User Manual

Diabetes Management System

Ver 10.11.x

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

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

Manufacturer: METEDA S.r.l. (METEDA)
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Product Name: ALLY
Version: 10.11

Distributor:
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Symbols explanation:

2023	Manufacturer
0051	Medical Device complying with the requirements established by the Regulation 2017/745. Medical Device in Class IIa as certified by the Notified Body coded as 0051 (IMQ s.p.a.)

SYMBOLS

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

Medical Device complying with the requirements established by the Regulation 2017/745.
Medical Device in Class IIa as certified by the Notified Body coded as 0051 (IMQ s.p.a.)

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Introduction

ALLY is an innovative platform that offers support for the management of patients with diabetes. AgaMatrix ALLY:

- Saves time by enabling the Healthcare Professional (HCP) to focus on meaningful information which optimises the decision-making process.
- Aids quicker intervention by allowing remote assessment of blood glucose results so that a patient of concern can be identified and treated quickly to help prevent long-term health complications.
- Helps to prioritise patients so those who have poorer diabetes control receive clinic time and those that are doing well can continue without the inconvenience of a clinic appointment interrupting their daily routine.
- Increases patient satisfaction since clinic appointments can be a source of frustration and stress, especially for patients who manage their diabetes well and do not need to be seen as frequently.
- Enables remote management of patients when face-to-face consultations are not possible, e.g. due to geographical distance or social distancing rules.

ALLY allows HCPs to download data effortlessly from supported devices, store the data in a database and easily analyse the information obtained through reports and graphs.

1. Intended use

ALLY is a diabetes management system, designed to store and process clinical and self-monitoring data, for the management of patients with diabetes.

ALLY displays a wide range of data on patients, shown with symbols, colours, codes and graphs.

ALLY allows manual data entry and, also interfaces with other devices (blood glucose meters, mobile phones etc.) to download, store, process and revise the clinical data.

ALLY is a modular system that supports the HCP to review and optimise the therapy for patients. This is accomplished by storing registered data and allowing its optimal and prompt use.

ALLY is designed to be used by HCPs.

2. Disclaimer

This document is intended for HCPs with a good knowledge of procedures and specific medical terminology. Before using ALLY, please read this User Manual and all information carefully.

The use of ALLY by any person other than the intended recipients, for any purpose or application other than that specified in the User Manual, or failure to comply with any of the instructions, will be considered IMPROPER USE.

AGAMATRIX and METEDA will not be held responsible for any incorrect user settings.

IMPORTANT: It is recommended that the HCP computer is kept up to date with the latest security software.

3. Minimum system requirements

The functionality of the application is guaranteed by the following system requirements:

Client hardware and software requirements

ALLY 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 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 (1280 x 800 pixels are recommended).

4. Which blood glucose meters can be downloaded to ALLY?

Data from the AgaMatrix WaveSense JAZZ and WaveSense JAZZ Wireless meters can be downloaded to the ALLY Blood Glucose Monitoring System. The WaveSense JAZZ Wireless meter requires the use of the AgaMatrix Diabetes Manager app to transfer data to ALLY Home.

IMPORTANT: Please use only the AgaMatrix cable to connect your WaveSense JAZZ meter to ALLY.

When the device is connected to the computer, the functions are disabled. Do not perform a blood glucose test whilst the device is connected to the computer.

5. How to install ALLY

Download the installation file from the link provided by AGAMATRIX. Call AgaMatrix Customer Care if you have questions. Click on 'launch' to complete installation. When the software installation is complete, the software starts automatically.

6. Login

To access ALLY a User Account is required. The Site Administrator is required to create User Accounts for all members of staff that will use ALLY in the Site.

Once a User Profile has been set up ALLY can be accessed by entering the 'User Name' and 'Password', in the following screen:

7. Navigating ALLY

The ALLY interface is easy to understand and navigate.

This section of the manual will demonstrate how to navigate through the main functions of the software.

The software displays data for diabetes management in a single screen using symbols, colours and graphics in order to:

- Help focus on significant diabetes information to support the HCP in deciding how to manage therapy and provide the best possible care to patients
- Reduce information overload and save time, helping to provide the knowledge needed to optimise the clinical decision-making process whilst prioritising patients by need

HCPs have the following main functions available:

- Menus visible when accessing ALLY
- Menus visible after selecting a patient
- General functions

7.1 Menus visible when accessing ALLY

'ALL PATIENTS' - Displays the list of patients registered in the software

'TELEHEALTH PATIENTS' - Displays the list of patients activated with ALLY Home or AgaMatrix Diabetes Manager integrations (see chapter 8.3)

'USERS' - Displays the module containing the list of registered users in ALLY (visible only to administrator users)

'STATISTICS' - Displays statistics and graphs to assist the interpretation of data.

7.2 Menus visible after selecting a patient

'DASHBOARD' - Useful for examining the general status of patients and easily identifying areas that need attention

'DATA MANAGEMENT' - For the review and management of patient self-monitoring data, viewable in graphs. The software allows an HCP to choose from five types of data reports to help identify data trends: 'Daily Trend', 'Modal Day', 'Modal Week', 'Modal Meals' and 'Logbook'. In this module blood glucose data from compatible devices can be downloaded, with the function 'Device download', and the blood glucose target for the patient viewed and updated.

'MEDICAL HISTORY' - Displays the medical history of the selected patient

'TEST RESULTS' - View and record the results of laboratory tests

‘TREATMENT‘ - Verify and update the therapy prescribed to the patient;

7.3 General functions

The following general functions are available on the right side of the blue navigation bar:

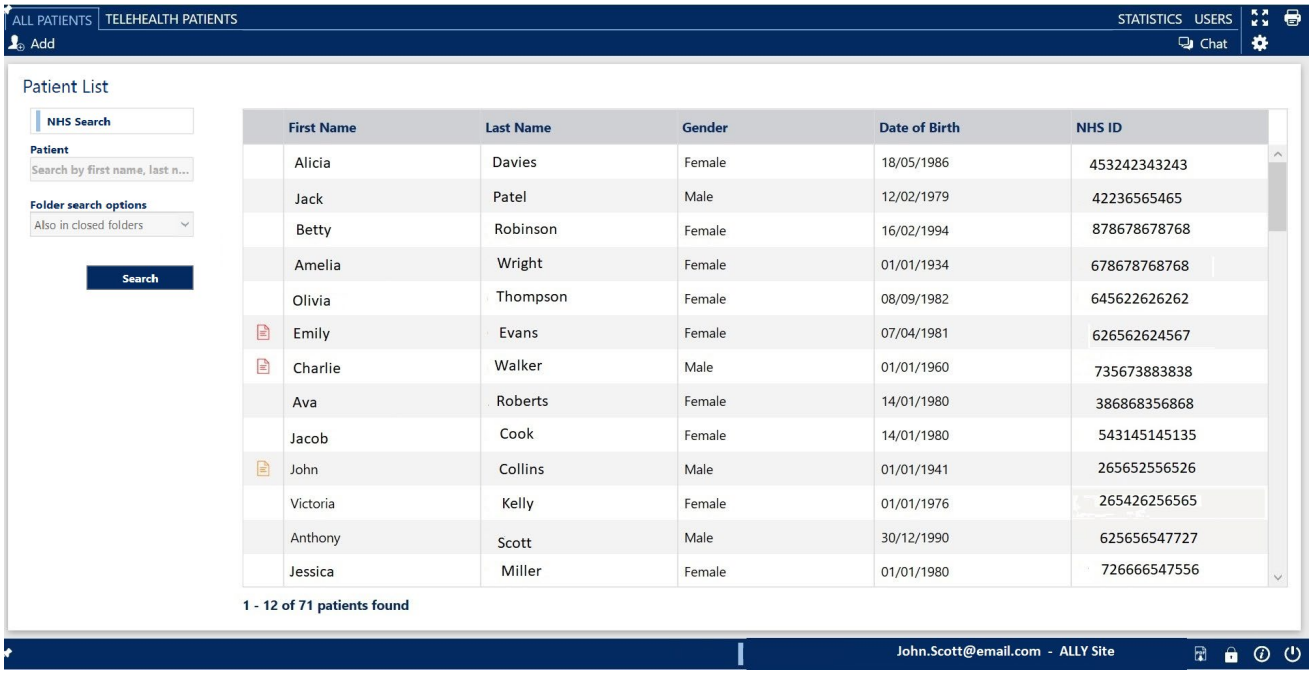
View of the current page in full screen**;**

Print the current page;

Management and customise software settings**.**

8. Patients

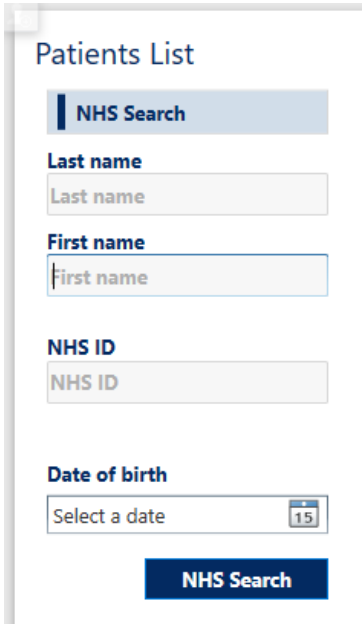
The ‘ALL PATIENTS’ module allows viewing and managing the list of patients registered in the Site’s ALLY database.



The search for patients, who are already registered, can be performed in two different ways:

- Patient search: search by last name and/or first name. This search finds patients that are already listed within the Site’s ALLY system.
- NHS Search: this function allows the HCP to carry out a search entering First Name, Last Name, Date of Birth and NHS ID. This search finds any patient that is listed within the ALLY cloud.

To run the NHS Search, click on



IMPORTANT: All the search fields must be filled to perform the 'NHS Search'.

Based on the search criteria, the system will display the results.

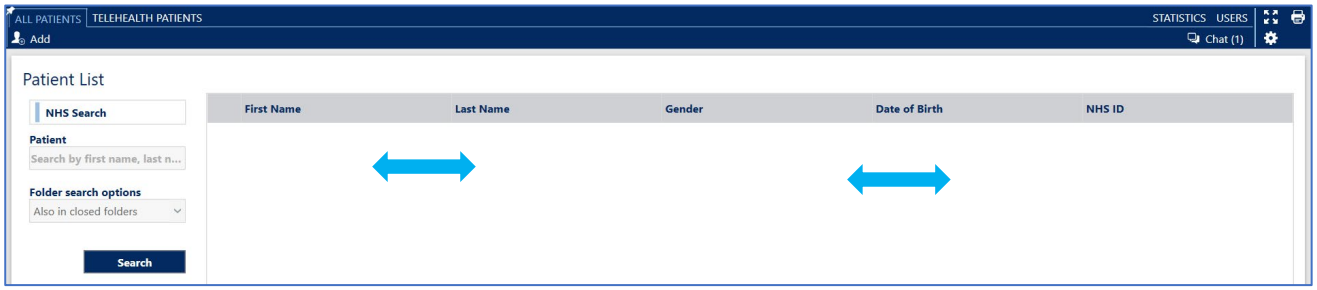
The results table can include different fields related to personal data, contacts, contact details, health data and other details.

To graphically customise the information displayed in the patient list, click the 'Show application settings' icon then 'Visible Fields' of the 'Personal data'. This will access the complete list of viewable details.

Click on the title of each column to display an arrow that

allows the HCP to change the data display order.

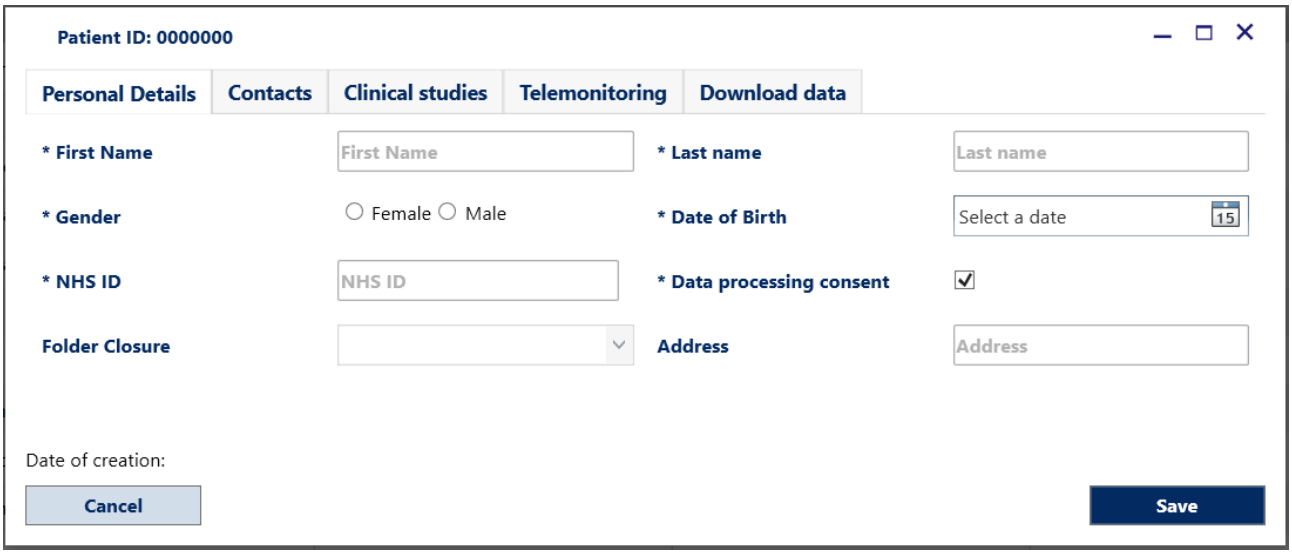
By clicking on the columns title and dragging them, it is possible to change the order (of the columns) in the patient list.



Changes made to the layout will be saved when exiting the software. The changes apply only to the current user.

To add a new patient, click the button present in the 'ALL PATIENTS' module.

The system will display a page composed of several tabs as shown in the following image:

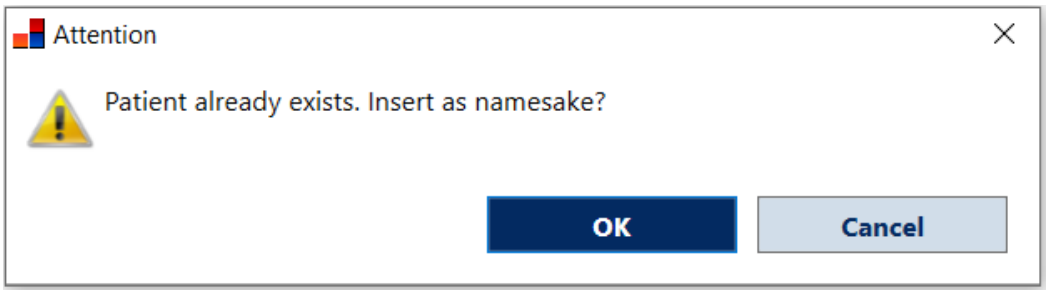


When adding a new patient, it is necessary to fill the mandatory fields marked with an asterisk (*) which are 'First Name', 'Last Name', 'Gender', 'Date of Birth', 'NHS ID', 'Site' and tick the 'Data processing consent' box.

At the end, click the button to store the entered data in the database. The system will automatically close the window and select the new patient created.

The button is also present in the data entry window of a new patient which, if pressed, will close the window without storing the entered data.

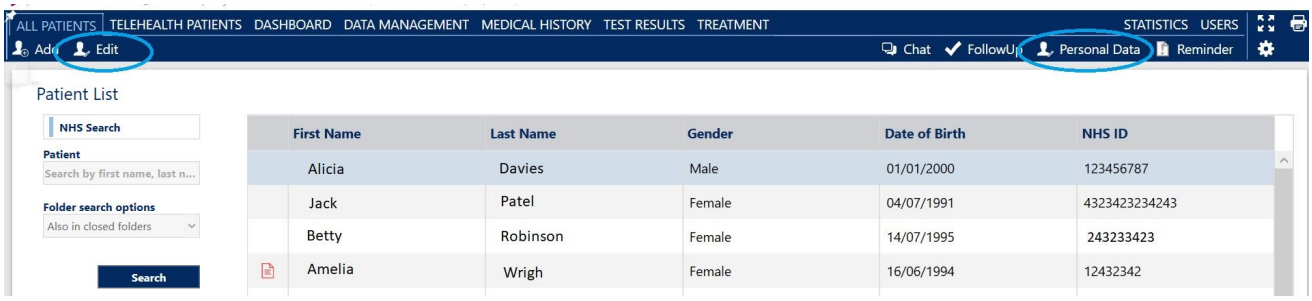
The system alerts the HCP to the registration of a patient with the same name as an already registered patient. When clicking on the button , a warning message will be displayed:



By clicking the 'OK' button, it will save the additional patient with the same name and surname in the database.

8.1 Modify personal data

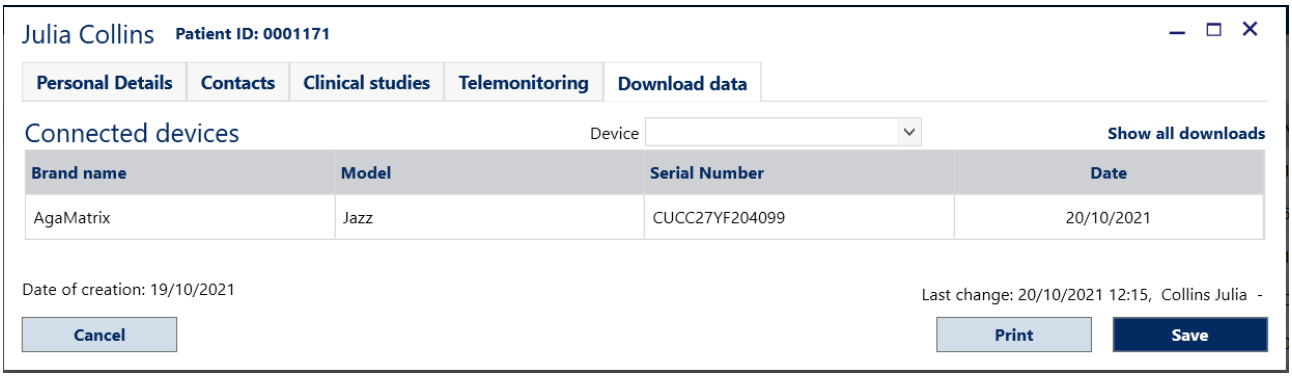
To modify the personal data associated with a recorded patient, search for the patient and click on the line corresponding to the name in order to select the patient and click on 'Personal data' or 'Edit':



The window, with the previously stored data of the selected patient, will open.
After making the necessary changes, the HCP will need to click the 'Save' button.

The 'Personal data' button shown on the right of the menu, highlighted in the previous image, is visible in all the modules of the software for quick access to the personal data.

The tab 'Download data', included on the 'Personal data' window, lists the connected device details for the selected patients. Specifically, it shows the device brand, model, serial number and date of last download.



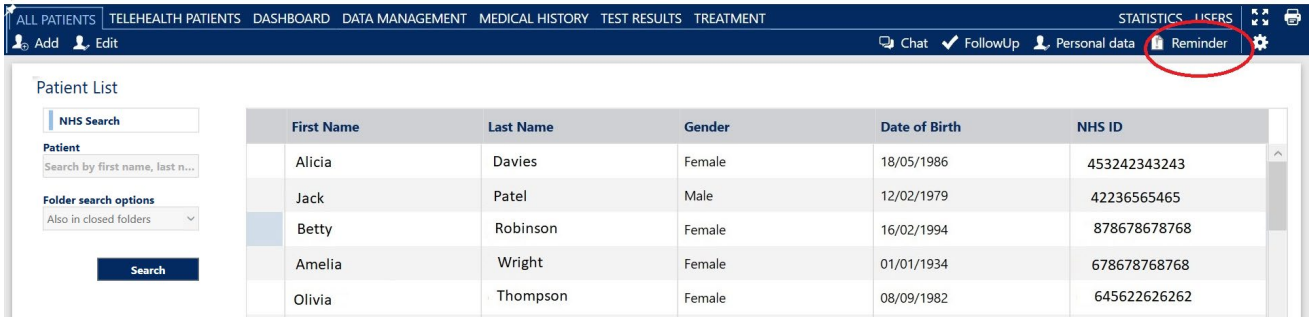
The following information is displayed:

- DEVICE: a drop-down list with the 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.

To filter the devices listed click on Device .

8.2 Reminder

Select the patient that you want to set a reminder for, this will highlight the row and open the option to set the reminder. To add the reminder to the selected patient, click on the 'Reminder' button.



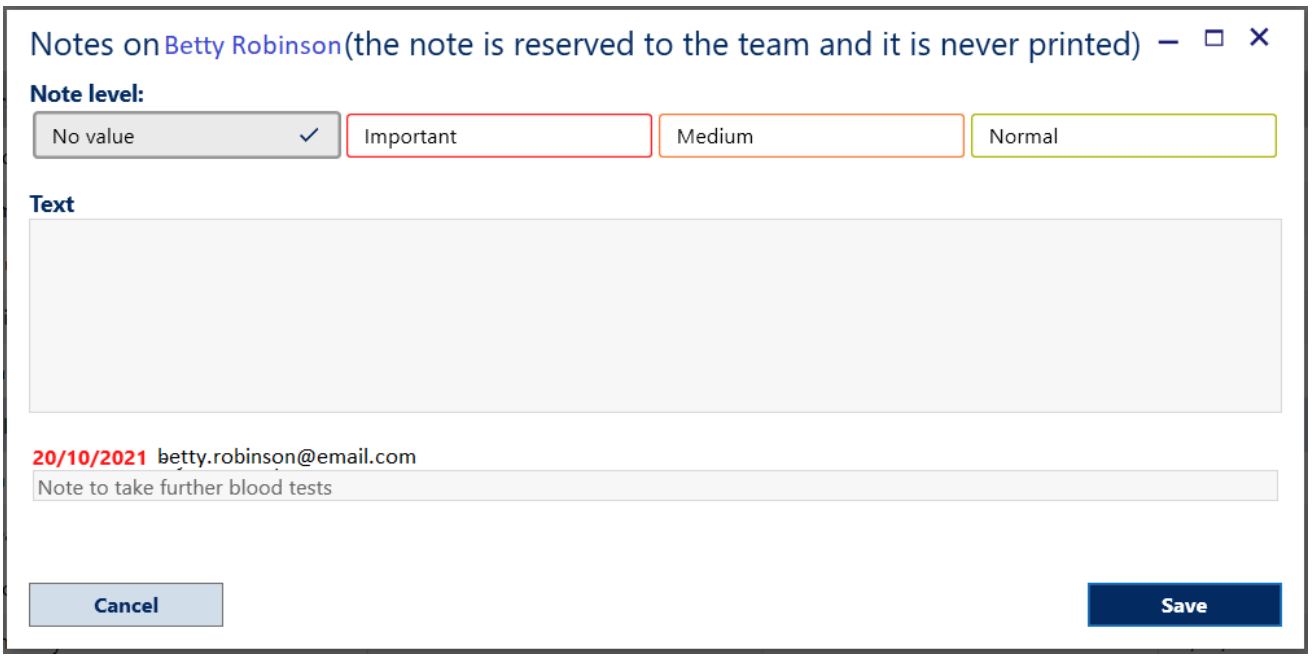
The software will open a window as in the example image below that will allow the user to:

- Assign a level of importance to the recorded information. The states can be: No Value, Important, Medium, Normal
- Enter the reminder in the 'Text' field

By clicking the 'Cancel' button, the reminder will not be saved.

By clicking the 'Save' button, the text will be saved and editable for the rest of the day only.

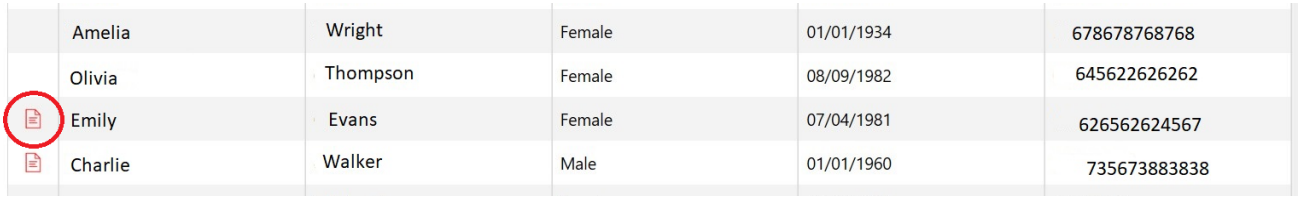
The following day the inserted note will be displayed in the reminder history, under the 'Text' box, with the date and colour relative to the level of importance that was selected during the creation of the reminder.



The records of patients who have a registered note, will be marked with a document symbol that is colour-coded corresponding to the level of importance assigned to the note:

- No value
- Important
- Medium
- Normal

Below there is an example image showing patient reminder icons:



	Amelia	Wright	Female	01/01/1934	678678768768
	Olivia	Thompson	Female	08/09/1982	645622626262
	Emily	Evans	Female	07/04/1981	626562624567
	Charlie	Walker	Male	01/01/1960	735673883838

8.3 ALLY Home and AgaMatrix Diabetes Manager - Activate and deactivate a patient account

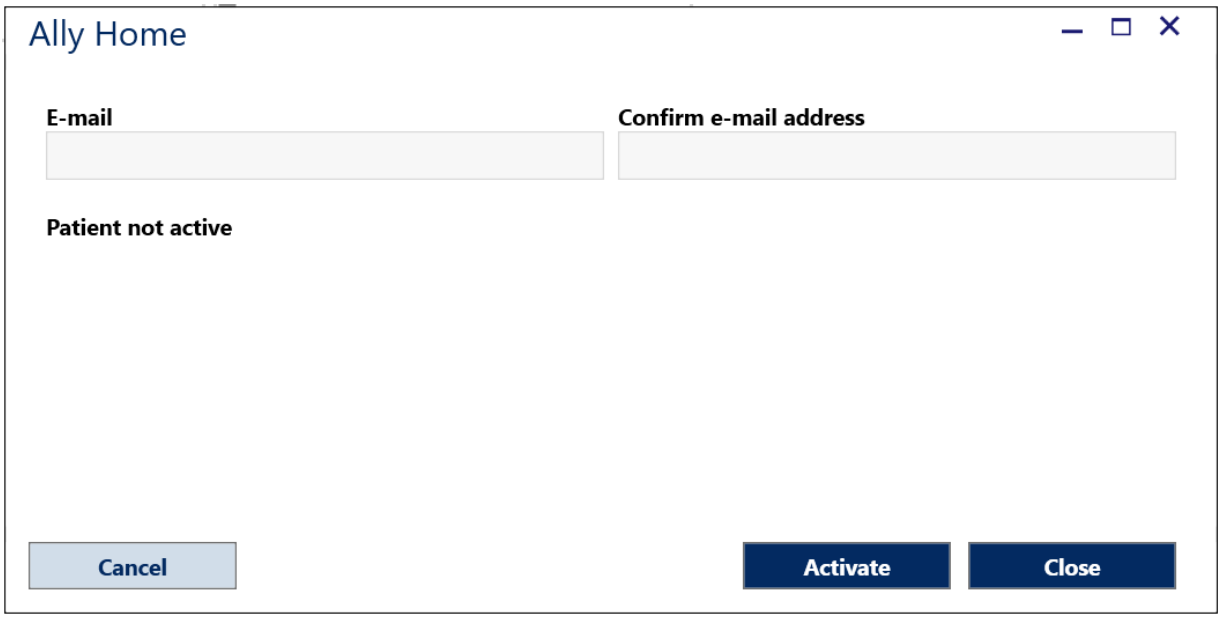
ALLY allows the sharing of data with patients through ALLY Home and the AgaMatrix Diabetes Manager. ALLY Home is a PC software and AgaMatrix Diabetes Manager is a mobile application that allows patients to share their diabetes with their HCP.

To start receiving patient data, the HCP needs to activate the patient's account. Once the ALLY Home account for the patient is activated, HCPs will be able to receive data downloaded by the patient, and exchange messages.

To activate a patient already registered in ALLY, follow the steps below:

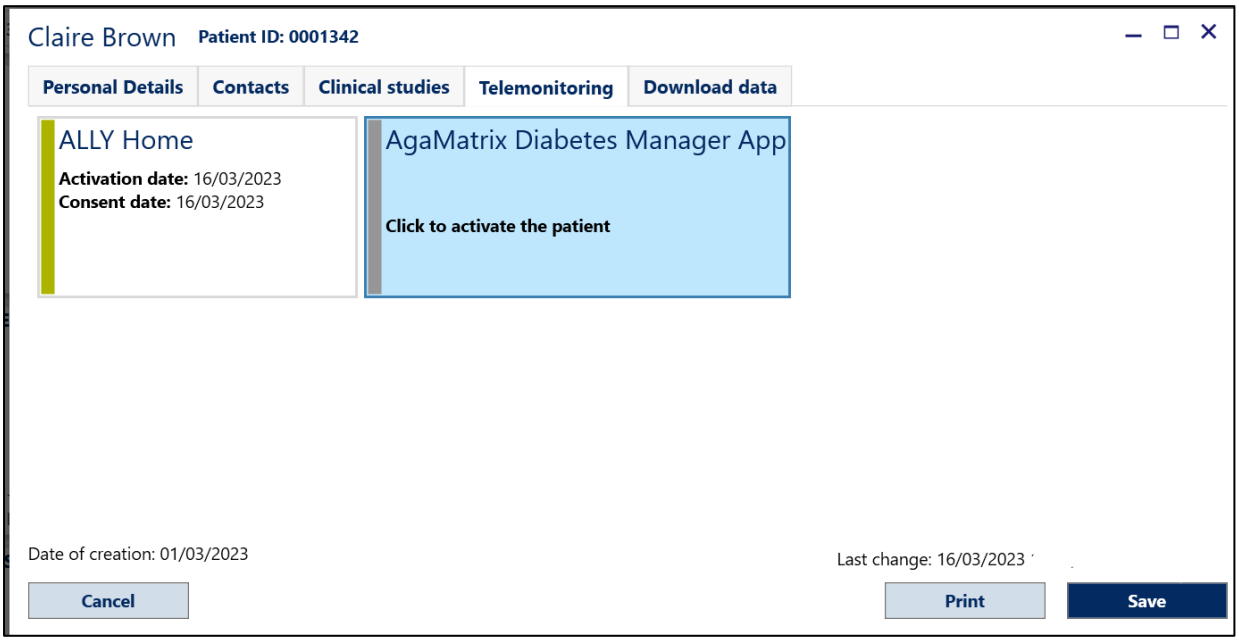
- Click on Personal data on the navigation bar
- Click on the 'Telemonitoring' tab

- Click on the tile ‘ALLY Home’ or ‘AgaMatrix Diabetes Manager App’ depending on which application the patient is using.



To start receiving data from the patient, enter their email address and click on the button.

The patient will receive a welcome email including the link to access their ALLY Home account and the system will display the activation date.



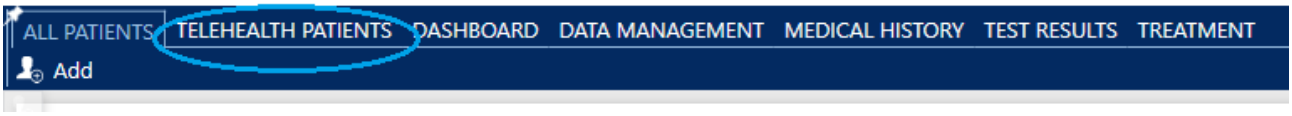
Click the button in order to close the ‘Personal Data‘ window without saving.

To deactivate a patient account, click on the **Disable** button displayed within the activation tile. To complete the deactivation, the HCP will be asked to enter their login password. Once a patient is deactivated the system displays the 'Deactivation date'.

A deactivated patient account can be reactivated by clicking **Reactivate** .

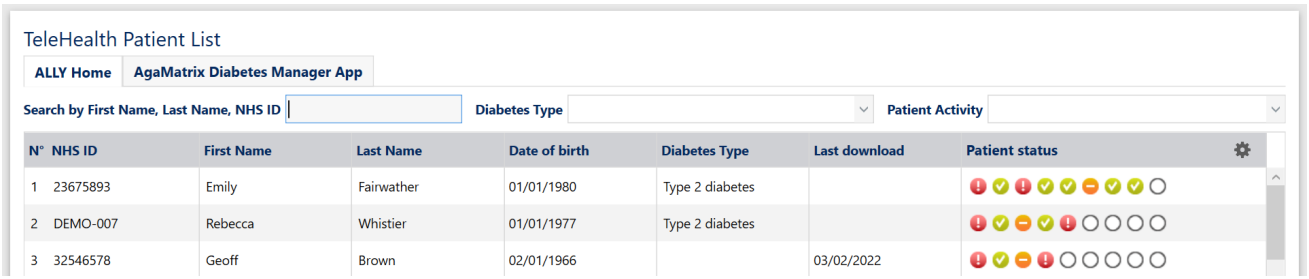
8.3.1 How to manage connected TeleHealth Patients

Click on 'TeleHealth Patients' to show the patients connected via ALLY Home and/or AgaMatrix Diabetes Manager.



