

Sultanate of Oman

Ministry of Health

Directorate General of Pharmaceutical Affairs
and Drug Control

MUSCAT



سلطنة عمان
وزارة الصحة
المديرية العامة للصيدل
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. 202 dated 28/10/20 Regarding NCMDR Field Safety Corrective Action of Flow anesthesia machines from (mfr: Getinge International 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

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Circular No. 202 / 2020

11 -03-1442 H

28 -10-2020

Field Safety Corrective Action of Flow anesthesia machines from Getinge International AB.

Source	National Centre for Medical Devices Reporting- NCMDR https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=15398
Product	Flow anesthesia machines.
Description	Anesthesia machines.
Manufacturer	Getinge International AB.
Local agent	Waleed pharmacy & Stores LLC.
The affected products	Attached.
Reason	At a few occasions, a pilot valve has been found to malfunction, as the pilot valve didn't open when supposed to.
Action	1. Getinge will initiate an immediate update of all affected Flow anesthesia machines and replace all pilot valves from the faulty batches. 2. 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 an E-mail: Med-device@moh.gov.om

Dr. Mohammed Hamdan Al Rubaie

Director General

Field Safety Notice

2020-10-14 | MX-8005 |

Please forward this information to all relevant users, biomedical staff and risk management department concerned in your facility.

Subject: Flow anesthesia machines – pilot valves

Products affected:

Product	Article No.	S/N within this range
Flow-c	6887700	4194, 4318, 4325, 4373, 4454, 4520, 4522, 4530, 4544, 4557-4573, 4575-4612, 4623, 4624, 4630-4717, 4719-4750, 4762-4776, 4778-4782, 4784-4801, 4804, 4806, 4810-4813, 4818-4825, 4827-4829
Flow-e	6887900	50005-50011
Flow-i C20	6888520	20043, 20045, 20063, 20072, 20074, 20075, 20077-20111, 20114-20128, 20137-20142, 20161-20176, 20187-20215, 20217-20230, 20236, 20239-20248, 20250-20255, 20258, 20259
Flow-i C30	6888530	20076, 20012, 20113, 20129-20136, 20143-20160, 20232-20235
Flow-i C40	6888530	20216, 20237, 203238

Dear Customer,

The purpose of this letter is to inform about a potential issue found in Flow-c, Flow-e and Flow-i (serial number above 20000) related to pilot valves and the actions to be taken. Our records indicate that your facility has received one or more of these anesthesia machines.

Normal use and Indications

The function of the pilot valve is to control and direct the gas flow in the anesthesia machines. There are several pilot valves, controlling the gas flow, used in one anesthesia machine.