

10 October 2018

URGENT – PRODUCT DEFECT CORRECTION

MiniMed™ 640G Insulin Pump (MMT-1711)

TGA Reference: RC-2018-RN-01321-1

ARTG: 95763


Dear Valued Customer

We have received reports of occurrences in which 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 your personal setting, or it could make no sound. Either of these occurrences could cause you to miss system notifications, alarms or sirens associated with how the pump is working, and with high and low glucose alerts. You are receiving this letter because our records indicate you may have one of the potentially affected insulin pumps.

Customer Action Required:

1. Acknowledge receipt of this notification [by clicking here](#).
2. If you have not already done so, enable the Vibrate feature on your pump and verify it remains enabled with every set change. Even if the Audio Beep test passes, you should enable the Vibrate feature (in addition to your Audio feature) since it will add an additional notification to any alerts or alarms you may receive on your pump.

Follow the steps below to enable both the Vibrate feature and Audio feature on your pump.

Press  to open the **Menu**, Scroll down to **Audio Options**

Set **Audio & Vibrate** to “**On**” and **Save**

3. Perform an Audio Beep test to see if your pump is experiencing this potential issue. This test will identify if your pump audio is working. The steps for this test can be found at the end of this letter or you can also access our website that will guide you through this process [here](#)

Important note: You should repeat this test with every set change and once mid-way through the infusion set use to verify the continued audio functionality of your pump.

If your pump fails the beep test, it will not permanently regain its audio capabilities and a replacement will be required in order for you to use the audio features of your pump. Even if your pump passes the Audio Beep test, you should continue to perform regular beep tests to ensure continued audio functionality.

Problem/Issue Description:

This issue occurs when a specific electronic component in your pump malfunctions; it can result in the loss of all audio, problems adjusting the audio volume, or the loss of only the emergency audio siren. This potential loss of audio could delay your response to the underlying reason for the alert, alarm, or siren, which could then lead to possible health and safety risks such as hypoglycemia or hyperglycemia. If this issue occurs with your pump, the audio cannot be permanently repaired or regained. The only way to permanently regain your audio capabilities is to exchange the affected pump with a replacement. Even if your pump has the audio issue, it will continue to deliver insulin as expected. Loss of the Vibrate feature has not been reported to occur as part of the above audio failure mode. If you have a pump that contains the specific electronic component, and your pump passes the Audio Beep test described below, there is still a chance that your pump may lose its audio capabilities at some future date. The occurrence rate for this malfunction is between 0.14% and 0.3%.

To address this issue, Medtronic Australia has updated the Diabetes Support Guides and Manuals webpage to include the Audio Beep Test Instructions which can be found here: <https://www.medtronic-diabetes.com.au/support/guides-and-manuals>

Additional Information

Medtronic is initiating this action in consultation with the Therapeutic Goods Administration.

Local contact details

Should you have concerns about monitoring your pump for this issue, please register [here](#) and our Helpline will contact you within 5 business days to discuss potential options.

At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies that undergo rigorous clinical, quality, manufacturing, and regulatory controls for our customers. We 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 support line at 1800 777 808.

Sincerely,

Sarah Timms

Post Market Quality Operational Excellence Manager | Quality and Regulatory Affairs

Medtronic


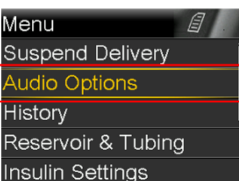
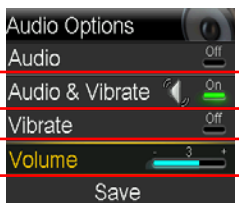
Medtronic Australasia Pty Ltd
2 Alma Road | Macquarie Park, NSW, 2113 | Australia
Office: +61 2 9857 9384 | Mobile: +61 (0)400 050 398 | Fax: 1800 929 645
sarah.timms@medtronic.com
[medtronic.com.au](https://www.medtronic.com.au) | [Facebook](#) | [LinkedIn](#) | [Twitter](#) | [YouTube](#)

LET'S TAKE HEALTHCARE
FURTHER, TOGETHER

AUDIO BEEP TEST

Follow the steps listed below to determine if your pump is experiencing this issue.

You may also use the following website to help you go through [this process](#):

Step	MiniMed™ 640G insulin pump
1	Press  to open the Menu
2	<p>Select Audio Options</p> 
3	<p>Ensure Audio & Vibrate is set to "On" and scroll down to the Volume option.</p> 
4	<p>Adjust the volume to 1, Press Save, and listen for the beep A quieter audible beep should sound.</p>
5	<p>Select Audio Options again, go to the Volume option and adjust the volume to 5. Press Save, and listen for the beep A louder audible beep should sound.</p>

Audio <u>is</u> working if...	Audio may <u>not</u> be working if...
<p>✓ <u>You HEARD a beep</u> when you pressed save on your volume settings AND</p> <p>✓ <u>You HEARD the difference</u> between the two audio beep volumes (1 & 5)</p>	<p>✗ <u>You DID NOT hear a beep</u> when you pressed save on your volume settings OR</p> <p>✓ <u>You HEARD a beep</u> when you pressed save on your volume settings, but</p> <p>✗ <u>You DID NOT hear a difference</u> between the two audio beep volumes (1 & 5)</p>
Your pump is working as expected. Monitor your insulin pump closely and you can continue pump therapy.	Visit here to start the replacement request process. If further assistance is needed, contact our 24-Hour Helpline 1800 777 808 .

NOTE: We recommend you repeat the Audio Beep test with every set change and once mid-way through the infusion set use as you continue to use your pump, or whenever you notice you may have not heard an alert or alarm that was displayed on the screen or resulted in a vibration.