HUNTLEIGH

SF1

Anwendungshinweise

Kullanım Talimatları

Brugsvejledning

Instrucciones de uso

χρήσης

使用方

Mode d'emploi

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Anwendungshinweise

sonicaid™ Freedom

Contents

1. Safety

Before using this equipment, please study this manual carefully and familiarise yourself with the controls, display features and operation. Ensure that each user fully understands the safety and operation of the unit, as mis-use may cause harm to the user or patient, or damage to the product.

This device may only be used in combination with one of Huntleigh Heathcare's Sonicaid™ Encore monitors (FM820E /FM830E).

Please keep these Instructions for Use to hand for future reference.

Refer to the FM800E Instructions for Use for details of operation and handling.

Symbols

	General Warning / Residual risks are those risks that require a warning or caution to be entered into this manual. They are identified by the proximity of this symbol.
	Refer to Instructions for Use
	Attention, consult accompanying documents / Instructions for Use

1.1 WARNINGS

	***The Sonicaid™ Freedom should only be used by personnel familiar with the operation of electro-medical equipment, especially for electronic monitoring of the fetal heart rate.***
	***A possible explosion hazard exists if used in the presence of flammable anaesthetics.***
	***The Sonicaid™ Freedom should not be used at temperatures lower than 10 or higher than 40 degrees centigrade.***
	***Do not mount the unit directly above the patient. Locate the unit so that it will not cause harm should it fall.***

Do not operate the unit from the mains supply if the mains cable is damaged.

Do not immerse any portion of the receiver unit in water or other liquids. The transducers are watertight and may be used in water (IPX7 - TRANSDUCERS ONLY).

If there is any damage to the transducer housings, do not use the transducer under water. Refer the transducer to Huntleigh Healthcare qualified service personnel for repair.

The transducers are shock protected. Never run the transducer without its protective sleeve. It can be removed for cleaning.

If this product is connected to another item of electrical equipment, it is important that the system is fully compliant with EN60601-1.

The device is generating RF-radiation. It is designed for use in hospitals and doctor's offices, also outside of shielded areas. As in other medical electrical devices, fixed and mobile RF-communication devices may disrupt the performance of the Sonicaid™ Freedom.

The telemetry equipment is classified as IIb according to MDD. The receiver unit is connected to the AC line without a protective earth (class 2). The line voltage may be between 100 and 240V with 50 to 60Hz. The transducer units are powered by safe current limited low voltage re-chargeable batteries of 3.7V. Transducers are Class CF.

In case of a discharge of static electricity at the receiver, the functions of the receiver may be blocked. Please disconnect the mains lead for about 5 seconds. After re-connection all functions will be stable again.

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

The receiver unit should be plugged into the same mains supply circuit as other equipment in use on the same patient. Do not make any modifications to the power supply of the receiver and transducer units.

Use only recommended accessories listed in this manual.

2. Introduction

2.1 Recommended Clinical Applications

The Sonicaid™ Freedom (SF1) is a wireless transducer system, intended for use as an optional accessory with Huntleigh Healthcare's FM800 Encore fetal monitors (FM820E, FM830E) for non-invasive and cable free monitoring of fetal heart rate and maternal contractions during intrapartum and antepartum periods.

2.2 Intended Use

This device may only be used in combination with one of Huntleigh Heathcare's Sonicaid™ Encore monitors (FM820E /FM830E).

Sonicaid™ Freedom is intended for use by healthcare professsionals for monitoring pregnant women in clinical and hospital-type facilities.

Sonicaid™ Freedom is intended for the measurement of fetal heart rate and maternal contractions during intrapartum and antepartum periods.

Sonicaid™ Freedom can be used on patients that are resting, mobile or in water baths.

2.3 Indications of Use

- **Sonicaid™ Freedom is an accessory for use with Sonicaid FM820/830 Encore monitors.**
- **Sonicaid™ Freedom is re-useable and is intended for continuous monitoring.**
- **The Sonicaid™ Freedom is for use with patients that are resting, mobile or in water.**

2.4 Contraindications

Sonicaid™ Freedom and FM820/830 Encore monitors are not intended for use with patients fitted with cardiac pacemakers, during defibrillation, while undergoing surgery, or while MRI scanning is taking place.

Sonicaid™ Freedom and FM820/830 Encore monitors are not intended for use with high risk patients.

Sonicaid™ Freedom and FM820/830 Encore monitors are not intended for use if only very low signals are detected.

Sonicaid™ Freedom and FM820/830 Encore monitors must not be used in intensive care units, operating rooms or in transport monitoring applications.

Sonicaid™ Freedom should not be used to monitor patients giving birth to twins.

Ultrasound monitoring should be performed in accordance with current guidelines. The ALARA guideline (AIUM) recommends that ultrasound exposure should be kept As Low As Reasonably Achievable.

