

Medtronic MiniMed™ 640G Insulin Pump (MMT-1711, MMT-1712) Potential Loss of Audio Issue

October 2018

Medtronic reference: FA840

Dear pump user,

Medtronic 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 fixed at a 4 (out of 5) level regardless of your personal setting, or it could switch the volume to OFF. 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 blood glucose alerts. You are receiving this letter because our records indicate you may have one of the potentially affected insulin pumps.


Explanation of Issue:

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 malfunction and lose its audio capabilities at a future date.

What you should do:

1. If you have not already done so, enable the "vibrate" feature on your pump. Even if the Audio Beep test passes, you should enable the vibrate feature (in addition to your audio feature). The vibrate feature adds an additional notification to any alerts or alarms you may receive on your pump.

Follow the steps below to enable both the vibrate and audio feature on your device.

Press  to open the **Menu**, Scroll down to **Audio Options**
Set **Audio & Vibrate** to "On" and **SAVE**

2. Perform an Audio Beep test to see if your pump is experiencing this potential issue. This test will identify if your pump audio and emergency siren are working. The steps for this test can be found at the end of this letter or you can access our website that will guide you through this process at: www.medtronic-diabetes-look.com

Important note: You should repeat this test periodically 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.

Should you have concerns about monitoring your pump for this issue, please call our Helpline at Tel No. 01 511 1444 to discuss potential replacement options.

If you have any other concerns about the issue, we recommend that you access the website below.

www.medtronic-diabetes-look.com

Here you will find more information and answers to frequently asked questions. You can also call our Helpline at the number above if further assistance is required.

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.

Sincerely,

A handwritten signature in black ink, appearing to read 'Keith Taverner', is positioned above the typed name.


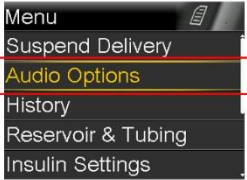
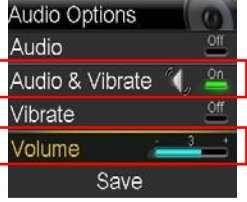
Keith Taverner
Regulatory Affairs Manager UK & Ireland

Enclosure:

- Audio Beep test

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: www.medtronic-diabetes-look.com

| Step | MiniMed™ 640G insulin pump | |
|--|--|--|
| 1 | Press  to open the Menu | |
| 2 | Select Audio Options  | |
| 3 | Ensure Audio & Vibrate is set to " On " and scroll down to the Volume option.  | |
| 4 | Adjust the volume to 1 , Press Save , and listen for the beep A quieter audible beep should sound. | |
| 5 | 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. | |
| Audio <u>is</u> working if... | | |
| ✓ You HEARD a beep when you pressed save on your volume settings AND ✓ You HEARD the difference between the two audio beep volumes (1 & 5) | | |
| Audio may <u>not</u> be working if... | | |
| ✗ You DID NOT hear a beep when you pressed save on your volume settings OR ✓ You HEARD a beep when you pressed save on your volume settings, but ✗ You DID NOT hear a difference between the two audio beep volumes (1 & 5) | | |
| Your device is working as expected. Monitor your insulin pump closely and you can continue pump therapy. | | Visit www.medtronic-diabetes-look.com for more information. If further assistance is needed or to start the replacement process, contact our Helpline at Tel No. 01 511 1444. |

NOTE: We recommend you repeat the Audio Beep test frequently as you continue to use your device, or whenever you notice you may have not heard an alert or alarm that was displayed on the screen or resulted in a vibration.