The list shows the patients information along with their status and 'last download' date.

To search for patients already registered and activated, type the patient's last name and/or first name in the search bar.



Based on the search criteria, the system will display the results as seen in the above image:

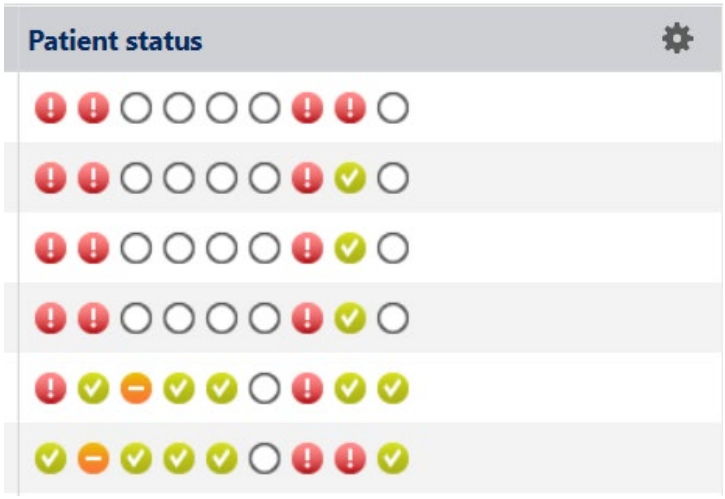
The 'Patient status' column (last column) contains symbols in different colours which match the side bar colours and symbols of the dashboard tiles. By pointing the mouse pointer on each symbol, you will see a tooltip with detailed information. The status is updated every time data is downloaded from a device or entered manually.

IMPORTANT: The patient status displays ◯ information related to the last month of available data

The status icons are white ◯ if no data is available.

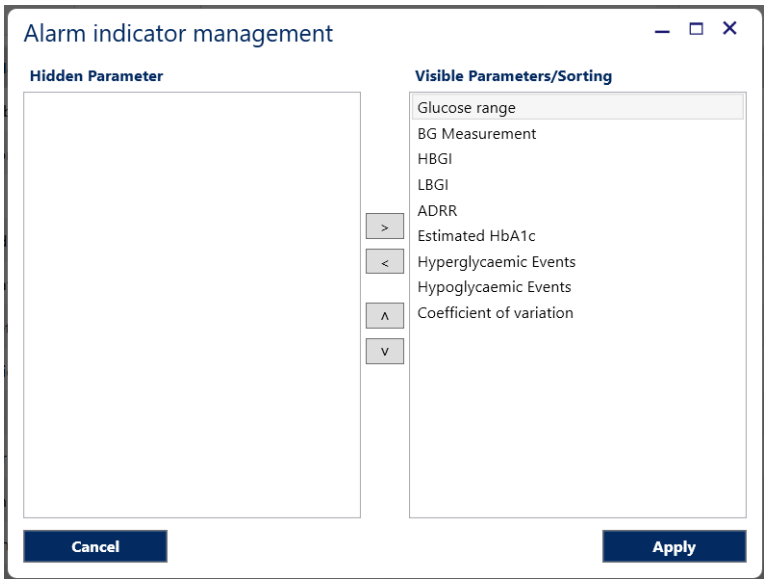
For details about colour coding and symbols refer to the Dashbord chapter (chapter 9).

Patients in the TeleHealth module are listed according to priority order in the ‘Patient Status’ column. The patients with the most red icons will be listed at the top, while the patients with the least red icons will be listed at the bottom.

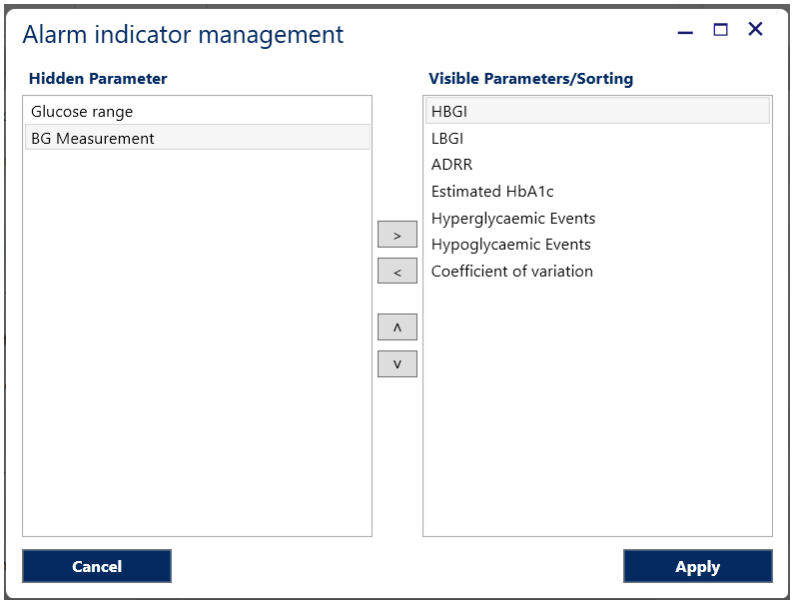


To change the priority list, click on the ‘Patient Status’ title.

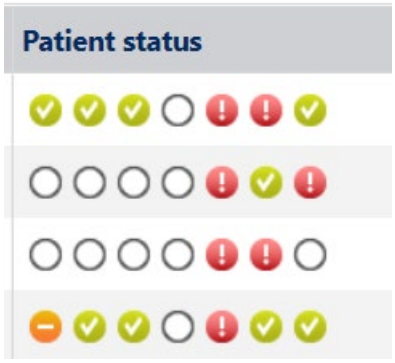
Click the ‘Settings’ icon to manage the the information included in the ‘Patient Status’ column.



Select the item to hide from the ‘Visible Paramenters/Sorting’ column and click < .



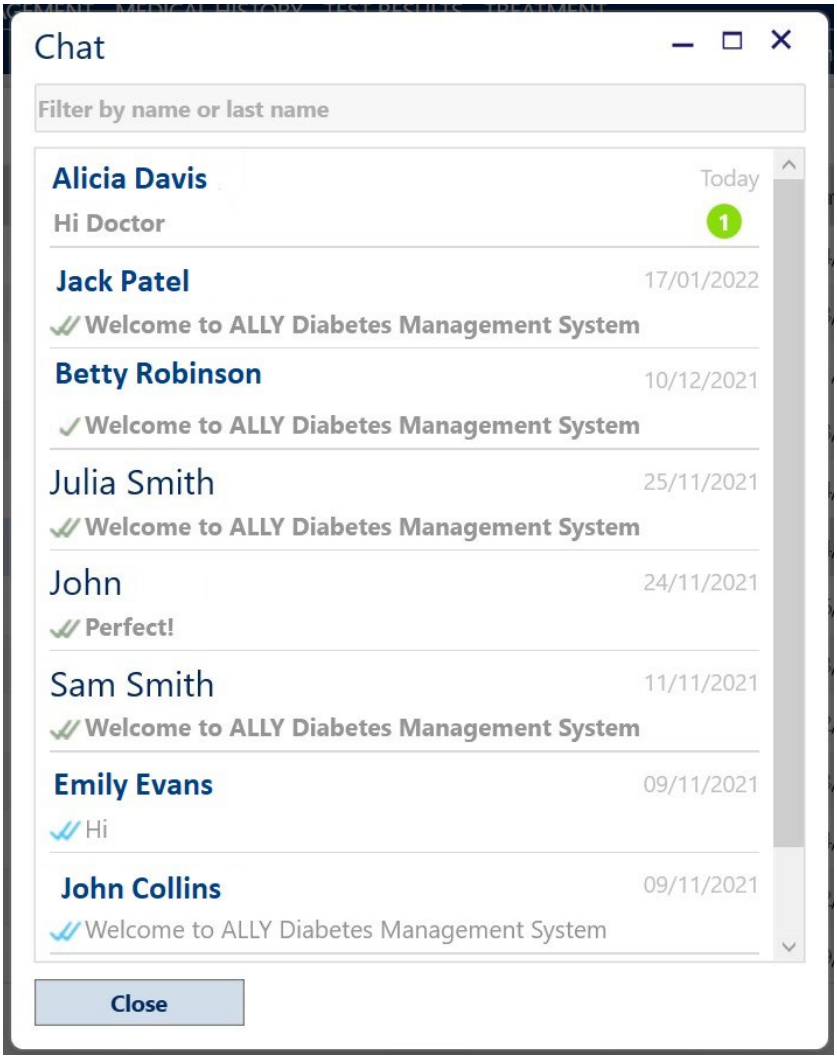
The items included in the ‘Hidden Parameter’ column will be automatically removed from the ‘Patient Status’ column.



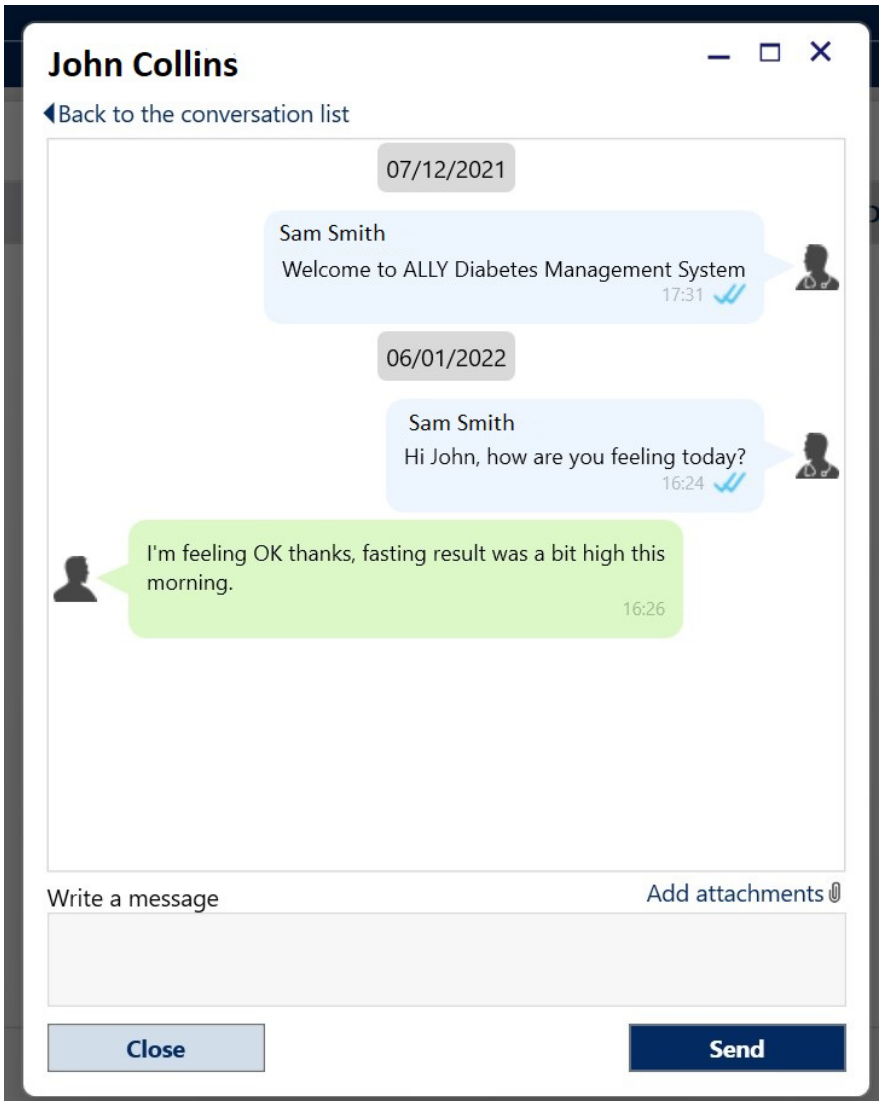
8.4 Chat with the patient

Either in the 'patient list' view or in the 'individual patient' view, the number of unread messages from patients will be shown next to the 'Chat' icon Chat (1) in the navigation bar.

Click on the Chat button in the navigation bar to open the message window. All unread messages from patients will be shown as seen here:



To send a new message or respond to messages from patients, click Chat in the navigation bar. This will open the message window. Click a patient's name to view the message history with that patient or to send a message. Enter the message text and then click the Send button.



IMPORTANT: Do not use the message system for communication of urgent topics with patients.

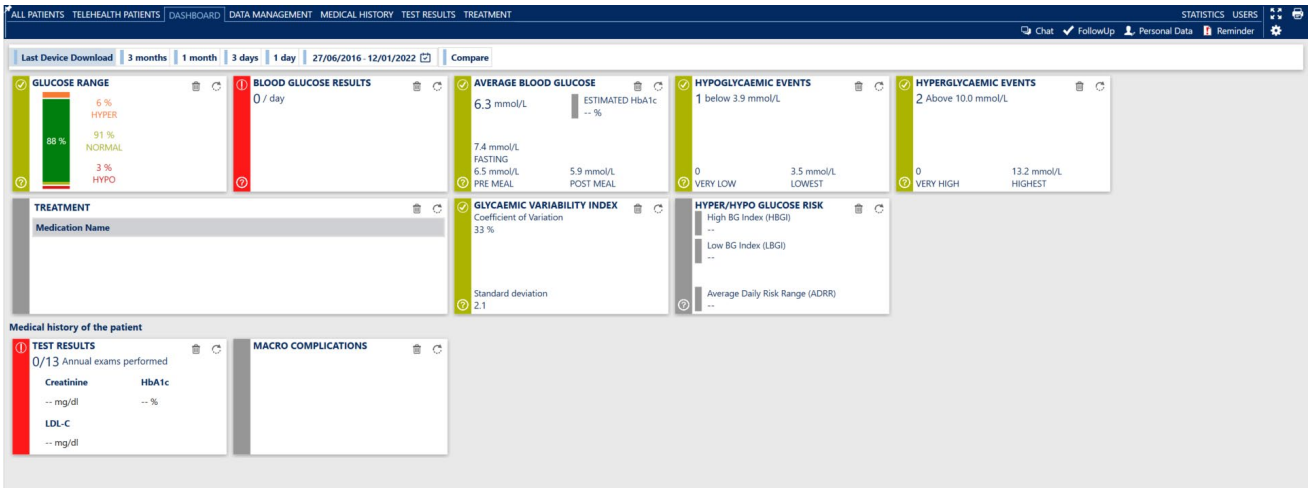
9. Dashboard

The Dashboard provides an instant overview of the overall diabetes trend for an individual patient.

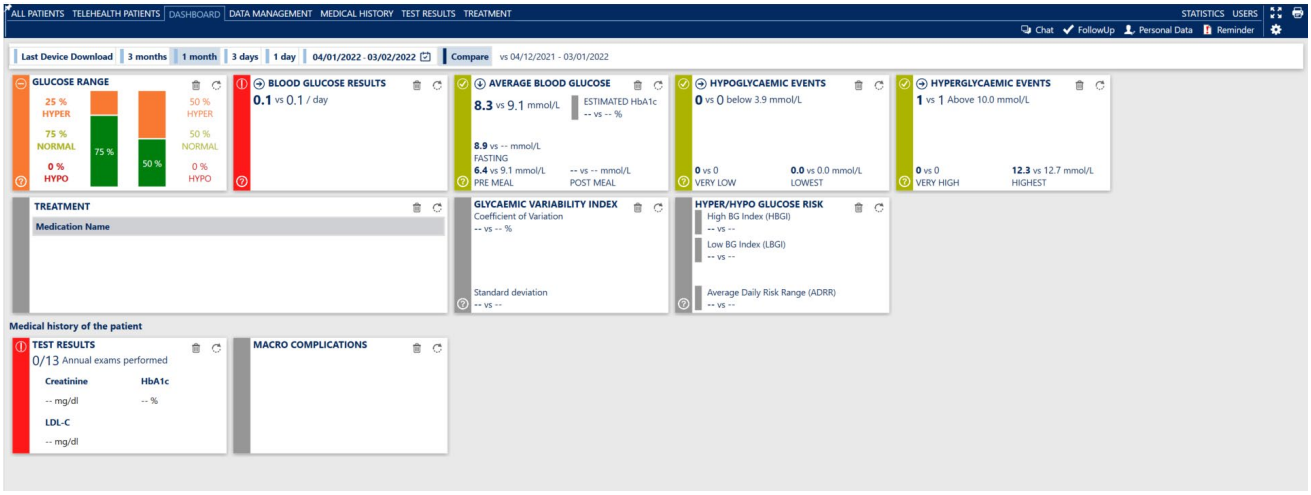
It is possible to view a summary of data of varying time intervals by clicking the buttons ‘Last meter download‘, ‘3 months’, ‘1 month’, ‘3 days’, ‘1 day‘ or it is possible to specify the dates by clicking the button.

In the Dashboard there are up to ten tiles that summarise the most relevant information related to the selected patient. The tiles display fundamental values and highlight whether the therapeutic goals set for these parameters have been reached or not by the patient during a given period.

The data enclosed in each single tile are associated with a traffic light colour code that indicates the relevance and risk level of the data itself, to facilitate a quick and concise assessment.



By clicking on the Compare button, a comparison with the immediately preceding period of the same length of time is made.



The Dashboard is divided into up to ten tiles, each one of them has two sides, by clicking the button the tiles rotate. The following information is displayed:

- Glucose Range
- Blood Glucose Results
- Average Blood Glucose
- Hypoglycaemic Events
- Hyperglycaemic Events
- Treatment
- Glycaemic Variability Index
- Hyper/Hypo Glucose Risk
- Test Results
- Macro Complications

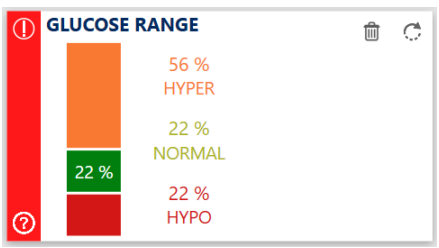
By clicking on the '?' icon, you can display a legend that explains how to interpret the information, the colours, and the icons in the tile.

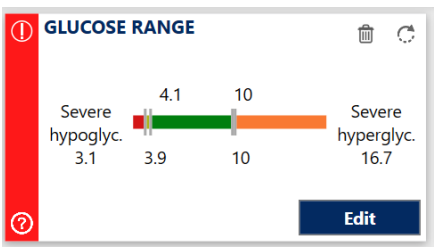
9.1 Glucose Range

This tile displays the breakdown of blood glucose readings expressed in percentage and based on the targets set in the 'Blood Glucose Targets' (% hyperglycaemic, % normal, % hypoglycaemic);

Below are two images in which both sides are visible. By clicking the

button, it will be possible to access the 'Patient Target' in the 'Glycaemic Target' setting window.



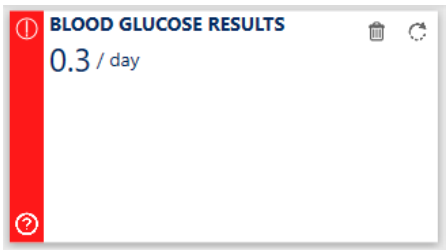


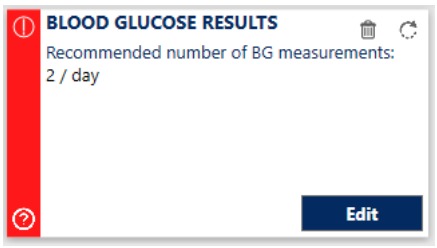
The vertical-coloured indicator changes according to the following conditions:

- If more than 80% of the results are included in the normal range
- If between 50 and 80% of the results are included in the normal range
- If less than 50% of the results are included in the normal range

9.2 Blood Glucose Results

This tile displays the average daily number of blood glucose measurements; on the second side it is possible to set the 'Recommended number of blood glucose measurements per day'.



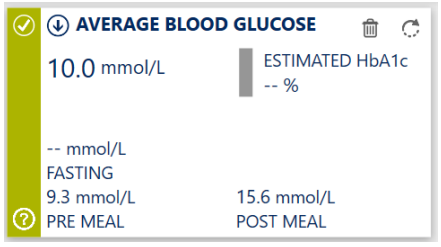


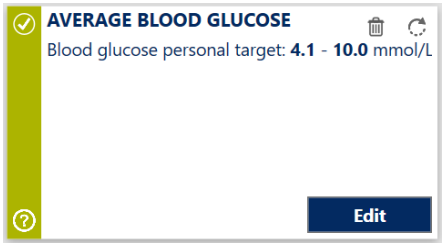
The vertical-coloured indicator changes according to the following conditions:

- if the value is equal to or greater than the target;
- if the value is lower than the target but equal to or greater than 75% of the target;
- if the value is less than 75% of the target.

9.3 Average blood glucose

This tile displays the average value of all recorded blood glucose readings (fasting, pre-meal, post-meal). By clicking the **Edit** button of the second box, the 'Patient Target' will be accessible in the 'Blood Glucose Target' setting window.





The vertical-coloured indicator changes according to the following conditions:

- If the value is within the normal range set as a personalised target
- If the value does not fall within the normal range set as a personalised target but falls between the thresholds set for hypoglycaemia and hyperglycaemia
- If the value is below the hypoglycaemia threshold or above the hyperglycaemia threshold

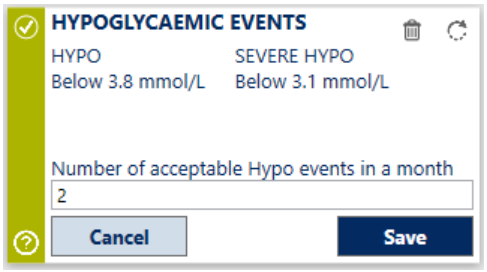
9.4 Hypoglycaemic Events

The following data are displayed:

- The number of hypoglycaemic events
- The number of ‘very low‘ hypoglycaemic events (‘very low‘ <3.1 mmol/L)
- The lowest blood glucose reading (‘lowest‘)

Hypoglycaemic events represent one or more hypoglycaemic readings recorded within thirty minutes.

On the reverse side it is possible to set the ‘Number of acceptable hypo events in a month’.



The vertical-coloured indicator changes according to the following conditions:

If the number of hypoglycaemic events is ≤ of the target and no ‘very low‘ hypoglycaemic events occurs

If the number of hypoglycaemic events is > of the target but ≤ 2 in respect to the target, without any ‘very low‘ hypoglycaemic events

If the hypoglycaemic events number is > 2 compared to the target or a ‘very low‘ hypoglycaemic event has been recorded

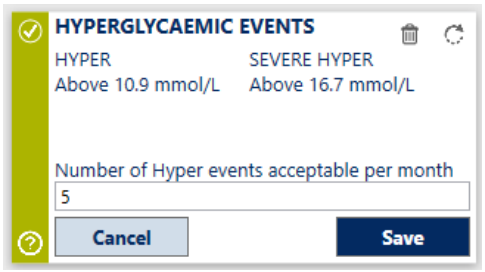
9.5 Hyperglycaemic Events

The following data are displayed:

- The number of ‘hyperglycaemic’ events
- The number of ‘very high‘ hyperglycaemic events (‘very high‘ >16.7 mmol/L)
- The highest blood glucose reading (‘highest‘)

Hyperglycaemic events represent one or more hyperglycaemic values recorded within a thirty-minute time period.

On the reverse side it is possible to set the ‘Number of hyperglycaemic events acceptable per month‘.



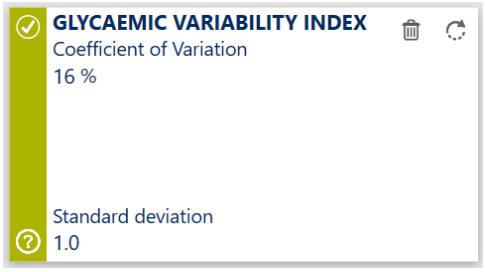
The vertical-coloured indicator changes according to the following conditions:

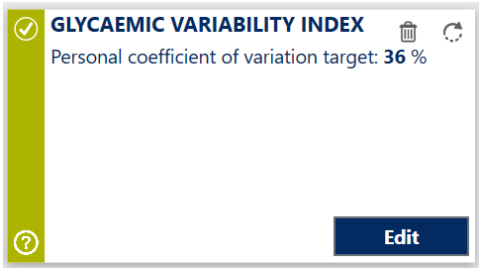
- If the number of hyperglycaemic events is ≤ the target and no 'very high' hyperglycaemic events occurs
- If the number of hyperglycaemic events is > the target but ≤ 2 with respect to the target, without 'very high' hyperglycaemic events
- If the hyperglycaemic events number is > 2 compared to the target or a 'very high' hyperglycaemic event is recorded

9.6 Glycaemic Variability Index

The following data are displayed:

- The value for the Coefficient of Variation
- The Standard Deviation





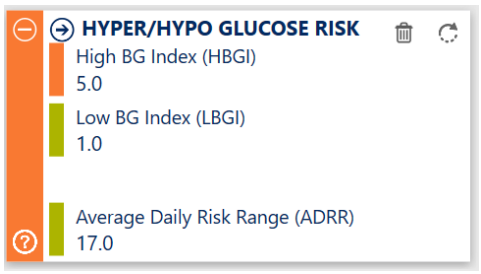
The vertical-coloured indicator changes according to the following conditions:

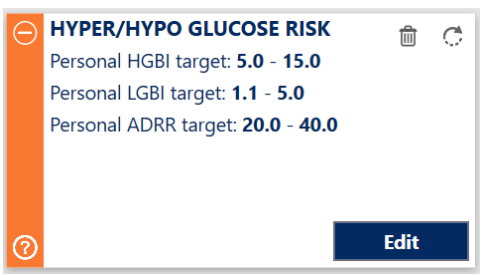
- if the Coefficient of Variation value is < the cut-off
- if the number of hyperglycaemic events is > the target but ≤ 2 with respect to the target, without 'very high' hyperglycaemic events
- If the hyperglycaemic events number is > 2 compared to the target or a 'very high' hyperglycaemic event is recorded

9.7 Hyper/Hypo Glucose Risk

The following data are displayed:

- High Blood Glucose Index (HBGI)
- Low Blood Glucose Index (LBGI)
- Average Daily Risk Range (ADRR)





The vertical-coloured indicator changes according to the following conditions:

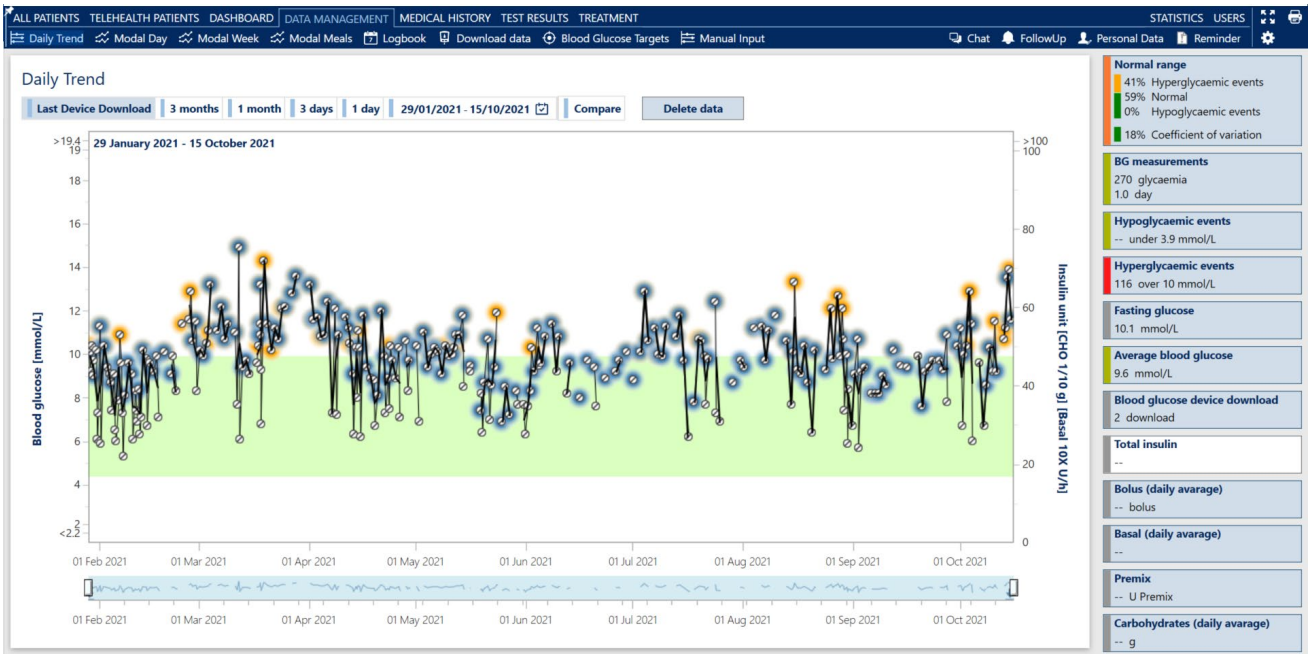
If HBGI, LBGI and ADRR values are < the normal limit set for the patient

If at least one of the HBGI, LBGI, ADRR values is between the normal and the risk cut-offs set for the patient and none of the three values is above the risk cut-off set for the patient

If the value of HBGI or LBGI or ADRR is > the risk cut-off set for the patient

10. Data Management

The Data Management module is for the review and management of patient self-monitoring data, also viewable in graphs.



Graphs of the ‘Daily Trend’, ‘Modal Day’, ‘Modal Week’, ‘Modal Meals‘ can be viewed. If used and interpreted correctly, these reports can prove to be extremely helpful tools for diabetes management.

The graphical presentation of the data is simple and intuitive and is designed to effectively support the identification of the most appropriate therapeutic interventions to improve clinical results, since they highlight the areas that need more attention.

In the Data Management module you can access the Logbook, download data from patient's devices and set the patient's blood glucose targets.

Each report displays the patient's results in a different way making it possible to choose the most useful by individual HCP preference.

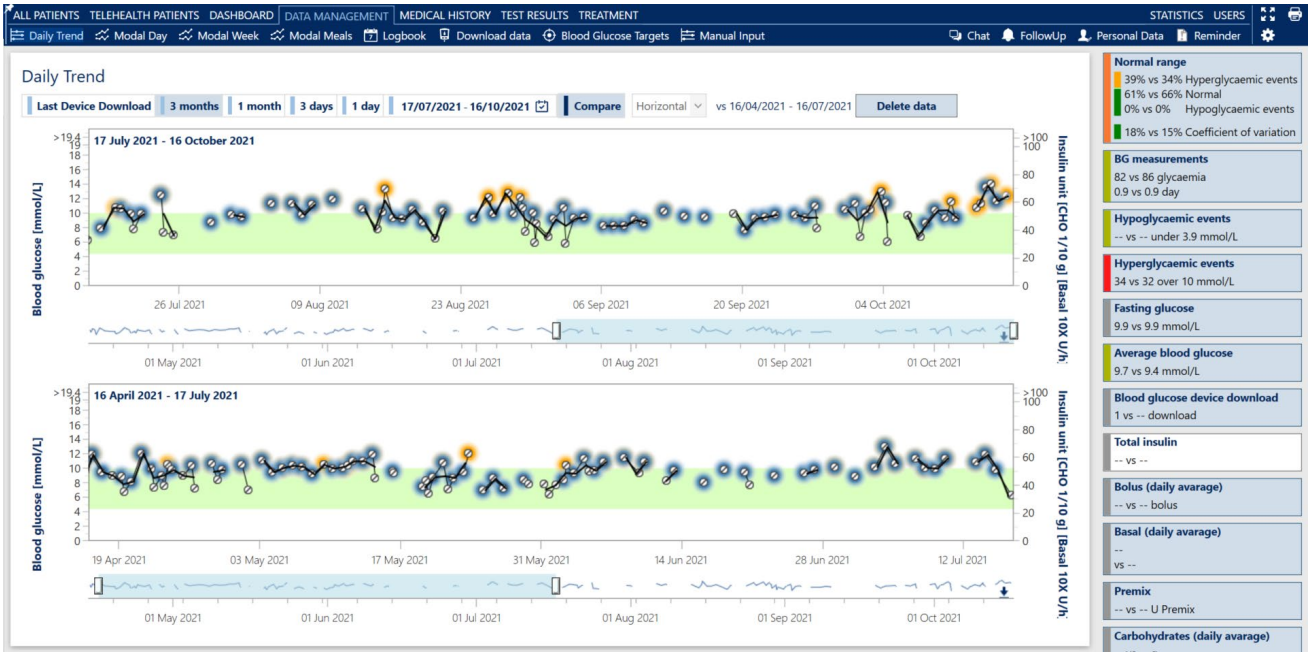
Each graph has a selection bar (shown below) for the period during which data will be displayed.

'Last Meter Download': displays a graph of the last blood glucose readings downloaded from the blood glucose meter.

'3 months', '1 month', '3 days', '1 day': displays a graph of blood glucose readings from the selected timeframe, it is also possible to set a personalised period by clicking the calendar icon and selecting a start and end date.

The 'Compare' button

: A graphic comparison with the immediately preceding period over the same length of time.



The

comparison can be made by setting graphs on two horizontal or vertical lines.

