URGENT MEDICAL DEVICE CORRECTION

December 20, 2024

Dear Facility Risk Manager, Biomedical Engineering Department and Durable Medical Equipment Providers:

Baxter Healthcare Corporation is issuing an Urgent Medical Device Correction for the **Life2000** ventilation system due to an issue with the ventilator battery charger that could lead to an audible and visual alarm. If the alarm is engaged, the ventilator becomes inoperable. The alarm is a high-pitched sound with repetitive beeping and a visual red flashing LED icon, alerting the user to an issue with the device.

Baxter identified the root cause of the issue to be a manufacturing process control issue that punctures the insulation of internal wires of the battery charger connector. Baxter has corrected the issue, and a Baxter representative will contact you to provide a replacement charger and arrange for the return of your defective battery charger.

Distribution of the affected product began on April 1, 2024, in the United States.

Affected Product

Product Code	Product Description	Impacted Devices	Device Identifier Number
MS-01-0118*	**Life2000** Ventilator	Refer to Attachment A	00887761978089 or 00815410020537

*Product code MS-01-0118 appears on the ventilator. Product codes BT-20-0002, BT-20-0002A, and BT-20-0002AP appear on the shipping cartons.

Hazard Involved

If the **Life2000** ventilator becomes inoperable due to a defective charger, this may leave the user unable to use the device. Patients requiring ventilator support may experience deterioration in respiratory status, leading to hypoxia (lack of oxygen), with resulting cognitive impairment (confusion), lethargy, changes in blood pressure and heart function, or even coma and death. If the patient is not quickly transitioned to an alternate means of ventilation or oxygen therapy, further lung damage could occur depending on the user's pre-existing medical condition and access to their recommended back-up device or oxygen therapy. To date, Baxter has received 105 potential complaints related to this issue, however, no reports of serious injury or death have been reported.

Actions to be Taken by Customers

1. Always have an alternate means of ventilation or oxygen therapy available.
2. Patients may continue using the **Life2000** ventilator if it is functioning correctly. If the ventilator becomes inoperable, place the patient on an alternate means of ventilation, if necessary, and contact Baxter Advanced Respiratory, Clinical Support team at 800-397-9071.
3. In the interim if patients experience this failure and have an additional charger available, connect it to the ventilator and verify that the ventilator is charging.
4. If you received this communication directly from Baxter, please 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.

5. 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.
6. If you distributed this product to other facilities or departments within your institution, please forward a copy of this communication to the Director of Respiratory Therapy, Patient Safety, and any other departments within your institution who use the affected product.
7. If you are a dealer, wholesaler, distributor/reseller, or original equipment manufacturer (OEM) 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. Durable Medical Equipment 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, please contact the Baxter Advanced Respiratory team at 800-426-4224, option 2, then option 1, between the hours of 8:00 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 product quality complaints or adverse events experienced with the use of these products may be reported using one of the following options:

- Baxter Advanced Respiratory team at 800-426-4224, option 2, then option 1, between the hours of 8:00 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 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
Attachment A: Affected Serial Numbers
Baxter Home Patient Letter