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

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. 175 dated 22/1/2 Regarding GHC FSCA of LUISA (LM150TD) ventilator from (mfr: Löwenstein Medical Technology GmbH).

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-padc@moh.gov.om

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Circular No. 175 / 2022

25 -02-1444 H

22 -09-2022

Field Safety Corrective Action of LUISA (LM150TD) ventilator from Löwenstein Medical Technology GmbH.

Source	GHC-Gulf Health Council.
Product	LUISA (LM150TD) ventilator.
Manufacturer	Löwenstein Medical Technology GmbH.
The affected products	LUISA series (LM150TD) with firmware version 1.5.0030 Serial number ragne of the devices produced with this firmware version: 50013752 - 50017318.
Reason	A malfunction of the inspiratory trigger of the LUISA ventilators with firmware version 1.5.0030 may occur in rare cases if the ventilator is used with a single circuit valve system. Under certain circumstances the device can independently trigger additional inspiration cycles. As a result, the respiratory rate may increase significantly, causing the risk of insufficient ventilation. Devices that are operated together with a double limb circuit or a leakage circuit system, and devices with a different firmware version are not affected.
Action	1. Inform your employees, affected customers, and users immediately of the potential hazard. 2. Update all devices with affected firmware version to firmware version 1.5.0031 or higher Update devices before delivery to operators / patients. 3. If therapy shell be continued with affected devices that are currently used with single circuit valve system until the device is updated, it is necessary to change to a double limb circuit or a leakage circuit system. 4. Devices with older firmware version must not be updated to version 1.5.0030. 5. 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

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