

Urgent Field Safety Notice

Dexcom G4 PLATINUM and Dexcom G5 Mobile CGM System FAS-SD-19-002 Advise from Manufacturer

Date: June 20, 2019

Attention: Valued Dexcom Customer


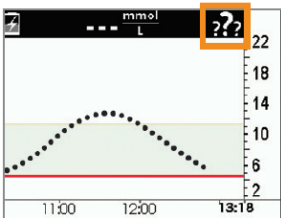
Details on affected devices:

This field safety notice applies to all users of G4 PLATINUM and G5 Mobile CGM System.

Description of the problem:

The Dexcom G4 PLATINUM or Dexcom G5 Mobile CGM System User Guide describes many icons intended to communicate information about your device. Some have audible prompts, and others do not.

The icon in the example from your User Guide below does not have an audible prompt and indicates that you are not receiving your sensor glucose readings. You will not receive alarms/alerts during times that you are not receiving your sensor glucose readings.

Device	What you see	Problem	What you do
Smart Device: In App		Not getting sensor glucose readings	<i>Do not calibrate.</i> Wait for more prompts. System may correct problem itself and continue to provide sensor glucose readings.
Receiver			3 hours since last sensor reading: Contact your local Dexcom representative.

User Guide Reference: LBL013137 Rev 010 MT23201, G5 Mobile OUS English/mmol

Advise on action to be taken by the user:

- Periodically check your App and/or Receiver for status of your sensor glucose readings.
- Check your App and/or Receiver more frequently before or during activities involving higher risk of injury to yourself or others, such as driving a car or operating heavy machinery.
- Do not ignore symptoms of low or high glucose. If your glucose alerts and readings do not match your symptoms or expectations, you should obtain a fingerstick blood glucose value from your blood glucose meter to make diabetes treatment decisions or seek immediate medical attention.

Transmission of this Field Safety Notice:

Please pass this notice to all those that need to be aware of it.

Contact reference person:

Please contact Dexcom Technical Support **0800 724 6449** if you have any questions regarding this notice.

The undersign confirms that this notice has been sent to the appropriate Regulatory Agency.

Sincerely,

Anita Rees
Dexcom Quality Compliance