

UPDATE TO 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

July 2024

Medtronic Reference: FA1249

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

Dear Physician, Healthcare Professional,

You are receiving this letter because our records indicate that one or more of your patients have a MiniMed™ 600 series and/or MiniMed™ 700 series insulin pump. In 2022, we informed you of a potential issue with the battery cap on these pumps and provided actions you and your patients should take. We are pleased to inform you that we have developed a new battery cap for these specific pumps, which addresses the potential issues with the previous battery cap (model ACC-1527). Thanks for your patience as we work to continuously improve the experience of your patients, their safety is our top priority.

To keep you updated on the latest communication with your patients, we would like to inform you that Medtronic is contacting users of these pumps and is shipping them the newly designed battery cap with instructions to replace their current battery cap with the new one. A copy of the patient notice is included with this communication.

We are sharing this information with you for your awareness about the issue should your patients contact you. Please carefully review the information below.

Pump Cases:

Separately from the new design of the battery cap, it is important to note that Medtronic has also changed the design of the outer case on some MiniMed™ 700 series insulin pumps, the cases are very similar from a look and feel perspective. **Each case has a unique battery cap, these replacement battery caps are only compatible with this previous case design.**

The outer case of MiniMed 600 series insulin pumps has not changed. **Pumps impacted by this battery cap issue have the previous case design only.**

Actions Required by Healthcare Professionals:

1. If contacted by your patient:
 - Provide them with the patient letter (enclosed), so they will have information on the required steps for them to take.
 - Medtronic will ship directly new battery caps (ACC-1529) to patients.
 - Please assist them in identifying the new battery cap (model number ACC-1529) for the previous case pump, installing the new battery cap on their previous case insulin pump, and discarding of the previous battery cap (model number ACC-1527) for previous case pumps per the instructions provided in the patient letter (enclosed).

Your patients may also reach Medtronic online or via phone to get help or request a new battery cap at our Helpline.
2. Discard any inventory of the previous battery cap (model number ACC-1527) you may have.

Patient Actions:

The enclosed Pump User letter contains instructions on how to identify the new battery cap (model number ACC-1529) and the previous battery cap (model number ACC-1527) and instructs patients to install the new battery cap onto their **previous case insulin pump**. If a patient has more than one active **previous case pump**, they can request an additional cap by contacting our Helpline at 0800 633 333.

The other enclosed letter is addressed to users of the MiniMed™ 700 series insulin pumps with the **modified outer case design**, but who could additionally still have the previous case model. Pumps with the modified outer case are **not affected by the battery cap contact issue as these have a specific battery cap**.

Issue Description:

The previous battery cap (model ACC-1527), used on previous case insulin pumps, has a contact issue that can potentially 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 will increase to a siren, and the **pump will turn off**.

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

Medtronic

series and MiniMed™ 700 series previous pump case 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 explained above. Please notify Medtronic of any adverse events, if the metal contact on your battery cap is damaged, or other problems associated with your use of this product by calling our Helpline at 0800 633 333.

The Competent Authority of your country has been notified of this action.

Patient safety is our top priority, and we appreciate your time and attention in reading this important notification. We apologize for any inconvenience. If you have any questions, please contact your Medtronic Representative.

Sincerely,

Medtronic Diabetes

Enclosure: Pump User Letter

700 Series Pump with modified outer case design User Letter