



Medtronic

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Urgent Field Safety Notice
Medtronic MiniMed™ 640G System
Screen Timeout Report Notification

June 19, 2015

Medtronic reference: FA641

Dear Healthcare Professional:

Medtronic is committed to keeping you and your patients informed of issues and solutions concerning our products and services. The purpose of this letter is to inform you that when using the MiniMed 640G insulin pump, that there are certain scenarios where some pump screens will not timeout, which could cause confusion to the patient.

We have updated our user guide to address this and will be sending you this new user guide for distribution to your existing MiniMed 640G patients who did not receive the training material, explaining these screen timeout scenarios, as part of their pump kit. The updated user guide includes the updates outlined below. The updated User Guide(s) will be sent to you within the coming 3 weeks. The new user guide will also be included in all pump kits sent to new pump users.

Because Medtronic does not have your patients' records on file, we kindly ask you to inform patients who use the affected MiniMed 640G pumps using the enclosed letter and provide them with a copy of the new User Guide.

Summary of changes in the MiniMed 640G insulin pump user guide:

- We advise patients to promptly respond to any message displayed on the pump screen. Their prompt response is needed to complete the task.
- We advise patients that when using the Bolus Wizard, that it is important to promptly respond to any message displayed on the pump screen to correctly deliver the bolus. For example:
 - To complete a bolus, message screens must be responded to promptly. We advise never to give a bolus that was calculated more than 12 minutes ago because that bolus amount was based on a blood glucose (BG) value that is no longer current. Patients are advised to instead take a new BG meter test and have the Bolus Wizard re-calculate the necessary bolus amount.
 - If the patient receives the Max Bolus exceeded warning, they must continue through the message screens in order to complete the intended bolus. If they routinely receive the Max Bolus exceeded warning, we advise patients to notify you, their healthcare professional, so that you can adjust the pump settings.
- We advise that when calibrating, patients should not respond to a calibration request message screen that's more than 12 minutes old because that BG value is no longer considered valid. Patients should always calibrate immediately after testing their BG.

Pump versions related to this report notification:

- MiniMed 640G (MMT-1511, MMT-1512, MMT-1711 & MMT-1712)

Note: This does not affect previous Paradigm pump models.

Medtronic has notified the Competent Authority of your country of this action.

Please contact your Medtronic Field Representative directly or via Customer Services Tel No. 353 1 511 1400, if you have any questions.

We appreciate your time and attention to this important notification.

Sincerely,

Keith Taverner Regulatory Affairs Manager UK & Ireland
Enclosure: Patient Notification Letter