

## MCC/21/005/IU: Sevoflurane vaporizers for Flow Family Anesthesia systems



### Products affected:

Item number	Getinge Order Reference	Serial number
6886601	Vaporizer Sevoflurane Maquet filling	See consignee list EVU-222645
6887523	Vaporizer Sevoflurane SAFE-T-SEAL	See consignee list EVU-222645
6886611	Vaporizer Sevoflurane, Quik-Fil	See consignee list EVU-224748

We have earlier communicated about field action MCC/21/005/IU in the documents MX-8398 and MX-8467.

A root cause analysis has been performed to find out the reason for the formation of hydrogen fluoride within sevoflurane vaporizers. The root cause analysis found that changes in design and manufacturing process introduced in 2018 was the reason for the formation of hydrogen fluoride. The main reason for the manufacturing change in 2018 was to facilitate easier assembling in production and to get a better sourcing of certain components. The surface treatment in the aluminum canister that form the main part of the liquid container in the vaporizer was found to be inadequate.

All of Vaporizer Sevoflurane Maquet filling '6886601' and Vaporizer Sevoflurane SAFE-T-SEAL '6887523' will be replaced according to table below. However, we are facing problem sourcing a component (Printed Circuit Board) due to the global supply chain crisis, which is affecting our production capacity. Therefore, we will start production of replacement vaporizers with one refurbished component.

Affected vaporizer		Replacement vaporizer
6886601, Vaporizer Sevoflurane, Maquet filling*		6682282 Vaporizer Sevoflurane, Maquet filling
6887523, Vaporizer Sevoflurane, SAFE-T-SEAL		6887135, Vaporizer Sevoflurane, SAFE-T-SEAL

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## Field Safety Notice | March 18, 2022 | MX-8523 | Rev 1

\* Please note, 6886601 may remain in use until a replacement vaporizer is available if it is, and has only been used with AbbVie Sevoflurane®/Ultane®.

Replacement vaporizers 6682282 and 6887135 are produced with the same technical specification, electronic and software platform, equal performance, same intended use and same User's Manual as 6886601 and 6887523. All vaporizer models are compatible with all Flow Family anesthesia machines. Both vaporizer versions are equal in the capability to support upcoming features and product improvements of the Flow Family anesthesia machines.

Vaporizer Sevoflurane, Quik-Fil '6886611' will not be replaced

### Distribution

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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.

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

Sincerely,

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

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

MX-8523 - MCC\_21\_005\_IU\_FSN\_Sevoflurane vaporizers 6886601 & 6887523 & 6886611 replacement Version: 02 Approved at 2022-03-21 by: Lena Evander u2140243, Jerker Åberg u2773956

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