



Pic Safe Gluco Monitor™ Software

Before using the software, read carefully and understand the instructions provided in this manual and save it for further consultation. For additional details, contact the consumers' toll-free number for Italy 800 900 080.

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CHAPTER 1: ABOUT THIS PRODUCT

1. About Pic Safe Gluco Monitor™ Software

Pic Safe Gluco Monitor™ Software is a PC software. The software provides users to below features:

- upload the data from blood glucose meters;
- stores and display the data;
- convert the data in graphs.

The features can help users and healthcare professionals to better control and manage diabetes.

2. Hardware and software requirements

2.1 Software operating system

MicroSoft® Windows Vista

MicroSoft® Windows 7

MicroSoft® Windows 10

With installed.NEF Framework v4.0 or upper version.

2.2 Hardware requirement

- Minimum hardware requirements

| | |
|---------|---|
| CPU | 1 GHz 32/64-bit processor |
| RAM | 1 GB or above |
| GPU | Direct x 9128M or above |
| Display | 1024 x 768 |
| HDD | 30 MB |
| Other | <ul style="list-style-type: none"> • USB port • PIC Safe Gluco Monitor™ USB Cable |

- Interface
 - printers
 - monitors
 - keyboard
 - mouse

2.3 Compatible devices

- Pic Safe Gluco Monitor™ Blood Glucose Meter

3. Safety

3.1 Intended use

Pic Safe Gluco Monitor™ Software is a PC-based software for use in the home and in professional settings to help people with diabetes and their healthcare professionals in review, analysis and evaluation of glucose test results for an effective diabetes management.

3.2 Warnings

- The software does not recommend your therapy instructions.
- Never make significant changes to your diabetes control program or ignore physical symptom without consulting with your healthcare professional. Always consult your physician or healthcare professional before making any adjustment with the glucose data.
- The device is realized to carry out the blood glucose measurement only when disconnected by the PC and supplied by internal batteries. It is forbidden to use the meter when connected to the PC. Compliance to electrical safety and electromagnetic compatibility requirements could be affected by this misuse connection.

CHAPTER 2: BEFORE STARTING PIC SAFE GLUCO MONITOR™ SOFTWARE

1. Before installation

Before installing the software, you must follow the instructions below for cybersecurity. The instructions help to protect against cyber security threats.

- Prior to installing and using the software, scan your computer with anti-virus and anti-spyware programs from a trusted source;
- Install, set up and enable adequate anti-virus software;
- Maintain up-to-date anti-virus software;
- Make sure that your OS has the latest security updates applied;
- Make sure your PC's firewall is on.

2. Installing the USB driver

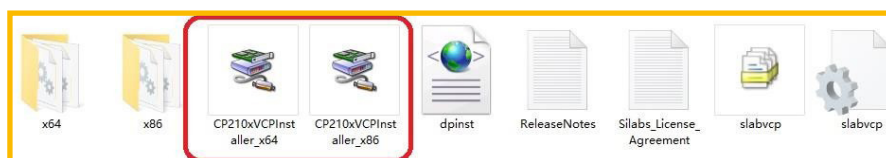
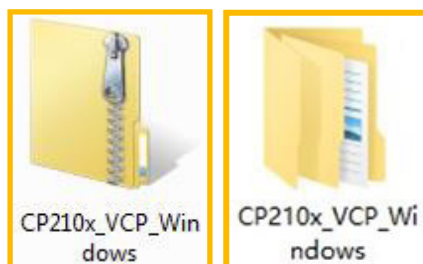
In order to recognize and link the meter with the computer, it is necessary to install a specific USB driver. Generally the driver is automatically installed at the first connection between the meter and the computer through USB cable. In this case, please refer to paragraph no. 3 "Installation" – Chapter 2. In case of failure, proceed to install it manually following the instructions below.

2.1 Visit the website: <http://web.picsolution.com/picsafeglucomonitor.html>

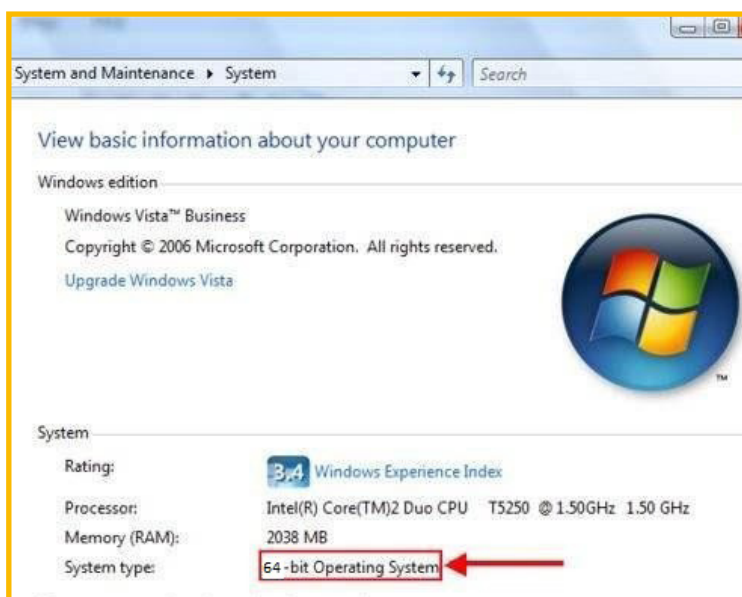
2.2 Download the USB driver "CP210x_VCP_Windows"



2.3 Unzip the file "CP210x_VCP_Windows", and click the file "CP210xVCPInstaller_x64" or "CP210xVCPInstaller_x86" in "CP210x_VCP_Windows" folder, in accordance with your OS type.



Check your OS type in x64 or x86 and choose the correct driver to install.



Installation is now completed.

3. Installation

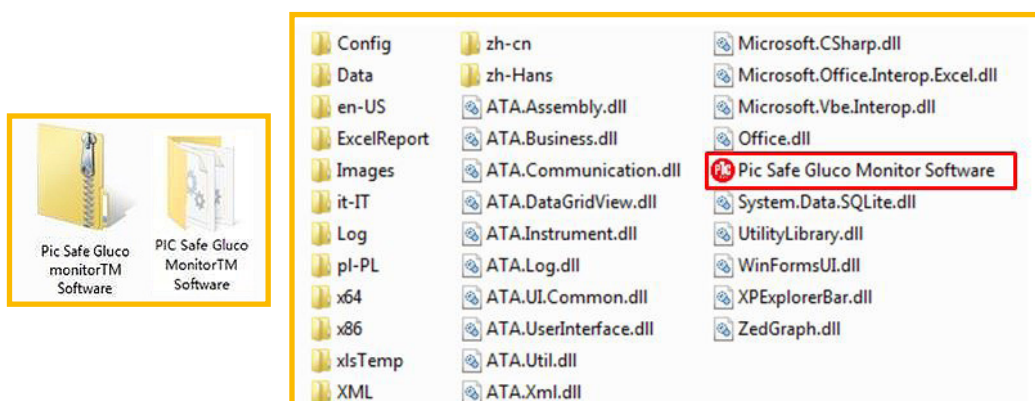
Please read the following instructions

3.1 Visit the website: <http://web.picsolution.com/picsafeglucomonitor.html>

3.2 Download the software in the desired language



3.3 Unzip the file and you will have the same name folder. No need to install the software; just double click on “Pic Safe Gluco Monitor Software” file and the software will be opened.



4. Connection between a blood glucose meter and PC

Connect the meter to PC with Pic connection cable according to the following steps.

4.1 Make sure that the meter is off

4.2 Connect the Pic USB Cable and USB port on PC

For the blood glucose meter to support USB communication, connect the meter and USB port on PC by using Pic USB Cable.

NOTE:

Pic USB Cable is the optional accessory. To request the software connection cable please contact the consumers' toll-free number for Italy **800 900 080**.

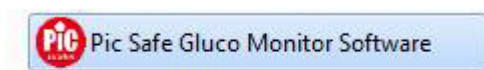
5. Uninstallation

No need to run 'Uninstall' under program, simply delete the unzipped folder.

