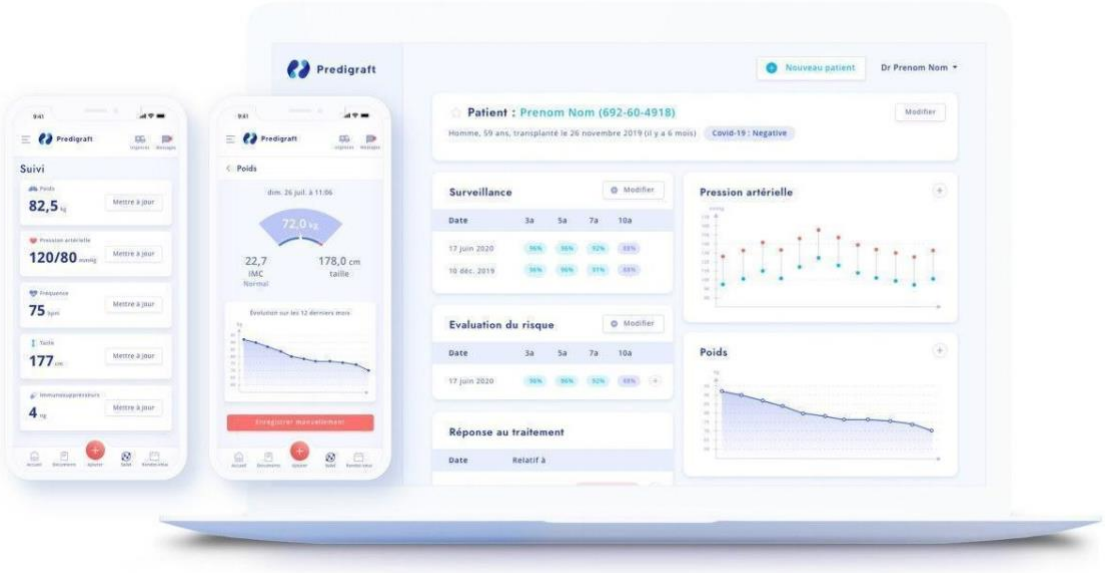
Predigraft v1.13
User Manual

Patient



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

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This manual complies with **EU** Medical Device **Regulation 2017/745.**

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1. About this manual

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

The electronic version of this manual is available online at www.cibiltech.com. If required, a printed version can be provided upon request at the following address: contact@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 Predigraft application as part of their medical follow-up.

2. Security Information

2.1. Primary risks related to the use of Predigraft

The primary risks identified are related to the entry of health data into the Predigraft software. A false entry can lead to:

- **An overestimation of your current or predicted health status:**
  When you do not enter a parameter correctly or when a healthcare professional makes a mistake when entering the parameter, the probabilities of graft survival may be higher than expected.
- **An underestimation of your current or predicted health status:**
  When you do not enter a parameter correctly or when a healthcare professional makes a mistake when entering the parameter, the probabilities of graft survival may be lower than expected.

Caution: Predigraft is a decision support tool. The clinical assessment of your health status by your healthcare professional is not based solely on the prognosis of Predigraft.

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 Predigraft 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.

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2.3. Description of product labeling

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

Symbol/Text	Meaning
	Manufacturer's address
Predigraft v1.13	Device name and version identification
	Consult the user manual
CE 2797	CE Marking 2797: identification of the notified body

3. Intended use

Predigraft is a medical device intended to be used as a predictive tool to inform healthcare professionals of the probability of survival of allograft kidney transplants following kidney transplantation. These probabilities, along with available standard clinical data, help describe the condition of the allograft, and provide additional information concerning the patient's care and treatment decisions. Specifically, Predigraft provides probabilities of allograft survival at +3 / +5 / +7 years after evaluation, based on the combination of a set of clinical, biological, and histological parameters.

Predigraft is also intended to be used as a telehealth tool after kidney transplantation to facilitate communication between clinicians and patients by providing a customizable alert system.

Warning:
Remote monitoring is not an emergency response system. In the event of a medical problem, patients should contact a healthcare professional or Emergency Medical Services.

3.1. Intended users

The Predigraft solution is intended to be used by:

- Healthcare professionals involved in the treatment and follow-up of kidney transplant patients such as nephrologists, nurses, etc.
- Kidney transplant patients.

