

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

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

Dear Pump User,

We've previously reached out to you about a potential issue with the battery cap on the MiniMed™ 600 series and MiniMed™ 700 series insulin pumps and provided actions you 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). We have included the new battery cap (model ACC-1529) for use with your previous case insulin pump with this letter. Thanks for your patience as we work to continuously improve your experience, your safety is our top priority.

Pump Cases:

Separately from the new design of the battery cap, Medtronic has also changed the design of the outer case on some MiniMed™ 700 series insulin pumps. The outer case of MiniMed™ 600 series insulin pumps has not

changed. **Pumps impacted by this battery cap contact issue have the previous case design. Each case has a unique battery cap, these replacement battery caps are only compatible with this previous case design.** The actions section below lists steps to identify the case on your insulin pump and the compatible battery cap.

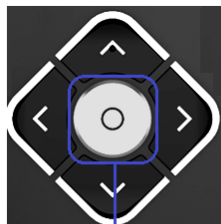
You are receiving this letter as you were identified as having a pump with the previous case design.

Actions:

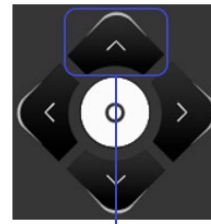
Replace the battery cap on your **previous case insulin pump** by following the steps below.

If you have a MiniMed™ 700 series pump, identify your insulin pump(s) as a previous case pump or a new case insulin pump. If you have a MiniMed™ 600 series pump, the pump has a previous case design only.

1. To identify if you have a new pump case on your MiniMed™ 700 series pump, navigate to **Menu** by clicking the 'Select' or Up" button.

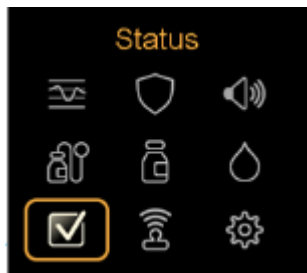


Select
MiniMed™ 780G



Select
MiniMed™ 770G, MiniMed™ 740G, MiniMed™ 720G,
MiniMed™ 700

2. On the Menu screen select **Status**. On MiniMed™ 780G insulin pumps this will be the icon in the bottom left corner.

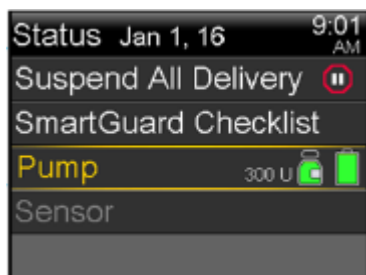


MiniMed™ 780G

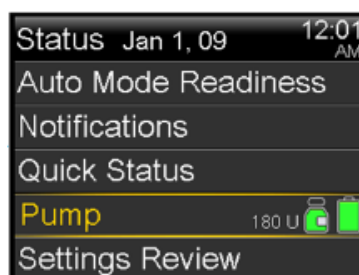


MiniMed™ 770G, MiniMed™ 740G, MiniMed™ 720G,
MiniMed™ 700

3. On the Status screen select **Pump**

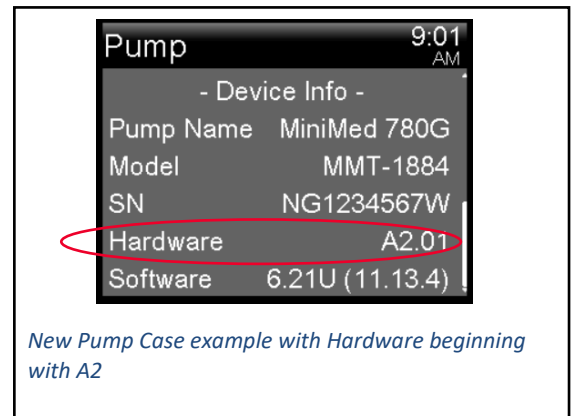
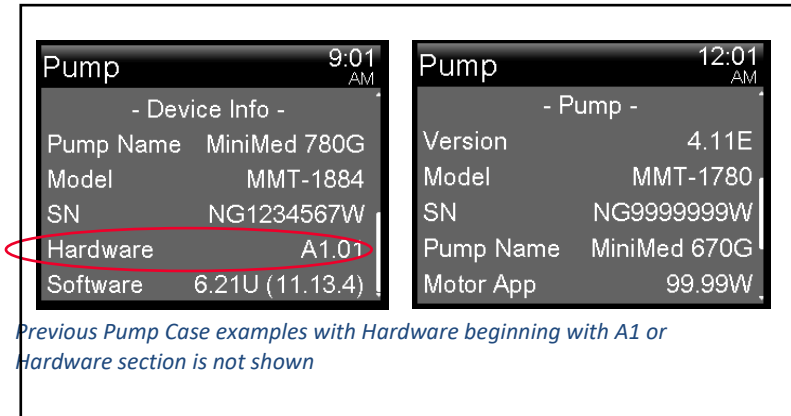


MiniMed™ 780G



MiniMed™ 770G, MiniMed™ 740G, MiniMed™ 720G,
MiniMed™ 700

4. On the Pump screen, scroll down to check the **Hardware** version. If you have a new pump case, the **Hardware** version will begin with **A2**. If you have a previous case pump, the **Hardware** version either will not appear on the screen or shows **A1**.



