INSTRUCTIONS FOR USE

Sonicaid® Team3

FTS-3 Fetal Telemetry System
(Wireless Transducer System)

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HUNTLEIGH
A MEMBER OF THE ARJO FAMILY

About this Manual

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About this Manual

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 the manufacturer can not be held liable.

The manufacturer owns the copyrights of this manual. Without prior written consent of the manufacturer, any materials contained in this manual shall not be photocopied, reproduced or translated into other languages.

Materials protected by the copyright law, including but not limited to confidential information such as technical information and patent information are contained in this manual, the user shall not disclose such information to any irrelevant third party.

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

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

Responsibility of the Manufacturer

The manufacturer 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 authorised by the manufacturer.

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.

Regulatory Approval Remarks

MECG and DECG function ARE NOT available in the USA and Canada at the time of release of this user manual. Consult your local representatives for the availability of the functions.

Contents

1. Safety Guide

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

NOTE: In order to ensure the operator and patient's safety, read through this chapter before using this system.

NOTE: 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.

1.1 Intended Purpose

The product is intended for the monitoring, displaying and transferring of multiple physiological parameters for fetus and pregnant women.

1.2 Intended Use/Indications for Use

The FTS-3 wireless telemetry system is a wireless system that is compatible with fetal & maternal monitors. It is intended for invasive or noninvasive monitoring of fetal/maternal physiological parameters, including fetal heart rate (FHR), fetal movement (FM), uterine activity , direct ECG (DECG) and maternal ECG (MECG) for pregnant women >28 weeks gestation. It is intended for monitoring in a bath or shower and only by trained and qualified personnel in antepartum examination rooms, labour and delivery rooms.

1.3 Instruction for Safe Operation

NOTE: In this manual, System refers to FTS-3.

- 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 ºC (+41 ºF) and +40 ºC (+104 ºF). Ambient temperatures that exceed these limits could affect the accuracy of the instrument and cause damage to the modules and circuits. Allow at least 2 inches (5 cm) clearance around the instrument for proper air circulation
- You must check that the equipment, cables and transducers do not have visible evidence of damage that may affect patient safety or monitoring capability before use. If damage is evident, replacement is recommended before use.
- The system must be serviced only by authorised and qualified personnel. The manufacturer does not accept responsibility for safety compliance, reliability and performance if modifications or repairs are carried out by unauthorised personnel. Identical replacement parts must be used.

- The typical operator's position is in front of the system. Please position the device in a location where the operator can easily access the operating controls.
- The protective degree against electric shock of the patient connections is :

Ultrasound (FHR1, FHR2) External TOCO	Type BF	
Direct Electrocardiography (DECG)	Type CF	
Maternal Electrocardiography (MECG)	Type CF with defibrillation protection	

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

a) The effects of high frequency currents

b) The interference of electrosurgery equipment

1.4 Ultrasound Safety Guide

Fetal Use

The monitor is designed for continuous fetal heart rate monitoring during pregnancy and labour. Clinical interpretation of fetal heart rate traces can diagnose fetal and/or maternal problems and complications.

Instructions for Use in Minimizing Patient Exposure

The acoustic output of the monitor is internally controlled and can not be varied by the operator in the course of the examination. The duration of exposure is, however, fully under the control of the operator. Expertise in 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.

1.5.1 Warnings

For using safely:

FTS-3 is provided for the use of qualified physicians or personnel professionally trained.

FTS-3 is not intended for use in intensive care units (ICU), operating rooms or for home use.

No modification of this system is allowed.

Do not switch on FTS-3 until all cables have been properly connected and verified.

EXPLOSION HAZARD - Do not use FTS-3 in the presence of flammable anesthetics or other materials.

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 FTS-3.

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

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

Additional multiple socket-outlet or extension cord must not be connected to the system.

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 an electrical device that does not belong to the system is plugged into the socket, the total power may exceed the maximum load of the separating transformer causing high temperature and fire. Enclosure leakage current within the system may exceed the standard limit, which may lead to an electrical risk.

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.

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

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.

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.

Connecting any accessory (such as external printer) or other device (such as the computer) to this 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.

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

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

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.

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

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.

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

Do not connect any equipment or accessories that are not approved by the manufacturer or that are not IEC 60601-1 approved to FTS-3. The operation or use of non-approved equipment or accessories with FTS-3 is not tested or supported, and system operation and safety are not guaranteed.

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

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

FTS-3 must only be used on one patient at a time.

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

Equipment and devices that connect to FTS-3 should form an equipotential body to ensure effective grounding.

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

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

FTS-3 should be operated by a trained healthcare professional.

Do not apply FTS-3 during electro-surgery or MRI; otherwise it might result in harming the patient or the operator.

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

⚠	**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.**
⚠	**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.**
⚠	**Never reuse disposable transducers, sensors, accessories, and so forth that are intended for single use, or single patient use only. Reuse may compromise device functionality and system performance, and cause a potential hazard.**
⚠	**Do not use a damaged transducer or one with exposed electrical contacts.**
⚠	**Do not service or maintain FTS-3 or any accessory whilst in use with the patient.**
⚠	**Assembly of FTS-3 and modifications during actual service life shall be evaluated based on the requirements of IEC60601-1.**
⚠	**The disposable ECG electrode must not be reused and must not be used if the packaging is damaged.**
⚠	**The instrument is precise. Therefore, to avoid instrument damage, do not operate the instrument violently, and avoid falling and impacting during use.**

Battery Use:

⚠	**Before using the rechargeable lithium-ion battery (hereinafter called battery), be sure to read the user manual and safety precautions thoroughly.**
⚠	**Use the battery only in FTS-3.**
⚠	**Do not reverse the battery pole or it will cause explosion.**
⚠	**Do not unplug the battery when monitoring.**
⚠	**Do not heat or throw the battery into a fire.**
⚠	**Do not use or leave the battery close to a fire or other places where temperatures may be above +40 ºC (+104 ºF).**

	**Do not immerse, throw, or wet the battery in water/ seawater.**
	**Do not destroy the battery: Do not pierce battery with a sharp object such as a needle. Do not hit with a hammer, step on or throw or drop to cause strong shock. Do not disassemble or modify the battery.**
	**Do not use the battery if it has been dropped or knocked against a hard surface, or if it is visibly damaged.**
	**Keep batteries out of the reach of children.**
	**Do not short-circuit the battery by connecting the battery cable connector or battery socket with metal objects or solder.**
	**If a liquid leak from the battery spills onto your skin or clothes, wash well with fresh water immediately.**
	**If a liquid leak from the battery gets into the eyes, do not rub the eyes. Wash them well with clean water and see a doctor immediately.**
	**Keep the battery away from fire immediately when leakage or foul odor is detected.**
	**Stop using the battery if abnormal heat, odor, discoloration, deformation or abnormal condition is detected during use, charging, or storage. Keep it away from FTS-3.**
	**Remove the battery and store it at a cool and dry environment if FTS-3 is not used for a long time.**
	**Unplug FTS-3 before installing and removing the battery.**
	**Do not connect the battery directly to an electric outlet or cigarette lighter charger.**
	**Batteries have a life cycle. If the battery operating time becomes much shorter than usual, the battery life is at an end. Replace the battery with a new one of the same specification as the one provided or recommended by the manufacturer.**
	**When the battery is aged, either after 3 years from manufacturing date or after 300 charge-discharge cycles, it is recommended to replace the battery. If the battery is stored alone and not used for a long time, we recommend that the battery should be charged at least once every 6 months to prevent overdischarge.**

⚠	**If the battery is stored inside FTS-3 for a long time without AC power connection, it will discharge over time and the battery indicator for "remaining capacity" will become less accurate.**
⚠	**High internal temperature may prevent the battery from charging. Keep FTS-3 at room temperature and move it away from heat sources or out of direct sunlight. The battery will resume charging when the temperature is within range again.**
⚠	**Only the battery supplied or recommended by the manufacturer can be used. Use of a different battery may present a risk of fire or explosion.**
⚠	**Please arrange a function test periodically for the system.**
⚠	**Do not move the system when it is powered on and do not soak it in any liquid.**
⚠	**Please check the transducer, cable and base station periodically. If the transducers are damaged, do not use them.**
⚠	**The battery in the wireless transducer should be replaced by service personnel authorised by the manufacturer.**
⚠	**If the transducer has been dropped or knocked, please check whether the cover is airproof or damaged. If you have any doubt, please contact the manufacturer or local agent.**
⚠	**If the battery is removed from the base station and not used for a long time, we recommend that the battery should be charged at least once every 6 months to prevent over discharge.**

1.5.2 Cautions

DECG (FECG) and maternal heart rate (MHR/MECG) must not be monitored underwater.
The device is designed for continuous operation. Avoid liquid splashing on the device.
Servicing should be performed only by Huntleigh Healthcare Ltd or their appointed service agent. If you have difficulty obtaining service for FTS-3, contact Huntleigh Healthcare Ltd.
Keep the environment clean. Avoid vibration. Keep it far from corrosive medicine, dusty areas, high-temperature and humid environments.
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.

