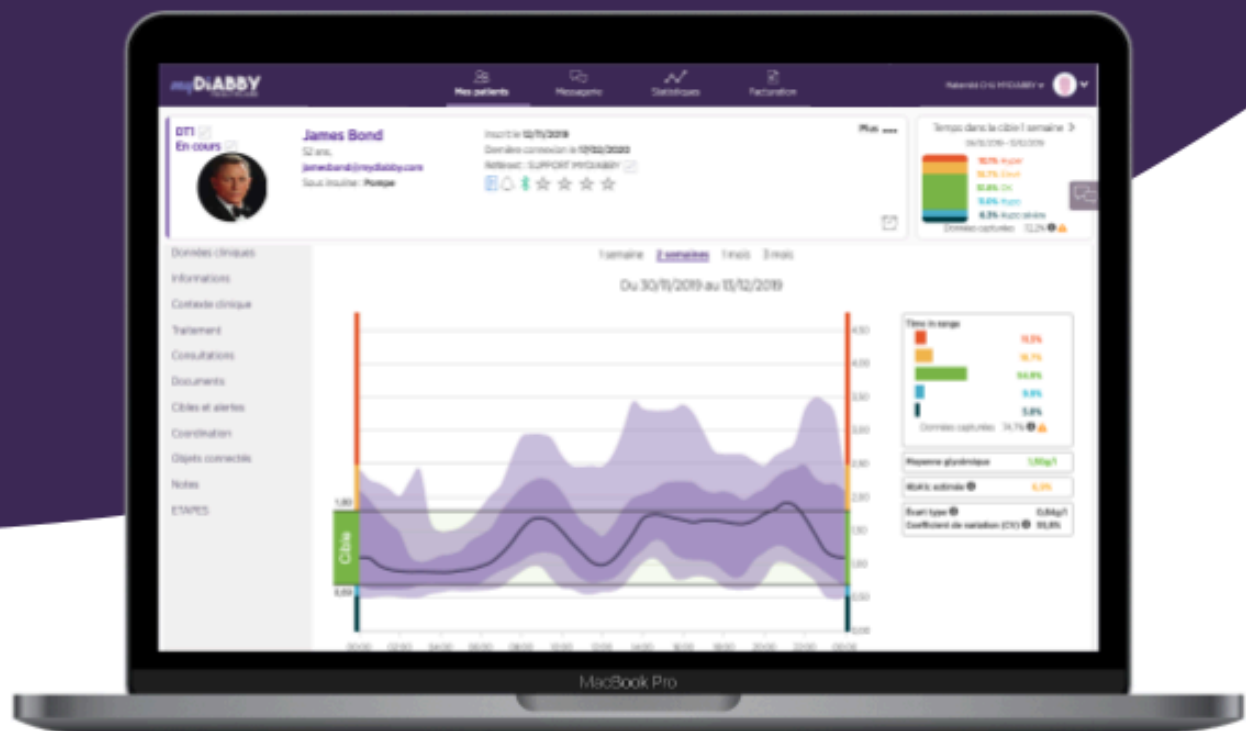


myDiABBY HEALTHCARE

Remote monitoring software for diabetes management



Instruction for use *Healthcare Professionals*

Notice applicable from version 2.24.0 of the medical device

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 in non-emergency situations.

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.
- The patient or carer is physically or mentally unable to use myDiabby Healthcare independently or without the support of a healthcare professional.

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 healthcare professionals familiar with diabetes management.

2. Clinical benefit

myDiabby Healthcare is a device designed for remote patient monitoring in non-emergency situations, with no direct clinical claims.

The expected clinical performance of the myDiabby Healthcare software is the monitoring of patient follow-up and treatment data and the detection of out-of-threshold glycaemic results in order to decide on the need to adapt the patient's management. This decision-making aid for healthcare professionals produces indirect clinical benefits. The direct clinical benefits come from the healthcare professional's adaptation of patient management.

3. Device performance

The technical performance expected of the myDiabby Healthcare device is as follows:

- Collection of monitoring data (blood glucose, insulin dose, oral treatments, meal content, HBA1c, physical activity, weight, patient history, etc.);
- Data transfer
- Data analysis
- Generation of alerts

4. Principal of operation

myDiabby Healthcare consists of a patient portal and a healthcare professional portal.

myDiabby Healthcare enables patients to collect their monitoring and treatment data in their application, either manually or connected to their devices. In the case of monitoring by a medical team, this data is collected at a frequency determined by the healthcare professional in charge of monitoring the patient, and the information recorded on myDiabby Healthcare is accessible to healthcare professionals with access to the patient file.

myDiabby Healthcare enables authorised healthcare professionals to monitor patients by including them in remote monitoring. In this case, the patient monitoring and treatment data collected in the patient portal is analysed against the parameters determined by the healthcare professional on the platform, in order to trigger the alerts defined when the patient's blood glucose results exceed the thresholds.

myDiabby Healthcare can also be used to monitor patients without including them in remote monitoring. In this case, the patient monitoring and treatment data collected in its portal is only made available to the healthcare professionals attached to the file, without generating alerts.

myDiabby Healthcare can also be used independently by patients. The blood glucose data entered by patients in their portal is analysed against thresholds set by default, or customised, in the application to trigger hypoglycaemia and hyperglycaemia alerts (colour-coded) when patients' blood glucose results exceed the thresholds.

