

## Medtronic – Recall of MiniMed<sup>™</sup> 600 Series Insulin Pumps

- On February 12, 2020, the <u>FDA announced</u> a Class I recall of MiniMed 600 Series Insulin Pumps
  due to a missing or broken <u>retainer ring</u> which helps to lock the insulin cartridge into place in the
  pump's reservoir compartment. If the cartridge is not locked firmly into place, under or over delivery
  of insulin may occur, which could result in hypoglycemia or hyperglycemia.
- The recalled insulin: pumps are as follows

Product Description	Lots	Distribution Dates
MiniMed 630G Insulin Pump	All lots before October 2019	September 2016 - October 2019
MiniMed 670G Insulin Pump	All lots before August 2019	June 2017 - August 2019

- People who have type 1 diabetes may use the MiniMed insulin pump to deliver insulin for the management of their diabetes. The Model 630G insulin pump may be used by persons ≥ sixteen years of age. The Model 670G insulin pump may be used by persons ≥ fourteen years of age.
- Medtronic has received a total of 26,421 complaints in which the device malfunctioned in this manner. Medtronic is aware of 2,175 injuries and 1 death.
- On November 21, 2019, <u>Medtronic notified</u> affected customers with an urgent field safety notification and advised them to:
  - Examine the retainer ring of their pump.
  - Stop use of the pump and contact Medtronic for a replacement pump if the reservoir does not lock into the pump or if the retainer ring is loose, damaged, or missing. If you stop using the pump, you should follow your doctor's recommendations and perform manual insulin injections.
  - Continue using the pump if the reservoir locks in place correctly.
  - If the pump is dropped by accident, check the pump and retainer ring for damage and stop use if it is damaged.
  - Check the pump retainer ring and verify that the reservoir is locked correctly at every set change.
- Customers who have questions or need additional information or support about this recall should call the 24-hour Medtronic Technical Support at 1-877-585-0166.



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