CamAPS FX

User Manual

1   IMPORTANT SAFETY INFORMATION

Indications for use

CamAPS FX is a mobile app intended for managing glucose levels in people with type 1 diabetes including type 1 diabetes pregnancy, aged 2 years and over, using a hybrid closed loop approach (automated basal insulin delivery with manual bolusing for meals).

CamAPS FX requires an android smartphone, and insulin pump and a continuous glucose monitor (CGM) to fulfil its intended use. CamAPS FX is compatible with mylife YpsoPump (Ypsomed, Switzerland) and Dexcom G6 (Dexcom, USA).

CamAPS FX should only be used during pregnancy if the linked CGM Canadian labelling is explicitly labelled for use in pregnant women. Refer to the compatible CGM labelling to determine if the CGM can be used during pregnancy.

CamAPS FX is indicated for use with NovoRapid U-100, HumaLog U-100, and Fiasp U-100 (age 2 years and over), and Lyumjev U-100 (age 18 and over).

CamAPS FX is indicated in individuals who require a total daily insulin dose greater than or equal to 5 U/day (or as further limited by linked insulin pump) and minimum body weight of 10kg. Refer to the connected insulin pump user guide for pump compatible insulins and infusion sets.

CamAPS FX is for prescription use only.

Contraindications

- CamAPS FX should not be used by anyone who is unable to notice alerts, alarms and reminders because of physical limitations.

- CamAPS FX should not be used by anyone that is unable to monitor glucose as recommended by their health care provider.

- CamAPS FX should not be used by anyone who is unable to maintain contact with their health care provider.

- CamAPS FX should not be used by anyone who is unwilling or unable to follow the instructions for use and intended uses of compatible insulin pumps and continuous glucose monitor devices.

Warnings

- Please review the product instructions before using the CamAPS FX app. The instructions contain important information on the performance characteristics of the app.

- Parents/guardians of young children utilizing the CamAPS FX app are advised to become familiar with the operation of the app and ensure the status of the system is regularly reviewed.

- Failure to use the CamAPS FX app and the required devices according to the instructions for use and all indications, contraindications, warnings, precautions and cautions may result in hypoglycemia (low blood glucose) or hyperglycemia (high blood glucose) occurrence.

- Before you decide to stop using the CamAPS FX app, it is important that you consult your health care professional who may review your insulin pump settings.

1 Important safety information

- Before utilizing continuous glucose monitoring readings to inform the bolus calculator and administer bolus insulin, please consult the user manual of the connected continuous glucose monitoring device for guidance on the appropriateness of utilizing continuous glucose monitoring readings for treatment decisions.

- Do not use the CamAPS FX app if sensor glucose reading is unreliable especially when the sensor is over-reading. If your sensor reading does not match your symptoms or expectations, use a capillary blood glucose value to assess the sensor accuracy and to calibrate the sensor, as appropriate. Sensor over-reading could result in over delivery of insulin, which may lead to hypoglycemia.

- Avoid administering insulin, such as by injection or inhalation, while wearing an insulin pump, as this could result in hypoglycemia. The CamAPS FX app cannot track insulin that is administered outside of the system. Consult your health care provider about how long to wait after manually administering insulin before you start "Auto mode".

- Do not use the CamAPS FX app if you are receiving renal dialysis or intensive care treatment. The CamAPS FX has not been evaluated in these populations and its safety and efficacy has not been confirmed.

- Prior to using "Auto mode", ensure that the glucose sensor is calibrated in accordance with the manufacturer recommended calibration procedure.

- Automatic updates of the app or your device's operating system can change settings or shut down the app without warning and possibly overnight. It is recommended to update your App and your operating system manually as recommended by the developers, at a time when you can verify correct device settings afterward. Otherwise, your device may reset and your app may cease functioning at a time when you are unaware of the situation and may be relying on the app to maintain your blood levels without your intervention.

1 Important safety information

- CamAPS FX account holders are advised to create strong passwords and to change their password at regular (3 month) intervals.

- Do not share your CamAPS FX account login details with anyone, except your close carer/guardian as appropriate, as a safety precaution and to prevent misuse of your data.

- You should exclude the CamAPS FX app from "Private space" on your smart device to allow it to operate continuously in the background.

- The CamAPS FX app shall not function on a host device that has a non-supported operating system, or a phone modified for root access. For a list of smart devices and operating systems compatible with CamAPS FX see the "System Specifications" section of this User Manual.

- Do not use the CamAPS FX app on a mobile device where you are sideloading (installation via means other than the Google Play™ store) other applications as these may introduce vulnerabilities or malware to your mobile device and possibly disrupt the functioning of the CamAPS FX app which could lead to harm.

- Refrain from installing and using software keyboards developed by unknown entities. The usage of such keyboards may not be compliant with the management of patient information and can lead to inadvertent disclosure of sensitive information.

- You are responsible for securing your smart device and using it safely. If you suspect a cybersecurity incident involving CamAPS FX, contact customer support.

- Although the CamAPS FX app is a medical device, the smart device on which it is hosted is not, and as such is not built to the same electrical safety standards as a medical device.

1 Important safety information

- Ensure display settings of your smart device, such as brightness or screen resolution, are appropriate for the level of ambient light and quality of your sight. Adjust display settings accordingly.

- If the display or the audio of the smart device malfunctions to the extent that you are unable to determine status of the CamAPS FX app or hear the alerts, or your smart device is damaged, it is advised not to use the app until device is repaired and performance verified. If it is not possible to deactivate the CamAPS FX app, turn-off the phone and revert to manual control of pump.

- It is advised not to silence alerts on the smart device during use of the CamAPS FX app, unless essential.

- To use CamAPS FX in "Auto mode" during a flight, switch to "flight mode" then turn Bluetooth on. Follow any additional advice related to the connected devices. Contact your airline for their policy.

- When using the CamAPS FX app for glucose control, it is very important that users comply with national driving standards and recommendations to avoid hypoglycemia when driving.

Note: Any serious incident that has occurred in relation to CamAPS FX should be reported to CamDiab or CamDiab Distributor, and to the relevant authority in the country of residence.

Precautions

- In general, sensor accuracy is less studied in infants, pregnant women and therefore greater caution may be required in these user groups.

- Taking medication containing acetaminophen may falsely raise Dexcom G6 sensor readings and could result in over delivery of insulin by CamAPS FX. The level of inaccuracy may be different depending on the person. When taking acetaminophen containing medication users are advised to turn off "Auto mode".

- Hydroxyurea is a medication used in treatment of diseases including cancer and sickle cell anemia. It is known to interfere with glucose readings of Dexcom G6 sensor. The use of hydroxyurea will result in sensor glucose readings that are higher than actual glucose, which could lead to over delivery of insulin by CamAPS FX. When taking hydroxyurea, users are advised to turn off "Auto mode".

- When using the CamAPS FX app it is important that all boluses and meals are recorded within system, as to ensure these are taken into consideration by the Control Algorithm. Failure to record all meal/boluses could result in under/over delivery of insulin during "Auto mode".

- Users are advised to set correct time on the smart device hosting CamAPS FX app. All graphs displayed on the CamAPS FX app shall display all activity using the time of occurrence on the smart device hosting the app.

- Ensure your smart device is locked using a PIN or a more secure method such as a password or your fingerprint. Without a secure lock, you will not be able to use the bolus calculator.

- Ensure that the insulin pump and CamAPS FX bolus settings are correctly configured by a health care professional prior to using with the CamAPS FX app.

1 Important safety information

- When using/charging your smart device that hosts an active CamAPS FX app, good housekeeping is advised to mitigate against trip hazards from trailing cables. The smart device should also be easily accessible to the user during the night and positioned to avoid accidental user-initiated input.

Note: Any serious incident that has occurred in relation to CamAPS FX should be reported to CamDiab or CamDiab Distributor, and to the relevant authority in the country of residence.

2   GETTING ACQUAINTED

Definitions

Term	Meaning
Android	Operating system used in smart devices
App or Application	Software installed on a smart or mobile device
Auto mode	Mode of operation where insulin infusion is modulated by Control Algorithm; consists of repeated closed loop cycles
Basal (insulin) profile	A sequence of basal insulin rates over 24 hours pre-programmed on an insulin pump
Basal (insulin) rate	The insulin infusion rate pre-programmed to be delivered by insulin pump at a given time
Bluetooth	A technology that allows devices to communicate wirelessly with each other
Boost	Mode of operation when an increase in insulin needs is assumed
CamAPS	Cambridge Artificial Pancreas System
CGM	Continuous Glucose Monitor
Closed Loop (CL)	Mode of operation where the insulin infusion is modulated by Control Algorithm; consists of repeated closed loop cycles; also known as "Auto mode"
Closed loop cycle (CLC)	A periodically repeated sequence of events comprising: (i) running the Control Algorithm and (ii) initiating the recommended insulin delivery on the insulin pump
Confirmatory message	A message that is displayed on the smart device to confirm execution of a desired command
Control algorithm (CA)	Software running on the smart device calculating insulin delivery
Default	A manufacturer's preset option for a device setting
Ease-off	Mode of operation when a reduction in insulin needs is assumed

Hybrid closed loop	An approach where closed loop modulates basal insulin and the user is required to bolus for meals manually
Open loop (OL)	Mode of operation where insulin infusion is delivered at a pre-programmed basal rate or temporary rate set by the user
Temporary basal rate	Insulin infusion rate of limited duration overriding pre-programmed basal rate
Terminating condition	Condition which causes "Auto mode" to turn off
Total daily dose (TDD)	Insulin amounts administered from 00:00 to 24:00 over a given day
Warning message	A message that is displayed on a smart device when a potential problem is detected

Resources

Guides

This User Manual gives you the most comprehensive overview of the CamAPS FX app, covering the features, important safety information and more. You can view the manual from inside the app by tapping **Main Menu > Help > User Manual**.

Printed copy of the IFU can be requested by contacting CamDiab representative or distributor.

In-App Help

You will find an information icon in the top right corner of many of the CamAPS FX screens. Tapping on the icon brings up a pop-up window with additional information related to the screen. Frequently asked questions are accessible by tapping **Main Menu > Help > Frequently Asked Questions**.

Introduction to closed loop

A healthy pancreas releases insulin according to the body's needs. As a result a normal, narrow range of blood glucose is maintained. In type 1 diabetes this function of the pancreas is lost, leading to the need to inject insulin to control blood glucose. By inserting a very thin catheter under the skin we can mimic the action of the pancreas by using an insulin pump to infuse the correct dosage of insulin for the body's needs. A continuous glucose sensor, also known as continuous glucose monitor (CGM), measures glucose in the subcutaneous tissue allowing the calculation and delivery of insulin required in a continuous and uninterrupted fashion.

The continuous glucose sensor and the insulin pump are two of the three necessary components of a closed loop system also known as an artificial pancreas. The remaining component is a computer or a smart device running a closed loop algorithm that calculates the insulin dose based on the glucose sensor readings. Those three interlinked components form what we call a "closed loop" (see Figure 1).
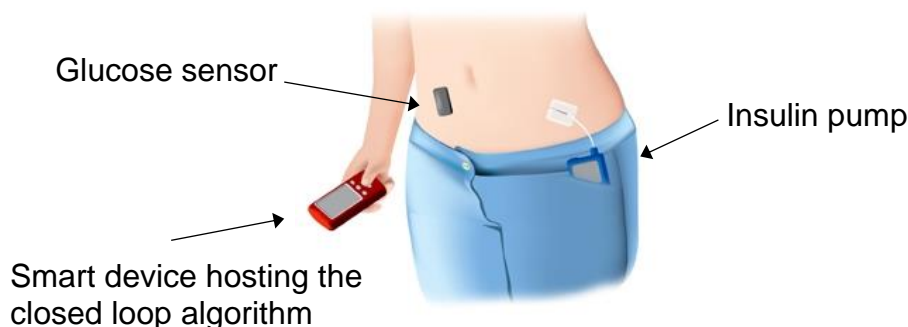

Figure 1. The components of a closed loop system

What is CamAPS FX?

CamAPS FX is an app that runs on an android smart device. The app is designed to work with a pre-defined selection of commercially available insulin pumps and continuous glucose monitors. Please refer to Appendix A for the list of supported pumps and for pump specific information; refer to Appendix B for the list supported CGM devices and for CGM specific information.

The app also allows data upload to the cloud for data visualisation and remote monitoring. See Figure 2 for an example configuration of a closed loop system with CamAPS FX app.
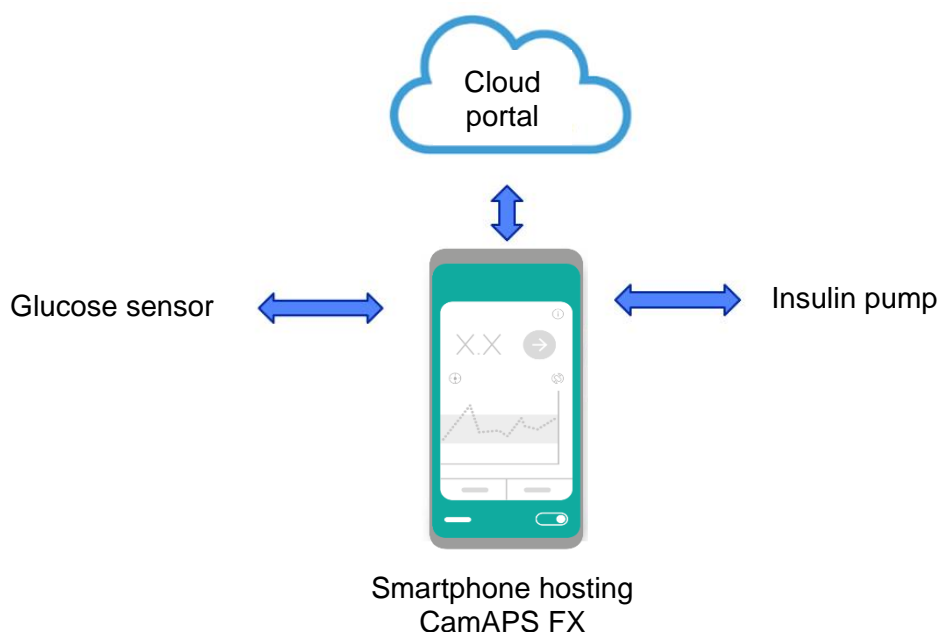
Figure 2. Example configuration of the closed loop system with the CamAPS FX app residing on a smartphone.

For a list of smart devices and operating systems compatible with CamAPS FX see the "System Specifications" section of this User Manual.

Modes of operation

The CamAPS FX app operates in one of the following modes:

"Auto mode Off" (open loop)

"Auto mode Off" is the mode of operation most familiar to current pump users. In this mode of operation, the pump operates at the pre-programmed basal profile, or as instructed by the user. The communication with the CGM is maintained and the sensor glucose information is displayed.

"Auto mode Off" is the default mode of operation on system start-up.

"Auto mode On" (closed loop)

"Auto mode" or closed loop mode is a mode of operation where insulin delivery is directed by the app replacing pre-programmed basal insulin delivery.

This mode applies when connectivity with the insulin pump is maintained and when regularly receiving CGM data. "Auto mode On" remains operational for up to 70 minutes in the absence of CGM data due to the control algorithm's ability to continue direct insulin delivery based on predicted glucose values.

"Auto mode Attempting"

"Auto mode Attempting" is a mode of operation when the app is attempting to enter "Auto mode" but a condition is preventing it from doing so. The reasons leading to "Attempting" "Auto mode" include:

- Sensor glucose data unavailable (includes sensor warmup)
- Loss of communication with insulin pump
- Pump insulin delivery suspended
- Bluetooth turned off (pump or smartphone)

The "Attempting" mode continues until the condition preventing the start of "Auto mode" is resolved. When in "Attempting" mode, insulin infusion will revert to the pre-programmed basal rate after approximately 30 minutes.

Note: Information on the condition preventing "Auto mode" operation can be found by tapping the "I" icon in the bottom left corner of the screen.

Once "Auto mode On" is activated by the user, the system will stay in this mode until the user deactivates it.

"Fail safe" mode

In the event of an unrecoverable error, loss of connection between your smart device and the pump, or your smart device powering off, your insulin pump will revert to the pre-programmed basal profile within 30 minutes. During this 30-minute period, your insulin pump will be delivering control algorithm-directed insulin delivery rate.

CamAPS FX availability, installation and updates

The CamAPS FX app is available to download from Google Play™ store. Follow the portal installation procedure and verify that the installation was successful. Once the app is installed, please check the online portal for updates at regular intervals and update the app when an update becomes available.

You are advised to turn off "Auto mode" prior to an update and to re-start "Auto mode" after the update completed.

3   YOUR CamAPS FX ACCOUNT

When running the app the first time, you will need to create a CamAPS FX account by providing an email address and setting up a password. You can also use an existing CamAPS FX account if you already have one.

4   SCOPE OF THE USER MANUAL

This user manual relates to the set up and operation of the CamAPS FX app **ONLY**. Please refer to the manufacturers' documentation for all issues relating to:

- Insulin pump
- CGM transmitter
- CGM receiver (optional)
- Cloud data upload system
- Smart device

5   GETTING STARTED

In this section you will learn how to:

- Setup your CamAPS FX account
- Complete in-app training
- Link your insulin pump and your continuous glucose monitor (CGM)
- Start a new sensor

Setting up your CamAPS FX Account

Open the CamAPS FX app, you will see the login screen. If you already have a CamAPS FX account, simply login with your credentials. A verification code will be sent to the account email address. Check your email and enter the verification code into the verification code field of the login screen.

If you do not have an account, tap on the "Sign up" button at the bottom of the screen to register. You must give a valid email address; a confirmation code will be sent to this address. Enter the code to confirm your account.

Do not share your CamAPS FX account login details with anyone to prevent misuse of your data. Report any cybersecurity incidents to CamDiab customer support.

Note: To log out of your CamAPS FX account go to the *Account* in the app Menu. Please be aware that logging out will permanently remove all app data from your smart device. You will need to log in again to continue using the app.

Note: You will be automatically logged out of your CamAPS FX account, if you do not use the CamAPS FX app for 90 days.
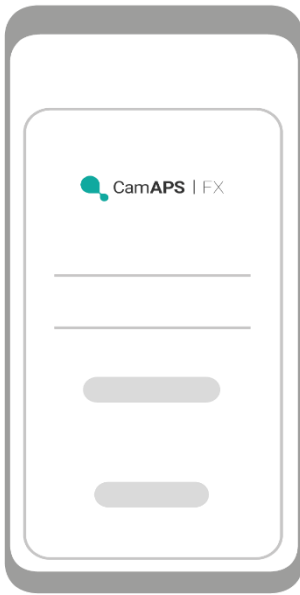
Once you have logged in to your account the Welcome screen will appear. Read the information on the screen and tap "Start" to proceed. You will now be able to select the in-app training. If you wish to access the user manual, you can do it via the link at the bottom of the Welcome screen.

Using existing CamAPS FX account

Once you login into an existing CamAPS FX account, such as when you re-install CamAPS FX app or when you install CamAPS FX app on a different smart device, you may receive a notification that CamAPS FX settings have been restored.

The following CamAPS FX settings are restored from cloud CamAPS FX repository:

- Alarm/alert settings
- CGM transmitter details (if using Dexcom, Dexcom G6 transmitter serial number)
- Followers settings
- Cloud data upload settings
- Hidden messages
- Personal glucose target
- Personalised meal sizes
- Bolus calculator settings

You will be able to review these settings after you completed the remaining login steps.

In-App training

Before you start using the CamAPS FX with real devices, you will need to familiarise yourself with the app and its functionality. After you have logged in to the CamAPS FX personal account for the first time, you will be taken directly to the in-App training. You will have to complete the mandatory sections of the training to be able to proceed to pairing the App with a real insulin pump and CGM.

The essential training comprises several animations that must be watched and competency-based tasks that need to be completed in a virtual mode, using virtual devices, to progress to the next step. Once the training is completed you could stay in the virtual mode or proceed to pairing with your insulin pump and CGM to start using the App with real devices.

A record of successfully completing the training is stored on CamDiab cloud against the user's account details. Users will not have to re-do this mandatory in-App training if the same account is used in future, for example following re-installation of the App.

Should you need a refresher training at any time later, you will be able access the training resources by going to the Help menu of the App.

Linking your pump and CGM to CamAPS FX

The app needs to link with an insulin pump and a glucose sensor. The app will pair with the pump and CGM sensor using Bluetooth Low Energy. You may need to refer to your pump and CGM system User Guides for pairing instructions. Do not pair your sensor over Bluetooth in public or populated areas. Bluetooth pairing should be done in a private and safe location to reduce cybersecurity risks such as eavesdropping and spoofing. Additionally, Bluetooth in a public environment may have reduced quality of service due to the number of active devices which could slow or disrupt pairing.