4.1. 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, ketones, 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, connector for insulin pen 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 healthcare professional portal:** accessible from an Internet browser in their web application version.

The healthcare 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 personalised by the healthcare professional (only for patients included in remote monitoring or as part of the management of patients with gestational diabetes).
- > A patient medical record to gather clinical and contextual information relevant to the patient's care.
- > A "Treatment" tab allowing the healthcare 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 healthcare 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 healthcare professionals attached to the patient medical record on myDiabby Healthcare.
- > A remote consultation module enabling the healthcare 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 healthcare 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.

4.2. 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 healthcare professionals with access to the myDiabby Healthcare 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.

4.3. 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
Capillary blood glucose meter	Fora	Diamond Mini	Bluetooth on mobile app
Capillary blood glucose meter	Lifescan	OneTouch Verio Flex	Bluetooth on mobile app + via API of OneTouch Reveal app
Capillary blood glucose meter	Lifescan	OneTouch Verio Reflect	Bluetooth on mobile app + via API of OneTouch Reveal app
Capillary blood glucose meter	Lifescan	OneTouch Ultra Plus Reflect1	Bluetooth on mobile app
Capillary blood glucose meter	Ascensia	Contour next One	Bluetooth on mobile app
Capillary blood glucose meter	Ascensia	Contour next	Bluetooth on mobile app
Capillary blood glucose meter	Roche	Accu-chek Guide	Bluetooth on mobile app
Capillary blood glucose meter	Roche	Accu-chek Mobile	Bluetooth on mobile app
Capillary blood glucose meter	Dinno Santé	Dinno Premier CareSens	Bluetooth on mobile app
Capillary blood glucose meter	Ypsomed	mylife Unio Neva	Via API of the mylife app
Capillary blood glucose meter	Menarini	Glucofix® Tech	NFC on smartphone (wireless)
Capillary blood glucose meter	Menarini	Glucofix® Tech 2K	NFC on smartphone (wireless)
Continuous glucose sensor	Abbott	FreeStyle Libre	Wired to Android smartphone, Wired to myDiabby Uploader, CSV data file import Via API LibreView
Continuous glucose sensor	Abbott	FreeStyle Libre 2	Import of CSV data file Via API LibreView
Continuous glucose sensor	Abbott	FreeStyle Libre 3	Import of CSV data file Via API LibreView
Continuous glucose sensor	Medtronic	Enlite	Via Contour next link 2.4 in USB connector on myDiabby Uploader
Continuous glucose sensor	Medtronic	Guardian Sensor 3	Manual or automatic import of CSV data file

Continuous glucose sensor	Medtronic	Guardian Sensor 4	Manual or automatic import of CSV data file
Continuous glucose sensor	Medtrum	CGM TouchCare Nano	Via EasyView API
Continuous glucose sensor	Dexcom	One	Via Dexcom Clarity API
Continuous glucose sensor	Dexcom	G6	Via Dexcom Clarity API, Wired via Tandem t:slim X2 pump on myDiabby Uploader
Insulin pump	Medtronic	523	Via Contour next link meter in USB on myDiabby Uploader
Insulin pump	Medtronic	723	Via Contour next link meter in USB on myDiabby Uploader
Insulin pump	Medtronic	Veo	Via Contour next link meter in USB on myDiabby Uploader
Insulin pump	Medtronic	530G	Via Contour next link meter in USB on myDiabby Uploader
Insulin pump	Medtronic	630G	Via Contour next link 2.4 meter in USB on myDiabby Uploader
Insulin pump	Medtronic	640G	Via Contour next link 2.4 meter in USB on myDiabby Uploader
Insulin pump	Medtronic	670G	Via Contour next link 2.4 meter in USB on myDiabby Uploader
Insulin pump	Medtronic	740G	Manual or automatic import of CSV data file
Insulin pump	Medtronic	780G	Manual or automatic import of CSV data file
Insulin pump	Insulet	Omnipod	Wired to Android smartphone, Wired to myDiabby Uploader
Insulin pump	Insulet	Omnipod Dash	Wired to Android smartphone, Wired to myDiabby Uploader
Insulin pump	Tandem	t:slim X2	Wired to Android smartphone, Wired to myDiabby Uploader
Insulin pump	Ypsomed	Ypsopump	Via API of the mylife app

Insulin pump	Medtrum	TouchCare Nano	Via EasyView API
Insulin pump	Medtrum	TouchCare 300	Via EasyView API
Insulin Pen	Novo nordisk	NovoPen 6	NFC on smartphone (wireless)
Insulin Pen	Novo nordisk	NovoPen Echo Plus	NFC on smartphone (wireless)

¹The Lifescan One Touch Ultra Plus Reflect meter is only available in Belgium.

5. Prerequisites before use and instructions for use

5.1. 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 healthcare professionals, only patients can access myDiabby Healthcare with a mobile application on a smartphone :

Support	Minimum system version
iOS patient mobile application	iOS 15
Android patient mobile application	9.0
Uploader for Windows	Windows 10
Uploader for MacOS	MacOS 10.14
Patients web app	Chrome 48, Edge 79
Web App Pros	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 4.3 above.

5.2. Steps for using the patient portal

You can find all the instructions for using the portal and the patient application in the patient leaflet: <https://www.mydiabby.com/notice-patients>

5.3. Exporting data from a myDiabby Healthcare account

From the 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 to CSV":

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
- Messages

From the professional portal, to export the same data, click on the "Other actions" button and then "Export CSV data".

