

Attachment B: ADC FA1027-2020 Field Safety Notification (Users in Germany & Switzerland)
FreeStyle Libre 2 Sensor Alarm Issue + 2.4.2 App Update Messaging
For Markets: Germany, Switzerland and Austria
ADC-22785 Ver. 3.0

E-mail: FreeStyle Libre 2 + FreeStyle LibreLink Android Users in affected countries (DE & CH)

URGENT FIELD SAFETY NOTICE

Products: FreeStyle LibreLink app and FreeStyle Libre 2
Reference: ADC FA1022-2020 and ADC FA1027-2020
Communication from Manufacturer

Dear Customer:

We want to inform you about two recent situations pertaining to the FreeStyle Libre product portfolio.

1. FreeStyle LibreLink 2.4.2 App Update - (FA1022-2020)

We recently sent you an e-mail about a small number of reports that FreeStyle LibreLink (version 2.4.1) Android users were not able to share notifications with their LibreLinkUp connections or see their recent data in LibreView. We have since resolved this by releasing an update to the Android version of FreeStyle LibreLink app.

Please update FreeStyle LibreLink to the latest version (2.4.2) as soon as possible to resume sharing your glucose data and notifications with your LibreLinkUp connections or your healthcare professionals who use LibreView.

If you had chosen to uninstall the previous version of the FreeStyle LibreLink Android app (version 2.4.1) and downloaded an older version of the app (version 2.4.0), please update to the latest version (2.4.2). This will ensure you're able to continue to share data with your connections, and restore the feature to have your data viewable in LibreView from when you updated the latest version.

To check which version of the app you have, view the "About" screen in the app. Make sure you are using version 2.4.2 if you're running a minimum of Android 8.0 on your phone.

2. FreeStyle Libre 2 Sensor and Optional Glucose Alarms - (FA1027-2020)

Some users of the FreeStyle Libre 2 sensor in [COUNTRY] who choose to use the optional glucose alarm feature are not receiving alarms due to a manufacturing issue that impacted a limited number of sensor lots. We have identified and resolved this. You have been identified as someone who **has** received an impacted sensor and we will contact you directly to provide a free-of-charge replacement sensor initially. Eventually, all your impacted sensors will be replaced.

You can still scan the FreeStyle Libre 2 sensor to receive your glucose levels on your smartphone or reader. Your data continues to be uploaded to LibreView from the FreeStyle LibreLink app or can be uploaded from the FreeStyle Libre 2 reader. If you have an impacted FreeStyle Libre 2 sensor, your LibreLinkUp connections will not be receiving alarm notifications through their mobile app.

The impacted lot numbers are listed below for reference. To determine if you have an affected sensor, please compare the lot number on your FreeStyle Libre 2 packaging to the list below.

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SKU: 71988-01		
K60000166	K60000305	K60000368
K60000168	K60000307	K60000369
K60000251	K60000309	K60000371
K60000268	K60000311	K60000373
K60000282	K60000319	K60000374
K60000283	K60000326	K60000375
K60000284	K60000327	K60000376
K60000285	K60000328	K60000379
K60000293	K60000336	K60000380
K60000294	K60000337	K60000386
K60000295	K60000338	K60000387
K60000296	K60000339	K60000388
K60000297	K60000340	K60000389
K60000298	K60000342	K60000390

Thank you for your patience as we resolve these situations. We apologize for any disruptions. If you need further support, please contact FreeStyle Customer Care [insert local contact information].

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

Sincerely,
Abbott's diabetes care division