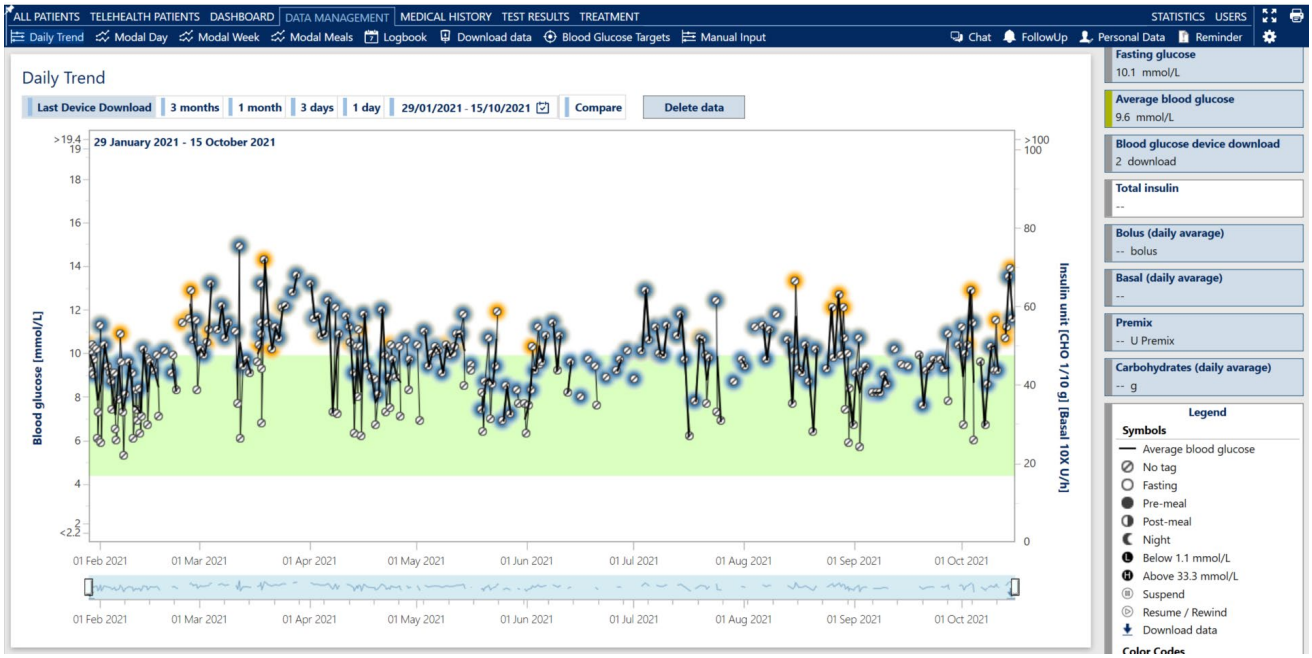
Click the button again to return to the single graph display.

The "Mini-dashboard" located to the right of the data report allows you to review the values of key dashboard metrics additional functionalities related to each data report.

10.1 Daily trend

The ‘Daily Trend‘ graph shows the blood glucose readings that have been downloaded from devices or entered manually in ALLY as well as the other information that is useful for the evaluation of the general status of the patient.

Below is a sample image of a graph for patients using connected devices:



The blood glucose scale is displayed on the left vertical axis, while the insulin and carbohydrate data are projected on the right vertical axis.

The green horizontal bar identifies the personal blood glucose target (‘Normal Range‘), for the selected patient.

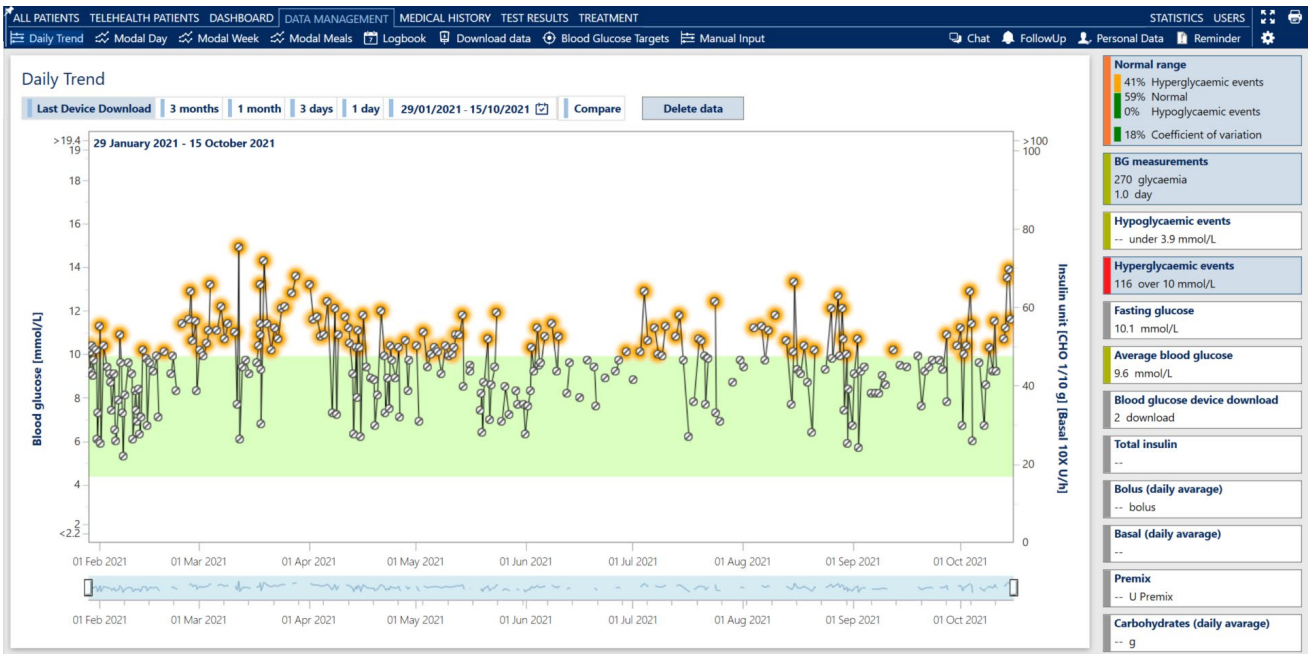
The scroll bar below the graph allows a quick overview of blood glucose readings.

The arrows indicate when the blood glucose data was downloaded.

The period displayed can be changed by moving the time selectors.

In the right column there is the list of values displayed. To activate or deactivate the display, click the corresponding name. The tiles of the self-monitoring blood glucose in addition to the summaries of the numerical values that are related to the item indicated in the text, have an automatic traffic light colour code that indicates the relevance and risk level of the given data.

Below there is an example of a graph showing the ‘Normal range’, ‘Blood glucose measurement’ and ‘Hyperglycaemic events‘:



The blood glucose scale is displayed on the left vertical axis, while insulin and carbohydrate data are on the right vertical axis. Blood glucose values higher than the maximum value displayed on the left vertical axis are plotted on one line at the top of the chart.

Additional presentation options are provided by the “Mini-dashboard” tiles:

- If you click on the “Hypoglycaemic events” tile, the hypoglycaemic values are highlighted in red
- If you click on the “Hyperglycaemic events” tile, the hyperglycaemic values are highlighted in orange
- If you click on the “Average blood glucose” tile, a black line representing the average blood glucose for each day is displayed

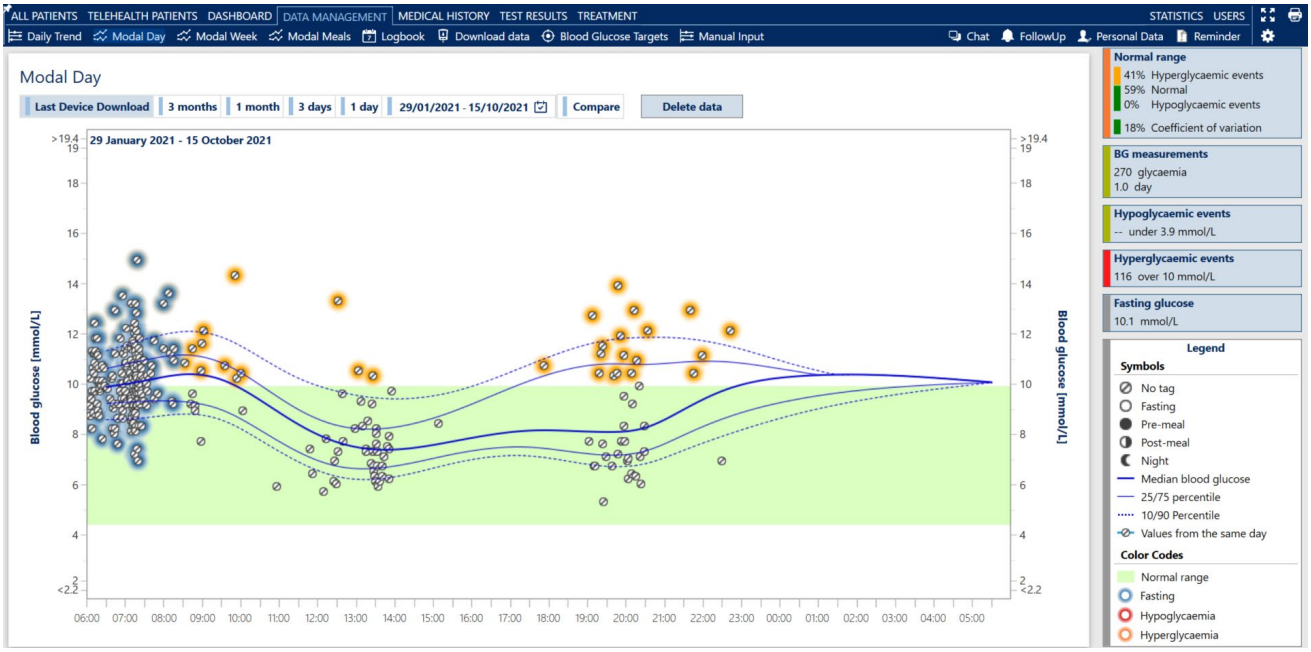
10.2 Modal Day

The Modal Day graph provides a presentation of the amount of fluctuation in the patient's blood glucose levels and allows the identification of blood glucose readings within the area of the patient’s personal target (‘Normal Range‘) as well as ‘hypoglycaemic‘ and ‘hyperglycaemic events‘.

The graph shows the moments of the day in which the patient finds most difficult to maintain good glycaemic control, thus making it easier to identify the most appropriate therapeutic intervention.

The graph shows the patient's average blood glucose results over 24 hours, highlighting each hypoglycaemic or hyperglycaemic event.

The graph overlays each day's results for the time period selected.



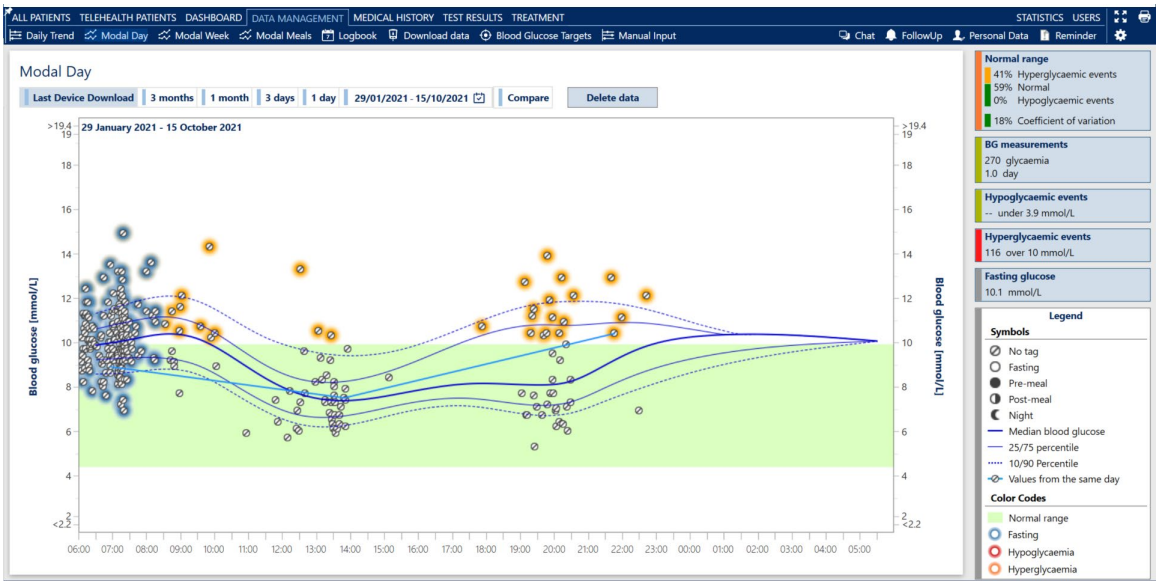
The black line in bold represents the median of the blood glucose results recorded.

The thin black 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 on the right side of the screen provides a key to assist interpretation of the graph.

The 'Modal Day' graph visually shows the range of fluctuation. The greater the distance between the 25th and 75th percentile, the greater the daily blood glucose variability.

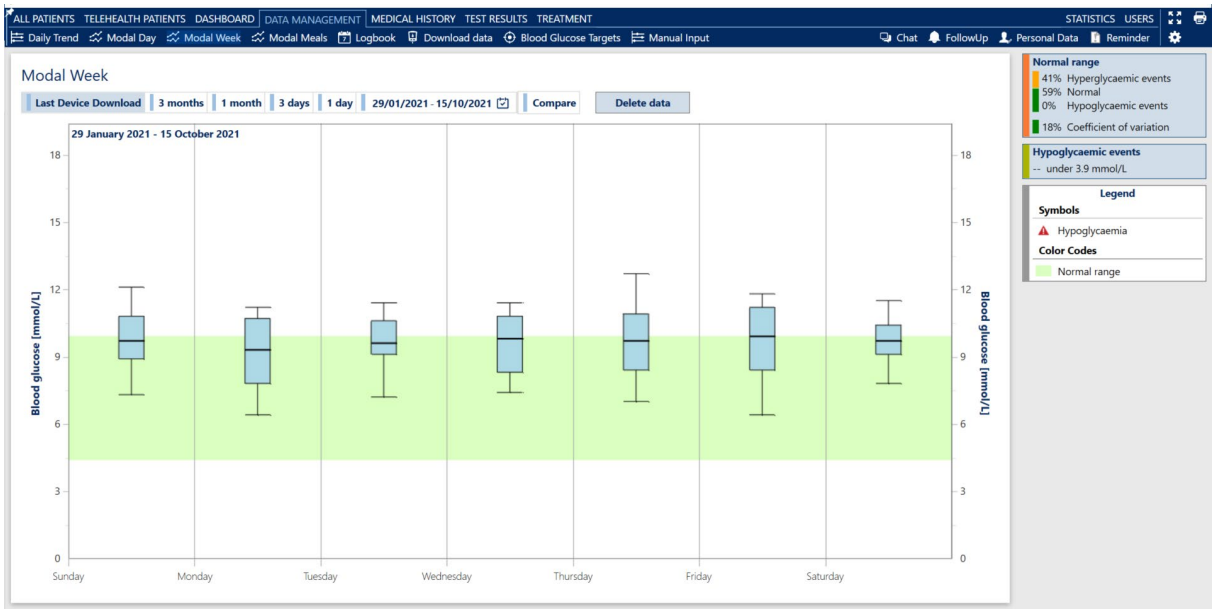
By clicking on a blood glucose result, the data collected on the same day are connected with a blue line that will display the blood glucose trend within 24 hours, as shown in the following image:



As in the ‘Daily trend‘ graph, it is possible to activate or deactivate the display of the ‘Normal range’, ‘Blood glucose measurements’, ‘Hypoglycaemic events’, ‘Hyperglycaemic events’ and ‘Fasting blood glucose‘.

10.3 Modal Week

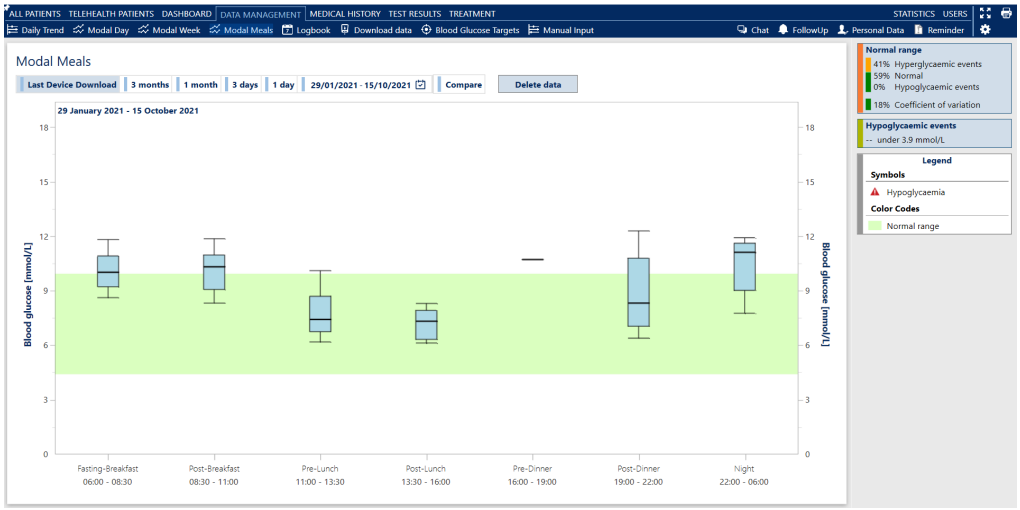
The ‘Modal Week‘ graph displays the days of the week in which the patient finds most difficult to maintain a good glycaemic control, thus making it easier to identify the most appropriate therapeutic intervention.



The percentiles and average of the blood glucose results recorded by the patient are displayed daily, highlighting hypoglycaemic events by the appearance of red warning triangle.

10.4 Modal Meals

The ‘Modal Meals‘ graph displays the meals in which the patient experiences the greatest difficulty in maintaining good glycaemic control, making it easier to identify the most appropriate therapeutic intervention.

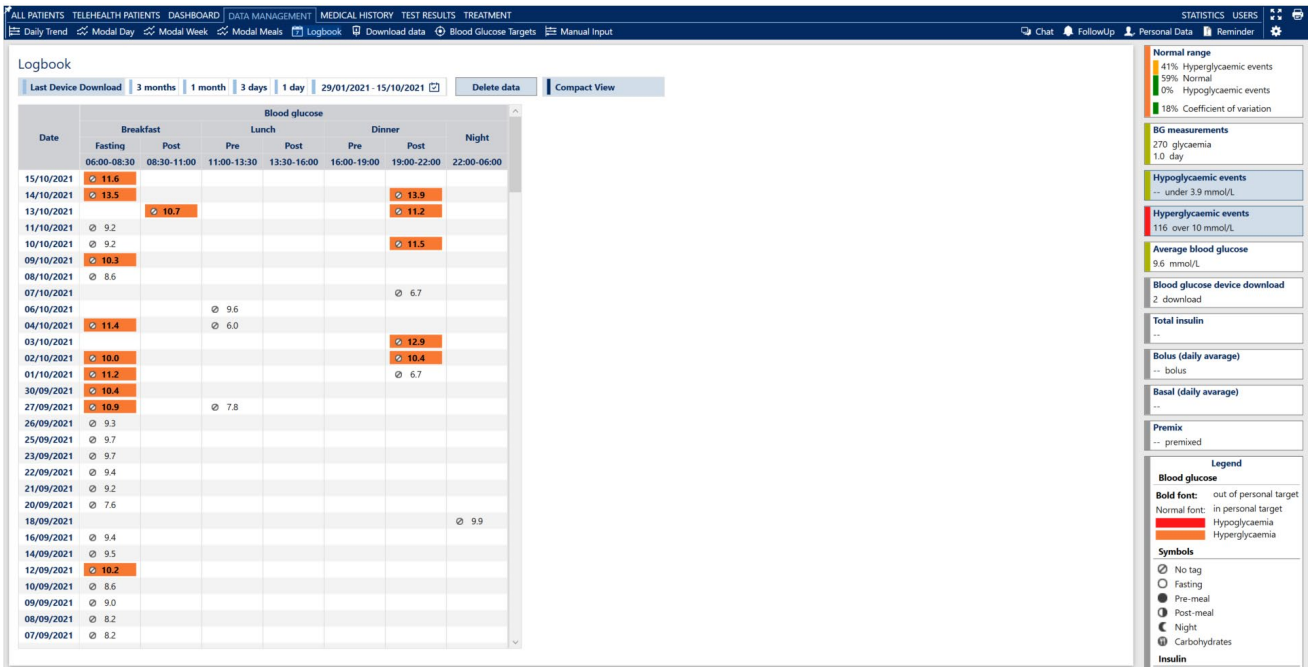


The ‘Modal Meals‘ graph displays both the percentiles and the average blood glucose results recorded by the patient during the day relative to the timeframe defined in the patient target. It highlights hypoglycaemic events by displaying a red danger triangle.

10.5 Logbook

The Logbook displays the blood glucose readings for: ‘Pre‘ and ‘Post‘ meals as well as the insulin doses and carbohydrate intake for each meal.

The Logbook is very similar to the patient's diary, widely recognised as an educational tool for patients. It helps the patient to understand the impact of their choices and behaviour on blood glucose levels.



All the blood glucose readings are marked as “Fasting”, “Pre” or “Post” meal, based on the settings defined by the HCP in the Patient’s specific ‘Blood Glucose Targets‘.

Similarly, all insulin units are labelled according to the meal during which they have been administered.

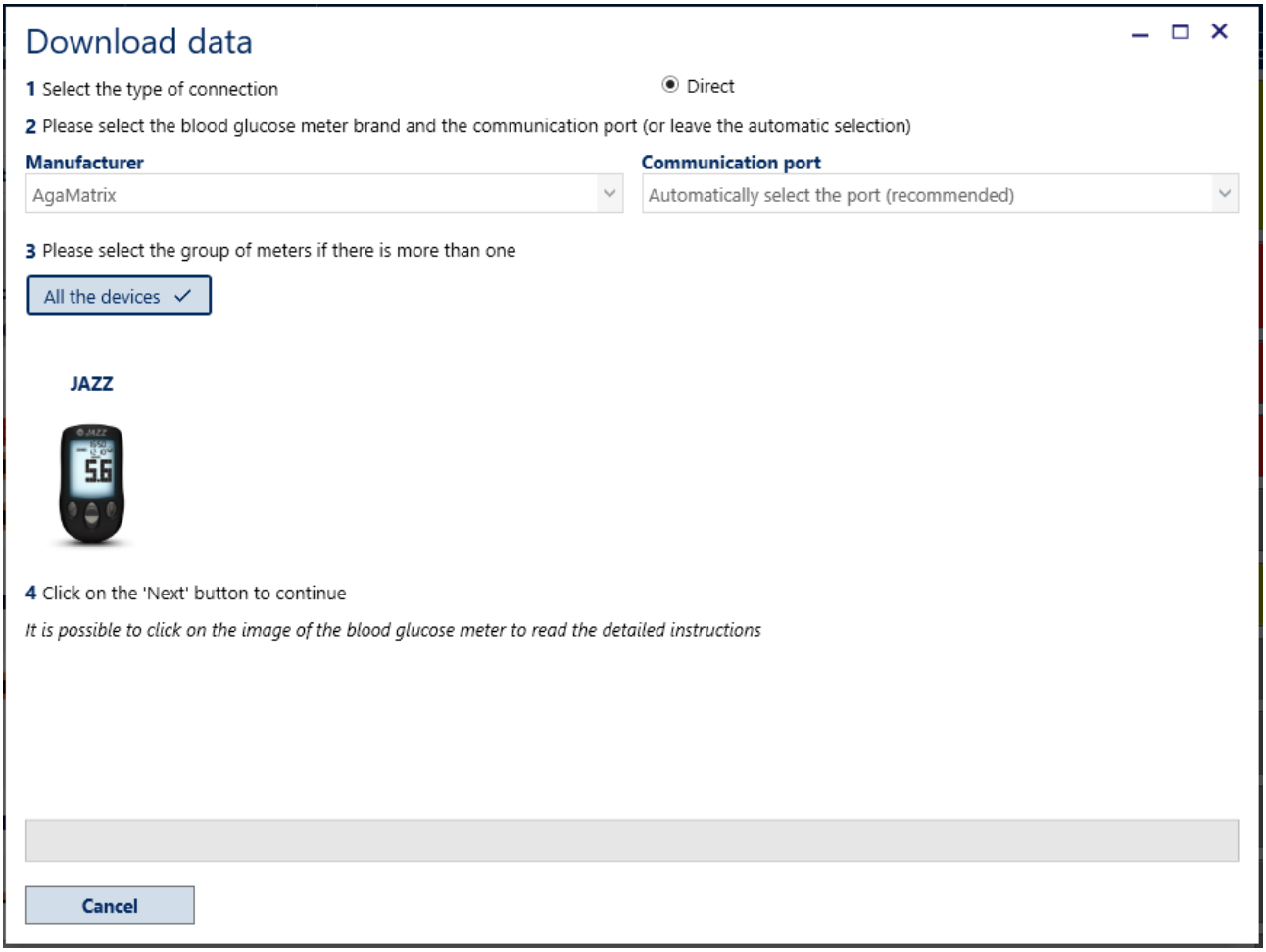
An icon indicates whether the carbohydrate intake data is available and therefore only the columns in which data are present are displayed.

The blood glucose readings within the target range are shown in normal font, while the readings outside the target are indicated in bold, so that they can be easily recognised.

By clicking on the options in the right column it is possible to highlight the ‘Hypoglycaemic events’ (in red) and the ‘Hyperglycaemic events’ (in orange).

10.6 Download data from theWaveSense JAZZ Meter

The ‘Download data‘ module, makes it possible to transfer the data stored in a patient’s AgaMatrix WaveSense JAZZ blood glucose meter to ALLY.



ALLY will automatically save the blood glucose readings stored in the devices which will then be viewable in the graphs described in the previous section of this manual.

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

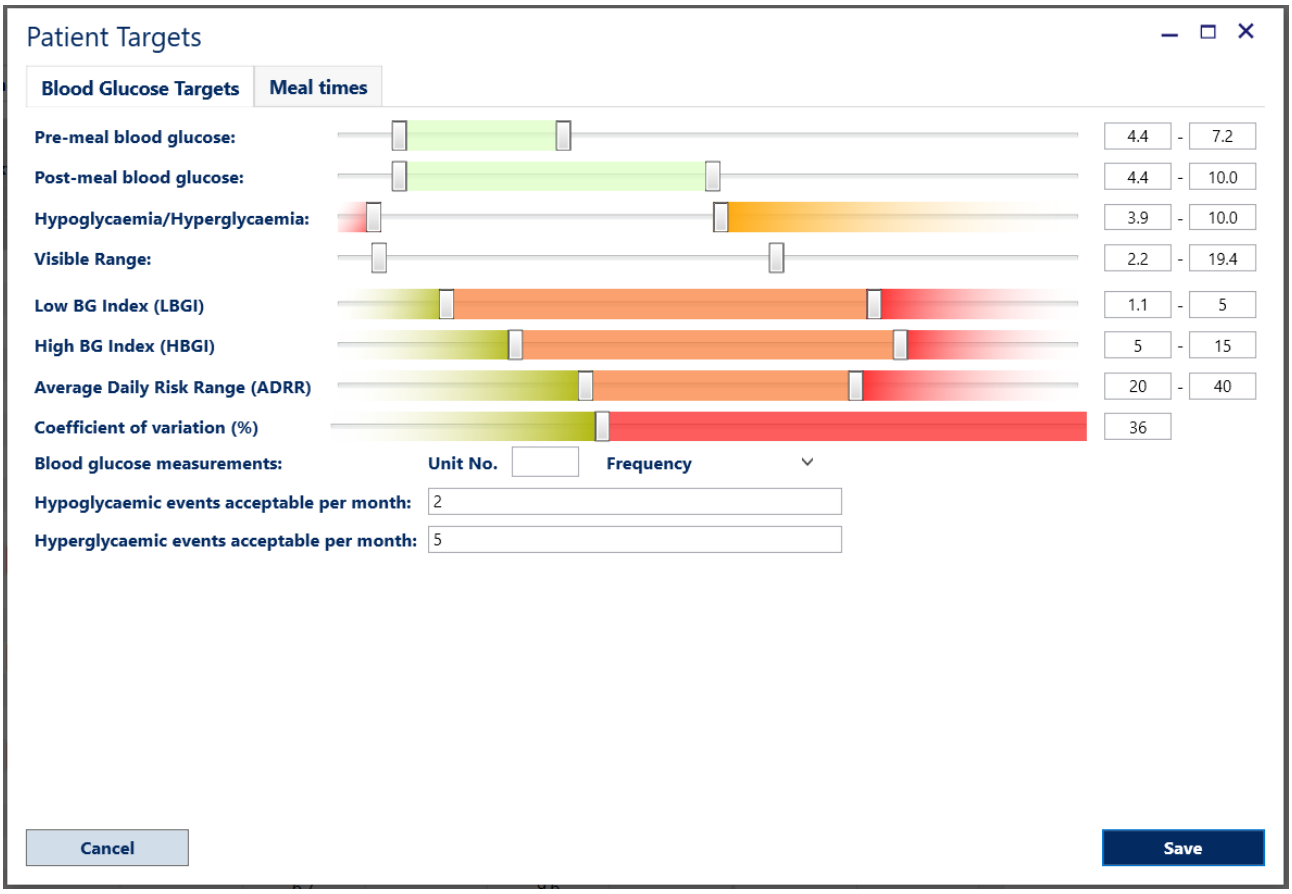
To download data from a meter, select the type of ‘Communication Port‘ if known. Otherwise, the system will automatically search for them. By selecting the device and clicking the Next button it will start the procedure that downloads data from the blood glucose meter to ALLY.

The system will automatically download the data from the blood glucose meter and attach it to the selected patient.

10.7 Blood glucose target

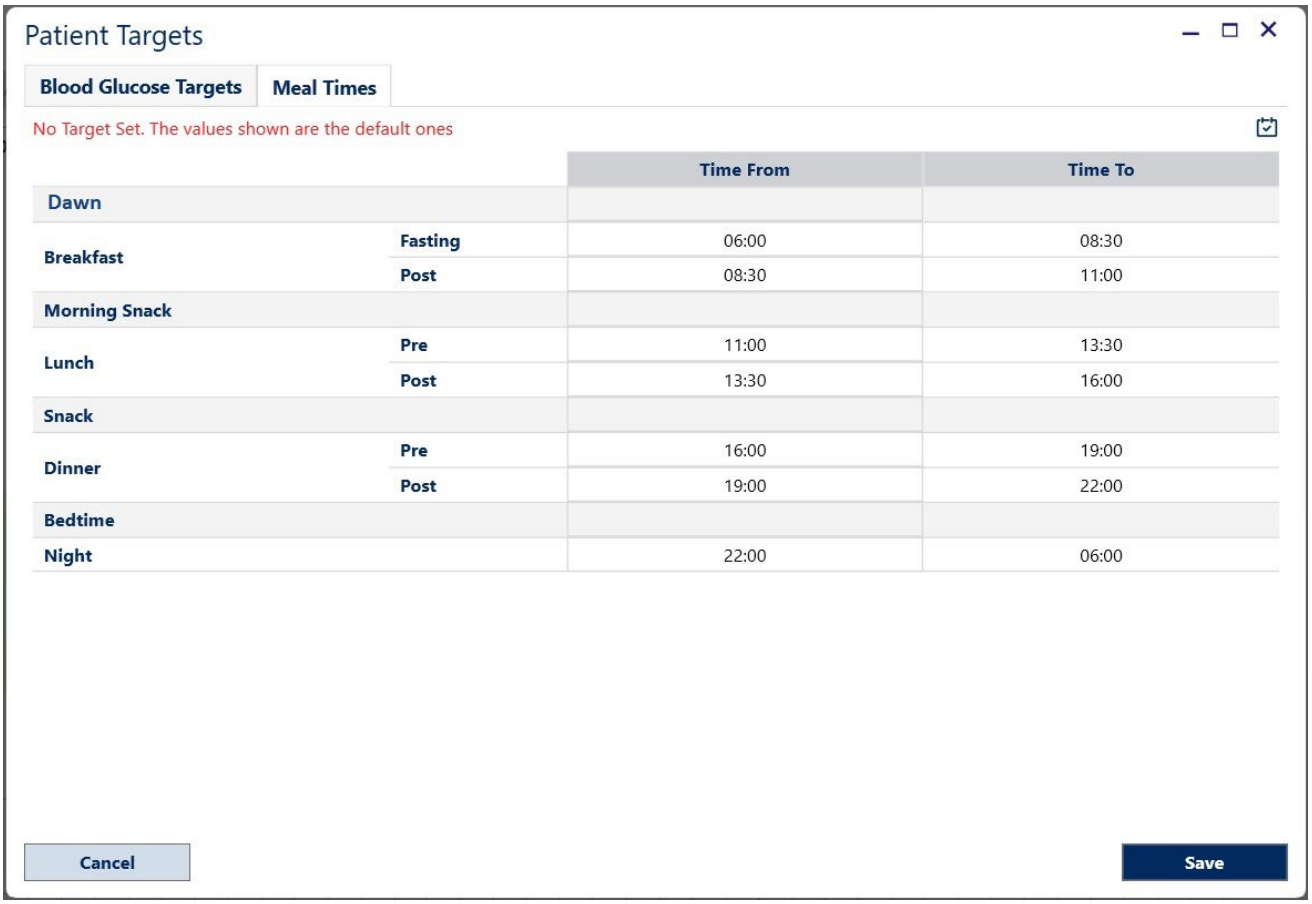
This module allows the HCP to define customised meal schedules and target ranges to be set for each patient.

