

UPDATE: MEDICAL DEVICE CORRECTION

Insulin Pump Battery Cap

April 2024

Dear Valued Customer:

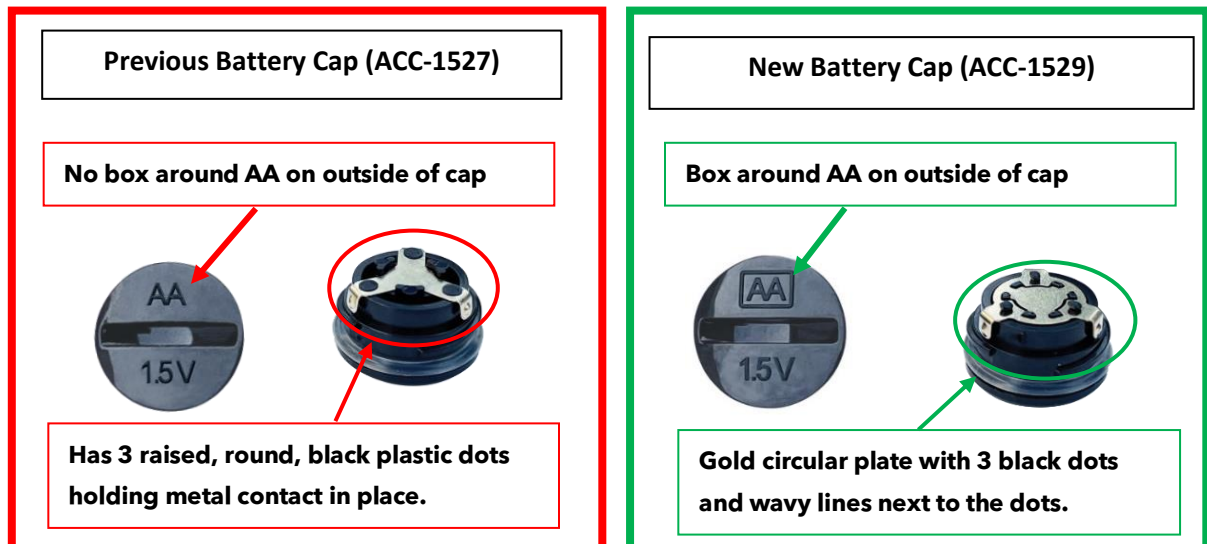
We've previously reached out to you about a potential issue with the battery cap on the MiniMed™ 600 series and MiniMed™ 770G insulin pumps and sent actions you should take. We are pleased to inform you that we have developed a new battery cap for these pumps, which addresses the potential issues with 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.

For more details on the issue, refer to Issue Description below.

Actions:

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

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 previous battery cap(s) (model number ACC-1527) using the pictures below:



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4. Discard all previous 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. The battery cap provided is for your primary insulin pump. If you are using more than one pump impacted by this issue, please request an additional cap by visiting Diabetes.shop or calling Medtronic 24-hour Technical Support at 1-800-646-4633 and select option 1.

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**.

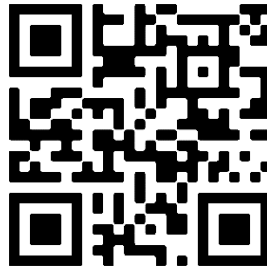
If the pump stops delivery of insulin due to power loss, this could lead to varying degrees of high blood sugar, including diabetic ketoacidosis (DKA). Serious injuries have been reported with the use of the MiniMed™ 600 series and MiniMed™ 700 series insulin pumps associated with the damaged cap, but 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 1-877-496-7933.

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail, or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular mail or fax: Download form at www.fda.gov/medwatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA-0178.

Please acknowledge that you have read and understood this notification and have followed the actions listed in this letter. Please use the QR code below or visit info.medtronicdiabetes.com/battery-cap-acknowledgement to acknowledge this communication. [insert steps to acknowledge digitally or by mail].

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To scan the QR code, open the built-in camera app on your phone or tablet. Point the camera at the QR code. Tap the banner that appears on your phone or tablet and the instructions on the screen to finish.

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 877-496-7933.

Sincerely,

A handwritten signature in black ink, appearing to read 'Julio Salwen', with a long horizontal stroke extending to the right.

Julio Salwen

Vice President, Quality

Medtronic Diabetes