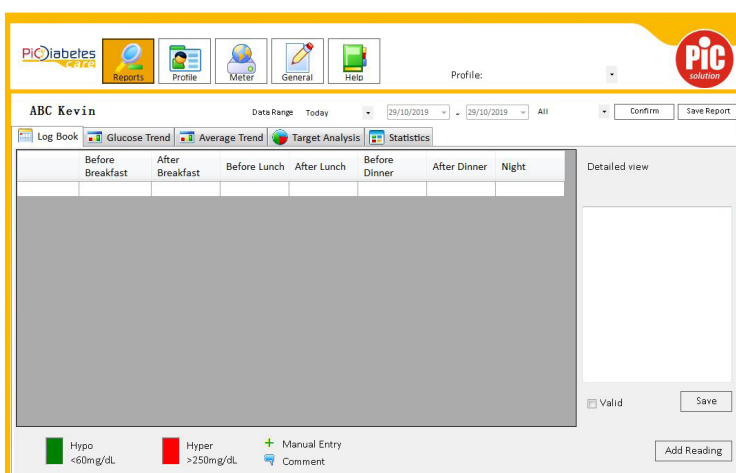
CHAPTER 3: START PIC SAFE GLUCO MONITOR™ SOFTWARE

1. Import the data from the meter

1.1 Double click on the 'Pic Safe Gluco Monitor Software.exe' file in the folder to run the program.

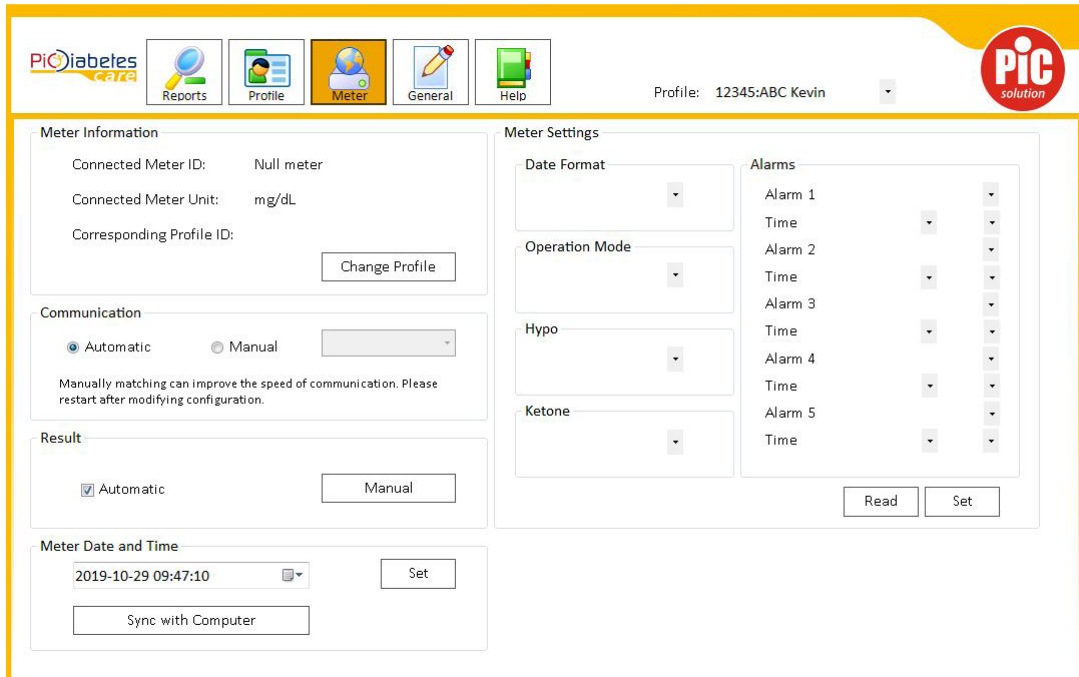


Software is loading the internal setting.



1.2 Press power button on the meter to turn it on.

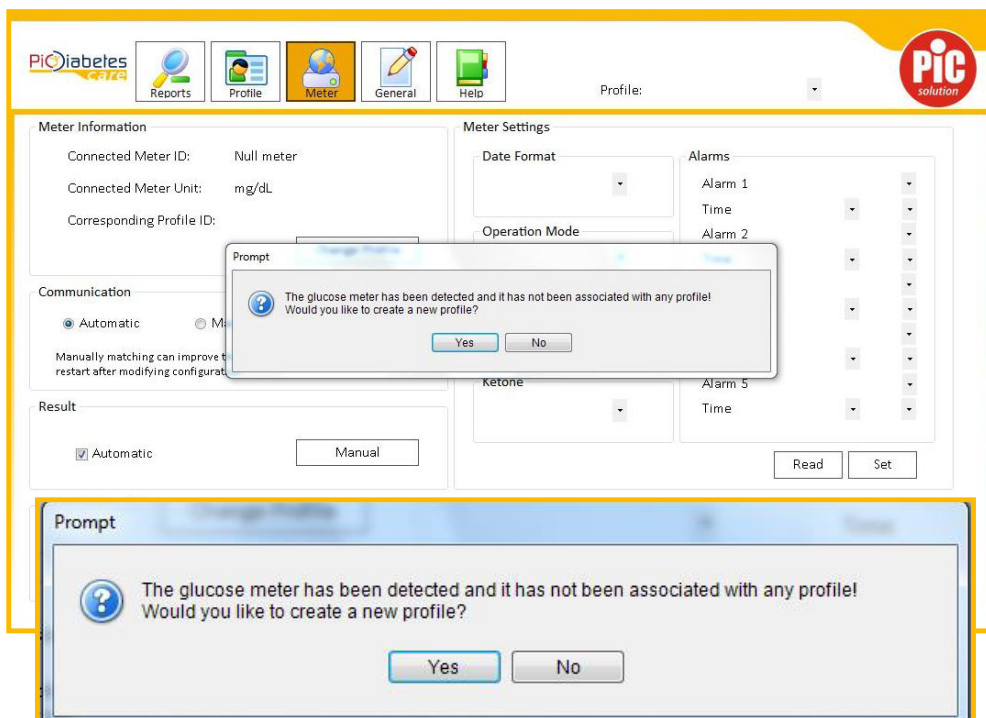
1.3 Select “Meter” on top bar.



It shows all settings and parameters of the glucose meter.

1.4 Connect the meter

Connect the meter with computer/laptop through Pic USB Cable, wait for 20-30 seconds for the first connection until below information is displayed:



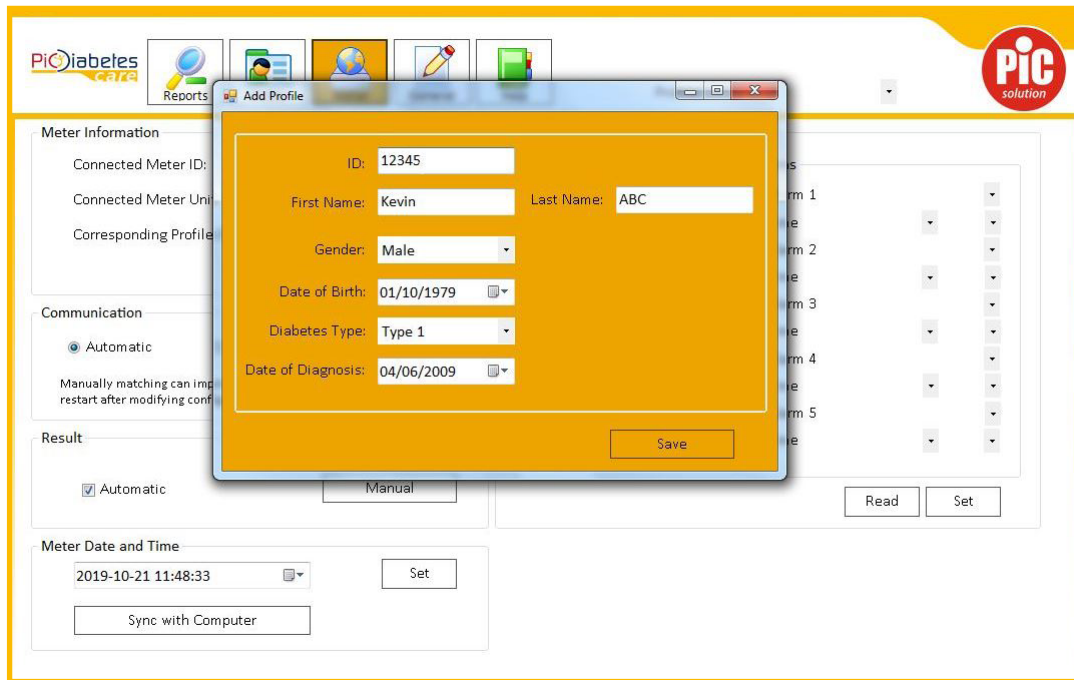
Press 'YES' to process.

NOTE:

- Once meter is connected, second time connection takes 1 second.

- While the meter is connected to the PC, it is unable to perform a blood glucose test.

