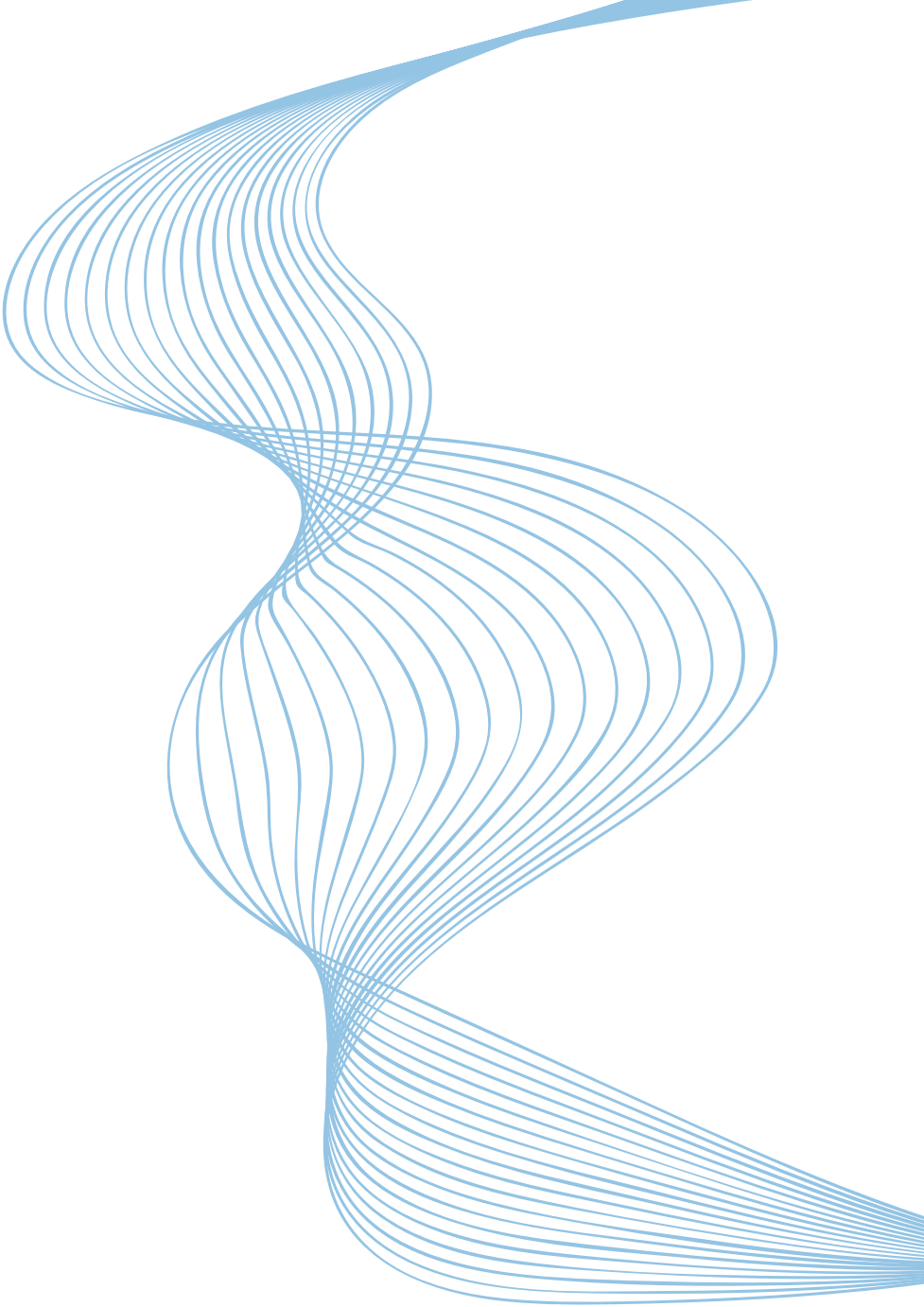
eCelsius Medical system

TELEMETRIC SYSTEM FOR CONTINUOUS MONITORING OF CORE BODY TEMPERATURE

QUICK START GUIDE



Dear customers,

thank you for purchasing the eCelsius Medical system.

This quick start guide is designed to introduce you to the basic functions of the system.

Hereby you will find some recommendations related to its first use.

BodyCAP
Your e-health partner

This document does not replace the user manual.
For an optimal use of the device, we recommend that you take note of all the instructions in the user manual.
Please note the contraindications, warnings, risks and complications detailed in the manual.

The *eCelsius Medical* system is not claimed MRI compatible, it is imperative that the patient ingesting a capsule does not undergo any MRI.

