Manual

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SiDiary Online

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

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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 app for Windows PC and mobile apps for Android and iOS 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 for Windows PC and mobile apps for Android and iOS are 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. The SiDiary app saves the data and displays it over the period 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 online web app can be used on all browsers under any operating system.

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 for Windows PC and mobile apps for Android and iOS 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

User 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 the autonomous person with 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 for Windows PC or Android/iOS 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 web server in Germany. It can be used several times a day. It has an uptime if 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).

3.9 Maintenance calibration measures

The SiDiary app requires no special maintenance or calibration.

3.10 Preparing the product before use

Before the SiDiary web app can be used, an account must be created for the user. This requires a real e-mail address, to which the confirmation link can then be sent, with which the user can finally activate their account.

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 app. 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 Overview

SiDiary-Online is an essential part of the whole system "SiDiary". On the one hand it serves as a link for data transfer between your mobile versions on smartphone and tablet and your PC version.
On the other hand, it also serves to transfer data from your SiDiary versions to the professional version of your doctor (if you wish to do so and explicitly and revocably release the data to him). This way you can provide your data paperless to your treating diabetes team and do not have to remember to print them out before the next doctor visit.
Furthermore, SiDiary-Online is mandatory if you want to use your license as subscription version to be able to always use the latest version of it.

5 Registering

If you do not have an account at SiDiary-Online yet, you can create one for free at any time. Just click on "Don't have an account? Register now" on the homepage https://diabetes.sinovo.net.
You will receive an email with a confirmation link. If you clicked this link your account is activated, and you can use it directly.

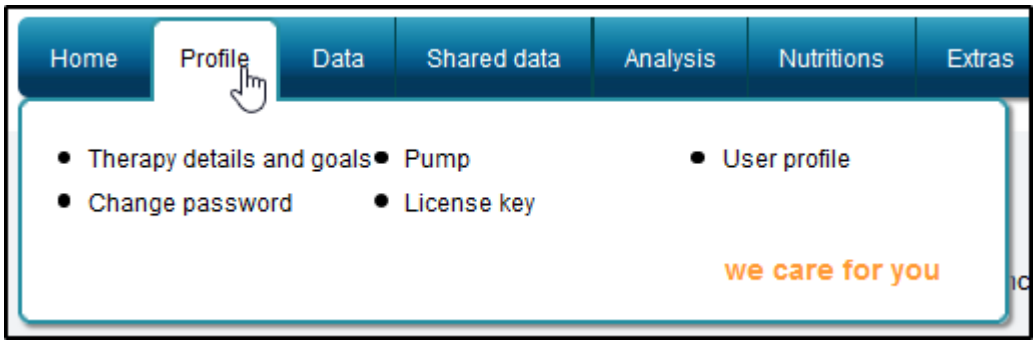
At the bottom of the registration page, you will find a field "HCP-ID". If your doctor uses "SiDiary Professional" he can give you such an ID to transfer your data from SiDiary-Online automatically to his practice computer and he can see it there. You can stop this sharing at any time by clicking on "Delete" under "Data sharing" in SiDiary-Online. From then on, no more data will be transferred to your doctor.

6 Home

You can get to the start page in SiDiary-Online by clicking on "Home" in the top navigation.

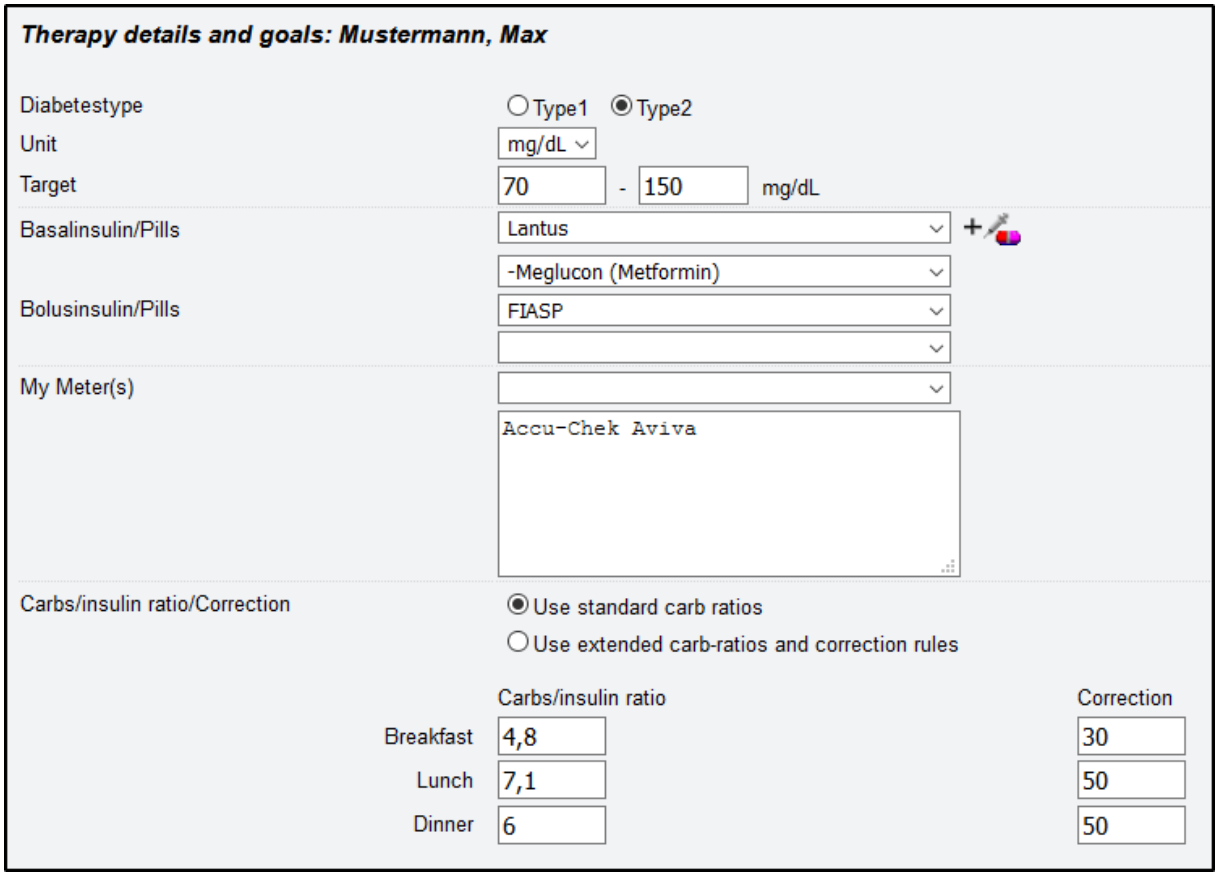
You can see there in a table the last news from our website in the left column, and in the right column your personal messages, which were sent to you by the system or by befriended users in SiDiary Online.

If you move the mouse arrow over the navigation at the top of the page, you will see the possibly existing subitems for each entry, so you can navigate through SiDiary-Online.

