

URGENT MEDICAL DEVICE SAFETY NOTICE

Basal Setting Programming

MiniMed™ 630G: MMT-01714, MMT-1714K, MMT-1714KRP

MiniMed™ 670G: MMT-1782, MMT-1782k, MMT-1782KRP, MMT-1782CRP, MMT-1762KCN, MMT-1762CRP

MiniMed™ 770G: MMT-1881, MMT-1891CN

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

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Serious injuries have been reported globally 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. If you have not already started using your new pump, 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 3 (b) and (c) below.**

Existing Users: Replacement, Upgrade devices or users who have started using a new pump**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.

3. Check if the basal rate settings are present on your pump***If the basal rate settings are present on your pump:***

No action is required. For future reference, you may also access your settings on 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:

- a. Locate the settings for your pump, including basal rate settings, and consult with your healthcare professional to verify they are the most recent settings.

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- 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.
- b. 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 Technical Support at 1-800 284-4416.
- c. 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.



The exact Basal rates shown above are for example only.

Please contact Medtronic Technical Support at 1-800 284-4416 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.

Health Canada has been notified of this communication and actions.

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

As always, we are here to support you. If you have further questions or need assistance, please call the Medtronic Technical Support at 1-800 284-4416.

Sincerely,



Zachary Zoltek
Manager, Post-Market Vigilance
Medtronic Canada ULC

Appendix**Helpful Links**

1. MiniMed™ 630G User Guides and Manuals https://www.medtronic.com/content/dam/medtronic-com/ca-en/patients/documents/diabetes/630g/CA_EN_630G_UserGuide_MP6026120-023DOC_A_FINAL.pdf
2. MiniMed™ 670G User Guides and Manuals [https://www.medtronic.com/content/dam/medtronic-com/ca-en/patients/education/diabetes/670G/MiniMed_670G_User_Guide.pdf]
3. MiniMed™ 770G User Guides and Manuals [https://www.medtronic.com/content/dam/medtronic-com/ca-en/patients/education/diabetes/770g-support/IFU_FINAL_EN.pdf].
4. Carelink Personal <https://carelink.minimed.com/>