

URGENT MEDICAL DEVICE CORRECTION

MiniMed™ Paradigm™, 600 series, and 700 series insulin pump systems Pump Placement with Respect to Infusion Site

Products impacted:

MiniMed™ Paradigm™ Insulin Pumps (*all models*)

MiniMed™ 630G, 670G, 770G, 780G Insulin Pumps (*all models*)

Please visit <https://info.medtronicdiabetes.com/pump-placement> for affected user guide versions.

February 2026

Medtronic reference: FA1514

Dear Valued Customer,

We are contacting you with guidance about how to position your pump and infusion set. Please note that this issue and the required actions apply to all MiniMed™ Paradigm™, MiniMed™ 600 Series, and MiniMed™ 700 Series pump models.

Issue Description

- 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 14 inches above or below your infusion set location.
- This variability in insulin delivery will not be captured in your pump's history or CareLink reports.

Risk to Health:

- Individuals who require lower daily insulin doses and those with high insulin sensitivity may experience changes to their blood sugar (hypoglycemia or hyperglycemia) because of this

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phenomenon.

- If you are unsure whether this applies to you, it is important that you seek guidance from your healthcare professional.

As of February 9, 2026, Medtronic has not identified any user complaints that can be attributed to this issue.

Medtronic MiniMed will update the User Guides for our currently distributed insulin pumps to include the following:

"It is important to keep the location of your pump stable relative to your infusion site. Do not wear or place your pump more than 14 in (35.5 cm) above your infusion site. Doing so can cause an over-delivery of insulin, which may result in hypoglycemia."

User guides that are updated will be available at:

<https://www.medtronicdiabetes.com/download-library>.

Your Required Actions:

- Keep the location of your insulin pump close to your infusion site.
- 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.
- 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.
- If you have any concerns about how this may impact insulin delivery and blood glucose, please contact your healthcare professional. You may also contact us at 1-855-587-4950 with any questions about this notification.
- **Please acknowledge that you have read and understood this notification and have followed the actions listed in this notification by either clicking the acknowledgment button below, completing and returning the confirmation form, scanning the QR code below with your phone or tablet, or by visiting [©2026 Medtronic. All rights reserved. Medtronic, Medtronic logo and Engineering the extraordinary are trademarks of Medtronic. All other brands are trademarks of a Medtronic company.](https://info.medtronicdiabetes.com/pump-</div><div data-bbox=)**

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[placement](#) 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.
- 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 deliver the highest quality products possible. If you have further questions or need assistance, please contact the Medtronic 24-Hour Technical Support line at 1-855-587-4950.

Sincerely,

Medtronic Diabetes