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**Date:** May 2025

### **Urgent: Medical Device Correction**

#### **Dexcom G6 Receiver – MT27408-1, Dexcom G7 Receiver – MT26403-0**

Attention: Valued Dexcom Customer,

We are contacting you as Dexcom has become aware that users of certain Dexcom Receivers may experience an issue where alarm/alerts do not function as designed, due to a speaker malfunction. In such instances, the alarm/alert may not provide audio output when an audio prompt would be expected. Please read this message, as it contains important safety information, and it will help you identify if your Dexcom receiver may be impacted by this issue.

#### **Details on Affected Devices:**

This Urgent Medical Device Correction applies ONLY to users of Dexcom Receivers with a part number listed in Table 1 below. Although not every device with one of the listed part numbers may be impacted, it is recommended for all users with receivers featuring a part number listed in Table 1 to follow the Recommended Customer Actions listed below (See part number location in Reference Image 4):

**Table 1: Impacted Receiver Information - US**

<b>Part Number</b>	<b>SKUs</b>	<b>Part Description</b>
MT27408-1	STK-FE-001, STK-FM-001, STK-FR-001	Dexcom G6 Receiver
MT26403-0	STK-AT-011, STK-AT-012, STK-AT-013	Dexcom G7 Receiver

#### **Description of the Problem:**

Users of the Dexcom G6 or G7 Receiver have reported an issue in which the receiver may not provide audio output to alerts/alarms as expected.

**Note:** An impacted receiver will still provide an alert through vibration and visual prompts. Other receiver and system functions, including accuracy, are not impacted.

#### **Risk to Health:**

If a user experiences a lack of receiver audio due to this issue, it could potentially result in missed detection or treatment of severe hypoglycemia or hyperglycemia. As of April 2025, 109 complaints have been received globally with confirmed association to this speaker malfunction. Globally, there have been 12 reports of hypoglycemic events (seizure, loss of consciousness, vomiting, or unspecified hypoglycemic symptoms; All 12 users recovered after treatment) associated with this issue. Complaint investigations did not confirm these events were caused by this speaker malfunction but were unable to definitively rule out this malfunction as a causal or contributing factor.

#### **Recommended Customer Action:**

- Test speaker function when you charge your receiver. When you charge, a prompt will invite you to test speaker function. See Reference Images 1-3 below.
- Electively test the receiver speaker at any point through the menu:  
Menu>Information>Receiver>Speaker>Test

- Elective testing is recommended after configuration changes and updates.
- If the speaker test is not successful, contact Dexcom Technical Support at the contact reference provided in this notice, for troubleshooting and assessment of whether the receiver should be replaced. Use your phone app, watch app, or blood glucose meter until the receiver issue is resolved.
- If the speaker test is successful, continue to test speaker function each time you charge your receiver.

### Contact reference information:

If you need assistance related to this issue or notification, please call **Dexcom Technical Support at 1-844-478-1600**. Technical Support is available 24 hours a day/7 days a week to assist you.

Adverse reactions or quality problems experienced with the use of this product may be reported to the FDA's MedWatch Adverse Event Reporting program either online, by regular mail or by fax. This issue has been reported to the U.S. Food & Drug Administration. On behalf of Dexcom, we apologize for any inconvenience this may cause.

### Reference Images:

Image 1: Receiver Speaker Test

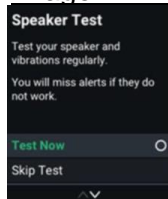


Image 2: User Guide Excerpt – G6

#### Test Speaker and Vibrations

You have to hear or feel alarm/alerts to react to them, so test your receiver speaker and vibrations regularly.

To make sure the speaker and vibrations work, plug in the receiver to charge. The Speaker Test screen appears for a few seconds. Follow the directions on the screen to test the speaker and vibrations. If you hear and feel them, great! But if it doesn't beep and vibrate – perhaps it got wet or was dropped – contact Technical Support and use your app until the receiver is fixed.

Image 3: User Guide Excerpt – G7

**Test speaker and vibrations:** Test your receiver speaker and vibrations regularly.

To make sure the speaker and vibrations work, plug in the receiver to charge. The Speaker Test screen appears for a few seconds. Follow the directions on the screen to test the speaker and vibrations. If it doesn't beep and vibrate, contact technical support and use your phone app, watch app, or BG meter until the receiver is fixed.

Image 4: Example Images of Affected Receiver:

Note: The part number is listed on the back of the receiver as shown in the image to the right/below:

Front of Receiver  
Example Rendering:



Back of Receiver  
Example Rendering:



Sincerely,  
Dexcom Quality Compliance Team