Manual

Revision: 02.11.2026

SiDiary

for iOS

www.sidiary.org
https://diabetes.sinovo.net

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SINOVO health solutions GmbH

SINOVO health solutions GmbH
Willy-Brandt-Str. 4
61118 Bad Vilbel (Germany)
info@sinovo.de
www.sinovo.de

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1 General

This software is certified and regulated as a medical device within the European Union and Switzerland. Use of this software outside of these jurisdictions is not covered under its regulatory approval. Users operating this software outside the EU and Switzerland do so at their own risk and are responsible for ensuring compliance with applicable local regulations.

1.1 Program interface in other languages

SiDiary offers numerous translation packages for users of other nationalities so that the interface is available in more than 20 languages.
For details on available languages, please visit **www.sidiary.org/languages**

2 Purpose

The medical device is a stand-alone software for diabetes therapy management. The software can read data from health devices, but it is also possible to enter data manually. Statistical and graphical evaluations of the software support the monitoring of diabetes therapy, which enables improved therapy decisions.
The medical device is intended for people with diabetes and/or their caregivers.

3 Intended use

The SiDiary app is designed to support patients and caregivers in managing diabetes therapy. It provides information on blood glucose levels and other parameters that can be determined individually. The SiDiary app is used to read out displayed values from diagnostic devices used at home, such as blood glucose, blood pressure, scales, pedometers, etc., and to record these individually determinable parameters over a longer period of time. The SiDiary app saves the data and displays it over the period of time used. In addition, the SiDiary app offers the exchange of data with mobile devices or other SiDiary applications to record measured variables or transmit data from the diary to the doctor in charge. The ability to record relevant data over a long period of time means that the SiDiary app supports patients in self-monitoring their therapy.

3.1 System requirements

The SiDiary app is a smartphone app for iOS. It runs on all iPhones/iPads/iPod Touch that support an iOS version between 11 and above.

3.2 Indication

SiDiary supports all types of diabetes mellitus. Persons with diabetes mellitus or their caregivers must be able to interpret the information in the app and act accordingly. The bolus suggestion calculator is only intended for use with short-acting insulin.

3.3 Contraindication

There are contraindications for the bolus suggestion calculator. It must not be used in the following situations:

- All therapies with mixed insulin or exclusively long-acting insulins
- Basal-assisted oral therapy (BOT) with or without GLP-1 receptor agonists

There is no contraindication for the other functions of the app with regard to the health situation of the person in need of care, with the exception of their mental abilities (see 3.2 Indication)

3.4 User of SiDiary

Users of SiDiary are

- People with Diabetes (PwD)
  - This group includes insulin-dependent people with diabetes as well as people on pure weight reduction therapy or tablet treatment
  - Some of the PwD have visual, hearing and/or motor impairments (e.g. retinopathy, neuropathy).

- Supervisor
  - The participants in this group are typically laypersons who operate the SiDiary app for people with diabetes who are unable to operate the SiDiary app themselves due to various limitations.

3.4.1 User profiles

The SiDiary app is operated by users who require certain mental, physical and demographic characteristics as well as special features.

People with Diabetes (PwD)

In general, the user group of the SiDiary app from a clinical perspective is people with diabetes and intended as the main users of the device. The PwD user group is divided into two subgroups:

1. **Autonomous PwD:** These PwD operate the SiDiary app completely by themselves. They can,
   - interpret the information displayed and act accordingly independently,
   - and are typically 14 years and older. For details and restrictions see point no. 2 below.

2. **Non-autonomous people with disabilities:** All other people with disabilities. People with diabetes who do not meet the requirements for self-service need the support and/or supervision of caregivers to ensure safe and correct operation of the SiDiary app. This subgroup includes, for example:
   - Users with a lack of skills in understanding therapy management, including the associated consequences, e.g.:
     - Children (typically up to 14 years)
     - People with mental and physical disabilities (e.g. people with disabilities)
   - Users with a complete or partial lack of ability to self-serve the SiDiary app and to understand therapy management and the associated consequences, e.g: Persons with a lack of skills (e.g. adolescent users, dependent persons, non-autonomous older persons)

Supervisor

A supervisor assumes responsibility for people with disabilities who do not fall under the above definition of autonomous people with disabilities, e.g. pediatric patients, non-autonomous elderly people.

The supervisor must have similar mental, physical and demographic characteristics to an autonomous person without a disability. They must be able to interpret the event history and act accordingly.

Age: To assume responsibility, the supervisor is usually an adult or at least ≥ 18 years old.

In this document, the term “patient” is only used for persons associated with diabetes therapy management. It is not used to refer to a user of the software.

3.5 Combination with other medical devices

SiDiary is a stand-alone software that can read out displayed values from diagnostic devices used at home, such as blood sugar, blood pressure, weight scales,

pedometers, etc., and record these individually determined parameters over a longer period. The SiDiary app can be used in combination with the SiDiary online version. The data recorded in the SiDiary app can be synchronized with the SiDiary online version and vice versa. SiDiary saves the data and displays it over the period used. SiDiary must be assigned to a patient as described in the instructions for use.

3.6 Use of substances/energies

SiDiary does not administer insulin or other substances to the patient. It does not supply the patient with energy.

3.7 Application time

SiDiary is permanently installed on a smartphone. It can be used several times a day. It has an uptime as long as compatible devices are used by people with disabilities or the supervisors. The software does not deteriorate by nature, so a specific lifetime is not applicable. There is no contact with the user, so there is no cumulative handling time over the entire duration of patient treatment.

3.8 Ambient conditions

During storage or operation, the SiDiary app is limited to the respective hardware requirements (temperature, humidity) of the smartphone.

3.9 Maintenance calibration measures

The SiDiary app requires no special maintenance or calibration.

3.10 Preparing the product before use

Before the SiDiary app can be used, it must be downloaded from an app store (Apple App Store) and installed on a smartphone or tablet.

3.11 End of service life

SiDiary reaches its end of life after a maximum of one year on the market or when a new version is available on the market. After this time, no bug fixes or other improvements are expected for the old version.

