



Medtronic

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Medtronic MiniMed™ 640G System

Screen Timeout Report Notification

22 June 2015

Medtronic reference: FA641

Dear Valued Customer:

Medtronic is committed to keeping you and your healthcare professional 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, there are certain scenarios where the pump message screens will not timeout, which could cause confusion. Therefore, we have updated our user guide which includes the updates outlined below. A copy of the updated User Guide will be sent to you in the coming 3 weeks.

Additionally, please be sure of the following as it relates to screen timeouts:

- Promptly respond to any message displayed on the pump screen. A prompt response is needed to complete the task.
- When using the Bolus Wizard, 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. Never 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that was calculated more than 12 minutes ago because that bolus amount was based on a blood glucose (BG) value that is no longer current. Instead, take a new BG meter test and have the Bolus Wizard re-calculate the necessary bolus amount.
 - If you receive the Max Bolus exceeded warning, you must continue through the message screens in order to complete the intended bolus. If you routinely receive the Max Bolus exceeded warning, please notify your healthcare professional, so that they can adjust your pump settings.
- When calibrating, do not respond to a calibration request message screen that's more than 12 minutes old because that BG value is no longer considered valid. Always calibrate immediately after testing your BG.

Please contact your healthcare professional if you have any questions.

We appreciate your time and attention to this important notification.

Sincerely,

Keith Taverner Regulatory Affairs Manager UK & Ireland