

URGENT RECALL

PUMP RETAINER RING

MiniMed™ 630G Insulin Pump (MMT-1715)

MiniMed™ 670G Insulin Pump (MMT-1780)

March 5, 2020

Dear Valued Customer:

Our records indicate you may be using a MiniMed™ 600 series insulin pump. Your safety is our top priority and we want to make sure you know what to do. You may have already received a notice about this issue and acknowledged receipt, but we wanted to reinforce this important safety information.

In November 2019, we issued a safety notification in response to incidents reported to us of a loose or missing retainer ring resulting in the reservoir no longer locking into the pump. We also shared a link to www.medtronicdiabetes.com/PumpRing, which we launched to ensure our customers know what to do — including how to check your pump and to submit a replacement request if an issue is observed.

In February 2020, the U.S. Food and Drug Administration (FDA) classified our November voluntary action as a Class I recall. **It is important to note that this classification does not introduce any new issues or generate new instructions.** We know the FDA announcement understandably prompted many questions and concerns. Please note that a “recall” as defined by the FDA “does not always mean that you stop using the product or return it to the company.” **If your reservoir properly locks in place by the retainer ring and the pump is functioning, you may continue to use your pump.**

See below for a full description of the issue, actions required, and recommended precautions.

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 a delay in the delivery of insulin or delivering the previously programmed amount of insulin later than expected. This could result in a high blood sugar (hyperglycemia). Another possibility is that the programmed amount of insulin could be delivered faster than expected which could then result in a low blood sugar (hypoglycemia). Two examples are shown below:

1. 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, it could result in hyperglycemia.
2. If the pump retainer ring is broken or becomes detached from the pump and the reservoir is protruding (sticking out) of the pump, and you insert 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.

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™ 630G Insulin Pump	MMT-1715
MiniMed™ 670G Insulin Pump	MMT-1780

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**, and go to www.medtronicdiabetes.com/PumpRing or contact our Medtronic 24-Hour Technical Support line at **1-877-585-0166**.
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. Because it is important to examine the retainer ring on a regular basis, you can expect to see reminders coming from us in the future. We appreciate your time and attention in reading this important notification.

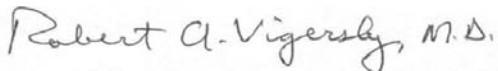
As always, we are here to support you. If you have further questions or need assistance, please call our 24-Hour Technical Support at: 1-877-585-0166.

Sincerely,



James Dabbs

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Robert Vigersky, M.D.

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