myDiabby

HEALTHCARE

Remote monitoring software for diabetes management

Instruction for use
Healthcare Professionals

Notice applicable from version 2.15.0 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.

MDHC SAS
66 avenue des Champs Elysées
75008 Paris
 FRANCE

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Contents of the instruction for use

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.

myDiabby Healthcare enables authorised health 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 set by the health professional on the platform to trigger alerts when the patient's blood glucose results exceed the thresholds.

myDiabby Healthcare also enables patients to be monitored without including them in remote monitoring. In this case, patient monitoring and treatment data collected in the patient portal is only made available to health professionals linked to the record, without generating alerts.

Finally, myDiabby Healthcare can also be used independently by adult and pediatric patients (aged 15 and over) with type 1 or type 2 diabetes and by gestational diabetes patients.

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, 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 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 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 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
Capillary blood glucose meter	Fora	Diamond Mini	Bluetooth on mobile app
Capillary blood glucose meter	Lifescan	OneTouch Verio Flex	Bluetooth on mobile app1 + via API of OneTouch Reveal app
Capillary blood glucose meter	Lifescan	OneTouch Verio Reflect	Bluetooth on mobile app1 + via API of OneTouch Reveal app
Capillary blood glucose meter	Lifescan	OneTouch Ultra Plus Reflect2	Bluetooth on mobile app1
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 N	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
Continuous glucose sensor	Abbott	FreeStyle Libre 2	Import of CSV data file
Continuous glucose sensor	Medtronic	Enlite	Via Contour next link 2.4 in USB connector on myDiabby Uploader
Continuous glucose sensor	Dexcom	G4	Via Dexcom Clarity API
Continuous glucose sensor	Dexcom	G5	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	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 Pen	Novo nordisk	NovoPen 6	NFC on smartphone (wireless)
Insulin Pen	Novo nordisk	NovoPen Echo Plus	NFC on smartphone (wireless)

[1]The 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.

[2]The 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 :

Support	Minimum system version
iOS patient mobile application	iOS 11
Android patient mobile application	9.0
Uploader for Windows	Windows 8.1
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 3.3 above.

4.2. 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

4.3. 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	Birth name
E	maidenname	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"

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

5. Instructions for use of the health professional portal

5.1. Opening of myDiabby Healthcare

Open a web browser (preferably Chrome or Firefox for best performance) and go to https://app.mydiabby.com/pro/#/login.

You can also go to www.mydiabby.com and click on "Login" at the top right of the page.

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 service[1].

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

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[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.
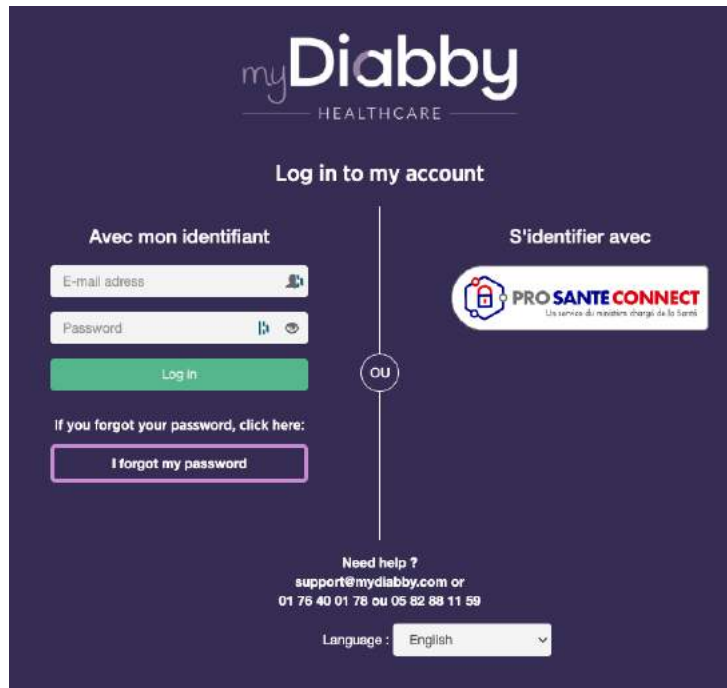
5.2. Patient registration

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.

5.3. The dashboard, notifications and alerts

When you log in to your myDiabby Health professional account, you will be taken to the dashboard which lists your patients on the platform.

Your different types of patients
(the selected type of diabetes is shown in bold)

Access to your lists of patients

All messaging feeds

Statistics on your cohorts of patients

Name of the department/ practice, where you are located
(click to change department if you work in several sites)

Your profile and settings

Your lists of patients
(underlined list displayed on the screen)

Search for a patient in the list displayed on the screen

Notifications and alerts

Search for a patient in the myDiabby database
(search by email address)

Customise the table columns

Export the displayed list as an Excel file

Alternative method for registering a new patient. We advise you to use the method on the flyer

Click on the arrows to sort the patients
(here by age)

Drag and drop columns to change their position in the table

Click on the patient's name to open their record

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):

1. View the alert displayed on a patient's record on the Dashboard

2. Click on the patient's last name, first name or email address to access their record

3. The record opens, you see the alert displayed on the patient's record

An alert is displayed on the patient record
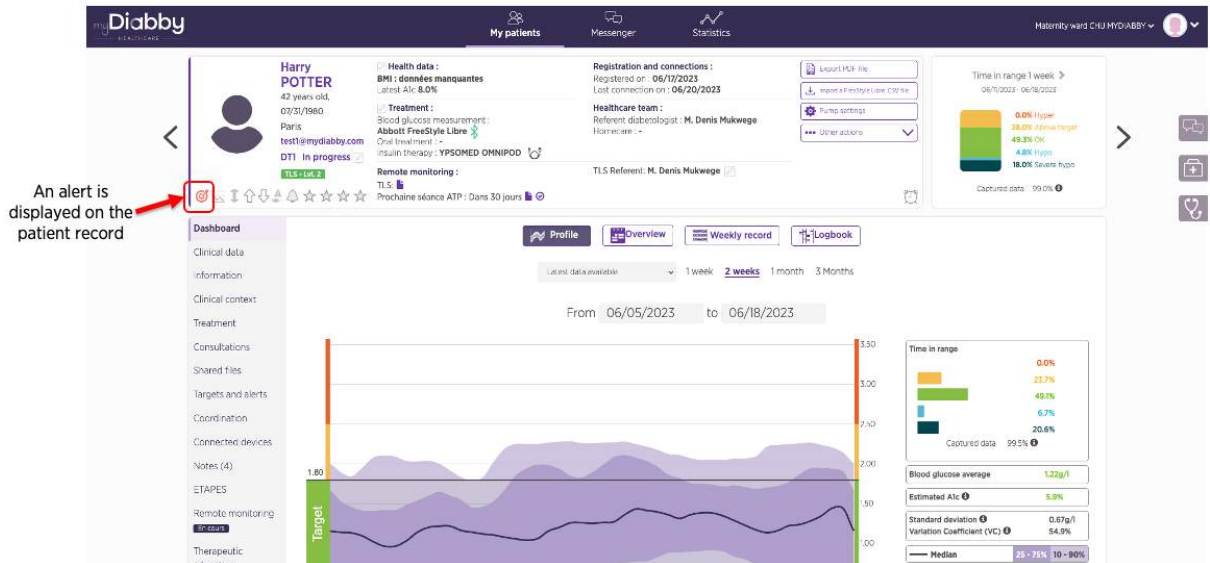
4. After analysing the alert that has been displayed, you can indicate that it has been taken into account by clicking on the pictogram.

