



CamDiab Ltd
Level 4, Institute of Metabolic Science
Box 289, Addenbrooke's Hospital
Cambridge, CB2 0QQ, UK
Tel: +44 20 3695 3780
support@camdiab.com
www.camdiab.com

Urgent FIELD SAFETY NOTICE | mylife CamAPS FX
Advice from manufacturer
CamDiab reference: ET4339

4 October 2022

Dear mylife CamAPS FX user,

You are receiving this letter because our records indicate that you are using mylife CamAPS FX app that is subject to an ongoing Field Safety Notice. This notice affects mylife CamAPS FX app version 1.4 (153) and all previous versions.

Issue Description:

A software error has been identified in the mylife CamAPS FX app version 1.4(153) and earlier versions when a standard bolus is initiated from the app. **This error is rare but may lead to repeated delivery of standard insulin bolus when initiated from the app.** One instance of such error was reported to us to date. On review, this error was attributable to a particular unanticipated sequence of events; the mylife CamAPS FX app did not fully consider all scenarios when processing information from the pump following standard bolus initiation and possible failure modes when communicating with the pump.

We stress that there was no issue with mylife YpsoPump.

What you should do:

The following guidelines should be followed:

1. Update to the new mylife CamAPS FX version **1.4(154) which is available on Google Play**; the updated version is free from this error.
2. If using earlier mylife CamAPS FX versions **do not instruct bolus delivery on the mylife CamAPS FX app**
 - a. You can still use bolus calculator on mylife CamAPS FX app to calculate the bolus amount
 - b. You can bolus directly from your mylife YpsoPump
 - c. You can continue using "Auto mode"; this functionality is not affected by the error.
3. mylife CamAPS FX version 1.4(153) and all earlier versions will be discontinued on 7 October 2022.

At CamDiab, safety is our top priority. We are committed to delivering safe and effective closed-loop insulin delivery.

We appreciate your time and attention in reading this important notification. If you have further questions or need assistance, please contact Ypsomed customer support. Ypsomed helpline numbers can be found at [Customer Care & Helpline - mylife Diabetescare – International \(mylife-diabetescare.com\)](https://www.ypsomed.com/customer-care).

The undersigned confirms that this notice has been provided to the appropriate Regulatory Agency.

Sincerely,

CamDiab Quality Team