The patient must wear the wrist band supplied with the system showing that he is wearing an electronic device non compatible with the exposure to a strong magnetic field.

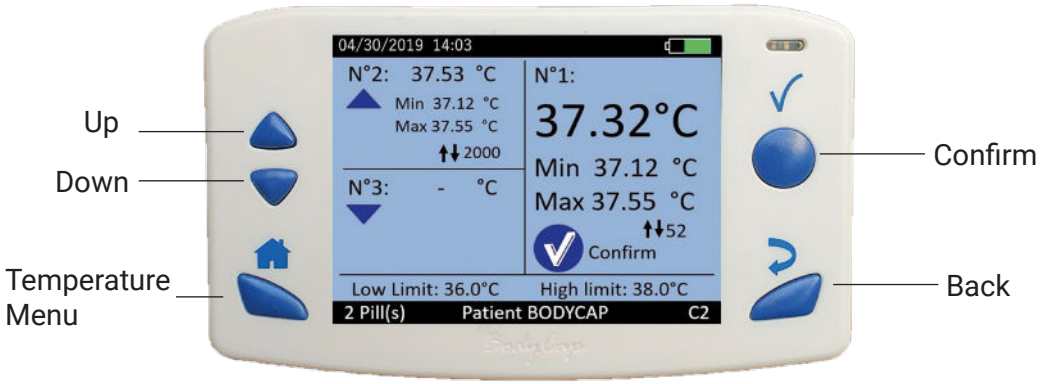
The wrist band is fixed just before the ingestion and must only be removed after the last capsule ejection.

The User guide is available as a PDF version (Adobe Reader needed) on the secured USB stick provided with the system.

BodyCAP may provide the user manual in paper format within 7 days if necessary.

SYSTEM COMPONENTS

eViewer Medical monitor



Collect, record and display temperature data from *eCelsius Medical* capsules.

eCelsius Medical capsule

After activation, it collects and sends data to *eViewer Medical* monitor.

Signaletic bracelet

It is attached to the wrist before ingestion of a capsule and then removed after the expulsion of the last capsule.

Activator medical

Allows to activate capsules.

BodyCAP secured USB stick

The user manual and installer of the *eCelsius Manager* software are included on the secured USB stick.

USB adapter and 2 micro USB / USB cables

Allows to supply Activator Medical or *eViewer Medical* monitor and allows the connection to *eCelsius Manager* software through the USB port.

First Use

Basic Instructions

These instructions will allow you to boot your system.
To be aware of all the features, the use claims and contra-indications, please refer to the user manual included on the secured USB stick.
Before the first use of your system, you have to perform a set of operations.

1. *eCelsius Manager* SOFTWARE INSTALLATION

Make sure the security label is intact on the activator and the monitor, do not use if seal is tampered.

You must install your HMI before using your system.

To install *eCelsius Manager* software and to set your monitor, it is necessary to have the secured USB stick, its password and the minimum system requirements are detailled below.

Minimum System Requirements:

- Processor 1GHz
- 500 Mo of disk space
- Windows version 10 or Windows 11, or a minimum version MAC OS X 10.15.
- 1024x768 for screen resolution

Secured USB stick operating mode:

First, the USB stick may need to be charged 30min.
The secured USB key password is sent to the dedicated contact via separate delivery. The IT department uses the secured USB stick with the given passcode to unlock the USB stick and to install the software, on the authorized HCP computer account.

Installation, password and updates are only sent to the IT department.

After receiving the passcode, follow the steps below in order to install the *eCelsius Manager* software and to access the user manual.

Action	Result
1. Press the KEY button	LEDs blink together
2. Within 10s enter Passcode sent by BodyCAP services and press KEY Button	LEDs will illuminate together for approximately 4s. and then change to blinking
3. Connect the USB stick into USB port within 30s	LEDs illuminates and remains solid (blue LED can flicker)
4. Get access to USB stick content	You can access to user manual and/or *eCelsius Manager* installer.
5. When finish, unplug the drive	All indicators will turn off. Drive is lock again.

To install the *eCelsius Manager* software and the drivers of the *eViewer Medical* monitor:

- Get the passcode to access the content of the secured USB stick.
- Verify the certificate for Cyber security matters.
- Choose the authorized HCP account on which will be installed the software.
- Launch the installer "**e-Celsius®_setup_Windows**" or "**e-Celsius®_setup_Mac**" according to your operating system.
- Follow the instructions step by step.

During the installation of the *eCelsius Manager* software, you must read and accept the proposed license agreement.

