



Abbott Diabetes Care Inc.
1360 South Loop Road
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USA

30 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
10 South Colonnade, Canary Wharf,
London, E14 4PU
inga.bellahn@mhra.gov.uk

Dear Inga,

We thank you for the meeting today to further collaborate in this respect.

Further to our response of 27 January 2023, we provide ADC's responses to further 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

1. We acknowledge receipt of your email today in which you note the following:
 - a. As part of the connectivity, Field Safety Notice, the focus is currently on the non-functioning alarms; however, the lack of transfer of glucose readings should be more highlighted and the resulting need to use the phone as a scanner.
 - b. In the first paragraph it states that "... and FreeStyle Libre 3 users will not receive real time glucose results", but this applies to FreeStyle Libre users, too. In both cases the phone app can be used to scan the sensor, which would also be important to point out. I suggest removing the 4th bullet point, as FreeStyle Libre users are affected by the lack of data transfer. Using the phone to scan is a remedy to this situation, especially as there is a recommendation to keep the signal loss alarm enabled.

We note your comments and will review with a view to addressing within the draft Field Safety Notice.

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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 live their best lives.

Kind Regards,
Abbott Diabetes Care