The CSV files are organised as follows:

CSV "Patient informations"

Column	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	Last name at birth
E	firstnames	First name(s) at birth
F	usedFirstname	First name used
G	usedLastname	Last name used
H	address1	1st line of the postal address
I	address2	2nd line of the postal address
J	cp	Postal code of the mailing address
K	city	City of the patient's postal address
L	nirpp	Social security number French
M	ins	Patient's INS number
N	country	Country of the patient's postal address

O	timezone	Patient's time zone
P	birthday	Date of birth
Q	phone	Phone number
R	gender	Sex
S	pathology	Pathology

CSV "Blood glucose, insulin and occasional data"

Column	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	bloodpressure systolic(mmHg)	Systolic blood pressure in mmHg

R	bloodpressure 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 description	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 description	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 description	If the event is a context this column contains the free text entered

6. Instructions for use of the healthcare professional portal

6.1. Opening of myDiabby Healthcare

Go to <https://app.mydiabby.com/pro/#/login>.

You have two options for logging in:

- Enter your login details (email address and password) to log in to the portal.
- Log in using the Pro Santé Connect service¹.

Note: If you have a myDiabby Healthcare account but have forgotten your password, on the login page, click on "Forgotten my password". Enter your email address used to create the account and confirm. You will receive an email to create a new password.

6.2. Patient registration

1. Whether you are in a medical office, a hospital department, registering patients in a consultation or a workshop, you simply need to give the patient the myDiabby Healthcare [registration flyer](#) when you explain what their monitoring will be. This flyer tells the patient how to register with myDiabby Healthcare.

It also gives them **the tracking code (indicated on the registration flyer)** specific to your medical team to be entered on registration in order to be attached to your team.

2. The patient registers with myDiabby Healthcare at the hospital/medical office or at home.

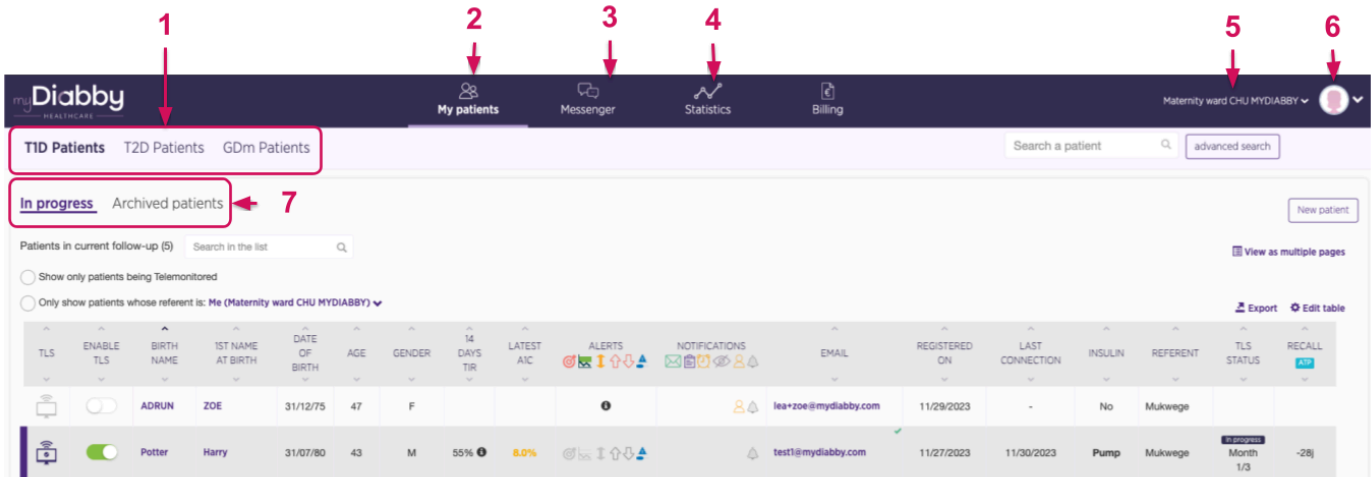
As soon as their account is created by entering the tracking code you gave them, they automatically appear in your list of patients being monitored.

The patient can then start entering their results into myDiabby Healthcare.

¹ Pro Santé Connect is a French service that allows professionals to authenticate themselves with either an e-CPS or a physical CPS card to all digital health services connected to Pro Santé Connect. More information on <https://esante.gouv.fr/produits-services/pro-sante-connect>.