To link your pump to the app, begin by tapping "Start" on the Welcome screen. "Select pump" screen appears: Please allow CamAPS FX to access your location should the pop-up window appear.

Note: Linking instructions for insulin pumps differ slightly. Please refer to the relevant section below depending on the type of pump you wish to link.

Linking to mylife YpsoPump

- Select "mylife YpsoPump" from the list
- Read the information on the Help screens then tap "Continue"
- Select your country of residence
- Wait until serial number of your pump appears on the "Scanning" screen, select it and tap "Continue"
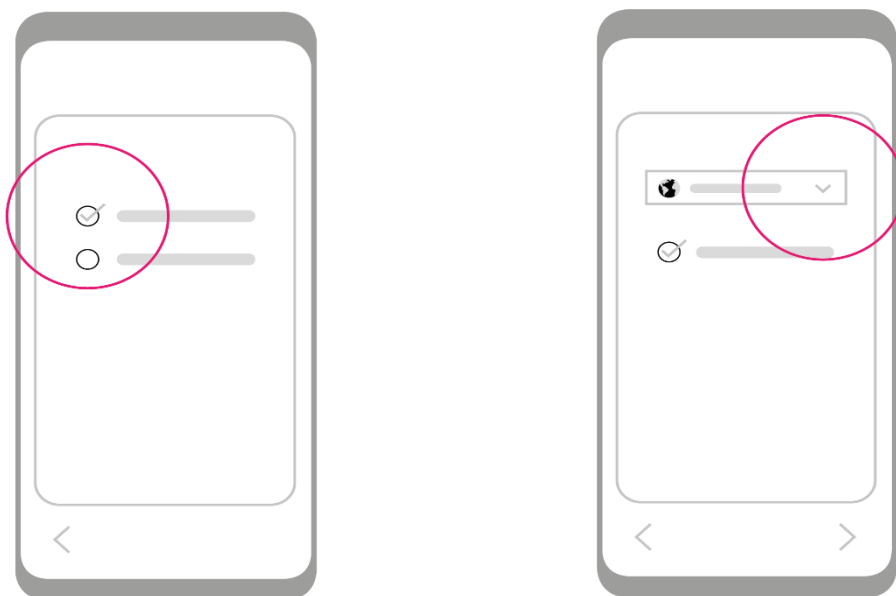
- **Activate pairing on your pump**
- Pop-up window appears: confirm the pump serial number
- When prompted enter pairing code displayed on your pump
- A confirmation message appears that the pump is now linked
- You will be required to set up your bolus calculator settings, see details in section
  [Bolus Calculator Settings](#)

Linking to virtual pump

- Select "Virtual pump" from the list
- Read the information on the Help screens then tap "Continue"
- Select the suggested serial number of virtual pump and tap "Continue"
- Pop-up window appears: confirm the virtual pump serial number
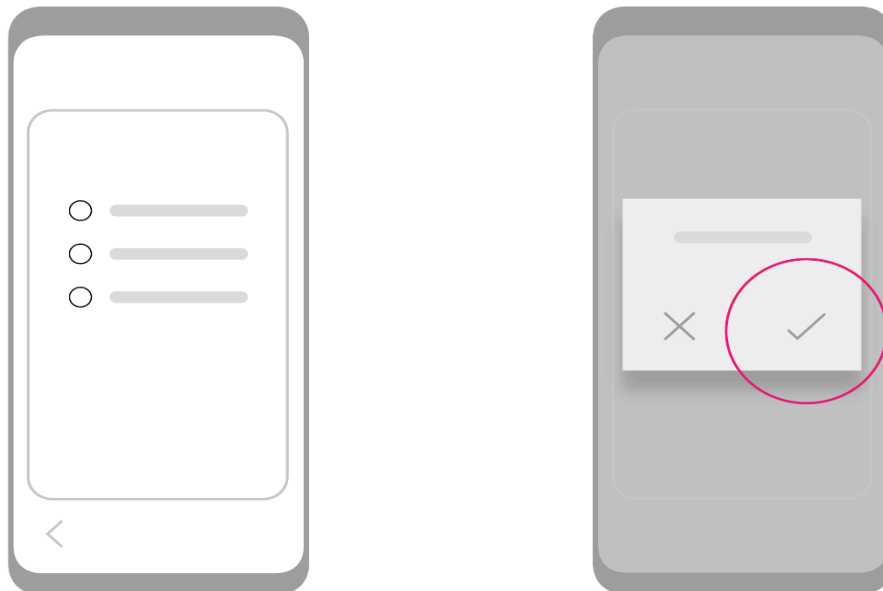
Note: Virtual pump should be used for **training and demonstration purposes** only. Not all CamAPS FX features are available when using virtual pump. No insulin is actually administered.

Linking to Companion
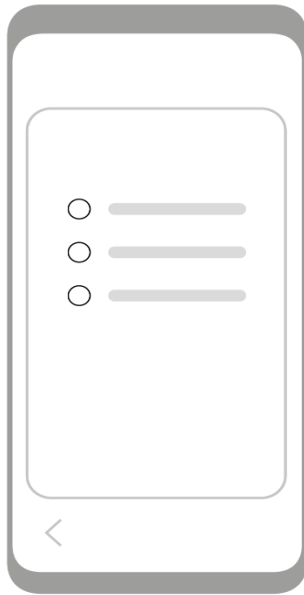
- Select "Companion" from the list
- Read the information on the Help screen, then tap "Continue"
- Select your invitation from the list of invitations and tap "Continue"
- Pop-up window appears: confirm the invitation

Note: "Companion" is used to receive and display data from a pump and glucose sensor worn by another person. Not all CamAPS FX features are available when using "Companion".

Linking to your continuous glucose monitor

Note: Linking instructions for CGM monitor differ slightly. Please refer to the relevant section below depending on the type of CGM Monitor you wish to link.

Linking to Dexcom G6

Note: Before linking, insert a sensor and attach the transmitter.

- Select CGM device screen appears: select Dexcom G6 from the list
- Enter your CGM transmitter Serial Number and tap "Continue"
- Confirm the serial number of your CGM transmitter

Linking to virtual CGM

- Select CGM device screen appears: select your device from the list
- Confirm the suggested serial number of your CGM transmitter

Note: A virtual CGM is available for use with virtual pump only. It cannot be used in combination with a real pump.

Note: A virtual CGM should be used for **demonstration and training purposes** only. No alerts and alarms will be sounded. Not all CGM features will be available. For example, you will not be able to start and stop sensor.

Entering weight and total daily insulin dose

- Weight screen appears
- Tap in the field to enter body weight in kg (*allowed range 10 to 300kg in 1kg increments*) then tap "Continue"
- Confirmation screen appears – check the entered value and tap "Confirm" or tap "Cancel" if you wish to make a correction
- Total daily insulin dose (TDD) screen appears
- **Enter an average of TDD over the past 5 days** (*allowed range 8 to 350 Units in 1U increments*) and press "Continue"
- Confirmation screen appears – check the entered value and tap "Confirm" or tap "Cancel" if you wish to make a correction

Connecting to Dexcom G6 transmitter

- Message appears "Now connecting to transmitter": make sure the sensor is inserted and the transmitter is attached and ready for pairing
- Screen appears "Now connecting to transmitter": note the time delay and the timer at the top right of the screen
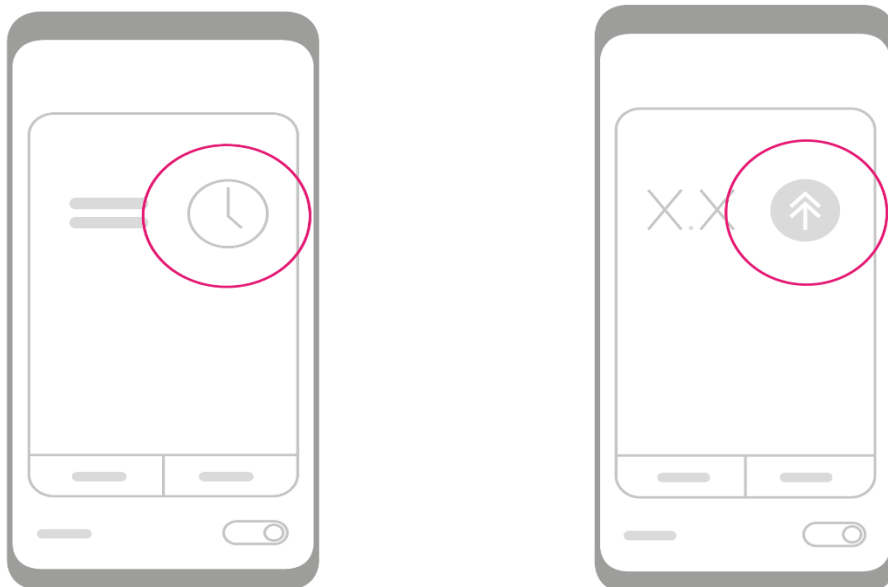
- The Home Screen appears. If your sensor had already been started, you should see sensor glucose displayed on the screen and the set-up is complete.
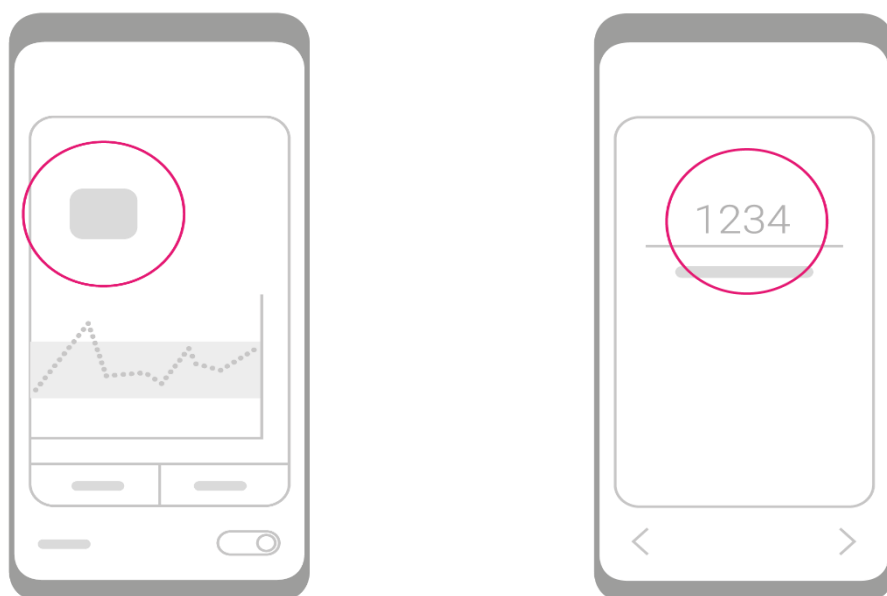
Starting a new sensor

If your sensor had not been started yet, or the current sensor session has ended, you will see a "Start Sensor" button on the screen.

To initiate a new sensor:

- o Tap on the "Start Sensor" button; sensor code entry screen appears
- o Tap in the entry field and enter the sensor code, then tap "Continue"
- o Confirmation screen appears, tap "Confirm"

- o Pop-up window appears informing you that a 2-hour long sensor warmup has started; read then dismiss
- o Message "Sensor warmup. Wait 120 minutes" appears on the screen; timer to the right of the message shows how much time is left until the end of warmup
- o After 120 minutes, your sensor glucose value will appear on the screen

The set-up is now complete and the closed loop system is ready to use.

Note: Before you turn "Auto mode" on, familiarise yourself with the information on the Home Screen (The "Home Screen" section), learn how to navigate between the different screens and access additional information ("Status and Navigation" section) and how to personalise the system settings ("Settings").

Replacing CGM transmitter when using Dexcom G6

To replace a transmitter that has expired or needs to be changed:

- Go to the Main Menu and tap on the current transmitter Serial Number
- "Select CGM device" screen appears; select CGM type and press "Continue"
- Follow linking instructions for the selected CGM device.

Replacing or re-linking insulin pump

To replace or re-link the insulin pump:

- Go to the Main Menu and tap on the current pump Serial Number
- "Select pump" screen appears; select the pump type and press "Continue"
- Follow linking instructions for the selected pump type.

6   THE BASICS

This section includes:

- An overview of the Home Screen and the Main Menu

- Instructions on how to access additional information

- Information about alarms and alerts and how to personalise them

- Instructions on how to start and stop closed loop

The Home Screen

The Home Screen consists of three main sections:

- The top section shows the phone status and displays the navigation icons

- The middle section displays closed loop and sensor glucose information, your sensor glucose profile, and has the "Boost" and the "Ease off" tabs at the bottom

- The bottom section shows closed loop status and the "Auto mode" On/Off button
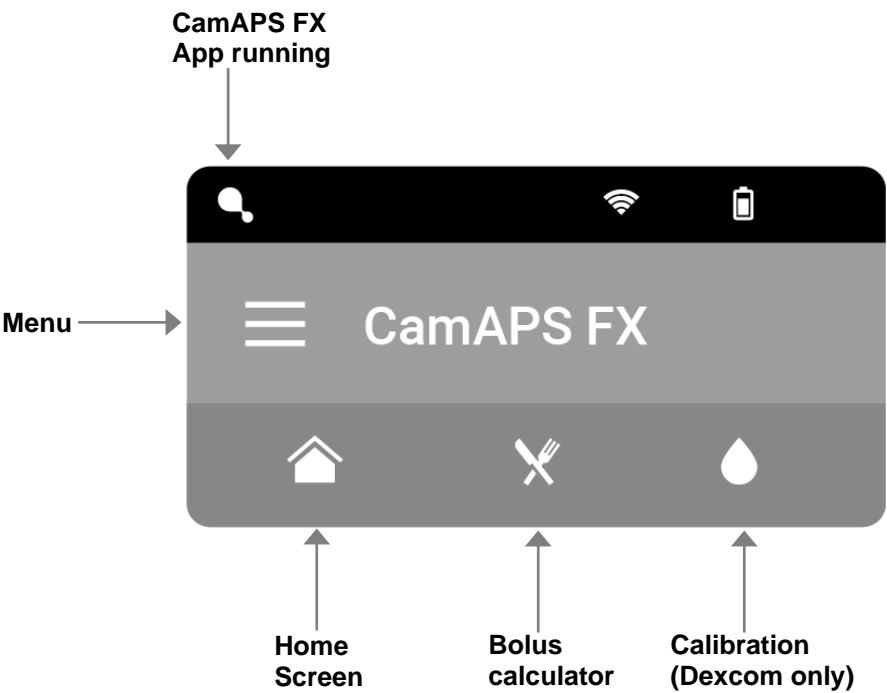
Note: The accuracy of the sensor glucose measurement is determined by the manufacturer of your CGM device. Please refer to the manufacturer's documentation.

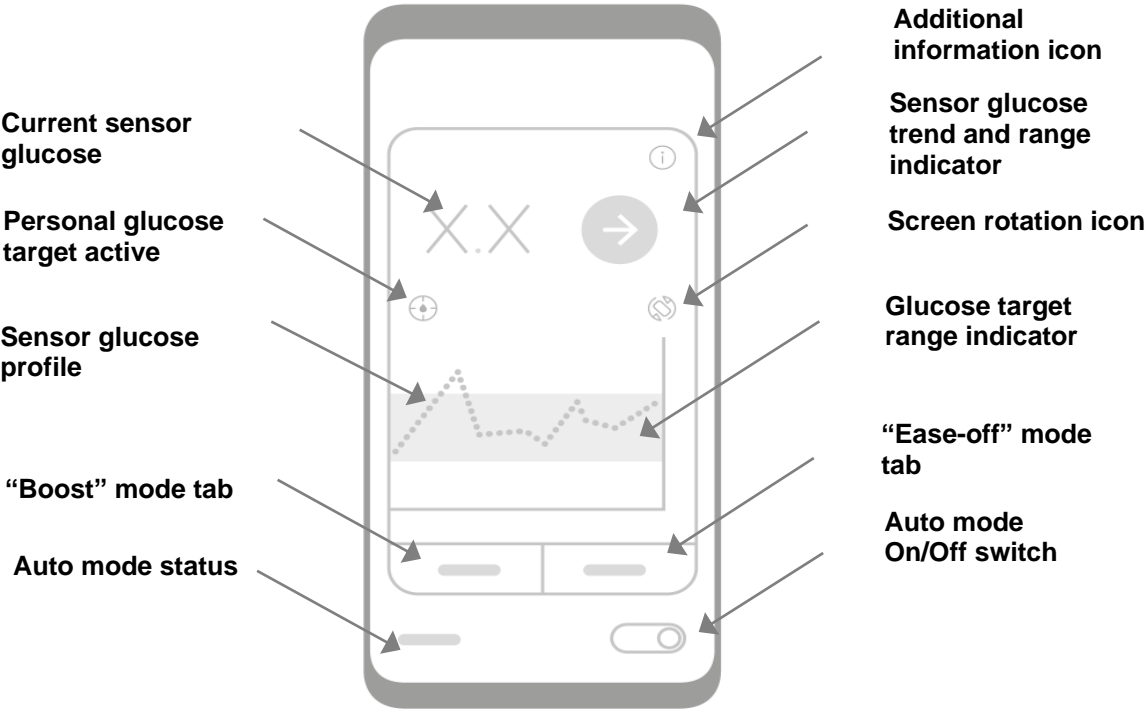The colour of the Home Screen background changes depending on the status of the "Auto mode":

- "Auto mode Off" (**Dark grey**)

- "Auto mode Attempting" (**Orange**)

- "Auto mode On" (**Green**)

Home Screen overview

The navigation icons and other symbols shown at the top of the Home Screen:

**CamAPS FX
App running**

Menu

CamAPS FX

**Home
Screen**

**Bolus
calculator**

**Calibration
(Dexcom only)**

Other Home Screen information is shown below.

**Additional
information icon**

**Sensor glucose
trend and range
indicator**

**Current sensor
glucose**

**Personal glucose
target active**

Screen rotation icon

**Sensor glucose
profile**

**Glucose target
range indicator**

"Boost" mode tab

**"Ease-off" mode
tab**

Auto mode status

**Auto mode
On/Off switch**

6 The basics

Tap on the "Additional information icon" at the top right corner of the Home Screen to view additional useful information:

- Active insulin (also known as insulin-on-board)
- Current insulin infusion rate
- Amount of insulin remaining in the pump reservoir
- Pump battery level
- Last time connected to pump
- Last time sensor glucose received
- Average glucose today
- Average glucose yesterday
- Insulin today
- Insulin yesterday
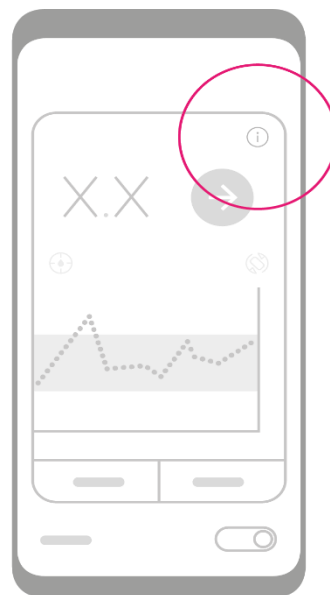
Sensor glucose trend and range

The sensor glucose trend and range indicator is represented by a large coloured circle at the top right corner of the main section of the Home Screen.

The background colour of the circle indicates sensor glucose status:
- Above high glucose alert level (**yellow**)
- Below low glucose alert level or will be below within 20 minutes in urgent low soon alert state (**red**)
- Within target range (**grey**)

The white arrow inside the circle shows the speed and direction of your glucose trend based on recent readings. A double arrow head indicates a rapid glucose rise or fall.

Glucose within target range and steady

Glucose within target range and falling

Glucose within target range and rising

Glucose within target range and falling fast

Glucose within target range and rising fast

Glucose below low glucose alert range and falling slowly

Glucose above high glucose alert range and steady

Status and navigation

This section includes:

- How to get around the app
- How to take a quick view of the closed loop and the glucose sensor status

The navigation icons

Tapping on one of the four icons at the top of the Home Screen will take you to the following relevant screen:

- Tap on the "Bolus Calculator" icon to open the Bolus Calculator screen where you will be able to initiate your meal bolus
- Tap on the "Calibration" icon to open the calibration screen where you will be able to calibrate your glucose sensor
- Tap on the "Home" icon to return to the Home Screen
- Tap on the "Menu" icon at the top left of the screen to open the main menu

The menu overview

Tapping on the "Menu" icon at the top left of the screen, or swiping from left to right, opens up the main menu. From the main menu, you can access the following:

- Add a meal

- Your pump and sensor information

- Personalise your settings

- Add followers to share your data

- Setup cloud data upload account

- View your account details

- Access the help screen

- Stop sensor when using Dexcom G6 sensor

Scroll down the list to view all items. Tap on an item to move to the selected item.

The middle sections provide information about your insulin pump and the continuous glucose monitor. In these two sections, only fields in blue can be edited.

