# HUNTLEIGH

# SF1

Anwendungshinweise

Kullanım Talimatları

Brugsvejledning

Instrucciones de uso

χρήσης

使用方

Mode d'emploi

Gebruiksaanwijzing

Bruksanvisning

# INSTRUCTIONS FOR USE

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Anwendungshinweise

sonicaid™ Freedom

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# 1. Safety

**Before using this equipment, please study this manual carefully and familiarise yourself with the receiver, transducers, the indicators 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.**

**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.**

***This device may only be used in combination with one of Huntleigh Heathcare Ltd's ('Huntleigh') Sonicaid™ FM800E fetal monitor range. The FM800E monitor range includes model numbers FM820E and 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 |
| **Rx Only** | This system should only be used by, or under supervision of, a licensed physician or other health practitioner who is trained in the use of fetal heart monitors. |

## 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 (IPX8 - 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 protected from damage if dropped. Never use the transducer without its protective sleeve. It can be removed for cleaning in accordance with the Cleaning and Disinfection Procedure in Section 6.***

***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 other clinical settings, 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 Medical Devices Directive 93/42/EEC. 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 become disabled. Please disconnect the mains lead for about 5 seconds.***

***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.***

***Use only recommended accessories listed in this manual.***

# 2. Introduction

## 2.1 Indications of Use

**The Sonicaid™ Freedom ('Freedom') is a wireless fetal monitoring system for the monitoring of fetal heart movement and maternal contractions during intrapartum and antepartum periods of pregnancy.**

**It is an optional accessory for use with Huntleigh Healthcare Limited's Sonicaid FM820 and FM830 Encore Fetal Monitors ('FM800E Monitors') as an alternative to their wired transducers. When connected to an FM800E Monitor, the system monitors:**

- **Uterine activity by using an external, pressure-sensitive TOCO transducer, and**
- **Fetal heart rate (FHR) by pulsed Doppler ultrasound using an external Ultrasound transducer.**

**Freedom is suitable for use in clinical and hospital facilities for use on pregnant woman. The transducers are water tight allowing pregnant women to be monitored while they are mobile, stationary or in a bath or shower environment.**

**This system should only be used by, or under the supervision of, a licensed physician or other health practitioner who is trained in the use of FHR monitors.**

## 2.2 Contraindications

***Sonicaid™ Freedom is not intended for use with patients fitted with cardiac pacemakers, during defibrillation, while undergoing surgery, or while MRI scanning is taking place.***

***Sonicaid™ Freedom must not be used in intensive care units or operating rooms.***

## 2.3 Unpacking / Preliminary Checks

***Contents (supplied with each system)***

| Item | Item | Item |
|---|---|---|
| 1 x Sonicaid™ Freedom Receiver Unit (SF1-UNIT-SL) | 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 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 or your distributor 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

Freedom consists of three components: the Ultrasound transducer (SF1-US), the TOCO transducer (SF1-TOCO) and the Receiver (SF1-Unit). There are two formats for the Receiver. SF1- Unit is for use with ISM and SF1-Unit-SL is for use in areas compatible with WMTS. 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 physiological parameters:

- Fetal Heart Rate
- Uterine activity

**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 docked with 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 location and local regulations. The SF1- Unit (ISM) has 26 channels, and SF1-Unit-SL (WMTS) has 100 channels. The range depends on the local conditions. 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 green LEDs; four LEDs indicating that the transducer is fully charged. When the battery becomes discharged the transducer is automatically shut off.

**Receiver**

The receiver has two docking 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 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 undocked, 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 undocked from the receiver and applied to the patient. It is recommended that the US transducer be applied to the patient first.

The TOCO-Transducer transmits its signal to the US-transducer. The US transducer transmits both the US and TOCO signals to the receiver.

