

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.

15-October-2024

Dear Valued Customer:

Medtronic is contacting you to reinforce the importance of following the pump's built-in alerts and alarms for battery status, to always carry extra batteries as outlined in the User Guide, and 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 training on your insulin pump is available, and support is available if you're impacted by this issue. We can be contacted at 1-800-284-4416 and select 'option 1' 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.

Medtronic has received 271 reports of hyperglycemia $>400\text{mg/dL}$ or $>22.2\text{mmol/L}$ and 22 reports of diabetic ketoacidosis from January 2023 to September 2024 globally potentially related to this issue. There have been no confirmed serious injuries associated with this issue.

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 1-800-284-4416 and select 'option 1', 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.

Please acknowledge that you have read and understood this updated notification and have followed the actions listed in this letter by scanning the QR code below, or acknowledging it online at:

<https://info.medtronicdiabetes.com/battery-status-ca-en>



Additional Information:

Medtronic will notify all applicable regulatory agencies about this matter.

As is standard practice, adverse event or quality problems experienced with the use of this product should be reported to technical service team at 1-800-284-4416.

Your safety is our top priority, and we appreciate your time and attention in reading this important notification. We apologize for the inconvenience. If you have any questions, please contact us at 1-800-284-4416 or medtronicdiabetescc@medtronic.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Zoltek', written over a light blue horizontal line.

Zachary Zoltek

Manager, Post-Market Vigilance
Medtronic Canada ULC