2.5 Unpacking / Preliminary Checks

Contents (supplied with each system)

Item	Item	Item
1 x Sonicaid™ Freedom Receiver Unit (SF1-Base)	1 x Instructions for Use CD	1 x Receiving Antenna (Gainflex - GF430TNC)
1 x Ultrasound Transducer (SF1-US)	1 x Interface Cable	2 x Transducer Clips
1 x TOCO Transducer (SF1-TOCO)	1 x Mains Lead	1 x FM800E to Sonicaid™ Freedom Fixing Kit

Delivery Inspection

Huntleigh Healthcare takes every precaution to ensure that goods reach you in perfect condition. However, accidental damage can occur in transit and storage. For this reason we recommend that a thorough visual inspection is made immediately the unit is received. Should any damage be evident or any parts missing, ensure that Huntleigh Healthcare is informed at once.

Storage

Should the unit not be required for immediate use, it should be re-sealed into its original packing after carrying out the initial delivery inspection, and stored under covered conditions at a temperature between -10°C to +50°C, and relative humidity of 10% to 93% non-condensing.

3. Product Information

3.1 System Overview

The Sonicaid™ Freedom ('Freedom') is an accessory medical device intended to be used with Huntleigh Healthcare's range of Sonicaid™ Fetal Monitors ('FM800E'). The FM800E monitors come with wired US (ultrasound) and TOCO (contractions) transducers. In situations where wireless transducers are desired, the Freedom receiver may be connected to an FM800E monitor to enable use of the wireless transducers.

Freedom consists of three components: the Ultrasound transducer (SF1-US), the TOCO transducer (SF1-TOCO) and the Receiver (SF1-Base). When in use, the TOCO transducer sends signals to the US transducer, which then transmits both signals to the Freedom receiver unit. The receiver converts these signals into the required format for input to the attached FM800E system. The system monitors two types of analogue signals:

- Pulsed Doppler Ultrasound signals to determine the fetal heart rate
- Relative pressure within the uterus by the TOCO transducer.

Key features:

- Transducers are small, light in weight and water tight
- Low voltage wireless transmission is safe for use in water
- No cable attachment means that the patient may be resting or mobile
- The system is easy for the users to operate
- The transducers are powered by rechargeable Li-Ion batteries
- Batteries will automatically recharge when attached to the receiver

Transducers

The transducers contain all necessary components to function properly including radio frequency (RF) transmitters. These signals are transmitted in an ISM or WMTS band according to local regulations. Up to 64 channels can work in parallel without interference. The range depends on the local conditions. The transmission inside a hospital is reliable, but the exact range of any telemetry system can only be determined by a field test. When the US transducer is used under water the range will be reduced compared with transmission in air.

During use the battery capacity of the transducers are monitored. The receiver has a battery indicator for each transducer consisting of four LED lights; four lights indicating that the transducer is fully charged. When the battery becomes weak the transducer is automatically shut off.

Receiver

The receiver has two storage and charging areas for the TOCO and US transducers, three sets of visual indicators (charging, battery level and transducer status) and the antenna for receiving transmissions from the US transducer when in use. In addition, the rear panel includes the connecting area for the receiving antenna, RF-Channel selector, interface for connecting to the FM800 Encore Monitors, and line voltage input for power.

The receiver and transducers have no buttons to operate. When the transducers are taken out of the charging position they are switched on automatically and the receiver indicates the status of batteries and the quality of the incoming RF-signal.

To start a measurement, the transducers are removed and applied to the patient; the Freedom and Fetal Monitor will do the rest.

The TOCO-Transducer transmits its signals over a short range to the US-transducer. Here US and TOCO signals are combined and are transmitted as pooled information over a long range to the receiver.

Note: the TOCO can only be measured when the US-transducer is near to the TOCO-transducer (radius of about 30cm).

If the transducer goes out of range the output signals are switched off until normal conditions return.

3.2 The Receiver Unit (SF1-Base)

3.2.1 Mains Switch

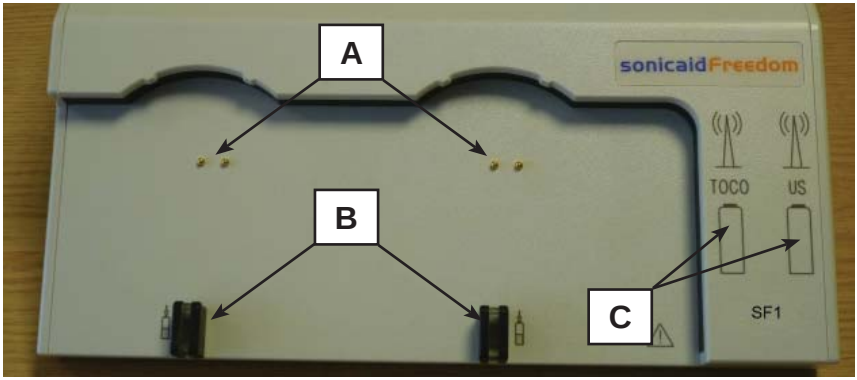
The receiver has no mains switch. To turn on, connect the mains lead from the rear mains input to mains supply. Always leave the receiver connected to allow the transducers to be charged. If you want to switch off Freedom, plug in both transducers first, wait for charging indication, then disconnect the supply. All units are now switched off. Leave the transducers on the receiver, so they are easily located when you want to use the system. All modules are turned on when the receiver is powered again. To activate a transducer, plug it into the charging position while the receiver is on.

