INSTRUCTIONS FOR USE

# Sonicaid® Freedom

## Wireless Fetal Monitoring System


**NOTE: Before operating this device ensure that the RF channel has been set-up in accordance with section 4.1 – Selecting / Changing the RF-channel.**

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# 1. Introduction

## 1.1 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 approved Fetal Monitors such as Sonicaid FM820, FM830 Encore Fetal Monitors ('FM800E Monitors') and Team Monitors *(Excluding TeamIP)* as an alternative to their wired transducers. When connected to a suitably approved 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.**

## 1.2 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.**

## 1.3 Unpacking / Preliminary Checks

**Contents (supplied with each system)**

| Item | Item | Item |
|---|---|---|
| 1 x Sonicaid™ Freedom Receiver Unit (WMTS: SF1-SL or ISM: SF1-EUR) | 1 x Instructions for Use | 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.

## 1.4 Service Life

This has been defined as the minimum time period during which the device is expected to remain safe and suitable to meet its intended use, and all risk control measures remain effective.
Huntleigh Healthcare Ltd's commitment is that the expected service life for this Device has been defined as 7 years.

# 2. Safety

**Before using this equipment, please study this manual carefully and familiarise yourself with the RF-channel setting (section 4.1), receiver, transducers, the indicators and operation. Ensure that each user fully understands the safety and operation of the unit, as misuse 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.**

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.

**This device may only be used in combination with one of Huntleigh Heathcare Ltd's ('Huntleigh') Sonicaid™ FM800E or Team fetal monitor range (excluding TeamIP). The FM800E monitor range includes model numbers FM820E and FM830E.**

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

**Refer to the appropriate Fetal Monitor Instructions for Use for details of operation and handling.**

**Refer to Section 3.4 of this manual for definitions of all symbols used on product labelling.**

## 2.1 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 bumper. 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.** |
| ⚠ | **Do not modify this equipment without authorisation of the manufacturer.** |

# 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-EUR or SF1-SL). There are two receiver models operating at different radio frequencies for different markets. "SF1-EUR" is for use in regions that use the ISM wireless standard; "SF1-SL" is for use in regions that use the WMTS wireless standard. 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 Fetal Monitor 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 cables gives the patient greater freedom of movement in & out of bed
- 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 radio frequency (RF) transmitters. Signals are transmitted in an ISM or WMTS band according to location and local regulations. The SF1-EUR (ISM) has 26 channels, and SF1-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 Fetal Monitor, and line voltage input for power.

The receiver and transducers have no buttons to operate. When identified transducers are undocked, they are switched on automatically and the receiver indicates the status of batteries and the quality of the incoming RF-signal. When unidentified transducers are undocked, they are switched off.

To start monitoring, 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

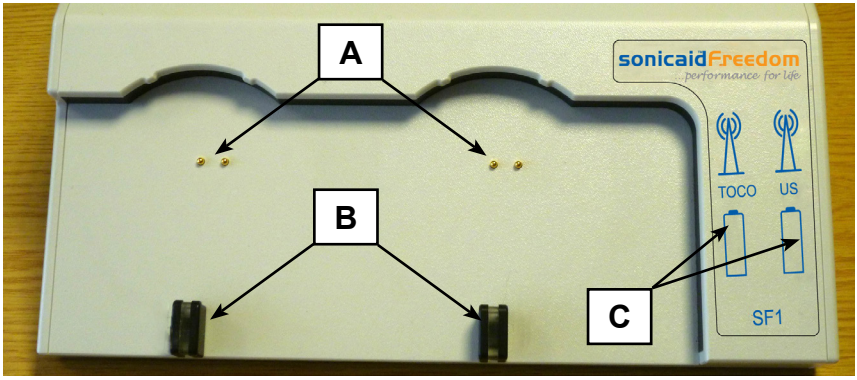
### 3.2.1 Operation

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, wait 10 seconds. All units are now switched off. All modules are turned on when the receiver is powered again. When power is applied with an ultrasound transducer docked in the charging bay, it is automatically registered as belonging to this particular receiver (referred to as "pairing" or "paired"). This ensures that, where multiple wireless systems are being used in close proximity, there is no interference between systems. Successful pairing is indicated by the charge position LED switching on (not flashing).

