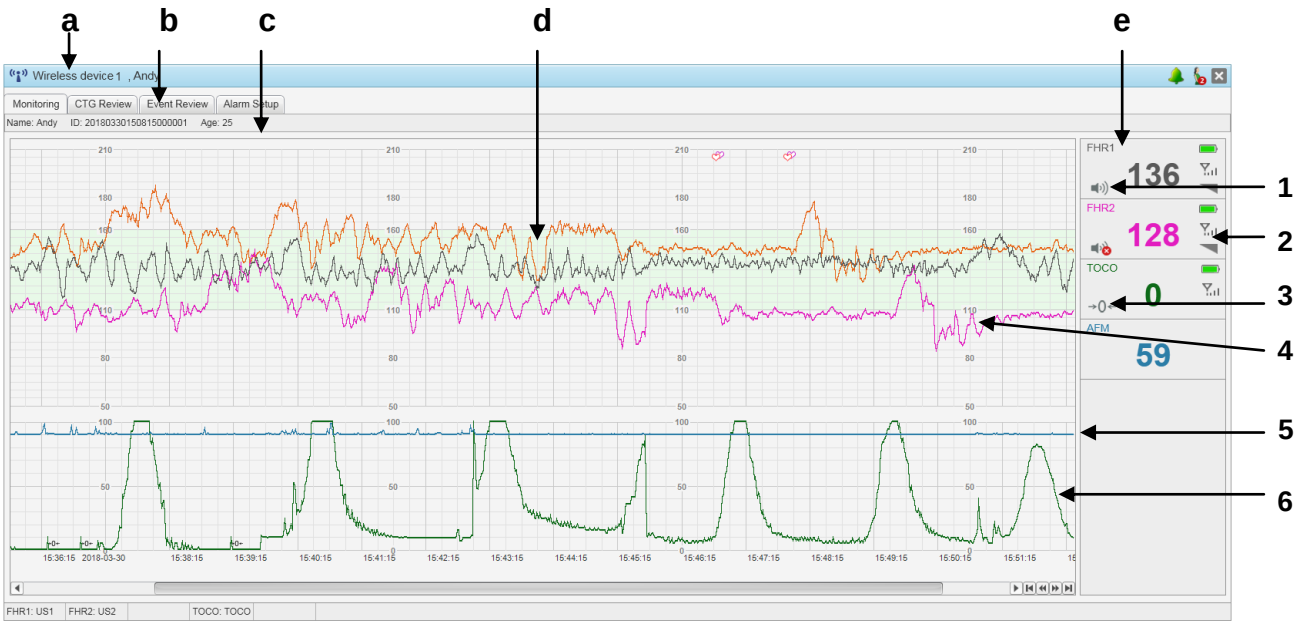


Figure 5-4 Sub-window of Wireless Transducers

a) Title Bar

Device number, patient name, alarm message and alarm indicator are displayed here.

If the wireless binding mode is automatic binding, icon indicating singleton/twins/triplets monitoring mode is also displayed in the title bar.

If patient name is empty, icon will be shown in the title bar and maternal information input interface will prompt out, informing user to input patient name.

b) Frames

Each sub-window has 6 frames: monitoring frame, CTG review frame, trend review frame, NIBP review frame, event review frame and alarm setup frame. You can open a frame by simply clicking on it. But for CTG review frame, trend review frame, NIBP review frame and event review frame, they are gray and cannot be opened until they have review data.

c) Maternal Information

You can check information of the patient being monitored here.

d) Traces

FHR trace(s), TOCO trace and AFM trace are displayed in this area.

e) Parameters

Parameters, wireless transducer status and related operation keys are shown here.

If a wireless transducer is connected to the sub-window, the numeric area will display parameters and information of the transducer. While the connection mode is set to Auto, an icon for FHR number switch (Single/Double/Triplet) will appear on the upper right of the sub-window. For example, when you monitor twins, you need to set the mode to Double.

The picture above shows a sub-window of 3 US transducers and 1 TOCO transducer, and it contains the following information:

(1) FH sound switch:

Every FH value has a sound switch following it. Click it to turn the sound on or off.

(2) Signal quality and battery power:

From above to blow shows US signal quality, signal quality of wireless transducers, battery power of wireless transducers.

(3) Return UA to zero:

By pressing this button, the UA of the sub-window returns to the value preset.

(4) FHR1/FHR2/ FHR3 trace:

The dark band in between the fetal heart rate panes indicates the FHR safety range, which can be set within 100bpm~180bpm. It makes it easy to observe if the FHR exceeds the normal range.

(5) AFMtrace:

When the AFM display in the **Monitoring Setup** interface is set to Black Block, the AFM curve will be hidden and the black blocks only appear when the AFM amplitude exceeds 93 (The baseline is 90). If the AFM display is set to None, no curves and black blocks can be seen.

(6) UA trace

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

The software displays the following data if the connected transducers are wireless US transducers only:

- FHR1/FHR2/FHR3
- FHR value
- FH sound switch
- US signal quality: bad, weak, and good.
- Signal quality of wireless US transducers: 0, 1, 2, and 3.
- Battery power of wireless US transducers: 0, 1, 2, 3, and 4.
- AFM data: starts from 0.

The software displays the following data if the connected transducer is only a wireless TOCO transducer:

- UA
- UA value

- Signal quality of wireless TOCO transducers: 0, 1, 2, and 3.
- Battery power of wireless TOCO transducers: 0, 1, 2, 3, and 4.
- Return UA to zero

5.3.2 Sub-window of a Monitor

Figure 5-5 Fetal Monitoring Window

Every monitoring interface of a bedside monitor has three display mode options: **Fetal Monitoring** mode, **Mat. Fet. Monitoring** mode and **Mat.Monitoring** mode.

When the **Mat.Monitoring** mode is selected, the icon is switched to  and only maternal monitoring data is displayed in the curve area, including MHR, SpO_2, RESP, and NIBP. Under the **Fetal Monitoring** mode or the**Mat. Fet. Monitoring** mode, you can obtain the following information on this interface:

(a, b) FHR1/DFHR Trace, FHR2 Trace

The dark band in between the fetal heart rate panes indicates the FHR safety range, which can be set within 100bpm~180bpm. It makes it easy to observe if the FHR exceeds the normal range. So you can tell if the fetal heart rate is too low or too high.

NOTE:

1 To avoid the overlap of FHR1 trace and FHR2 trace, there is an FHR2 offset which can be set in the **Monitoring Setup** interface. The FHR2 offset value can be +20, 0, or -20 (default setting). That means theFHR2 trace in the curve trend may not show the real

data of FHR2 but the data affected by the offset value.

2 Due to the screen resolution and window size, the traces may look different on different LCDs. A screen with high resolution and of big size provides better reading experience. Analysis should be made according to the printed monitoring report.

(c) MHR Trace

Maternal heart rate trace, the y-axis of the trace indicates the numerics of MHR. The default setting is off.

(d) SpO_2 Trace

Maternal SpO2 trace, the y-axis of the trace indicates the numerics of SpO2. The default setting is off.

(e) AFM Trace

The y-axis indicates the scope of fetal movement. When the AFM display in the **Monitoring Setup** interface is set to Black Block, the AFM curve will be hidden and the black blocks only appear when the AFM amplitude exceeds 93 (The baseline is 90). If the AFM display is set to **None**, no curves and black blocks can be seen.

(f) UA Trace

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

(g) Maternal Vital Signs

If maternal monitoring is in process, the MHR, SpO_2 and TEMP are listed every 10 minutes, and NIBP is listed when it is performed.

(h) Signal Sources

The sources of FHR, UA and MHR are shown beneath the trends.

Parameter	**Source**	**Description**
FHR1	US	FHR1 signal comes from an ultrasound transducer.
	DECG	FHR1 signal comes from a fetal scalp electrode.
FHR2	US	FHR2 signal comes from an ultrasound transducer.
UA	TOCO	UA signal comes from a TOCO transducer.
	IUP	UA signal comes from an IUP.
MHR	ECG	MHR signal comes from ECG leads.
	Pulse	MHR signal comes from a SpO_2 sensor.

Besides, some other symbols appear among the traces:

	New monitoring, it indicates the screen starts advancing.
	The bedside monitor starts new monitoring by pressing the **START** key.
	A manual fetal movement. It appears after a patient presses the FM marker when she feels a fetal movement.
	Note icon, indicating a note is added on the software or the **MARK** key is pressed on the bedside monitor.
	The monitor is zeroed by pressing the **AUTO ZERO** key.
	A patient alarm is active.
	Signals overlap.
	Maternal vital sign list, or maternal NIBP result.

NOTE:

The screen starts advancing when there is valid fetal heart signal or UA change. It stops advancing if no valid fetal heart signal is received in 1 minute, and the UA change in 1 minute is smaller than 3.

5.3.3 Selecting a Section Manually

The auto section length in the **CTG Review** frame is preset and fixed. You can also select a section manually. The manually selected section has the priority when making a analysis and printing, compared to the automatically selected section.

Right-click in the fetal heart curve area and then choose **Select Section Start**. Then, a "☞" symbol shows up. Move the cursor to the target position and right-click to choose **Select Section End**. A "☜" symbol shows up, rendering the selected are aencircled.

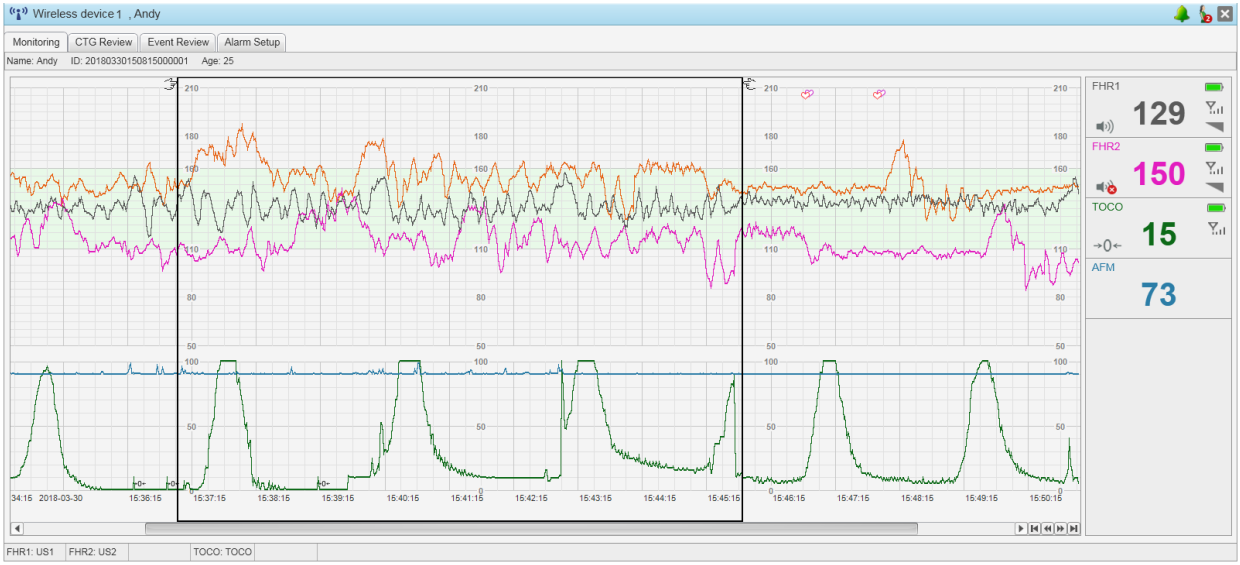


Figure 5-6 Select a Section

NOTE:

The manually selected section should include at least1-minute CTG data, and the start/end can only be selected in the valid data area. If the section start and (or) end points are located between the gridlines, the software moves them to the closest gridline automatically when printing the report or making an analysis.

The manual section is cleared after you perform diagnosing, printing, saving, clearing, or clicking on another window.

5.3.4 Making Notes

When there is a significant event, for example, when the patient takes injection or changes position, you can make a note on the trend.

1) **Adding a note**

   Move the cursor to the fetal monitoring curve area, right-click the mouse and then select **Add Note**.

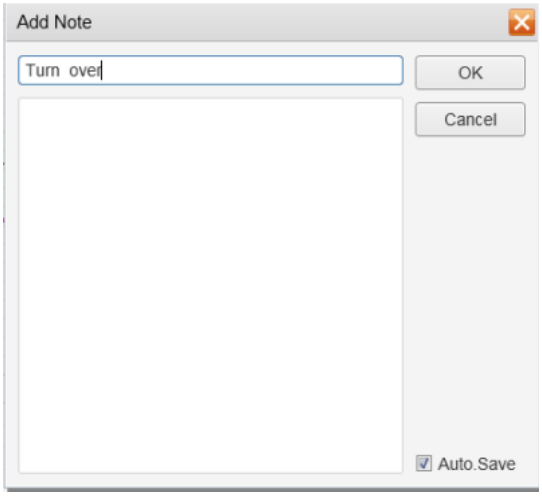


Figure 5-7 Adding a Note

   In the pop-up dialog box, you can type in the note content (At most 50 letters are allowed.), or select one of the notes from the note list below, and then click **OK**.

   A note icon " " appears in the CTG area where the mouse is clicked. For example:

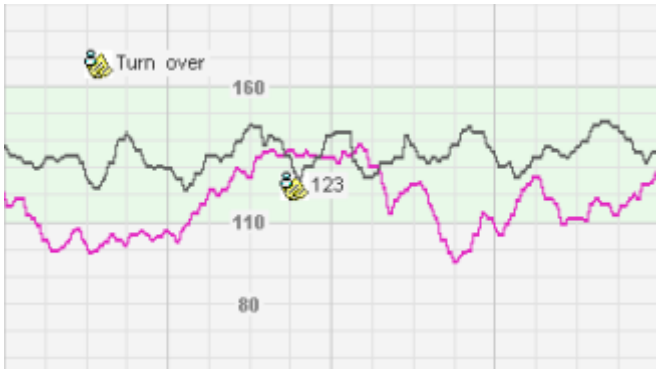


Figure 5-8 Note on CTG

NOTE:

1 Click the mouse in a vacant area in case the note covers the curve on the area.

2 At most 1024 events can be included in a monitoring window.

2) **Modifying a note**

To change the content of a note, move the cursor to this note icon, right-click the mouse and select **Modify Note**. Type in the new content and then click **OK**.

3) **Deleting a note**

To delete a note, move the cursor to the note icon, right-click the mouse and then select **Delete Note**.

5.3.5 Highlighting a Section

You can highlight a section of a FHR1, FHR2 or UA trace to make the section noticeable.

To highlight a section,

1) Right-click a FHR1, FHR2 or UA trace and click **Select Highlight Start**. A"" symbol shows up.
2) Move the cursor to the next point, right-click to **Select Highlight End**, and this section of the trace will be shown in bold.

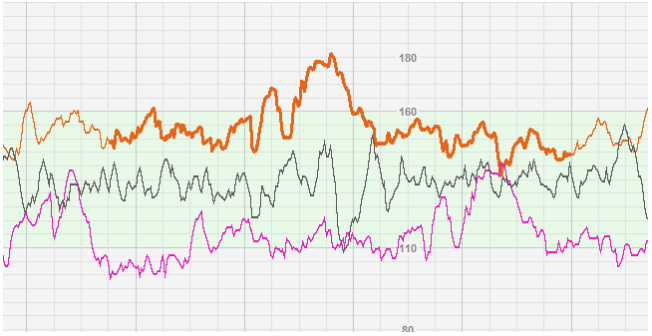


Figure 5-9 Highlight a Section

NOTE:

If the mouse is not clicked on a FHR1, FHR2 or UA trace, the software highlights the closest trace automatically.

5.3.6 NST Timer

The NST timer measures the NST monitoring duration and signals when the time is out.

Right-click in the fetal monitoring curve area, click **NST Timer** and then select a length.

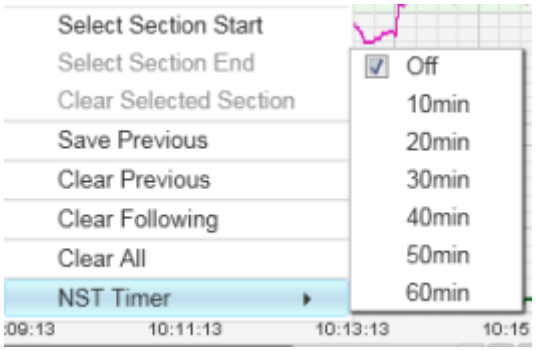


Figure 5-10Setting NST Timer

The elapsed time appears in the top right corner of the curve area, with a blue background 00:07:34.

When the time is out, the timer background turns into all green, like 00:12:00, followed by a message "NST timeout" in the title bar.

After the data is saved, a new monitoring cycle starts. Then, the timer starts to count time all over again.

NOTE:

NST Timer counts time according to the time length during which effective CTG data has been received instead of the time length during which the software has been running. The timer stops if no CTG data is transferred to the software (for example, when the bedside monitor is offline/ does not have any signal, or when the software is closed).

5.3.7 Saving Data

After a patient finishes monitoring, you should save her data as a history record in the archives. If it is not saved, data of the new patient will be connected to that of the previous patient, making it difficult to distinguish and analyze.

If the current window contains data of more than one patient, you can save it separately. Drag the scroll bar or click the playback key to the new monitoring mark➡, right-click the mouse and select **Save Previous**. Click **OK** to confirm saving. The software saves the previous data as a record in the

archives, and clears it from the current window.

If the current window contains data of only one patient, you can click the **Save** button 

in the toolbar. All data will be saved as a record in the archives. The data includes patient information, CTG trends, maternal vital sign trend and NIBP list, and analysis records. You can load the record for review, analysis and printing.

After the device is offline, the software automatically saves the un-archived data at the saving time preset. If the data contains patient name, it will be saved automatically. If it doesn't, patient name must be input.

