

Medtronic

Medtronic International, Ltd. (Singapore Branch)

(Co.Reg.No. S98FC5604C)

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Singapore 117384

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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

Attention: Risk Management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear 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. We want to inform you of a potential issue relating to the battery cap on your patients' pumps and provide actions they should be complete.

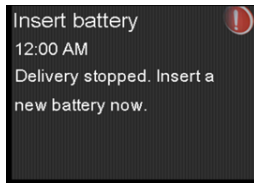
Patients with a MiniMed™ 600 series and/or MiniMed™ 700 series are receiving emails and/or letters that direct them to check during their battery replacement whether their battery cap and metal contact are damaged. The letter advises patients if the metal contact becomes loose or falls off from the battery 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 advise patients to notify Medtronic of any adverse events, if the metal contact on their battery cap is damaged, or other quality problems associated with their use of this product by sharing your local Medtronic field representative's contact details or have them call the helpline at below 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

Adverse reactions or quality problems experienced with the use of this product should be reported to your local Medtronic field representative.

ACTIONS REQUIRED BY HEALTHCARE PROFESSIONALS:

1. Complete and return the attached Confirmation Form to acknowledge that you have reviewed and understood this notification.
2. If contacted by your patient, please assist them in locating and inspecting the battery cap on their insulin pumps per the instructions provided below. Your patients may also reach Medtronic via your local Medtronic field representative or via the helpline to get help or request a new battery cap. Please share your local Medtronic field representative's contact details with your patient if there are no helpline numbers listed for your country.

MEDTRONIC PROVIDED THE FOLLOWING INSTRUCTIONS TO PATIENTS:

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.
 - a. **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 in the previous page.
 - b. **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.
 - c. **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.
 - d. 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 notify patients when 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 are here to support you. If you have further questions, please call your local Medtronic field representative or the helpline.

Sincerely,

DocuSigned by:


Signer Name: Diana Teo
Signing Reason: I approve this document
Signing Time: 01 June 2022 | 08:14 SGT
05FB18D83D7745D787A6E905DEAE1FD1

Medtronic QRA Lead
Singapore & Malaysia

DocuSigned by:

Signer Name: Chloe Tan
Signing Reason: I approve this document
Signing Time: 01 June 2022 | 15:28 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 | 17:05 SEAST
1EE8203B3B0D401EAAC8FA853EBB987A

Medtronic QRA Lead
Thailand



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Healthcare Professional 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:	

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:

DD	

MMM			

YYYY			

For questions, contact your local Medtronic field representative or our helpline.

As always, thanks for your support.