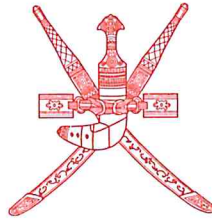


Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
الديريّة العامّة للصيدلّة
والسرّاقبّة الدوائيّة
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. 109 dated 28/5/2010 Regarding Gulf Health Council Safety Alerts of Anaesthesia Machine (Mfr: Getinge)

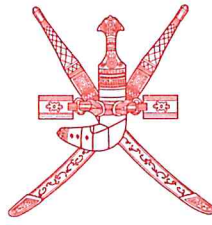
Copy to:

- 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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وزارة الصحة
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والرقابة الدوائية
مسقط

Circular No. 109 / 2020

05 -10-1441 H

28 -5-2020

Safety Alerts of Anaesthesia Machine from Getinge

Source	Gulf Health Council file:///C:/Users/96896/Downloads/Anesthesia%20machines.pdf
Product	Anaesthesia Machine
Manufacturer	Getinge
The affected products	N/A
Reason	<p>Due to the situation with the Novel Coronavirus (2019-nCoV), and the possibility to repurpose Flow-i, Flow-c and Flow-e anesthesia machines for use in the ICU as a ventilator only, the manufacturer would like to draw your attention to important information in the following three sections:</p> <ol style="list-style-type: none">1. General information and warnings2. Preparations for use3. Key system differences (between Flow anesthesia machines and ICU ventilators) <ul style="list-style-type: none">• Rebreathing• Manual and automatic ventilation (MAN/AUTO) and APL• O2 flush• Sampling line and water trap• AGSS (Anesthesia Gas Scavenging System)• Emergency ventilation• Alarms and monitoring• System checkout
Action	<ol style="list-style-type: none">1. Use of the device in an off-label manner is the sole responsibility of the device owner and is done at his/her own (liability) risk.2. Anesthesia machines are life supporting/life sustaining devices. There is a risk of serious injury or death if the devices are not used by properly trained clinicians, continuously monitored, and used in accordance with the instructions for use.3. Contact the local agent to provide advice, training and demonstration.
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

Directorate General of Pharmaceutical Affairs & Drug Control
Sultanate of Oman