3.12 Important note for use for health purposes

If the software is used to record the relevant data for therapy (e.g. diabetes), the software serves only as an aid for recording the measured values entered by you. Of course, the software can in no way replace medical care and therapy. Any changes to

your therapy (e.g. BE factors, correction rules, insulin doses) must be agreed with your doctor, as you had to or should have done before using the program. SINOVO is therefore not liable for health complications of any kind resulting from incorrect therapy (e.g. incorrect insulin doses). This also applies if the program should submit a calculation. Any calculations are completely non-binding and must always be checked in detail with the attending physician for accuracy and applicability.
Particularly, when using the software for medical, especially diagnostic or health monitoring purposes, it may be advisable to keep other records in addition to the evaluation by this software and to make frequent data backups so that the data is not inadvertently lost or so that monitoring can be ensured by other means.
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3.13 Improving blood glucose control with SiDiary

If you record and manage your blood glucose values with SiDiary and can always see a graphical evaluation and the current (calculated) HbA1c value immediately after an entry, you will quickly notice a real improvement in your glucose levels: The graphical evaluation immediately visualizes a series of poorer values and encourages you to achieve better values again. Although the HbA1c value calculated with SiDiary cannot be directly compared with a laboratory value, it still provides a good indication of trends in your metabolic control.

One thing has been proven and recognized by numerous clinical studies: Keeping a blood glucose diary (even in paper form) is always associated with an improvement in diabetes control; as a rough guide, a one percentage point improvement in HbA1c is not unrealistic. Keeping an electronic diary also opens up further potential for improvement, as recurring error situations can be identified more quickly and even the smallest optimizations can be made with the overall better database.
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3.14 Data security

As the logged data is health-related data that could become relevant for the preparation of certificates, expert opinions, etc. even after a very long time, you should treat this data with appropriate care. This includes regular data backups.
One way of backing up data is to use SiDiary-Online. (https://diabetes.sinovo.net) You can regularly synchronize your blood glucose data with the online server so that you only have to reinstall SiDiary after damage to your device and have your last backed-up data on your device again by synchronizing it once more with SiDiary-Online..

Due to operating system updates and/or hardware updates of your device, the SiDiary software may be affected. Please check if there is also an update for SiDiary or contact us by mail at support.sidiary@sinovo.de

3.15 Procedure in the event of a serious incident

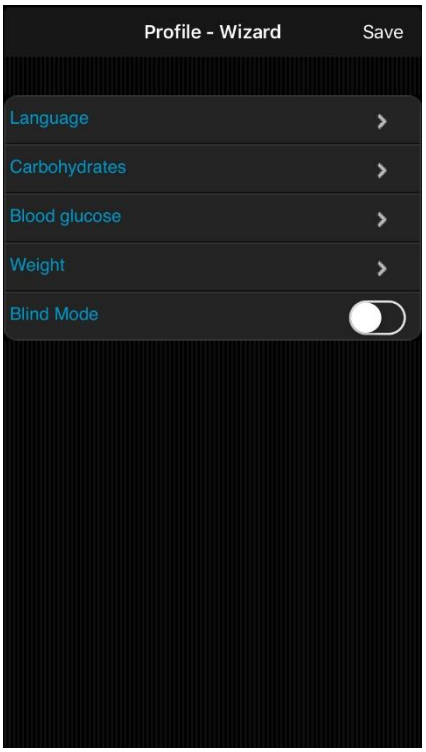
Please inform SINOVO health solutions GmbH and your local health authority in the event of serious health effects (e.g. serious injuries or hospitalization) and/or malfunctions of the SiDiary application.

4 Installation

SiDiary can be downloaded directly at iTunes:

https://itunes.apple.com/us/app/sidiary/id389582724?mt=8

Then it will be available directly on your iOS device (iPhone, iPod Touch and iPad)



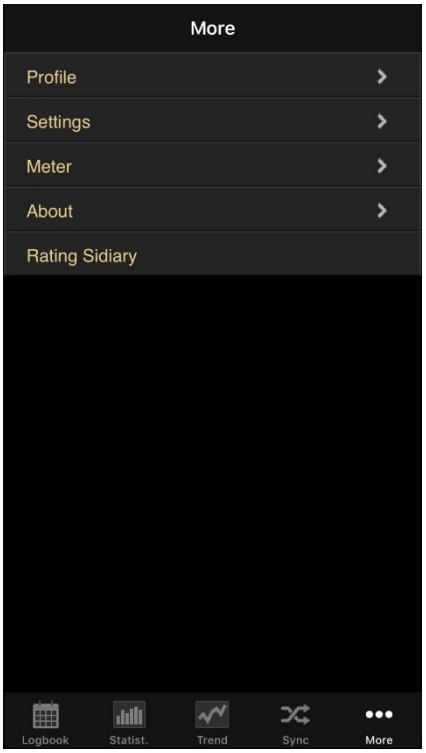
After you have started the app you will see this profile wizard, which will help you to make the main settings. There you can select the language of the app, then you can select, if you want to enter your BG readings in mg/dl or mmol/l and the unit of your weight.
Very important: You can choose, if you want to use an exchange unit for your carbohydrates, like BE or KE.

If you don't select an exchange unit, your carb intake will be stored in gram!
In this case the bolus calculator works according to the American formula:
Bolus = Carbohydrates divided by carb/insulin ratio.

If you activate the exchange unit, the bolus calculator works according to the European formula:
Bolus = BE multiplied with BE-Factor

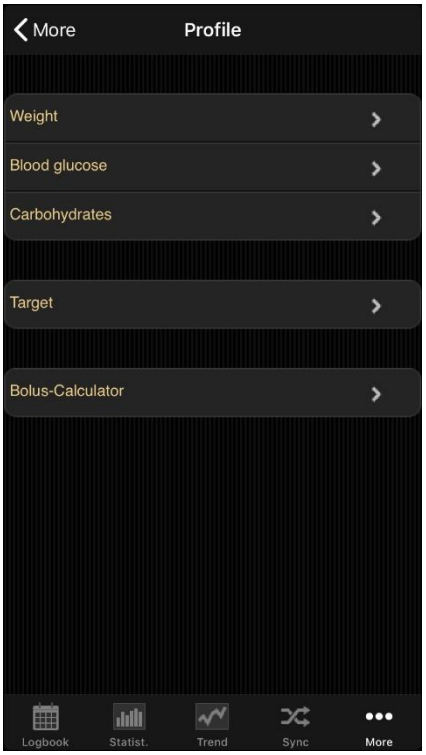
The blind mode is recommended, if you want to use the app with Apple's built-in screen reader, VoiceOver '. Is this mode is activated no graphical elements will be displayed in the statistics.

