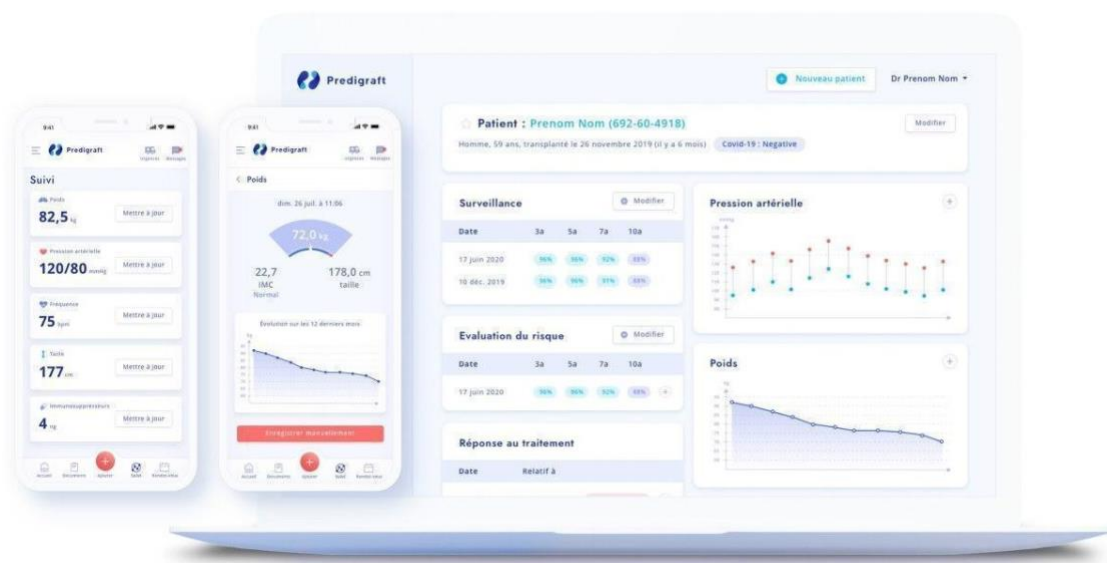


Predigrift v1.16

User Manual

Patient



Please read this entire manual carefully before using Predigrift 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.

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 v1.16	Device name and version identification
	Consult the user manual
	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

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.

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.

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.



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).

A report is generated by Predigraft and helps to describe the status of the allograft. This report provides additional information in the care and treatment decision of the patient.

Predigraft is also used as a remote monitoring tool after renal 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) and biological information (biological and histological reports) to their healthcare professional.

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 81
Firefox	Version 75
Safari	Version 14
Edge	Version 81

Note: An internet connection is required to use Predigraft. No special training is required to use Predigraft.

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

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

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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.

Warning: The login link is only valid for 24 hours.

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.



The screenshot shows the Predigraft login interface. At the top, there is the Predigraft logo and the word "PREDIGRAFT". Below this, the word "Connexion" is displayed in blue, followed by the text "ou Créer un compte" in a smaller blue font. There are two input fields: "Adresse mail" and "Mot de passe". Below the "Mot de passe" field, there is a checkbox labeled "Se souvenir de moi" and a link "Mot de passe oublié ?". At the bottom, there is a blue button labeled "Connexion".

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.

6.3. Home page




This is the home page of the Predigraft web application. This page is composed of:

- The indication of your service at the top of the page,
- The menu at the top left,
- A message in case of an emergency can be found in the "Emergencies" section,
- A welcome message,
- A button (+) at the bottom of the page, allowing you to download your documents, or to update your blood pressure or your weight.

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

- "Welcome to Predigraft, your daily monitoring companion!"
- "Send your biological and clinical data to your medical team using the (+) button at the bottom of your screen."
- "A new therapeutic education video will be sent to you regularly."

6.4. Menu

You can access the support menu by clicking on the emoticon of the lines  at the top left of the screen. You will then be redirected to the menu consisting of several blocks.



6.4.1 Weight monitoring

The "Weight Monitoring" section is your weight data entered into Predigraft. This data can be provided by your healthcare professional from your patient file or you can fill in your weight directly from your application.

By accessing this page, you have the possibility to:

- View the history of all the data,
- View the data as graphs by choosing (1 week, 1 month, 6 months, 1 year or all),
- Delete the data of your choice, by clicking on the cross,
- Add data using the button "+" at the bottom of the page.

6.4.2 Blood pressure monitoring

The "Blood Pressure Monitoring" section is your blood pressure data entered into Predigraft. This data can be provided by your healthcare professional from your patient file or you can enter your blood pressure directly from your application.

By accessing this page, you have the possibility to:

- View the history of all the data,
- View the data as graphs by choosing (1 week, 1 month, 6 months, 1 year or all),
- Delete the data of your choice, by clicking on the cross,
- Add data using the "+" button at the bottom of the page.


6.4.3 My documents sent

The "My documents sent" section corresponds to the various documents (histological, biological, medical reports) that you have uploaded to the Predigraft 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:

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

Warning: you cannot delete documents that have already been confirmed by your doctor.

6.4.4 My documents received

The "My documents received" 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.

6.4.5 My account

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

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

6.4.6. Emergencies

This section contains an important message in case of an emergency: "We remind you that Predigraft is not an emergency channel. If you have any worrisome symptoms such as fever, diarrhea, vomiting, or Covid-19 symptoms), please call your hospital department at XXX (nephrology department) or the front desk at XXX."

