User Guide

Ver 1.0.x

ALLY HOME

For AgaMatrix Customer Care please contact:

Telephone: 0800 093 1812

Email: customercare@agamatrix.co.uk

In case of emergency, contact your doctor or nurse or emergency medical response.

Caution: Please read all the instructions in this User Guide before using ALLY Home.

Manufacturer: METEDA S.r.l. (METEDA)
Via Antonio Bosio 2 – 00161 Roma – Italy
Product Name: ALLY Home
Version: 1.0.X

Distributor: AgaMatrix Europe Ltd (AgaMatrix)

Harwell Innovation Centre, 173 Curie Avenue, Harwell Oxford, Oxfordshire, OX11 0QG

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Symbols explanation:

2022	Manufacturer
CE	This product fulfils the requirements of the European Regulations 2017/745 on medical devices (MDR).

SYMBOLS RELATED TO DOCUMENTATION

WARNING. Read carefully. FAILURE TO OBSERVE THE FOLLOWING INDICATIONS MAY RESULT IN THE MALFUNCTION OF THE DEVICE AND / OR INJURY TO THE PATIENT.

SYMBOLS RELATED TO THE DEVICE

Company name and full address of the Manufacturer: METEDA Srl
The year of production of the medical device is shown at the bottom of the symbol

Device complying with the requirements established by the EC regulations2017/745 and subsequent modifications (Medical Device in Class IIa) as certified by the Notified Body coded as 0051 (IMQ s.p.a.).

Contents

1   Before you begin

This User Guide contains important safety information about ALLY Home and will help you use it correctly.

ALLY Home can help you manage your diabetes in the following ways:

- Automatic data download – You can download data from the WaveSense JAZZ blood glucose meter and the WaveSense JAZZ WIRELESS blood glucose meters (via the AgaMatrix Diabetes Manager app).
- Manual data entry - You can also enter other values (carbohydrates intake, blood glucose readings, insulin doses) manually.
- Data review – You can conveniently review your diabetes data using reports and graphs.
- Data sharing – Your healthcare professional (HCP) will be able to review your data remotely, to help you manage your diabetes.
- Message exchange – You can exchange messages with your HCP.

IMPORTANT: Do not use the message exchange for emergency communication

1.1   Intended use

ALLY Home is indicated for use by people with diabetes and their caregivers.

ALLY Home allows you (the user) to download data from any compatible device or enter data manually.

Once you have downloaded your data or entered them manually, ALLY Home allows you to review all blood glucose readings, insulin doses and other data on screen.

ALLY Home allows you to share your data with your HCP and to exchange messages with them.

ALLY Home is intended for use by individuals aged 18+.

ALLY Home is intended for personal use only.

Users are expected to use the ALLY Home software at home or at another non-clinical setting.

1.2   Important safety information

IMPORTANT: follow the instructions in this User's Guide.
            If you are not sure how to use ALLY Home, please contact your HCP.

The use of ALLY Home by anyone different from the intended user, or for any purpose or application other than what specified in this User's Guide, or the non-compliance with any of the instructions herein will be considered as improper use.

AgaMatrix and METEDA shall not be held responsible for any adverse outcomes due to improper use of ALLY Home, or due to inaccurate or missing patient data.

1.3   System / browser requirements

ALLY Home hardware and software requirements:

- ALLY Home client is supported by computers with Intel Pentium Dual Core 2GHz processors (2.4 GHz recommended) and newer (or compatible) processors with at least 4 Gb of RAM and at least 1 Gb of free disk space.
- ALLY Home is compatible with Windows XP sp3 or later (Windows 10 or later recommended) with Framework .NET version 4.0 or later (4.5.2 recommended).
- The monitor must have a minimum resolution of 1024 x 768 pixels. However, 1280 x 800 pixels are recommended.
- One USB 2.0 port or higher
- PDF Reader (needed to view the User Guide electronically)
- Printer (optional)

2   Log in to ALLY Home

To access ALLY Home you have the following options:

1. Your HCP has registered you and activated your account (follow the steps in 2.1)
2. User self-registration (follow the steps in 2.2)

2.1   HCP account registration and activation

Once Your HCP has registered you and activated your account, you will receive an email with:

- A link to download ALLY Home
- Your personal ALLY Home credentials

To download ALLY Home, click the link in the email, or copy and paste it into the address bar of your browser. Download the installation file and click on '*Launch*' to complete installation. When the software installation is complete, you will be directed to the ALLY Home Login page.
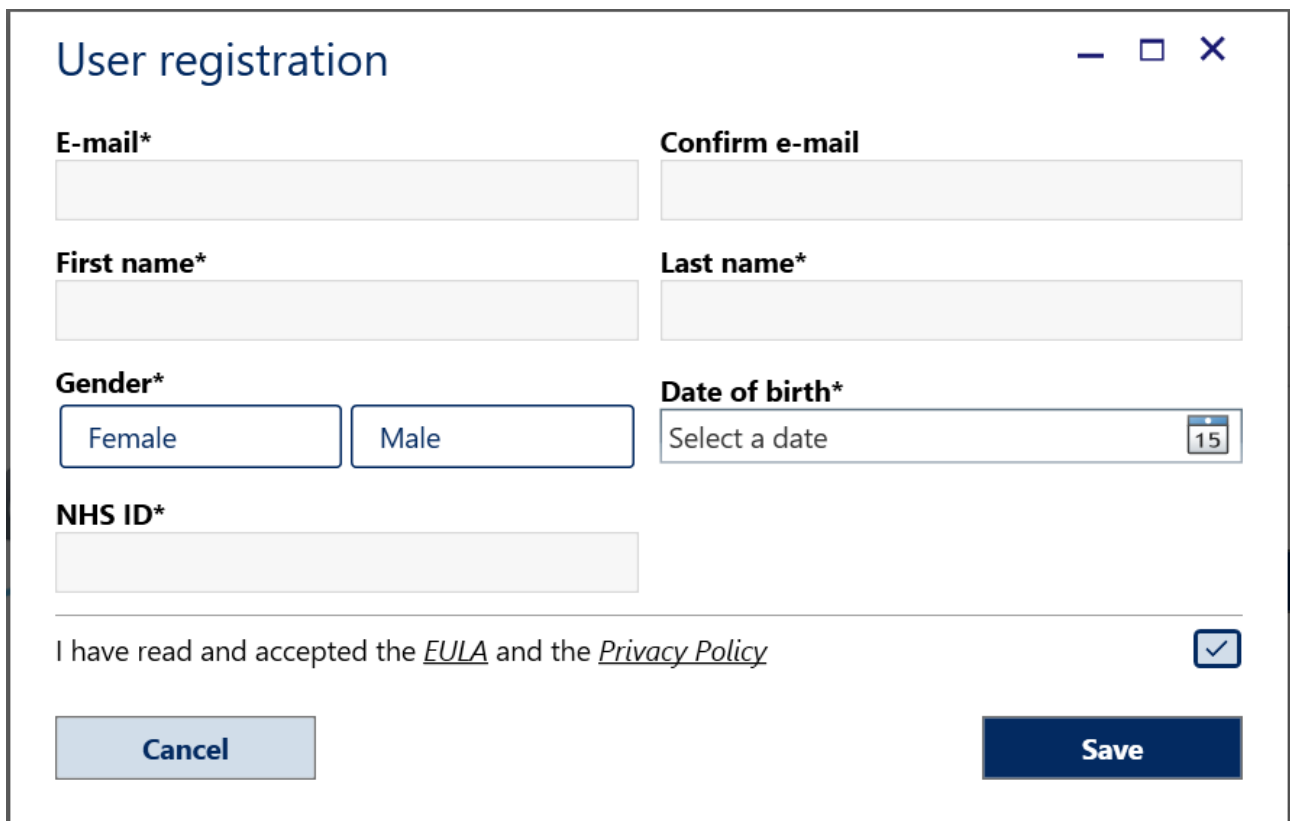

On the login page, enter your personal ALLY Home credentials received via email.

IMPORTANT: Your email address will be your username

The system will ask you to change the initial password at your first login.

2.2   User self-registration

The user registration is a form that allows new users to register themselves on the system. It can be reached by clicking on the 'User registration' button on the login page. In order to register, you must fill out the fields that are marked required (*) and click the 'Save' button.

If all fields have been filled out correctly and the 'Save' button is clicked, the system is able to register the new user account and a confirmation window will be displayed. You will get your username and temporary password sent to your email address.

On entering the username and temporary password in the ALLY Home login page you will be prompted to change your password.

Once your new password has been updated you will be logged in to the System.

3   Features of ALLY Home

The blue navigation bar at the top and at the bottom of the ALLY Home homepage allows you to access the following features:

Dashboard: Review your overall status

Data Management: view and manage graphs and charts of self-monitoring data (See section 8)

Chat: Exchange messages with your HCP

Personal Data: View your personal details, view the devices downloaded on ALLY Home, import data from Zero-Click