Quick status check

Sensor glucose and closed loop status information, including alerts and alarm information, is displayed on the locked screen for quick viewing. To access this information on an unlocked screen on your device, just swipe the screen from the top down to bring it to view.
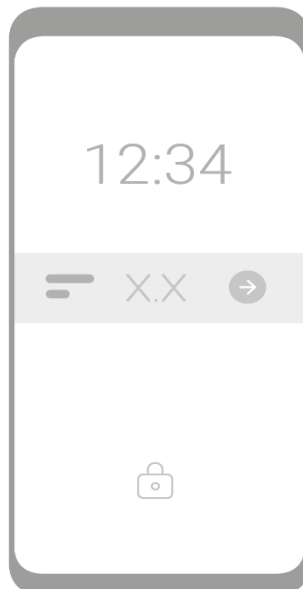
Starting Auto mode

To start "Auto mode", tap the "Auto mode" On/Off button at the bottom right of the screen or slide the button to the right. The confirmation screen will appear, tap "Confirm" or "Cancel".

Once confirmed the following changes will be observed:

- Information screen appears: review the provided information
- The screen background turns orange indicating that "Auto mode" is attempting to start – the initialisation may take a few minutes
- "Auto mode" status at the bottom of the screen changes to "starting"

If sensor glucose data are available and after a short while, "Auto mode" should be successfully started.

The following changes will be observed on the screen:

- The screen background turns green
- "Auto mode" status changes to "On"

Stopping Auto mode

To stop "Auto mode", tap the "Auto mode" On/Off button at the bottom right of the screen or slide it to the left. The confirmation screen will appear, tap "Confirm" or "Cancel".
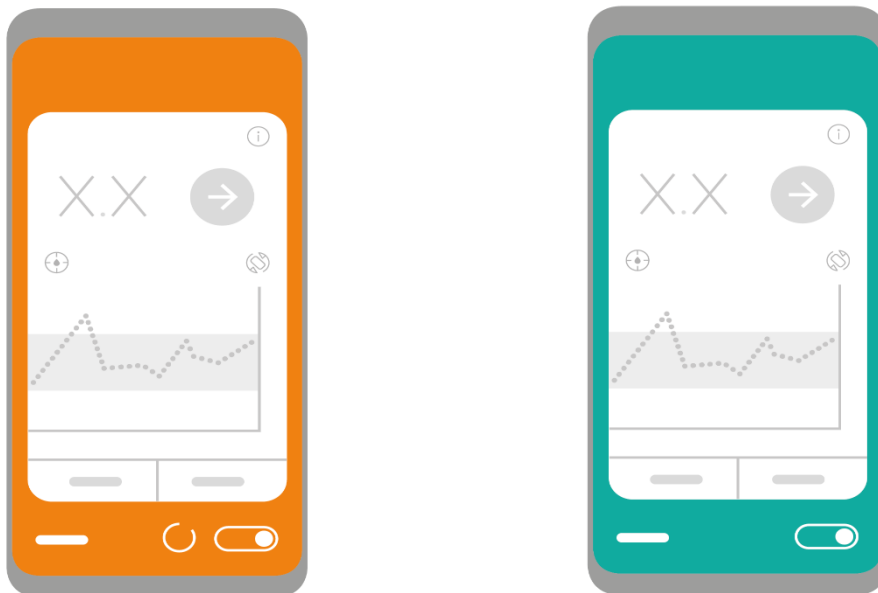
Once confirmed:

- The screen background turns orange
- "Auto mode" status changes to "stopping"

After a short while, the screen background will turn dark grey and the "Auto mode" status will change to "Off".
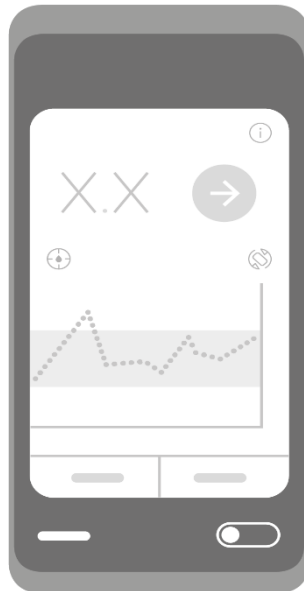
Note: Turning "Auto mode" On and Off is disallowed when the "Block" feature is turned On.

7 THE NEXT STEPS

In this section you will learn how to:

- Access and interpret the detailed graph
- View summary statistics
- Use the Boost/Ease-off modes
- Use the Bolus Calculator
- Add a meal
- Calibrate your sensor (Dexcom G6 sensor only)

Detailed graph

To view the detailed graph, featuring sensor glucose values and insulin delivery, turn the Home Screen to a landscape position or tap on the "rotate screen" icon.

As well as your sensor glucose and insulin delivery, the graph displays usual (pre-programmed) basal rate, meals, insulin boluses, target glucose range, high and low glucose range and the closed loop status with a resolution as obtained during data acquisition.

The "Auto mode" status is indicated by a black horizontal bar at the top of the graph ("closed loop status bar")

- The solid bar indicates "Auto mode On"
- The dashed bar indicates "Auto mode Attempting"
- No line indicates "Auto mode Off"

The glucose range is shown on the right side of the graph. The yellow line represents the high glucose range (if high glucose alert is on) and the red line represents the low glucose range (if low glucose alert is activated).

The horizontal grey shaded area represents the target glucose range used for visual display and to calculate statistics.

The vertical pink shaded area represents the period when "Boost" was active.

The vertical yellow shaded area represents the period when "Ease-off" was active.
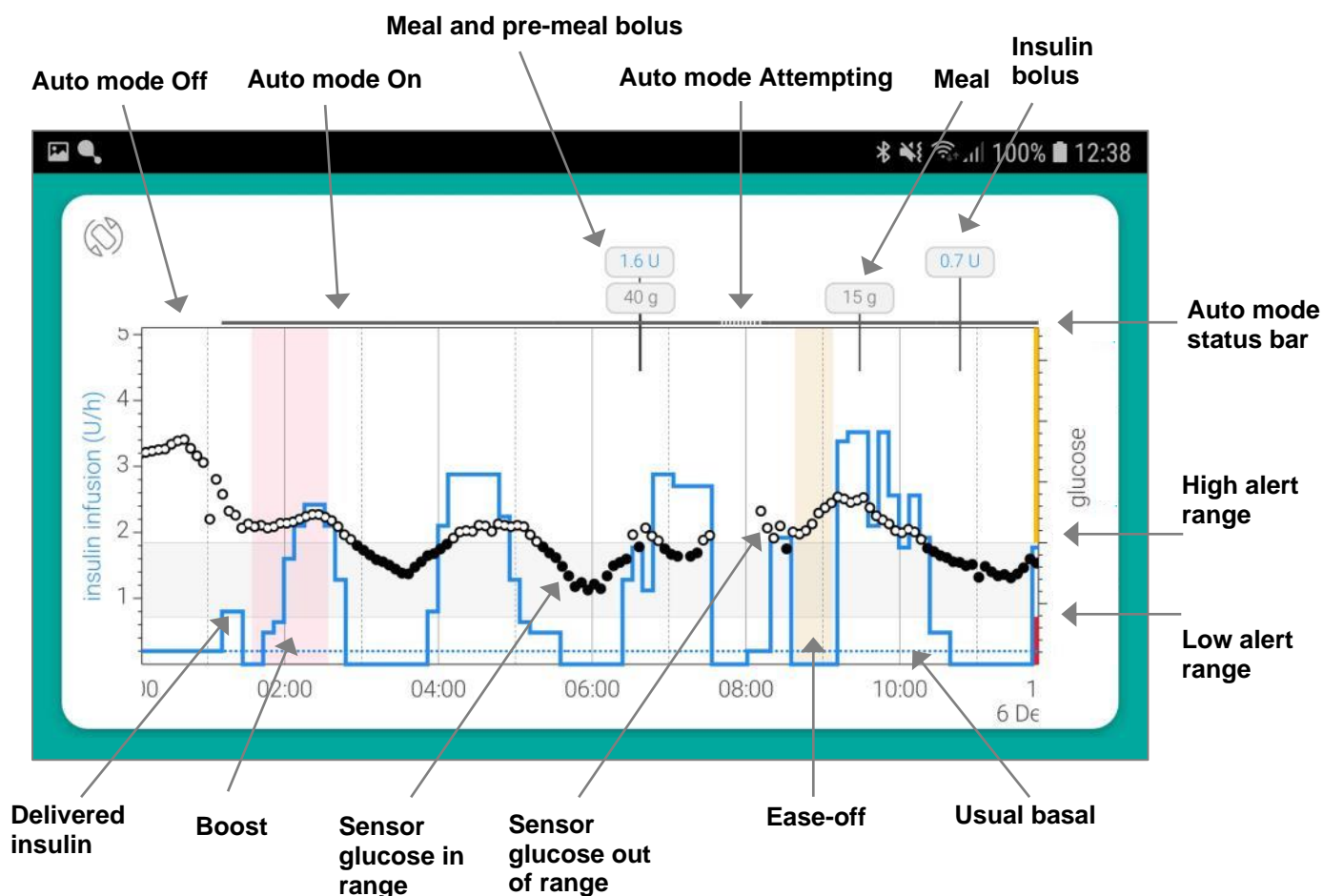
Pinch the time axis to extend or to shrink it, swipe the screen to move the graph back and forth in time. The maximum time-period that can be displayed on the graph is about 15 days. The data are retained when your smart device is turned off or its battery is depleted.

Summary statistics

To view summary statistics over a chosen period, go to the main menu and tap on "Statistics". You will be able to choose between daily, weekly and monthly summaries, and a summary of the past three months (the maximum period). Once on the daily/weekly/monthly summary screen swipe left and right to move back and forth. Scroll down to view more data.

You can change the threshold values used to calculate the time when glucose was in, above and below target by going to "Statistics" in the "Settings" menu.

It is possible to generate a two-week summary statistics and detailed data review as a PDF file by selecting the relevant option in the "Statistics" screen.

It is also possible to export your data into a text file. Make sure you have a text file editor/viewer installed on your smart device.

Note: Daily, weekly, monthly, and three months summaries are calculated using data stored on your smart device. Data used to generate the PDF report are retrieved from CamAPS service cloud.

Note: PDF reader is required to generate the report.

Boost

What is "Boost" and when should you use it?

- "Boost" is a mode that provides extra insulin when needed.
- CamAPS FX adjusts insulin delivery to maintain glucose levels, but if they are higher than usual, use "Boost".
- "Boost" makes CamAPS FX more responsive, helping bring glucose levels back into range quickly.
- During "Boost", CamAPS FX still targets personal glucose levels, reducing or stopping insulin to prevent low blood glucose levels.
- Extended use of "Boost", for over 9 hours, can increase time spent below the target range (<3.9mmol/L for non-pregnancy and <3.5mmol/L for pregnancy) to over 4%.

Causes of high glucose levels

- Temporary highs may result from illness, pain, stress, hormones, or medications like steroids.
- Forgetting or delaying a meal bolus, or consuming hard-to-count carbs, can cause a one-off high.
- If the infusion set or cannula is blocked, replace them before using "Boost".
- Consistently high glucose? Check for ketones and contact your clinical team if present.

Use of "Boost" during pregnancy

- If your glucose levels are consistently going above your target during pregnancy, think about activating the "Boost" feature. This is particularly helpful around meal times from 16 to 20 weeks of pregnancy, when insulin resistance is rising.
- You may want to preset "Boost" to start before waking up and during breakfast to better control post-meal glucose levels.
- "Boost" can be a useful tool to limit the impact of hyperglycemia following antenatal corticosteroids, if they are needed before delivery.

To start "Boost":

- Tap the "Boost" tab on the Home Screen.
- Read and dismiss the help screen.
- In the "Boost duration" window, tap the Hrs/Mins fields to set the duration (0 -12 hours). Initially, try 2-4 hours, then adjust as needed.

7 The next steps
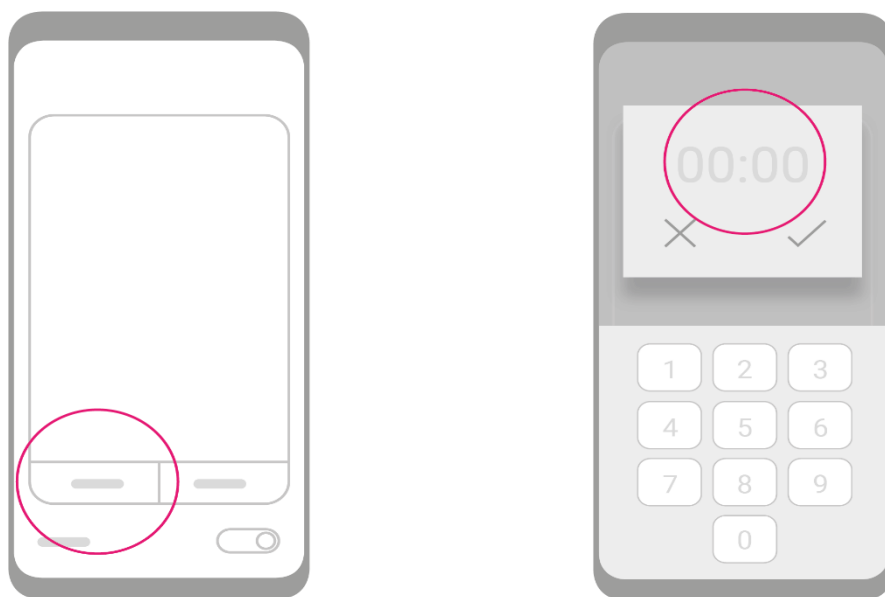
- Tap "Next"
- "Boost start" window appears; tap "Confirm" if you want Boost to start immediately
- Blue "Boost" status tab appears below the graph showing that the Boost mode is now active; note the timer on the left of the tab indicating how much time is left before Boost expires
- Should you wish "Boost" to start at a later time, select the desired duration as before and tap "Next"; then in the "Boost start" window select "Later"
- Clock dial appears; select time to start "Boost" then tap "Confirm"
- "Planned Boost" status tab appears below the graph showing that the "Boost" mode is due to start at a set time; note the clock symbol and the time on the left of the tab indicating the planned time of "Boost"

Note: "Boost" and "Planned Boost" can be cancelled at any time by tapping on "Cancel" icon on the right. When cancelled, the "Confirmation" screen appears; tap "Confirm" to proceed.

⚠️ *Note:* It is strongly recommended that the user closely monitors CGM during periods when "Boost" is active, as to ensure setting is correct.

Ease-off

What is "Ease-off" and when should it be used?

- "Ease-off" is a setting that can be used by people of any age when they require less insulin.

- The CamAPS FX app usually determines the right amount of insulin needed throughout the day. However, if someone needs less insulin than usual, they can activate "Ease-off".

- "Ease-off" reduces the amount of insulin delivered by CamAPS FX to minimize the risk of low glucose levels.

- When "Ease-off" is active, the algorithm targets a slightly higher glucose level. It uses more cautious settings, such as sensitivity factors, to calculate insulin delivery.

- It is suggested to start "Ease-off" 60 to 90 minutes before a period of heightened insulin sensitivity, such as before exercise, following guidelines for managing exercise in closed-loop systems. It is advisable to continue "Ease-off" during the exercise/activity period if the activity heightens the risk of low glucose levels.

- Extended use of "Ease-off", for over 9 hours, can increase time spent above the target range (>10.0mmol/L) to over 30%.

What might make someone require less insulin than usual?

- Your need for insulin might temporarily decrease if you are more active than usual. This could be due to planned sports, a school gym class, a workout at the gym, or any physical activity you engage in once or twice a week.

- Everyday activities like gardening, shopping, or doing housework can also reduce the need for insulin. Physical activity increases your body's sensitivity to insulin during and after exercise.

- If a certain activity is part of your daily routine, you might not need to make adjustments. For instance, if you walk your dog every morning before breakfast, the insulin delivery algorithm will automatically account for this regular exercise.

- Factors like drinking alcohol, hot weather, certain illnesses causing vomiting and diarrhea, and hormonal changes (such as the start of a woman's period) can increase the risk of low blood sugar. In such situations, "Ease-off" can be beneficial to manage insulin levels.


Use of "Ease-off" during pregnancy

- "Ease-off" can be especially beneficial during the first trimester when sensitivity to insulin may increase.

7 The next steps

- Think about using "Ease-off" whenever you face a series of low glucose events.
- Consider incorporating "Ease-off" during planned or unplanned periods of activity or exercise.
- "Ease-off" can also be useful to avoid hypoglycemia during labor and in the initial hours after giving birth, when there are rapid changes in insulin sensitivity and reduce insulin dose requirements.

To start "Ease off":
- Tap on the "Ease-off" tab on the Home Screen
- Help screen appears, read then dismiss
- "Ease-off duration" window appears; tap in the Hrs/Mins entry fields to enter duration
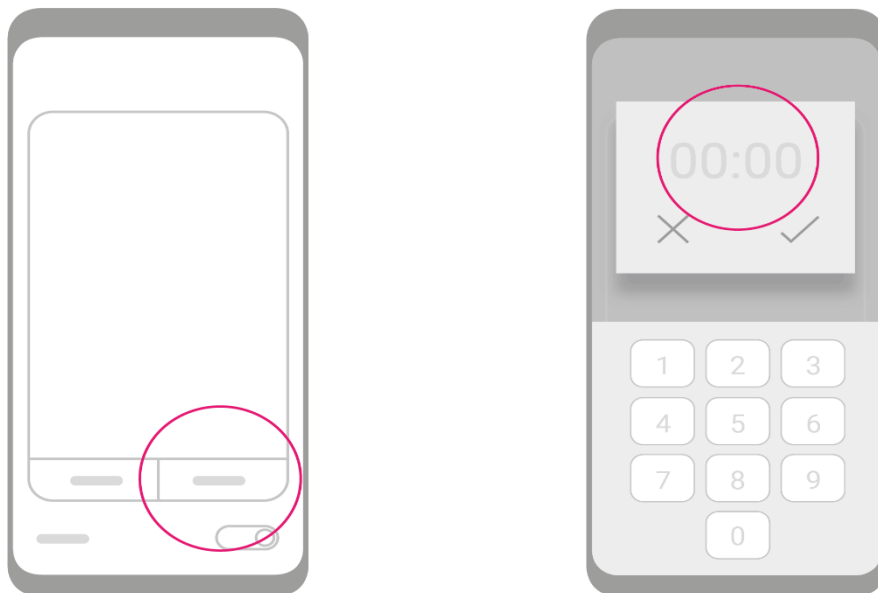
- Tap "Next"
- "Ease-off start" window appears; tap "Confirm" if you want "Ease-off" to start immediately
- Blue "Ease-off" status tab appears below the graph showing that "Ease-off" is now active; note the timer on the left of the tab indicating how much time is left before "Ease-off" expires

If you wish to start "Ease-off" at a later time, select the desired duration as before and tap "Next"; then in "Ease-off start" window select "Later"
- Clock dial appears; select the time to start "Ease-off" then tap "Confirm"

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- Blue "Planned Ease-off" status tab appears below the graph showing that the "Ease-off" is due to start at a set time; note the clock symbol and the time on the left of the tab indicating the planned time of start

"Block" icon

"Boost" and "Ease-off" tabs inactive
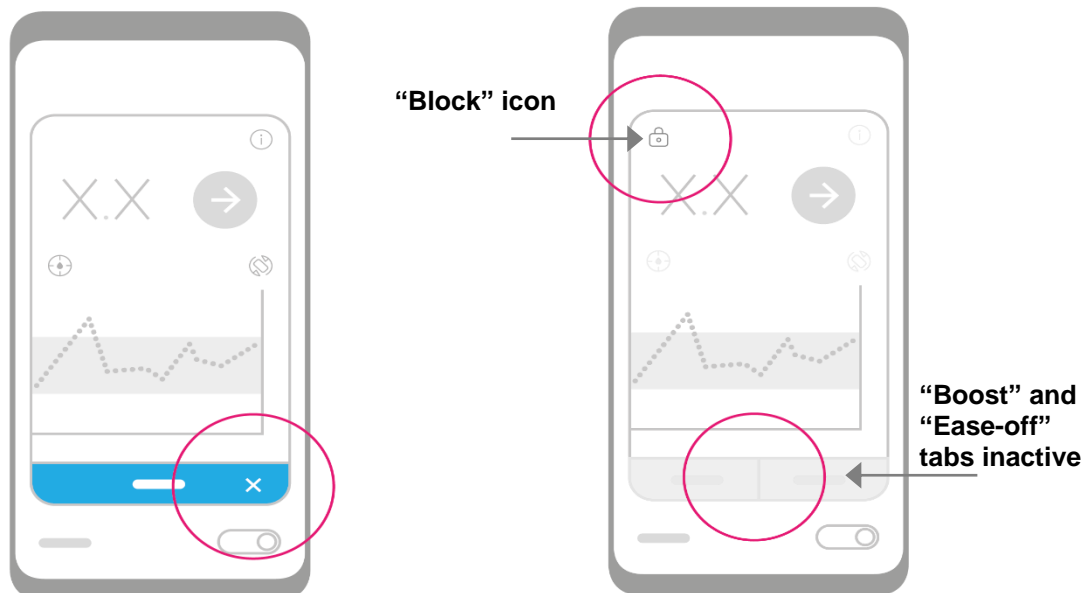
Note*:* "Ease-off" and "Planned Ease-off" can be cancelled at any time by tapping on the "Cancel" icon on the right. When cancelled, the "Confirmation" screen appears; tap "Confirm" to proceed.

