

Field Safety Notice

December 10, 2024 | MX-9255 | Rev 1



MCC/24/001/IU: Sevoflurane vaporizers

Additional information for all Getinge/Maquet sevoflurane vaporizers

Products affected:

Item number	Getinge Order Reference	Serial number
6682282	Vaporizer Sevoflurane Maquet filling	All units Consignee list EVU-262259
6887135	Vaporizer Sevoflurane SAFE-T-SEAL	All units Consignee list EVU-262259
6682285/6886611	Vaporizer Sevoflurane, Quik-Fil	All units Consignee list EVU-262259

Background

Sevoflurane is susceptible to degradation, which can occur through contamination with strong Lewis acids. The aluminum container in the vaporizer is designed to ensure product stability during expected clinical practice but is not intended for long-term storage of sevoflurane. Furthermore, product stability is only verified with the specific brand of anesthetic agent it is intended to be used with.

Therefore, we want to inform all users of Getinge/Maquet sevoflurane vaporizers, both existing and new, to pay attention to the following information.

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

Additional information for existing and new sevoflurane vaporizers

1. Do not leave sevoflurane in the vaporizer for a longer period than 30 days or during external transportation. The vaporizers must be emptied if the sevoflurane is not planned to be used within the next 30 days or before external transportation. Empty and dry-run the vaporizer according to instructions in the User's Manual and Appendix 1.
2. Prior to using a vaporizer containing sevoflurane, ensure that the vaporizer has been in use within the most recent 30 days. If the sevoflurane has not been used during the most recent 30 days, it must be discarded. Empty and dry-run the vaporizer according to instructions in the User's Manual and Appendix 1.
3. As already stated in the User's Manual, Sevoflurane vaporizers are only tested for use according to the table below:

Vaporizer	Sevoflurane brand
Maquet filling	Piramal
	AbbVie
	Maruishi
	Baxter
Quik Fil®	AbbVie
	Maruishi
SAFE-T-SEAL	Baxter

This information is complementary to the existing User's Manual and will be added to the next revision of the User's Manual.

Distribution

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.

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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,



Malin Graufelds
Director Product Mgmt. Anesthesia
Maquet Critical Care AB



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

Appendix 1

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 it

or

-fill it again with fresh sevoflurane if the vaporizer is to be used.