Urgent Medical Device Recall

May 29, 2024

Dear Home Patients:

Problem Description

Baxter Healthcare Corporation is issuing a voluntary Urgent Medical Device Recall for the **Life2000** ventilator system. Baxter has received reports relating to the new battery charger dongle which was implemented in July 2023 [see Figure 1 below]. Baxter has determined that the **Life2000** ventilator systems were either failing to charge or had intermittent charging behavior due to damage to the battery charger dongle. Damage to the battery charger dongle prevents the ventilator's internal battery from charging.

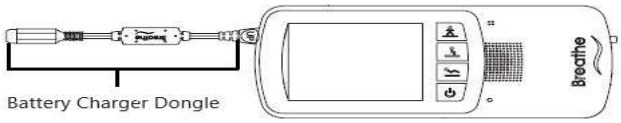

Figure 1. Battery Charger Dongle

The affected product was distributed to customers in the United States between 8/21/2023 and 4/2/2024.

Affected Product

Product Name	Product Code	UDI Number
Life2000 Ventilator	MS-01-0118	00887761978089

Hazard Involved

If the **Life2000** ventilator system fails to charge or has intermittent charging behavior, this may leave the user unable to use the device. Users requiring ventilator support may experience oxygen desaturation episodes that range from mild to potentially life threatening, depending on the user's pre-existing medical condition and access to their recommended back-up device or oxygen therapy. Baxter has received one serious injury complaint potentially related to this issue. No deaths have been reported.

Actions to be taken by patients

1. Patients should always have an alternate means of ventilator or oxygen therapy available.
2. Inspect the condition of the battery charger dongle. If damage is observed or if the unit is not charging, users should contact Baxter Home Care Customer Service at 800-426-4224, option 3, to replace your **Life2000** ventilator system immediately.
3. Patients may continue to use the **Life2000** ventilator system once they inspect and confirm that there is:
    - no damage to the battery charger dongle, and
    - the battery is charging appropriately

4. When charging the ventilator from low battery state, check that the ventilator battery charge icon is displayed on the touch screen to ensure the battery is charging the ventilator. [see Figure 2 below]

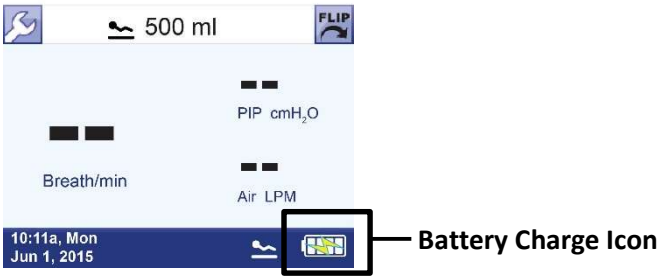

Figure 2. Battery Charge Icon

5. Patients should observe any alarms from the **Life2000** ventilator system and contact Baxter Clinical Support at 800-397-9071, for assistance with any observed alarms. Review the Quick Reference Guide for more details about the approximate ventilator battery charge, approximate time remaining, and associated alarms. See online guide link below, or scan the QR code and follow the instructions below.

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

   - Click “Education & Documentation”
   - Scroll down to “Instructions for Use” and click the down arrow to expand this tab
   - Select “DOWNLOAD” under the documents “Life2000 Ventilator System Quick Reference Guide”

6. Baxter will replace your ventilator device upon your next scheduled in-home visit with a clinical trainer. The clinical trainer will be contacting you to arrange this in-home visit.
7. **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

For general questions regarding this Medical Device Recall, please contact Baxter Home Care Customer Service at 800-426-4224, option 3, or Baxter Clinical Support 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 Baxter 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 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 appreciate your attention to this matter.

Sincerely,

Brian Ray
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Home Patient Reply Form Instruction Sheet