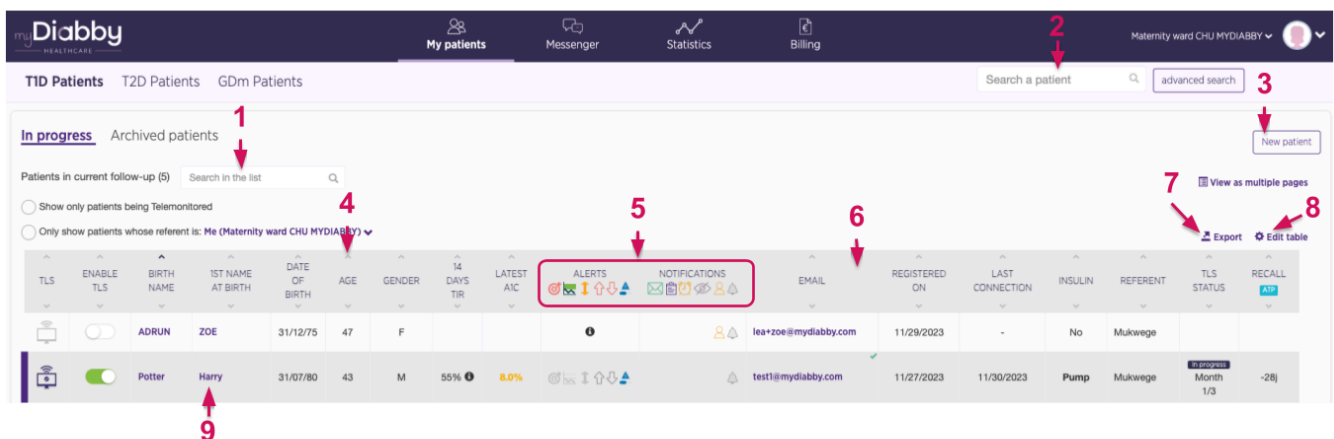
6.3. The dashboard, notifications and alerts

When you log in to your myDiabby Healthcare professional account, you will be taken to the dashboard which lists your patients on the platform. The main tabs structuring your dashboard are as follows:



1. Your different lists of patients sorted by pathology (the type of diabetes selected appears in bold)
2. Access to your patient lists
3. All email feeds
4. Statistics on your patient cohorts
5. Name of the department/practice where you are located (click to change department if you work on several sites)
6. Your profile and settings
7. Your patient lists (underlined list displayed on screen)

The elements that make up the table with the list of patients by selected list are detailed below:



1. Search for a patient in the list displayed on the screen
2. Search for a patient in the myDiabby Healthcare database (search by email address)

- Alternative method for registering a new patient. We advise you to use the flyer method
- Click on the arrows to sort the patients (here by age)
- Alerts and notifications
- Drag and drop columns to change their position in the table
- Export the list displayed as an Excel file
- Customise the table columns
- Click on the patient's 1st given name, surname or email address to open their file

The following picture lists the alerts and notifications that can appear on your dashboard, which can be set and customised for each patient:

Time in target alert



Triggered when the time spent in the target by the patient is below the threshold set in the algorithm

Alert Time spent in hypoglycemia



Triggered when the time spent in hypoglycaemia by the patient is higher than the threshold set in the algorithm

Coefficient of variation alert



Triggered when the variability of continuous blood sugar levels is above the threshold set in the algorithm

Hyperglycemia alert



Triggered when the patient's capillary blood glucose levels meet the conditions set in the algorithm.

Hypoglycemia alert



Triggered when the patient's capillary blood glucose levels meet the conditions set in the algorithm.

Data not transmitted alert



Triggered when the patient has not filled blood glucose tests for more than X days (configurable duration).

Unread message



New message sent by a patient

New document



New document shared by a patient

Reminder



Possibility of setting a reminder on the patient's record, at the end of which the notification is displayed.

Patient record not seen



When no member of the healthcare team has opened this record for more than X days (configurable duration). Ensures that no record is forgotten.

New patient



Patient who registered less than X days ago (configurable duration).

Customised indicators



Customised indicators to organise the management of records. Click on it to change its colour.

Please note: alerts can only be generated for patients being monitored remotely.

To acknowledge an alert on a patient's record (as in the left-hand column above):

- View the alert displayed on a patient's record on the Dashboard.
- Click on the patient's surname, 1st given name or email address to access their file.
- The file will open and you will see the coloured pictogram of the alert displayed on the patient's file in the left-hand section of the banner (surname at birth, first name at birth, date of birth, etc.).
- Once you have analysed the alert displayed, you can indicate that it has been taken into account by clicking on the corresponding pictogram. It will then turn grey again.
- The alert is now processed, it is no longer displayed on the patient's record.

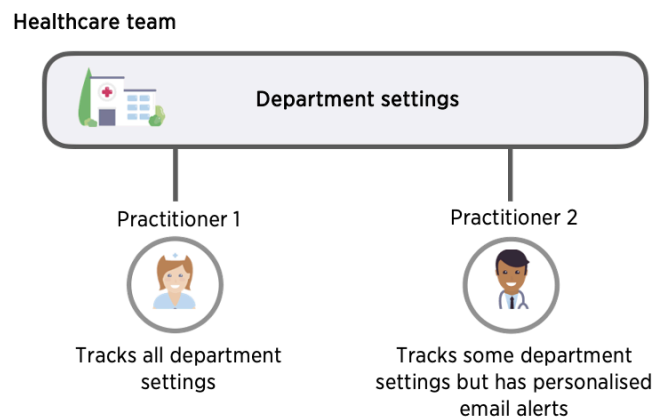
6.4. Setting up the healthcare professional account

The myDiabby Healthcare software has default settings for monitoring your patients. However, before using myDiabby Healthcare, it is necessary to ensure that the settings are appropriate for your patients.

Setting up your myDiabby Healthcare account will allow you to have a platform that is adapted to your way of working and to your organisation.


You can set up your myDiabby Healthcare account at 2 levels:

- "Department settings: these apply to all practitioners with a myDiabby account within the healthcare team
- "My settings": these apply to your practitioner account only



Advice:

- First, set the parameters of the department team;
- Then customise your account settings by choosing to follow the department settings, or by setting your preferences.