5 More (Setup)



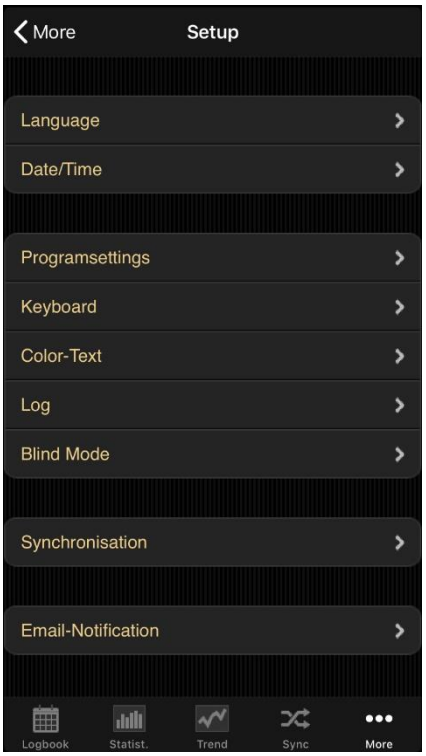
In 'More' you can adjust the settings for the app or get the information which version of the app you are currently using.
You can also rate the app in iTunes. Please consider: If you want to complain about something, please contact us prior to the review. Usually we're able to elucidate misunderstandings or help with problems you may have.

5.1 Profile



In the profile settings you can adjust which unit you prefer for measurements (weight, blood glucose, carbohydrates) and which is your target range for blood glucose.
If you want to track your carbohydrates in 'gram' then let the exchange unit deactivated. Otherwise activate and name it (as 'BE' or other name) and set a ratio (here it is for example '12', which means that 1 BE = 12 gram carbohydrates).
You can adjust the target range for your blood glucose with min. and max. value. This range will be shown in the logbook as green fields. (The display in this example shows the value in mg/dl, but of course you can also use mmol/l)
In '**Bolus-Calculator**' you can choose whether the results of the calculator should be stored in the App separately in correcting and meal bolus (e.g. 3+7) or as a sum (e.g. 10).

5.2 Settings



For more settings like language, time/date format or numbers of columns in the logbook, please tap on 'Settings' in the section 'Setup'.

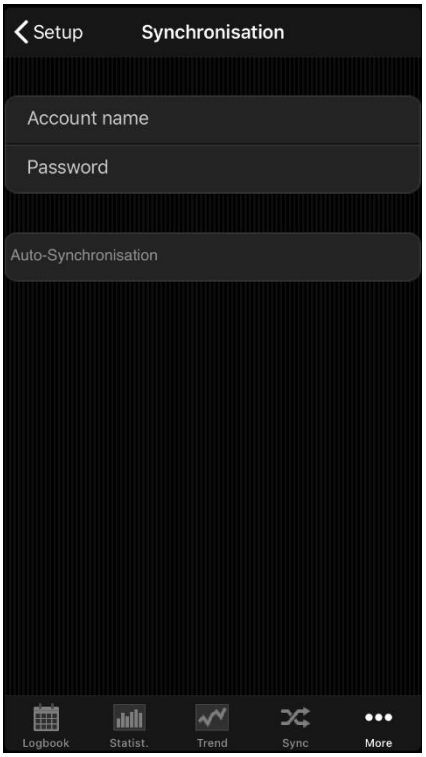
The '**Programsettings**' section is divided in 'Main logbook data' (like BG, carbs, bolus and so on) and 'Data types'. You can adjust here which lines you want to use in the logbook. Data types must be synchronized from 'SiDiary Online' first before you can adjust them. The app supports all data types which you can also use with the PC version of SiDiary or 'SiDiary Online'. So, you are free to track everything you can imagine.

In '**Keyboard**' you can adjust, if you want to use our optimized keyboard layout for the app or the iOS standard layout.

Under '**Color-Text**' you can change the text color of the app (the default color is blue) according to your wishes.

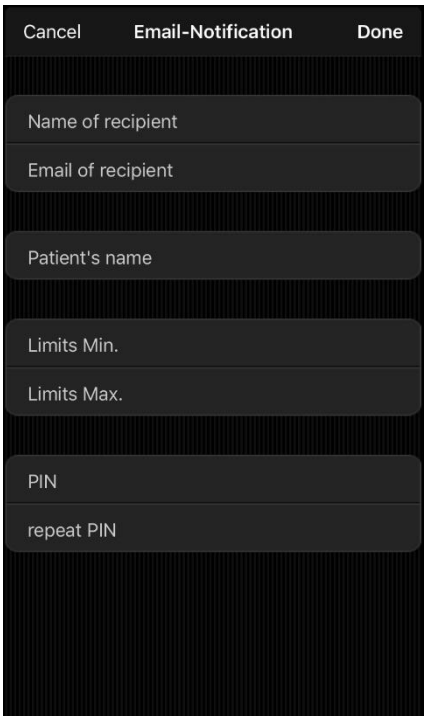
In the section ‚**Log**' you can enable the writing of a log protocol, if it should come to problems. This protocol (which you can see in plain text before you send it out) our developers can then analyse the possible errors faster and more accurately.

The '**Blind mode**' prepares the app to use with the screen reader 'VoiceOver'. In this case the statistics uses no graphical elements only the tabular detail statistics.



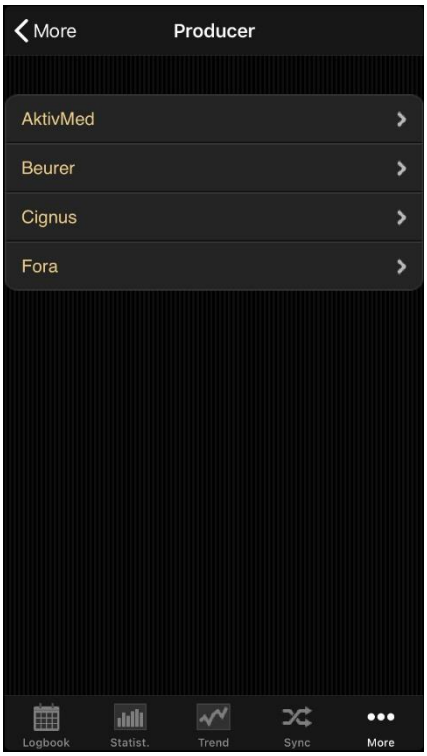
In the item '**Synchronization**' please enter (optional) your username and password that you have chosen for the login in SiDiary Online. After that you can always sync your data from the app with SiDiary Online in the Sync tab.