## 3.2 The Receiver Unit

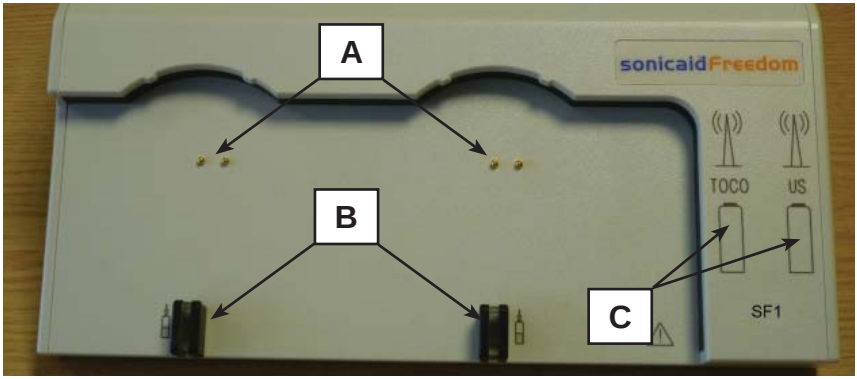
### *3.2.1 Operation*

The receiver does not have a 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, dock both transducers first, wait for charging indication, then disconnect the supply. All units are now switched off. All modules are turned on when the receiver is powered again.

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

### *3.2.2 Front Panel Indicators*

#### *Docking Transducers*




**A - Docking/Charge Position**

Ensure there is no water or gel on the contact panels of the receiver or transducer when charging, as this may prevent good contact.

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

The transducers are equipped with re-chargeable lithium polymer batteries. When the transducer is docked the battery is charged automatically, provided the receiver is connected to the mains supply.

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

It doesn't matter in which of the two positions a transducer is docked, 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.

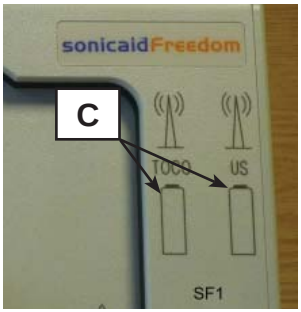
### B - Charge Position LEDs

The battery state during charging is indicated as follows:

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

If the LED is constantly on, the transducer has been recognised to belong to the receiver unit.
If the LED flashes slowly, this indicates an unrecognised item is being charged. If this happens with a transducer belonging to the receiver, re-dock the transducer. If you re-dock the transducer too slowly or tentatively, the receiver may not recognise the transducer.

### C - Battery Indicators



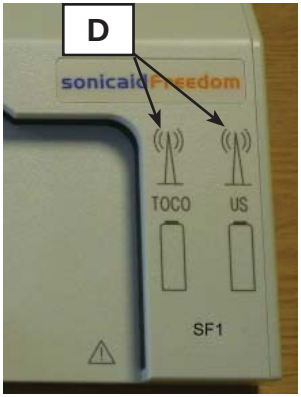

Once a transducer has been identified by the receiver, the corresponding battery indicator (C), shows the actual capacity during operation and the status of recharged energy during charging. Each LED represents about a quarter of the capacity. When the battery is fully charged, all 4 LED's are continuously 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 fully discharged, a 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 docked on the receiver when not in use.

### *Transmission Indicators*

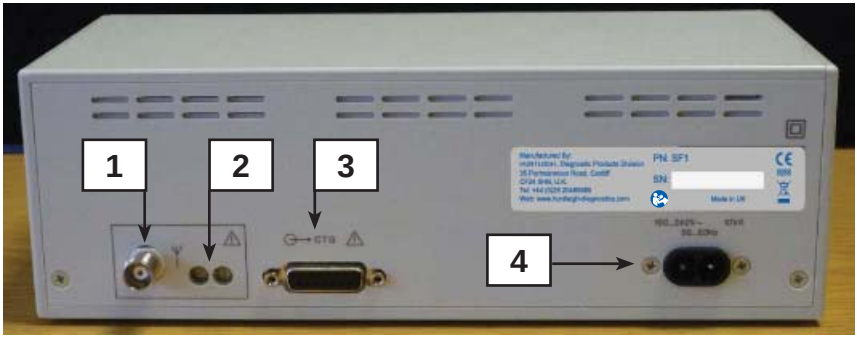



The transmission indicators are located on the upper right corner of the receiver (D). These indicators show the status of TOCO and US transducer transmission:

**LED flickering amber:**
US Transducers off or out of range
**LED amber**
Transducers docked or TOCO Transducers out of range
**LED green:**
Transducer in range and good signal quality
**LED flickering green/amber:**
Transducer near end of range, or disturbance by another RF-transmitter.

