Medtronic
18000 Devonshire St.
Northridge, CA 91325
www.medtronicdiabetes.com

URGENT MEDICAL DEVICE CORRECTION
MiniMed™ 780G Insulin Pump
6.62 Software Update

Product Impact	Model/CFN Number
MiniMed™ 780G Insulin Pump	MMT-1884 (Software Version 6.60 & 6.61)

January 2026

Dear Valued Customer,

We sincerely apologize for any concern this message may cause. Your safety and experience are our top priorities. You are receiving this notification because our records indicate you may be using a MiniMed™ 780G insulin pump with software version 6.60 or 6.61, which could cause, (1) a pump error indicating that insulin delivery is being stopped (Pump error 53) or, (2) your pump may not respond correctly to a manually entered blood glucose (BG) check if the sensor glucose (SG) value is beyond limits. This notification provides important information and actions for you to take.

Issue Description

(1) Pump Error 53:

An issue may cause the MiniMed™ 780G pump to display Pump error 53, indicating insulin delivery is being stopped. This error occurs when the 780G pump software detects and mitigates an unexpected software condition. When this error occurs, insulin delivery is stopped, including all programmed boluses, and the pump is required to restart. If the pump alarm is not acknowledged within 10 minutes, the pump will vibrate and sound a siren at maximum volume. After clearing the pump alarm, the pump will reset, and insulin delivery will remain suspended. **All on-screen prompts must be followed to resume insulin delivery.**

(2) Blood Glucose (BG) Check Functionality:

When an Instinct sensor is used, the system may, at times, request the user to enter a manual BG to check the system's performance. However, due to a software anomaly, this verification may not occur as expected when the SG reading is above 400 mg/dL or below 50 mg/dL. In this case, SmartGuard will continue to deliver insulin based on the SG value or exit to manual mode. If this situation occurs, place the pump into manual mode, and use your BG meter for treatment decisions until you are able to complete the pump software update to version 6.62 listed in the “Actions Required” below.

Risk to Health:

(1) Pump Error 53:

If on-screen prompts on the pump are not addressed as detailed above, **insulin delivery will not resume**, which may lead to delayed therapy and an increased risk of hyperglycemia or diabetic ketoacidosis (DKA).

(2) BG Check Functionality:

When the BG check is not performed, (1) the pump continues to display the SG value and uses the SG value for SmartGuard insulin delivery, which may lead to insulin over- or under delivery and an increased risk of hypoglycemia and/or hyperglycemia, or (2) the pump may exit to manual mode.

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As of January 22, 2026, eighty-one complaints have been received related to (1) the Pump error 53 issue; however, no adverse events have been reported. (2) There have been no complaints received related to the BG check issue.

Actions Required:

1. Ensure your MiniMed™ Mobile app is updated to version 3.1.1 (iOS) and 3.1.2 (Android) or higher. If it is not, complete that update. **Click Here** for instructions on updating your app. *Note: To identify your current Mobile App version, Go to Menu (top left), tap on 'About'.*
2. Update your MiniMed™ 780G insulin pump software to version 6.62. **Click Here** to refer to the detailed software update guide and update your pump software.
   Note: For instructions on how to find your pump software version, ***Click Here*****.**
3. If you need assistance with updating your MiniMed™ Mobile app to the latest version or your insulin pump software to version 6.62, or have any questions about the process, please contact 24-Hour Technical Support Team at 1-800-646-4633, option 1.

Please note that the pump software update process to version 6.62 is the same as the one that you performed to upgrade your pump software version (6.60 and/or 6.61) and may take up to 3 hours to complete.

Please acknowledge that you have read and understood this notification and have followed the required actions listed by visiting - https://info.medtronicdiabetes.com/FA1544

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're here to support you and remain committed to delivering the highest quality products. If you have further questions or need assistance, please call the Medtronic 24-Hour Technical Support line at 1-800-646-4633, option 1.

Thank you for your understanding and continued trust in Medtronic Diabetes.

Sincerely,

Julio Salwen
Vice President, Quality
Medtronic Diabetes

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