Do not sterilize FTS-3 or any accessory with autoclave or gas.

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.

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

Electromagnetic Interference - Ensure that the environment in which FTS-3 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, FTS-3 may suffer interference.

Electromagnetic Interference - Do not use in close proximity to mobile phones.

Electromagnetic Interference - Fetal parameters, especially ultrasound and ECG, are sensitive measurements involving small signals, and the monitoring equipment contains very sensitive high gain front-end amplifiers. Immunity levels for radiated RF electromagnetic fields and conducted disturbances induced by RF fields are subject to technological limitations. To ensure that external electromagnetic fields do not cause erroneous measurements, it is recommended to avoid the use of electrically radiating equipment in close proximity to these measurements.

Electromagnetic Interference - FTS-3 should not be used adjacent to or stacked with other equipment, refer to section A6.2 Recommended Separation Distances.

Electromagnetic interference is not unique to this system but is characteristic of fetal patient monitoring equipment in use today. This performance is due to very sensitive high gain front-end amplifiers required to process the small physiological signals from the patient. Among the various monitoring systems already in clinical use, interference from electromagnetic sources is rarely a problem.

The medical electrical equipment needs to be installed and put into service according to Appendix 6 EMC Information.

Portable and mobile RF communications equipment can affect medical electrical equipment, refer to section A6.2 Recommended Separation Distances.

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

Accessories and consumables are subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.

The wireless transducers are rated IPX8, but the base station should be kept dry and away from water. Condensation may occur during transportation in high humidity or low temperature.

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

This equipment generates, uses and radiates radio-frequency energy, and if it is not installed and used in accordance with its accompanying documentation, it may cause interference to radio communications.

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

The recommended charging temperature for the battery is between 0° ~ +40° (+32 ºF ~ +104 ºF). Please do not exceed the temperature range.

1.6 Definitions and Symbols

Rx Only	Federal (U.S.) Law restricts this device to sale by or on the order of a physician		
IPX1	Protected against vertically falling water drops		
IPX8	Protected against the effects of continuous immersion in water to a depth of 1.1 metres for a period of up to 24 hours of monitoring.		
	This product, including its accessories and consumables, is subject to the WEEE (Waste Electrical and Electronic Equipment) regulations and should be disposed of responsibly in accordance with local procedures.		
	AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY		
	CE Mark		Date of Manufacture
	Manufacturer		Applied parts type BF
	Applied parts type CF		Applied parts type CF with defibrillator protection
	Follow Instructions for Use		Refer to Instructions for Use
	General Warning or Caution.		Caution, consult Accompanying Documents

SN	Serial Number	P/N	Part Number
MD	Medical Device	UDI	Unique Device Identifier
	Fragile , handle with care		General symbol for recovery/ recyclable
	Keep Dry		This way up
	HANDLE WITH CARE		DO NOT STEP ON
	STACKING LIMIT BY NUMBER		Channel Adjustment
	Non-ionizing electromagnetic radiation		USB Connection (Reserved)
	Ethernet Port (Reserved)		Wireless Transducer Working Indicator
	Importer		Distributor

2. Introducing the FTS-3 Fetal Telemetry System

2.1 Brief Introduction

FTS-3 Fetal Telemetry System (hereinafter called FTS-3) provides monitoring for FHR, DECG *, MHR, AFM and TOCO for pregnant women. When connected to a compatible fetal monitor, FTS-3 provides wireless patient monitoring in the antepartum period and during labour and delivery.

It is intended to be used only by trained and qualified personnel in antepartum examination rooms, labour and delivery rooms. It is not intended for use in intensive care units, operating rooms or for home use.

FTS-3 is used with fetal/maternal monitor and connects to the monitor by an interface cable supplied with the product. The wireless transducers monitor the FHR, and TOCO parameters up to 110 Metres line of sight, and then the base station transfers the data to the monitor via the interface cable. The monitor can display, alarm, print or review the parameters.

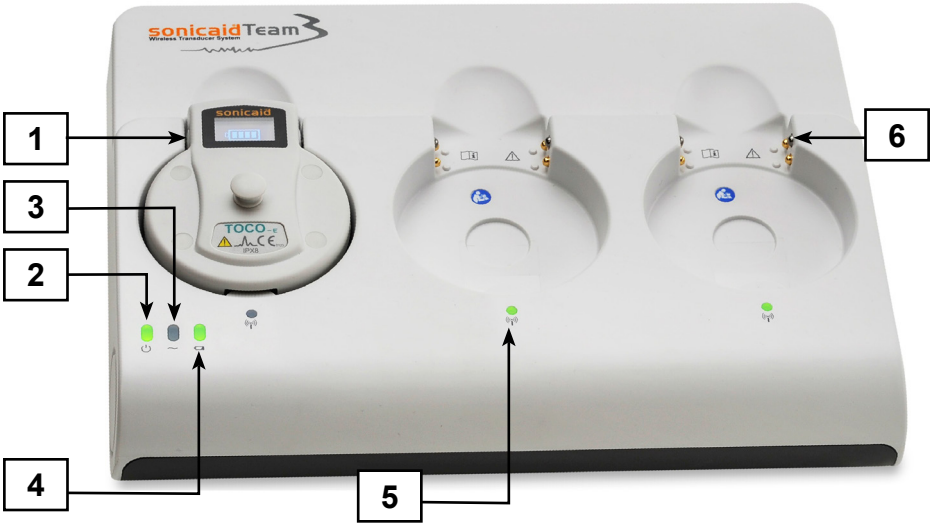
FTS-3 consists of the wireless US transducers (US-T transducers), the wireless TOCO transducer (TOCO-T transducer or TOCO-E transducer) and the base station.

The wireless signal is transmitted in the Industrial Scientific Medical Band (ISM) according to the local regulations. The transmission range depends on where the system is used. It is recommended to use in hospital for better transmission. The transmission range is shorter in water than that in the air.

* DECG is equivalent to FECG (Fetal ECG)

2.1.1 Base Station

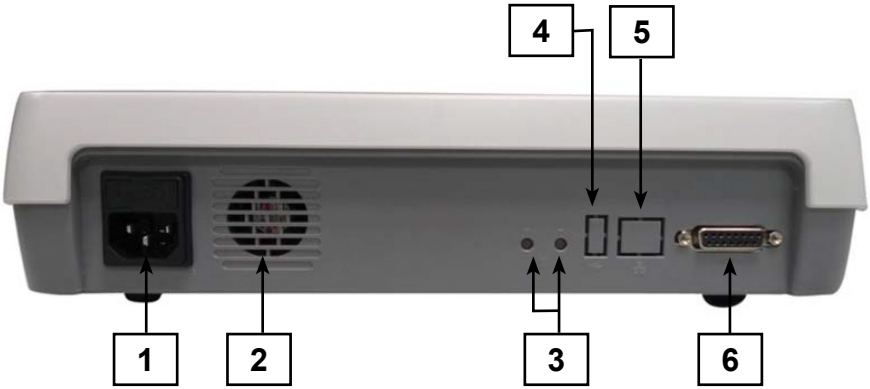
Top Panel



	Item	Description
1	Docking Slot	Locate and charge the transducer.
2	Power Indicator	When you turn the power supply, the indicator is on.
3	AC Indicator	When AC power is supplied, the indicator is on.
4	Battery Indicator	When the base station battery is charging, the indicator is on. When the battery level is low, it is flashing.
5	Wireless Connection Indicator	When the transducer connects to the base station successfully, the green light is on.
6	Charging Point	When you place the transducer in the docking slot, you can charge the transducer by these contacts.

WARNING.
The charging contacts are specifically for charging the transducers.
Do not touch the charging point and the patient at the same time.

