CIBILTECH

apilife Medical

Apilife Medical 1.2
User manual

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English version

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CE 2797

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

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Table des matières

1.   About this manual

This manual is an integral part of the Apilife Medical software. It details the presentation of the application, its configuration, and its use. The electronic version is available online on the product page of the company's website: www.cibiltech.com.

If needed, a printed version can be provided on request at the following address: support@cibiltech.com.

Note: The screen shots reproduced in this user manual are for illustrative purposes only, they are not exhaustive and may differ slightly from the views available in the user interface.

Target audience: This manual is intended for healthcare professionals.

2.   Safety information

2.1 Main 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 their 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.

Caution: 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 Warning

Be sure to open websites only via a secure SSL/TLS connection.

In this case, the Internet address begins with "https". Simple connections that only begin with "http" are a security risk.

Make sure you use the latest version of your web browser (compatible with Apilife Medical see chapter "Technical specifications/requirements") and update your operating system regularly.

Keep your passwords up to date. Use a separate password for each application and do not use old passwords.

Do not click on links in emails from unknown senders, as this may take you to a website containing malicious software.

2.3 Description de l'étiquetage produit

Symbol/Text	Signification

![CIBILTECH logo]

![Factory/manufacturer symbol]	Address of the manufacturer
Apilife Medical v1.2	Identification of the product name and version
![Consult instructions symbol]	Consult the user manual
![CE marking]	CE marking - Identification of the notified body: 2797

3. Indication for use

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

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

3.1 Intended users

The Apilife Medical solution is intended to be used by:

- Healthcare professionals involved in monitoring patients suffering from chronic diseases of the following organs: heart, lung, liver, intestine, stomach, kidney (such as nurses, pulmonologists, cardiologists, nephrologists, gastroenterologists...).
- Patients suffering from chronic diseases of one of these organs: heart, lung, liver, intestine, stomach, kidney.

3.2 Contraindications

There are no contraindications to use Apilife Medical.

4 Working 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 system of customizable alerts. The patient can send clinical (blood pressure, weight) and biological (biological and histological reports) information to his health care professional.

5 Technical characteristics/requirements

The Apilife Medical tool is dedicated to the healthcare professional and is available in SaaS (Software as a Service) mode via the web. The application is compatible with the main browsers below:

Navigateur	Version compatible
Chrome	≥ Version 81
Firefox	≥ Version 75
Safari	≥ Version 14
Edge	≥ Version 81

6 Alerts

Apilife Medical calculates alerts on clinical, biological, and immunological data of patients.

6.1 Setting up alerts

Apilife Medical calculates alerts based on alert parameters. There are three levels of parameters:

- (Default) Apilife Medical level: Cibiltech sets the default values.

- Department level: the department manager can modify the department alert parameters. This setting is then valid for all patients in the department.

- Patient level: the members of the department can change the alert settings for each patient. This setting is only valid for the patient concerned.

6.1.1 Cibiltech settings: default settings

At Apilife Medical level, Cibiltech has defined default values that departments can modify as soon as they start using the solution.

<u>Blood pressure</u>
- Maximum systolic pressure value: 140 mmHg.
- Maximum diastolic pressure value: 90 mmHg.
- Systolic pressure value for hypertension (Grade 3): 180 mmHg.
- Diastolic pressure value for hypertension (Grade 3): 110 mmHg.

The maximum values for each parameter are:
- Maximum systolic pressure value: 250 mmHg.
- Maximum diastolic pressure value: 130 mmHg.

<u>Weight</u>
- Weight gain: 1 kg.
- Weight loss in one month: 5%.
- Weight loss in six months: 10%.

Maximum values for each parameter are:

- Weight gain: 20 kg

Immunosuppressive drugs
- T0 Tacrolimus minimum threshold: 4 ng/mL
- T0 Tacrolimus maximum threshold: 12 ng/mL
- T2 Cyclosporin minimum threshold: 600 ng/mL
- T2 Cyclosporin maximum threshold: 1200 ng/mL
- T0 Cyclosporin minimum threshold: 50 ng/mL
- T0 Cyclosporin maximum threshold: 150 ng/mL
- T0 Everolimus minimum threshold: 3 ng/mL
- T0 Everolimus maximum threshold: 8 ng/mL
- T0 Sirolimus minimum threshold: 4 ng/mL
- T0 Sirolimus maximum threshold: 12 ng/mL

The maximum values for each parameter are:
- T0 Tacrolimus minimum threshold: 12 ng/mL
- T0 Tacrolimus maximum threshold: 13 ng/mL
- T2 Cyclosporin minimum threshold: 1000 ng/mL
- T2 Cyclosporin maximum threshold: 1500 ng/mL
- T0 Cyclosporin minimum threshold: 250 ng/mL
- T0 Cyclosporin maximum threshold: 300 ng/mL
- T0 Everolimus minimum threshold: 12 ng/mL
- T0 Everolimus maximum threshold: 13 ng/mL
- T0 Sirolimus minimum threshold: 12 ng/mL
- T0 Sirolimus maximum threshold: 13 ng/mL

Blood biology data
- Potassium minimum: 3.2 mmol/L
- Potassium maximum: 5.3 mmol/L
- Minimum hemoglobin: 10 g/dL
- Hemoglobin maximum: 16.5 g/dL
- Minimum HbA1c: 4.5 %.
- Maximum HbA1c: 9 %.
- Platelets minimum: 80 000 /mm3
- Platelets maximum: 550 000 /mm3
- Neutropenia (minimum neutrophils): 1 000 /mm3
- Troponin maximum: 0.6 µg/L
- Minimum INR: 1
- Maximum INR: 5