For the MAC version, please also run the second file provided with the installer to install the driver required for communication between the monitor and the MAC.

2. MATERIAL

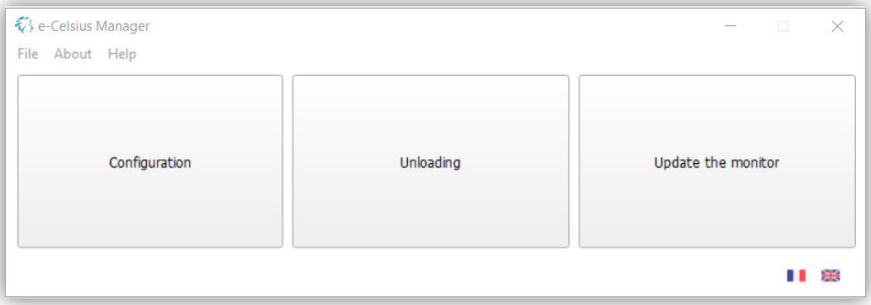
- PC or Mac including the *eCelsius Manager* software,
- *eViewer Medical* monitor provided with protection pouch and USB cable,
- *eCelsius Medical* capsule,
- Activator Medical provided with USB cable and ferrite,
- Power supply adapter.

3. SET UP

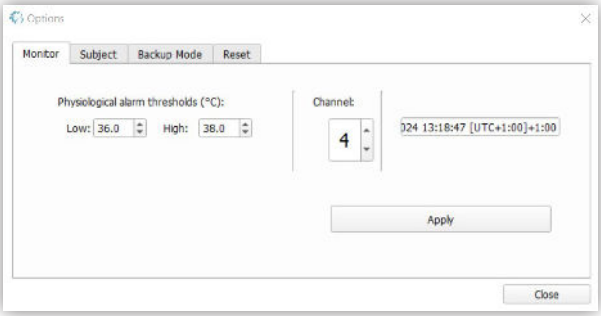
Please follow these steps before swallowing the capsule:

- To switch on the monitor, press and hold the button .
- Connect the monitor to a power supply source if needed.
- Connect the monitor to a PC using the USB cable provided and run the *eCelsius Manager* software.

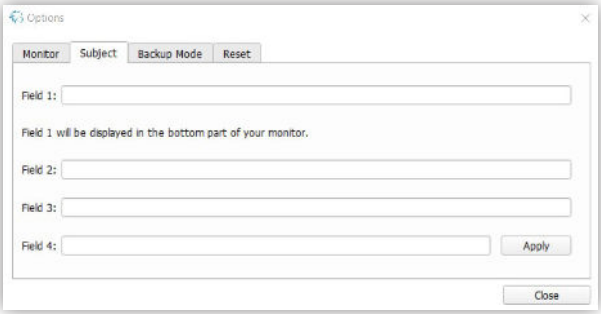
Select **Configuration** item:



Set up the monitor :



<u>Monitor tab:</u>
Configure the communication channel, date / time and physiological alarm thresholds.



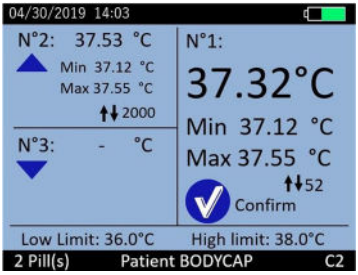
<u>Subjet tab:</u>
Fill in the identification fields of the monitor according to the desired criteria.
Write an ID, not the patient's name, to secure patient data.

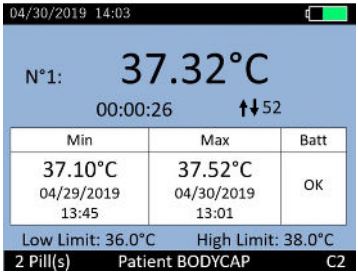
• Shutdown the software and unplug the monitor.
• Connect the activator to a power supply.
• On the Monitor, select the Menu **"Pill"** and select **"Pill Activation".**
• The monitor will guide you, step by step until the association of the capsule to the monitor. The capsule can be activated through the blister to keep it sterile.
• **It is required to rotate the capsule into the hole of the activator after pushing the activator button.**
• Note the ID of the capsule, the ID of the patient, the monitor channel displayed on the monitor screen (it is required for Backup mode).
• The capsule is now associated with the monitor and can be swallowed after positionning the bracelet.

4. DATA COLLECTION

The monitor collects the data from the associated capsules.
During a monitoring:

• It is possible to follow the temperature data in real time if the capsule is in the communication range (about 1m).
• For this, press the button .
• When pressing the button **Confirm** on the main screen displaying the data of the 3 capsules, the detailed information of the selected capsule is displayed.