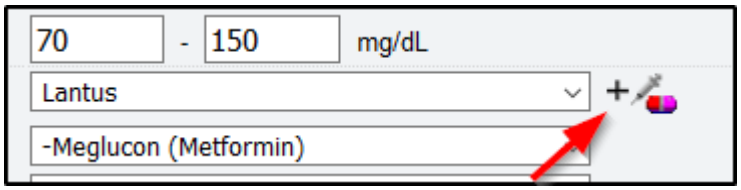


7 Profile

7.1 Therapy details and goals

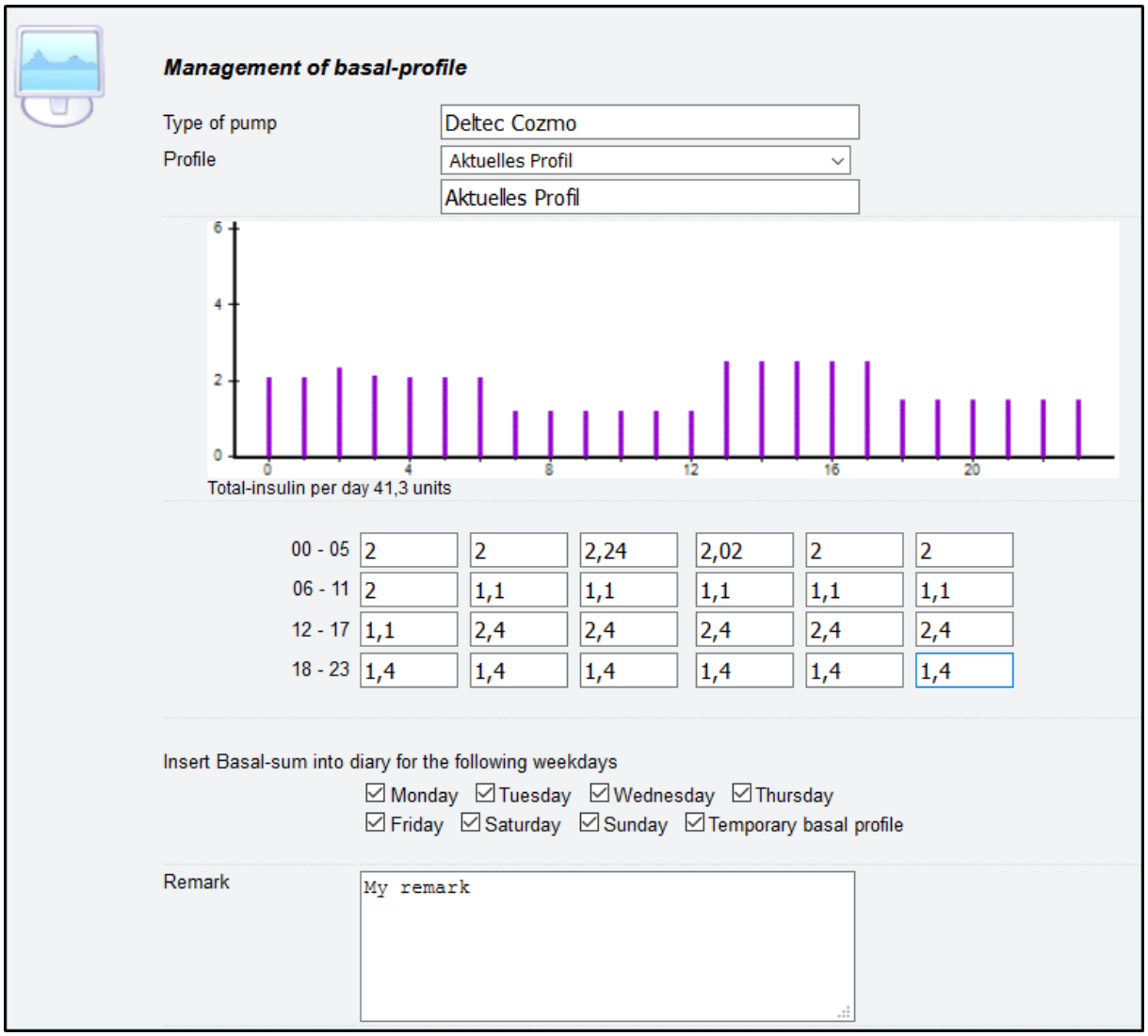


In the therapy data, you can enter information about your diabetes type and how you treat it, or which measuring devices you use for this purpose.
If your medication is not listed there, you can easily add it by clicking on this icon:

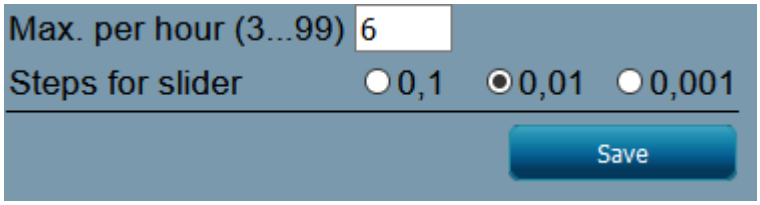


After adding it, you will also find it in the selection list.

7.2 Pump

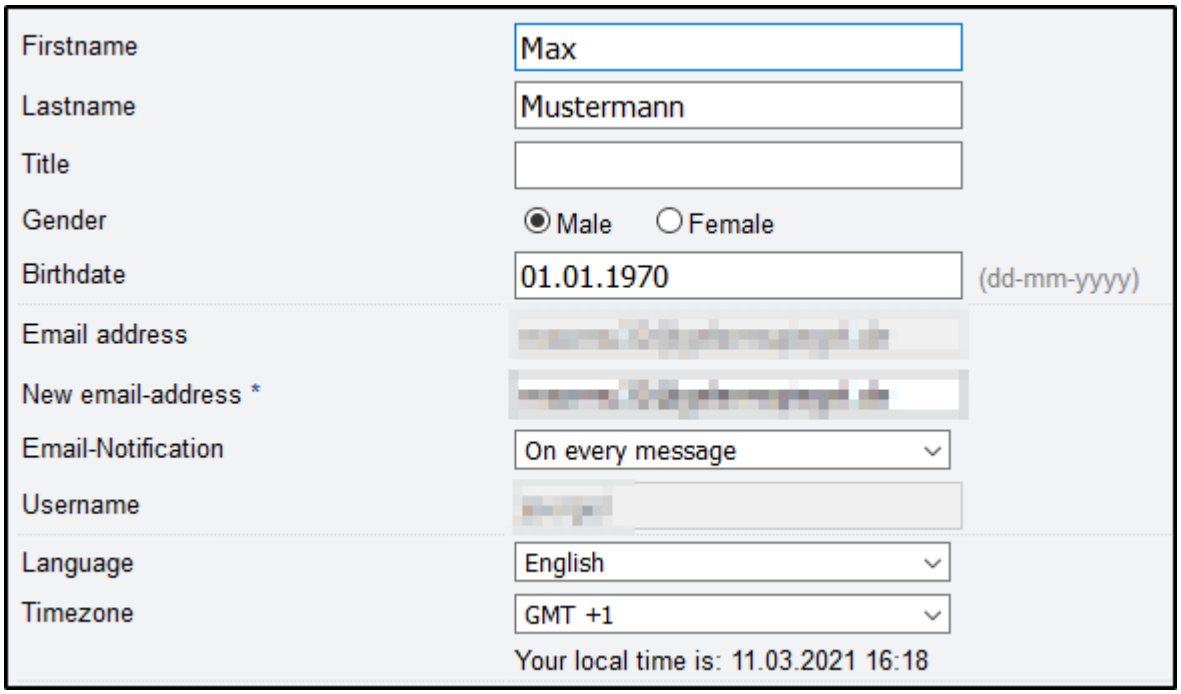


If you are an insulin pump user, you can enter your basal rates here. If you wish, these can then also be automatically applied to the diary.
On this page you will also find a **"Settings"** button at the bottom.



This allows you to specify the maximum number of units that can be entered per hour (as a little help to avoid accidental typing errors) and the step size at which you want to enter your basal rates.

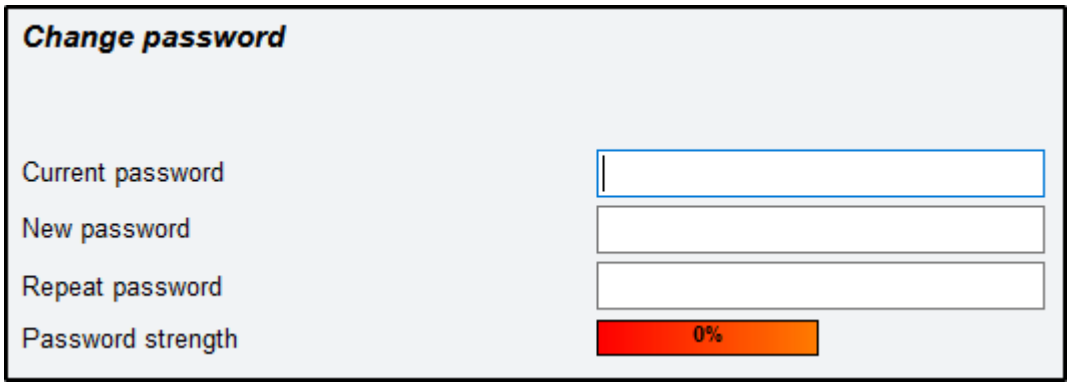
7.3 User profile



In the user profile you can choose in which language and which time zone you want to use SiDiary-Online. Furthermore, you have the possibility to enter a new e-mail address, if your e-mail address has changed.

