

# 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

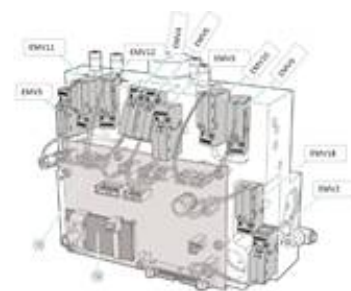
The function of the pilot valve is to control and direct the gas flow in the anesthesia machines. There are several pilot valves, controlling the gas flow, used in one anesthesia machine.

**The following has been discovered**

At a few occasions, a pilot valve has been found to malfunction, as the pilot valve didn't open when supposed to. This is related to bad soldering in the concerned component found in certain identified batches from the sub-supplier. No patient injuries have been reported. If a pilot valve does not open when it should, it will have different consequences depending on which pilot valve is used, see table below.



Picture of pilot valves



Different valves where the pilot valve is used

Valve	Function	System Error mode during Malfunction of pilot valve
EMV2	Manual Ventilation Valve	Manual ventilation bag stays pneumatically connected to the breathing circuit when automatic ventilation is activated
EMV3	System Checkout Valve	System Checkout (SCO) fails, Scavenging through SCO valve at AFGO not possible
EMV4	Vaporizer Bypass Valve	Occlusion in Fresh gas line.
EMV5, EMV6	Vaporizer Selection Valve	Occlusion in Fresh gas line.
EMV11, EMV9	Vaporizer Pressure Valve	Lower Anesthetic agent concentration than expected in fresh gas.
EMV12, EMV10	Vaporizer Scavenging Valve	Not possible to depressurize vaporizer
EMV18	AFGO Valve	Fresh gas to normal breathing circuit (not AFGO) when AFGO is selected.

A faulty pilot valve will in most cases be detected during the system check-out.

If a malfunction, despite a passed system check-out, would happen during use, the anesthesia system will activate audible and visible alarms such as low FiO<sub>2</sub>, high pressure, PEEP low, minute volume and low agent concentration.

Note: A fault related to the valve adjusting the AFGO will not generate an alarm. However the waveforms on the graphical user interface will indicate that the AFGO is not functioning. Absence of gas supply to the external system will be noticed by the operator as the manual breathing bag of the external system will not fill up.

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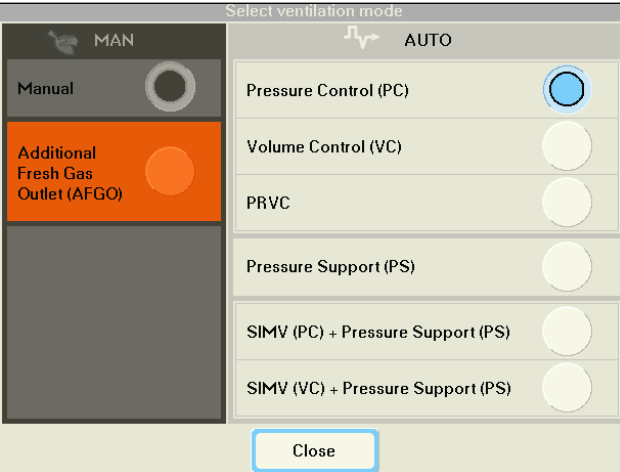
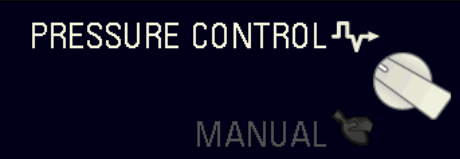
**Potential hazards**

Different errors depending on which valve that's affected, see table above. AFGO valve failure may cause hypoventilation and hypoxia, due to lack of alarms in this failure mode.

**Precautions**

The Flow anesthesia machines can be used in accordance to the instructions for use, with extra attention to the following:

- Do not use the AFGO function until valves have been replaced.

<p><u>Make sure Manual is selected in the ventilation mode window.</u></p>	
<p>When Manual is selected the upper right corner of the user interface looks like this. (In this example Pressure control is selected as ventilation mode)</p>	

- Always perform a system check-out every 24 hour and after each patient
- Act as instructed on alarms
- If a problem occur contact your local Getinge representative

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## Corrective action

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Getinge will initiate an immediate update of all affected Flow anesthesia machines and replace all pilot valves from the faulty batches. You will be contacted by your Getinge sales or service representative to plan for the update of your anesthesia machine.

Please maintain awareness on this notice and related actions until your anesthesia machine has been updated to ensure effectiveness of the corrective action.

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

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

Sincerely,

Peter Wedar  
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**Maquet Critical Care AB**

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**Maquet Critical Care AB**