Rear Panel



	Item	Description
1	AC Outlet	Mains supply
2	Cooling Fan	Air ventilation
3	Channel Adjustment Button	Adjust the base station channel
4	USB port	Reserved
5	Ethernet port	Reserved
6	Communication Socket	Fetal monitor interface

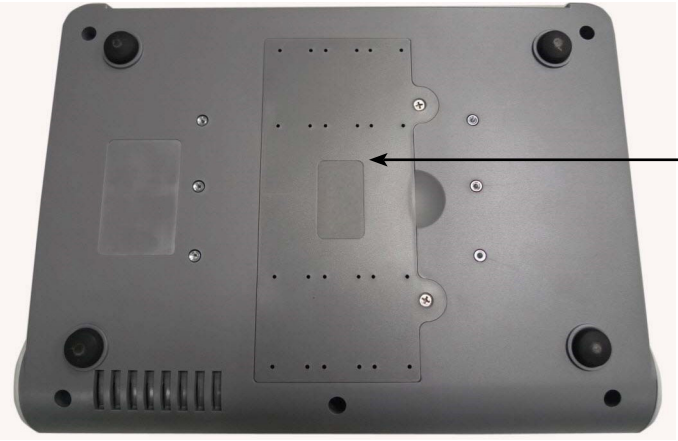
Right Panel

	Item	Description
1	Power Switch	Turn the base station on or off.

CAUTION. This system is a normal medical device.
Do not switch the unit on and off repeatedly as damage could occur.

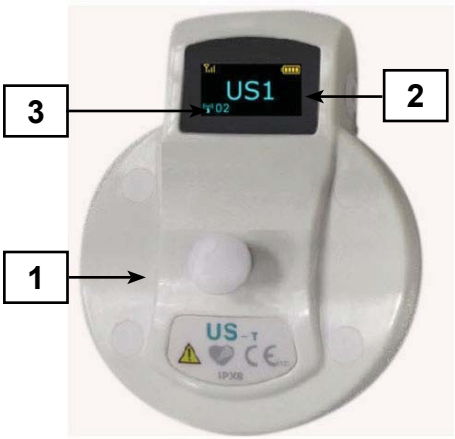
CAUTION. Do not switch the unit off when the transducers are in use.

Base Panel



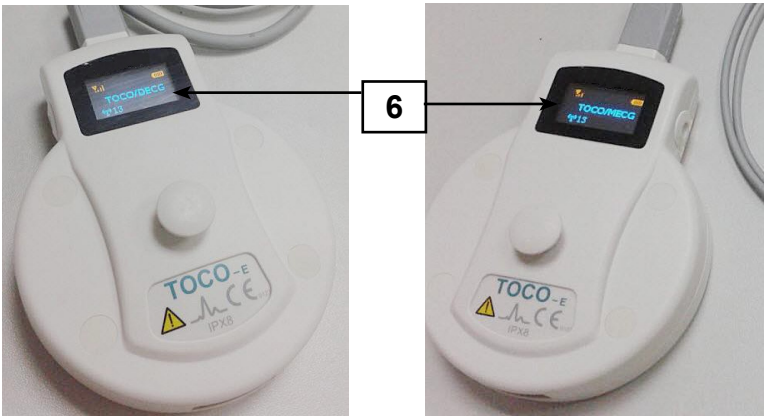
	Item	Description
1	Battery Compartment	Battery location

2.1.2 The Transducers



US-T Transducer

TOCO-T Transducer

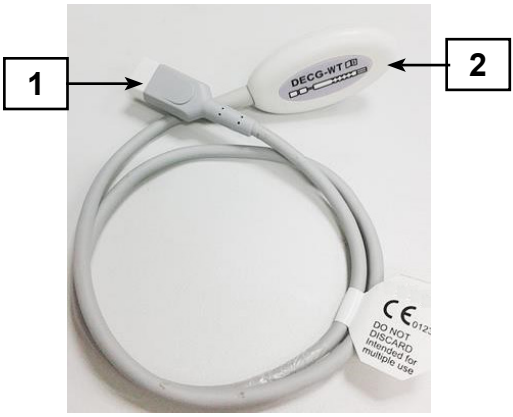


TOCO-E Transducer

	Item	Description
1	Transducer	Apply to the pregnant women.
2	Transducer Type	Indicates the transducer type.
3	System Working Channel	Indicates the system working channel.
4	Signal Indicator	Indicates wireless signal strength.
5	Battery Indicator	Indicates battery level.
6	TOCO-E Display	Display “TOCO/DECG” when connected to DECG cable; Display “TOCO/MECG” when connected to MECG cable; Display “TOCO” when not connected to DECG cable or MECG cable.

2.1.3 Accessories

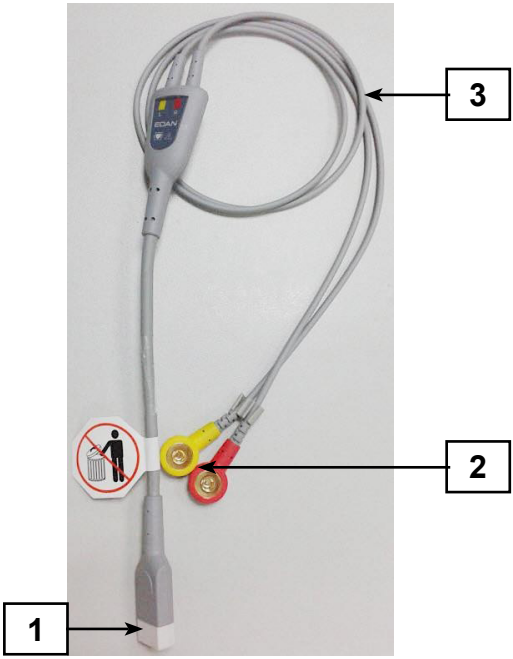
FTS-3 DECG Cable



	Item
1	DECG Cable Plug
2	DECG Cable Connector

WARNING. Connecting the fetal spiral electrode to the DECG cable: make sure that you have chosen the correct connector for the fetal spiral electrode according to the marking on the DECG cable.

FTS-3 MECG Cable



	Item
1	MECG Connector
2	MECG Fastener
3	Lead Wire

2.2 Installation Guide

WARNING. Installation must be carried out by qualified personnel authorised by the manufacturer.

2.2.1 Opening the Package and Checking

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

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

- Check for any mechanical damage.
- Check all the cables and accessories.

Should any damage be evident or any parts missing, ensure that Huntleigh Healthcare Ltd is informed at once.

2.2.2 Installing the Battery

WARNING. The Lithium battery pack should only be installed by suitably qualified personnel.

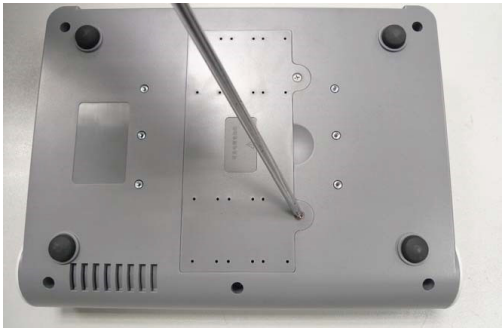
WARNING. Switch off Sonicaid FTS-3 and unplug it before installing or removing the battery.

WARNING. To disconnect from the mains, the plug must be removed. Always ensure that the plug is easily accessible.

NOTE. If the system is provided with a rechargeable base station battery, charge the battery after transportation and storage.

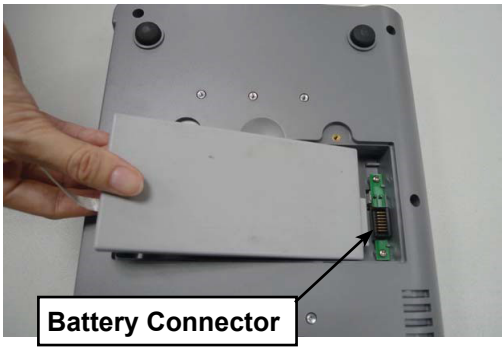
NOTE. Fully charge the battery after each use. The battery will automatically charge when the system is powered on with the AC power supply. Do not switch off until the battery is fully charged.

If the system is provided with a rechargeable lithium-ion battery, follow these steps to install the battery:



1. Place Sonicaid FTS-3 upside down on a flat surface covered with cloth or another type of protecting pad.
2. Remove the screws of the battery compartment using a cross-head screw driver.

   Remove the battery compartment cover.



3. Take the battery out from package and put it into the compartment. Make sure the battery connector is on the left and the battery label faces down.

