

UPDATE: MEDICAL DEVICE CORRECTION

Insulin Pump Battery Cap

**All MiniMed™ 600 series and MiniMed™ 700 series insulin pump models,
including MiniMed™ 630G, MiniMed™ 670G, MiniMed™ 770G, and MiniMed™ 780G**

July 2024

Dear Valued Customer,

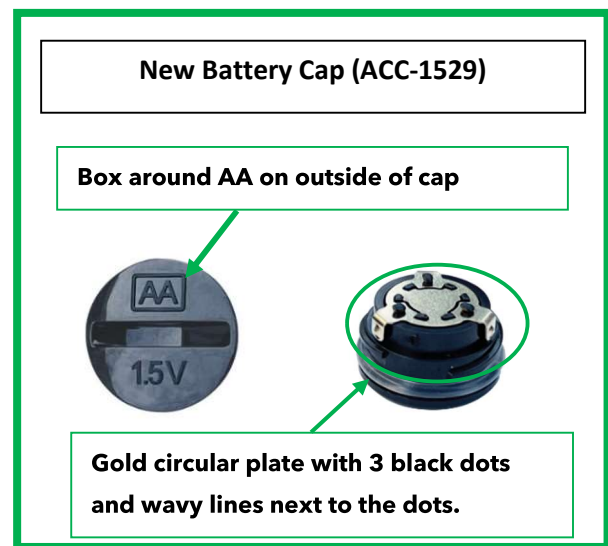
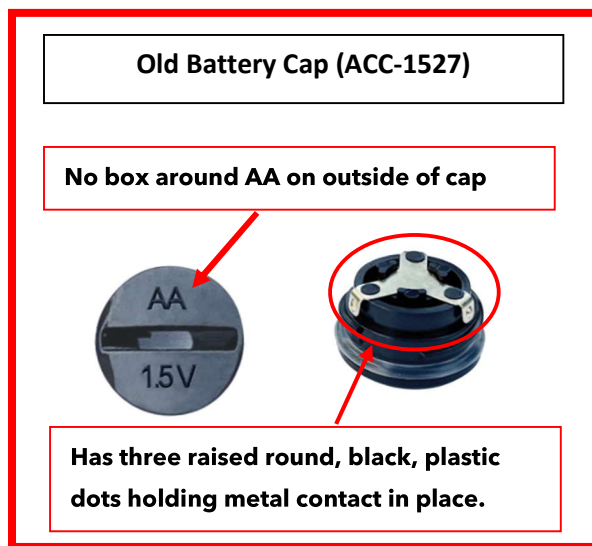
We have previously reached out to you about a potential issue with the battery cap on the MiniMed™ 600 series and MiniMed™ 700 series insulin pumps and provided actions that should be taken. We are pleased to inform you that we have developed a new battery cap for these pumps, which addresses the potential issues with the previous battery cap (model ACC-1527). We have included the new battery cap (model ACC-1529) with this letter. Thanks for your patience as we work to continuously improve your experience, your safety is our top priority.

Please acknowledge that you have read and understood this notification and have followed the actions listed below.

ACTIONS REQUIRED:

Replace the battery cap on your insulin pump by following the steps below. If you did not receive the new battery cap for your insulin pump (model number ACC-1529), please call Medtronic at 1-800-284-4416 and select 'option 2' to request a new battery cap.

1. Gather your insulin pump and **all** battery caps in your possession.
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) and which is the old battery cap(s) (model number ACC-1527) using the pictures below:



4. Discard all old battery caps, (model number ACC-1527). There is no need to return anything to Medtronic.
5. Install the new battery cap (model number ACC-1529) onto your insulin pump.
6. Always pay close attention to the pump and pump battery status after installing the new cap.

7. If you are using more than one pump impacted by this issue, please request an additional cap calling Medtronic at 1-800-284-4416 and select 'option 2'.

8. Acknowledge that you have read and understood this notification and have followed the actions listed above using one of the following options:

- **Acknowledgement link:** <https://info.medtronicdiabetes.com/bat-cap-ca-en>
- **QR code**

Digital Customer Confirmation Form:



Issue Description:

The previous battery cap (model ACC-1527) 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 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 the Medtronic 24-Hour Technical Support line at 1-800-284-4416 and select 'option 1'.

Please acknowledge that you have read and understood this notification and have followed the actions listed in this letter. Please be aware that you may continue to receive communications regarding this notification until an acknowledgement has been received.

Additional Information:

Medtronic will notify all applicable regulatory agencies about this matter.

As is standard practice, adverse event or quality problems experienced with the use of this product should be reported to Technical service team at 1-800-284-4416.

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 1-800-284-4416 or medtronicdiabetescc@medtronic.com.

Sincerely,

A handwritten signature in black ink, appearing to read 'Zachary Zoltek'.

Zachary Zoltek
Manager, Post-Market Vigilance
Medtronic Canada ULC