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3.2. Intended patient population

Patient selection criteria:

- Patient having received a kidney transplant from a living or deceased donor,
- Patient must be at least 18 years old.

3.3. Contraindications

Predigraft cannot be used for the follow-up of patients who have had:

- Previous non-functional kidney transplantation,
- A combined transplant (e.g. kidney - heart transplant, kidney - liver transplant).
- A transplant within the past month.

4. Operating principle and mode of action

4.1. iBox technology

Predigraft was developed using the "integrative BOX" (iBox) technology. The iBox predicts the probability that the graft will still be functional at 3, 5, and 7 years after evaluation by the care staff.

Read more about it:

The iBox is a predictive algorithm developed by the Paris Transplant Group (INSERM UMR 970; Principal Investigator: Professor Alexandre LOUPY). The algorithm predicts allograft survival at 3, 5, and 7 years after risk assessment with accurate calibration and discrimination (concordance index 0.81, 95% confidence interval 0.79 to 0.83). It was developed in a cohort of 4000 kidney transplant patients in France and validated in a cohort of 2129 patients in Europe and a second cohort of 1428 patients in three centers in the United States.

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4.2. Mode of action

Predigraft is used as a risk monitoring/assessment tool.

During your follow-up, your healthcare professional will use Predigraft to assess the risk of graft loss. An initial prediction of graft survival can be obtained on the basis of biological parameters used in standard clinical follow-up, namely:

- Creatinine (to estimate glomerular filtration rate according to the MDRD formula; unit: ml/min/1.73 m2).
- The urine protein/creatinine ratio (unit g/g).

Your healthcare professional can refine the prediction of your graft's survival by providing the additional information from a biopsy and the measurement of donor-specific anti-HLA antibodies (DSA).

5. Technical data/Prerequisites

The Predigraft patient tool is available in a mobile version on devices with a minimum size of 320 x 568 px and a maximum size of 414 x 896 px. It is compatible with devices supporting the following browsers:

Browser	Compatible version
Chrome	Version 79.0.3945.130
Firefox	Version 72.0.2
Safari	Version 13.0.5 (15608.5.11)

Note: The use of Predigraft does not require any training. Only an internet connection is required to use Predigraft.

6. Predigraft Mobile Application

To access the Patient application, you will need to ask your doctor to create an account for you.

6.1. First connection

A healthcare professional in charge of your follow-up will create an account for you using your email address. You will receive an invitation email and a random password will be generated. Click on the link in the email to update your password.

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

6.2. Forgot your password?

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

Please note: *if your email address is invalid because it does not correspond to a user account, you will not receive the email allowing you to change your password.*

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6.3. Home page

6.4. Menu

You can access the support menu by clicking on the emoticon of the lines at the top left of the screen.

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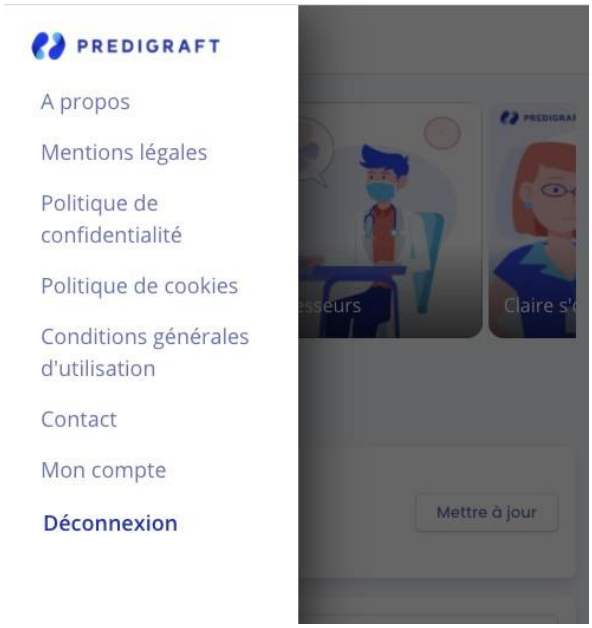

6.4.1. About us

The "About" section contains the Predigraft label as well as the link to this user guide.

6.4.2. Legal Notice

The "Legal Notice" section contains the legal notice of the Predigraft platform as well as details about the data host.

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6.4.3 Privacy Policy, Cookie Policy and Terms of Use

The sections "Privacy Policy", "Cookie Policy" and "General Conditions of Use" include the respective documents.