Please note: After a change you will get a confirmation link to your new email address again. Only by clicking on this confirmation link your email address will be permanently changed in the system.

7.4 Change password



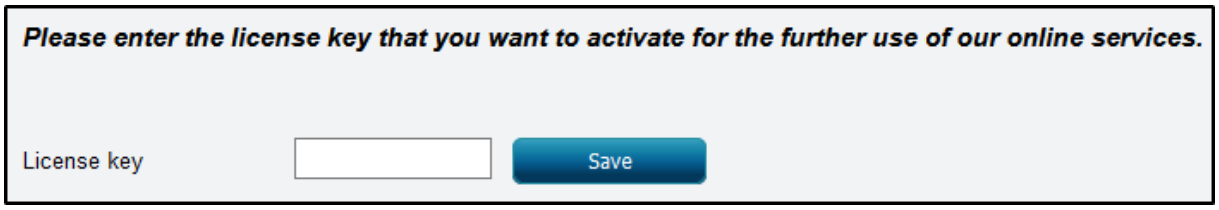
On this page you can change your password for accessing SiDiary-Online. Please remember to change your password in the apps you use (for PC, Android, and iOS) as well, so that you can continue to synchronize your data and use your subscription without any problems.

For your data security, a password will only be accepted if it has at least eight characters and at least one:

- Uppercase letter
- Lowercase letter
- Numeral
- Special character

The color bar at the bottom of the page gives you an indication of how secure the password you have chosen is.

7.5 License key



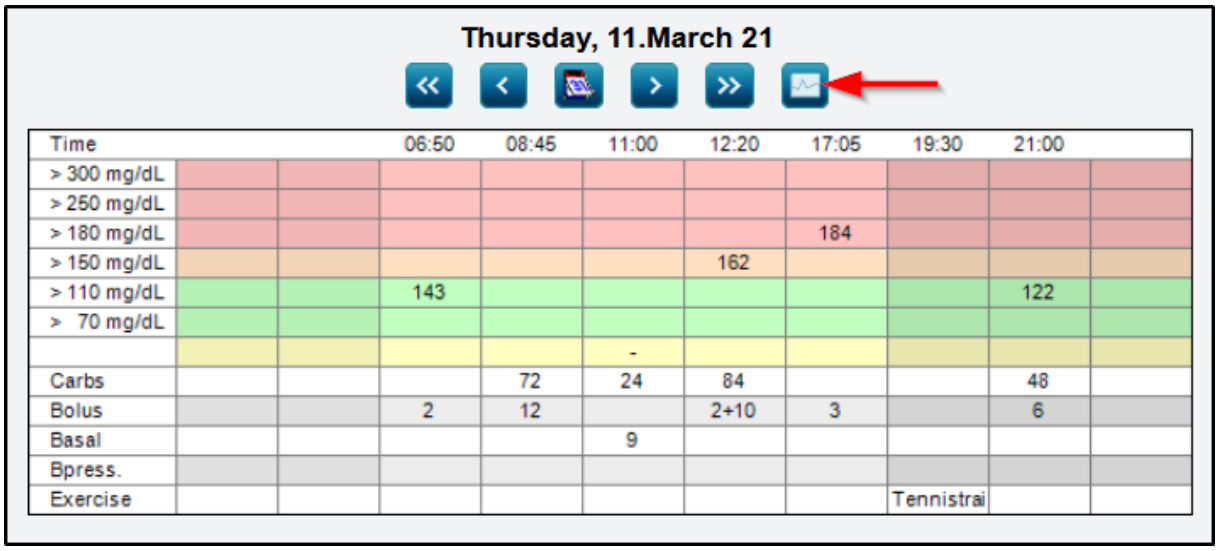
Under this item you must enter your subscription license number, if you have selected a subscription as your license. This activates the subscription, and it can then be used for at least one year. If you have already purchased a successor license before the end of this one year, you can still enter it directly there. You will not lose any days; the existing subscription will simply be extended by 366 days.

But even if you have chosen a purchase version as license you can enter your transaction number there, because by entering a license in any form no more advertisement will be shown on SiDiary-Online.

8 Data

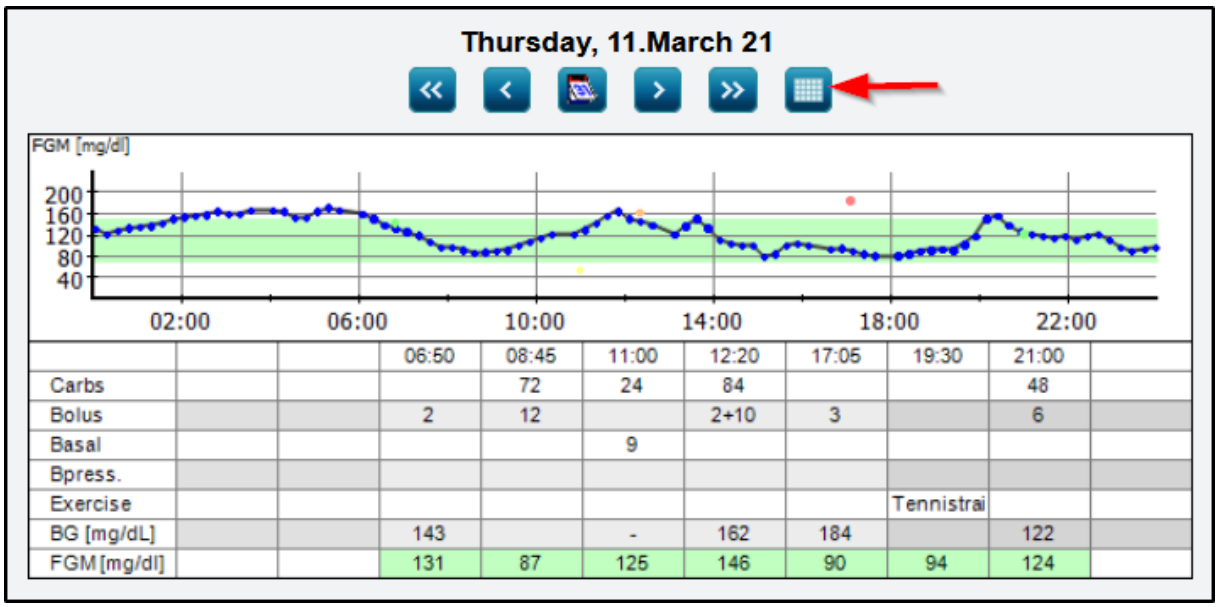
8.1 Logbook

The logbook in SiDiary Online corresponds to the detailed logbook of the PC version and can be displayed the same way. Either as a BG table…



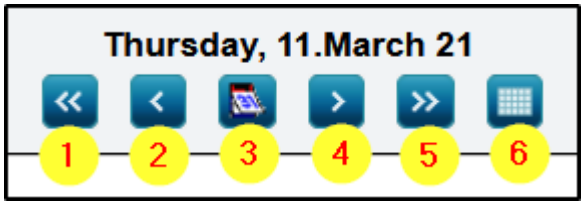
Time	06:50	08:45	11:00	12:20	17:05	19:30	21:00
> 300 mg/dL							
> 250 mg/dL							
> 180 mg/dL					184		
> 150 mg/dL				162			
> 110 mg/dL	143						122
> 70 mg/dL							
			-				
Carbs		72	24	84			48
Bolus	2	12		2+10	3		6
Basal			9				
Bpress.							
Exercise						Tennistrai	

Or by clicking on the button marked with a red arrow as CGMS history curve:



	06:50	08:45	11:00	12:20	17:05	19:30	21:00
Carbs		72	24	84			48
Bolus	2	12		2+10	3		6
Basal			9				
Bpress.							
Exercise						Tennistrai	
BG [mg/dL]	143		-	162	184		122
FGM [mg/dl]	131	87	125	146	90	94	124

The buttons above - under the date - are used to navigate through your data:



1 = One week backwards
2 = One day backwards
3 = Calling the calendar control
4 = One day forward
5 = One week forward
6 = Switching between blood glucose table and CGMS progress curve
(Button 6 is only visible if CGMS/FGM values are included in this account)

At the bottom of the logbook, you will find more buttons:

Pic for forum
This allows you to create an image of your diary to embed in a forum, Facebook group or website.

