

Urgent Field Safety Notice

MiniMed™ 600 series insulin pump retainer ring

Recall

October 2021

Medtronic Reference: FA896 phase II

Dear Physician, Healthcare Professional,

You are receiving this letter because our records indicate that one or more of your pump users have a MiniMed™ 600 series insulin pump that is subject to an ongoing Field Safety Notice. This notice affects MiniMed™ 600 series insulin pumps with a clear retainer ring. Medtronic first communicated about this in November 2019 with instructions to examine the 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 Field Safety Notice 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 notice. 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. Replacement pumps will become available in the coming months, and pump users will be notified when their pump is ready to ship. Replacement pumps will continue to be immediately available if your pump user experiences an issue with the retainer ring on their current pump.

The purpose of this letter is to make you aware that we will be notifying all pump users who may have an affected MiniMed™ 600 series insulin 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 Field Safety Notice for 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 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 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.

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

ACTIONS REQUIRED BY YOU:

Medtronic is requesting pump users to **Visit www.medtronic-diabetes.com/FA896 / call Medtronic at 01 511 1444** to indicate their decision to receive a replacement pump at no charge. **Replacement pumps will become available in the coming months and pump users will be notified when their pump is ready to ship.** Please assist pump users in making replacement decision considering the safety risk associated with the retainer ring issue.

MEDTRONIC PROVIDED THE FOLLOWING INSTRUCTIONS TO PUMP USERS:

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 Field Safety Notice. The model numbers can be found on the bottom or on the back of your device.

Insulin Pump	Model Number
MiniMed™ 640G Insulin Pump	MMT-1711, MMT-1712, MMT-1751, MMT-1752
MiniMed™ 670G Insulin Pump	MMT-1761, MMT-1762, 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 FIELD SAFETY NOTICE)	BLACK RETAINER RING PUMP (NOT AFFECTED BY FIELD SAFETY NOTICE)
 <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;"> <div data-bbox="521 1016 659 1180">  <p>NORMAL pump retainer ring</p> </div> <div data-bbox="699 1016 837 1180">  <p>DAMAGED pump retainer ring</p> </div> <div data-bbox="846 1016 984 1180">  <p>MISSING pump retainer ring</p> </div> </div> <p><small>Image: Location of the retainer ring on the MiniMed™ 600 series insulin pump</small></p>	 <p>Normal pump with black retainer ring</p>

1. 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 insulin bolus.** You should immediately contact our Helpline at 01 511 1444.
2. 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.
3. 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.
4. **Visit www.medtronic-diabetes.com/FA896 / call Medtronic at 01 511 1444 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.

Medtronic

The Competent Authority of your country has been notified of this action.

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,

A handwritten signature in black ink that reads "S. Baxter". The signature is written in a cursive style with a horizontal line underlining the name.

Samantha Baxter
Regulatory Affairs Manager
UK and Ireland

Enclosure:

- Pump User Letter