Sultanate of Oman
Ministry of Health
Directorate General of Pharmaceutical Affairs and Drug Control
Muscat

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 26 / 2023

07 -07-1444 H

29 -01-2023

Field Safety Corrective Action of Monnal T60 ventilators from Air Liquide Medical Systems.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18416
Product	Monnal T60 ventilators.
Description	Ventilators.
Manufacturer	Air Liquide Medical Systems.
Local Agent	Global Source Trading LLC.
The affected products	Monnal T60 range: References: KA010000 - KA013700 - KA017114 - KA017115 Monnal T60 Advanced range: References: KA017119 - KA017124 - KA017122 - KA017127 - KA017128 - KA017129 - KA017130.
Reason	Air Liquide Medical Systems has assessed three situations concerning the settings of ventilation parameters for the Monnal T60 range that could pose a risk, despite the existing software safety features: Situation 1: Possibility of having an Fio2 setpoint applied that is different to the setpoint displayed after using the 100% O2 function. Situation 2: Inheritance of setpoints. Situation 3: Oxygen therapy.
Action	1. Air Liquide Medical Systems requests installation of the latest available software version correcting the listed situations . 2. Contact the local agent for remedial action.
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-padc@moh.gov.om

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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 26 **dated** 29/1/2023 **Regarding NCMDR FSCA of DR-XD 1000(FDR Nano) from Ethicon Inc from (mfr: FUJIFILM Medical Systems).**

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**

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Kingdom of Saudi Arabia
Saudi Food & Drug Authority

Medical Devices Sector

قطاع الأجهزة الطبية

NCMDR

National Center for Medical Devices Reporting

المركز الوطني لبلاغات الأجهزة والمنتجات الطبية

BfArM Recall

Back

Reference Number: mdprc 009 01 23 000
Date submitted: 1/17/2023

Manufacturer:	FUJIFILM Medical Systems
Device Type:	DR-XD 1000(FDR Nano)
Description:	Radiological technology - mobile radiological diagnostic facilities
Medical Device Identifier:	DR-XD1000 Serial No. with last 4 numbers 1993 or less, see attachment for detailed instructions to identify the Serial Number of the DR-XD1000.
Reason of Field Safety Corrective Action:	The arm part wobbled while moving this device and that an arm broke during arm movement.
Remedy Action:	FUJIFILM service engineer will contact all of the medical facilities where the applicable products have been installed to arrange a visit for this correction and implement the measures.
Athorized Representative/Importer/Distributor:	FAROUK, MAAMOUN TAMER & COMPANY
Report Source:	BfArM
Source Ref. Number:	32113/22
SFDA Comments:	SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company.
Attachments:	FUJIFILM.pdf

View History