



URGENT MEDICAL DEVICE RECALL FOR PRODUCT CORRECTION
(No actual Product is being recalled from the Market)

MiniMed® 640G Insulin Pump - Screen Timeout Notification

Model Numbers – MMT - 1511, 1512, 1711, 1712

ARTG 95763

July 20, 2015

Dear Valued Customer:

Medtronic, after consultation with the TGA (TGA Ref# RC-2015-RN-00632), is initialling a voluntary recall for product correction for its Minimed 640G insulin pump.

This is not a product recall, but only an update to IFU and no product needs to be returned.

Issue:

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 and may potentially result in over or under delivery of insulin. Therefore, we have updated our user guide which includes the updates outlined below. Enclosed you will find a copy of the updated user guide for your use. Please dispose of the previous version of the user guide.

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that was calculated more than 12 minutes ago because that bolus amount was based on a blood glucose (BG) value that is no longer current.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 further questions.



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Alternatively, as always, please call the Medtronic HelpLine at 1800 777 808, option 1 with any product concerns. Medtronic is committed to delivering high quality products and services. We appreciate your time and attention to this important notification.

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Sincerely,

A handwritten signature in black ink, appearing to read 'M. Blanshard', written in a cursive style.

Michele Blanshard
Business Director
Australia and New Zealand