

myDiabby

HEALTHCARE

Remote monitoring software for diabetes management



Instruction for use
Patient

Notice applicable from version 2.7.6 of the medical device



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Please read this entire instruction for use carefully before using myDiabby Healthcare, as it contains information relevant to the understanding and use of the software.

This instruction for use is available and downloadable online, you can store it on your device (computer, smartphone, tablet).

You may wish to keep a copy of this instruction for use, as you may need to refer to it later.

Technical support is available to assist you in using myDiabby Healthcare:

If you have any questions regarding the use of myDiabby Healthcare, please contact the technical support team by email at support@mydiabby.com or by phone at + 33 1 76 40 01 78 (France) or +32 2 320 11 96 (Belgium) (Mon-Fri 09:00-17:00, excluding public holidays). An online help centre is also available at <https://help.mydiabby.com>.

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1. Indications

1.1.Intended purpose

myDiabby Healthcare is designed to remotely monitor the blood glucose status of diabetic patients and inform their medical team of abnormal blood glucose levels to enable rapid patient management.

1.2.Indications

myDiabby Healthcare is indicated for the remote monitoring of adult and paediatric patients with type 1 or type 2 diabetes and patients with gestational diabetes.

1.3.Contraindications

The use of myDiabby Healthcare is contraindicated in the following cases:

When the patient or caregiver is physically or psychologically unable to use myDiabby Healthcare as determined by the medical professional wishing to include the patient in a remote monitoring project.

1.4.User groups intended to use the device

The myDiabby Healthcare software is intended to be used:

- By adult and paediatric patients with type 1 or type 2 diabetes and patients with gestational diabetes.
- By caregiver of patients with type 1 or type 2 diabetes and patients with gestational diabetes.
- By health professionals familiar with diabetes management.

2. Clinical benefit

myDiabby Healthcare enables close monitoring with medical teams, improves patient self-monitoring with increased commitment and compliance as part of overall diabetes management.

3. Principal of operation

myDiabby Healthcare consists of a patient portal and a health professional portal. The patient's monitoring and treatment data collected in the patient portal are analysed against

the parameters set by the healthcare professional on the platform to trigger the defined alerts when the patient's blood glucose results exceed the thresholds.

3.1.Features

myDiabby Healthcare offers the following features:

- **A patient portal:** accessible from the "myDiabby" mobile application downloadable from the Apple and Android smartphone stores (AppStore & Google Play Store) and from an internet browser in their web application version.

The patient portal offers:

> A digital diabetes logbook that captures monitoring data such as blood glucose levels, insulin doses and oral treatments, meal content, physical activity, weight, HbA1c, blood pressure and any other information relevant to understanding the disease.

> A connection to diabetes monitoring and treatment devices for easy data entry into the myDiabby Healthcare application, such as capillary blood glucose meters, continuous glucose monitors, insulin pumps or any other type of device used in the management of diabetes. All login information can be found at <https://help.mydiabby.com>

> Statistical visualisation of patient data trends for a better understanding of the patient's pathology.

> Access to the goals set by the medical team as well as the treatment adjustments recommended by the team. *(Optional, only for patients attached to a healthcare team on myDiabby Healthcare).*

> Sharing of documents and prescriptions with the medical team in charge of monitoring the patient's diabetes. *(Optional, only for patients attached to a healthcare team on myDiabby Healthcare).*

> Secure messaging with the patient's healthcare team(s) on myDiabby Healthcare *(optional, only for patients attached to a healthcare team on myDiabby Healthcare).*

> A library of therapeutic education materials and information on everyday diabetes, customisable by the patient's healthcare team on myDiabby Healthcare *(optional, only for patients attached to a healthcare team on myDiabby Healthcare).*

> The history of past and future medical procedures related to diabetes management.

> A remote consultation module enabling patients to carry out remote consultations with their healthcare team attached to myDiabby Healthcare(*optional, only for patients attached to a healthcare team on myDiabby Healthcare*).

- **A health professional portal:** accessible from an Internet browser in their web application version.

The health professional portal offers:

> Access to the list of patients monitored with myDiabby Healthcare, which are attached to the healthcare team.

> Access to all the diabetes monitoring data entered by the patient (manually or automatically transferred) on myDiabby Healthcare.

> Statistical visualisation in "AGP model", weekly or blood glucose logbook format, allowing for easy interpretation of the monitoring results and trends of the diabetic patient.

> The setting of targets and objectives specific to each patient.

> Alerts that can be customised by the health professional in order to be alerted to patients whose data entered or transmitted using a connected object on the platform exceeds the set alert thresholds.

> A patient medical record to gather clinical and contextual information relevant to the patient's care.

> A "Treatment" tab allowing the health professional to propose treatment adjustment recommendations to the patient, and to follow the history of these modifications.

> A "Consultations" tab to track the history of past and future medical procedures in the context of the management of the diabetic patient.

> A coordination tool enabling several health professionals and/or institutions to be involved in the management of a patient, thanks to shared access to the patient file on myDiabby Healthcare.

> A secure messaging system for communicating with the patient and/or other health professionals attached to the patient medical record on myDiabby Healthcare.

> A remote consultation module enabling the health professional to carry out remote video consultations with the patients attached to him/her on myDiabby Healthcare.

> The creation of reports on patient data over a chosen period.

> A statistics module for the cohort of patients followed by the health professional.

- **Software to be installed locally on a computer (Windows or Mac) "myDiabby Uploader"**: for patients and health professionals, this software allows data to be uploaded from certain blood glucose meters or monitors and insulin pumps by cable transfer, in order to send them to the myDiabby Healthcare software. To download and install this software, please visit <https://mydiabby.com/uploader> and follow the instructions.

Note: The 3 portals described above are all connected in real time via the internet to the myDiabby Healthcare cloud, allowing for immediate communication and sharing of data between user accounts on different media and between patient and health professional accounts connected to myDiabby Healthcare.

Note: For instructions on how to connect and upload data from various medical devices to the myDiabby Healthcare platform, please refer to help.mydiabby.com which lists the procedures for connecting each device to the platform.

3.2. Technical support

If you have any questions regarding the use of myDiabby Healthcare, please contact the technical support by telephone on +33 1 76 40 01 78 (France) or +32 2 320 11 96 (Belgium) (Mon-Fri 9am to 5pm) or by email on support@mydiabby.com

An online help center is also available on help.mydiabby.com

For health professionals with access to the myDiabby Health professional portal, technical support is available by chat from Monday to Friday from 9am to 6pm (5pm on Fridays) by clicking on the "Support" button at the bottom right of the screen.

