

MCC/26/003: Flow – No agent delivery

Products affected:

Our records indicate that the below listed products have been delivered to your location.

Part number	Device model	Serial Number
6677200	Flow-i C20	< 20000, See consignee list EVU-275372
6888520	Flow-i C20	> 20000, See consignee list EVU-275372
6677300	Flow-i C30	< 20000, See consignee list EVU-275372
6888530	Flow-i C30	> 20000, See consignee list EVU-275372
6677400	Flow-i C40	< 20000, See consignee list EVU-275372
6888540	Flow-i C40	> 20000, See consignee list EVU-275372
6887700	Flow-c	See consignee list EVU-275372
6887900	Flow-e	See consignee list EVU-275372

Description of the Issue

Maquet Critical Care AB has identified a problem that under certain conditions might prevent the device from performing as intended. In some cases, Flow family anesthesia machines have not delivered anesthetic agent when the vaporizer(s) were switched on. These events have only been observed during the start-up phase of a case.

Potential hazards

This problem may stop the intended functioning of the device, resulting in failure to deliver anesthetic agent. This may result in the patient receiving insufficient anesthesia and may lead to intraoperative awareness.

Please note: No serious injury or death has been reported.

Precautions

In order to identify and mitigate the issue should it arise, Getinge requests that you review the following:

1. Always confirm that anesthetic agent is being delivered after activating the vaporizer(s), particularly at the start of a case.
2. According to the Instructions for Use, this indication signifies that concentration levels are below detectable limits, serving as confirmation that no agent is present.
** / gas analyzer has no information to display
3. Continuously monitor end-tidal anesthetic agent concentration and patient vital signs to ensure adequate anesthesia is maintained.
4. If delivery is not confirmed - end case and start up again. This measure will normally resolve the issue.

Corrective Actions

Maquet Critical Care AB is initiating a Field Safety Corrective Action for all affected devices. There will be a coming release containing software improvement for software versions 4.10 and 4.11 to handle the no agent delivery issue. The software update will improve stability during case start-up by optimizing vaporizer initialization, thereby reducing the risk of no anesthetic agent delivery events. You will be contacted by your Maquet Critical Care AB sales or service representative, when software is available, to plan for the software upgrade.

Please maintain awareness of this notice and complete and return the attached acknowledgment form, [MX-9621] Confirmation of FSN Receipt.

Distribution

This Field Safety 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. In cases where you as customer choose not to proceed with completion of the corrective actions, Maquet Critical Care AB cannot accept any responsibility for safety related issues or legal liabilities arising from the failure to respond to this Field Safety Notice. The relevant competent authorities have been informed about this Field Safety Corrective Action.

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

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

Sincerely,

Malin Graufelds
Director Product Management Anesthesia
Maquet Critical Care AB
Röntgenvägen 2
171 54 Solna
Sweden
www.getinge.com

Jerker Åberg
Director Regulatory Affairs & Product Compliance
Maquet Critical Care AB
Röntgenvägen 2
171 54 Solna
Sweden
www.getinge.com