Consent Management: To grant/revoke the chat consent

Full screen: The current page in full screen

Print: Print your reports

Settings: Software settings

User Guide: View the User Guide

Lock session: Lock your session

Resources: Shows the following information

- User Guide
- Legal Documents (Privacy Policy, EULA and Cloud Security Policy)
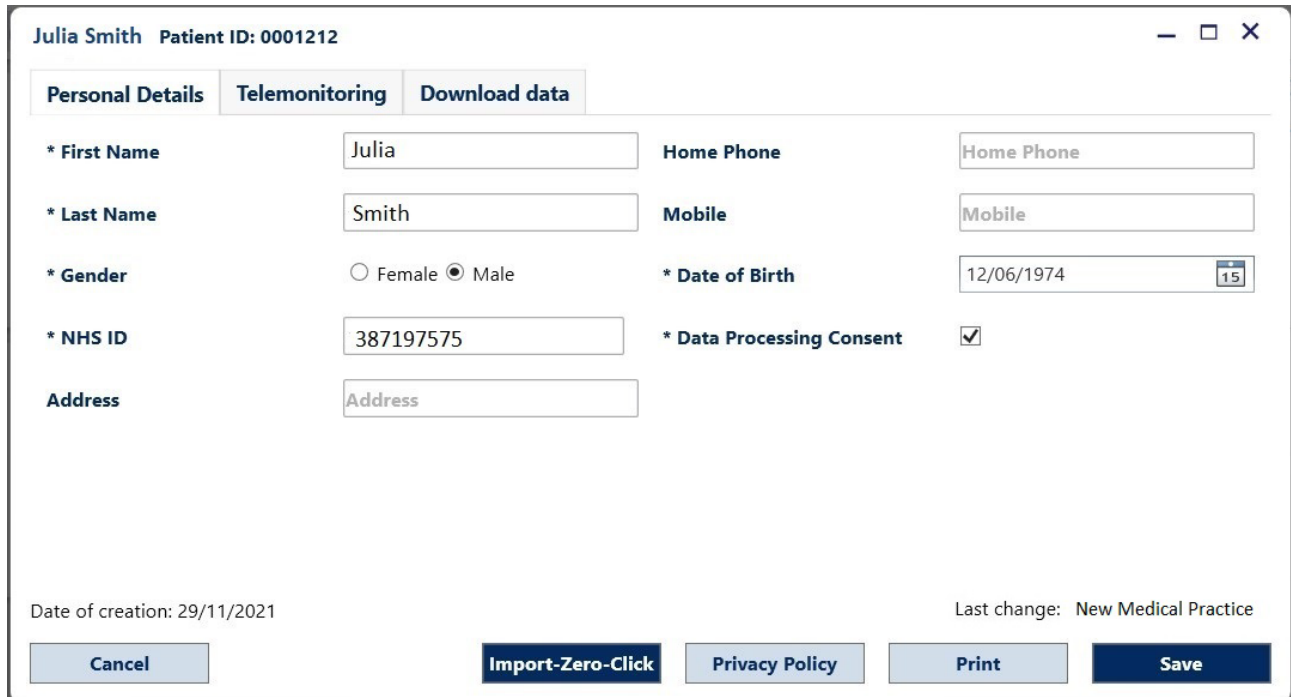- Customer Service details
- Manufacturer details.

Log out

Hover the mouse over each icon to see a description of what it does.

4　View or change my details

Click 　 **👤 Personal data** 　 in the navigation bar to view your personal details. Your 'Personal data' window opens.

IMPORTANT: If your account has been set up by your HCP, you can view your data only. If changes are needed, contact your HCP.
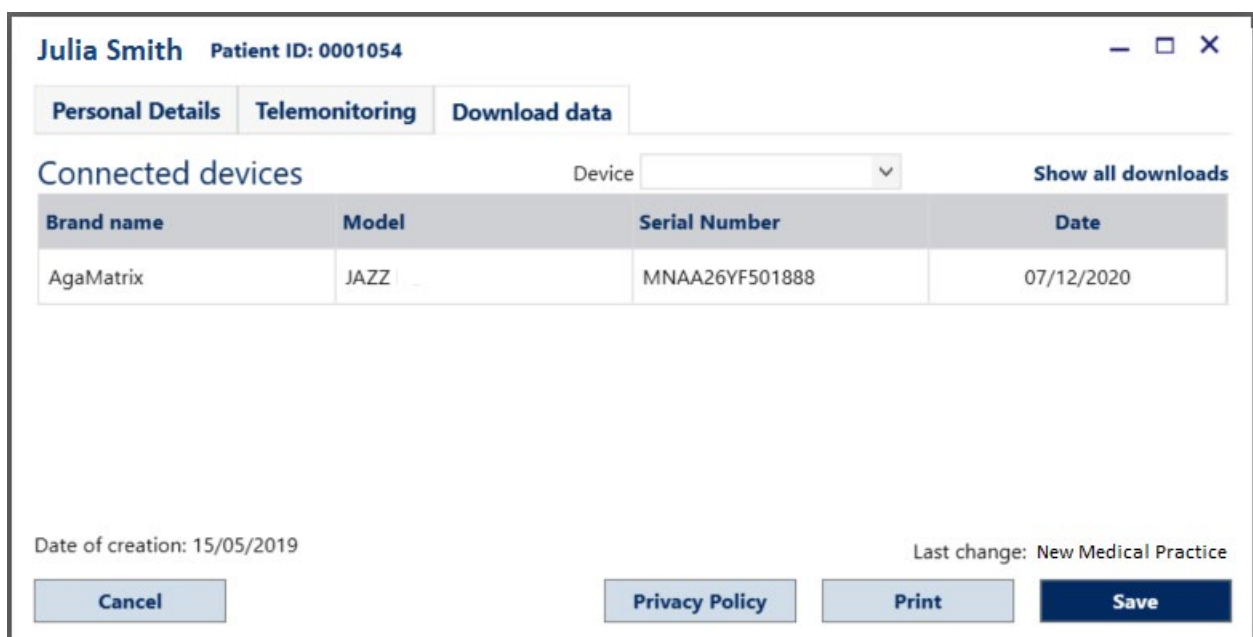
If you have downloaded data from a compatible device to ALLY Home, the 'Download data' tab shows details of your device(s):

- DEVICE: A drop-down list of devices you have downloaded data from
- CONNECTED DEVICES: Shows the brand, model, serial number and download date of the selected device
- Toggle between **Show last downloads** and **Show all downloads** to see either the date of the last download and its associated meter or the entire list of meters and their associated last download dates

5   Zero-Click Import

If you would like to import data from your Zero-Click software, you should follow the steps below:

- Log in to your Zero-Click software and check the number of your **Profile ID** is identical to the **NHS ID** number you have entered in the **Personal Data** section of your ALLY Home account. If it is not identical you will need to complete step 2 and amend your **Profile ID** in Zero-Click to you **NHS ID**. Please note that data will only be imported into ALLY Home if both numbers are identical.
- To amend your **Profile ID,** select **Profile > Setup Personal Info**, type in your **NHS ID** number in the **Profile ID** field and select **Save This Page.**
- To begin the data export from Zero-Click select **File > File Maintenance,** the **File Maintenance Wizard** will then appear.
- Within the **File Maintenance Wizard** select **Next > Export a profile > Next.** Select the profile you wish to export and select **Next.**
- Select **Open format text file** > **Next**
- The **File Maintenance Wizard** will ask you to select a file location. The file location field will already be prepopulated, and you will just need to select **Next.**
- Select **Finish** and the data will automatically export into an excel csv file. The file will automatically save in the **Documents** folder on your PC.
- Log in to ALLY Home and select **Personal Data** > **Import Zero-Click.**

You will then be directed to your **Documents** folder.

- Select the same excel csv file that is saved within your **Documents** folder and select **Open.**
- ALLY Home will display a pop-up-message to say that the data transfer is complete.
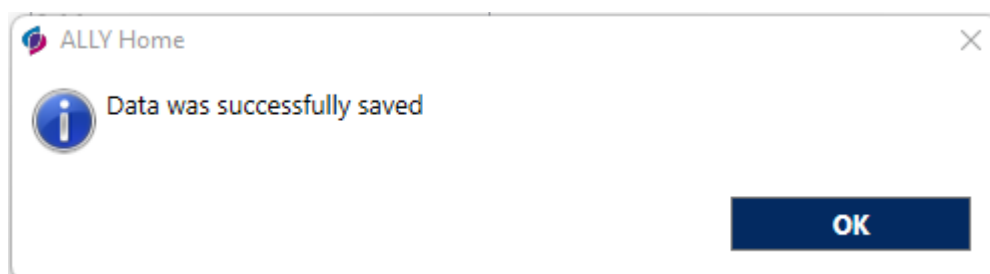
- You will now be able to view your Zero-Click data in the **Data Management** section of ALLY Home.

6   Chat with your HCP

You can send a message via ALLY Home to your HCP or connected site. Click [Chat] to open the 'Chat' window.

IMPORTANT: You cannot send a message to a specific person. The message may be read by any doctor or nurse in the site. If you send a message to your HCP, the next time they use ALLY, they will see an indicator that there is a new message to be read.
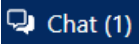
Type your message, then click "send".

The number of unread messages from your HCP will be shown next to the 'Chat' icon [📝 Chat (1)] in the navigation bar.

IMPORTANT: Do not use the message system for urgent topics. If you need urgent advice, call your HCP or contact emergency medical response.
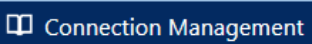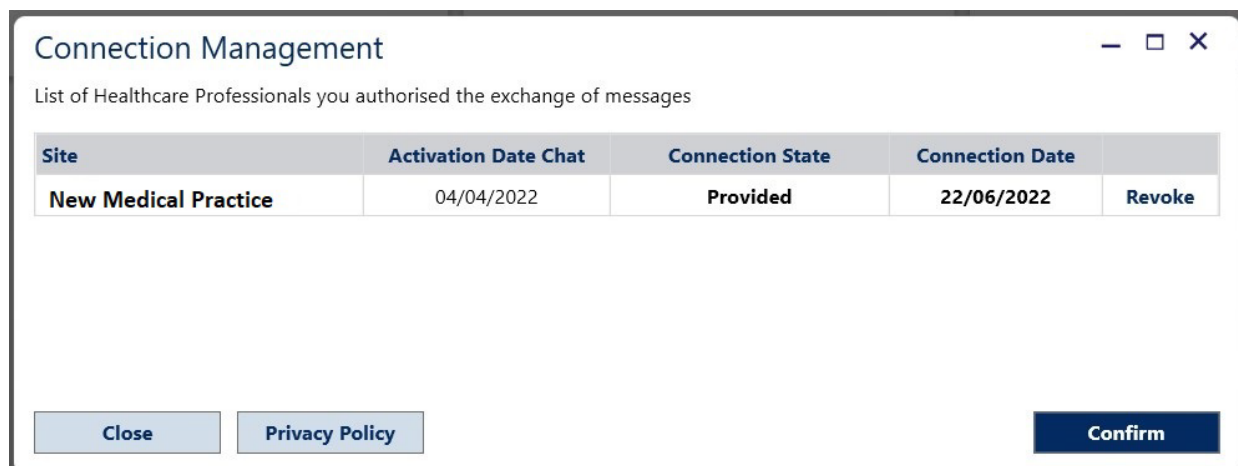
7   Connection Management

The first time you log in to ALLY Home, you will get the following message from the system to confirm the 'Connection Request' received by your HCP:
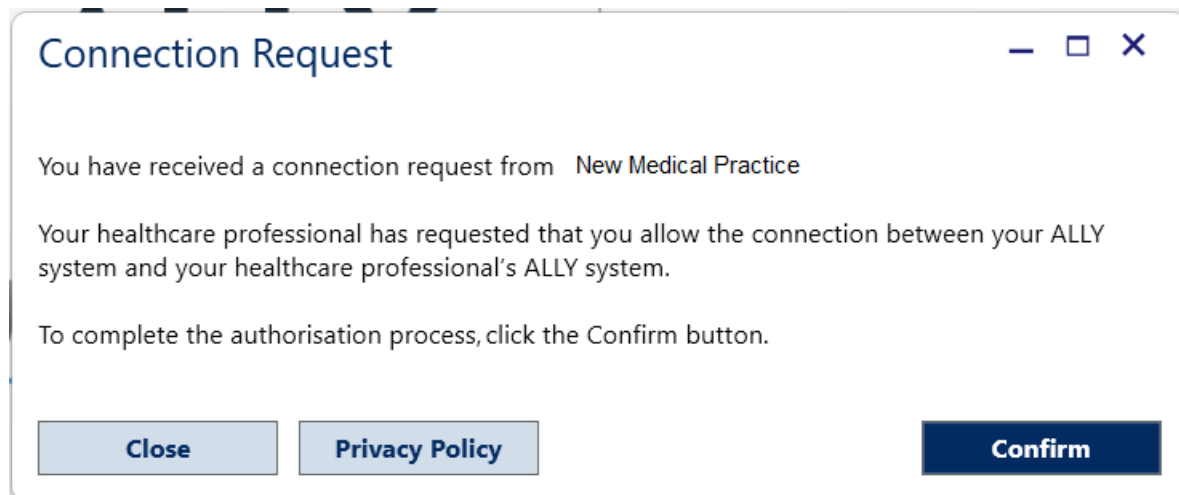

You will be able to access ALLY Home and chat with your HCP once you confirm the connection request.