5. The alert is now processed, it is no longer displayed on the patient's record.


After acknowledging the alert, I can click on the pictogram to indicate that I have dealt with it
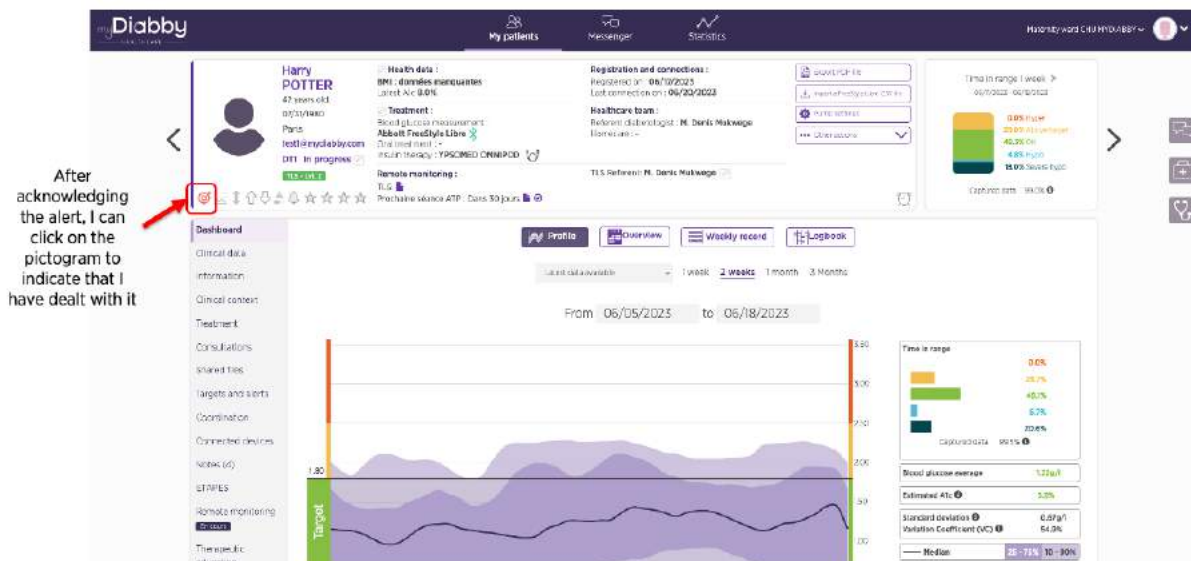
5.4. Setting up the health professional account

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
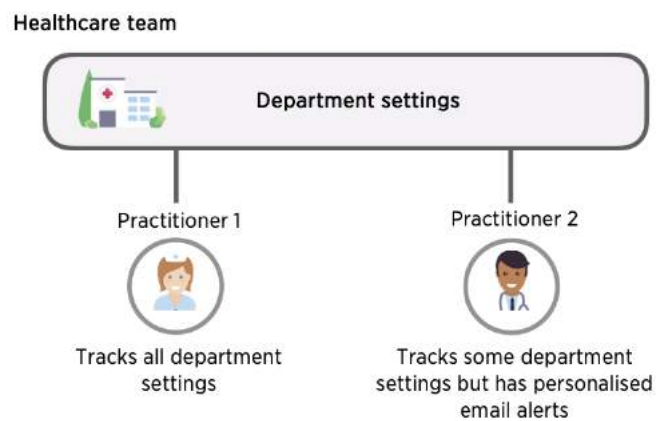
Advice:

- 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.

All your platform settings can be found here:
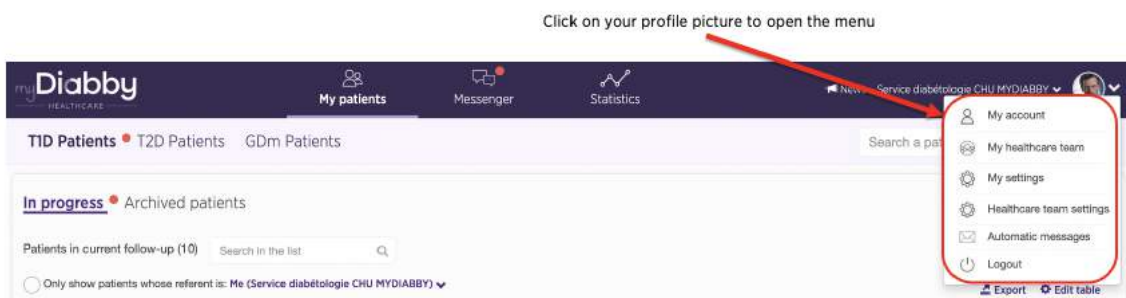
- "My Account" tab: your myDiabby Healthcare profile with your contact details and your preferences in terms of units of measurement (blood glucose, weight, height etc.)

- "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.

1 — Open Healthcare team settings

My account
My healthcare team
My settings
Healthcare team settings
Automatic messages
Logout
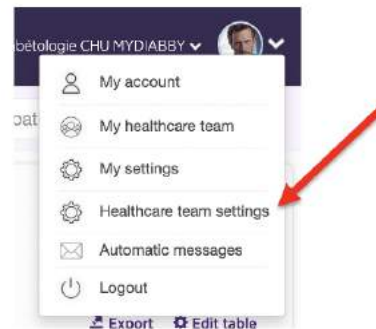
2 — Choose the type of patients to whom these settings will apply

The various settings are in the left-hand menu.

Healthcare team settings: T1D settings T2D settings GDm Settings

Targets and alerts
Notifications
Options
Patient headband
Lists of patients
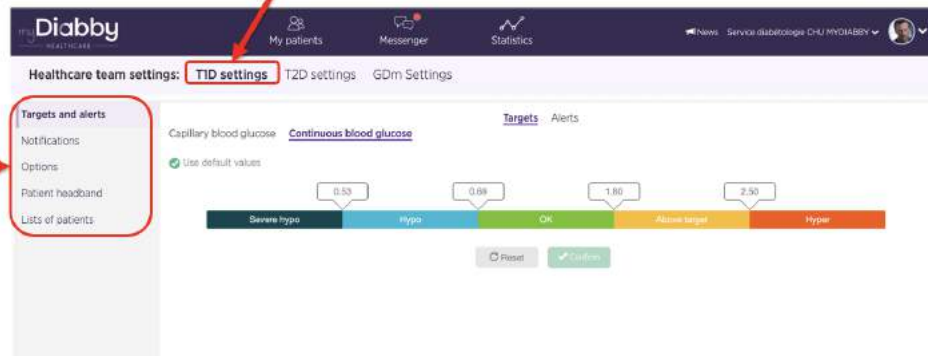
Customising the department settings: colour coding

The colour coding applies **to blood sugar levels in the patient's logbook** and is displayed on the patient's and the practitioner's screen.