The power consumption of the receiver is less than 1W during stand-by.

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

3.2.2 Front Panel controls and Indicators

Charging / Storing Transducers



A - Storage/Charge Position

Store the transducers in position A when not in use. Place the transducers with the golden charging rings facing the charging position and snap into place.

The transducers are equipped with re-chargeable lithium polymer batteries. When the transducer is in the storing position the battery is re-charged automatically, provided the receiver is connected to the mains supply. Ensure there is no water or gel on the contact panels of the receiver or transducer when charging, as this may prevent good contact.

Once a transducer has been positioned correctly for charging, the LED in the corresponding holder (B) turns on.

It doesn't matter in which of the two positions a transducer is stored, they will be correctly recognised by the receiver. However, to ensure the transducers are recognised without delay, the Ultrasound transducer should be placed in the holder first. If the TOCO transducer is inserted first, there may be a delay in the transducer being recognised.

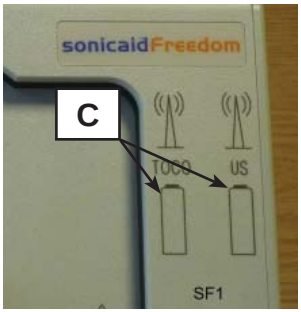
B - Charge Position LED's

The condition during charging is indicated as follows:

- LED off: No transducer applied
- LED on: Transducer is being charged, battery capacity is displayed in corresponding battery Indicator (C)
- LED blinking: Transducer not identified but charging is activated, however no display is provided.

If the light is constantly on, the transducer has been recognised to belong to the receiver unit.
If the LED blinks in a slow rhythm, this indicates an unrecognised item is to be charged. If this happens with a transducer belonging to the receiver, remove it and insert it again. If you position the transducer too slowly or tentatively, the logging-in might become disturbed, which will lead to an "ignored item".

C - Battery Indicators



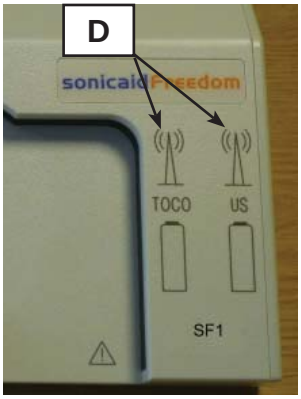
Once a transducer has been identified, the corresponding battery indicator (C), shows the actual capacity during operation and the status of recharged energy during charging. Each LED represents about a quarter of the capacity. When the battery is fully charged, all 4 LED's are continuously on. An operating time of about 16 hours is available on a full charge.
A complete charging process takes approximately 2.5 hours.

If the transducer has become completely empty, a re-charging time of about 15 minutes allows for an operation of more than 1 hour.

LED assignment: **US -** Ultrasound-transducer
TOCO - TOCO-transducer

It is recommended to leave the transducers stored on the receiver when not in use.

Transmission Indicators



The transmission indicators are located on the upper right corner of the receiver (D). These indicators show the status of TOCO and US transducer transmission:

LED flickering red: US Transducers off or out of range

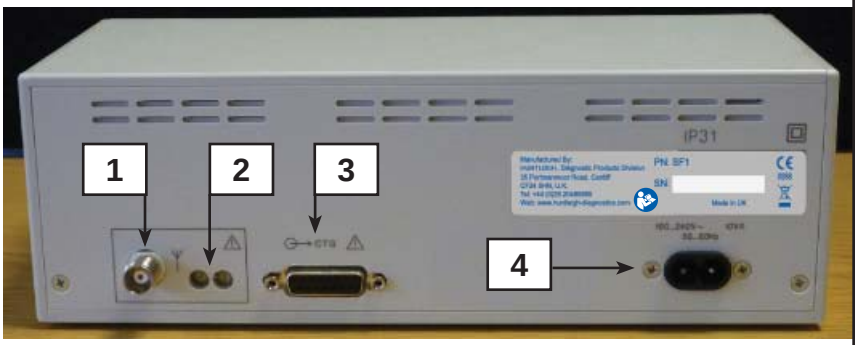
LED red: Transducers docked or TOCO Transducers out of range

LED green: Transducer in range and good Signal quality

LED flickering green/red: Transducer near end of range, or disturbance by another RF-transmitter.

If known to be in range, refer to Section 6.4 to change the channel of the Freedom unit.

3.2.3 Rear Panel controls and Indicators



1	Connector for the Receiving Antenna
2	RF-Channel sector (range 00,01,…25)
3	Interface to Fetal Monitor CTG
4	Mains Input, 100…240V, 50…60Hz, 10VA.

3.3 The Transducers

3.3.1 Controls and Connections of SF1-US and SF1-TOCO

Controls : There are no controls on the transducer.

Indicator

On the top of each transducer is a green indicator LED which shines through the panel.

This LED is OFF when the transducer is turned off or when being recharged.