NOTE:

1 The software automatically saves data every minute. You only need to save the data once at the end of every monitoring.

2 If the monitoring continues after 24 hours, the software saves the data as a record in the archives, and starts a new monitoring circle.

3 If you want to save the previous data, ensure the data is generated at least one minute before the latest time. Besides, the duration of the data saved by a click on **Save Previous** should be at least one minute.

5.3.8 Clearing Data

For the useless data, you can clear it.

To clear the data partially, move the cursor to a point, right-click in the CTG area and then select **Clear Previous**. Click **Yes** to delete the data before the point, or click **No** to cancel the selection.

If you want to clear all data of the current window, right-click to select **Clear All**. Click **Yes** to delete all data, or click **No** to cancel.

NOTE:

The cleared data cannot be restored. Make sure the data is useless before clearing it.

5.4 Intensive View of a Bed

The monitoring windows of all the monitors in a ward are arranged equally on the main interface, and the selected window is marked with dark title bar. In order to clearly and intensively observe the data on a bedside monitor, you need to select it first and then click 

in the toolbar or double-click in the trend display area.

The **ViewBed** window includes several frames: **Monitoring, CTG Review, Trend Review, NIBP Review, Event Review**, **Alarm Setup**, and **Labor Info**..

In the **ViewBed** window, click the **MainScreen** button  in the toolbar or double-click in the CTG area to return to the main interface.

5.4.1 Monitoring Frame

By default, the software enters the **Monitoring** frame after the **ViewBed** window is open. You can perform all operations introduced in section 5.3 on the **Monitoring** frame.

5.4.2 CTG Review Frame

Figure 5-11 CTG Review Frame

The top half of the **CTG Review** frame is the CTG trend of the whole monitoring process (24 hours at most).

Click in the top half area, and the software marks a section (auto section) with a red pane. The bottom half shows its details.

5.4.3 Trend Review Frame

The **Trend Review** frame lists maternal monitoring parameters of 24 hours. The data is saved every minute. The parameters include MHR, $MSpO_2$, NIBP and TEMP.

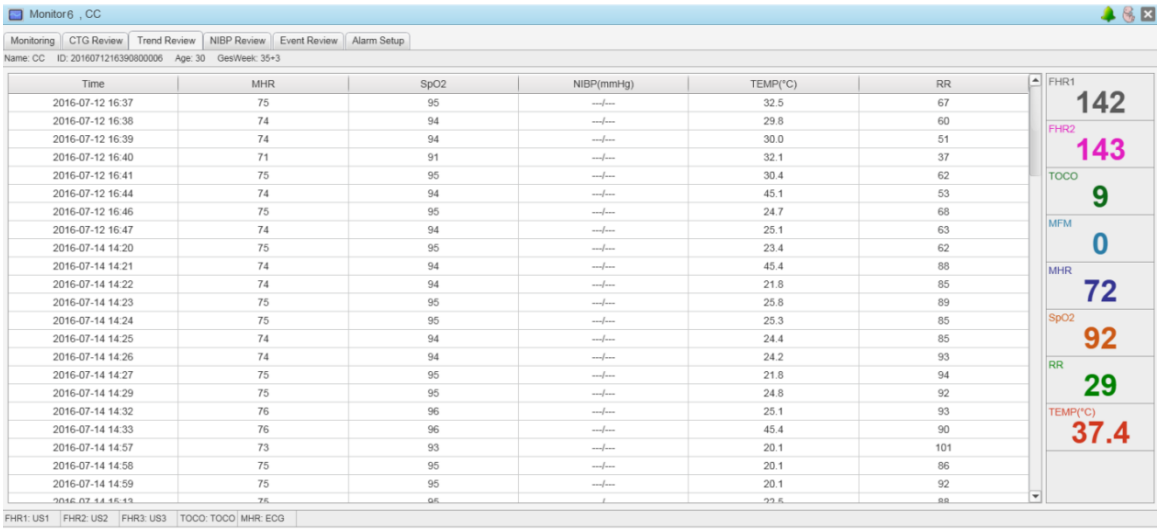


Figure 5-12 Trend Review Frame

5.4.4 NIBP Review Frame

NIBP Review frame can list 200 groups of NIBP measured during monitoring. The software saves a group of data after every NIBP measurement.

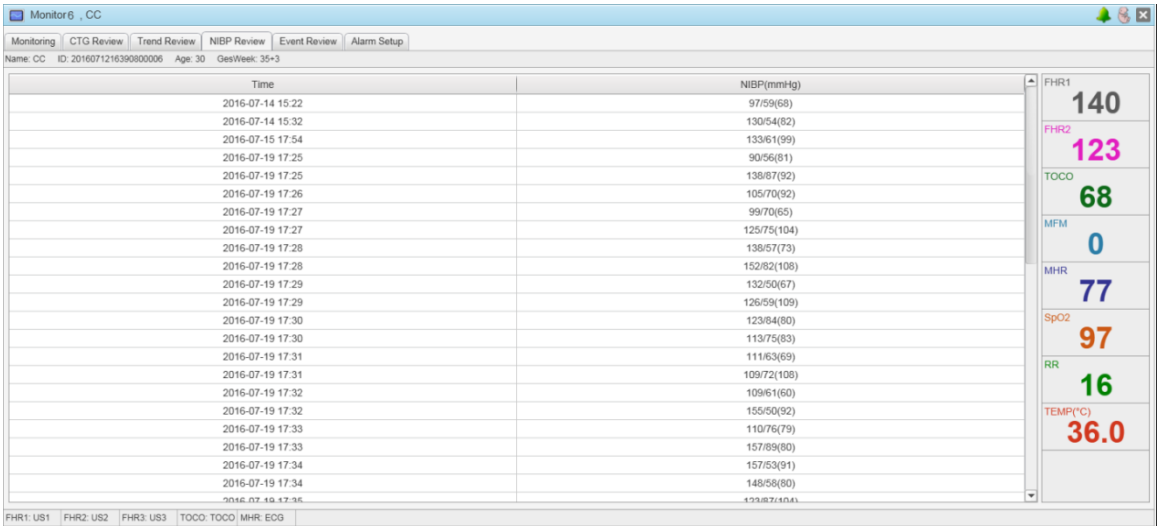


Figure 5-13NIBP Review Frame

5.4.5 Event Review Frame

The top half of the **Event Review** frame shows the CTG curves, while the bottom half of the **Event Review** frame lists all the events.

The software will position an event on the screen with a pink vertical line if you click it.

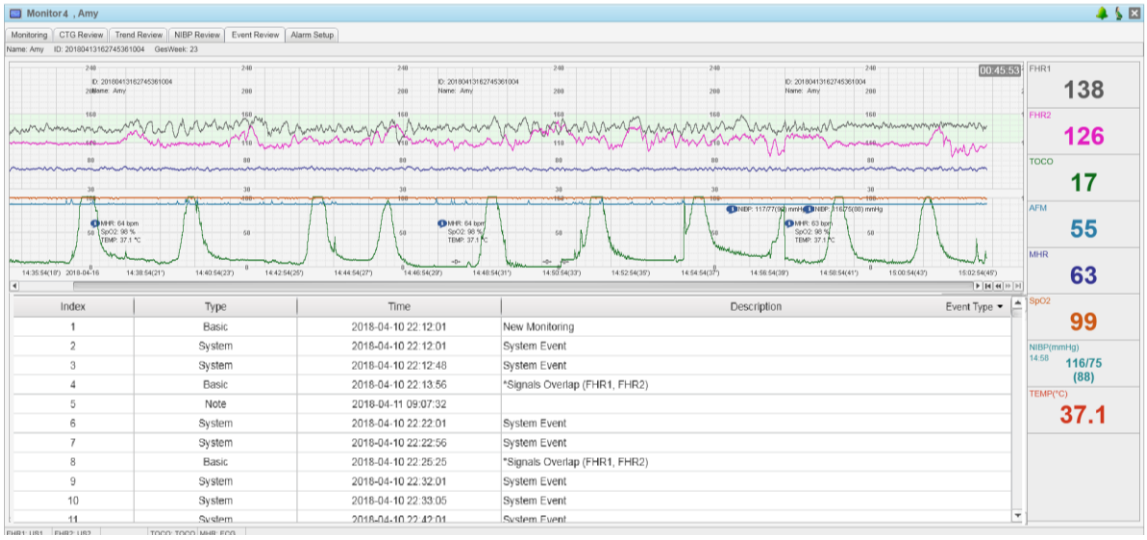


Figure 5-14 Event review frame

The events in the list are divided into four types: **Basic**, **Note**, **Alarm** and **Software**. You can choose to show some or all types of events. Tick the type(s) of the event you want to show.

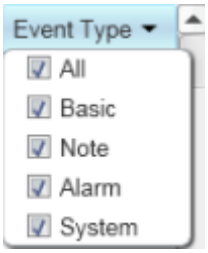


Figure 5-15Event type

5.4.6 Alarm Setup Frame

The **Alarm Setup** frame shows alarm settings of this window. You can change the setting or load default settings.

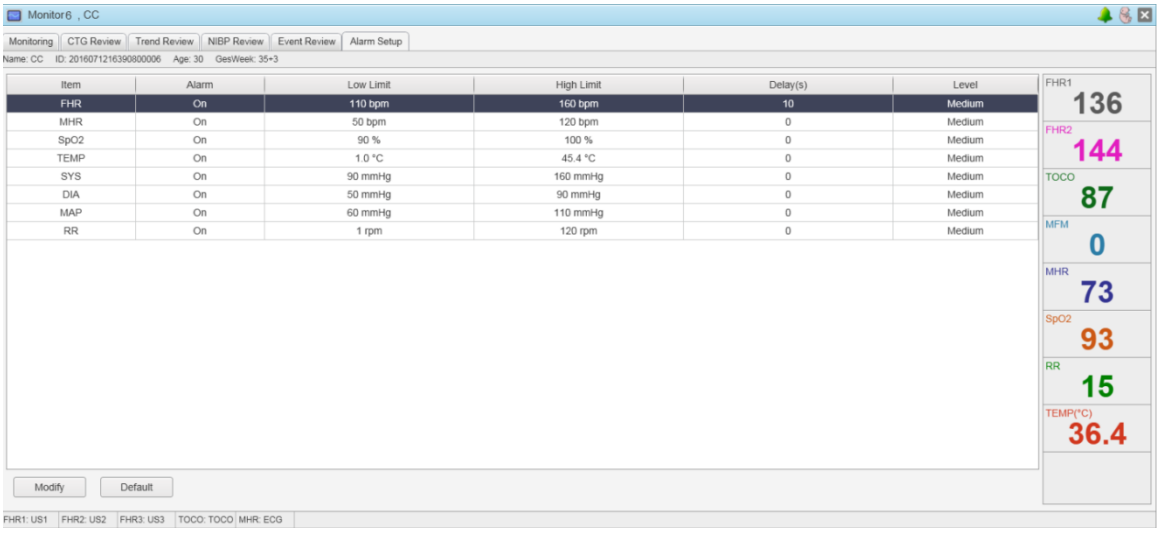
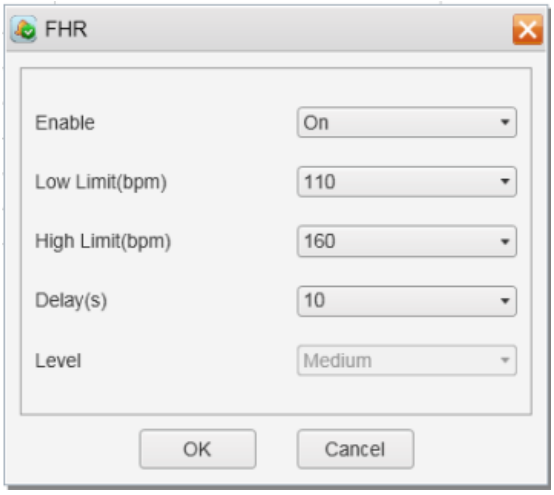


Figure 5-16 Alarm setup frame

The alarm items, their status, and other information are listed. If you want to change the alarm settings, select the alarm item and then click **Modify**. The following figure shows the box of changing FHR alarm settings.



- **Enable:**

To switch the alarm on or off

- **Low Alarm Limit:**

The value lower than which an alarm will be triggered

- **High Alarm Limit:**

The value higher than which an alarm will be triggered

- **Alarm Delay:**

The time during which a vital sign exceeds its limit before an alarm is triggered

Figure 5-17FHR alarm setup

When the alarm is set to **Off** in the **Enable** list, an icon will appear beside the related parameter.

If you want to load the user default alarm settings, click **Default** in the lower left corner.

The table below lists options and default settings of each alarm item:

Item	**Options**	**Default Setting**
FHR (bpm)		
Alarm	On/Off	On
Low Alarm Limit (bpm)	60~205	110

High Alarm Limit (bpm)	65~210	160
Alarm Delay (s)	0~20	10
MHR (bpm)		
Alarm	On/Off	On
Low Alarm Limit (bpm)	30~239	50
High Alarm Limit (bpm)	31~240	120
SpO2 (%)		
Alarm	On/Off	On
Low Alarm Limit (%)	50~99	90
High Alarm Limit (%)	51~100	100
Temp (℃)		
Alarm	On/Off	On
Low Alarm Limit (℃)	0~49.9	36.0
High Alarm Limit (℃)	0.1~50	39.0
SYS (mmHg)		
Alarm	On/Off	On
Low Alarm Limit (mmHg)	40~269	90
High Alarm Limit (mmHg)	41~270	160
DIA (mmHg)		
Alarm	On/Off	On
Low Alarm Limit (mmHg)	10~214	50
High Alarm Limit (mmHg)	11~215	90
MAP (mmHg)		
Alarm	On/Off	On

Low Alarm Limit (mmHg)	20~234	60
High Alarm Limit (mmHg)	21~235	110
RR (rpm)		
Alarm	On/Off	On
Low Alarm Limit (rpm)	0~119	8
High Alarm Limit (rpm)	1~120	30

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.

WARNING

Setting alarm limits to extreme values may cause the alarm software to become ineffective. It is recommended to use the default settings.

NOTE:

The alarm setting change is valid only for the current monitoring of the window. When the monitor starts new monitoring, or after data saving or clearing is performed, the user default alarm settings are restored. The factory default alarm settings remain.

5.5 Reservation

Click **Reserve** 

in the toolbar, and the **Reservation Management** window opens, as shown in the following figure.

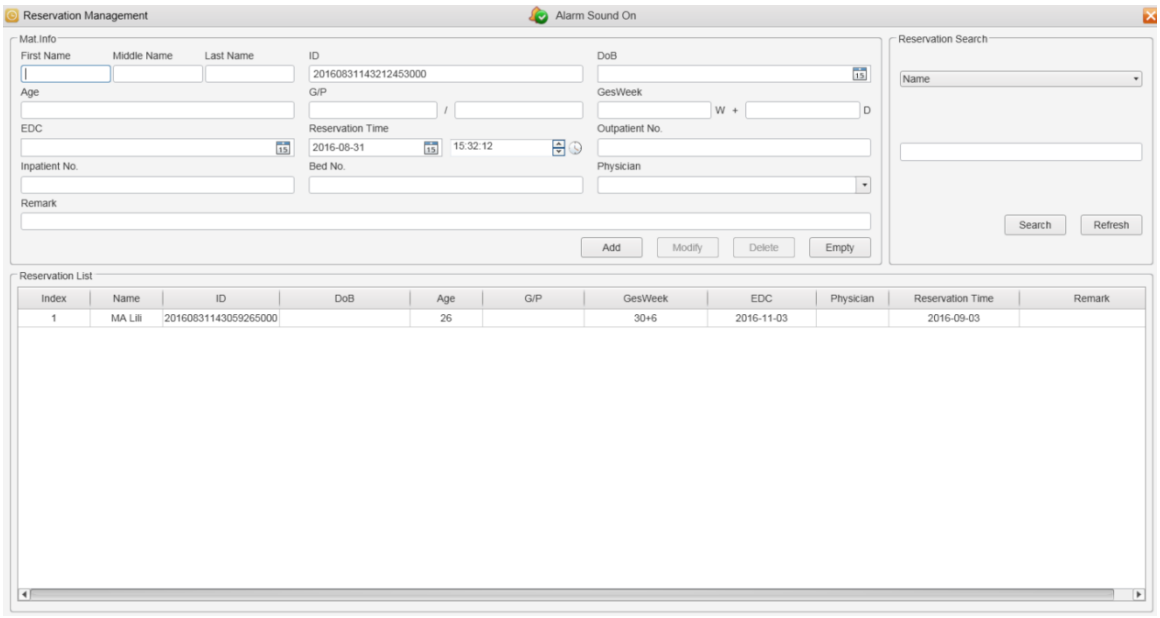


Figure 5-18 Reservation management window

Input maternal information as required and click **Add**. Then the reservation information of the patient will show up in the **Reservation List**.

To modify a reservation record,

1) Select the record to modify in the reservation list.
2) Modify the record in the Mat.Info window above the Reservation List.
3) Click **Modify**.

To add a new maternal reservation record, click **Add** after you input the maternal information. If you need to search a reservation record from the list, select a search parameter (including name, ID, and reservation time) and then click **Search**. You can refresh the interface by clicking **Refresh**.

If the reserved date expires (i.e. later than the system time), the system will automatically delete the reservation record.

NOTE:

If you need to import reservation information from HIS, please finish HIS settings in **Setup**>**System Setup** (only available for advanced users).

5.6 Maternal Information

You are recommended to enter the maternal information at the beginning of every monitoring, to make sure that one monitoring record is corresponding to one patient.

NOTE:

By default, the software does not accept the patient information from bedside monitors. You should enter the patient information on the software.

Follow the steps below to add maternal information:

1) Click **Mat.Info** 

in the toolbar.

2) Input the maternal information, including the name, ID, Age, etc.