WARNING. Do not touch the battery terminals with fingers or metal materials. This may cause a short circuit and be hazardous.

4. Arrange the battery flat in the compartment, and push the strip at the end of the battery into the gap.
5. Shut the battery compartment cover and fix it with the screws.

Battery Removal

Battery removal is the reverse of installation. Pull the strip at the end to take the battery out from the compartment.

2.2.3 Installing the System

FTS-3 should be placed on a flat surface. It should be away from any device with strong radiation and avoid being in a shielded room. More than 2 similar systems should be kept at a distance of over 1.5m.

Alternatively, it can be installed on a wall or a trolley approved by Huntleigh. Consult the sales representative for more information.

CAUTION. Installation must be carried out by qualified personnel authorised by the manufacturer.

CAUTION. If you choose to install FTS-3 on a trolley, it is the user's responsibility to ensure their integrity and solidity evaluated by a registered, professional structural or mechanical engineer and compliance with all local regulations. The manufacturer will not be responsible for the failure and loss of any improper installation.

2.2.4 Connecting the Power Cable

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

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

To disconnect from the mains, the plug must be removed. Always ensure that the power switch and plug are easily accessible.

NOTE. If the mains supply is interrupted and a battery is installed, the device will switch to internal power supply and operate normally. If a battery is not installed, the system will shut down and resume the previous settings at the subsequent operation.

NOTE. After the AC power supply is connected, wait for at least 2 seconds before pressing the POWER switch to turn on the system.

2.2.5 Configuration

The system can support, at most,

- 2 US-T transducers and 1 TOCO-T transducer
- 2 US-T transducers and 1 TOCO-E transducer (DECG and MHR not enabled),
- 1 US-T transducer and 1 TOCO-E transducer connected with DECG cable,
- 2 US-T transducers and 1 TOCO-E transducer connected with MECG cable.

Please do not exceed the maximum number.

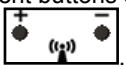
NOTE. The TOCO-T transducer and the TOCO-E transducer cannot be used simultaneously.

2.2.6 Connecting to the Monitor

Use the interface cable supplied to connect the FTS-3 system to the monitor. Switch on the monitor and the FTS-3 system.

2.2.7 Adjusting the Working Channel

Wireless transmission can be interrupted by other transmitters operating on the same frequency. If there are several FTS-3 units in one ward, all base stations must be set to different channel numbers. The operating channel is set using the adjustment buttons located on the rear panel of the base station. This is performed as follows:

1. Put all the transducers back in the docking slots.
2. Use the adjustment buttons on the rear panel of the base station to select the new channel number  . The channel range is 1-14.
3. Restart the system when it enters the charging interface. 

NOTE. The working channel number used by a system cannot be duplicated with that used by a device of the same type.

2.3 Basic Operation

2.3.1 Charging the Transducers

Place the transducer in the docking slot and it displays the charging state on the transducer screen.

NOTE. When the TOCO-E transducer is connected with the DECG or MECG cable, it cannot be charged due to poor contact with the charging points. Please remove the DECG or MECG cable before charging.

CAUTION. Wait for 2 minutes to use the transducers after charging.

2.3.2 Charge the Battery

Pay attention to the battery level during the monitoring process. The battery symbol is displayed in the top right corner of the transducer screen. A low battery level may influence the monitoring.

CAUTION. When the transducer indicates the power is low, replace the transducer with a fully charged one or the monitoring will be interrupted.

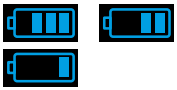
CAUTION. When docking the transducer into the docking slot for charging, check that the transducer is well placed and whether it is charging.

Battery indicator	Status
	Battery is fully charged.
	Battery is charged but not at maximum level.
	Battery level is low and requires recharging. Alarm information will be displayed on the screen.
	Battery is out of power. Charge the battery immediately.

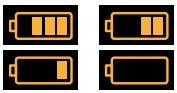
Wipe the transducer and the charging point with a dry cloth before charging the transducer.

Do not scratch the charging point.

The battery is installed in the transducer. If the base station is supplied by AC, the battery will be charged automatically when it is placed in the docking slot. Keep the transducer free of water and coupling gel during charging.
When you charge the battery, the screen will display as follows:

	Full charging icon: fully charged.
	Increasing charging icon: charging
	No charging icon: the transducer is placed in the docking slot incorrectly.
	If the screen displays ERROR, it indicates that the transducer is not connected well or you have placed a transducer from another system by mistake.

The transducer has a screensaver function:

	When the transducer is fully charged in the docking slot for more than 10min (±1min) and the base station is supplied by AC, a small yellow full charging icon will be displayed and floating on the screen and other icons will disappear.
	When the transducer is charging in the docking slot for more than 10min (±1min) but the base station is not supplied by AC, a small yellow charging icon of real battery level will be displayed and floating on the screen and other icons will disappear.

It takes about 3.5 hours to charge the battery. It is recommended to place the transducer in the docking slot when the transducer is not used for a long time.

Install the transducer in the base station and the transducer icon will be displayed on the screen.

NOTE. A complete charging process takes approximately 3.5 hours.

2.3.3 General Application

Take out the transducer from the docking slot and it will power on automatically. The transducer screen displays the signal strength, battery level and working channel. After the transducer is successfully connected to the base station, it will also display the transducer type. All the indicators are green. If the transducer is not successfully connected, it will power off automatically.

Take the transducer up and keep the transducer at a distance of over 30cm from the base station. The wireless connection indicator is on, and it indicates the transducer is taken out. If you want to power off the transducer, put it back in the docking slot. If the transducer connects to the base station successfully, the wireless connection indicator is always on and do not put back the inactivated transducer in the docking slot. Place the transducer on the patient

WARNING. The MECG cable is defibrillation-proof.
The DECG cable is not defibrillation-proof.

NOTE. Detailed operations please refer to the user manual of fetal&maternal monitor.

NOTE. If the working status indicator is on, please do not put the uncharged transducer in the docking slot.

NOTE. Fix the US-T transducer, TOCO-T transducer and TOCO transducer tightly to ensure that they will not shift during movement.

NOTE. It is recommended that the transducer should be placed when the patient stands for better monitoring.

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

NOTE. The wireless ultrasound transducer may warm slightly (less than 3°C (5.4ºF) above ambient temperature).

NOTE. The US-T transducer taken up first displays US1 on the screen, and the one taken up later displays US2. Please do not take two US transducers simultaneously and wait 2 seconds to take the other one. Restart the transducers if you take up two US-T transducers at the same time by mistake.

NOTE. Please apply coupling gel to the US-T transducer before use and move the transducer to get the desired fetal heart and belt it to the belly. Underwater monitoring requires less coupling gel or no coupling gel. The TOCO-T transducer and TOCO-E transducer can be applied to the belly directly without coupling gel.

NOTE. Use the minimum amount of gel required, to prevent the transducer from sliding too easily on the skin.

NOTE. The TOCO-E transducer monitors DECG or MHR only when it is connected with the DECG or MECG cable. If the TOCO-E transducer is not connected with the DECG or MECG cable, it only monitors TOCO. Besides, the DECG cable and the MECG cable cannot be connected to the TOCO-E transducer at the same time.

NOTE. When using the TOCO-E transducer to monitor DECG or MHR, it is recommended that the DECG cable or the MECG cable be kept straight to avoid damage to the TOCO-E transducer's interface caused by twisted cable.

2.3.4 Relocation of the Transducers

Transducers may be belted on the patient for a long time. In rare cases, this may lead to irritations to the patient skin. To avoid skin irritations, please inspect the application site at least every half an hour. 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 half an hour.

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.

2.3.5 Ambulatory Monitoring

IMPORTANT: Apply the transducers while the patient is standing for ambulatory monitoring.

For ambulatory monitoring of a patient, undock the transducers from the base station and apply them to the patient as described in Section 5.2.

During monitoring take care that:

- The transducers do not become displaced.
- A good fetal heart sound is recorded.
- The patient should not walk in strong steps
- The patient stays within operating range of the base station.
- The patient should be under monitoring when the wireless signal is good.

Note

When the transducer is placed in the docking slot, the system stops transmission. It starts when the monitor is connected to the transducer.

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

Within the wireless range, there may be dead spots where there is no signal due to building construction or interference from other sources.

The FHR may not be detected clearly when the patient moves in virtue of artificial interference. The transducer is easy to shift underwater and it may lead to temporary signal loss.

