



Australian Government

Department of Health and Aged Care
Therapeutic Goods Administration

URGENT PRODUCT DEFECT CORRECTION*

LEVEL: Consumer

CLASS: Class II

REFERENCE: RC-2023-RN-00217-1

DATE AGREED: 17/03/2023

PRODUCT: **MyLife App**

Software versions 2.0.1, 2.0.2 and 2.1.0

ARTG 296368

(Ypsomed Australia Pty Ltd - Diabetes patient management software)

SPONSOR: Ypsomed Australia Pty Ltd

CONTACT INFORMATION: 1800 447 042 - info@ypsomed.com.au - Customer Care

REASON: Users have reported that a recently delivered bolus is not displayed on the Last Value page and is also not displayed in the logbook of the mylife app.

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 the mylife Cloud account, it is possible 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 hypoglycaemia.

PROPOSED CUSTOMER ACTIONS:

Customers are advised to institute the following workaround while awaiting the software update:

1. In the mylife App, go to Settings - Personal Data.
2. Tap "Sign out".
3. Then tap "Sign in" to log in to their 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. The software update is expected mid-March 2023.

To check the last bolus delivery in the history of the mylife YpsoPump follow these instructions:

1. Press the function button on the pump.
2. Swipe left and unlock the screen.

3. Then swipe right on the status screen.
4. Now the last bolus is visible. Compare it with the last bolus in the logbook of the app.

The sponsor is expected to dispatch letters to all affected customers within two working days of the agreed date. **Please do not contact the sponsor for further information unless you believe that you have the goods under recall and have not received a recall letter.**

Product Distribution: 43 affected Australian individuals

Product export status:

This issue was first identified by the Sponsor

This information has been published in the TGA's searchable database, the System for Australian Recall Actions (SARA) –

<https://apps.tga.gov.au/Prod/sara/arn-detail.aspx?k=RC-2023-RN-00217-1>

*For further details about Recall Actions, please refer to <http://tga.gov.au/safety/recalls-about.htm>