

15.02.2023

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 in coordination with responsible health authorities and on behalf of SINOVO health solutions GmbH (legal manufacturer of the product) and Ypsomed AG (distributor of the product).

Affected users

The identified defect concerns persons with diabetes who use the mylife App as follows. The conditions are cumulative.

- Users on pump therapy (CSII), using a mylife YpsoPump with software version V05.000.XX and higher
- Users with a mylife Cloud account who use the automatic synchronisation of the mylife App with their cloud account

Affected app installations

The affected installations of the mylife App are limited as follows:

- mylife App versions **2.0.1, 2.0.2 and 2.1.0** (check the installed version of the app in the About menu)
- Installations on **iOS** (UDI: 111784431122.V2.0.1 // 111784431122.V2.0.2 // 111784431122.V2.1.0)
- Installations on **Android** (UDI: 111652811196V2.0.1 // 111652811196V2.0.2 // 111652811196V2.1.0)

Description of the safety-relevant defect

If a running bolus on the mylife YpsoPump is ending and communicated to the app at the same time as the app attempts to synchronise with your mylife Cloud account, it is possible in rare instances that the mylife App fails to log the finished bolus.

Consequently, the calculated insulin on board in the mylife App will be too low. With subsequent insulin deliveries, this might lead to an increased risk of hypoglycemia.

How can you recognise this situation?

On the mylife App itself, there is no simple way to recognise the situation at a glance. You may become aware that a recently delivered bolus is not shown on the home screen or in the logbook or that the insulin on board seems too low. However, the app does not indicate this situation.

How should you react in this situation?

There is a workaround to prevent the issue from happening:

1. In your mylife App, go to Settings à Personal Data.
2. Tap "Sign out".
3. Then tap "Sign in" to log in to your mylife Cloud again. **Important: do not** select "Keep me logged in".
4. Until the bug fix release is available, perform the synchronisation manually once a day by tapping the cloud sync button on the home screen.

Furthermore, if you are unsure about your insulin on board, you can check your last bolus delivery in the bolus history on your mylife Ypsomed Pump. To do this:

1. Press the function button on your pump.
2. Swipe left and unlock the screen.
3. Then swipe right on the status screen.
4. Now you can see your last bolus. Compare it with the last bolus in the logbook of the app.

Countermeasures and next steps

We are working with full focus on the correction of this software defect. The update of the corrected mylife App is targeted for release in the Google Play Store and in the Apple App Store until approx. mid of March 2023.

Once the new app release is available, you will receive a notification in the app to update your current installation. Perform the update immediately when you are notified.

Contact details

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

Australia

Ypsomed Australia PTY Limited // 602/20 Bungan St //
Mona Vale NSW 2103 //
info@mylife-diabetescare.com.au // www.mylife-diabetescare.com.au //
Customer Care Free Call: 1800 447 042

Ireland

Ypsomed Ltd. // 1 Park Court // Riccall Road // Escrick //
(Republic of) North Yorkshire // YO19 6ED // United Kingdom //
info@ypsomed.co.uk // www.mylife-diabetescare.co.uk //
Customer Care: 1800 911 522
(Calls to this number are free of charge from mobile phones
and landlines, plus your phone company's access charge.)

New Zealand

Pharmaco (N.Z.) Ltd // 4 Fisher Crescent, Mt Wellington //
Auckland 1060 // support@pharmacodiabetes.co.nz //
www.PharmacoDiabetes.co.nz //
Customer Care: 0800 GLUCOSE (0800 45 82 67)

United Kindom

Ypsomed Ltd. // 1 Park Court // Riccall Road // Escrick //
Kingdom North Yorkshire // YO19 6ED // info@ypsomed.co.uk //
www.mylife-diabetescare.co.uk // Customer Care: 0344 856 7820
(Calls to this number are free of charge from mobile phones
and landlines, plus your phone company's access charge.)

We apologise for any inconvenience that this might cause you.

Yours sincerely

SINOVO health solutions GmbH / Ypsomed AG