6.4.7 About

The "About" menu consists of several sections:

- Product information where you can download the Predigraft instruction manual,
- Legal notice containing legal information about the Predigraft solution, as well as details of our data host,
- Privacy policy,
- Cookie policy,
- Terms and conditions of use,
- A contact page allowing you to communicate directly with Cibiltech support, by email, at the following address: support@cibiltech.com

6.4.8 FAQ

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

to the questions you might have about the use of the application.

6.4.9 Log out

To log out, click on the "Logout" button in the menu.

6.5 Deactivate your account

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

6.6 Send biological analysis

To transfer your biological analysis results, you can click on the (+) button on the homepage, then click on the "Analyses" button. On your computer, you can directly choose the document you want to import, which can be protected by a password.



You can upload a document in different image formats (png, jpeg, HEIC and jpg) or PDF.

For image format you can upload 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 Photo", take a photo 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.

You can also scroll through the different documents you are going to import. In case of error, you can delete the selected image by clicking on "Delete this page".

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 healthcare professional in the "My received documents" section.

6.7 Messaging

You have the possibility to send messages to your healthcare professional by clicking on the textbox.



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

You have the possibility to receive messages sent by your healthcare professional.



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

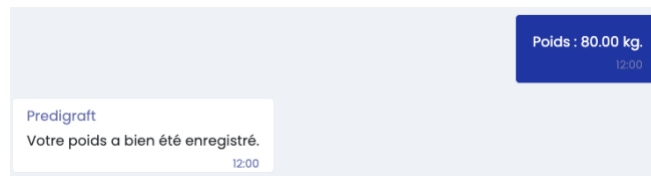
6.8 Clinical data

6.8.1 Weight

Accessible from the homepage, by clicking on the (+) button, the "Weight" section allows you to view and update your weight (in kg).



To add or update it, enter your weight in the available field. By clicking on the arrow to send it, you are redirected to your messaging, where a confirmation message appears with the weight entered and the date of addition.

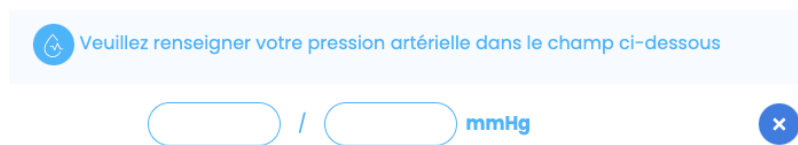


Note: This data is sent to your patient file in your healthcare professional application and can be accessed by him/her.

You can view the data history entered in the "Weight monitoring" section and delete a data by clicking on the cross.

6.8.2 Blood pressure

As for the weight, by clicking on the (+) button, the "Blood pressure" section allows you to view and update your blood pressure (in mmHg).

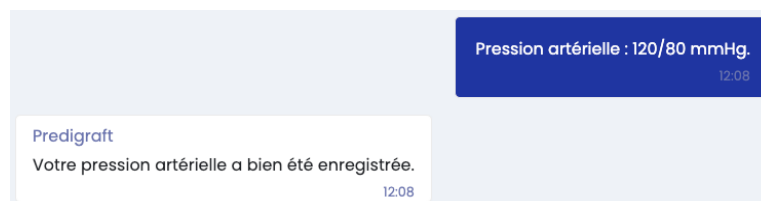


To add or update it, fill in your blood pressure in the available field. You must provide two values to complete your blood pressure:

- The systolic value (the high value),
- The diastolic value (the low value).

By clicking on the arrow to send it, you are redirected to your messaging, where a confirmation message appears with the blood pressure and the date of addition.

Note: This data is sent in your patient file and is accessible by your healthcare professional.



You have the possibility to visualize the data history fill in on the section "Blood Pressure monitoring" and to delete the data by clicking on the cross.

7 Therapeutic support program

With Predigraft, we want to help you adopt a healthy lifestyle and a thorough knowledge of your disease and treatments.

A complete therapy program will be sent to you each week to help guide you:

- Therapeutic support videos to help you in the early stages of your transplant,
- Quizzes to accompany the videos to test your knowledge; each answer will be justified to help you better understand certain aspects of your lifestyle, transplant or treatments for example,

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- Messages entitled "The right thing to do" or "Did you know", to enrich your knowledge about transplantation,
- Articles composed of a set of practical cards and recipes.

This program has been designed to send you content tailored to your needs. For example:

- If a biopsy is scheduled, you will receive a video explaining the exam,
- If you are diabetic, you will receive associated dietary advice,
- If you are at risk of non-adherence, you will receive regular reminders about the importance of taking medication.

Note: You will receive an email notification to let you know that new therapeutic content is available on your Predigraft messenger.

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.

Throughout the telemonitoring project, this support is essential to allow you to get involved in your daily follow-up and to adhere to your care plan.

The therapeutic support videos are accessible in the "Therapeutic Support" section of the menu.

8 Support/Maintenance

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

MATERIOVIGILANCE: Any malfunction (as defined in Article L.5212-2 of the French Public Health Code) found during the use of the Predigraft medical device must be reported to the manufacturer at the following address: materiovigilance@cibiltech.com

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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

9 Personal data

For any questions, requests or statements regarding your personal data, please refer to Cibiltech's Privacy Policy. It is available online on the company's website: www.cibiltech.com.