

SAFETY ALERT – MiniMed™ 600 series and 700 series pump systems — battery status alerts and alarms

Products: All MiniMed™ 600 series and MiniMed™ 700 series insulin pump models, including MiniMed™ 630G, MiniMed™ 670G, MiniMed™ 770G, and MiniMed™ 780G

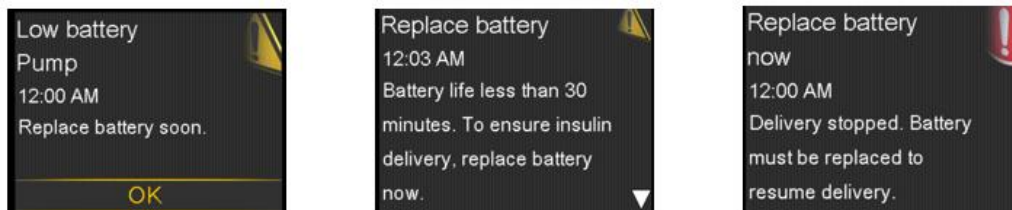
July 2024

Dear Valued Customer:

Medtronic is contacting you with a reminder about the importance of following your pump's built-in alerts and alarms for battery status when they are displayed on the pump, as outlined in the instructions for use. The MiniMed™ 600 series and 700 series pump systems are designed to monitor the pump's battery life over time and will generate a series of visual, audible, and vibratory low battery alerts and alarms to remind you when it is time to replace the battery.

- The “Low Battery Pump” alert will display when your pump has up to 10 hours of battery life left.
- The “Replace Battery” alert will display when the pump has less than 30 minutes of battery life left.
- If the battery is not replaced within 10 minutes, a siren will sound and repeat once every minute until the “Replace Battery Now” alarm is displayed. At that time, the pump will stop insulin delivery.

If the battery is not replaced within 10 minutes of this alarm, a siren will sound, and the pump will shut down.



Visual Pump Notifications before Battery Depletion

- In addition, the pump displays the battery status on the home screen.



Example of Battery Icon on Pump Home Screen Status Bar

Issue Description:

We have found that in some instances, pumps that have been dropped, bumped, or experienced physical impact, may have damage to internal electrical components, which may cause reduced battery life on the pump. Please note that even a single drop could result in reduced battery life, either immediately after the drop, or over time. Your pump will still generate low battery and replace battery alerts and alarms; however, these notifications may display sooner than expected, resulting in the battery needing to be replaced sooner than expected. No serious injuries have been confirmed to be related to the battery depleting sooner than expected on MiniMed™ 600 and 700 series pumps.

Recommended Actions for Customers:

- Always pay attention to alerts and alarms displayed on your pump.
- Be aware that you can check your pump's battery level anytime on the status bar located on the pump home screen.
- If your pump has been dropped, bumped, or has experienced physical impact, pay special attention to any pump alerts and alarms, including low battery alerts, as they may occur earlier than expected. Follow any prompts on the pump to replace the battery. Refer to your pump's user guide for instructions on how to replace the battery. If you notice any significant changes in battery life or need additional troubleshooting assistance, please contact the Medtronic 24-Hour Technical Support line for further help.
- Ensure you always have extra new AA lithium or alkaline batteries or fully charged NiMH batteries available, along with your other emergency kit supplies.
- As indicated in the pump's user guide, keep an emergency kit available at all times to confirm that necessary supplies are ready.

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.
- Regular mail or fax: Download format 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 notification and have followed the actions listed in this letter by either completing and returning the confirmation form, scanning the QR code below, or

Medtronic

visiting <https://info.medtronicdiabetes.com/battery-status-acknowledgement> to acknowledge this communication.



To scan the QR code open the built-in camera app on your phone or tablet. Point the camera at the QR code. Tap the banner that appears on your phone or tablet and the instructions on the screen to finish.

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 800-646-4633, option 1.

Sincerely,

Julio Salwen
Vice President, Quality
Medtronic Diabetes