

MCC/24/001/IU: Sevoflurane vaporizers – additional units

Products affected:

Item number	Getinge Order Reference	Serial number
6682282	Vaporizer Sevoflurane Maquet filling	SN 8457 – 14094 Consignee list EVU-262260
6887135	Vaporizer Sevoflurane SAFE-T-SEAL	SN 10506 – 16142 Consignee list EVU-262260
6682285*	Vaporizer Sevoflurane, Quik-Fil	SN 8407 – 15859 Consignee list EVU-262260

* When being used with third party filling adapters that are not approved according to the User's manual, to enable usage of Sevoflurane from other manufacturers than AbbVie.

Background and description of the product problem

The Sevoflurane vaporizers are used with the following brands: AbbVie Sevoflurane®, Ultane®, Maruishi Sevoflurane, Piramal Sevoflurane and Sevoflurane Baxter.

- Item No. 6682282, Vaporizer Sevoflurane Maquet filling is used with AbbVie Sevoflurane®, Ultane®, Maruishi Sevoflurane, Piramal Sevoflurane and Sevoflurane Baxter.
- Item No. 6887135, Vaporizer Sevoflurane SAFE-T-SEAL is used with Sevoflurane Baxter.
- Item No. 6682285, Vaporizer Sevoflurane Quik-Fil is used with AbbVie Sevoflurane®.

Maquet Critical Care AB has received complaints where a discoloration/corrosion inside the vaporizer have been observed under normal operating conditions. Analysis has revealed, chemical degradation of sevoflurane, resulting in formation of hydrogen fluoride within the vaporizer.

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The vaporizer is a component in the Flow family anesthesia systems, used to contain and vaporize the anesthetic agent. Sevoflurane is a sweet-smelling, nonflammable, highly fluorinated methyl isopropyl ether used as an inhalational anesthetic for induction and maintenance of general anesthesia.

There is an inherent risk for chemical degradation of sevoflurane to hydrogen fluoride acid. This may result in inhalation and/or skin exposure of hydrogen fluoride when the vaporizer is used with low water content sevoflurane.

This issue has only been observed when using low water content Sevoflurane, Piramal Sevoflurane and Sevoflurane Baxter. No complaints have been reported with the use of Abbvie Sevoflurane®/Ultane® or Maruishi Sevoflurane.

To date, no patient or operator injuries have been reported.

The item number (REF) and serial number (SN) are found on the label located underneath each vaporizer, see image below.



Potential hazards

The potential hazards that have been identified includes inhalation of hydrogen fluoride. Potential harms may include irritation of respiratory tract and in worst case may lead to lung edema and/or severe hypocalcemia which may be delayed for 24-48 hours after exposure.

To date, no patient or operator injuries have been reported.

Root cause analysis

Root cause investigation on affected vaporizers have been performed with the conclusion that the presence of hydrogen fluoride (HF) is due to sevoflurane in contact with anodized aluminum with cold sealing leading to degradation of the anesthetic agent.

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The vaporizers are assembled by several parts, of which some are manufactured from aluminum. The aluminum parts undergo a surface treatment step, anodization. Most of the aluminum parts in the affected vaporizers comprise of cold sealed aluminum.

A change will be implemented on affected vaporizers with change of cold sealing anodizing to hot sealing anodizing.

New vaporizers will be produced with hot sealed anodized aluminum parts.

Action to be taken by the Customer and action to be taken by Getinge

All Vaporizer Sevoflurane Maquet filling, 6682282 and Vaporizer Sevoflurane SAFE-T-SEAL, 6887135 will be replaced with new vaporizers free of charge. Until replacement vaporizers are available do not use them.

Vaporizer Quik-Fil, 6682285, will not be replaced free of charge if being used with third party filling adapters that are not approved according to the User's manual and used with another sevoflurane than AbbVie Sevorane®/Ultane® or Maruishi Sevofrane. If not used according to instructions do not use the vaporizer.

