

Medtronic

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URGENT FIELD SAFETY NOTIFICATION

PUMP RETAINER RING

MiniMed™ 620G: MMT-1510, MMT-1710

MiniMed™ 630G: MMT-1515, MMT-1715, MMT-1714, MMT-1755

MiniMed™ 640G: MMT-1511, MMT-1711, MMT-1512, MMT-1712, MMT-1751, MMT-1752

MiniMed™ 670G: MMT-1580, MMT-1581, MMT-1582, MMT-1780, MMT-1781, MMT-1782

22 November 2019

Attention: Risk management Director and O.R Materials Management

CC: The Chairman Medical Board and relevant Head of Departments

Dear Valued Customer:

You are receiving this letter because our records indicate you may be using a MiniMed™ 600 series insulin pump. Because your safety is our top priority, we are making you aware of a potential safety risk.

Issue Description:

The MiniMed™ 600 series insulin pump is designed with a pump retainer ring to lock the reservoir in the insulin pump. There have been reported incidents of a loose reservoir that can no longer be locked into the pump. The reservoir can become loose due to a broken or missing retainer ring that prevents a proper lock. The retainer ring can be broken, for example as a result of dropping or bumping your pump on a hard surface.

If the reservoir is not properly locked into the pump, it could lead to over or under delivery of insulin, which could then result in hypoglycemia or hyperglycemia.

- For example, if the pump retainer ring is broken or becomes detached from the pump, and the user inserts the reservoir back into the pump while the infusion set is still connected to the body, it could result in a rapid infusion of insulin, which could cause hypoglycemia. The under delivery of insulin could occur if the reservoir is not properly locked in place by the retainer ring, creating a space between the pump and the reservoir, and prevent the pump from pushing the expected insulin into the body, which could cause hyperglycemia.

This issue may affect users on the MiniMed™ 600 series insulin pump. The pump model number can be found directly on the bottom or on the back of your device.

Insulin Pump	Model Number
MiniMed™ 620G pump	MMT-1510, MMT-1710
MiniMed™ 630G pump	MMT-1515, MMT-1715, MMT-1714, MMT-1755
MiniMed™ 640G pump	MMT-1511, MMT-1711, MMT-1512, MMT-1712, MMT-1725, MMT-1751, MMT-1752
MiniMed™ 670G pump	MMT-1580, MMT-1581, MMT-1582, MMT-1780, MMT-1781, MMT-1782

ACTIONS REQUIRED:

1. Examine the retainer ring on your pump.



Image: Location of the retainer ring on the MiniMed™ 600 series insulin pump

The images show a **normal** pump retainer ring vs a **damaged or missing** pump retainer ring.



2. If the reservoir does not lock into the pump or the retainer ring is loose, damaged or missing, **discontinue using the insulin pump** and revert to a back-up plan of manual insulin injections per your doctor's recommendations. **DO NOT insert the reservoir back into your pump while connected because you could mistakenly give yourself a large insulin bolus**, contact your local Medtronic Representative and /or our 24 hours Hotline Tel: 1800-81-6672
3. If your reservoir properly locks in place by the retainer ring, continue to use your pump. Remember to always follow the Instructions for Use on how to correctly insert the reservoir.

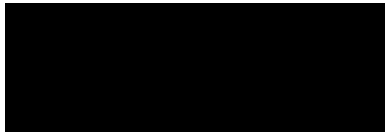
PRECAUTIONS RECOMMENDED FOR ALL PATIENTS

1. If by accident you drop or bump your pump, check your pump and retainer ring for damage.
2. Routinely examine your pump retainer ring and check that your reservoir locks in place at every set change.

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies of the highest quality and reliability possible. We appreciate your time and attention in reading this important notification.

As always, we are here to support you. If you have further questions or need assistance, please call our 24-Hour Hotline Tel: 1800-81-6672. Alternatively, you may contact your local Medtronic Representative.

Sincerely,



Diana Teo
QRA Lead
SEA Region (Cluster 1)

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Customer Confirmation Form

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MiniMed™ 670G: MMT-1580, MMT-1581, MMT-1582, MMT-1780, MMT-1781, MMT-1782

ALL CUSTOMERS PLEASE COMPLETE THE FORM IN ITS ENTIRETY

Customer Contact Details	Medtronic/Distributor Contact Details
Hospital / HCP:	Name
Address:	Email Address
Telephone no:	Telephone:
Fax no:	
E-mail:	

Item code	Serial #	QTY (Each)

By signing this form, I confirm that I have read and acknowledged the Urgent Field Safety Notification Letter, dated 22 November 2019 from Medtronic regarding the MiniMed™ 600 series insulin pumps.

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