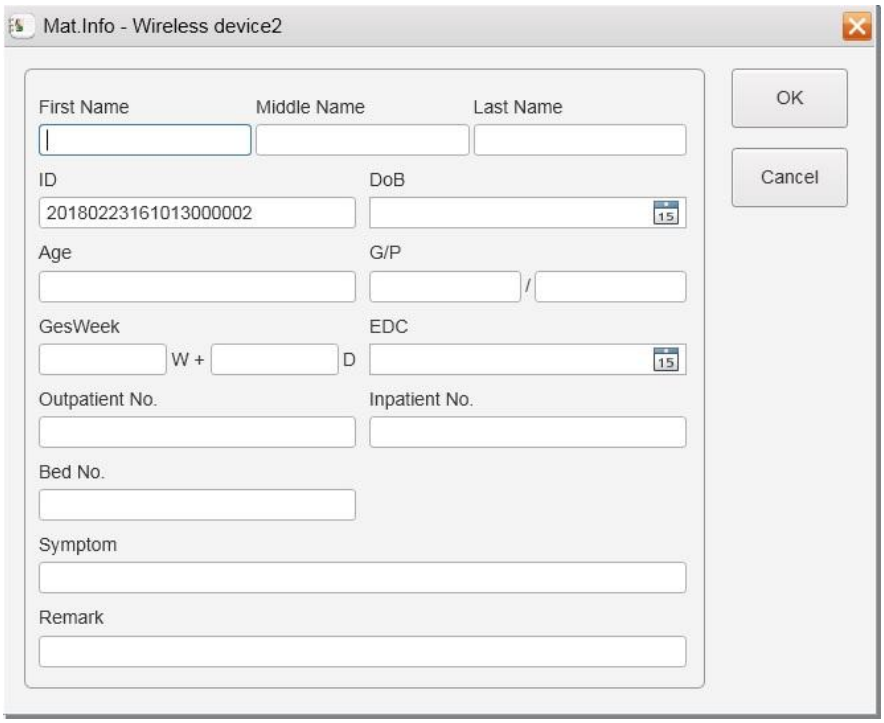


Figure 5-19 Maternal Information Window

3) Input **DOB** or **EDC**, click in the calendar  next to the **DOB** or **EDC** box.

Double-click the date August, 2012 to enter the following window to choose a specific year and month. Click the arrowheads to select a year and click the month icon to select a month.

4) Click **OK**.

NOTE:

1 **Age** is displayed automatically in accordance with **DOB**. You can also input the age.
2 The software automatically updates the patient's **GesWeek** until it reaches 40+0.
3 Before **GesWeek** reaches 40+0, the software automatically calculates **EDC** accordingly.
4 Double-click a record in the reservation list and the maternal information in the record will appear in the Mat.Info box above. Also, you can load maternal information from HIS with a click on **Search from HIS**.
5 Some of the items in the figure above may not be shown, depending on the items ticked in the **Setup** >**General Setup**.

5.7 Saving

Follow the two steps below to save data:

1) Select the monitor that has data to save.
2) Click **Save** 

.

If the maternal name is left empty when you click **Save**, a dialog box will be displayed to remind you. Click **OK** to save the data or **Cancel** to input the maternal information in the **Mat.Info** window. If you click **OK**, the maternal data on the monitor is saved to Archives. The data, which can be loaded from archives to the **ViewBed** window for analysis and printing, includes the patient's basic information, FM trend, maternal vital signs, NIBP, etc.

5.8 Analyzing

In the **Analyze** window, you can analyze CTG and give comments. Two types of section selection are available: manual section selection and auto section selection. The manual section (at least 10-minute data) selection has the priority for analysis.

The analysis method falls into 3 types: point rating method, NICHD analytical method and CTG analytical method. You can set the type in the **Setup**>**General Setup**. If CTG analytical method is adopted, you can manually select a section after the **Analyze** button is clicked. However, if the other two methods are adopted, manual section selection is unavailable after the **Analyze** button is clicked.

a) Point rating method

If point rating method is selected in **Setup**> **General Setup**, you will see the following interface if you click the **Analyze** icon 

. You can enter or select test type, test result, comments, etc, or just click the [**FMExpert**] button to gain an automatic analysis result.

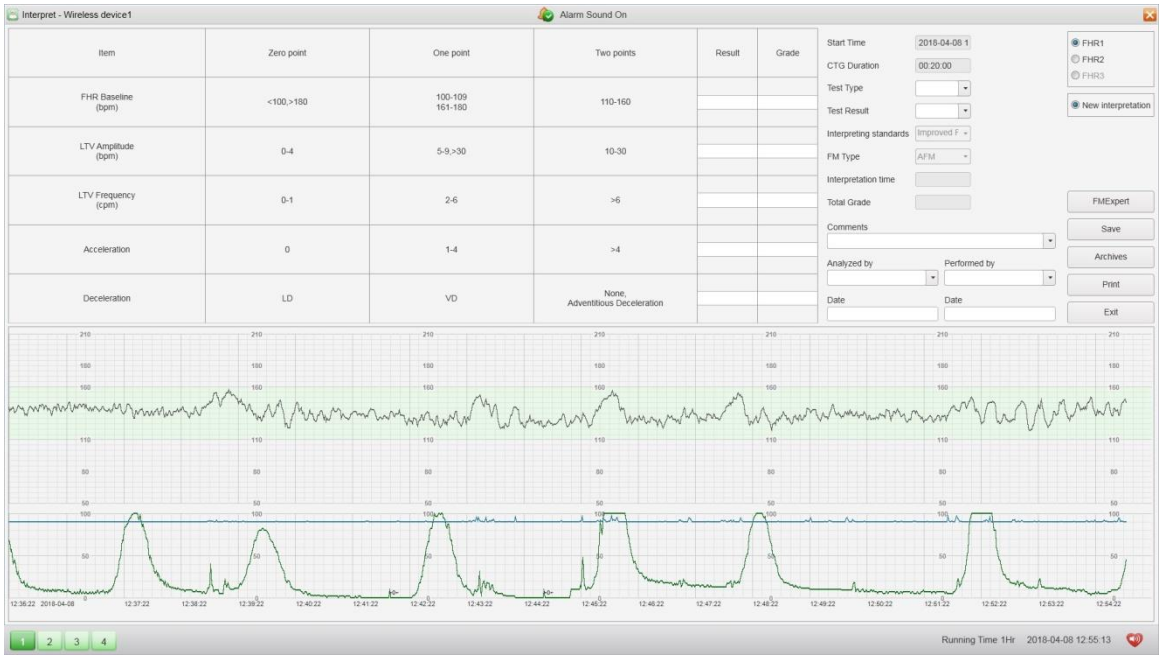


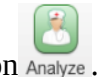
Figure 5-20 Analyze with Point Rating Method

- **Start Time**: Start time and date of CTG curves being Analyzed.
- **CTG duration**: The time length of CTG curves being Analyzed (If you did not select a section manually before you do CTG analysis, the software will only analyze a certain length of the CTG curve, according to the setting at **Setup**> **Monitoring Setup**: 20min, 30min, and 40min).
- **Test Type**: Select NST, OCT, or CST from the pull-down menu.
- **Test Result**: Varies according to different test types. If the test type is NST, five test results are optional: Reactive, Non-Reactive, Combined, Sinusoidal, and Failed. If the test type is OCT or CST, four test results are optional: Negative, Positive, Suspected, and Dissatisfactory.
- **Grade Criterion**: You can select KREBS, Fischer, improved Fischer (by default), or NST.
- **FM Type**: AFM or MFM.
- **Performed by** and **Analyzed by**: The names in the two bars are by default the current username. You can select a name for the "Performed by" bar from the drop-down list if necessary.
- **FHR1**/ **FHR2**: You can choose either FHR1 or FHR2 to analyze at a time.
- **New Analysis**: To clear the previous analysis result and make a new analysis if necessary.
- **FMExpert**: To gain the automatic analysis result provided by the software.
- **Print**: To preview or print the analysis report.
- **Archives**: To check the analysis history. Right-click a record, select **Load**, and the record will be loaded to the analysis interface (or you can simply double-click the record to load it).
- **Save**: To save the analysis result.
- **Exit**: To exit.

After the analysis is done, click **Save** to save the result to analysis archives. Anytime you want to

check an analysis record, click **Archives** on the **Analyze** interface, and right-click the record to load it to the interface (or double-click it). If you need to modify the analysis result of the record, load it to the interface and then tick **New Analysis** on the interface. Click **Exit** to switch back to the main interface.

b) CTG analytical method

If CTG analytical method is selected (the default setting), you will see the following interface if you click the **Analyze** icon 

.

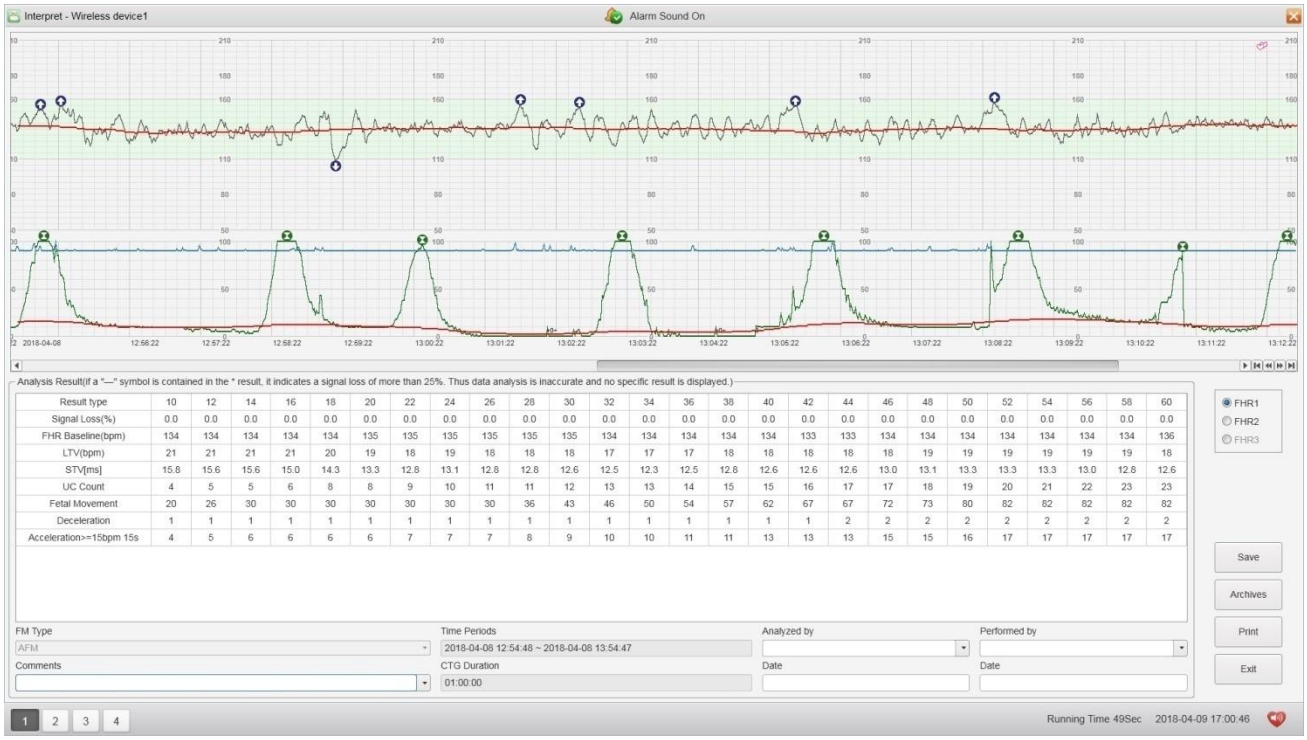


Figure 5-21CTG Analysis Window

- **Performed by** and **Analyzed by**: The names in the two bars are by default the current username. You can select a name for the "Performed by" bar from the drop-down list if necessary.
- **FHR1**/ **FHR2**: You can choose either FHR1 or FHR2 to analyze at a time.
- **Time Periods**: The date and time of CTG curves being Analyzed.
- **CTG duration**: The time length of CTG curves being Analyzed (If you did not select a section manually before you do CTG analysis, the software will automatically make an analysis of the data within 10 to 60 minutes. If the monitoring time exceeds 60 minutes, the automatically selected section will be the trend within the latest 60 minutes).
- **Comments**: Input the comments manually.
- **Print**: To preview or print the analysis report.
- **Archives**: To check the analysis history. Right-click a record, select **Load**, and the record will be loaded to the analysis interface (or you can simply double-click the record to load it).

- **Save**: To save the analysis result.
- **Exit**: To exit.

c) NICHD analytical method

If NICHD analytical method is selected in **General Setup**, the following interface will appear when you click **Analyze**.

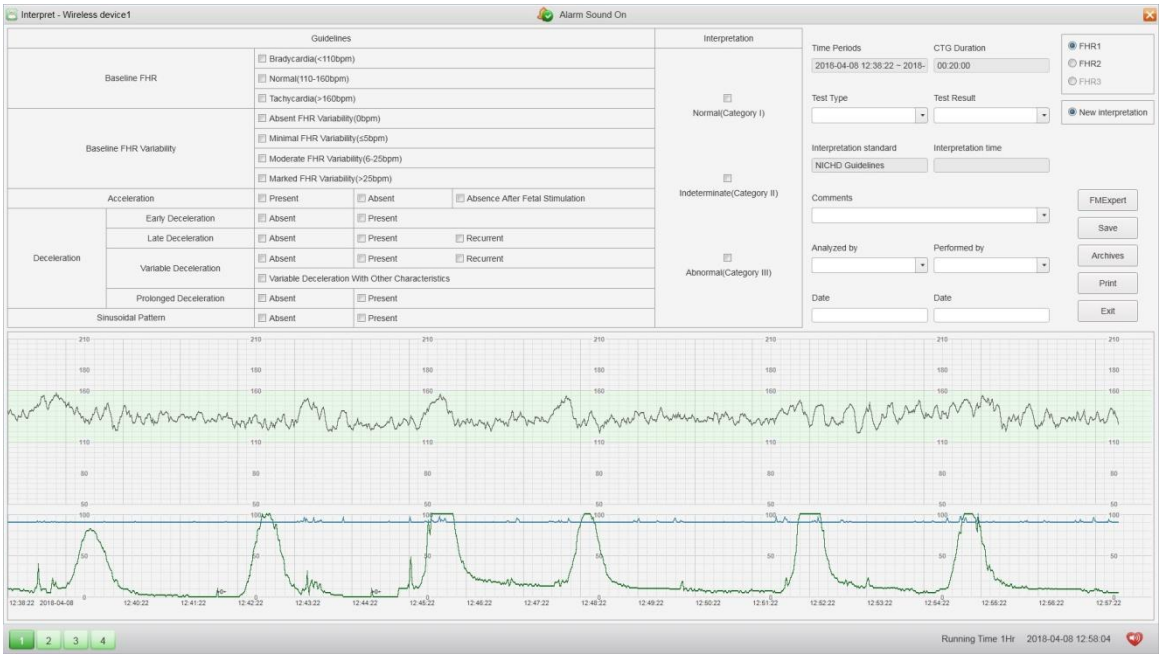


Figure 5-22NICHD Analysis Window

- **Baseline FHR**: Select **Bradycardia (<110bpm)**, **Normal (110-160bpm)**, or **Tachycardia (>160bpm)** according to the analysis result.
- **Baseline FHR Variability**: Select **Absent FHR Variability (0bpm)**, **Minimal FHR Variability (≤5bpm)**, **Moderate FHR Variability (6-25bpm)**, or **Marked FHR Variability (>25bpm)** according to the analysis result.
- **Acceleration**: Select **Absent**, **Present**, or **Absence After Fetal Stimulation** according to the analysis result.
- **Deceleration**: Can be categorized into **Early Deceleration**, **Variable Deceleration**, and **Late Deceleration**. As for **Early Deceleration**, select **Absent** or **Present**. As for **Variable Deceleration**, select **Absent**, **Present**, **Recurrent**, **Prolonged Deceleration**, or **Variable Deceleration With Other Characteristics**. If you choose **Absent**, you can no longer choose the other four options that can go with each other. As for **Late Deceleration**, select **Absent**, **Present**, or **Recurrent**. If you choose **Absent**, you can no longer choose the other two options that can go with each other.
- **Sinusoidal Pattern**: Select **Absent** or **Present** according to the analysis result.
- **Interpretation**: The software automatically displays the interpretation result according to the

guidelines selected in the left list. Three categories are offered: **Normal (Category I)**, **Indeterminate (Category II)**, and **Abnormal (Category III)**. You can also revise the result manually. If the result is left unselected, the **Save** button is unavailable.

- **Test Type**: Select NST, OCT, or CST from the pull-down menu.
- **Test Result**: Varies according to different test types. If the test type is NST, five test results are optional: Reactive, Non-Reactive, Combined, Sinusoidal, and Failed. If the test type is OCT or CST, four test results are optional: Negative, Positive, Suspected, and Dissatisfactory.
- **Criteria**: NICHD Guidelines.
- **Time**: The time when the analysis result is saved.
- **New Analysis**: To clear the previous analysis result and make a new analysis if necessary.
- **FMExpert**: To gain the automatic analysis result provided by the software.
- **Print**: To preview or print the analysis report.
- **Archives**: To check the analysis history. Right-click a record, select **Load**, and the record will be loaded to the analysis interface (or you can simply double-click the record to load it).
- **Save**: To save the analysis result.
- **Exit**: To exit.

WARNING

1 The software only provides analysis function. Analysis-making should be left to the discretion of doctors.

2 The analysis results provided by the software are just for reference.

5.9 Printing

5.9.1 Printing Reports

There are four types of monitoring report: fetal monitoring graph, maternal trend list, NIBP list, event list, and labor information. You can print them with a printer.

1) Fetal Monitoring Graph

Click **Print** 

in the **Monitoring** frame or the **CTG Review** frame of a bed.