**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 Bays

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. 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.

**Note: The gold plated contact rings MUST be clean & dry before the transducer is docked. Failure to ensure this may cause corrosion, poor contact and may invalidate the warranty.**

## B - Charge Bay LEDs

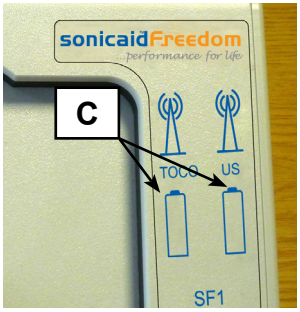
The battery state during charging is indicated as follows:

- **LED off:** No transducer detected
- **LED on:** Transducer is being charged. The battery capacity is displayed in the corresponding battery Indicator (C)
- **LED flashing:** Transducer not paired but charging. This allows transducers to be charged on any receiver unit. Note, however, that no battery charge indicator is displayed in this mode.

If the LED flashes with a transducer which is correctly paired, remove the transducer and re-dock it using a rapid snap-in action. Hesitation when docking may result in the transducer not being recognised.

**Note: Flashing LED - If the problem persists, rotating the transducer in the docked position may clear the problem. A flashing LED may also occur if the docking contacts, or the contact rings on the transducer, are contaminated with fluids, gel, etc. Refer to the cleaning instructions for cleaning these contacts.**

## C - Battery Indicators




Once a transducer has been identified by the receiver, the corresponding battery indicator (C), shows the battery level during operation and the recharge level during charging. Each LED represents about a quarter of the capacity. When the battery is fully charged, all 4 LEDs 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.

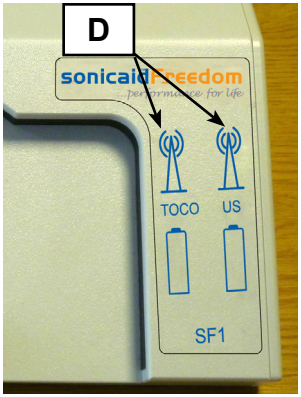
If the transducer has fully discharged, a charging time of about 15 minutes allows for an operation of more than 1 hour.

**LED assignment:**

**US -** Ultrasound-transducer
**TOCO -** TOCO-transducer

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

## D - Transmission Indicators

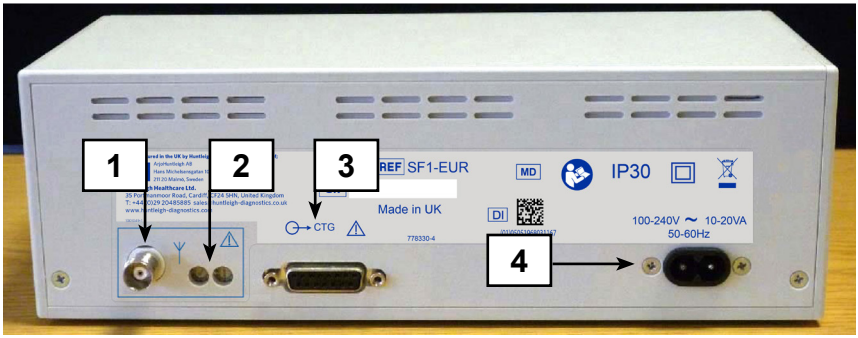



The transmission indicators are located on the upper right corner of the receiver (D). These indicators show the status of TOCO and US transducer transmission:

