

Urgent Field Safety Notice **MiniMed™ 780G insulin pump: MMT-1885, MMT-1886** **Pump Kit: MMT-1895, MMT-1896** **Pump Errors After Quick Bolus**

March 2021

Medtronic reference: FA963

Dear Pump User,

You are receiving this letter because our records indicate you are using a MiniMed™ 780G insulin pump with software version 6.5 that could present pump errors after delivering a large bolus under certain conditions. Because your safety is our top priority, we are making you aware of this issue and important actions.

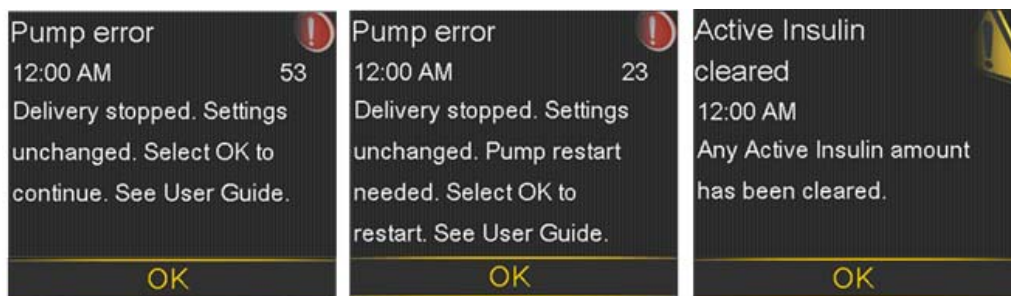
Explanation of issue:

A software issue has been identified in the MiniMed™ 780G pump using software version 6.5 when a large bolus is delivered at quick bolus speed. **These errors may occur if ALL the following conditions are met:**

- 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. As of January 21, 2021, Medtronic has received no reports of serious patient harm or serious injury related to this issue.

What you should do:

If your pump screen indicates that Active Insulin has cleared, please be aware of the following:

1. Although insulin was delivered before the error and you may have insulin on board, Active Insulin is reset to 0.0 units on the pump screen.
2. Before delivering additional boluses, check your graph or history to understand how much insulin was delivered before the error.
3. Consult your healthcare professional about your active insulin absorption and how to plan a bolus if active insulin has been reset to 0.0.

Please follow these steps **if you're using Quick Bolus and require large bolus amounts while in SmartGuard™ feature:**

1. **Wait** at least 2 minutes between boluses if you need to deliver multiple boluses that exceed 17.1U in total.
2. **Consult** your healthcare professional about setting your maximum bolus limit to 17U or less.
Note: The default setting is 10U.

At Medtronic, patient safety, awareness and customer satisfaction are our top priorities. We apologize for any inconvenience this issue may cause you and 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 our Helpline.

Sincerely,