

نقدم بثقة
Moving Forward
with Confidence



To:

THE DIRECTOR GENERAL OF HEALTH SERVICES IN ALL GOVERNORATES

Commanding Officer, Armed Forces Hospital (Al Khoudh & Salalah)

Director General of Engineering Affairs, MOH

Director General of Royal Hospital

Director General of Khoula Hospital

Director General of Medical Supplies (MOH)

Director General of Pvt. Health Est. Affairs (to kindly arrange distribution to all Pvt. Hospitals)

Hospital Director (Al Nahda Hospital)

Hospital Director (Al Massara Hospital)

The Head of Medical Services in SQU Hospital

The Head of Medical Services in Royal Oman Police

The Head of Medical Services in Ministry of Defence

The Head of Medical Services in The Diwan

The Head of Medical Services in The Sultan's Special Force

The Head of Medical Services in Internal Security Services

The Head of Medical Services in Petroleum Development of Oman

The Head of Medical Services in LNG Oman

ALL PRIVATE PHARMACIES & DRUG STORES

After Compliments,

Please find attached our Circular No 207 dated 14 / 11 / 2022 Regarding NCMDR FSN of Sonicaid Freedom from (mfr: Huntleigh Healthcare).

Copy to:

- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information



PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489

dgpa_dc Email: dg-padcc@moh.gov.om



Circular No. 207/2022

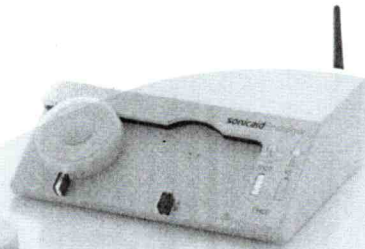
لنقدم
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20-04-1444 H

14-11-2022

Field Safety Notice of Sonicaid Freedom from Huntleigh Healthcare

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=6&rid=17320
Product	Sonicaid Freedom.
Description	Wireless Fetal Monitoring System.
Manufacturer	Huntleigh Healthcare.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	Affected Serial Numbers: All Order / Ident Codes: SF1-EUR (DI: 05051968031167) Product First Sold: March 2014
Reason	Potential issue concerning the incorrect setup of the RF channel when using multiple units.
Action	1. Refer to "What to do" in the attached FSN. 2. Contact the local agent for remedial action.
Product image	
comments	Healthcare professionals are encouraged to report any adverse events Suspected to be associated with the above device or any other medical device to Department of Medical Device Control through the E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
Director General



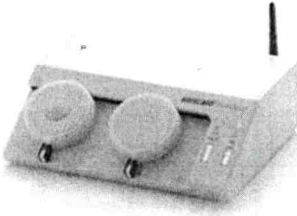
PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control



ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩

P.O. Box: 393 Muscat - Postal Code : 100 - Tel: 22357111 - Fax: 22358489

dgpa_dc Email: dg-padcc@moh.gov.om



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: **March 2014**

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,



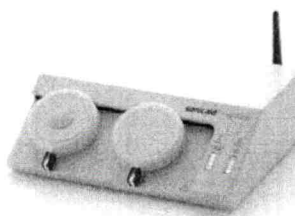
Managing Director



QRE Director

Selecting the Appropriate RF Channel

Sonicaid® Freedom

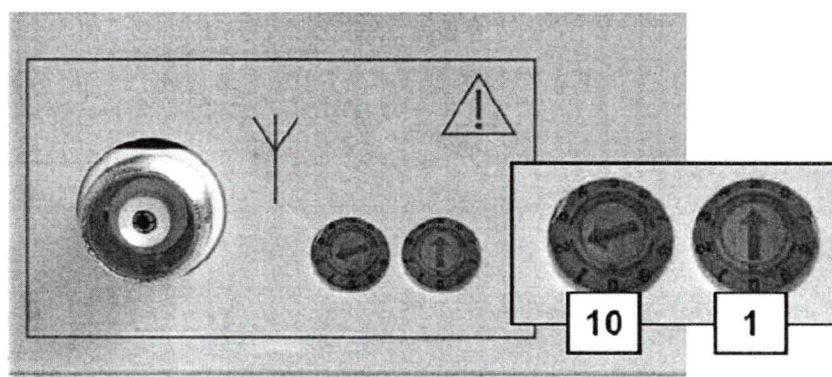


The following is an excerpt for the Sonicaid Freedom IFU 778332EN-8 page 32. Also available to download from www.huntleigh-diagnostics.com/ifus-fetal-monitoring



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.

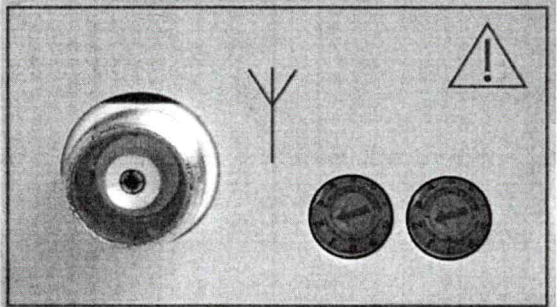

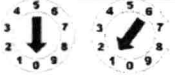








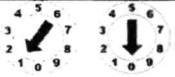


ISM : 00 - 25 (26 channels)







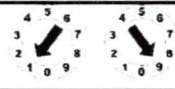
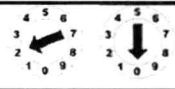
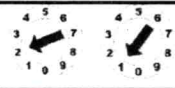
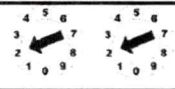
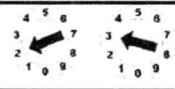
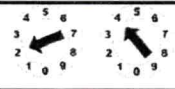

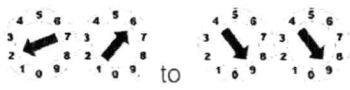
(channels 26-99 are same as channel 99)

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	 to 	DO NOT USE

Declaration Form

FSN02-22

Sonicaid Freedom – Wireless Fetal Monitoring System

(To be submitted to Huntleigh, email [REDACTED])

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: _____