Ask a question
This allows you to ask someone to whom you have shared your data a specific question about the current day.
The person will then receive an email with your question and a link to the day you asked them the question about.

Find
This allows you to start a full text search in the entire diary over the period you entered.

Edit
Shows you a data list of the displayed day, which you can then edit.

For easy data entry, you can simply click on an empty column of the diary to get to an input mask. If you click on an already existing value, you can edit the column where this value is located.

The option to enter data in this way directly into SiDiary-Online is rather intended for the case that you use SiDiary neither on the PC nor as an app on your smartphone/tablet. Because there the data entry is more comfortable, and you can transfer the data to SiDiary-Online by synchronizing afterwards.

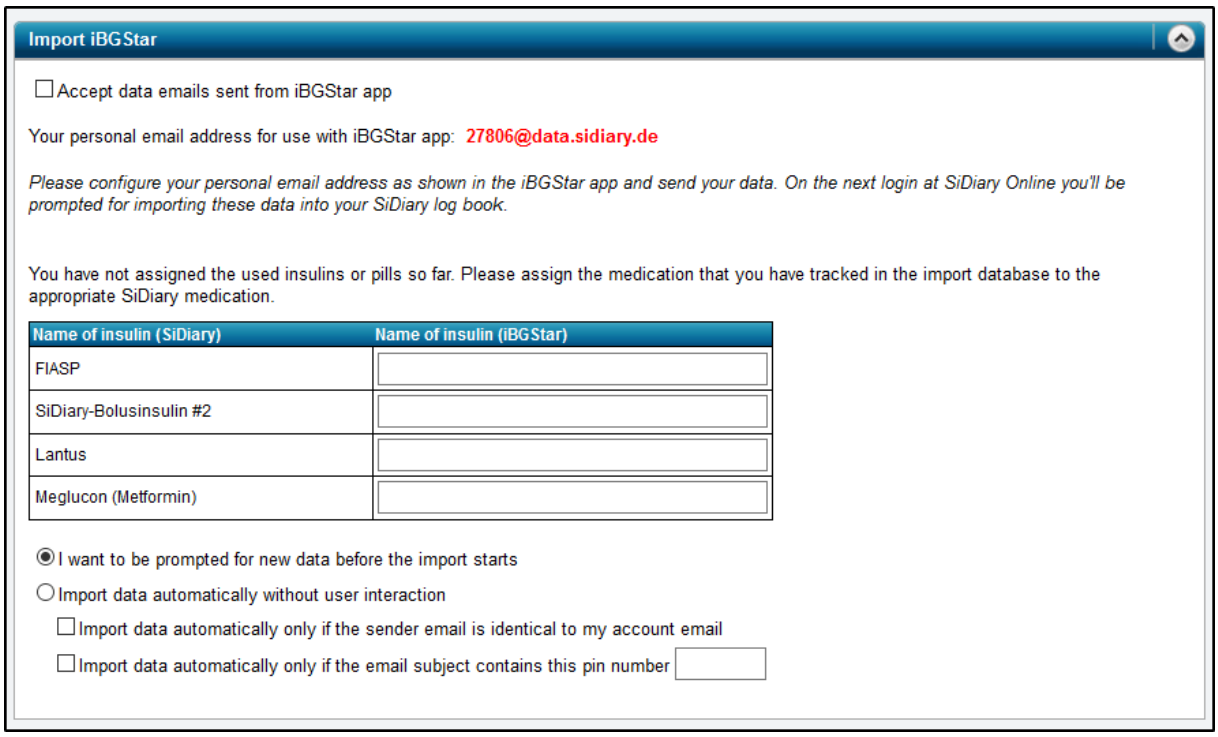
8.2 Data list

Shows you the data list that you also know from the "Edit" button, called from the navigation but always the one for the current day.

8.3 Enter single data

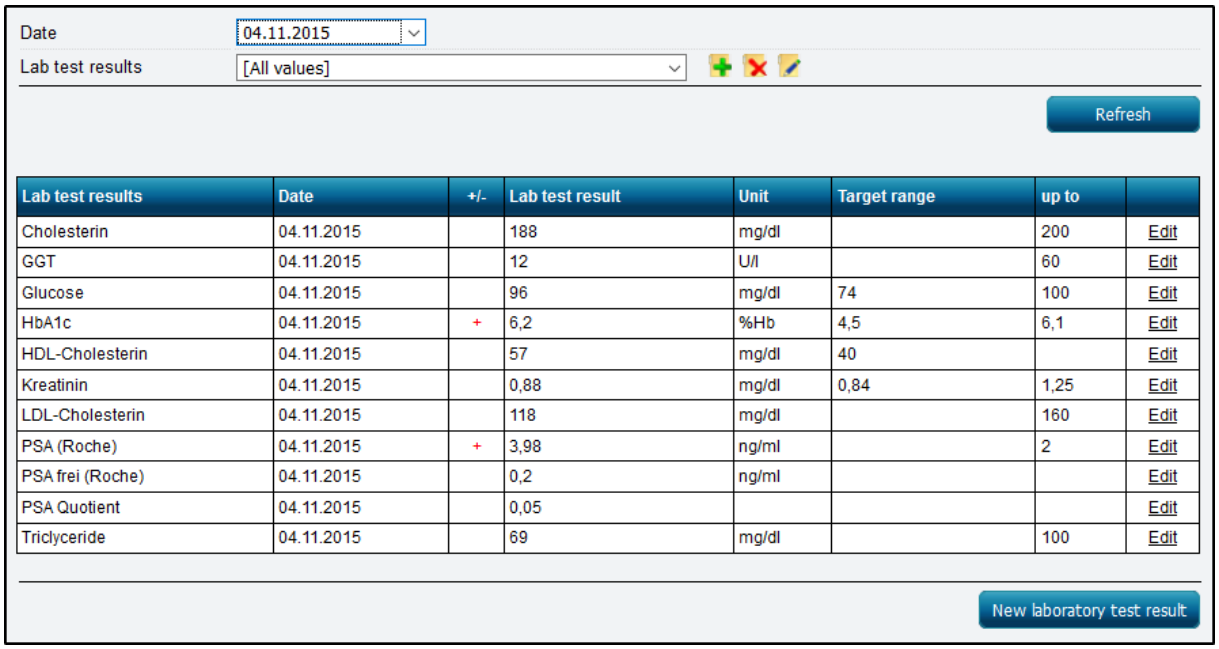
Shows you the single value input mask, which you can also open by clicking on an empty column of the day.

8.4 Import



If you use the app "iBGStar" on your iPhone, you can send a mail with your data directly to SiDiary-Online. In the mask under "Import" you see your personal address on SiDiary-Online and you can make further entries how to proceed with the values from this app.

8.5 Lab test results



Lab test results	Date	+/-	Lab test result	Unit	Target range	up to	
Cholesterin	04.11.2015		188	mg/dl		200	Edit
GGT	04.11.2015		12	U/l		60	Edit
Glucose	04.11.2015		96	mg/dl	74	100	Edit
HbA1c	04.11.2015	+	6,2	%Hb	4,5	6,1	Edit
HDL-Cholesterin	04.11.2015		57	mg/dl	40		Edit
Kreatinin	04.11.2015		0,88	mg/dl	0,84	1,25	Edit
LDL-Cholesterin	04.11.2015		118	mg/dl		160	Edit
PSA (Roche)	04.11.2015	+	3,98	ng/ml		2	Edit
PSA frei (Roche)	04.11.2015		0,2	ng/ml			Edit
PSA Quotient	04.11.2015		0,05				Edit
Triclyceride	04.11.2015		69	mg/dl		100	Edit

The laboratory value management in SiDiary-Online is the same as in the PC version. This means that you can also add new laboratory results and/or define new parameters there. By synchronization, these values will be transferred to or from the PC to this view.

