

Medtronic

Medtronic Australasia Pty Ltd
ABN 47 001 162 661
2 Alma Road
Macquarie Park NSW 2113
Australia
www.medtronic.com.au
Tel: 61 2 9857 9000
Fax: 61 2 9878 5100

February 2025

URGENT – PRODUCT DEFECT CORRECTION

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

TGA Reference: RC-2025-RN-00061-1

ARTG: 308140/ 332201 / 376091

Insulin Pump	Model/CFN Number
Paradigm™	MMT-512, MMT-522, MMT-523, MMT-551, MMT-554, MMT-712, MMT-715, MMT-722, MMT-723, MMT-751, MMT-754
MiniMed™ 640G Insulin Pump	MMT-1711, MMT-1712, MMT-1751, MMT-1752
MiniMed™ 670G Insulin Pump	MMT-1762, MMT-1782
MiniMed™ 770G Insulin Pump	MMT-1881, MMT-1891
MiniMed™ 780G Insulin Pump	MMT-1885, MMT-1895

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.

Problem 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 received 138 complaints potentially related to this problem, 19 of which reported serious injuries, but none were confirmed to be related to this problem. 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.

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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 scanning the QR code below with your contact details.



Additional Information

Medtronic is initiating this action in consultation with the Therapeutic Goods Administration.

Local contact details

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 1800-777 808.

Sincerely,

Signed by:
Tasheena Gul
Signer Name: Tasheena Gul
Signing Reason: I am the author of this document
Signing Time: 06 February 2025 | 19:52 AEDT
0C637FA7735740458FA6BC1708AB436D

Tasheena Gul

Post Market Vigilance Specialist | Quality and Regulatory Affairs

Medtronic

Medtronic Australasia Pty Ltd

2 Alma Road | Macquarie Park, NSW, 2113 | Australia

rs.anzpmv@medtronic.com

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Medtronic Australasia acknowledges the ancestors and traditional custodians of the land on which our offices stand and pay respect to Elders past and present. pay respect to Elders past and present.