

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...⁸⁶..... dated ^{8/5/22}..... Regarding FSN of Flow-c and Flow-e anesthesia systems from (mrf: Maquet Critical Care AB).

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





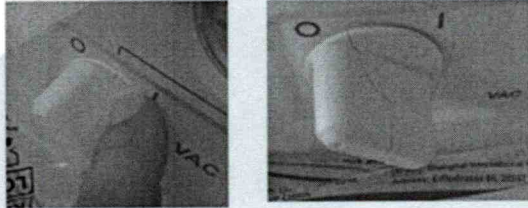
Circular No. 86 / 2022

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Field Safety Notice of Flow-c and Flow-e anesthesia systems from Maquet Critical Care AB

Source	NCMDR-National Center for Medical Device Reporting https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=16122
Product	Flow-c and Flow-e anesthesia systems.
Description	Anesthesia system.
Manufacturer	Maquet Critical Care AB.
Local Agent	Taiba Medserv LLC.
The affected products	Getinge Flow-c; Item number: 6887700 Getinge Flow-e; Item number: 6887900.
Reason	The suction unit on/off knob material on the Getinge Flow-c and Getinge Flow-e anesthesia systems have a tendency to crack.
Action	<ol style="list-style-type: none">1. The suction unit, including on/off knob, shall be checked both when performing daily SCO (system check out) but also prior to starting a new case.2. If staff detects a cracked or broken on/off knob before starting a new case, they are obliged not to let the anesthesia machine pass SCO and replace it with a fully functioning anesthesia machine or ensure that a temporary alternative suction substitution is available.3. A solution that will correct this issue has been developed replacing the on/off knob with a new more durable one.4. Getinge will initiate an immediate field action of all affected device units.5. Contact the local agent for remedial action.
Product Picture	
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 contact E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie
DIRECTOR GENERAL

