REACTHEALTH

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Email Sent to Recall Team.

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Reacthealth.com

Date: October 15, 2026

URGENT: MEDICAL DEVICE RECALL NOTIFICATION

Luna G3 BPAP System (Model LG3800-30VT)

16644 Binson's Hospital Supplies, Inc. DBA Binson's Medical Equipment and Sales
26330 Lawrence
Center Line MI 48015

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):

UDI-DI	06948538365731	
As labeled SN #	B3C22537381	10/10/2025
	B3C22533470	10/10/2025
	B3C22524315	10/10/2025
	B3C22537257	10/10/2025
Total Quantity of Affected product:	4	

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

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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

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

Enclosure(s): Customer Recall Notification Response Form