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Urgent FIELD SAFETY NOTICE | CamAPS FX
Advice from manufacturer
CamDiab reference: ET5604-User

6th November 2023

Dear CamAPS FX User,

You are receiving this letter because our records indicate that you are using CamAPS FX app that is subject to an ongoing Field Safety Notice. This notice affects CamAPS FX app version 1.4 (174) and all previous versions.

Issue Description:

A software error has been identified in the CamAPS FX app version 1.4(174) and earlier versions, where the countdown to bolus delivery was initiated twice. **This error is extremely rare but may lead to repeated delivery of a standard insulin bolus when initiated from the app.** One instance of this error was reported to us to date. On review, the issue was caused by unexpected function of the Operating system, which reinitiated the countdown to the bolus being launched. Protection against repeated countdown at the start of a bolus was already in place in the present CamAPS FX version, but it did not account for this specific scenario, where a countdown is initiated within a narrow (1 second) time window, after the completion of the first countdown.

In order address this error, we have updated the software by incorporating protections to prevent countdown to the bolus being launched more than once in all circumstances. We have also added an additional robust control measure, preventing the delivery of a bolus within 1 minute of the previous bolus. This will prevent the issue recurring whilst also not restricting users from initiating boluses in a timely fashion required for effective management of diabetes. **These software changes have been added to App version 1.4(175).**

We stress that there was no issue with Dana insulin pump.

Potential Harm:

The delivery of a double bolus can lead to over delivery of insulin and potential hypoglycaemia.

What You Should Do:

1. Check the version of the CamAPS FX Application you are running (App main menu>About>(UI)1.4(xxx))
If you are already on version 1.4(175) or above, no action is required.
2. For users on version 1.4(173) or 1.4(174) please update to the new CamAPS FX version **1.4(175) which is available on Amazon App store**; the updated version includes this additional safety measure.
3. All earlier versions will be discontinued on 15th December 2023.

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 CamDiab customer support: support@camdiab.com

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

Sincerely,

CamDiab Quality Team