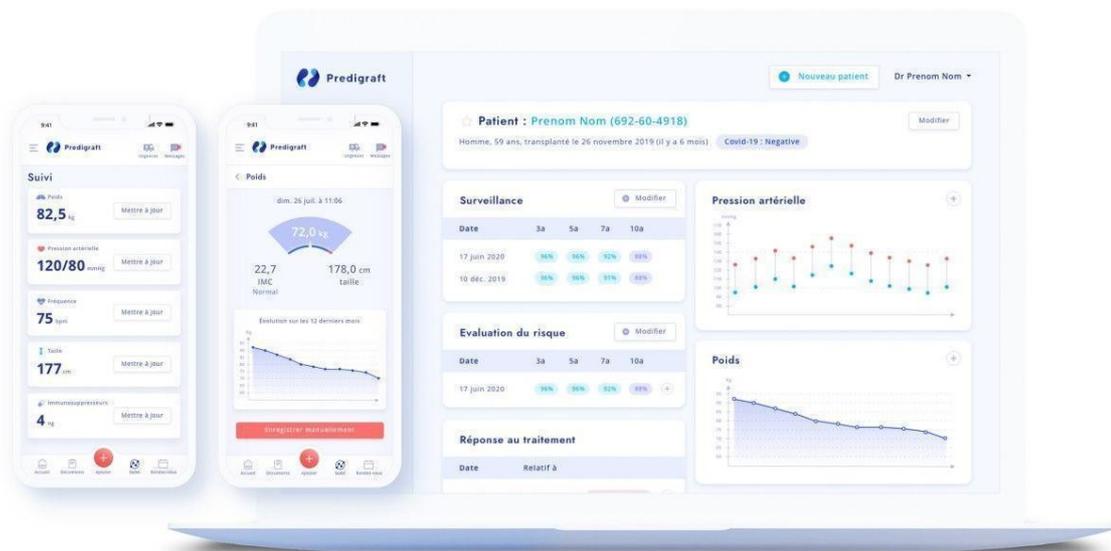


# User Manual

## Patient



**Please read this entire manual carefully before using Apilife Medical software, a class IIa medical device.**

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This manual complies with Regulation (EU) 2017/745 on medical devices.

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## 1. About this manual

This manual is an integral part of the Apilife Medical software. It details the presentation of the patient application, its configuration, and its use.

The electronic version is available online in the help center of the company's website: <https://basedeconnaissances.cibiltech.com/fr/knowledge/manuel-utilisateur>.

If required, a printed version can be provided upon request at the following address: [support@cibiltech.com](mailto:support@cibiltech.com)

**Note:** The screenshots shown in this user manual are examples only, they are not exhaustive and may differ slightly from the views available in the user interface.

**Intended audience:** This manual is intended for patients who use the Apilife Medical application as part of their medical follow-up.

## 2. Security Information

### 2.1 Primary risks related to the use of Apilife Medical

The main risks of using Apilife Medical are the following:

- The patient cannot send information (clinical, biological, histological, etc.) to his/her healthcare professional,
- The healthcare professional does not receive the information (clinical, biological, histological, etc.) that has been sent by the patient,
- The healthcare professional receives incorrect information.

**Warning:** Healthcare professionals are not expected to base their clinical assessment of the patient's overall health status solely on the results of Apilife Medical. The information provided by Apilife Medical informs the clinician along with other clinical information available at the time of the clinical assessment and should assist in decision making but should not be used alone.

### 2.2 Warnings

- Always ensure that you open only websites via a secure SSL/TLS connection. In this case, the Internet address starts with "https". Connections that only start with "http" are a security risk.
- Make sure you are using the latest version of your web browser (for a list of browsers that are compatible with Apilife Medical see the *technical specifications chapter*) and regularly update your operating system.
- Keep your passwords up to date. Use a separate password for each application and do not use previous passwords.
- Do not click on links in emails from unknown senders, as this could direct you to a

website containing malware.

### 2.3 Description of product labeling

The following symbols may appear in the application or in the documentation:

Symbol/Text	Meaning
	Manufacturer's address
Apilife Medical v1.2	Device name and version identification
	Consult the user manual
	CE Marking 2797: identification of the notified body

## 3. Intended use

Apilife Medical is a standalone software medical device (under Regulation (EU) 2017/745 on medical devices).

It is intended to be used as a monitoring tool to facilitate patient self-awareness and communication with healthcare professionals. Apilife Medical is reserved for patients suffering from chronic diseases on the following organs: heart, lung, liver, intestine, stomach, kidney, and their healthcare professionals.

**Warning:** Remote monitoring is not an emergency system. In case of a medical problem, patients must contact a health professional or the ambulance.

### 3.1 Intended users

The Apilife Medical solution is intended to be used by:

Health professionals involved in the follow-up of patients suffering from chronic diseases of the following organs: heart, lung, liver, intestine, stomach, kidney (such as nurses, pulmonologists, cardiologists, nephrologists, gastroenterologists...).

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Patients with chronic diseases of one of these organs: heart, lung, liver, intestine, stomach, kidney.