In the 'Blood Glucose Targets' tab, ranges of the glucose values can be set by moving the relevant cursors or entering the value directly, as shown in the following image:



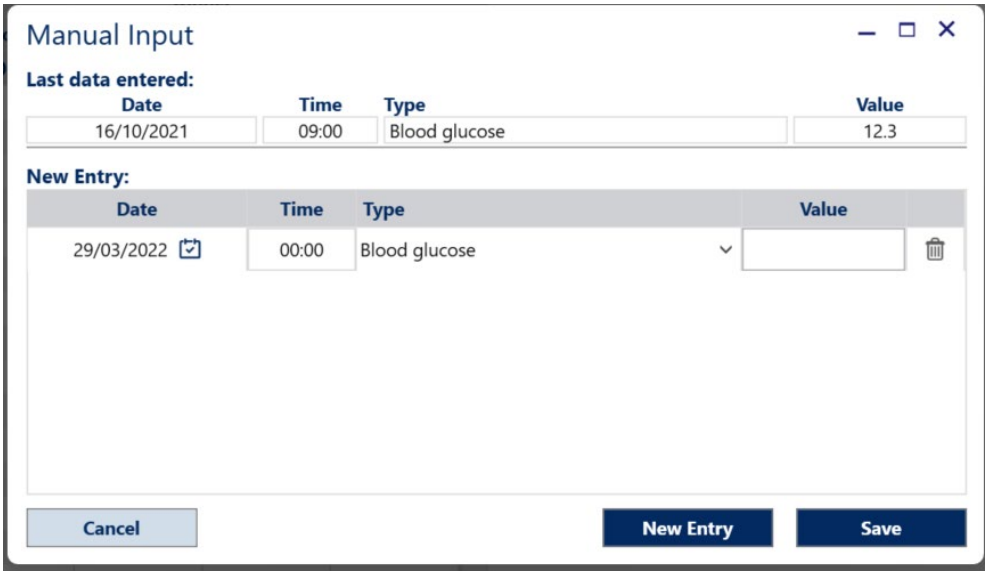
Recommended blood glucose measurements per day can be set. Acceptable hypoglycaemic and hyperglycaemic events per month can also be set.

Below there is an image showing an example of the 'Meal Times'. It is possible to adjust the meal-time windows by creating new dates (in order to record new times), by clicking the button.



10.8 Manual input

The software allows manual data entry for the selected patient.

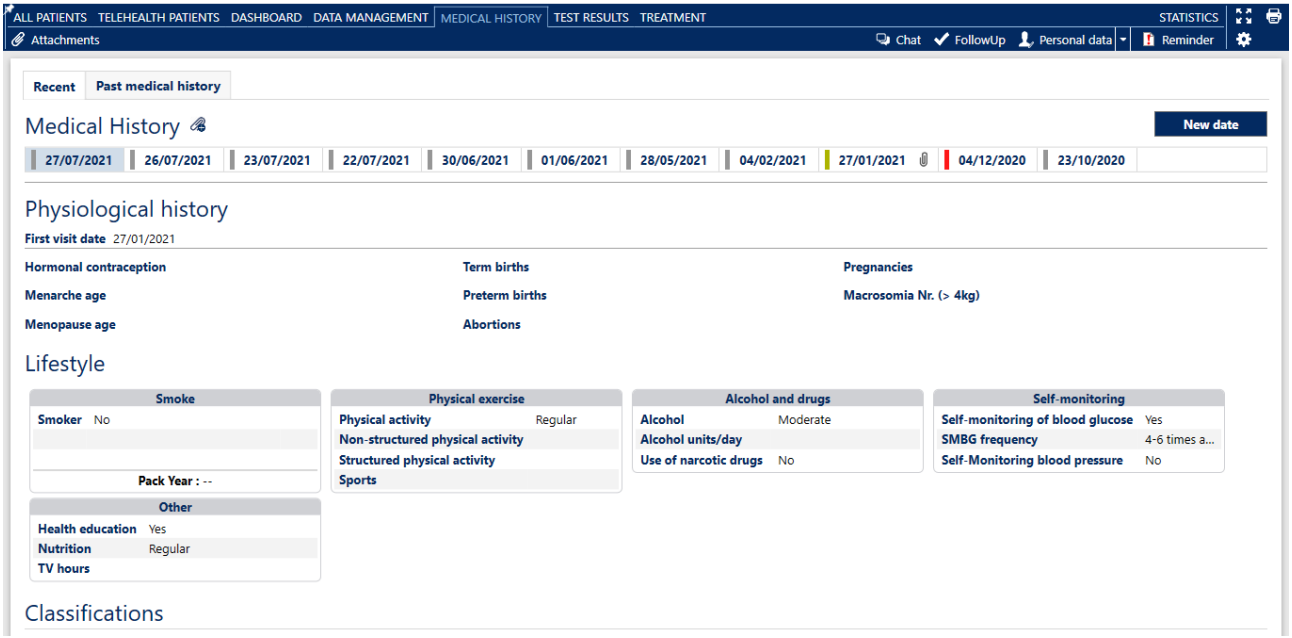


To add new data, enter the date, time, type and value of the data and click on the Save button.

11. Medical History

The Medical History module is divided into two tabs:

- *Recent* Medical History which defines the significant physiological events and the current lifestyle of the patient
- *Past* Medical History which shows the patient's diabetes history, family history and history of diagnosis



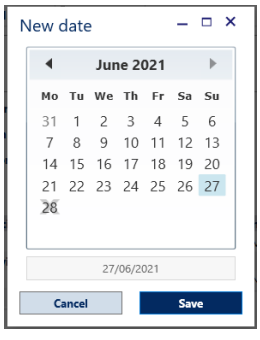
When registering the information for the first time, click the **Add** button to enter the data.

The updating of previously entered information and the insertion of new is made possible by using the **Edit** button.

11.1 Recent Medical History

To update the *Recent Medical History* tab click the **New date** button.

The system opens a window with the calendar from which it is possible to select or type the desired date.



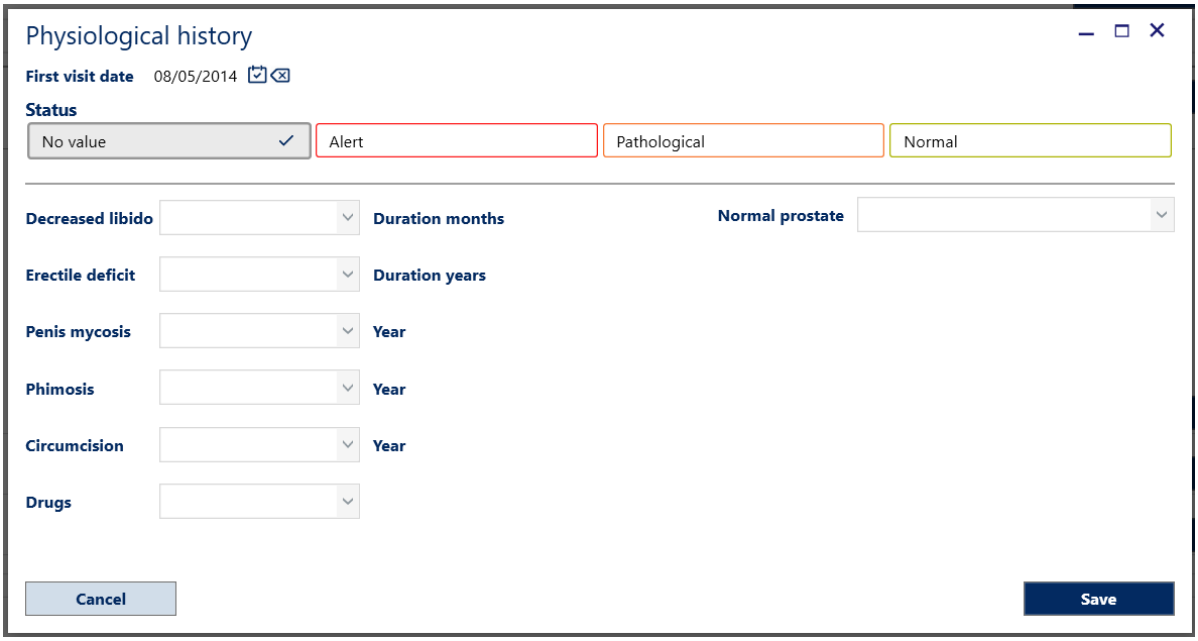
Click the **Save** button to register the new date.

11.1.1 Physiological History

The physiological medical history is differentiated on the basis of the patient's gender and age.

To update the information on the physiological medical history, click on the **Edit** button. The tab of the recorded data will open.

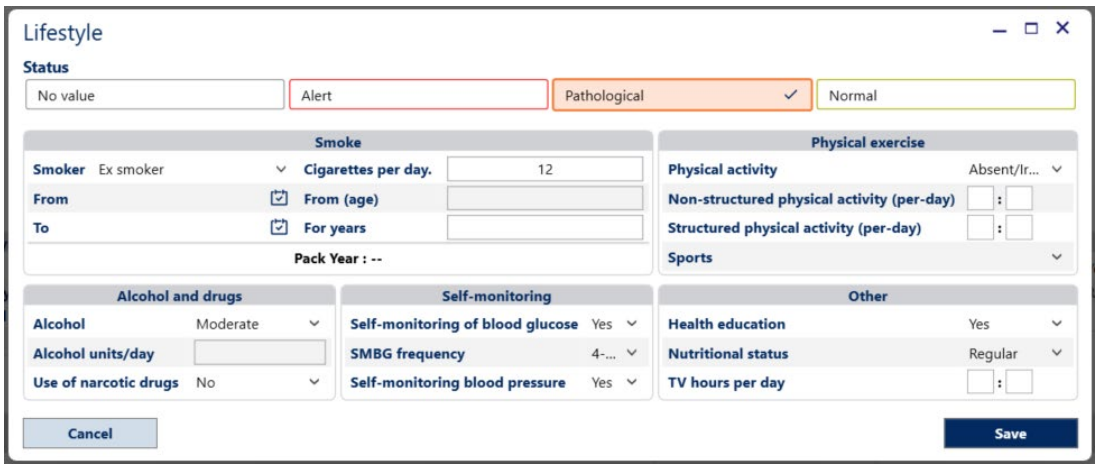
Below is an example of the *Physiological Medical History* sheet of a male patient.



It is possible to enter information in all or only some of the fields. Click the **Save** button to store the information.

11.1.2 Lifestyle

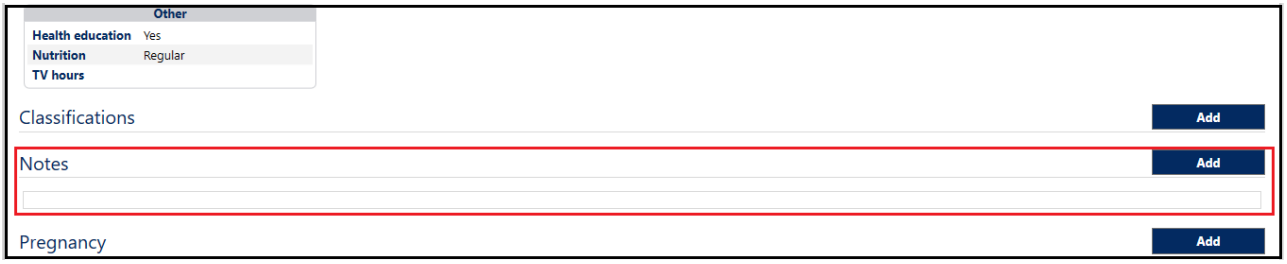
Click the **Add** **Edit** or button to access the window where you can enter information about the patient's *lifestyle*.



Click the **Save** button to store the information entered or the **Cancel** button to return to the main window without saving the data.

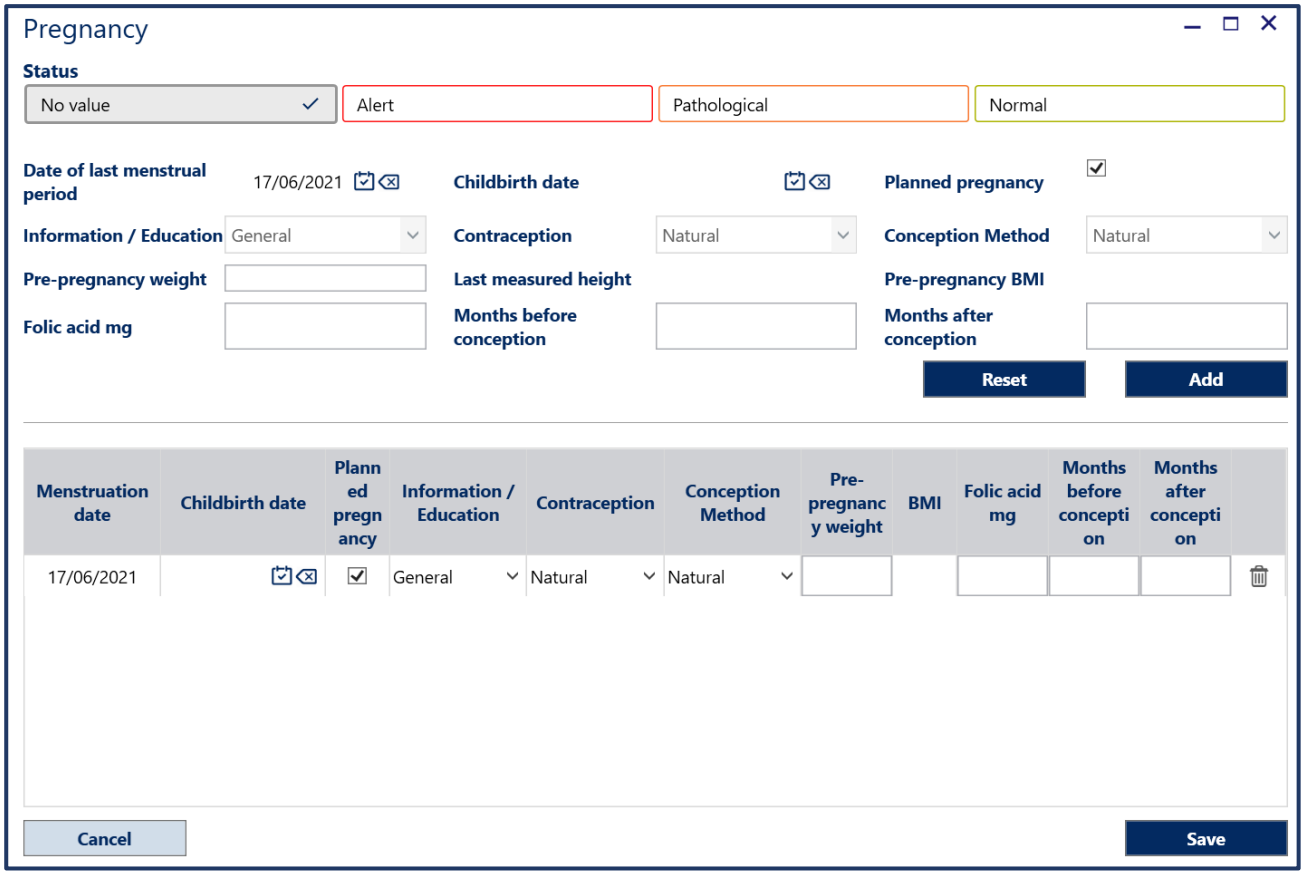
11.1.3 Notes

Insert a note by clicking the **Add** button corresponding to the *Notes*, as shown in the following image:



11.1.4 Pregnancy

A specific form is available for female patients to enter information about pregnancy as shown below.



Enter the data relating to the pregnancy and click the **Add** button. The data will be copied in a row at the bottom of the window. By clicking the **Save** button it will be stored in the database.

11.2 Past Medical History

The section summarises the patient's pathological history. The tab is divided into:

- *Diabetes History*: it allows the archiving of the specific diagnosis of diabetes
- *Family History*: it contains information on any family pathologies
- *Past Medical History:* it is the register of all the pathologies that occurred before the visit and of those detected in the course of the recurrent diabetological visits
- *Pregnancy:* it is possible to store data concerning the pregnancy of female patients

11.2.1 Diabetes History

'Diabetes History' records the specific diagnosis of diabetes and its date.

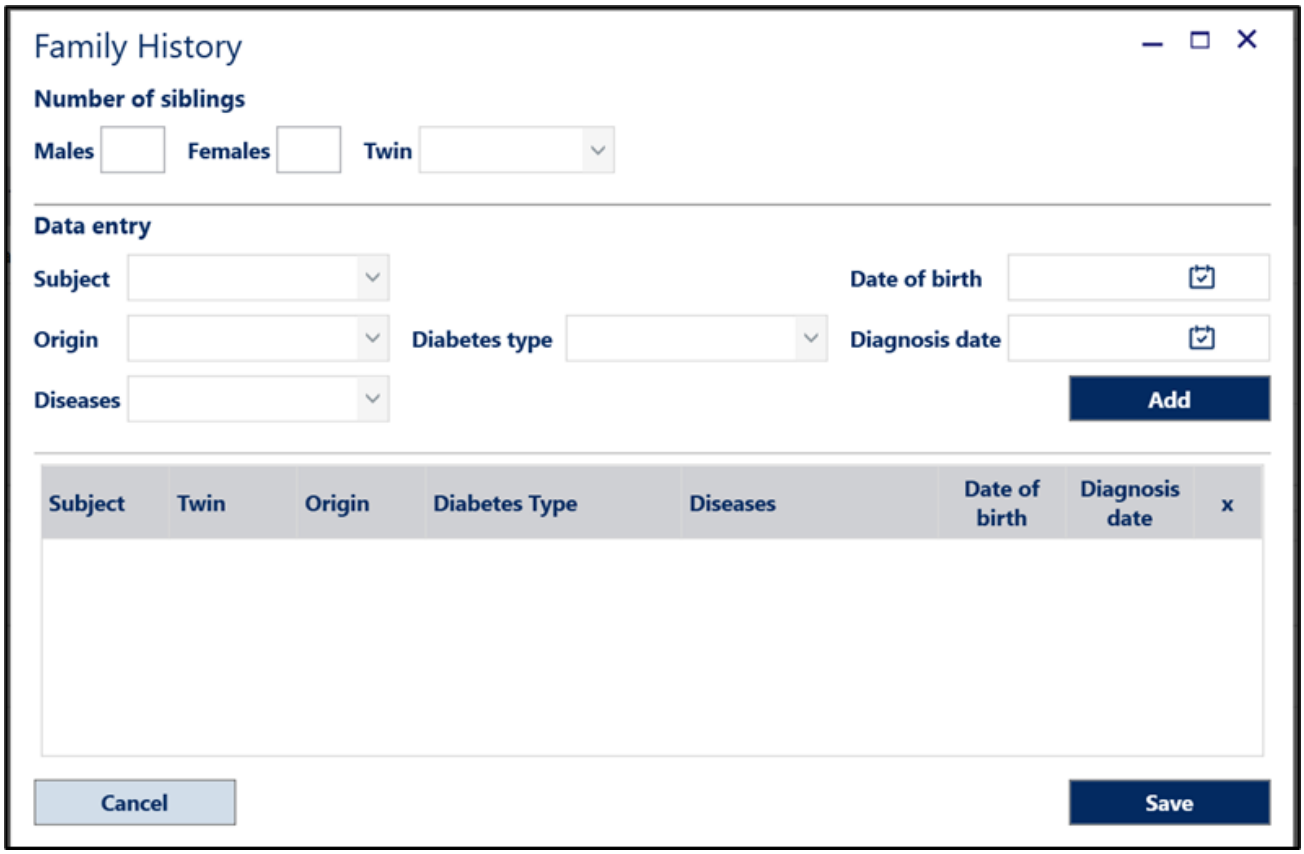
To change the diagnosis, click on the *edit* button within the 'Past Medical History' tab.

This allows access to fields where *Insulin Start Date, Diabetes diagnosis date* and *Diabetes type* can be entered.

After having selected the dates and the type of diabetes, click the Add button to attach the data to the patient. Then, click the Save button to save it.

11.2.2 Family History

In the *Family History* section, data relating to diabetes and other pathologies that run in the patient's family can be entered.



11.2.3 Past Medical History

In the 'Past Medical History', the illnesses, traumas and operations the patient has had can be recorded.

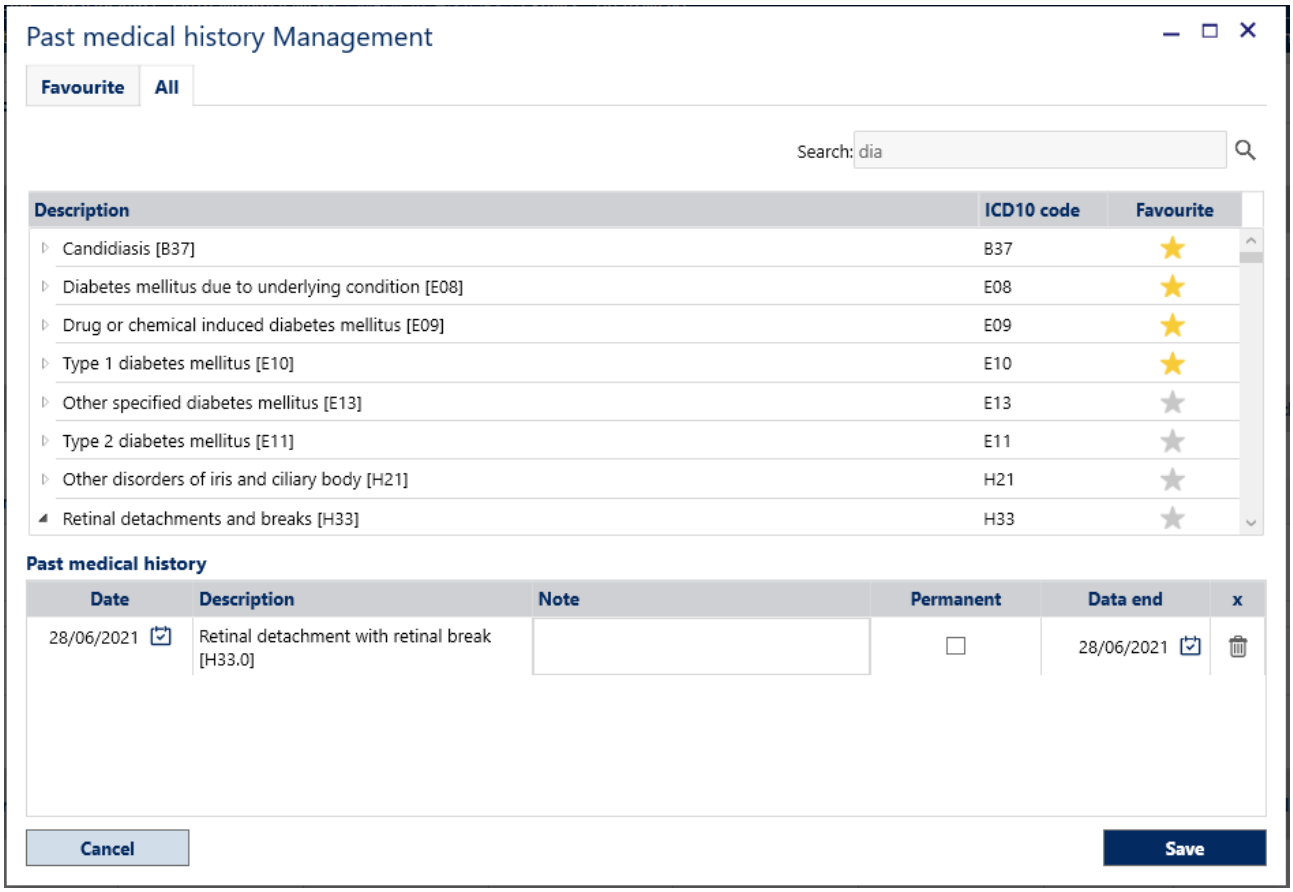
Upon opening the form, the list of additional illnesses and traumas, operations and additional classifications will be displayed. Alternatively, it is possible to click the single tab to get the complete list.

On the *All* tab, you can search by keyword within the entire database.

In addition to the *Description* of the illness (as well as operation or trauma) the ICD10 code is visible.

If the element is among the *Favorites* a yellow star will be visible.

Otherwise, the star will be grey .



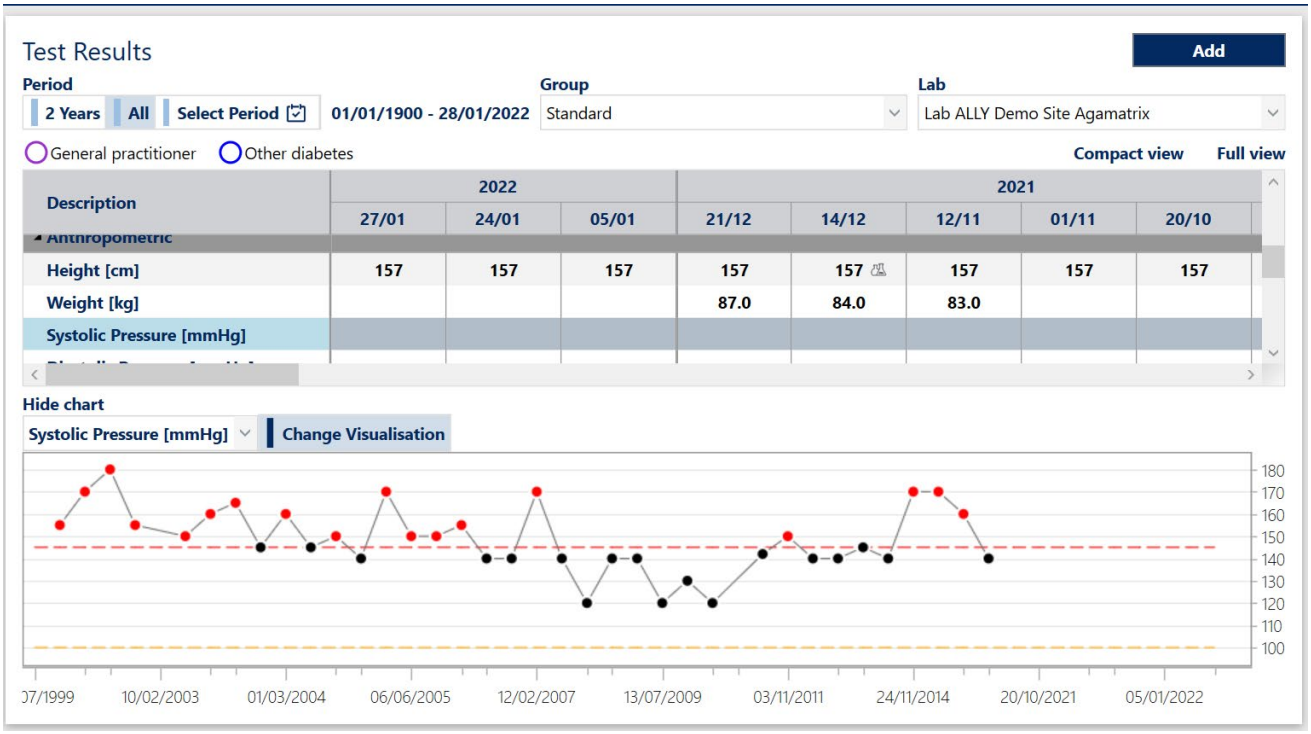
Once the data is entered it is possible to save the data by clicking on the Save button .

12. Test results

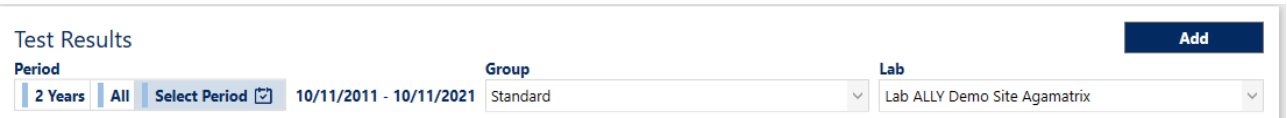
The *Test results* module records the results of laboratory tests and displays them in tabular as well as graphical format.

In the center of the module there is information regarding the tests and in the right column the most recent therapies are displayed.

Below there is an example of the *Test results* module:



At the top of the exam window, the viewing period, group and lab can be selected. An example image is shown below:



By clicking the preset intervals, *2 years, 5 years* or by selecting a range of dates by clicking *Select Period*, it is possible to filter the display of the tests by period.

The default exam group that is displayed is the *Standard* one but is possible to create new groups according to specific needs.

12.1 Add a new registration

To insert a new registration of test values, click the **Add** button. A window will be displayed from which to select or type in the registration date.

Once the registration date has been selected, a new column will be created in which to enter the test values.

The values entered and stored can appear in different colours:

- *Black:* refers to all the data that fall within normal target for the selected laboratory
- *Red:* refers to all the data above the normal target for the laboratory
- *Orange:* refers to all data below the normal target for the laboratory

During the registration of previously entered results, in correspondence with each entered value, a note can be added or modified by clicking the icon.

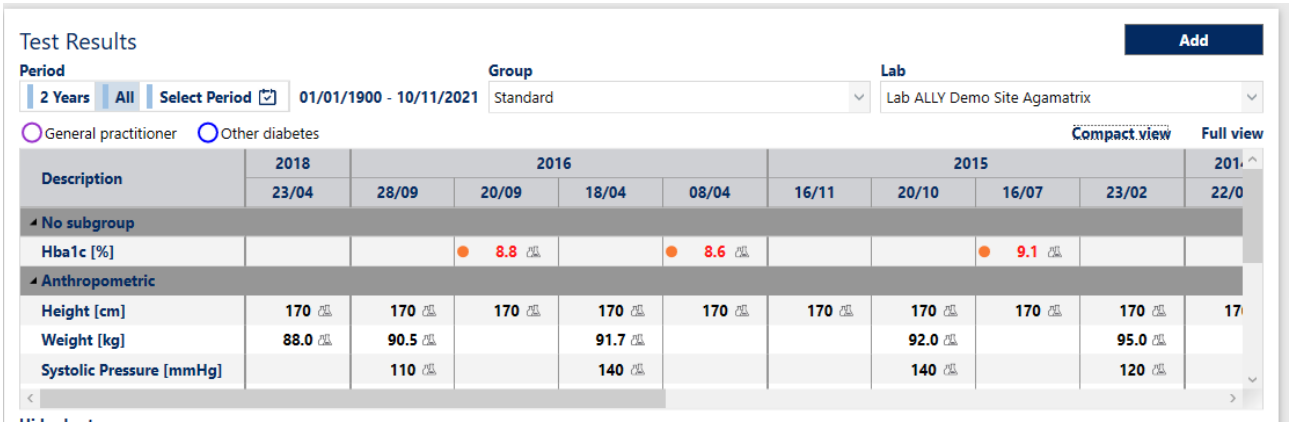
The icon can be displayed next to the results. This symbol indicates that a laboratory other than the default one has been used.

In correspondence with the values of the test for the cardiovascular risk, a colored dot may appear. The dot is intended for decision-making support relative to therapy.

