

URGENT MEDICAL DEVICE RECALL

PUMP RETAINER RING

MiniMed™ 620G: MMT-1510, MMT-1550, MMT-1710, MMT-1750

MiniMed™ 630G: MMT-1714, MMT-1715, MMT-1754, MMT-1755

MiniMed™ 640G: MMT-1511, MMT-1512, MMT-1551, MMT-1552, MMT-1711, MMT-1712, MMT-1751, MMT-1752

MiniMed™ 670G: MMT-1580, MMT-1741, MMT-1742, MMT-1760, MMT-1761, MMT-1762, MMT-1780, MMT-1781, MMT-1782

October 2021

Dear Valued Patient:

You are receiving this letter because our records indicate that you have a MiniMed™ 600 series insulin pump that is subject to an ongoing recall. This recall affects MiniMed™ 600 series insulin pumps with a clear retainer ring. Medtronic first communicated about this recall in November 2019 with instructions to examine your pump for potential retainer ring damage and instructions to contact us if the retainer ring appeared to be loose, damaged or missing.

Medtronic is updating this recall to replace any MiniMed™ 600 series insulin pump that has a clear retainer ring with a MiniMed™ 600 series insulin pump that has the updated black retainer ring design. Insulin pumps with the updated black retainer ring design are not impacted by this recall. There is no charge for the replacement, and it will be provided even if the clear retainer ring is not damaged and regardless of the warranty status of the pump.

Please visit www.medtronicdiabetes.com/PumpRing and complete the form online or call us at 1-877-585-0166 to indicate your decision to receive a replacement pump at no charge. Replacement pumps will become available in the coming months, and you will be notified when your pump is ready to ship. Replacement pumps will continue to be immediately available if you experience an issue with the retainer ring on your current pump.

Issue Description:

The MiniMed™ 600 series insulin pump is designed with a retainer ring to lock the reservoir in the pump. Medtronic initiated a recall of MiniMed™ 600 series insulin pumps with a damaged clear retainer ring in November 2019 due to 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, the improper locking could lead to over or under delivery of insulin, which could then result in hypoglycemia or hyperglycemia. Severe hypoglycemia and hyperglycemia can be life-threatening or may result in death. For example, if the 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 and potentially large 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 prevents the pump from pushing the expected insulin into the body, or if the pump stops working due to water entering the pump, all of which could cause hyperglycemia and may contribute to Diabetic ketoacidosis.

Serious injuries and deaths have been reported with the use of the MiniMed™ 600 series insulin pumps, but have not been directly correlated with damaged clear retainer rings based on information available to Medtronic and review with independent clinical experts. Damaged clear retainer rings could potentially lead to those events as explained above. Please notify Medtronic of any adverse events or quality problems associated with your use of this product by calling Medtronic 24-Hour Technical Support at 1-877-585-0166.

Adverse reactions or quality problems experienced with the use of this product may also be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax.

- Complete and submit the report online: www.fda.gov/medwatch/report.htm
- Regular Mail or Fax: Download form www.fda.gov/MedWatch/getforms.htm or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the pre-addressed form, or submit by fax to 1-800-FDA- 0178

Medtronic has stopped manufacturing and distributing MiniMed™ 600 series insulin pumps with clear retainer rings.

ACTIONS REQUIRED:

The MiniMed™ 600 series insulin pump with a clear retainer ring and the following pump model numbers are eligible for replacement as part of the recall. The model numbers can be found on the bottom or on the back of your device.

Insulin Pump	Model Number
MiniMed™ 620G Insulin Pump	MMT-1510, MMT-1550, MMT-1710, MMT-1750
MiniMed™ 630G Insulin Pump	MMT-1714, MMT-1715, MMT-1754, MMT-1755
MiniMed™ 640G Insulin Pump	MMT-1511, MMT-1512, MMT-1551, MMT-1552, MMT-1711, MMT-1712, MMT-1751, MMT-1752
MiniMed™ 670G Insulin Pump	MMT-1580, MMT-1741, MMT-1742, MMT-1760, MMT-1761, MMT-1762, MMT-1780, MMT-1781, MMT-1782

1. Examine the retainer ring on your pump to determine if you have a clear retainer ring and whether it is loose, damaged or missing.

CLEAR RETAINER RING PUMP (SUBJECT OF RECALL)	BLACK RETAINER RING PUMP (NOT AFFECTED BY RECALL)
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2. If the reservoir does not lock into the pump or the retainer ring is loose, damaged or missing, immediately **discontinue using the insulin pump** and revert to a back-up plan per your healthcare provider's recommendations. **DO NOT insert the reservoir back into your pump while connected because you could mistakenly give yourself a rapid, and possibly large, insulin bolus.** You should immediately contact the Medtronic 24-Hour Technical Support line at 1-877-585-0166 or complete the [replacement request form](#).
3. If your reservoir properly locks in place with the retainer ring and the retainer ring is not loose, damaged, or broken, you may continue to use your pump until you receive your replacement pump. Follow the replacement instructions below.
4. Remember to always follow the Instructions for Use on how to correctly insert the reservoir and examine your retainer ring for damage every time you change your infusion set. The black retainer ring in newer MiniMed™ 600 series insulin pumps is designed to improve durability. However, you should check your pump and retainer ring for damage every time you replace the insulin reservoir, or any time it is dropped or bumped.
5. Visit www.medtronicdiabetes.com/PumpRing, or call Medtronic at 1-877-585-0166, or complete and return the attached Confirmation Form to acknowledge that you have reviewed and understood this notification and to indicate your decision to receive a replacement pump at no charge. If you have any questions about your therapy, contact your healthcare professional to discuss your options.

Note: Your replacement pump arrives without settings and requires transferring the current settings on your clear retainer ring pump to the black retainer ring pump prior to its use.

Please visit www.medtronicdiabetes.com/PumpRing for additional information and answers to frequently asked questions.

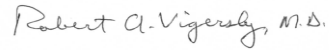
You received this letter because our records indicate that you have a MiniMed™ 600 series insulin pump with a clear retainer ring. However, if you want to confirm that your pump has a clear retainer ring, please visit www.medtronicdiabetes.com/retainer-ring-serial-number-look-up and enter the serial number of your pump to check.

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies. Thank you in advance for your patience as we work to support all our customers as quickly as possible. We appreciate your time and attention in reading this important notification.

Sincerely,



Chirag Tilara
Vice President, Quality
Medtronic Diabetes



Robert Vigersky, M.D.
Chief Medical Officer
Medtronic Diabetes