Note*:* "Boost" and "Ease-off" cannot be activated when the "Block" setting is On.

Note: It is strongly recommended that the user closely monitors CGM during periods when "Ease-off" is active, as to ensure setting is correct.

Bolus Calculator

The Bolus Calculator allows you to bolus for meals and snacks, or to calculate and deliver a correction bolus. You are able to initiate a bolus when the "Auto mode" is On or Off. Only a standard bolus can be administered via the Bolus Calculator. An extended bolus or combination bolus (standard bolus combined with an extended bolus) cannot be delivered.

Note: You will not be able to start the bolus calculator if your smart device is not secure, e.g. not protected by a PIN.

To start a correction bolus:

- Tap on the Bolus Calculator icon at the top of the screen and wait for a connection to the pump to be established; this may take a short while
- Bolus Calculator set-up screen appears
- Tap in the "Glucose" entry field; the current sensor glucose level appears; you can change it by tapping on the value in blue; tap "Confirm" when ready
- Bolus amount based on your insulin sensitivity factor appears to the right of the glucose level; below in brackets is the active insulin-on-board (this amount will be subtracted) Total amount of insulin to be delivered as bolus is shown at the bottom
- For a correction bolus, leave the Carbs field empty and tap "Next" to start the delivery
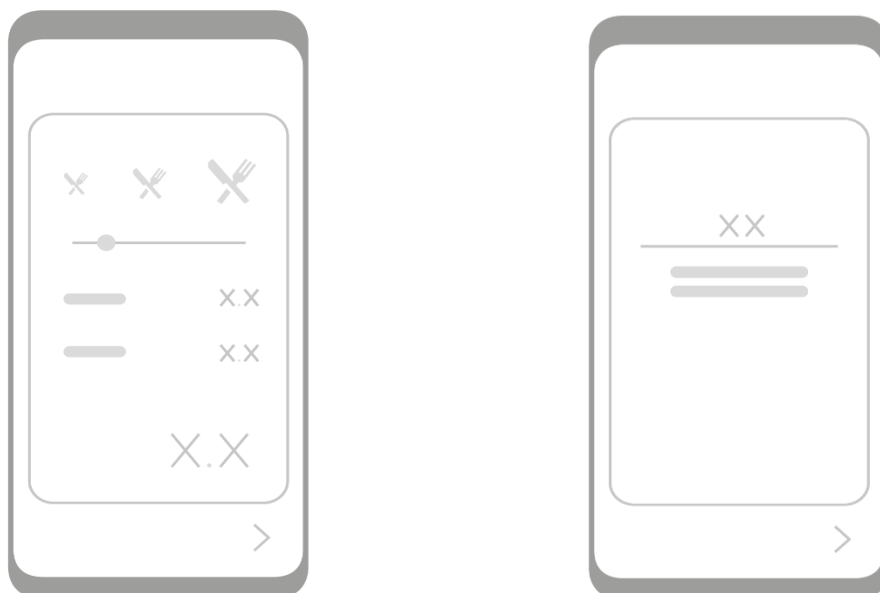
- Bolus delivery screen appears; tap on "Deliver" to proceed or tap on the amount in blue to edit and change the amount
- Delivery screen appears and the countdown begins;

7 The next steps

- Once the insulin has been delivered a confirmation screen appears

To start a meal bolus:

- Tap the "Carbs" entry field and enter the size of meal in the units shown; alternatively, tap on one of the pre-defined meal size icons along the selection line at the top to select a small, medium, large or a very large meal (these can be personalised via "Meal size" in "Settings"); tap "Confirm" when ready
- While in "Auto mode" it is advised not to enter the glucose level when bolusing for a meal, current sensor glucose is greyed out in the "Glucose" entry field and will not be used in the bolus calculation; if "Auto mode" is Off or you wish the glucose level to be taken into account just tap in the "Glucose" entry field and change or confirm the sensor glucose value; then tap "Confirm"
- Bolus amount based on your pump insulin-to-carb ratio appears to the right of the "Carbs" amount;
- Total amount of insulin to be delivered as bolus is shown at the bottom; tap "Next" to start the delivery
- Bolus delivery screen appears; tap on "Deliver" to proceed or tap on the amount in blue to edit and change the amount
- Delivery screen appears and the countdown begins;
- Once the insulin has been delivered a confirmation screen appears

Note: You can stop the delivery at any time by tapping on the "Cancel" icon at the bottom of the screen.

Note: Glucose and carbs can be entered when "Auto mode" is Off.

Note: Bolus Calculator is disallowed when "Block" feature is turned On.

Add a meal

To add a meal/snack outside of the Bolus Calculator, go to main menu:

- Select "Add meal"
- Tap the "Amount" field to enter the size of the meal
- You may indicate that this is
    - a *meal or snack*, or
    - a *hypoglycemia treatment*, or
    - a *slowly absorbed meal*
- Tap "Continue"
- "Meal" confirmation screen appears; confirm the amount to return to the Home Screen

Note: When hypoglycemia treatment is selected, the meal is shown on the detailed graph. However, the control algorithm is prevented from delivering insulin to cover the meal. This reduces the risk of follow up hypoglycemia.

Note: When slowly absorbed meal is selected, insulin for these carbohydrates will be delivered gradually over the following three (3) to four (4) hours in response to rising glucose levels. "Auto mode" must be turned on to receive this additional insulin.

Calibrate (Dexcom G6 sensor only)

When calibration of your CGM is required a red blood drop symbol appears on the "Calibration" icon at the top right of the screen. To calibrate your glucose sensor:

- Perform a fingerstick test
    - o Wash and dry your hands
    - o Take fingerstick with your meter
- Tap on the "Calibration" icon; "BG value" screen appears
- Enter glucose value and tap "Confirm"

8 SETTINGS

In this section, you will learn how to:

- Setup alarms and alerts
- Change weight
- Personalise meal sizes
- Setup a personal glucose target
- Bolus calculator settings
- Use the Block feature

Go to the CamAPS FX menu and scroll down the list to below the CGM section to access the "Settings". From the "Settings" menu you can also access statistics settings, restore hidden messages and personalise notifications.

Alarm and alerts

When your glucose level exceeds the set alarm or alert threshold a message accompanied by an audio sound or vibration is displayed on the screen.

The alarm or alert threshold, repeat time and the type of sound can be personalised. Tap on "Alerts" at the top of the main dropdown menu to open the submenu with all available alarms and alerts. Alarms and alerts are specific to the CGM device you are using. Please refer to your CGM user guide for more detailed information about the alarm and alerts.

Menu items from top down (may differ depending on CGM device):

- **Urgent low alarm**: alarms when glucose falls below the set level (cannot be turned off)
- **Urgent low soon:** alerts when glucose is falling fast and will be at Urgent low level in < 20mins
- **Low:** alerts when glucose falls below the set level
- **High:** alerts when glucose rises above the set level
- **Rise rate:** alerts when glucose is rising at or above the set rate
- **Fall rate:** alerts when glucose is falling at or below the set rate
- **Sensor signal loss:** alerts when the app stops receiving glucose readings from your sensor
- **Pump refill:** when it is time to refill your pump with insulin

All alerts can be turned off using the On and Off toggle at the top of the "Alerts" menu.

Note: The "Urgent low" glucose alarm cannot be turned off.

Note: If the smart device sound setting is on the most restrictive **Do Not Disturb** setting, alarm/alerts may not sound. While the smart device is on a telephone call, alarm/alerts may not sound.

"Silenced alerts" icon
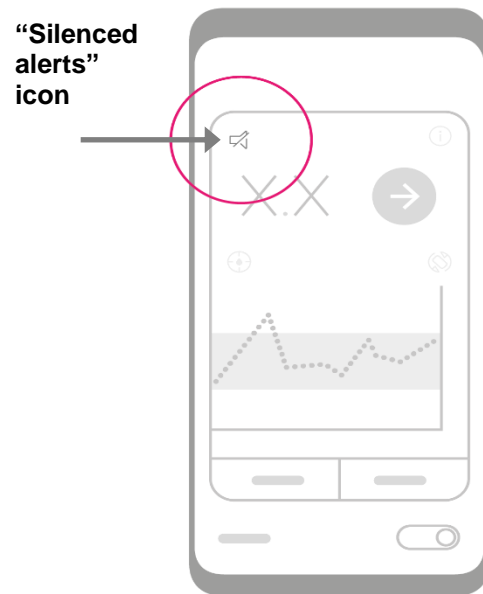
It is also possible to "Snooze" alerts for between 10 and 120 minutes.

Tap on the alarm or alert name to change the settings such as the alarm threshold, repeat time and the type of sound, or to turn the individual alert on or off.

The "Alert Schedule" lets you pick how your alarm/alerts notify you at different times and on different days. For example, you may choose loud alarm/alerts when you are not at work, but have them only vibrate during work hours.

The "Alert Schedule" lets you add one schedule.

When you turn on the "Alert Schedule" for the first time, your glucose alert settings are copied into your schedule. The "Alert Schedule" guides you through creating the name, start time and end time of an additional schedule. You can then change glucose alert settings and select days of the week when "Alert Schedule" should be used to fit your needs.

Change weight

During "Auto mode", body weight is used to approximate glucose and insulin concentrations within the body. It is advisable to update weight when it has increased or reduced significantly.

To change weight:

- Tap "Settings" and then "Change weight"
- "Enter body weight" screen appears showing your current weight
- Tap in the entry field to update the weight and tap "Continue"
- Confirmation window appears; tap to confirm the change
- Confirmation message appears

Personalise Meal Size

The meal size icons at the top of the Bolus Calculator represent a small, medium, large and a very large meal. These categories can be personalised.

To personalise meal sizes:

- Tap on "Meal size" in the "Settings" menu; "Meal size" screen appears
- Select each of the categories to update the corresponding meal size
- When updating the "Small meal" size, tap on the icon at the top
- "Meal size" entry screen appears; dial to the desired amount and tap "Confirm"
- Note the updated meal size corresponding to the "Small meal".

Setting up a personal glucose target

The default glucose target of 5.8 mmol/L used during "Auto mode" can be personalised. You can set your own target in 30min steps via the "Personal glucose target" option in "Settings". Before activating, please read the help information about personal targets by tapping the information icon at the top right of the "Personal target" screen.

To activate your personal target:
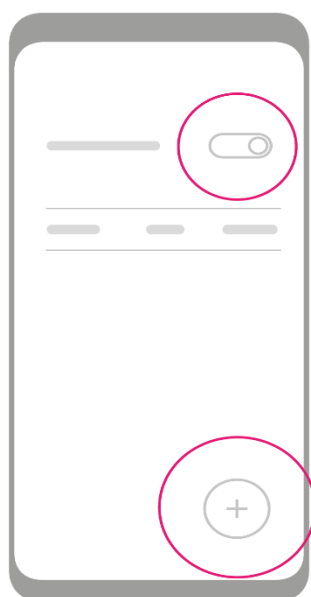
- Tap on "Personal glucose target" in "Settings"
- "Personal glucose target" screen appears; tap on the information icon to familiarise yourself with the personal target feature
- Tap the toggle at the top right of the screen to turn the personal target feature on
- To add new target, tap on the green "+" button at the bottom right of the screen

Example: In order to have a glucose target of 6.5mmol/L between 6:00 am and 8:00 pm followed by the default target of 5.8mmol/L for the rest of the day, complete the following steps:

- Tap the green "+" icon
- A window labeled "Start time" will pop up. The app uses your phone's time format, either 12 or 24 hours. Enter your desired start time, like 6:00 am, and tap confirm. The "End time" window will then appear. Enter the end time, such as 8:00 pm, then tap "Confirm"
- Next, a window for "Target glucose" will appear. Enter your target glucose value, like 6.5mmol/L, and tap confirm.
- Your personal target will now be displayed on the screen for the selected hours, with the default value of 5.8 mmol/L shown for the remaining hours of the day. For example, if you set a target from 6:00 am to 8:00 pm, your target of 6.5 mmol/L will be shown during that time, and the default value of 5.8 mmol/L will be displayed for the rest of the day.

- To make another entry, tap the green "+" icon again.
- If needed, you can tap on the blue text to edit any time block.

Once activated, the personal target icon will be shown on the Home Screen (see "Home Screen overview"). To deactivate, slide or tap the toggle in the top part of the "Personal glucose target screen". The nominal (i.e., default) glucose target will then apply and the personal target icon will disappear from the Home Screen.

When should you set a personal glucose target?

- Some people prefer to have a slightly lower target from midnight to waking, slightly higher during the daytime and then a slightly lower from bedtime to midnight, as shown in the example above.
- On starting the system, users may consider a slightly higher personal glucose target while they are optimizing their settings and the system is learning. This starting personal glucose target should be discussed and agreed with your diabetes team. If the personal glucose target has been raised for a particular reason, it should be gradually reduced by 0.5-1.0 mmol/L over time to achieve desired time in range.
- Personal glucose target of <5.0mmol/L should not be used outside of pregnancy.
- Utilizing a higher personal glucose target results in extended periods above the target range (>10mmol/L). A higher personal glucose target of ≥8.9mmol/L may not be suitable for all individuals without guidance from their health care provider.

Consider temporarily setting a higher personal glucose target for one to two weeks or longer if needed when

- You are experiencing frequent low glucose levels or hypoglycemia events.
- Your glucose levels fluctuate widely.
- Your HbA1c has been considerably higher than your target before using the system, or you have difficulty sensing low glucose levels known as hypo unawareness.
- Your daily routine changes, like
  - starting a new job
  - returning to school or work after a holiday
  - going on a day trip with all-day activity,
  - participating in an active holiday,
  - or consuming more alcohol than usual.

Think about setting a lower personal glucose target in these situations

- At night, once you are familiar with the system, to increase the time your blood sugar stays in the right range.
- During pregnancy or when you are getting ready to have a baby.
- If your glucose levels consistently stay in a narrow range (with minimal ups and downs).

Use of personal glucose target during pregnancy

- For the first trimester, aim for a personal glucose level of 5.5mmol/L since insulin sensitivity is higher during this time.
- Starting from the second trimester, target a personal glucose level of 5.0mmol/L.
- If you notice low glucose variability, especially overnight, think about setting a personal glucose target of 4.5mmol/L from dinner until midnight and midnight until waking up.
- After giving birth, consider raising your personal glucose target to 6.0 to 6.6mmol/L to adapt to the quick changes in insulin sensitivity and needs.

Note: We recommend discussing any adjustments to your personal glucose target with your health care team.

Bolus calculator settings

Bolus calculator settings must be setup on the CamAPS FX app when the app is linked to mylife YpsoPump.

The bolus calculator settings determine how the bolus calculator calculates your suggested bolus. It is therefore very important that these settings are correct. Do not make any settings without discussing these previously with your physician or diabetes counsellor. Please make sure that a trained health care professional with experience in diabetes management supervises the initiation and programming of the bolus calculator.

Note: The bolus calculator settings do not affect how "Auto mode" operates.

Note: Refer to section "Setting Up a Personal Glucose Target" for information how to set up personal glucose target during "Auto mode".

Bolus calculator settings include the following items

- Minimum glucose value for calculation
- Maximum bolus suggestion
- Bolus glucose target value
- Correction factor
- Insulin-to-carb ratio
- Duration of insulin action

Minimum glucose value for calculation

Here, you can set the minimum threshold for glucose values used in bolus calculations. If the current glucose value falls below this threshold, the bolus calculator will notify you that the glucose level is too low, and a bolus cannot be delivered.

The permitted range for the minimum glucose value used in bolus calculation is between 2.8 and 4.4 mmol/L.

Maximum bolus suggestion

You can specify the maximum dose of insulin that the bolus calculator is permitted to suggest. If the calculated dose exceeds this limit, it will be capped at the specified maximum.

The permitted range for the maximum dose is between 0.5 and 30 units of insulin in 0.5 unit increments.

Bolus glucose target value

The bolus calculator will determine the bolus amount needed to adjust high or low blood glucose measurements to the bolus target glucose value. Glucose measurements above this value will trigger a (positive) correction bolus dose. Conversely, a glucose measurement below the target value will prompt a negative correction bolus dose, which will be applied to reduce the total suggested bolus.

The permitted range for the bolus glucose target value is between 4.4 and 11.0 mmol/L.

Note: The bolus glucose target value is SOLELY used to calculate the insulin bolus dose by bolus calculator. It does not impact how the CamAPS FX algorithm determines automated insulin delivery when "Auto mode" is active.

If you have different bolus glucose target value throughout the day, you can define those in the corresponding time segments in 30-minute increments. The process of entering insulin-to-carb ratio throughout the day is identical to that when entering personal glucose target value, refer to section "Setting Up a Personal Glucose Target".

Correction factor

Enter your correction factor here (example: if 1 unit of insulin lowers your blood glucose by 2 mmol/L, your correction factor is 2).

If you have different correction factors throughout the day, you can define those in the corresponding time segments in 30-minute increments. The permitted range of correction factor values is between 0.1 and 22. The process of entering correction factor throughout the day is identical to that when entering personal glucose target value, refer to section "Setting Up a Personal Glucose Target".

Insulin-to-carb ratio

The insulin-to-carb ratio describes the number of grams of carbohydrates covered by one unit of insulin.

If you have different insulin-to-carb ratios over the course of the day, you can define those in the corresponding time segments in 30-minute increments. The permitted range of

insulin-to-carb ratio is between 1 and 150. The process of entering insulin-to-carb ratio throughout the day is identical to that when entering glucose target value, refer to section "Setting Up a Personal Glucose Target".

Duration of insulin action

This setting defines how long your bolus insulin remains active in your body to lower your blood glucose. The permitted range of duration of insulin action is between 2 and 8 hours. This setting is used for insulin-on-board calculation.

Note: The duration of insulin action is SOLELY used to calculate the insulin bolus dose by bolus calculator. It does not impact how the CamAPS FX algorithm determines automated insulin delivery when "Auto mode" is active.

Insulin-on-board calculation

Insulin-on-board (IOB) is calculated using a linear decay model. For example, after 25% of the duration since the last bolus delivery has passed, it is assumed that 75% of that bolus insulin remains active; after 50% of the duration has passed, 50% of the insulin remains active, and so forth. The following equation is used for the calculation:

$$\text{IOB} = \frac{\text{Bolus} \times (\text{Duration of insulin action} - \text{Time since bolus})}{\text{Duration of insulin action}}$$

Note: Insulin-on-board is sometimes called active insulin.

Bolus calculation

Meal bolus dose

A meal bolus dose compensates for carbohydrate intake:

$$\text{Meal bolus} = \frac{\text{Carbohydrates in grams}}{\text{Insulin to carb ratio}}$$

Correction bolus dose

When a glucose level is entered in the CamAPS FX bolus calculator, an additional correction bolus dose will be calculated.

A correction bolus dose is used to adjust the measured blood glucose value to the bolus target glucose value. If the entered glucose level is above the bolus target glucose value, the correction bolus dose will be positive; if the entered glucose level is below the bolus target value, it will be negative:

$$\text{Correction bolus} = \frac{\text{Measured glucose} - \text{Bolus target glucose value}}{\text{Correction factor}}$$

If the correction bolus dose is positive, it will be adjusted by subtracting the insulin-on-board. However, the resulting correction bolus cannot be negative in this case:

$$\text{Correction bolus} = \begin{cases} 0, & \text{if (Correction bolus} - \text{IOB)} < 0 \\ \text{Correction bolus} - \text{IOB}, & \text{if (Correction bolus} - \text{IOB)} \geq 0 \end{cases}$$

Total bolus dose

A total bolus dose includes both the meal bolus and the correction bolus, as follows:

$$\text{Total bolus} = \text{Meal bolus} + \text{Correction bolus}$$

Note: Insulin-on-board is subtracted only from the correction bolus

Note: Insulin-on-board is never subtracted from the meal bolus

Using Block feature

The Block feature is used to prevent the use of certain app functionality in order to prevent unauthorised or unintended entry. This may be helpful when the app is used by children. When the Block feature is activated, certain app functionality will not be allowed including:

- Stopping or starting "Auto mode"
- Bolus calculator
- Sensor calibration
- "Boost" and "Ease-off"

Deactivate the Block feature in the Settings menu to be able to use these functions again.