If you do not confirm the connection request, you will be able to access ALLY Home, but you cannot chat and/or receive messages from your HCP.

You can always revoke your consent for a connected site by clicking [📖 Connection Management] in the navigation bar and then 'Revoke'.

If you revoke the connection, you cannot chat with that site anymore and you will get the following message:
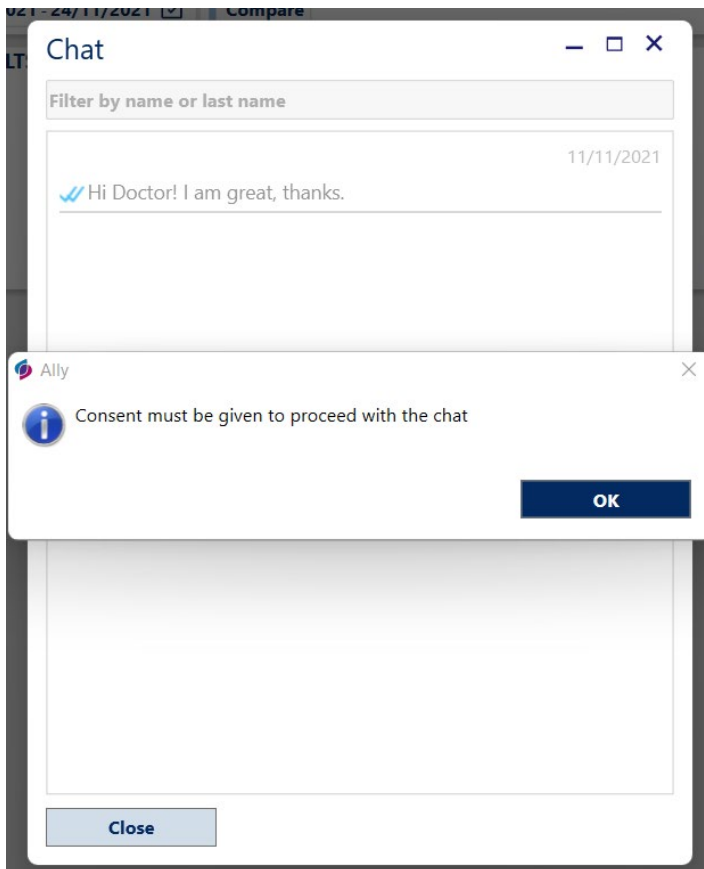
To chat with the site again click on 'Connection Management' and then 'Grant' the connection to the relevant site.
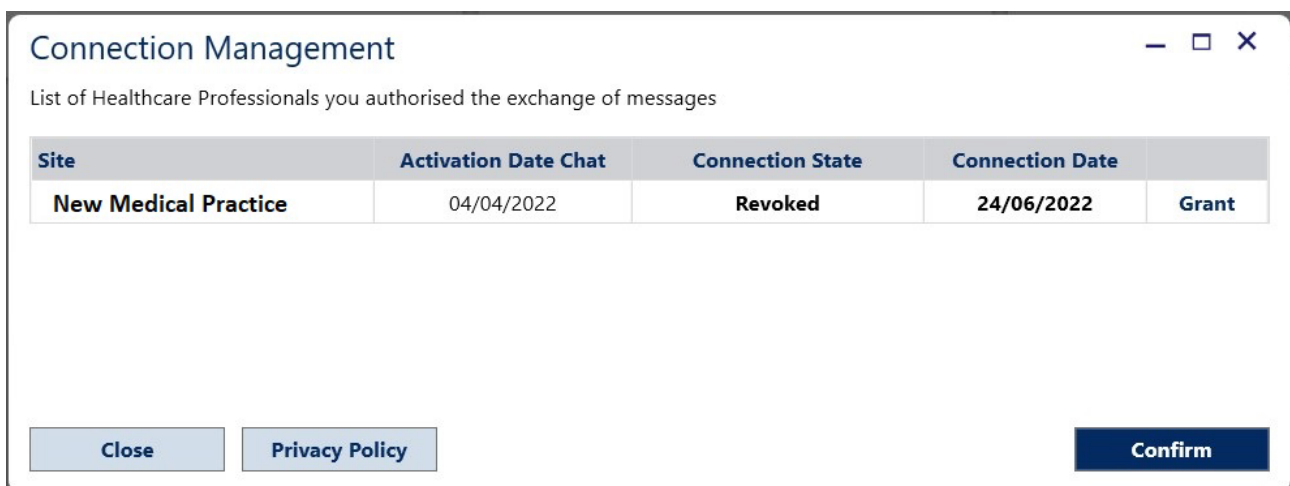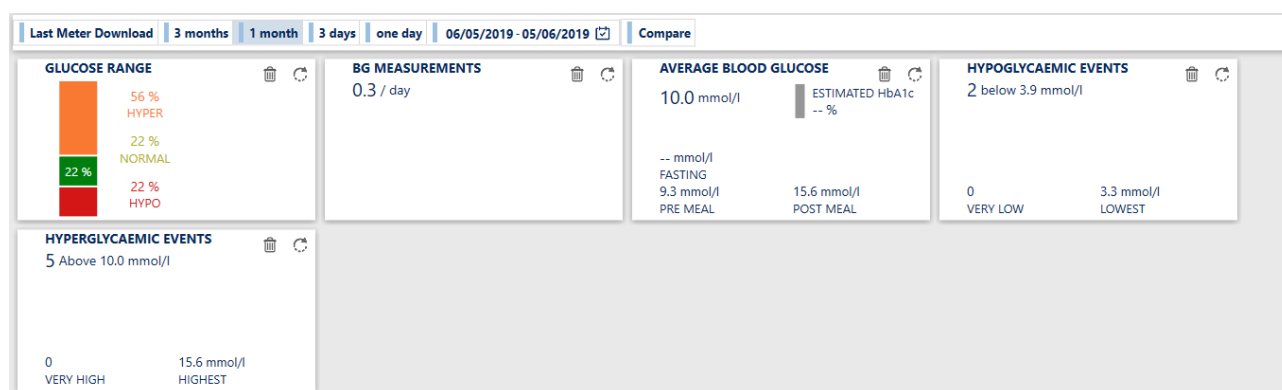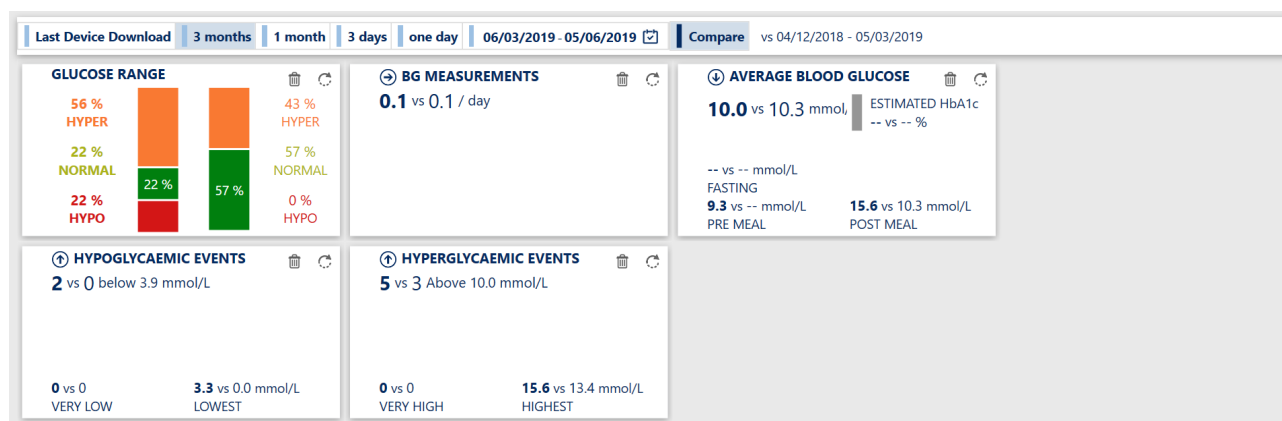
8 Dashboard

The Dashboard provides an instant overview of your overall diabetes trend.

You can view a summary of your data and choose a time interval by clicking the buttons, 'Last Meter Download', '3 months', '1 month', '3 days', '1 day' or it is possible to specify the dates by clicking the calendar button .

In the Dashboard there are five boxes that summarise the most relevant information. The boxes display fundamental values and highlight whether the therapeutic goals set for these parameters have been reached or not during a given period.

By clicking on the [Compare] button, you can compare the current data with the immediately preceding period of the same length of time;

The Dashboard is divided into five tiles in which the following information is displayed:
- Glucose Range
- Blood Glucose Results
- Average Blood Glucose
- Hypoglycaemic Events
- Hyperglycaemic Events

Each tile has two sides. Click the button to rotate the tiles.

