



## UPDATE: URGENT MEDICAL DEVICE CORRECTION

### MiniMed™ 600 series and 700 series pump systems – battery status alerts and alarms

Pump models include the MiniMed™ 630G, 670G, 770G, and 780G systems.

October 2024

Dear Valued Customer:

In July 2024, Medtronic sent a safety alert to customers to reinforce the importance of following the pump's built-in alerts and alarms for battery status, and to always carry extra batteries, as outlined in the User Guide. You can view our previous communication [here](#). This update is intended to inform you about situations that may result in shortened pump battery life with the potential for the pump to stop insulin delivery significantly sooner than expected. We also wanted to reinforce that support is available if you're impacted by this issue and you can contact us at 1-800-378-2292 to determine the need for a replacement pump.

#### Issue Description:

In some instances, pumps that have been dropped, bumped, or experienced physical impact, may experience damage to internal electrical components, which may result in reduced battery life, causing the battery alerts to occur when less battery life remains than the User Guide states. Even a single drop could result in reduced battery life, either immediately after the drop, or over time, and will continue to affect the pump even after replacing the battery. Affected pumps will still show "Low Battery Pump" alert which is intended to signal that there are up to 10 hours of battery life remaining, however the actual amount of battery life may be significantly shorter. Following the "Low Battery Pump" alert, escalating alerts and sirens may activate. When the "Replace Battery Now" alarm appears, insulin delivery stops. Extended time without insulin delivery can lead to health risks like hyperglycemia or diabetic ketoacidosis (DKA), potentially requiring medical intervention.

Most recently, Medtronic has received 170 reports of hyperglycemia >400mg/dL and 11 reports of diabetic ketoacidosis from January 2023 to September 2024 in the US potentially related to this issue.

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## Actions Required:

- Ensure you carry an extra set of new AA lithium or alkaline batteries or fully charged NiMH batteries should you need to replace your pump battery sooner than expected.
- Always pay attention to alerts and alarms displayed on your pump and be prepared to replace the battery as soon as you receive the “Low Battery Pump” alert. Do not wait for the later battery alerts as these may occur when less battery life remains than the User Guide states. Refer to your pump’s User Guide for instructions on how to replace the battery.
- **If you notice any significant decrease in battery life, regardless of whether your pump has been dropped, bumped, or has experienced physical impact, contact the Medtronic 24-Hour Technical Support team at 1-800-378-2292, for troubleshooting support to determine if a replacement pump is needed.**
- Ensure you have back-up insulin therapy available at all times in your emergency kit in case it's needed.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

Complete and submit the report online: [www.fda.gov/MedWatch/report.htm](http://www.fda.gov/MedWatch/report.htm).

Regular mail or fax: Download format <http://www.fda.gov/MedWatch/getforms.htm> or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form or submit by fax to 1-800-FDA-0178.

**Please acknowledge that you have read and understood this updated notification and have followed the actions listed in this letter** by either completing and returning the confirmation form, scanning the QR code below, or acknowledging it online at [this link](#). It is important to acknowledge receipt of this notice even if you've completed this step for the initial letter sent in July.



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As always, we are here to support you. If you have further questions or need assistance, please call the Medtronic 24-Hour Technical Support line at 1-800-378-2292.

Sincerely,

**Julio Salwen**

Vice President, Quality  
Medtronic Diabetes

**Joshua Miller, MD, MPH**

Senior Medical Director, Medical Safety  
Medtronic Diabetes