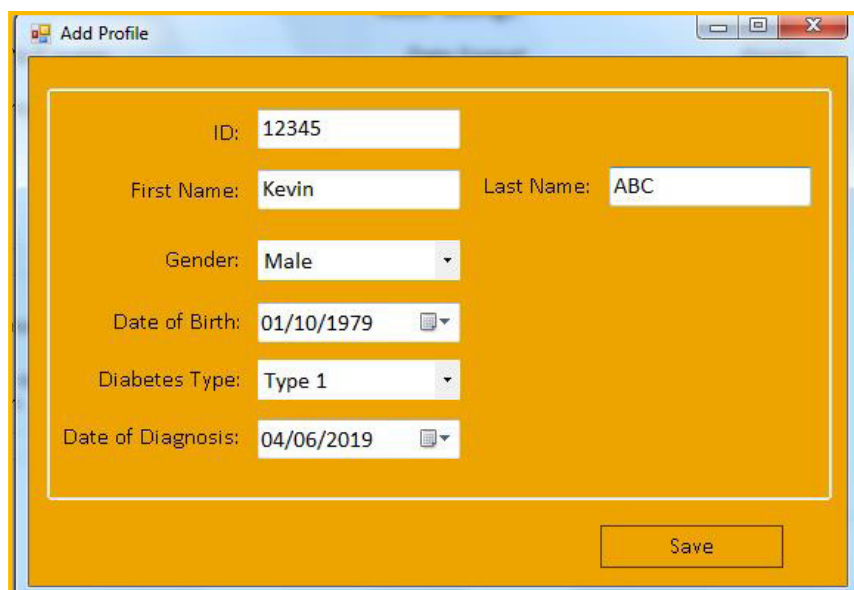
1.5 For first time use, it requires to create a new Profile before data transfer.



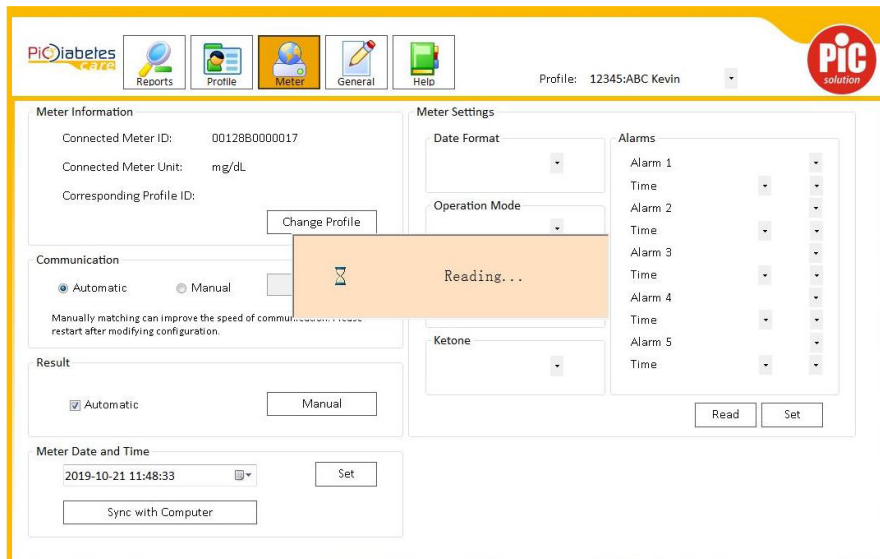
1.6 In the “Add Profile” dialog you can enter the following information:

- ID: to differentiate patients, if several use the same software;
- First Name;
- Last name;
- Gender: male, female;
- Date of birth;
- Diabetes Type : Type 1,2, GDM**, other (** Gestational diabetes mellitus, GDM);
- Date of diagnosis.

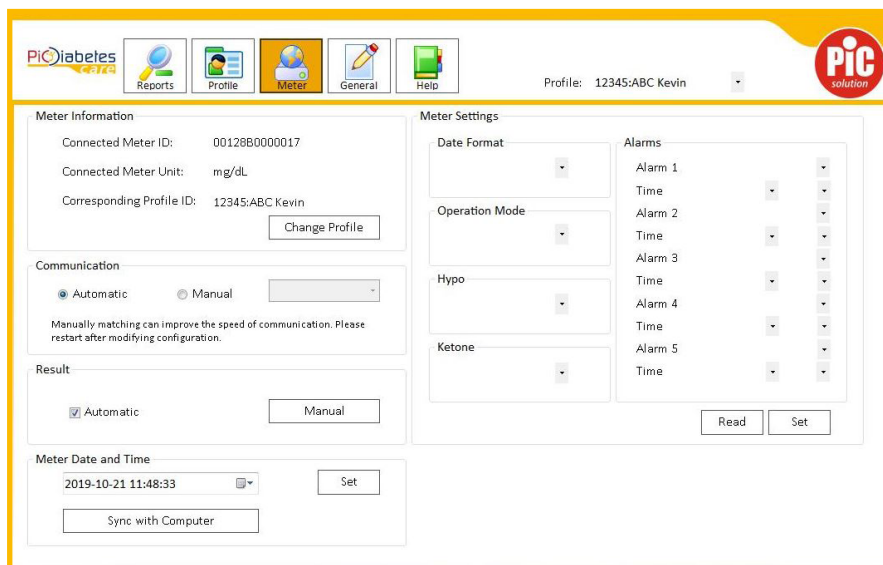
Press “Save” button to record your data.



The program takes about 20-30 seconds to read the data in the connected meter.



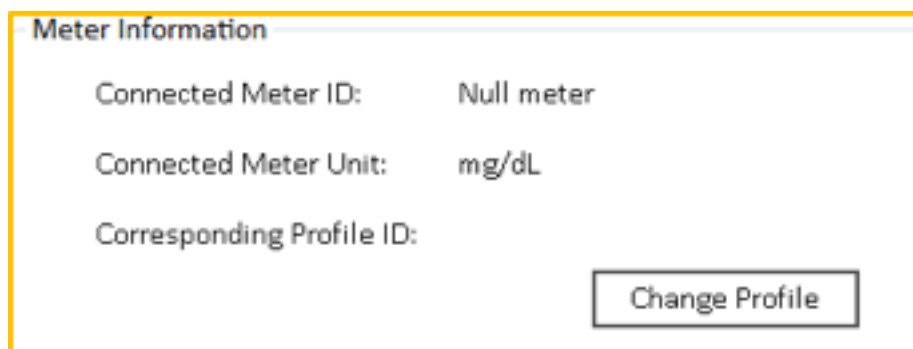
After data transfer is completed, you can find all info of the meter & your profile displayed on the screen.

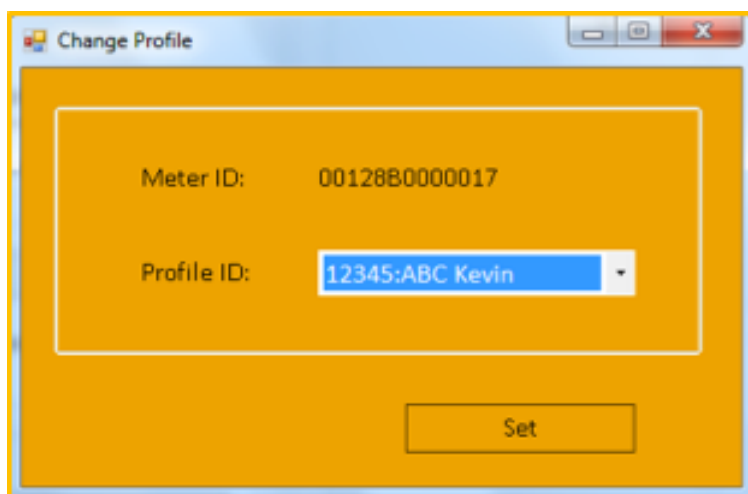


2. Other functions at METER interface

2.1 Meter information

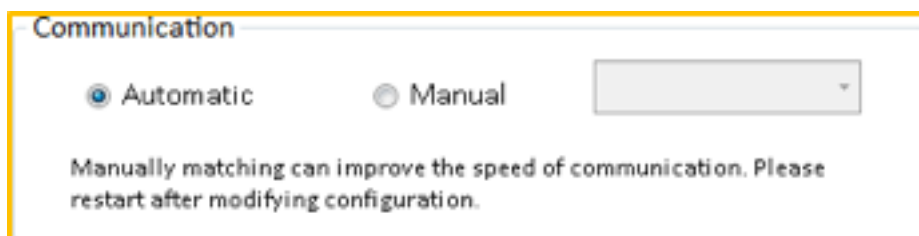
Connected meter info is displayed as in the below graphic. User can change profile by clicking 'Change Profile'.





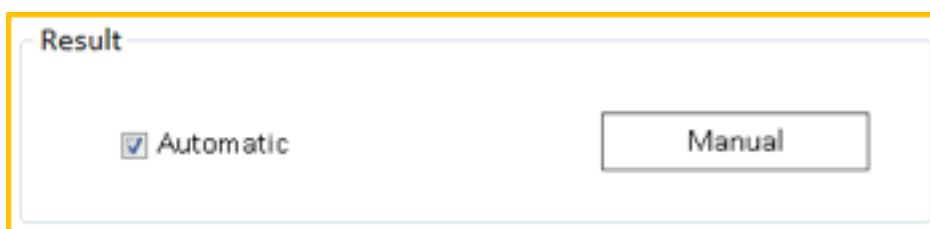
2.2 Communication

Communication mode is pre-set to 'Automatic' in order to automatically recognize the glucometer. However, you can change the meter connection mode by choosing 'Manual'.