NOTE:

There must be more than 1-minute data before you have access to the printing interface.

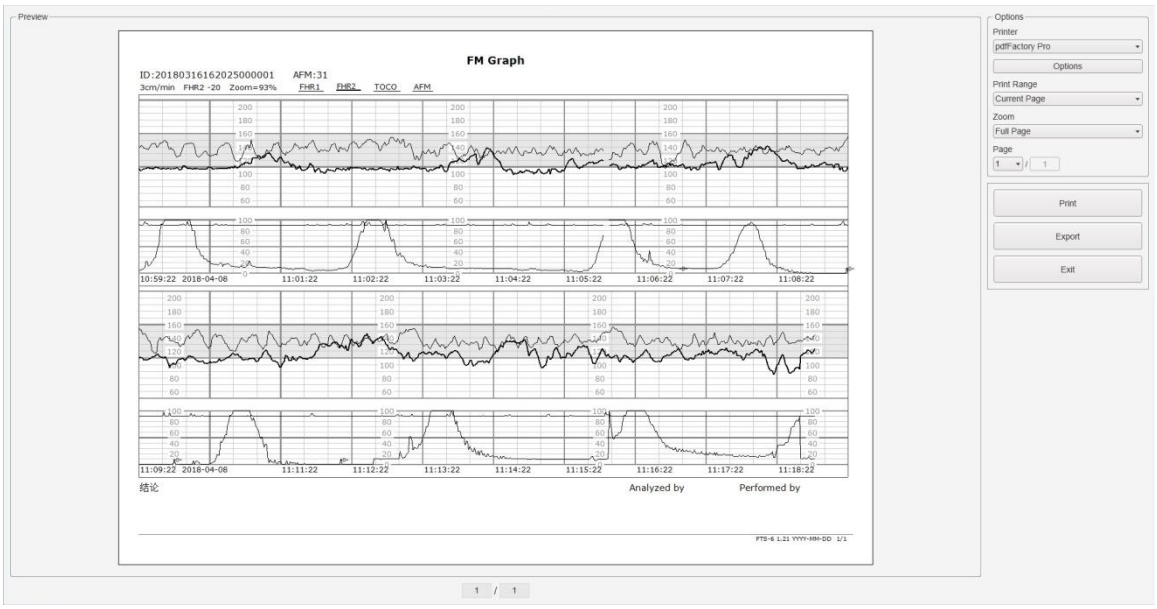


Figure 5-23 Fetal Monitoring Graph

To acquire the required report, all the items should be set properly according to the content.

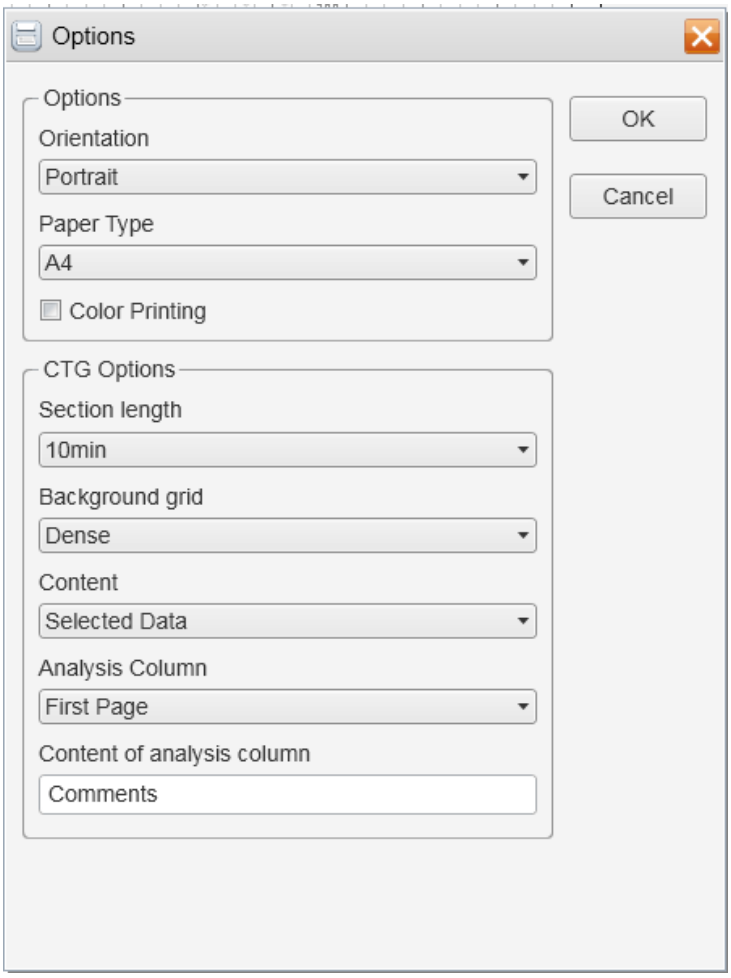


Figure 5-24Printing options

- **To select the report orientation:** The monitoring report is either in **Portrait** or **Landscape** orientation.
- **To select report color:** Tick **Color Printing**, and the report will be chromatic; otherwise the report is monochromatic.

  NOTE:

  The report is printed chromatically only if a color printer is used, and if the screen color is set to **Orange** or **Green**. Do not tick this item if a mono printer is used.
- **To select section length:**

  You can set **Section Length** to 10 minutes(default), 15 minutes, 20 minutes and Thermal Paper Manner(print according to paper width, 1 row/page).

- **Background grid**：You can set **Background grid** to dense(default) or simplified. The dense format keeps the same with the sub-window. The simplified format omits some of the grids based on the sub-window, and keep 1cm/grid horizontally and 10 units/grid vertically.
- **To select the analysis column:** Choose whether to print the analysis column on the report, or where to print it.
- **To set the report:** Select **One Page** to print the report on one page; select **Double Page** to print the report on two pages; select **Multipage Landscape** to print the report on multi-pages in l**andscape** orientation; select **Multipage Portrait** to print the report on multi-pages in portrait orientation.
- **To select simplified point rating analysis:** Print an analysis report without point rating criterion.
- **To print NICHD Criteria:** Select it to print the detailed interpretation result when the report is not printed on one page.
- **To print complementary CTG analysis information:** Display analysis information on a CTG report.

After the options are set up, click **Print** to print the report or click **Exit** to exit from the preview window.

NOTE:

The printer settings can only be made or modified by the maintenance personnel of the manufacturer. You should not change the printer settings at your discretion.

2) Maternal Vital Sign List

Open the **Trend Review** frame of a bed and click **Print** 

to print the maternal vital sign list. Set the items as introduced above.

3) NIBP List

Open the **NIBP Review** frame of a bed and click **Print** to print the NIBP list. Set the items as introduced above.

4) Event List

Open the **Event Review** frame of a bed and click **Print** to print the event list. Set the items as introduced above.

5.9.2 Sending Emails

You can email a report to others. The report is in PDF format.

To email the report,

1) Open the **Print** window.
2) Set all the items properly.
3) Click **Send Mails**, select a recipient, type in the subject and content, and then click **Send**.

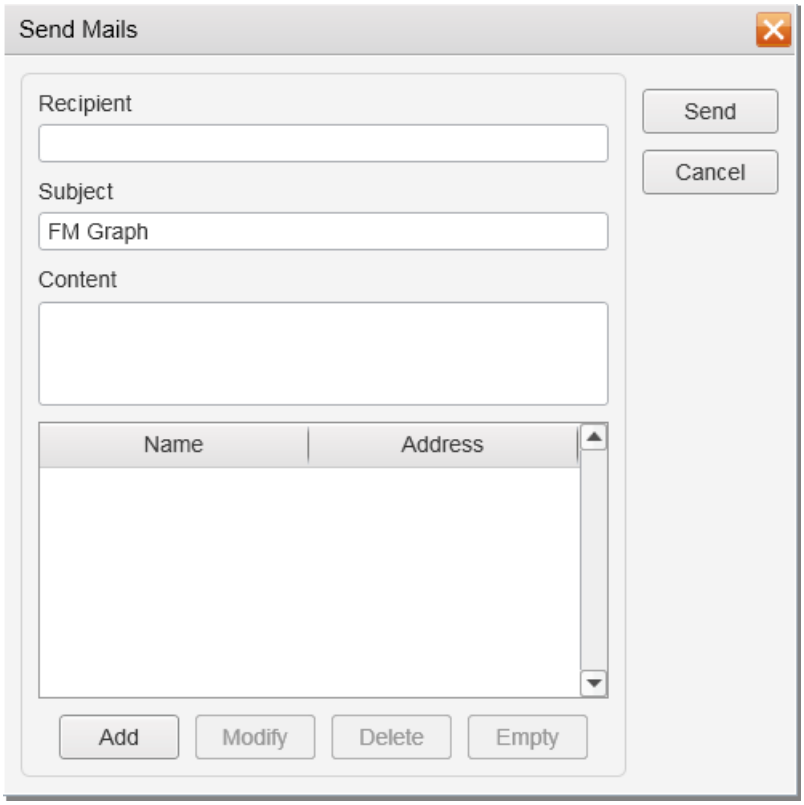


Figure 5-25 Email a Report

The report is then attached in the email and sent to the recipient.

Follow the steps below to add a recipient:

1) Open the **Send Mails** window, and click **Add**.

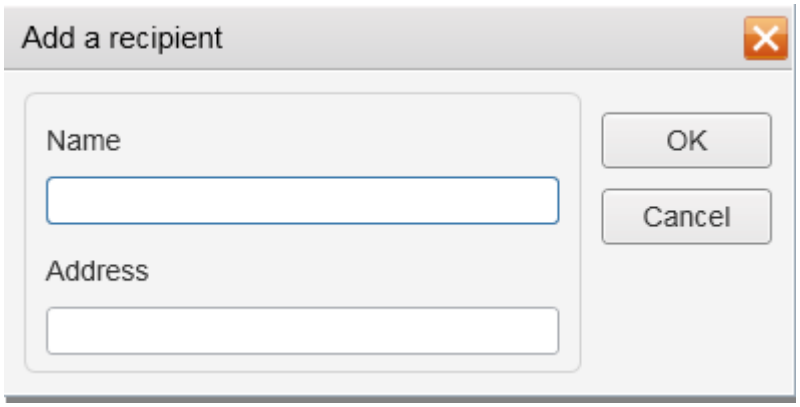


Figure 5-26 Adding a Recipient

2) Type in the recipient name and Email address.
3) Click **OK** and the recipient is added.

To change a recipient information,

1) Open the **Send Mails** window and select the recipient.
2) Click **Modify**.
3) Edit the recipient name and/or Email address.
4) Click **OK** and the new information is saved.

To delete a recipient,

1) Open the **Send Mails** window and select the recipient.
2) Click **Delete**.
3) Click **OK** and the recipient is deleted.

NOTE:

Mail-sending configuration should be done by a super user or service engineer in the **General Setup** window before you send reports by email on the **Print** interface.

5.10 Alarms

5.10.1 Outline

Alarms of software and those of bedside monitors are separate. The alarm generated by software is either a patient alarm (indicating the situation of a vital sign exceeding its configured limit) or a technical alarm (indicating the disconnection of the transducers or signal loss of the bedside monitor).Software evaluates whether to trigger a patient alarm according to its own alarm settings and a technical alarm according to the alarm information coming from a monitor.

Warning

1. If the patient safety may be endangered, do not switch off the audio 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 audio alarm is equivalent to the ambient noise, it may be difficult for the operator to distinguish the audible alarm.
4. The alarm system of FTS-6 is independent of the alarm system connecting with the obstetric monitor, and they are non-synchronous.

NOTE:

Alarm delay includes alarm condition delay and alarm signal delay. Alarm condition delay is mainly the algorithm operating time and it takes no more than 15 seconds to computing fetal heart rate. Alarm signal delay involves the inherent delay of the network and the adjustable alarm delay of the device, but the inherent delay of the network is less than 5 seconds.

5.10.2 Alarm Classification

The software has two types of alarm: patient alarm and technical alarm. Patient alarms indicate the situation of a vital sign exceeding its configured limit. Technical alarms indicate the disconnection of the transducers or signal loss of the bedside monitor, which makes it impossible for the monitor to detect critical patient condition.

NOTE:

If wireless signal quality is not good and cause data transmission error and signal loss alarm is triggered, please contact professional service personnel when it cannot be solved.

5.10.3 Alarm Level

In terms of severity, the alarms have two levels: medium and low. Medium-level alarm is a moderate warning, labeled with the symbol **; while low-level alarm is a general warning, labeled with the symbol *.The alarm levels are preset and cannot be changed.

5.10.4 Alarm Priority

The medium-level alarms have priority over low-level alarms. If both types of alarms are active at the same time, the system will give the sound for the medium level alarm.

5.10.5 Alarm Mode

When an alarm is active, the software issues both audio and visible signals to draw your attention.

(1) Audio alarm given by speakers

- Medium-level alarm: a "Do" tone is repeated three times, with a pause of 3 seconds.
- Low-level alarm: a "Do" tone is sounded once, with a pause of 16 seconds.

The indicator of audio alarm status is displayed in the upper middle of the main interface, and what the indicator displays is related to alarm silence duration settings (see Section 5.10.6).

WARNING

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

2 Do not rely exclusively on the audible alarm software 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 audio alarm is equivalent to the ambient noise, it may be difficult for the operator to distinguish the audible alarm.

NOTE:

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

2 When the fetal heart sound is switched on, the device gives out a thumping sound, like “boom-boom-boom”.

3 When you click **Search Transducer**, the transducer you are looking for will make a buzzing sound.

(2) Visual alarms in the title bar area of each monitor frame

When an alarm is active, the software shows the following information on the interface:

- **Simulated Alarm indicator**: the simulated alarm indicator is shown on the right end of the title bar. It is illuminated in green if there is no alarm, and it turns yellow when a low-level alarm occurs, or flickers in yellow when a medium level alarm is active.

Simulated alarm indicator	**Alarm Frequency**	**Alarm Level**
Yellow with 0.5Hz flicker frequency	Interval between two alarm sounds is 3 seconds	Medium
Yellow with no flicker	Interval between two alarm sounds is 16 seconds	Low

- **Alarm message**: the alarm message appears in the middle of the title bar. If there are more than one message, they appear at the same area in succession. The alarm messages that might appear during monitoring are listed in the table in Appendix 1.
- **Alarm symbol**  : the software marks an alarm symbol on the CTG at the place where a patient alarm occurs.

5.10.6 Setting Alarm Silence Duration

The alarm silence duration has several options: **Alarm Reset**, **Alarm Pause** (for 1min, 2 min or 3) and **Alarm Sound Off**. It can be set in **Alarm Setup**.

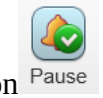
If the alarm silence duration is set to **Alarm Reset**. A **Silence** button 

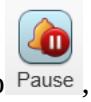
appears in the toolbar. When an alarm is active, you can click this button to disable the alarm sound. Once you click, it changes to 

, and the alarm status indicator 

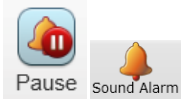
appears at the top of the interface and flickers once every second. During the restoration period, if another alarm presents, the software enables the alarm sound automatically. Alternatively, you can click 

to enable alarm sound manually.

If the alarm silence duration is set to **Alarm Pause**. A **Pause** button 

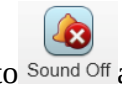
appears in the toolbar. When an alarm is active, you can click this button to disable the alarm sound temporarily. Once you click, it changes to 

, and the alarm status indicator 

appears at the top of the interface. The indicator flickers once every second and the remaining time is shown next to it, e.g. 2:20 (2 minutes and 20 seconds). When the remaining time is out, the software enables the alarm sound automatically. Alternatively, you can click 

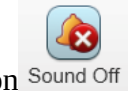
to enable alarm sound manually.

If the alarm silence duration is set to **Alarm Sound Off**. A button 

appears in the toolbar. When an alarm is active, you can click this button to disable the alarm sound. Once you click, it changes to 

and the alarm status indicator 

appears at the top of the interface

and flickers once every second. The sound is not enabled until the button 

is pressed.

NOTE:

The software evaluates whether to trigger a patient alarm according to its alarm settings, so the alarm information provided by the software is just for reference.

1. The alarm of this system is independent of that of bedside monitor. The system decides whether triggering the alarm signal or not according to its own alarm setting, thus, the alarm signal is only for reference.
2. When alarm occurs the main interface will display "alarm sound from device X" on which X represents the device number.
3. After the status of alarm sound off is end, whether recovering the alarm sound depends on whether the alarm status still exists.

5.10.7 Adjusting Alarm Sound Volume

You can adjust alarm sound volume. The sound pressure range is 45dB ~ 85dB.

Alarm sound volume has 5 adjustable degrees: 20%, 40%, 60%, 80% and 100%, and they are respectively equal to the 50%, 60%, 70%, 80% and 90% of the system sound volume.

To adjust the alarm sound volume of a sub-window, first select the sub-window, double-click to enter its intensive view interface, click the loudspeaker icon at the lower right corner of the interface, and choose a preferred sound volume degree.

5.10.8 Reviewing Alarms

The **Event Review** frame shows the event records, including patient alarm messages, signal overlap alarm massages and their occurring time.

Choose a sub-window, enter its intensive view interface, and click to enter the event review frame. By default, the frame displays alarm messages and they are listed in time order. You can select basic event type to review signal overlap alarm messages. If you choose one of the alarm messages, the message will be marked by a pink vertical line on the CTG curve area at the top of the interface.

The system displays a maximum of 1024event messages. When the storage is full, a note will prompt out to inform you that new event messages cannot be saved any more.