To find all the settings for your platform, click at the top right on the pictogram  or your photo if you have added one, available on all the pages of the healthcare professional portal. A drop-down menu will then appear with various selectable tabs:

- "My Account" tab: your myDiabby Healthcare profile with your contact details and your preferences in terms of units of measurement (blood glucose, weight, height etc.).
- "My healthcare team" tab: your department's contact details, the list of practitioners in the department, the monitoring code(s) for your department.
- "My settings" tab: the settings (alerts, notifications, options) specific to your account.
- "Healthcare team settings" tab: the settings (alerts, notifications, options) valid for all practitioners in the department.
- "Automatic messages" tab: automatic messages that you can program for your patients based on certain conditions and triggers
- "Logout" tab: click here to log out of your myDiabby session.

Customise your service settings :

1. Click on the "Service settings" tab
2. Choose the type of patients to whom these settings will apply.
 - A. Select the pathology
 - B. Select the parameters you wish to adapt

The screenshot shows the 'myDiabby Healthcare' interface. At the top, there are navigation tabs: 'Healthcare team settings', 'T1D settings' (highlighted with a red box and arrow 'A'), 'T2D settings', and 'GDM settings'. Below this, there's a 'Targets and alerts' section for 'Continuous blood glucose'. A checkbox 'Use default values' is checked. A horizontal bar represents the glucose scale with color-coded zones: 'Severe hypo' (dark green, 0.53), 'Hypo' (light green, 0.69), 'OK' (yellow, 1.80), 'Above target' (orange, 2.50), and 'Hyper' (red). A 'Reset' button and a 'Confirm' button are at the bottom of the scale.

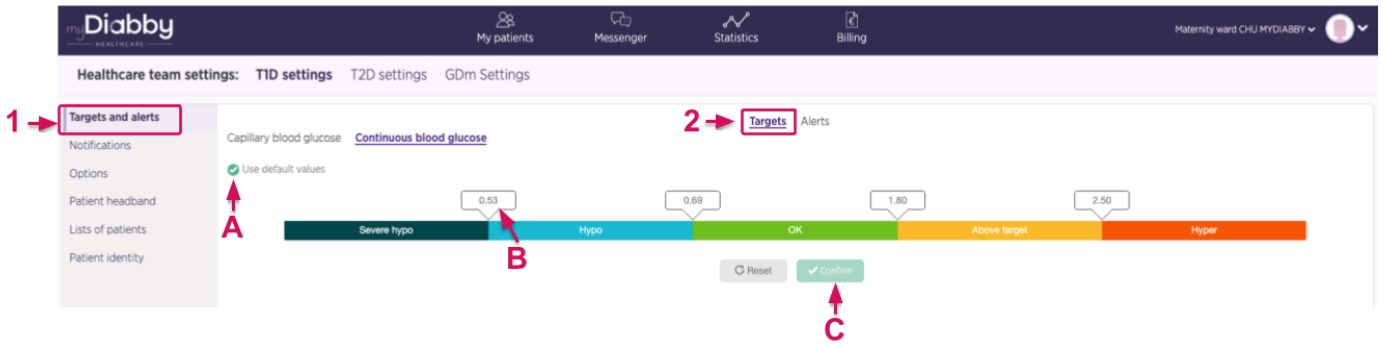
Customising service parameters: colour codes

The colour codes apply to the patient's blood glucose levels on the different displays available on the platform. They apply to both the healthcare professional's and the patient's display. To customise the colour codes for your service :

1. Select the "Colour codes and alerts" tab on the left of the screen
2. Then "colour code".

The customisation options are as follows:

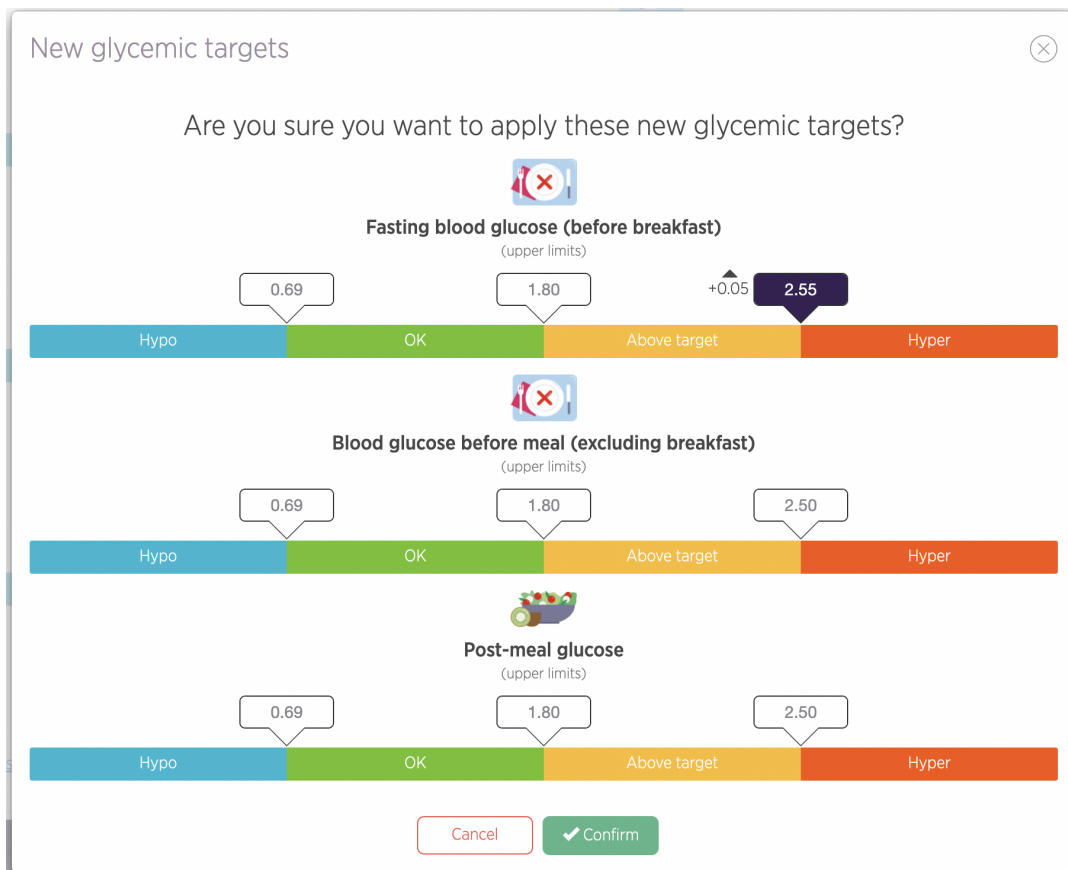
- A. Tick the "Use default values" box to use the colours proposed by default in myDiabby Healthcare, otherwise untick this box.
- B. Modify the value directly in the fields corresponding to the different limits.
- C. Remember to validate your parameter changes once they have been made.



