



[February XX, 2023]

Urgent Field Safety Notice

Product: [FreeStyle LibreLink App for Android and FreeStyle Libre 3 App for Android] [all versions]

Reference: ADC FA1010-2023

Communication from Manufacturer

Dear Customer:

Extended periods of signal loss, which could impact your ability to receive glucose alarms or readings, may be experienced by users who are using the Android operating system 13 with the FreeStyle LibreLink app (with alarms ON) or the FreeStyle Libre 3 app. If this occurs, turn your Bluetooth OFF and then ON or turn your smartphone OFF and then ON. Please read below for additional information. Note: If you are not sure what operating system you are using, see the “**Find Your Operating System Version**” section below.

Problem / Issue

Abbott has recently discovered that when using smartphones with the Android 13 Operating System (OS), customers may experience extended periods of signal loss in the FreeStyle LibreLink and FreeStyle Libre 3 Android apps. During these extended periods of signal loss, users of glucose alarms will not receive low glucose or high glucose alarms and FreeStyle Libre 3 users will not receive glucose readings. If you are a FreeStyle LibreLink user, this does not impact your ability to get glucose readings by scanning your Sensor with the FreeStyle LibreLink app on your smartphone or with your Reader.

Potential Harms

- Missed glucose alarms could lead to undetected low or high glucose, which could result in delayed treatment, such as not taking insulin (for high glucose), or not taking glucose (for low glucose) when required
- Missed glucose results (FreeStyle Libre 3 only) could lead to undetected low or high glucose, which could result in delayed treatment, such as not taking insulin (for high glucose), or not taking glucose (for low glucose) when required

Actions for Users

If you experience extended periods of signal loss, either of the following actions should assist in reconnection:

- Turn Bluetooth OFF and then ON again from your Android smartphone settings
- Turn your smartphone OFF and then ON again

Configure your signal loss alarm to be ON with “Override Do Not Disturb” enabled. Please refer to www.FreeStyleandroid.com for more information on how to configure alarms.

If you have not already upgraded your smartphone OS to Android 13 and are using the FreeStyle LibreLink or FreeStyle Libre 3 App, we advise you to delay upgrading until you receive additional notice from Abbott.

If these steps do not resolve the issue please call Abbott Customer Service at [### country to insert correct CS Phone #].

You will know that you are connected when the symbols (see below) no **longer** appear on your app.



You will need to repeat one of these steps above if you experience an extended period of signal loss in the future.

It is important to note that signal loss conditions can occur that are unrelated to this issue. For example, signal loss may occur if your smartphone is too far away from your sensor. If this occurs, follow instructions as outlined in the User Manual troubleshooting section.

This does not impact you if:

- you use a reader to start your sensor
- you use FreeStyle LibreLink with FreeStyle Libre Sensors
- you use FreeStyle LibreLink or FreeStyle Libre 3 app on an Apple iPhone
- you use FreeStyle LibreLink or FreeStyle Libre 3 app on a smartphone running Android 12 OS or below
- you use FreeStyle LibreLink and you are not using alarms on your app

Find your Operating System Version

If you want to check which operating system version is running on your smartphone, follow the instructions below:

- Open your Android smartphone Settings
- Near the bottom, tap **About phone**, then **Android version**

We sincerely apologize for any inconvenience this may cause.

We have notified [local regulatory authority] and we are working to correct this issue. We will notify you when the issue has been resolved.

If you have any further questions or would like to report a device fault, please call Abbott Customer Service at [### country to insert correct CS Phone #].

Sincerely,

Abbott, Diabetes Care