

URGENT FIELD SAFETY NOTICE

MiniMed™ Paradigm™, MiniMed™ 600 series, and MiniMed™ 700 series insulin pump systems

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

Insulin Pump	Model/CFN Number
Paradigm™	MMT-554, MMT-715, MMT-722, MMT-754
MiniMed™ 640G Insulin Pump	MMT-1711, MMT-1712, MMT-1751, MMT-1752
MiniMed™ 670G Insulin Pump	MMT-1761, MMT-1762, MMT-1781, MMT-1782
MiniMed™ 720G Insulin Pump	MMT-1809, MMT-1810, MMT-1859, MMT-1860
MiniMed™ 740G Insulin Pump	MMT-1811, MMT-1812, MMT-1861, MMT-1862
MiniMed™ 770G Insulin Pump	MMT-1881, MMT-1882, MMT-1891, MMT-1892
MiniMed™ 780G Insulin Pump	MMT-1885, MMT-1886, MMT-1895, MMT-1896 <i>[For countries with EU MDR approved pump released: Include GTIN and UDI information]</i>

January 2025

Medtronic reference: FA1446

For use in countries that follow EU MDR: [EU Manufacturer Single Registration Number \(SRN\): US-MF-000023100](#)

Dear Medtronic Diabetes Community member,

Medtronic is contacting you with important safety information 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. This could result in more insulin being delivered during flight takeoff, potentially leading to hypoglycemia, or less insulin being delivered during landing, potentially leading to hyperglycemia.

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.

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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 landing), less insulin may be released than expected.

While changing air pressure conditions may impact the volume of insulin released, the risk of developing hyperglycemia or hypoglycemia as a result is low.

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 updated notification and have followed the actions listed in this letter [by clicking on the link contained in your email notification.](#)

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 [our Helpline / your Medtronic contact.](#)

Sincerely,

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Notification

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Dear Valued Healthcare Professional,

You are receiving this letter because our records indicate that one or more of your patients have a MiniMed™ Paradigm™, MiniMed™ 600 series and/or MiniMed™ 700 series insulin pump. We would like to share with you a communication Medtronic has shared with your patients to inform them of the importance of monitoring their glucose levels during dynamic atmospheric pressure conditions - such as flight takeoff and landing, as insulin delivery volume accuracy may be impacted.

Please carefully review the information below and acknowledge that you have received this notification.

We are sending you this notification for information purposes only.

Issue Description:

Recent testing has shown that changes in atmospheric pressure can sometimes cause unintended insulin delivery. For example, atmospheric pressure in an airplane can change rapidly during flight, which may

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cause expansion of air bubbles inside the reservoir when **air pressure decreases** (e.g., during flight takeoff). This could result in more insulin being delivered, potentially leading to hypoglycemia. The **unintended insulin** may be released even if the pump's delivery is suspended or programmed to zero units per hour.

Conversely, there may be compression of air bubbles when **air pressure increases** (e.g., during flight landing). This could result in less insulin being delivered during landing, potentially leading to hyperglycemia.

While changing air pressure conditions may impact the volume of insulin released, the risk of developing hyperglycemia or hypoglycemia as a result is low. However, 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. Therefore, it is important for your patients to monitor their glucose frequently while flying and be prepared to treat hypoglycemia or hyperglycemia should it occur.

Please be advised that patients are encouraged to reach out to their healthcare professional in the attached letter we sent them.

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

Patient safety is our top priority, and we appreciate your time and attention in reading this important notification. We apologize for any inconvenience. If you have any questions, please contact your Medtronic contact.

Sincerely,



Federico Gavioli

Sr Vice President Diabetes EMEA & Americas
Medtronic Diabetes



Ohad Cohen M.D.

Global Sr. Medical Affairs Director
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Enclosure: Pump User Letter