Australian Government

Department of Health

Therapeutic Goods Administration

URGENT PRODUCT DEFECT CORRECTION*

LEVEL: Consumer

CLASS: Class II

REFERENCE: RC-2018-RN-01321-1

DATE AGREED: 10/10/2018

PRODUCT: **Medtronic MiniMed 640G Insulin Pumps with version 4.10 software**

Model Numbers: MMT-1711 & MMT-1712

ARTG Number: 95763
(Medtronic Australasia Pty Ltd Infusion pump, insulin, ambulatory)

SPONSOR: Medtronic Australasia Pty Ltd

PHONE: 1800 777 808 - Medtronic Customer Support Line

REASON: Medtronic has confirmed reports of occurrences at a rate of between 0.14% and 0.3% where the MiniMed 640G insulin pump with version 4.10 software has failed to make expected audio sounds during alerts, alarms, or sirens. This failure could either cause the alarm volume to be stuck at a 4 (out of 5) level regardless of personal settings, or it could make no sound. Either of these occurrences could cause users to miss system notifications, alarms or sirens associated with how the pump is working, and with high and low glucose alerts. If this issue occurs, audio cannot be permanently repaired or regained. However, pumps experiencing this issue will continue to deliver insulin as expected.

The issue is characterised by:
1. Change in audio level that user did not initiate (Piezo volume could be changed to volume OFF (worst case) or to a volume level close to 4);
2. Inability to change the volume level (volume will remain constant, despite changes to the user settings); and
3. No audio during escalation of alarm to Siren.

PROPOSED CUSTOMER ACTIONS: Medtronic is advising users to ensure the Vibrate and Audio features are enabled on devices. To date, loss of vibrate feature has not been reported to occur as part of the audio failure mode.

Users are also requested to perform an Audio Beep test to identify pumps that may be experiencing this potential issue. The test will identify if the pumps audio is working.

The steps for performing the test are provided in the Customer Letter and are also available at http://www.medtronicdiabetes.com/checkaudio

In the event that the audio beep test fails, users are advised to contact Medtronic to start the replacement process.

Where the audio beep test passes, users are now advised to repeat the Audio Beep test as a matter of routine along with every set change and on one more occasion mid-way through the infusion set and also with continued use of the pump, or as a precaution, whenever users happen to notice they may have not heard an alert or alarm that was displayed on the screen or resulted in a vibration.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: Supplied to 2653 users nationally

Product export status: New Zealand

This issue was first identified by the Sponsor

*For further details about Recall Actions, please refer to http://tga.gov.au/safety/recalls-about.htm