

Medtronic Ireland Limited

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URGENT FIELD SAFETY NOTICE

MiniMed™ 600 series and 700 series pump systems

Battery status alerts and alarms

Notification

Insulin Pump	Model Number
MiniMed™ 620G Insulin Pump	MMT-1710, MMT-1750
MiniMed™ 630G Insulin Pump	MMT-1714, MMT-1715, MMT-1754, MMT-1755
MiniMed™ 640G Insulin Pump	MMT-1711, MMT-1712, MMT-1751, MMT-1752
MiniMed™ 670G Insulin Pump	MMT-1760, MMT-1761, MMT-1762, MMT-1780, MMT-1781, MMT-1782
MiniMed™ 700G Insulin pump	MMT-1801, MMT-1805, MMT-1850, MMT-1851
MiniMed™ 720G Insulin Pump	MMT-1809, MMT-1810, MMT-1859, MMT-1860, MMT-1867
MiniMed™ 740G Insulin Pump	MMT-1811, MMT-1812, MMT-1861, MMT-1862
MiniMed™ 770G Insulin Pump	MMT-1880, MMT-1881, MMT-1882, MMT-1890, MMT-1891, MMT-1892
MiniMed™ 780G Insulin Pump	MMT-1884, MMT-1885, MMT-1886, MMT-1894, MMT-1895, MMT-1896

October 2024

Medtronic reference: FA1435

EU Manufacturer Single Registration Number (SRN): US-MF-000023100

Dear Medtronic Diabetes Community member,

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

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the pump to stop insulin delivery significantly sooner than expected.

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 >400mg/dL or >22.2mmol/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 our Helpline on Tel No: 01 5111 444 option 2 then option 0 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.



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Please acknowledge that you have read and understood this updated notification and have followed the actions listed in this letter.

As always, we are here to support you. If you have further questions or need assistance, please call our Helpline on Tel No: 01 5111 444 option 2 then option 0.

Sincerely,

A handwritten signature in black ink that reads "Federico Gavioli".

Federico Gavioli

Sr Vice President Diabetes EMEA & Americas
Medtronic Diabetes

A handwritten signature in black ink, appearing to be "O. Cohen", with a stylized flourish.

Ohad Cohen M.D.

Global Sr. Medical Affairs Director
Medtronic Diabetes