URGENT MEDICAL DEVICE CORRECTION

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

October 3, 2024

Dear Home Patient:

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 Patients section of this letter 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 Patients

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).

1. Acknowledge receipt of this letter using one of the two methods detailed in the enclosed Home Patient Reply Form Instruction Sheet. This step is required per FDA guidelines. Acknowledging receipt promptly will prevent you from receiving repeat notifications. 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.

Further Information and Support

For general questions regarding this letter, please contact Hillrom Advanced Respiratory, Inc. Home Care Customer Service at 800-426-4224, option 3, between the hours of 7:30 am and 6:00 pm Central Time or the Advanced Respiratory, Inc. clinical support team at 800-397-9071.

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. Home Care Customer Service at 800-426-4224, option 3, between the hours of 7:30 am and 6:00 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 appreciate your attention to this matter.

Sincerely,

Brian Ray
Senior Director, Quality
Baxter Healthcare Corporation

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

