



Dexcom, Inc. | Corporate Headquarters  
6340 Sequence Drive | San Diego, CA 92121  
888.738.3646 | dexcom.com

**Date:** July 2025

**Urgent: Field Safety Notice**

**Dexcom Non-Touchscreen Receiver – FAS-SD-25-001 - US-MF-000010694**

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 Field Safety Notice applies ONLY to users of Dexcom Receivers with the part number listed in Table 1 below. Users of a receiver with a part number listed in Table 1 should follow the Recommended Customer Actions to check the receiver serial number to find out if the receiver is affected by this issue.

- Note: Table #1 includes parts distributed throughout EMEA countries + Argentina
- See part number location in Reference Image 2, toward the end of this notice

**Table 1: Impacted Receiver Information – EMEA + Argentina**

| Part Number | Description                    | SKUs                      | UDI                                                        |
|-------------|--------------------------------|---------------------------|------------------------------------------------------------|
| MT26403-1   | G7 Receiver mg/dL              | STK-GT-013,<br>STK-GT-001 | 00386270002273 (STK-GT-013)<br>00386270004291 (STK-GT-001) |
| MT26403-2   | G7 Receiver mmol/L             | STK-GT-100,<br>STK-GT-109 | 00386270002921 (STK-GT-100)<br>00386270002129 (STK-GT-109) |
| MT28285-1   | Dexcom ONE+ Receiver mg/dL     | STK-D7-013,<br>STK-D7-014 | 00386270003812 (STK-D7-013)<br>00386270003843 (STK-D7-014) |
| MT28285-2   | Dexcom ONE+ Receiver<br>mmol/L | STK-D7-103                | 00386270003836 (STK-D7-103)                                |
| MT27409-1   | Dexcom ONE Receiver mg/dL      | STK-DO-006,<br>STK-DO-013 | 00386270003188 (STK-DO-006)<br>00386270002327 (STK-DO-013) |
| MT27409-2   | Dexcom ONE Receiver mmol/L     | STK-DO-103,<br>STK-DO-109 | 00386270002969 (STK-DO-103)<br>00386270002792 (STK-DO-109) |

**Description of the Problem:**

Users of the Dexcom G7, Dexcom ONE, and Dexcom ONE+ Receivers 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. Although a speaker test could identify a defective receiver, the malfunction can occur at any time without warning, even if the receiver has recently passed the speaker test. As of April 2025, there have been 48 complaints in EMEA with confirmed association to this speaker malfunction. Of those complaints there have been no serious deteriorations of health. There have been no complaints in Argentina with confirmed association to this speaker malfunction.

### **Recommended Customer Actions:**

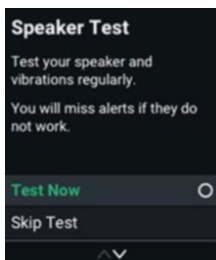
- Verify if your receiver is affected by this issue: Check the serial number (reference image 2 below for serial number location) for any receiver(s) you use, with a part number listed in Table 1, by visiting this webpage: <https://www.dexcom.com/checkreceiver>
  - If you need assistance with the serial number verification process, please contact Dexcom Technical Support at the phone number provided in this notice.
  - If your receiver is affected, please contact Dexcom Technical Support to obtain a replacement for no charge, using the contact reference provided below.
- Whether or not your receiver is affected by this notification, Dexcom continues to recommend regular testing of the speaker. Test speaker function every time you charge your receiver. When you charge, a reminder prompt will invite you to test speaker function. See Reference Image 1 below.
  - Electively test the receiver speaker at any point through the menu: Menu>Information>Receiver>Speaker>Test
  - 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 a speaker test is successful, continue to test speaker function regularly.

### **Contact reference information:**

If you need assistance related to this issue or notification, please call **Dexcom Technical Support at 0800 724 6449**.

### **Reference Images:**

Image 1: Receiver Speaker Test



**Image 2: Example Images of Affected Receiver:**

Note: The part number and serial number are both listed on the back of the receiver as shown in the image to the right/below:



Please forward this Field Safety Notification to all those who may be impacted by the device malfunction or the corrective action(s) taken. Please maintain awareness of this safety notice and the recommended customer action for an appropriate period of time.

This issue has been reported to the applicable National Competent Authorities. Please report all device-related suspected serious incidents to the manufacturer, distributor, local contact point or to the National Competent Authority, if appropriate, as this provides important feedback to the manufacturer.

On behalf of Dexcom, we apologize for any inconvenience this may cause.

Sincerely,  
Dexcom Quality Compliance Team