Check to use the default colours offered in myDiabby. Otherwise, uncheck.

Change the value by entering it directly here

Remember to confim once your settings are complete

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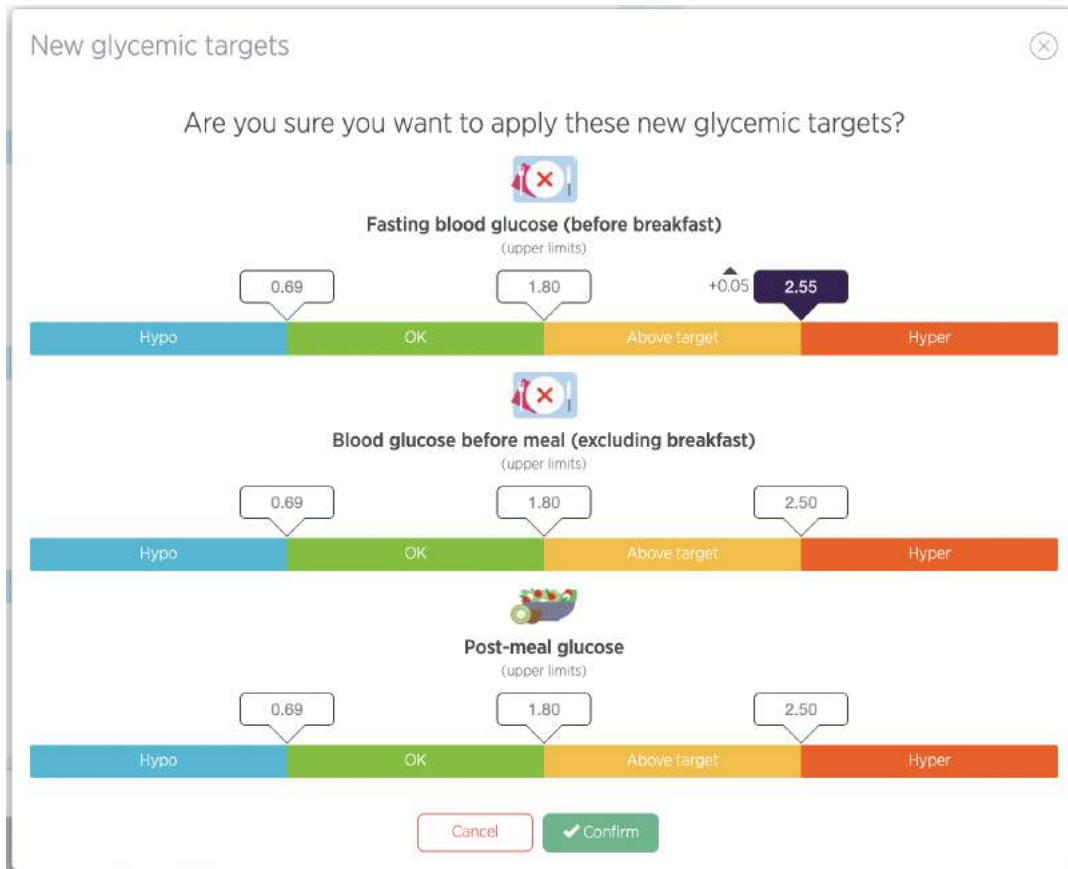
The modified value is highlighted, an up arrow indicates that the value is higher than the previous threshold and the unit is increased by + 0.05 g/l.

Customising the department settings: hyper/hypoglycaemia alerts

The settings for the alerts define the **conditions under which** they are activated on your dashboard.
They will allow you to **identify which patient records to look at first**. Feel free to **adapt your alerts** as you use myDiabby if you find them too soft or too hard.

myDiabby offers you default conditions for activating alerts for capillary and continuous blood glucose levels

Click here to add a new activation condition

Click on the fields to change the activation conditions

Click here to remove an alert activation condition

Remember to confirm once your settings are complete

Customising the department settings: notifications to department practitioners

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

Here you can find all the alerts and notifications of the dashboard

Here you can adjust the durations of the configurable notifications

Check the circles for each alert/notification you wish to receive by email in addition to the dashboard.
N.B.: Note: by setting up email messages from the department settings, they will apply to all practitioners who track the department settings.

Customising the department settings: additional options

We offer several additional options to help you save time on myDiabby.

Check the options you want to activate for all patients of the department

Customise the options that have a notion of duration

1 Patients see on their application the date when the healthcare team last opened their record
2 When a patient enters 3 or more insulin doses in 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 (French national experimentation in telemedicine for the improvement of healthcare pathways): automatically share telemedicine reports with the patient

Customising the department settings: lists of patients (only for DT1/2)

The lists of patients allow you to sort your T1/2 patients monitored on myDiabby according to criteria specific to your department

Click here to add a list for your department, in addition to the two default lists on myDiabby: "in progress" and "archived".

Indicate the name you want for your list, then confirm

You can delete your list at any time, but you must first check that there are no more patients on the list in your department

=> When registering, your patient will be in the "in progress" list, to change the list you can click on the small pencil next to his/her profile picture in the patient record