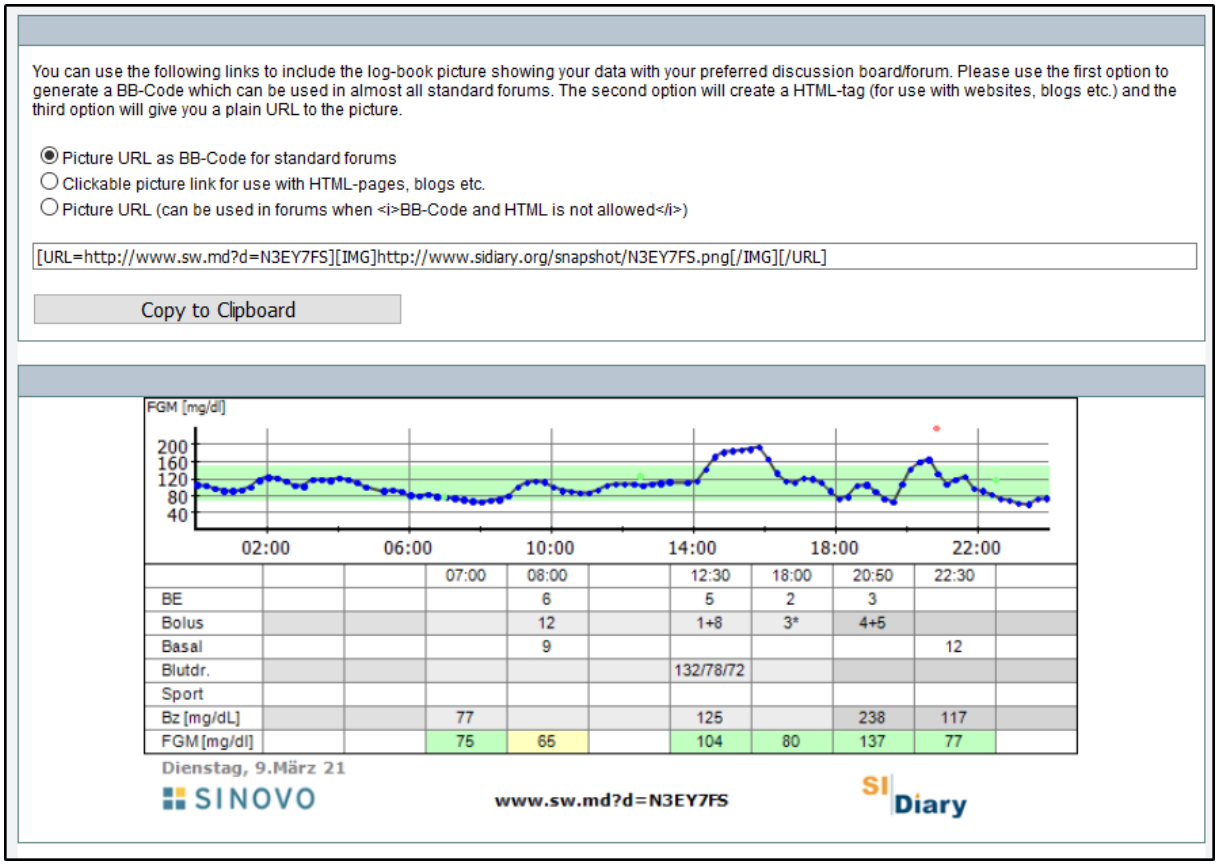
This way you always have the possibility to view the lab results that you have recorded in your PC version at home: by simply using the browser of your smartphone/tablet and logging in at https://diabetes.sinovo.net.

8.6 Data types

Key	Sorting	Name	Unit	
doc		Arztbesuch		Edit
CGMS		CGMS	mg/dl	Edit
DiabGSchlaf		DG-Schlafqualität		Edit
DiabGStress		DG-Stress		Edit
Dist		Distanz (SZ)	km	Edit
Eiw		Eiweiß	g	Edit
Fett		Fett	g	Edit
For		Forxiga	mg	Edit
GI		Glyk. Index	%	Edit
Joule		Joule	J	Edit

Just like in the PC version you can also create your own data types in SiDiary-Online, i.e., your own categories, which will then be displayed to you in the diary as a new row. You can use this option e.g. to create a data type on the road, which is then available on your smartphone/tablet after a synchronization. Or of course also on your PC, to which this new data type is then also transferred by a sync.

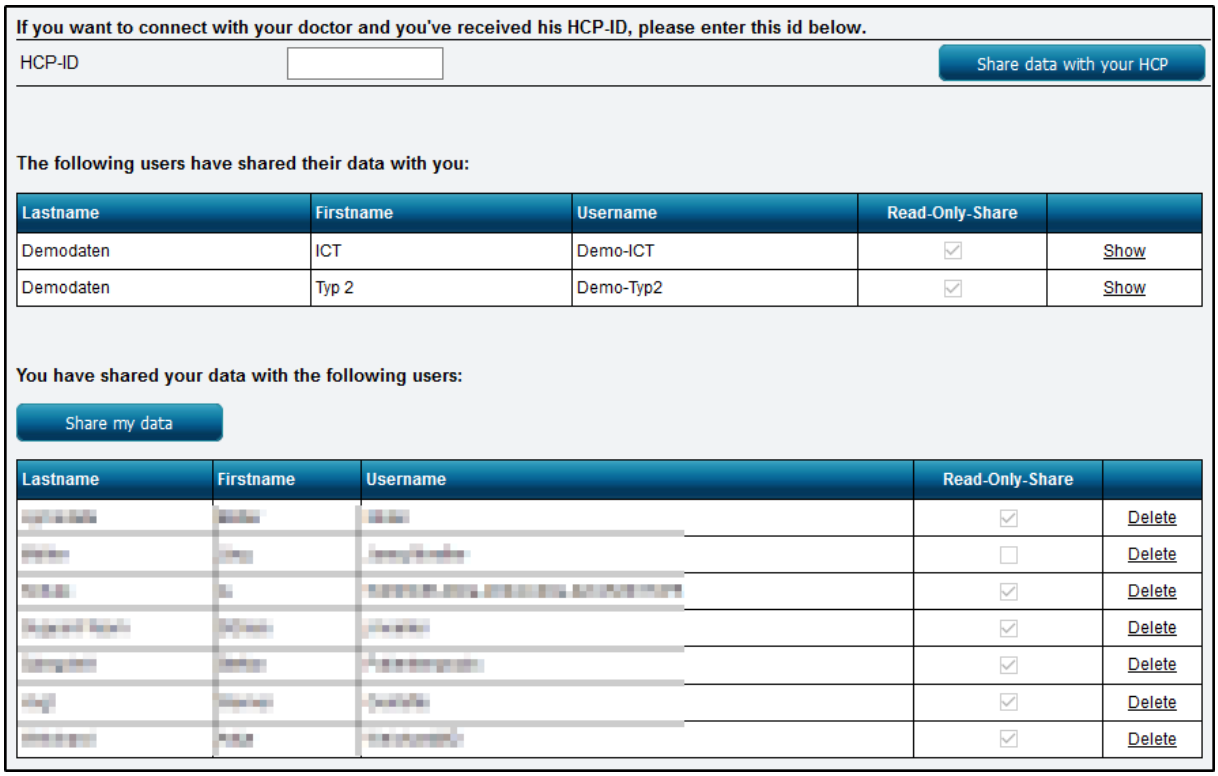
8.7 Pic for forum



You can use this option to create an image of your logbook, which you can then embed in a forum, Facebook group, or website.

This way you can then discuss your current day via social media and get suggestions and help there, if needed.

9 Shared data



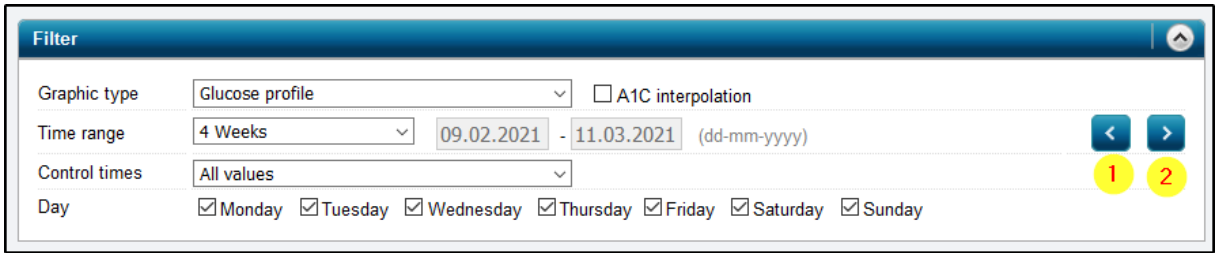
On this page you can see briefly which users have released their data to you or who has received a data release from you.
Such a data release can make sense to discuss one's data with a trusted person to get help from there, if necessary.

