Medtronic

Medtronic
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URGENT MEDICAL DEVICE CORRECTION

New Notification: Basal Setting Programming

MiniMed™ 630G: MMT-1715, MMT-1755, MMT-1754

MiniMed™ 670G: MMT-1780, MMT-1781, MMT-1782, MMT-1760, MMT-1761, MMT-1762, MMT-1740, MMT-1741, MMT-1742

MiniMed™ 770G: MMT-1880, MMT-1881, MMT-1882, MMT-1892, MMT-1891, MMT-1890

February 2022

Dear Valued Customer:

You are receiving this letter because our records indicate that in the last 6 months, you have either received a new insulin pump or a replacement insulin pump. We want to remind you that the pump you received was NOT pre-programmed with your basal rates or other verified settings (i.e., bolus wizard settings, sensor settings, etc.), which must be set up and saved on your pump prior to use. Please carefully review the instructions below and refer to the user guide in order to confirm that your settings have been saved and, if not, to program your insulin pump with these important settings and ensure that they are saved correctly.

Basal insulin is the "background" insulin needed throughout the day to maintain your target glucose values when you are not eating. Your basal insulin accounts for about half of your daily insulin requirements[1]. Basal insulin delivery is an important component of your total insulin dose. If the basal rate settings are intended to be set but not entered at all or if they are entered but not saved prior to pump use, it could result in an under-delivery of basal insulin. Under-delivery of insulin can potentially cause severe hyperglycemia, which may lead to life-threatening diabetic ketoacidosis (DKA). As described in the user guide, when programming basal rate settings, you must scroll down to select "**Done**" and then select

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[1] https://www.medtronicdiabetes.com/customer-support/device-settings-and-features/basal-settings/basal-rate

"**Save**" on the next screen to activate the basal rate settings. If "**Save**" is not selected, then basal settings will not be set.

Serious injuries have been reported with the use of the MiniMed™ 600 series and MiniMed™ 700 series insulin pumps which may be directly attributed to not setting basal rates. In addition, one death has been reported, although a review by independent clinical experts did not directly attribute this to not setting basal rates. If basal rates are not set in the pump when they should be, it could potentially lead to those events as explained above.

ACTIONS REQUIRED

New Users with New Device:

1. **Do not use your pump until you have consulted with your healthcare professional to determine the settings.**
2. **Program your settings as described in Steps 5 (c) and (d) below.**
3. **Acknowledge the notification as described Step 6 below.**

Existing Users: Replacement or Upgrade devices

4. **Verify current basal rate settings**

   To check the current basal rate settings in your pump, follow the instructions on the pump user guide for your pump model under "Viewing your basal information" section. The user guides can also be found on our website through the links provided in the appendix below.

5. **Check if the basal rate settings are present on your pump**
   If the basal rate settings are present on your pump:
   a. Proceed to step 6 to acknowledge this notification. For future reference, you may also save your settings to CareLink™, or write them down on a paper and keep it securely.

   If the basal rate settings are not present on your pump, please take all the following actions:
   b. Locate the settings for your pump, including basal rate settings, and consult with your healthcare professional to verify they are the most recent settings.
      i. If you cannot get in touch with your healthcare professional, but your previous settings were uploaded to CareLink™ in the past 90 days, you may log into your CareLink™ Personal, navigate to "Reports", then "Select

custom range" to choose a week that had the previous pump's upload, select "DEVICE SETTINGS SNAPSHOT", and select "Generate reports". The settings should have a non-zero basal rate.

c. Program your new or replaced insulin pump with all your verified settings. Refer to the pump user guide for detailed instructions on programming your insulin pump. If you have your settings but require assistance programming your pump, please contact Medtronic 24-Hour Technical Support at 1-800-646-4633, option 1.

d. As stated in the user guide, during programming the basal settings on your pump, make sure you respond to all pump screens to ensure your basal settings are saved. As shown in the screen sequence below, you **must** first scroll down to select "**Done**", and then select "**Save**" on the following screen. The settings are successfully saved when the message "**Changes saved**" is shown on the screen.

Edit Basal 1		
Start	End	U/hr
12:00 A	10:30 A	0.100
10:30 A	12:00 A	0.175
	Done	

Basal 1		
24 hr Total: 3.4 U		
Start	End	U/hr
12:00 A	10:30 A	0.100
10:30 A	12:00 A	0.175
	Save	

Changes saved ✓

The exact Basal rates shown above are for example only.

6. **Acknowledge notification**

Acknowledge that you have read and understood this notification by completing and returning the confirmation form.

For additional information and answers to frequently asked questions, please visit [www.medtronicdiabetes.com/basal-setting-programming].

Please contact Medtronic 24-Hour Technical Support at 1-800-646-4633, option 1 for the following:

- If you encounter any issues with setting basal rates or notice that basal rates are missing.
- If you experience any adverse events or quality problems associated with your use of this product.

Adverse reactions or quality problems experienced with the use of this product may also 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 form 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.
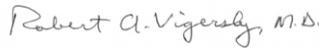
As always, we are here to support you. If you have further questions or need assistance, please call the Medtronic 24-Hour Technical Support line at: 1-800-646-4633, option 1.

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies. We apologize for any inconvenience this issue may cause you and we appreciate your time and attention in reading this important notification.

Sincerely,

Chirag Tilara
Vice President, Quality
Medtronic Diabetes

Robert Vigersky, M.D.
Chief Medical Officer
Medtronic Diabetes

<u>Appendix</u>

Helpful Links

1. Pump Basal Setting Programming Support [medtronicdiabetes.com/basal-setting-support]
2. MiniMed™ 630G User Guides and Manuals [medtronicdiabetes.com/630g-user-guide]
3. MiniMed™ 670G User Guides and Manuals [medtronicdiabetes.com/670g-user-guide]
4. MiniMed™ 770G User Guides and Manuals [medtronicdiabetes.com/770g-user-guide]
5. CareLink™ Personal [carelink.minimed.com]

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Customer Confirmation Form

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By signing this form, I confirm that I have read and acknowledged the Urgent Medical Device Correction letter dated February 2022 from Medtronic regarding Basal Setting Programming for the MiniMed™ 600 series and MiniMed™ 700 series insulin pumps and have taken all the appropriate actions listed in the letter.

Please complete and sign the form as indicated below and return by mail using the attached prepaid envelope. You can also email this form to our Field Corrective Action Department at **rs.safetyinformation@medtronic.com** or send via fax to **1-888-844-8084** to the attention of **FCA Department**.

Name (Print): _____ Date: _____
                           (First Name, Last Name)

Signature (ink): _____

Telephone: _____

Notes: _____

For questions, contact our 24-Hour Technical Support line at 1-800-646-4633, option 1.

As always, thanks for your support.