9 DATA UPLOAD AND REMOTE MONITORING

Data upload to the cloud

The CamAPS FX app supports data upload to the cloud. Data including glucose, insulin, meal intake, "Auto mode", "Boost" and "Ease-off" status, will be uploaded every 5 to 10 minutes during "Auto mode" and when "Auto mode" is Off.

Data shared to the cloud does not have any impact on CamAPS FX app functioning. If the cloud is not available, the app will continue to function normally, but will not alert you if it cannot connect to the cloud. If you notice a prolonged period where your cloud is not updating based on CamAPS FX app data, you should contact customer support.

Supported cloud upload portals are listed in Appendix C. You may need to register with the cloud upload system provider in advance and provide your account details to the app.

You can link to up to two cloud upload accounts via the "Share" option in the main menu:
- Tap on the "User 1" or "User 2" field to open the account details entry screen
- Enter your account details including email address and password
- Tap on "Link" to link the account to the app

To stop uploading data to this account, turn the toggle to "Off". To unlink the account, tap on the active user then tap "Unlink".

Please refer to the cloud upload provider user guide for detailed instructions regarding the account setup and data viewing.

Note: Prior to taking any action in response to analysis of CamAPS FX data on the Cloud, it is advised that user/guardian or clinician validates the information by speaking to the user or reviewing graphs on the active system.

Companion remote monitoring

The CamAPS FX app allows glucose levels, insulin delivery and other data to be shared with "Companions".

Companion setup is located in "Share" option of the main menu:
- For each Companion, provide a nickname and a valid email address

9 Data upload and remote monitoring

- An invitation email is sent to Companion's email address
- The Companion must **install the CamAPS FX app, create personal CamAPS** account using the same email address, and select **"Companion"** when initialising the CamAPS FX app
- Data are sent to the Companion using end-to-end encryption

Data shared with Companions include:

- Sensor and blood glucose levels
- Insulin delivery
- Meal intake
- "Auto mode" status
- "Ease-off" and "Boost" (except planned "Ease-off" and "Boost")
- Amount of insulin remaining in the pump reservoir
- Pump battery level

Note: Internet connectivity is required to share data with Companions.

Note: It is not possible to share data with Companion while using virtual pump.

SMS-based remote monitoring

The CamAPS FX app supports SMS-based remote monitoring during "Auto mode" On and Off. All app generated alarms and alerts will be sent via SMS message to active "Followers". Follower setup is located in the "Share" option of the main menu:

- For each Follower, provide a nickname and a valid mobile number; an authentication code will be sent to that mobile number for verification purposes
- Once verified, the Follower nickname will be shown on the "Share" screen

To stop sending messages to a Follower, turn off the toggle next to the Follower's nickname.

To remove a Follower, tap on the Follower's nickname and tap "Unlink".

To test sending an alert, tap on "Send test SMS". A SMS message will be sent to all active Followers.

Note: SMS messages are sent directly from the smartphone to the Follower(s) and a SIM card has to be inserted in the smartphone to send the SMS messages.

*Note:* Please be aware that any SMS messages sent or received as part of this service may incur charges from your mobile service provider. You are responsible for any associated costs according to your carrier's pricing plan.

10   TECHNICAL INFORMATION

How does it work?

The CamAPS FX app uses a mathematical model of insulin action to determine insulin infusion leading to a target glucose of around 5.8mmol/L.

For the model of insulin action to operate correctly, information is needed at setup and then during the system operation. The **body weight** is used to approximate glucose and insulin concentrations within the body. The **total daily dose** of insulin is an initial indicator of **insulin sensitivity**, which is further refined by analysing continuous glucose monitor (CGM) data, previously administered insulin infusion and boluses, and meal intake.
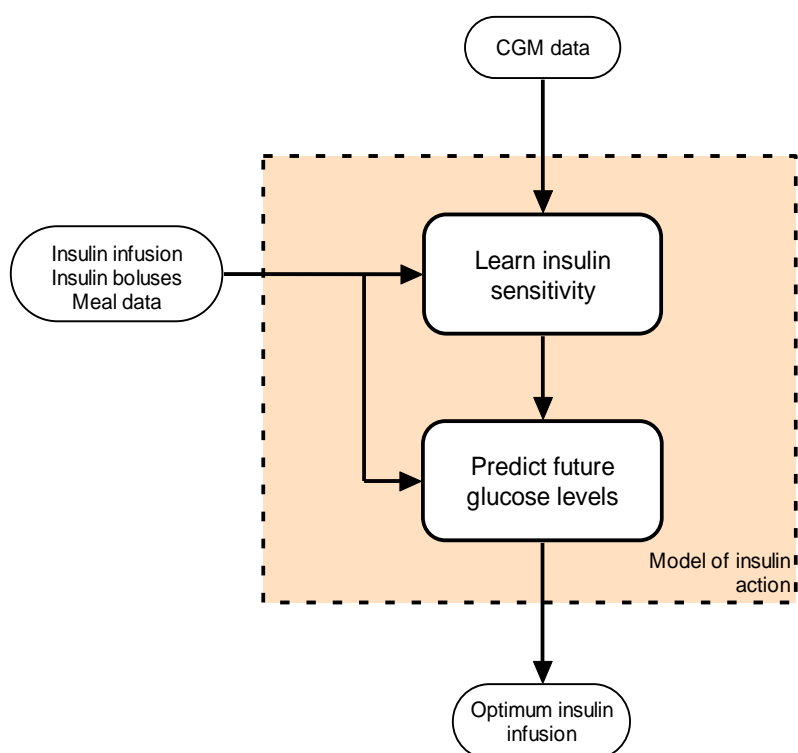
Previous insulin infusion and boluses, together with CGM and meal data are used to update insulin sensitivity and other subject specific characteristics. The mathematical model then uses these characteristics together with information about active insulin and active meals to predict future glucose concentrations and to determine the optimum insulin infusion leading to the target glucose level. The maximum of insulin infusion rate is determined on individual basis and is limited to reduce the risk of hypoglycemia. In certain situations such as when CGM glucose is low or is decreasing fast, the control algorithm may further reduce insulin to reduce the risk of hypoglycemia.

11 SPECIFICATION AND PERFORMANCE CHARACTERISTICS

Medical indication

Type 1 diabetes (including type 1 diabetes pregnancy)

Target population

Age	2 years and older
Sex	Male/Female
Weight	10kg – 300kg
Total daily insulin	5 U/day – 350 U/day (or as further limited by linked insulin pump)
Condition	Adequate hearing to hear alarms
	Adequate vision to view display

User profile

People with type 1 diabetes and their guardians

User training requirements

CamAPS FX users need to complete a mandatory in-App training.

Target operating environment

The CamAPS FX is intended for use in home health care environment.

CamAPS FX relies on Bluetooth communication to communicate with CGM and insulin pump. CamAPS FX relies on Wi-Fi or cellular communications to share data over the internet with cloud (partner, "Companion"), and using SMS to communicate alerts.

Wireless quality of service summary

For CamAPS FX, Bluetooth "Best Effort" quality of service is assumed for this electronic interface.

The quality of service of the CamAPS FX System is defined as:

- The receipt of 95% of CGM data.
- Sounding CGM Alert conditions as they are generated.

- 100% of closed loop cycles start within 10mins of their initiation.
- 100% of meal/correction bolus instructions received by the pump.
- Closed loop control staying active for 90% of test period.

Quality of service for the Dexcom G6 System and the pump is assured within the effective range of 6 metres or 20ft, unobstructed, between the Dexcom G6 transmitter/Pump and paired device hosting the CamAPS FX App, unless there is wireless interference caused by other devices in the 2.4 GHz band. This interference may impact the smartphone's ability to maintain this quality of service. To improve the quality of service in the presence of other devices operating in the 2.4 GHz band, decrease the distance between the smartphone and the pump. If connectivity is lost, the CamAPS FX will provide notification.

Data transmitted between the Pump/Dexcom G6 transmitter and the CamAPS FX App is in accordance with the industry standard BLE protocols. Both the CGM and pump used with CamAPS FX shall support secure authentication to protect against unauthorized access.

Supported devices

Insulin pumps

Compatible insulin pumps must have the following characteristics:

- Receive regulatory approval in the territory, where used including regulatory approval of secure Bluetooth communication protocol for remote pump control
- Allow "Auto mode" to be carried out using (i) 15 to 30 minute long temporary basal insulin rates, or (ii) 15 to 30 minute long extended boluses, or (iii) a combination of (i) and (ii)
- Have delivery accuracy for basal rate ±5% [±0.05U/h for rates < 1.0U/h] or better
- Have delivery accuracy for bolus ±5% [±0.05U for boluses < 1.0U] or better
- Enable maximum delivery of at least 10 U per 5 to 15 minute long closed loop cycle during "Auto mode"
- Enable resolution of insulin delivery of at least 0.05 U per 5- to 15-minute-long closed loop cycle during "Auto mode"
- Communicate via Bluetooth over a range of at least 1.5 metres
- Provide downloadable time-stamped history of insulin delivery
- Provide status information including time, pre-programmed basal settings, ongoing bolus, ongoing temporary basal rate, suspended state, and error status.

A complete list of insulin pumps that can be presently used with the CamAPS FX app is provided in **Appendix A.** Additional pumps may be added in the future.

11 Specification and performance characteristics

Continuous glucose monitoring devices

Compatible continuous glucose monitoring devices must have the following characteristics:

- Receive regulatory approval in the territory, where used including regulatory approval of secure Bluetooth communication protocol
- Provide sensor glucose readings with a resolution of at least 0.1mmol/L
- Provide nominally glucose reading at least once every 5 minutes
- Communicate via Bluetooth over a range of at least 1.5 metres
- Provide downloadable time-stamped history of sensor glucose readings
- Provide status information including calibration state, sensor expiry, and error status.

A complete list of continuous glucose monitoring devices that can be presently used with the CamAPS FX app is provided in **Appendix B.** Additional continuous glucose monitoring devices may be added in the future.

Cloud upload portals

Compatible cloud upload portals must have the following characteristics:

- Receive regulatory approval in the territory, where used including approval of secure communication protocol
- Allow secure authentication for individual users
- Enable upload of relevant diabetes therapy related information.

A complete list of cloud upload portals that can be used with the CamAPS FX app is provided in **Appendix C.** Additional cloud upload portals may be added in the future.

Compatible smart devices

The minimum requirements for CamAPS FX app is a smart device running Android 12.0 OS or above.

For an up-to-date list of supported mobile devices and operating systems, please visit www.camdiab.com/en-ca/faq.

Communication protocols

Secure communication protocols are used by the CamAPS FX app for communicating with your insulin pump, your continuous glucose monitoring device, and cloud portals.

Cybersecurity considerations

Your smartphone's biometric security or PIN/password prevents unauthorized access to the device and your CamAPS FX app. You should not share your security PIN/password or authorize any other person to access your smartphone via their biometric information to avoid unintentional changes in your delivery of insulin or your application configuration.

As noted in Section1, the "*Important Safety Information"*, DO NOT use a smartphone that has been rooted, or with Android developer mode on. Your data may become vulnerable if you install the CamAPS FX mobile app on a smartphone that has been rooted, or that uses an unreleased or pre-released operating system. Only download the CamAPS FX app on Google Play™. See Section 2, subsection "*CamAPS FX Availability, Installation and Updates"* for CamAPS FX app for installation instructions.

The mobile app has a feature that allows you to check if the mobile phone passes an integrity check and confirms that the app has not been modified or had its signature altered, and that it was properly installed from the Google Play™ store rather than being sideloaded. If your device fails this integrity check or your app fails, you should contact customer support. The application may cease functioning if it identifies an integrity failure, so you should work to correct the situation immediately.

If the app becomes corrupted or compromised, uninstall the CamAPS FX app and follow the instructions in Section 2, subsection "*CamAPS FX Availability, Installation and Updates"* to regain a known configuration of the CamAPS FX app.

Once we have validated the CamAPS FX app, CamDiab intends to support a particular smartphone and OS combination for at least one year. When the mobile app is no longer compatible with a particular smartphone or OS, no further security updates will be provided. A list of compatible devices and operating systems can be found in Section 11, subsection "*Compatible Smart Devices"*.

Note: You are responsible for securing your smart device and using it safely. If you suspect a cybersecurity incident involving CamAPS FX app, contact customer support.

Insulin

The following rapid or ultra-rapid insulin analogues, including their biosimilars, are compatible with CamAPS FX[1]:

- NovoRapid U-100 (Novo Nordisk, Denmark)
  - age 2+
- HumaLog U-100 (Eli Lily, USA)
  - age 2+
- Fiasp U-100 (Novo Nordisk, Denmark)
  - age 2+
- Lyumjev U-100 (Eli Lily, USA)
  - age 18+

In pregnant women, CamAPS FX has not been studied with Fiasp or Lyumjev.

Note: Consult the Canadian Product Monograph for the biosimilar insulin to verify that it is authorized as a biosimilar to one of the originator insulins indicated above.

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[1] Refer to the connected insulin pump user guide to confirm compatibility of the specific insulin product (including biosimilars) with your insulin pump.
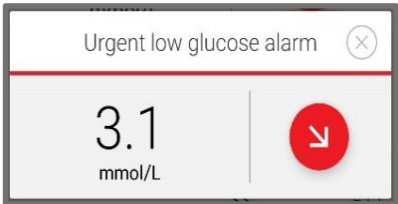
12 ALERTS AND NOTIFICATIONS

The CamAPS FX alerts

The alerts found in the "Alerts" menu of the CamAPS FX app and described in Section 8 can be customized. For each of the alerts you are able to:

- Select your preferred sound from the list of sound options
- Choose how often you want the alert to repeat once acknowledged
- Replace sound with vibration by turning "vibrate" on (except for the Urgent Low alert)
- Use the "snooze" option to mute all alerts (except for the Urgent Low) for a duration between 10 and 120 minutes.

Note: Alerts will sound or vibrate repeatedly every 5 minutes until they are acknowledged.
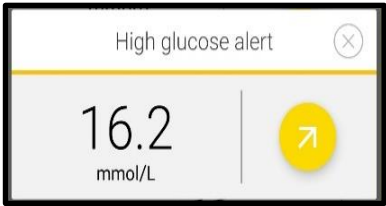
The table below displays alert screens and additional details related to these alerts, including the default alert settings and the allowable range for each setting.

Urgent low Urgent low glucose alarm (×) 3.1 mmol/L ↘ **Warning:** Always treat very low glucose promptly; if left untreated, it could lead to loss of consciousness, seizure or even death. Always follow your health care provider's guidance.	What does it mean?	The alert will notify you when your glucose falls below the set level. It is not possible to turn off the Urgent Low Alert or to set it to "vibrate" only
	Default settings (range)	**Threshold:** 3.1 mmol/L (threshold not modifiable) **Status:** On **Sound**: On **Repeat:** every 30 minutes (range 30 to 60 minutes)
	How should I respond?	Acknowledge the Alert. Follow hypoglycemia protocol provided by your health care professional

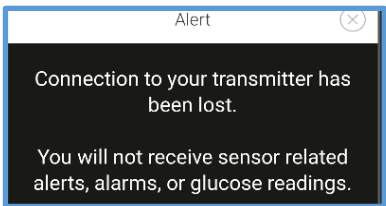| Urgent low soon	What does it mean?	The alert will notify you when glucose is falling quickly and will be at the Urgent Low threshold in less than 20 minutes
Warning: Always treat very low glucose promptly; if left untreated, it could lead to loss of consciousness, seizure or even death. Always follow your health care provider's guidance.	Default settings (range)	**Threshold:** 3.1 mmol/L (threshold not modifiable) **Status:** On **Vibrate:** On **Repeat:** every 30 minutes (range 15 to 30 minutes)
	How should I respond?	Acknowledge the Alert. Follow hypoglycemia protocol provided by your health care professional
Low	What does it mean?	The alert will notify you when your glucose falls below the set threshold
	Default settings (range)	**Threshold:** 3.9 mmol/L (range 3.3 to 5.6 mmol/L) **Status:** On **Sound:** On **Repeat:** Never (range 15 to 240 minutes)
	How should I respond?	Acknowledge the Alert. Follow hypoglycemia protocol provided by your health care professional

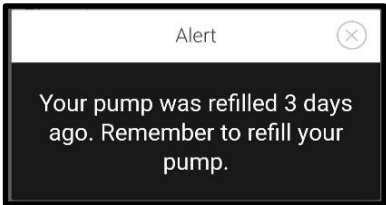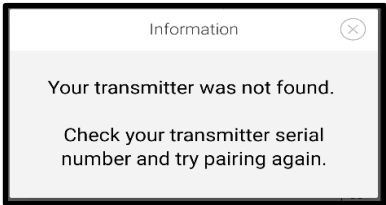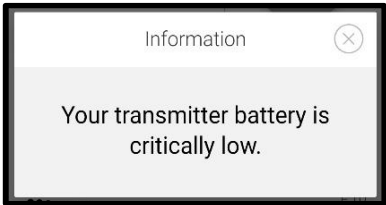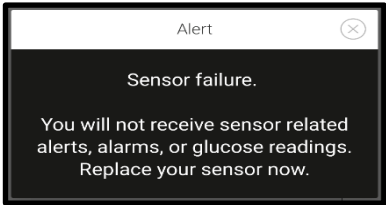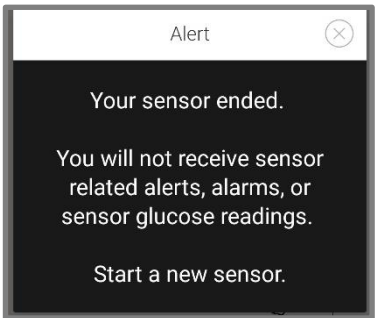| High glucose alert	What does it mean?	The alert will notify you when your glucose rises above the set level
High glucose alert ⊗ 16.2 mmol/L ↗	Default settings (range)	**Threshold:** 16.7 mmol/L (range 6.7 to 22.2 mmol/L) **Status:** On **Vibrate:** On **Repeat:** Never (range 15 to 240 minutes)
	How should I respond?	Acknowledge the Alert. Follow hyperglycemia protocol provided by your health care professional.
Rise rate	What does it mean?	The alert will notify you when your glucose is rising at or above the set rate
Rising glucose alert ⊗ 7.0 mmol/L ⤊	Default settings (range)	**Rate:** 0.2 mmol/L/min (range 0.1 to 0.2 mmol/L/min) **Status:** Off
	How should I respond?	Acknowledge the Alert. Check if the "High glucose alert" is turned on, turn it on if required
Fall rate	What does it mean?	The alert will notify you when your glucose is falling at or below the set rate
Falling glucose alert ⊗ 7.0 mmol/L ⤋	Default settings (range)	**Rate:** 0.2 mmol/L/min (range 0.1 to 0.2 mmol/L/min) **Status:** Off
	How should I respond?	Acknowledge the Alert. Check if the "Low glucose alert" is turned on, turn it on if required.
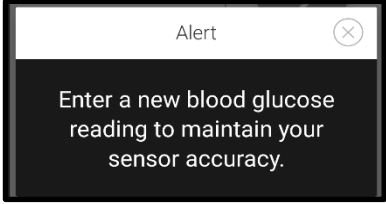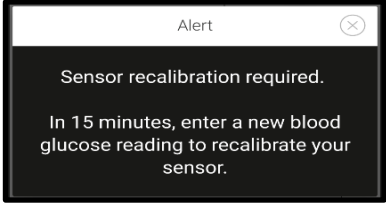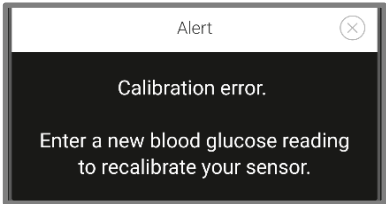
Signal loss	What does it mean?	The alert will notify you when the app stops receiving glucose readings from your CGM device for given duration
	Default settings (range)	**Duration:** 20 minutes (range 20 to 240 minutes) **Status:** On **Sound:** On
	How should I respond?	Acknowledge the Alert. Ensure CGM device is within 6 metres (20 feet). Check for interference from devices like a Wi-Fi booster, microwave, induction hob, baby monitor etc.
Pump refill	What does it mean?	The alert will notify you when it is time to refill your pump with insulin
	Default settings (range)	**Refill frequency:** 3 days (range 1 to 10 days) **Status:** On **Repeat:** Never (range 0 to 12 hours)
	How should I respond?	Acknowledge the Alert. Refill your pump with insulin at the earliest convenience.

CGM specific alerts and notifications

The following alerts and notifications are related to the connected CGM device. These alerts have a default sound lasting 2 seconds. The alert/notification will be repeated every 5 minutes until acknowledged.

