

Important safety notice for mylife App users

Dear mylife App user,

We would like to inform you of a software defect in the mylife App that might have an impact on patient safety. The following notice is sent out on behalf of SINOVO health solutions GmbH (legal manufacturer of the product). Please find information about Customer Care contact details at the bottom of this notice in case that you have questions.

Summary

In rare cases, the discovered software defect prevents delivered boluses from being correctly saved in the mylife App logbook, resulting in the incorrect display and use of "Insulin on Board" for bolus calculations. A workaround exists and the root cause has been identified. We aim to publish a hotfix in the second half of October 2024.

Affected users

The identified defect impacts all users of the mylife App who use a mylife YpsoPump, synchronise their data with the mylife Cloud and use the app's bolus calculator to calculate (and deliver) bolus insulin.

Please note: Users in pen mode (MDI therapy) are not affected by this issue.

Affected app installations

The identified defect affects all app versions from v2.1.1 upwards:

Android:

- v2.4.0 (UDI 111652811196.V2.4.0)
- v2.3.1 (UDI 111652811196.V2.3.1)
- v2.3.0 (UDI 111652811196.V2.3.0)
- v2.2.0 (UDI 111652811196.V2.2.0)
- v2.1.2 (UDI 111652811196.V2.1.2)
- v2.1.1 (UDI 111652811196.V2.1.1)

iOS:

- v2.4.0 (UDI 111784431122.V2.4.0)
- v2.3.1 (UDI 111784431122.V2.3.1)
- v2.3.0 (UDI 111784431122.V2.3.0)
- v2.2.0 (UDI 111784431122.V2.2.0)
- v2.1.1 (UDI 111784431122.V2.1.1)

Description of the safety-relevant defect

In rare cases, when a bolus is being delivered and, concurrently, the mylife App is automatically synchronising with the mylife Cloud, the bolus might not be permanently saved in the mylife App logbook. In the synchronisation between both processes there is a short time window where saving and synchronising may overlap, leading to an automatic and unintended removal of the delivered bolus from the app's logbook.

The missing bolus in the mylife App logbook causes the "Insulin on Board" in the app to be lower than it actually is in your body. This may lead to a heightened risk of hypoglycaemia (low blood glucose) due to an incorrect calculation and dosing of subsequent boluses.

How can you recognise this defect?

The mylife App main screen displays an incorrect amount of “Insulin on Board” and might display incorrect last bolus information.

You can check whether the mylife App logbook has correctly saved the delivered bolus by comparing the boluses recorded in the mylife YpsoPump logbook with the boluses recorded in the mylife App logbook.

How should you react in this situation?

As a preventative measure we recommend all mylife App users to temporarily disable the automatic cloud synchronisation until the software hotfix will have been published.

1. Go to Settings – Personal data
2. Sign out
3. Sign in again
4. Switch off the “Keep me logged in” option

Use the manual cloud synchronisation once a day to synchronise your data with the mylife Cloud. To manually synchronise your data tap the “Synchronise” button for the mylife Cloud in the lower section of the “Last Values screen”.

Countermeasures and next steps

We have identified the faulty code section related to this defect. We are working with full focus on the correction of it. The update of the corrected mylife App is targeted for release in the Google PlayStore and in the Apple App Store in the second half of October 2024. Once the new app release is available, you will receive a notification in the app to update your current installation.

Perform the update of your mylife App immediately when you are notified.

Customer Care contact details

If you have any questions regarding this notice, do not hesitate to contact your [local Ypsomed / mylife Diabetescare representative](#).

We apologise for any inconvenience that this might cause you.

Yours sincerely

SINOVO health solutions GmbH