



Date: 08-April-2025

Important Safety Notice

Affected Product

This notice is applicable to the Glooko Web Application, UDI 00855093008026, under the manufacturer Glooko Inc, SRN US-MF-000023483.

Description of the Problem

Glooko imports data from diabetes devices and displays the data according to the settings on the device. If the time settings on the diabetes device differ from the actual time (for example, due to an erroneous time setting on the diabetes device or during travel through time zones), the data will be displayed using the device time setting. This could potentially mean that the retrospective data displayed on Glooko is shown with a time offset.

Users may be unaware of the time difference at the time of their diabetes data upload to Glooko. No adverse health consequences is the most likely scenario in all cases, but there is a remote possibility for the need to adjust insulin doses.

Actions to be Taken by the User

In order to avoid this behavior, users are urged to ensure that the time setting on their personal diabetes device corresponds to the local time so it displays correctly on the Glooko Web Application.

Actions Taken by Manufacturer

Glooko is unable to modify the patient diabetes data to the correct time without violating data integrity standards. Therefore, to prevent recurrence of time differences, Glooko is updating the current Instructions for Use with a Warning to users on the existence of this problem and how to correct it. The updated IFU may be reviewed [here](#). Additional information and FAQ may be viewed [here](#).

Additionally, please complete the attached Customer Reply Form and email the completed form to regulatory-org@glooko.com.

Contact

Should you have any further questions regarding this matter, please contact support at <https://support.glooko.com> or by email at help@glooko.com.

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