Customising the department settings: automatic messages

You can **set up automatic messages for your patients** to save time on repetitive tasks.
These messages concern all patients of the department, differentiated by type of diabetes.
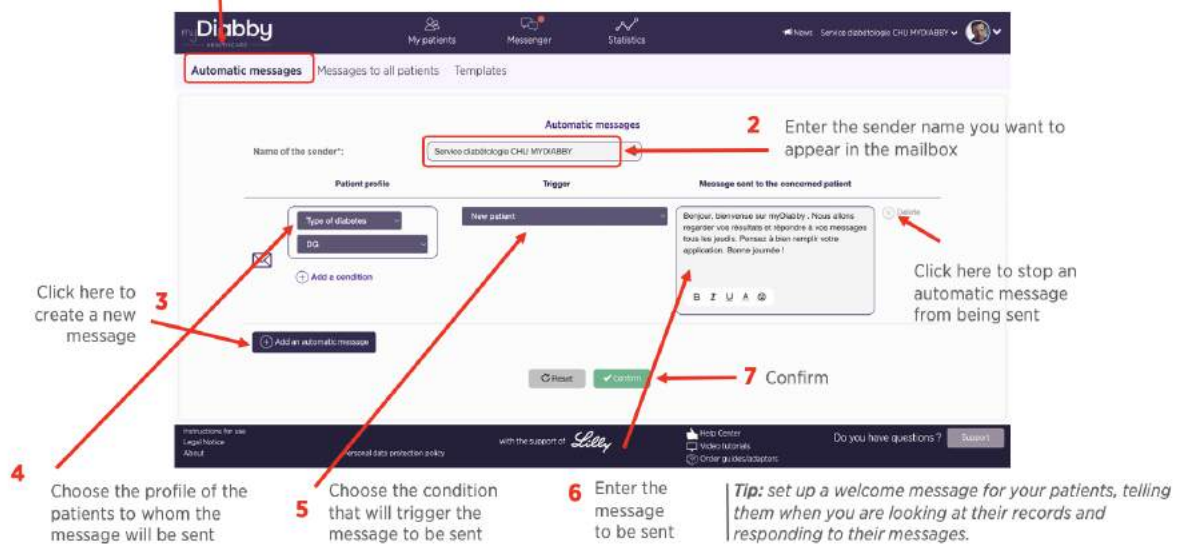
Click on your profile picture to open the menu

Select the "**Automatic Messages**" tab.
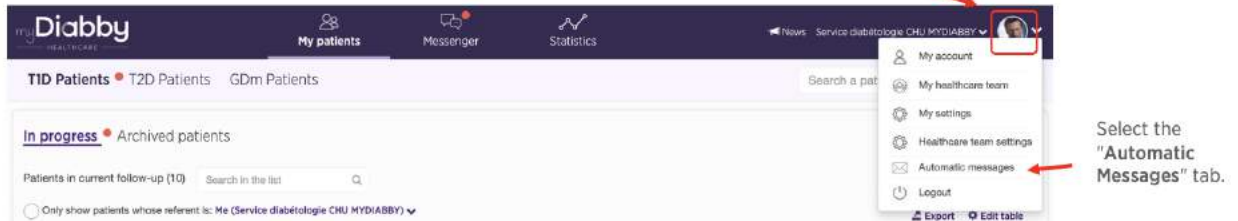
Customising the department settings: automatic messages

You can **set up two types of automatic messages for your patients:**
- Automatic messages: messages triggered by an alert or condition
- **Messages to all patients**: one-off messages to all your patients with one type of diabetes

1 Check that you are on automatic messages

2 Enter the sender name you want to appear in the mailbox

3 Click here to create a new message

Click here to stop an automatic message from being sent

7 Confirm

4 Choose the profile of the patients to whom the message will be sent

5 Choose the condition that will trigger the message to be sent

6 Enter the message to be sent

Tip: set up a welcome message for your patients, telling them when you are looking at their records and responding to their messages.

Customising the department settings: automatic messages

1 Check that you are addressing the right type of patient

2 Enter the sender name you want to appear in the mailbox

3 Enter your message here

4 Click on "Send".

The history of messages sent to all patients can be found below

All-patient messages are sent once to all selected patients being monitored in the department.

Customising the department settings: automatic messages

1 Check that you are addressing the right type of patient

2 Enter the sender name you want to appear in the mailbox

3 Enter your message here

4 Click on "Send".

The history of messages sent to all patients can be found below

All-patient messages are sent once to all selected patients being monitored in the department.

5.5.   The patient record

From your dashboard, click on a patient's first or last name to open their record.

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

In the messaging feed, you can find all the history of messages with the patient and other healthcare professionals who have access to their record on myDiabby. You can use the messaging system with the logbook in front of you.

In the patient record, you can open the instant messaging system on the right

In the messaging feed, you can find all the history of messages with the patient and other health professionals who have access to their record on myDiabby. You can use the messaging system with the logbook in front of you.

myDiabby Healthcare allows different users to edit or upload documents to patient records. For this reason, the "Shared files" tab of the patient record is divided into 3 sections depending on the author of the document: **the patient, the medical team or the home healthcare provider (HHP).**

1) Files shared by the patient

- The shared files can be found in the "*Files uploaded by the patient*" section.

- The file is shared with all the professionals attached to the record
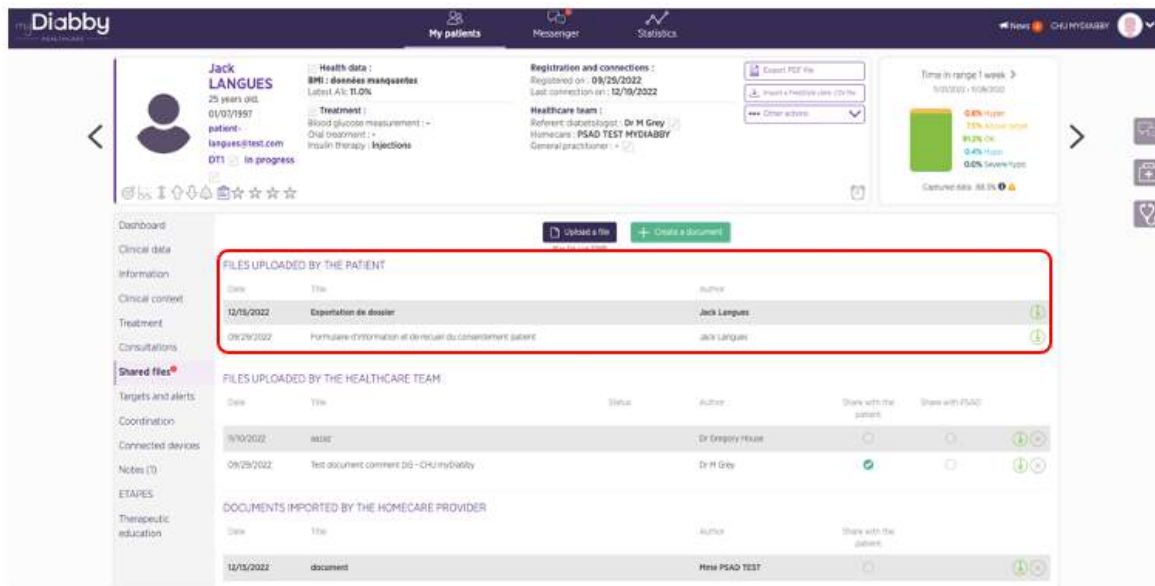
2) As a health professional within a medical team (excluding HHP)

- The files you upload can be found in the section "Files *uploaded by the healthcare team*".