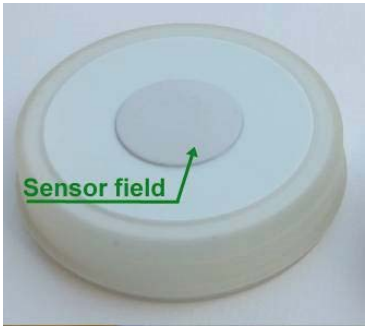
Once the transducer is taken out of the charging position, the LED is switched ON and should flash approximately every 2 seconds.

If the LED stays off, re-charge the transducer and try again. If the LED is on continuously, an internal fault may have occurred. Please have the transducer checked by a Huntleigh Healthcare qualified service technician.

Connections

On the top surface of the transducer is a contacting plate. These two golden rings connect to the receiver when in position for charging, but all rings are internally disconnected during operation.

Sensor Field - SF1-TOCO



In the center on the bottom of the TOCO-transducer is the sensor area, which measures uterine activity.

Do not stress this field with too much mechanical load.

Do not depress the membrane.

Shock Protection

The transducers are protected against damage by a silicone sheath. Never operate the transducer without this protective sheath. It can be removed for cleaning if required. Refer to Section 6.2 for instructions.

Transducer Application

The silicone sheath helps prevent the transducer from sliding on the skin, but it is highly recommended to use a belt strap and clips to secure the transducers in the correct position.

Two belt clips are supplied, but the belts must be purchased seperately.

The belt clips should be clipped onto the transducer side with the contacting plate, as shown.

3.4 Product Labelling

	Attention, consult accompanying documents / Instructions for Use
	Sonicaid Freedom is Class II, double insulated according to the definitions in EN 60601-1:2006
	Applied parts type CF
IP31	Rating for protection against ingress of fluids and particulate:
IPX7	Rating for protection against ingress of fluids and particulate: The transducers are designed for operation under water.
	Alternating current (AC)
	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.
	Connect only the recommended and provided accessories. General Warning or Caution.
	This product complies with the essential requirements of the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC
	Refer to Instructions for Use
SN:	Serial Number
PN:	Product Number / Model Number

4. Setup

4.1 Line (Mains) Power Operation

Freedom is supplied with a plug-in mains lead, fitted with a 3 pin mains plug. The cores use the European colour code :

BROWN	LIVE
BLUE	NEUTRAL

If it becomes necessary to fit a new mains plug take care that the wires have correct lengths, so that in the event of extreme strain, the earth wire will be the last to break. Make sure that the cable clamp secures the outer sheathing so that there is no direct strain on any individual wires at the terminals.
Where the plug is fused, a 5A fuse should be fitted.

Connect the power cable to the line power socket.

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

4.2 System Connection

WARNING: These requirements must be met when Freedom is connected to any other electrical equipment.

1 Non-medical equipment must comply with the relevant IEC or ISO safety standard.

2 Medical equipment must comply with IEC601-1/EN60601-1, or equivalent.

3 The configured system must comply with the requirements of IEC60601-1:2005; clause 16.

4 If non-medical equipment with enclosure leakage currents greater than those allowed by IEC601-1/EN60601-1 is to be used in the patient environment (within 1.5m of the patient), the enclosure leakage currents must be brought within the limits laid down by IEC601-1/EN60601-1. This may be achieved by using a medical grade isolating transformer. Suitable types are available via Huntleigh Healthcare sales agents.

5 Anyone who connects additional equipment to signal input or signal output parts of the system is configuring a medical system, and is therefore responsible for ensuring that the system complies with the requirements of IEC60601-1:2005; clause 16. If there is any doubt as to whether your system complies, consult the technical service department or your local Huntleigh Healthcare representative.

4.3 Receiver Connection

The receiver unit should be plugged into the same mains supply circuit as other equipment in use on the same patient. Do not make any modifications to the power supply of the receiver and transducer units.

- Connect the interface cable from output of the receiver unit to the interface input of the fetal monitor.
- Connect the receiving antenna.
- Connect the mains lead from the receiver unit to mains circuit supply and switch on.

4.3.1 Setting Up for Monitoring

- Charge the transducer batteries
- Switch on the fetal monitor (refer to its operator's manual)

The system is ready for monitoring if the field strength indicator and transducer battery indicators are illuminated green.

Testing the Basic Functions

A functional test should now be performed after initial installation. Ensure that the specifications are met following each step below:

1. Remove TOCO-transducer, while the US-transducer is charging:

- charge position LED and battery indicator LED's turn off
- LED in TOCO-transducer starts blinking
- no further action (no signal transmission, because the US-transducer is not running)

2. Plug in TOCO-transducer for charging again:

- charge position LED and battery indicator LED's turn on

3. Remove US-transducer:

- charge position LED turns off
- LED in US-transducer starts blinking
- US-Transmission indicator LED turns green
- US battery indicator LED's indicate charge status
- US enable becomes active: US is indicated on fetal monitor

4. Simulate audio signal:

- fetal monitor shows heart rate

5. Remove the TOCO-transducer:

- charge position LED turns off
- LED in TOCO-transducer starts blinking
- TOCO-Transmission indicator LED turns green
- TOCO battery indicator LED's indicate charge status
- TOCO enable becomes active: TOCO is indicated on fetal monitor

