carecentrix

Provider Newsflash
September 2026

FDA Recall – BMC Medical Co., Ltd. Luna G3 APAP (Model LG3600)

Purpose of this communication:

We are writing to inform you that the FDA has issued a Class I recall for BMC Medical Co., Ltd. Luna G3 APAP (Model LG3600) device with firmware version G3-2.00.76. The firmware defect may trigger an "Error" message and automatic shutdown when the device operates simultaneously under high pressure, high respiratory rate, and high peak flow, resulting in failure to deliver therapy and possible serious adverse health consequences. Affected devices were manufactured from September 11, 2024, through October 18, 2024, and distributed nationwide from October 29, 2024, through July 6, 2026. BMC identified up to 196 devices that may not have received the firmware upgrade to G3-2.00.77.

Users should check the device serial number and firmware version, consult their physician and durable medical equipment provider, and contact React Health for replacement. Devices with affected firmware should be discontinued immediately until a replacement is provided. BMC reported no complaints or serious adverse reports associated with this firmware failure.

What do I need to do?

- Please review the following recall notice: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/bmc-medical-co-ltd-recalls-luna-g3-apap-model-lg3600-firmware-g3-20076-due-firmware-defect?utm_medium=email&utm_source=govdelivery
- Notify impacted patients and facilitate the repair, replacement and/or resolution of the recall, according to the guidelines issued by the manufacturer in the FDA notification.
- Confirm if you have any CareCentrix patients affected by this recall and notify the CareCentrix Quality Department by faxing information to: 919-792-6718 Attn: Quality Department.

Thank you in advance for your cooperation and continued partnership.