Once you have changed the blood glucose (capillary or continuous) level value, a confirmation window appears on the screen:

- The new threshold value is highlighted
- The difference between the new threshold and the old threshold is displayed

Example: here a capillary blood glucose target value is changed, this is how it appears on the display before confirmation:



The modified value is highlighted, an up arrow indicates that the value is higher than the previous threshold and the unit is increased by + 0.05 g/l.

Customising service parameters: blood glucose alerts

The alert settings define the conditions under which alerts are triggered on your dashboard. They will enable you to identify which patient files to look at first.

Feel free to adapt your alerts as you use myDiabby Healthcare if you find they are too flexible or too severe.

To customise alerts:

1. Select the tab corresponding to the type of measure you wish to customise.
2. Then "alerts".

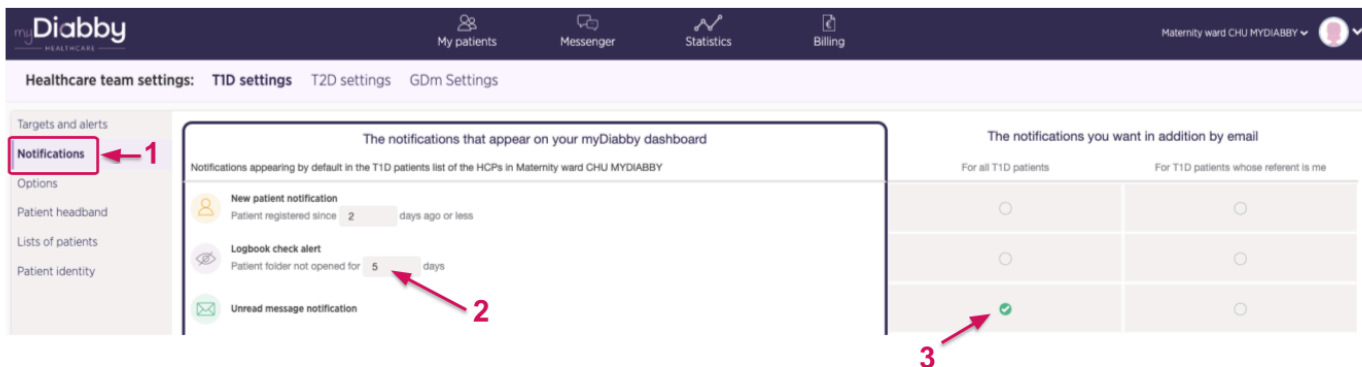
The essential elements are shown below:

- A. By default, myDiabby Healthcare provides you with conditions for triggering alerts for capillary and continuous blood glucose tests.
- B. Click here to add a new trigger condition.
- C. Click on the fields to modify the trigger conditions.
- D. Click here to delete an alert trigger condition.
- E. Don't forget to validate once you've made your parameter changes.

The screenshot displays the 'myDiabby Healthcare' interface. At the top, there are navigation tabs: 'My patients', 'Messenger', 'Statistics', and 'Billing'. Below this, there are settings tabs: 'Healthcare team settings', 'T1D settings', 'T2D settings', and 'GDM settings'. The 'T1D settings' tab is active, and the 'Alerts' sub-tab is selected. The main content area shows the configuration for 'Continuous blood glucose' alerts. It includes a sidebar on the left with options like 'Notifications', 'Options', 'Patient headband', 'Lists of patients', and 'Patient identity'. The main area lists three alert types: 'Low TIR Alert', 'High % of hypo CGM glucose Alert', and 'High variation Alert'. Each alert has a description, a target value, a duration, and a 'Delete' button. There are 'Add a condition' buttons for each alert. At the bottom, there are 'Reset' and 'Confirm' buttons. Red arrows labeled A through E point to specific elements: A points to the 'Patient identity' sidebar; B points to the 'Add a condition' button for the 'High variation Alert'; C points to the '14' in the duration field of the 'High variation Alert'; D points to the 'Delete' button for the 'High % of hypo CGM glucose Alert'; and E points to the 'Confirm' button.

