



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

FIELD SAFETY NOTICE | mylife CamAPS FX
Advice from manufacturer
CamDiab reference: ET4929-mylife-HCP

15th August 2023

Dear Healthcare Professional,

The purpose of this letter is to make you aware that we are notifying users of the mylife CamAPS FX about an ongoing Field Safety Notice. This notice affects users of mylife CamAPS FX app version 1.4(172) and all previous versions.

Issue Description:

The mylife CamAPS FX application constantly reviews and adjusts a user's total daily dose of insulin used for automated insulin delivery calculations. The user's entry of total daily dose at re-initialisation of mylife CamAPS FX is therefore, gradually adjusted and corrected as required. This means, any over estimation of total daily dose by the user will be corrected within 3 to 4 days. Until this point, if a largely over estimated total daily dose was entered by the user incorrectly, there is a risk of over delivery of insulin during automode. This risk is the highest on the first day and reduces gradually over subsequent days.

The mylife CamAPS FX calculated total daily dose of insulin is stored daily on the CamAPS service cloud as long as the phone is connected to the internet.

While there are already safety checks in place, where the user is asked to confirm the total daily dose entered and the mylife CamAPS FX automatically adjusts the total daily dose as required, we have taken the additional step to limit the total daily dose entry on re-initialisation. The decision to implement this additional mitigation was made following an incident that took place in Germany, where a largely over-estimated total daily dose was entered by the user at re-initialisation of the mylife CamAPS FX application.

Potential Harm:

Large overestimation of total daily dose of insulin at re-initialisation of the mylife CamAPS FX application, can lead to over delivery of insulin and potential hypoglycaemia during Auto mode. This risk is the highest on the first day and reduces gradually over subsequent days.

What you should do?

The following guidelines should be followed:

1. Check the version of the mylife CamAPS FX Application the user is running (App main menu>About>(UI)1.4(xxx))
If the user is on version 1.4(173) or above, no action is required.
2. For users on version 1.4(172) or earlier, please update to the new mylife CamAPS FX version **1.4(173) which is available on Google Play**; the updated version includes this additional safety measure.
3. All earlier versions will be discontinued on 31st October 2023.

At CamDiab, safety is our top priority. We are committed to delivering safe and effective closed-loop insulin delivery. We stress that there was no issue with mylife Ypsopump.

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 <https://www.mylife-diabetescare.com/en/services/customer-care-contact.html>.

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

Yours sincerely

CamDiab Quality Team