6. Press gently on the sensor area of the transducer:

- fetal monitor shows adequate TOCO values

7. Plug in US-transducer for charging

- US and TOCO-Transmission indicator LED's turns Red
- charge position LED turns on
- US battery indicator LED's indicate charge status
- US and receiver communicate for RF channel number
  - if successful: charge position LED turns on
  - if not successful: charge position LED blinking (remove the transducer for 10 seconds and plug in again)
- No reading on fetal monitor

8. Plug in TOCO transducer for charging

- TOCO and receiver communicate for compatibility
  - if successful: charge position LED turns on
  - if not successful: charge position LED blinking (remove the transducer for 10 seconds and plug in again)
- TOCO battery LED's indicate charge status

9. Wait until both Battery Indicators show all 4 LEDs on (battery fully charged)

Note : a complete charge cycle takes approximately 2.5 hours.

5. Operation

5.1 Getting Started

- Charge the transducer batteries
- Switch on the fetal monitor (refer to its operator's manual)
- Apply transducers to the patient

When the US-transducer is taken out of the storing position, the unit is automatically switched on and is ready to use.

The system is ready for monitoring if the transmission indicator LED and battery indicator LED's are illuminated green.

NOTE: ***The TOCO can only be measured when the US-transducer is near to the TOCO-transducer (radius of about 30cm). The TOCO-transducer needs the US-transducer for operation.***

IMPORTANT: ***The transducers must be fastened securely to the patient in order to avoid displacement during movement (belt strap and clips recommended).***

IMPORTANT: ***Apply the transducers while the patient is standing for ambulatory monitoring.***
Apply the transducers when the patient is in the water for monitoring under water.

IMPORTANT: ***Explain proper handling and limitations of range and movement to the patient, if applicable.***

- Use the minimum amount of gel required on the US-transducer, to prevent it from sliding too easily on the skin. DO NOT USE GEL WITH THE TOCO TRANSDUCER. Wipe off any gel present on the abdomen, in and around the area where you are applying the TOCO transducer.
- If necessary, instruct the patient how to reposition the transducers.
- Explain the limitations of range and movement to the patient. Indicate restricted rooms and areas.

5.2 Application of the Transducers

TOCO transducer

- Position the transducer as usual and fasten it securely.
- Adjust the baseline at the fetal monitor of TOCO after application.

Note: The TOCO-transducer transmits its signals to the US-transducer. The distance between both transducers should not exceed 30cm. In a correct position the TOCO-indicator on the front panel of the receiver turns green no later than 20 to 30 Seconds after application. Avoid a right angle between both transducer surfaces.

Ultrasound transducer

Apply ultrasound gel to the surface of the transducer

- Use the minimum amount of gel required, to prevent it from sliding too easily on the skin.
- When the transducer is to be used in water, use only a little gel, or no gel if possible.
- Position the transducer at the point of maximum signal of the fetal heart sound. Fix the transducer by means of a belt strap and clips (clips provided).

False recording of FHR

When monitoring FHR using Doppler ultrasound, the heart rate may be falsely reported. This can be caused by a number of effects including double-rating or half rating, and is characteristic of ultrasound fetal monitoring. Another cause may be detection of maternal signals, (particularly in the absence of fetal signals). Doubling of the maternal rate can result in a trace looking very like a normal fetal trace.

If the fetal heart signal has large variations in rate, is weak, or is in the presence of large maternal signals, noise or artefact, it is possible for the system to double count or half rate for short periods of time. This is characteristic of monitoring fetal heart rates with ultrasound.

How to minimise the chances of double rating, half rating or other types of artefact occurring

Always palpate the abdomen and listen to the fetal heart with a Pinard stetho¬scope or hand-held Doppler unit before applying the ultrasound transducers. This helps to verify the fetal heart and to locate the area where best signal quality can be expected.

5.3 Ambulatory Monitoring

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

For ambulatory monitoring of a patient, remove the transducers from their charging position and apply them to the patient.

During monitoring take care that:

- The transducers do not become displaced.
- A good fetal heart sound is recorded.
- The patient walks about normally.
- The patient stays inside the allowed area.

When the transducers are charging, the telemetry transmission is stopped. The fetal monitor can operate with the transducers connected to its own inputs if necessary or desired.

Possible Problems

Any movement of the patient generates artifacts, especially walking. RF-transmission is limited by some physical effects. Also, moving the transducer in different surroundings can cause drop outs and various interferences. A certain amount of artifacts should be expected. However, if there is an unacceptable amount of artifacts observe the signal behavior:

- Do the artifacts appear in combination with a certain movement?
- Remedy: Secure the transducer by strap and clip.
  Check the connectors for damage.
  Restrict movement.

- Do the artifacts occur only at certain locations?
- Remedy: Avoid this location if clear transmission is not possible (e.g. elevator, windows with metal net, etc.).
  Reposition the receiving antenna.

Other transmitters working on the same frequency can also interrupt ambulatory monitoring. In this case, one of the transducers should be set to a different frequency. To change the frequency of the receiver, please refer to section 6.4.

Because of physical reasons, in some cases it is not possible to get a clean record of heart rate. This may happen when the patient is pressing during delivery.

