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**URGENT FIELD SAFETY NOTIFICATION
PUMP RETAINER RING**

MiniMed™ 620G insulin pump: MMT-1510, MMT-1710
MiniMed™ 630G insulin pump: MMT-1714
MiniMed™ 640G insulin pump: MMT-1711, MMT-1712, MMT-1752
MiniMed™ 670G insulin pump: MMT-1781, MMT-1782

This is a reminder of a safety notification initiated in November 2019.

29th June 2021

**Attention: Risk management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments**

Dear Valued Customer:

We wanted to follow up with you regarding a safety notification we sent back in November 2019. This notice is a reminder for you to please continue to examine the retainer ring on your pump, so the reservoir properly locks in place by the retainer ring. As you were previously informed, you are receiving this reminder because our records indicate you may be using a MiniMed™ 600 series insulin pump.

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 preventing 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-1714 |
| MiniMed™ 640G pump | MMT-1711, MMT-1712, MMT-1725 |
| MiniMed™ 670G pump | MMT-1781, MMT-1782 |

Actions required:

1. Examine the retainer ring on your pump.



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



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

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**, and contact our Medtronic local representative.
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 technologies that undergo rigorous clinical, quality, manufacturing, and regulatory controls for our customers. We appreciate your time and attention in reading this important reminder notification.

As always, we are here to support you. If you have further questions or need assistance please reach out to your local Medtronic Representative OR alternatively, call our 24-Hour Hotline:

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Malaysia: 1800-81-6672

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Sincerely,



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