If known to be in range, refer to Section 8.3 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 selector :<br>ISM : 00 - 25 (26 channels)<br>WTMS : 00-99 (100 channels) |
| 3 | Interface to Fetal Monitor CTG |
| 4 | Mains Input, 100…240V, 50…60Hz, 10VA. |

## 3.3 The Transducers


### Indicator

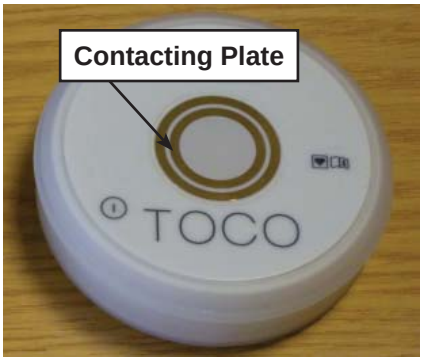
On the top of each transducer is a green indicator LED.

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

Once the transducer is undocked, the LED is switched ON and flashes to indicate normal operation.

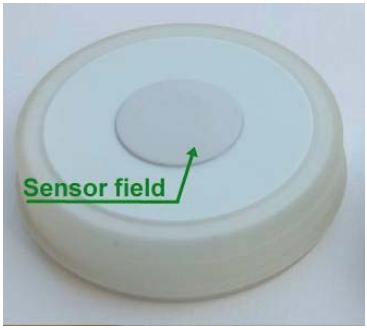
If the LED stays off, charge the transducer and try again. If the LED is on continuously, please refer to the Troubleshooting Guide in Section 8.

### Connections




On the top surface of the transducer is a contacting plate. These two connecting rings connect to the charging pins on the receiver when the transducer is docked for charging. All rings are internally disconnected during operation.

### Sensor Field - SF1-TOCO




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

Avoid applying excess pressure to the sensor area.

### Mechanical 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 with the Freedom unit (ACC-OBS-051), but the belts must be purchased separately. Refer to section 9.7 for Recommended Consumables and Accessories.

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 |
| **IP30** | Receiving Unit rating for protection against ingress of fluids and particulate. |
| **IPX8** | Transducer rating for protection against ingress of fluids and particulate: The transducers are designed for operation under water. (1M for 16 hours) |
|  | 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 or use only the recommended and provided accessories.<br><br>General Warning or Caution. |
|  0088 | 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



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

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

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

## 4.1 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 which is clearly identified, from output of the receiver unit to the interface input of the fetal monitor.
- Connect the receiving antenna.
- Connect the mains supply lead from the receiver unit to mains supply
- Charge the transducer batteries
- Switch on the FM800E 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.

## 4.2 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 LEDs turn off
- LED in TOCO-transducer starts flashing
- no further action (no signal transmission, because the US-transducer is not running)

**2. Dock TOCO-transducer for charging again:**

- charge position LED and battery indicator LEDs turn on

**3. Remove US-transducer (US):**

- charge position LED turns off
- LED in US-transducer starts flashing
- US-transmission indicator LED turns green
- US battery indicator LEDs 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 flashing
- 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. Dock US-transducer for charging**

- US and TOCO-transmission indicator LEDs turn Amber
- charge position LED turns on
- US battery indicator LEDs indicate charge status
- US and receiver communicate to establish RF channel number
  - if successful: charge position LED turns on
  - if not successful: charge position LED flashes (remove the transducer for 10 seconds and re-dock)
- No reading on fetal monitor

**8. Dock TOCO transducer for charging**

- TOCO and receiver communicate for compatibility
  - if successful: charge position LED turns on
  - if not successful: charge position LED flashes (remove the transducer for 10 seconds and re-dock)
- TOCO battery LEDs indicate charge status

**9. Wait until both Battery Indicators show all 4 LEDs on (battery fully charged). A complete charge cycle takes approximately 2.5 hours**

***Note :*** ***It is recommended that the serial numbers from installed and matched receiver and transducer units are recorded for future use if required. This may be important if several telemetry systems are used within a ward or confined area.***

# 5. Operation

## 5.1 Getting Started

- Charge the transducer batteries
- Switch on the FM800E monitor (refer to its operator's manual)
- Apply transducers to the patient (Refer to Section 5.2).