Glucose Range

Glucose Range displays the breakdown of blood glucose levels, expressed in percentage and based on the targets set by your HCP (% Hyperglycaemic values, % Normal values, % Hypoglycaemic values);

Below there are two images in which the two sides are visible. By clicking the **Edit** button, it will be possible to view the Blood Glucose Targets set by your HCP.
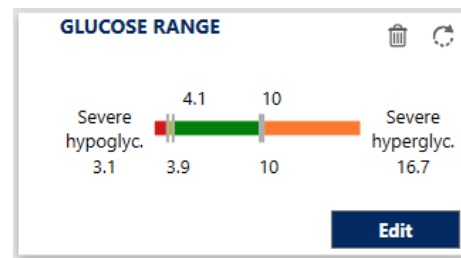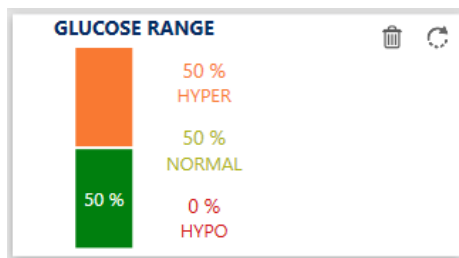
Blood Glucose Results

Blood Glucose Results displays the average daily number of blood glucose tests.
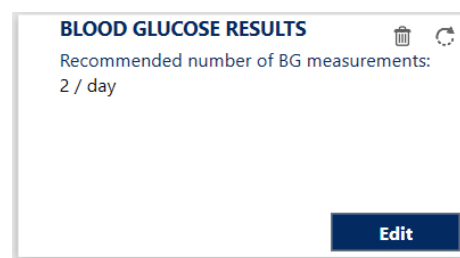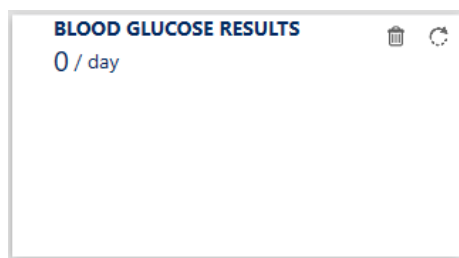
Average Blood Glucose

Average Blood Glucose displays the average value of all recorded blood glucose levels (fasting, pre-meal, post-meal); by clicking the **Edit** button, you can view the Blood Glucose Targets set by your HCP.
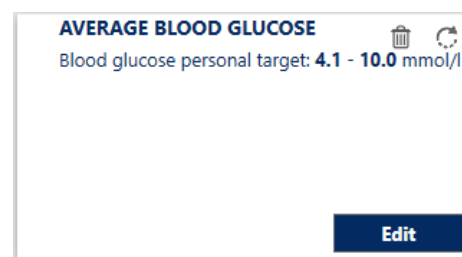
Hypoglycaemic Events

The following data is displayed:

- The number of Hypoglycaemic events (<3.9 mmol / L)
- The number of *Very Low/Severe* Hypoglycaemic number (<3.1 mmol / L)
- The *Lowest* blood glucose value

Hyperglycaemic Events

The following data is displayed:

- the number of Hyperglycaemic events (>10.0 mmol / L)
- a number of *Very High/Severe* Hyperglycaemic Events (>16.7 mmol / L)
- the *Highest* blood glucose value

9   Data Management

Data Management is accessible from the Navigation Bar and allows you to view the saved data in ALLY Home:
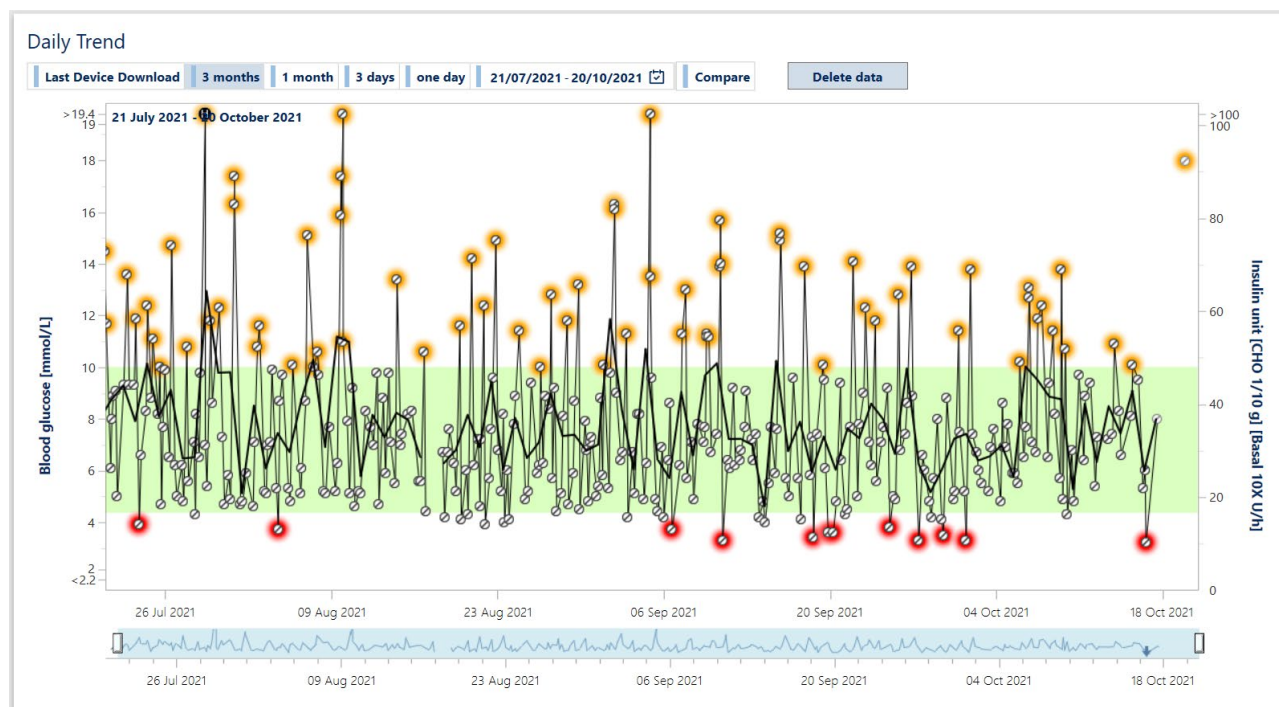
You can view the following graphs: Daily Trend, Modal Day, Modal Week and Modal Meals. Each graph has a 'selection bar' (shown below) for the period of which data will be displayed.

Last Device Download: Displays the graph of the values of the last blood glucose levels downloaded from the blood glucose meter

3 months, 1 month, 3 days, 1 day: Displays the graph of the blood glucose values in the selected period, it is also possible to set a personalised period by clicking the calendar icon and selecting a Start date and an End date.

Compare button ⎮ **Compare** ⎮ : Graphical comparison with the immediately preceding period of the same length of time
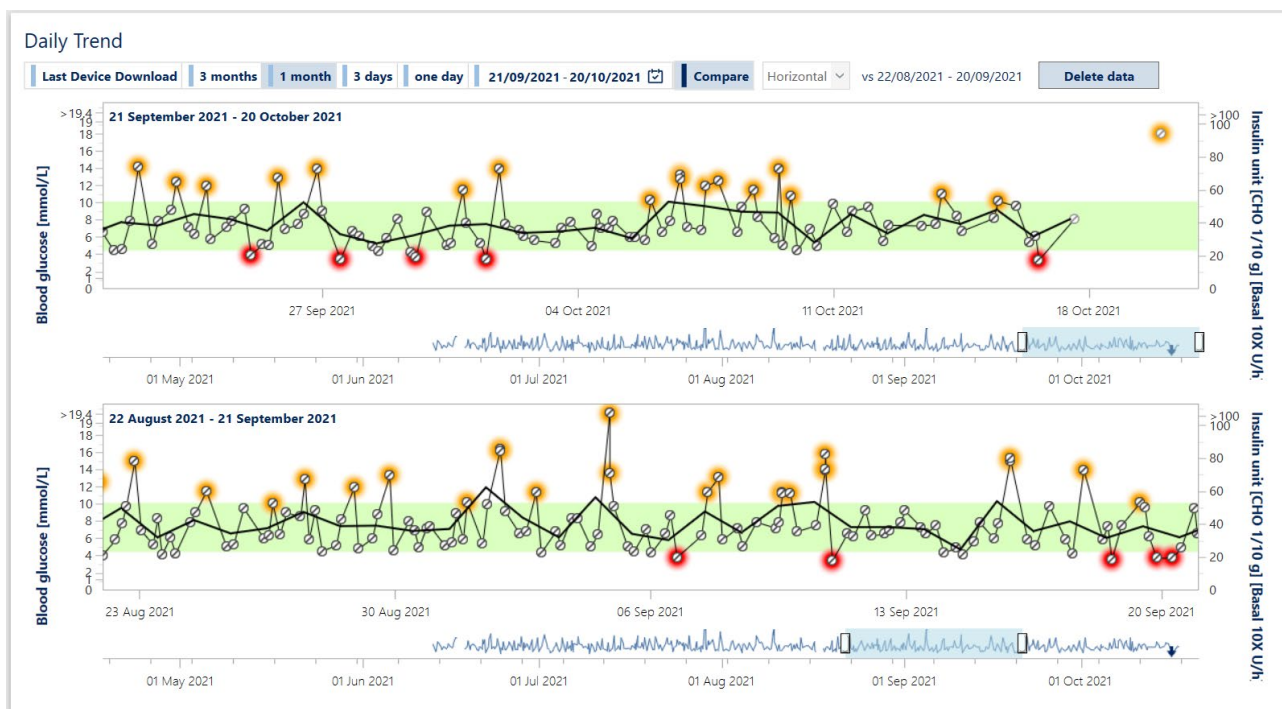
A comparison can be made by setting graphs on two horizontal or vertical lines.

