

MCC/24/001/IU: Sevoflurane vaporizers

Products affected:

Item number	Getinge Order Reference	Serial number
6682282	Vaporizer Sevoflurane Maquet filling	SN 17003 - 23454
6887135	Vaporizer Sevoflurane SAFE-T-SEAL	SN 17984 - 23430
6682285*	Vaporizer Sevoflurane, Quik-Fil	SN 17111 - 23424

* 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 Sevorane®/Ultane®, Maruishi Sevofrane, Piramal Sevoflurane and Sevoflurane Baxter.

- Item No. 6682282, Vaporizer Sevoflurane Maquet filling is used with AbbVie Sevorane®/Ultane®, Maruishi Sevofrane, 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 Sevorane®.

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.

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 Sevorane®/Ultane® or Maruishi Sevofrane.

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This issue has only been observed on vaporizers of specific batches, please see table above. Today, there are no indications or technical prerequisites indicating that other batches are affected.

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.

Action to be taken by the Customer.

Until further notice:

Do not use Piramal Sevoflurane or Sevoflurane Baxter or other low water content Sevoflurane with:

- 6887135, Vaporizer Sevoflurane SAFE-T-SEAL (SN 17984 - 23430)
- 6682282, Vaporizer Sevoflurane Maquet filling (SN 17003 - 23454)

Do not use AbbVie Sevoflurane®/Ultane® or Maruishi Sevoflurane with:

- 6682282, Vaporizer Sevoflurane Maquet filling (SN 17003 - 23454) 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 Sevoflurane®/Ultane® or Maruishi Sevoflurane.

Do not use 6682285, Vaporizer Sevoflurane Quik-Fil (SN 17111 - 23424):

- 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 Sevoflurane®/Ultane® or Maruishi Sevoflurane.

NOTE: Getinge vaporizers which can be used with Flow family anesthesia systems are listed in Appendix 1.

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 2.
- 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.

We urge to maintain awareness on this notice and related actions until further communication from Getinge.

Please complete & return the attached acknowledgement form.

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Action to be taken by Getinge.

While the investigation is ongoing a root cause has not been determined. Getinge will continue to investigate and will provide an updated Field Safety Notice when the root cause and/or corrective actions are identified.

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.

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

Vaporizers can be used with Flow family anesthesia systems under the conditions listed below:

Sevoflurane Maquet filling

	Can be used with Piramal Sevoflurane	Can be used with Sevoflurane Baxter	Can be used with Abbvie Sevoflurane®/Ultane® or Maruishi Sevoflurane
6682282 Serial number < 17003	YES	YES	YES
6682282 Serial number within 17003-23454	NO	NO	YES, if it has only been used with Abbvie Sevoflurane®/Ultane® or Maruishi Sevoflurane
6886601*	NO	NO	YES, if it has only been used with Abbvie Sevoflurane®/Ultane® or Maruishi Sevoflurane

Sevoflurane Quik-Fil

	Can be used with Abbvie Sevoflurane®/Ultane® or Maruishi Sevoflurane
6682285 Serial number within 17111-23424	YES, if it has been used according to instructions with Abbvie Sevoflurane®/Ultane® or Maruishi Sevoflurane only
6886611*	YES, if it has been used according to instructions with Abbvie Sevoflurane®/Ultane® or Maruishi Sevoflurane only

Sevoflurane Safe-T-Seal

	Can be used with Sevoflurane Baxter
6887135 Serial number < 17984	YES
6887135 Serial number within 17984-23430	NO

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Appendix 1 cont.

Vaporizers can be used with Flow family anesthesia systems under the conditions listed below:

Isoflurane & Desflurane vaporizers (not affected by this issue)

	OK to use
6682280*	YES
6886621	YES
6682287*	YES
6886631	YES

*Not manufactured any longer

Appendix 2

Instructions for emptying and storage.

The vaporizers must be emptied before storage.

Emptying instructions:

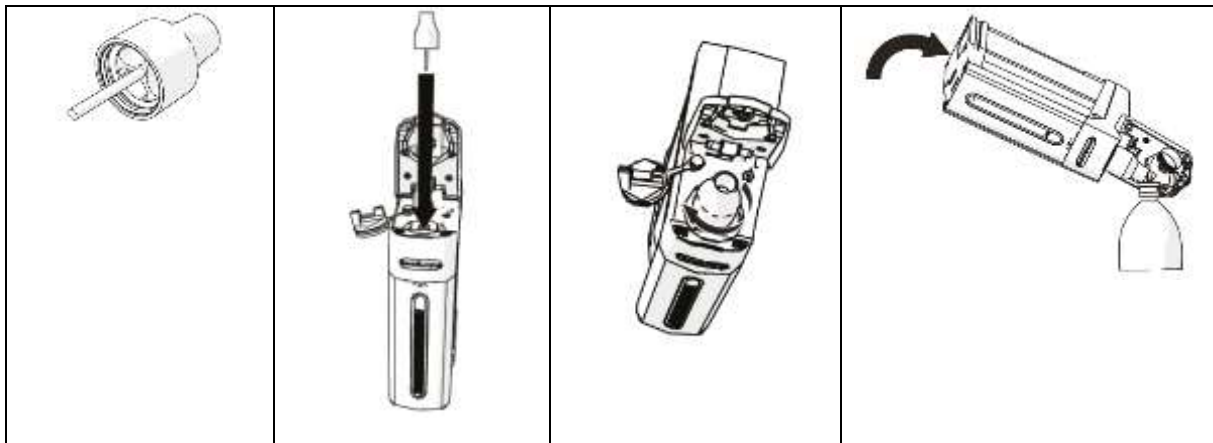
6682282, Vaporizer Sevoflurane Maquet filling & 6682285, Vaporizer Sevoflurane Quik-Fil

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 2 cont.

Instructions for emptying and storage.

Dry run instructions:

After the vaporizer has been emptied according to above instructions 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 system and store it until further notice.