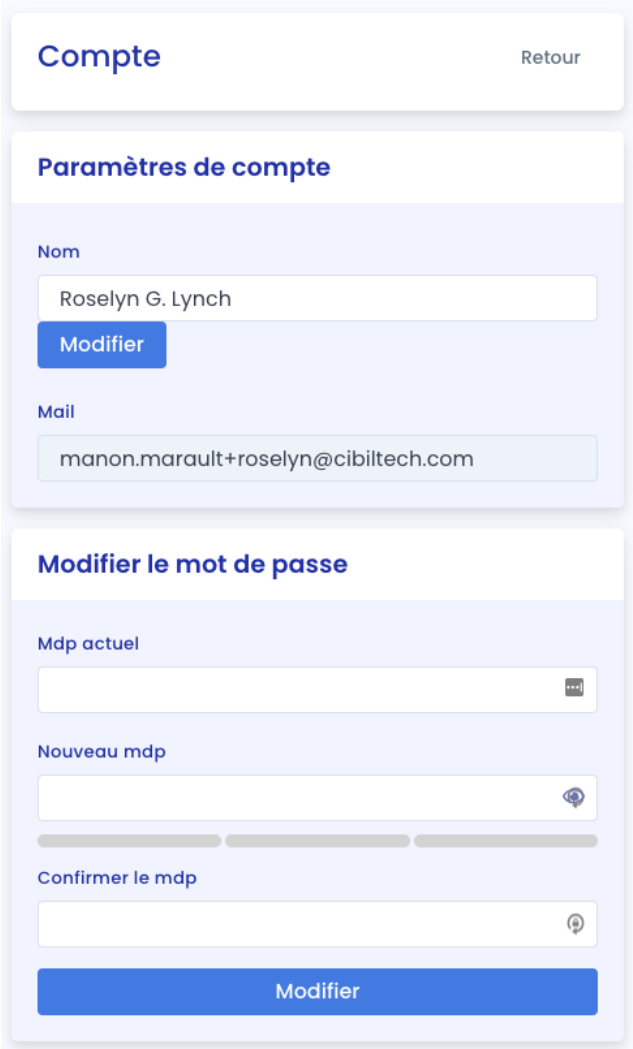
6.4.4 Contact

The "Contact" section in the menu allows you to contact Cibiltech support directly by email.

6.4.5 My Account

The heading "My account" in the menu allows you to enter and/or modify your:

- Name,
- Password.



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6.5 Log out

Click on "Logout" in the top left menu to log out of your account.

6.6 Deactivate your account

If you wish to deactivate your Predigraft account, please contact Cibiltech technical support and submit your request at the following address

- Email: support@cibiltech.com

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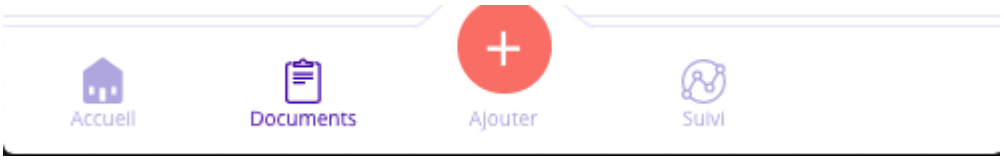
7 Submit an analysis report(s)

To upload laboratory analysis results, you can click on:

a) Submit a biological analysis

b) Document toolbar



c) Add (+) button

Choose a document to upload from your device:

Confirm your choice by pressing **Submit**. You can also change the document by pressing **Change**.