5.4 Under Water 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.

When the US-transducer is completely under water, a lot of the radiated RF-power will be absorbed by the surrounding water. This reduces the range to a couple of metres and a line-of-sight situation of receiver and transducer. The receiving antenna must be near the bath. Exact information can only be found by a field test. If you are in doubt, please contact your sales partner for assistance.

Possible Problems

Because of physical reasons, in some cases it is not possible to get a clean record of heart rate. This may happen when the patient is pressing during delivery. When the delivery is done in water the transducers can easily be displaced. This may cause additional temporary signal losses

5.5 Ending Monitoring / Switching Off

Once monitoring is complete and the transducers and receiver have been cleaned (see Section 6.2), return the transducers to the charging position on the receiver, so they are easily located when you want to use the system, and so the transducer batteries can be charged.

For charging the transducer batteries, the system must be connected to the mains supply (see Section 3.2).

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

6. Care and Cleaning

Warning: Maintenance and servicing must only be carried out by suitably qualified personnel.

6.1 General Care

Although the Freedom is robust and has been designed to withstand normal clinical use, the unit contains delicate components, which should be handled and treated with care.

Periodically, and whenever the integrity of the system is in doubt, carry out a check of all functions as described in Section 4.3.1. If there are any defects to the housing of a transducer do not use it in water. Contact Huntleigh Healthcare Customer Services or your distributor to get repaired.

If a transducer is dropped, check that the seal and the housing are not damaged. If you are in doubt please contact Huntleigh Healthcare's Customer Services or your distributor.

Carry out regular checks of the transducers, cables and connectors for external damage. If repair is required please contact Huntleigh Healthcare's Customer Services or your distributor.

Please ensure that you check with your facility's local infection control policy and medical equipment cleaning procedures.

Observe warnings and guidance on cleaning fluid labelling regarding use and personal protective equipment (PPE).

Do not use abrasive cloths or cleaners on the transducer, receiver or accessories.

Do not use automatic washers or autoclaves to clean the transducers.

Phenolic detergent based disinfectants, solutions containing cationic surfactants, ammonia based compounds or perfumes and antiseptic solutions such as Steriscol or Hibiscrub should never be used on any part of the Freedom system.

If detergent or disinfectant wipes are used to clean the transducers or the receiver ensure that excess solution is squeezed from the wipe prior to use.

Always switch off the Receiver by disconnecting the unit from the AC supply before cleaning and disinfecting, do not allow any fluid to enter the Receiver and do not immerse the receiver in any solution.

6.2 Cleaning and Disinfecting

6.2.1 Transducers

Clean the two transducers before examining a patient using cleaning Method 1 below.
Following patient examination clean and/or disinfect the transducers by the appropriate method based upon the risk of transferring an infection from one patient to another. Risk definitions are defined in the table below:

Risk Level Definitions	
Low Risk	Normal use or low risk situations include patients having intact skin and no known infection and the transducers have not been contaminated with blood.
Medium Risk:	The patient has a known infection, skin is not intact, the transducer is heavily soiled or the patient has given birth in a water bath.
High Risk:	This procedure should only be used when the transducer has been contaminated by blood.

Cleaning & Disinfecting Methods

Ensure the coupling gel used with the ultrasound transducer is removed before cleaning in all three methods.

Method 1 (Low Risk):

Do not remove the protective silicone sleeves (‘sleeve’).

1. Wipe the sleeves and the transducers using a mild detergent and then rinse in water.
2. Completely dry the sleeves and the transducers with a clean lint free cloth.

Method 2 (Medium Risk)

Remove the sleeves before cleaning.

1. Remove soiling and clean the transducers and the internal and external surfaces of sleeves with a mild detergent and then rinse in water.
2. Completely dry the transducers and the inside and external surfaces of the sleeve.
3. Wipe transducers and sleeves with a cloth dampened in Sodium Hypochlorite (1000ppm).
4. After two minutes rinse with water and then dry with a clean lint free cloth.
5. Re-attach the sleeve ensuring sure that they are assembled correctly (see pictures below).

Method 3 (High Risk)

Warning: Sodium Hypochlorite @ 10000 ppm for disinfecting should only be used in situations described in the High Risk definition. Unnecessary use of this concentrated solution for Low and Medium risk situations may result in damage to the transducer over time.

Remove the sleeves before cleaning.

1. Remove soiling and clean the transducers and the internal and external surfaces of the sleeves with a mild detergent and then rinse in water.
2. Completely dry the transducers and the inside and external surfaces of the sleeves.
3. Wipe transducers and sleeves with a cloth dampened in Sodium Hypochlorite (10000ppm).
4. After two minutes rinse with water and then dry with a clean lint free cloth.
5. Re-attach the sleeve ensuring that they are assembled correctly (see pictures below).

Warning: Before docking the transducers onto the Receiver ensure that the transducers are dry and that the receiver has been cleaned following the procedure below.

6.2.2 Receiver Unit

General Comments

- Always keep the external surfaces clean and free of dirt and fluids using a clean dry cloth to remove.
- Clean the charging contacts regularly with a dry cloth.
- Ensure that the charging contacts are completely dry following the cleaning and disinfecting procedure.