Important to know: You can always undo this sharing by simply clicking "Delete" on this page.

"Normal" users like friends or relatives can only view this data directly on SiDiary-Online, whereas physicians who use SiDiary in a professional version get this data automatically transferred to their practice computer. Especially for using telemedicine this is very helpful: You read out your devices at home, synchronize your data to SiDiary-Online and can discuss your data live during a phone or video call, because the doctor sees the same on his PC as you see on yours.
It is then no longer necessary to print out your data before a visit to the doctor (if your own doctor also uses SiDiary).

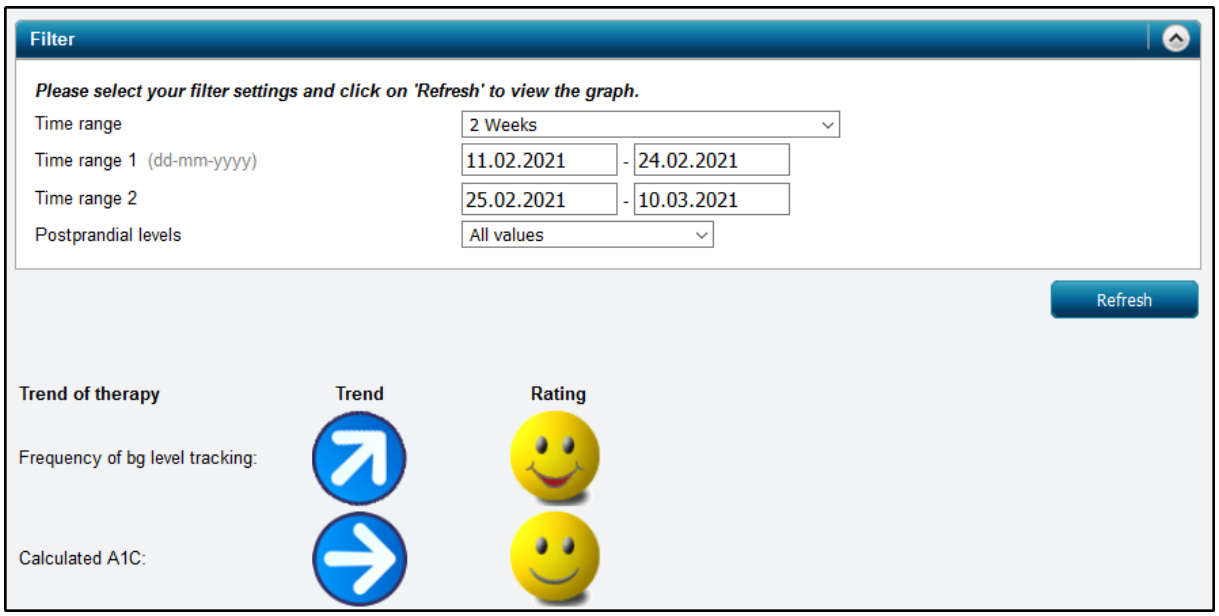
10 Analysis

10.1 Statistics



In the statistics of SiDiary-Online you will also find the graph types already known from the PC version, between which you can freely decide. You can either choose one of the predefined periods or switch to "Free period", where you can set start and end date day exactly. With the two buttons on the right, you can easily move the period to scroll through your values. *Button 1* moves the period backwards, *button 2* moves it forwards. If a statistic does not turn out as you expected, please check if there is a filter active that only considers certain times of the day or days of the week.

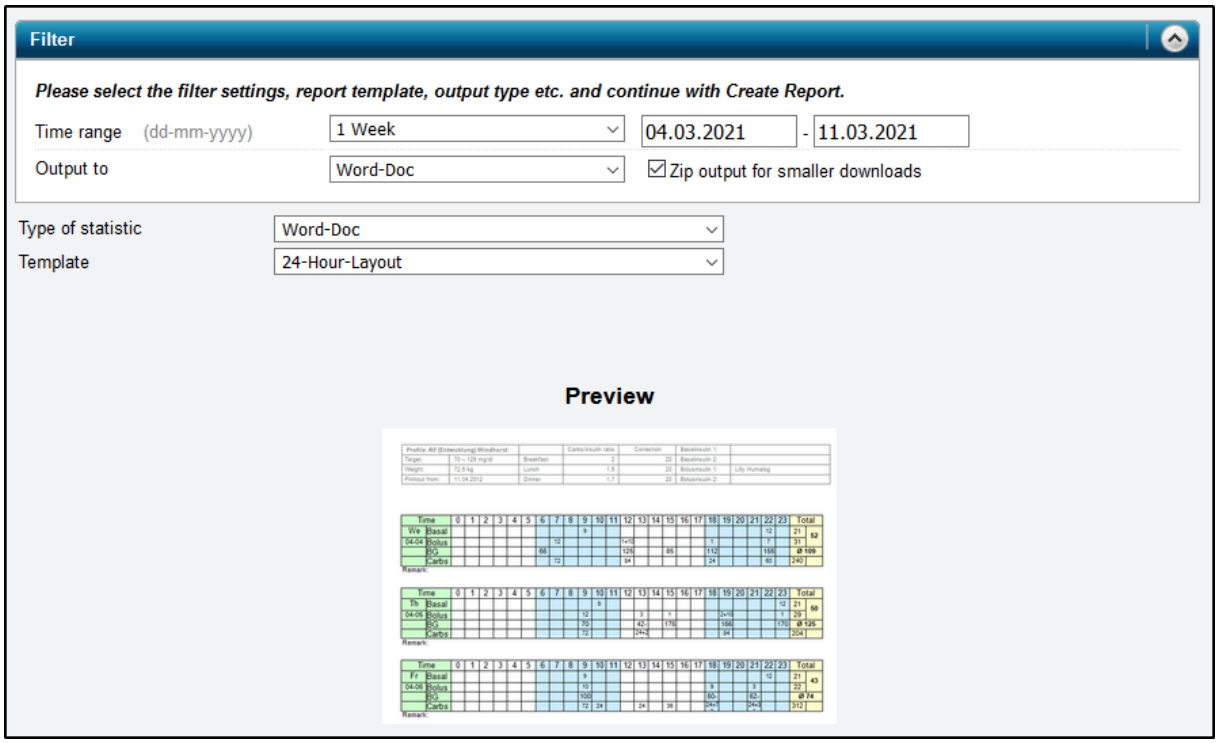
10.2 Trends



Here, too, you will find the same evaluation as in the PC version: two adjacent time periods are compared with each other in the parameters "measurement frequency, calculated HbA1c, standard deviation and postprandial position (BG value after eating". The arrow indicates how this parameter has developed and the smiley assesses the position of the current period.

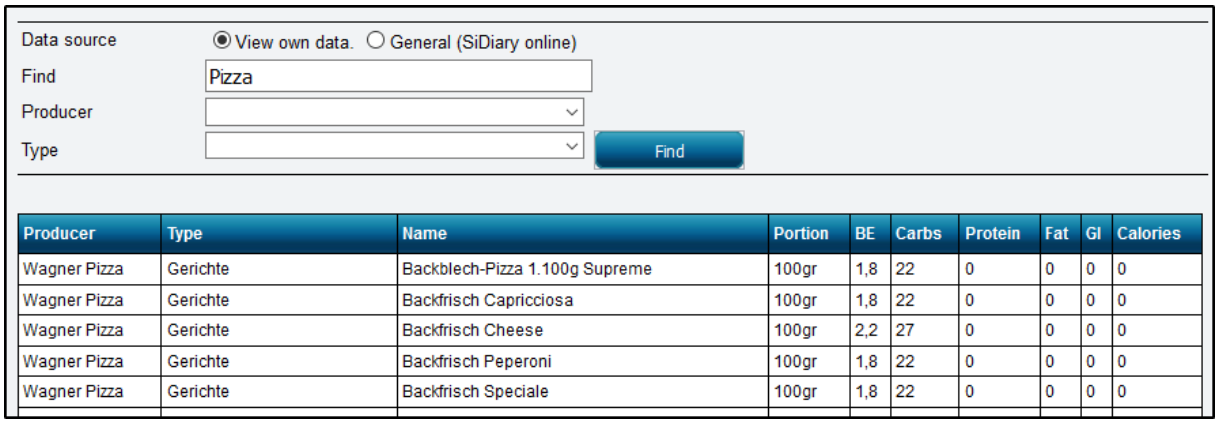
Please note that only blood glucose values and no CGMS/FGM values are used for evaluation.