3.3. Devices that can be connected or downloaded to myDiabby Healthcare

The myDiabby Healthcare software supports data from the following devices:

Type of device	Manufacturer	Model	Type of data sharing
Lecteur de glycémie capillaire	Fora	Diamond Mini	Bluetooth on mobile app

Lecteur de glycémie capillaire	Lifescan	OneTouch Verio Flex	Bluetooth on mobile app1 + via API of OneTouch Reveal app
Lecteur de glycémie capillaire	Lifescan	OneTouch Verio Reflect	Bluetooth on mobile app1 + via API of OneTouch Reveal app
Lecteur de glycémie capillaire	Lifescan	OneTouch Ultra Plus Reflect2	Bluetooth on mobile app1
Lecteur de glycémie capillaire	Ascensia	Contour next One	Bluetooth on mobile app
Lecteur de glycémie capillaire	Ascensia	Contour next	Bluetooth on mobile app
Lecteur de glycémie capillaire	Roche	Accu-chek Guide	Bluetooth on mobile app
Lecteur de glycémie capillaire	Roche	Accu-chek Mobile	Bluetooth on mobile app
Lecteur de glycémie capillaire	Dinno Santé	Dinno Premier CareSens N	Bluetooth on mobile app
Lecteur de glycémie capillaire	Ypsomed	mylife Unio Neva	Via API of the mylife app
Capteur de glycémie en continu	Abbott	FreeStyle Libre	Wired to Android smartphone, Wired to myDiabby Uploader, CSV data file import
Capteur de glycémie en	Abbott	FreeStyle Libre 2	Import of CSV data file
Capteur de glycémie en	Medtronic	Enlite	Via Contour next link 2.4 in USB connector on myDiabby Uploader
Capteur de glycémie en	Dexcom	G4	Via Dexcom Clarity API
Capteur de glycémie en	Dexcom	G5	Via Dexcom Clarity API
Capteur de glycémie en continu	Dexcom	G6	Via Dexcom Clarity API, Wired via Tandem t:slim X2 pump on myDiabby Uploader
Pompe à insuline	Medtronic	523	Via Contour next link meter in USB on myDiabby Uploader
Pompe à insuline	Medtronic	723	Via Contour next link meter in USB on myDiabby Uploader
Pompe à insuline	Medtronic	Veo	Via Contour next link meter in USB on myDiabby Uploader
Pompe à insuline	Medtronic	530G	Via Contour next link meter in USB on myDiabby Uploader

Pompe à insuline	Medtronic	630G	Via Contour next link 2.4 meter in USB on myDiabby Uploader
Pompe à insuline	Medtronic	640G	Via Contour next link 2.4 meter in USB on myDiabby Uploader
Pompe à insuline	Medtronic	670G	Via Contour next link 2.4 meter in USB on myDiabby Uploader
Pompe à insuline	Insulet	Omnipod	Wired to Android smartphone, Wired to myDiabby Uploader
Pompe à insuline	Insulet	Omnipod Dash	Wired to Android smartphone, Wired to myDiabby Uploader
Pompe à insuline	Tandem	t:slim X2	Wired to Android smartphone, Wired to myDiabby Uploader
Pompe à insuline	Ypsomed	Ypsopump	Via API of the mylife app
Stylo à insuline	Novo	NovoPen 6	NFC on smartphone (wireless)
Stylo à insuline	Novo	NovoPen Echo Plus	NFC on smartphone (wireless)

¹The Lifescan OneTouch Verio Reflect and OneTouch Verio Reflect / Ultra Plus Reflect meters require a minimum version of iOS 13 to work with Bluetooth on Apple devices.

²The Lifescan One Touch Ultra Plus Reflect meter is only available in Belgium.

4. Prerequisites before use and instructions for use

4.1. Prerequisites

- myDiabby Healthcare is a software accessible from the internet, please ensure you have an internet connection to use it.
- The use of myDiabby Healthcare software requires mastery of basic computer functions (internet browsing, reading and interpreting information, connecting wired and/or wireless devices).
- Before using myDiabby Healthcare, please ensure that you are trying to access the software from a minimum version included in the table below. The software is browser based for patients and health professionals, only patients can access myDiabby Healthcare with a mobile application on a smartphone :

S U P P O R T	Minimum system version
i O S	iOS 11

A n d r o p p r i e n t i o b i e a p p r i c a t i o n	4.4
U p d a t e r o f f i c i a l W i n d o w s	Windows 8.1

U p l o a d e r f o r M a c O S	MacOS 10.14
P a t i e n t s W e b a p p	Chrome 48, Edge 79
W e b A p p P r o s	Chrome 48, Edge 79

- Before sending data from your connected device (capillary blood glucose meter, continuous glucose monitor, insulin pump, connector for insulin pen), please make sure that you have the compatible hardware and software version needed to download the data.

Please see the list of connected objects and their compatibility in section 3.3 above.

4.2. Steps for using the patient portal

4.2.1. Installing and creating the patient account

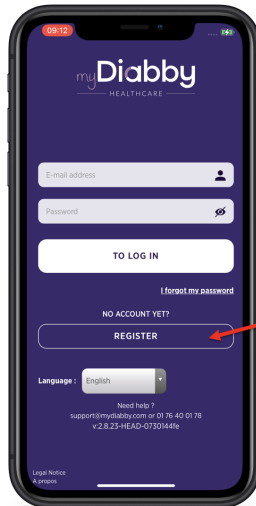
Here are the steps to follow to create an account on the myDiabby Healthcare patient portal:

1. **Download the myDiabby Healthcare mobile app** to your smartphone or tablet (available on iOS and Android)

You can also use myDiabby Healthcare on a computer from www.mydiabby.com in which case you don't have to install anything.



2. When you **open the application for the first time**, you will be taken to this page:

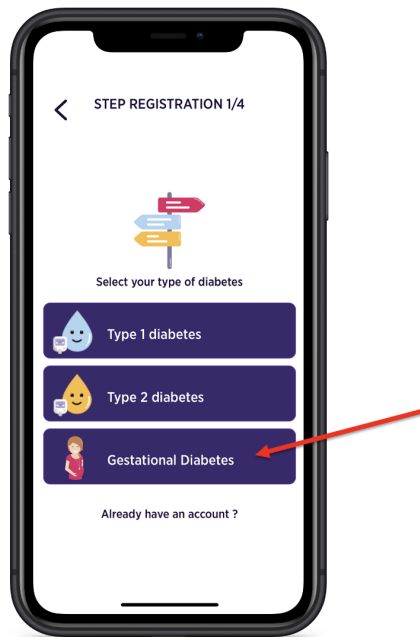


- **If this is your first time using myDiabby Healthcare**, click on "Register".