No matter how good a telemetry system is, occasional US-T/TOCO-T/TOCO-E dropouts may occur. If it is not acceptable for certain patients, please connect the wired transducer to the bedside monitor.

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

CAUTION. Do not mistake the patient's steps for the fetal heartbeats. The patient's steps may interfere with the monitoring of fetal heartbeats. It is recommended that the patient walks as little as possible.

CAUTION. Avoid excessive motion or vigorous movement as it may interfere with the monitoring and computing of FHR.

2.3.6 Underwater Monitoring

IMPORTANT: Apply the transducers when the patient is in the water for monitoring under water.
Use little, or no gel if possible on the US-transducer.

Most wireless signal can be absorbed by water. Wireless transmission distances are shorter when monitoring under water. If you have any questions, contact the manufacturer or the local agent.

CAUTION. DECG (FECG) and maternal heart rate (MHR /MECG) must not be monitored underwater.

CAUTION. Avoid splashing the transducer during underwater monitoring, or it may cause wireless signal interference.

CAUTION. All Transducers have a water resistance rating of IPX8; the device will function correctly after being submerged in water to a depth of 1.1 metres for a period of up to 24 hours of monitoring. The base station is not waterproof and not to be immersed; do not allow fluids to enter Base Station Unit.

CAUTION. Underwater monitoring may influence the TOCO baseline in virtue of water temperature and depth or other reasons. Please adjust the TOCO baseline until the pressure of the transducer in water is steady and keep checking it.

CAUTION. A metal bath tub and underwater monitoring both reduce the operating range.

2.3.7 Basic Function Test

A functional test should be performed after initial installation and after each service, following each step below:

1. **Power on the base station and connect it to the fetal monitor.**
2. **Charge the transducer.**
3. **Power on the monitor.**
4. **Remove the US-T transducer and test the following function:**
   - The US transducer screen displays the standard start interface.
   - The US transducer indicator is green.
   - The fetal monitor screen displays US.
5. **Simulate the audio frequency signal:**

- Stroke bottom face of transducer at approximately 2 strokes per second to simulate a fetal heart signal.
- The fetal monitor displays FHR.

6. Remove the TOCO-T or TOCO-E transducer and test the following function:

- The TOCO-T or TOCO-E transducer screen displays the standard start interface.
- The TOCO-T or TOCO-E transducer indicator is green.
- The monitor screen displays TOCO.

7. Touch the measuring area of the TOCO-T or TOCO-E transducer gently:

- The fetal monitor displays TOCO value change.

8. Install the US-T transducer to charge:

- The US-T transducer screen displays charging interface and charging state.
- The US-T transducer indicator is off.
- The fetal monitor screen is blank.

9. Install the TOCO-T or TOCO-E transducer to charge:

- The TOCO-T or TOCO-E transducer screen displays charging interface and charging state.
- The TOCO-T or TOCO-E transducer indicator is off.
- The fetal monitor screen is blank.

10. It will take about 3.5 hours to charge the US-T, TOCO-T or TOCO-E transducers.

2.3.8 Performance Test

To test a US transducer:

1 Connect the FTS-3 system to the monitor and switch it on.

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

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.

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

To test a TOCO transducer:

1 Connect the FTS-3 system to the monitor and switch it on.

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

3 Gently press the center of the transducer.

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

If a 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.

2.4 Ending Monitoring / Switching Off

Once monitoring is complete and the transducers and base station have been cleaned, dock the transducers on the base station, so that they are easily located when you want to use the system again, and the transducer batteries can be charged.

For charging the transducer batteries, the system must be connected to the mains supply (see Section 2).

WARNING. To disconnect from the mains, the plug must be removed. Always ensure that the plug is easily accessible.

Note: After the fetus is delivered, the monitor 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 monitor immediately after the fetus is delivered.

3. Maintenance and Cleaning

3.1 Maintenance

WARNING. All corrective maintenance must be performed by qualified engineers, approved by Huntleigh.

The Sonicaid FTS-3 Service manual (PN 777882) is designed as an aid to engineers in maintenance and service of repairable parts.

3.1.1 Maintaining Inspection

1. Visual Inspection

Prior to using FTS-3, do the following 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 any 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.

2. Routine Inspection

The overall check of the base station and the accessories, including safety check and function check, should be performed by qualified personnel every 6 to 12 months, and each time after service.

The equipment should undergo periodic safety testing to ensure proper patient isolation from leakage currents. This should include leakage current measurement and insulation testing. The recommended testing interval is once a year or as specified in the institution's test and inspection protocol.

3. Mechanical Inspection

Make sure all exposed screws are tight.

Check the external cables for splits, cracks or signs of twisting.

Replace any cable that shows serious damage.

Pay particular attention to the supply socket.

WARNING. Failure on the part of the responsible individual hospital or institution employing the use of this equipment to implement a satisfactory maintenance schedule may cause undue equipment failure and possible health hazards.

CAUTION. Besides the maintenance requirements recommended in this manual, comply with local regulations on maintenance and measurement.

3.1.2 Base Station Maintenance

Keep the exterior surface of the monitor and the base station clean, free of dust and dirt.
Stop using the base station and contact the service personnel immediately if accidental wetting occurs.

3.1.3 Transducer Maintenance

WARNING. The transducers must be cleaned before docking in the base station after each use. Make sure that there is no residual coupling gel.

WARNING. The transducers are delicate and sensitive. Please handle them with care and try to avoid dropping on to the ground or any hard surfaces.

Although transducers are designed for durability, they should be handled with care.

Rough handling could damage the cover, piezoelectric crystals and mechanical movement. Avoid contact with hard or sharp objects.

The transducers must be cleaned before docking in the base station after each use.

In case of unsuccessful charge or poor contact, please use detergent with abrasive effect to rub the electrodes of the transducers in order to clear away the oxide of coupling gel.

Charge and discharge the wireless transducer battery every 3 months.

3.1.4 Battery Maintenance

It is required to follow the instructions in this user manual during installation, storage and maintenance of the battery.

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

The recommended charge temperature range is from 0 ºC (+32 ºF) to +40 ºC (+104 ºF). Do not exceed this range.

When not using battery for a long time, remove it from the system and store it in a place with low humidity and low temperature. Batteries should be charged to a maximum of 50% for storage.

Batteries have life cycles. If the time that the system uses the battery becomes much shorter than usual, the battery life is at an end. Replace it with a new one the same as the one provided or recommended by the manufacturer.

The performance of batteries may deteriorate over time. Maintaining the battery as recommended can help to slow down this process.

The battery is designed for frequent recharging. A complete charging cycle is only reached and counted, when all recharging periods equal a 100% charge (900 mAh equal 8 hours continued operation).

3.2 Cleaning and Disinfecting

WARNING. Unplug the base station from the AC power source and detach all accessories before cleaning. Do not immerse the unit in water or allow liquids to enter the case.

WARNING. If liquid is splashed on or into the main unit inadvertently, or enters the conduit, stop using the system and contact the manufacturer for service immediately.

WARNING. Do not use abrasive cloths or cleaners on the transducer, base station or accessories.

CAUTION. Although the base station are chemically resistant to most common hospital cleaners and non-caustic detergents, different cleaners are not recommended and may stain the base station.

CAUTION. Many cleansers must be diluted before use. Follow the manufacturer's directions carefully to avoid damaging the base station.

CAUTION. Do not use strong solvent, for example, acetone.

CAUTION. Never use an abrasive such as steel wool or metal polish.

CAUTION. Do not allow any liquid to enter the product, and do not immerse any part of the base station into any liquid.

CAUTION. Avoid pouring liquids on the base station while cleaning.

CAUTION. Do not allow any remaining solution on the surface of the base station.

NOTE. The base station surface can be cleaned with hospital-grade ethanol and dried in air or wiped with a lint free clean cloth.

CAUTION. Do not use any disinfectant containing additional active ingredients other than those listed.

CAUTION. Follow the manufacturer's instruction to dilute the solution, or adopt the lowest possible density.

CAUTION. After disinfection, no remaining disinfectant is allowed on the surface.

CAUTION. Check if the base station is 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.

CAUTION. 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.

In order to avoid infection, clean and disinfect the base station and accessories after each use.

The recommended cleansers for accessories are listed below:

Accessory	Cleansers
Wireless US and TOCO Transducers	Mild near neutral detergent Ethanol 75% Isopropanol 70%
DECG Leads	
ECG Leads	

CAUTION.

