



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

Initiation of an Urgent: Medical Device Correction (see attachment) - Dexcom Non-Touchscreen Receiver:

I am writing to inform you that Dexcom has initiated a Medical Device Correction Notice (MDCN) for the Non-Touchscreen receiver. The following part numbers are impacted by this MDCN:

Table 1: Products Affected by this Field Action

Part Number	NDC/NRC Number	SKUs	Part Description
MT27408-1	08627-0091-11	STK-FM-001, STK-FR-001	Dexcom G6 Receiver
MT26403-0	08627-0078-01	STK-AT-011, STK-AT-012, STK-AT-013	Dexcom G7 Receiver

Background information and reason for the MDCN:

Dexcom recently became aware that users of the Non-Touchscreen receivers (SKUs listed above) may experience an issue where alarms/alerts may not function as designed. In such instances, the alarm/alert may not provide audio output when an audio prompt would be expected. A missed or delayed alarm/alert could potentially result in missed detection or treatment of severe hypoglycemia or hyperglycemia. Refer to Urgent Medical Device Correction Notification for additional details on Risk to Health. Dexcom has assessed that it is necessary to conduct an Urgent Medical Device correction to remind users to check their systems regularly in accordance with their instructions for use.

An impacted receiver will still provide an alert through vibration and visual prompts. Other receiver and system functions, including accuracy, are not impacted and there is no impact to Dexcom sensors or applications.

Required actions:

Please provide the MDCN to customers who have received product(s) listed in Table 1 via **one or more** of the following methods:

- Post the attached MDCN in a location in the pharmacy where it is visible to the public. Please keep the MDCN posted for a minimum of 3 months to promote awareness.
- Post the attached MDCN on the pharmacy website. Please keep the MDCN posted for a minimum of 3 months to promote awareness.
- Provide a print-out of the attached MDCN to customers when they fill a prescription for an affected Dexcom product
- Contact customers who have been sold affected product, to provide them with the MDCN

Dexcom will provide a list of affected lots that were shipped to your facility. We additionally request the following actions:

1. Screen inventory for affected lots
2. Quarantine affected product
3. Return affected product to wholesaler/distributor for replacement



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Should you have any questions regarding this letter, your obligations, or the MDCN, please reach out to your Dexcom Account contact.

Thank you for your help with this situation.

Sincerely,
Dexcom Quality Compliance