# Field Safety Notice

12 April 2022 | MX-8563 | Rev 1

# MCC/22/004/IU on-off knob suction unit Flow-c and Flow-e anesthesia systems

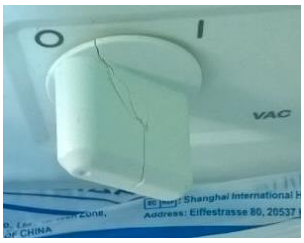
## Products affected:

Our records indicate that the below listed products were delivered to your location. Please verify if you have any of the listed products and complete the information below.

| Item number | Getinge Order Reference | Serial number |
|---|---|---|
| 6887700 | Getinge Flow-c | See consignee list EVU-227453 |
| 6887900 | Getinge Flow-e | See consignee list EVU-227453 |

### Description of the issue

It has come to our attention that the suction unit on/off knob material on the Getinge Flow-c and Getinge Flow-e anesthesia systems have a tendency to crack as shown in the pictures below. The issue has not been identified to begin at any specific time, or with any particular batch, therefore all units that are installed may be affected.


### Potential hazards

In worst case the knob can break and then the suction unit cannot be activated. If it breaks in active mode the vacuum regulator knob can still be used to regulate the pressure of the suction.

## Precautions

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. 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.

## Corrective action

A solution that will correct this issue has been developed replacing the on/off knob with a new more durable one. Getinge will initiate an immediate field action of all affected device units. You will be contacted by your Getinge sales or service representative to plan for the update of your device.

## Distribution

This Getinge Field Notice needs to be distributed to those individuals who need to be aware within your organization - or to any organization where the potentially affected devices have been transferred. Please maintain awareness of this notice and resulting action for the use period of the device to ensure effectiveness of the corrective action. In cases where you as customer choose not to proceed with completion of the corrective action requirements described above, Getinge cannot accept any responsibility for safety related issues or legal liabilities caused by the failure to respond to this Field Safety Notice. The competent authority TÜV Süd has been informed about this communication and issue.

We apologize for any inconvenience this may cause and we will do our outmost to carry through this action as swiftly as possible.

Should you have questions or require additional information, please let us know.

Sincerely,

Lena Evander
Director Product Mgmt Anesthesia
**Maquet Critical Care AB**

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