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

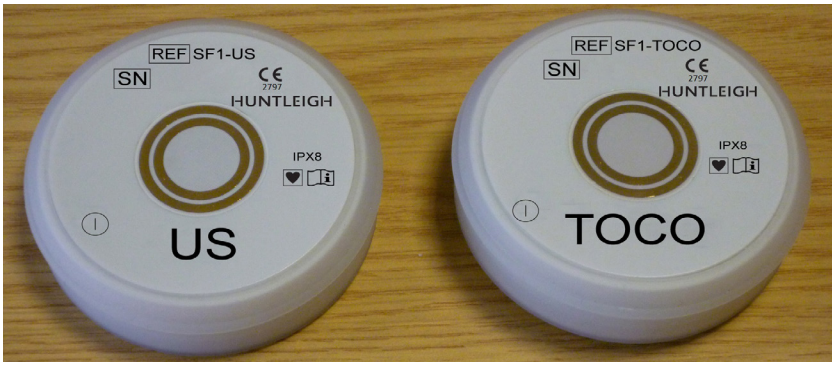
If known to be in range, refer to Section 4.1 to change the channel of the Freedom unit.

### 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>WMTS : 00-99 (100 channels) |
| 3 | Interface to Fetal Monitor CTG |
| 4 | Mains Input, 100…240V, 50…60Hz, 10VA. |

## 3.3 The Transducers



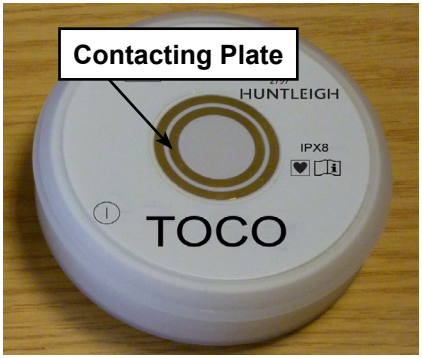

### Indicator

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

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

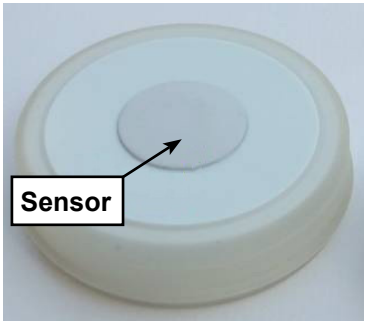
Note that unpaired transducers will switch off when undocked.
If the LED on a paired transducer stays off, refer to the troubleshooting guide (section 8).

### Connections




On the top surface of the transducer is a contact plate. The 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.

## SF1 TOCO - Sensor




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.

## Mechanical Protection



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

## Transducer Application


The transducers are applied using the belt clips supplied, together with the same belts as for the wired transducers.

Replacement belts & clips are available.
Refer to section 9.7 for Recommended Consumables and Accessories.

The belt clips should be clipped over the top face of the transducer, over the gold contact 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 | | |
| **IP30** | Receiving Unit rating for protection against ingress of fluids and particulate. | | |
| **IPX8** | Transdducer rating for protection against ingress of fluids and particulate: The transducers are designed for operation under water. (1M for 16 hours) | | |
| CE 2797 | This symbol signifies that this product complies with the essential requirements of the Medical Device Directive (93/42/EEC) - Medical Device Regulation (EU/2017/745). | | |
| **Manufactured By:** | **Huntleigh Healthcare Ltd.**<br>35 Portmanmoor Road, Cardiff, CF24 5HN, United Kingdom<br>T: +44 (0)29 20485885 sales@huntleigh-diagnostics.co.uk<br>www.huntleigh-diagnostics.com | | |
|  | Legal Manufacturer in association with the CE mark in Europe<br>ArjoHuntleigh AB<br>Hans Michelsensgatan 10 211 20 Malmö, Sweden | | |
|  | 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. | | |
|  | Applied parts type CF |  | Alternating current (AC) |
|  | General Warning or Caution. |  | Refer to Instructions for Use |
| **SN** | Serial Number | **REF** | Product Number / Model Number |
|  | Transducer Indicator (On / Off Symbol) |  | Fetal monitor (CTG) connection point |
|  | Antenna or Aerial connection point |  | Battery Indicator |
| **MD** | Medical Device | **DI** | Device Identifier |
| **US** | Ultrasound Transdducer | **TOCO** | ContractionsTransducer |
|  | Transmission Symbol | **NOTE** | **A NOTE provides useful information regarding a function or a procedure.** |

