Field Safety Notice

May 7, 2024 | MX-9168 | Rev 1

MCC/24/001/IU: Sevoflurane vaporizers

Products affected:

Item number	Getinge Order Reference	Serial number
6682282	Vaporizer Sevoflurane Maquet filling	From SN 17003 →
6682285*	Vaporizer Sevoflurane, Quik-Fil	From SN 17111 →

* 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.

Important information for sevoflurane vaporizers:

6682282, Vaporizer Sevoflurane Maquet filling (From SN 17003 →) may only be used with AbbVie Sevorane®/Ultane® or Maruishi Sevofrane.

6682285, Vaporizer Sevoflurane Quik-Fil (From SN 17111 →) may only be used with AbbVie Sevorane®/Ultane® or Maruishi Sevofrane.

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. 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.

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.

Please note - Important information about sevoflurane vaporizer

6682282, Vaporizer Sevoflurane Maquet filling (From SN 17003 →) may only be used with AbbVie Sevorane®/Ultane® or Maruishi Sevofrane.

6682285, Vaporizer Sevoflurane Quik-Fil (From SN 17111 →) may only be used with AbbVie Sevorane®/Ultane® or Maruishi Sevofrane.

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

Please complete & return the attached acknowledgement form.

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.

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