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

سلطنة عُمان
وزارة الصحة
المديرية العامة للصيدلة
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 245 **dated** 29/12/2022 **Regarding NCMDR FSCA of Flow anesthesia systems from (mfr: 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**

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Circular No. 245/ 2022

05 -06-1444 H

29 -12-2022

Field Safety Corrective Action of Flow anesthesia systems from Maquet Critical Care AB.

Source	NCMDR- National Center for Medical Devices Reporting- SFDA https://ncmdr.sfda.gov.sa/Secure/CA/CaViewRecall.aspx?caid=4&rid=18385
Product	Flow anesthesia systems.
Description	Anesthesia systems.
Manufacturer	Maquet Critical Care AB.
Local agent	Taiba Medserv LLC.
The affected products	Product : Flow-I Article number: 6677200, 6677300, 6677400, 6888520, 6888530, 6888540 Product : Flow-c Article number: 6887700 Product : Flow-e Article number: 6887900 SW version 04.08.00, 04.08.01, 04.08.02 or 04.08.03
Reason	In certain cases it has been reported that when the "High Continuous pressure" alarm has been triggered AND at the same time the user switches to manual mode with the alarm still active, the safety valve stay open even after the "High Continuous pressure" is below the trigger point. The pressure cannot be built up, resulting in no ventilation.
Action	1. If gas delivery is stopped during the circumstances described in the FSN, the machine needs to be restarted or Emergency ventilation activated. 2. Getinge authorized service personnel will visit your site to install SW 04.08.04 or higher. 3. Contact the local agent for remedial action.
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

PADC
المديرية العامة للصيدلة والرقابة الدوائية
Directorate General of Pharmaceutical Affairs & Drug Control

ص.ب: ٣٩٣ مسقط - الرمز البريدي: ١٠٠ - هاتف: ٢٢٣٥٧١١١ - فاكس: ٢٢٣٥٨٤٨٩
P.O. Box: 393 Muscat - Postal Code: 100 - Tel: 22357111 - Fax: 22358489
dgpa_dc Email: dg-padc@moh.gov.om

GETINGE

MCC/22/010/IU: Disabled valves - SW 4.8

Products affected:

Product	Article number
Flow-i	6677200, 6677300, 6677400, 6888520, 6888530, 6888540
Flow-c	6887700
Flow-e	6887900

Flow anesthesia systems listed above with SW version 04.08.00, 04.08.01, 04.08.02 or 04.08.03 installed are affected by this field action.

(Please note that Flow anesthesia systems with a SW below 04.08.00 are not affected by this issue and thus don´t need to be upgraded to 04.08.04 or higher. However, we always recommend that the latest released SW is used.)

Description of the issue

The alarm "High Continuous pressure" is triggered when the pressure in the system is too high (constantly above set PEEP level +15 cmH2O for more than 15 seconds). This alarm is active in automatic mode and cannot be altered by the user. It is de-activated when the pressure in the system decreases below set trigger point.

The system will respond to "High Continuous pressure" alarm by activating a function called "disabled valves". When "disabled valves" function is activated, the safety valve opens and gas delivery is stopped to relieve the pressure in the patient circuit.

After the pressure is below the trigger point the safety valve is closed and gas delivery is resumed.

In certain cases it has been reported that when the "High Continuous pressure" alarm has been triggered AND at the same time the user switches to manual mode with the alarm still active, the safety valve stay open even after the "High Continuous pressure" is below the trigger point. The pressure cannot be built up, resulting in no ventilation. Investigation has shown that same situation will occur if user ends the case/goes to standby with the "High Continuous pressure" alarm active.

The system needs to be turned off to reset the disabled valves function (which also can be done by activating the Emergency ventilation).

The underlying issue causing the "High Continuous pressure" alarm will not be solved by only restarting the system.

Potential hazards

No gas delivery is possible when valves are disabled.

Precautions

If gas delivery is stopped during the circumstances described above the machine needs to be restarted or Emergency ventilation activated.

Corrective action

Getinge authorized service personnel will visit your site to install SW 04.08.04 or higher.

Action to be taken by user:

- We urge to maintain awareness on this notice and related actions until further communication from Getinge.
- Please complete & return the attached acknowledgement form.

Please note that Flow anesthesia systems with a SW below 04.08.00 are not affected by this issue and thus don´t need to be upgraded to 04.08.04 or higher. However, we always recommend that the latest released SW is used.

Distribution

The respective competent health authorities have been informed about this communication and issue.

This Getinge Field Safety Notice distribution must include those individuals that need notification within your organization - or any organization where the potentially affected devices have been transferred. Please keep notice of this and subsequent communications to ensure that the appropriate corrective actions are taken while using the device. It is understood that failure to respond to this Field Safety Notice or to proceed with the corrective action requests described above may dispense Getinge from any liability connected with or arising out of this Field Safety Notice. The submission of this notice shall not be construed as an admission of liability for the issue described herein and its consequences.

We apologize for any inconvenience that this may have caused and will do our utmost effort to provide a reasonable solution as swiftly as possible.

Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,

Malin Graufelds
Director Product Mgmt. Anesthesia
Maquet Critical Care AB

Jerker Åberg
Director Regulatory Affairs & Product Compliance
Maquet Critical Care AB