# 4. Setup

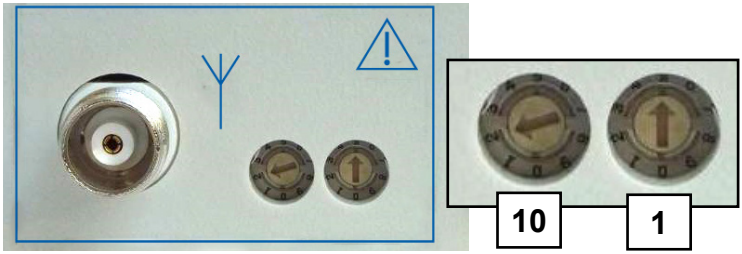
**WARNING: These requirements must be met when Sonicaid™ Freedom is connected to any other electrical equipment.**

1 Medical equipment must comply with IEC60601-1/EN60601-1, or equivalent.

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

## 4.1 Selecting / Changing the RF-channel

Wireless transmission can be disturbed by other transmitters running on the same frequency. **If there are several Freedom units in one ward, all receivers must be set to different channel numbers**. The operating channel is set using the controls located on the rear panel of the Freedom receiver. This is performed as follows:




Use the code-switches on the rear panel of the receiver to select the new channel number.

| | |
|---|---|
| ISM : | 00 - 25 (26 channels) |
| | (channels 26-99 are same as channel 99) |
| WMTS (USA) : | 01 - 99 (100 channels) |
| | (channel 00 is same as channel 01) |

**Note : Check and ensure that for all Sonicaid Freedom units deployed within your facility; that all receivers are set to different channels. This means that in the UK & Europe (ISM Region), each individual unit in your facility MUST be set to an individual channel number, from Channel 00 to channel 25. Please note that in the ISM region, selecting channels 26-99 will NOT result in separate RF channels and this must be avoided.**

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

## 4.2 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 receiving antenna.**

1. Connect the interface cable which is clearly identified, from output of the receiver unit to the interface input of the fetal monitor.
2. Dock the transducers with the receiver powered off.
3. Connect the mains supply lead from the receiver unit to mains supply. This will pair the receiver and transducers.
4. Charge the transducer batteries.
5. Switch on the Fetal Monitor (refer to its Instructions for Use).

The system is ready for monitoring.

## 4.3 Testing the Basic Functions

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

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

- charge bay 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 bay LED and battery indicator LEDs turn on

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

- charge bay LED turns off
- LED in US-transducer starts flashing
- US-transmission indicator LED turns green
- US battery indicator LEDs indicate charge status
- US channel becomes active: US is indicated on fetal monitor

**4. Simulate audio signal:**

- Stroke bottom face of transducer at approximately 2 strokes per second to simulate a fetal heart signal.
- fetal monitor shows heart rate, after a short delay.

**5. Remove the TOCO-transducer:**

- charge bay LED turns off
- LED in TOCO-transducer starts flashing
- TOCO-transmission indicator LED turns green
- TOCO battery indicator LED's indicate charge status
- TOCO channel becomes active: TOCO is indicated on fetal monitor

**Note : The TOCO transducer must be in operating range of the US transducer (Maximum range 30cm).**

**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 bay LED turns on
- US battery bay LEDs indicate charge status
- Fetal monitor returns to normal operating mode with wired transducers.

**8. Dock TOCO transducer for charging**

- charge bay LED turns on
- TOCO battery indicator 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 Fetal Monitor (refer to its Instructions for Use)
- Apply transducers to the patient (Refer to Section 5.2).

When the US-transducer is undocked from the charging bay, 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.

## 5.2 Application of the Transducers

**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. Adjust for best, clear, fetal heart sounds. Refer to the Fetal Monitor instructions for use for further information.
- Secure firmly with the belt. For optimum performance during periods of mobility, ensure that the belt is tight enough to prevent the transducer slipping. Avoid patient discomfort through excessive tightening.