- **Be sure the temperature of cleaning solutions does not exceed +45 ºC (+113ºF).**
- **Only wipe the outer surface of accessories. Do not immerse them in any liquid.**
- **Make sure no liquid enters the connector.**
- **After cleaning, no remaining cleanser is allowed on the surface.**
- **Clean the charging point periodically or it will not be charged.**

3.2.1 Cleaning the Base Station

Regular cleaning of the base station enclosure is strongly recommended.

The solutions recommended for system cleaning are: mild near neutral detergent, ethanol 75% and isopropanol 70%.

Clean the base station enclosure with a soft cloth and diluted non-caustic detergents recommended above.

Clean the charging point in the docking slot with a dry soft cloth.

3.2.2 Cleaning the Transducers and Leads

Cleaning the Transducers

Make sure that there is no residual coupling gel.

The transducers must be thoroughly cleaned and disinfected at least once a month. When cleaning, please firstly use a lint-free cloth moistened with mild near neutral detergent, ethanol 75% solution or isopropanol 70% alcohol-based solution to clean the transducers. Wipe using a cotton cloth moistened with water.

Use a dry, soft cloth to dry them.

Cleaning the Leads

To disinfect the leads, follow these steps:

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

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

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

3.3 Sterilising

Do not sterilise the base station or the accessories, unless this is necessary according to your hospital regulation.

3.4 Before Use

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

Visual	Inspect the base station and cables etc. for any damage.
Power On	Power on the system. Does it boot up successfully without errors?
Functionality Test	When the monitor is connected to FTS-3, after power up, check whether the battery status indicator and base station working channel display on the screen of transducer as stated in section 2.1.2
Performance	Please check the US transducer and TOCO transducer according to section 2.3.8.

4. Warranty & Service

Huntleigh Healthcare Diagnostic Products Division standard terms and conditions apply to all sales. A copy is available on request. These contain full details of warranty terms and do not limit the statutory rights of the consumer.

Service Returns

If for any reason the Sonicaid FTS-3 has to be returned, please:

- Clean the product following the instructions in this manual.
- Pack it in suitable packaging materials.
- Attach a decontamination certificate (or other statement declaring that the product has been cleaned) to the outside of the package.
- Mark the package 'Service Department '

For further details, refer to NHS document HSG(93)26 (UK only).
Huntleigh Healthcare Ltd reserve the right to return product that does not contain a decontamination certificate.
Customer Care Department.
Huntleigh Healthcare Ltd, Diagnostic Products Division,
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5. Manufacturers Information

CE 0123	
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Appendix 1 Product Specifications

A1.1 Environmental Specifications

Operating		Storage
+5 ºC ~ +40 ºC (+41ºF ~ +104ºF)	**Temperature range**	-20 ºC ~ +55 ºC (-4ºF ~ +131 ºF)
15% to 93% (non condensing)	**Relative Humidity**	15% to 93% (non condensing)
86 kPa to 106 kPa	**Pressure**	70 kPa to 106 kPa

A1.2 Physical Specifications

Power Supply	Operating Voltage	100V-240V~
	Operating Frequency	50Hz/60Hz
	Input Power	0.8A-0.3A
	Battery	14.8VDC/5000mAh
Standards Compliance	IEC 60601:2005+A1:2012, EN 60601-1:2006+A1:2013, IEC 60601-1-2:2014, EN 60601-1-2:2015, IEC/EN 60601-2-37, IEC 60601-2-27, EN 62479:2010, ETSI EN 301 489-1, ETSI EN 301 489-3, ETSI EN 300 220-1, ETSI EN 300 220-2.	
Anti-electric Shock Type	Class I equipment with internal power supply	
Anti-electric Shock Degree	FHR1, FHR2, TOCO DECG MHR (from MECG)	BF CF CF with defib. protection
Degree of Protection against Harmful Ingress of Water	Base station: IPX1 (protected against vertically falling water drops) Transducers: IPX8 (Protected against the effects of continuous immersion in water to a depth of 1.1 metres for a period of up to 24 hours of monitoring.)	
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	

Leakage Current	
Ground Leakage Current (Limit)	N.C. S.F.C. 500μA 1000μA
Enclosure Leakage Current (Limit)	N.C. S.F.C. 100μA 500μA
Patient Leakage Current (Limit) FHR1, FHR2, TOCO	N.C. S.F.C. d.c. 10μA 50μA a.c. 100μA 500μA
Patient Auxiliary Current (Limit) FHR1, FHR2, TOCO	N.C. S.F.C. d.c. 10μA 50μA a.c. 100μA 500μA
Patient Leakage Current (Limit) DECG, MHR(from MECG)	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Patient Auxiliary Current (Limit) DECG, MHR(from MECG	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
Base Station	
Weight	About1.8 kg
Size	310mm x 235mm x81mm
US-T Transducer	
Weight	About 150 g
Size	Ø81 mm × 35 mm
TOCO-T Transducer & TOCO-E Transducer	
Weight	About 150 g
Size	Ø81 mm × 35 mm

A1.3 Performance Specifications

Ultrasound	
*FHR Measurement Range	50 bpm ~ 240 bpm
*Resolution	1 bpm
*Accuracy	±2 bpm
Technique	Ultrasound Pulse Doppler with autocorrelation
Pulse Repetition Rate	2 kHz
Pulse Duration	92 μs
Ultrasound Frequency	(1+10%) MHz
p_	< 1 MPa

I_{ob}	<10 mW/cm2
I_{spta}	<100 mW/cm2
Dielectric Strength	4000 Vrms
TOCO	
***TOCO Range**	0~ 100
***Non-linear Error**	±1 0%
***Resolution**	1
Baseline Drift due to Temperature Changes	1 unit/min/°C (free air)
	5 units/min/°C (underwater)
Zero Mode	Automatic/ Manual
Dielectric Strength	4000 Vrms
RF Index	
Transmission Power	Wireless transducer:< 1mW e.r.p Base station:< 10mW e.r.p
Frequency Range (Area Conforms to CE)	433.050MHz~434.790MHz
Frequency Range (Area Conform to FCC)	608.00MHz ~ 614.00MHz
***Transmission Range (Without Obstacles)**	>110m (when performing underwater monitoring using US-T and TOCO-T transducers, keep the transducer at a distance ≤30cm from the water surface and a distance ≤8m from the base station.)
Modem Mode	GFSK
Transmission Rate	About 25kbps
Channel Range	1~14
Transducer Antenna	FM antenna
Base Station Antenna	Internal antenna

DECG	Technique	Peak-peak detection technique
	*DFHR Measurement Range	30bpm ~ 240bpm
	*Resolution	1bpm
	*Accuracy	±1bpm
	Input Impedance	> 10MΩ (Differential, DC50/60Hz)
	Input Impedance	> 20MΩ (Common Mode)
	CMRR	> 110dB
	Skin Voltage Tolerance	±500mV
	Fetal Input Voltage Current	20μV-6mV

MHR	* MHR Measurement Range	30 bpm ~ 240 bpm
	Input Signal Range	±8 mV PP
	* MHR Measuring Accuracy	±2 bpm
MHR	* MHR Alarm Limits	30 bpm ~ 240 bpm
	*Anti-electric Shock Type	Defibrillating-proof
	ECG falls off	Detect automatically
	Patient Leakage Current (Limit)	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
	Patient Auxiliary Current (Limit)	N.C. S.F.C. d.c. 10μA 50μA a.c. 10μA 50μA
	Differential Input Impedance	>5MΩ
	Electrode Offset Potential Tolerance	±500mV
	Auxiliary Current (Leads off detection	Active electrode: < 100 nA Reference electrode < 900 nA
	Accuracy and Response to Irregular Rhythm	Not Supported
	Response time to Change in MHR	MHR range: 80bpm ~ 120bpm Range: 7s~11s (average:9s) MHR range:80bpm ~ 40bpm Range : 8s ~ 12s (average: 10s)
	Tall T-wave Rejection	Exceeds ANSI/AAMI EC13-2002 Sect. 3.1.2.1 (C) maximum recommended 1.5mV T-Wave amplitude
AFM	*Display Range	0 ~ 999
	*FM Mode	Automatic
	*AFM Mode	Trace (default) or Black Mark
	Technique	Pulsed Doppler ultrasound

NOTE: The essential performance is marked with an asterisk *.