When the US-transducer is undocked from 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 LEDs are illuminated green.

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

***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

### *Ultrasound transducer*

Remove the ultrasound transducer. Fix the transducer to the belt clip. Apply ultrasound gel to the surface of the transducer.

***Note: Use recommended gel only. Do not use oil based gels.***

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 to the belt strap.

### *TOCO transducer*

- Position the TOCO transducer as usual and fasten it securely.
- Adjust the TOCO baseline using the FM800E monitor 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.*

### *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.

***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 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, undock the transducers from the receiver 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 stays within operating range of the receiver.

### *Possible Problems*

Any movement of the patient generates artefacts, especially walking. As a patient moves to a different area, a drop out may occur. A certain amount of artefacts should be expected. However, if there is an unacceptable level of artefacts observe the following:

- Do the artefacts appear in combination with a certain movement?
- Remedy: Secure the transducer by strap and clip.
  Restrict movement.

- Does the artefact 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 8.3.

## 5.4 Water Birth 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. If you are in doubt, please contact Huntleigh or your distributor for assistance.

## 5.5 Ending Monitoring / Switching Off

Once monitoring is complete and the transducers and receiver have been cleaned (see Section 6.2), dock the transducers on the receiver, so they are easily located when you want to use the system again, 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

## 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 4.2. If there are any defects to the housing of a transducer do not use it in water. Contact Huntleigh or your distributor to get it repaired or to order a replacement.

If a transducer is dropped, check that the seal and the housing are not damaged. If you are in doubt please contact Huntleigh or your distributor for further instructions.

***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. If this is not followed, damage to transducer will result.***

### *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.
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.

# 7. Maintenance

## 7.1 Mechanical Inspection

Inspect the AC supply cable, FM800E connection cable, receiver, transducer protective sleeves and transducers for loose or broken parts or any other damage. Pay particular attention to the AC supply socket.

Look carefully for cracks which may allow the ingress of liquids or gels.

Contact Huntleigh or your distributor for service or replacement of any broken or damaged cables, transducers or transducer protective sleeves.

If there is damage to the receiver, do not use and contact Huntleigh or your distributor.

## 7.2 Corrective Maintenance

All corrective maintenance must be performed by qualified engineers, approved by Huntleigh.
The Sonicaid Freedom Service manual (PN 778345) is designed as an aid to engineers in maintenance and service of repairable parts.

## 7.3 Charging Transducer Batteries

Refer to Section 3.2

## 7.4 Transducer 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 working time of a charged battery when the battery is due for replacement.

Do not attempt to change the battery yourself.

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

## 7.5 Servicing

Servicing should be performed by Huntleigh or their appointed service agent.

# 8. 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 the 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 amber, even though the US-transducer is removed.** | |
|---|---|
| **POSSIBLE CAUSE** | **SOLUTION** |
| Transducer battery discharged. | Charge transducer |
| Receiver and transducer are working on different RF-channels. | Select the correct transducer |
| | Dock the transducer for charging, allow communication, now the transducer can be used. |

| **Transmission Indicators flicker sporadically amber/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 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. If necessary change RF channel. Refer to 8.3. |

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

| No TOCO signal on fetal monitor from telemetry. | |
|---|---|
| **POSSIBLE CAUSE** | **SOLUTION** |
| US-transducer not receiving signal from TOCO. | Bring the transducers closer together until US receives signal from TOCO. |
| TOCO not running (LED not flashing). | Charge TOCO-transducer and try again. |