Cleaning & Disinfecting Procedure

Following patient examination, clean and disinfect the receiver's exterior surface as described below:

1. Wipe any fluids from the surface of the unit using a clean dry cloth.
2. Wipe the receiver with a cloth dampened in 70% Isopropyl Alcohol avoiding connector sockets and charging pins. Repeat this step using water.
3. Completely dry the receiver with a clean, dry lint free cloth.
4. If the receiver has been contaminated with blood disinfect the contaminated area using a cloth dampened in Sodium Hypochlorite solution @ 10000ppm.
5. After two minutes wipe this area with a cloth dampened in water to remove residue and then dry with a lint free cloth.

6.3 Charging the Transducer Batteries

Refer to Section 3.2.

6.3.1 Battery Replacement

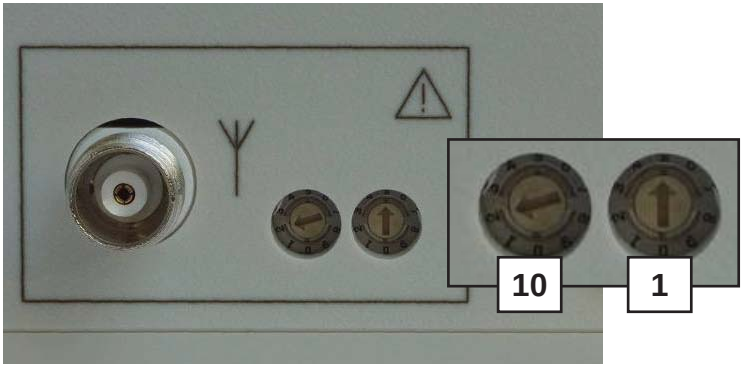
The lifetime of the battery is estimated to be 2 to 3 years, depending on use patterns. You will notice a significantly reduced charge time and working time of a charged battery when the battery is due for replacement.

Contact Huntleigh Healthcare or your distributor for battery replacement. Battery replacement must be done by a Huntleigh Healthcare trained service technician.

6.4 Changing the RF-channel

A telemetric measurement can be disturbed by other transmitters running on the same frequency. In case there are several telemetry units in one ward, all receivers must be set to different channel numbers. In such a case, set or change the RF-channel located on the rear panel of the Freedom receiver. This is performed as follows:

1. Disconnect the receiver from the mains and wait until all LED's are off.



2. Use the code-switches at the rear panel of the receiver to select the new channel number in the range of 00, 01… to 25. If you select a number greater than 25, 25 will be set in any case.
3. Re-connect the receiver unit to mains and wait until the LED test is finished.
4. Insert the US-transducer unit into a charging compartment and wait until charging is indicated.

Now the new channel is installed for receiver and transducer. This procedure takes about 20 seconds; please do not interrupt this process. In case of unusual behavior of this process please retry this procedure.

7. Trouble Shooting

This section gives some of the more common problems encountered during use together with possible causes. If the problem cannot be located after consulting the table below, the receiver should be disconnected from mains power source and a qualified technician should be consulted.
Before attempting trouble-shooting, verify that all cables are properly connected to both the receiver, FM800E and the main power source.

Transmission Indicator LED always red, even though the US-transducer is removed.	
POSSIBLE CAUSE	**SOLUTION**
Battery of transducer empty.	Re-charge transducer
Receiver and transducer are working on different RF-channels.	Select the correct transducer
	Connect transducer for charging, allow communication, now the transducer can be used.

Transmission Indicators flicker sporadically red/green when patient is walking.	
POSSIBLE CAUSE	**SOLUTION**
Patient out of range.	Show the patient the area and distance which allows good signal reception. Indicate restricted rooms, areas and limits.

No signal on Fetal Monitor even though the indicators on receiver 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.
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 in position.	
POSSIBLE CAUSE	**SOLUTION**
Transducer not sited properly.	Re-position the transducer.
Receiver not connected to the AC line.	Connect the receiver.

No TOCO signal on fetal Monitor from telemetry.	
POSSIBLE CAUSE	**SOLUTION**
US-transducer receiving signal from TOCO.	Bring US-transducer nearer than 30cm to TOCO transducer.
TOCO not running (no lamp blinking).	Charge TOCO-transducer and try again.

Charging panel or contacts show corrosion.	
POSSIBLE CAUSE	**SOLUTION**
Transducer was wet or contaminated with gel when plugged in for charging.	Always clean and dry the transducer before charging. If necessary have the contact panel exchanged.

No response of receiver to transducers.	
POSSIBLE CAUSE	**SOLUTION**
The discharge of static electricity may have blocked the receiver.	Disconnect the power cord for about 5 seconds. Re-connect the cable. Regular functions will be stable.

