



نقدم بثقة
Moving Forward
with Confidence

رؤية عمان
2040
Oman Vision

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 99 dated 24/5/23 Regarding NCMDR Field Safety Corrective Action of Team3 Fetal Monitor 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



PADDC
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

Twitter: dgpa_dc Email: dg-padc@moh.gov.om



Circular No. 99/2023


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04 -11-1444 H

24 -05-2023

Field Safety Corrective Action of Team3 Fetal Monitor from Huntleigh Healthcare.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=19546
Product	Team3 Fetal Monitor.
Description	Medical electronics / Electromedical devices – electrodiagnostics.
Manufacturer	Huntleigh Healthcare.
Local agent	Muscat Pharmacy & Stores LLC.
The affected products	TEAM3A & TEAM3I See appendix 1 for all variants
Reason	A software vulnerability, which manifests itself with the fetal monitor's touch screen freezing.
Action	1. Upgrade Fetal Monitor with revised software (VI 9.4). 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



FIELD SAFETY NOTICE ALERT

Team3 Fetal Monitor

Product affected by this notice :

Product Name(s):	TEAM3A & TEAM3I
Affected Serial Numbers:	All
Order / Ident Codes (DI):	See appendix 1 for all variants
Product First Sold:	October 2016

GMDN:	37796
EMDN:	Z12080101
SRN:	SE-MF-000000696
Basic UDI-DI:	5060693520389WY
510k/Clearance Number:	K200975/D410520
HC License number:	104905 (Antepartum) & 104907 (Intrapartum)
ARTG Identifier:	116216

Resolution in summary:	Upgrade Fetal Monitor with revised software (v19.4)
No pages:	15 inclusive of the declaration form

FSN01-23

Date of issue: 3rd April 2023

HUNTLEIGH

A MEMBER OF THE ARJO FAMILY

To whom it may concern;

We are contacting you to provide information regarding a Field Safety Corrective Action.

Description of problem;

Huntleigh Healthcare Ltd has become aware of a software vulnerability, which manifests itself with the fetal monitor's touch screen freezing. This freeze disables the functions that are being displayed. Whilst the occurrence of this vulnerability is extremely rare and audio remains present throughout the screen freeze, user intervention is required to restart the fetal monitor.

Risk based approach;

Through discussions with the UK competent authority (MHRA) it has been agreed to remove the necessity for user intervention by automatically restarting the fetal monitor when the device detects any power loss and/or interference. The automatic restart will reinstate all functions/features and settings. The restart will appear as a normal ON/OFF action and will take approximately 20 seconds from start to finish with the action noted on the CTG trace as well as a transient note on the touch screen.

Please note that Dawes Redman CTG analysis will reset to the beginning of the analysis after the system automatically restarts.

Actions to be taken by the User and/or Distributor;

A software upgrade – V19.4 - must be installed on the TEAM3 Fetal Monitors listed in Appendix 1. This upgrade will be available to download from the Huntleigh Healthcare website (<https://www.huntleigh-diagnostics.com/Team3Upgrade19.4>) together with clear instructions on how to install the software on the fetal monitor. Appendix 2 also details instructions regarding the software download and installation.

Once the upgrade is complete on all devices within your facility, please return the completed Declaration (refer to Appendix 3) to:

FSN01-23HHL@Arjo.com

Transmission of Field Safety Notice;

Please ensure that this notice is circulated to all appropriate personnel.

Patient safety and customer satisfaction are of paramount importance to Huntleigh Healthcare Ltd and we regret the obvious inconvenience that this notice will cause.

FSN01-23

Date of issue: 3rd April 2023

HUNTLEIGH

A MEMBER OF THE ARJO FAMILY

Contact

Please do not hesitate to contact the following personnel should you have any further questions or require any assistance:

Declaration Form to be sent to Email: FSN01-23HHL@Arjo.com

QRE Director	Email: steve.monks@arjo.com	Tel: +44 (0) 2920485885 Ext: 7107
Complaints Specialist	Email: michael.James@arjo.com	Tel: +44 (0) 2920485885 Ext: 7016
Service Manager	Email: gary.newton@arjo.com	Tel: +44 (0) 2920485885 Ext: 7112
Product Management	Email: David.dobbs@arjo.com	Tel: +44 (0) 2920485885

Sincerely,



Document Introduction/Revision History

Rev.	Date	Description of Introduction	Compiled By
1	03/04/2023	Introduction of FSN.	