- You have the possibility of sharing an uploaded file on the record with:

    - The patient

    - The HHP(s) who have access to the patient's record

=> *To do so, check the box in the desired column "Share with patient" and/or "Share with HHP".*

=> *By default, when a file is uploaded, it is not shared with the patient or the HHP.*

=> *The files created are systematically shared with other the non-HHP health professionals (professionals in private practice, hospitals, etc.)*
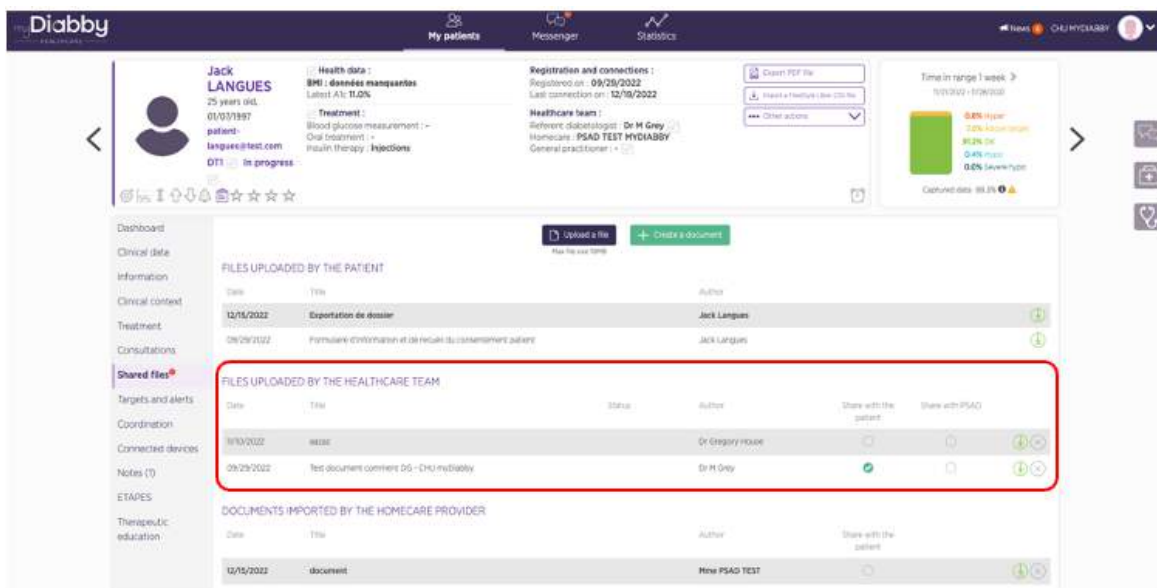
- A **HHP** can create a document and then **have it signed** by another health professional.

If you are interested in this feature, this article gives you more details

Signature of a document by a third party

Once the document is edited by the HHP, it appears in "Files *uploaded by the medical team*" but with **default sharing with the HHP**.

3) As a HHP

- The files you import can be found under the heading "Files *uploaded by the home healthcare provider*".

- You have the possibility of sharing an imported document on the record with:

    ○ The patient

    ○ Other health professionals who access the patient's record

=> *To do so, check the box in the desired column "Share with the patient" and/or "Share with the healthcare team"*

=> *By default, when creating or uploading a file, it is NOT shared with the patient, nor with the healthcare team.*
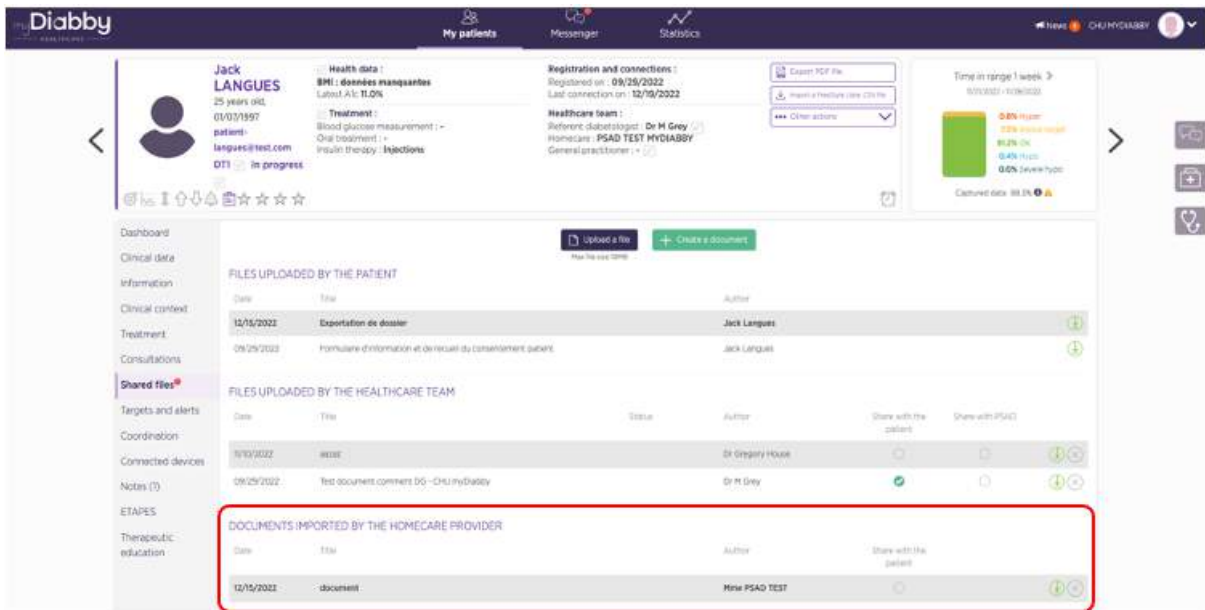
The Coordination tab: all myDiabby Healthcare user facilities and practices can share and/or transfer patient records to each other. The Coordination tab allows you to see which professionals are part of the patient's care pathway
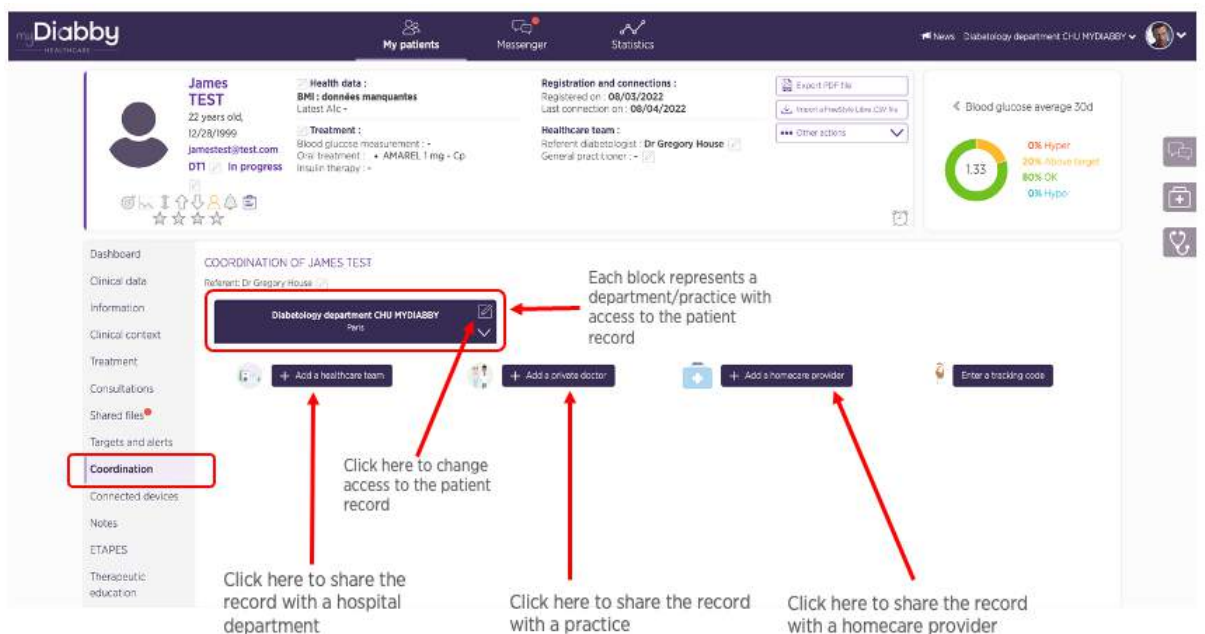
The Notes and Remarks tab: you can use this tab to indicate specific details of the record, the notes are not visible to the patient.