Customising service settings: Notifications to service practitioners

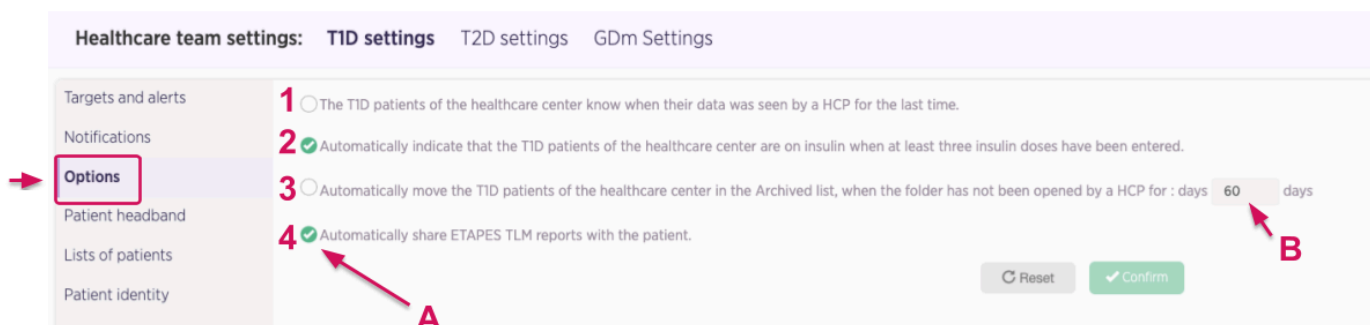
You can customise the display of certain notifications on the dashboard, and choose to receive email notifications in addition to the dashboard.



1. This is where you'll find all the alerts and notifications on the dashboard.
2. You can adjust the duration of the notifications here
3. Tick the circles for each alert/notification you wish to receive by email in addition to the dashboard. Note: By setting up email notifications from the service settings, they will apply to all practitioners who follow the service settings.

Customising service settings : Additional options

We offer a number of additional options to help you save time on myDiabby Healthcare.



- A. Tick the options you want to activate for all patients on the ward.
- B. Customise the options that have a time limit.

The following options are available:

1. Patients see on their application the date on which the medical team last opened their file.
2. When a patient enters at least 3 doses of insulin on myDiabby, their status automatically changes to "on insulin".
3. After X days without being opened, the patient record is automatically moved to the "Archived" list.
4. ETAPES programme only: Automatically share TLS reports with the patient.


Other customisation of service parameters

You can also create personalised sub-lists of patients for your entire service on myDiabby Healthcare. To create new personalised lists, go to the "Patient lists" tab and click on the (+) icon.

You can also set up automatic messages for your patients to save time on repetitive tasks.

For more information, visit our help centre: www.help.mydiabby.com

Customise your myDiabby Healthcare settings.

The settings specific to your account work in the same way as the service settings. To change them, click on the "My settings" menu in the drop-down menu that appears after clicking on the pictogram  at the top right of all the pages of the healthcare professional portal.

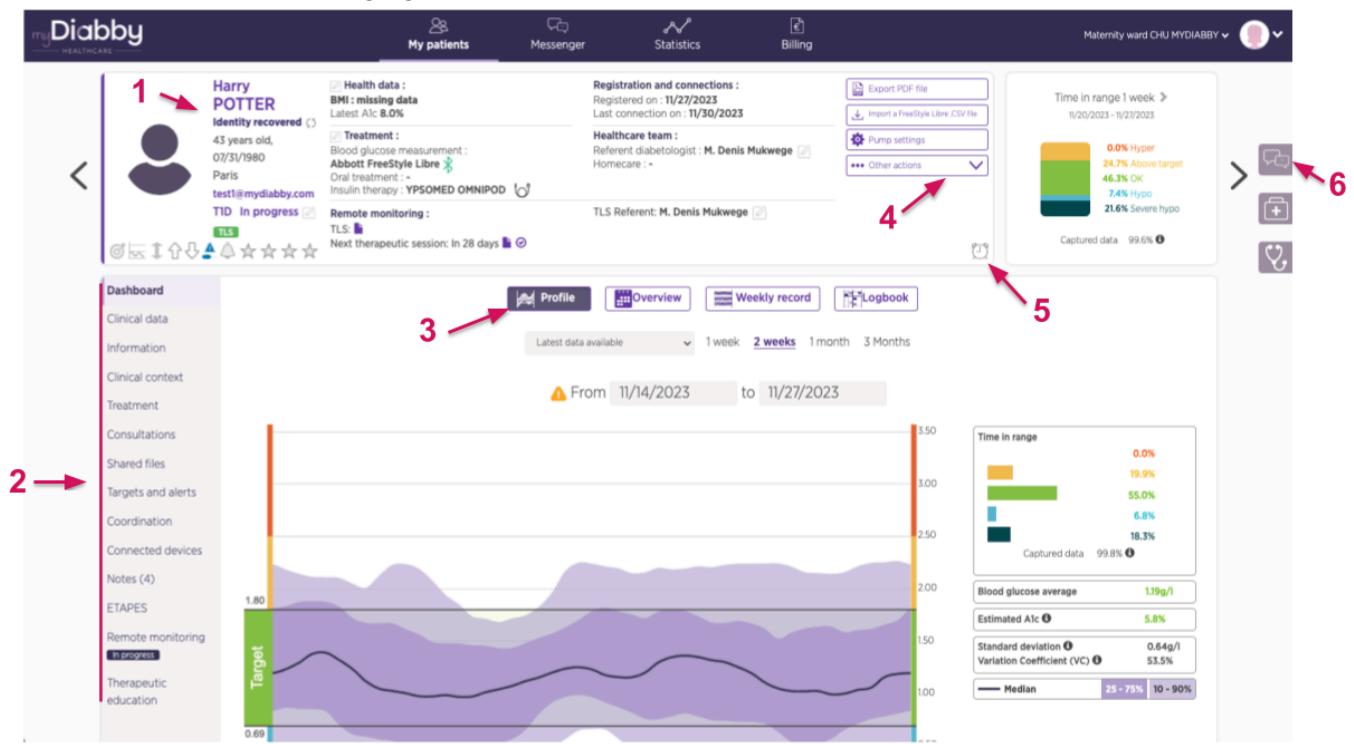
In each configurable item, you will have the option of following the service settings, or choosing your own settings. By default, when you create your account, your settings will follow the service settings.