Transmitter not found	What does it mean?	Your CGM transmitter could not be paired/linked with the CamAPS FX app
	How should I respond?	Acknowledge the Alert. Check your transmitter Serial Number and try pairing it again.
Transmitter battery critically low	What does it mean?	Your CGM transmitter battery is critically low
	How should I respond?	Acknowledge the Alert. Replace your CGM transmitter to continue receiving sensor glucose readings and related alerts
Sensor failure	What does it mean?	Sensor failure was detected. You will no longer receive glucose readings and glucose related alerts
	How should I respond?	Acknowledge the alert and replace your sensor. END the current sensor from the app main menu before starting a new sensor session
Sensor session has ended	What does it mean?	Your glucose sensor session has ended
	How should I respond?	Acknowledge the alert. Insert and start a new sensor to continue receiving sensor glucose readings and glucose related alerts
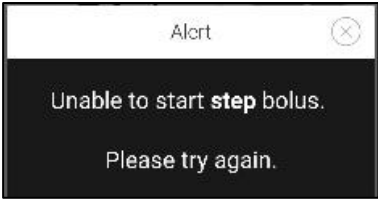
Calibrate	What does it mean?	The alert will notify you when the calibration of your sensor is required
Alert ⊗ Enter a new blood glucose reading to maintain your sensor accuracy.	How should I respond?	Acknowledge the alert. Take blood glucose measurement and enter the reading on the Calibration screen of the CamAPS FX app
Recalibrate	What does it mean?	The alert will notify you when recalibration of your sensor is required
Alert ⊗ Sensor recalibration required. In 15 minutes, enter a new blood glucose reading to recalibrate your sensor.	How should I respond?	Acknowledge the alert. Wait 15 minutes, then take blood glucose measurement and enter the reading on the Calibration screen of the CamAPS FX app
Calibration error	What does it mean?	The alert will notify you when the calibration reading has not been accepted
Alert ⊗ Calibration error. Enter a new blood glucose reading to recalibrate your sensor.	How should I respond?	Acknowledge the alert. Take a new blood glucose measurement and enter the reading on the Calibration screen of the CamAPS FX app

Insulin pump and bolus specific alerts and notifications

The following alerts and notifications are related to the linked insulin pump or to insulin bolus. These alerts have a default sound lasting 2 seconds. The alert/notification will be repeated every 5 min until acknowledged.
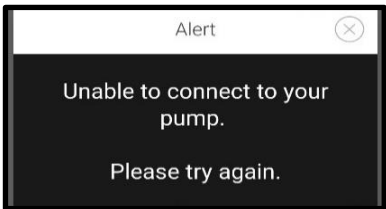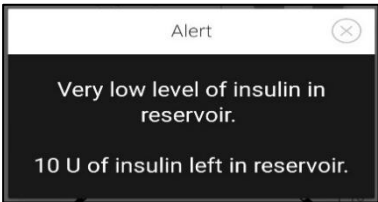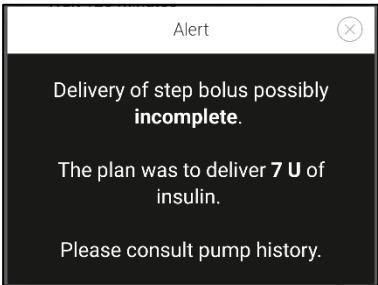
Unable to connect to pump	What does it mean?	The alert will notify you when connection to your insulin pump is lost
	How should I respond?	Acknowledge the alert. Position your pump within 6 metres (20 feet) of the CamAPS FX app and ensure it is away from other devices that could cause interference. If you still cannot administer a bolus from the CamAPS FX app, you can manually initiate bolus delivery on your pump
Low insulin alert	What does it mean?	The alert will notify you when the level of insulin in your pump reservoir is very low
	How should I respond?	Acknowledge the alert. Refill pump reservoir with insulin at your earliest convenience
Incomplete bolus alert	What does it mean?	The alert will notify you when bolus delivery was interrupted
	How should I respond?	Acknowledge the alert. Review the insulin pump history to verify the delivered amount of the planned bolus and administer an additional bolus if the previous one was incomplete

12 Alerts and notifications

Unable to start bolus	What does it mean?	The alert will notify you if bolus delivery could not be initiated by the CamAPS FX app
	How should I respond?	Bring your pump within 6 metres (20 feet) from the CamAPS FX app and move away from other devices that may cause interference. If you still cannot administer a bolus from the CamAPS FX app, you can manually initiate bolus delivery on your pump

13   FAILURE MODES AND TROUBLESHOOTING

Introduction

This section will help you figure out what to do if you encounter problems. The next section describes typical failure modes and their possible causes. The following subsections provide troubleshooting advice categorised by components, i.e. the CamAPS FX app, insulin pump, CGM, and the cloud upload portal.

Failure modes

The table below depicts common failure modes, how they appear on the screen, and what you should do to resolve them.

Failure mode	Screen appearance	Cause and resolution
Unable to use bolus calculator	*Information* *Unable to start bolus calculator as your device is not **secure**.* ***Set PIN or similar** on your mobile device to be able to use bolus calculator.*	This information screen appears when your smart device does not have a secure lock. Please set up a PIN or other secure method such as a password, fingerprint or face recognition.
Unable to connect to pump during bolus delivery attempt	*Alert* *Unable to start **step** bolus.* *Please try again.*	This alert screen appears when the CamAPS FX App is unable to connect to the pump to start bolus delivery. Try moving smart device closer to the pump. Ensure Bluetooth on your smart device is turned on.
Unable to reconnect to YpsoPump*	*"Your pump cannot be accessed as key exchange failed. Please connect to the internet. If the issue does not resolve in 10 to 20 minutes, then re-link your pump to be able to connect to it."*	The App must be connected to the internet at least once every 30 days in order to exchange the pairing keys
Transmitter not found (Dexcom G6 only)	*Transmitter not found.*	This screen indicates that the transmitter could not be linked. To resolve, follow the troubleshooting steps in "Dexcom G6" section below.
Lost connection to transmitter/sensor	*Signal loss.*	This screen indicates that the connection to transmitter/sensor

		has been lost. To resolve, follow the troubleshooting steps in the relevant CGM device section below.
Transmitter/sensor not providing sensor data	*Sensor error. Wait up to 3 hours.*	The screen indicates that the transmitter/sensor and smart device are communicating but there is a problem with the data arriving from the sensor. The issue could be due to (i) a sensor error or (ii) disrupted communication between the sensor and transmitter. As applicable, please check if the transmitter is snapped in properly.
"Boost"and "Ease-off"features disabled	*Boost / Ease-off* *"Auto mode"* *Off*	The screen shows that "Boost" and "Ease-off" features have been disabled. This could be due to (i) "Block" feature being turned on, (ii) insecure lock on your smart device. To resolve, disable the "Block" feature or secure your smart device with a PIN, a password or a more secure method.

* If you have a reliable internet connection on your mobile device and are still unable to connect to your pump, please contact customer service to troubleshoot.

CamAPS FX App

Unable to login to CamAPS FX account

Likely cause

- No internet connection
- Unregistered account
- Incorrect login details

Solution

- Make sure your smart device is connected to the internet; confirm the connection by opening a popular website
- If not already registered, open CamAPS FX app and click on "Register" to create your CamAPS FX account
- Make sure your login details, i.e. the username and password are correct; request the password reminder to be sent to the email address linked with your account

Unable to setup a SMS follower

Likely cause

- Unable to send SMS from the smart device hosting the CamAPS FX app
- No phone signal or no data on the SIM. Incorrect mobile number of the follower

Solution

- Make sure mobile number of the follower is correct
- Confirm the phone hosting the CamAPS FX app has an active SIM card with sufficient funds available to send SMS
- Attempt to send SMS or make a call using the phone
- Check balance on the SIM account
- If in doubt, use another SIM card to setup a follower
- Check mobile network reception on the smartphone

Cannot hear alarm/alerts

Likely cause

- Your smartphone volume is turned off
- The sound setting on your smartphone is on "*Do Not Disturb*"
- Alerts are turned off in the app
- Individual pre-selected alerts are turned off or set to "vibration only"

13 Failure modes and troubleshooting

- Selected ring tone is not easily heard

Solution

- Make sure the volume on your smart device is turned on and sufficiently high
- Make sure "*Do Not Disturb"* setting on your smart device is turned off
- Make sure all alerts are turned on in *Main Menu > Alerts*
- Check individual alerts settings to ensure your selected alert is turned on and "vibration only" option is turned off; if desirable, change the ring tone and make sure you can hear it well

Alarm/alerts repeat too often

Likely cause

- Alarm/Alert not acknowledged on the smart device
- "Repeat" option in Alarm/Alert settings is set too short

Solution

- Acknowledge every alarm/alert message on the smart device
- Set the "Repeat" option in alarm/alert settings to a longer period

CamAPS FX app stops working/crashes

Likely cause

- Internal error, e.g. error message *"CamAPS stopping. Update info or close app*"

Solution

- Turn off your smart device
- Wait for 1 minute and turn your smart device back on
- If CamAPS FX app is still not working uninstall, re-install the app (follow steps below "Having to re-install the CamAPS FX app").

Having to re-install the CamAPS FX app

Before uninstalling

- Make sure you have your CamAPS FX account details at hand
- Make a note of the average total daily insulin dose (TDD) from your insulin pump or from the app: *Main Menu > Statistics > Week > TDD*
- Make a note of your weight from the app: *Main Menu > Settings > Change weight*

- Although the rest of settings will be restored such as alarm settings, meal sizes, personal target settings, share/followers settings, and Dexcom G6 transmitter serial number (if using Dexcom G6 sensor), you may want to take note of these settings.

After uninstalling

- Install the CamAPS FX app from app store
- Open the app and log in with your CamAPS FX username and password
- Proceed with linking the pump
- Enter weight and TDD when prompted
- In the rare case your settings were not restored and before initiating the "Auto mode" please remember to set the following settings (in any case, you may want to review these settings after they were restored):
- Reset your alarm/alerts settings and other personal settings
- Link your Glooko account with the app: *Main Menu > Share > User 1 account details*
- Add any followers: *Main Menu > Share > Follower*

Dexcom G6

General guidelines and troubleshooting about Dexcom G6 system are provided in Dexcom user manual. The following section covers issues related to the use of Dexcom G6 from within the CamAPS FX app.

Unable to link the app with Dexcom G6 transmitter

Likely cause

- Dexcom G6 transmitter already linked to another app, i.e. Dexcom app
- Incorrect Dexcom G6 transmitter serial number
- Electronic background noise interference, e.g. the use of a mobile phone signal booster or a close proximity of WiFi router may affect connectivity

Solution

- Check Bluetooth is turned on in your smart device settings
- Turn Bluetooth off and on
- Check "Location" is set to "On" in your smart device privacy/security settings
- Restart your smart device
- If linking for the first time, check transmitter not already linked to Dexcom app; unlink and try again

13 Failure modes and troubleshooting

Transmitter already linked with CamAPS FX

- Unpair the transmitter in Bluetooth settings on the phone: *Settings > Connections> Bluetooth > Paired devices > Dexcom device Settings > Unpair*

- Enter Dexcom transmitter serial number into CamAPS FX app: *Main Menu > Dexcom G6;* wait a while

- If all above fails after several tries, link **Dexcom G6 receiver** or **Dexcom app** to the transmitter to check that it works

  Note*:* Only one app, Dexcom app or CamAPS FX app, can connect to the Dexcom transmitter at any one time, while Dexcom G6 receiver and CamAPS FX app can be connected at the same time

The app losing communication with G6 transmitter

Likely Cause

- Use of unapproved Android smart device/phone

- High level of electronic background noise interferes with connection

Solution

- Keep your transmitter and the smart device within 20 feet / 6 metres of each other; if you are showering or swimming keep them closer as the Bluetooth range is reduced in water; wait 30 minutes

- Reduce the level of electronic background noise – it may be helpful to restart the smart device every few days to improve connectivity

- Follow solutions in "Unable to link the app with Dexcom G6 transmitter"

No G6 readings for the last 20 minutes: "No Readings" alert

Likely cause

- Sensor error or sensor failure

- G6 transmitter not providing sensor signal

Solution

- Tap on the information icon in the message alert window to get more information

- Make sure your sensor is secure and G6 transmitter is snapped flat in its holder

No G6 readings for the last 20 minutes: "Signal Loss" alert

Likely cause

- G6 transmitter not communicating with your smart device

Solution

- Keep your transmitter and your smart device within 20 feet / 6 metres of each other; wait 30 minutes
- Turn Bluetooth on and off on your smart device; wait 10 minutes
- Restart your smart device and reopen CamAPS FX app
- Follow solutions in "The app losing communication with G6 transmitter"

New sensor not starting

Likely cause

- Previous sensor not stopped in the CamAPS FX app
- Sensor ended prematurely or fell out

Solution

- Stop previous sensor in the app: *Main Menu > Stop sensor*
- Wait for "Start Warm up" message to appear on the Home Screen

mylife YpsoPump

General guidelines and troubleshooting about mylife YpsoPump, are provided in the pump's user manual. The following section covers issues related to the use of the pump from within the CamAPS FX app.

Unable to link the insulin pump to the CamAPS FX app

Likely cause

- Bluetooth communication issues:
  - Your smart device Bluetooth not working
  - Pump Bluetooth not working
  - High level of electronic background noise interferes with connection
- Internet connection issues:
  - Your smart device lost connection to the internet and is unable to confirm if your pump is registered
- Other issues:
  - Privacy/security settings of your smart device
  - Unregistered pump used

Solution

- Update the CamAPS FX app to the latest version; check for updates on app store

- Check Bluetooth is turned on in your smart device settings; turn Bluetooth off and on again

- Check your smart device is connected to the internet by opening a known website in browser

- Check Bluetooth is turned on in the pump, i.e. the pump is not in "flight mode"

- Check "Location" is turned on in the privacy/security settings on your smart device

- Initiate bolus calculator using the CamAPS FX app and observe if pump connection is established

- Try re-linking the pump; make sure to confirm the linking on the pump screen

- If still unsuccessful, restart your smart device and try again

App losing communication with the insulin pump

Likely cause

- Bluetooth communication between the pump and your smart device interrupted

- Internet connection is required at least once every 30 days in order to stay connected.

- Pump too far away from your smart device

Solution

- Check Bluetooth is turned on your smart device; turn it off and on

- Check your smart device is connected to the internet by opening a known website in browser

- Initiate bolus calculator on the CamAPS FX app and observe if pump connection is established

- Restart your smart device and reopen the app

- Try re-linking the pump: make sure to confirm the linking on the pump screen

- Remove pump battery and reinsert after a few minutes

Glooko[2]

Unable to link Glooko account to CamAPS FX app

Likely cause

- No internet connection

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[2] Also applicable to other cloud upload portals compatible with the CamAPS FX and available in Canada

13 Failure modes and troubleshooting

- Incorrect login details
- Unregistered Glooko account

Solution

- Make sure your smart device is connected to the internet; confirm the connection by opening a known website
- If not already registered, create a personal account on Glooko website
- Log in to Glooko website with your personal account

14   APPENDIX A SUPPORTED INSULIN PUMPS

The following insulin pumps are supported:

- mylife YpsoPump (Ypsomed, Switzerland)
- Virtual pump
- Companion

mylife YpsoPump specific instructions

- Use mylife YpsoPump compatible with CamAPS FX (consult insulin pump instructions for use).
- Bolus calculator settings must be entered on the CamAPS FX app.
- mylife YpsoPump pump will become unlinked from the app if the pump is linked to another app such as mylife App. If you want to continue to use the pump, you must reinitiate linking the pump by tapping **Main Menu > mylife YpsoPump**.
- During "Auto mode", delayed bolus initiated manually by the user will be stopped. When in "Auto mode", apply standard boluses to bolus for meals and snacks.
- The maximum recommended distance between the smart device hosting CamAPS FX app and the pump is 5 to 10 metres or 16 to 30 feet.
- Internet connection is required at least once every 30 days in order to stay connected.

Virtual pump specific instructions

- Virtual pump should be used for **training and demonstration purposes** only.
- Not all CamAPS features are available when using virtual pump.
- No insulin is actually administered.

Companion specific instructions

- "Companion" is used to display data from a pump and glucose sensor worn by another person.
- The other person must invite you to view his/her data, see "Companion remote monitoring" section of this User Manual.
- When using "Companion", not all CamAPS FX features are available. Data cannot be shared, data entry and control of the actual insulin pump is not possible.
- You can set up your own alarms and alerts.

- Data are received using end-to-end encryption.
- Internet connectivity is required to receive the data.
- The top of the Home Screen shows the name of the person whose data are being displayed.
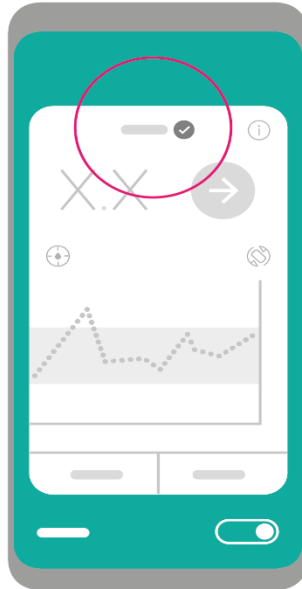
- When no data are received for more than 12 minutes, a disconnect icon is shown next to the name of the person whose data are being followed. Tapping on the icon shows the last time data have been received.
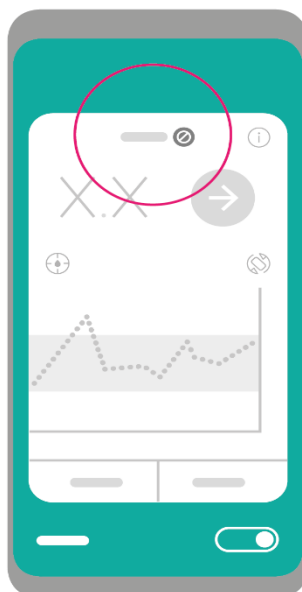
15   APPENDIX B SUPPORTED CGM SYSTEMS

The following CGM systems are supported:

- Dexcom G6 (Dexcom, San Diego, CA, USA)
- Virtual CGM

Dexcom G6 specific instructions/information

- The maximum recommended distance between the smart device hosting CamAPS FX app and the Dexcom G6 transmitter is 6 metres or 20 feet.
- When starting a new sensor, you must enter the sensor code into your smart device to use G6 sensor without fingerstick calibrations; if you do not enter the sensor code you will be expected to calibrate the sensor every 12 hours.
- When calibrating the sensor, calibrations must be entered within 5 minutes of taking fingerstick glucose measurement.
- Before utilizing Dexcom G6 continuous glucose monitoring readings to inform the bolus calculator and administer bolus insulin, please consult Dexcom G6 user manual for guidance on the appropriateness of utilizing continuous glucose monitoring readings for treatment decisions.
- G6 sensor reading updates every 5 minutes.

Note: The Dexcom G6 app cannot be used while using the CamAPS FX app. This is due to the restriction of the Dexcom G6 transmitter being connected to a single app/smart device.

Virtual CGM specific instructions/information

- A virtual CGM should be used for **demonstration and training purposes** only.
- No alerts and alarms will be sounded.
- Not all CGM features will be available. For example, you will not be able to start and stop sensor.

16 APPENDIX C SUPPORTED CLOUD UPLOAD PORTALS

The following cloud upload portals are supported:

- Glooko
- mylife Cloud

17 APPENDIX D CLINICAL BENEFITS

Summary

The CamAPS FX app uses a control algorithm which has been evaluated in a series of randomised clinical studies to assess its safety and efficacy [1]. Early clinical studies focused on iterative enhancements and optimisation of algorithm performance. This was followed by longer clinical studies demonstrating improved glucose control and reduced burden of diabetes [2-4]. The use of the control algorithm led to increased time when sensor glucose was in the target range, reduced glycated haemoglobin, reduced mean sensor glucose and reduced time when glucose was in the hypoglycemia range. These benefits were particularly pronounced overnight.

Key clinical study - APCam11

The APCam11 study was a multinational study evaluating day-and-night closed-loop insulin delivery in the home setting in youth and adults, aged 6 years and above with sub-optimally controlled type 1 diabetes [3].

Study participants

All participants had type 1 diabetes for at least one year, were on insulin pump therapy for at least three months, and had glycated haemoglobin between 7.5% and 10% (58 to 86 mmol/mol). Participants were at least six years old with an equal proportion of youths between six and 21 years, and adults aged 22 years and older. Key exclusion criteria included regular use of real-time continuous glucose monitoring in preceding three months, history of one or more episodes of severe hypoglycemia in preceding six months, and significantly reduced hypoglycemia awareness in subjects aged 18 years and older defined by Gold score of greater than four.

