

Medtronic

Medtronic Ireland Limited

T Block 3090-3094
Lake Drive
Citywest Business Campus
Dublin
DN24 XN47
Ireland
Tel: 01 511 1400
Fax: 01 807 7220
www.medtronic.ie

Urgent Field Safety Notice

MiniMed™ 780G insulin pump

Pump Errors After Quick Bolus - Software Update

Insulin Pump	Model Number
MiniMed™ 780G	MMT-1885, MMT-1886, MMT-1895, MMT-1896

May 2023

Medtronic reference: FA963

EU MDR: EU Manufacturer Single Registration Number (SRN): US-MF-000023100

Dear Pump User,

In March 2021, Medtronic first communicated that MiniMed™ 780G insulin pumps with software version 6.5 could present pump errors after delivering a large bolus under certain conditions. This letter is to notify you that your MiniMed™ 780G insulin pump software version can now be upgraded from version 6.5 to version 6.7 via the Medtronic Diabetes Updater app. Upgrading your insulin pump software to version 6.7 will eliminate the potential occurrence of these errors so that you can safely use your pump for boluses over 17.1 units at quick bolus speed. Instructions for upgrading your pump to version 6.7 are included at the bottom of this letter.

Important Note: This issue only impacts customers using MiniMed™ 780G insulin pumps with software version 6.5. There is no action required if you are using a MiniMed™ 780G insulin pump with software version 6.7.

To identify your MiniMed™ 780G pump software, simply navigate to **Menu > Status > Pump** and scroll down to check the 'Software' version. If the 'Software' version is 6.5, please carefully follow the instructions in the Actions Required for Software Version 6.5 section below.

ISSUE DESCRIPTION

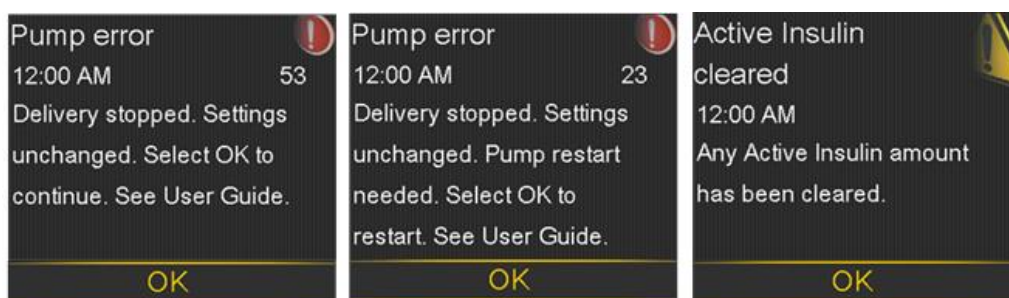
A software issue was identified in the MiniMed™ 780G pump with software version 6.5 when a large bolus is delivered at quick bolus speed.

This issue may result in pump errors if ALL of the following conditions are met:

- You have a MiniMed™ 780G pump with software version 6.5 and have not upgraded to software version 6.7.
- The bolus delivery speed is programmed to “Quick” in the pump settings (default is “Standard”).
- The SmartGuard™ feature is in use.
- The pump needs to be on the bolus delivery screen when an auto correction bolus is triggered. *Auto corrections are triggered when sensor glucose (SG) is running high and Active Insulin is low.*
- The bolus amount programmed to be delivered is greater than 17.1U.

Note: This can be a single bolus greater than 17.1U or a combination of boluses totaling greater than 17.1U.

If all the above conditions are met, within 2 minutes of bolus delivery completion, the pump initiates Pump error 53, followed by Pump error 23 alarm. The following screens are presented in the pump screen:



Upon clearing the pump errors, the pump resets and indicates Active Insulin has been cleared. The pump then guides the user to resume operation in Manual Mode. The SmartGuard™ status screen indicates the warm-up period has started. After approximately 5 hours, the SmartGuard™ feature will be available.

Since Active Insulin will display 0.0 units in the pump after experiencing the pump errors above, if the user is not aware of the amount of active insulin and delivers an additional bolus, there is a risk of insulin over delivery, which may result in low blood sugar (hypoglycemia) or severe hypoglycemia. In rare cases, severe hypoglycemia, if left untreated, may lead to a life-threatening situation.

Important Note: No action is required for users with MiniMed™ 780G insulin pumps with software version 6.7.

ACTIONS REQUIRED FOR SOFTWARE VERSION 6.5:

Upgrade your MiniMed™ 780G insulin pump software to version 6.7 using one of the three options below:

1. Follow the step-by-step instructions contained in the Software Update Guide attached to this communication. The Software Update Guide can also be found by visiting our website at: <https://www.medtronic-diabetes.com/en-IE>.
2. Contact our Helpline on 015 111444 if you need assistance with performing the software update.

If you need to deliver large boluses (17.1U) at quick speed using your pump, the best step you can take now is to upgrade your MiniMed™ 780G insulin pump to software version 6.7.

We regret any inconvenience this may cause. We are committed to patient safety and appreciate your prompt attention to this matter. If you have any questions regarding this communication, please contact our helpline on 015 111444.

Sincerely,



Bethany Moxon
Associate Regulatory Affairs Specialist - UK and Ireland

Enclosures:

- Software Update Guide