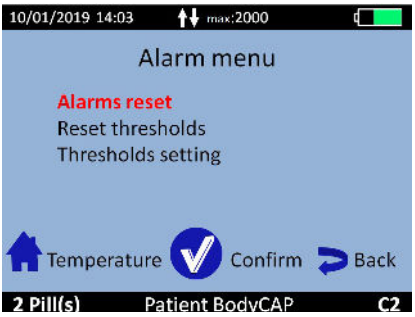


It is possible to add Markers by selecting the menu **"Marker"** in the **"Main Menu"** of the monitor. Those markers are used to identify a specific event and are plotted on the graph of the *eCelsius Manager* and in the .CSV file after export.
An automatical synchronization of the data is possible between the monitor and the associated capsule if the data are not received in real time.
Further information is provided in the *eCelsius Medical* user manual.

5. THRESHOLDS ALARMS

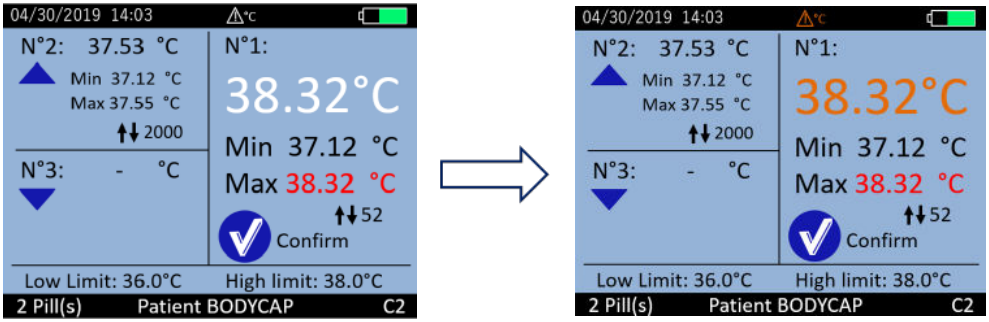
Minimum and maximum temperature thresholds may be used to trigger a visual alarm. The values of thresholds are bounded between 33°C and 41°C. To set up the thresholds, you can use *eCelsius Manager* software or the menus on the monitor.

- Through the monitor, go to the menu “Alarm” and select “Threshold setting”.
- The button “Confirm” allows to switch from one number to another, from the left to the right, the button “Back” allows to return to the previous digit and the arrows allow to modify the value of the digit in progress (red).
- At any time, you can go back to default thresholds values (low = 36°C and up = 38°C) by selecting the menu “Alarm reset” and then “Reset thresholds”.



This alarm signal is indicated by alternating color for the text of the current temperature value (orange and white) to draw attention to it. The minimum or maximum values that would have exceeded these thresholds are red. An alert icon is also permanently displayed in the top banner of the monitor screen.
These different signals remain visible until the alarm is reset.

Further information is provided in the *eCelsius Medical* user manual.

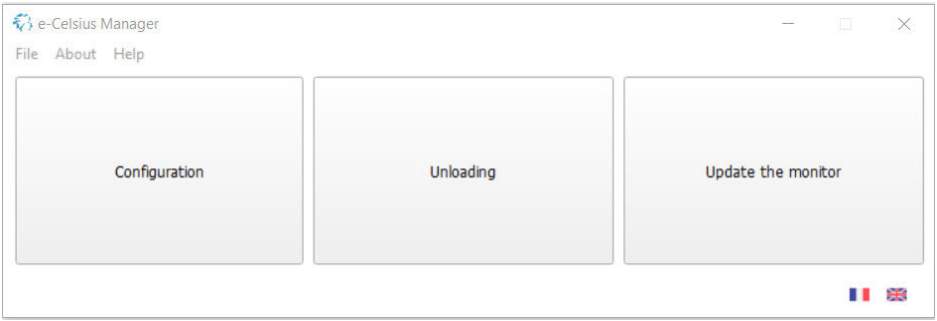


6. VISUALIZATION OF THE DATA AFTER MONITORING

To retrieve the data stored in the monitor:

- Plug the monitor to the PC/Mac and select "**Unloading**". The curve displayed is not saved by the application.
- You have to Export the curve as a PDF or the data as a .CSV file and save it on your PC/Mac disk.

As you want you can visualize the data curves during a monitoring.



7. SWITCH OFF THE SYSTEM

At the end of the monitoring:

- Deactivation of the capsules from the monitor has to be done using the menu **"Pill"** and then "**Pill Status** / **Deactivation"**.
- Visualize the curve via *eCelsius Manager* software and export the data in .CSV file to save/print them. The monitor slot is free.