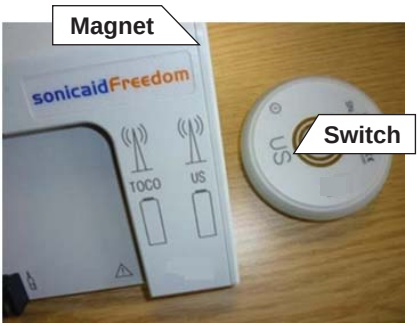
| Charging panel or contacts show corrosion. | |
|---|---|
| **POSSIBLE CAUSE** | **SOLUTION** |
| Transducer was wet or contaminated with gel when docked on the receiver. | Always clean and dry the transducer before docking and charging. If necessary have the contact panel exchanged. |

| Receiver does not respond to transducers. | |
|---|---|
| **POSSIBLE CAUSE** | **SOLUTION** |
| The discharge of static electricity may have disabled the receiver. | Disconnect the power cord for about 5 seconds. Re-connect the cable. Regular functions will be stable. |

| Green LED of US and / or TOCO remain illuminated. | |
|---|---|
| **POSSIBLE CAUSE** | **SOLUTION** |
| Transducers may be locked | Manually Switch off Transducers (Refer to 8.1 and 8.2) |

## 8.1 Manually Switching off the Transducers

If the green LED of the ultrasound and or Toco transducer remain illuminated or the transducers lock up, the following procedure must be adhered to;




### Position of Magnet and Switch

Inside the housing by the upper right edge of the receiver unit there is a magnet. This is used to manually switch off the transducer. The transducers have an internal magnetic switch, which is mounted within the transducer and positioned under the C of “TOCO” and the S of "US" respectively

**Switching Off**

Hold the transducer at the right hand side of the receiver as shown on the pictures below.
Position the letters so that the “TO” or “US” are as shown and the direction of the writing upper most.

By moving the transducers along the right hand side of the receiver wall the transducers will switch off and reset accordingly
The process will take approximately 2-3 seconds.


## 8.2 Re-enabling Transducers

After manually switching off the transducers it is essential that they are docked for recharging and enabling. Both LEDs will then turn on denoting they are ready for the next measurement. However please note, if the transducer was disabled and had no LED indication or it is in a status which looked like being off, there will be no visual indication on the transducer or receiver.

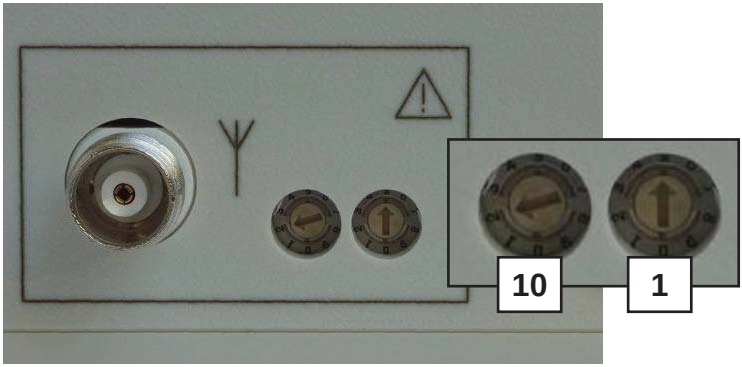
*It is recommended that the user gets familiar with this procedure to identify the immediate effect of turning off the LED.*

As a note it may also be necessary to switch off the transducer after a static discharge over the charging contacts, this may cause the transducer to lockup in a safety condition.

## 8.3 Changing the RF-channel

Wireless transmission 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.
   ISM : 00 - 25 (26 channels)
   WTMS : 00 - 99 (100 channels)
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 behaviour of this process please retry this procedure.

***Note :*** ***The serial numbers from installed and matched receiver and transducer units should be recorded for future use if required. This may be important if several telemetry systems are used within a ward or confined area.***

# 9. Specifications

## 9.1 Equipment Classification

| | |
|---|---|
| **Type of protection against electric shock.** | 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<br>Transducer - SF1-TOCO : Class CF applied parts |
| **Mode of operation.** | Continuous |
| **Degree of protection against harmful ingress of particles and/or water.** | Receiver - SF1-Unit : IP30<br>Transducer - SF1-US : IPX8 (1M for 16Hours)<br>Transducer - SF1-TOCO : IPX8 (1M for 16Hours) |
| **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 |