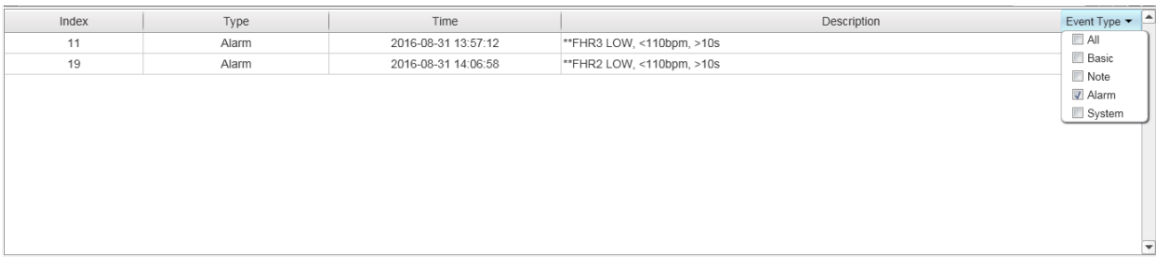


Figure 5-27 Reviewing Alarms

5.10.9 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 system gives out an alarm and catches your attention, you should:

- Locate where the alarm comes out and specify which kind the alarm is.
- 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 system stops giving out the alarm.

If "Transducer Unplugged" is enabled (set to "ON"), and you press the confirming transducer unplugged alarm key on the intensive view interface to confirm any active transducer unplugged alarms: US1 UNPLUGGED, US2 UNPLUGGED, TOCO UNPLUGGED, IUP UNPLUGGED, DECGUNPLUGGED, SpO2 SENSOR OFF, TEMP UNPLUGGED during the monitoring process, the transducer unplugged alarm(s) will be turned off until any of them occurs again. But the transducer unplugged alarm(s) still exist(s) in the alarms review list.

5.10.10 Testing Alarms

Test the alarm system according to the stated maintenance period, or when you have doubts about the reliability of the alarm system.

To test the functions of visible and audible alarms, please stand by the workstation and follow the procedures below:

1 Switch on the system and start up the software.

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 on the system, for example, TOCO transducer.

5 Verify if a visible and audible alarm is generated by the software properly, and can be clearly seen or heard.

5.11 Archives

Click **Archives** 

to open the **Archives** window. It lists all the monitoring records and the patient information. By clicking on the page turners in the left corner, you can review more records.

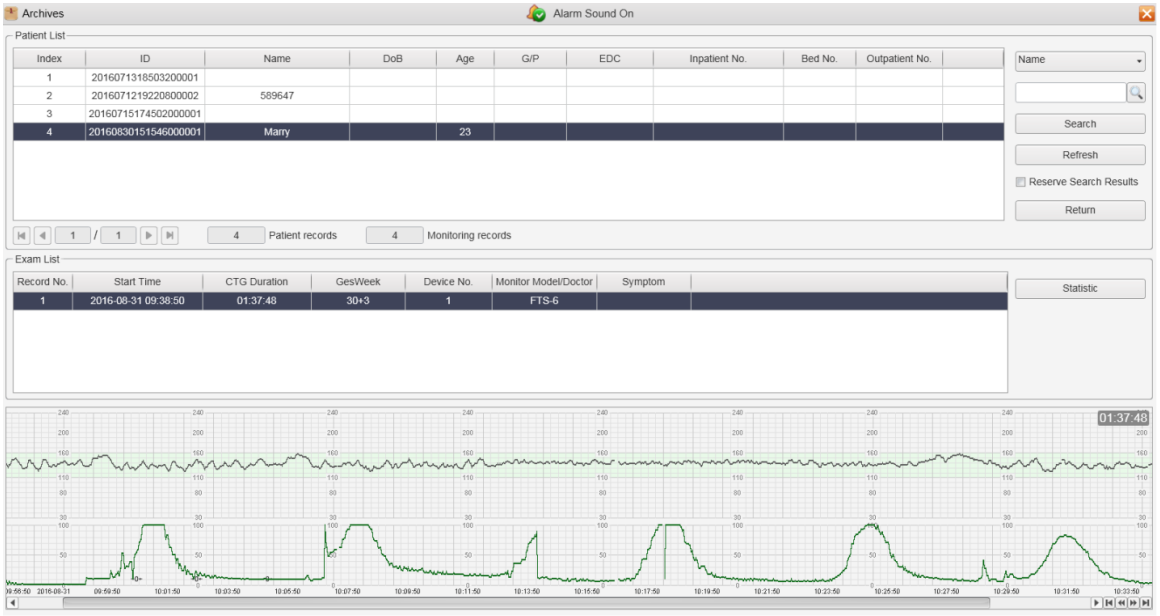


Figure 5-28 Archive Window

5.11.1 Searching for a Record

When you are looking for a record, use the search tool to find it quickly.

Follow the steps below to search for a record:

1) Select a search condition in the pull-down menu on the right of the interface, e.g. "Name".
2) Input the key word (either part or full spelling of the key word).
3) Click **Search**. All the monitoring records that meet the requirements are listed in the window.

Figure 5-29Searching for a Record

If you need to return to the previous archives window, click **Refresh**.

5.11.2 Loading a Record

Select the record of the patient you want to check in the **Exam List**, right-click the record, select **Load** or double-click it, and it will be loaded to the **ViewBed** window. If you have loaded the record, a prompt will pop up reading "Close the record window first." the second time you click **Load**. You can review the trend, make analysis or print the record.

Click to close the window.

NOTE:

1 The modification of maternal information takes effect after the **Archives** window is closed.

2 With a right click on a record in the **Exam List**, you can also select Delete/Export to delete or export it.

5.11.3 Statistics for Archives

You can query all the historic records between two dates by clicking **Statistic**. Select a start date and an end date and then click **OK** to do the query.

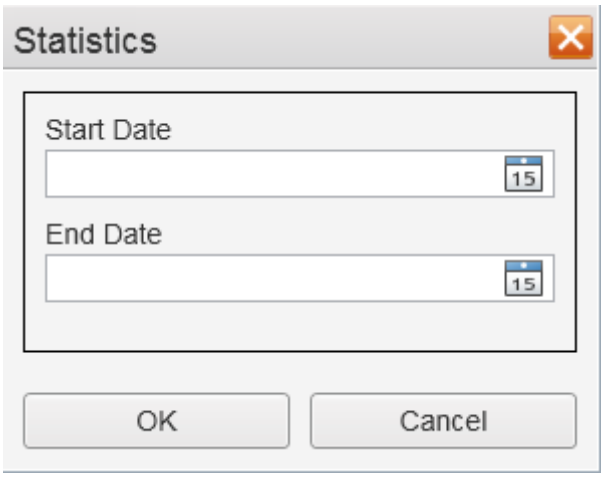


Figure 5-30 Statistics for Archives

5.11.4 Assigning

You can assign a record in the **Exam List** to a specific patient with a right click on the record. Click **Assign** and the record will be assigned to the patient. This function aims to correct the mismatch between the patient and the record resulted from abnormal operation.

5.12 Setup

Click **Setup** 

in the toolbar to open the **Setup** window. In this window, four interfaces are displayed: **User Setup**, **Monitoring Setup**, **Alarm Setup**, and **General Setup**.

You can set up information including username and password, monitoring parameters, alarm parameters, and maternal information in this window. Click **OK** to save your settings.

NOTE:

1 User levels fall into three types: Super, High, and General. Super users can only be the service engineers authorized by the manufacturer.

2 A high user can view the four interfaces in the setup window and modify the information in each option. A general user can only modify the **Monitoring Setup** interface and **General Setup** interface.

3 If **Modify System Setup** is selected when a super user adds a high user or modifies a high user's information, then the high user can visit the **System Setup** interface. The **Modify System Setup** option is not set for a general user in any case.

4 Settings of the software and bedside monitors are separated. They do not affect each other.

5.12.1 User Setup

On the **User Setup** interface, you can:

- Input hospital information. You can input the hospital name and contact under the **Hospital** item. The information will be saved after a click **OK** in the lower right corner. You need to input hospital information before a new monitoring cycle starts so that the hospital information will be displayed on the printed FM Graph.
- Set user information. You can add or delete a user, or modify a user's information. Besides, you can set up the user's authority and level. Click **Modify** to save your setup.

(1) Adding a user

Follow the steps below to add a user:

1) On the **User Setup** interface, type a username and a password (the password can only be case

insensitive letters a-z or numbers 0-9); select a profession (**Nurse**, **Midwife**, **Technologist**, **Physician** or **Manager**), level (**High**, or **General**), and user authority (**Read & Write**, **Read Only**, or **Access Denied**).

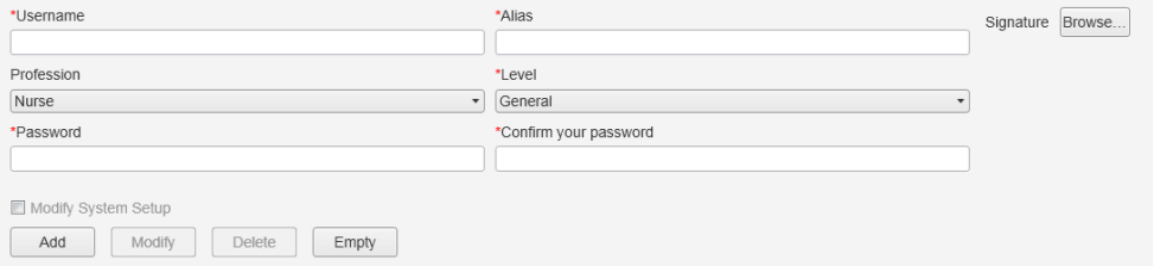


Figure 5-31Adding a User

2) Click the **Browse…** icon and choose a *.jpg file as your signature if you want.

3) Click **Add** and the user is added to the user list.

NOTE:

1 Scan the signature and save it in a *.jpg file in advance. The optimum size of the *.jpg file is 113x49. After the customized picture signature is added, the software saves the *.jpg file in the database. Do not delete it.

2 If you have selected a user in the user list, you have to click **Cancel Selection** before you add a user.

(2) Modifying a user's information

Follow the steps below to modify a user's information:

1) Select a user on the **User Setup** interface.

2) Retype in the user's information.

3) Click **Modify**.

4) Click **OK**.

(3) Deleting a user

Follow the steps below to delete a user:

1) Select a user on the **User Setup** interface.

2) Click **Delete**.

3) Click **OK** and the user is deleted from the user list.

(4) Modifying a password

Follow the steps below to modify a password:

1) Select a username in the user list.

2) Enter a new password and confirm the password.

3) Click **Modify**.

4) Click **OK**.

NOTE:

High users can change their own passwords and those of General users.

5.12.2 Monitoring Setup

After you click **Setup**, the software enters the **Monitoring Setup** interface. On the interface, you can set the following items: **FM**, **Mat. Monitoring**, **Note Management**, and **CTG Options**.

(1)FM

You can set the fetal monitoring items listed in the following table. The parameters underlined are default values.

Item	Options	Explanation
Paper Speed	1cm/min 2cm/mim 3cm/min	Speed of the CTG trend paper advancing.
FHR2 Offset	-20 0 +20	When monitoring twins, set FHR2 offset to separate the two FHR trends.
FHR3 Offset	-20 0 +20	When monitoring triplets, set FHR3 offset to separate the three FHR trends.
Paper Type	Compact (USA) USA International	The background paper style for CTG trend. − Compact (USA): 60bpm ~ 210bpm, vertical ordinate is 30bpm/cm; − USA: 30bpm ~ 240bpm, vertical ordinate is 30bpm/cm; − International: 50bpm ~ 210bpm, vertical ordinate is 20bpm/cm.
AFM Display	Curve Black Block None	Either curves or black blocks can display AFM trend.
Time Scale	Real Time Relative Time Real Time +Relative Time	Real Time: Time of PC on the interface Relative Time: Starts from 0 and increases by 1 minute Real Time + Relative Time: Displays both

Auto Segment Length	20 30 40	Auto segment time length: Time length of the segment automatically selected by the software when you do analysis
Segment Position	Start Point Midpoint	If the position is set to Start Point, CTG review will start from where you click the mouse; on the other hand, if the position is set to Midpoint, CTG review will consider where you click the mouse as the midpoint
Grid Line Type	Solid Dashed	Grid Line Type: Can be solid or dashed lines
FM Source	Manual Automatic	Manual: Displays MFM counting Auto: Displays AFM counting
UA Baseline	5 10 15 20	Baseline for UA to return to zero

(2) Mat. Monitoring

You can set the maternal monitoring items listed in the following table, and the parameters underlined are default values.

Item	**Options**	**Explanation**
NIBP Unit	mmHg kPa	Select NIBP unit.
Temp Unit	℃ ℉	Select temperature unit.
HR Source	Priority to ECG Priority to Pulse	Select maternal HR source priority. If the set HR source does not have input signal, the software switches the source to the other automatically.

If **Fill Waves** is ticked (by default), the maternal curves will be displayed with waves; otherwise, they are just curves.

(3) Note Management

You can manage the note list on the **Note Management** interface.

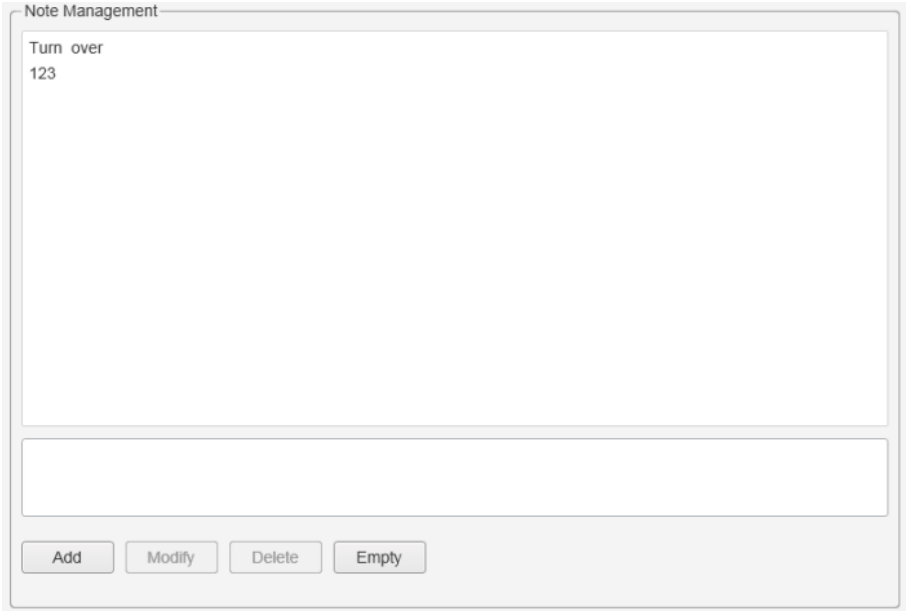


Figure 3-1Note management text box

- **Adding a note to the list:** Input the note content in the dialogue box and then click **Add**. The note will be added to the note list after you click **OK**.
- **Modifying a note in the list:** Select a note and then click **Modify**. Input the new note content in the dialogue box. The note will be modified from the note list after you click **OK**.
- **Deleting a note from the list:** Select a note and then click **Delete**. The note will be deleted from the note list after you click **OK**.
- **Saving a note to the list automatically:** If the **Auto. Save** item is ticked on the **Add Note** interface when adding a note on the monitoring window, the software saves a new note to the note list for future use after it is inputted. If this item is not ticked, the inputted note is not saved.

(4) CTG Options

On the **Monitoring Setup** interface, you can set the CTG items listed below:

- **Show normal FHR range**: Choose whether to show FHR safe range with green background in the FHR trend display area, and the default is☑.

  The green band 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, and you can tell if the fetal heart rate is too low or too high.
- **Show mat.name synchronously**: Show maternal name synchronously when showing date and time every 10 minutes, and the default is☐.
- **Show fetal movement count**: choose whether to show the count of fetal movement mark on the CTG, and the default is☑;
- **Show MSpO2 trace**: Choose whether to show MSpO2 trace, and the default is☐;
- **Show MHR trace**: Choose whether to show MHR trace, and the default is☐;

- **Show time length**: choose whether to show the monitoring duration timer for each bed, and the default is ☐.

5.12.3 Alarm Setup

Enter the **Setup** interface and then click **Alarm Setup** to change the alarm settings.

- **Default Alarm Setup**: You can change the alarm settings here and save them as user default. You can also set all user default to factory default by clicking on the **DefaultFactorySetup** button. For details, see section **Error! Reference Source not Found**.

  To change the default alarm setup, you should:

  1) Click **Modify**.

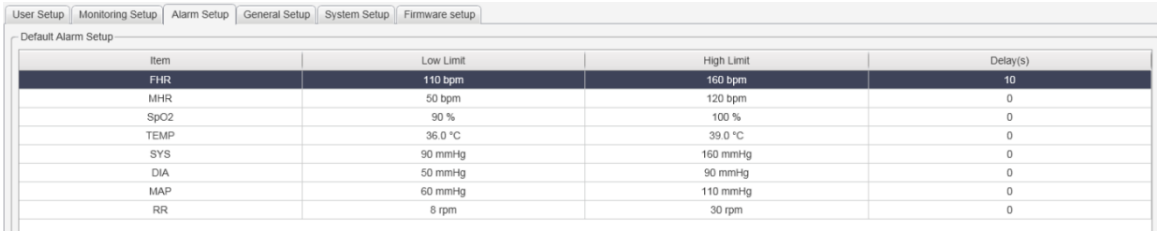


Figure 5-32Modify Alarm Default

  2) Select an alarm item (e.g. FHR), and then click **Modify**.