Number of notes in the record

Click here to delete a note

Enter your note or comment here

Click here to register

5.6.   Adjusting a patient's treatment

You can suggest a change of insulin doses to your patients, while keeping the logbook in front of you.
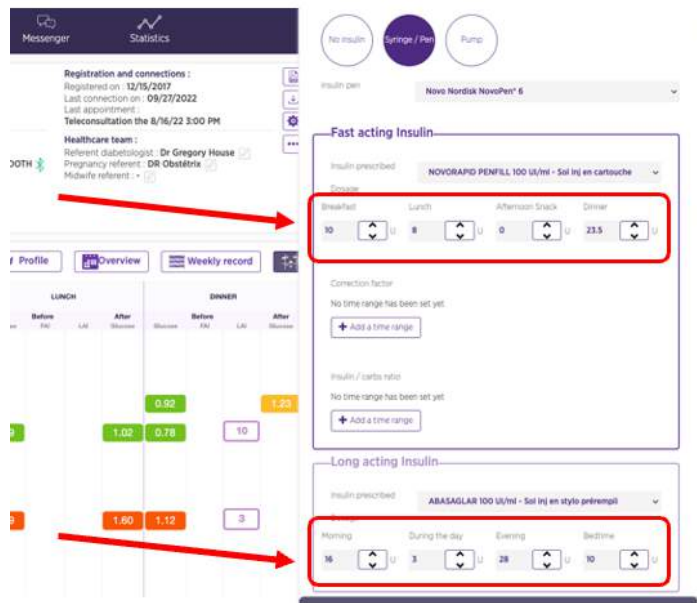
To save even more time, the change of doses can be sent automatically in the messaging system.

> This is how to do it:

1. Access the current treatment with the logbook in front of you using the tab on the right:

2. Adjust the doses from the treatment section and send the new recommendations **automatically to the messaging system** *(or confirm without sending a message)***:**


3. A preview of the message containing the treatment recommendations is displayed to check the doses you will be recommending to the patient:
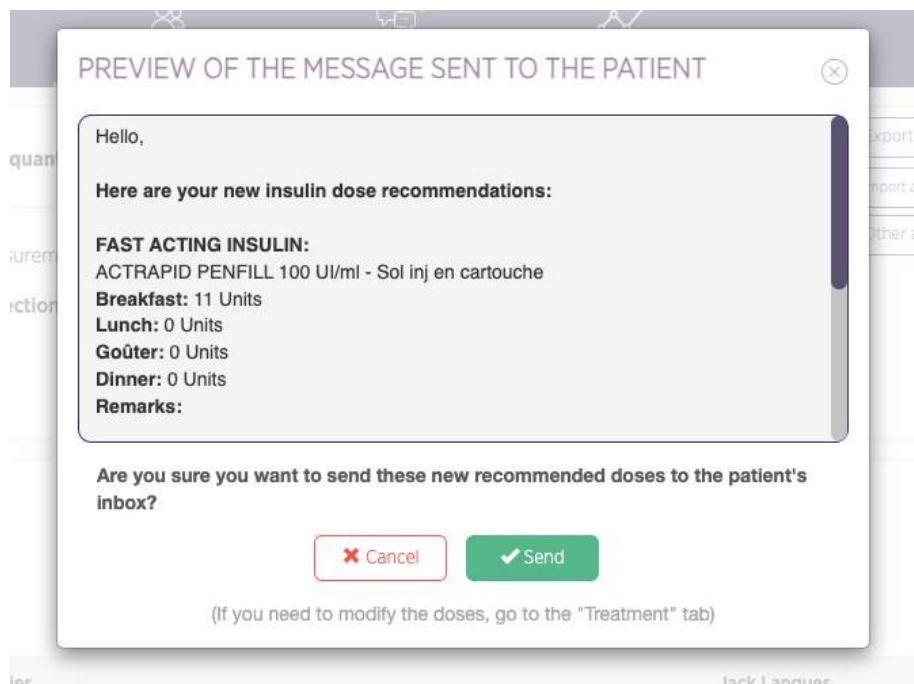
- If you find that these are not the correct doses, click on "Cancel", you will then return to the Treatment formatting

- If you wish to send these dose recommendations, click on "Send".
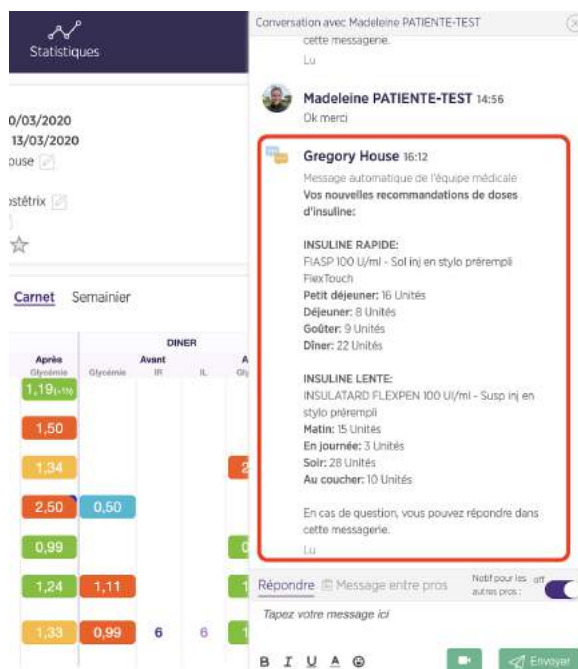
If you notice an error in the message sent, despite the previous confirmation phase, whether it is an automatic message or a message entered manually, you now have 30 minutes to delete it: Hover over the message with the mouse and an X appears to delete it.
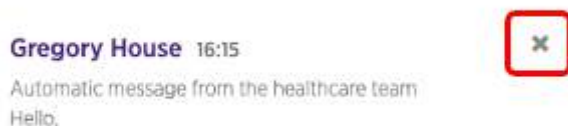
5.7. Creating a document or prescription template

This document creation tool can be used for documents such as prescriptions, reports, letters to colleagues, information to patients, etc.