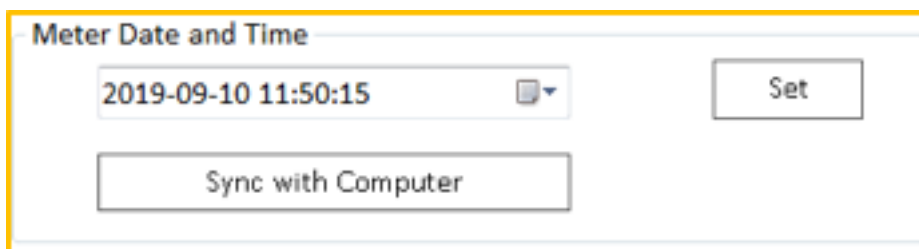
2.3 Result

Default import is automatic. Click 'Manual' to import data in connected meter.



2.4 Meter Date and Time

Date and time of connected meter can be reset, or sync with PC. Once you sync or set the time, a 'Succeeded' signal will appear.



2.5 Meter Settings

2.5.1 Date Format

Can be changed to 2 modes - month/day and day/month.

Date Format

month/day

Date Format

day/month

2.5.2 Operation Mode

L-1 is default simple mode, all preferences in connected meter is pre-setting in factory.

Meter Settings

Date Format

month/day

Operation Mode

L-1

Hypo

Ketone

Alarms

Alarm 1

Time

Alarm 2

Time

Alarm 3

Time

Alarm 4

Time

Alarm 5

Time

Read

Set

NOTE:

In L-1 mode, Hypo, Ketone warning and Alarm setting are not available.

L-2 is advanced mode, user can switch on/off Hypo warning and Ketone warning. Can also set the 5 Alarms time.

Meter Settings

Date Format

month/day

Operation Mode

L-2

Hypo

On

Ketone

Off

Alarms

Alarm 1

Time

Alarm 2

Time

Alarm 3

Time

Alarm 4

Time

Alarm 5

Time

Read

Set

NOTE:

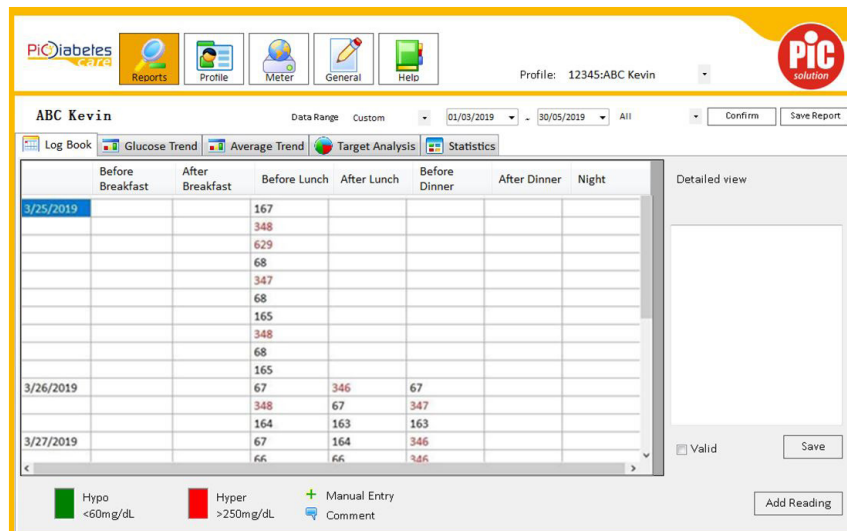
In L-2 mode, Hypo, Ketone warning and Alarm setting are available. More information can be found in meter manual.

3. Reviewing Report

3.1 Overall report interface

- A) Log book – to see the testing results in the selected period.
- B) Glucose Trend – to see the graphic of curve of testing results.
- C) Average Trend – to see the average trend on daily basis.
- D) Target Analysis – cake chart with percentage of testing results.
- E) Statistics – summary of A) – D).
- F) Save report – export detail report in Excel format.

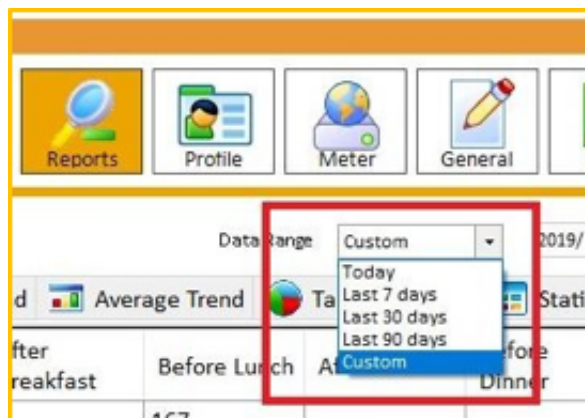
Push the button «Reports» and you will enter the report interface.

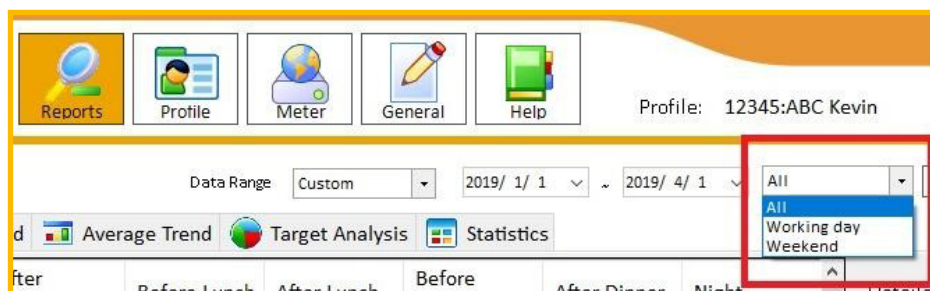


3.2 Review data in selected period

User can select the desired period on the Data range section

- Today
- Last 7 days
- Last 30 days
- Last 90 days
- Custom : in this case you can select the starting and ending date
- For all the above options, you can select the view
- All
- Working day
- Weekend Then press 'Confirm' button.



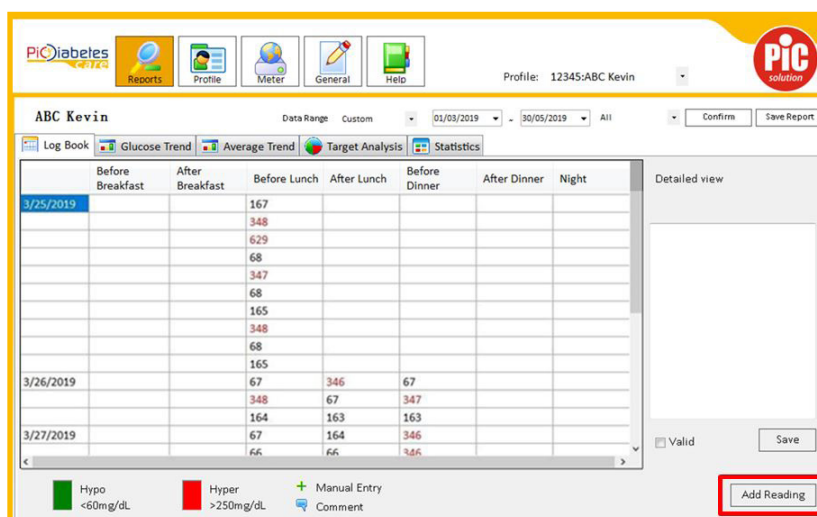


3.3 Log Book

To see the testing results in figures.

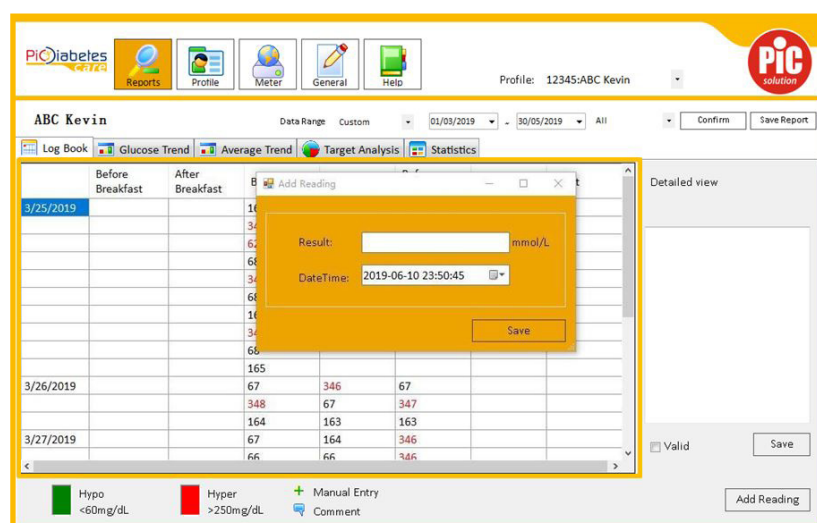
It is possible also to enter manually the glycemetic measurements:

- Press 'Add reading' button;
- Insert the glycemetic value into the Result box;
- Select date and time;
- Press 'Save' button;
- The value will be added in the log book.