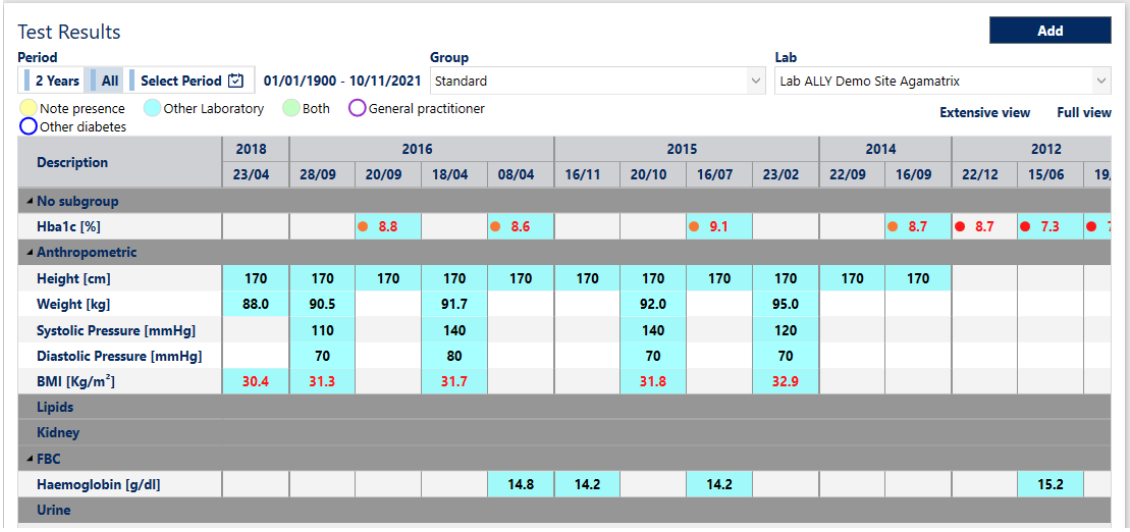
By positioning the mouse over the dot, details related to the color will be displayed:

- Therapy present, and values within target
- Therapy present, but values not within target
- No therapy, and values not within target

Below is an example image showing the laboratory tests:



By clicking on the **Compact View** button, the size of the columns in which the exam values are stored will be reduced and in the presence of a note or an exam from another laboratory, the relative icons will no longer be displayed but the value box will change colour as visible in the following image:

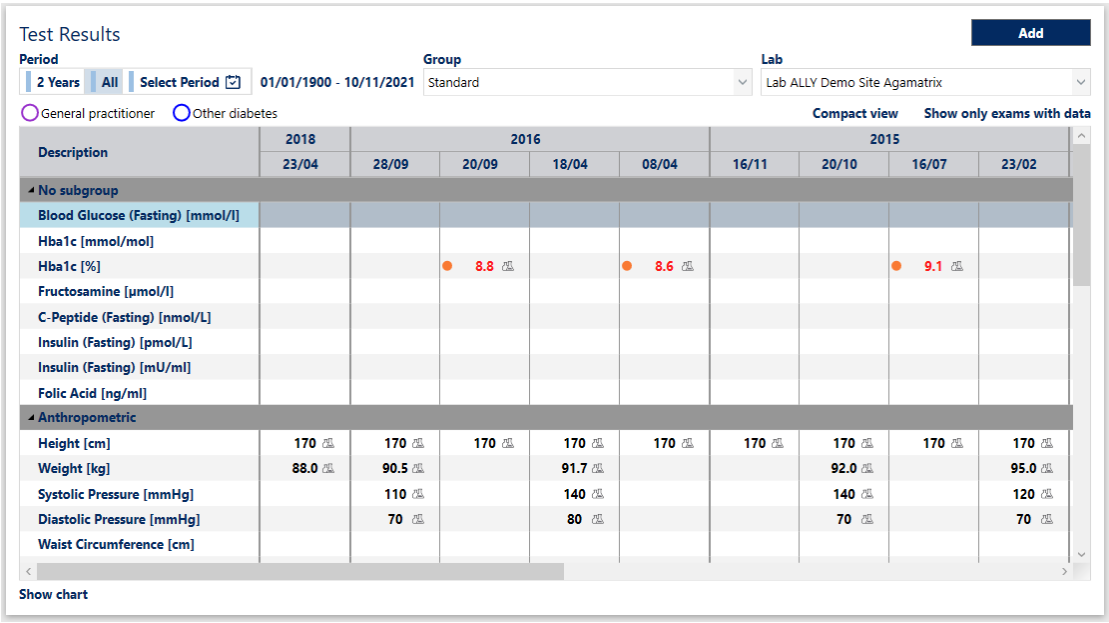


In the presence of examinations performed by other laboratories, the box will be highlighted in blue. In the presence of a note the box will be highlighted in yellow. In the presence of a note for an examination in another laboratory, the box will be highlighted in green.

Click the **Extensive View** button to return to the standard column size.

There is also a **Full view** button which, if clicked, displays all the exams associated with the current group even if they do not contain stored values.

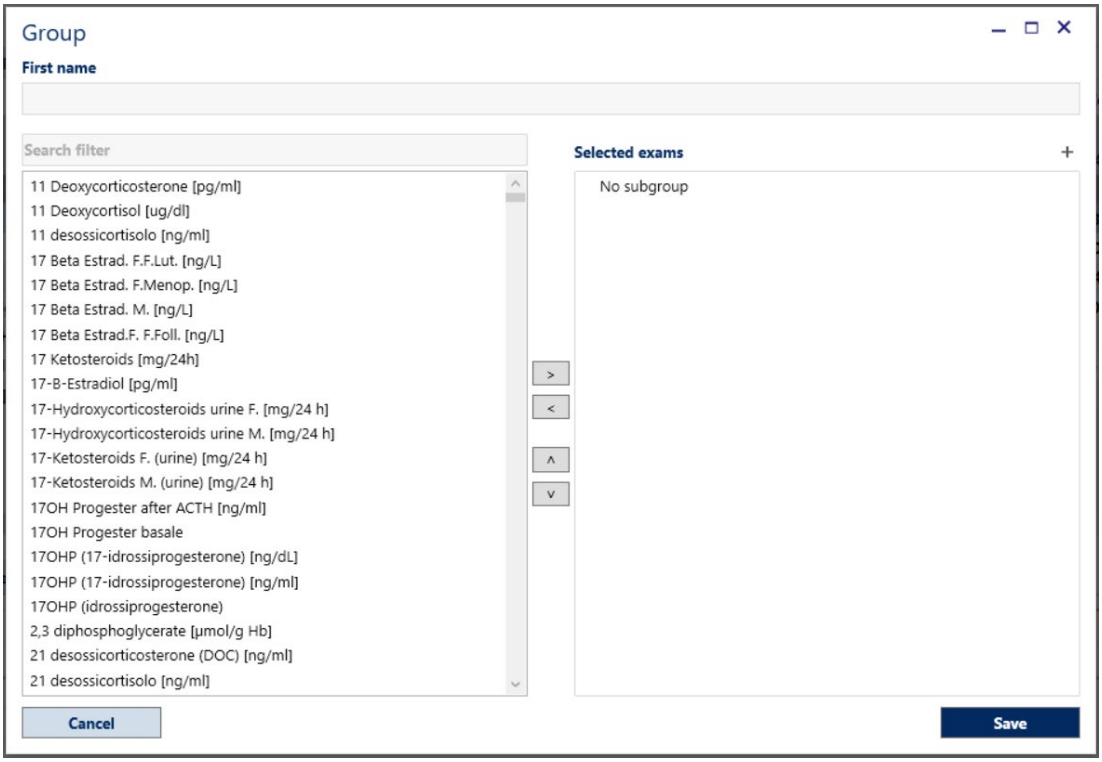
Click **Show only exams with data** to return to the standard view and hide the exams that have no recorded values.Below there is an example image in which the display of all exams is activated, including those that do not have saved values:



The Site Administrator can create new Laboratories, Groups and Subgroups of tests.

12.2 Groups of tests

By clicking the New Group button a Group window will open, as visible in the following image:



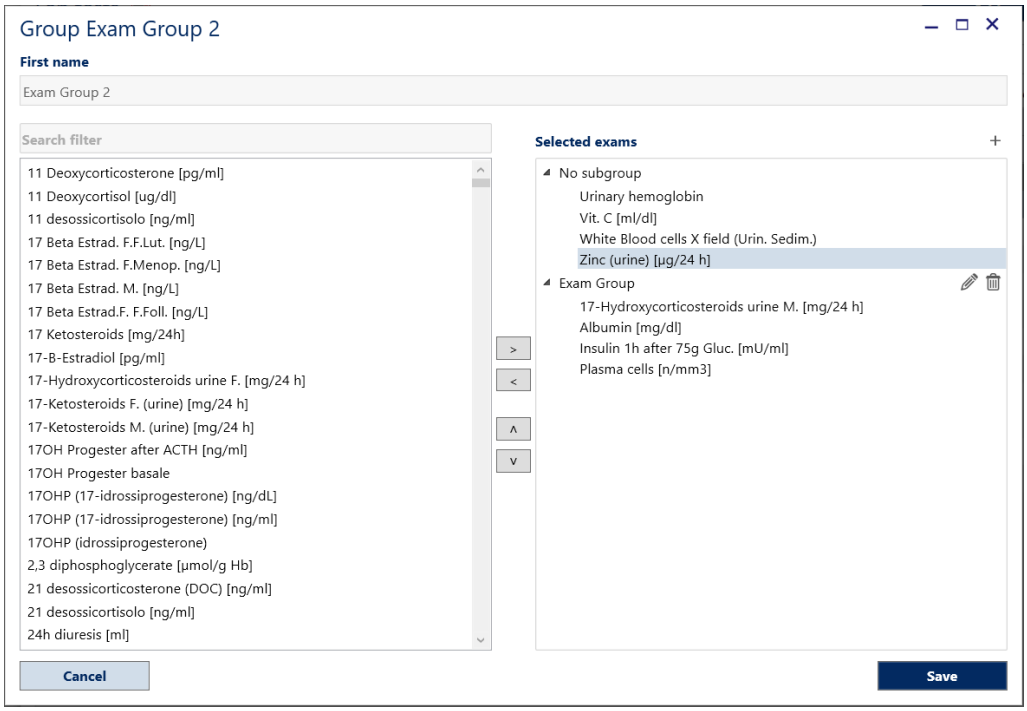
By organising laboratory tests in groups, it is possible to present the exams that are most frequently used by the department, in the desired order (ease of reading and input for the HCP). Enter the Name of the new group then attach the exams by selecting them from the left column and move them with the > button into the right column.

It is possible to search for one or more exams by name (or part of the name) by typing it in the 'Search Filter'.

To remove an exam from a group, select the exam from the right column and then click the < button to move it to the left column.

One or more subgroups can be created by clicking the + button. It is necessary to associate at least one exam to the newly created subgroup, otherwise it will not be possible to save the data. In the following image a new group of exams named 'Exam Group' is created.

By using the ^ and v buttons the order in which exams are displayed can be changed and exams can be moved from one subgroup to another.



By clicking the **Save** button, the new group and the selected tests relative to it will be saved.

By clicking the **Edit group** button, a window similar to the previous one will open. However, the **Delete** button will also be visible. By clicking it, the current group will be deleted. The group name can be changed, subgroups created or deleted, associated exams (add new ones or remove existing ones) managed.

12.3 Test subgroups

In order to have a logical division of tests, it is possible to create more subgroups within each group. For each group it is possible to create more subgroups if the HCP wants to have a logical division of the exams.

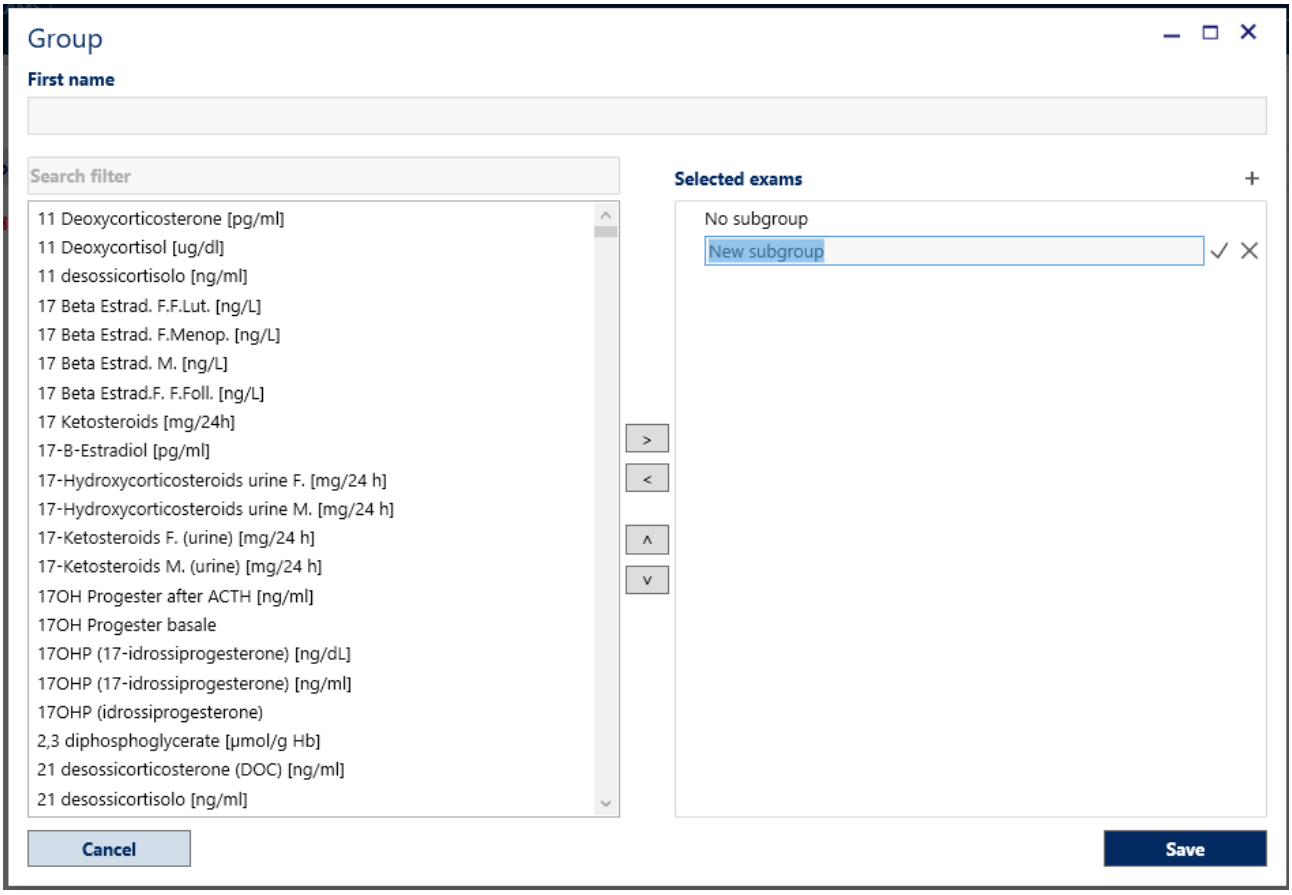
Description	2019 21/06	16/11
No subgroup		
Height [cm]	178	
Weight [kg]		
BMI [Kg/m^2]		
Systolic pressure [mmHg]		
Diastolic pressure [mmHg]		
Glycated hemoglobin HbA1c [%]		7.4
Glycated hemoglobin HbA1c [mmol/mol]		
LDL Cholesterol [mg/dl]		
Steps		
Calories intake [kcal]		
Calories burned [kcal]		
Required exams		
Prealbumin [mg/dl]		
Albumin/creatinine [mg/l]		
Right ankle Diastolic Pressure [mmHg]		
Preß-Lipoprotein [%]		

The organisation of laboratory examinations in subgroups allows the viewing of exams that have clinical affinities and therefore facilitate the diagnostic reading by the physician (e.g. haemochrome, liver function, endocrinology).

The subgroups can be created by clicking the New Group button and subsequently modified by the Administrator User by clicking the Edit group button. A window will open where the HCP can add new groups by clicking the + button.

A new subgroup will be created with a default name 'New subgroup'. The HCP can change the name according to their needs by confirming the new name by clicking the ✓ key.

Click the ✕ button to cancel the new subgroup.

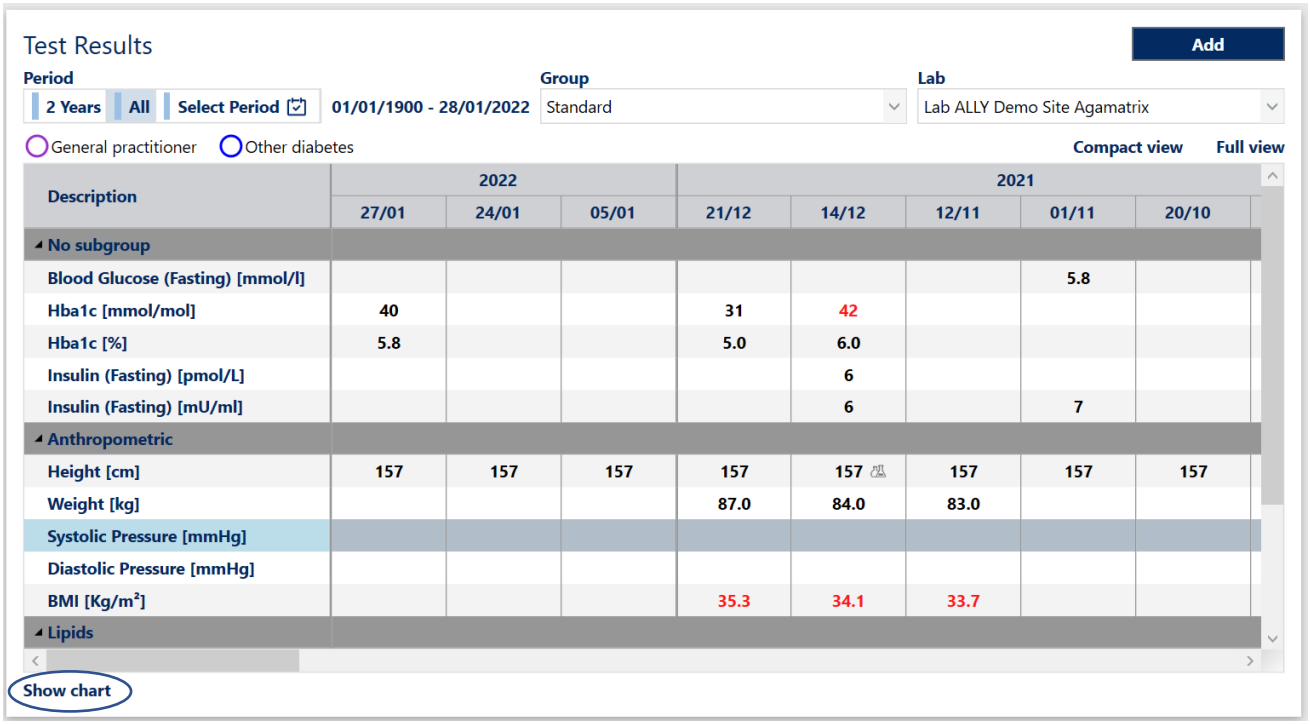


It is necessary to add some exams to the newly created subgroup before saving the data, otherwise the subgroup will not be stored.

Click the Save button to register the newly created subgroup.

12.4 The Graph

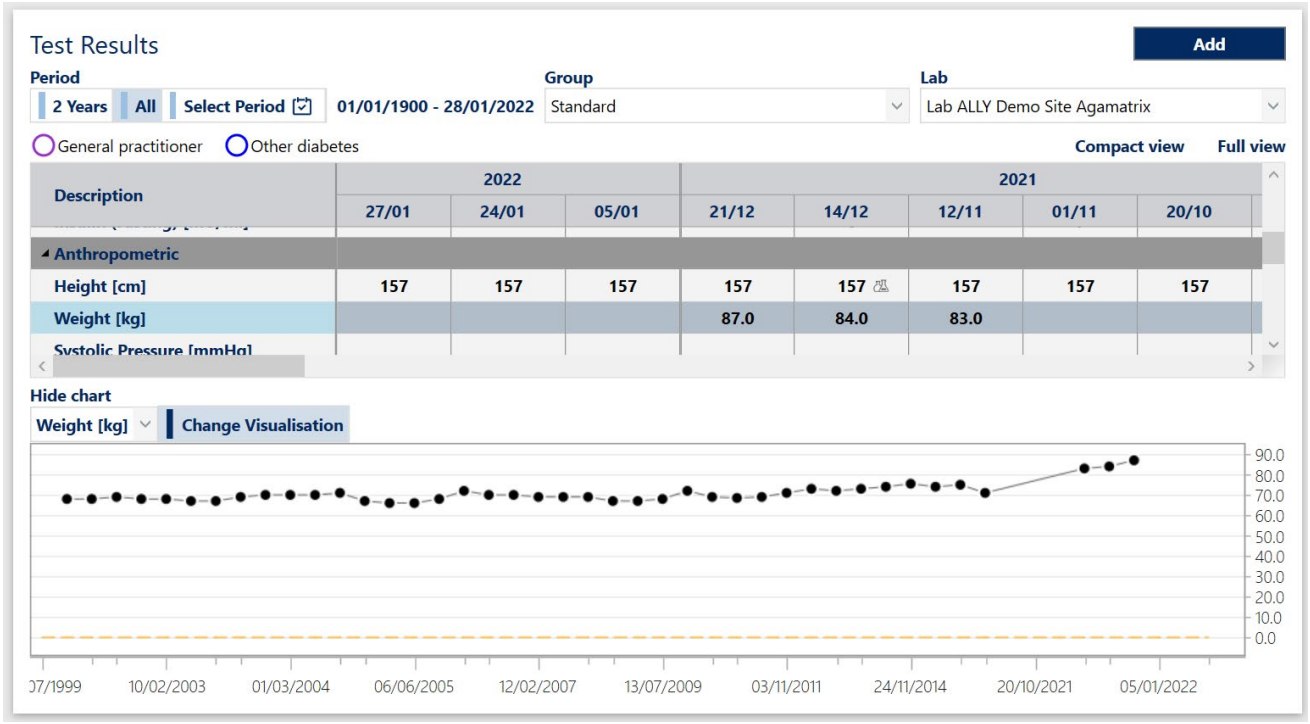
In the lower part of the Test Results module, for each exam, the graph of the values which have been recorded over time can be viewed.



Description	2022			2021				
	27/01	24/01	05/01	21/12	14/12	12/11	01/11	20/10
No subgroup								
Blood Glucose (Fasting) [mmol/l]							5.8	
Hba1c [mmol/mol]	40			31	42			
Hba1c [%]	5.8			5.0	6.0			
Insulin (Fasting) [pmol/L]					6			
Insulin (Fasting) [mU/ml]					6		7	
Anthropometric								
Height [cm]	157	157	157	157	157	157	157	157
Weight [kg]				87.0	84.0	83.0		
Systolic Pressure [mmHg]								
Diastolic Pressure [mmHg]								
BMI [Kg/m²]				35.3	34.1	33.7		
Lipids								

The graph is displayed by clicking the **Show chart** button.

View test results in graphical format by clicking on the name of the test in the column to the left of the values or from the drop-down menu available immediately above the graph.



Description	2022			2021				
	27/01	24/01	05/01	21/12	14/12	12/11	01/11	20/10
Anthropometric								
Height [cm]	157	157	157	157	157	157	157	157
Weight [kg]				87.0	84.0	83.0		
Systolic Pressure [mmHg]								

The graph displayed as in the previous figure, does not consider the temporal distance among the dates in which the tests have been recorded, therefore the points representing the values are all equidistant. However, by clicking the Change Visualisation button, the chart will adjust to display the data relative to the time between tests.

By clicking the Hide chart button, the graph of the test display will be closed.

13. Treatment

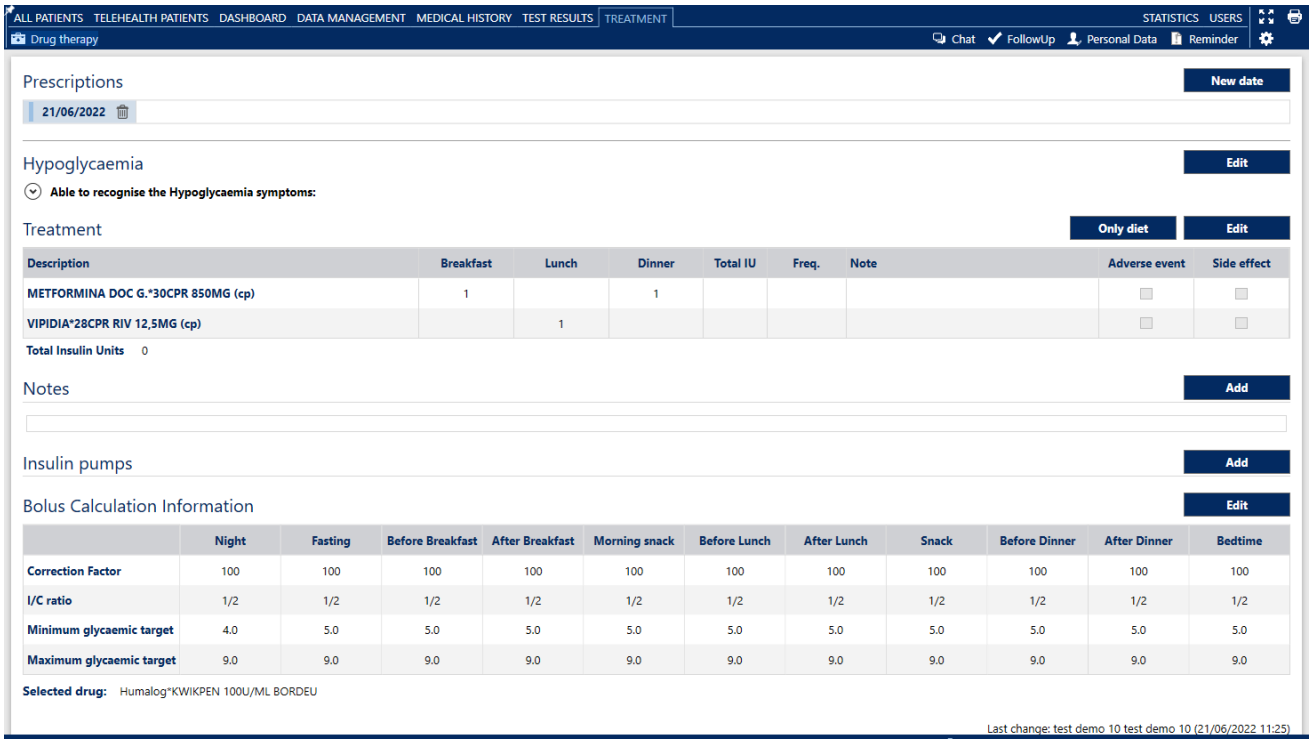
The *Treatment* module allows the recording of the prescribed therapy for the patient.

By clicking the TREATMENT button, the form where the HCP can view and record the medication that the patient takes will open.

Diabetes therapies will be recorded based on the dose timing (breakfast, lunch, dinner, and before bedtime), in which the quantity of intake will be specified.

If insulin pump devices are used, it will be possible to record separate doses and quantity of intake by adding customisable dosing times.

The values of the Correction Factor (CF), Insulin carbohydrate ratio (*I/Cho*) and minimum and maximum glycaemic targets for the calculation of boluses can be recorded and displayed.



To save a new prescription click the New date button. The calendar will be displayed from which to select or type a date. The new data will be recorded.

The new date will be displayed in the page header.

Clicking the icon will cancel the data that has been entered within that day. From the following day onwards only the administrators can change or remove data.

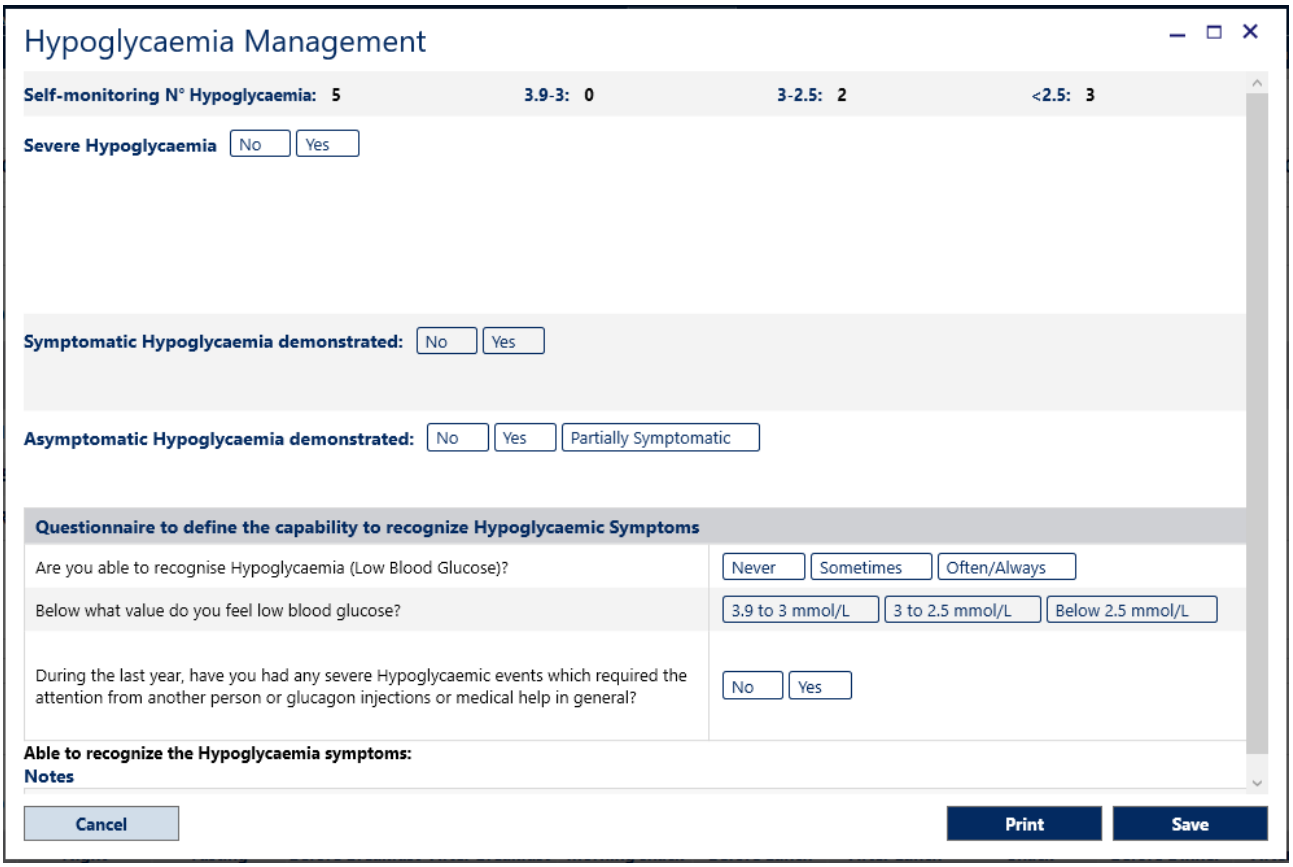
In the absence of a previous treatment, after creating a new date it will be possible to add the prescriptions by clicking the **Add** button. In the presence of previous treatment, click the **Edit** button**1**

13.1 Hypoglycaemia

Record the history of previous severe hypoglycaemic events experienced by the patient, also logging the symptomatic or asymptomatic nature.

Information about the patient's ability to recognize symptoms of hypoglycaemia can be added.

Below there is a sample image of the *Hypoglycaemia Management* window, where it will be possible to enter the related data:



The card is divided into five sections: *Self-Monitoring, Severe Hypoglycaemia, Symptomatic Hypoglycaemia Demonstrated, Asymptomatic Hypoglyacemia Demonstrated, Questionnaire to define the capability to Recognize Hypoglycaemia Symptoms*.

Self-monitoring

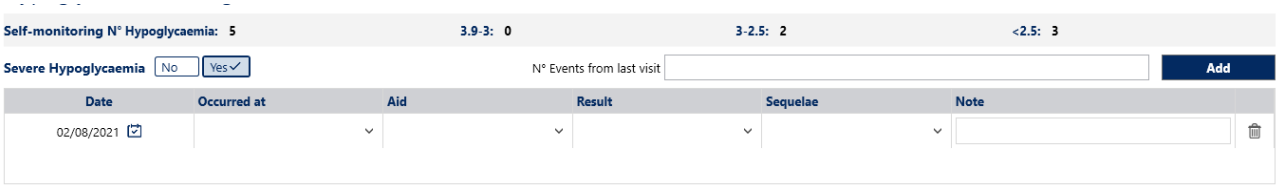
In the presence of values of blood glucose downloaded from *Data Management*, ALLY will automatically calculate the *N ° hypoglycaemias* relative to the patient being treated.

The number of blood glucose measurements with values between *3.9* and *3*, *3* and *2.5* and less than *2.5* will also be shown in detail.

Severe hypoglycaemia

By clicking the Yes button the *N° Events from last visit* can be specified.

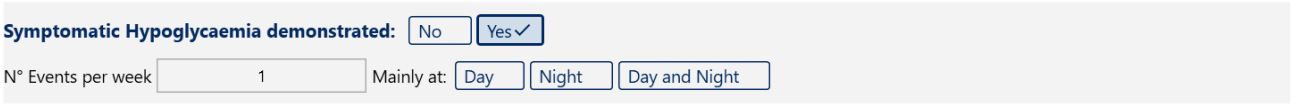
By clicking the **Add** button, a new line will be created. In this line it will be possible to specify the data of the last hypoglycaemia as visible in the following image:



Having entered the hypoglycaemia data, data in another section can be added or the **Save** button clicked to save data already entered.