Here's how to **create your own prescription and document templates** on myDiabby.

1. Go to **a patient record** (any one), then open the "**Shared files**" tab
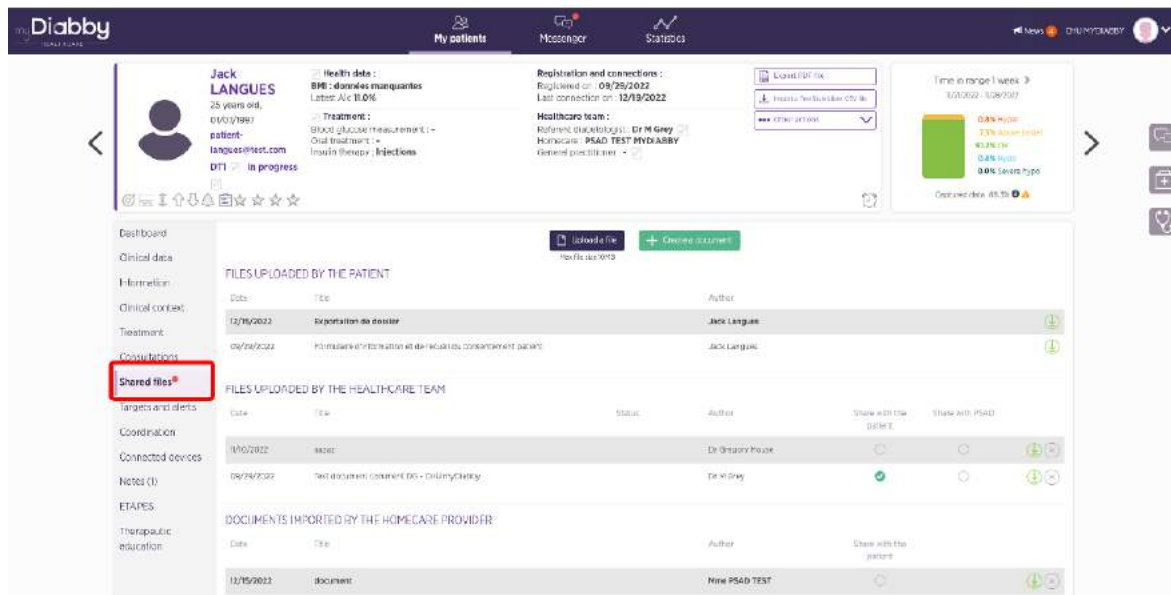
2. Click on the "**New document**" button and choose "**Create a new template**".
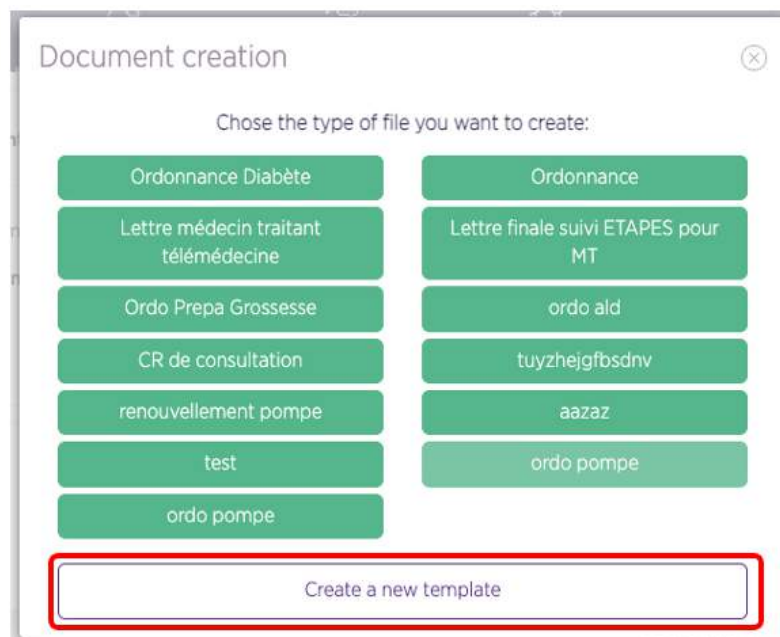
3. **Choose the type of document** you wish to create:

> Text: A completely free document, without a header, which you can layout as you wish *(you can still create a header if necessary)*

> **Prescription**: A prescription-type document with a header indicating the name of the health professional, the centre, the French directory of healthcare professionals and the FINESS number
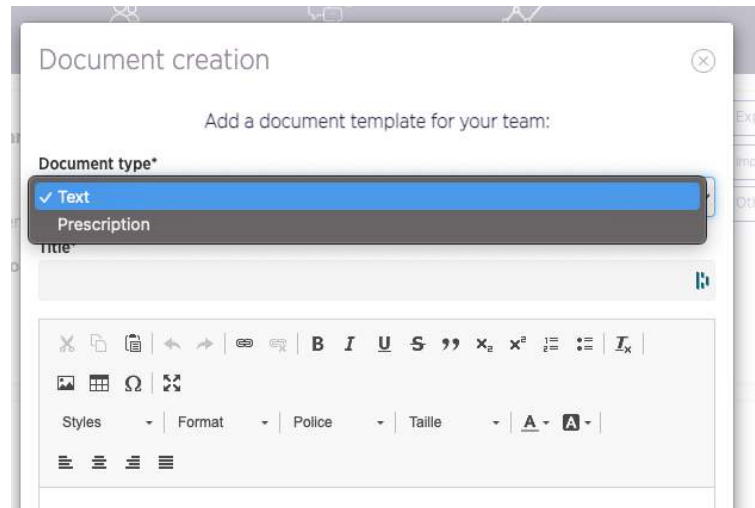
4. Choose a **title** for your template and enter the **content** of your template.
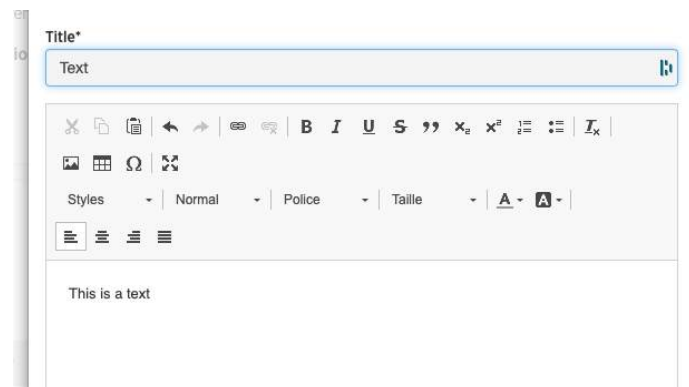
TIPS:

> The "**Test**" button allows you to preview your document template before confirmation

> Use the **variables in square brackets** as indicated at the bottom of the window to automatically fill in the information from the patient record from which the document will be created. You can click directly on these variables to add them to your template.

