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 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.

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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,

Local /BU Manager

Enclosure:

- Pump User Letter