

Medtronic

Medtronic International, Ltd. (Singapore Branch)

(Co.Reg.No. S98FC5604C)

50 Pasir Panjang Road

#04-51

Mapletree Business City

Singapore 117384

Tel: 165.6870.5300

Fax: 65.6482.0300

www.medtronic.com

URGENT MEDICAL DEVICE CORRECTION

Insulin Pump Battery Cap

Impacted Products: All MiniMed™ 600 series and MiniMed™ 700 series insulin pump models, including MiniMed™ 620G, MiniMed™ 630G, MiniMed™ 640G, MiniMed™ 670G, MiniMed™ 700, MiniMed™ 720G, MiniMed™ 740G, MiniMed™ 770G, and MiniMed™ 780G

01 June 2022

Dear Valued Customer:

You are receiving this letter because our records indicate that you have a MiniMed™ 600 series and/or MiniMed™ 700 series insulin pump. For your safety, we want to inform you of a potential issue relating to your pump's battery cap and provide actions you should take. Please carefully review the information below.

ISSUE DESCRIPTION

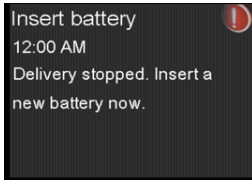
The battery cap on the pump consists of a plastic cap and a metal contact that work together with the AA battery to power the pump. The metal contact should be held in place by three raised, round, black, plastic dots, as pictured below. If the metal contact becomes loose or falls off from the battery 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**.



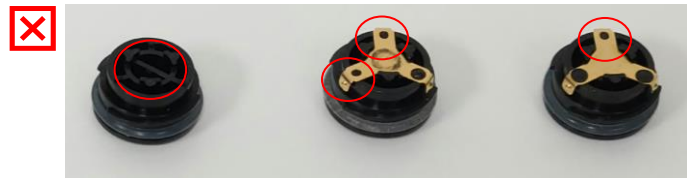
The battery cap can be found on the top of the pump where the AA battery compartment is located



Undamaged battery cap - Continue to use
Has three raised, round, black, plastic dots holding metal contact in place



Sample screen image of "Insert battery" alarm



Damaged battery caps - Do not use
Metal contact is missing, or fewer than 3 raised dots can be seen

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 as explained above. Please notify your local Medtronic field representative of any adverse events, if the metal contact on your battery cap is damaged, or other quality problems associated with your use of this product.

ACTIONS REQUIRED

Before you begin: Do not remove the battery cap unless you have a new battery available. If you have a spare undamaged battery cap, ensure it is available nearby.

1. **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 damaged**, immediately replace it with a spare cap that you may have received with your original pump shipment, 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, request a spare battery cap by contacting your local Medtronic field representative or by calling our helpline at the numbers listed at the end of this letter.

- **If you are unsure if the battery cap contact is damaged,** replace it with a spare cap or request a spare battery cap by contacting your local Medtronic field representative or by calling our helpline at the numbers listed at the end of this letter.
 - **If the battery cap contact is not damaged,** continue to use your pump and monitor for cap damage during battery replacement, and complete and return the attached confirmation form. We will send you a spare cap in the coming months.
 - Always pay close attention to the pump and pump battery status after inserting the new battery.
2. **Acknowledge that you have read and understood this notification and have followed the steps listed above** by completing and returning the confirmation form by hand or by emailing a scanned copy to your local Medtronic field representative. We will continue to remind you of this communication until we receive your response.


OUR COMMITMENT

We are working on a new design for the cap and we will keep you updated when we ship one once it is approved and available for use. 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 reach out to your local Medtronic field representative or call our helpline at the following numbers:

Malaysia	local number	(+60)-3-7883-8290
	toll free	1-800-8-16672
Philippines	local number	(+63)-2-8-6728470
Singapore	local number	(+65)-6-5064874
	toll free	1-800-120-6276

Sincerely,


DocuSigned by:

Signer Name: Diana Teo
Signing Reason: I approve this document
Signing Time: 01 June 2022 | 08:15 SGT
05FB18D83D7745D787A6E905DEAE1FD1

Medtronic QRA Lead
Singapore & Malaysia

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 01 June 2022 | 15:29 SGT
90D0724C9B1C402A99B286449A1644B8

Medtronic QRA Lead
Indochina & Frontier Markets Plus

DocuSigned by:

Signer Name: Parichart Bunjobchokchai
Signing Reason: I approve this document
Signing Time: 01 มิถุนายน 2022 | 17:06 SEAST
1EE8203B3B0D401EAAC8FA853EBB987A

Medtronic QRA Lead
Thailand

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Patient Confirmation Form

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PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic Contact Details
Distributor/HCP/Patient name:	Name:
	Contact:
Address:	Email:
Phone no:	
E-mail:	

Indicate your pump serial number:

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By signing this form, I confirm that I have read and acknowledged the Urgent Medical Device Correction letter dated 01 June 2022 from Medtronic regarding Insulin Pump Battery Cap for the MiniMed™ 600 series and MiniMed™ 700 series insulin pumps and have taken all the appropriate actions listed in the letter.

Notes: _____

Name (print): _____ Signature: _____ Stamp: _____ Date:

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