**TOCO transducer**

- Position the TOCO transducer over the fundus of the uterus (refer to the Fetal Monitor instructions for use for further application information), and fasten it securely.
- Allow the system to stabilise for 20-30 seconds while communication is fully established with the fetal monitor.
- Adjust the TOCO baseline using the toco zero button on the Fetal Monitor, once the system has stabilised.
- After any drop-out in the wireless link, it will be necessary to re-zero the toco channel when communication is re-established. Allow the system to stabilise as above before re-zeroing.

**Note: The TOCO-transducer transmits its signals to the US-transducer. The distance between them should not exceed 30cm. If this range is exceeded, toco data will be lost. When it comes back in range, the stabilisation period & re-zeroing as detailed above will need to be repeated.**

**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. For further information on this, refer to the Fetal Monitor instructions for use.**

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. For further information on this refer to the Fetal Monitor instructions for use.**

## 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.

**Note**

Monitoring while the patient is moving or walking may result in increased artefact or drop-out on the trace. To minimise this, ensure the transducers are securely strapped on using good quality belts. It may be necessary to tighten these more than usual to keep the transducers in position.

If the patient moves outside the wireless range, the signal will be lost. This is indicated by the transmission indicators on the receiver flickering or turning amber. Note also that within the wireless range, there may be “dead spots” where there is no signal due to building construction or interference from other sources.

Other wireless systems working on the same frequency can also interrupt ambulatory monitoring. In this case, the system should be set to a different frequency. To change the frequency, please refer to Section 4.1.

## 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 transducers are under water, this reduces the range. Positioning the receiver in line of sight of the transducers may improve reception. 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 bumpers (‘bumper’).

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

### Method 2 (Medium Risk)

**Remove the bumpers before cleaning.**

1. Remove soiling and clean the transducers and the internal and external surfaces of bumpers with a mild detergent and then rinse in water.
2. Completely dry the transducers and the inside and external surfaces of the bumper.
3. Wipe transducers and bumpers 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 bumper ensuring 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 bumpers before cleaning.**

1. Remove soiling and clean the transducers and the internal and external surfaces of the bumpers with a mild detergent and then rinse in water.
2. Completely dry the transducers and the inside and external surfaces of the bumpers.
3. Wipe transducers and bumpers 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 bumper 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, Fetal Monitor connection cable, receiver, transducer protective bumpers 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 bumpers

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, Fetal Monitor 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 |
| | Re-pair the transducers to receiver. (See section 4). |

| Transmission Indicators flicker sporadically amber/green when patient is walking. | |
|---|---|
| **POSSIBLE CAUSE** | **SOLUTION** |
| Patient out of range. | Ensure the patient understands the range limits and any local "dead spots" to avoid. |

| 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 4.1. |

| Charging indicator is off even though the transducer is 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. |
| TOCO baseline zeroed before wireless system has stabilised | Wait for 20-30s after activating the wireless system before using the fetal monitor contractions zero function. Note that it may be necessary to repeat the contractions zero function after any drop-out in the wireless link, allowing the system to re-stabilise on each occasion. |

| 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 replaced. |

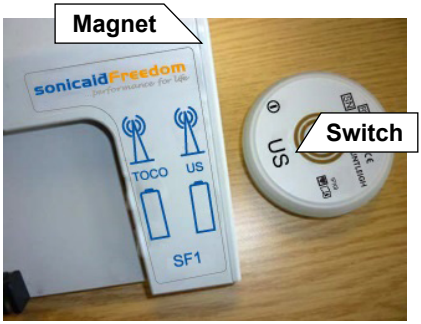
| Receiver or Transducer does not respond | |
|---|---|
| **POSSIBLE CAUSE** | **SOLUTION** |
| The discharge of static electricity may have disabled the receiver. | Disconnect the power cord for about 5 seconds. Re-connect the cable. |
| The discharge of static electricity may have disabled the transducer. | Refer to section 8 for re-setting transducers. |

