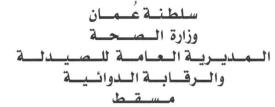
Sultanate of Oman Ministry of Health Directorate General of Pharmaceutical Affairs and Drug Control Muscat







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:

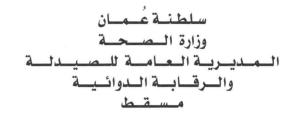
- Director, Office of H.E. The Undersecretary for Health Affairs
- Director of Medical Device Control, DGPA&DC
- Director of Pharmacovigilance & Drug Information Dept, DGPA&DC
- Director of Drug Control Department, DGPA&DC
- Director of Pharmaceutical Licensing Department, DGPA&DC
- Director of Central Quality Control Lab., DGPA&DC
- Supdt. of Central Drug Information





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





Circular No. |75/2022

2.5 -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	 Inform your employees, affected customers, and users immediately of the potential hazard. Update all devices with affected firmware version to firmware version 1.5.0031 or higher Update devices before delivery to operators / patients. 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. Devices with older firmware version must not be updated to version 1.5.0030. 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