10.3 Reports



In this area you can have printouts/exports made from your data. For this purpose, a rich selection of templates is available. Alternatively, you can have the data generated in the selected template as a PDF file, which you can then also easily send by email. However, you cannot select your own templates or templates that have been edited by you. But you have this option in the PC version of SiDiary.

11 Nutritions

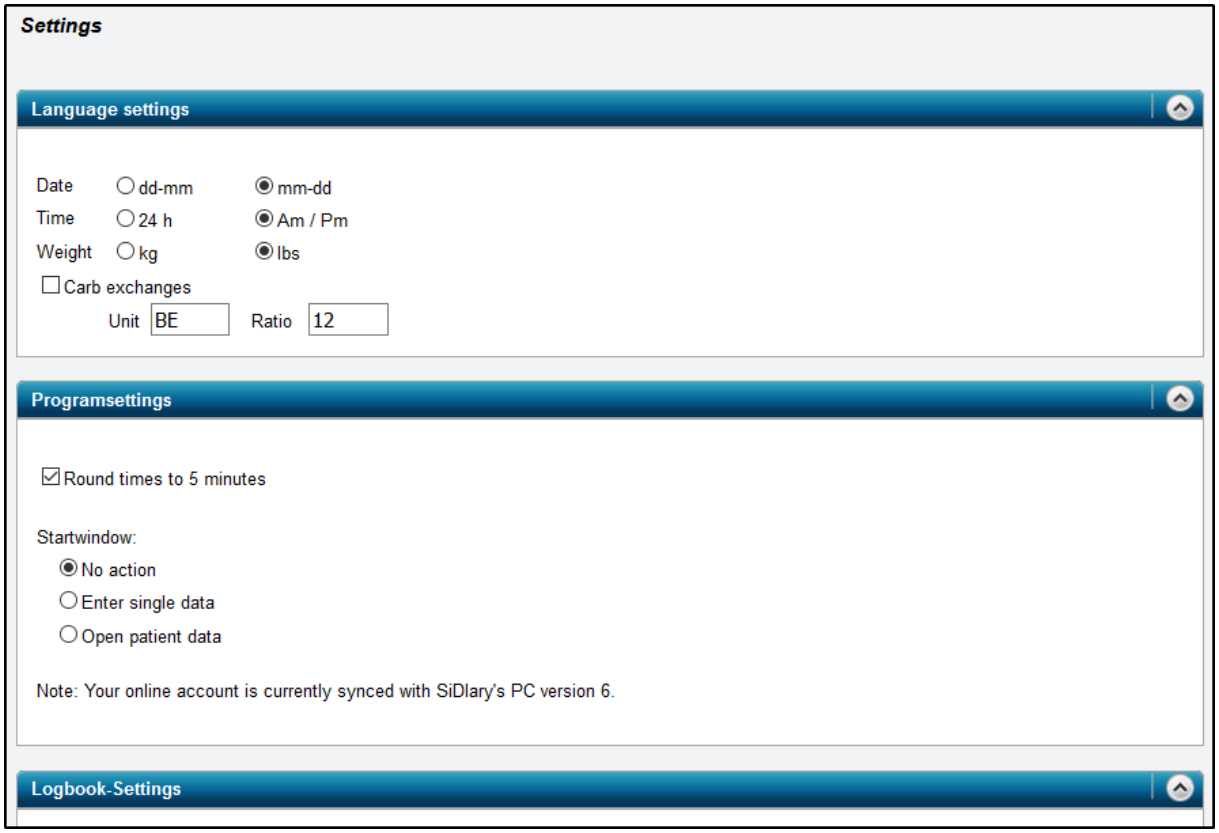


Producer	Type	Name	Portion	BE	Carbs	Protein	Fat	GI	Calories
Wagner Pizza	Gerichte	Backblech-Pizza 1.100g Supreme	100gr	1,8	22	0	0	0	0
Wagner Pizza	Gerichte	Backfrisch Capricciosa	100gr	1,8	22	0	0	0	0
Wagner Pizza	Gerichte	Backfrisch Cheese	100gr	2,2	27	0	0	0	0
Wagner Pizza	Gerichte	Backfrisch Peperoni	100gr	1,8	22	0	0	0	0
Wagner Pizza	Gerichte	Backfrisch Speciale	100gr	1,8	22	0	0	0	0

Here you can look up the nutritional values of various foods, or how many grams of carbohydrates they contain. Since this database is also transferred during synchronization, you will also find foods there that you have entered yourself in the PC version.

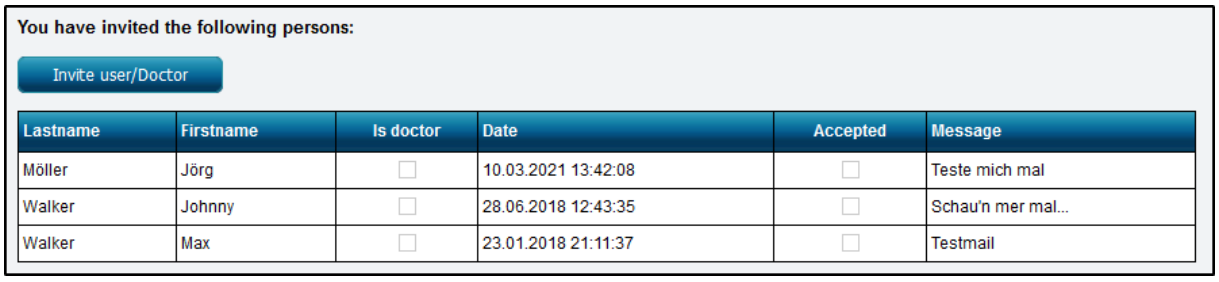
12 Extras

12.1 Settings



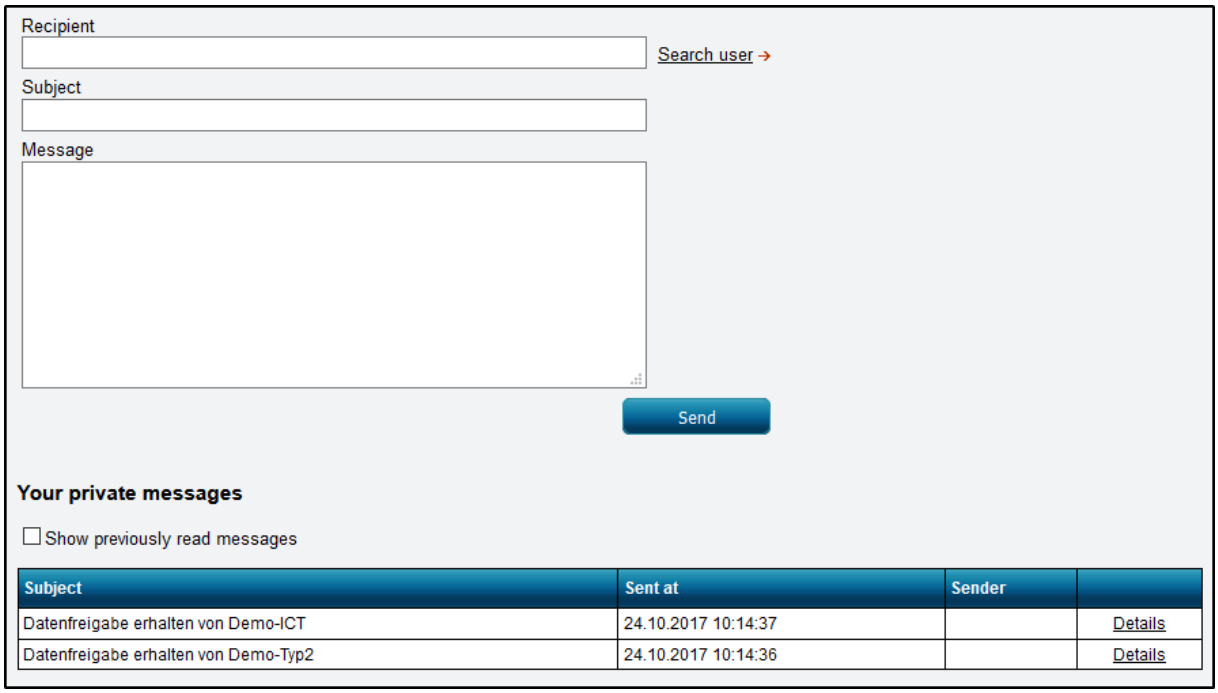
Here, you can make various settings how your personal SiDiary-Online should look like/work. You will also find settings options for the diary and the statistics.