When you exit the app or move it to the background, the app tries directly to synchronize your data with SiDiary-Online. If it does not work right then, the app will try again the next time it's been activated.



The '**Email-notification**' can be used, so that the app automatically sends an email to a person of your trust, if a blood glucose reading exceeds the limit of the Min./Max. range that you have specified.
The settings you make here, can be protected with a freely selectable PIN code. Changes then can only be made after you have entered the correct PIN.

5.3 Meter



Here you can check, if the app and the hardware of your iOS device supports a meter of the manufacturers listed there and then - if necessary –select some further options.

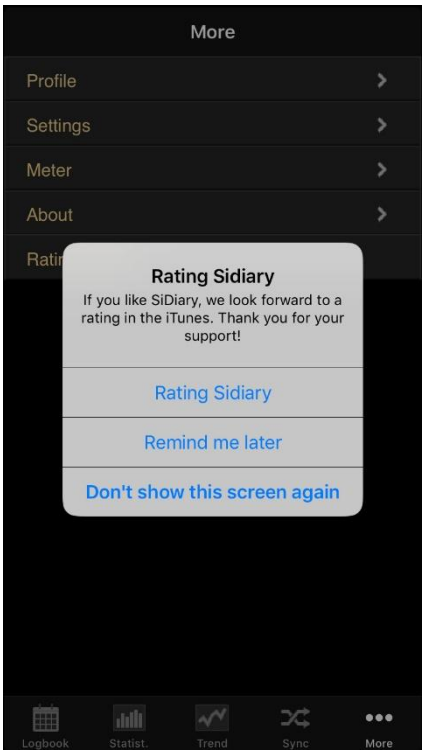
Please note that there are only those devices are available, for which we have received the necessary specifications from the manufacturers.
If a new device is added by an update, you will always find this info in the changelog of the update.

You can find a list of all medical devices that are compatible with SiDiary on this website:
https://www.sidiary.org/sidiary-supported-meters-140.asp?IDSprache=2

5.4 About

In the section 'More' please tap at 'About' to see the version number of your app.

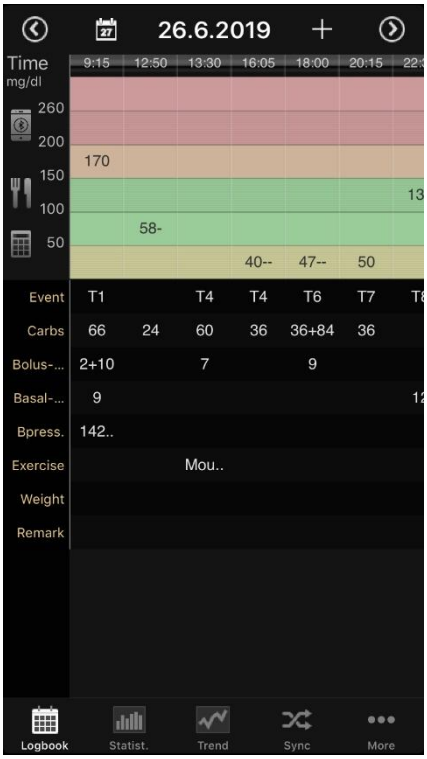
5.5 Rating SiDiary



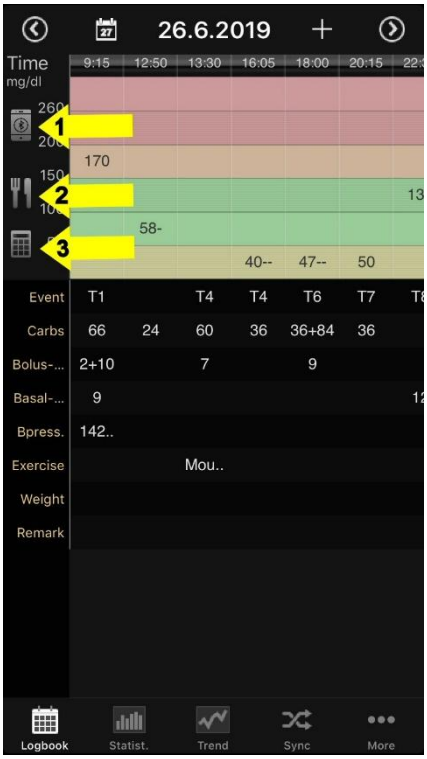
Of course, we would be grateful if you would also share your experiences of our app with other users. The easiest way to do so is with the option ‘Rating SiDiary’.
It allows you in a very easy way to post your opinion on iTunes.

A request in this regard:
If you have a problem or a function could not be found right away, please contact us at info@sinovo.de before you rate the app.
In most cases we can help you very fast solving the problem.

6 Logbook



On the left you see the logbook view, in which the app starts. If there is more data for a day than you can see at one glance, you can move this sheet by touch in all directions. Above you will see the date of the displayed day. On the left the calendar button to select a specific date. On the right a plus button to enter new data in the mask. The arrow buttons change the day forward or backward.
Below you can see the apps navigation line.



