

URGENT MEDICAL DEVICE CORRECTION

Pump Delivery Volume Accuracy (DVA) during Changes in Air Pressure

Insulin Pump	Model/CFN Number
Paradigm™	MMT-554, MMT-754
MiniMed™ 630G Insulin Pump	MMT-1714
MiniMed™ 670G Insulin Pump	MMT-1762, MMT-1782
MiniMed™ 770G Insulin Pump	MMT-1881, MMT-1891
MiniMed™ 780G Insulin Pump	MMT-1885, MMT-1895

February 2025

Dear Valued Customer,

Medtronic is contacting you about an urgent Medical Device Correction regarding your MiniMed™ insulin pump. During quality testing performed by Medtronic, we recently found that changes in air pressure can cause unintended insulin delivery. For example, air pressure in an airplane can change rapidly during flight, which may cause expansion of tiny air bubbles inside the insulin reservoir.

Issue Description:

- When **air pressure decreases** (e.g., during flight takeoff), more insulin may be released than expected. Additionally, **unintended insulin** may be released even if the pump's delivery is suspended or programmed to zero units per hour.
- When **air pressure increases** (e.g., during flight landing), less insulin may be released than expected.

Risk to Health:

The changing air pressure conditions could result in more insulin being delivered during flight takeoff, potentially leading to hypoglycemia, or less insulin being delivered during flight, potentially leading to hyperglycemia.

Between July 2003 and May 2024, Medtronic received 138 complaints potentially related to this issue, 19 of which reported serious injuries, but none were confirmed to be related to this issue.

It is important to monitor your glucose frequently while flying and be prepared to treat hypoglycemia or hyperglycemia. Individuals with lower daily insulin doses and those with high insulin sensitivity may experience greater changes in glucose during changes in air pressure than individuals with higher insulin doses and/or lower insulin sensitivity. If you are unsure as to whether this applies to you, it is important that you seek your healthcare professional's treatment guidance.

Recommended Actions for Pump Users:

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1. **Monitor Your Glucose Levels:** Check your glucose frequently during activities like air travel, amusement park rides, or other situations where sudden changes or extremes of air pressure, altitude, or gravity may occur.
2. **Discuss how to prepare for situations like this with your healthcare professional.** Keep an emergency kit with rapid-acting glucose and backup insulin therapy available at all times.
3. **Respond to Alerts and Symptoms:** Pay attention to any alerts from your pump as well as symptoms of hypoglycemia or hyperglycemia. Follow your healthcare professional's treatment instructions in these situations.

Please acknowledge that you have read and understood this notification and will follow the actions listed in this letter by scanning the QR code below, or acknowledging it online at

https://info.medtronicdiabetes.com/pump_delivery_volume_accuracy_en:



Additional Information:

Medtronic will notify all applicable regulatory agencies about this matter. As is standard practice, adverse event or quality problems experienced with the use of this product should be reported to the Technical Support team at 1-800-284-4416 option 1.

Your safety is our top priority, and we appreciate your time and attention in reading this important notification. We apologize for the inconvenience. If you have any questions, please contact Technical Support at 1-800-284-4416 option 1.

Sincerely,

A handwritten signature in black ink, appearing to read 'Zoltek', written over a light blue horizontal line.

Zachary Zoltek
Sr. Manager, Quality Systems
Medtronic Canada ULC