URGENT MEDICAL DEVICE CORRECTION

September 12, 2024

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

Baxter Healthcare Corporation is issuing a voluntary Urgent Medical Device Correction for the **Life2000** ventilation system. Baxter identified that the **Life2000** Ventilator may fail to initiate the Low Gas Pressure alarm if the pressure gas source (**Life2000** compressor, oxygen cylinder or wall source) is not supplied to the ventilator before initiating therapy.

Baxter is currently working on a software update to address this issue for the **Life2000** ventilation system and will contact all impacted customers to update their devices once the update is available.

The affected product began distribution on 8/11/2020 in the United States.

Affected Product

Product Code	Product Description	Impacted Devices	Device Identifier Number
MS-01-0118	**Life2000** Ventilator	All **Life2000** Ventilators with software version 06.08.00.00	00887761978089 or 00815410020537

Hazard Involved

The **Life2000** ventilation system devices with ventilator software version 06.08.00.00 may fail to alarm for Low Gas Pressure at startup if the steps in the Instructions for Use and Quick Reference Guide are not adhered to by the patient/user. Although unlikely, respiratory compromise may occur if inadequate gas flow or declining patient condition (e.g., shortness of breath and/or oxygen desaturation) is not identified in a timely manner during troubleshooting and inspection of the system. Once the gas source is turned on, the device operates as intended. To date, Baxter has received one report of serious injury potentially related to this issue.

Actions to be Taken by Customers

1. Prior to starting therapy, healthcare providers and patients should ensure that the **Life2000** ventilator is connected to a pressure gas source first (**Life2000** compressor, oxygen cylinder, or wall source) and then turned on. The system setup instructions can be found on the Quick Reference Guide, page 11-13.
2. Refer to Attachment A for the website link and QR code for the Quick Reference Guide, Instructions for Use and additional information regarding troubleshooting guidance.
3. 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. 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.
4. 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.

5. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to them.
6. 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 home patient letter.

Further Information and Support

For general questions regarding this Urgent Medical Device Correction, contact 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 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 Home Patient Letter
Attachment A: Online Resources and Troubleshooting Guidance