9.1 Daily Trend

Daily Trend shows your blood glucose readings, insulin doses and carbohydrate intake on the days they were measured or taken.
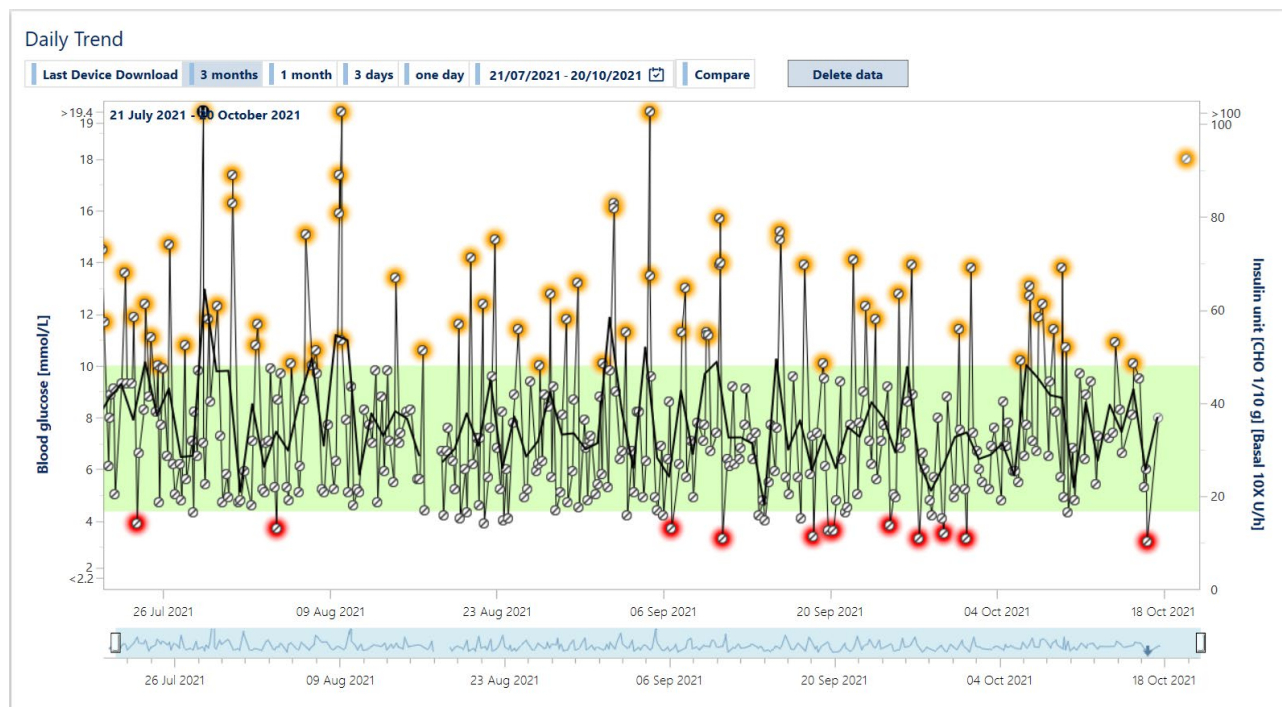
The blood glucose scale is displayed on the left vertical axis, while the insulin and carbohydrate data are on the right vertical axis.

The green horizontal bar identifies the personal blood glucose target (*Normal Range*).

The scroll bar below the graph allows a quick overview of blood glucose values.

The arrows indicate when the blood glucose data have been downloaded.

You can change the period displayed by the time selectors.

| 09 Aug 2021 | 23 Aug 2021 | 06 Sep 2021 | 20 Sep 2021 | 04 Oct 2021 | 18 Oct 2021 |
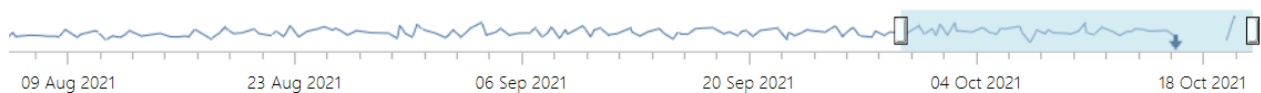
In the right column there is a list of the displayable values. To activate one or more value, click on the relevant tiles and the value will be presented in the graph. Click on the tile again to toggle between active and inactive.

Normal Range
50 Hyperglycaemic events
50 Normal
0 Hypoglycaemic events
17 Coefficient of variation

Blood Glucose measurements
6 glycaemia
1.0 day

Hypoglycaemic events
-- under 3.8 mmol/L

Hyperglycaemic events
3 over 10 mmol/L

Fasting glucose
-- mmol/L

Average blood glucose
10.5 mmol/L

Blood glucose device download
2 download

Bolus
-- bolus

Basal
17 basal

Premix
-- U Premix

Legend
Symbols
— Average BG
⊘ No tag
○ Fasting
● Pre meal
◑ Post meal
☾ Night
◔ Below 1.1 mmol/L
◓ Above 33.3 mmol/L

Colour Key
Normal Range
Manual Input
Data download from device
Hypoglycaemia
Hyperglycaemia
Bolus
Basal
Premix
Carbohydrates
Basal infusion
Extended bolus

9.2   Modal Day

The *Modal Day* graph provides a visualisation of the amount of fluctuation in your blood glucose levels and you to identify blood glucose values within your personal target (*Normal Range*) as well as *Hypoglycaemic* and *Hyperglycaemic events*.

The graph shows your blood glucose levels overlayed over 24 hours, highlighting each hypoglycaemic or hyperglycaemic event.

The graph summarises the average glucose values calculated over a span of 24 hours over the time period selected.

The blue line in bold represents the median of the blood glucose values collected at different times and in different days.

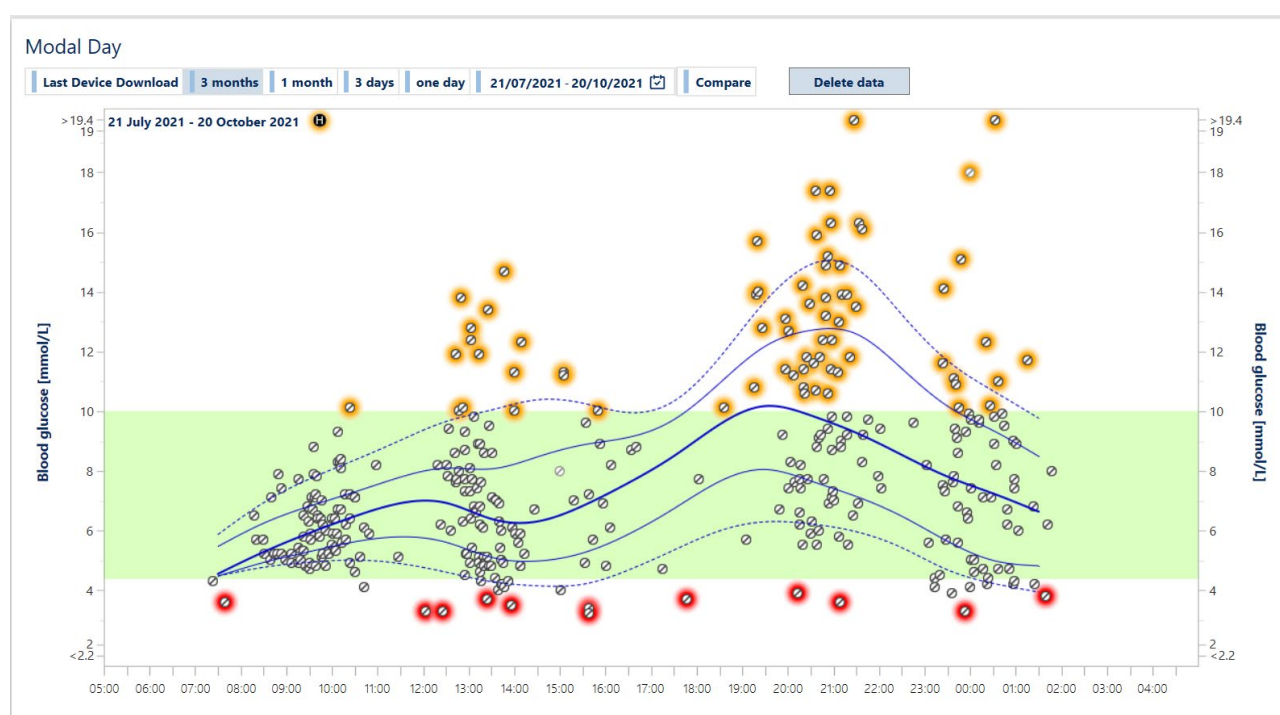The thin blue lines of the graph represent, in order, from the highest to the lowest, respectively: the 75th percentile, the median, and the 25th percentile.

The table of legends on the right side of the screen is there to help you interpret the graph.

The *Modal Day* graph visually shows the range of fluctuation in blood glucose values. The greater the distance between the 25th and 75th percentile, the greater the inter-day blood glucose variability.

By clicking on a blood glucose value, the data collected on the same day are connected with a blue line that will display the blood glucose trend within 24 hours, as shown in the following image:
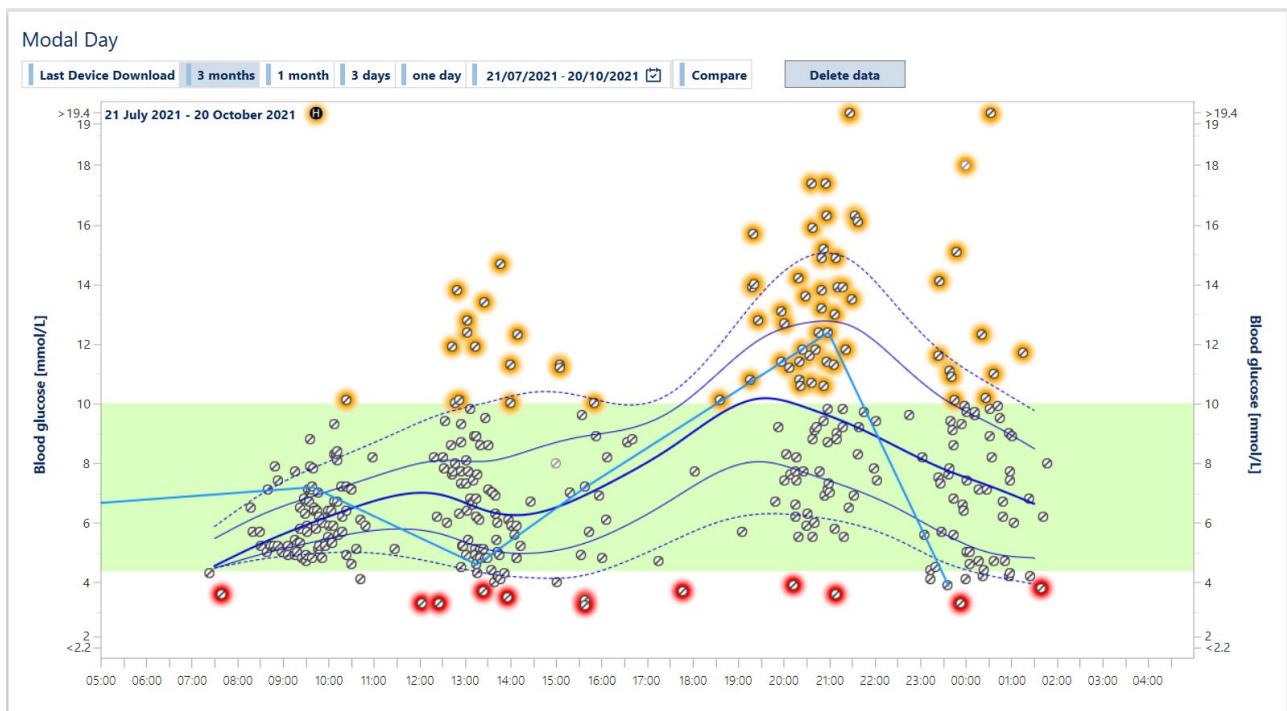
As in the *Daily trend* graph, you can activate or deactivate the display of the *Normal Range, Blood Glucose Measurements, Hypoglycaemic Events, Hyperglycaemic Events* and *Fasting Blood Glucose*.

