

Urgent Field Safety Notice

MiniMed™ 600 and 700 series insulin pump Battery Cap Notification

Insulin Pump	Model Number
MiniMed™ 640G Insulin Pump	MMT-1711, MMT-1712, MMT-1751, MMT-1752
MiniMed™ 670G Insulin Pump	MMT-1761, MMT-1762, MMT-1781, MMT-1782
MiniMed™ 720G Insulin Pump	MMT-1809, MMT-1810, MMT-1859, MMT-1860
MiniMed™ 740G Insulin Pump	MMT-1811, MMT-1812, MMT-1861, MMT-1862
MiniMed™ 770G Insulin Pump	MMT-1881, MMT-1882, MMT-1891, MMT-1892
MiniMed™ 780G Insulin Pump	MMT, 1885, MMT-1886, MMT-1895, MMT-1896

May 2022

Medtronic Reference: FA1249

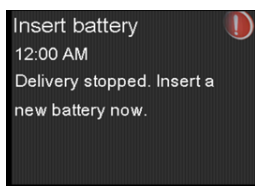
Dear Physician, Healthcare Professional,

You are receiving this letter because our records indicate that one or more of your pump users have a MiniMed™ 600 series and/or MiniMed™ 700 series insulin pump. We want to inform you of a potential issue relating to the battery cap on your pump users pumps and provided actions they should complete.

Medtronic is sending a letter to all pump users with a MiniMed™ 600 series and/or MiniMed™ 700 series that direct them to check during their battery replacement whether their battery cap and metal contact are damaged. The letter advises patients if the metal contact becomes loose or falls off from the battery cap, it can result in an incomplete battery connection, leading to no power source to the pump. When the pump detects no power source, an "Insert battery" alarm will occur, and **insulin delivery will immediately stop**. After 10 minutes, the alarm sound may increase to a siren, and **the pump will turn off**.



The battery cap can be found on the top of the pump where the AA battery compartment is located



Sample screen image of "Insert battery" alarm

Undamaged battery cap - Continue to use
Has three raised, round, black, plastic dots holding metal contact in place



Damaged battery caps - Do not use
Metal contact is missing, or fewer than 3 raised

If the pump stops delivery of insulin due to power loss, this could lead to varying degrees of high blood sugar, including Diabetic Ketoacidosis (DKA). Serious injuries have been reported with the use of the MiniMed™ 600 series and MiniMed™ 700 series insulin pumps associated with the damaged cap, but not all have been directly correlated to this issue based on review with independent clinical experts. Damaged battery cap contacts could potentially lead to those events as explained above.

ACTIONS REQUIRED BY HEALTHCARE PROFESSIONALS:

If contacted by your pump user, please assist them in locating and inspecting the battery cap on their insulin pumps per the instructions provided below.

MEDTRONIC PROVIDED THE FOLLOWING INSTRUCTIONS TO PATIENTS:

Before you begin: Do not remove the battery cap unless you have a new battery available. If you have a spare undamaged battery cap, ensure it is available nearby.

During routine battery replacement, check the metal contact on your pump battery cap to see if it is loose, damaged, or missing. Do not try to lift or move the metal contact upon inspection (see picture above).

- **If the battery cap contact is not damaged**, continue to use your pump and monitor for cap damage during battery replacement.
- **If the battery cap contact is damaged**, immediately replace it with a spare cap that you may have received with your original pump shipment, and discard the damaged cap. If you do not have a spare cap, stop using your pump and revert to a back-up plan per your healthcare provider's recommendations. Then, contact our Helpline on Tel No: 01 5111 444 option 2 then option 0 to request a spare battery cap.
- **If you are unsure if the battery cap contact is damaged**, replace it with a spare cap or contact our Helpline on Tel No: 01 5111 444 option 2 then option 0
- Always pay close attention to the pump and pump battery status after inserting the new battery.

Medtronic Actions:

We are working on a new design for the cap and we will notify pump users when it is approved and available for use.

The Competent Authority of your country has been notified of this action. We are committed to continuously monitoring and improving your experience with our products and will proactively share important safety updates. If you have further questions, please contact your Medtronic Representative.

Sincerely,



Keith Taverner
Regulatory Affairs Manager UK & Ireland

Enclosure:

- Pump User Letter