| Green LED of undocked Transducer does not have normal operational pattern. | |
|---|---|
| **POSSIBLE CAUSE** | **SOLUTION** |
| No LED (Not paired- Normal operation)<br><br>No LED<br>Unusual green LED pattern<br>Solid green LED<br><br>Transducers may be locked | Pair transducers (See Section 4)<br><br>Redock transducer, wait for identification.<br>Undock and recheck. Try 3 times.<br><br>Manually Switch off Transducers (Refer to 8.1 and 8.2)<br>If problem persists, transducer is faulty. |

| No battery indicator LEDs illuminated | |
|---|---|
| **POSSIBLE CAUSE** | **SOLUTION** |
| RF Interference | Occasionally, the battery indicator LEDs may show absence of charge. As long as the transducers have been properly docked, with the charge bay LEDs showing that charging is in progress for a minimum of 15 minutes, the transducers should operate normally. (Refer to Section 3.2) |

## 8.1 Manually Switching off the Transducers

If the green LED of the ultrasound 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 “TOCO” or “US” are as shown.

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. After a short delay, the operating status will be indicated (refer to section 3.2).

# 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-EUR / SF1-SL : IP30<br>Transducer - SF1-US : IPX8 (1m for 16 Hours)<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-EUR / SF1-SL)

| | |
|---|---|
| **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 bays for SF1-US and SF1-TOCO |
| **Charging time** | Maximum:  3 hours, 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 |
| **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-EUR / SF1-SL) |
| **Range** | Up to 30m, from under-water up to 8m (subject to local environment) |
| **Modulation** | Digital, FSK |
| **Antenna** | Helix |
| **RF-Transmitter** | According to receiver: SF1-EUR (ISM), SF1-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 90% (non condensing) | **Relative Humidity** | 10% to 93% (non condensing) |
| 86 kPa to 106 kPa | **Pressure** | 86 kPa to 106 kPa |

## 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>EN60601-1-6:2010, IEC 60601-2-37:2007 |
| **Electromagnetic Compatibility** | EN60601-1-2:2007<br>FCC 47 Part 15 Subpart B |
| **Radio** | ETSI EN 300 220-2: V2.3.1 (2009-12)<br>ETSI EN 301 489-1 V1.9.2 (2011-09)<br>ETSI EN 301 489-3 V1.6.1 (2013-06)<br>FCC 47 CFR Part 15 Subpart C and Part 95; Subpart H (WMTS), RSS-210 |
| **Labelling** | BS EN15223-1:2012 |

## 9.7 Recommended Consumables & Accessories*

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

| Item | PN |
|---|---|
| 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 |
| Transducer Clips | ACC-OBS-051 |
| Ultrasound Transducer (SF1-US) | ACC-OBS-055 |
| TOCO Transducer (SF1-TOCO) | ACC- OBS-053 |
| Transducer Bumper | 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, it 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:

- Re-orienting 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 Sonicaid Freedom’s ultrasound transducer, which is used with Huntleigh's approved fetal monitors, has a single mode of operation, with fixed acoustic output parameters that are not user adjustable.  Refer to Table 1 for the Acoustic Output Reporting Table used for ultrasound devices following FDA Track 1.

| Table 1<br>Acoustic Output Reporting Table for Track 1 – Non-Auto-scanning Mode<br>Sonicaid Freedom Wireless Fetal Monitoring System<br>Operating Mode: PWD<br>Application(s): Fetal Monitoring | | | | | |
|---|---|---|---|---|---|
| **Acoustic Output** | | | **MI** | **$I_{SPTA.3}$ (mW/cm²)** | **$I_{SPPA.3}$ (mW/cm²)** |
| **Global Maximum Value*** | | | 0.0261 | 4.64 | 17.5 |
| **Associated Acoustic Parameters** | **$Pr_{.3}$ (MPa)*** | | 0.0258 | | |
| | **$W_o$ total (mW)*** | | | 27.5 | 27.5 |
| | **$f_c$ (MHz)** | | 1.024 | 1.024 | 1.024 |
| | **$Z_{sp}$ (cm)** | | 4.50 | 4.50 | 4.50 |
| | **Beam Dimensions** | **$x_{-6}$ (cm)** | | 4.64 | 4.64 |
| | | **$y_{-6}$ (cm)** | | 4.95 | 4.95 |
| | **PD (μS)** | | 91.5 | | 91.5 |
| | **PRF (Hz)** | | 2900 | | 2900 |
| | **Overall EBD (cm)** | **Az. (cm)** | | 5.0 | |
| | | **Elev. (cm)** | | 5.0 | |