9.3   Modal Week

The *Modal Week* graph helps you identify daily trends in blood glucose management. For example, you can determine if a certain day is more difficult to keep blood glucose levels in-range.
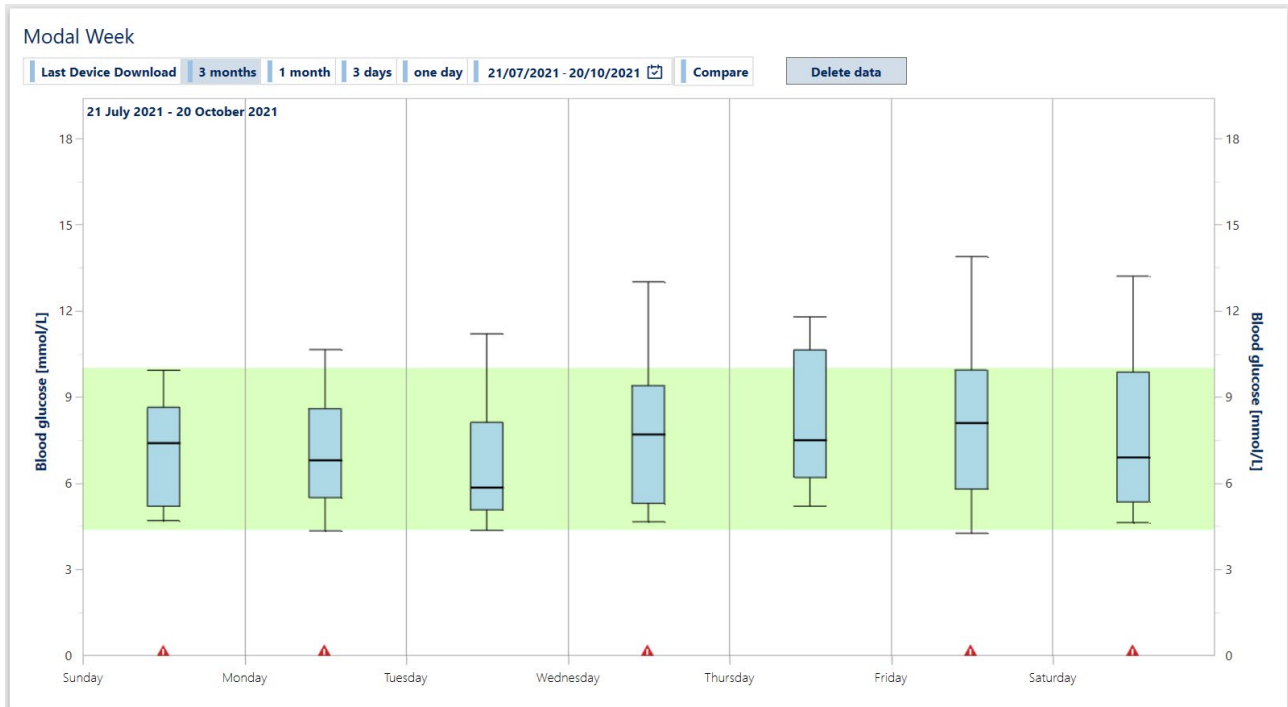
The percentiles and average of the blood glucose values recorded by the patient are displayed daily, highlighting hypoglycaemic events by the appearance of red warning triangle.

9.4 Modal Meals

The *Modal Meals* graph displays the meals in which you meet the greatest difficulty in maintaining good glycaemic control.
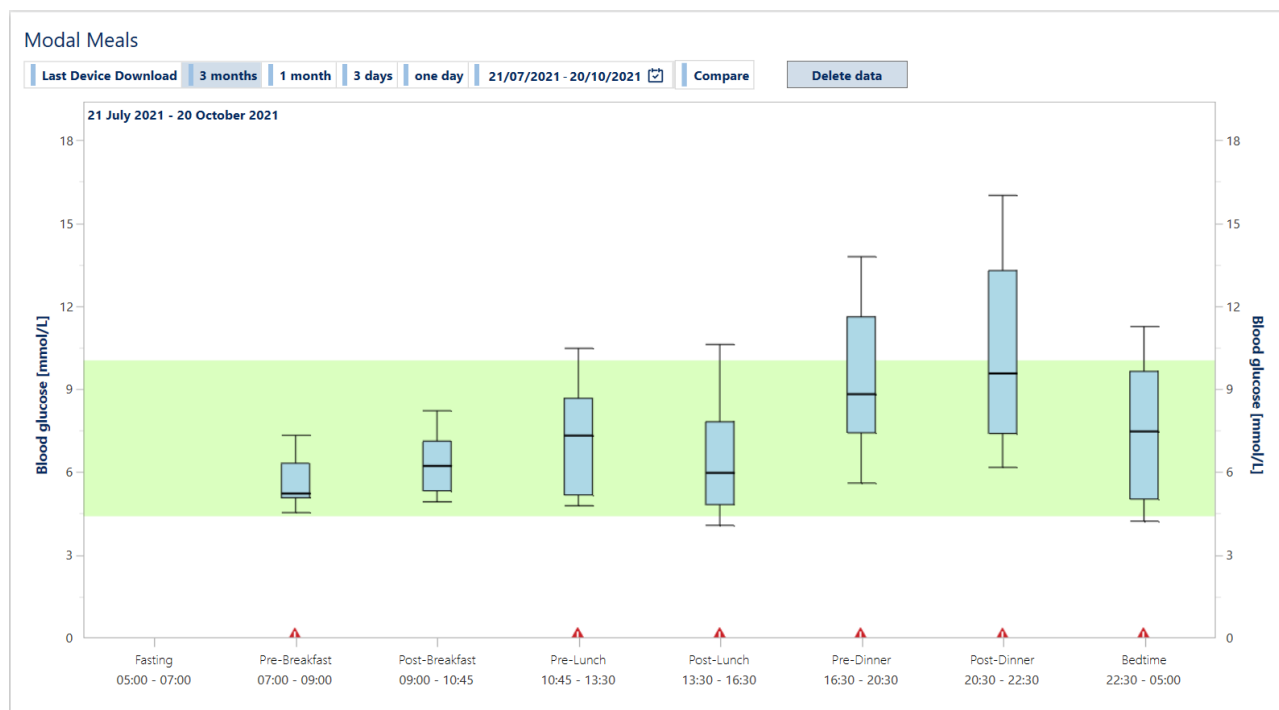
The *Modal Meals* graph displays both the percentiles and the average blood glucose values recorded by the patient during the day relative to the timeframe defined in the patient target. It highlights hypoglycaemic events by the appearance of a red warning triangle.

9.5   Logbook

The *Logbook* shows your blood glucose measurements, insulin doses and carbohydrate intake sorted by date and time.

Blood glucose values are displayed as fasting, pre-meal or post-meal, according to your mealtime settings.   A   icon indicates if carbohydrate intake data are available. Only the columns in which data are available are displayed.

Blood glucose values that fall within the target range are shown in normal font, while values outside the target are shown in bold, so that they can be easily recognised.

Click '**Date**' (first column) to toggle the date order between newest and oldest.

IMPORTANT: Hover the mouse over any data point to see details about the data.

By clicking on the options in the right column it is possible to highlight the Hypoglycemic Events (in red) and the Hyperglycemic Events (in orange).

9.6   Download Data from a WaveSense JAZZ meter

You can download your data to ALLY Home from your WaveSense JAZZ meter.

An AgaMatrix cable is required to download your device.

To successfully download data from your device, you need:

- Your WaveSense JAZZ meter
- An AgaMatrix cable to connect your meter to your PC. If you do not have an AgaMatrix cable call AgaMatrix Customer Care on 0800 093 1812.

IMPORTANT: When the device is connected to your PC, all functions are disabled. **Do not** try to use the device while it is connected to your PC.

The ALLY Home system will automatically save the blood glucose readings and any other data stored on your WaveSense JAZZ meter.

The ALLY Home system will display images related to the supported devices which, if clicked, will display detailed instructions for downloading data to ALLY Home.

To download data from a meter, select the type of 'Communication Port' if known. Otherwise, the system will automatically search them. By selecting the device and clicking the **Next** button it will start the procedure that downloads data from the blood glucose meter to ALLY Home.
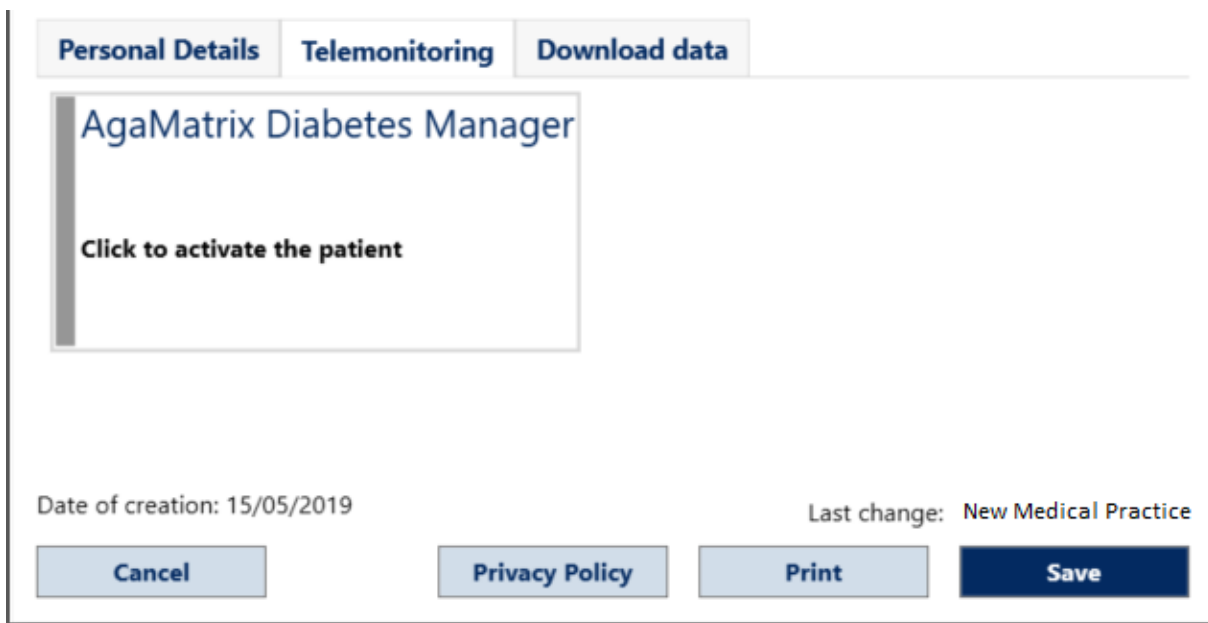
All data stored in the device and not already recorded in ALLY Home will be downloaded and the data will then be viewable in ALLY Home.

