

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.

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

MX-9228 - MCC_24_001_IU_FSN_Sevoflurane_vaporizers_replacement_Version: 01 Approved at 2024-12-11 by: Malin Graufelds u2823494, Jerker Åberg u2773956, Page 2 of 4

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. 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

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.

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 Fill®	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.

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

Field Safety Notice | December 10, 2024 | MX-9255 | Rev 1

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

MX-9255 - MCC_24_001_IU_FSN_Sevoflurane vaporizers_ additional information Version: 01 Approved at 2024-12-11 by:
Malin Graufelds u2823494, Jerker Åberg u2773956,
Page 3 of 4

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

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.