Eligible adults were identified from diabetes clinics attending Addenbrooke's Hospital (Cambridge, UK), Manchester Royal Infirmary (Manchester, UK), International Diabetes Center at Park Nicollet (Minneapolis, USA), and Barbara Davis Center for Childhood Diabetes (Aurora, USA). Children and adolescents were recruited from paediatric diabetes centres at Addenbrooke's Hospital (Cambridge, UK), Royal Hospital for Sick Children (Edinburgh, UK), Leeds Teaching Hospital (Leeds, UK), and the International Diabetes Center at Park Nicollet, (Minneapolis, USA).

Study design and procedures

The study had an open-label, multi-centre, multi-national (UK, USA), randomised, one-period, parallel design contrasting day-and-night hybrid closed-loop (closed-loop group) and sensor-augmented pump therapy (control group) during free-living over 12 weeks.

Participants in both study groups used modified 640G insulin pump (Medtronic, Northridge, CA, USA), Enlite 3 glucose sensor (Medtronic), and Contour Next Link 2.4 glucometer (Ascensia Diabetes Care, Basel, Switzerland). Participants were not remotely monitored or supervised. They were free to consume any meals of their choice and were allowed to choose any indoor or outdoor physical activity. Blood samples were drawn for glycated haemoglobin measurements at enrolment, before and after each treatment period.

On enrolment following training on the study pump and continuous glucose monitoring, participants underwent at least a 4-week run-in period. Eligible subjects were randomised using randomisation software to the use of day-and-night hybrid closed-loop or sensor-augmented pump therapy.

Participants randomised to the closed-loop group attended the clinical research facility for a two- to three-hour visit. Training was provided on initiation and discontinuation of the hybrid closed-loop system which comprised the CamAPS FX control algorithm running on a lockdown Android smartphone, switching between closed-loop and standard insulin pump therapy, meal bolus procedure, and the use of study devices during exercise. After discharge, participants applied the closed-loop system for the following 12 weeks.

Participants randomised to the control group (sensor-augmented insulin pump therapy), received additional training on the effective use of real-time continuous glucose monitoring for optimisation of insulin therapy. Participants were instructed not to activate pump's threshold suspend or predictive low-glucose features. Participants were free to optimise their treatment independently or on advice from health care professionals.

Table 1. Baseline characteristics of study participants.

	Closed-loop (N=46)	Control (N=40)
Sex no.(%)		
Female	22 (48)	22 (55)
Male	24 (52)	18 (45)
Age (years)	22 (13 to 36)	21 (11 to 36)

Age subgroup no.(%)
  6-<13 yr
  13-<22 yr
  22-<40 yr
  >40yr
	11(24)
	11(24)
	18(39)
	6(13)
		12(30)
		8(20)
		14(35)
		6(15)

BMI (for age>20)	28 ± 4 (N=24)	27 ± 3 (N=21)
BMI* Z Score (for age≤20)	0.70±0.92 (N=22)	0.69±0.86 (N=19)
Duration of diabetes (years)	13 (7 to 20)	10 (7 to 19)
Total daily insulin dose (U/kg/day)	0.62±0.15	0.89±0.24

Glycated haemoglobin at screening
  (mmol/mol)
  (%)
	
	67±7
	8.3±0.6
		
		66±6
		8.2±0.5

Data are mean (SD) or median (IQR), unless otherwise stated
*BMI z-score adjusted for age and gender based on 2000 CDC growth charts

Results

86 eligible participants were randomised, 46 participants assigned to the closed-loop group and 40 participants to the control group. Of those, 43 participants were 22 years and older, 19 were 13 to 21 years old, and 33 were 6 to 12 years old. Baseline characteristics are shown in Table 1.

The proportion of time when sensor glucose was in the target range between 3.9 and 10.0 mmol/L, was 10.8 percentage points higher (95% CI 8.2 to 13.5 percentage points, p<0.001) in the closed-loop group (65±8%, mean±SD) than in the control group (54±9%) (Table 2). Improvements in time in range did not differ among the three age groups (< 13 years, 13 to 22 years, ≥22 years). All participants in the closed-loop group experienced an improvement in percentage time spent with glucose levels in target range compared to run-in period.

In both groups, glycated haemoglobin reduced from a screening value (closed-loop: 8.3±0.6%; control: 8.2 ± 0.5%) to post run-in assessment (closed-loop: 8.0±0.6%; control: 7.8±0.6%). Glycated haemoglobin levels were significantly lower post closed-loop intervention (7.4 ± 0.6%) compared to control intervention (7.7±0.5%) with a mean difference between groups favouring the closed-loop group by 0.36% (95% CI, 0.19% to

0.53%; p<0.001). Glycated haemoglobin improvements were not different among children, adolescents and adults.

Day-and-night closed-loop significantly reduced mean glucose (p<0.001) and time spent above target (p<0.001) compared to the control group. Glucose variability measured as the standard deviation of sensor glucose was lower in the closed-loop group (p<0.001). The coefficient of variation of sensor glucose was not different between groups (p=0.5).

Closed-loop significantly reduced the percentage of time sensor glucose was below 3.9 mmol/L (p=0.008). The percentage of time spent with sensor readings below 3.5 mmol/L and below 2.8 mmol/L were low and not different between interventions.

Increased time when glucose was in target range, reduced mean glucose, reduced time when glucose was below target, and a reduction in glycated haemoglobin was brought about by closed-loop without significantly increasing total daily insulin (p=0.09). Higher basal insulin delivery during closed-loop (p<0.001) was offset by lower bolus delivery (p<0.001) presumably due to lower glucose levels resulting in a reduced amount of insulin delivered as correction boluses. There was no significant between-group difference in the change of body weight from the screening value (2.2±2.3 vs. 1.4±2.6, closed-loop vs. control; p=0.19).

Adverse events

After randomisation, no severe hypoglycemia occurred in either study group. One diabetic ketoacidosis presented in closed-loop group due to infusion set failure and was not closed-loop related. Two participants in each study group experienced significant hyperglycemia with capillary glucose greater than 16.7 mmol/L and elevated plasma ketones (>0.6 mmol/L). There were other 13 adverse events in the closed-loop group and 3 in the control group. All participants recovered fully without clinical sequelae.

Table 2. Comparison of day-and-night glucose control during closed-loop and control periods.

	Baseline		12 weeks			
	Closed-loop (N=46)	Control (N=40)	Closed-loop (N=46)	Control (N=40)	Difference (95% Confidence Interval)*	P value*
Time spent at glucose level in range (%)						
3.9 to 10.0 mmol/L	**62 ± 10**	**52 ± 9**	**65 ± 8**	**54 ± 9**	**+10.8 (+8.2 to +13.5)**	**<0.0001**
< 3.9 mmol/L	3.5 (2.0 to 5.4)	3.3 (1.2 to 5.5)	2.6 (1.9 to 3.6)	3.9 (1.7 to 5.3)	-0.83 (-1.40 to -0.16)‡	0.0130
< 3.5 mmol/L	1.8 (0.8 to 3.2)	1.9 (0.6 to 3.3)	1.4 (0.9 to 1.9)	2.0 (0.9 to 3.0)	-0.33 (-0.81 to +0.04)‡	0.08
<2.8 mmol/L	0.4 (0.1 to 1.0)	0.5 (0.1 to 1.0)	0.3 (0.2 to 0.6)	0.5 (0.2 to 0.9)	-0.09 (-0.24 to +0.01)‡	0.11
>10.0 mmol/L	44 ± 11	44 ± 11	32 ± 8	42 ± 10	-10.3 (-13.2 to +7.5)	<0.0001
>16.7 mmol/L	5.5 (3.3 to 8.3)	4.9 (2.7 to 7.3)	3.5 (1.9 to 4.6)	4.4 (2.9 to 6.5)	-1.42 (-2.20 to -0.69)‡	<0.0001
Glycated haemoglobin (%)	8.0 ± 0.6	7.8 ± 0.6	7.4 ± 0.6	7.7 ± 0.5	-0.36 (-0.53 to -0.19)	<0.0001
Glycated haemoglobin (mmol/mol)	63 ± 7	62 ± 6	57 ± 7	60 ± 6	-4.0 (-5.8 to -2.2)	<0.0001
Mean glucose (mmol/L)	9.8 ± 1.1	9.8 ± 1.1	8.9 ± 0.7	9.7 ± 1.0	-0.82 (-1.06 to -0.57)	<0.0001
Glucose SD (mmol/L)	3.9 ± 0.5	3.8 ± 0.5	3.5 ± 0.5	3.8 ± 0.5	-0.35 (-0.48 to -0.22)	<0.0001
Glucose CV (%)	40 ± 5	39 ± 5	40 ± 4	40 ± 4	-0.4 (-1.4 to +0.7)	0.5
Total daily insulin (U/kg/day)	0.75 ± 0.22	0.70 ± 0.18	0.81 ± 0.25	0.71 ± 0.19	+0.031 (-0.005 to +0.067)	0.09
Total daily basal insulin (U/kg/day)	0.32 ± 0.07	0.31 ± 0.08	0.46 ± 0.13	0.32 ± 0.10	+0.124 (+0.099 to +0.150)	<0.0001
Total daily bolus insulin (U/kg/day)	0.43 ± 0.19	0.39 ± 0.14	0.34 ± 0.17	0.39 ± 0.13	-0.087 (-0.114 to -0.060)	<0.0001
Body weight change from screening (kg)			2.2 ± 2.3	1.4 ± 2.6	+0.68 (-0.34 to +1.69)	0.19

Data are mean (SD) or median (IQR)
* Difference is "Closed-loop minus Control"

Conclusions

This multinational, multi-centre, open-label, randomised trial demonstrated that 12-week use of a day-and-night hybrid closed-loop insulin delivery system compared to sensor-augmented insulin pump therapy was associated with an improvement in overall glucose control and a reduction in hypoglycemia risk in sub-optimally controlled type 1 diabetes including children, adolescents and adults. The hybrid closed-loop system was used safely during daily living without supervision or remote monitoring.

The study reports a 10.8 percentage point increase in time with glucose levels in target glucose range across all age groups. This improvement resulted from a reduction of time spent in hyperglycemia without change in total insulin delivery. The study observed a lower amount of bolus insulin and a higher amount of basal insulin in the closed-loop group compared to the control group. Lower bolus insulin requirements could be explained by lower glucose levels during closed-loop use lessening the need for correction boluses. Insulin to carbohydrate ratio did not need to be increased. Benefits of closed-loop appeared greater overnight as daytime control is confounded by meals and physical activity even with the use of a closed-loop system. These improvements are attributable to the use of the closed-loop system alone as no regular health-care professional driven adjustments of insulin pump therapy took place.

Key clinical study – KidsAP02

The KidsAP02 study was a multinational study evaluating day-and-night hybrid closed-loop insulin delivery in the home setting in young children, aged 1 to 7 years with type 1 diabetes and comparing it to sensor-augmented pump therapy [5].

Study participants

Key inclusion criteria were type 1 diabetes for ≥6 months, insulin pump therapy for ≥3 months, and screening HbA1c ≤11% (96.7mmol/mol). Participants were aged 1 to 7 years. Key exclusion criteria included current use of closed-loop therapy and concomitant disease affecting metabolic control or interpretation of HbA1c levels.

Study design and procedures

The study adopted an open-label, multicenter, multinational, randomized, crossover design comparing 16-week use of hybrid closed-loop insulin delivery followed by 16-week use of sensor-augmented pump therapy, or vice versa. Participants were recruited from outpatient clinics at diabetes centers in the UK (Cambridge, Leeds), Austria (Graz, Innsbruck, Vienna), Germany (Leipzig), and Luxembourg (Luxembourg).

The hybrid closed-loop system comprised an unlocked smartphone hosting CamAPS FX app, which ran the Cambridge model predictive control algorithm (version 0.3.71). CamAPS FX communicated wirelessly with the Dana Diabecare RS insulin pump (Sooil, South Korea), and Dexcom G6 transmitter (Dexcom, USA).

The CamAPS FX app was used during both study periods. During the sensor-augmented pump therapy period, closed-loop functionality was disabled.

Participants were screened for eligibility, including HbA1c measurement. Following enrolment, parents/guardians were trained on the use of the study glucose sensor, study insulin pump, and the CamAPS FX app. The app was used in open-loop mode for two to four weeks during run-in. Investigators were free to adjust insulin therapy according to clinical judgement prior to randomization. A minimum of 8 days of sensor data and demonstrated safe use of study devices was required for a child to be eligible for randomization.

Following randomization, the parents/guardians of participants allocated to initial use of closed-loop insulin delivery were trained on the use of the closed-loop system, while those

allocated to initial use of sensor-augmented pump therapy received refresher training. Participants used their allocated initial treatment for 16 weeks, following which participants crossed over to the second study arm after 1 to 4 weeks washout.

Results

Overall, 74 children were randomized (mean±SD age 5.6±1.6 years, baseline HbA1c 7.3±0.7% (56.6 ± 7.2mmol/mol) (Table 3). There was one post-randomization withdrawal; that participant withdrew after commencing sensor-augmented pump therapy in the first period due to difficulties accessing study consumables at their local clinic.

The study endpoints for all randomized participants are shown in Table 4. The time in target range 3.9 to 10mmol/L was 8.7 percentage points (95% confidence interval [CI] 7.4 to 9.9; p<0.001) higher in the 16-week closed-loop period compared to the 16-week sensor-augmented pump (SAP). The time in hyperglycemia (>10mmol/L) was 8.5 percentage points (95% CI 7.1 to 9.9; p<0.001) lower in closed-loop compared to the SAP period. At the end of the closed-loop period, HbA1c was 0.4% ([3.9mmol/mol], 95% CI 0.3 to 0.5 [2.9 to 4.9]; p<0.001) lower compared to the SAP period. Mean sensor glucose was 0.7mmol/L (95% CI 0.5 to 0.8; p<0.001) lower in closed-loop period. The time in hypoglycemia <3.9mmol/L, which was not different between interventions (p=0.74).

Percentage time with glucose <3.5mmol/L and <3.0mmol/L was not different between interventions (Table 4). Time in hyperglycemia >16.7mmol/L was 1.0% (95% CI 0.6 to 1.6) lower in closed-loop compared to SAP period. Glucose variability as measured by standard deviation of glucose was lower in closed-loop period (3.3 vs 3.6mmol/L), but there was no difference in the coefficient of variation of glucose between closed-loop and SAP periods.

While total daily insulin dose was similar between treatment periods, basal insulin dose, i.e., insulin delivered by the closed-loop algorithm, was higher during closed-loop compared to SAP period, with a reduction in bolus insulin dose (Table 4).

Glucose sensor use was high in both treatment periods at >99% (99%, >99%) in closed-loop and 96% (94%, 97%) in SAP period. In the closed-loop period, closed-loop was used for 95% (92%, 97%) of the time.

Table 3. Characteristics of study participants at baseline (KidsAP02 study).

	Overall	Closed-loop first	Sensor-augmented pump first
No. of participants	**74**	**39**	**35**
Age, years			
Mean	5.6 ± 1.6	5.5 ± 1.5	5.6 ± 1.7
Range	2.3 to 7.9	2.5 to 7.9	2.3 to 7.9
2-<5 years	27 (36%)	14 (36%)	13 (37%)
5-<7 years	29 (39%)	17 (44%)	12 (34%)
7-<8 years	18 (24%)	8 (21%)	10 (29%)
Sex, n (%)			
Female	31 (42)	21 (54)	10 (29)
Male	43 (58)	18 (46)	25 (71)
Ethnicity, n (%)			
White	66 (89)	34 (87)	32 (91)
Black / African-American	2 (3)	2 (5)	0 (0)
Asian	2 (3)	1 (3)	1 (3)
Native Hawaiian/Other Pacific Islander	0 (0)	0 (0)	0 (0)
More than one race	4 (5)	2 (5)	2 (6)
Unknown / Not reported	0 (0)	0 (0)	0 (0)
Duration of diabetes, years [range]	2.6 ± 1.8 [0 to 6]	2.5 ± 1.7 [0 to 6]	2.7 ± 1.9 [0 to 6]
Glycated hemoglobin at screening %	7.3 ± 0.7	7.3 ± 0.7	7.4 ± 0.6
[mmol/mol]	[56.6 ± 7.2]	[56.3 ± 7.4]	[57.0 ± 7.1]
Total daily insulin dose (U/kg/day)	0.76 (0.67 to 0.85)	0.76 (0.67 to 0.83)	0.77 (0.69 to 0.86)
Age-gender adjusted BMI percentile	69.1% ± 23.8%	67.3% ± 23.2%	71.1% ± 24.6%
Use of continuous glucose monitor, n (%)			
Current	67 (91)	35 (90)	32 (91)
In past, but not current	1 (1)	0 (0)	1 (3)
Never	6 (8)	4 (10)	2 (6)
CGM metrics at baseline			
Time in range 3.9-10mmol/L (%)	61.2 ± 10.1	61.5 ± 9.5	60.8 ± 10.9
Mean sensor glucose (mmol/L)	9.0±1.2	9.0±1.2	9.0±1.2
Glucose SD (mmol/L)	3.7 (3.2 to 4.1)	3.7 (3.3 to 4.1)	3.7 (3.1 to 4.3)
Coefficient of variation (%)	41.6 (36.7 to 44.5)	42.4 (36.9 to 45.0)	41.1 (36.6 to 43.9)
Percentage time with sensor glucose (%)			
>10mmol/L	34.4 (24.0 to 42.2)	32.2 (24.0 to 42.7)	36.7 (21.6 to 41.8)
>16.7mmol/L	3.7 (1.8 to 7.9)	3.4 (2.0 to 7.9)	3.8 (1.2 to 8.5)
<3.9mmol/L	4.4 (2.3 to 7.0)	4.5 (2.4 to 6.7)	3.9 (2.0 to 7.4)
<3.0mmol/L	0.7 (0.3 to 1.6)	0.8 (0.2 to 1.8)	0.6 (0.3 to 1.4)

Data are n (%), mean ± SD, or median (IQR).

Adverse events

One severe hypoglycemic event occurred in the closed-loop period. The event occurred as a result of a very low nocturnal personal glucose target and parents not responding to hypoglycemia alarms over the 3 hours prior to the event. The closed-loop system functioned as intended. There were no episodes of diabetic ketoacidosis. One non-treatment related serious adverse event (hospital admission for gastroenteritis) occurred in the SAP period.

Conclusions

The KidsAP02 study demonstrated that the Cambridge hybrid closed-loop algorithm significantly improves glycemic control over 16-weeks compared with sensor-augmented pump therapy in very young children with type 1 diabetes, and with an acceptable safety profile. The HbA1c reduction of 0.4% (3.9mmol/mol) is important in a population that had tight glycemic control at baseline. This result was achieved without an increase in hypoglycemic episodes.

The result of 71.6±5.9% time in target range 3.9 to 10mmol/L in the closed-loop group is similar to other studies in very young children but was sustained over 16-weeks of home use. The increase of 8.7 percentage points in the time in target range translates to a clinically meaningful 125 minutes per day.

The study was of sufficient duration to report HbA1c outcomes in the very young participants who used the hybrid closed-loop therapy, and results are similar to those reported in studies of commercially available closed-loop systems in older children and adolescents. Given the low baseline HbA1c the improved levels in the present study are noteworthy, as higher baseline HbA1c levels are associated with greater HbA1c reduction when using hybrid closed-loop therapy. Closed-loop usage was consistently high at 95%, supporting longer-term usability in this age group.

Table 4. Comparison of day-and-night glucose control during closed-loop and sensor-augmented pump therapy (KidsAP02 study).

	Closed-loop (N=73)	Sensor augmented pump therapy (N=74)	Mean adjusted difference (95% Confidence Interval)*	P value
Time spent at glucose level in range (%)				
3.9 to 10 mmol/L	**71.6 ± 5.9**	**62.9 ± 9.0**	**8.7 (7.4 to 9.9)**	**<0.001**
< 3.9 mmol/L	4.9 (3.3 to 6.7)	4.5 (2.9 to 7.3)	0.1 (-0.4 to 0.5)	0.74
< 3.5 mmol/L	2.6 (1.8 to 3.7)	2.4 (1.4 to 4.2)	0.04 (-0.3 to 0.3)	-
< 3.0 mmol/L	1.0 (0.6 to 1.4)	0.9 (0.4 to 1.6)	0.02 (-0.1 to 0.1)	-
> 10 mmol/L	22.9 (19.3 to 27.3)	31.7 (23.4 to 40.1)	-8.5 (-9.9 to -7.1)	<0.001
> 16.7 mmol/L	2.0 (1.2 to 3.1)	3.1 (1.3 to 5.7)	-1.0 (-1.6 to -0.6)	-
HbA1c (%)	6.6 ± 0.6	7.0 ± 0.7	-0.36 (-0.53 to -0.19)	<0.001
[mmol/mol]	[49.0 ± 5.9]	[52.8 ± 7.2]	[-3.9 (-4.9 to -2.9)]	<0.001
Mean glucose (mmol/L)	8.1 ± 0.7	8.9 ± 1.0	-0.7 (-0.8 to -0.5)	<0.001
Glucose SD (mmol/L)	3.3 (3.0 to 3.6)	3.6 (3.2 to 4.0)	0.3 (0.3 to 0.4)	-
Glucose CV (%)	41 (39 to 43)	41 (38 to 44)	-0.7 (-1.5 to 0.05)	-
Total daily insulin (U/day)	16.9 (13.2 to 21.5)	17.6 (13.6 to 20.3)	0.3 (-0.1 to 0.8)	-
Total daily basal insulin (U/kg/day)	8.0 (5.8 to 10.9)	5.7 (4.0 to 6.9)	2.5 (2.1 to 2.9)	-
Total daily bolus insulin (U/kg/day)	8.6 (6.9 to 10.6)	11.0 (9.1 to 13.5)	-2.3 (-2.7 to -1.9)	-

Data are mean ± SD or median (IQR)
* Difference is "Closed-loop minus sensor augmented pump therapy"

Key clinical study - AiDAPT

The AiDAPT study was a multicenter, parallel-group randomized clinical trial evaluating automated insulin delivery with CamAPS FX in the home setting in women with pregnancy complicated by type 1 diabetes [6].

