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Urgent Field Safety Notice
Medtronic MiniMed™ 640G (MMT-1711, MMT-1712)
Potential Loss of Audio Issue

October 2018

Medtronic reference: FA840

Dear Physician, Healthcare Professional,

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 patient's personal setting, or it could switch the volume to OFF. Either of these occurrences could cause your patient to miss system notifications, alarms or sirens associated with how the pump is working, and with high and low blood glucose alerts.

Because Medtronic does not have your patients' records on file, we ask you to inform users of the MiniMed™ 640G insulin pump with version 4.10 software, using the enclosed letter.

Explanation of Issue:

This issue occurs when a specific electronic component in the 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 the patient's ability to respond 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 the pump, the audio cannot be permanently repaired or regained. The only way to permanently regain the audio capabilities is to exchange the affected pump with a replacement. Even if the 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 the pump contains the specific electronic component, and the pump passes the Audio Beep test described below, there is still a chance that the pump may malfunction and lose its audio capabilities at a future date.

What the user should do:

1. The "vibrate" feature should be enabled on the pump. Even if the Audio Beep test passes, the vibrate feature should be enabled (in addition to the audio feature). The vibrate feature adds an additional notification to any alerts or alarms received on the 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. An Audio Beep test should be performed to see if the pump is experiencing this potential issue. This test will identify if the pump audio and emergency siren are working. The steps for this test can be found in the pump user letter, and users can also access our website that will guide them through this process at: www.medtronic-diabetes-look.com

Important note: They should repeat this test periodically to verify the continued audio functionality of their pump.

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

Should they have concerns about monitoring the pump for this issue, please call our Helpline at <XXXX> to discuss potential replacement options.

If there are 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,

Country/BU manager

Enclosures:
- Audio Beep test
- Pump User Letter

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AUDIO BEEP TEST

Follow the steps listed below to determine if the pump is experiencing this issue. The following website may also be used to help 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...	Audio <u>not</u> be 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)	χ 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 χ You **DID NOT** hear a difference between the two audio beep volumes (1 & 5)
The device is working as expected. Have your patient monitor their insulin pump closely and they can continue pump therapy.	Visit www.medtronic-diabetes-look.com for more information. If there are concerns about monitoring the pump for this issue, patients should contact our Helpline at <mark><XXXX>.</mark>

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