



Field Safety Notice

FSN02-22

Sonicaid Freedom – Wireless Fetal Monitoring System

Products affected by this notice:

Product Name(s): **Sonicaid Freedom**

Affected Serial Numbers: **All**

Order / Ident Codes: **SF1-EUR (DI: 05051968031167)**

Product First Sold: **January 2013**

Dear Customer,

Our records indicate that you have one or more Sonicaid Freedom Wireless Monitoring systems within your facility.

We are contacting you to provide information regarding an urgent medical device notification initiated by our company to address a recently detected potential issue concerning the incorrect setup of the RF channel when using multiple units.

Huntleigh has received a report from a user regarding the potential for inappropriate clinical diagnosis and the potential to cause an adverse event due to the incorrect setup of the RF channels. In the particular case in question, both units had been inadvertently set to the same RF channel and were placed in close proximity to each other, leading to the second unit displaying the FHR from the first unit. Please be assured that there have been no injuries reported concerning this issue.

This Notice is firstly to inform all users of the importance of reading the Instruction For Use (IFU) before using any medical device supplied by Huntleigh Healthcare Ltd to ensure correct set up is achieved avoiding any harm to users and/or patients. Secondly to reiterate the set up for the Sonicaid Freedom (where there is more than one device in use), specifically focusing on the selection of the RF channels on each asset.

We would like to reiterate that the Sonicaid Freedom, together with the connected Huntleigh Fetal monitor, provides just one indicator of fetal condition. This should be assessed as part of an holistic approach to obstetric care together with other factors. A complete assessment must be made before taking appropriate action. If there is any doubt concerning the accuracy of any measurement, an alternative method should be used.

What to do (distributor/end user);

1. Make sure to read and follow IFU: 778332EN before using the Sonicaid Freedom system.
2. Check and ensure that for all Sonicaid Freedom units deployed within your facility; **that all receivers are set to different channels.**
3. This means that in the UK & Europe (ISM Region) that 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.
4. **The process of channel selection is** documented in this notice and in the IFU (778332EN-8 page 32). The IFU is available to download from www.huntleigh-diagnostics.com/ifus-fetal-monitoring
5. We also recommend that you make use of the accompanying deployment record that is included in this FSN, to ensure that all receivers are set-up correctly in accordance with the IFU.

Huntleigh is taking this issue seriously, as customer satisfaction and safety are of primary importance to us. We regret any inconvenience that this may cause, however we greatly appreciate your understanding as we take actions to ensure the safety of our caregivers and patients.

Contact

If you have any further questions or require any further assistance, please contact your regional sales manager or email Huntleigh at sales@huntleigh-diagnostics.co.uk

Sincerely,



Simon Larsen
Managing Director



Steve Monks
QRE Director

Document Introduction/Revision History

Rev.	Date	Description of Introduction	Compiled By
1	19/10/2022	Introudction of FSN.	S.Monks
2	28/10/2022	Revised 'Product First Sold' from March 2014 to January 2013	S.Monks

Date of Issue: 19th October 2022
Revised: 28th October 2022 Rev2

HUNTLEIGH
A MEMBER OF THE ARJO FAMILY

Huntleigh Healthcare Limited
35 Portmanmoor Road
Cardiff CF24 5HN
United Kingdom

Phone: +44 (0)29 2048 5885
Fax: +44 (0)29 2049 2520
Email: sales@huntleigh-diagnostics.co.uk
www.huntleigh-diagnostics.com

VAT Reg: GB 382 474 630
Registered No: 942245 England & Wales.
Registered Office: ArjoHuntleigh House,
Houghton Hall Business Park, Houghton Regis,
Bedfordshire, LU5 5XF

Selecting the Appropriate RF Channel

Sonicaid® Freedom

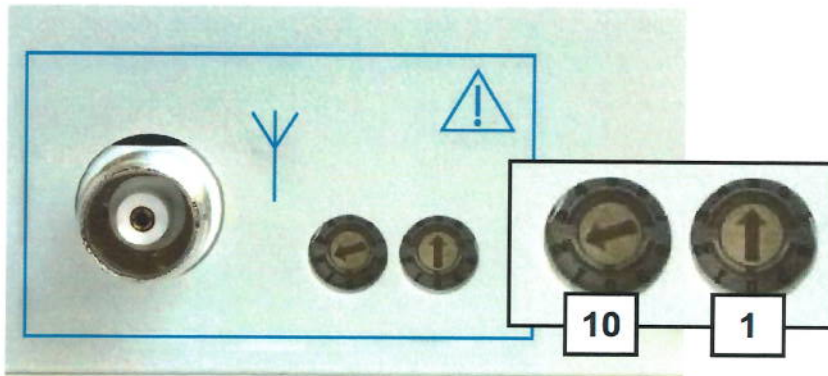


The following is an excerpt for the Sonicaid Freedom IFU 778332EN-8 page 32. Also available to download from www.huntleigh-diagnostics.com/ifus-fetal-monitoring



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:

1. Disconnect the receiver from the mains and wait until all LEDs are off.



2. 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)













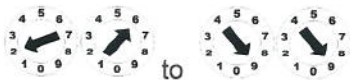
3. Re-connect the receiver unit to mains and wait until the LED test is finished.
4. Insert the US-transducer unit into a charging bay and wait until charging is indicated. Now the new channel is installed for receiver and transducer. This procedure takes about 20 seconds; please do not interrupt this 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.

Sonicaid Freedom Deployment Record, ISM channel settings,

Relevant to all countries outside North America

ISM Channel	RF Channel Setting	Freedom Location/Ref
00		
01		
02		
03		
04		
05		
06		
07		
08		
09		
10		
11		
12		

13		
14		
15		
16		
17		
18		
19		
20		
21		
22		
23		
24		
25		
ISM Channels set at 26 to 99 will ALL be the same channel		DO NOT USE

Declaration Form

FSN02-22

Sonicaid Freedom – Wireless Fetal Monitoring System

(To be submitted to Huntleigh, email steve.monks@arjo.com)

Name:	
Position/Job Title:	
Facility Name / Address:	
Email:	
Tel:	

I declare that:

- I have read fully and understood the importance of this Field Safety Notice (FSN02-22).
- I have read and followed the Instructions For Use (778332EN-8) before deploying and using the Sonicaid Freedom Wireless Fetal Monitoring System.
- All receivers have been set to different allowable RF channels as documented in the Instructions For Use 778332EN-8.
- The deployment record has been completed to ensure that all receivers are set-up correctly in accordance with the IFU.

Name (PRINT): _____

Signature: _____

Date: _____