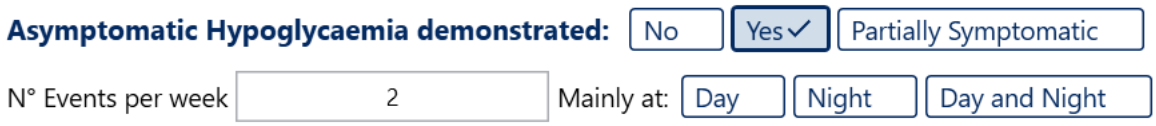
Symptomatic Hypoglycaemia Demonstrated

By clicking the Yes button the HCP will be able to specify the *N ° Events per Week* and the time of day when episodes of symptomatic hypoglycaemia occur more frequently. An example image is shown below:



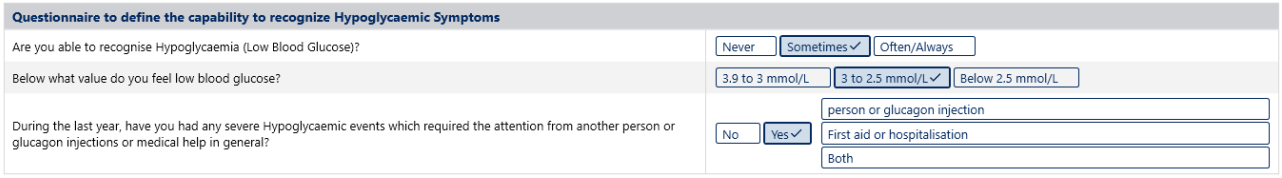
Asymptomatic Hypoglycaemia Demonstrated

By clicking the Yes button, it will be possible to specify *N° Events per Week* and the time of day in which asymptomatic hypoglycaemia episodes occur most frequently. An example image is shown below:



Questionnaire to define the capability to Recognize Hypoglycaemia Symptoms

This questionnaire allows the evaluation of the patient's ability to recognize the symptoms of hypoglycaemia.



After completing the questionnaire, ALLY will display a result indicating the patient's ability to recognise the symptoms of hypoglycaemia.

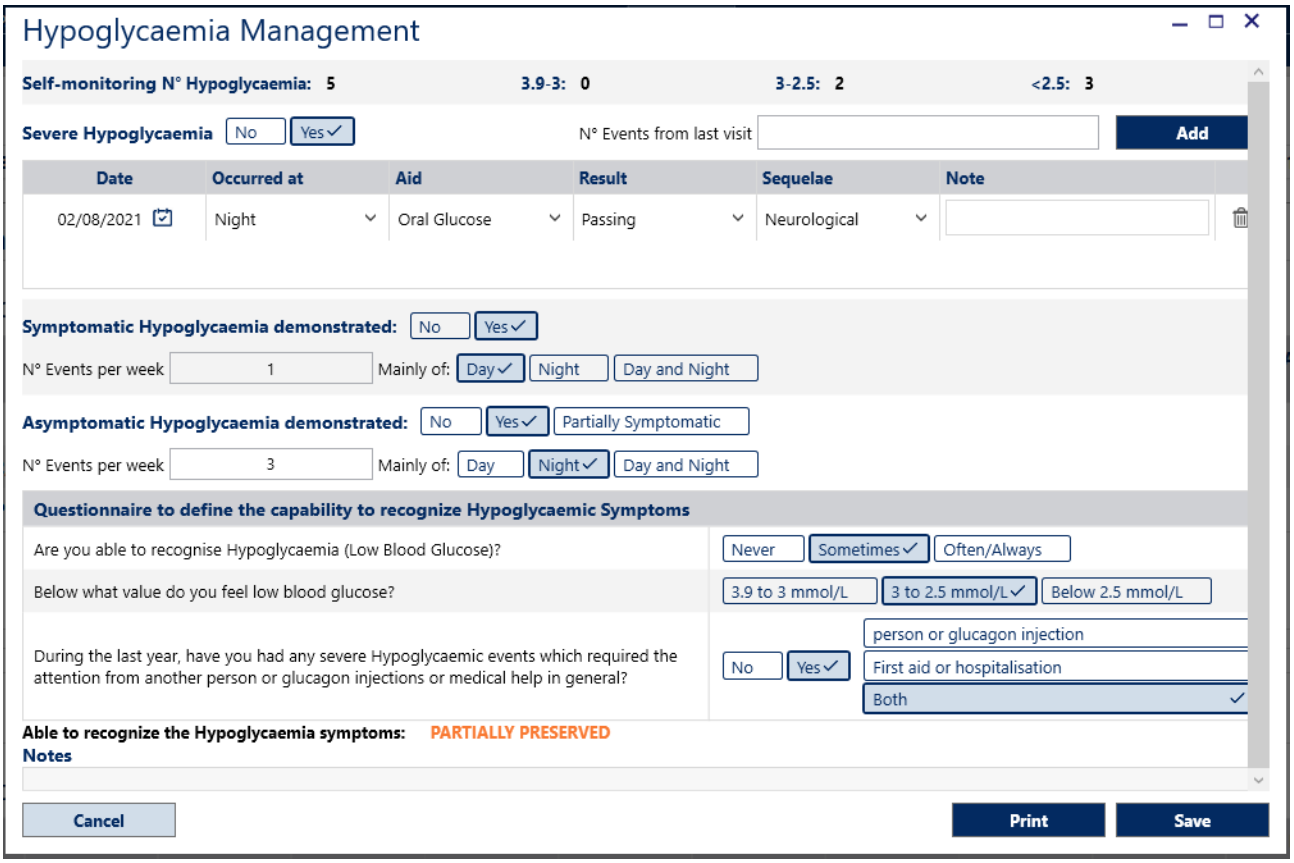
The following are possible results:

- Preserved (green colour)
- Partially preserved (orange colour)
- Absent (red colour)

The result of the questionnaire is also displayed on the tabs *Eye, Heart, Peripheral Nervous, Cerebral Vessels*.

Annotations to the *Notes* field can be made.

The following image shows a completed *Hypoglycaemia Management* tab.



13.2 Treatment

The section summarises the detail of the treatment prescribed to the patient.

After creating a *new date* a prescription can be added by clicking the **Add** button. In the presence of a previous treatment, click the **Edit** button.

The following image shows an example of the *Drugs management* window. The system automatically repeats the previous treatment prescribed to the patient that can be modified either by deleting or adding medications or changing the units of insulin associated with individual meals.

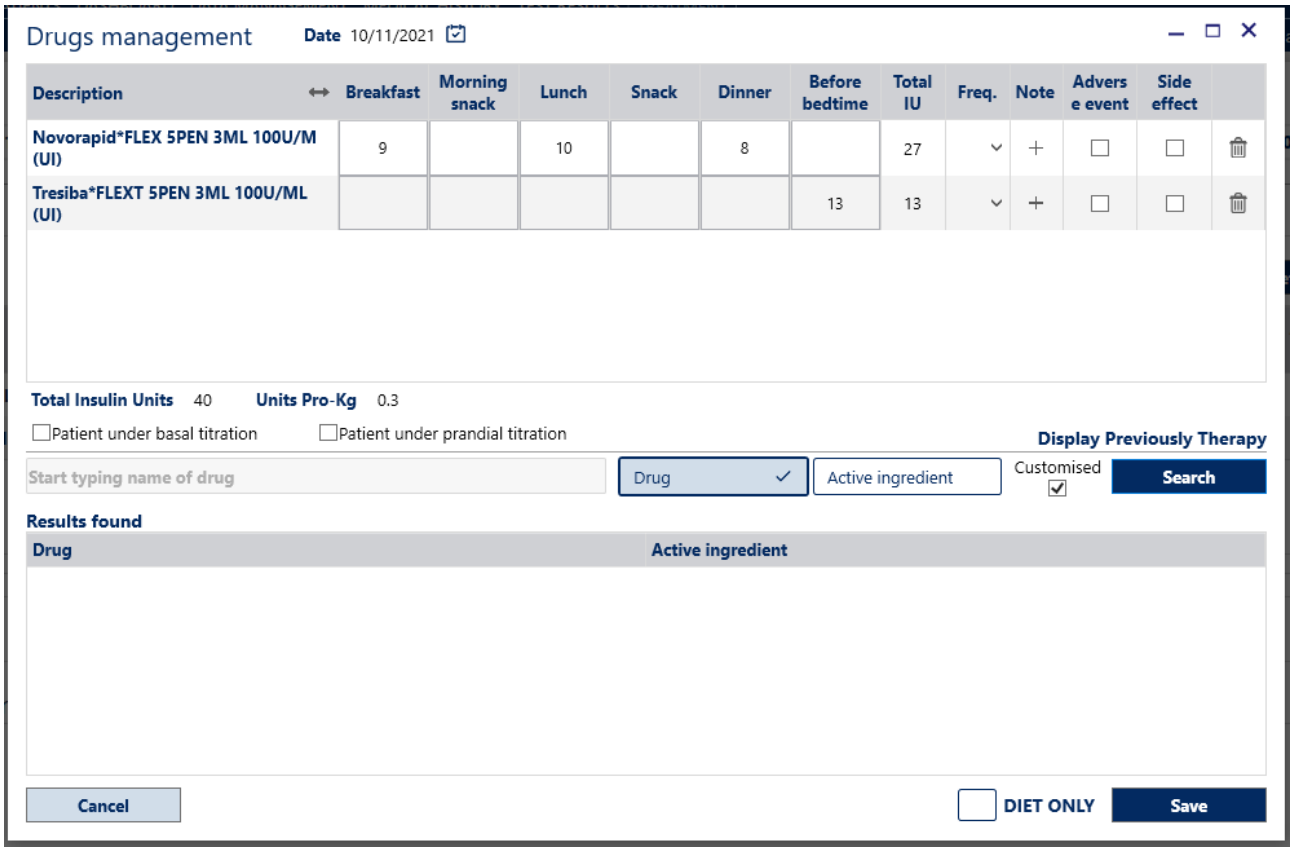
The reason for each individual medication that has been prescribed can be recorded and a note added by clicking the + button corresponding to the medication for which a note is needed.

Once a note is added, a icon will be displayed.

By clicking the icon the system deletes the corresponding medication.

The medication in the current prescription will no longer appear in *Drugs management*.

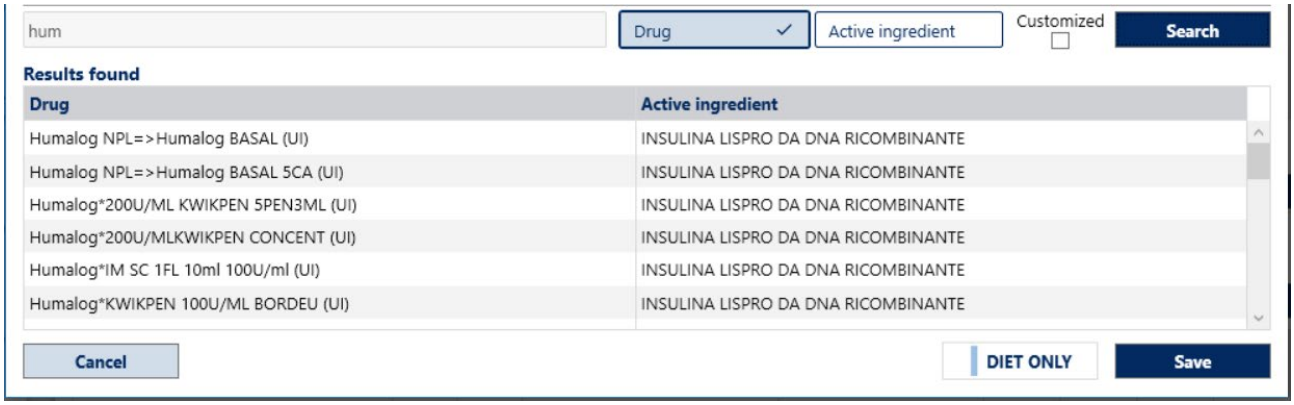
The last two prescribed treatments are always visible in the lower part of the window.



At the base of the table that summarises the therapeutical medications, the system displays two automatic calculations: *Total Insulin Units* and *Units per Kg.*

Whether the patient is prescribed *prandial* or *basal titration* can be specified.

By clicking **Display Drugs Search** in the lower part of the window medications can be searched for.



Type the drug or active ingredient to be prescribed and click the **Search** button.

By clicking the required drug displayed in the search list, the drug will be added to the patient's therapy and the dose can be added to the meal columns.

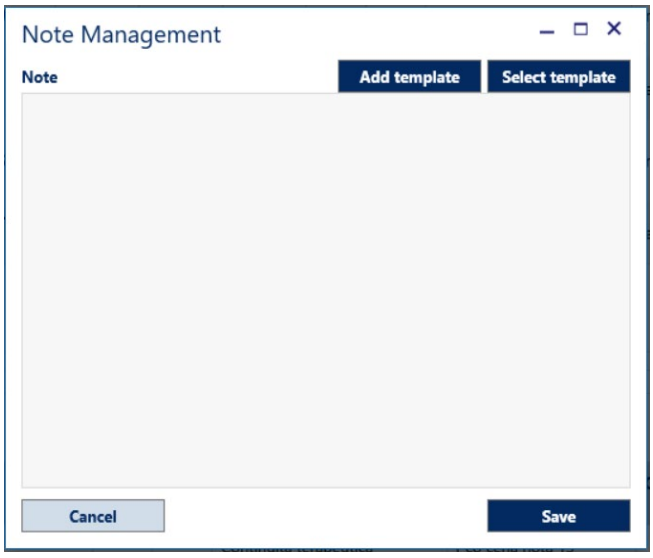
Click on **Display Previously Therapy** to return to the previous view.

In the *Drugs Management* window, by clicking the DIET ONLY button the addition of medication is not possible.

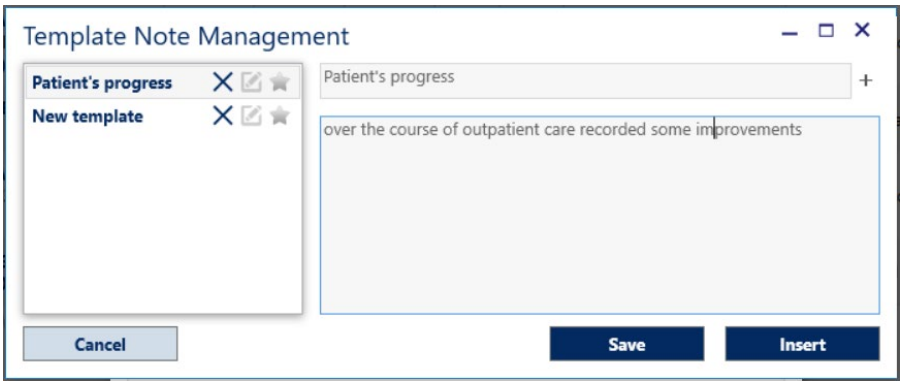
By clicking the **Save** button, the treatment will be saved.

13.3 Notes

By clicking the **Add** button or the **Edit** button, the following window will be displayed. In this window a note can be added and also saved as a template.t



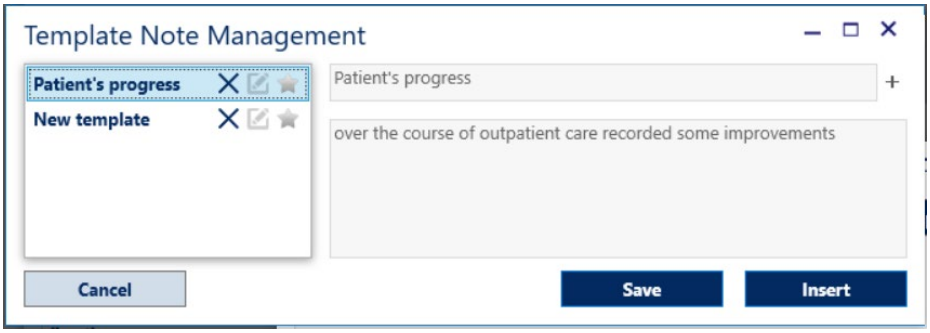
By writing a note and clicking the **Save** button, the note will be stored in the date of the current prescription. By clicking the **Add template** button a template with the current note will be created, as shown in the following image:



The creation of templates allows the preparation of repetitive standard phrases, self-control prescription schemes etc. which can be entered with a single click in the therapy text note. This is generally delivered at the end of the visit to the diabetic patient.

After specifying the name of the new template, click the **Save** button to save it.

To insert a note from the saved templates, click the **Select template** button and a window will appear as shown below:

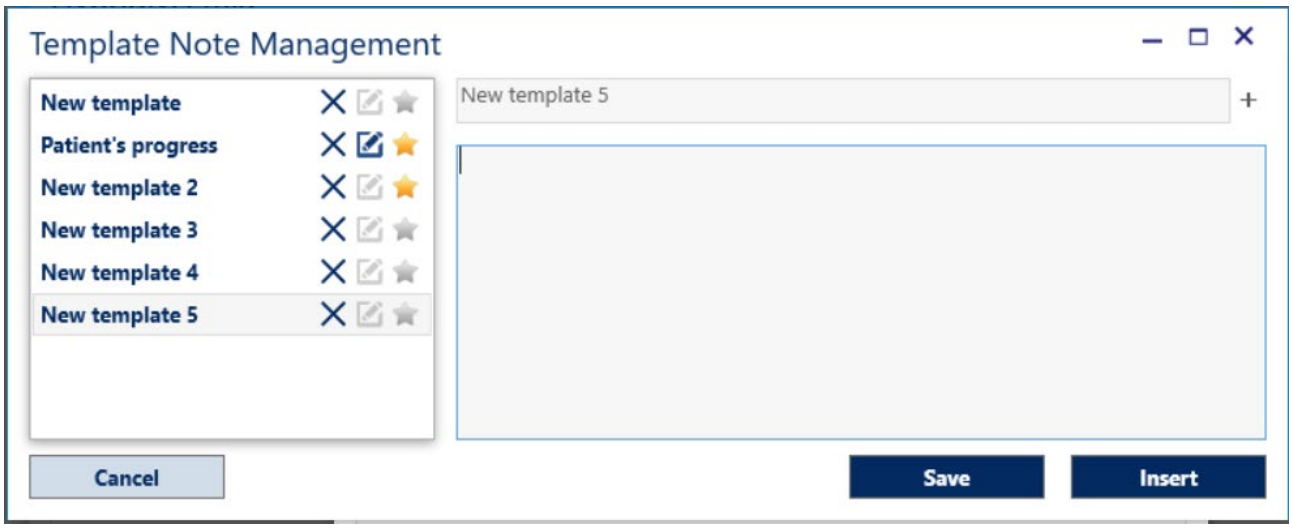


In the left column, the titles of the available templates are visible. By click the desired template, the text of the note will be displayed in the right area. Click the **Insert** button to add it.

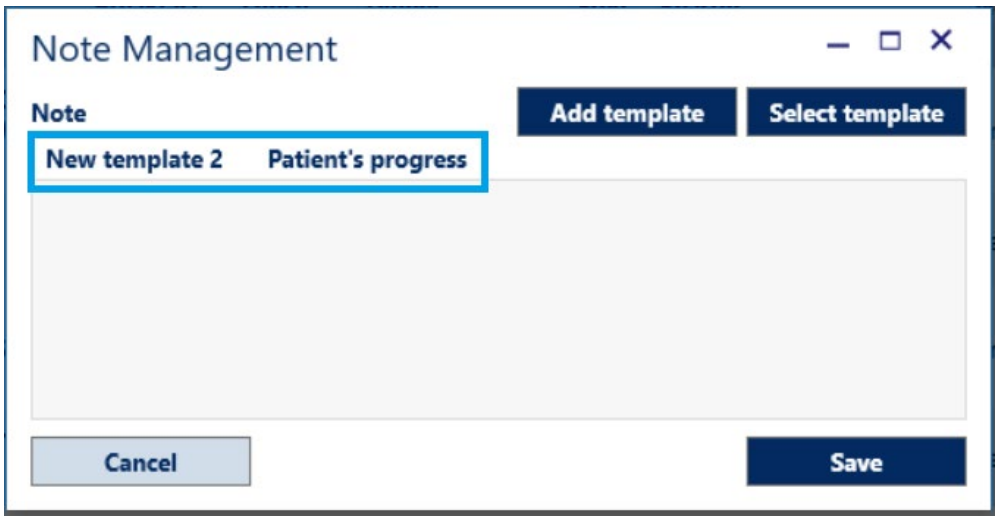
The templates can be deleted by clicking the button in the template corresponding to the template to be deleted.

Templates can be shared by clicking the button. Once the sharing is activated, the corresponding icon will turn blue .

A list of favorite notes can be created by clicking the button. The notes added to the favorite list will have a icon as shown in the following image:



The notes in the favourites list will be visible in the *Note Management* window (as shown below) as "quick entry keys". If they are clicked, they produce text entry without opening the *template selection* window.

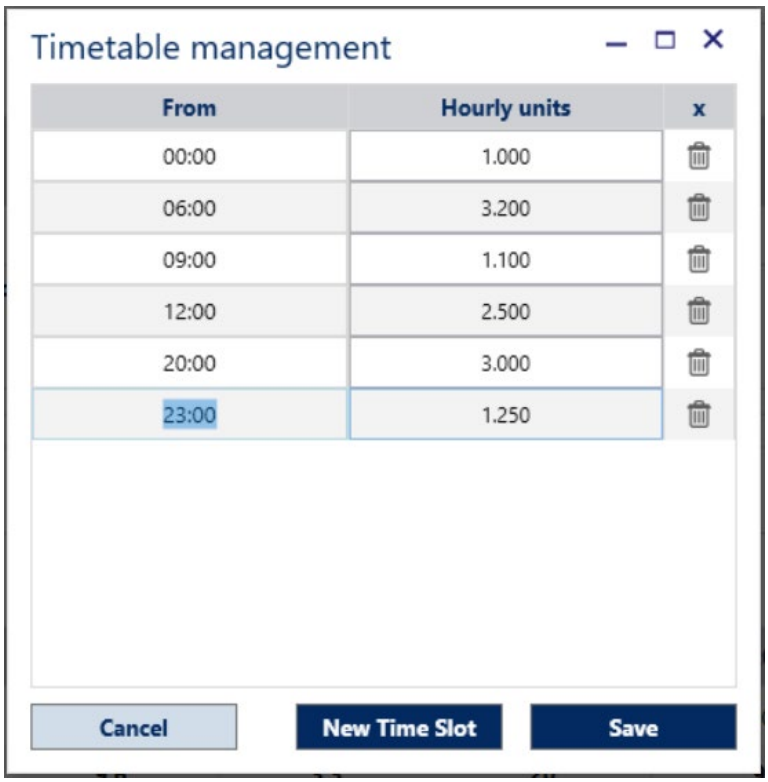


13.4 Insulin pumps

The section summarises the details of the *Hourly Units* (insulin) which are set by times.

After creating a new date, in the absence of a previous setting, click on the **Add** button to customise the time slots and the relative *Time Units*. If there are previous settings, it will be necessary to click the **Edit** button.

A sample image of the *Timetable Management* window follows:



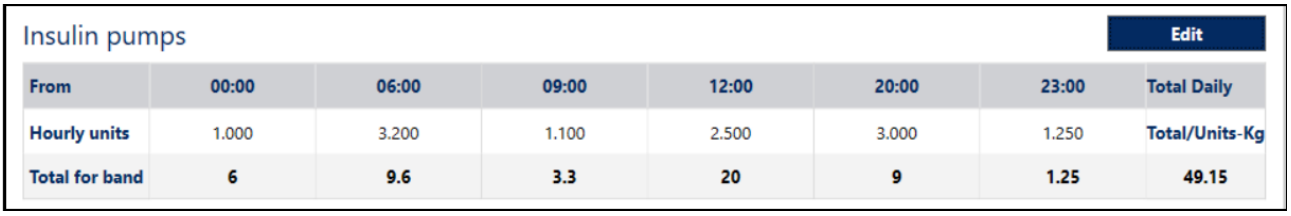
By clicking the Cancel button, it will be possible to exit the *Timetable Management* without saving any entered or modified data.

By clicking the New Time Slot button, a new line will be created where the time and the *Hourly Units* of insulin can be set.

In the absence of previous set times, ALLY will create the first line with starting at 00:00. By clicking the button several times, more rows will be created with an increment of your choice (the default is 60 minutes).

It is possible to change the time by clicking on it and typing in the desired time. It will be necessary to specify the *Time Units* before clicking the Save button, to save the new data.

In the *Treatment* module there is a summary of the settings that have been made for the insulin pumps as shown in the following image:



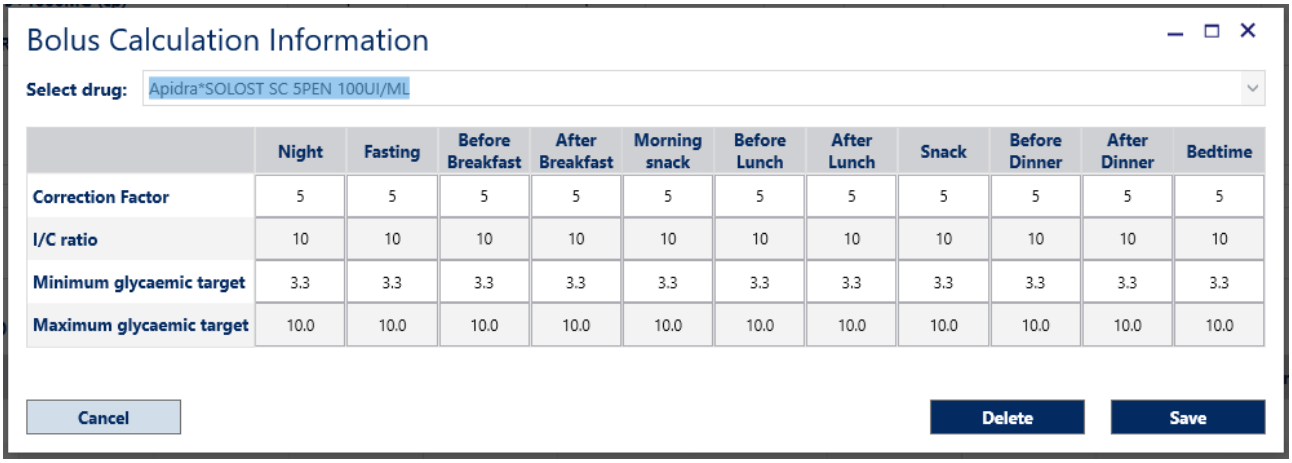
13.5 Calculation of the boluses

The bolus calculation section enables the calculation of the insulin bolus based on the Carbohydrate count (Correction Factor, CHO Insulin Ratio and Glycaemic Target).

Firstly, select the type of ready-made insulin that is used for the calculation.

The calculation parameters are then saved. If only one glycaemic target is used, it is sufficient to use just one of the two parameters which are indicated (Min or Max).

When a new date is entered, the data is resubmitted and can be modified to speed up the prescription calculation.



	Night	Fasting	Before Breakfast	After Breakfast	Morning snack	Before Lunch	After Lunch	Snack	Before Dinner	After Dinner	Bedtime
Correction Factor	5	5	5	5	5	5	5	5	5	5	5
I/C ratio	10	10	10	10	10	10	10	10	10	10	10
Minimum glycaemic target	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3	3.3
Maximum glycaemic target	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0	10.0

14. Statistics

The *Statistics* module allows data to be interpreted and analysed with the added aid of graphs.

By comparing and cross referencing the data, the system processes the information stored in the database and displays the list of patients who meet the search criteria that have been set.

For example, it is possible to find out how many, and which patients with type 1 diabetes have developed non-proliferating retinopathy and isolate those who have undergone laser treatment for macular involvement; the number of hospitalisations due to diabetic ketoacidosis in a given period of time, and so forth.

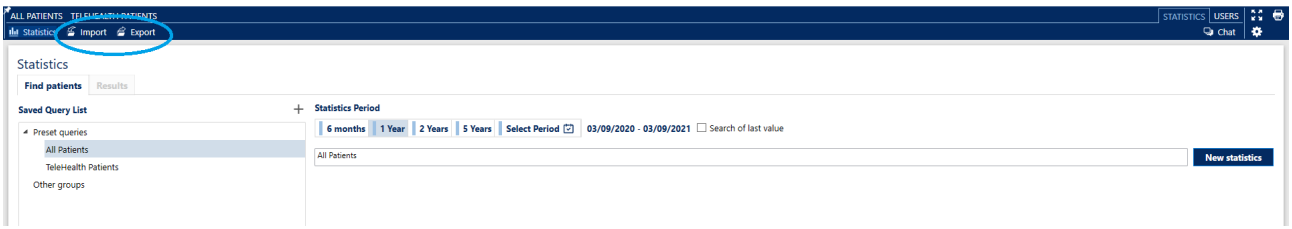
The investigations can have varying degrees of complexity, assembling more information (e.g. how many patients have undergone amputation of the lower limbs due to peripheral artery disease after a certain number of years of illness, subdivided by gender and/or type of antidiabetic treatment).

Once a distinct list of patients has been selected based on specific characteristics, (for example, patients presenting the onset of kidney disease after 20 years of illness), it is then possible to further study the statistical research. For example, the average value of glycosylated haemoglobin among such patients can be calculated.

Additionally, the list of such patients in the Patient Archive can be viewed and all of their data directly accessed.

From the *Statistics* module the conditions of the statistics can be imported and exported.

Below there is an image in which the two buttons are highlighted to import and export a statistic:



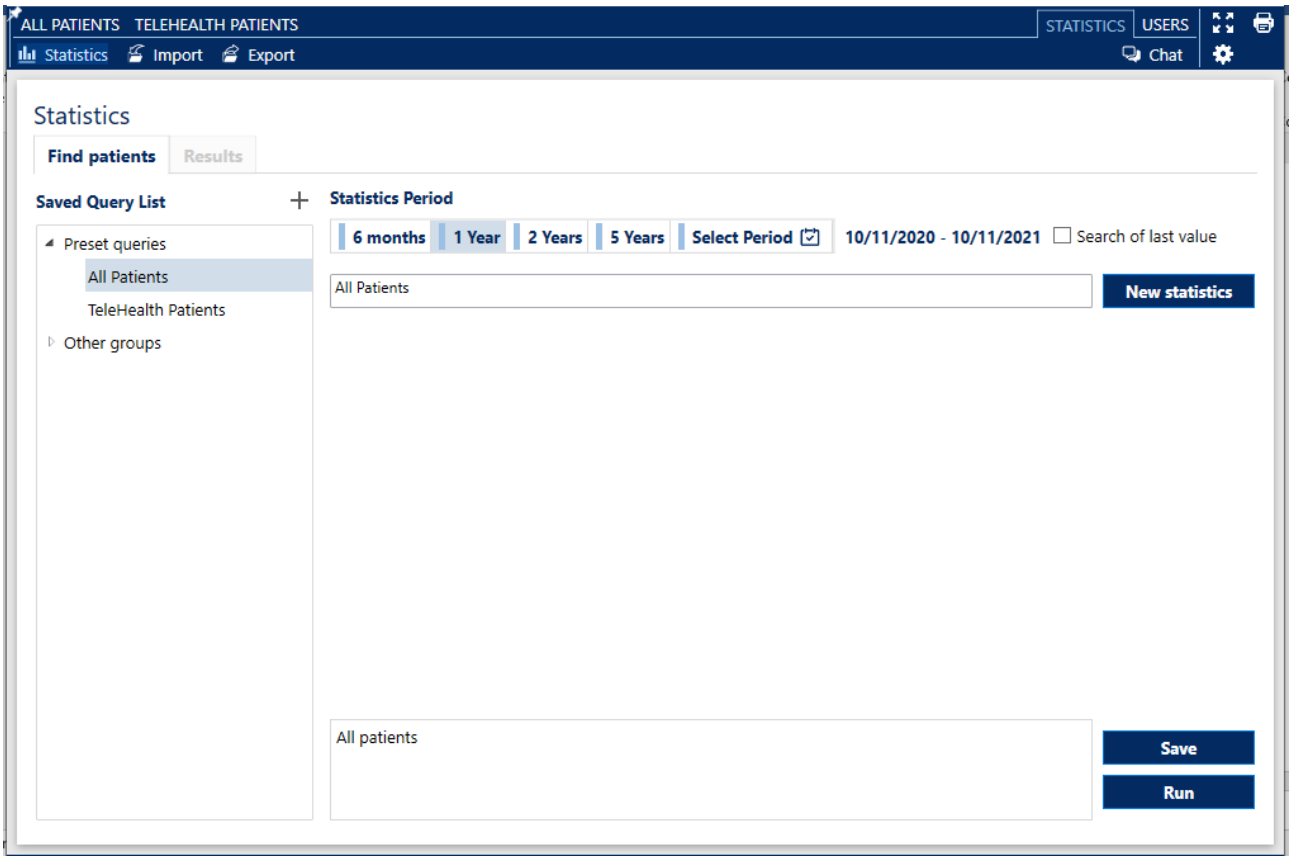
14.1 How to develop a statistic

The *Statistics* module displays a page structured by default in two main tabs:

- *Find Patients*
- *Results*

Find patients

The criteria (queries) used to process a statistic can be selected from the *Saved Query List* or by creating new conditions based on the requisites of the research.

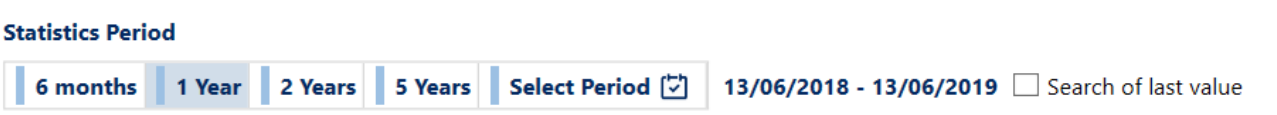


By clicking the Export button statistics queries can be exported and saved in a file. The statistics can then be imported into other ALLY installations by clicking the Import button in that installation.

