Baxter

URGENT MEDICAL DEVICE CORRECTION

Life2000 Ventilation System – Desaturation Events Due to Potential Interaction with Oxygen Concentrators

January 25, 2023

Dear Home Patient:

Problem Description

Baxter Healthcare Corporation (Hillrom is now a Baxter company) is issuing an Urgent Medical Device Correction 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**. The Life2000 system may continue to be used with the support of the following reminders and instructions included under actions to be taken by patients.

Affected Product

Product Code	Product Description	Impacted devices	UDI Number
BT-20-0002	Life2000 Ventilator Packaged	All Life2000 ventilation systems used with an oxygen concentrator.	00887761978089
BT-20-0002A	Life2000 Ventilator Packaged A		
BT200007	Life2000 System AC Package		
BT-20-0007	Breathe Life2000 Ventilator PA		
BT200011	Life2000 System HC Package		
BT-20-0011	Breathe Technology Life2000 VE		
MS-01-0118	Life2000 Ventilator V6.X		

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. Based on analysis to date, no deaths have been reported 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 system
- Non-compliance with recommended cleaning and maintenance of the Life2000 system and the oxygen concentrator

Actions to be taken by patients

Please follow the daily checks and preventive maintenance requirements below to ensure the best oxygen delivery with the Life2000 ventilation system when used with a third-party oxygen concentrator.

1- Daily Checks

a) Check the CombO_2 hose and Breathe Pillow Interface for kinks, dirt, moisture, or damage and contact Baxter Customer Service at 800-426-4224, option 3, if replacement parts are needed. Baxter recommends replacing the Breathe Pillow Interface every 90 days and the CombO_2 hose every six months.

b) Do not modify, alter, or extend tubing, connectors, or interface. Additionally, when using the Life2000 system with an oxygen concentrator, only use Baxter's approved 6-foot, 20-foot or 50-foot CombO_2 hose.

c) Address alarms as described in the Life2000 Quick Reference Guide (PL-20-0044-D) pages 17-19.

d) Make sure the CombO_2hose is correctly attached to the Life2000 compressor and the oxygen concentrator, as shown in Attachment A, Figure 1. Make sure all connections are tight.

e) Ensure the setting on the oxygen concentrator remains at the prescribed liter flow while connected to the Life2000 system as shown in the Life2000 Extended Range Configuration Quick Start Guide (APR186301). If the liter flow drops when you connect to the Life2000 system, take the following steps:

- Stop using the Life2000 system and go back to your traditional oxygen cannula and concentrator.
- Call Baxter's Clinical Support team at 800-397-9071 for troubleshooting.

f) Please notify your health care team of any concerns or seek medical attention if you are exhibiting signs of respiratory distress (increased breathing rate, wheezing, bluish color around the mouth, lips or fingernails, changes in alertness, or drop in oxygen saturation level) that are unresolved following these troubleshooting actions advised.

2- Periodic Maintenance

a) Follow Baxter's recommendation for cleaning the Life2000 system and accessories found in the Life2000 Quick Reference Guide. See online guide link below or scan the QR code and follow the instructions:

https://www.hillrom.com/en/products/life2000-system/

Instructions

- Click "Education & Documentation"
- Scroll down to "Instructions for Use" and click the down arrow to expand this tab.
- Select "DOWNLOAD" under the document "Life2000 Ventilation System Quick Start Guide"

b) Every oxygen concentrator requires routine maintenance to work efficiently. It is important to follow the oxygen concentrator user manual for recommended guidelines for maintenance and cleaning. You may also call your oxygen concentrator provider for support.

3- Customer Communication Acknowledgement

a) Acknowledge receipt of this letter using one of the two methods detailed on 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

Baxter is continuing to monitor and investigate reports received and is currently investigating improvement opportunities and will provide a follow up once available.

– For general questions regarding this communication, contact Baxter's Clinical Support Team at 800-397-9071.

– For parts replacement, contact Baxter Customer Service at 800-426-4224, option 3, between the hours of 7:30 am and 6:00 pm Central Time, Monday through Friday.

The United States Food and Drug Administration (FDA) has been notified of this action. Any adverse events or quality problems experienced with the use of these products 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 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 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

We thank you for your attention to this important safety information.

Sincerely,

Brian R. Ray
Quality Assurance Director
Baxter Healthcare Corporation

Enclosure: Home Patient Reply Form Instruction Sheet
Attachment A