A1.4 Rechargeable Lithium-ion Battery

Base Station Battery	
Nominal Capacity	5000 mAh
Operating time	≥ 40 Hours
Nominal Voltage	14.8 V
Charging time	≤ 14 Hours
Cycle Life	>300 times
Transducer Battery	
Nominal Capacity	1600 mAh
Charge Current (Standard)	700 mA
Nominal Voltage	3.7 V
Charge Voltage (Standard)	(4.2±0.1) V
Operating time	>17h (full new battery used in transducer) >12h (full new battery used in TOCO-E transducer connected with DECG or MECG cable)
Cycle Life	≥ 500 times

A1.5 Low Output Summary Table

(For systems with no transducers having global maximum index values exceeding 1.0)
System: Fetal Telemetry System.
Transducer: 12-Crystal Wafer

Transducer Model	$I_{SPTA.3}$ [mW/cm²]	TI Type	TI Value	MI	$I_{pa}.3@MI_{max}$ (W/cm²)
PW1.0MHz	1.66	TIS	0.0079	.017	0.0092
		TIB	0.064		

Appendix 2 Troubleshooting

US-transducer is removed but no power	
POSSIBLE CAUSE	**SOLUTION**
Transducer battery discharged.	Charge transducer
Base station and transducer are working on different RF-channels.	Replace the transducer then remove again.
	Restart the Base station

No signal on Fetal Monitor even though the indicators on base station are green.	
POSSIBLE CAUSE	**SOLUTION**
Interface cable to Fetal Monitor is disconnected or broken.	Connect cable or repair.

Interrupted recording of fetal heart rate or uterine activity.	
POSSIBLE CAUSE	**SOLUTION**
Transducer position.	Check position of transducers for best signal.
Transducer is sliding on the skin.	Reposition and fasten securely. Use less gel on the US transducer.
Excessive movement	Ask the patient to restrict movement.
RF-interference or patient at the end of range.	Instruct patient to stay inside the area where reception is good.

Charging indicator is off even though the transducer is docked for charging.	
POSSIBLE CAUSE	**SOLUTION**
Transducer not docked properly.	Re-position the transducer.
Base station not connected to the mains power supply.	Connect the base station.

Charging panel or contacts show corrosion.	
POSSIBLE CAUSE	**SOLUTION**
Transducer was wet or contaminated with gel when docked on the base station.	Always clean and dry the transducer before docking and charging. If necessary have the contact panel replaced.

Appendix 3 Ultrasound Intensity and Safety

A3.1 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.

A3.2 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).

A3.3 Explanation of MI/TI

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 f ultrasound output is exceeded. The threshold is related to the type of tissue. Although no onfirmed adverse mechanical effects on patients or mammals caused by exposure at intensities typical of present diagnostic ultrasound instruments have ever been reported, the threshold for cavitation is still undetermined. Generally speaking, the higher the acoustic pressure, the greater the potential for mechanical bioeffects; the lower the acoustic frequency, the greater the potential for mechanical bioeffects.
The AIUM and NEMA formulate mechanical index (MI) in order to indicate the potential for mechanical effects. The MI is defined as the ratio of the peak-rarefactional acoustic pressure (should be calculated by tissue acoustic attenuation coefficient 0.3dB/cm/MHz) to the acoustic frequency.

$$MI = \frac{Pr,\alpha}{f_{awf} <?>C_{MI}}$$

C_{MI} = 1 (MPa / MHz)

TI (Thermal Index)

Heating of tissues is caused by absorption of ultrasound when the ultrasound energy is applied.nThe temperature rise is determined by the acoustic intensity, exposed area and thermophysicalbproperties of the tissue.
In order to indicate the potential for temperature rise caused by thermal effects, the AIUM andNEMA formulate thermal index (TI). It is defined as the ratio of the total acoustic power to the acoustic power required to raise the tissue temperature by 1ºC (1.8ºF).
According to different thermophysical properties of the tissue, TI is divided into three kinds: TIS, TIB and TIC.

TIS (Soft Tissue Thermal Index): It provides an estimate of potential temperature rise in soft or similar tissues.

TIB (Bone Thermal Index): It provides an estimate of potential temperature rise when the ultrasound beam passes through soft tissue and a focal region is in the immediate vicinity of bone.

TIC (Cranial Bone Thermal Index): It provides an estimate of potential temperature rise in the cranial bones or superficial bones..

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% forintensity 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.

A3.4 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.

A3.5 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—Part 2-37: Particular requirements for the basic safety and essential performance of ultrasonic medical diagnostic and monitoring equipment" issued by IEC in 2007.

A3.6 Transducer Acoustic Output Parameters List

A3.6.1 Test of Wireless Transducer (FTS-3)

12-Crystal Wafer Transducer

Acoustic output reporting table for IEC60601-2-37 (IEC60601-2-37, Edition 2.1, 2015-06, table 201.103)

Operating Mode: PW mode Working Frequency: 1.0MHz

Index label			MI	TIS		TIB		TIC
				At surface	Below surface	At surface	Below surface	
Maximum index value			0.017	0.0079		0.064		N/A
Index component value				N/A	0.0079	N/A	0.064	
Acoustic Parameters	$pr.^{\alpha}$ at z_{MI}	(MPa)	0.017					
	P	(mW)		9.69		9.69		N/A
	P_{1x1}	(mW)		N/A		N/A		
	z_s	(cm)			6.55			
	z_b	(cm)					6.55	
	z_{MI}	(cm)	6.55					
	$z_{PII}.^{\alpha}$	(cm)	6.55					
	f_{awf}	(MHz)	1.00	1.00		1.00		N/A

Other	prr	(Hz)	2000.00					
	srr	(Hz)	N/A					
	npps		N/A					
	$I_{pa.}\alpha$ at $z_{PII.}\alpha$	(W/cm^2)	0.0092					
	$I_{spta.}\alpha$ at $z_{PII.}\alpha$ or $z_{SII.}\alpha$	mW/cm^2)	1.66					
	I_{spta} at z_{PII} or z_{SII}	mW/cm^2)	4.34					
	pr. at z_{PII}	(MPa)	0.023					
Operating Control Conditions	Focus(mm)		Fixed					
	Depth(mm)		Fixed					
	Frequency(MHz)		1.00					

Operating Mode: PW mode
Working Frequency: 1.0MHz

Acoustic Output			MI	$I_{SPTA.3}$ (mW/cm^2)	$I_{SPPA.3}$ (mW/cm^2)
Global Maximum Value*			0.017	1.66	0.0092
Associated Acoustic Parameters	$Pr_{.3}$ (MPa)*		0.017		
	W_o total (mW)*			9.69	9.69
	f_c (MHz)		1.00	1.00	1.00
	Z_{sp} (cm)		6.55	6.55	6.55
	Beam Dimensions	x_{-6} (cm)		0.48	0.48
		y_{-6} (cm)		0.56	0.56
	PD (μS)		90.07		90.07
	PRF (Hz)		2000.00		2000.00
	Overall EBD (cm)	Az. (cm)		Φ3.46	
		Elev. (cm)		Φ3.46	
Operating Control Conditions	Focus(mm)		Fixed		
	Depth(mm)		Fixed		
	Frequency(MHz)		1.00		

IEC60601-2-37 standard parameter equal contrast list	
IEC60601-2-37 parameter	NOTE
pr.α	Attenuated Peak-rare-factional Acoustic Pressure
pr	Peak-rare-factional Acoustic Pressure
P	Output Power
zs	Depth for Soft Tissue Thermal Index
Pα(Zs)	Attenuated Output Power

Ita.α(Zs)	Attenuated Temporal-average Intensity
zbp	Break-point Depth
zb	Depth for Bone Thermal Index
Ipi.α	Attenuated Pulse-intensity Integral
Ipi	Pulse-intensity Integral
deq(Zb)	Equivalent Beam Diameter at the point of Zsp
fawf	Center Frequency, Acoustic Working Frequency
X	-12dB Output Beam Dimensions
Y	
td	Pulse Duration
prr	Pulse Repetition Frequency (Pulse Repetition Rate)
deq	Equivalent Beam Diameter
FLx	Focal Length
FLy	
Ipi.α at max MI	Attenuated Pulse-average Intensity at the point of Maximum MI
Aaprt	-12dB Output Beam Area
MI	Mechanical Index
TIS	Soft Tissue Thermal Index
TIB	Bone Thermal Index
TIC	Cranial-bone Thermal Index
parameter specified in TRACK1 of FDA Guidance	
TRACK1 parameter	**NOTE**
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	-6dB Beamwidth
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 4 Abbreviations