The saved queries will appear in the *Saved Query List* that appears in the left column of the *Find Patients* tab of the *Statistics* module.

By clicking the name of a query stored in the *Saved Query List,* the statistic criterion will be retrieved and displayed. By clicking the Run button the list of the relevant patients can be viewed.

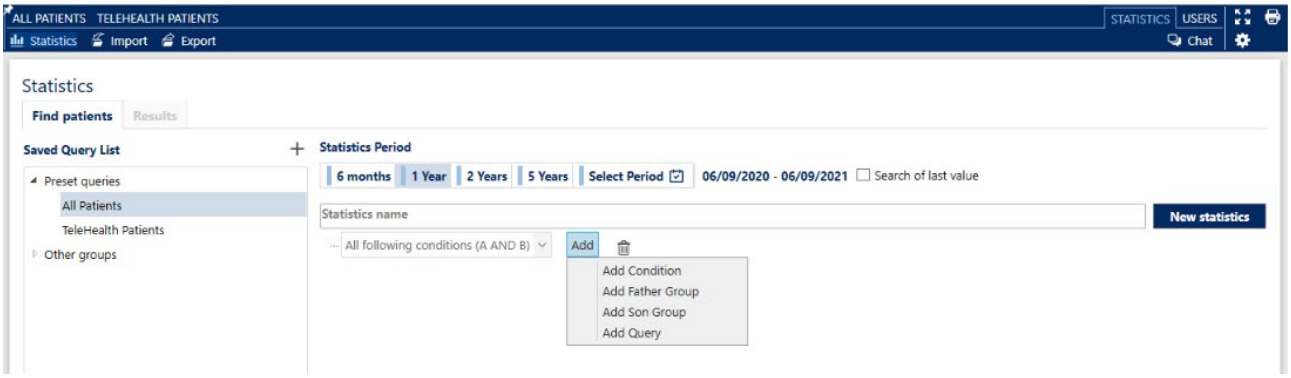
During the setting of some statistics, it is necessary to select a period of time in which the research can be performed. This is obtained by clicking the intervals already set or by choosing specific dates from the calendar, as shown in the following image:



In order to process a new statistic which is not included in the saved statistics, click the New statistics button.

The description of the query can be inserted in the 'Statistics name' field that can be located to the left of the **New statistics** button.

Next, select the desired condition from the drop-down list.



By moving the mouse over the description of the condition, the Add button and the icon are displayed.

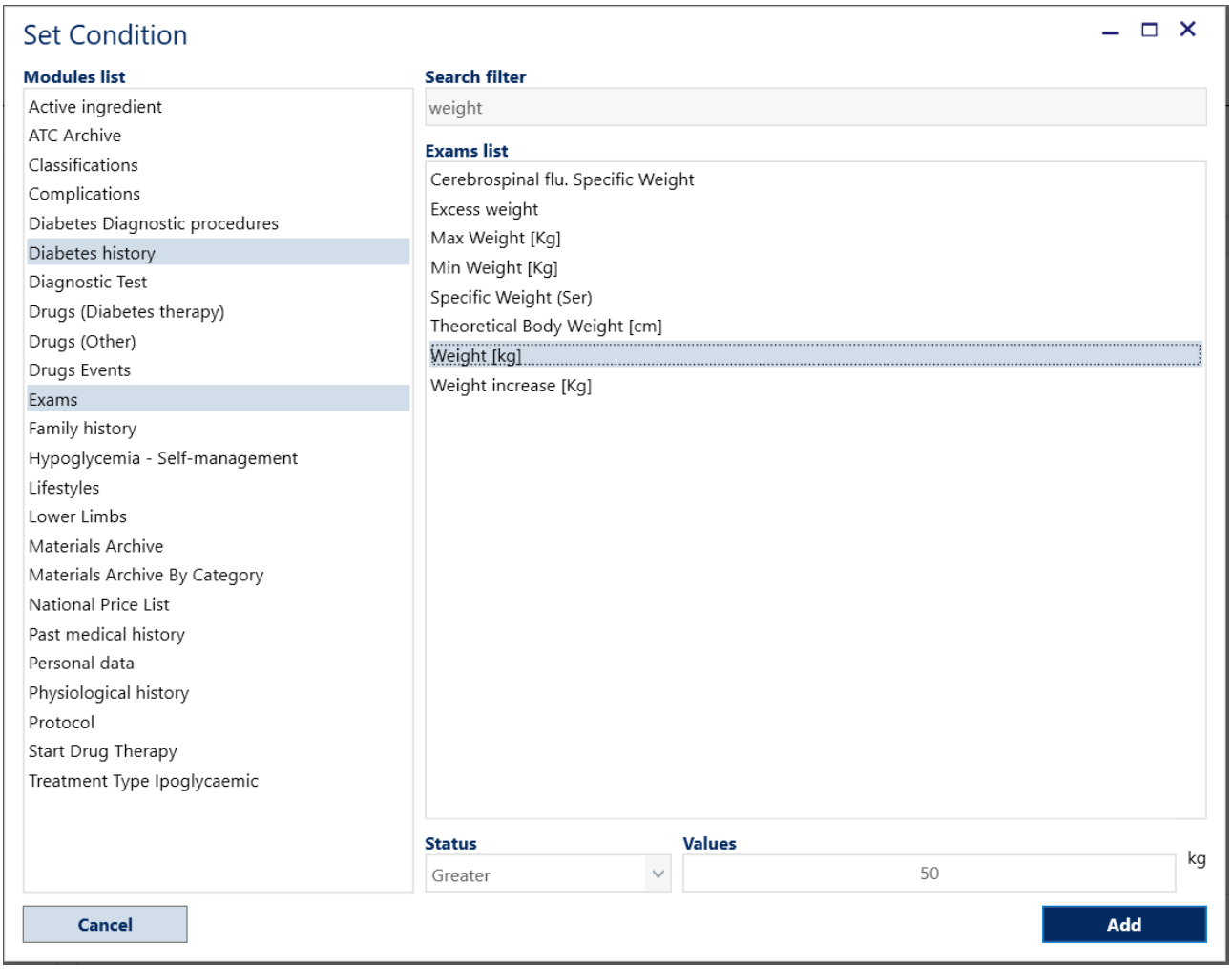
The Add button allows the user to:

- *Add Condition:* conditions related to a specific query
- *Add Father Group:* add a condition group belonging to a level which is higher than the previously set one
- *Add Son Group:* add a group of conditions belonging to a level which is lower than the previously created group
- *Add Query:* add conditions belonging to a previously saved query

The button deletes all set conditions.

Add condition

By selecting the function *Add Condition* the system opens a dialogue box as shown in the following image:



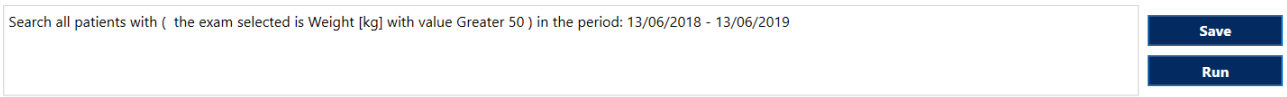
To set the condition, select the module from those in the *Modules List*.

In the example image above, the *Exam* module has been selected. Afterwards, the "Weight" *search filter* has been set, then the *Weight* [*kg*], the "Greater" *Condition* and the "50" *Value* have also been selected.

By clicking the **Add** button the condition created in the *Statistics* start page will be set and displayed.

In order to add new conditions, click the Add button and repeat the sequence of activities as described above.

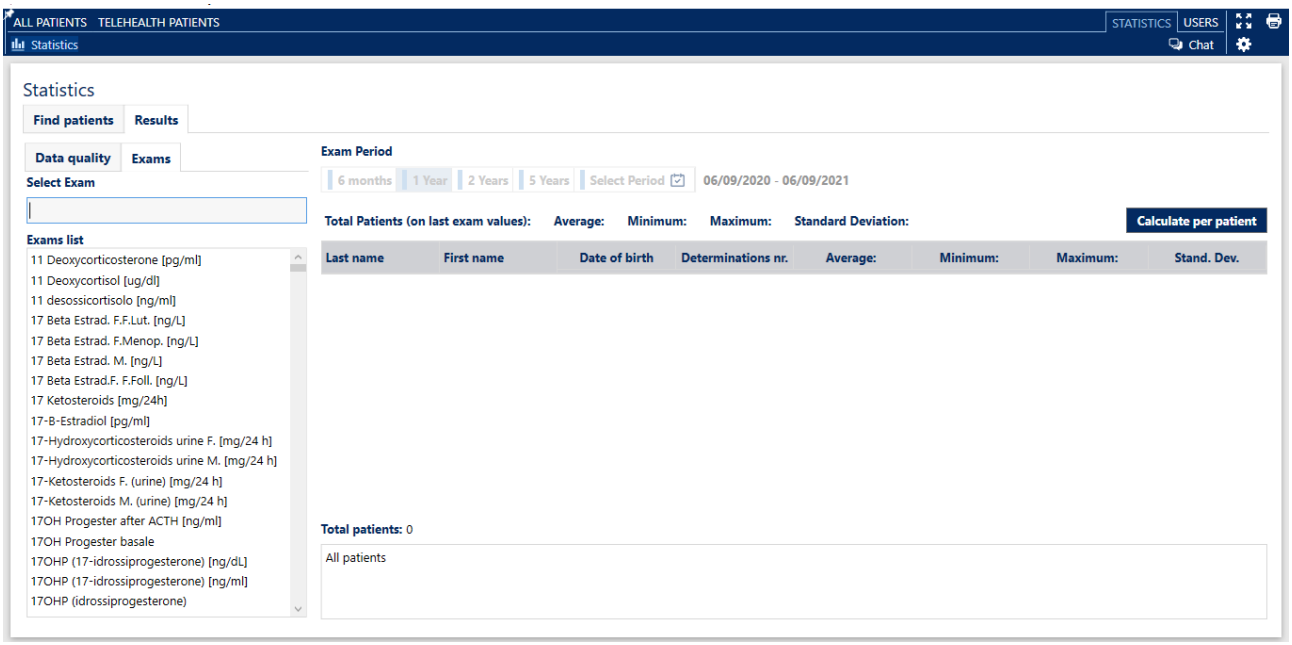
In the lower section of the *Statistics* tab the conditions set are summarised as in the following image:



To view the list of patients related to the statistic, click the **Run** button. A request to save the statistics will appear in the *Saved Query List,* after which, the result will be automatically displayed.

Results

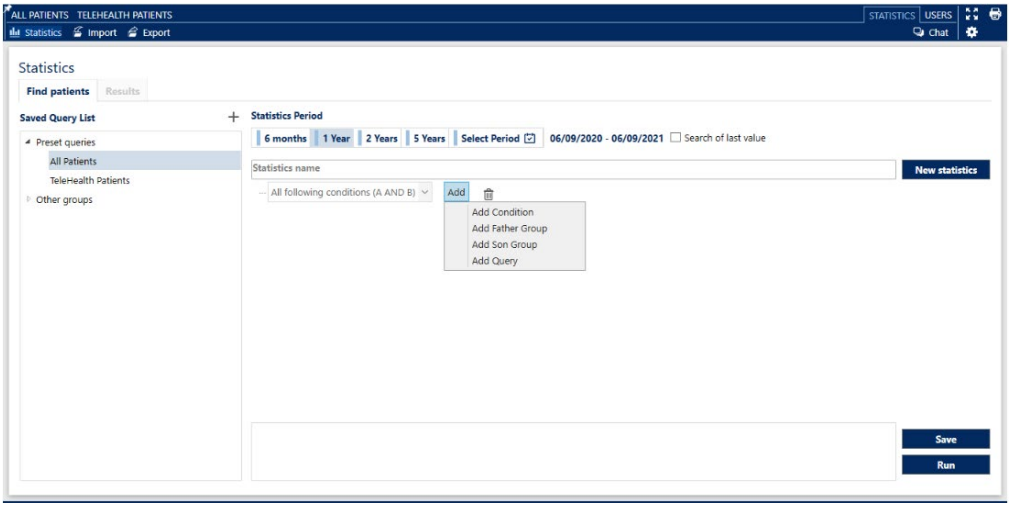
The list of patients resulting from the query will be displayed in this section. In the left column, the list of laboratory exams will appear, which, if selected, will activate the *Calculate per patient* button **Calculate per patient** allowing the calculation of the *Average, Minimum, Maximum* and *Standard Deviation*, for the patients who are on display.



It also allows the calculation of the Average, Minimum, Maximum and Standard Deviation. over the selected population, with reference to a specific laboratory test.

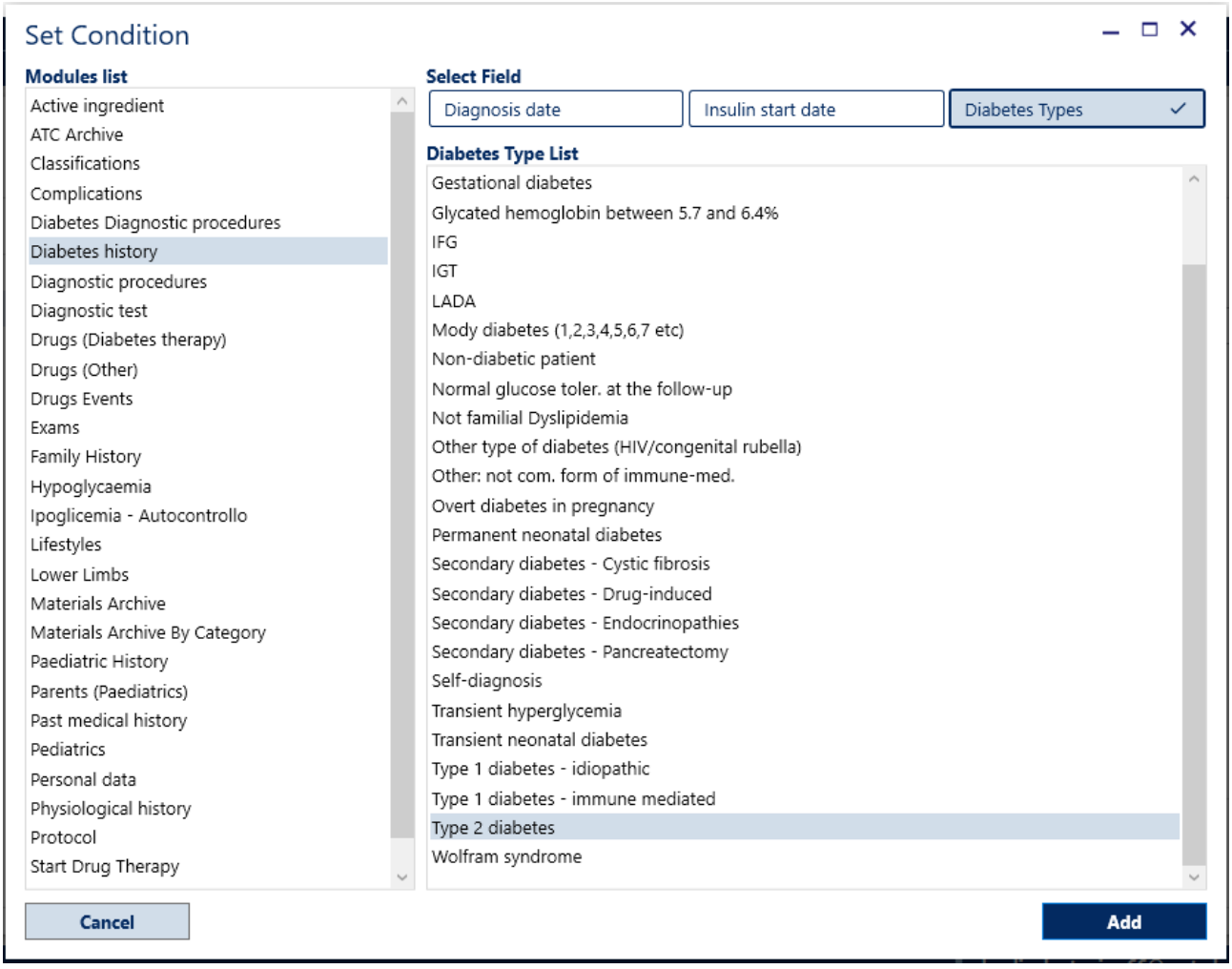
Assemble and perform a complete statistic

To search for all patients who have been suffering from type 2 diabetes for more than ten years, click the **New statistics** button and position the mouse on the drop-down menu where the conditions are chosen. On the right side, the Add button will appear. This button, once clicked, will display the menu to select the option *Add Condition,* as shown in the following image:



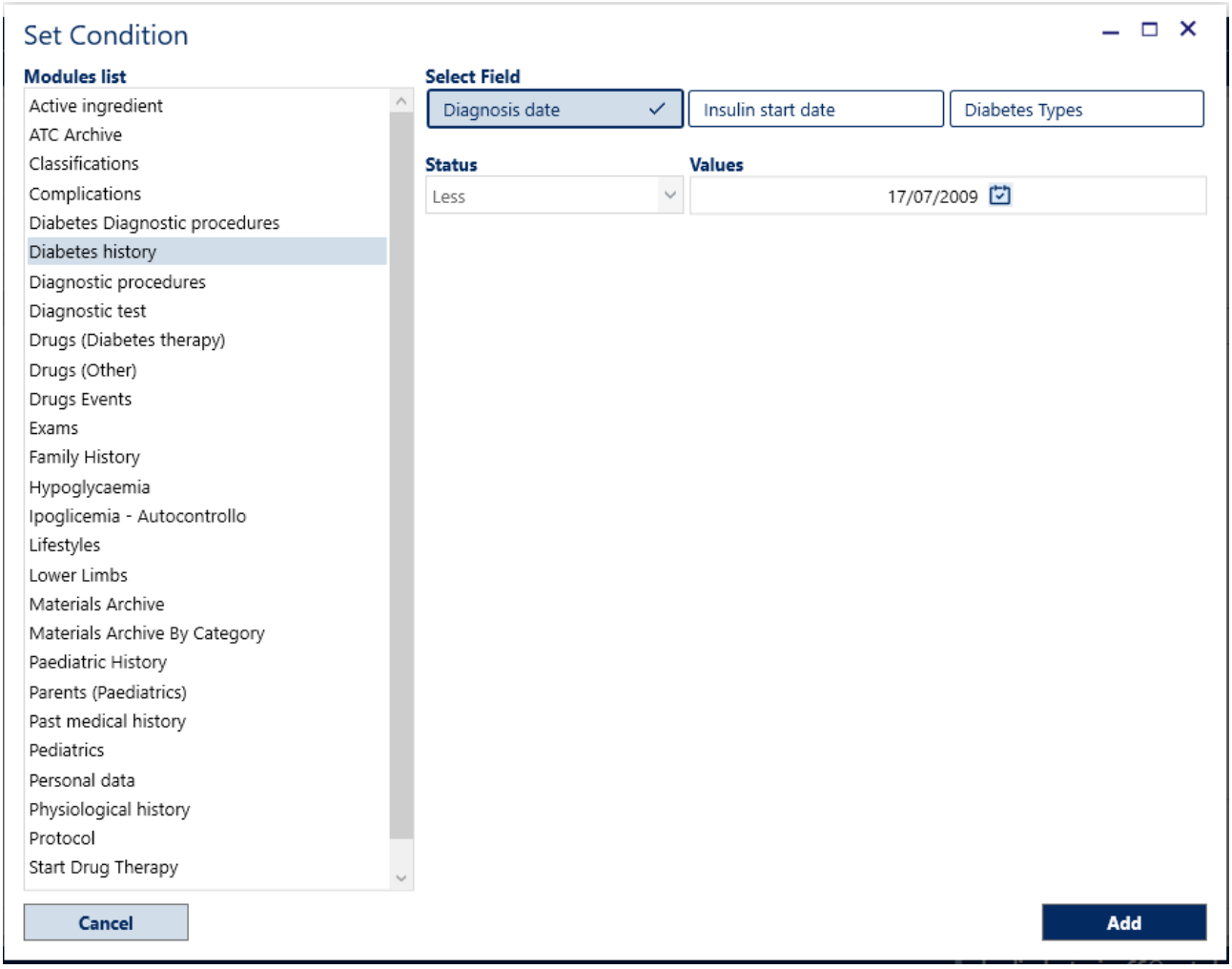
By clicking *Add Condition* a window will appear. From this window the first condition can be set.

Then, select *Diabetes history* in the modules list followed by *Diabetes Types* under Select Field. Choose Type 2 Diabetes from the *Diabetes Type List*, as shown in the following image:



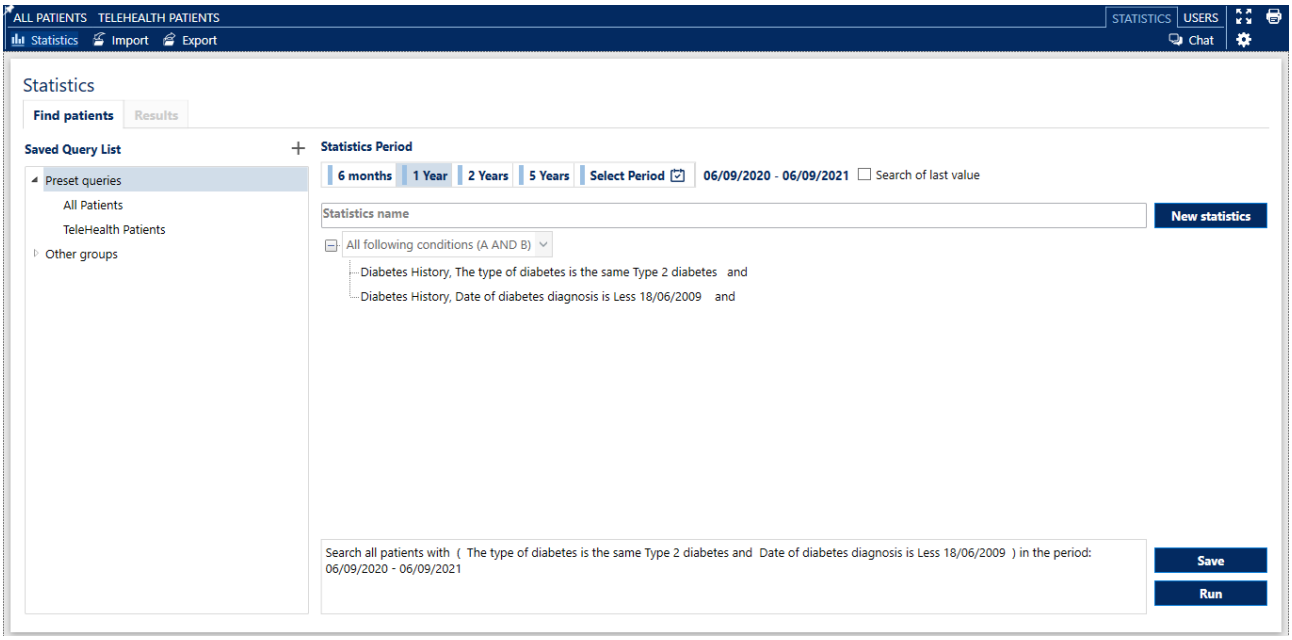
By clicking the **Add** button the first condition can be set.

To set the second condition, position the mouse on the drop-down menu where the conditions are chosen, click the Add button and select *Add Condition.* Select *Diabetes History* again in the *Modules list*. However, this time it will be necessary to select the *Diagnosis Date* option and select *Less* in the *Condition* drop-down menu. Afterwards, in the *Values* field set a preceding date of 10 years as shown in the following image:



By clicking the **Add** button the second condition that will search for patients whose diagnosis dates back at least ten years can be set.

The summary of the set conditions will be visible, shown as follows:



After selecting the search criteria, by pressing the **Save** button, the statistics query is saved and may be re-run in the future.

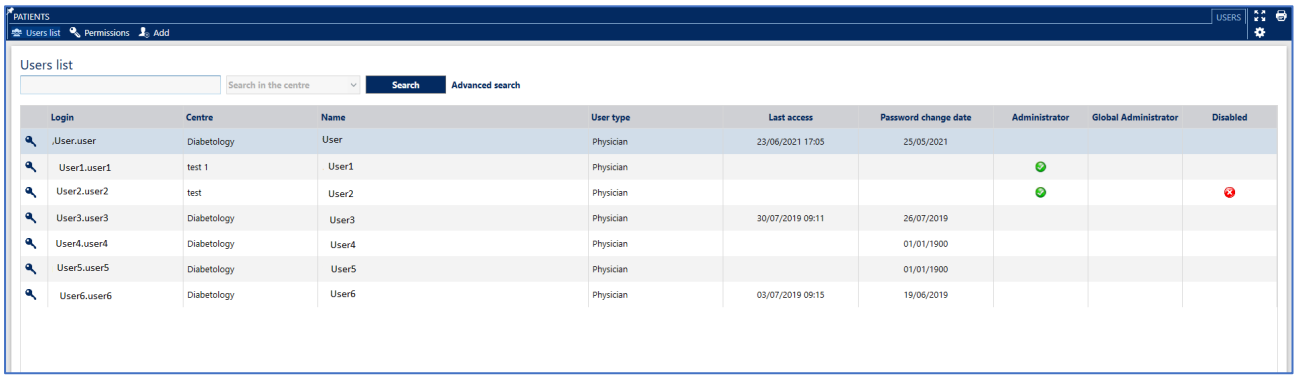
15. Users

It is necessary to be a Site Administrator user in order to display the 'Users' module.
The 'Users' module permits the viewing of the list of authorised users and the managing of the related accounts and permissions.

The User navigation bar contains the following functions:

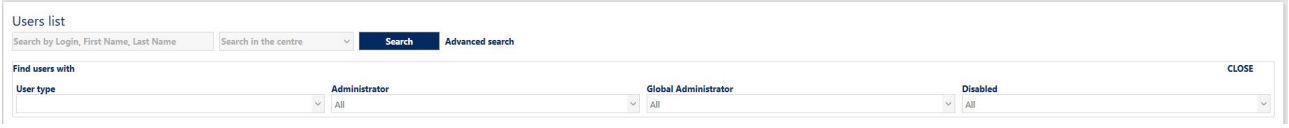
- 'Users list' (Site Administrator only): displays the list of users stored in the ALLY database
- 'Add' (Site Administrator only): Creation of a new user
- 'Edit' (Site Administrator only): Edit recorded users
- 'Add Community User' (Site Administrator only): Add users already recorded in other sites

By accessing the 'Users list', the list of users stored in the database is displayed.



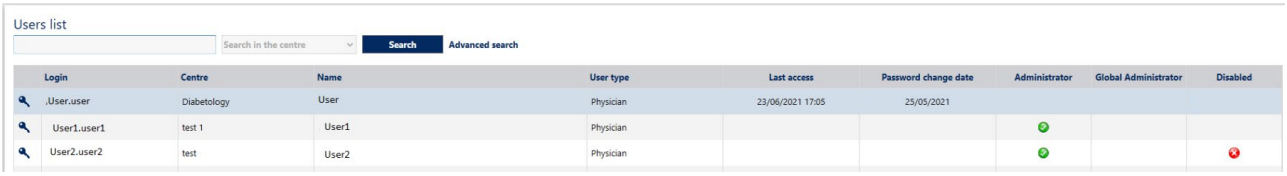
The search for a user already registered in the database can be performed in two different ways:

- 'Search' button; the search will be performed by entering either the 'login' name or the 'First name'/'Last name' of the user and the centre to which they have access.
- 'Advanced search' function; the function allows a search using further criteria in order to select personal data: 'User type', 'Administrator' and 'Disabled'.

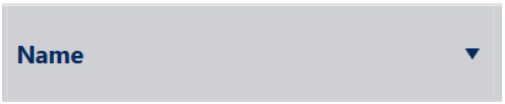


The User list table shows the following data for each user: 'Login', 'Centre', 'Name', 'User Group' and the data related to the use of the account: 'last access', 'password change date', 'administrator', 'disabled'.

The icons in the last two columns indicate the administrator permissions; a green icon if the user is enabled and a red icon if the user is disabled.



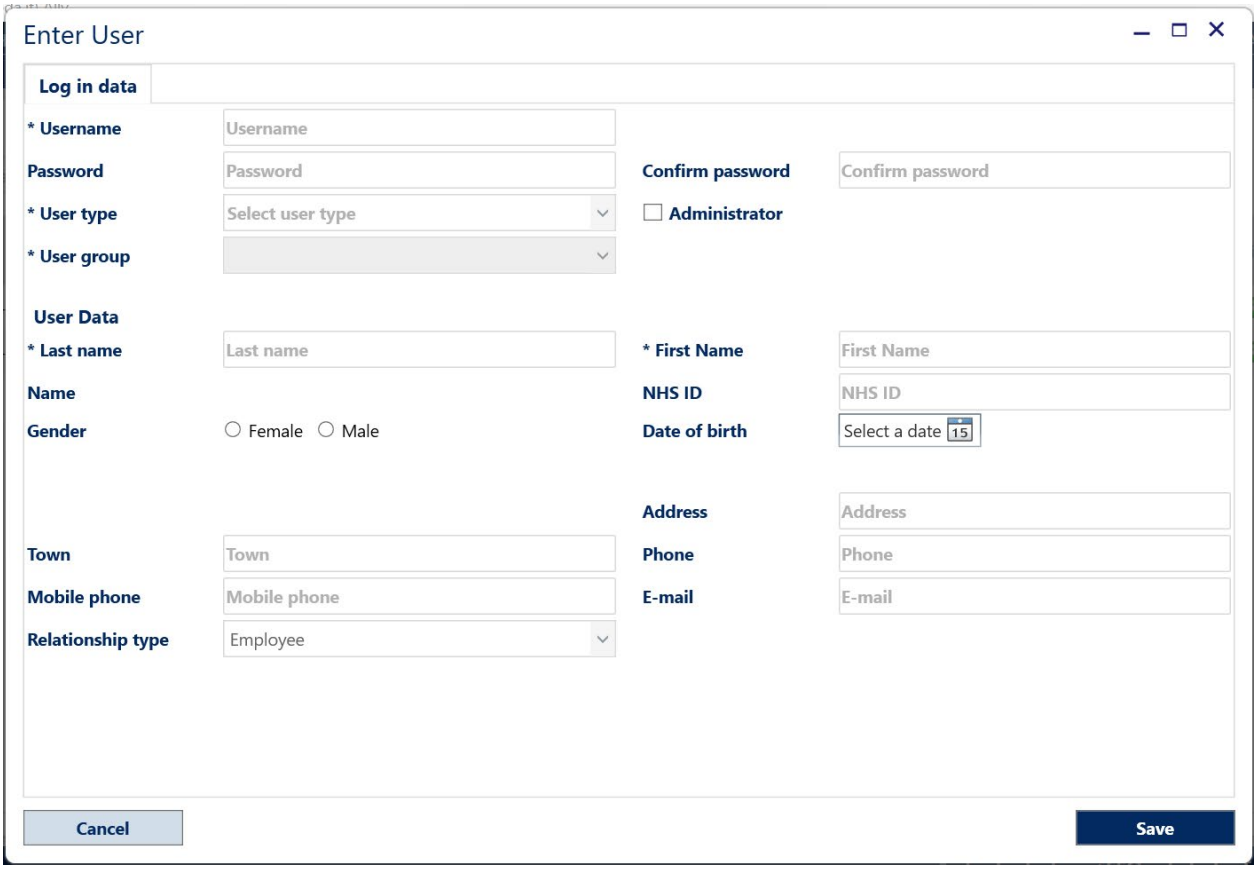
By clicking the title of the columns, the Site Administrator can change the sorting of the displayed data in ascending or descending order.



Changes made to the layout will be saved by exiting the program. These changes are saved for the current user allowing customisation for each user of ALLY.

