



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

10 February 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  
10 South Colonnade, Canary Wharf, London, E14 4PU  
inga.bellahn@mhra.gov.uk

Dear Inga,

We provide Abbott's responses to items raised in the MHRA letter of 24 January 2023.  
We again thank MHRA for the opportunities given to meet and collaborate in this respect:

### **Loss of Connection**

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, 27<sup>th</sup> January**

Consistent with the update provided through the Initial FSCA report [REDACTED] Abbott has provided the investigation below for your convenience. Future updates will be provided through follow-up FSCA reports. If MHRA would like to discuss any of the content of the Initial or follow-up reports, ADC are happy to have a call at MHRAs convenience.

### **Background**

[REDACTED]  
[REDACTED]  
[REDACTED] The applications experience intermittent Signal Loss when used with the Android 13 OS. As a result, the app user may not receive glucose results and / or glucose alarms are not presented. In conversations with MHRA, it was advised that a Field Safety Corrective Action (FSCA) should be issued in order to notify the field of this defect.

**Investigation Update:**

[REDACTED]

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

[REDACTED]

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

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

[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]

[REDACTED]

[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 and reopening the app
- Power-cycling the phone

Abbott has reported the issue [REDACTED]

[REDACTED]

In January 2023, Google released a new Android 13 operating system software update compatible with Google Pixel phones. As per Google communications (<https://support.google.com/pixelphone/thread/195623748/google-pixel-update-january-2023?hl=en>) a reason for the OS software update was “Fix for issue occasionally preventing certain Bluetooth Low Energy devices or accessories from pairing or reconnecting”.

[REDACTED]

[REDACTED]

[REDACTED]

[REDACTED]

**Corrective/Preventive Action**

1. Corrective and / or Preventive Actions will be managed through [REDACTED]
2. Risk Evaluation, [REDACTED], which was initiated on 31-Jan-2023 to address the risk to the user as a result of this issue, is currently in process.
3. User notification will be sent via email or postal mail as a Field Safety Notification (FSN) to impacted Users of the FreeStyle LibreLink and FreeStyle Libre 3 Mobile Applications.
4. The FSN will be posted as a referenced link in the Google Play Store
5. Quality Directive, [REDACTED] and FAQs were issued to the field on 08-Feb-2023 to advise Customer Support of [REDACTED] and how to handle customer calls related to the issue

[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]  
[REDACTED]  
[REDACTED]

[REDACTED]  
[REDACTED]

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

Kind Regards,

Abbott, Diabetes Care