12.2 Invitations



If you want to share your data with a person you trust and this person does not have an account at SiDiary-Online yet, you can send an invitation from the system here. You can also define, if this person should be able to see your data directly after accepting the invitation.

12.3 Messages

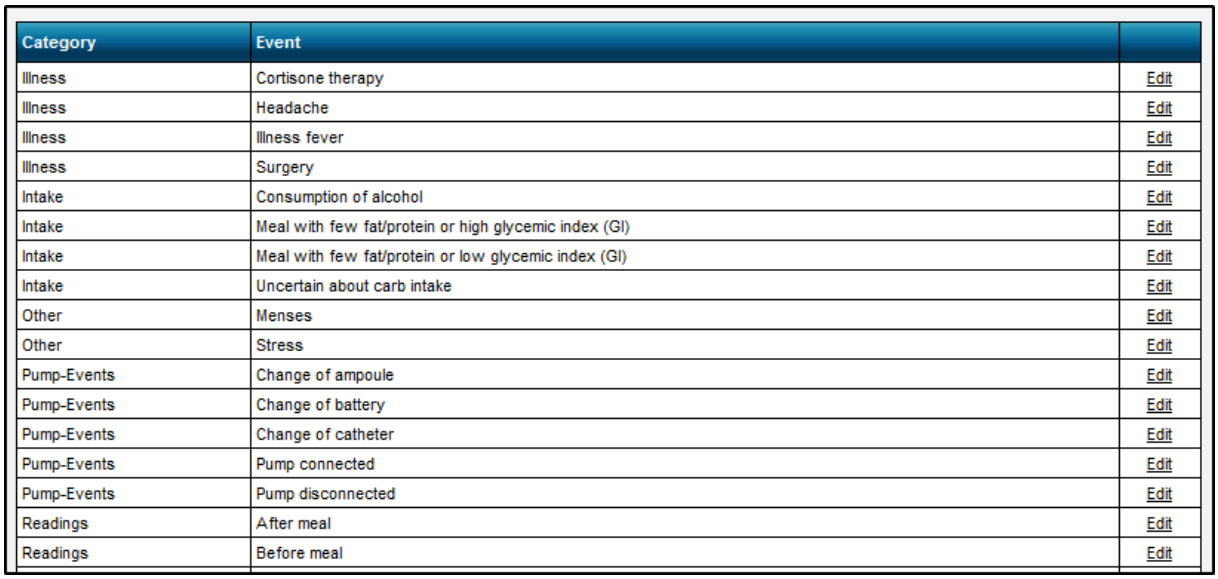


In this section you can write messages to other users of SiDiary-Online. They will receive a notification by email (if they have not deactivated this option in their user profile) and will also see it on the start page when logging in to SiDiary-Online.

12.4 Data types

This is the same function that was explained in chapter 6.6.

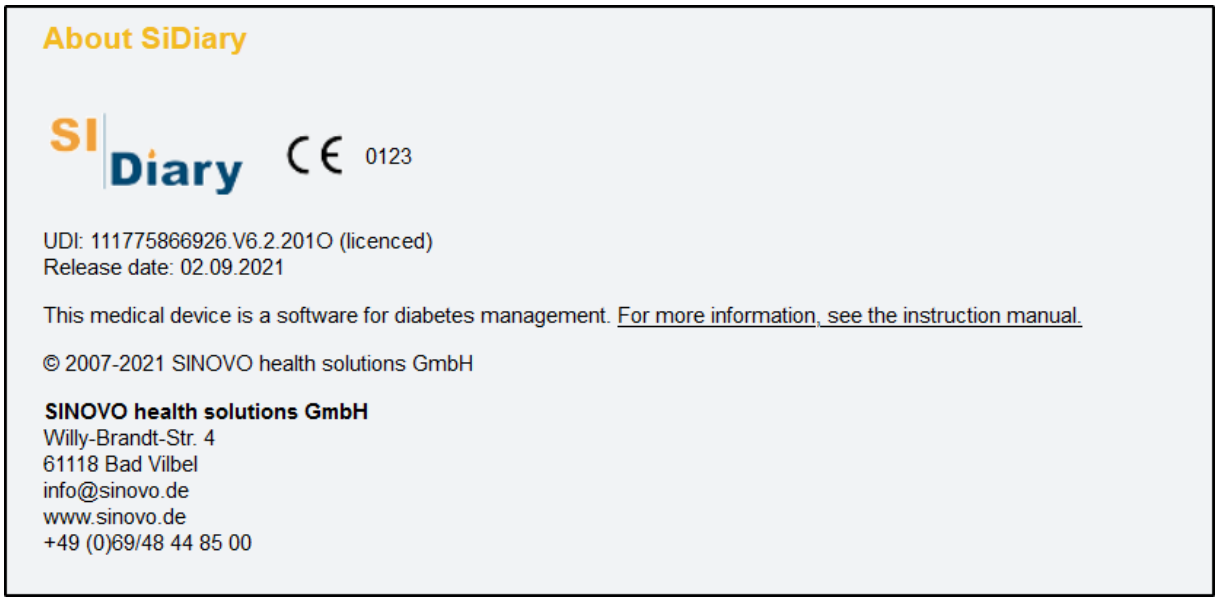
12.5 Events



Category	Event	
Illness	Cortisone therapy	Edit
Illness	Headache	Edit
Illness	Illness fever	Edit
Illness	Surgery	Edit
Intake	Consumption of alcohol	Edit
Intake	Meal with few fat/protein or high glycemic index (GI)	Edit
Intake	Meal with few fat/protein or low glycemic index (GI)	Edit
Intake	Uncertain about carb intake	Edit
Other	Menses	Edit
Other	Stress	Edit
Pump-Events	Change of ampoule	Edit
Pump-Events	Change of battery	Edit
Pump-Events	Change of catheter	Edit
Pump-Events	Pump connected	Edit
Pump-Events	Pump disconnected	Edit
Readings	After meal	Edit
Readings	Before meal	Edit

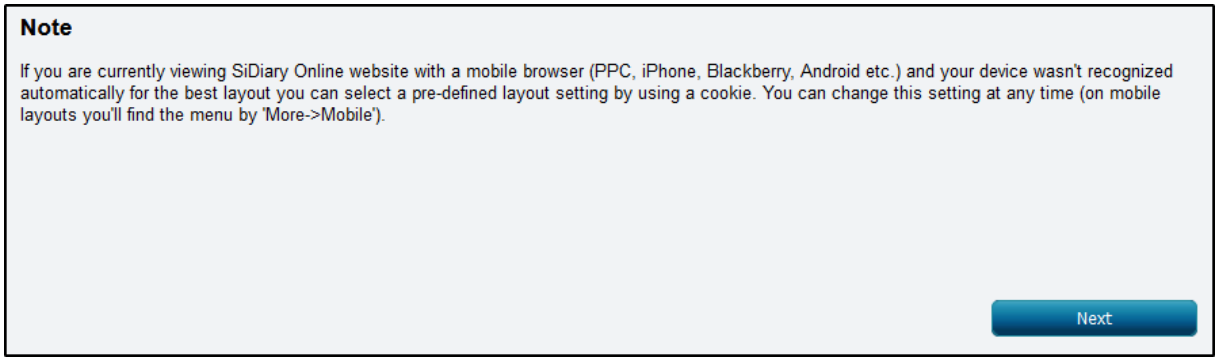
Here you can define events with which you can mark a certain column in the logbook.

12.6 About



Which version of SiDiary-Online you are currently using and when it was released by us can always be found under this menu item.

13 Mobile



This menu item is mainly for use on a mobile device (smartphone/tablet). If your mobile browser is not automatically detected, so that SiDiary-Online switches to a view optimized for mobile browsers, you can do that yourself here by simply tapping on "Next”.

14 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

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