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Urgent FIELD SAFETY NOTICE | CamAPS FX
Advice from manufacturer
CamDiab reference: ET8374-Dana-user

28 October 2025

Dear CamAPS FX User,

Our records indicate that you are using CamAPS FX app, which is subject to a Field Safety Notice. This notice affects CamAPS FX app version 1.4(189) and all previous versions.

Issue Description:

The current CamAPS FX Instructions for Use (IFU) does not provide adequate clarity on smart device and operating system (OS) compatibility.

To address this, the “**Compatible Smart Devices and Operating Systems**” section of “*Supported Devices*”, found in Chapter 11 of the IFU has been updated to direct users to the most up-to-date compatibility information on our website and make it clear that **both** the smart device and operating system need to be compatible with CamAPS FX and the linked continuous glucose monitor.

Potential Harm:

No harm is anticipated. If an unsupported device or OS is used, users may experience app unavailability or reduced responsiveness.

In such circumstances, the system is designed to revert to its safety default: delivering the pre-set pump basal rate.

What You Should Do:

1. Please access the updated IFU “**CamAPS FX user manual**” dated 10th October 2025 via the Help menu within the CamAPS FX app
2. Review the “**Compatible Smart Devices and Operating Systems**” section of “*Supported Devices*”, found in Chapter 11 of IFU, for information on smart device and OS compatibility.

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 Advanced Therapeutics UK customer support via www.advancedtherapeutics.org.uk/contact/

We confirm that this Field Safety Notice has been communicated to the appropriate Regulatory Authority in accordance with applicable medical device regulations.

Sincerely,

CamDiab Quality Team