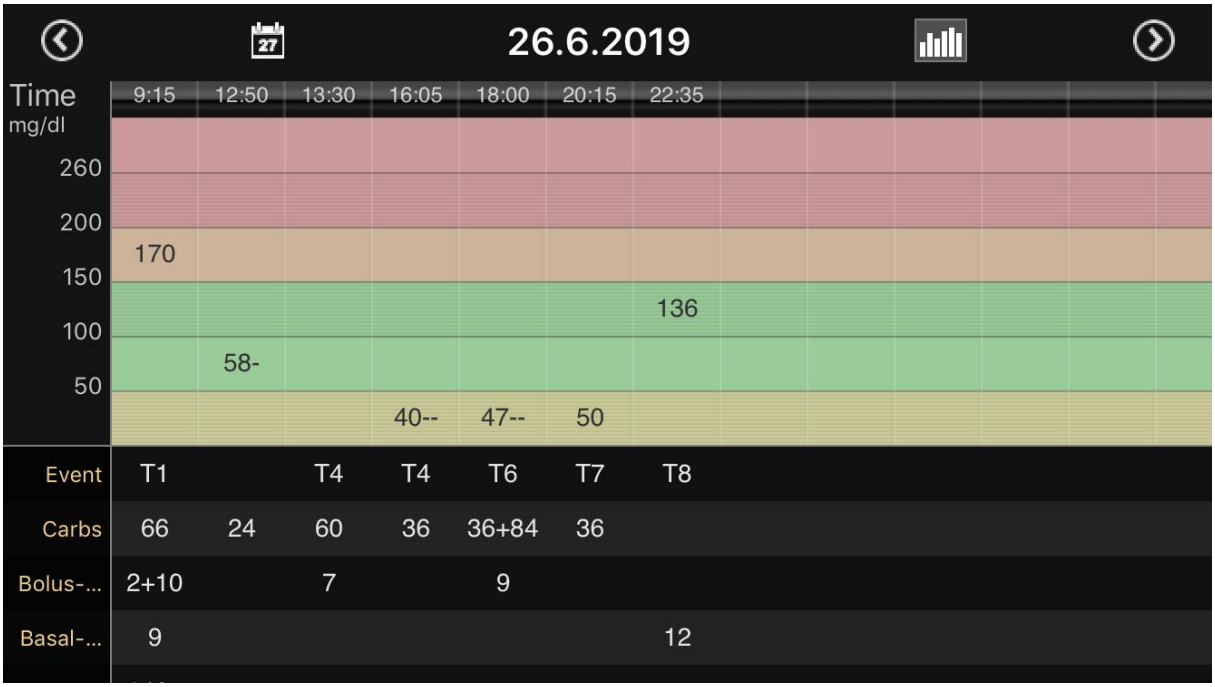
You can use the three buttons shown here to perform further actions:

1 = With this button you can use Bluetooth to read out a meter that has already been paired with the iOS device. Therefore, you do not need to take the detour via "Read more device".

2 = With this button you can establish a connection to your food database at SiDiary-Online.

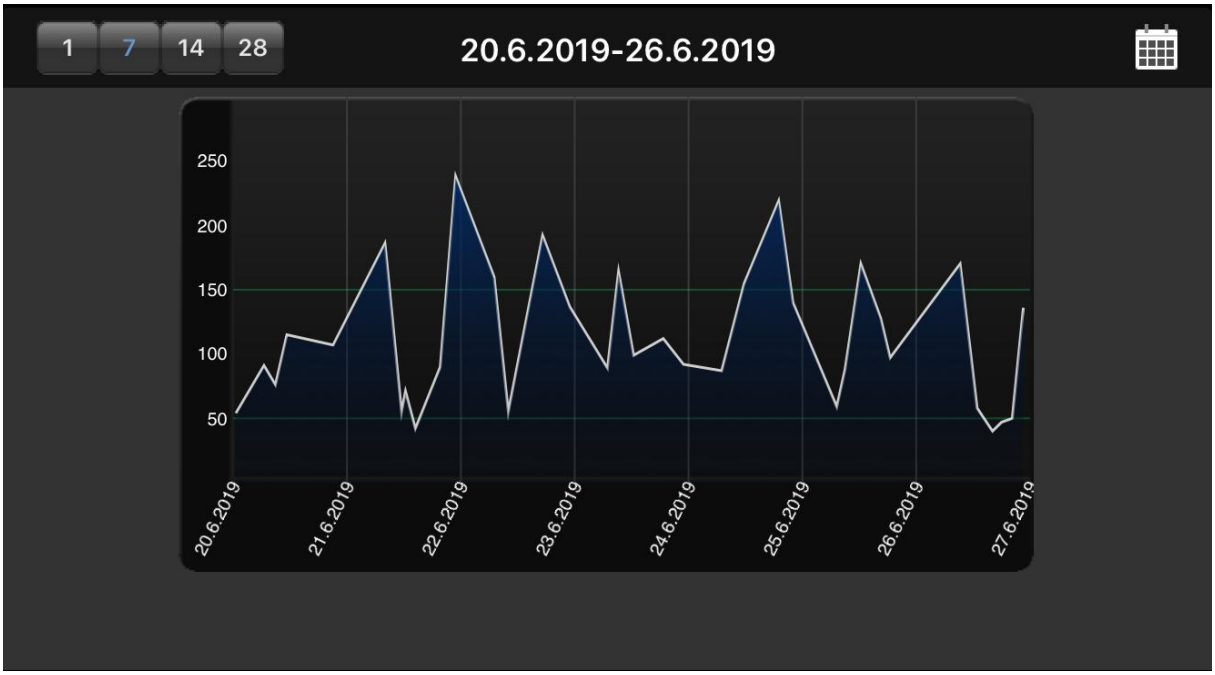
3 = With this button you start the bolus calculator where no factors are preset. Unlike the bolus calculator in the input mask, you cannot transfer the data to the diary from here. Basically, this bolus calculator is intended for simulation purposes, or if you want to calculate a bolus for another diabetic.

SiDiary also offers the option to view the logbook in the so called ‚Landscape format‘:



Please note: Currently the landscape format is for viewing only, but not for editing.

Furthermore, you can view a line graph of your blood glucose levels by pressing the button left to the date to see the last 1, 7, 14 or 28 days:



To enter/modify/add data to a specific column just tap at the column of your choice. Then the single data mask can scroll to any field you wish. On the right side you can add, modify or delete every entry. Click on save in the upper right corner when you are done.

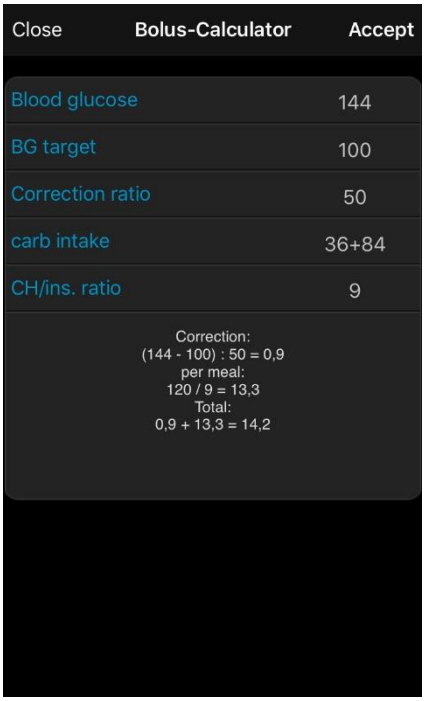
To enter new data with the current time just click at the plus button at the top of the logbook view. Please note, that this entry uses the current time AND the same date of the displayed day!