15.1 Add a new user

By clicking the Add button a window will open where the Site Administrator can enter the data relating to the new user, as shown in the following image:

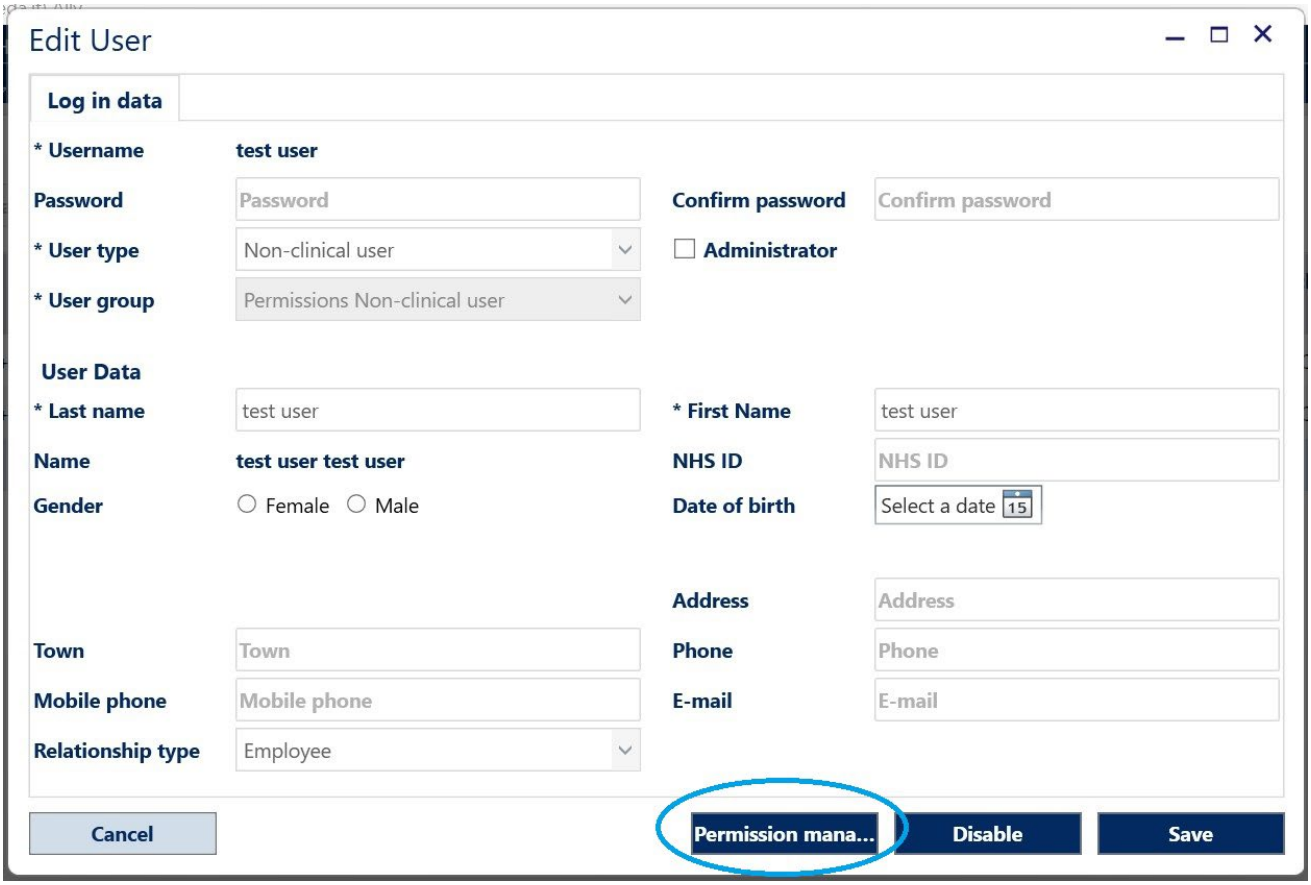


The fields marked with an asterisk (*) are mandatory and cannot be omitted. They are: 'Username', 'User Type', 'User Group', 'Last Name' and 'First Name.'

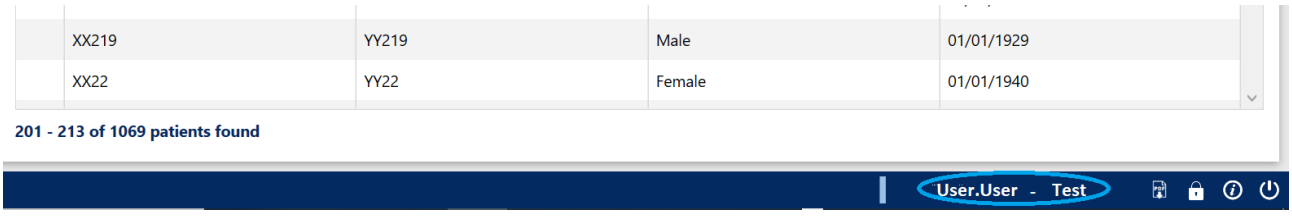
After entering the necessary data, click the Save button' to create the new user and store the data in the database.

15.2 Modify a user's data

By double-clicking the line corresponding to a user or the Edit button, after selecting the user, the window containing the details will open:



Click on "Permission management' to change the user permissions.
After changing or integrating the user details, click the 'Save' button to store the data in the database.
It is possible to access the details of the current user from any module of the program by clicking the name of the authenticated user which is shown at the bottom right of all screens.



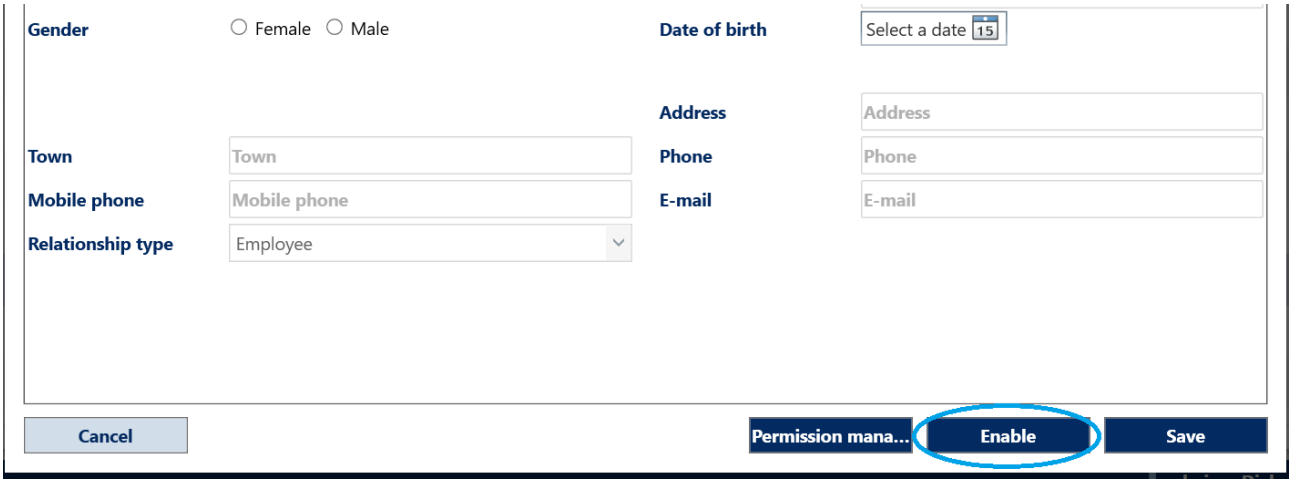
15.3 Management of user permissions

In the user details window, there are two buttons:

- - 'Disable': clicking the **Disable** button the corresponding account will be deactivated and the related user will no longer be able to access ALLY.

  In the user list, a red icon will appear in the 'Disabled' column of the corresponding user.

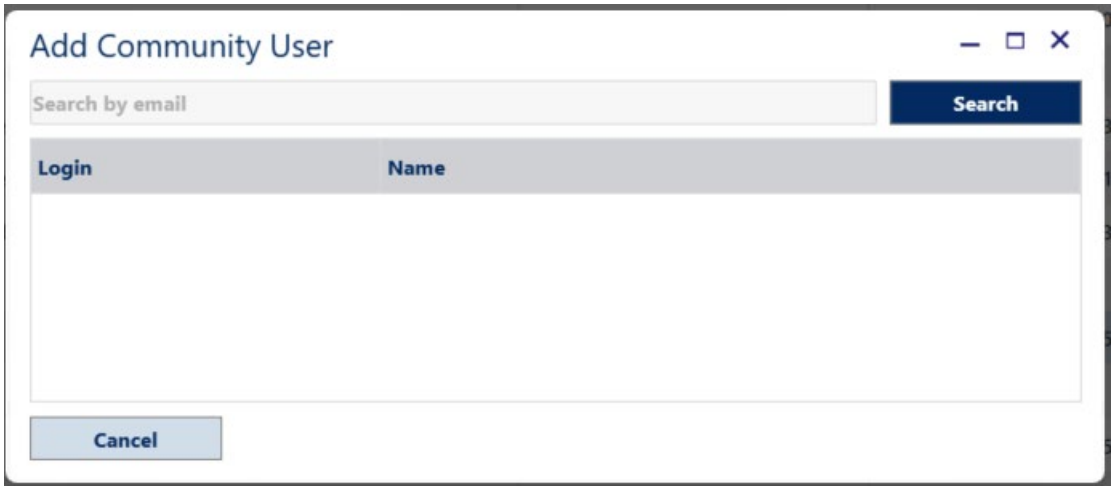
To enable the user account again, open the user detail sheet as described above and click on the **Enable** button.



- 'Save' Clicking the **Save** button ensures all changes are saved in the system.

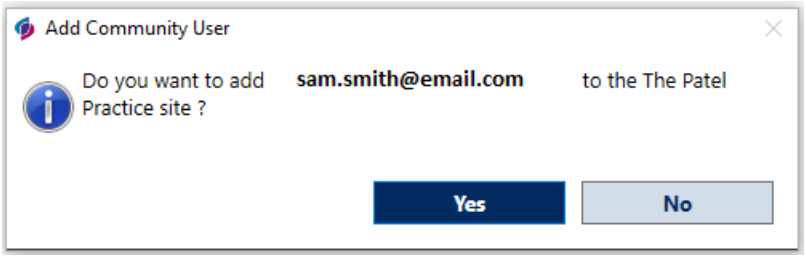
15.4 Add Community User

By clicking the **Add Community User** button a window will open where the Site Administrator can enter the email address relating to a user already registered in another site, as shown in the following image:

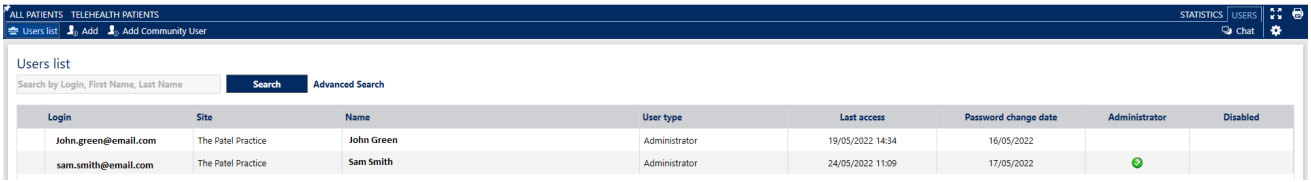


Enter the user email address and click ‘Search’.

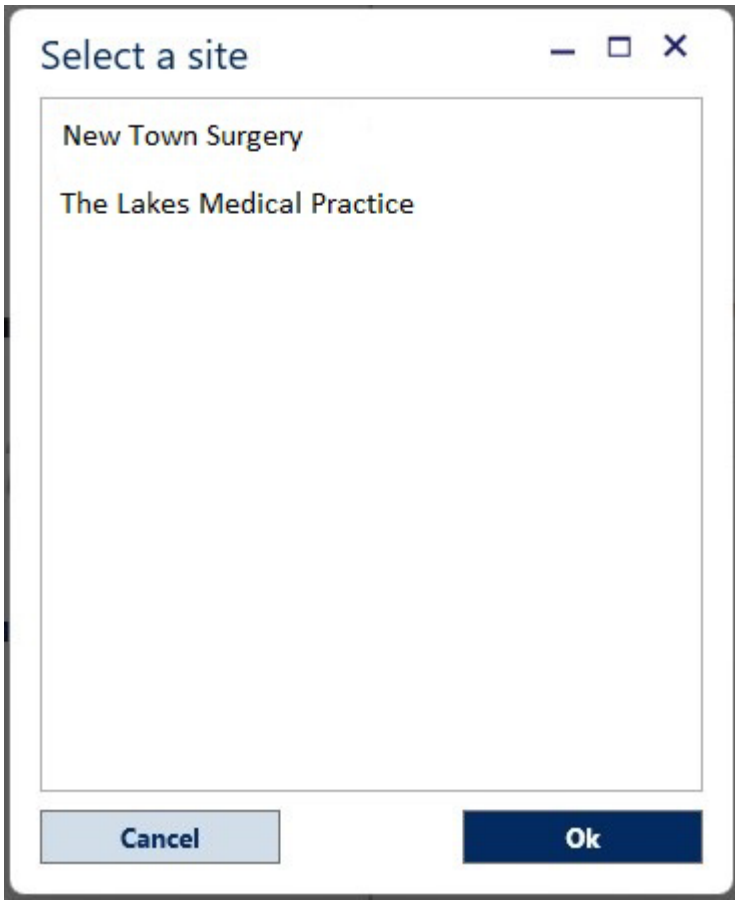
Select the user dispayed in the table and click ‘Yes’ in the ‘Add Community User’ window to add the user to the current site, as shown in the following image:



The user will be automatically added to the user list of the current site.



Next time the user enters their login details into ALLY, the following window will be displayed:

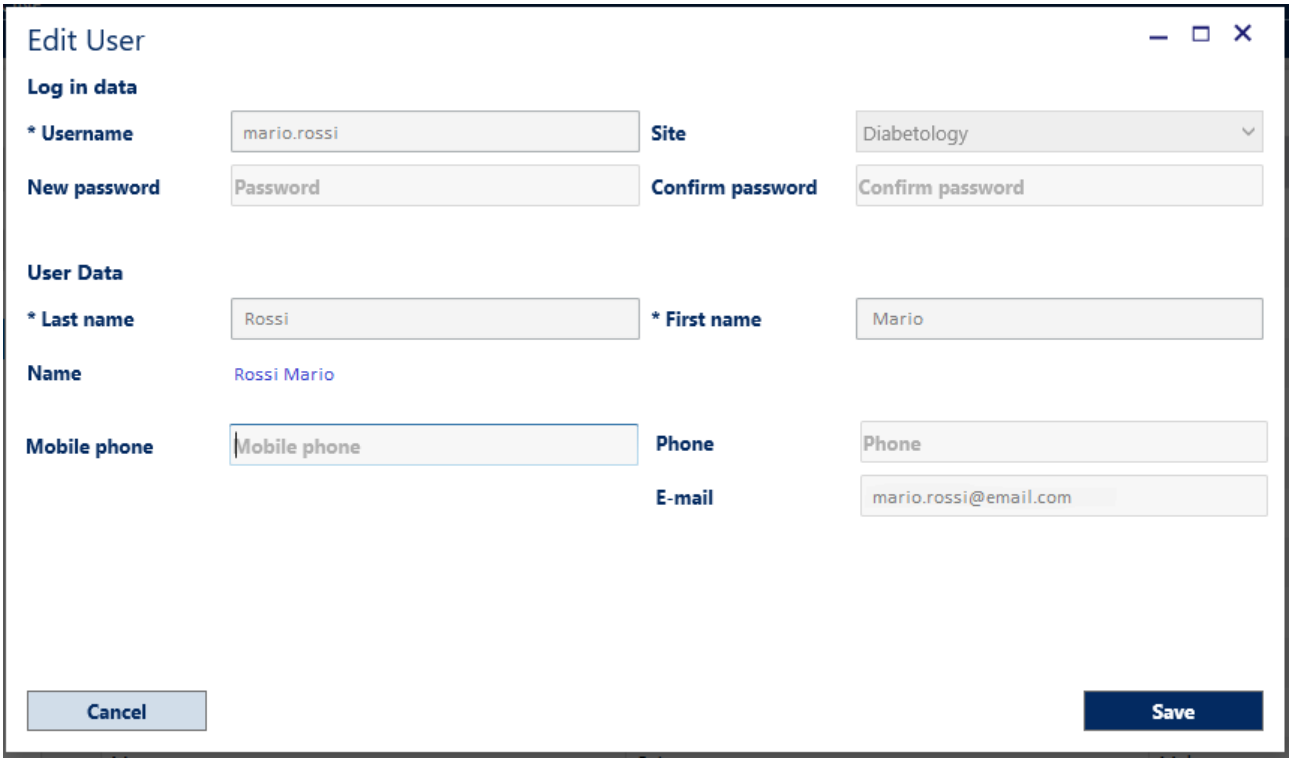


To proceed the user will need to select the site they wish to access and click ‘Ok’.

16. Change or reset password

The password or your account information can be changed by clicking on the username on the bottom navigation bar.

Information such as e-mail address, telephone number and password can also be changed.

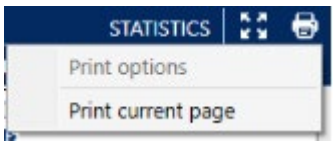


Select the ‘Reset Password’ option on the ALLY login page if you have forgotten your password.

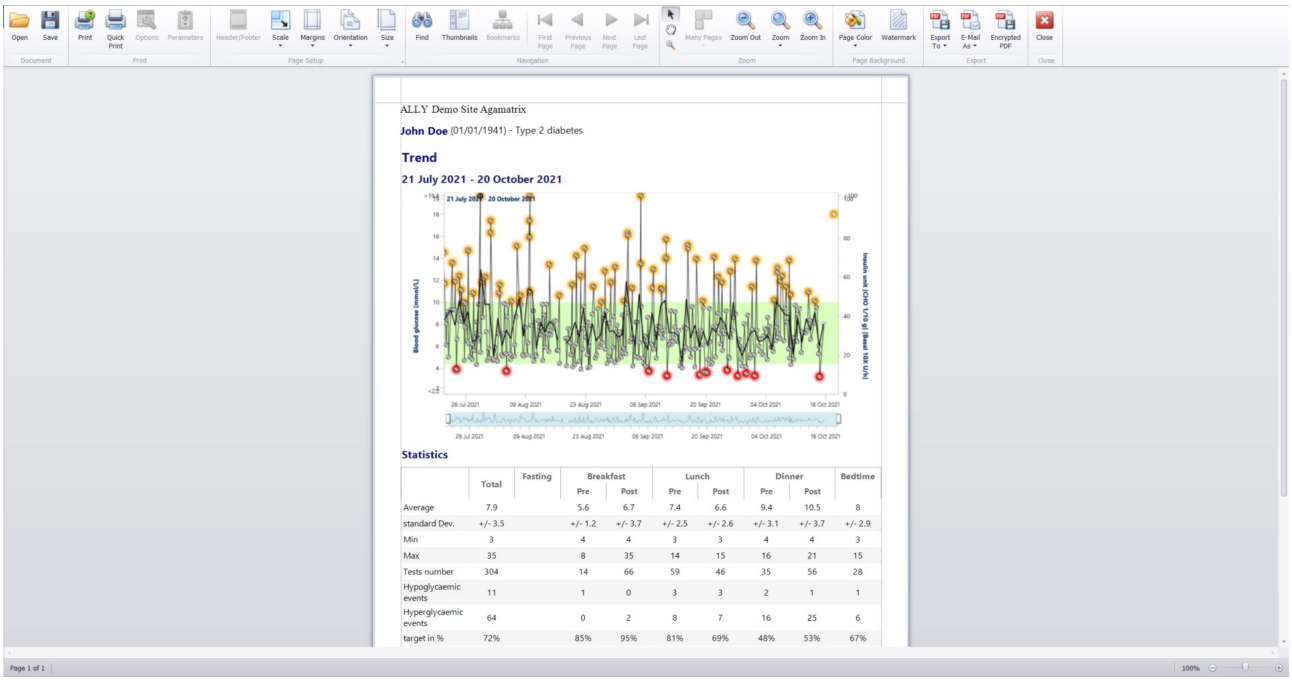
17. Print

In each ALLY module a summary of the current window can be printed.

In the upper right corner, there is the icon which, if clicked, will display a menu with the 'Print current page' as shown in the following image:



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:



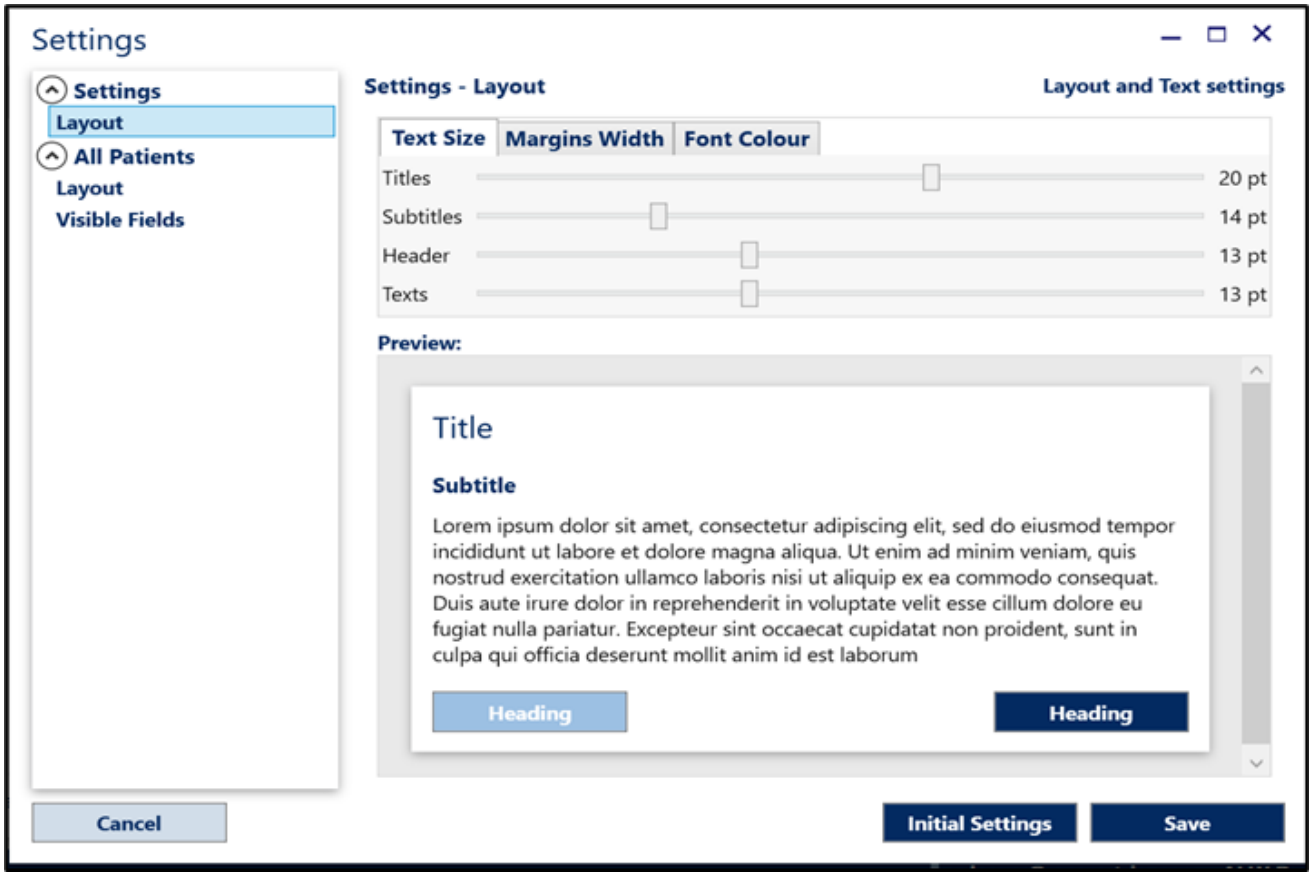
On the print preview page, clicking the button will allow a change of printer, change the printing margins and enable the export of the document to pdf.

To print the document as visible from the preview, click the button.

To select a printer other than the default, click the button.

18. Settings

By clicking the icon on the right of the menu, some ALLY modules can be customised, as shown in the following image:



In the left column there is the list of modules where it is possible to make customisations.

18.1 ALLY settings

Layout

In this section the font sizes of all the text present in ALLY and the size of the text margins can be modified.

By modifying an element, immediate feedback in the 'Preview' area in the lower part of the window is given.

18.2 All Patients

Customise the module in which the patients are searched.

Layout

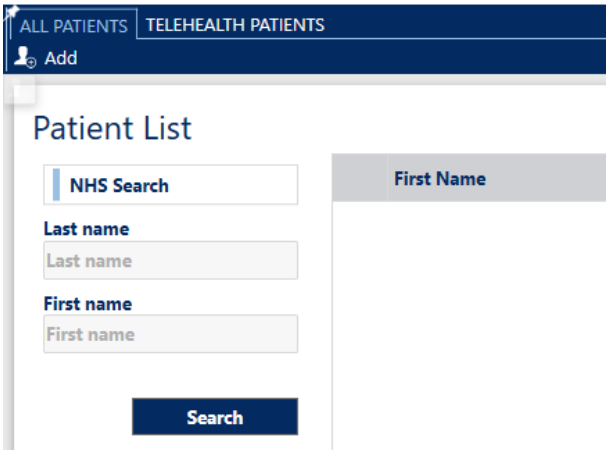
The following options are available:

- ‘Position of the patients search bar‘: Position the search bar at the top or on the left of the personal data search form
- ‘First Name’ and ‘Last Name’ search fields: Set a single line in which to insert ‘First Name’, ‘Last Name‘ or ‘Last Name‘, ‘First Name‘ during the search phase a distinct line each for ‘First Name‘ and ‘Last Name‘
- ‘Patient's main page‘: Set which module is opened, after performing a patient search and double-clicking on the patient’s name.

By default, the ‘Patient Search Bar Position‘ is positioned ‘at the top‘ and the search module will be displayed as shown in the following image:

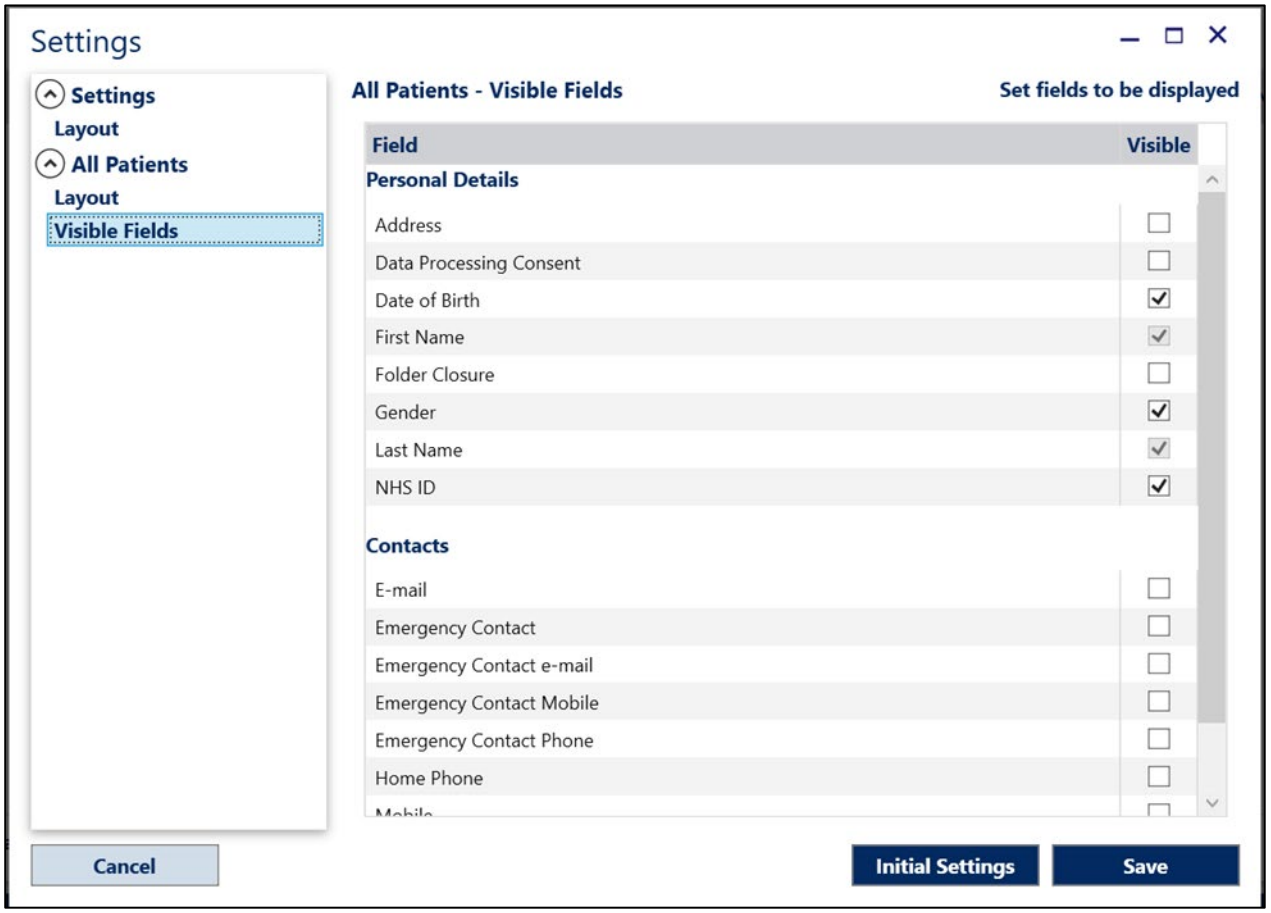
There will be a single text field where the HCP can search by ‘First Name‘, ‘Last Name‘ or ‘Last Name‘, ‘First Name‘ of a patient.

By changing the setting of ‘Position of the patients search bar’ onto the left side, the search module will be displayed as shown in the following image. The ‘First Name’ and ‘Last Name’ search field options will be separate ‘First Name’ and ‘Last Name’ fields as shown in the following image:



Visible fields

Which fields to display in the grid of the personal data search results can be decided, as shown in the following image:

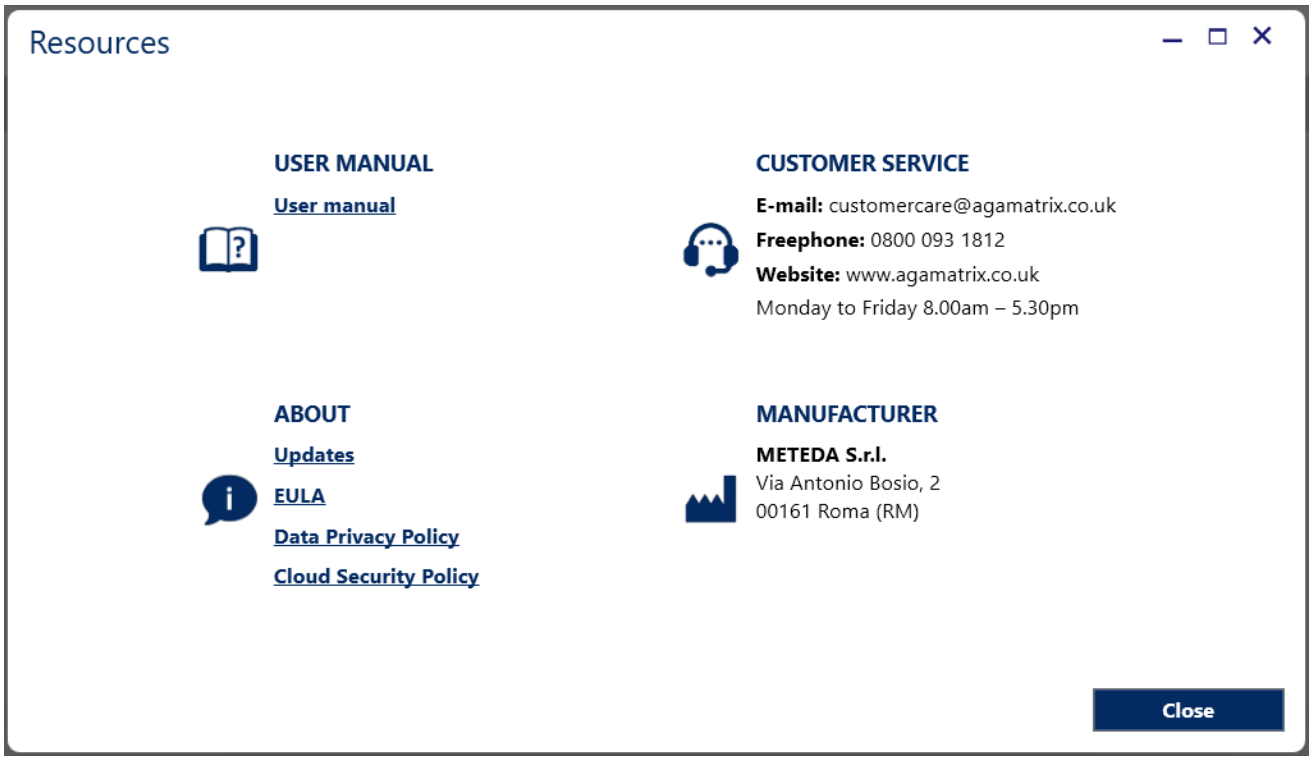


The only mandatory fields which cannot be hidden are: ‘First Name’ and ‘Last Name‘.

19. Information

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

- User Manual
- Regulatory Documents (EULA, Data Privacy Policy, Cloud Security Policy)
- Last software updates
- Customer Service details
- Manufacturer details



20. Directives and reference standards

This device was designed in compliance with the requirements established by the Regulation 2017/745 and with the following standards:

- UNI CEI EN ISO 13485 - Medical devices - Quality management systems - Requirements for regulatory purposes
- EN 62304 - Software for medical devices - Software life cycle processes
- UNI CEI EN ISO 14971 - Application of risk management to medical devices
- CEI EN 62366 - "Medical devices - Application of engineering features for the use of medical devices".
- ISO 15223-1 - Symbols to be used in medical devices, labeling and information to be provided.