Example: *If you use a document template with the sentence "Patient [PATIENT] has been managed" on the Harry Potter patient record, the document generated from this template will display the sentence "Patient Harry Potter has been managed".*
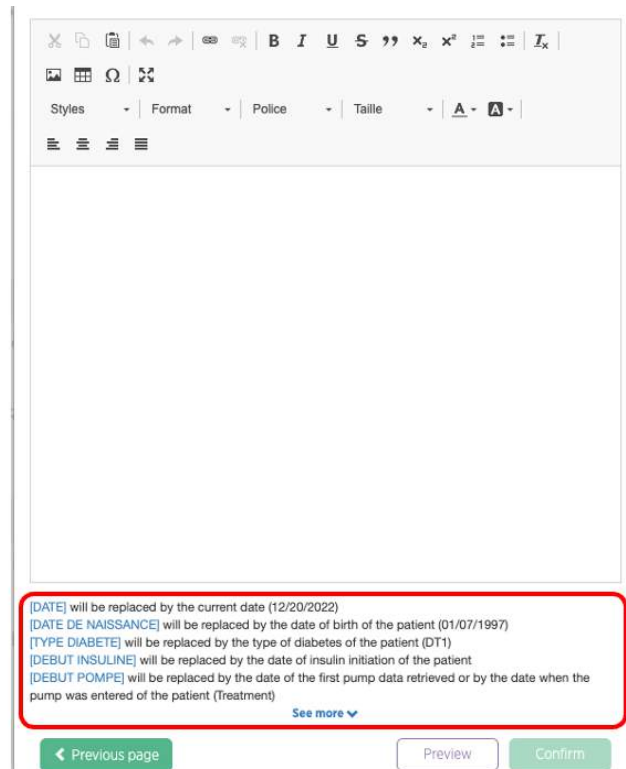
5. Once you have created your template, click on **"Confirm"**.

The template will now appear in the **Document Generator** on **all patient** records for **all health professionals in your team.**
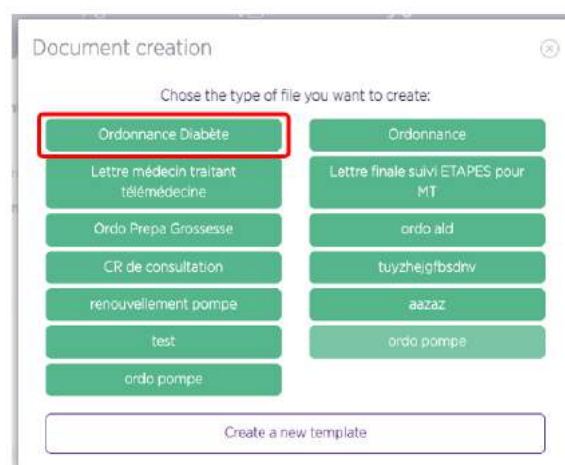
> *To **delete a template**, open the template from any patient record and click on the **"Delete template"** link at the bottom of the page.*

This action can be performed by all the health professionals in the team and removes the document template from the list. Documents that have previously been generated from this template are retained in the patient records.

5.8. The remote consultation tool

1. How do I access the remote consultation feature on myDiabby?

> PATIENT: the patient can participate in a remote consultation from their myDiabby Healthcare mobile application. They can also **benefit from the remote consultation** by logging into their account on the mydiabby.com website **from a computer**.

> HEALTH PROFESSIONAL: there is nothing to install or set up. The remote consultation feature is accessible from your usual myDiabby Healthcare portal.

2. Technical requirements of the medical team

The healthcare professional will have to connect from a **computer connected to the internet**, as is currently the case with myDiabby Healthcare.

To carry out the remote consultation, the practitioner will also need a **webcam + microphone + speakers (or headset).**

Please note: *as far as your browser is concerned, give preference to **Chrome** or **Firefox**, avoiding Internet Explorer as much as possible.*

If the computer is not equipped, the practitioner can use a **smartphone**, **logging into his or her myDiabby account from the phone's web browser.**

> *If, despite meeting the hardware requirements, the remote consultation is not accessible, it is possible that the hospital's IT system is blocking the feature. You can put the Information Systems Department of the health institution in touch with the myDiabby Healthcare team to quickly unblock the remote consultation.*

You can test the remote consultation with a test patient beforehand by contacting the myDiabby team, or you can start directly with your patients.

3. Arrange an appointment with the patient

To arrange a remote consultation, you need to make **an appointment with the patient in the same way** as you would for a face-to-face consultation.

When you start the remote consultation, patient can see a displayed notification on the screen (only in the case of using the mobile APP)

Before launching a remote consultation, we would advise you to make sure that the patient is ready, by sending them a quick message in the platform's messaging system.

4. TUTORIAL: Launching and using remote consultation on myDiabby

It is up to the health professional to launch the remote consultation. **The patient must be ready** at the time of the remote consultation with their myDiabby application open, to take the call.

> HEALTH PROFESSIONAL:

1. On the relevant **patient record**, open the **messaging** section on the right hand side of the screen:

2. Click on the "Camera" button: The web browser will probably ask for access permissions to the camera and microphone, which you will have to accept to open the remote consultation.

3. Your camera is activated, **click on the "Call" button** to start the remote consultation with the patient:

4. When the patient answers, the remote consultation starts:

PLEASE NOTE:

- ***During the remote consultation, you have access to all the features of the patient record*** *(access to the blood glucose record, prescriptions, treatment, etc.)*

- *During the remote consultation, you can minimise the sidebar by clicking on the top right cross, then reopen the messaging tab to access the video again.*

- *To hang up: click on the red phone at the top of the screen. To close the remote consultation feature, click on the "Close" button.*

> PATIENT:

This is the patient's point of view:

1. The patient must open their myDiabby application and be ready at the time of the <u>remote consultation.</u> He/she can also log in to his/her account on a computer at www.mydiabby.com

2. The patient receives the call from his or her healthcare professional:

If the patient was not ready with their myDiabby application open, a notification on their phone prompts them to open myDiabby Healthcare.

Once the patient answers, the remote consultation begins. At the end of the discussion, the patient or the healthcare professional can hang up.

Please note*: if the remote consultation does not start, in most cases it is because your browser is blocking access to the camera and/or microphone.*

6.   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 01 76 40 01 78.

7. 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.

8. Removal
8.1. 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.

8.2. 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 **Health Professionals**

  https://www.mydiabby.com/politique-donnees-praticiens