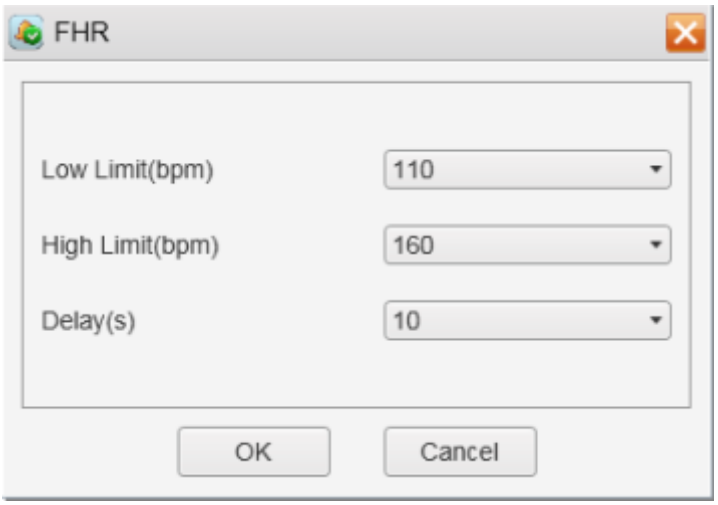


Figure 5-33 Modify FHR Default

  3) Change the editable items, and then click **OK**.

NOTE:

Only a high or super user can view the **Alarm Setup** interface in the setup window and modify the information in each option.

- **Silence Duration**: You can select a silence mode for the alarm (**Alarm Reset**, **Alarm Pause 1min**, **Alarm Pause 2min**, **Alarm Pause 3min**, or **Alarm Sound Off**). The default is **Alarm**

Reset.

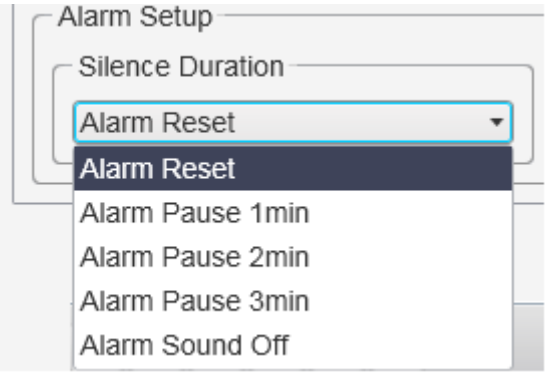


Figure 5-34Silence duration

5.12.4 General Setup

Enter the **Setup** interface and then click **General Setup**. You can set the interface items listed below:

- **Mat Info**: You can select or deselect the items as required in the **Mat Info** area. After an item is ticked, it will appear in the maternal information menu, the archives interface and the pull-down menu of searching condition. For example, if **AutoNumbering** is ticked, the maternal ID will be set automatically when you input a patient's information on the **Mat Info** interface.
- **Options**: You can tick the items you need in the list.
  1) **NST Timer**: After choosing NST duration, the software shows the elapse time of the monitoring, and gives a message when time is out. The default setting is off.
  2) **Show RESP**: Show RESP waveform and numeric. The default setting is off.
  3) **Send Mails**: Send the exported file in the PDF format as an attachment by email. The default setting is off.
  4) **Highlight**: To emphasize a curve. The default setting is on.
  5) **Segment Manually**: To select the start and end of a section manually. The default setting is on.
  6) **Clear Previous**: To clear the data previous to a point on CTG interface. The default setting is on.
  7) **Clear Following**: To clear the data following a point on CTG interface. The default setting is off.
  8) **Save Previous**: To save the data previous to a point on CTG interface. The default setting is on.
  9) **Show Initials (notes)**: To show initials of the user next to the note. The default setting is off.
  10) **Receive ID from monitors**: The software receives the ID (made up of digitals or English letters) inputted on the bedside monitor. The default setting is off.
  11) **Send ID to monitors**: The software sends the inputted ID (made up of digitals or English

letters) to the bedside monitor. This feature is reserved, and the default setting is off.

12) **Display Deleted Note**s: Shows notes already deleted with a red X.

13) **Fixed CTG Duration (ViewBed)**: CTG length on one screen is that of auto segment.

14) **Preview CTG curve (Archives)**: Previews CTG curves on the Archives interface.

15) **Automatically Switch Window**: When the item is ticked and a sub-window is full of singleton/twins/triplets FHR monitoring data and there is still US data that needs to be uploaded, the workstation will assign a sub-window automatically for it by searching from the current activated sub-window(if there are no available sub-windows after it then it will search from sub-window 1) and find the closest offline sub-window and activate it. At this time, take up a TOCO transducer and it will send data to the current activated sub-window automatically. For example, during singleton mode and select sub-window 1, the US transducer taken up will be displayed in sub-window 1, and then take another US transducer, the workstation will assign sub-window 2 for it and the allocated sub-window is sub-window 2. At this time, take up a TOCO transducer and it will send data to sub-window 2; when the item is unticked, the current allocated sub-window will still be sub-window 1, i.e. the focus won't switch to sub-window 2; the default setting is open.

16) **Automatically Open Fetal Heart Sounds** : When the item is ticked, if there is free loudspeaker available, then the new online transducer will open the corresponding fetal heart beat sound(occupies the loudspeaker); when all the loudspeakers are occupied, only when the newly online transducer is US1 will the system force to close the occupied loudspeakers(close US2/US3 firstly) and open the corresponding fetal heart beat sound of US1 that just gets on line; the default setting is open.

17) **Full Print**: When the item is ticked and "Selected Data" in "Printing Options" is ticked, then the data less than 1 minute in the end will be abandoned; the default setting is close.

- **Date Format**: You can set the date in one of the three available formats.
- **Auto Saving Timer:** None (by default), 10 min, 20 min, 30 min, 40 min, 50 min, or 60 min. After a monitor is offline, the software automatically saves the un-archived data at the saving time preset.
- **Interface**: You can set the following options for the interface.

Screen Color: You can select the green (by default), orange or gray for color of the **Monitoring** window.

- **Analysis Type**: You can select NICHD analytical method, CTG analytical method, and point rating analytical method.

NOTE:

You can set the patient ID manually, but the patient ID should differ from each other.

5.12.5 System Setup

If **Modify System Setup** is selected when a super user adds a high user or modifies a high user's information, then the high user can visit the **System Setup** interface. If any change is done to the **System Setup** interface, you have to log in to the software again. Therefore, do not change the software settings during monitoring.

On the **System Setup** interface, you can set:

1) **Device List**. You can add or delete a device in the window, or select a device type. Select a device in the **Device List** if you need to modify its information. Click **Modify** to save the modification.
2) **Monitor Interconnection**. You can choose a serial port or/and an Ethernet port here. The serial port is automatic by default while the Ethernet port is 5510 by default.
3) **Language**. You can choose English or Chinese.

5.13 Chalkboard

The Chalkboard window summarizes all the patient information in a small window for quick review. The default setting is off.

Click **Chalkboard** on the toolbar to check the information of all the devices in the current ward, including the connection status, maternal information, CTG duration, etc.

5.14 Help

Click **Help** 

in the toolbar to get help information of the software.

5.15 Switching User

Click **SwitchUser** 

in the toolbar, and you will log out. Enter another user's username and password to log in to the software if you want to switch the user.

5.16 Database Backup

Click **Start**>**All Programs**>**FTS-6**>**DbBackup** to back up database.

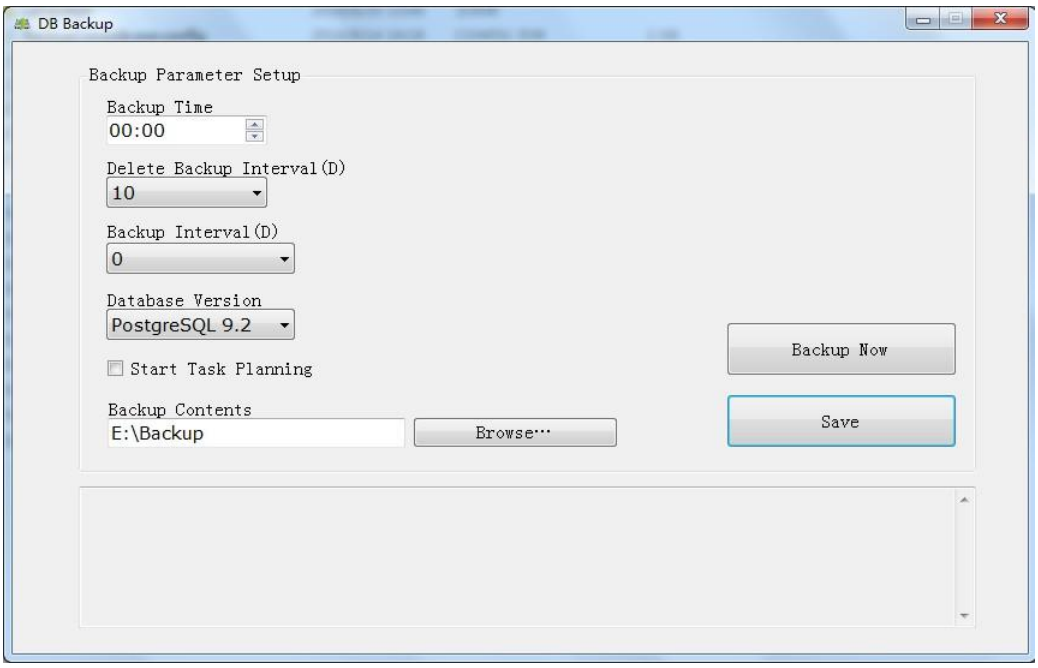


Figure 5-35 Database backup

Backup Parameter Setup: Choose the backup time, back interval (day as the unit), interval of deleting the backup, database version, and backup contents.

Backup Now: Start to back up with a click on it.

5.17 Database Restoration

Click **Start**>**All Programs**>**software**>**DbRestore** to restore database.

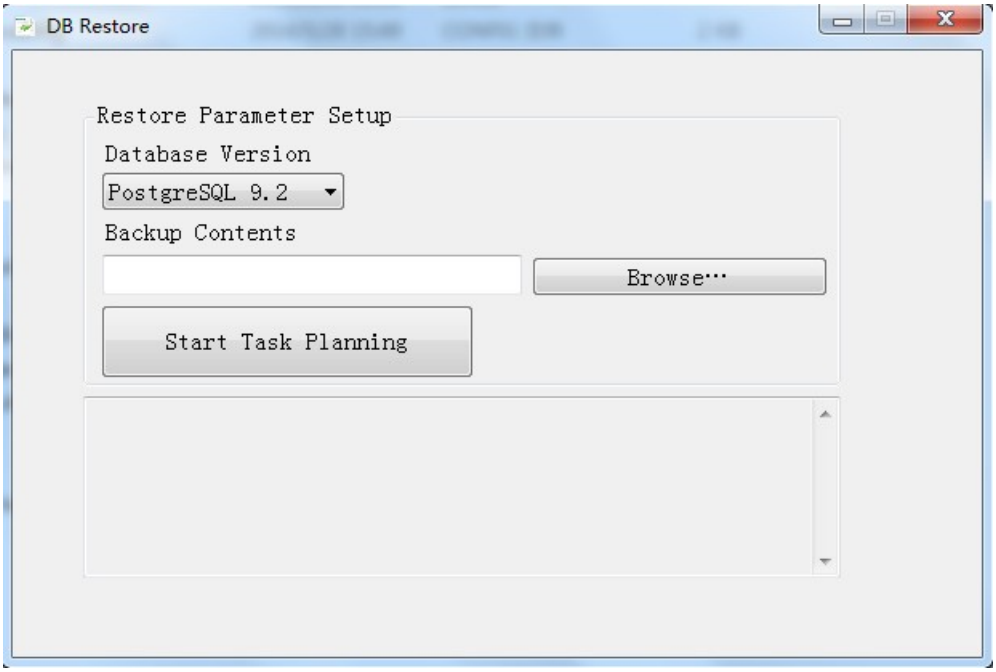


Figure 5-36 Database restore

Restore Parameter Setup: Choose the database version and backup contents.

Start Task Planning: Start to restore the database with a click.

Before you restore the database, please close the DCS server first.

5.18 Performance Tools

NOTE:

Before you use the Offline State tool on the Performance interface, please install Microsoft Office Excel, or you may fail to export query results.

Click **Start**>**All Programs**>**software**>**Performance** to open the performance window.

The monitors use the Ethernet protocol. On the Ethernet window will the following information be displayed: Device No., Identify, Monitor Model, Protocol, Configuration, Status, Changed Time, Message Number, Average/Expected Data to Receive, Requesting Data Length, Total Received Data, Average Receiving Time, Average Consuming Time, Offline Times, Latest Offline Time, and Detailed Information.

By the Offline State tool you can check a monitor's offline time, the IP address of a unit, etc.

5.19 Importation TRC Files

Click **Start**>**All Programs**>**software**>**ImportTrc** to import TRC files.

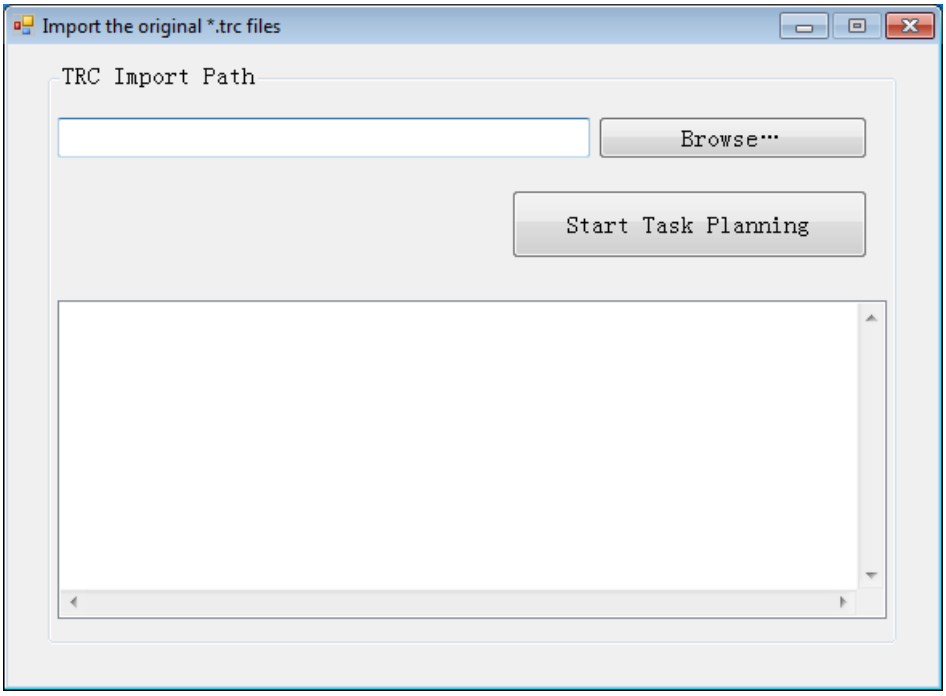


Figure 5-37Import TRC files

TRC Import Path: Click **Browse…** to select the path for *.trc file importing.

Start Task Planning: Click it to start the importing.

Chapter 6 Maintenance and Cleaning

6.1 Maintenance

6.1.1 Visual Inspection

Before each use, you should perform, with the system switched off, the following visual inspections:

- Check the system 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 system functions properly.

If any damage is detected, stop using the system on the patient. Replace the damage part(s) or contact the manufacturer for service before reusing it.

6.1.2 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.

6.1.3 Routine Inspection

The overall check of the system 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.

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.

6.1.4 Care

6.1.4.1 Care of Computer

Keep the exterior surface of the computer clean and 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 computer 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.

6.1.4.2 Care of Transducers

WARNING

The US transducers must be cleaned before docking into the docking slots after each use. Make sure that there is no residual coupling gel.

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.

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 or ethanol 75% 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 transducer battery every 3 months.

6.2 Cleaning

To avoid infection, clean and disinfect the equipment after each use,

6.2.1 Cleaning of Computer

Regular cleaning of the computer enclosure and the screen is strongly recommended.

WARNING

1 Unplug the system from the AC power source and detach all accessories before cleaning.
2 If liquid is splashed on or into the computer inadvertently, or enters the conduit, stop using it and contact the manufacturer for service immediately.
3 Do not use the heating units, such as heater, oven, microwave oven, blower, heating light, etc. to dry the device.

The solutions recommended for computer cleaning are: mild near neutral detergent andethanol 75%.

Clean the computer enclosure with soft cloth and diluent non-caustic detergents recommended above. Then clean it with a soft cloth dampened in water, and air-dry it or wipe the remaining moisture with a soft dry cloth.

Clean the screen with a dry soft cloth.

CAUTION

1 Do not immerse the computer in water or allow liquids to enter the case.
2 Although the computer chemically resistant to most common hospital cleaners and non-caustic detergents, different cleaners are not recommended and may stain the computer.
3 Many cleansers must be diluted before use. Follow the manufacturer’s directions carefully to avoid damaging the computer.
4 Do not use strong solvent, for example, acetone.
5 Never use an abrasive such as steel wool or metal polish.
6 Do not allow any liquid to enter the product, and do not immerse any part of the computer into any liquid.
7 Avoid pouring liquids on the computer while cleaning.
8 Do not allow any remaining solution on the surface of the computer.

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.

6.2.2 Cleaning of Transducers

To clean the transducers, please follow the steps:

a) Wipe them with a soft cloth dampened in cleaning solution.

b) Clean them with a soft cloth dampened in water

c) Air-dry them or wipe the remaining moisture with a soft dry cloth.

Recommended cleansers are listed below:

Transducer	**Cleansers**
Ultrasound Transducer TOCO Transducer	Mild near neutral detergent Ethanol 75%

CAUTION

1 Do not immerse the transducer into cleaning solutions during the process of cleaning.
2 Be sure the temperature of cleaning solutions does not exceed +45 ºC (+113 ºF).
3 Only wipe the outer surface of the transducer.
4 After cleaning, no remaining cleanser is allowed on the surface.
5 Please clean the charging point periodically or it will not be charged.

6.2.3 Cleaning of Trolley

The solutions recommended for computer cleaning are: mild near neutral detergent and ethanol 75%.

Clean the computer enclosure with soft cloth and diluent non-caustic detergents recommended above. Then clean it with a soft cloth dampened in water, and air-dry it or wipe the remaining moisture with a soft dry cloth.