IMPORTANT: Do not disconnect your device from the computer during the download.

9.7 Download data from the AgaMatrix Diabetes Manager app

If you are using a WaveSense JAZZ WIRELESS blood glucose meter and the '*AgaMatrix Diabetes Manager*' mobile app and you would like to download your data to ALLY Home, please follow the below steps:

- Click on 👤 Personal data on the navigation bar
- Click on the 'Telemonitoring' tab
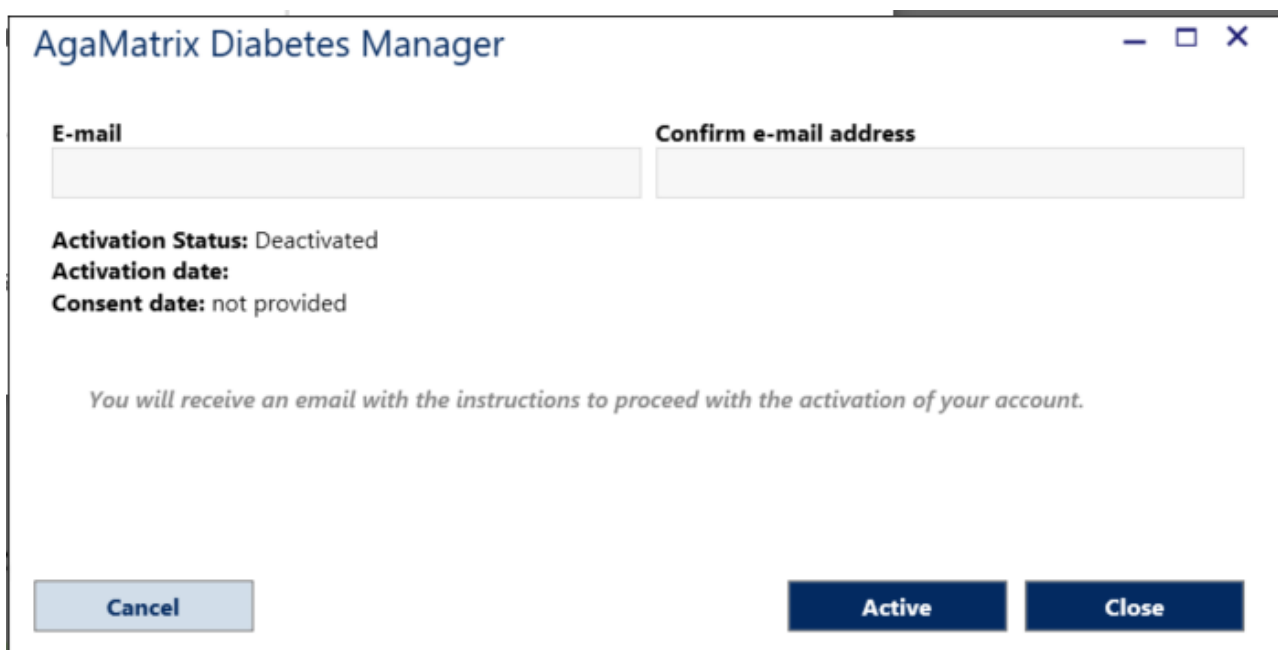
- Click on the 'AgaMatrix Diabetes Manager' tile

- Enter your email address and click on the **Active** button. A window will ask you to enter your login password
- Enter the login password and then click 'OK'
- You will receive an email to 'with a link to confirm the connection request and complete the authorisation process.
- The 'AgaMatrix Diabetes Manager' will turn yellow, and the system will display the 'Activation date'

AgaMatrix Diabetes Manager

Activation Status: Pending
Activation date: 09/11/2021
Consent date: not provided

Last synchronisation:
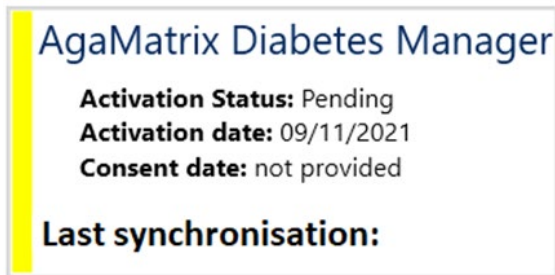
- Click on the authorisation link received via email and follow the instructions displayed to activate the connection with your 'AgaMatrix Diabetes Manager' app
- Once the authorisation process is complete the 'AgaMatrix Diabetes Manager' tile will turn green

AgaMatrix Diabetes Manager

Activation Status: Activated
Activation date: 25/11/2021
Consent date: 25/11/2021

Last synchronisation:
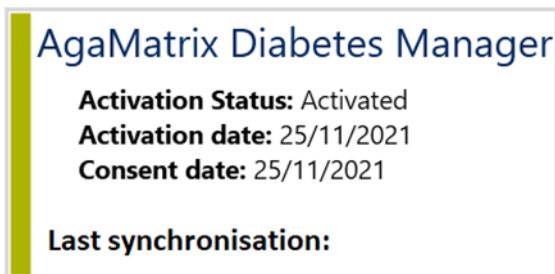
9.8   Blood glucose target

Click   ⊕ Blood Glucose Targets   to view your personal blood glucose targets set by your HCP.
You can set your own targets if you are a self-registered user only. Otherwise, if your account has been created by your HCP, please contact your HCP to change your targets.

Patient activated by HCP

Self-registered patient

The following targets are shown:
- Blood glucose personal targets
- Recommended blood glucose measurements per day
- Hypoglyceamic and hyperglycaemic monthly frequency limit
- Hypoglycaemia and hyperglycaemia thresholds

In the Meal Times tab, you can save different meal schedules by clicking the ☑ icon to select the date.

Patient Targets — □ X

Blood Glucose Targets | **Meal Times**

No Target Set. The values shown are the default ones ☑

		Time From	Time To
Night			
Fasting		00:00	06:00
Breakfast	Pre	06:00	09:00
	Post	09:00	10:45
Morning Snack			
Lunch	Pre	10:45	13:30
	Post	13:30	16:30
Snack			
Dinner	Pre	16:30	20:30
	Post	20:30	22:30
Bedtime		22:30	00:00

Cancel | Save

10   Manual Data Inputs

ALLY Home allows you to enter data manually by clicking on [☰ Manual Input] .

To add a new entry, select the date, time and data type. Then enter the value of the data. Click on the [Save] button to complete the entry.

If you wish to enter data manually for more than one day, click on the 'New Entry' button and select a new date.

11   Print

From any view in ALLY Home, click   🖨   .

By clicking the Print current page option, a window will open with the preview of the page that will be printed. An example image is shown below:
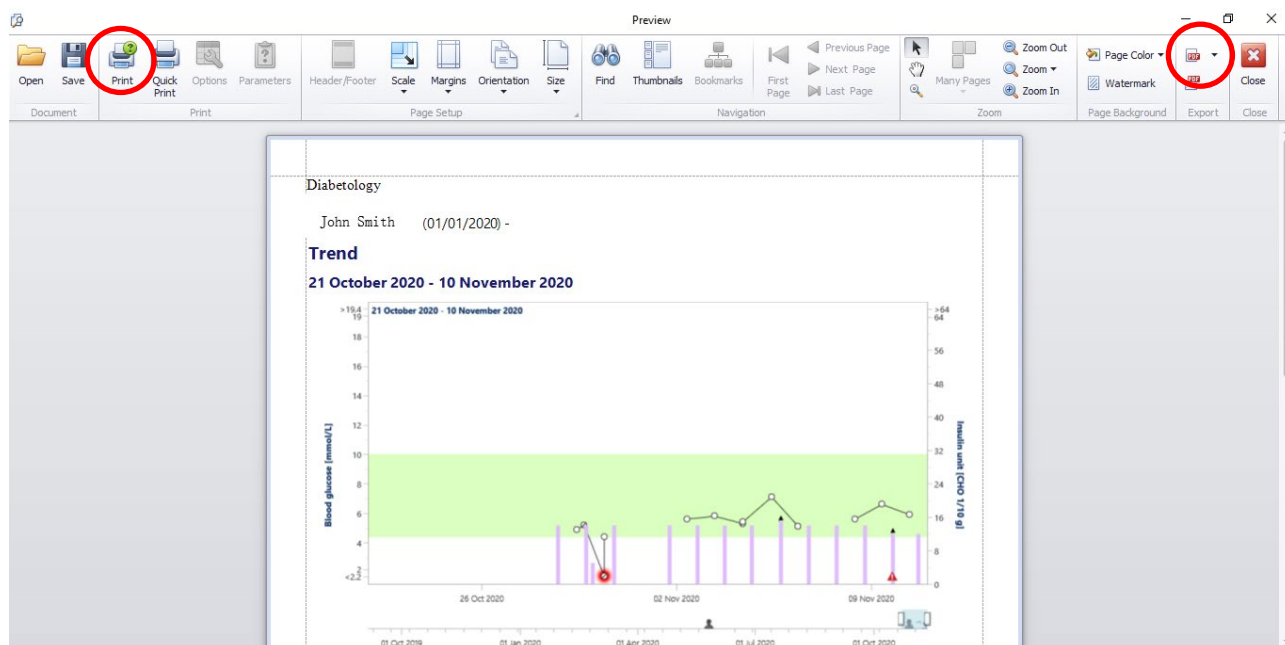
From this 'Preview' screen you can choose to 'Print' (see red circle on the left) or you can select 'Export to PDF' (see red circle on right). To save the PDF select OK and save to your PC filing system.