It is not possible to add manually if the measurement has been taken before/after breakfast, lunch, dinner or night.

The system recognizes automatically the right positioning in the daily routine.

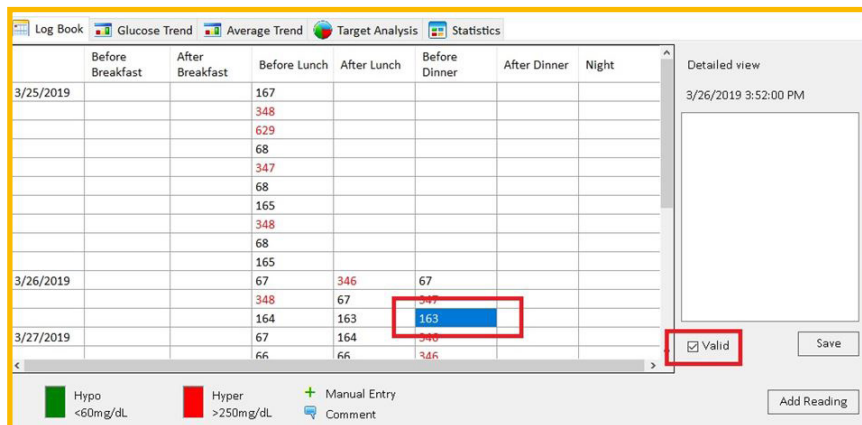


Default setting of daily routine, e.g. before/after breakfast and etc., can be changed at 'PROFILE' – 'TEST SCHEDULE' section.

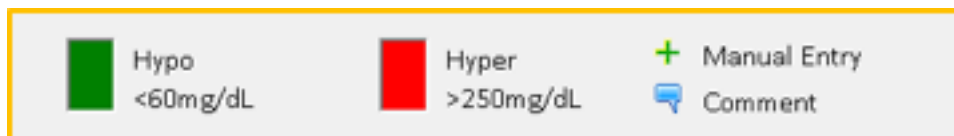
For every value (both automatically and manually inserted), if you select it into the table, you can add manually in the white box on the right the desired comments.

Press button 'Save' to store the comment.

If you do not want to consider a specific value in the graph or statistical analysis, select it into the 'Detailed View' table, deselect 'Valid' and press the button 'Save'. Reselect 'Valid' in order to reconsider it.



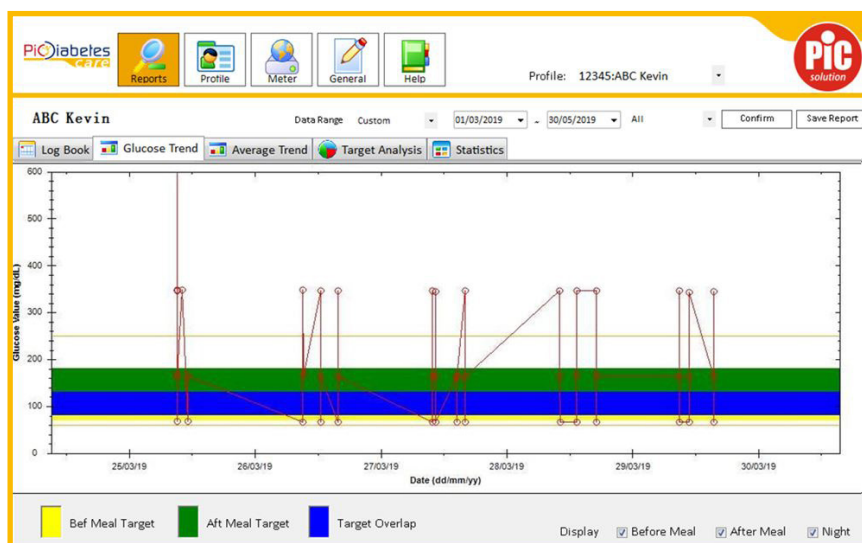
Please find the legend under the table.



You can set up your target range of blood glucose in "Profile" section. The displayed glucose values in Logbook will show your "Hypoglycemia Target" and "Hyperglycemia Target" with different colours. These targets help you to check and better control your blood glucose values.

3.4 Glucose trend

User's blood glucose trend in color and chart can be reviewed here.



You can select the desired period on the Data range section with the same modality whereby you operate on “Log Book” mode.

The two horizontal lines in the graph represent the hypoglycemia and hyperglycemia limits you set.

You can select the measurement time ‘Before Meal’, ‘After Meal’, ‘Night’ to display in the graph the corresponding results.

Display
☒ Before Meal
☒ After Meal
☒ Night

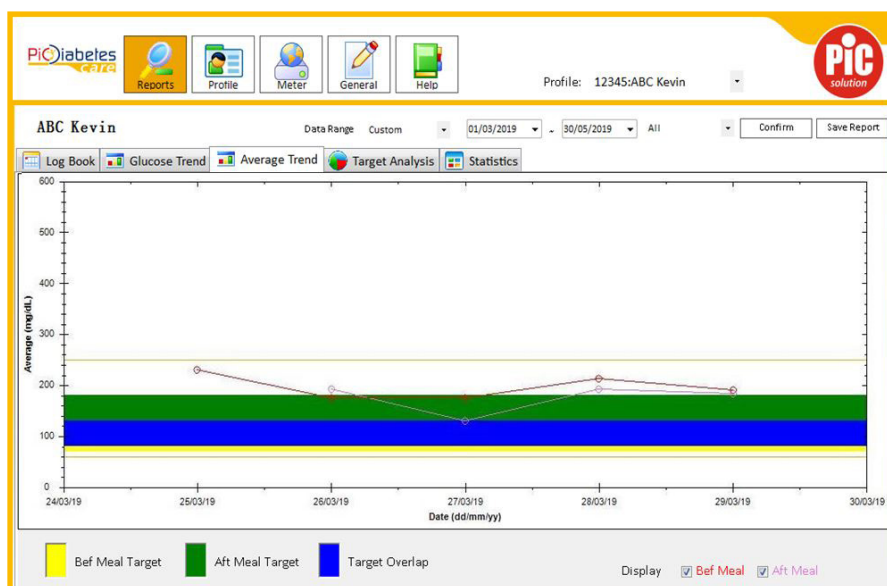
Please find the legend under the table.

Bef Meal Target
 Aft Meal Target
 Target Overlap

You can set up your target range of blood glucose in “Profile” section. The displayed glucose values in Logbook will show your “Hypoglycemia Target” and “Hyperglycemia Target” with different colours. These targets help you to check and better control your blood glucose values.

3.5 Average Trend

User’s average blood glucose trend in color and chart can be reviewed here.



You can select the desired period on the Data range section same as what you operate on “Log Book” mode. The two horizontal lines in the graph represent the hypoglycemia and hyperglycemia limits you set.

You can select the measurement time ‘Before Meal’, ‘After Meal’ to display in the graph the corresponding results.

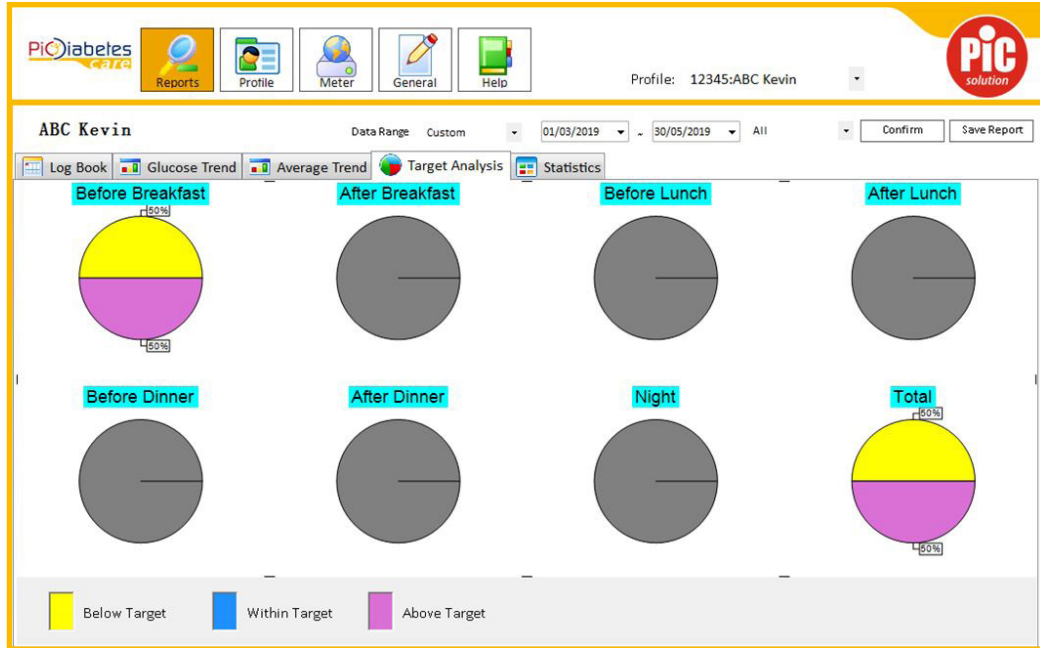
Display
☒ Bef Meal
☒ Aft Meal

Please find the legend under the table.

