



FOR IMMEDIATE RELEASE

BAXTER ISSUES URGENT MEDICAL DEVICE CORRECTION TO REINFORCE IMPORTANT SAFETY INFORMATION REGARDING POSSIBLE RISK OF OXYGEN DESATURATION WHILE USING VOLARA DEVICE IN LINE WITH VENTILATOR IN A HOME CARE ENVIRONMENT

DEERFIELD, Ill., JUNE 1, 2022 – Baxter International Inc. announced today it has issued an Urgent Medical Device Correction for the **Volara** System (home care) to reinforce important safety information regarding a possible risk of decrease in oxygen levels (oxygen desaturation) or injury that may result in lung tissue damage due to over-expansion (barotrauma) in the home care environment. These potential events may occur while using the **Volara** device in line with a ventilator with the required **Volara** ventilator adaptor or **Volara** patient circuit kit oscillation and lung expansion (OLE) therapy. This product is manufactured by Hillrom, which was acquired by Baxter in late 2021.

As described in the Urgent Medical Device Correction, current patients should continue to use their **Volara** therapy as prescribed by their physician. Caregivers and/or patients should monitor for signs of respiratory distress (increased breathing rate, wheezing, bluish color around the mouth, inside the lips or in the fingernails, changes in alertness or drop in oxygen level) during **Volara** therapy when used in line with a ventilator. Caregivers and/or patients who observe signs of respiratory distress should stop the **Volara** therapy immediately. If patients do not see improvement after stopping the **Volara** therapy, they should seek medical attention. **Baxter received one report of a patient experiencing oxygen desaturation while using the Volara device in line with a ventilator in a home care environment.**

In addition, Baxter will mitigate this risk by updating the Instructions For Use (IFU) manual to help ensure correct usage of the device. Once the updated IFU is available, Baxter will contact patients to arrange for a trainer to conduct a home visit to provide additional training. Baxter will also issue a follow-up letter to patients to communicate further details on the actions being taken to address this issue.



This Urgent Medical Device Correction applies to **Volara** System model numbers PVL1HCBA; M08594; and M08594A with in-line VENTILATOR adaptor (M07937 MODULE, OPTIMUS HANDSET 2) or **Volara** Patient Circuit Kit (M08473 OPTIMUS OLE AC PAT.CIRCUIT KIT that include M07937).

The **Volara** System is distributed in the United States. Customers with additional questions can contact Hillrom Customer Service Support at 800-426-4224, option 3 or Hillrom Clinical Support at 800-397-9071. Any adverse events experienced with the use of this product may be reported using one of the following options:

- Calling Baxter Product Surveillance at 800-437-5176 Monday through Friday between 8 a.m. and 5 p.m. Central Time.
- Emailing Baxter at: corporate_product_complaints_round_lake@baxter.com
- Reporting to the FDA MedWatch Adverse Event Reporting Program:
 - Online: By completing and submitting the report online at <https://www.accessdata.fda.gov/scripts/medwatch>
 - Regular mail or Fax: Download the form from www.fda.gov/MedWatch/getforms.htm or call 800-332-1088 to request a reporting form, then complete and mail it to the address on the pre-addressed form or submit by fax to 800-332-0178.

Baxter is voluntarily issuing this Urgent Medical Device Correction with the knowledge of the U.S. Food and Drug Administration.

About Baxter

Every day, millions of patients, caregivers and healthcare providers rely on Baxter's leading portfolio of diagnostic, critical care, kidney care, nutrition, hospital and surgical products used across patient homes, hospitals, physician offices and other sites of care. For 90 years, we've been operating at the critical intersection where innovations that save and sustain lives meet the healthcare providers who make it happen. With products, digital health solutions and therapies available in more than 100 countries, Baxter's employees worldwide are now building upon the company's rich heritage of medical breakthroughs to advance the next generation of transformative healthcare innovations. To learn more, visit www.baxter.com and follow us on [Twitter](#), [LinkedIn](#) and [Facebook](#).

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