

Field Safety Notice

December 10, 2024 | MX-9228 | Rev 1



MCC/24/001/IU: Sevoflurane vaporizers

Replacement information

Products affected:

Item number	Getinge Order Reference	Serial number
6682282	Vaporizer Sevoflurane Maquet filling	SN 17003 – 23784 Consignee list EVU-262843
6887135	Vaporizer Sevoflurane SAFE-T-SEAL	SN 17984 – 23430 Consignee list EVU-262843
6682285	Vaporizer Sevoflurane, Quik-Fil	SN 23523 -26092 Consignee list EVU-262843

Background & root cause analysis

In April 2024, we communicated field corrective action MCC/24/001/IU in document MX-9154, which included instructions on how to handle the affected vaporizers.

The root cause investigation concluded that the presence of hydrogen fluoride (HF) is due to sevoflurane in contact with anodized aluminum with cold sealing, leading to the degradation of the anesthetic agent.




The vaporizers are assembled from several parts, some of which are made from aluminum. These aluminum parts undergo a surface treatment process called anodization. Most of the aluminum parts in the affected vaporizers are cold-sealed. We will implement a change in the affected vaporizers by switching from cold sealing anodizing to hot sealing anodizing. Replacement vaporizers will be produced using a hot sealing anodization process.

Copies must not be used unless their validity has been verified.

Replacement of vaporizers

All Vaporizer Sevoflurane Maquet filling, 6682282 and Vaporizer Sevoflurane SAFE-T-SEAL, 6887135 taken out of use according to instructions in MX-9154 will be replaced with new vaporizers free of charge.

Vaporizer Sevoflurane Quik-Fil, 6682285, provided as a temporary “bridging” vaporizer for 6682282 or 6887135 taken out use, may be replaced with a new vaporizer free of charge.

Affected vaporizer		Replacement vaporizer
6682282, Vaporizer Sevoflurane Maquet filling Serial number: 17003 - 23784		6682282, Vaporizer Sevoflurane Maquet filling Serial number > 30000
6887135, Vaporizer Sevoflurane SAFE-T-SEAL Serial number: 17984 - 23430		6887135, Vaporizer Sevoflurane SAFE-T-SEAL Serial number > 30000
6682285 Vaporizer Sevoflurane Quik-Fil* Serial 23523 -26092 (Bridging units)	 Can be replaced upon customer request	6682282, Vaporizer Sevoflurane Maquet filling Serial number > 30000 or 6887135, Vaporizer Sevoflurane SAFE-T-SEAL Serial number > 30000

The updated vaporizer design may require regulatory approval before delivery. Regulatory status and further instructions about the replacement process will be provided by your local Getinge representative. Bridging Vaporizer Sevoflurane Quik-Fil, 6682285 used as temporary solution needs to be emptied before storage according to instructions in appendix 1.

Production capacity has been increased to make the replacement period as short as possible.

Action to be taken by Getinge

Getinge will contact you and replace the affected vaporizers as soon as replacement vaporizers are available.

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Distribution

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

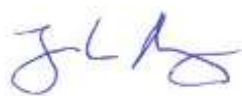
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Should you have questions or require additional information, please contact your local Getinge representative.

Sincerely,



Malin Graufelds
Director Product Mgmt. Anesthesia
Maquet Critical Care AB



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

Appendix 1

Empty and dry run instructions:

After the vaporizer has been emptied according to instructions in the User's Manual it needs to be inserted back into the Flow Family anesthesia system.

- Start a case and set the Flow Family anesthesia system to manual mode.
- Increase the fresh gas flow to 20 l/min
- Set the sevoflurane concentration to 8%.
- Let it run for 5 minutes to make sure the vaporizer is completely empty.
- Remove the empty vaporizer from the anesthesia system and store until it's returned to Getinge.