

URGENT MEDICAL DEVICE RECALL PUMP RETAINER RING

MiniMed™ 630G: MMT-1714K, MMT-1714KRP
MiniMed™ 670G: MMT-1782K

5 October 2021

Dear Valued Customer

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.ca/PumpRing and complete the form online to indicate your decision to receive a replacement pump at no charge. If you experience any difficulties completing this online form, please call Medtronic at 1-800-284-4407, available 8am to 8pm (ET). 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 no longer locks 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, this 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

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occur if the reservoir is not properly locked in place by the retainer ring, creating a space between the pump and the reservoir, which could prevent 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 MiniMed™ 600 series insulin pumps, but, based on information available to Medtronic and review with independent clinical experts, have not been directly correlated with damaged clear retainer rings. Damaged clear retainer rings could potentially lead to the events described 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 1.800.284.4416.



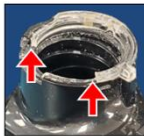
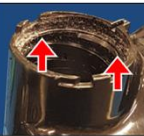

Medtronic has stopped manufacturing and distributing MiniMed™ 600 series insulin pumps with clear retainer rings.

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™ 630G Insulin Pump	MMT-1714K, MMT-1714KRP
MiniMed™ 670G Insulin Pump	MMT-1782K

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)
<div style="display: flex; align-items: center;">  <div style="margin-left: 20px;"> <p>The images show a normal pump retainer ring vs a damaged or missing pump retainer ring.</p> <div style="display: flex; justify-content: space-around; align-items: flex-end;"> <div style="text-align: center;">  <p>NORMAL pump retainer ring</p> </div> <div style="text-align: center;">  <p>DAMAGED pump retainer ring</p> </div> <div style="text-align: center;">  <p>MISSING pump retainer ring</p> </div> </div> </div> </div> <p style="font-size: small; margin-top: 10px;">Image: Location of the retainer ring on the MiniMed™ 600 series insulin pump</p>	<div style="text-align: center;">  <p>Normal pump with black retainer ring</p> </div>

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

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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 a large, insulin bolus.** You should immediately contact the Medtronic 24-Hour Technical Support line at **1 (800) 284-4416** or complete the replacement request form www.medtronicdiabetes.ca/PumpRing.

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 pump 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.ca/PumpRing 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 experience any difficulties completing the online form, please call Medtronic at **1-800-284-4407**, available 8am to 8pm (ET), or complete and return the attached **Confirmation Form**. 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.ca/PumpRing for additional information and answers to frequently asked questions.

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Health Canada has been notified of these actions. As is standard practice, any adverse events or quality problem experienced with the use of this product should be reported to Medtronic at 1.800.284.4416.

At Medtronic, customer safety is our top priority, and we are committed to delivering safe and effective products. 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,



Isabelle Gerges
Sr. Director, Quality and Regulatory Affairs
Medtronic Canada ULC