



FOR IMMEDIATE RELEASE

BAXTER ISSUES URGENT MEDICAL DEVICE CORRECTION FOR LIFE2000 VENTILATION SYSTEM DUE TO POTENTIAL FOR PATIENT DESATURATION WHEN CONNECTED WITH AN OXYGEN CONCENTRATOR

DEERFIELD, Ill., MARCH 9, 2023 – Baxter International Inc. announced today it has issued an Urgent Medical Device Correction for the **Life2000** Ventilation System due to the potential for patient oxygen desaturation (low blood oxygen) events that can occur under certain conditions when the **Life2000** system is connected with a third-party oxygen concentrator. The **Life2000** system is manufactured by Hillrom, which was acquired by Baxter in late 2021.

Low oxygen saturation may lead to symptoms such as shortness of breath, confusion, rapid heart rate or bluish skin. Among the most vulnerable patients, death, life-threatening events or permanent impairment may occur if patients or caregivers do not recognize lower oxygen levels. Scenarios that could lead to oxygen desaturation include hoses that are kinked or have excessive moisture; modified, extended or loose/disconnected tubing; oxygen liter flow from the concentrator that has fallen below the prescribed level while using the **Life2000** system; and/or non-compliance with recommended cleaning and maintenance of the **Life2000** system and oxygen concentrator. **Baxter has received reports of patient desaturation that required hospitalization. Based on analysis to date, no deaths have been reported related to this issue.**

As described in the Urgent Medical Device Correction issued on January 25, 2023, patients can continue to use the **Life2000** system if they follow daily checks and preventive maintenance requirements as detailed in the patient letter and Instructions for Use for both the **Life2000** Ventilation System and third-party oxygen concentrators. These actions will help ensure the best oxygen delivery with the **Life2000** system when used with a third-party oxygen concentrator.

Baxter is continuing to monitor and investigate reports received and is currently investigating improvement opportunities. Baxter will 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 all **Life2000** Ventilation Systems used with an oxygen concentrator, including the **Life2000** Ventilator Packaged (BT-20-0002); the **Life2000** Ventilator Packaged A (BT-20-0002A); the **Life2000** System AC Package (BT200007); the Breathe **Life2000** Ventilator PA (BT-20-0007); the **Life2000** System HC Package (BT200011); the Breathe Technology **Life2000** VE (BT-20-0011); and the **Life2000** Ventilator V6.X (MS-01-0118).

The **Life2000** System is distributed in the United States. Customers with additional questions can contact Baxter's Clinical Support Team at 800-397-9071. For parts replacement, customers can contact Baxter Customer Service at 800-426-4224, option 3 between the hours of 7:30 a.m. and 6 p.m. Central Time, Monday through Friday.

Any adverse events experienced with the use of this product may be reported using one of the following options:

- Calling Baxter Customer Service at 800-426-4224, option 3, between the hours of 7:30 a.m. and 6 p.m. Central Time, Monday through Friday.
- Reporting to the FDA MedWatch Serious Injury 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 and the U.S. Food and Drug Administration has been notified of this action.

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 more than 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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