You also can use your own datatypes in the app to track anything you can imagine. Please do this as follows:

1. Add a datatype with the PC version (Menu 'Diabetesprofile ->Data types ->Add'; Press the F1-Key to get help)
2. Synchronize your PC version with 'SiDiary Online' Alternative you can add datatypes even without the PC version, if you open in 'SiDiary Online' in the section 'Data' the menu 'Data types' and click on 'Add'.

3. Synchronize your app with 'SiDiary Online'
4. Activate the selected datatype with the button 'More ->Settings ->Programsettings'
5. If necessary, re-start the app

Now you can enter the values for your datatype in the single data mask as shown on the left



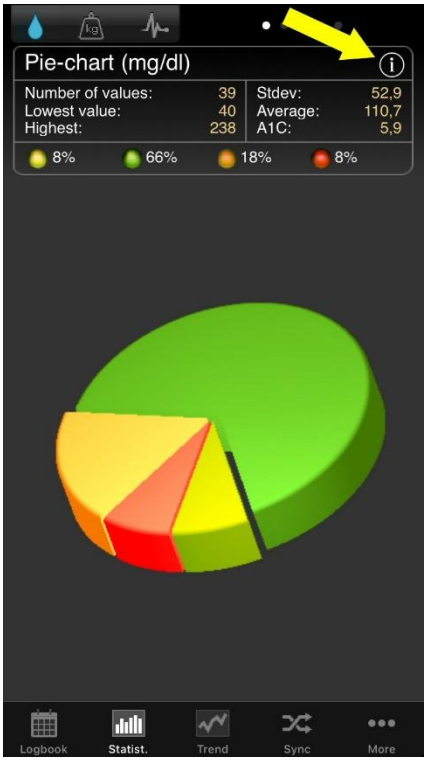
If you want to use the bolus calculator, please press the appropriate line.
Once you have accepted the notes about the bolus calculator you can enter your appropriate values to calculate your bolus dose.
If you have entered in SiDiary Online your carb- and correction factors and then synced the app with SiDiary Online, these factors are also known in the bolus calculator and will be used automatically. Otherwise, you can enter all of your data manually here.
By clicking the ‘Accept’ button in the upper right corner you can transfer the result directly to your logbook.

Please note: The result of the bolus calculation will not be rounded. We have deliberately refrained it since it depends on the situation, if it should be round up or down. This decision cannot be made by the app for you.

Some notes/hints:

- In the ‘events’ and in ‘sport’ the app will store your entries in a list. So, the next time you will enter the same event/sport, you can simply select it from this list.
- The weight will be saved once a day. So, it’s possible that you see a weight in in the entry mask which you have entered previously on that day.
- The same as for weight is for remarks: one field for a day. To assign a remark to a column, it is therefore advisable to also track the time for that remark.

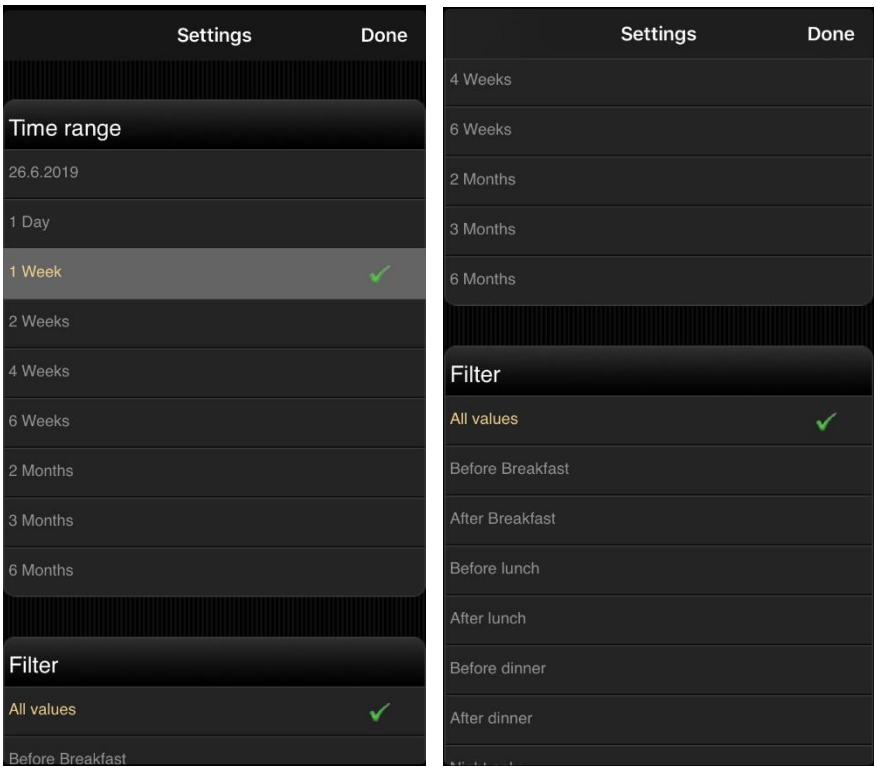
7 Statistics

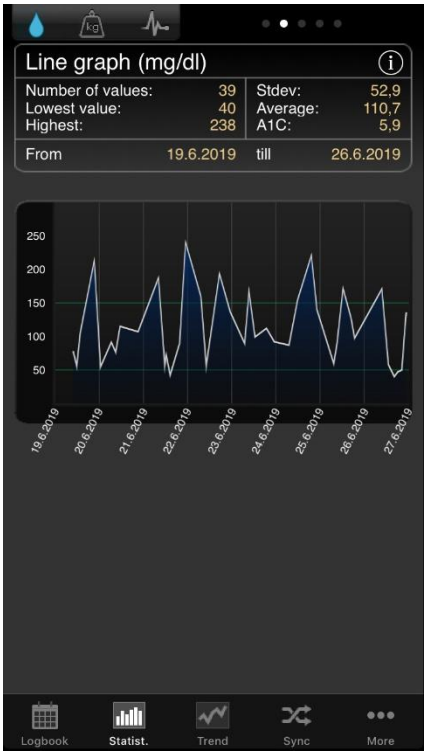


First you see the pie chart in the statistics with the spreading of all your blood glucose measurements. All values within your target range are green, yellow means you are below your target range, orange means above your target range and red means more than 200 mg/dl (11,1 mmol/l).

