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

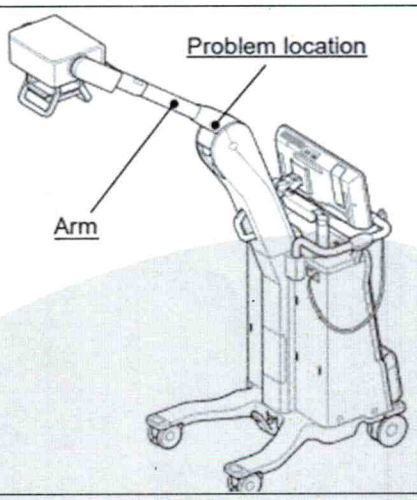
سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة والرقابة الدوائية
مسقط

Circular No. 23 **/ 2023**

07-07-1444 H

29 -01-2023

Field Safety Corrective Action of DR-XD 1000(FDR Nano) from FUJIFILM Medical Systems

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=6&rid=18417
Product	DR-XD 1000(FDR Nano).
Description	Radiological technology - mobile radiological diagnostic facilities.
Manufacturer	Fujifilm Medical Systems.
Local Agent	Advanced International Business Group (AIBG).
The affected products	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	The arm part wobbled while moving this device and that an arm broke during arm movement.
Action	1. FUJIFILM will correct and implement the measures. 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-padc@moh.gov.om

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نتقدم بثقة
Moving Forward with Confidence

رؤية عُمان 2040

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 23 **dated** 29/01/2023 **Regarding NCMDR FSCA of Monnal T60 ventilators from (mfr: Air Liquide 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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Directorate General of Pharmaceutical Affairs & Drug Control

ISO 9001:2015 CERTIFIED

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

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NCMDR Recall

Reference Number: mdprc 008 01 23 000 Back
Date submitted: 1/15/2023

Manufacturer:	Air Liquide Medical Systems.
Device Type:	Monnal T60 ventilators
Description:	Ventilators
Medical Device Identifier:	Monnal T60 range: References: KA010000 - KA013700 - KA017114 - KA017115 Monnal T60 Advanced range: References: KA017119 - KA017124 - KA017122 - KA017127 - KA017128 - KA017129 - KA017130.
Reason of Field Safety Corrective Action:	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.
Remedy Action:	Air Liquide Medical Systems requests installation of the latest available software version correcting the listed situations during the next maintenance of the device (preventive or corrective), and at the latest within one year.
Athorized Representative/Importer/Distributor:	Bio Standards
Report Source:	NCMDR
Source Ref. Number:	A7E50F3BE32B9
SFDA Comments:	SFDA urges all healthcare providers that have devices subjected to this safety alert to contact the company.
Attachments:	FSN R2218602 Air Liquide Medical Systems.pdf

View History