6.5. The patient record

From your dashboard, click on a patient's birth name, 1st name or email address to open their file. By default, you are taken to the patient record dashboard.

The different types of information available are as follows:

1. General patient information
2. Here you will find all the patient record tabs
3. Select the data view you want: notebook, weekly or AGP profile mode
4. Additional menu: file export, event history, archiving, etc.
5. Set a reminder here
6. Patient messaging



Coordinating a patient file :

All myDiabby Healthcare user facilities and practices can share and/or transfer patient records to each other. The Coordination tab allows you to see which professionals are part of the patient's care pathway

The screenshot displays the myDiabby Healthcare interface for a patient named Harry Potter. The interface is divided into several sections: a patient profile, health data, treatment, registration and connections, and a coordination section. The coordination section is highlighted in the left sidebar. The main content area shows 'COORDINATION ON MYDIABBY HEALTHCARE' with a list of departments, including 'Maternity ward CHU MYDIABBY'. Red arrows point to specific elements: 1. A checkmark icon next to the department name. 2. A dropdown arrow next to the department name. 3. A plus icon next to 'Add a healthcare team'. 4. A plus icon next to 'Add a private doctor'. 5. A plus icon next to 'Add a homecare provider'. The 'CORRESPONDENTS' section is also visible, with a search bar for healthcare professionals.

1. Each block represents a department/cabinet with access to the patient file.
2. Click here to modify access to the patient record
3. Click here to share the file with a hospital department
4. Click here to share the record with a practice
5. Click here to share the record with a home healthcare provider

The Notes and Remarks tab: you can use this tab to indicate specific details of the record, the notes are not visible to the patient.

The myDiabby Healthcare messaging system:

In the patient record, you can open the instant messaging system on the right, using the "Messaging" button (in the form of chat bubbles).

In the message thread, you will find all the history of messages with the patient and other healthcare professionals who have access to the patient's file on myDiabby. You can use the messaging system with the notebook in front of you. All messages are associated with their author and the date and time they were sent.

6.6. Features to take you further

Documents associated with a patient account:

myDiabby Healthcare allows different users to edit or upload documents to patient records. This is why the "Documents" tab in the patient record is divided into 3 sections depending on who created the document: the patient, the medical team or the home healthcare provider (HHP). This document creation tool can be used for documents such as prescriptions, reports, letters to colleagues, patient information, etc.

Adjusting a patient's treatment:

You can suggest a change in insulin doses to your patients, while keeping the patient's information in front of you.

The teleconsultation tool:

myDiabby Healthcare allows you to carry out teleconsultations directly from the messaging system with your patient.

For more information, visit our help centre: www.help.mydiabby.com

7. 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 device requires a minimum command of basic IT functions (office automation, internet browsing, use of mobile applications for patients).
- Interference with other software may disrupt the sending of data from connected objects when using myDiabby Uploader. Make sure you have not installed any other data transfer software on your computer if you are transferring data from a device (sensor or pump) by cable.
- Informed consent must be obtained from the patient before registering their personal information and health data on the myDiabby Healthcare platform. The patient must accept 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 sent directly to the patient by his or her referring healthcare professional.

- The accuracy of the medical device depends on patients completing and/or sending data to the myDiabby Healthcare software on a regular basis. This frequency is defined by the referring healthcare professional.
- The performance of the medical device depends on the healthcare professional correctly managing and interpreting the alerts issued by myDiabby Healthcare. Failure to manage or mismanage the alert would be detrimental to the patient.
- In the event of a malfunction of myDiabby Healthcare (impossible access to the software, inability to transfer data from your connected device, incorrect information/data, etc.), please contact myDiabby support by e-mail at support@mydiabby.com or by telephone on 01 76 40 01 78.

8. 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 of the country in which you are established.

9. Removal

9.1. Deleting the user account

- 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.

9.2. 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>
- Link to privacy and security policy of personal data for **Healthcare Professionals**
<https://www.mydiabby.com/politique-donnees-praticiens>