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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 Health Care Professional:

We are reaching out to let you know about some important information regarding the FreeStyle LibreLink and FreeStyle Libre 3 Android apps.

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. This does not impact the ability of FreeStyle Libre 2 users to get glucose readings by scanning their 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 You and Your Patients

Please communicate the following actions if you or your patients experience extended periods of signal loss, either of the following actions should allow reconnection:

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

Configure 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 0800 170 11 77.

You or your patients will know that connection is established when the symbols (see below) no longer appear on your app.



One of the steps above will need to be repeated if an extended period of signal loss is experienced 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 a user's smartphone is too far away from their sensor. If this occurs, follow instructions as outlined in the User Manual's troubleshooting section.

This does not impact users if they:

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

Find your Operating System Version

To check which operating system version is running on a smartphone, follow the instructions below:

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

We sincerely apologise for any inconvenience this may cause.

We have notified the Medicines and Healthcare Products Regulatory Agency (MHRA), 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 your Abbott Diabetes Care sales representative or Abbott Customer Service at 0800 170 11 77.

Sincerely,

Abbott, Diabetes Care

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