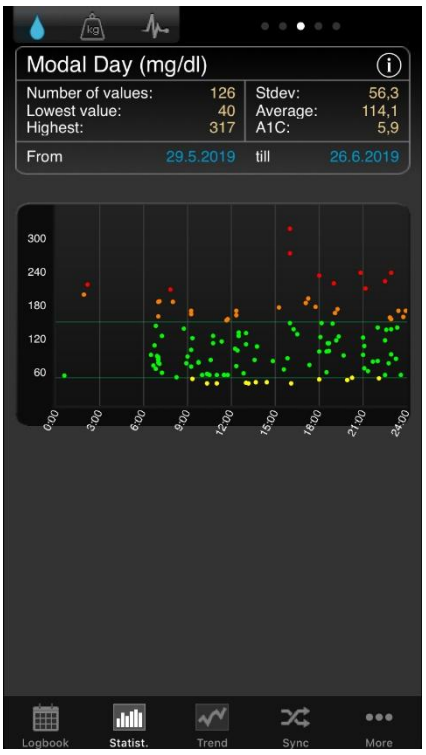
Above the pie chart you see more details regarding this time range: Number of values, standard deviation, calculated A1C and so on.
With a movement of your finger to the left you see the other graphs; with a tap on the i-symbol you will enter the statistics settings.

In the statistics settings you can set the time range for the statistic and which parts of a day should be processed.

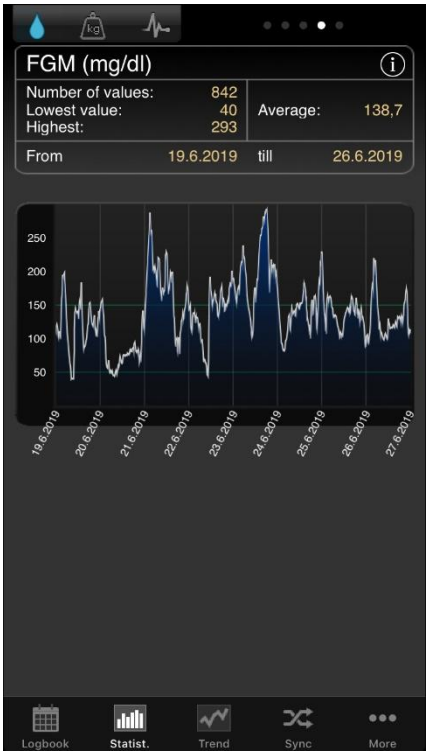




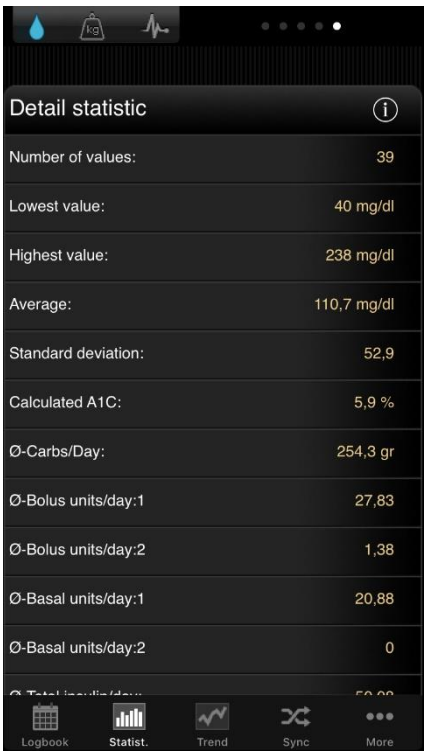
In the line graph you see the curve progression of your blood glucose measurements for the selected time range.



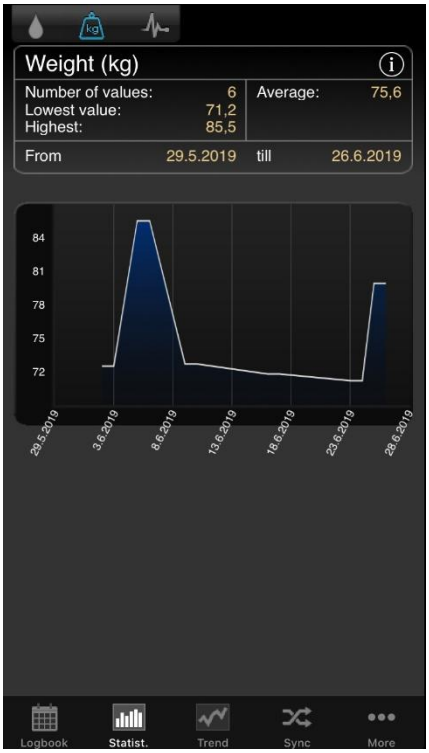
The modal day shows you all measurements of your selected time range projected to a 24-hour day. So, you have a quick overview in which parts of the day you have measured mostly and when the values have the biggest spread. In the example on the left you can see that in the evening between 15:00 and 21:00 the spread is the biggest, which means the blood glucose is here mostly instable.



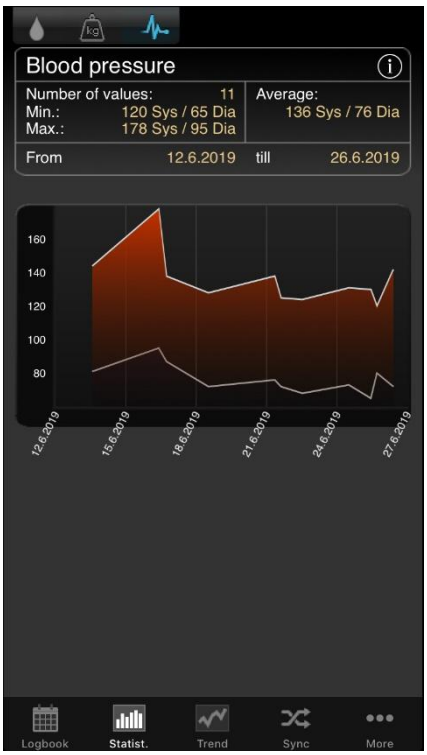
Also, the data of your CGMS or FGM (as shown here in the picture) can be displayed in the app. Since there is far too much data for a meaningful representation in the logbook, we recommend using this curve graphic in the statistics on your Smartphone.



Additionally, to the details from the previous graph screens the detail statistic shows more utilization like the average values of carbs, bolus or basal insulin.