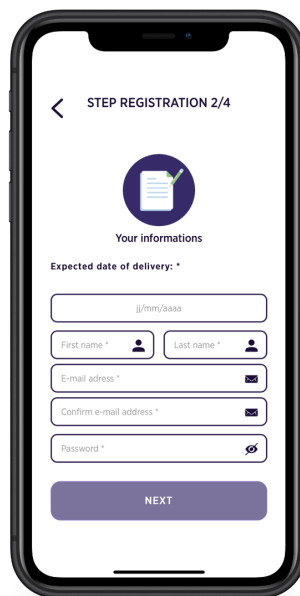
> *If you have already created an account (even on the computer version, or for a previous pregnancy in the case of gestational diabetes), log in directly with your username (email) and the password associated with your account.*

> *If you have forgotten your password, click on "I forgot my password" to create a new one).*

3. **Choose your diabetes type:**



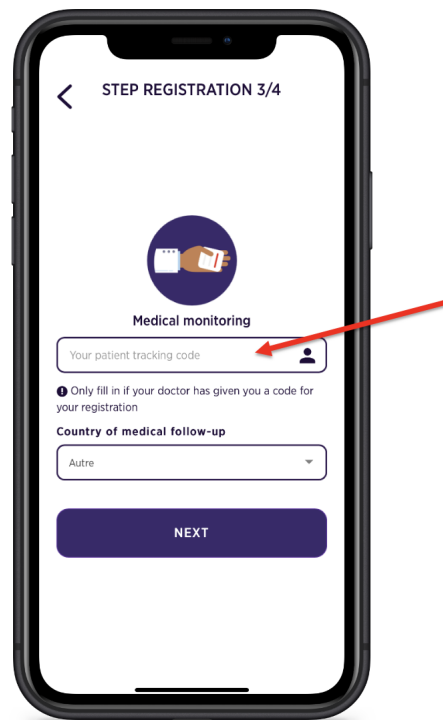
4. Fill in the registration form with your information:



- Your planned delivery date (if gestational diabetes)
- Your gender (if T1 or T2)
- Your first and last name
- Your email address (*twice so as not to make a typo*)

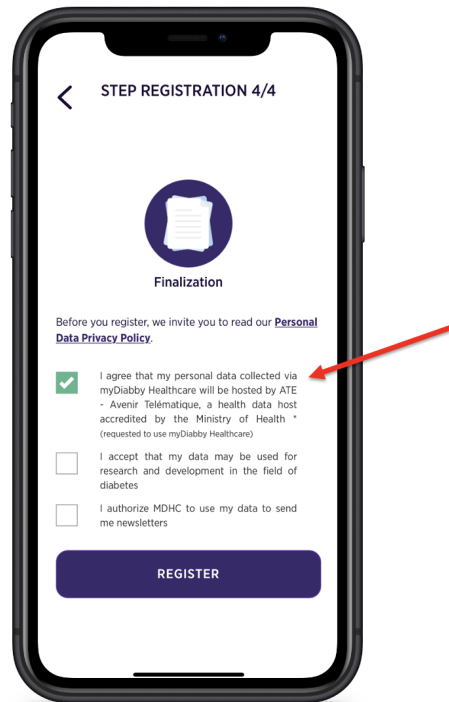
- Create a password (*minimum 10 characters, including upper and lower case and digits for example*)
- Click on the "Next" button

5. To link to your medical team, enter the **tracking code** provided by your medical team. If you have not yet received a code from your medical team, do not fill in this box.

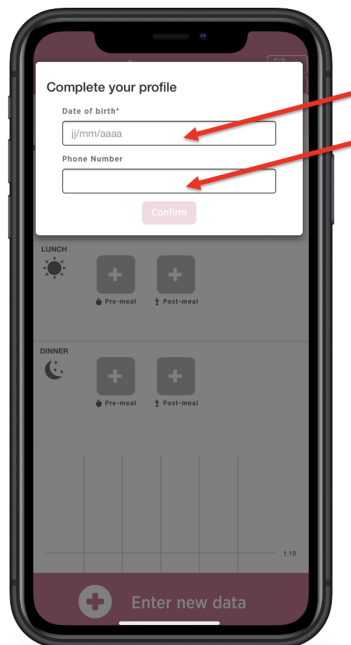


- Indicate the country of your medical monitoring (if you do not have a monitoring code)
- Click on the "Next" button

6. Finalise the creation of the account by agreeing to the storage of your health data on myDiabby Healthcare, then click on the **"Register"** button.



7. **Last step:** Fill in **your date of birth + a telephone** number where your healthcare team can reach you.

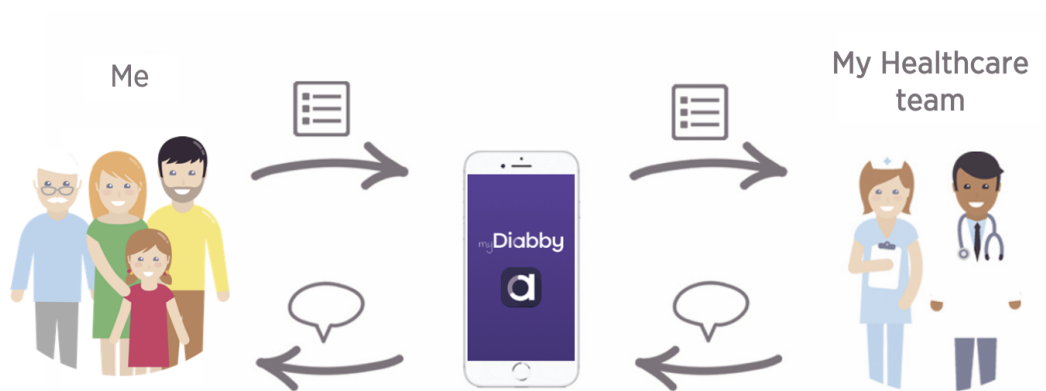


Your myDiabby Healthcare account is now created and you can access your **dashboard**.

4.2.2.Using the patient application for patients with type 1 or type 2 diabetes

The myDiabby Healthcare application is your link to your healthcare team for monitoring your diabetes:

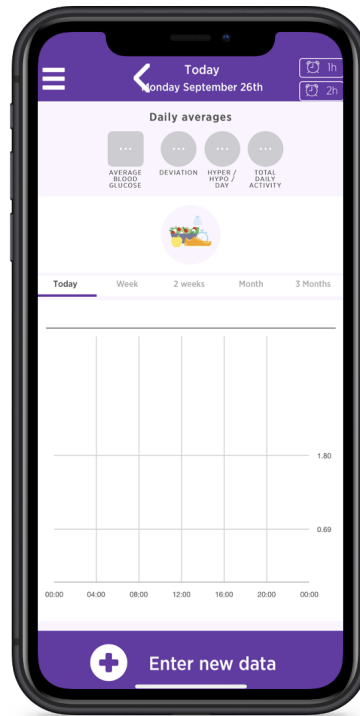
- You **share your results and other data in the application**
- Your **healthcare team can consult them** remotely
- Your healthcare team can therefore **give you advice in the application**



Here's how to use your myDiabby Healthcare application:

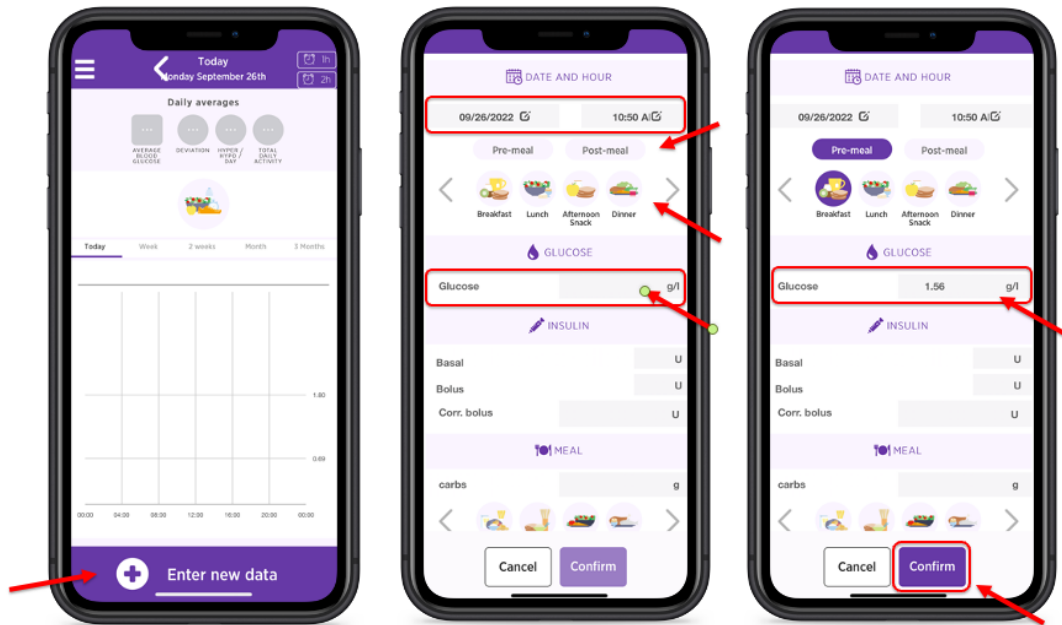
1. When you open the application, you are taken to your dashboard to:

- See your results for the day
- Record your results (or share them automatically from your devices)



2. To record a blood glucose reading, you must:

- Press the [+ Add Data] button
- Check the time and moment of the blood glucose test (*you can change it by pressing on it*)
- Indicate the blood glucose value
- Confirm

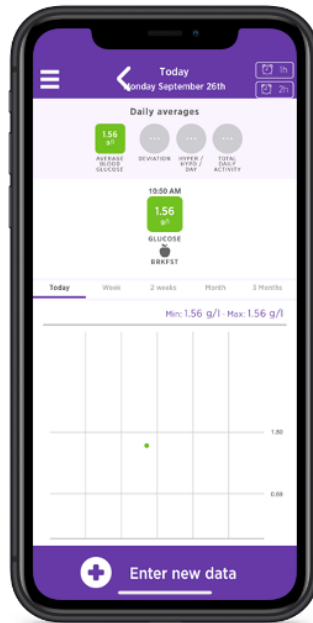


3. Once you have confirmed, your result appears on the dashboard:

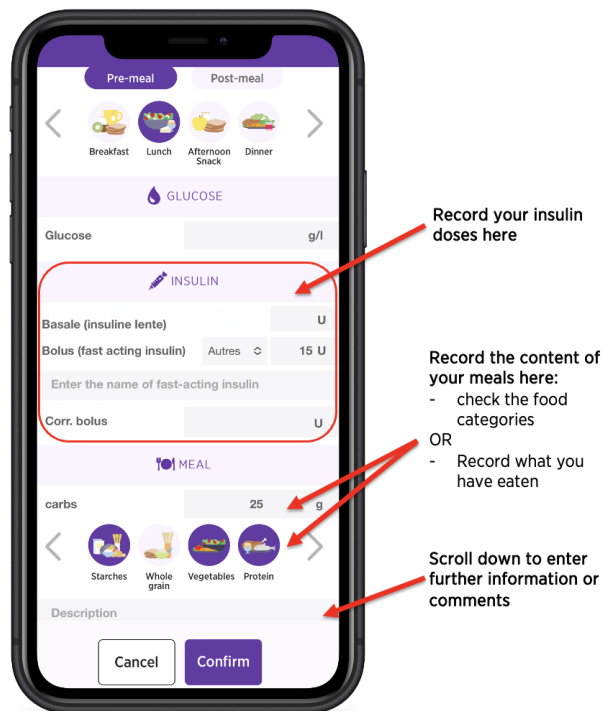
The **colour of the blood glucose level** tells you whether you are within the ideal target set by your healthcare team:

- Blue = Hypoglycaemia (too low)
- Green = OK 👍 !
- Yellow = A little too high
- Red = Too high

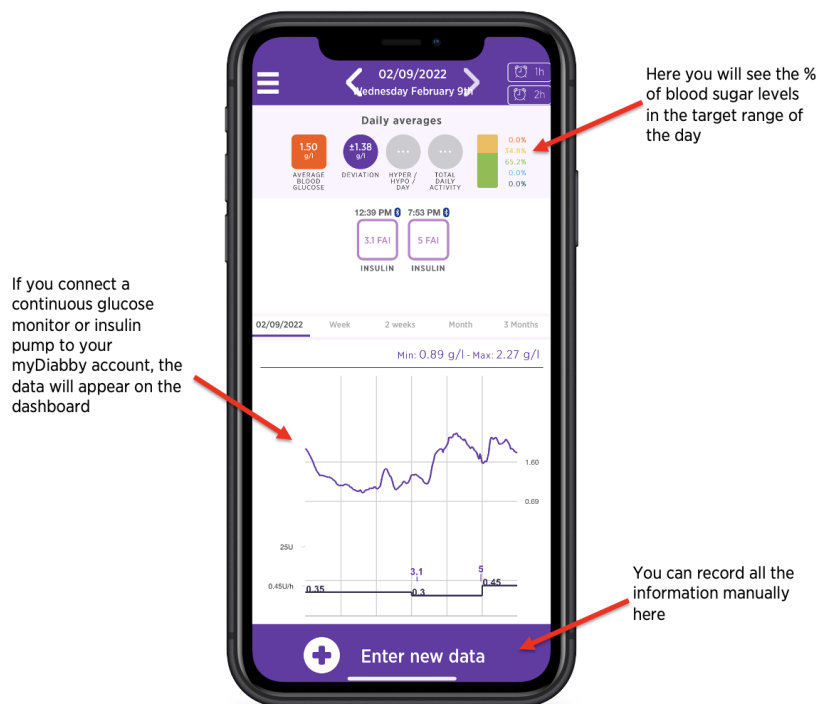
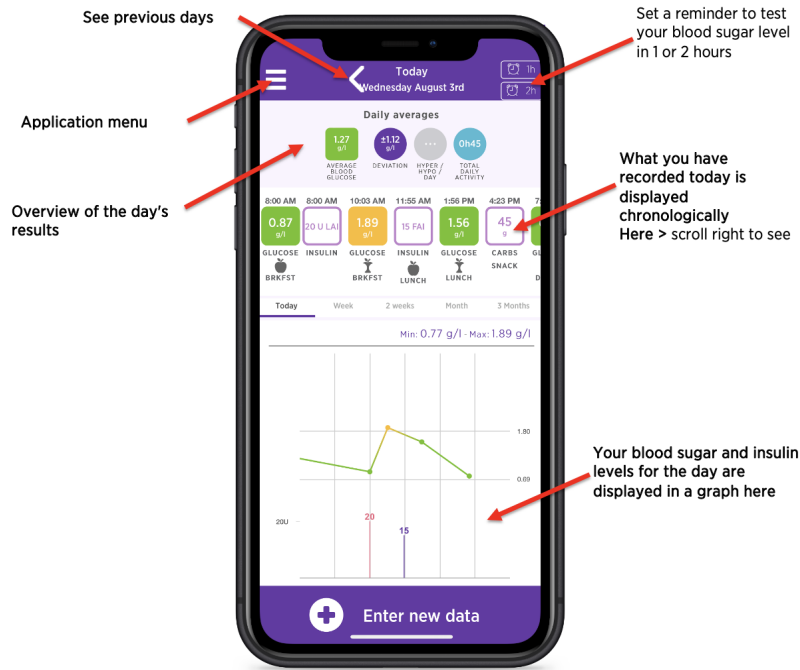
Your healthcare team can see your results directly on myDiabby Healthcare and can adapt your medical monitoring accordingly.