Abbreviation	Full Name
AC	Alternative Current
AFM	Automatic Fetal Movement [Detection]
BPM	Beat(s) Per Minute
CTG	Cardiotocography
DC	Direct Current
DECG	Direct ECG (or Fetal ECG)
DFHR	Direct FHR
DIA	Diastolic Blood Pressure
ECG	Electrocardiogram
FH	Fetal Heart
FHR	Fetal Heart Rate
FM	Fetal Movement
FS	Fetal Stimulator
MHR	Maternal Heart Rate
ICU	Intensive Care Unit
ID	Identity
IUP	Intra-Uterine Pressure
IUPC	Intra-Uterine Pressure Catheter
LCD	Liquid Crystal Display
MAP	Mean Artery Blood Pressure
MECG	Maternal ECG
MFM	Manual Fetal Movement [Detection]
MRI	Magnetic Resonance Imaging
NIBP	Non-Invasive Blood Pressure
NST	Non Stress Test
PR	Pulse Rate
RF	Radio Frequency
SOV	Signals Overlap Verification
SpO2	Pulse Oximetry
STV	Short-Term Variation
SYS	Systolic Blood Pressure
TEMP	Temperature
TOCO	Tocotonometer
UA	Uterine Activity [TOCO/IUP]
US	Ultrasound [Transducer]

Appendix 5 Ordering Information

Accessories (standard and optional configuration) supplied or approved by the manufacturer can be used with the system. Please refer to Huntleigh Healthcare's Accessories and Consumables catalogue which is available on request from local Huntleigh representatives.

The accessories employed by the manufacturer, such as the rechargeable battery, are products having passed the authentication of CE, and they have the characteristics specified by their manufacturers. The materials with which the patient can come into contact conform to the standard of ISO 10993.

CAUTION
Replacement of all accessories can be performed by the operator. Only the accessories supplied or recommended by the manufacturer are allowed connected to the FTS-3 system.

Appendix 6 EMC Information

A6.1 Electromagnetic Emissions

Guidance and Manufacturer's declaration - electromagnetic emissions		
FTS-3 Fetal Telemetry System is intended for use in the electromagnetic environment specified below. The customer of the user of FTS-3 should assure that it is used in such and environment.		
Emissions Test	**Compliance**	**Electromagnetic Environment - guidance**
RF emissions CISPR 11	Group 1	FTS-3 Fetal Telemetry 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.
RF emissions CISPR 11	Class A	FTS-3 Fetal Telemetry 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.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Complies	

A6.2 Recommended Separation Distances

Recommended separation distances between portable and mobile RF communications equipment and the FTS-3 Fetal Telemetry System			
The FTS-3 Fetal Telemetry System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FTS-3 Fetal Telemetry System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FTS-3 Fetal Telemetry 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**		
	150kHz to 80MHz $d = 1.2\sqrt{P}$	**80MHz to 800MHz** $d = 1.2\sqrt{P}$	**800MHz to 2.5GHz** $d = 2.3\sqrt{P}$
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 metres (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 80MHz and 800MHz, 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.			

A6.3 Electromagnetic Immunity

Guidance and Manufacturer's declaration - electromagnetic immunity			
FTS-3 is intended for use in the electromagnetic environment specified below. The customer or the user of FTS-3 should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines 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 earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70% UT; 25/30 cycles) Single phase: at 0° 0 % UT; 50/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70% UT; 25/30 cycles) Single phase: at 0° 0 % UT; 50/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FTS-3 Fetal Telemetry System requires continued operation during power mains interruptions, it is recommended that the FTS-3 Fetal Telemetry System be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	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.
NOTE U_r is the a.c. mains voltage prior to the application of the test level.			

Guidance and Manufacturer's declaration - electromagnetic immunity			
The FTS-3 Fetal Telemetry System is intended for use in the electromagnetic environment specified below. The customer or the user of FTS-3 Fetal Telemetry System should assure that it is used in such an environment.			
Immunity Test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic Environment - guidance**
			Portable and mobile RF communications equipment should be used no closer to any part of the FTS-3 Fetal Telemetry System including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6Vrms [c] in ISM bands between 0,15 MHz and 80 MHz	3Vrms 6Vrms [c] in ISM bands between 0,15 MHz and 80 MHz	$d = 1.2\sqrt{P}$ 150 KHz to 80 MHz
Radiated RF IEC 61000-4-3	3 V/m 80MHz to 2.5GHz	3V/m	$d = 1.2\sqrt{P}$ 80MHz to 800MHz $d = 2.3\sqrt{P}$ 800MHz to 2.5GHz
			d √ 6 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 monitor, including cables specified by the manufacturer). Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80MHz and 800MHz, 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-3 Fetal Telemetry System is used exceeds the applicable RF compliance level above, FTS-3 Fetal Telemetry System should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating FTS-3 Fetal Telemetry 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.

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test Frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum Power(W)	IMMUNITY TEST LEVEL (V/m)
385	380-390	TETRA 400	Pulse modulation [b] 18Hz	1.8	27
450	30-470	GMRS 460, FRS 460	FM [c] ±5 kHz deviation 1kHz sine	2	28
710	704-787	LTE Brand 13, 17	Pulse modulation [b] 217 Hz	0.2	9
745					
780					
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	28
870					
930					
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation [b] 217 Hz	2	28
1845					
1970					
2450	2400-2570	Bluetooth, WLAN,802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0.2	9
5500					
5785					

Note: If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM maybe reduce to 1m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.
[b] The carrier shall be modulated using a 50% duty cycle square wave signal.
[c] As an alternative FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		
Test Frequency	**Modulation**	**Immunity Test Level (A/m)**
30 kHz [a)]	CW	8
134,2 kHz	Pulse Modulation [b)] 2,1 kHz	65 [c)]
13,56 MHz	Pulse Modulation [b)] 50 kHz	7,5 [c)]

[a)] This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE environment.
[b)] The carrier shall be modulated using a 50% duty cycle square wae signal.
[c)] r.m.s. before modulation is applied.

Appendix 7 Limitations of Ultrasonic Monitoring

A7.1 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.

A7.2 Artifacts in Fetal Heart Monitoring

(1) How does artifact happen?

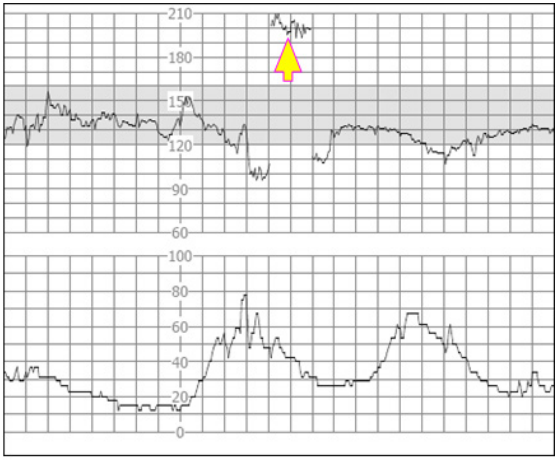
The transducer detects sound waves as they bounce off or echo back from the fetal heart. However, the sound waves bouncing off from maternal blood vessels may be detected by the transducer and then be processed by the monitor as well. As a result, artifacts may be produced.

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.

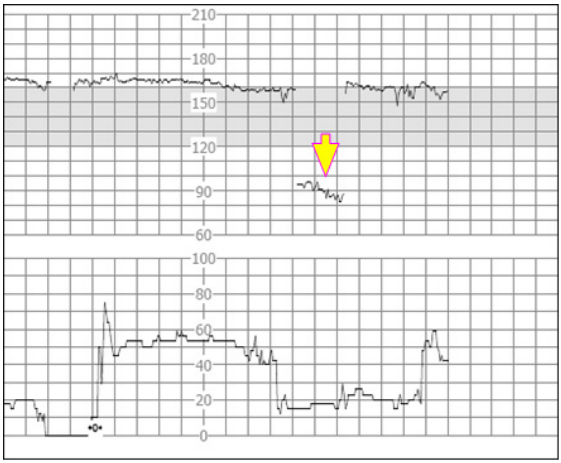
(2) Doubling:

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.

If a serious incident occurs in relation to this medical device, affecting the user, or the patient then the user or patient should report the serious incident to the medical device manufacturer or the distributor.
In the European Union, the user should also report the serious incident to the Competent Authority in the member state where they are located.

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