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OCT 20 2026

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16422 PEDIATRIC HOME RESPIRATORY SERVICE, LLC DBA PEDIATRIC HOME SERVICE LLC
2800 CLEVELAND AVE N.
ROSEVILLE MN 55113-1126

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Date: October 15, 2026

URGENT: MEDICAL DEVICE RECALL NOTIFICATION

Luna G3 BPAP System (Model LG3800-30VT)

16422 Pediatric Home Respiratory Service, LLC DBA Pediatric Home Service LLC
2800 Cleveland Ave N.
Roseville MN 55113

Dear Valued Partner,

The purpose of this letter is to advise you that 3B Medical Inc. (dba React Health) is voluntarily initiating a correction(recall) of specific Luna G3 BPAP System (Model LG3800-30VT) devices due to a device data handling issue that may result in incorrect therapy pressure statistical data being displayed on the device and the related cloud platform when the device is operated with Targeted VT enabled. Please refer to the Details on Affected Devices section of this letter for the specific serial numbers affected by this recall.

Please ensure that you read this notification immediately, and in its entirety, to determine if you still have the affected product; to learn how we are resolving the issue; and the mitigation steps to take until these devices have been corrected. Your prompt action as described below is required and appreciated.

Explanation of the Issue:
React Health is recalling specific units (listed below) of the Luna G3 BPAP System (Model LG3800-30VT) due to a data storage and transmission error while Targeted VT is enabled. Devices operating with Targeted VT enabled will not record the actual pressure statistical data delivered to the patient on the internal SD card or transmit the pressure to the cloud-based management system (React Health Connect). While the device does provide the intended patient ventilation support when this feature is enabled and displays the correct information on the device itself during therapy, the incorrect pressure statistical data is displayed on the device and remotely after therapy is completed.

Users that have not enabled the Targeted VT feature on their Model LG3800-30VT device will not experience this issue. Usage data on React Health Connect shows that 80% of users have never enabled this feature on their device.

Potential Risk:
The hazardous condition requires the device to be operated with Targeted VT enabled and monitored remotely via either data downloaded to the SD card or via wireless communication to the cloud-based management system (React Health Connect). The consequence of the inaccurate pressure data in historical therapy reports could lead a clinician to adjust device settings based on inaccurate therapy pressure data, which could result in temporary suboptimal therapy settings until corrected. Design features that reduce the risk of this issue include the device adjusting pressure delivered to the patient within the clinician defined minimum and maximum pressures delivering a tidal volume equal to the clinician set tidal volume, within tolerance. The Luna® G3 BPAP System is a Bi-level PAP (Bi-level Positive Airway Pressure) device designed for the treatment of adult Obstructive Sleep Apnea (OSA). The device delivers two pressure levels: a higher pressure during inhalation and

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a lower pressure during exhalation to support breathing and improve patient comfort. The device continuously monitors the patient's breathing and delivers therapy based on the configured mode and clinician-defined settings. The device is primarily used in the home during sleep, typically placed on a bedside table or similar indoor environment. It may also be used in clinical or institutional settings while the patient is asleep or awake under the supervision of trained healthcare professionals.

Actions Taken by React Health:
The subject product will be updated by the customer with a firmware correction provided by React Health to ensure conformance to product requirements. The firmware correction will be sent out upon receipt of the completed customer response form as described below.

Details on Affected Devices:
Our records indicate that you are the owner of affected Luna G3 BPAP System (Model LG3800-30VT) devices with the following serial number(s):

CATALOG (REF) #	Luna G3 BPAP System (Model LG3800-30VT)	Date Shipped:
UDI-DI	06948538365731	
As labeled SN #	B3C22518315	12/21/2023
	B3C22533018	2/21/2024
	B3C22534383	4/8/2024
	B3C22535190	4/8/2024
	B3C22529426	4/8/2024
	B3C22412206	10/26/2023
	B3C22517176	12/21/2023
	B3C22533036	2/21/2024
	B3C22529280	6/3/2024
	B3C22518166	12/21/2023
	B3C22518204	12/21/2023
	B3C22533350	2/21/2024
	B3C22533372	2/21/2024
	B3C22529037	4/8/2024

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	B3C22533083	4/29/2024
	B3C22824319	6/3/2024
	B3C22826058	6/3/2024
	B3C22723530	6/3/2024
	B3C22537054	2/26/2025
	B3C22413125	6/3/2024
	B3C22824315	6/3/2024
	B3C22537044	2/26/2025
	B3C22825410	6/3/2024
	B3C22826006	6/3/2024
	B3C22536035	3/27/2025
	B3C22524100	1/29/2025
	B3C22824423	6/3/2024
	B3C22524151	5/16/2024
	B3C22825058	6/3/2024
	B3C22536050	2/26/2025
	B3C22529425	3/24/2025
	B3C22A23298	3/20/2025
	B3C22826093	6/3/2024
	B3C22824311	6/3/2024
	B3C22A24220	3/27/2025
	B3C22826030	6/3/2024
	B3C22533537	3/27/2025
	B3C22A21091	4/9/2025

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	B3C22524370	5/16/2024
	B3C22A27053	3/20/2025
	B3C22524411	10/17/2025
	B3C22534034	1/29/2025
	B3C22826094	6/3/2024
	B3C22824512	6/3/2024
	B3C22A23194	9/2/2025
	B3C22533046	5/16/2024
	B3C22533109	1/29/2025
	B3C22536059	2/26/2025
	B3C22525269	5/16/2024
	B3C22A22171	3/20/2025
	B3C22826092	6/3/2024
	B3C22722075	9/12/2024
	B3C22825161	6/3/2024
	B3C22A28141	3/20/2025
	B3C22524130	10/21/2025
	B3C22533190	3/3/2025
	B3C22525052	10/17/2025
	B3C22A21048	12/3/2025
	B3C22825308	6/3/2024
	B3C22537137	3/27/2025
	B3C22524029	1/29/2025
Total Quantity of Affected product:	61	

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Action to be Taken by the Customer:

React Health requests the customer(s) follow the clinical action below and acknowledge receipt.