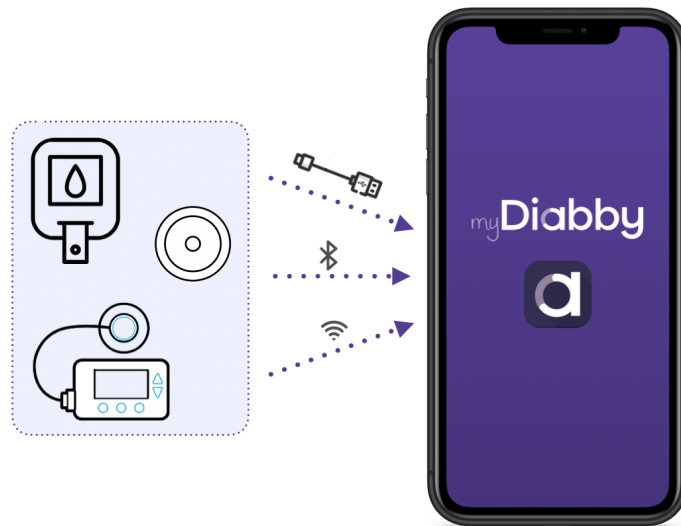
4. You can also write down other monitoring information such as your insulin doses, the contents of your meals, your physical activity, remarks, etc., if your healthcare team has asked you to do so:



5. Here are some tips from the dashboard:



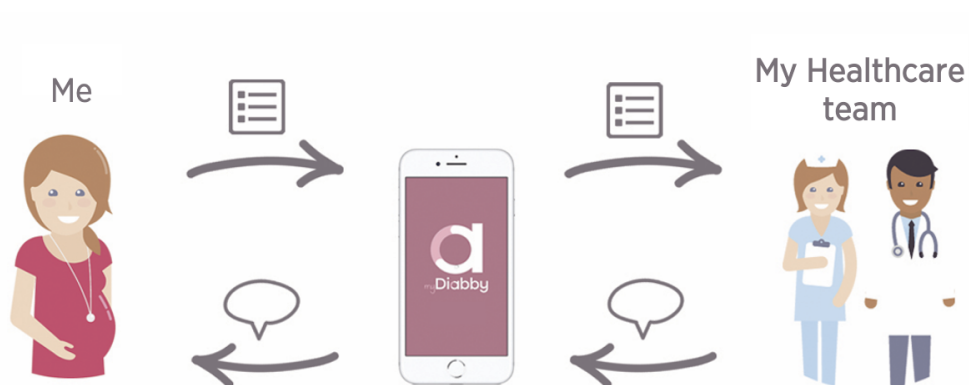
To connect your medical devices to myDiabby Healthcare and automatically send your results to the application, follow the explanations available on help.mydiabby.com (To help you, you will also find connection tutorials in the "My connected devices" section of your patient access).



4.2.3. Using the patient application for patients with gestational diabetes

The myDiabby Healthcare application is your link to your healthcare team for monitoring your gestational diabetes:

- You **record your blood glucose results and other data in the application**
- Your **healthcare team can consult them** remotely
- Your healthcare team can therefore **give you advice in the application**

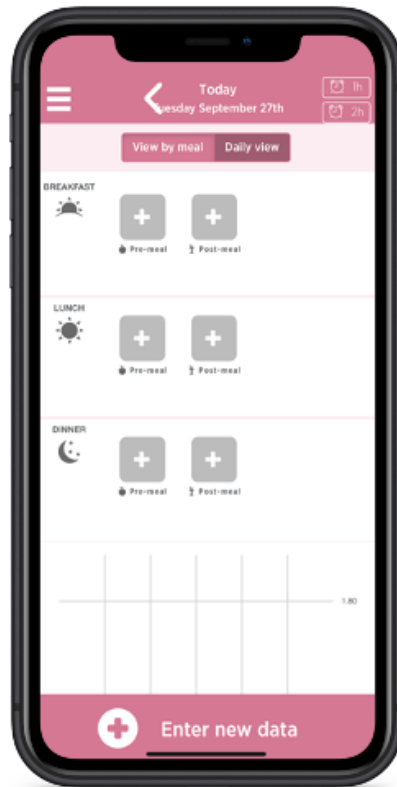


Here's how to use your myDiabby Healthcare application:

1. When you open the application, you are taken to your dashboard to:

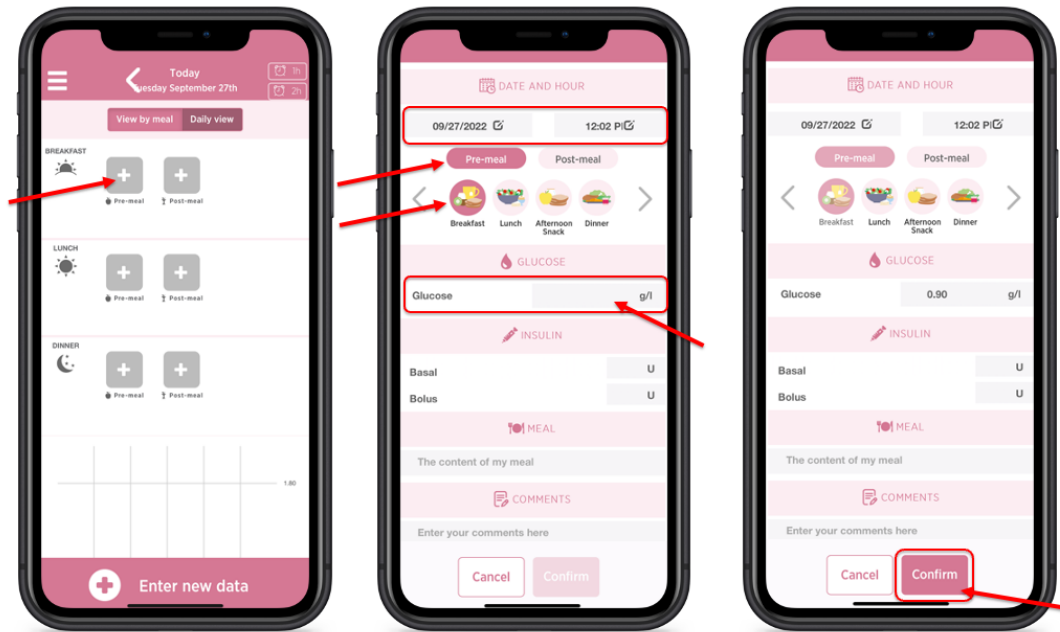
- See your results for the day

- Record your results



2. To record a blood glucose level, you must:

- **Press the [+] button** corresponding to the **time of the test** (here: Breakfast BEFORE meal)
- **Check the blood glucose test time** (*you can change the time by pressing on it*)
- **Record the blood glucose level**
- **Confirm**

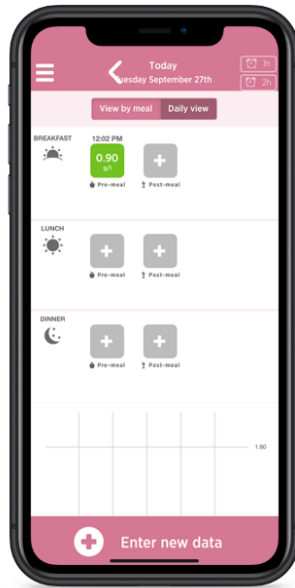


3. Once you have confirmed, your result appears on the dashboard:

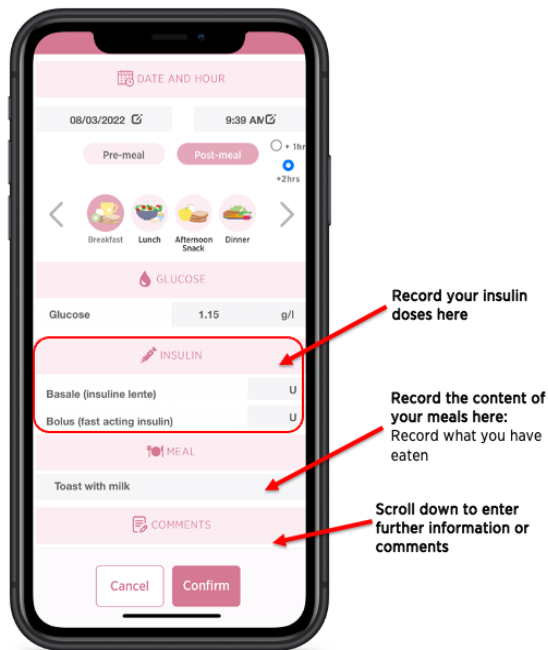
The **colour of the blood glucose level** tells you whether you are within the ideal target set by your medical team:

- Blue = Hypoglycaemia (too low)
- Green = OK 👍 !
- Yellow = A little too high
- Red = Too high

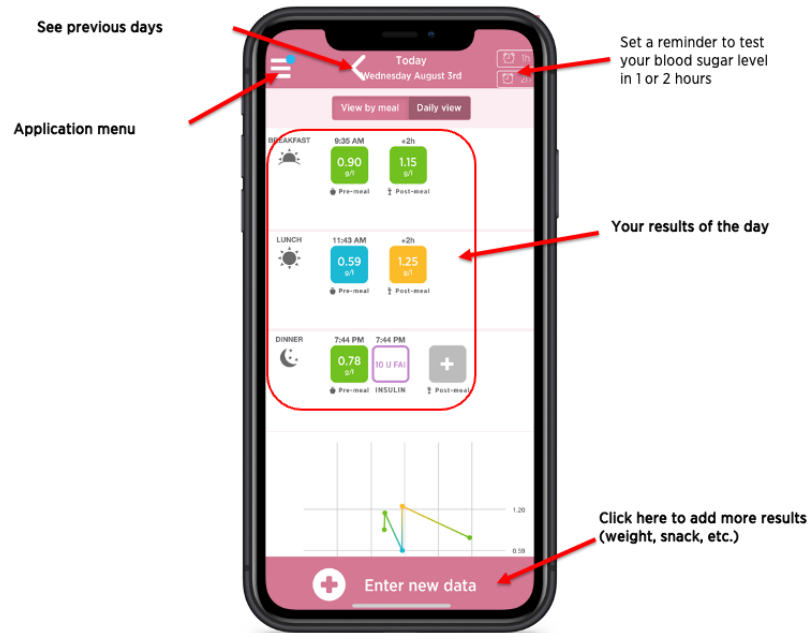
Your healthcare team can see your results directly on myDiabby Healthcare and can adapt your medical monitoring accordingly.



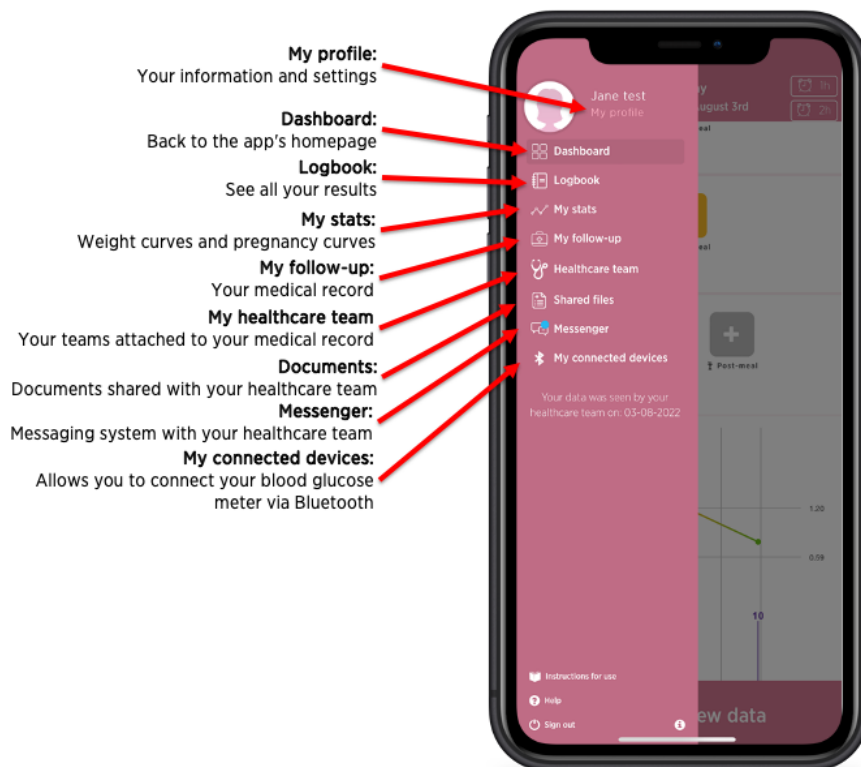
4. You can also record other monitoring information, such as your **insulin** doses, or the **contents of your meals** if your healthcare team has asked you to do so:



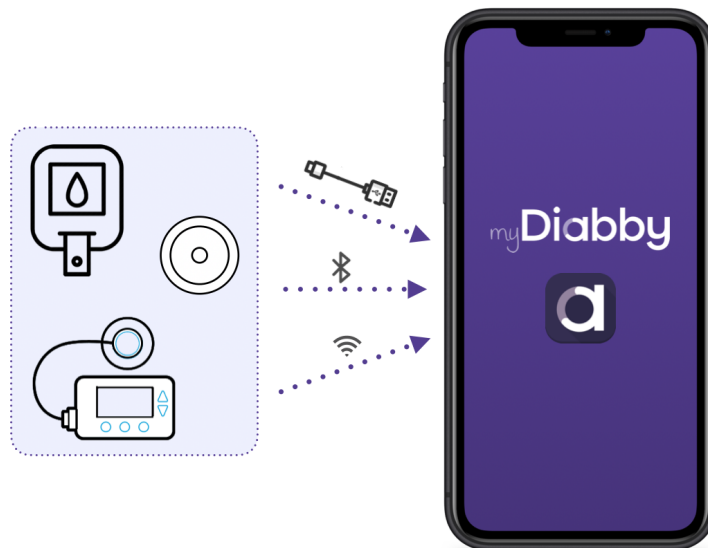
5. Here are some tips from the dashboard:



6. These are the tools you will find in the application menu



To connect your medical devices to myDiabby Healthcare and automatically send your results to the application, follow the explanations available on help.mydiabby.com (To help you, you will also find connection tutorials in the "My connected devices" section of your patient access).



4.3. Exporting data from a myDiabby Healthcare account

From your patient account, it is possible to export all data associated with the account in .csv format. To do so :

Click on "My profile" and then "Export data in CSV format". You can then choose the data you wish to export:

- Blood glucose, insulin and ad hoc data
- Patient information

The CSV files are organised as follows:

CSV "Patient informations"

Colum	Heading	Details
A	email	Email address used as a login to myDiabby Healthcare
B	title	Title used: Mr or Mrs.
C	firstname	1st given name at birth
D	lastname	Birth name
E	maidenna me	Maiden name
F	address1	1st line of the postal address
G	address2	2nd line of the postal address
H	cp	Postal code of the mailing address
I	city	City of the patient's postal address

J	nirpp	Social security number French
K	country	Country of the patient's postal address
L	timezone	Patient's time zone
M	birthday	Date of birth
N	phone	Phone number
O	gender	Sex
P	pathology	Pathology

CSV "Blood glucose, insulin and occasional data"

Colum	Heading	Details
A	date	Date of the event (YYYY-MM-DD)
B	time	Hour of the event (HH:MM)
C	glycemia (g/l)	Blood glucose value
D	post-prandial	If the event is a capillary blood glucose selected as postprandial, this column contains the value 1. Otherwise, no value.
E	type meal	If the event is a capillary blood glucose level associated with a meal, this column specifies the meal: 0 for breakfast, 1 for lunch, 2 for dinner, 3 for morning snack, 4 for bedtime, 5 for night, 6 for snack
F	device	Serial number of the device from which the data was taken
G	bolus	If the event is a non-automatic bolus, this column contains the value of the bolus in units (U)
H	bolus corr	If the event is a corrective bolus, this column contains the value of the corrective bolus in units (U)
I	bolus auto	If the event is an automatic bolus, this column contains the value of the automatic bolus in units (U)
J	basal	If the event is a basal, this column contains the value of the basal in units (U)
K	basal rate (U/h)	If the event is a basal, this column contains the value of the basal in units (U/h)
L	pump events	Pump event: error messages or alarms recovered
M	control IQ	If the event is a control IQ event, this column contains the mode change (ON / OFF / Sleep / Exercise / End Sleep / End Exercise)
N	weight(kg)	Weight in Kg
O	hba1c(%)	glycated haemoglobin or HbA1c in %.

P	ketones(mmol/l)	Ketones in mmol/l
Q	bloodpres sure systolic(m mHg)	Systolic blood pressure in mmHg
R	bloodpres sure diastolic(mmHg)	Diastolic blood pressure in mmHg
S	carb	If the event is a meal period, this column contains the carbohydrate value in g
T	meal list	If the event is a meal period, this column contains the list of meal items ticked by the patient and associated with the event
U	meal descriptio	If the event is a meal period, this column contains the description of the meal entered by the patient
V	sport duration	If the event is a period of physical activity, this column contains the duration of this activity (HH:MM)
W	sport footstep	If the event is a period of physical activity, this column contains the number of steps
X	sport list	If the event is a period of physical activity, this column contains the list of activities ticked by the patient
Y	sport descriptio	If the event is a period of physical activity, this column contains the description of the physical activity entered by the patient
Z	context list	If the event is a context, this column contains the type of context: Stress (stress), Disease (disease), Allergy (allergy), Event (event), Medication (pharma)
AA	context descriptio	If the event is a context this column contains the free text entered

5. Warnings and precautions

This user instruction for use contains examples of screens. The actual screens of the software and applications may differ slightly.

Warnings

- This software is designed to be used by a healthcare professional familiar with diabetes management.

- This device requires a minimum mastery of basic computer functions (office automation, internet browsing, use of mobile applications for patients)
- **The results obtained do not constitute medical advice and should not, under any circumstances, be considered as such.** Never adapt your treatment solely on the basis of the data from myDiabby Healthcare, but refer to the treatment recommendations of your medical team
- **myDiabby Healthcare is not an emergency device, please consult a healthcare professional if you experience unusual symptoms or an emergency situation**
- Interference with other software can disrupt the sending of data from connected objects when using the myDiabby Uploader. Make sure you do not have any other data transfer software installed on your computer, if you are transferring data from a device (monitor or pump) by cable.
- Informed consent should be obtained from the patient before registering their personal information and health data on the myDiabby Healthcare platform. The patient must agree to a consent form when they are first attached to a medical team.
- Access codes for access to myDiabby Healthcare are strictly personal and confidential. They must not be communicated or shared with a third party
- The follow up code is strictly confidential and can only be transmitted to the patient directly by the referring health professional.
- The accuracy of the medical device is conditional on the regular completion and/or submission of patient data to the myDiabby Healthcare software. This frequency is defined by the referring health professional.
- The performance of the medical device depends on the correct management and interpretation by the healthcare professional of the alerts issued by myDiabby Healthcare. Failure to manage or mismanagement of the alert would be detrimental to the patient.
- In the event of a malfunction of myDiabby Healthcare (impossible to access the software, inability to transfer data from your connected device, incorrect information/data, etc.), contact myDiabby support by e-mail at support@mydiabby.com or by telephone on +33 1 76 40 01 78.

