Medtronic

URGENT MEDICAL DEVICE CORRECTION

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

Insulin Pump	Model/CFN Number
Paradigm™	MMT-512, MMT-522, MMT-523, MMT-551, MMT-712, MMT-715, MMT-722, MMT-723, MMT-751
MiniMed™ 630G Insulin Pump	MMT-1715, MMT-1755
MiniMed™ 670G Insulin Pump	MMT-1760, MMT-1780
MiniMed™ 770G Insulin Pump	MMT-1880, MMT-1890
MiniMed™ 780G Insulin Pump	MMT-1884, MMT-1894

January 2025

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 landing, potentially leading to hyperglycemia.

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

Medtronic

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:

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 have followed the actions listed in this letter by either completing and returning the confirmation form, scanning the QR code below with your phone or tablet, or by visiting https://info.medtronicdiabetes.com/pump-delivery-volume to acknowledge this communication.

Adverse reactions or quality problems experienced with the use of this product may 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.

Medtronic

- Regular mail or fax: Download the form at 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.

As always, we are here to support you and ensure we are delivering the highest quality products possible. If you have further questions or need assistance, please call the Medtronic 24-Hour Technical Support line at 1-800-646-4633 option 1.

Sincerely,

Julio Salwen
Vice President, Quality
Medtronic Diabetes

Joshua Miller, MD, MPH
Sr. Medical Director, Medical Safety
Medtronic Diabetes