

Urgent Field Safety Notice

Dexcom ONE Android CGM App FAS-SD-22-001 Advise from Manufacturer

Date: May XX, 2022

Attention: Valued Customer

Details on affected devices:

This field safety notice applies to users of the Dexcom ONE Android App versions **1.1.0** and **1.2.0**, when used as the smart device app for the Dexcom ONE CGM System.

Description of the problem:

Users of the current Dexcom ONE Android App may not receive alerts including visual, vibration, or audio alerts when their glucose levels are low or high. The risk associated with missing “low” or “high” alerts is a potential missed detection of a hypoglycemic or hyperglycemic event.

Dexcom is working on releasing an updated version of the app imminently to correct the issue. In the next few weeks, you will receive a series of additional messages from Dexcom directly through your app informing you of the upcoming app update, when the app update is available, and a final message to inform you of when your current app version will no longer be available for use. You must update your app to continue using the Dexcom ONE CGM System.

We are diligently working on fixing the issue with the app. In the meantime, we recommend that you:

- Ensure location settings are set to “Always Allow” and not changed, or toggled back and forth
- Do not customize your alert settings
- Check your glucose trend graph and sensor reading on the App home screen for color changes associated with low (red) and high (yellow) alerts (See Figure 1 below from your user guide)
- Do not ignore low/high symptoms; if your glucose alerts and Dexcom ONE readings 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.



Figure 1 : Android App home screen



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Advice on action to be taken by the user:

Once you receive messages directly through your app, please update your Dexcom ONE Android App from the Google Play Store. Failure to update your App may cause your alerts to not work as intended.

Approximately 2 weeks after the app update is released the current version **1.1.0** and **1.2.0** of the app will be blocked from use. You must update your app to continue using the Dexcom ONE CGM System.

To confirm that you have installed the updated version, you can check by following the instructions below:

Within the Dexcom ONE Android App, navigate to Settings > About. The version of the app you currently have installed will be displayed next to "Software Revision"

Contact reference person:

Please contact Dexcom Technical Support toll free numbers listed below if you require assistance or have any questions regarding this notice.

Opening hours, Mon-Fri, 9:00am-6:00pm EET

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

Sincerely,

Dexcom Quality Compliance