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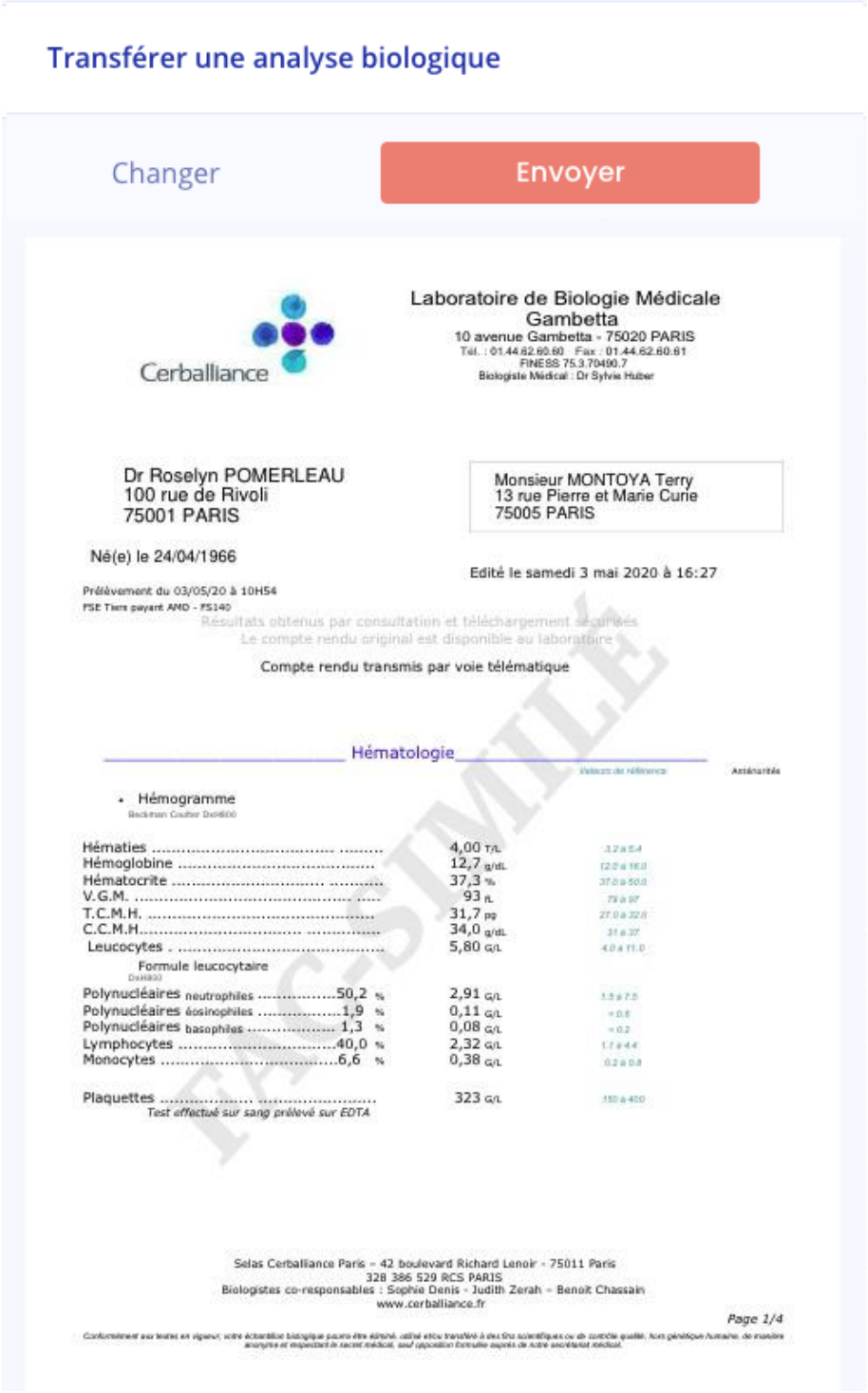

Warning:
Make sure that the correct document was uploaded.

By clicking on **Submit**, you will be redirected to the list of sent documents.

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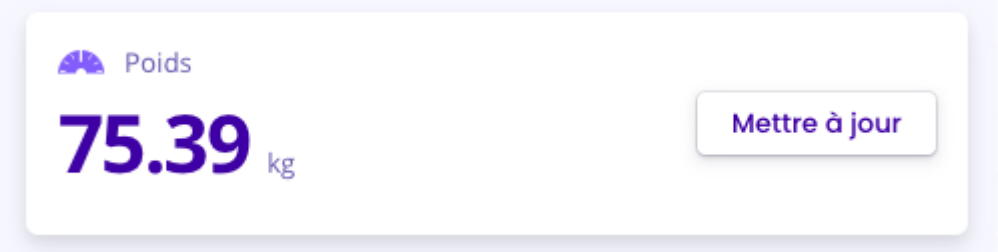
8 Clinical Data

8.4 Weight

Also accessible on the home page, the **monitoring** section allows you to view and update your weight (in kg).

To update your weight, click on "update".



If you clicked "Update", enter your weight. The entry date is the date the document is uploaded. Press "**Confirm**" to confirm.

Note: This data is added to your patient record and is accessible to your health professional.