12   Change your password

You can change your password by clicking on your email address on the bottom navigation bar.

Click   **Save**   to save any changes.

IMPORTANT: You will need to change your password periodically (usually every three months).

13   Logout

Click on ⏻ in bottom the navigation bar. A confirmation pop-up opens.
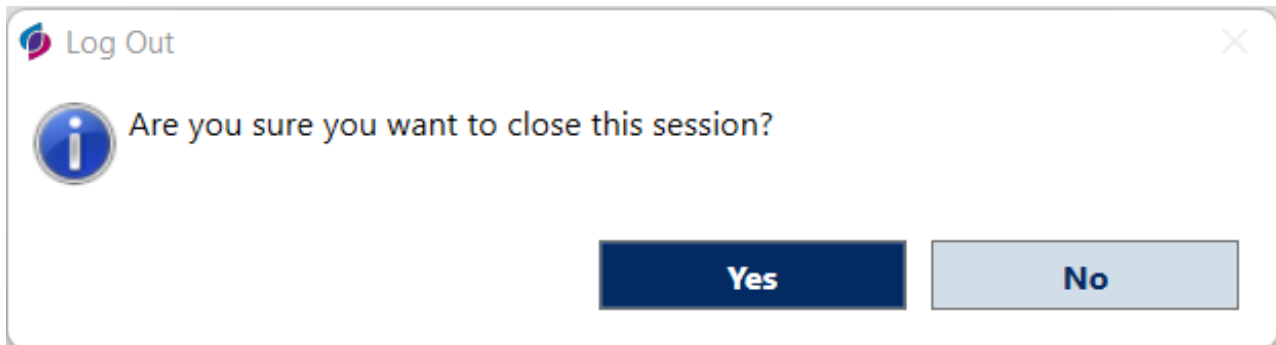
Click 'Yes' to confirm the log out.

14   Information

By clicking the ⓘ icon on the bottom navigation bar links to the following are displayed:

- User Guide
- Regulatory Documents (EULA, Data Privacy Policy, Cloud Security Policy)
- Last software updates
- Customer Service details
- Manufacturer details
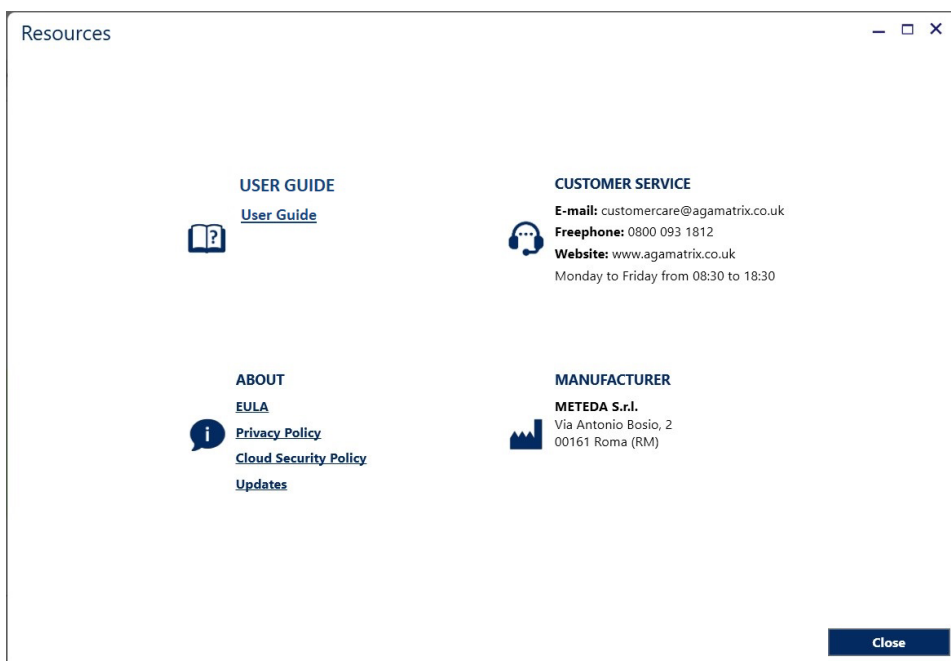
15   Directives and reference standards

The Device is developed in conformity with directive 93/42/CEE as amended by Directive 2007/47/CE and with the following standards:

- EN ISO 14971– 'Application of risk management to Medical Devices'
- EN 62304 – 'Medical Device Software — Processes of the software life-cycle'
- ISO 15223-1 – 'Medical devices Symbols to be used with medical device labels, labelling and information to be supplied'
- EN 62366 - 'Medical devices – Application of usability engineering to medical devices'
- EN 1041 - 'Information Supplied by the Manufacturer with Medical Devices'

16 Questions and answers about ALLY Home

GENERAL

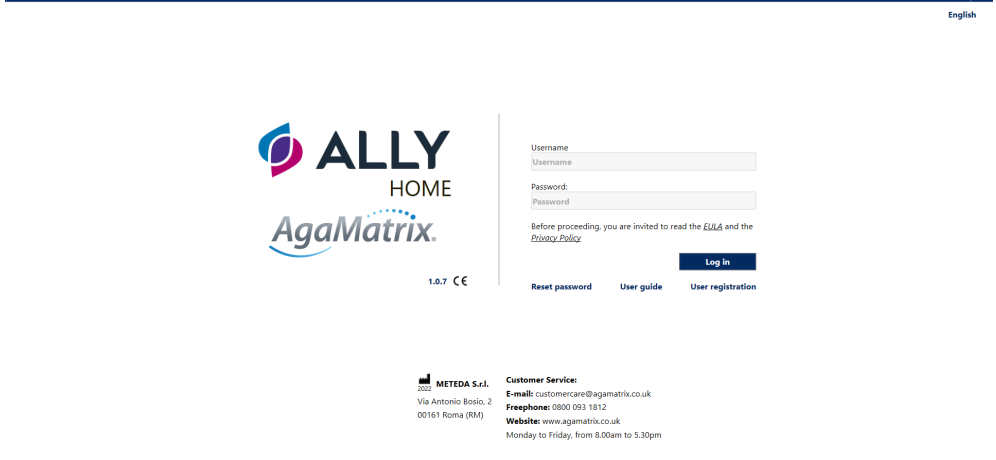| Question / Problem	Answer
I wrote a message to my doctor via ALLY Home, but I did not receive an answer.	The message system is not for urgent issues. If you need advice, call your doctor or nurse or contact your emergency medical response.
I can't open the "User Guide"	A PDF reader is needed to view the User's Guide. Please make sure you have one installed. You will need to open the Control Panel on your computer and check the list of installed programs. If you do not have one installed, you can download Acrobat Reader.
I can't print	The print function creates a 'Preview' of the currently viewed report, which you can then either print or 'Export to PDF' and save. A PDF reader is needed to open the saved file. Please make sure you have one installed. You will need to open the Control Panel on your computer and check the list of installed programs If you do not have one installed, you can download Acrobat Reader.
Why am I having problems viewing some windows?	The resolution required by ALLY Home is 1024x768 or higher, with a scaling setting of 100%

DEVICE

Question / Problem	Answer
I think my BG meter readings might be wrong.	If you have any concerns about your blood glucose meter readings, contact your AgaMatrix Customer Care on 0800 093 1812.
Can I change the glucose measurement unit?	The glucose measurement unit for ALLY Home is preset in mmol/L and cannot be changed. It is of utmost importance that both your blood glucose meter and your ALLY Home have the same unit of measure. Using the wrong unit of measure can lead to erroneous blood glucose values. If your blood glucose meter uses a different unit of measure from your ALLY Home, do not use ALLY Home. Contact your doctor or nurse.

ACCOUNTS, PASSWORDS AND ACCESS

Question/Problem	Answer
Can I share my account for ALLY Home with someone?	No. ALLY Home is intended for your personal use only. Do not let anyone else use your ALLY Home login details or account.
Where is my data stored or backed up?	Data is stored on the secure cloud server only. No data is stored locally.
How do I change my password?	To change your password, see Section 11. You will need to change your password periodically.
How do I reset my password?	If you have forgotten your password, you can reset it. Go to ALLY Home, enter your email address and click '**Reset your password**' (below the login button). A confirmation message appears. Check your email for a message that contains instructions how to create a new password, then log in as usual. The password must be changed during the next login.

ENTERING AND CORRECTING DATA

Question / Problem	Answer
Is it possible to delete a blood glucose reading, an insulin dose, or other data?	No. Once the data has been saved into the system, they cannot be deleted, whether you entered them manually or downloaded them from a meter or other device. If you are not sure about what to do now, contact your HCP.
Do my readings get double counted if I enter them manually and then download my meter?	If the blood glucose readings is different, or they have different time stamps, then both the manually entered and downloaded data will be shown in the data history.

DOWNLOADING DATA FROM A DEVICE

Question / Problem	Answer
What devices does ALLY Home support?	ALLY Home can download data from the WaveSense JAZZ meter. See Section 8.6 for full instructions on how to download data from your WaveSense JAZZ meter.
I can't download data from my device.	To successfully download data from your meter, you need: • a WaveSense JAZZ and download cable or • a WaveSense JAZZ WIRELESS and AgaMatrix Diabetes Manager app account See Section 8.6 for full instructions on how to download data from your device. If you still have a problem, call AgaMatrix Customer Care.
What if the time or date is wrong on my device?	The time and date saved with your data will be taken from your meter, not from the ALLY Home system. If the time or date of your device is different from the real time, data may be saved with the wrong time stamp and counted in the wrong time period (mealtime).
Can I download a device used by another person?	No. ALLY Home is intended for your personal use only. Do not download a device used by another person to your ALLY Home.

LOGBOOK AND TREND CHART

Question / Problem	Answer
What is the Daily Trend chart useful for?	The Daily Trend chart displays blood glucose readings over time and highlights any hypoglycaemic events and hyperglycaemic events. It may also include information on insulin type and doses, changes in insulin dose vs. treatment plan, and carbohydrate intake.
What is the Logbook useful for?	The Logbook displays blood glucose values, insulin doses and carbohydrate intake sorted by date and mealtime.
How do I see exact values or more information about data shown in the Daily Trend chart?	Hover the mouse over any data point in the Trend chart to see details about the data. See Section 6.1 for more information.