URGENT MEDICAL DEVICE CORRECTION

Follow-up Communication to January 25, 2023, Urgent Medical Device Correction

October 3, 2024

Dear Healthcare Providers, Wholesalers, Distributors/Resellers and Durable Medical Equipment (DME) Providers:

On January 25, 2023, Baxter Healthcare Corporation issued an Urgent Medical Device Correction communication for the **Life2000** ventilation system due to the potential for patient desaturation events that can occur under certain scenarios when connected with an oxygen concentrator.

Baxter has updated the Instructions for Use (IFU) documents to provide additional guidance for using the **Life2000** ventilation system when connected with an oxygen concentrator. See the Actions to be Taken by Customers section below for instructions to access these documents on Baxter's website.

Affected Product

Product Code	Product Description	Impacted Devices	Unique Device Identifier
BT-20-0002	**Life2000** Ventilation System	All when used with an oxygen concentrator	00887761978089
BT-20-0002A	**Life2000** Ventilation System		
BT200007	**Life2000** Ventilator Package, Hospital		
BT-20-0007	**Life2000** Ventilator Package, Hospital		
BT200011	Breathe Technology **Life2000** Ventilation System		
BT-20-0011	Breathe Technology **Life2000** Ventilation System		
MS-01-0118	**Life2000** Ventilator		

Hazard Involved

Baxter has received reports that in certain scenarios, the oxygen concentrator may not deliver the prescribed oxygen liter flow when connected to the **Life2000** ventilation system. This could potentially result in lower oxygen saturation which may include symptoms such as increased breathlessness, confusion, rapid heart rate or bluish skin. Amongst the most vulnerable patients, death, life-threatening events, or permanent impairment may also occur if the lower oxygen liter flow is not recognized. To date, Baxter has received reports of two deaths possibly related to this issue.

The scenarios that could lead to these hazards include:

- Hoses that are kinked or have excessive moisture
- Modified or extended tubing, or loose/disconnected tubing
- Oxygen liter flow from the concentrator that has fallen below the prescribed level while using the **Life2000** ventilation system
- Non-compliance with recommended cleaning and maintenance of the **Life2000** ventilation system and the oxygen concentrator

Actions to be Taken by Customers

1. Access the website link www.hillrom.com/en/products/life2000-system/ or scan the QR code and follow the instructions below to download the **Life2000** ventilation system IFU documents.
    - Click "Education & Documentation" tab
    - Scroll down to "Instructions for Use" and click the down arrow to expand this tab
    - Select "DOWNLOAD" to view documents

For convenience, the updated system setup instructions are enclosed with this letter. Please refer to Attachment A System Setup - Extended Range Configuration (Wearable in the Home).

2. If you received this communication directly from Baxter, acknowledge receipt of this notification by responding on our customer portal at https://BaxterFieldActionCustomerPortal.onprocess.com, even if you do not have any remaining inventory. Log in to the portal using the account number listed in the enclosed reply form instruction sheet. This step is required per FDA guidelines. Acknowledging receipt of this notification will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.
3. If you purchased this product from a distributor or wholesaler, please note that responding on the Baxter customer portal is not applicable. If a response is requested by your distributor or wholesaler, please respond to the supplier according to their instructions.
4. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
5. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) provider that distributed any affected product to other facilities, please notify your customers of this Urgent Medical Device Correction in accordance with your customary procedures and check the associated box on the customer portal. DME providers are required to notify patients of this Urgent Medical Device Correction by forwarding the attached Baxter Home Patient letter.

Further Information and Support

For general questions regarding this Urgent Medical Device Correction, contact Hillrom Advanced Respiratory, Inc. Acute Care Customer Service Team at 800-426-4224, option 2, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any product quality complaints or adverse events experienced with the use of these products may be reported using one of the following options:

- Calling Hillrom Advanced Respiratory, Inc., at 800-426-4224, option 2, between the hours of 8:00 am and 5:00 pm Central Time, Monday through Friday.
- Reporting to the FDA MedWatch Serious Injury Reporting Program:
  - **Online:** By completing and submitting the report at 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

We apologize for any inconvenience this may cause you and your staff.

Sincerely,

Brian Ray
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Baxter Customer Reply Form Instruction Sheet
Baxter's Urgent Medical Device Correction letter dated January 25, 2023
Attachment A
Baxter Home Patient Letter