Baxter

URGENT MEDICAL DEVICE RECALL

April 10, 2025

Dear Home Patient:

After careful consideration, Baxter is ending the manufacture, distribution and service of the **Life2000** Ventilation System. We are voluntarily initiating a permanent removal of all **Life2000** ventilators currently in use with patients due to a cybersecurity issue discovered through internal testing. If an unauthorized person were to gain physical access to your device while it's unattended, they would potentially be able to change device therapy settings or access device data. Although this is unlikely to occur, it could lead to the life-supporting air delivery function not working as intended, which may result in serious adverse health consequences. To date, Baxter is not aware of any incidents of this issue or related patient injury occurring.

We apologize for the inconvenience this may cause and will work to support you in your transition from the **Life2000** ventilator. Baxter is advising patients to reach out to their healthcare provider to discuss therapy replacement options and transfer your care to an alternative medical equipment supplier. We will continue to support your therapy on the **Life2000** ventilator until an alternative therapy and medical equipment supplier are identified, Baxter will then assist you with the permanent return of the **Life2000** Ventilation System.

If you received Baxter's Urgent Medical Device Correction dated September 12, 2024, related to Low Gas Pressure alarms (Baxter reference # FA-2024-053), please note that Baxter will not be updating affected devices.

If you received Baxter's Urgent Medical Device Correction dated December 20, 2024, regarding battery charger failures (Baxter reference # FA-2024-066), please note that Baxter will continue to provide replacement chargers for those experiencing failures until the **Life2000** ventilators are removed.

Affected Product

Product Code	UDI-DI Number	Product Code on Shipping Carton	Product Description	Serial Numbers
MS-01-0100	00815410020278	BT-20-0002, BT-20-0002A, BT-20-0002AP, BT-20-0007, BT200007, BT-20-0011, BT200011, and RMS010118CP	**Life2000** Ventilator	All
MS-01-0118	00887761978089 or 00815410020537			
MS-01-0093	00887761978072 or 00815410020292	BT-80-0004, BT-80-0004A, BT-80-0008, BT-80-0008A, and RMS010093CP	**Life2000** Compressor	All
MS-01-0121	00887761978041			
MS-01-0125	00887761976283			

Actions to be Taken by Patients

1. Please reach out to your healthcare provider to discuss therapy replacement options and transfer your care to an alternative medical equipment supplier.
2. Once alternative therapy and medical equipment suppliers have been identified, please contact Baxter Advanced Respiratory, Inc, Home Care Customer Service team at 800-426-4224, option 3, to arrange the permanent return of the **Life2000** Ventilation System.

3. Baxter recommends that users of the **Life2000** Ventilation System not leave their ventilators unattended in public or unsecured areas. Maintaining physical possession and control of the ventilator reduces the likelihood of an unauthorized person gaining access to the device.

   If you suspect that your device has been exposed to unauthorized personnel, contact your healthcare team, and then contact Baxter Advanced Respiratory, Inc, Home Care Customer Service team. The team can help verify whether the device settings are correct and if the device is performing as expected. They can be reached by email at HRC_HCCS_Web@baxter.com, or by phone at 800-426-4224, option 3.

4. If you received this communication directly from Baxter, acknowledge receipt using one of the two methods detailed on the enclosed Home Patient Reply Instruction Sheet. Acknowledging receipt of this notification promptly will prevent you from receiving repeat notices. If you do not complete the acknowledgement, you will receive a phone call or email from OnProcess Technology on behalf of Baxter to confirm your receipt of this notification.
5. If you received this communication from a medical equipment supplier other than Baxter, please note that responding to Baxter is not applicable. If a response is requested by your supplier, please respond to them according to their instructions. If you have questions regarding your supplier's communication, please contact them.

Further Information and Support

For general questions regarding this communication, please contact Baxter Advanced Respiratory, Inc, Home Care Customer Service team at 800-426-4224, option 3, or Baxter Clinical Support at 800-397-9071, 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:

- Contacting Baxter 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

Again, we apologize for any inconvenience this may cause you and we will work to support your ventilator transition.

Sincerely,

Brian Ray
Senior Director, Quality
Baxter Healthcare Corporation

Enclosure: Home Patient Reply Instruction Sheet