

Voluntary recall notifying Medtronic insulin pump users of potential risks of shortened pump battery life

Customers are being notified of the importance of checking built-in alerts and alarms for battery status and to contact Medtronic for pump replacement if affected by this issue

GALWAY, Ireland, Oct. 4, 2024 /PRNewswire/ -- Medtronic plc (NYSE: MDT), a global leader in healthcare technology, voluntarily issued a field action starting on July 31, 2024, notifying global customers of its MiniMed™ 600 series or 700 series insulin pumps to follow their pump's built-in alerts and alarms for battery status and to contact Medtronic if they observe changes in the battery life of their pump. Medtronic began investigating this issue upon receiving customer reports of shortened battery life and a comprehensive analysis found that pumps that have been dropped, bumped, or experienced physical impact even once may result in shortened battery life due to damage to internal electrical components. This electrical issue also causes battery alerts to occur when less battery life remains than the User Guide states. This may result in the pump stopping insulin delivery significantly sooner than usually expected and could 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. The FDA has classified this action as a class I recall.

Medtronic issued an updated notification to customers stating the following:

- Even a single drop of the pump could result in reduced battery life, either immediately after the drop, or over time, and the issue will continue even after replacing the battery.
- The pump will still generate battery alerts and alarms, but these alerts and alarms may not be delivered with the usual amount of battery life remaining before the battery must be replaced to avoid the pump stopping insulin delivery. Be prepared to replace the battery as soon as the "Low Battery Pump" alarm sounds.
- Users should always carry an extra set of new AA lithium or alkaline batteries or fully charged NiMH batteries should they need to replace the battery sooner than expected.
- Users who notice a significant decrease in battery life from their usual experience, regardless of whether their pump has been dropped, bumped, or has experienced physical impact, should contact their local Medtronic team to determine whether a replacement pump is needed. Customers in the U.S. can call 1-800-378-2292 for 24-hour technical support. Customer outside the U.S. can click on [this link](#) to find the number for their local support team.
- Users are advised to have a back-up therapy available in case it's needed.

"Medtronic began proactively notifying impacted pump users in July because of the high priority we place on patient safety and understand the important role of pumps in the care and management of diabetes," said Robert Vigersky, MD, Chief Medical Officer, Medtronic Diabetes. "Our team is here 24 hours a day, 7 days a week to help if you experience battery depletion or any other issue with your pump. Patient safety is our priority, as is continuity of therapy, which is why we made the decision to voluntarily notify patients and will replace pumps when needed."

The [original notification](#) and the [updated notification](#) are available on the Medtronic Diabetes website.

About the Diabetes Business at Medtronic (www.medtronicdiabetes.com)

Medtronic is working together with the global community to change the way people manage diabetes. The company aims to transform diabetes care by expanding access, integrating care and improving outcomes, so people living with diabetes can enjoy greater freedom and better health.

About Medtronic

Bold thinking. Bolder actions. We are Medtronic. Medtronic plc, headquartered in Galway, Ireland, is the leading global healthcare technology company that boldly attacks the most challenging health problems facing humanity by searching out and finding solutions. Our Mission – to alleviate pain, restore health, and extend life – unites a global team of 95,000+ passionate people across more than 150 countries. Our technologies and therapies treat 70 health conditions and include cardiac devices, surgical robotics, insulin pumps, surgical tools, patient monitoring systems, and more. Powered by our diverse knowledge, insatiable curiosity, and desire to help all those who need it, we deliver innovative technologies that transform the lives of two people every second, every hour, every day. Expect more from us as we empower insight-driven care, experiences that put people first, and better outcomes for our world. In everything we do, we are engineering the extraordinary. For more information on Medtronic, visit www.Medtronic.com and follow Medtronic on [LinkedIn](#).

Any forward-looking statements are subject to risks and uncertainties such as those described in Medtronic's periodic reports on file with the Securities and Exchange Commission. Actual results may differ materially from anticipated results.



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