The accepted thresholds for each parameter are:
- Potassium minimum: [3 - 3.5] mmol/L
- Potassium maximum: [4.8 - 5.5] mmol/L
- Hemoglobin minimum: [8.5 - 10] g/dL
- Maximum hemoglobin: [16 - 17.5] g/dL
- HbA1c minimum: [4 - 6] %
- HbA1c maximum: [6.5 - 13.5] %
- Platelets minimum: [10 000 - 150 000] /mm3

- Platelets maximum: [550,000 - 1,000,000] /mm3
- Neutropenia (minimum neutrophils): [500 - 1,000] /mm3
- Troponin maximum: [0.6 - 2] µg/L
- INR minimum: [1 - 3.5]
- Maximum INR: [3.5 - 5]

Renal function (estimated GFR, proteinuria)
- Increase in serum creatinine: 50

Maximum values for each parameter are:
- Serum creatinine increase: 9999.99%.
Other parameters
- De novo proteinuria
- Systolic pressure for hypertension (Grade 3): ≥ 180 mmHg.
- Diastolic pressure for hypertension (Grade 3): ≥ 110 mmHg.
- Weight loss in one month: ≥ 5%.
- Weight loss in six months: ≥ 10%.

6.1.2 Service level settings

To set up alerts for the service, click on "Alerts" in the main menu on the left, then on "Alert settings".

Alertes

⚙ Paramétrage d'alertes

Nom	ID	Dernière évaluation	Date de transplantation	Créé le
Sophie Q. Lanreau	68730	26 août 2020	25 août 2015	9 oct. 2020

You arrive on the page "Service alert settings". To modify a parameter: modify the value in the corresponding field then click on the "Modify" button. A confirmation window appears and contains the following information
- The parameter value you have entered,
- The calculation that generates the alert.

Example of modification of the minimum Tacrolimus threshold, at the department level:

Confirmation du changement ✖

Tous les patients du service seront en alerte si :
Concentration résiduelle de Tacrolimus < 5 ng/mL

Annuler   Modifier pour tous les patients

Click on "Modify for all patients" to validate or on "Cancel" so that the update of the parameter is not effective.

Once you have updated a parameter, a "Parameter history" button allows you to access the modification history. In this history, you can see the name of the user who modified the parameters, the date of the modification and the list of each alert parameter with its value.

Next to the history button, a message shows the date of the last update of the parameters and the name of the user who performed the action.

Under each parameter that does not have the default value, a text indicates: "Default (Apilife): <value of Apilife Medical parameter>".
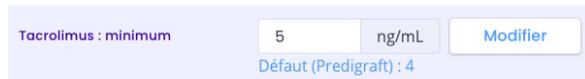
6.1.3 Patient level settings

To set up alerts for a patient, access the patient record and click on the three small dots next to the patient's name, then click on "Alert settings". This will take you to the "Alert settings: <full name of patient>".
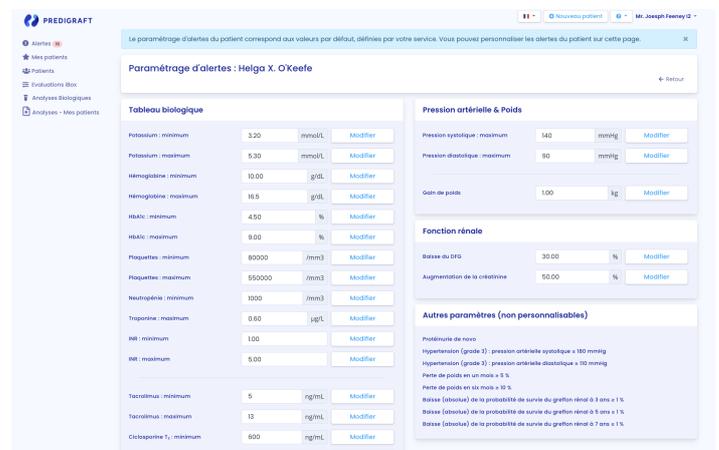
Note: modifying a parameter is done in the same way as modifying a parameter of a service.

You can view the history of the alert settings of a patient by clicking on the three small dots next to the patient's name from his file, then click on "History of settings". In this history, you can see the name of the user who modified the parameters, the date of the modification and the list of each alert parameter with their value.

6.2 Alert management

If a patient has a data outside the pre-defined alert thresholds, an alert is triggered and is then visible from the patient record.

Each alert contains the date of creation of the alert, the details of the alert and a button "mark as read".

![CIBILTECH logo]

You have the possibility to click on the button "Mark as read", this action means that you have considered the alert. The button is changed to "Read at <date and time> by <user>" and this message is visible to all members of the service.
An alert marked as read is moved to the alert history page and accessed by the "Alert History" button on the patient page.

The alert history page lists a patient's alerts in order of most recent first. The history page lists the alerts that have been read (in gray) and the alerts that have not been read (in red). You can read an alert from this page.

7   Notification of your patients' activity

If you are a member of a team, you will receive a daily email about the Apilife Medical activity of your patients in your "My Patients" list.
This email contains in particular:
  - The number of your patients in the "My Patients" list who have a weight or blood pressure alert.

If you are a department manager, you will receive a daily email about the Apilife Medical activity of all the patients in your department. This email contains the following information:
  - The number of patients in your "My Patients" list who have a weight or blood pressure alert,
  - The number of your patients not on any of your team members' "My Patients" list who have weight and blood pressure alerts.

Notes: Clinical and biological data are not contained in the email.

8 Support/Maintenance

For any questions, requests, or reports of malfunctions, send an e-mail to support@Cibiltech.com.

MATERIAL SAFETY: Any incident or risk of serious incident (defined according to article L5212-2 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: contact@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

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