### 3.2 Contraindications

There are no contraindications to using Apilife Medical.

## 4. Operating principle and mode of action

Apilife Medical is used as a remote monitoring tool before or after transplantation to facilitate communication between the healthcare professional and the patient by providing a customizable alert system. The patient can send clinical information (blood pressure, weight, temperature, blood glucose, heart rate, FEV1) and biological information (biological and histological reports) to his healthcare professional.

## 5. Technical data/Prerequisites

The Apilife Medical patient tool is available in mobile version on models with dimensions of minimum 320 x 568 px and maximum 414 x 896 px and supporting the following browsers:

Browser	Compatible version
Chrome	Version 81
Firefox	Version 75
Safari	Version 14
Edge	Version 81

**Note:** It is necessary to have an internet connection to use Apilife Medical. No special training is required to use Apilife Medical.

If you wish to have access to the patient application, ask your doctor to create an account for you. You can use the patient application from your web browser.

## 6. Apilife Medical Mobile Application

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## 6.1 First connection

One of the health professionals in charge of your follow-up will create an account for you using your email address.

You will receive an invitation email, click on the link in the email to create your password.

**Please note:** The login link is only valid for 24 hours. If you exceed the 24 hours, click on "forgot password" on the Apilife Medical login page and request a link to reset your password.

A screenshot of the Apilife Medical web application's password creation page. The page has a light blue header with the Apilife logo. Below the header, the title "Création du mot de passe" is displayed. There are three input fields: "Adresse mail", "Mot de passe", and "Confirmer le mot de passe". Each field has a small 'D' icon on the right. At the bottom of the form is a blue button labeled "Créer un mot de passe".

From the application you can also click on "Forgot Password" and enter your email address to receive a link to change your password and access the application.

## 6.2 Forgot your password?

If you forget your password, on the login page you can click on "Forgot your password? On this page, enter your email address to receive a reset link. By clicking on the link from your email, you will be redirected to a page where you can fill in your password and a password confirmation.

**Note:** If your email address is not valid (it does not correspond to a user account), you will not receive the email allowing you to change your password.

## 6.3 Home page

This is the home page of the Apilife Medical web application.

This page is composed of:

- The name of your hospital department at the top of the page,
- A message in case of emergency referring to the "Emergencies" section,
- A menu at the top left,
- A welcome message,
- A button (+) at the bottom of the page, allowing you to download your documents, or to update your clinical data.

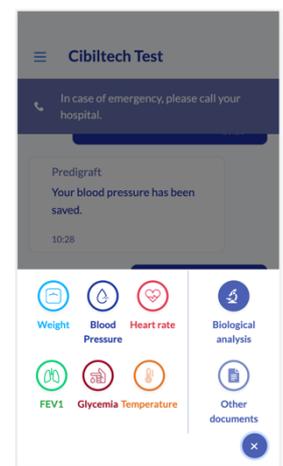
When you first connect, you will be directed to a home page with the following welcome messages:

"Welcome to Apilife Medical, your daily monitoring companion!"

"Send your biological and clinical data to your medical team right now using the (+) button at the bottom of your screen."

## 6.4 Menu

To access the menu, simply click on the menu icon at the top left of the home page. You will then be redirected to the menu consisting of several blocks.





#### 6.4.1 My Data

The "My data" section corresponds to your clinical data entered in Apilife Medical. This data can be provided by your health professional from your patient file, or you can enter your weight directly from your application.

By accessing this page, you are redirected to all your clinical data: weight, blood pressure, temperature, FEV1 and blood glucose.



By clicking on each data, you have the possibility to:

- Consult the history of all your data,
- Visualize your data as a graph by choosing: "1 week", "1 month", "6 months", "1 year" or "all" for all your data,
- Delete the data you want by clicking on the cross at the end of the line,
- Add data by using the "+" button at the bottom of the page.

You can also send clinical data to your doctor by clicking on the (+) button on the home page.

By clicking on the (+) button on the home page, you can also send two types of documents to your doctor:

- Biological analysis,
- Other documents.

By choosing a data, you can also update your data directly on your messaging system.

To add or update your data, enter a data in the available field, then click on the arrow to send it.

You will be redirected to your mailbox, where a confirmation message appears with the data entered and the date of addition.

**Note:** This data is sent to your patient record in your healthcare provider's application and can be viewed by your healthcare provider.

#### 6.4.2 My sent documents

The section "My sent documents" corresponds to the different documents (histological, biological, medical reports) that you have uploaded in the Apilife Medical application.

The documents are listed from the most recent to the oldest. By clicking on one of them, you can directly access the entire document.

By accessing this page, you have the possibility to:

- View the history of all the documents you have sent,
- Delete or download the documents of your choice, by clicking on ,
- Add documents using the " " button at the bottom of the page.

**Please note:** you cannot delete documents already confirmed by your doctor.

#### 6.4.3 My received documents

The "My received documents" section corresponds to the different documents (histological, biological, medical reports) that your health professional has downloaded from your patient file.

The documents are listed from the most recent to the oldest. By clicking on one of them, you can directly access the entire document.

