

Urgent Field Safety Notice Dexcom G4 PLATINUM and Dexcom G5 Mobile Receiver FAS-SD-20-002 Advise from Manufacturer

Date: June x, 2020

Attention: Valued Customer

Details on affected devices:

This field safety notice applies to the G4 PLATINUM and G5 Mobile CGM Receiver.

Description of the problem:

It is possible for the receiver to shutdown after the device is exposed to certain external forces and/or impact (e.g. being dropped). A cracked battery integrated circuit (IC) chip may result in system performance issues including a receiver shutdown where the receiver would no longer provide glucose values or associated alerts.

The following warning and advise on action to be taken is a reinstatement of the IFU for your attention:

Warning Do Not Use Damaged Goods:

If the receiver is damaged or cracked, do not use it. A damaged or cracked receiver may cause the Dexcom CGM System not to function properly.

Advise on action to be taken by the user:

- Do not use damaged goods.
- Periodically check your receiver for status of your sensor glucose readings.
- 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.

Contact:

(DRAFT FSN - TO BE FILLED IN WITH FINAL FSN)

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

Sincerly,

Dexcom Quality Compliance