6.2.4 Cleaning of Belt

Wash soiled belts with soap and water. The water temperature must not exceed +60 ℃ (+140 ℉).

6.3 Disinfecting

Clean the equipment before disinfecting it.
Follow these steps to disinfect the equipment:

a) Clean the equipment and its accessories.

b) Wipe them with a soft cloth dampened in the recommended disinfectant.

c) Wipe them clean with a soft cloth dampened in water.

d) Air-dry them or wipe the remaining moisture with a soft dry cloth.

The table below lists the allowed disinfectant bases:

Parts	**Recommended**
Computer	Ethanol 75%
Transducer	
Trolley	

CAUTION

1 Do not use any disinfectant containing additional active ingredients other than those listed.
2 Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.
3 After disinfection, no remaining disinfectant is allowed on the surface.
4 Check if the equipment and accessories are in good condition. If any aging or damage is detected (e.g. the belt loses its elasticity), replace the damaged part(s) or contact the manufacturer for service before reusing them.
5 Please do not light the TOCO transducer with ultraviolet light for a long time.

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.

6.4 Sterilizing

Do not sterilize the equipment or the accessories.

NOTE:

Check if the equipment and accessories function well. If any problem is detected, please contact the manufacturer for service before reusing them.

Checking Item	**Checking Method**
Visual	Inspect the computer, trolley, transducers and cables etc. for any damage.
Power On	Power on the system. Does it boot up successfully without errors and enter the main menu?
Functionality Test	After the system is powered on, check whether the AC power indicator lights up.
Performance	Please check the US transducer and TOCO transducer according to section *4.7.1Testing US Transducers* and section*4.7.2Testing TOCO Transducers.*
System	When the equipment is connected to F series monitors, please check whether the transducers are successfully connected to the system

Chapter 7 Warranty and Service

7.1 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.

7.2 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

A1.1 Environmental Specifications

The equipment may not meet the performance specifications given here if stored or used outside the specified temperature and humidity ranges.

Working	Temperature	0℃ ~ + 40 ℃ (+32℉ ~ +104 ℉)
	Relative Humidity	15% ~ 95% (non-condensing)
	Atmospheric Pressure	86kPa ~ 106kPa
Transport and Storage	Temperature	-20 ℃ ~ +55 ℃ (-4℉ ~ +131 ℉)
	Relative Humidity	15% ~ 95% (non-condensing)
	Atmospheric Pressure	70 kPa ~ 106kPa

A1.2 Physical Specifications

Workstation	Size	Table-board diameter≤ 700mm Three heights are provided: ◆(1020±50)mm ◆(970±50)mm ◆(920±50)mm
	Weight	◆transducer：< 170g ◆workstation(complete set)：<55 kg
	Screen Diagonal	21.5’’
	Power Supply	Operating Voltage: 100V-240V~
		Operating Frequency: 50Hz/60Hz
		Input Power: 1.5A-0.7A
US Transducer	Size	Ø(81±1) mm×(35±1) mm
	Weight	< 170g
TOCO Transducer	Size	Ø(81±1) mm×(35±1) mm
	Weight	< 170g

Standards Compliance	EN 60601-1:2006/A1:2013 idt IEC 60601-1:2005/A1:2012 EN 60601-1-2:2007 idt IEC 60601-1-2:2007 EN 60601-1-6:2010 idt IEC 60601-1-6:2010 EN 60601-1-8:2007 idt IEC 60601-1-8:2006 EN 62304:2006 idt IEC 62304: 2006 EN 62366:2008 idt IEC 62366:2007 EN 60601-2-37:2008 idt IEC 60601-2-37:2007 IEC 60601-2-49:2011 ETSI EN 300 328 V1.9.1 ETSI EN 301 489-1 V1.9.2 ETSI EN 301 489-17 V2.2.1 EN 62479:2010
Anti-electric Shock Type	FTS-6: Class I equipment US Transducer: internal power supply TOCO Transducer: internal power supply
Anti-electric Shock Degree	FHR & TOCO: Type BF
Degree of Protection against Harmful Ingress of Water	Workstation: ordinary equipment, not protected from harmful ingress of water US/TOCO Transducers: IPX8, protected against the effects of continuous emersion in water
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	Continuously running equipment

A1.3 Performance Specifications

FHR	
*FHR Measurement Range	50 bpm ~ 240 bpm
*Resolution	1 bpm
*Accuracy	±2 bpm
*Alarm	FHR Alarm
*Ultrasound Output	$I_{sppa.3}$<190W/cm2 $I_{spta.3}$<94mW/cm2 I_{sata}<20 mW/cm2 TI<1.0 MI<1.0
*Temperature Rise	When applied to the patient, the ultrasound transducer may warm slightly (less than 10℃ (18℉) above ambient temperature). When NOT applied, at the ambient temperature of 40℃ (104℉), the ultrasound transducer may reach the highest temperature of 50℃ (122℉).
p- <1 MPa	
I_{ob}<10 mW/cm^2	
I_{spta}<100 mW/cm^2	
Max Output Power <15mW	
Effective Radiating Area	(942±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/℃ (free air)
	5 units/min/℃ (underwater)
Zero Mode	Automatic (TOCO value becomes zero or below lasting for 30 seconds)/ Manual
Dielectric Strength	4000Vrms

AFM	
AMF Technique	Pulsed Doppler ultrasound
*FM Mode	Automatic
*AFM Mode	Trace (default) or Black Mark
*Display Range	0 ~ 999
RF Index	
RF EIRP output power	<20dbm
Frequency Range	2.4GHz ~ 2.4835GHz
Transmission Range (line of sight)	>20m
TransducerRF Modulation Schemes	CCK\DSSS\OFDM\ MIMO-OFDM
APRF Modulation Schemes	CCK\DSSS
Transmission Rate	About 11Mbps
Channel Range	1~13
AP Input Sensitivity:	-99dBm at minimum at 1Mbps/DSSS
Transducer Input Sensitivity:	-93dBm at minimum at 1Mbps/DSSS
Wireless Security	WPA2-PSK
Transducer Antenna	FPC antenna
AP Antenna	Dipole antenna

NOTE:

The essential performance is marked with an asterisk*.

A1.4 Rechargeable Lithium-ion Battery

Type	Rechargeable Lithium-ion Battery
Continual Working Time	≥8 hours
Necessary Charge Time	Charging in the docking slot: ≤5hours; Charging by battery charger: ≤7hours
Nominal Capacity	1600 mAh
Nominal Voltage	3.7 V
Cycle Life	≥500 times

Appendix 2 Troubleshooting

A2.1 No Display

Problem	Possible Causes	Solutions
Power indicator doesn't light up.	Power cable is loose.	Plug the power cable into the sockets tightly.
	The fuse is blown.	Change the fuse.
	Power cable of the computer is loose.	Open the housing of the computer and connect the power cable well

A2.2 Noise

Problem	Possible Causes	Solutions
Noise	Volume is too high.	Turn down the volume.
	Excessive aquasonic coupling gel	Wipe off the excessive gel.
	Interfered by strong interfering sources nearby	Keep the interfering sources far away from the equipment.

A2.3 No FHR Sound

Problem	Possible Causes	Solutions
No FHR sound	IP address of the master control board is not set yet, or is not correct.	Set the IP address and port number of the master control board.
	Jumper caps for the FHR sound channel selection on the master control board are not installed or are not well connected.	Check whether the jumper caps (J10, J17 and J18) on the master control board are well connected and whether the loudspeakers on the setup interface are in normal condition. The number of the loudspeakers should be the same as that of the jumper caps and that of the configured FHR channels.

	Ethernet failure on the master control board	Open the command window on the computer and command the IP address on the master control board with PING command. If the command receives no response, check if there is a failure in the AP module.
	Loudspeaker is damaged.	Measure the electric resistance of the loudspeaker. Resistance within 16Ω±10% is acceptable. If there is open circuit or short circuit, replace the loudspeaker.
	FHR sound of the maximum three US transducers are activated to play.	Turn off any one of the tree FHR sound. Choose to play either of the rest two FHR sound.

A2.4 Trouble with Ultrasound FHR Monitoring

Problem	Possible Causes	Solutions
Traces and displays are not intermittent.	Misplaced US transducer	Relocate the transducer until the signal is strong.
	Loose Belt	Tighten the belt.
	Excessive aquasonic coupling gel	Wipe off the excessive gel.
	Frequent fetal movement	Postpone the monitoring.
	Maternal movement	Request the patient to calm down and stay still.
	Inadequate aquasonic coupling gel	Apply recommended quantity.
Doubtful FHR	Maternal heart rate is recorded by mistake.	Adjust the position of the US transducer.
	The transducer is not well-placed on the patient and mixed periodic signals are being recorded.	Adjust the position of the US transducer.

A2.5 Trouble with TOCO Monitoring

Problem	Possible Causes	Solutions
Doubtful TOCO	Little change or no change of TOCO value	Unloose the belt and re-fasten it well. Press“ZERO” when there is no contraction.

	Loose belt	Tighten the belt

A2.6 Network Problems

Problem	Possible Causes	Solutions
Transducer can't connect to the system	Incorrect IP address for the wired network of the computer	Set the IP address of the computer to the same as that of the transducer
	Port number of the transducer is incorrect, or there is IP address conflict among the transducer, the trolley and the master control board.	Set the correct port number and make sure there is no IP address conflict among the transducer, the trolley and the master control board.
	The wireless SSID and security code of the computer's AP module are not consistent with those of the transducer.	Make sure that the wireless SSID and security code of the computer's AP module are consistent with those of the transducer.
Inconstant trace	Interfered by strong interfering sources nearby	Change to another WIFI channel of less interference and configure the AP with b/g mode.
	Weak WIFI signal	Keep the system within the patient's visual range to reduce signal attenuation caused by walls.

A2.7 Transducer Communication Problems

Problem	Possible Causes	Solutions
US transducer can't power on after being taken up.	① It runs out of battery. ② RF communication between the system and the transducer failed.	① Charge the transducer battery. ② Put it back into the docking slot and take it up again. If the problem persists, restart the system.
Network failure	① Connecting cable of the main board is loose or damaged.	① Tighten or repair the cable.

FHR or TOCO recording interrupts.	① Transducer is placed incorrectly. ② Transducer slides. ③ The patient walks in strong tramps. ④ RF interference or out of prescriptive area.	① Check the transducer position. ② Tighten the transducer and apply little coupling gel. ③ Ask the patient to walk slightly. ④ Ask the patent to walk in the prescriptive area.
The battery icon does not display when charging the battery.	① The transducer does not connect to the charging point tightly. ② The system is not connected to AC power.	① Press the transducer until it touches the charging point closely. ② Connect the system to AC power.
The charging board or charging point is corrosive.	① The charging point is wet, or is polluted by coupling gel.	① Clean the transducer before charging. ② Replace the charging point if necessary.

A2.8 Keyboard Problems

Problem	Possible Causes	Solutions
Keyboard doesn't work.	Keyboard driver is damaged.	Check if the keyboard driver is functioning well. If there is no keyboard driver, rescan hardware and the driver will be installed automatically. This may require the keyboard USB to be unplugged and plugged in again, or you can restart the system instead.
	The keyboard USB cable is loose or damaged.	Tighten it or replace it.

	Cable connecting the keyboard panel and the master control board is loose or damaged.	Replace the cable.
	Keyboard USB module failure	Service or replace the module.
	Keyboard interface failure	Service or replace the keyboard interface panel.
	Master control board failure	Service or replace the master control board.

A2.9 Software Problems

WARNING

Software service must be provided by the maintenance personnel of the manufacturer.

Problem	Possible Causes	Solutions
Fail to install the software.	The operating system does not meet the requirements for installing the software.	Ensure the operating system meets all the requirements.
DCS Service fails to auto-start after the system is optimized by 360 Safeguard.	Function "Auto-start with the system" of DCS Service is disabled before system optimizing.	Do not disable DCS Service's auto-start function when optimizing the system.
The software shuts down when sending email and its desktop shortcut is out of work.	360 Safeguard removed the software as a virus.	Trust and recover the software in the recover area of 360 Safeguard.
System prompts a hint that Microsoft Office Excel is not installed when exporting query result using Offline State tool.	Microsoft Office Excel is not installed.	Install Microsoft Office Excel before using Offline State tool.

Fail to print report using the shared printer.	The shared printer is not correctly configured.	1. Ensure the computer connected with the printer and the computer where FTS-6 software is installed are online (the two computer must connect to the same LAN and have the same subnet number and subnet mask number). 2. Tick the document and printer share services: open Control Panel> All Control Panel Items>Network and Sharing Center>Advanced Sharing Settings, tick "Enable network finding ", "Enable printer and document sharing" and "Disable password protection sharing ".

A2.10 Blown Fuses

WARNING

Switch off the system and unplug it before replacing fuse.

Replace the fuse when it is blown.

The two fuses of the system are located on the back of the trolley, right under the power interface. Their specifications are:

Size: Φ5mm*20mm; Model: T3.15AH250V.

To replace a fuse:

a) Press the power switch on the left side of the trolley to off.

b) Move the trolley to a respectively open area. Unfasten the power cord buckle and unplug the power cord.

c) Use a straight screwdriver to prize out the fuse box.

d) Remove the blown fuses and replace them with new fuses supplied by the manufacturer or of the same specifications.

e) Push the fuse box back in position.

Appendix 3 EMC Information

A3.1 Electromagnetic Emissions

<table>
<tr><th colspan="3">Guidance and manufacture’s declaration – electromagnetic emission</th></tr>
<tr><td colspan="3">The FTS-6Central Monitoring System is intended for use in the electromagnetic environment specified below. The customer of the user of the FTS-6Central Monitoring System should assure that it is used in such and environment.</td></tr>
<tr><th>Emission test</th><th>Compliance</th><th>Electromagnetic environment – guidance</th></tr>
<tr><td>RF emissions
CISPR 11</td><td>Group 1</td><td>The FTS-6 Central Monitoring System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.</td></tr>
<tr><td>RF emission
CISPR 11</td><td>Class A</td><td rowspan="3">The FTS-6 Central Monitoring System is 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.</td></tr>
<tr><td>Harmonic emissions
IEC 61000-3-2</td><td>Class A</td></tr>
<tr><td>Voltage fluctuations/ flicker emissions
IEC 61000-3-3</td><td>Complies</td></tr>
</table>

A3.2 Electromagnetic Immunity

<table>
<tr><th colspan="4">Guidance and manufacture’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The FTS-6 Central Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of FTS-6 Central Monitoring System should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
</table>

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 differential mode ± 2 kV common mode	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 *FTS-6Central Monitoring System* requires continued operation during power mains interruptions, it is recommended that the *FTS-6Central Monitoring System* 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.			

A3.3 Electromagnetic Immunity

<table>
<tr><th colspan="4">Guidance and manufacture’s declaration – electromagnetic immunity</th></tr>
<tr><td colspan="4">The FTS-6Central Monitoring System is intended for use in the electromagnetic environment specified below. The customer or the user of FTS-6Central Monitoring System should assure that it is used in such an environment.</td></tr>
<tr><th>Immunity test</th><th>IEC 60601 test level</th><th>Compliance level</th><th>Electromagnetic environment - guidance</th></tr>
<tr><td></td><td></td><td></td><td>Portable and mobile RF communications equipment should be used no closer to any part of the FTS-6Central Monitoring System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Recommended separation distance</td></tr>
<tr><td>Conducted RF
IEC 61000-4-6</td><td>3 V_{rms}
150 kHz to 80 MHz
6Vrms[c)]in ISM bands between 0,15 MHz and 80 MHz</td><td>3 V_{rms}
150 kHz to 80 MHz
6Vrms[c)]in ISM bands between 0,15 MHz and 80 MHz</td><td>$d = 1.2\sqrt{P}$ 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 $\sqrt{P}$ /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 FTS-6 Central Monitoring System, including cables specified by the manufacturer).</td></tr>
<tr><td>Radiated RF
IEC 61000-4-3</td><td>3 V/m
80 MHz to 2.7 GHz</td><td>3 V/m
80 MHz to 2.7 GHz</td><td></td></tr>
<tr><td></td><td>See table 9</td><td>Comply with table 9</td><td>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:</td></tr>
</table>

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 *FTS-6Central Monitoring System* is used exceeds the applicable RF compliance level above, the *FTS-6Central Monitoring System* should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the *FTS-6Central Monitoring System*.

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	Pulse	2	0.3	28

870 930		800/900,TETRA 800, iDEN 820, CDMA 850, LTE Band 5	modulation[b)] 18 Hz			
1720 1845 1970	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
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 5500 5785	5100-5800	WLAN 802.11 a/n	Pulse modulation[b)] 217 Hz	0.2	0.3	9
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						

A3.4 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the FTS-6 Central Monitoring System

The *FTS-6Central Monitoring System* is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the*FTS-6Central Monitoring System* can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the *FTS-6Central Monitoring System* 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 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.

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 1℃ (1.8℉).

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. "Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3" issued by AIUM/NEMA in 2004
4. "Standard for real-time display of thermal and mechanical acoustic output indices on diagnostic ultrasound equipment, Revision 2" issued by AIUM/NEMA in 2004
5. "Information for Manufacturers Seeking Marketing Clearance of Diagnostic Ultrasound Systems and Transducers" issued in 2008.
6. “Medical electrical equipment—Part2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment" issued by IEC in 2007.