You can download a document by clicking on the three small dots.



#### 6.4.4 My account

The "My account" section corresponds to your personal information. It is composed of:

- Your last name,
- Your first name,
- Your email address,
- Your language preferences.



#### 6.4.5 Emergencies

This section indicates an important message in case of an emergency:

"Please note that Apilife is not an emergency channel. If you have symptoms of concern such as fever, diarrhea, vomiting, or COVID-related symptoms, please contact your hospital."

#### 6.4.6 About

The "About" menu consists of several sections:

- Product information where you can download the Apilife Medical instruction manual,
- The legal notice containing the legal information of the Apilife Medical solution, as well as the details of our data host,
- The privacy policy,
- The cookie policy,
- The General Terms of Use,
- A contact information allowing you to directly contact Cibiltech support, by email, at the following address: [support@cibiltech.com](mailto:support@cibiltech.com).

#### 6.4.7 FAQ (Frequently Asked Questions)

You can access the FAQ section from the Apilife Medical application menu, which redirects you directly to the Help Center and the FAQ of the Cibiltech website. This section gathers a list of questions and answers related to questions you might have about the application.

The FAQ is available online on the help center of the company's website:

<https://basedeconnaissances.cibiltech.com/fr/knowledge/faq>

#### 6.4.8 Disconnecting

To disconnect, click on the "Disconnect" button in the menu.

#### 6.5. Deactivate your account

If you wish to deactivate your Apilife Medical account, please contact Cibiltech technical support and send your request to the following address: [support@cibiltech.com](mailto:support@cibiltech.com).

#### 6.6. Send Biological analysis or other documents

To transfer your biological analysis, as well as any other document, you can click on the (+) button on the home page, then click on the "Analysis" button or "other documents" button depending on the file to be transmitted.

On your computer, you can directly choose the document you wish to import, which can be protected by a password.



You can upload a document in image format (png, jpeg, jpg and HEIC) or PDF. For the image format, you have the possibility to send several documents at the same time by clicking on "Add a page".

To transfer your biological analysis results from your cell phone, you have three possibilities:

- You can click on "Photo Library", select a document, and click on "Send",
- You can click on "Take a picture", take a picture and click on "Send",
- You can click on "Browse", select a PDF, and click on "Send". You can send a password protected document.

When you click on "Send", you are redirected to your email, where a confirmation message appears with the uploaded document. You can click on the document to view it.

If your document is in image format, you can add a second document in image format to be sent at the same time as the first, by clicking on "Add an image".



You can also scroll through the different documents you will import.

If you make a mistake, you can delete the selected image by clicking on "Delete this page".



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**Warning:** Make sure that the document selected corresponds to your biological analysis result. The document you import cannot exceed 20 MB. Moreover, you cannot send several PDF documents at the same time.

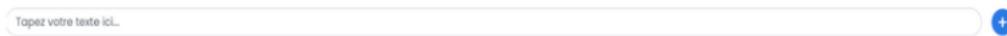
You can find the documents you have sent in the "My sent documents" section.

You can find the documents sent by your health professional in the "My received documents" section.

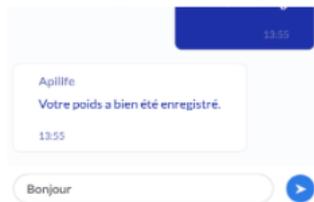


## 6.7. Messaging

You can send messages to your doctor by clicking on the text bar at the bottom of the home page.

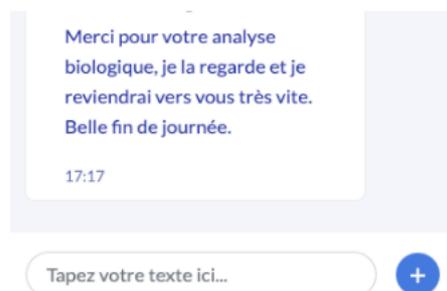


Enter your text and click on the arrow to send your message.



You also have the possibility to receive messages sent by your doctor.

When your doctor sends you a message, an email will automatically be sent to you.



## 7. Support / Maintenance

For any questions, requests, or reports of malfunctions, send an email to the manufacturer's support team at the following address: [support@cibiltech.com](mailto:support@cibiltech.com).

**MATERIAL SAFETY:** Any incident or risk of serious incident (defined according to article L.5212- 2 of the Public Health Code) detected during the use of the Apilife Medical, medical device must be reported to the manufacturer at the following address: [materiovigilance@cibiltech.com](mailto:materiovigilance@cibiltech.com).

You must report any event to the competent authority of the Member State in which you are

established:

[https://ec.europa.eu/health/sites/health/files/md\\_sector/docs/md\\_vigilance\\_contact\\_points.pdf](https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_vigilance_contact_points.pdf)

## **8. Personal data**

For any questions, requests, or statements regarding your personal data, please refer to Cibiltech's Privacy Policy. It is available online at the company's website: [www.cibiltech.com](http://www.cibiltech.com) at <https://www.cibiltech.com/privacy-policy>.