

HPRA Safety Notice

Medical Devices

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



Priority 2 – Warning

ISSUE DATE: 18th May 2026

DEVICE MANUFACTURER/SUPPLIER INFORMATION

Medtronic MiniMed

TARGET AUDIENCE

Patients / Users of these devices / Healthcare professionals and healthcare settings involved in the use and/or provision of these devices

WHAT DEVICES ARE AFFECTED?

MiniMed Paradigm, MiniMed 600 series, and MiniMed 700 series insulin pump systems. Please refer to accompanying field safety notices (FSNs) issued by Medtronic for additional information on affected model numbers.

PROBLEM OR ISSUE?

The HPRA is publishing this Safety Notice to raise awareness of a potential issue affecting Medtronic MiniMed and Paradigm insulin pumps. Medtronic has identified that

due to environmental conditions, there may be slight variability in the amount of insulin delivered when your pump is worn at distances above or below the location of your infusion set.

- This variability may increase with increasing distances above or below your infusion set location.
- Placing the pump above your infusion site can cause over-delivery and placing it below your infusion site can cause under-delivery.
- The greatest **variability in insulin delivery** may occur at **distances beyond 35.5 cm (14 inches) above or below your infusion set location.**

Please note, this variability in insulin delivery will not be captured in your pump's history or CareLink reports.

WHAT IS THE RISK?

Potential risks associated with the placement of the pump with respect to the infusion site can include changes to blood sugar (hypoglycemia or hyperglycemia) for individuals who require lower daily insulin doses and those with high insulin sensitivity.

The HPRA is not aware of any serious incidents in Ireland at this time associated with this issue, however, should this issue occur, it may affect insulin delivery as outlined above.

WHY IS THE HPRA ISSUING THIS SAFETY NOTICE?

The HPRA is issuing this notice to raise awareness of the issue so that users undertake the actions outlined in the manufacturer's FSN.

WHAT ADVICE HAS THE HPRA FOR PATIENTS / USERS OF THESE DEVICES?

1. Refer to the [accompanying FSN](#) and follow instructions provided by the manufacturer.
2. Keep the location of your insulin pump close to your infusion site.
3. If you need to raise the pump above your infusion site, such as when a parent or caregiver is using the pump for a child, limit the time that the pump is held above the infusion site.
4. Pay attention to any alerts from your pump as well as symptoms of hypoglycemia and hyperglycemia; follow your healthcare professional's treatment instructions in these situations.
5. Medtronic Minimed has indicated that user guide will be updated for currently distributed insulin pumps to include the above advice. User and patients will be able to download the latest version of the user guide from their website once available.
6. Report any safety issues associated with these devices to the manufacturer and the HPRA.
7. If you have any health concerns, please contact a healthcare professional.

WHAT ADVICE HAS THE HPRA FOR HEALTHCARE PROFESSIONALS AND HEALTHCARE SETTINGS INVOLVED IN THE USE AND/OR PROVISION OF THESE DEVICES?

1. Inform all patients who use MiniMed Paradigm and MiniMed 600 and 700 series pump systems of the issue outlined in the [accompanying FSN](#).

2. Ensure that a copy of the FSN is given to all patients / users and to all those that need to be aware within your organisation or to any organisation / person where these devices have been transferred.
3. Report any adverse incidents associated with these devices to the manufacturer and to the HPRA.

MANUFACTURER / AUTHORISED REPRESENTATIVE CONTACT INFORMATION

Enquiries to the **manufacturer** should be addressed to:

Name: Medtronic Diabetes Product Support
Email: rs.ukdiabetesproductsupport@medtronic.com
Telephone: 01 5111 444

Enquiries to the **authorised representative** should be addressed to:

Name: Medtronic B.V
Address: Earl Bakkenstraat 10, Heerlen,6422PJ, Netherlands
Email: rs.vigilance.eu@medtronic.com

REFERENCE DOCUMENTS

[Medtronic MiniMed Pump Users FSN](#)

[Medtronic MiniMed HCP FSN](#)

HPRA CONTACT INFORMATION

All safety issues relating to medical devices should be reported to the HPRA using any of the following reporting options:

- [HPRA online report form](#) available on the HPRA website
- Email: devicesafety@hpra.ie
- Telephone: +353-1-6764971

Further information on the role of the HPRA in relation to medical devices is available on the [regulation of medical devices section](#) of the HPRA website.

Any enquiries regarding this safety notice or any medical device safety issue should be emailed to devicesafety@hpra.ie.