

# **Urgent Field Safety Notice**

# Dexcom G6 iOS CGM App FAS-SD-19-003 Advise from Manufacturer

Date: December 2019

Attention: Valued Dexcom Customer

#### Details on affected devices:

This field safety notice applies to users of the Dexcom G6 iOS App that have not updated to version 1.5.4. If you have not yet updated, you are receiving a similar notification directly through you app.

# **Description of the problem:**

Users of the Dexcom G6 iOS App with versions prior to 1.5.4 may not receive their scheduled alerts. In the worst-case scenario, a user may not receive alarms/alerts when their glucose levels are low or high.

### Advise on action to be taken by the user:

Please update your Dexcom G6 iOS App from the Apple App Store. Failure to update your App may cause your alarms and alerts to not work as intended. Without alarms/alerts, you might miss a severe low or high glucose event.

If you do not update your app, the current version of the app that you are using will be blocked from use on 9 December 2019. You must update your Dexcom G6 iOS App now from the Apple App Store to continue use of the Dexcom G6 iOS App.

### What version of the Dexcom G6 iOS App should I be using?

Country	Software Version
Europe	SW11585 (mg/dL) or SW11586 (mmol/L) version 1.5.4

If you are not sure which version you have installed, you can check by following the instructions below:

Within the Dexcom G6 iOS App, navigate to Settings > About. The version of the app you currently have installed will be displayed next to "Software Revision"

### 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 your local distributor or Dexcom Technical Support if you require assistance or have any questions regarding this notice.

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

Sincerely,

**Dexcom Quality Compliance**