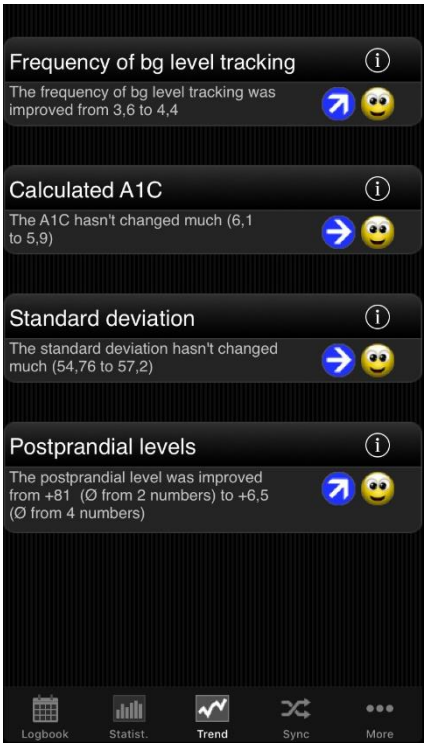


With the tabs at the top of the display, you can switch between the graphics for blood sugar, weight and blood pressure.
You'll see the value for the lowest and the highest reading in the selected period, and the mean value.



In the display for blood pressure you will see the highest or the lowest systolic and diastolic pressure, and the mean values for this parameter too.

8 Trend Analysis



The trend analysis compares two-time ranges to analyse the progression. Parameters are: Frequency (of BG level tracking), calculated A1C, standard deviation and postprandial levels (BG level after meals).

If you select '1 Week' in the settings for the analysis, then the last 7 days will be compared with the previous 7 days.
'Trend' shows you (with arrow symbols) if this parameter has become worse, is constant or has become better than in the previous time range.
'Level' shows you the current situation with a smiley symbol (in '1 Week' it shows the level of the last 7 days).

The set of criteria for the level:

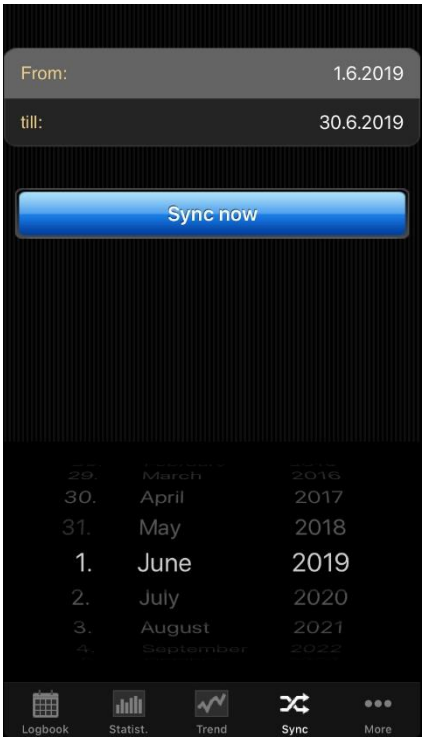
---	Excellent	Good	Satisfactory
Frequency	More than 3	equal to 3	less than 3
Calculated A1C	less than 6,5%	less than 7,5%	less than 9%
Standard deviation	less than 60 mg/dl (3,3 mmol/l)	less than 70 mg/dl (3,9 mmol/l)	less than 80 mg/dl (4,4 mmol/l)
Postprandial level	less than 60 mg/dl (3,3 mmol/l)	less than 80 mg/dl (4,4 mmol/l)	less than 100 mg/dl (5,5 mmol/l)

A blood glucose value will be calculated as 'postprandial' if the measurement comes 60-120 minutes after an entry for carbohydrates.
In the settings for 'Trends' (via the i-symbol at the top), you can select which time ranges should be calculated and which parts of a day you want to analyze for the postprandial levels.

The parts of day are:

- After breakfast: 10:00 - 11:59 (10:00am - 11:59am)
- After lunch: 15:00 - 16:59 (03:00pm - 04:59pm)
- After dinner: 20:00 - 03:59 (08:00pm - 03:59am)

9 Synchronisation



In the section 'Sync' you can synchronize your data from the app with 'SiDiary Online'.
All you need is an account at 'SiDiary Online' (which is free of charge). You can setup your username and password in the app under 'Setup ->Settings ->SiDiary Online' (don't forget to save your settings!). In the section 'Sync' you can adjust the time range which you want to sync and tap the button 'Sync now' to start the procedure.

Data which is not saved in 'SiDiary Online' will be transferred there and data which is not saved in the app but in 'SiDiary Online' will be transferred into your app. So, this is a 2-way transfer (bidirectional).

Please note that the syncing is field-by-field and the sync partner with the most recent change date has always priority.
That means for example if you enter a remark in the app and then do the same in 'SiDiary Online' after a sync you will find the remark from 'SiDiary Online' in your app.
It's completely different if you track for example a BG reading in the app for 09:15 and then add a bolus for the same time in 'SiDiary Online'. In this case both values will be merged, because the field for BG has nothing in common with the field for bolus.
If you track/add/edit your data only in the app you don't need to think about this issue.

The use of 'SiDiary Online' has three interesting aspects:

1. Synchronization of the data with the PC version of SiDiary
You can use for example the PC version to read out your blood glucose/blood pressure meter or insulin pump; print data or send it by email and so on. By a sync with 'SiDiary Online' you also have the data you have tracked with the app in your personal logbook.

2. Operating system independence
If you don't have the PC version of SiDiary because you have an Apple or Linux operating system (and don't want to install a virtual machine) you can print your data from 'SiDiary Online' or view it on a bigger screen.

3. Telemedicine
You can invite your diabetes team (endocrinologist / diabetes nurse) to create an account at 'SiDiary Online', so you can grant these people an access to view your data over the internet. You can share your data, even if you are on holiday and have an urgent problem.

You can also use 'SiDiary Online' with a pseudonym. You just need a real existing email account, to which the system will send you an activation link. Without clicking this activation link the usage of 'SiDiary Online' is impossible.

On the following site you can find a step-by-step manual on how to get the data from the app to your PC version of SiDiary:

https://www.sidiary.org/?id=2031&hidebanner=1&teaser=0

10 Registered Trademarks

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Note:
If you wish, we will be happy to send you a hard copy of these operating instructions immediately and free of charge. In this case, please email us with your postal address to support.sidiary@sinovo.de.

CE 0123

SINOVO health solutions GmbH
Willy-Brandt-Str. 4
61118 Bad Vilbel (Germany)
info@sinovo.de
www.sinovo.de