*** Note: The Global Maximum Values of MI and intensity, and also pressure and power, are statistical maxima calculated using a one-sided tolerance analysis for normal distributions using test data from three samples taken from a production batch**

| Table 2: Acoustic Output Parameters for Unfocused Fetal Heart Rate Monitors | |
|---|---|
| **Parameter** | **Value** |
| $I_{SATA}$ @ Transducer Face (Note 1) | 3.92 mW/cm² |
| $I_{SATA}$ @ Transducer Face / DF (Note 1) | 14.8 mW/cm² |
| Area of Entrance Beam Dimensions ($A_{EBD}$) (Note 2) | 7.02 cm² |

**Note1: The values $I_{SATA}$ are statistical maxima calculated using a one-sided tolerance analysis for normal distributions using test data from three samples taken from a production batch. See table 3 below.**

**Note 2: This is the area of the radiating elements, which is used in the calculation of $I_{SATA}$ @ Transducer Face.**

The derated pressure and intensity values were calculated in accordance with NEMA UD 2-2004 (R2009), *Acoustic Output Measurement Standard for Diagnostic Ultrasound Equipment, Revision 3*, from pressures measured in water using a derating factor of 0.3dB $cm^{-1}$ $MHz^{-1}$. Searches for the global maximum acoustic output were performed using derated values, because the derated maxima usually occur at a shorter axial range than the in-water maxima. The derating factor for pressure is exp (-0.115 * 0.3 * $f_c$ * z) and for intensity the factor is exp (-0.23 * 0.3 * $f_c$ * z) where $f_c$ is center frequency in MHz and z is axial distance in cm.

## Definition of Terms

| | |
|---|---|
| $I_{SPTA.3}$ | The derated spatial peak temporal average intensity |
| $I_{SPPA.3}$ | The derated spatial peak pulse average intensity |
| $I_{SATA}$ | The spatial average temporal average intensity |
| **MI** | The mechanical index |
| $Pr_{.3}$ | The derated peak rarefactional pressure |
| $W_o$ | The ultrasonic power |
| $f_c$ | The acoustic center frequency |
| $z_{sp}$ | The axial distance at which the reported parameter is measured |
| $x_{-6}$ $y_{-6}$ | respectively the in-plane (azimuthal) and out-of-plane (elevational) -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 azimuthal and elevational planes |

## Statistical Analysis of Measurement Data

**Table 3** contains the results from a statistical analysis 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:

$$X = \bar{x} + KS_x$$

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. K is chosen such that there is 90% confidence that the output levels of 90% of all units will not exceed the limit X.

**Table 3: Example of Statistical Measurement Data**

| Probe: SF1-US | Acoustic Output | Pulsed Doppler* | |
|---|---|---|---|
| **Parameter** | **$I_{SATA}$ @ Transducer Face / DF [mW/cm²]** | **MI** | **$I_{SPTA.3}$ [mW/cm²]** |
| Sample Size | 3 | 3 | 3 |
| K | 4.258 | 4.258 | 4.258 |
| Mean | 13.1 | 0.0182 | 2.53 |
| Standard Deviation | 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.**

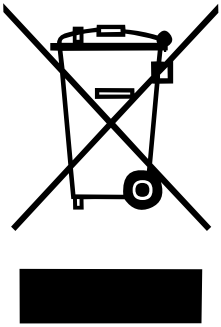
### Measurement Uncertainty

**Table 4** contains the measurement uncertainty of the acoustic output parameters stated in tables 1, 2 and 3 above.

**Table 4: Measurement Uncertainty of Acoustic Output Parameters**

| Parameter | Measurement Uncertainty |
|---|---|
| All Pressure Measurements | ± 6.4% |
| Mechanical Index | ± 6.4% |
| All Intensity Measurements | ± 12.7% |
| Center Frequency ($f_c$) | ± 2% |
| Ultrasonic Power ($W_0$) | ± 12.7% |

# 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 '

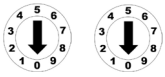
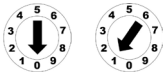
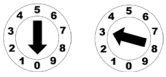
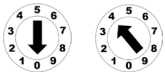
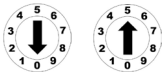
For further details, refer to NHS document HSG(93)26 (UK only).