Clinical Action:

1. Immediately discontinue use of Targeted VT if enabled on affected Luna G3 BPAP System (Model LG3800-30VT) device.
2. Inspect current stock, quarantine/segregate any unused affected products, remove affected devices from clinical service and segregate to prevent further use.
3. Use an unaffected PAP device for patient support.
4. If you have distributed or transferred affected devices to other facilities, caregivers, or end users, you must promptly notify them of this recall and provide a copy of this notification.

Acknowledge Receipt:

1. Confirm receipt of this notification letter by returning the enclosed Customer Response Form to React Health **WITHIN 7 DAYS OF RECEIPT**.
2. Upon receipt of the Customer Response Form, React Health will arrange for shipment of the firmware update along with instructions to load onto existing device(s) as well as an update confirmation letter.
3. Update the affected product and return the completed confirmation letter to React Health. Contact Customer Support at 863-226 -6285 to discuss completing the form, if necessary.
4. After upgrading the firmware to G3-2.00.80, please erase historical usage data via: Clinical Menu-Maintenance-Erase Data.

Additionally, this firmware update will allow the collection and display of reported pressure data of delivered therapy while Targeted VT is enabled. All historic data collected with Targeted VT enabled prior to this upgrade will not be changed and will reflect previously recorded non-fluctuating therapy pressures in device storage and the related cloud platform applications.

Please acknowledge receipt of this notification and respond via the enclosed Customer Response Form within 7 days of receipt.

For any questions, please contact React Health directly at 863-226 -6285, Monday through Friday between 8:00 a.m. - 5:00 p.m. Eastern Time (ET). Adverse reactions or quality problems experienced with the use of this device may be reported to the FDA's MedWatch Adverse Event Reporting program.

React Health appreciates your prompt attention to this matter and apologizes for any inconvenience caused by this problem and is committed to partner with you to minimize the effort required to respond to this voluntary recall. Patient safety is our number one priority, and we appreciate your continued trust in us to provide quality respiratory products to support patient care.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch program at www.fda.gov/medwatch.

Regards,

Atul Sinha

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Atul Sinha
Executive Vice President, Quality and Reg Affairs, React Health

Enclosure(s): Customer Recall Notification Response Form

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Customer Recall Notification Response Form
Luna G3 BPAP System (Model LG3800-30VT)
RESPONSE IS REQUIRED

16422 Pediatric Home Respiratory Service, LLC DBA Pediatric Home Service LLC
2800 Cleveland Ave N.
Roseville MN 55113

CATALOG (REF) #	Device Serial Number (as labeled)	Quantity on Hand	Device Confirmation
LG3800	B3C22518315		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22533018		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22534383		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22535190		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22529426		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22412206		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22517176		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22533036		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22529280		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22518166		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22518204		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22533350		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22533372		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22529037		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22533083		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22824319		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22826058		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22723530		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22537054		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22413125		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22824315		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22537044		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22825410		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22826006		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22536035		☐ In Use ☐ In inventory ☐ No longer in possession

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LG3800	B3C22524100		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22824423		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22524151		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22825058		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22536050		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22529425		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22A23298		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22826093		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22824311		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22A24220		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22826030		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22533537		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22A21091		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22524370		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22A27053		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22524411		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22534034		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22826094		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22824512		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22A23194		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22533046		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22533109		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22536059		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22525269		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22A22171		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22826092		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22722075		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22825161		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22A28141		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22524130		☐ In Use ☐ In inventory ☐ No longer in possession
LG3800	B3C22533190		☐ In Use ☐ In inventory ☐ No longer in possession

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LG3800	B3C22525052		☐ **In Use** ☐ **In inventory** ☐ **No longer in possession**
LG3800	B3C22A21048		☐ **In Use** ☐ **In inventory** ☐ **No longer in possession**
LG3800	B3C22825308		☐ **In Use** ☐ **In inventory** ☐ **No longer in possession**
LG3800	B3C22537137		☐ **In Use** ☐ **In inventory** ☐ **No longer in possession**
LG3800	B3C22524029		☐ **In Use** ☐ **In inventory** ☐ **No longer in possession**

Adverse Event / Product Issue Reporting

Have you identified any adverse events, device malfunctions, or patient safety concerns associated with the affected Luna G3 BPAP System (Model LG3800-30VT) devices?

☐ **No, we have not identified any adverse events or device malfunctions.**
☐ **Yes, an adverse event or malfunction has been identified.**
If yes, please provide details below, or complete on a separate page:

Device Serial Number (as labeled)	Date Identified	Description of Adverse Event or Malfunction

Please acknowledge receipt of this information by checking below:

☐ I have read the information within the accompanying **React Health – URGENT Medical Device Recall Notification Letter**. All relevant personnel have been informed of its contents, any necessary actions have been taken, and records retained as part of our documentation procedure.

☐ We do not have the product(s) listed. The products have been consumed or further distributed:

- ☐ Consumed (for single use devices)
- ☐ Distributed to: _____

Signature of Receipt _____

Please return by mail (WITHIN 7 days OF RECEIPT) to: Attention: Recall Coordinator
3B Medical, Inc. dba React Health
5475 Rings Rd., Suite 550
Dublin, OH 43017

Or return by email to: 3B-Recall@reacthealth.com

For questions, please call: 863.226.6285