You will be redirected to a page showing the most recent weight value:

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To view the list and changes in weight (in kg), click on "trend". This page is also accessible by clicking on the weight value from the home page.

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8.5 Blood pressure

As with weight, the **monitoring** section allows you to view and update your blood pressure.

To update your blood pressure, click on "Update".

Enter your blood pressure. The entry date is the date the information is entered and click "**Confirm**". You must provide two values to complete your blood pressure:

- The systolic value (the higher value),
- The diastolic value (the lower value).

Note: This data is added to your patient record and is accessible to your health professional.

You will be redirected to a page showing the most recent blood pressure value:

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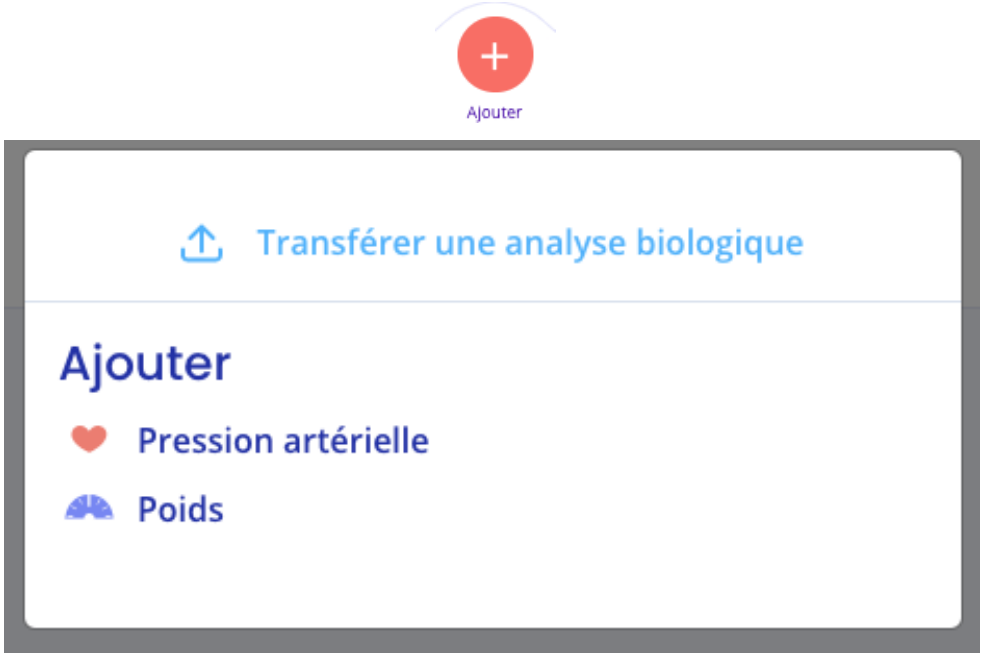
To view the list and changes in blood pressure (in mmHg), click on **"Trend".** This page is also accessible by clicking on the blood pressure value from the home page.

8.6 The (+) button

You can also enter your weight and blood pressure directly by clicking the (+) button.



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9 Therapeutic support: educational videos

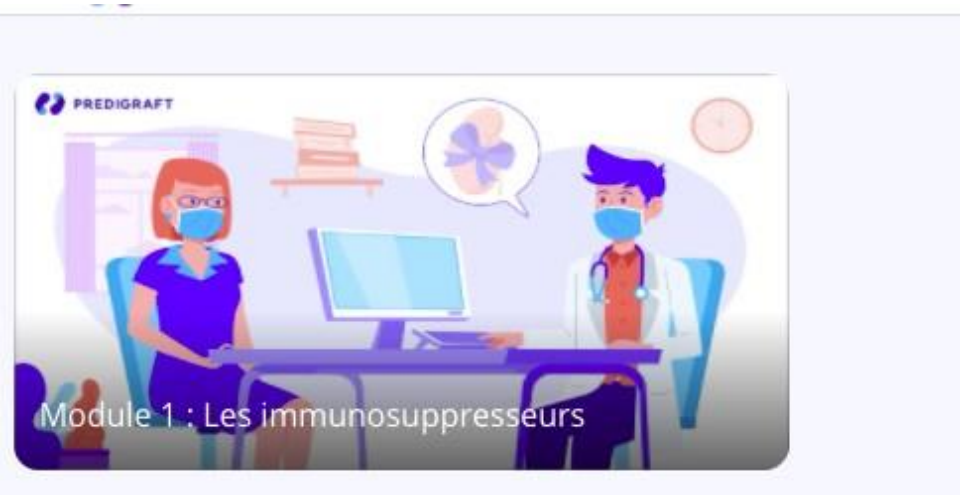
Therapeutic support is a supplemental tool and is not a substitute for therapeutic education. The aims include the following:

- To actively involve you in your healthcare journey,
- To better understand your symptoms and the various aspects of your treatment,
- To take the appropriate measures to be carried out in connection with your remote monitoring.

