



Abbott Diabetes Care Inc
1360 South Loop Road
Alameda, CA 94502
USA

27 January 2023

To: Inga Bellahn
Head of Metabolic Disorders and Renal Systems
Benefit/Risk Evaluation II, Safety and Surveillance Group
Medicines and Healthcare Products Regulatory Agency
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Dear Inga,

We would again like to thank MHRA for the opportunities given to meet and collaborate in respect of your letter dated 24 January 2023. Abbott Diabetes Care's (ADC) response to the items are as follows:

Loss of Connection.

1. Abbott stated that an internal investigation is underway as of the previous week. Please provide us with weekly progress updates, including what has been done to investigate the issue and planned steps, **starting COB Friday 27th January**

To investigate the issue, Abbott reviewed our internal complaint data, as well as, reviewed complaints via the Google Play store. Abbott identified that customers were raising concern of an increase in signal loss alarm with their app that began to occur right around the same time that they updated their phones to Android OS 13.

A cross functional team was assembled to investigate all the FreeStyle Libre Android app products. During the investigation the issue was reproduced on LibreLink app version 2.8.2 and FreeStyle Libre 3 App 3.4.0 using phones with Android OS 13.

Issue Description

[REDACTED]

In situations where the Bluetooth link is disconnected (e.g. if the Sensor and app are separated), the system alerts the user and attempts to automatically reconnect. When the system is performing as intended, the connection is automatically re-established once the sensor

is in range of the phone, clearing the Signal Loss condition. The actual behaviour of the app when the issue occurs is that BLE connectivity between phone and sensor will not automatically re-establish and the Signal Loss condition persists.

Initial Investigation Findings

The investigation to date has shown that there are no well-defined steps to reproduce the issue, because it appears to be a timing / race condition issue at the OS level. [REDACTED]

In normal operation, the apps are designed to automatically attempt to re-establish a Bluetooth connection when there is a BLE interruption. [REDACTED]

When the issue occurs, the app is not informed by the OS when a connection attempt is unsuccessful, and so the App does not reattempt to reconnect, resulting in the observed behaviour. [REDACTED]

The investigation has confirmed that the following standard troubleshooting steps can be performed to address the issue:

- Turning the phone's BLE OFF and then ON.
- Resetting the phone's network settings.
- Force closing the app
- Power-cycling the phone

Abbott has reported the issue [REDACTED]

2. Abbott stated that the complaints are weighted towards android users of Samsung phones and indicated that an update made by Samsung resulted in compatibility issues. **Please inform us by Friday 27th January** whether this is the case

Abbott's ongoing investigation has included both Samsung and Google Pixel phones. [REDACTED]

[Redacted]

3. With regards to loss of Bluetooth connection with the phone app, we are aware of the increasing number of user complaints; this may pose a safety risk due to alarms not functioning, which can be particularly precarious for patients who may not experience significant physical symptoms following change in glucose levels. Where there is a known error in the system, it is not sufficient to rely on directions provided in the IFU but Abbott should proactively communicate with users. **Please provide us with a draft Field Safety Notice within 48 hours of receipt of this letter**, informing users of this signal and current advice to mitigate the risk arising from lack of connectivity and alarms

As discussed in our meeting of 26 January 2023, ADC has agreed to perform a Field Safety Corrective Action and issue a Field Safety Notice. Please find attached the **draft** Field Safety Notice. As discussed, the investigation is ongoing and further investigation steps will ensure that the information is as accurate and complete as possible. As agreed in our meeting we will provide weekly updates on the status of the investigation while we prepare to issue the Notice, ensuring that MHRA agree on the status of the investigation and ADC have all the information to issue the letter to our customers.

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ADC would like to thank MHRA for their continued partnership and share your commitment to make sure our customers receive the highest quality product to get the best lives.

Kind Regards,

Abbott, Diabetes Care