Study participants

The study recruited pregnant women, aged between 18 and 45 years, with a duration of type 1 diabetes of at least 12 months, as soon as possible after ultrasound confirmation of a viable pregnancy and before 14 weeks gestation. Participants using intensive insulin therapy (multiple daily injections or insulin pump) were eligible if they had a glycated hemoglobin level of ≥6.5% during early pregnancy and ≤10% at randomization.

Study design and procedures

This was open-label, multicenter, randomized, controlled trial. The participants were recruited from nine National Health Service sites in England, Scotland and Northern Ireland. Participants were randomized to receive automated hybrid closed-loop insulin delivery (intervention group) or to continue standard intensive insulin therapy (via multiple daily injections or insulin pump) with continuous glucose monitoring (control group).

Participants were screened for eligibility by local clinic teams. All participants provided written informed consent and completed a 4 to 10-day run-in phase to provide a baseline glycemic assessment and to ensure continuous glucose monitoring use was tolerated. Eligible participants were randomized 1-2 weeks after recruitment and before 16 weeks' gestation, to either the "closed-loop system group" or "standard care group".

The hybrid closed-loop system comprised a smartphone (Galaxy S8-12, Samsung) hosting the CamAPS FX app (CamDiab, Cambridge, UK), running the Cambridge model predictive control algorithm (version 0.3.71). The smartphone communicated via Bluetooth with the insulin pump (Dana Diabecare RS, Sooil, South Korea) and continuous glucose monitor (Dexcom G6, Dexcom, CA, USA). Personal glucose targets were user-specified but recommended targets were 5.6mmol/L in early pregnancy, and 4.5-5.0mmol/L from 16-20 weeks' gestation onwards.

In the standard care group, participants continued multiple daily injections or insulin pump therapy with insulin dose adjustment as directed by their local clinical teams aiming for standard glucose targets (pre-meal 3.5-5.6mmol/L and one-hour post meal <7.8mmol/L).

Table 5. Characteristics of study participants at baseline (AiDAPT study).

	Closed-loop (N=61)	Standard care (N=63)
Age (years)	32.0 ± 5.0	30.2 ± 5.5
White race/ethnicity	58 (95%)	57 (90%)
Diabetes duration (years)	18 ± 8	16 ± 7
Maternal BMI (kg/m^2)	27.9 ± 5.9	26.9 ± 4.8
Higher education	36 (59%)	33 (52%)
Recruitment gestation (weeks)	10.3 (8.0 to 11.7)	10.0 (8.4 to 11.3)
Randomization gestation (weeks)	11.3 (9.6 to 13.0)	11.0 (9.6 to 12.4)
Past Diabetes / Medical History		
Diabetes complications	35 (57%)	35 (56%)
Retinopathy	35 (57%)	34 (54%)
Nephropathy	4 (7%)	5 (8%)
Neuropathy	4 (7%)	2 (3%)
Prior diabetic ketoacidosis [a]	1 (2%)	10 (16%)
Prior severe hypoglycemia [b]	4 (7%)	5 (8%)
Pregnancy history		
Primiparous / no previous births [c]	21 (34%)	38 (60%)
Previous pregnancy loss [d]	21 (34%)	20 (32%)
Pre-pregnancy factors		
Folic acid	38 (62%)	34 (54%)
Alcohol	36 (59%)	36 (57%)
Smoking	10 (16%)	14 (22%)
HbA1c during early pregnancy [e]		
≥ 6.0% - <7.0%	23 (38%)	13 (21%)
≥ 7.0% - <8.0%	21 (34%)	24 (38%)
≥ 8.0%	17 (28%)	26 (41%)
Mean ±SD	7.6 ± 1.1	7.9 ± 1.3
Range	6.0 to 11.6	6.5 to 14.0
Continuous glucose monitoring	59 (97%)	62 (98%)
Abbott Freestyle Libre	43 (73%)	47 (76%)
Dexcom CGM	12 (20%)	14 (23%)
Medtronic CGM	4 (7%)	1 (2%)
Insulin delivery		
Insulin pump	32 (52%)	25 (40%)
Multiple daily injections	27 (44%)	37 (59%)
Automated insulin delivery [f]	2 (3%)	1 (2%)
Total daily insulin (U/kg/day)	0.7 ± 0.2	0.7 ± 0.2

Data are n (%); mean ± SD; or median (IQR)
[a] Participants in standard care had more diabetic ketoacidosis events in the 12 months before enrollment
[b] Severe hypoglycemia events defined as requiring third party assistance in the 12 months before enrolment
[c] Participants in closed-loop had more previous births
[d] Includes previous miscarriages and pregnancy terminations
[e] One participant with HbA1c 6.0% was entered during the pandemic whilst experiencing frequent hypoglycemia using an alternative closed-loop (Tandem Control IQ) system
[f] Participants using alternative hybrid closed-loop systems were eligible

Results

A total of 124 participants with a mean age of 31.1 ± 5.3 years and a mean baseline glycated hemoglobin level of 7.7±1.2% were randomized, 61 to closed-loop intervention group and 63 to the standard care control group. Participants were from nine maternity clinics and were representative of the pregnant women with type 1 diabetes in the United Kingdom. The baseline characteristics of the study participants are presented in Table 5.

Almost all (98%) were using continuous glucose monitoring and approximately half were using insulin pump therapy at enrolment. Despite the impact of the Covid-19 pandemic, the proportion of completed study visits was high, ~95% from 16 weeks until delivery. The frequency of sensor use was consistently high, median 97% across both treatment groups. The frequency of closed-loop use was high (median 96%) and remained >95% throughout pregnancy.

The mean (±SD) percentage of time that maternal glucose levels were within the pregnancy target range differed between study arms from 47.8±16.4% to 68.2±10.5% in the closed-loop group and from 44.5±14.4% to 55.6±12.5% in the control group (Table 6). Mean adjusted difference was 10.5% percentage points, 95% CI 7.0% to 14%; P<0.001. There were no variations in the treatment effect among trial sites, and no differential effects across maternal age, glycated hemoglobin or insulin delivery categories.

Participants randomized to closed-loop spent less time with glucose levels above target range (mean difference -13.8% to -6.6%) (Table 6). The effects of the intervention during the overnight period (23.00 - 07.00) closely followed the 24-hour results (mean difference 12.3%; 95% CI 8.3% to 16.2%). This was accompanied by improved control in the closed-loop group including, lower mean glucose, lower glycated hemoglobin and fewer nocturnal hypoglycemic events, notable since participants spent ~70% time in the near-optimal (3.5-10mmol/L) target range at baseline (Table 6). Furthermore, participants who started closed-loop therapy during the first trimester had 5% higher time-in-range by the end of 12 weeks gestation.

Attainment of the sensor glucose target of >70% time (16 hours 48 mins) within the pregnancy-specific range was achieved by 28 (47%) closed-loop and 7 (11%) standard-care participants. Maternal glucose improvements were achieved with lower glucose targets (from 5.7±0.1 to 5.2±0.3 mmol/L) across gestation and without additional hypoglycemia, weight gain or total daily insulin dose.

Table 6. Primary and secondary maternal outcomes (AiDAPT study).

	Baseline [a]		Antenatal intervention phase [b]		Adjusted difference [c] (95% Confidence Interval)	P-value [c]
	Closed-loop (N=59)	Standard care (N=59)	Closed-loop (N=59)	Standard care (N=61)		
Time in range 3.5-7.8mmol/L (%) [d]	**47.8 ± 16.4**	**44.5 ± 14.4**	**68.2 ± 10.5**	**55.6 ± 12.5**	**10.5 (7.0, 14.0)**	**<0.001**
Key secondary endpoints						
Time >7.8mmol/L (%)	48.7 ± 18.0	51.8 ± 16.2	29.2 ± 10.6	41.4 ± 13.2	-10.2 (-13.8 to -6.6)	-
Overnight time in range 3.5-7.8mmol/L (2300-0700) (%)	47.4 ± 20.8	44.5 ± 16.6	70.8 ± 11.2	56.7 ± 13.6	12.3 (8.3 to 16.2)	-
Secondary endpoints						
Time 3.5-10.0 mmol/l (%)	71 ± 16	68 ± 15	87 ± 9	80 ± 10	6 (3 to 9)	-
Time >10mmol/L (%)	26 ± 17	28 ± 16	11 ± 9	17 ± 11	-6 (-9 to -3)	-
Mean glucose (mmol/L)	8.3 ± 1.6	8.4 ± 1.3	7.0 ± 0.8	7.6 ± 0.9	-0.5 (-0.8, -0.3)	-
Glycated hemoglobin (HbA1c) (%)	7.6 ± 1.1	7.9 ± 1.3	6.0 ± 0.5	6.4 ± 0.5	-0.31 (-0.50 to -0.12)	-
Glucose SD (mmol/L)	3.0 ± 0.8	3.1 ± 0.7	2.3 ± 0.6	2.6 ± 0.6	-0.3 (-0.4, -0.1)	-
Glucose CV (%)	36 ± 5	37 ± 6	33 ± 5	34 ± 5	-1.1 (-2.6 to 0.3)	-
Hypoglycemia						
Time < 3.5mmol/L (%)	2.75 (0.86 to 4.87)	2.22 (0.72 to 6.00)	2.26 (1.54 to 3.31)	2.02 (1.25 to 4.37)	-0.4 (-1 to 0.2)	-
Time < 3.0mmol/L (%)	1.05 (0.07 to 2.37)	0.79 (0.18 to 2.28)	0.71 (0.49 to 1.19)	0.73 (0.36 to 1.67)	-0.2 (-0.45 to 0.1)	-
Mild hypoglycemia [e]	6.4 (2.2 to 11.5)	5.5 (2.4 to 11.1)	6.7 (4.6 to 9.4)	5.7 (3.1 to 9.4)	0.2 (-1.1 to 1.4)	-
Moderate hypoglycemia [f]	2.2 (0.0 to 5.7)	2.2 (0.0 to 5.9)	2.3 (1.6 to 3.8)	2.1 (1.1 to 4.4)	0.0 (-0.47 to 0.7)	-

Data are mean ± SD or median (IQR)
[a] Baseline sensor glucose metrics calculated using data from the pre-randomization run-in phase
[b] Antenatal intervention phase is from 16 weeks gestation until delivery. Endpoints are calculated using sensor glucose data except for glycated hemoglobin which was measured at trial sites. The glycated hemoglobin level at 34-36 weeks reflects maternal glycemia over the preceding 10-12 weeks
[c] Difference is "Closed-loop minus standard care". Model adjusted for baseline value, insulin delivery modality, and site as a random effect
[d] Results were similar when adjusting for number of previous DKA events, or previous pregnancies as covariates and when treating site as a fixed effect (mean differernce 10.6% 95% CI 7.0% to 14.1%)
[e] Mild hypoglycemia is sensor glucose <3.5mmol/L for at least 15 consecutive minutes. Episodes separated by 30 minutes
[f] Moderate hypoglycemia is sensor glucose<3.0mmol/L for at least 15 consecutive minutes. Episodes separated by 30 minutes

There was one shoulder dystocia in the closed-loop group. There was one neonatal death and three serious birth injuries in the standard care group. We observed less new-onset hypertension and more repeat cesarean sections (scheduled prior to onset of labor) in the closed-loop group, likely related to their previous pregnancies. Babies of mothers in the closed-loop group were delivered 4.5 days earlier, without differences in preterm births, birthweight, neonatal complications, or neonatal care admissions.

Adverse events

There were six severe hypoglycemia events in the closed-loop group, and five in standard care. There was one diabetic ketoacidosis event in each group. One participant with severe hyperemesis experienced 20 non-acidotic ketosis events. She did not use closed-loop between 16 weeks and delivery but contributed to more ketosis and serious adverse events in the closed-loop group. The rate of adverse device events for the closed-loop system was 24.3 per 100 person years, with seven events related to closed-loop use and seven to the continuous glucose sensor.

Conclusions

We found that the percentage of time that glucose levels were within the pregnancy-specific target range of 3.5 to 7.8 mmol/L from 16 weeks gestation until delivery was 10.5 percentage points higher (additional 2.5 hours per day) in participants assigned to closed-loop, compared to those assigned to continuous glucose monitoring alongside their usual insulin-delivery method. The time-in-range benefits were achieved by reducing maternal hyperglycemia and increasing nocturnal time-in-range. Improvements in glucose outcomes were consistent across baseline maternal age, glycemic categories, clinical sites and pre-trial insulin delivery method.

Furthermore, there was no increase in gestational weight gain or maternal insulin doses. The incidence of hypoglycemia was low at baseline, and apart from nighttime reductions, did not differ between groups. A five-percentage point increased time-in-range was apparent by the end of the first trimester, suggesting that the benefits occurred soon after closed-loop initiation (~12 weeks gestation), which is crucially important for women and clinicians considering therapeutic changes during early pregnancy.

In conclusion, hybrid closed-loop with CamAPS FX was effective in pregnancy complicated by type 1 diabetes, accommodating the marked gestational changes in insulin doses in study participants.

Glucose outcomes according to personal target

In a real-world analysis of 8,604 users, sensor glucose outcomes were calculated and stratified by the glucose target values (Table 7).

The mean time in range between 3.9 and 10.0 mmol/L gradually decreased from 81% for targets less than 5.0 mmol/L (minimum target) to 54% for targets 10.0 - 11.0 mmol/L (maximum target), with the default target achieving 72%. Similarly, the median time below range (<3.9 mmol/L) gradually decreased from 3.9% to 0.7%, with the default glucose target achieving 2.0%.

In general, for the same glucose target, paediatric users had slightly higher mean sensor glucose values and lower time in range compared to adult users.

Table 7. CGM outcomes according to personal glucose target (using real world data)

	All users (N=8,604)	Young children aged 2-6 years (N=799)	Pre-pubertal children aged 7 to 13 years (N=1,113)	Teenagers aged 14 to 17 years (N=624)	Adults ≥18 years (N=6,068)
Age (yr)	32 ± 19	5 ± 1	10 ± 2	15 ± 1	41 ± 14
Amount of 24-hour CGM data per participant (days)	89 (58 to 119)	91 (58 to 124)	90 (58 to 124)	80 (54 to 109)	90 (59 to 118)
Number of participants using given target - N					
<5.0 mmol/L	378	29	37	17	295
5.0-5.5 mmol/L	1,407	138	191	93	985
5.6-6.9 mmol/L	6,411	648	870	437	4,456
7.0-7.9 mmol/L	1,940	377	337	93	1,133
8.0-8.9 mmol/L	879	185	124	38	532
9.0-9.9 mmol/L	224	48	26	6	144
10.0-11.0 mmol/L	230	36	19	5	170
Total amount of 24-hour CGM data using given target – days (%)					
<5.0 mmol/L	12,535 (2%)	700 (1%)	1,331 (2%)	446 (1%)	10,058 (3%)
5.0-5.5 mmol/L	56,802 (10%)	4,324 (8%)	8,446 (11%)	3,702 (11%)	40,330 (10%)
5.6-6.9 mmol/L	404,706 (73%)	34,343 (60%)	54,155 (72%)	26,311 (77%)	289,897 (74%)
7.0-7.9 mmol/L	59,135 (11%)	11,863 (21%)	9,119 (12%)	2,913 (9%)	35,240 (9%)
8.0-8.9 mmol/L	16,419 (3%)	4,093 (7%)	1,869 (2%)	683 (2%)	9,774 (3%)
9.0-9.9 mmol/L	3,419 (<1%)	814 (1%)	532 (<1%)	138 (<1%)	1,936 (<1%)
10.0-11.0 mmol/L	3,179 (<1%)	691 (1%)	263 (<1%)	61 (<1%)	2,165 (<1%)
Time in range 3.9-10.0 mmol/L when using given target (%)					
<5.0 mmol/L	81 ± 12	74 ± 11	76 ± 11	77 ± 12	82 ± 12
5.0-5.5 mmol/L	77 ± 12	71 ± 13	74 ± 11	74 ± 14	79 ± 12
5.6-6.9 mmol/L	72 ± 12	65 ± 12	70 ± 11	71 ± 13	73 ± 12
7.0-7.9 mmol/L	66 ± 15	63 ± 13	66 ± 15	67 ± 15	67 ± 15
8.0-8.9 mmol/L	62 ± 17	58 ± 15	60 ± 17	65 ± 16	64 ± 17
9.0-9.9 mmol/L	56 ± 19	55 ± 14	54 ± 13	63 ± 23	56 ± 21
10.0-11.0 mmol/L	54 ± 19	54 ± 16	49 ± 20	52 ± 40	54 ± 19

Mean glucose when using given target (mmol/L)					
<5.0 mmol/L	7.2 ± 1.1	7.9 ± 0.8	7.6 ± 1.0	7.5 ± 1.4	7.0 ± 1.0
5.0-5.5 mmol/L	7.7 ± 1.1	8.1 ± 1.1	7.9 ± 1.0	8.0 ± 1.3	7.6 ± 1.1
5.6-6.9 mmol/L	8.3 ± 1.1	8.7 ± 1.2	8.5 ± 1.1	8.4 ± 1.3	8.3 ± 1.1
7.0-7.9 mmol/L	8.9 ± 1.3	9.0 ± 1.2	8.8 ± 1.4	8.9 ± 1.6	8.9 ± 1.3
8.0-8.9 mmol/L	9.2 ± 1.5	9.4 ± 1.5	9.4 ± 1.6	9.1 ± 1.3	9.1 ± 1.5
9.0-9.9 mmol/L	9.8 ± 1.6	9.8 ± 1.6	10.0 ± 1.7	9.2 ± 1.3	9.8 ± 1.7
10.0-11.0 mmol/L	9.9 ± 1.9	9.9 ± 1.7	10.5 ± 2.3	10.8 ± 3.9	9.8 ± 1.8
Time <3.9 mmol/L when using given target (%)					
<5.0 mmol/L	3.9 (2.3 to 6.4)	4.7 (2.1 to 6.8)	5.0 (3.2 to 7.2)	4.4 (1.9 to 6.3)	3.7 (2.3 to 6.1)
5.0-5.5 mmol/L	2.8 (1.6 to 4.4)	3.8 (2.7 to 5.7)	3.3 (2.1 to 4.9)	2.4 (1.4 to 3.8)	2.5 (1.4 to 4.1)
5.6-6.9 mmol/L	2.0 (1.1 to 3.2)	3.2 (1.9 to 4.7)	2.6 (1.6 to 3.9)	2.1 (1.2 to 3.4)	1.7 (1.0 to 2.9)
7.0-7.9 mmol/L	1.4 (0.5 to 2.9)	2.6 (1.3 to 4.3)	2.0 (0.9 to 3.1)	1.6 (0.6 to 2.8)	1.0 (0.3 to 2.1)
8.0-8.9 mmol/L	1.2 (0.3 to 2.9)	2.5 (1.3 to 3.9)	1.8 (0.3 to 3.0)	0.9 (0.2 to 2.1)	0.9 (0.1 to 2.0)
9.0-9.9 mmol/L	0.7 (0.0 to 2.1)	1.9 (0.3 to 3.2)	1.2 (0.1 to 2.7)	0.4 (0.0 to 1.4)	0.2 (0.0 to 1.6)
10.0-11.0 mmol/L	0.7 (0.0 to 2.2)	1.8 (0.2 to 3.1)	1.3 (0.0 to 2.5)	0.9 (0.0 to 1.5)	0.4 (0.0 to 1.9)

Data are mean (SD) or median (IQR)

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18 APPENDIX E EXPLANATION OF UNIVERSAL SYMBOLS

	Refer to Instruction Manual/Booklet
	Warning
	Manufacturer
	Date of manufacture

CamDiab Ltd
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