To be able to activate a new capsule on the same slot, the data have to be unloaded **after deactivation of the capsule**.

To switch off the monitor, complete a long pressure on the button . Monitor switch off is only possible with no capsules associated.

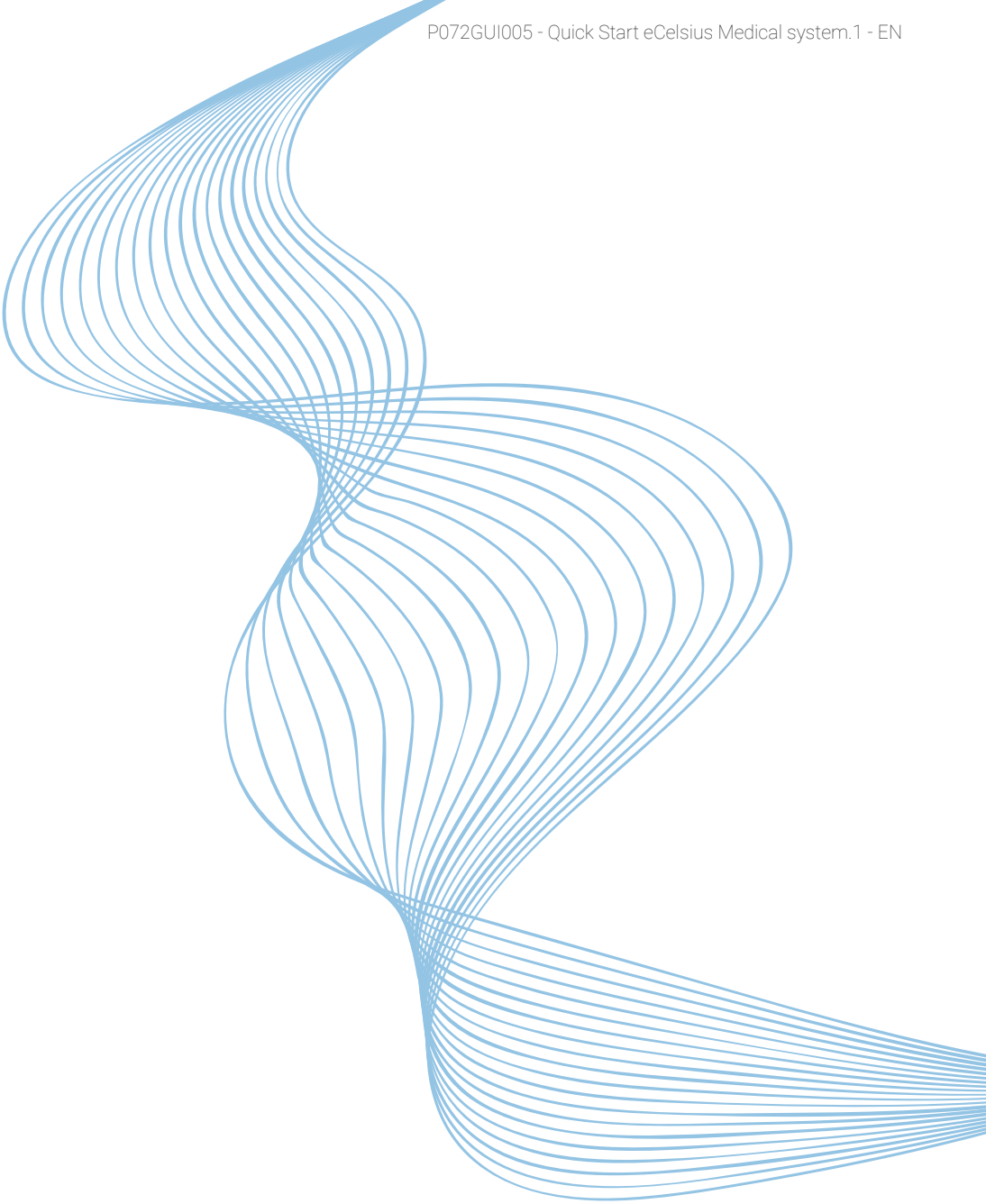
8. CHECK-LIST BEFORE INGESTION

Monitor:

- Battery level
- Monitor Time and Date
- Available channel setting (1 monitor per Channel)

Capsule:

- Single use
- Activated and associated to a monitor
- ID number identified
- Signaletic bracelet



If you have any question
and you did not found the answers in the user manual,
please request assistance from BodyCAP:

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