## 9.2 Receiver Unit (SF1-Unit)

| | |
|---|---|
| **RF-Receiver** | ISM : 434.05 - 434.7 MHz Band, 26 channels<br>WMTS : 608.0375 - 612.9875 MHz Band, 100 channels |
| **Channel selection** | Rotary switch |
| **Supply voltage** | 100V…240V, 50…60Hz, 10VA |
| **Stand by power consumption** | <0.8W |
| **Antenna** | Gainflex |
| **Transducer Charging** | Two docking and charging stations for SF1-US and SF1-TOCO |
| **Charging time** | Maximum: 3hours , regulated |
| **Operation** | Automatic, no controls |
| **Indicators** | - Transmission US transducer<br>- Transmission TOCO transducer<br>- Battery capacity during operation<br>- Battery capacity during charging<br>- Battery charging established (2 ports) |
| **Size** | 250 x 200 x 85mm |
| **Weight** | 1Kg |

## 9.3 US-Transducer (SF1-US)

| | |
|---|---|
| **Measurement** | External Fetal Heart Rate by Pulsed Doppler Ultrasound |
| **Ultrasound parameter** | Complies with IEC 60601-2-37 |
| **Transmission** | Cordless to receiver (SF1-Unit / SF1-Unit-SL) |
| **Range** | Up to 30m, from under-water up to 8m |
| **Modulation** | Digital, FSK |
| **Antenna** | Helix |
| **RF-Transmitter** | According to receiver: SF1-Unit (ISM), SF1-Unit -SL (WMTS) |
| **Power supply** | Lithium Polymer Battery |
| **Operating time** | Approximately 16 hours with fully charged battery |
| **Size** | Ø75x20mm |
| **Weight** | 105g |

## 9.4 TOCO-Transducer (SF1-TOCO)

| | |
|---|---|
| **Measurement** | External pressure measurement of uterine activity |
| **Transmission** | Cordless to Ultrasound-transducer SF1-US |
| **Range** | 30cm (TOCO to US Transdsucer) |
| **Modulation** | Digital, FSK |
| **Antenna** | Ferrite |
| **Transmitter** | 10kHz |
| **Power supply** | Li-Polymer-Battery |
| **Operating time** | Approximately 16 hours with fully charged battery |
| **Size** | Ø75x20mm |
| **Weight** | 92g |

## 9.5 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) |

## 9.6 Directives and Standards Compliance*

**European Directives:**

The Sonicaid™ Freedom complies with the essential requirements of the Medical Devices Directive (93/42/EEC) with amendments by 2007/42/EC and the Radio and Telecommunications Terminal Equipment Directive (1999/5EU).

**Standards:**

| | |
|---|---|
| **Safety** | IEC/UL/CSA/EN 60601-1 (Second Edition)<br>IEC/ANSI/AAMI/CSA/EN 60601-1 (Third Edition)<br>EN60601-1-6:2007 |
| **Electromagnetic Compatibility** | EN60601-1-2:2007<br>FCC 47 Part 15 Subpart B |
| **Radio** | ETSI EN 300 220-1:V2.3.1 (2010/02), ETSI EN 300 220-2: V2.3.1 (2010/02)<br>FCC 47 CFR Part 15 Subpart C and Part 95 (WMTS)<br>RSS-210 |
| **Labelling** | BS EN15223-1:2012 |

## 9.7 Recommended Consumables & Accessories

***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 |
| Transducer Clips | ACC-OBS-051 |
| Ultrasound Transducer | ACC-OBS-052 |
| TOCO Transducer | ACC- OBS-053 |
| Transducer Sleeve | ACC-OBS-054 |
| Mounting Bracket (To mount the Receiver to an FM800E Monitor) | ACC-OBS-050 |
| Service Manual | 778345 |

**This list is not fully comprehensive*

# 10. 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.

# 11. Ultrasound Safety Considerations

## General

Diagnostic ultrasound has been in use for over 35 years with no confirmed adverse effects on patients or instrument operators at the intensities typical of present diagnostic instruments. However, available data are not wholly conclusive, and the possibility remains that biological effects may be identified in the future.

Because fetal tissue could be more sensitive to biological effects by reason of rapid cell division, it is particularly desirable that ultrasound exposure of pregnant subjects be kept to a minimum.

Medical and scientific authorities therefore recommend that ultrasound procedures be performed in accordance with the “ALARA” principle, which states that the energy delivered to the patient should always be kept As Low As Reasonably Achievable.

