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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

October 2022

Medtronic Reference: FA1249

Dear Pump User,

You are receiving this letter because our records indicate that you have a MiniMed[™] 600 series and/or MiniMed[™] 700 series insulin pump. In May and June 2022, we informed you of a potential issue with the battery cap on the MiniMed[™] 600 series or MiniMed[™] 700 series insulin pump and provided actions you should take. Medtronic has started shipments of spare battery caps and are sending them to customers with the oldest pumps first. Enclosed with this letter is a spare battery cap. Kindly do not replace your current battery cap if not broken at this moment. Please follow instructions in this letter to replace your current battery cap when broken with the spare cap provided with this letter.

ISSUE DESCRIPTION

The battery cap on the pump consists of a plastic cap and a metal contact that work together with the AA battery to power the pump. The metal contact should be held in place by three raised, round,

black, plastic dots, as pictured below. 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**.







Battery cap on pump

Undamaged battery cap
- Continue to use

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 MiniMedTM 600 series and MiniMedTM 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

Before you begin: Do not remove the battery cap unless you have a new battery available. Ensure your spare undamaged battery cap, which is provided with this letter, 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.

- 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 which is provided with this letter, 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 / your Medtronic contact to request a spare battery cap.
- If you are unsure if the battery cap contact is damaged, replace it with the enclosed spare cap or contact our Helpline / your Medtronic contact.
- 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 battery cap and once it is approved and available for use, we will let you know. We are committed to continuously monitoring and improving your experience with our products and will proactively share important safety updates.

We understand this impacts your experience and are here to support you. If you have further questions, please call our Helpline / your Medtronic contact.

Sincerely,

Medtronic (Schweiz) AG