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Urgent: Field Safety Notification
Potential Loss of Audio Issue
MiniMed™ 640G

03 October 2018

Attention: Risk Management Director and O.R Materials Management
CC: The Chairman Medical Board and relevant Head of Departments

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 patient's personal setting, or it could make no sound. 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 glucose alerts. The purpose of this letter is to make you aware that we will be notifying all patients who may have one of the potentially affected insulin pumps. Patients will be emailed and/or sent a letter with information specific to the insulin pump model they are using.


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 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 lose its audio capabilities at some future date.

The letter being sent to your patients will explain that they should enable the Vibrate feature and perform an Audio Beep test:

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) since it will add 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 the insulin pump

MiniMed™ 640G insulin pumps	Press  to open the Menu , Scroll down to Audio Options Set Audio & Vibrate to "On" and Save
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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 is working. The steps for this test can be found in the patient letter.
3. Please complete the attached Confirmation Form in its entirety and return it as directed to confirm the receipt and understanding of this information.

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

If the pump fails the beep test, it will not permanently regain its audio capabilities and a replacement will be required 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.

If your patients have concerns about monitoring their pump for this issue, we recommend they call our Helpline Singapore : +65 6505 4874 to discuss potential replacement options.

Alternatively, please contact your local Medtronic representative should you have further enquiry.

This notification is being issued or will be notified to relevant regulatory bodies according to applicable regulations. We request that you contact Medtronic if you experienced quality problems or adverse events.


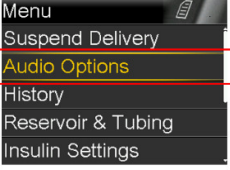
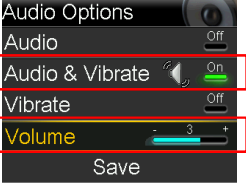
At Medtronic, patient safety is our top priority, and we are committed to delivering safe and effective therapies that undergo rigorous clinical, quality, manufacturing, and regulatory controls for our customers. We appreciate your time and attention in reading this important notification.

Sincerely,



Diana Teo
Quality System Manager
Medtronic

AUDIO BEEP TEST: Follow the steps listed below to determine if the pump is experiencing this issue.

MiniMed™ 640G insulin pump							
Step 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>						
<table border="1" style="width: 100%; border-collapse: collapse;"> <thead> <tr> <th style="width: 50%; text-align: center;">Audio <u>is</u> working if...</th> <th style="width: 50%; text-align: center;">Audio may <u>not</u> be working if...</th> </tr> </thead> <tbody> <tr> <td style="vertical-align: top;"> <p>✓ You HEARD a beep when you pressed save on your volume settings</p> <p style="text-align: center;">AND</p> <p>✓ You HEARD the difference between the two audio beep volumes (1 & 5)</p> </td> <td style="vertical-align: top;"> <p>☐ You DID NOT hear a beep when you pressed save on your volume settings</p> <p style="text-align: center;">OR</p> <p>✓ You HEARD a beep when you pressed save on your volume settings, but</p> <p>☐ You DID NOT hear a difference between the two audio beep volumes (1 & 5)</p> </td> </tr> <tr> <td style="vertical-align: top;"> <p>The pump is working as expected. Have your patient monitor their insulin pump closely and they can continue pump therapy.</p> </td> <td style="vertical-align: top;"> <p>If further assistance is needed, have your patient contact our Helpline as per customer letter Alternatively, please contact your local Medtronic representative should you have further enquiry.</p> </td> </tr> </tbody> </table>		Audio <u>is</u> working if...	Audio may <u>not</u> be working if...	<p>✓ You HEARD a beep when you pressed save on your volume settings</p> <p style="text-align: center;">AND</p> <p>✓ You HEARD the difference between the two audio beep volumes (1 & 5)</p>	<p>☐ You DID NOT hear a beep when you pressed save on your volume settings</p> <p style="text-align: center;">OR</p> <p>✓ You HEARD a beep when you pressed save on your volume settings, but</p> <p>☐ You DID NOT hear a difference between the two audio beep volumes (1 & 5)</p>	<p>The pump is working as expected. Have your patient monitor their insulin pump closely and they can continue pump therapy.</p>	<p>If further assistance is needed, have your patient contact our Helpline as per customer letter Alternatively, please contact your local Medtronic representative should you have further enquiry.</p>
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NOTE: We recommend your patient repeats the Audio Beep test frequently as they continue to use their pump, or whenever they notice they may not have heard an alert or alarm that was displayed on the screen or resulted in a vibration.



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Customer Confirmation Form
Potential Loss of Audio Issue
MiniMed™ 640G (MMT-1711, MMT-1712)

Customer Contact Details	Medtronic Contact Details
Name / HCP:	By E-mail:
Address:	By Post:
Telephone no:	Telephone:
Fax no:	
E-mail:	

By signing this form, I confirm that I have read the **Urgent: Field Safety Notification MiniMed™ 640G (MMT-1711, MMT-1712)** Letter, dated **03 October 2018** from Medtronic.

Name: _____ (print) Signature: _____ Stamp: _____ Date: _____



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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 lose its audio capabilities at some 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) 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**

2. 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 .
Important note: You should repeat this test periodically to verify the continued audio functionality of your pump.
3. Please complete the attached Confirmation Form in its entirety and return it as directed to confirm the receipt and understanding of this information.

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.

If you have concerns about monitoring their pump for this issue, we recommend they call our Helpline Singapore : +65 6505 4874 to discuss potential replacement options.

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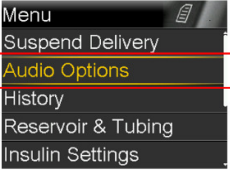

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Sincerely,



Diana Teo
Quality System Manager
Medtronic

AUDIO BEEP TEST: Follow the steps listed below to determine if the pump is experiencing this issue.

MiniMed™ 640G insulin pump	
Step 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 is working if...	
<p>✓ You HEARD a beep when you pressed save on your volume settings</p> <p>AND</p> <p>✓ You HEARD the difference between the two audio beep volumes (1 & 5)</p>	<p>✗ You DID NOT hear a beep when you pressed save on your volume settings</p> <p>OR</p> <p>✓ You HEARD a beep when you pressed save on your volume settings, but</p> <p>✗ You DID NOT hear a difference between the two audio beep volumes (1 & 5)</p>
<p>The pump is working as expected. Have your patient monitor their insulin pump closely and they can continue pump therapy.</p>	<p>If further assistance is needed, have your patient contact our 24-Hour Helpline as per customer letter. Alternatively, please contact your local Medtronic representative should you have further enquiry.</p>

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



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Customer Contact Details	Medtronic Contact Details
Name / HCP:	By E-mail:
Address:	By Post:
Telephone no:	
Fax no:	Telephone:
E-mail:	

Indicate in the columns below serial numbers you currently is/are having.

Product Code	Serial #

By signing this form, I confirm that I have read the **Urgent: Field Safety Notification Potential Loss of Audio Issue MiniMed™ 640G (MMT-1711, MMT-1712)** Letter, dated **03 October 2018** from Medtronic.

Name: _____ (print) Signature: _____ Stamp: _____ Date: _____