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,
35, Portmanmoor Rd.,
Cardiff. CF24 5HN
United Kingdom.

Tel: +44 (0)29 20496793 - Service (24hr answer machine)
Tel: +44 (0)29 20485885
Fax: +44 (0)29 20492520
Email: sales@huntleigh-diagnostics.co.uk
service@huntleigh-diagnostics.co.uk
www.huntleigh-diagnostics.com

# Appendix 1 Sonicaid Freedom RF Channel Setting and Location Record

| Channel # | ISM Channel | RF Channel Setting | Freedom Location/Ref |
|---|---|---|---|
| 1 | 00 |  | |
| 2 | 01 |  | |
| 3 | 02 |  | |
| 4 | 03 |  | |
| 5 | 04 |  | |
| 6 | 05 |  | |
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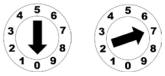
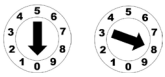
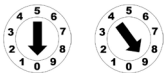
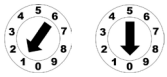
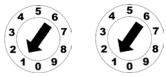
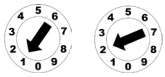
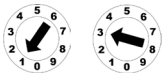
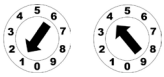
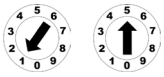
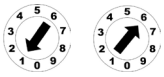
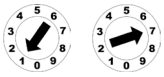
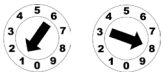
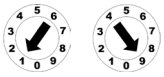
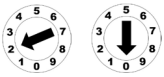
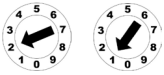
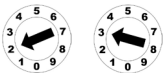
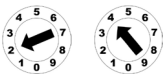
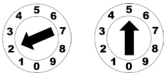
| 8 | 07 |  | |
| 9 | 08 |  | |
| 10 | 09 |  | |
| 11 | 10 |  | |
| 12 | 11 |  | |
| 13 | 12 |  | |

| Channel # | ISM Channel | RF Channel Setting | Freedom Location/Ref |
|---|---|---|---|
| 14 | 13 |  | |
| 15 | 14 |  | |
| 16 | 15 |  | |
| 17 | 16 |  | |
| 18 | 17 |  | |
| 19 | 18 |  | |
| 20 | 19 |  | |
| 21 | 20 |  | |
| 22 | 21 |  | |
| 23 | 22 |  | |
| 24 | 23 |  | |
| 25 | 24 |  | |
| 26 | 25 |  | |

This section is only applicable to United Kingdom (UK) market when UK marking is applied to the Arjo medical device labelling.

**UK Symbol:**

| | |
|---|---|
| UK CA 0086 | UK marking indicating conformity with UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended) Figures indicate UK Approval Body supervision. |

**UK Responsible Person & UK Importer:**

**Arjo (UK) Ltd., ArjoHuntleigh House, Houghton Regis. LU5 5XF**

Is the appointed UK Responsible Person as defined in UK Medical Devices Regulations 2002 (SI 2002 No 618, as amended).

For Northern Ireland (NI) CE marking will still apply until further amendment to applicable regulations.

**1001071-2**

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

**Manufactured in the UK by Huntleigh Healthcare Ltd on behalf of;**

ArjoHuntleigh AB
Hans Michelsensgatan 10
211 20 Malmö, Sweden

CE 2797

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**A Member of the Arjo Family**
As our policy is one of continuous improvement, we reserve the right to modify designs without prior notice.

HUNTLEIGH

**1001048-4**