5. Another way to identify the new pump case is to look at the serial number on the outside of the pump. The serial number is located on the back of the pump underneath the belt clip. The serial number on the new pump case is laser etched onto the back of the pump whereas the serial number is on a silver sticker on the previous case pump.



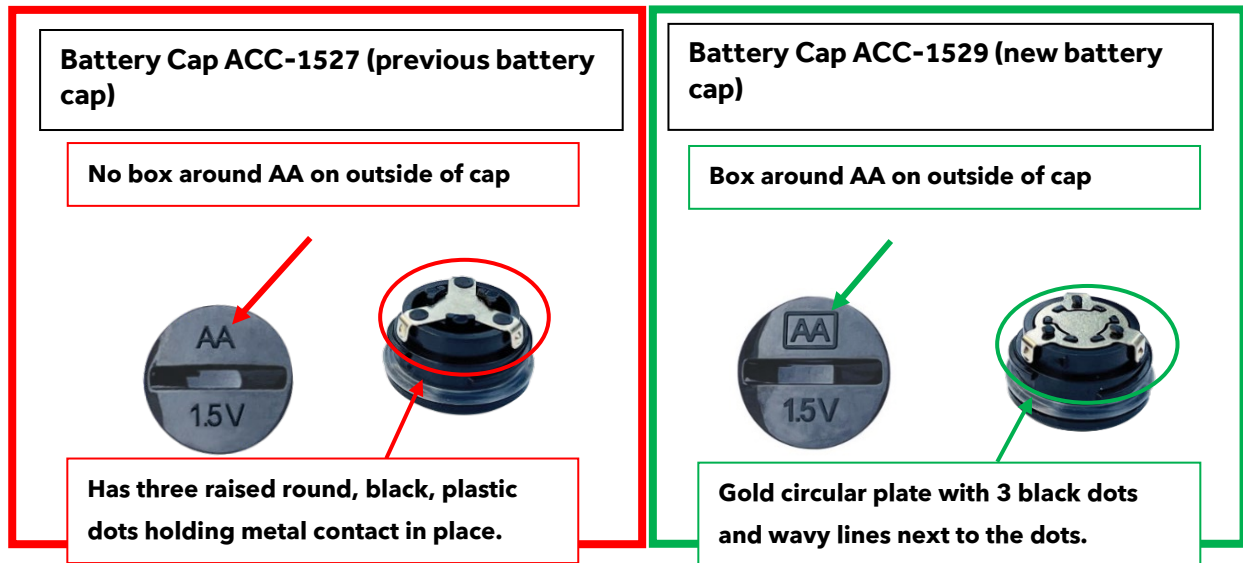
Previous pump case (left) and new pump case (right)

Pumps with **Hardware** version beginning with **A2** or having a **laser etched** serial number are not affected, these pumps must not use battery cap model number ACC-1529.

Replace the battery cap on your **previous case pump** by following the steps below.

1. Gather your **previous case** insulin pump and **all** battery caps in your possession.
 - a. Only replace the battery cap on your **previous case pump**. If you have a **new case pump, do not replace the cap on it**.
2. Before you begin, make sure you have a new battery available; do not remove the battery cap unless you have a new battery available.

3. Look at the bottom and top of each battery cap and identify which battery cap(s) is the new cap (model number ACC-1529) for your **previous case pump** and which is the previous battery cap(s) (model number ACC-1527) using the pictures below:



4. Discard all previous battery caps, model number ACC-1527 for the previous case pump. There is no need to return anything to Medtronic.
5. Install the new battery cap (model number ACC-1529) onto your **previous case pump**.
6. The battery cap provided is for your primary **previous case insulin pump**. If you are using more than one **previous case pump** impacted by this issue, please contact our Helpline 0800 633 333 for support.

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 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 0800 633 333.

Please acknowledge that you have read and understood this notification and have followed the actions listed in this letter by using the QR Code.



<https://www.medtronic-diabetes.com/FA1249>

Your safety is our top priority, and we appreciate your time and attention in reading this important notification. We apologize for the inconvenience. If you have any questions, please contact us at our Helpline at 0800 633 333.

Sincerely,

Medtronic (Schweiz) AG