Bef Meal Target
 Aft Meal Target
 Target Overlap

You can set up your target range of blood glucose in “Profile” section. The displayed glucose values in Logbook will show your “Hypoglycemia Target” and “Hyperglycemia Target” with different colours. These targets help you to check and better control your blood glucose values.

3.6 Target Analysis

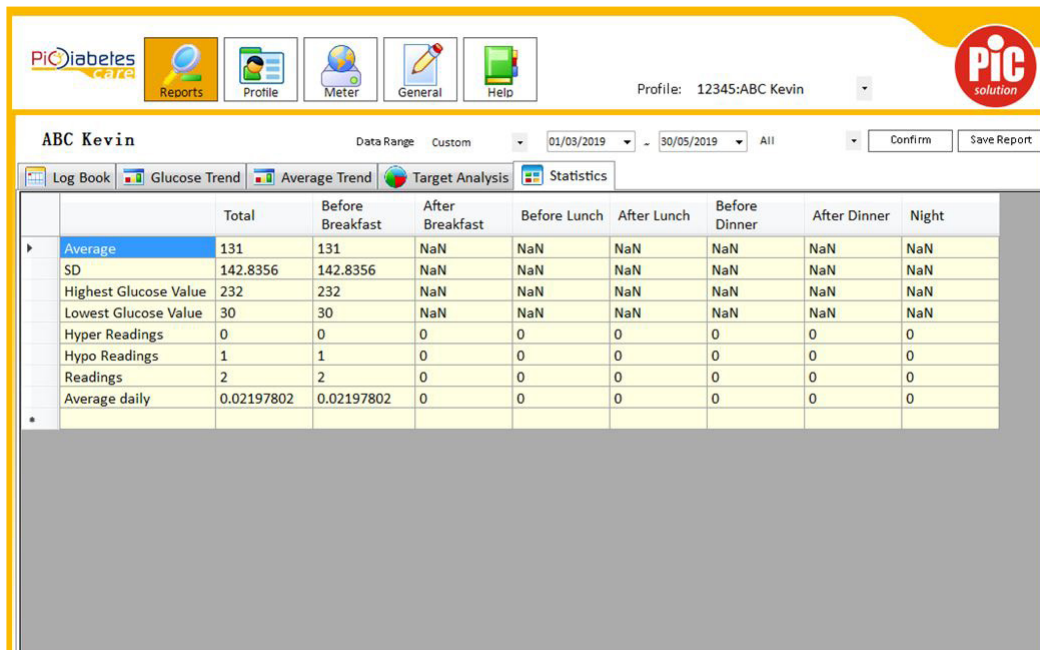


Display of the glycemic results in CAKE CHARTS, based on patients’ daily routine. Percentage information is calculated on 3 categories: Below target, Within target and Above target.

Target can be set under ‘PROFILE’ – ‘TARGET RANGE’ section.

You can select the desired period on the Data range section same as what you operate on “Log Book” mode. See details on part 3.2

3.7 Statistics



ABC Kevin

Data Range: Custom 01/03/2019 - 30/05/2019 All Confirm Save Report

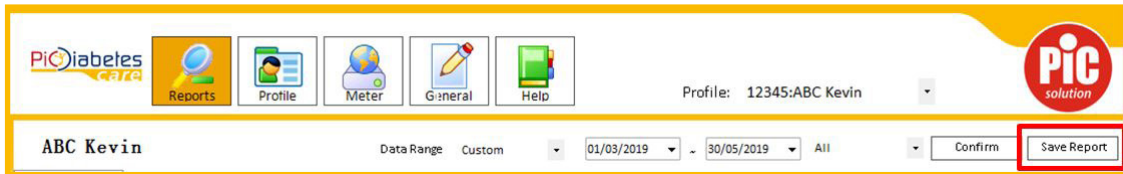
Log Book Glucose Trend Average Trend Target Analysis Statistics

| | Total | Before Breakfast | After Breakfast | Before Lunch | After Lunch | Before Dinner | After Dinner | Night |
|-----------------------|------------|------------------|-----------------|--------------|-------------|---------------|--------------|-------|
| Average | 131 | 131 | NaN | NaN | NaN | NaN | NaN | NaN |
| SD | 142.8356 | 142.8356 | NaN | NaN | NaN | NaN | NaN | NaN |
| Highest Glucose Value | 232 | 232 | NaN | NaN | NaN | NaN | NaN | NaN |
| Lowest Glucose Value | 30 | 30 | NaN | NaN | NaN | NaN | NaN | NaN |
| Hyper Readings | 0 | 0 | 0 | 0 | 0 | 0 | 0 | 0 |
| Hypo Readings | 1 | 1 | 0 | 0 | 0 | 0 | 0 | 0 |
| Readings | 2 | 2 | 0 | 0 | 0 | 0 | 0 | 0 |
| Average daily | 0.02197802 | 0.02197802 | 0 | 0 | 0 | 0 | 0 | 0 |

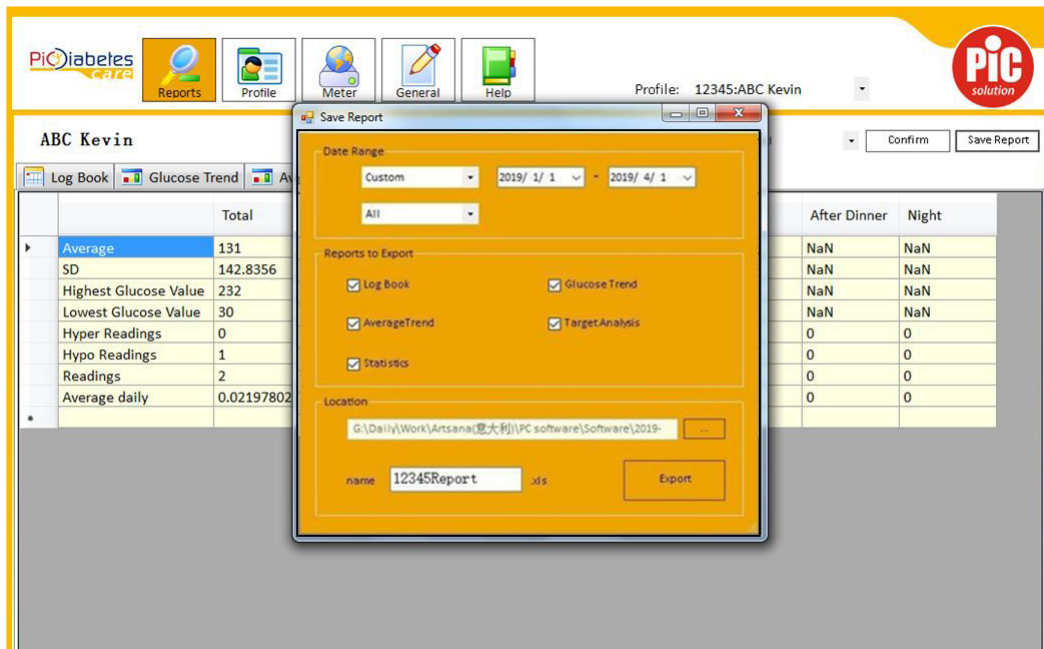
Display of the glycemic results in statistic values for the selected time period and working pattern.

3.8 Save Report

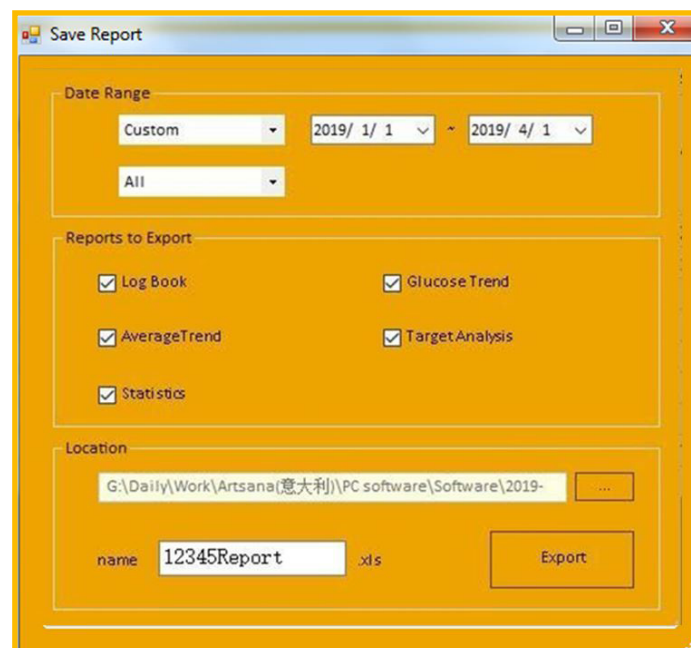
User can export data by clicking on the right on 'Save Report' button.



