



Circular No. 26 / 2023

07-07-1444 H

29-01-2023

نقدم بثقة
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2040
Oman Vision

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



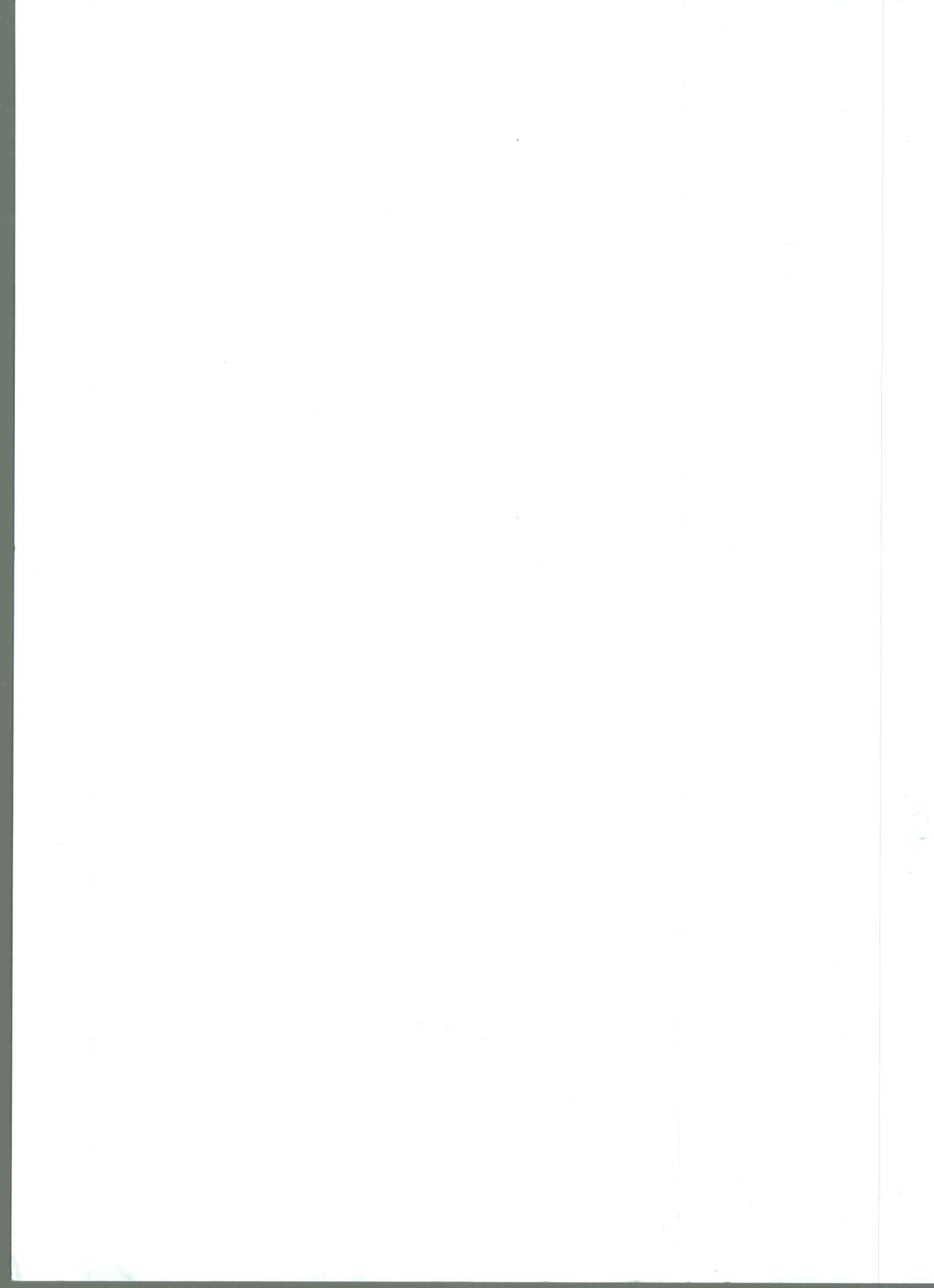
PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical
Affairs & Drug Control

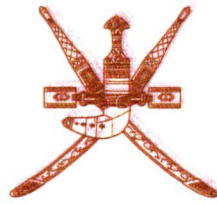


ص.ب: 393 مسقط - الرمز البريدي: 100 - هاتف: 22357111 - فاكس: 22358489

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

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





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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BfArM Recall

Reference Number: mdprc 009 01 23 000

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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](#)

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