The transmitted acoustic power of the Sonicaid Freedom Ultrasound transducer is fixed and cannot be adjusted by the operator. Therefore, the user can best observe the ALARA principle by ensuring that each examination is medically indicated and by limiting the duration of the study to the extent appropriate for the clinical objectives.

Acoustic output data for the transducers is summarized in the following tables.

## Acoustic Output

The ultrasound transducer used with the Sonicaid Freedom has a single mode of operation, with fixed acoustic output parameters that are not user adjustable.

Acoustic Output Reporting Table for Track 1 – Non-Auto-scanning Mode
Sonicaid Freedom
Operating Mode: PWD
Application(s): Fetal Monitoring

| Acoustic Output | | | MI | $I_{SPTA.3}$ (mW/cm$^2$) | $I_{SPPA.3}$ (mW/cm$^2$) |
|---|---|---|---|---|---|
| Global Maximum Value* | | | 0.0160 | 1.97 | 7.42E-3 |
| Associated Acoustic Parameters | $Pr_{.3}$ (MPa) | | 0.0162 | | |
| | $W_o$ total (mW) | | | 24.3 | 24.3 |
| | $f_c$ (MHz) | | 10.2 | 1.02 | 1.02 |
| | $Z_{sp}$ (cm) | | 4.60 | 4.60 | 4.60 |
| | Beam Dimensions | $x_{-6}$ (cm) | | 4.79 | 4.79 |
| | | $y_{-6}$ (cm) | | 4.86 | 4.86 |
| | PD (µS) | | 91.5 | | 91.5 |
| | PRF (Hz) | | 2900 | | 2900 |
| | Overall EBD (cm) | | | 5.00cm | |

## Definition of Terms

| | |
|---|---|
| $I_{SPTA.3}$ | The de-rated spatial peak temporal average intensity |
| $I_{SPPA.3}$ | The de-rated spatial peak pulse average intensity |
| $I_{SATA}$ | The spatial average temporal average intensity |
| **MI** | The mechanical index |
| $Pr_{.3}$ | The de-rated peak negative pressure |
| $W_o$ | The ultrasonic power |
| $f_c$ | The acoustic centre frequency |
| $z_{sp}$ | The axial distance at which the reported parameter is measured |
| $x_{-6}$ $y_{-6}$ | respectively the in-plane (azimuth) and out-of-plane (elevation) -6dB dimensions in the x-y plane where $z_{sp}$ is found |
| **PD** | Pulse duration |
| **PRF** | Pulse repetition frequency |
| **EBD** | Entrance beam dimensions for the azimuth and elevation planes |

## Statistical Analysis of Measurement Data

A statistical analysis was performed on the acoustic output data to examine the upper output limit, based on a one sided tolerance limit approach. The mean and standard deviation of the Spatial-Peak, Time-Average Intensity and Mechanical Index were found, and the upper output limits were calculated from the following formula:

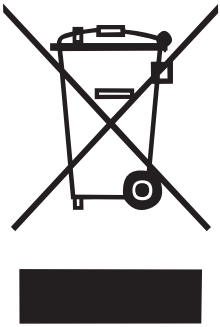
$$X = \bar{x} + k * S_x$$

where **X** is the upper output parameter limit, $\bar{x}$, is the average of the measured output parameter, $S_x$ is the standard deviation of the measured output parameter, and K is a factor from the following reference ; M. G. Natrella, Experimental Statistics, NBS Handbook 91, 1963

| Probe: SF1-US | Acoustic Output | Pulsed Doppler* | |
|---|---|---|---|
| Parameter | ISATA @ Transducer Face/ DF [mW/cm2] | MI [Unitless} | $I_{SPTA.3}$ [mW/cm$^2$] |
| Sample Size | 3 | 3 | 3 |
| K | 4.258 | 4.258 | 4.258 |
| Mean ( $\bar{x}$ ) | 13.1 | 0.0182 | 2.53 |
| Standard Deviation ($S_x$) | 0.406 | 1.88E-3 | 0.496 |
| Limit (X) | 14.8 | 0.0261 | 4.64 |

* Note: Values for reference only as these values are not used to define output limits for pulsed Doppler fetal heart rate monitors.

# 12. 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.

# 13. 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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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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