Then a new window will open:



- Under 'Data Range' select the desired period;
- Under 'Reports to Export' select the desired one/s;
- Specify the 'Location' where you want to store the file;
- 'Name' the file;
- Once selected all parameters, press 'Export' button.



Save Report

Date Range

Custom

2019/ 1/ 1

~

2019/ 4/ 1

All

Reports to Export

⌚

Export report results

Location

G:\Daily\Work\Artsana(意大利)\PC software\Software\2019-

...

name 12345Report.xls

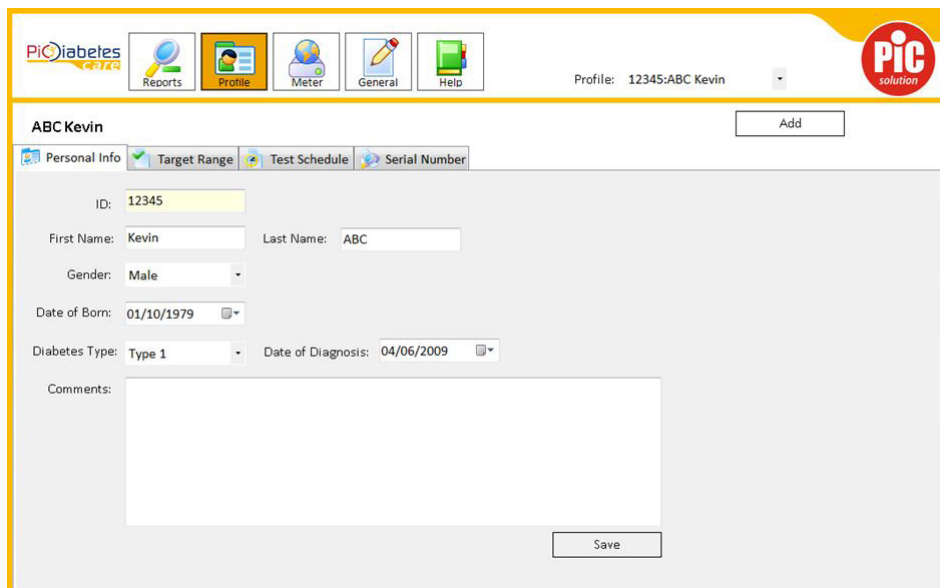
Export

An excel file will be opened automatically.

| L14 | | | | | | | | | |
|-----|---|-----------|------------|--------|--------|--------|--------|--------|-------|
| | A | B | C | D | E | F | G | H | I |
| 1 | | | | | | | | | |
| 2 | | Name: | ABC Kevin | | | | | | |
| 3 | | DOB: | 1/10/1979. | | | | | | |
| 4 | | Unit: | mg/dL | | | | | | |
| 5 | | | | | | | | | |
| 6 | | Date | Bef BF | Aft BF | Bef LU | Aft LU | Bef DI | Aft DI | Night |
| 7 | | 2019/3/25 | | | 167 | | | | |
| 8 | | 2019/3/25 | | | 348 | | | | |
| 9 | | 2019/3/25 | | | 629 | | | | |
| 10 | | 2019/3/25 | | | 68 | | | | |
| 11 | | 2019/3/25 | | | 347 | | | | |
| 12 | | 2019/3/25 | | | 68 | | | | |
| 13 | | 2019/3/25 | | | 165 | | | | |
| 14 | | 2019/3/25 | | | 348 | | | | |
| 15 | | 2019/3/25 | | | 68 | | | | |
| 16 | | 2019/3/25 | | | 165 | | | | |
| 17 | | 2019/3/26 | | | 67 | 346 | 67 | | |
| 18 | | 2019/3/26 | | | 348 | 67 | 347 | | |
| 19 | | 2019/3/26 | | | 164 | 163 | 163 | | |
| 20 | | 2019/3/27 | | | 67 | 164 | 346 | | |
| 21 | | 2019/3/27 | | | 66 | 66 | 346 | | |
| 22 | | 2019/3/27 | | | 346 | 162 | 66 | | |
| 23 | | 2019/3/27 | | | 163 | | 163 | | |
| 24 | | 2019/3/27 | | | 164 | | | | |
| 25 | | 2019/3/27 | | | 66 | | | | |
| 26 | | 2019/3/27 | | | 345 | | | | |
| 27 | | 2019/3/27 | | | 66 | | | | |

4. Profile Setup

4.1 Personal info



The screenshot shows the 'Personal Info' tab for a patient named Kevin. The form includes the following fields and options:

- ID:** 12345
- First Name:** Kevin
- Last Name:** ABC
- Gender:** Male
- Date of Born:** 01/10/1979
- Diabetes Type:** Type 1
- Date of Diagnosis:** 04/06/2009
- Comments:** (Empty text area)

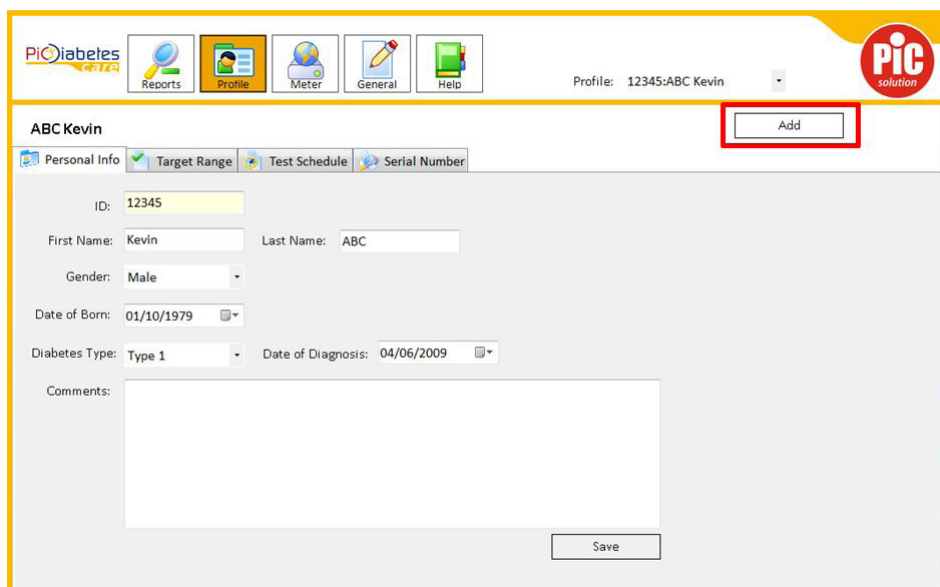
The 'Add' button is located in the top right corner of the form, and the 'Save' button is at the bottom right.

Input following information of user:

- ID: to differentiate patients, if several use the same software;
- First Name;
- Last name;
- Gender: male, female;
- Date of birth;
- Diabetes Type : Type 1,2, GDM**, other (** Gestational diabetes mellitus, GDM);
- Date of Diagnosis;
- Comments.

If you need to change any information, type the desired one in the relative section. Then, press 'Save' button.

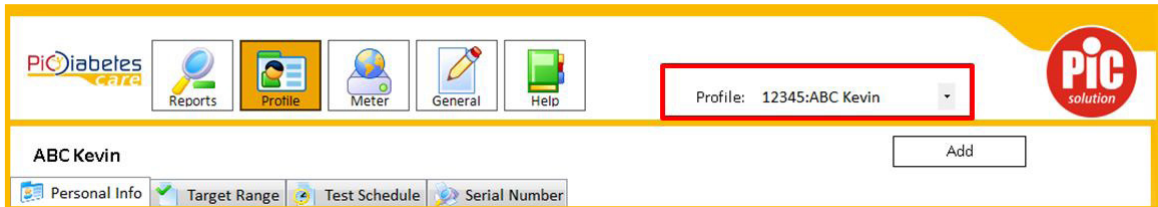
In order to add a new profile, press 'Add' button in the top right position. The following screen appears and you can type in the relative information.



This screenshot is identical to the one above, but the 'Add' button in the top right corner is highlighted with a red rectangular box to draw attention to it.

Once inserted, press 'Save' button.