This support throughout the entire remote monitoring process is essential to enable you to be involved in your monitoring and thus adhere to your care plan.

It is complementary to and does not replace the training in the use of the remote monitoring device that your healthcare professional will provide.

Videos of therapeutic accompaniment are available on the top of the home page:



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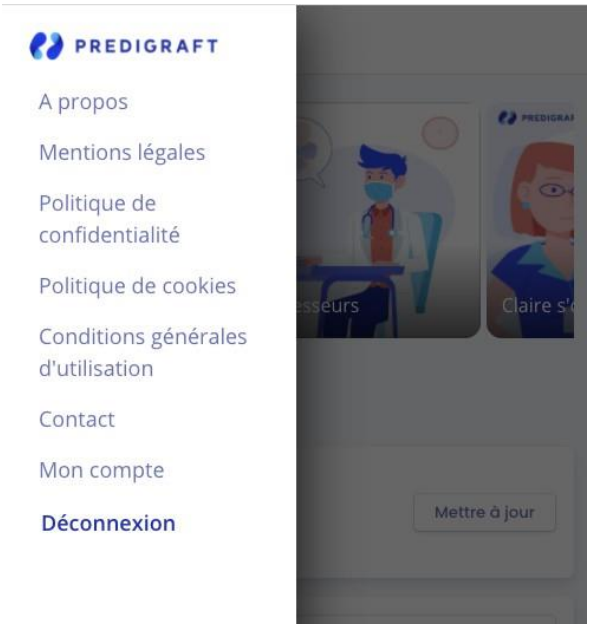
10 About



11 Support/Maintenance

For any questions, requests, or reports of malfunction, please send an email to support@cibiltech.com

MATERIOVIGILANCE: Any incident or risk of serious incident (defined according to article L5212-2 of the Public Health Code) detected during the use of the medical device Predigraft must be reported to the manufacturer at the following address: materiovigilance@cibiltech.com

You must report any event to the competent authority of the Member State in which youare established: https://ec.europa.eu/health/sites/health/files/md_sector/docs/md_vigilance_contact_points.pdf

12 Personal data

The use of the Predigraft application requires you to fill in certain personal data necessary for its operation. When using the application, you are required to provide us with your full name, first name, title, date of birth, gender, language, e-mail address, telephone number. Entering this personal data enables us to establish a regular means of communication with a given healthcare professional. We verify your identity, for example, using your e-mail address and phone number. Collecting your personal data also allows us to communicate with you for information on the use of the application itself, in the event of security issues related to the application and may be used for commercial purposes (manufacturer - healthcare center communication).

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When you contact our technical support, you are also informed that the call is likely to be recorded and we inform you that we also collect data. The purpose is to be able to improve the technical support. The technical, regulatory, quality and sales departments are the recipients of this information. Your personal data is kept for the time you use the application, for a given care center. As the Predigraft application is a regulated medical device, this information is then archived for regulatory traceability purposes for 10 years**.**

In accordance with the Data Protection Act and the European Regulation 2016/679 (GDPR) you have the following rights regarding your personal data:

- Right to access,
- Right to rectification,
- Right to erasure,
- Right to restriction of processing,
- Right to object,
- Right to data portability.

In order to request the exercise of your rights, you can contact our data protection officer at: privacy@cibiltech.com. In this request, please specify your surname, first name, e-mail address, institution/facility and the nature of the right(s) you wish to exercise, accompanied by a copy of your identity card in order to authenticate your identity. We make every effort to comply with Data Protection Regulations to ensure the security of your data and your rights. Nevertheless, in the event that you notice a breach of this regulation, you are entitled to file a complaint with the supervisory authority (the CNIL, www.cnil.fr, or the Data Protection Officer (DPP or DPO in English) of the person responsible for processing your data (DPO of the health establishment or DPO of the manufacturer of the application).

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