



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 199 dated 24/9/2023 Regarding NCMDR Field Safety Corrective Action of HAMILTON-C1/T1/MR1 Ventilators from (mfr: Hamilton Medical).

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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with Confidence



Circular No. 199 / 2023

08 -03-1445 H

24 -09-2023

Field Safety Corrective Action of HAMILTON-C1/T1/MR1 Ventilators from Hamilton Medical.

Source	NCMDR - National Center Medical Device Reporting- SFDA. https://ncmdr.sfda.gov.sa/Secure/CA/CAViewRecall.aspx?caid=4&rid=19682
Product	HAMILTON-C1/T1/MR1 Ventilators.
Description	Ventilator, transportable.
Manufacturer	Hamilton Medical.
Local agent	Industrial Management Technology and Contracting (IMTAC).
The affected products	Product numbers of affected devices: HAMILTON-C1: 161001 HAMILTON-T1: 161006 / 161009 HAMILTON-MR1: 161010
Reason	A degrading capacitor on the control board might leak electrolyte onto the control board causing a short circuit on the board and/or the capacitor might lose its function. As a result of the short circuit, affected HAMILTON-C1/T1/MR1 ventilators might switch to the "Ambient State" and "Realtime clock failure" maybe displayed also. In case of "Ambient State", active ventilation is no longer provided to the patient. The device is constantly alarming audibly and visually.
Action	In such a case, perform the following actions steps: 1. Provide alternative ventilation immediately. 2. Switch off ventilator power to exit the "Ambient State". 3. Once patient safety is ensured, it is required to have the ventilator serviced. - For further information see chapter "Ambient State" in the respective Operator's Manual. - You will be contacted by the company distributor to arrange replacement of the affected control boards.
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