Medtronic

Field Safety Notice

MiniMed™ 600 and 700 series insulin pump

Basal Setting Programming

MiniMed™ 640G	MMT-1711, MMT-1712, MMT-1751, MMT-1752
MiniMed™ 670G	MMT-1780, MMT-1781, MMT-1782, MMT-1760, MMT-1761, MMT-1762, MMT-1741, MMT-1742
MiniMed™ 720G	MMT-1809, MMT-1810, MMT-1859, MMT-1860
MiniMed™ 740G	MMT-1811, MMT-1812, MMT-1861, MMT-1862
MiniMed™ 770G	MMT-1881, MMT-1882, MMT-1892, MMT-1891
MiniMed™ 780G	MMT-1885, MMT-1886, MMT-1895, MMT-1896

January 2022

Medtronic Reference: FA1216

Dear Healthcare Professional,

You are receiving this letter because our records indicate that one or more of your patients have either received a new insulin pump or a replacement insulin pump in the last 6 months. The pump your patient received was NOT pre-programmed with their basal rates or other verified settings (i.e., bolus wizard settings, sensor settings, etc.), which must be set up and saved on their pump prior to use.

Patients receiving a new or replacement insulin pump are receiving a letter that directs them to confirm that their settings have been saved and, if not, to program their settings. The letter reminds them that once the basal rates are entered, they must scroll down to select "**Done**" and then select "**Save**" on the next screen to activate the basal rate settings. Not selecting "**Save**" will result in no basal insulin delivery and can potentially cause severe hyperglycemia which may lead to life-threatening diabetic ketoacidosis (DKA). Your patient(s) may be contacting you to verify what those settings are as shown below in the section titled **"MEDTRONIC PROVIDED THE FOLLOWING INSTRUCTIONS TO PATIENTS".**

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.

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ACTIONS REQUIRED BY YOU:

1. If contacted by your patient, please assist your patients in locating and verifying their prescribed settings on their insulin pumps.
2. Ensure that your patients' verified settings are correctly programmed and saved on their pumps.

MEDTRONIC PROVIDED THE FOLLOWING INSTRUCTIONS TO PATIENTS:

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 4 (c) and (d) below.**

Existing Users: Replacement or Upgrade devices

3. **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.

4. **Check if the basal rate settings are present on your pump**

   If the basal rate settings are present on your pump:

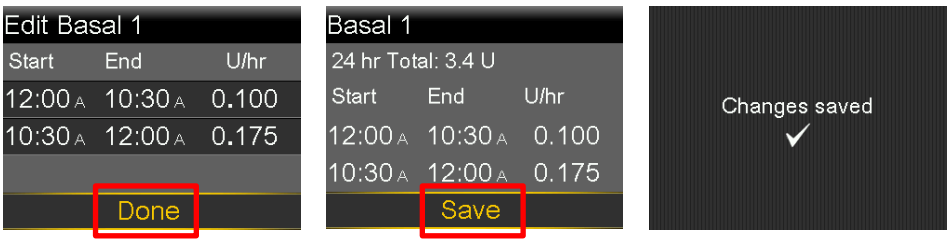
   a. No action is required. For future reference, you may also save your settings to CareLink™, or write them down on a paper and keep it securely.

   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 <our Helpline / your Medtronic contact at < XXXXX >.

Medtronic

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.



The exact Basal rates shown above are for example only.

The Competent Authority of your country has been notified of this action.

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.

Any patients who have further questions or need assistance can contact our Helpline at: <XXXXXXX>.

Sincerely,

Medtronic GmbH

Enclosure:

- Pump User Letter

Medtronic

Field Safety Notice

MiniMed™ 600 and 700 series insulin pump

Basal Setting Programming

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MiniMed™ 780G	MMT-1885, MMT-1886, MMT-1895, MMT-1896

January 2022

Medtronic Reference: FA1216

Dear Physician, Healthcare Professional,

You are receiving this letter because our records indicate that one or more of your patients have either received a new insulin pump or a replacement insulin pump in the last 6 months. The pump your patient received was NOT pre-programmed with their basal rates or other verified settings (i.e., bolus wizard settings, sensor settings, etc.), which must be set up and saved on their pump prior to use. 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, the patient 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.

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 BY YOU:

1) Inform impacted users of the MiniMed™ 600 and 700 series insulin pump using the enclosed letter.
2) Pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

Medtronic

The Competent Authority of your country has been notified of this action.

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.

If you have further questions or need assistance, please contact your Medtronic representative at <XXXXXXX>.

Sincerely,

Medtronic GmbH

Enclosure:

- Pump User Letter

Medtronic

Field Safety Notice

MiniMed™ 600 and 700 series insulin pump

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MiniMed™ 780G	MMT-1885, MMT-1886, MMT-1895, MMT-1896

January 2022

Medtronic Reference: FA1216

Dear Distributor Partner / Service Provider,

You are receiving this letter because our records indicate that one or more of your customers have either received a new insulin pump or a replacement insulin pump in the last 6 months. The pump your customer received was NOT pre-programmed with their basal rates or other verified settings (i.e., bolus wizard settings, sensor settings, etc.), which must be set up and saved on their pump prior to use. 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, the customer 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.

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 BY YOU:

1) Inform impacted customers of the MiniMed™ 600 and 700 series insulin pump using the enclosed letter(s).
2) Pass this notice on to all those who need to be aware within your organization or to any organization where the potentially affected devices have been transferred.

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3) Complete the Field Action Confirmation Sheet (FACS) and return it to your Medtronic representative.

The Competent Authority of your country has been notified of this action.

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.

If you have further questions or need assistance, please contact your Medtronic representative at <XXXXXXX>.

Sincerely,

Medtronic GmbH

Enclosure:

- Pump User Letter
- HCP Letter V1
- HCP Letter V2

Medtronic

Field Safety Notice

MiniMed™ 600 and 700 series insulin pump

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January 2022

Medtronic Reference: FA1216

Dear Pump User,

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.

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.

Medtronic

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 4 (c) and (d) below.**

Existing Users: Replacement or Upgrade devices

3. **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.

4. **Check if the basal rate settings are present on your pump**

   If the basal rate settings are present on your pump:

   a. No action is required. For future reference, you may also save your settings to CareLink™, or write them down on a paper and keep it securely.

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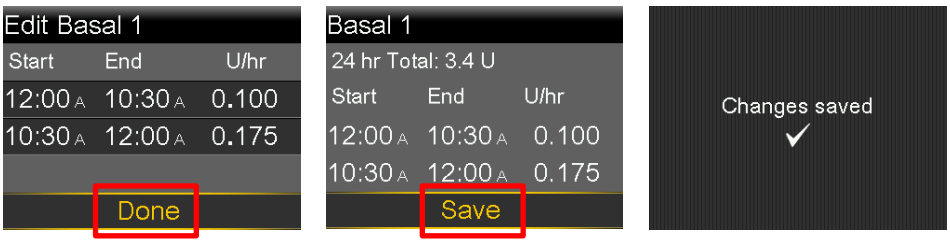
   c. Program your new or replaced insulin pump with all your verified settings. Refer to the pump user guide for detailed instructions on programming your insulin pump. If you have your settings but require assistance programming your pump, please contact <our Helpline / your Medtronic contact at < XXXXX >.

Medtronic

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.



The exact Basal rates shown above are for example only.

As always, we are here to support you. If you have further questions or need assistance, please call <our Helpline / your Medtronic contact at < XXXXX >.

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,

Medtronic GmbH