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Date: January/February 2025

Urgent: Medical Device Correction
Dexcom G6 Receiver – MT24078

Attention: Valued Dexcom Customer,

We are contacting you as Dexcom has become aware that users of certain G6 Receivers may experience an issue where alarm/alerts may not function as designed. In such instances, the alarm/alert may be missed or delayed. We have identified the source of the issue and will be releasing a software update to solve this. Please read this message, as it will help you identify if your Dexcom G6 receiver is in need of a software update.

Details on Affected Devices:

This Urgent Medical Device Correction applies ONLY to users of Dexcom G6 Receivers with the part number listed in Table 1 below (refer to images toward the end of this notice):

Table 1: Impacted G6 Receiver Information - US

Part Number	SKUs	Part Description
MT24078	STK-OE-001, STK-OM-001, STK-OR-001, STR-OM-001, STR-OR-001	Dexcom G6 Receiver

Description of the Problem:

Users of the Dexcom G6 Receiver with the impacted software have reported an issue which manifests as follows:

- Receiver may not alert as designed including missed or delayed alarm/alerts
- Missed/delayed alarm/alerts may include: Low/High Glucose Alerts, Urgent Low Alarm, Urgent Low Soon Alert, Rise/Fall Rate Alerts, Signal Loss Alert, or Sensor Alert

Note: CGM Glucose Values and Glucose Trend Information continue to be displayed on the receiver

Risk to Health:

If a user experiences a missed or delayed alarm/alert due to this issue, it could potentially result in missed detection or treatment of severe hypoglycemia or hyperglycemia. To date, (520) complaints have been received with confirmed association to the missed or delayed alarm/alert error. Of those, (4) were assessed as serious injuries, due to severe hypoglycemia.

We are working to provide a path whereby users can update their receiver to resolve this issue. Active G6 Receiver users will receive an Urgent: Medical Device Correction Update Notification, via email, regarding the software update availability.

In the meantime, we recommend that you:

- If available, use the G6 App as primary display device to receive glucose readings and alerts. The G6 transmitter allows simultaneous communication with an iOS or Android device as well as a receiver. The G6 App is not impacted by the issue documented in this notification and may be used in addition to or instead of the optional G6 Receiver. The G6 App can be installed on your compatible smartphone by visiting the Apple Store or Google Play Store. For compatible devices and operating systems see: <https://www.dexcom.com/compatibility>.
- If using an affected G6 Receiver, check CGM glucose values and glucose trend regularly as CGM glucose values and glucose trend graph information continue to be displayed. If you receive an alarm or alert, always check your glucose value prior to taking any additional steps.
- If you believe you may be experiencing the missed or delayed alarm/alerts issue, the issue can be corrected by shutting down the receiver and then turning it back on. Note: If the same triggering conditions occur after the reset, the issue may reoccur.

Steps to shut down and turn back on the receiver:

- Go to the receiver menu. The “menu” icon looks like this:



- Scroll-down until the “shutdown” option is visible
 - Select the “shutdown” option
 - Turn the receiver back on by pressing the select button for 3-5 seconds
- The use of optional alerts may increase the likelihood of getting an alert and is recommended. Always check your glucose value when receiving an alert, prior to taking any additional steps.
 - Do not ignore low/high symptoms; if the presence or absence of glucose alarm/alerts do not match what you are feeling, use your blood glucose meter (BGM) to make diabetes treatment decisions or, if needed, seek immediate medical attention.

Recommended Customer Action:

If you are or plan to be an active user of an affected Dexcom G6 Receiver, please complete the following actions related to an important software update:

1. Please navigate to the following webpage on your internet browser using your tablet or computer:

<https://www.dexcom.com/g6-receiver-update>



2. Please read the information provided on the webpage and any recommended actions regarding a software update for your receiver to permanently resolve this issue.

If you are not and do not plan to be an active user of an affected Dexcom G6 Receiver, no further additional action is needed. Examples of where this may apply include if you have switched to a non-G6 CGM product or if you have permanently discontinued use of your G6 receiver in favor of a different display device.

Contact reference information:

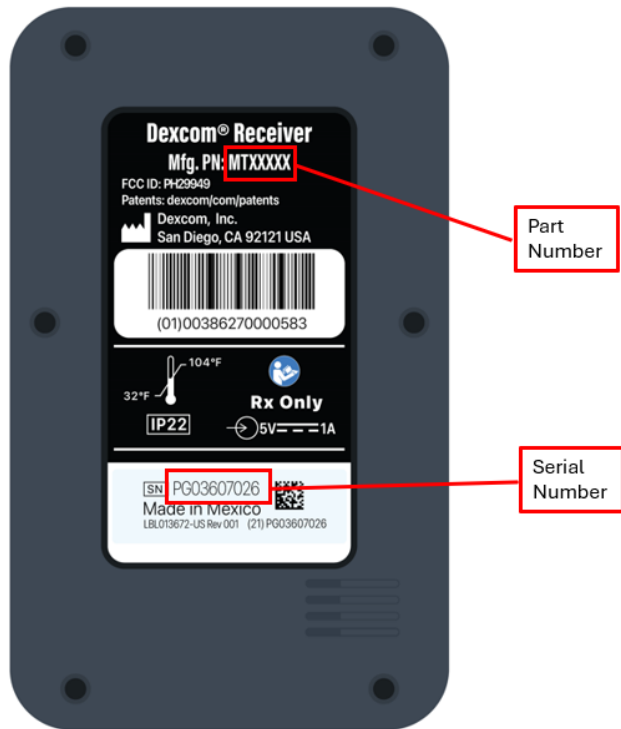
If you need assistance in fulfilling any of the steps outlined above or on the referenced webpage, please call **Dexcom Technical Support at 1-844-478-1600**. Technical Support is available 24 hours a day/7 days a week to assist you.

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:**



Note: If your receiver does not look like the images above and has a different part number, then it is not affected.

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.

Sincerely,
Dexcom Quality Compliance Team

To ensure receipt of this urgent medical device customer notification, Dexcom will send up to three communications to potentially impacted customers until an acknowledgement confirmation is received. If you do not acknowledge the alert after three communications, Dexcom will assume you are not impacted by the correction. As always, please contact Dexcom Technical Support if you are experiencing any issues.