8. Specifications

8.1 Equipment Classification

Type of protection against electric shock.	Class IIb according to MDD. The receiver unit is connected to the AC line without a protective earth (class 2).
Degree of protection against electric shock 	Transducer - SF1-US : Class CF applied parts Transducer - SF1-TOCO : Class CF applied parts
Mode of operation.	Continuous
Degree of protection against harmful ingress of particles and/or water.	Receiver - SF1-Base : IP31 Transducer - SF1-US : IPX7 Transducer - SF1-TOCO : IPX7
Degree of safety of application in the presence of a flammable anaesthetic	Equipment not suitable for use in the presence of a FLAMMABLE ANAESTHETIC MIXTURE WITH AIR, OXYGEN OR NITROUS OXIDE

8.2 Receiver Unit (SF1-Base)

RF-Receiver	434.05...434.7 MHz Band, 25 channels
Channel selection	rotary switch
Supply voltage	100V…240V, 50…60Hz, 10VA
Stand by power consumption	<0.8W
Antenna	Gainflex
Charging controller	for SF1-US and SF1-TOCO
Charging time	max. 3hours , regulated
Operation	automatic, no controls
Indicators	- Transmission US transducer - Transmission TOCO transducer - Battery capacity during operation - Battery capacity during charging - Battery charging established (2 ports)
Size	250 x 200 x 85mm
Weight	1Kg

8.3 US-Transducer (SF1-US)

Measurement	Pulsed Doppler Ultrasound
Ultrasound parameter	Complies with IEC 60601-2-37
Transmission	cordless to receiver (SF1-Base)
Range	up to 30m, from under-water up to 8m
Modulation	digital, FSK
Antenna	Helix
RF-Transmitter	according to receiver (SF1-Base), ISM bands
Power supply	Lithium Polymer Battery
Operating time	approx 16hours
Size	Ø75x20mm
Weight	105g

8.4 TOCO-Transducer (SF1-TOCO)

Measurement	external measurement of uterine activity
Transmission	cordless to Ultrasound-transducer SF1-US
Range	30cm
Modulation	digital, FSK
Antenna	Ferrite
Transmitter	10kHz
Power supply	Li-Polymer-Battery
Operating time	approx 16h
Size	Ø75x20mm
Weight	92g

8.5 Environmental

Operating		**Storage**
10°C to 40°C	**Temperature range**	-10°C to 50°C
10% to 75% (non condensing)	**Relative Humidity**	10% to 93% (non condensing)

8.6 Standards Compliance

EN60601-1: 2006	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance.
EN60601-1-2: 2007	Medical Electrical Equipment. General Requirements for Basic Safety and Essential Performance. Collateral Standard. Electromagnetic compatibility. Requirements and Tests
EN10993-1: 2009 & AC: 2010	Biological Evaluation of Medical Devices; Guidance on selection of tests
EN60601-1-6: 2007	General requirements for basic safety and essential performance - Collateral standard: Usability
IEC 62304: 2006	Medical device software - Software life cycle processes.
BS EN15223-1: 2012 Medical Devices	Symbols to be used with medical device labels, labelling and information to be supplied. General Requirements.

8.7 Consumables

WARNING: Use only recommended accessories/consumables listed in this manual.

Item	Part No
Aquasonic Gel 5ltr container (each)	ACC-1300-0154
Aquasonic Gel (box of 12 x 250ml)	ACC3
Ultrasonic Gel (box 12 x 60ml tubes)	ACC24
Latex free Reusable transducer belts (pair)	ACC-MI1136
Latex free Disposable transducer belts (box of 50)	ACC220

9. Electromagnetic Compatibility

Make sure the environment in which the Sonicaid™ Freedom is installed is not subject to strong sources of electromagnetic interference (e.g. radio transmitters, mobile phones).

This equipment generates and uses radio frequency energy. If not installed and used properly, in strict accordance with the manufacturer's instructions, it may cause or be subject to interference. Type-tested in a fully configured system, complies with EN60601-1-2, the standard intended to provide reasonable protection against such interference. Whether the equipment causes interference may be determined by turning the equipment off and on. If it does cause or is affected by interference, one or more of the following measures may correct the interference:

- Reorienting the equipment
- Relocating the equipment with respect to the source of interference
- Moving the equipment away from the device with which it is interfering

Adding accessories or components to a system, or modifying a medical device or system, may degrade the immunity performance. Consult qualified personnel before making changes to the system configuration.

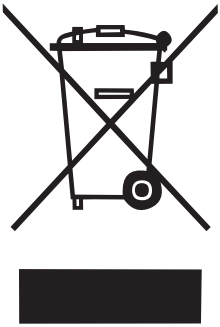
WARNING: The use of accessories, transducers and cables other than those specified, with the exception of transducers and cables sold by the manufacturer of the Sonicaid™ Freedom as replacement parts for internal components, may result in increased emissions or decreased immunity of the Sonicaid™ Freedom .

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

9.1 Electrostatic Discharge

Electrostatic discharge (ESD) is a known problem that can affect electrical equipment.

10. End of Life Disposal



This symbol signifies that 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.

11. 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™ Freedom 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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Cardiff. CF24 5HN
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The Sonicaid Freedom™ is in conformity with the Medical Devices Directive 93/42/EEC as amended by 2007/47/EC and has been subject to the conformity assurance procedures laid down by the Council Directive

Manufactured in the UK by Huntleigh Healthcare Ltd.
As part of the ongoing development programme the company reserves the right to modify specifications and materials without notice.

HUNTLEIGH …with people in mind

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