6. Side effects

No side effects have been detected with the use of myDiabby Healthcare.

Any serious incident related to the device should be reported to MDHC at qualite@mydiabby.com. You can also report any event to the health authorities on the dedicated website :

<https://solidarites-sante.gouv.fr/soins-etmaladies/signalement-sante-gouv-fr/>.

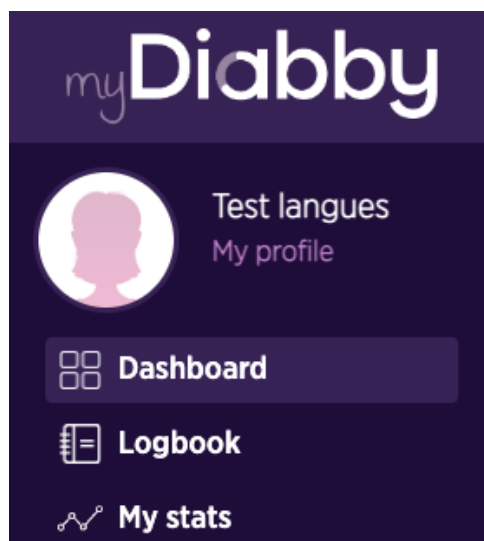
7. Removal

7.1. Deleting the user account (from version 2.7.10)

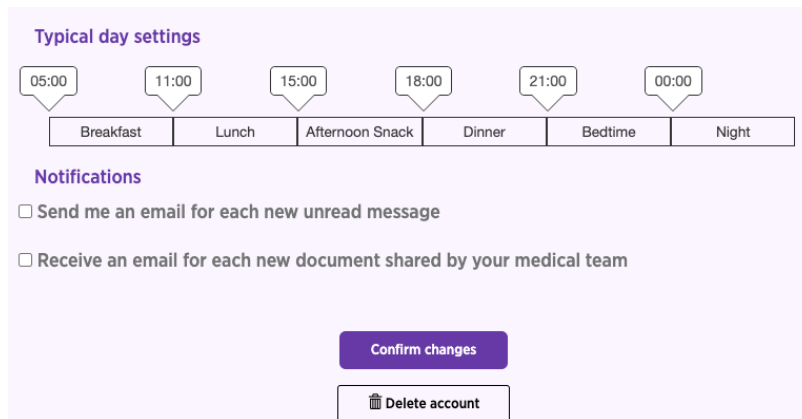
7.1.1. Patients

To delete a user account on myDiabby Healthcare:

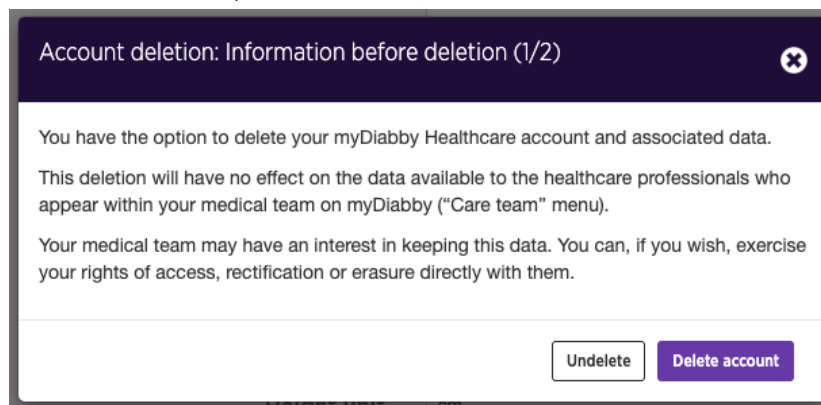
1. If you are under the care of a healthcare team, be sure to confirm with them that you can delete your user account.
2. Once you have agreed with your medical team to stop using myDiabby Healthcare, you can start the process of deleting your user account:
 - a. Go to your myDiabby account, "**My Profile**" menu



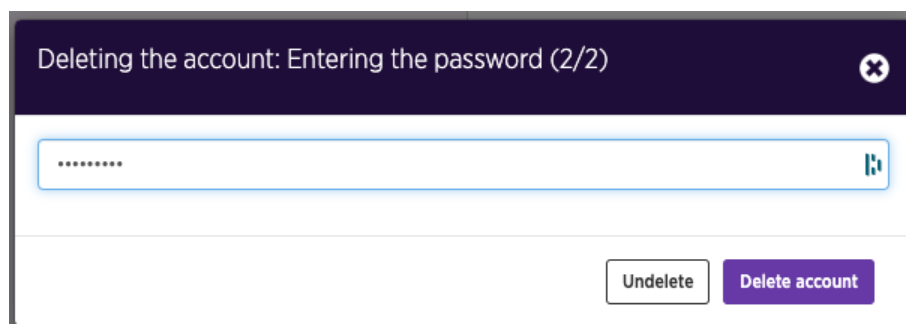
- b. Click or type Select "**Delete Account**".



- c. A pop-up window will appear detailing the consequences of deleting your myDiabby Healthcare account. If you wish to proceed select "**Delete account**", otherwise click on "**Cancel deletion**".



- d. Fill in your **password**, then continue by choosing "**Delete account**".



- e. A **confirmation** that your request for deletion has been processed is displayed on your screen (green banner)
3. A written response will be provided by the technical support team to confirm that your request to delete the account has been taken into account. The deletion may require a maximum of 15 days, which is the time required by the healthcare professional prescribing the device to archive the medical record as part of their legal obligation.

4. Once the file has been archived, you will receive confirmation by email that your data has been permanently deleted.

7.1.2. Healthcare professionals

- Before deleting a user account, be sure to communicate to your active patient feed your intention to stop using myDiabby Healthcare.
- If you leave an institution or healthcare team, please ensure that you transfer the patient records for which you are a referrer on myDiabby Healthcare to another referrer, in agreement with the patients.
- Once these precautions and actions have been taken, contact myDiabby Healthcare technical support at support@mydiabby.com, specifying the reason for your request in the content of the email and the user ID associated with the myDiabby Healthcare account you wish to delete.
- The technical support team will proceed with the anonymisation, then the definitive deletion of the account and associated data after having ensured that the patients monitored are no longer attached to the account that issued the deletion request.

7.2. Uninstalling the application on a smartphone

To uninstall the myDiabby Healthcare application on a Smartphone, long press the application icon and then:

- On Apple devices, by pressing the "Delete app" button and then pressing "Delete".
- On Android devices, by pressing the "Uninstall" button and then pressing "Ok".

All data associated with the application installed on the smartphone is then deleted from the device.

7.3. About your personal data

The privacy and security policy of personal data is available for viewing on the myDiabby Healthcare professional and patient access areas, please view it or click on the links below for more information on how we process your data.

- Link to privacy and security policy of personal data for **Patients**

<https://www.mydiabby.com/politique-donnees-patients>