A4.6 Transducer Acoustic Output Parameters List

A4.6.1 Test of Wireless Transducer

Acoustic Output Reporting Table

Operating Mode: PW mode

Working Frequency: 1.0MHz

Index label			MI	*TIS*			*TIB*	*TIC*
				Scan	Non-scan		Non-scan	
					A_{aprt}≤1 cm^2	A_{aprt}>1 cm^2		
Maximum index value			0.01749			0.007928	0.06407	N/A
Associated acoustic parameters	$p_{r.\alpha}$		0.01749					
	P						9.689	N/A
	minof $[P_\alpha(Z_s),I_{ta.\alpha}(Z_s)]$					1.6651		
	z_s					6.55		
	z_{bp}					5.1883		
	z_b						6.55	
	z at max $I_{pi.\alpha}$		6.55					
	$d_{eq}(Z_b)$						2.17	
	f_{awf}		0.9999			0.9999	0.9999	N/A
	Dim of A_{aprt}	X				Φ3.4641	Φ3.4641	N/A
		Y				Φ3.4641	Φ3.4641	N/A
Other information	t_d		90.0732					
	prr		2000					
	p_r at max I_{pi}		0.02286					
	d_{eq} at max I_{pi}						2.06	
	$I_{pi.\alpha}$ at max MI		0.009218					
	Focal Length	FL_x				N/A		
		FL_y				N/A		
Operating control conditions	Fixed							

A4.6.2 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 in TRACK1 of FDA Guidance	**NOTE**
pr.3	Derated Peak-rare-factional Acoustic Pressure

W0	Output Power
zsp	zsp =zB.3 , Depth for Bone Thermal Index
fc	Center Frequency, Acoustic
x-6	-6dBBeamwidth
y-6	
PD	Pulse Duration
PRF	Pulse Repetition Frequency
MI	Mechanical Index
ISPTA.3	Derated Spatial-peak Temporal-average Intensity
ISPPA.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 Limitations of Ultrasonic Monitoring

A5.1 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.

A5.2 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.

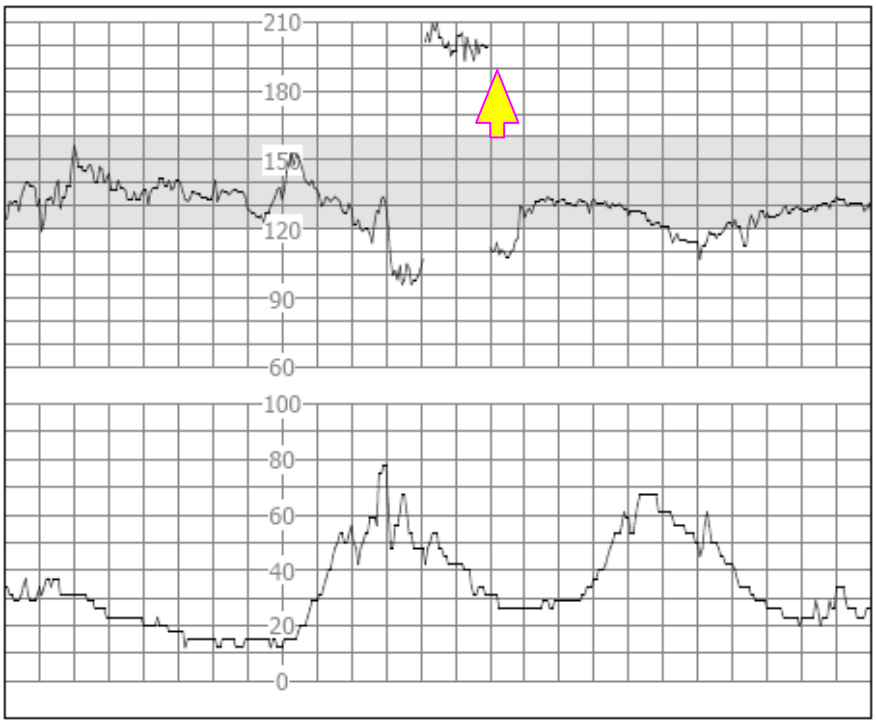
The artifacts, if not correctly interpreted, may cause the physicians to perform unnecessary interventions, or to fail to detect the fetal distress and the need for interventions.

The most common artifacts are doubling and halving.

(2) Doubling:

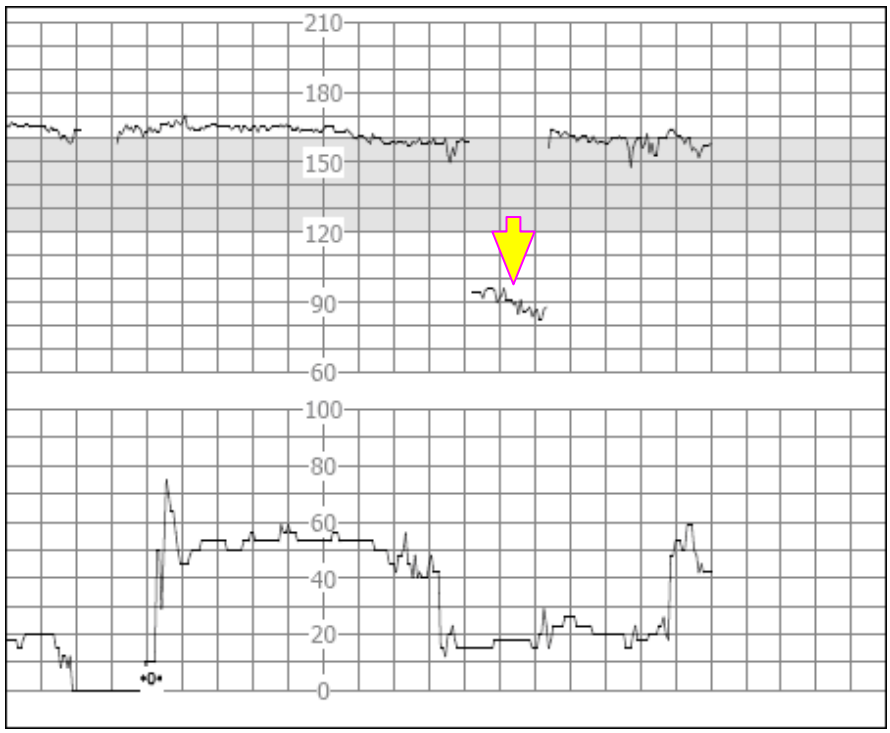
When the FHR drops to 120 bpm or lower, the diastole and systole become far apart, thereby the monitor may mistake these two movements of a single heartbeat for two separate heartbeats. As a result, a heart rate trace that is double the actual heart rate is produced. This often happens during severe 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.

A5.3 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 6 Alarm Messages

The following table lists the alarm/prompt messages that might appear during monitoring, their respective causes and countermeasures.

Alarm Message	Cause	Countermeasure
Patient Alarm (Medium Level)		
**FHR1 HIGH,>xxx bpm, > y s or **FHR2 HIGH, >xxx bpm, > y s or **FHR3 HIGH, >xxx bpm, > y s	FHR1, FHR2 or FHR3 measuring result is higher than the set upper limit(xxx) over the alarm delay time(y).	Check if the alarm limits are suitable; check the patient's condition.
**FHR1 LOW,<xxx bpm, > y s or **FHR2 LOW, <xxx bpm, > y s or **FHR3 LOW, <xxx bpm, > y s	FHR1, FHR2 or FHR3 measuring result is lower than the set lower limit (xxx) over the alarm delay time(y).	
**MHR HIGH,>xxx bpm, > 0 s	Maternal HR result is higher than the upper limit (xxx).	
**MHR LOW,< xxx bpm, > 0 s	Maternal HR result is lower than the lower limit (xxx).	
** SpO_2 HIGH, >xxx%, > 0 s	SpO_2 result is higher than the upper limit (xxx).	
** SpO_2 LOW, <xxx%, > 0 s	SpO_2 result is lower than the lower limit (xxx).	
**SYS HIGH, >xxx mmHg, > 0 s	SYS result is higher than the upper limit (xxx).	

**SYS LOW, <xxx mmHg, > 0 s	SYS result is lower than the lower limit (xxx).	
**DIA HIGH, >xxx mmHg, > 0 s	DIA result is higher than the upper limit (xxx).	
**DIA LOW, <xxx mmHg, > 0 s	DIA result is lower than the lower limit (xxx).	
**MAP HIGH, >xxx mmHg, > 0 s	MAP result is higher than the upper limit (xxx).	
**MAP LOW, <xxx mmHg, > 0 s	MAP result is lower than the lower limit (xxx).	
**TEMP HIGH, > xxx °C, > 0 s	TEMP result is higher than the upper limit (xxx).	
**TEMP LOW, < xxx °C, > 0 s	TEMP result is lower than the lower limit (xxx).	
Technical Alarm (Medium Level)		
**Wireless US1 Transducer Battery Low	The battery power is too low to support further work of the transducer.	Please charge the US1 transducer immediately.
** Wireless US2 Transducer Battery Low	The battery power is too low to support further work of the transducer.	Please charge the US2 transducer immediately.
** Wireless US3 Transducer Battery Low	The battery power is too low to support further work of the transducer.	Please charge the US3 transducer immediately.
** Wireless TOCO Transducer Battery Low	The battery power is too low to support further work of the wireless TOCO transducer.	Please charge the TOCO transducer immediately.
Technical Alarm (Low Level), Prompt Message		

*US1 UNPLUGGED or *US2 UNPLUGGED or *US3 UNPLUGGED	US transducer 1 or US transducer 2 is not well connected.	Check the connection of the transducer.
*US1 SIGNAL LOSS or *US2 SIGNAL LOSS or *US3 SIGNAL LOSS	FHR1 or FHR2 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.
*TOCO UNPLUGGED	TOCO transducer is not well connected.	Check the connection of the transducer.
*DECG LEADS OFF	The spiral electrode is not well connected.	Check the connection of the spiral electrode.
*DECG UNPLUGGED	The DECG cable is not well connected to the monitor.	Check the connection of the DECG cable.
*DECG SIGNAL LOSS	DFHR signal is too weak for the system to analyze.	Check if the spiral electrode is well attached to the fetus scalp; check if the alarm limits are suitable; check the patient's condition.
*IUP UNPLUGGED	The IUPC and/or connecting cable are/is not well connected to the monitor.	Check the connection of the IUPC and connecting cable.
*ECG LEADS OFF	ECG leads are not well connected.	Check the connection of ECG leads.
*SpO_2 SENSOR OFF	SpO_2 sensor is not well connected.	Check the connection of SpO_2 sensor and finger placement.
*TEMP UNPLUGGED	TEMP transducer is not well connected.	Check the connection of TEMP transducer.
*Signals Overlap (FHR1, FHR2)	Two ultrasound transducers are aimed at the same fetal heart.	Adjust one of the transducers to find the other fetal heart.
*Signals Overlap (FHR1, FHR3)	Two ultrasound transducers are aimed at the same fetal heart.	Adjust one of the transducers to find the other fetal heart.
*Signals Overlap (FHR2, FHR3)	Two ultrasound transducers are aimed at the same fetal heart.	Adjust one of the transducers to find the other fetal heart.
*Signals Overlap (FHR1, MHR)	US transducer 1 has picked the maternal heart signal.	Adjust the US transducer 1 to find the fetal heart.
*Signals Overlap (FHR2, MHR)	US transducer 2 has picked the maternal heart signal.	Adjust the US transducer 2 to find the fetal heart.

*Signals Overlap (DFHR, MHR)	DECG transducer has picked the maternal heart signal.	Adjust the US transducer 2 to find the fetal heart.
Wireless US1 Signal Loss	Wireless US1 signal is too weak or the system to analyze.	Check if the US1 transducer is aimed at the fetal heart; check if the alarm limits are suitable; check the patient's condition.
Wireless US2 Signal Loss	Wireless US2 signal is too weak or the system to analyze.	Check if the US2 transducer is aimed at the fetal heart; check if the alarm limits are suitable; check the patient's condition.
Wireless US3 Signal Loss	Wireless US3 signal is too weak or the system to analyze.	Check if the US3 transducer is aimed at the fetal heart; check if the alarm limits are suitable; check the patient's condition.
Wireless TOCO Transducer Signal Loss	Wireless Toco or TOCO&ECG signal is too weak or the system to analyze.	Check if the transducer is aimed at the right position; check if the alarm limits are suitable; check the patient's condition.
Device offline	Communication between the bedside monitor and the system is off.	Check the connection.
Paper out	No paper or the paper bin is open.	Supply paper or close the bin.
*NST timeout	The NST duration has exceeded the preset timer.	Complete the monitoring as required.
*Event list overflows.	The event amount of the window has reached the limit.	Save the data and start new monitoring.
*Trend list overflows.	The maternal trend amount of the window has reached the limit.	Save the data and start new monitoring.
*NIBP list overflows.	The NIBP amount of the window has reached the limit.	Save the data and start new monitoring.

Appendix 7 Ordering Information

02.01.212198	WirelessUS Transducer	WT6-US
02.01.212199	Wireless TOCO Transducer	WT6-TOCO
01.57.02264	Belt (Button Style)	/1400mm*58mm
01.57.78001	Aquasonic Coupling Gel	PARKER
01.13.036638-11	Power Cable	IEC Standard
01.13.114214	EarthWire	IEC Standard

Appendix 8 User's Authority

Users' Authority					
Functions		**Users of different levels**			**Comments**
		Super	**High**	**General**	
User Setup	Hospital information	Modify	Modify	None	
	User management	Modify	Modify	None	
	System setup modification	Modify	Readonly	None	
Monitoring Setup	FM	Modify	Modify	Modify	
	Maternal monitoring	Modify	Modify	Modify	
	Note management	Modify	Modify	Modify	
	CTG Options	Modify	Modify	Modify	
Alarm Setup	Default Alarm Setup	Modify	Modify	Readonly	
	Silence Duration	Modify	Modify	Readonly	
	Alarm Delay	Modify	Modify	Readonly	
General Setup	Mat Information	Modify	Modify	Modify	
	Options	Modify	Modify	Modify	
	Auto Saving Timer	Modify	Modify	Readonly	
	Analysis Type	Modify	Modify	Readonly	
	Mail sending	Modify	Modify	Modify	
Printing	Printing options	Modify	Modify	Modify	
System Setup	Device management	Modify	Modify	None	High users can visit this interface only after they are authorized to modify System Setup
	HIS setting	Modify	Readonly	None	
	Network setting	Modify	Modify	None	
	User setting	Modify	Modify	None	
	Factory setting	Modify	Modify	None	
Firmware Setup	Probe configuration	Modify	None	None	
	Speaker configuration	Modify	None	None	
	FM algorithm configuration	Modify	None	None	
	Online probe list	Modify	None	None	
Customized setting	Customized setting	Modify	Modify	None	

Appendix 3 Factory Default Settings

The factory default is a complete configuration predefined at factory (please refer to below sheet), users can change individual settings and save them as user defaults.

Factory Default Settings	
Items	**Default Value**
Monitoring Settings	
Fetal Monitoring Module	
Paper Speed	2cm/min
FHR2 Offset	-20
FHR3 Offset	20
Paper Type	International
Time Scale	Absolute Time
AFM Display	Trace
Segment Time	20 Minutes
Segment Position	Start Point
Grid Line Type	Solid
FM Source	Manual
UA Baseline	10
Maternal Monitoring Module	
NIBP Unit	mmHg
Temp Unit	℃
HR source	MECG
Fill Waves	Tick
CTG Options	
Show normal FHR range	Open
Show mat.name synchronously	Closed

Show fetal movement count	Open
Show time length	Closed
Show MSpO2 trace	Closed
Show MHR trace	Closed
Alarm Setup	
FHR	110bpm~160bpm
MHR	50bpm~120bpm
SpO_2	90%~100%
TEMP	36.0℃~39.0℃
SYS	90mmHg~160mmHg
DIA	50mmHg~90mmHg
MAP	60mmHg~110mmHg
RESP	8rpm~30rpm
Silence Duration	Alarm Reset
Reset probe off	Untick
Regular Settings	
Mat.Info	
Age	Open
DoB	Closed
Ges Week/Ges Day	Open
EDC	Closed
Inpatient No.	Open
Bed No.	Open
Outpatient No.	Closed
G/P	Open
Symptom	Closed

Remark	Closed
Auto Numbering	Open
Date Format	yyyy-MM-dd
Auto Saving Timer	None
Screen Color	Grey
Interpreting Standards	**Improved Fischer**
Options	
NST Timer	Closed
Show RESP	Closed
Import data	Closed
Send Mails	Closed
Chalkboard	Open
Segment Manually	Open
Clear Previous	Open
Save Previous	Open
Clear Following	Closed
Show Initials(notes)	Closed
Receive ID from devices	Closed
Display notes deleted	Closed
Fixed CTG duration(ViewBed)	Closed
Preview CTG curve	Open
Print and archive	Closed
Automatically clear invalid data	Closed
Full print	Closed
Automatically open fetal heart sounds	Open
Automatically switch window	Open

System Setup	
HL7	
Modify File Naming	Closed
Export Setup-Export During Analysis	Closed
Output Settings -Export Files During Saving	Closed
Device Interconnection	
Ethernet Port	5510
CTG Picture Printing-Printing Settings	
Printing Settings	
Direction	Vertical
Paper Type	A4
Color Printing	Untick
Large Font	Untick
Monitoring Picture Options	
Section Length	10 Minutes
Background grid	Dense
Content	Selected Data
Analysis Column	First page
Analysis Column Content	Conclusion
Analysis Report Printing-Printing Settings	
Printing Settings	
Direction	Vertical
Paper Type	A4
Color Printing	Untick
Large Font	Untick
CTG Options	

Section Length	10 minutes
Background grid	Dense
Analysis Report Settings	
Analysis report	Default Single Page
Print CTG assistant interpretation infor	Untick
Simplified Point Rating	Untick
Keep Proportion	Untick
Standard for printing NICHD guide	Untick
Only print the CTG	Untick
Event List Printing-Printing Settings	
Printing Settings	
Orientation	Portrait
Paper Type	A4
Color Printing	Untick
Large Font	Untick
Trend/NIBP Options	
One Page Trend	Untick
Signature Column	None

P/N: 01.54.457299
MPN: 01.54.457299012

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