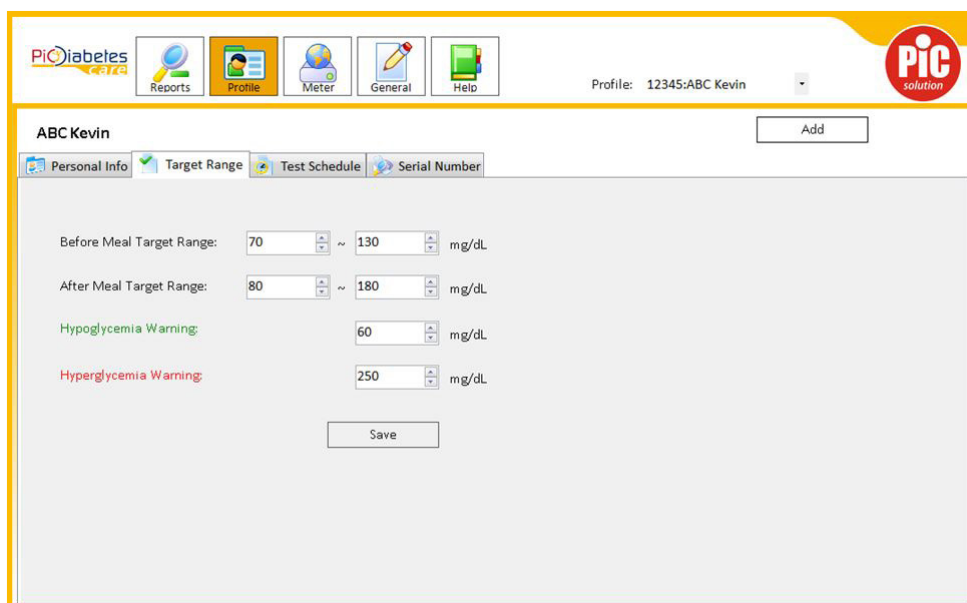
In order to select a different profile, click on the white box to the right of 'Profile:' and choose the desired one to manage his/her data.



The screenshot shows the top navigation bar of the software. It includes icons for Reports, Profile, Meter, General, and Help. A dropdown menu for 'Profile:' is open, showing '12345:ABC Kevin' as the selected profile. Below the navigation bar, there is a section for 'ABC Kevin' with an 'Add' button and tabs for Personal Info, Target Range, Test Schedule, and Serial Number.

4.2 Target range

Target range for people in various Diabetic stages is different. Setting of before/after meal range, Hypo and Hyper warning is available in this section.

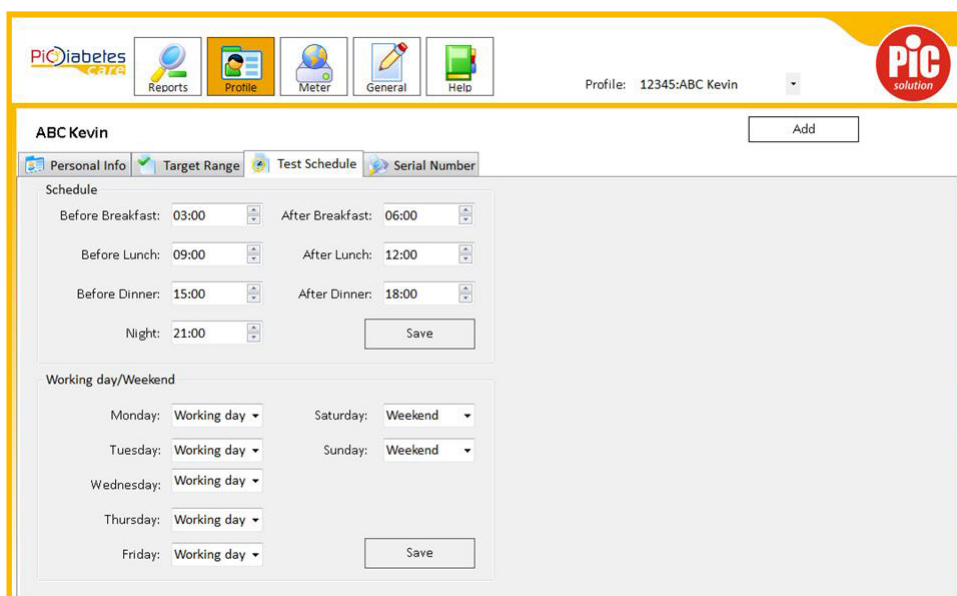


The screenshot shows the 'Target Range' tab for the 'ABC Kevin' profile. It contains input fields for 'Before Meal Target Range' (70 to 130 mg/dL), 'After Meal Target Range' (80 to 180 mg/dL), 'Hypoglycemia Warning' (60 mg/dL), and 'Hyperglycemia Warning' (250 mg/dL). A 'Save' button is located at the bottom of the form.

4.3 Test Schedule

Setting of classification of Before/after breakfast, lunch and dinner, and Night. REPORT page will change accordingly when this setting is modified.

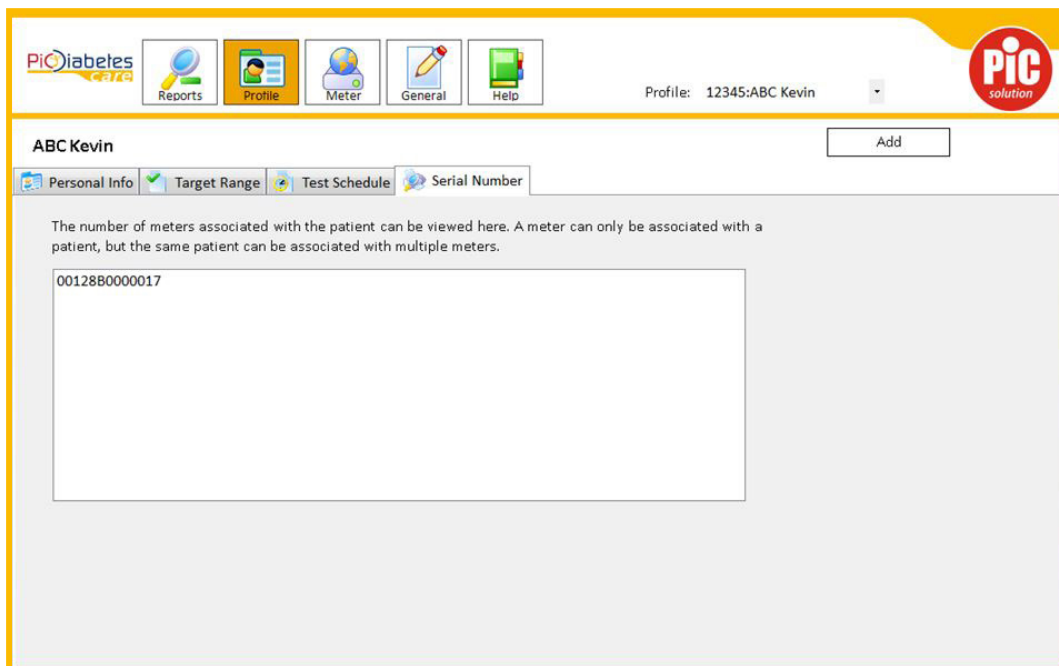
The same to 'Working day' and 'Weekend' setting.



The screenshot shows the 'Test Schedule' tab for the 'ABC Kevin' profile. It contains input fields for 'Before Breakfast' (03:00), 'After Breakfast' (06:00), 'Before Lunch' (09:00), 'After Lunch' (12:00), 'Before Dinner' (15:00), 'After Dinner' (18:00), and 'Night' (21:00). There is also a section for 'Working day/Weekend' with dropdown menus for each day of the week. A 'Save' button is located at the bottom of the form.

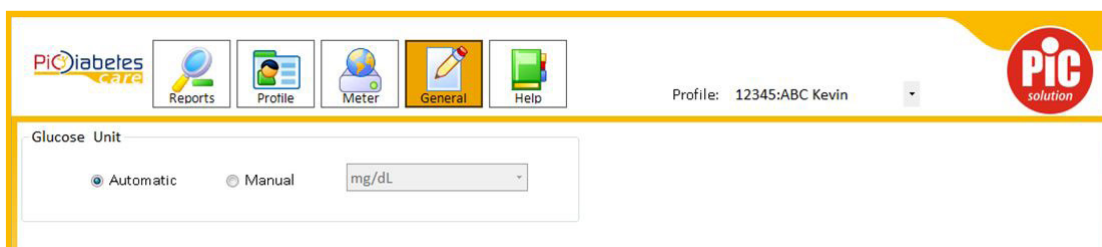
4.4 Serial number

Display of meter Serial Number, can double check with number printed on back label of meter.



5. General interface

User can switch the measurement display to mmol/L or mg/dL by selecting 'Manual'. Suggest to keep 'Automatic' and PC reads meter setting.



6. Help

Click 'Help' icon on top bar to open this manual.



CHAPTER 4: COMPUTER SECURITY

The software is meant to be installed on computers managed and maintained by the user of the software. It is therefore the user's responsibility to maintain up-to-date protection of the system against malicious software and attackers. This should include, but is not limited to, a fire-walled network connection, access control mechanisms, up-to-date virus protection software, and other state-of-the-art IT security controls.



Manufacturer
VivaCheck Laboratories, Inc.
913 N Market Street, Suite 200.
Wilmington, DE 129801, USA



Authorized Representative
Landlink GmbH
Dorfstrasse 2/4,
Emmendingen, Germany



Distributed by:
PIKDARE S.p.A.
Via Saldarini Catelli, 10
22070 - Casnate con Bernate (CO) - Italy



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