Affected vaporizer		Replacement vaporizer
6682282, Vaporizer Sevoflurane Maquet filling Serial number: 8457 - 14094		6682282, Vaporizer Sevoflurane Maquet filling Serial number > 30000
6887135, Vaporizer Sevoflurane SAFE-T-SEAL Serial number: 10506 – 16142		6887135, Vaporizer Sevoflurane SAFE-T-SEAL Serial number > 30000
6682285 Vaporizer Sevoflurane Quik-Fil Serial number: 8407 - 15859	If it has ever been used with Piramal Sevoflurane and/or Sevoflurane Baxter or other low water content Sevoflurane, even if currently used with AbbVie Sevorane®/Ultane® or Maruishi Sevofrane.	Order a new 6682285 and use with AbbVie Sevorane®/Ultane® or Maruishi Sevofrane.

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.

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

Additional usage information for sevoflurane vaporizers is provided in a separate letter and does not impact the replacement details above.

What to do with vaporizers not to be used:

- If no sign of discoloration/corrosion within the vaporizer or unusual smell, handle the vaporizer according to the instructions in appendix 1.
- If signs of discoloration/corrosion within the vaporizer or unusual smell, as a precaution use general safety aspects handling chemicals such as protective gloves and protective goggles when removing them for storage without emptying them. Do not empty the vaporizer. Contact your Getinge representative for return of vaporizers with signs of discoloration/corrosion.

Hydrogen fluoride is a toxic and hazardous acid and must be handled with care depending on its concentration for the safety of patients and operators. The observed concentrations are below the concentrations considered hazardous for handling by current literature.

In case of skin contact rinse with water immediately. If clothing has been contaminated, remove immediately and dispose them.

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.

We sincerely apologize for any inconvenience that this may have caused and will do our utmost effort to provide a reasonable solution as swiftly as possible.

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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

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Appendix 1

Instructions for emptying and storage.

The vaporizers must be emptied before storage.

Emptying instructions:

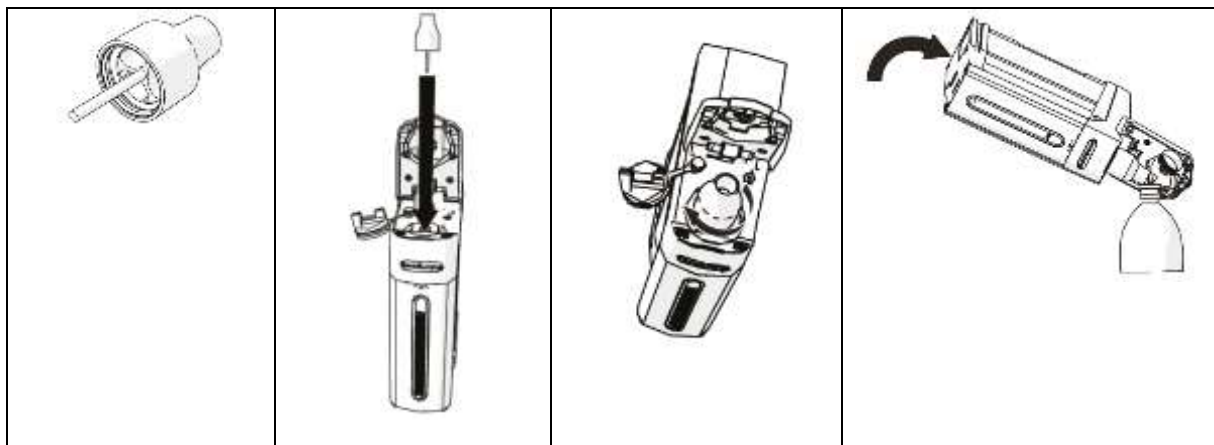
6682282, Vaporizer Sevoflurane Maquet filling & 6682285, Vaporizer Sevoflurane Quik-Fil

Connect the vaporizer to the corresponding filling adapter and turn it upside down. Press the bottle into the vaporizer to have the fluid flow back into the bottle.

Discard the bottle.

6887135, Vaporizer Sevoflurane SAFE-T-SEAL

A special drain adapter is included with the vaporizer. This should always be used for emptying the SAFE-T-SEAL vaporizer.



Empty the vaporizer by pouring any remaining agent into a suitable container, which should then be sealed.

When this has been done, unscrew the drain adapter, screw the vaporizer cap firmly back on (clockwise) and close the vaporizer lid.

Discard the container.

Appendix 1 cont.

Instructions for emptying and storage.

Dry run instructions:

After the vaporizer has been emptied 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.