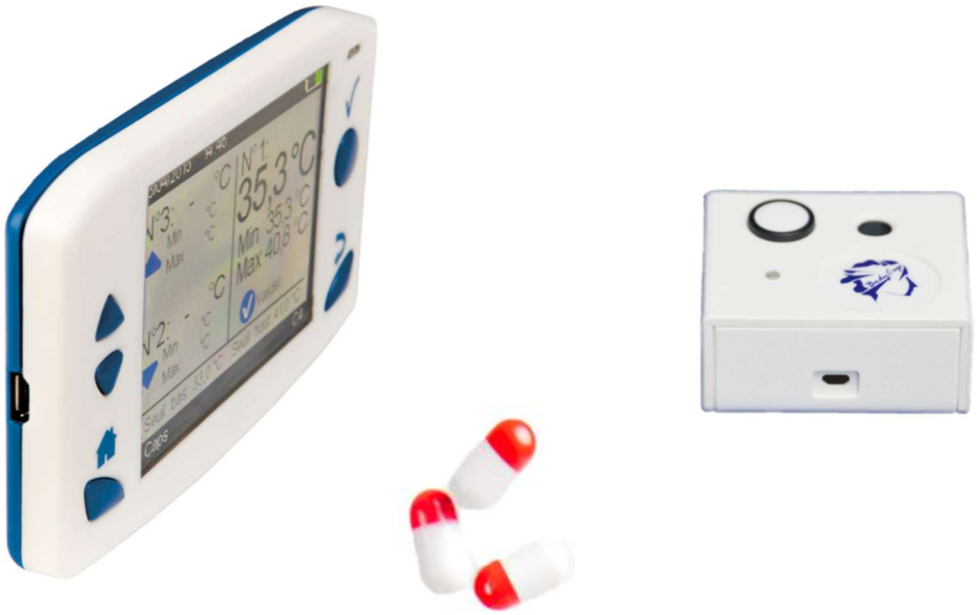
BodyCAP
Le compagnon santé connectée.

e-Celsius® Medical System

User Manual



MEASUREMENT SYSTEM CONTINUOUS RELIABLE AND PRECISE TEMPERATURE, AND RECORDING GASTROINTESTINAL BY TELEMETRY

Before use, please read entirely theses instructions

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To our customers, we thank you for purchasing the e-Celsius® Medical System. This medical device is manufactured by BodyCAP. This manual is designed to introduce the features and operation of your system and to assist you in the setup and using this product. The use of this device does not require training or specific skills; however, please read these instructions carefully and keep it handy in order to refer to it whenever you need.

Failure to follow these instructions may results in measurement failure, personal injuries, and property damage. The responsibility of the manufacturer and of his distributors cannot be engaged in case of bad use of the material having caused alterations of measures or any other physical injury and material damage. Inspection and repair operations must be carried out by approved persons who have undergone appropriate training.

This system is composed of:

- An e-Viewer® Medical monitor
- An activator
- A USB memory stick (including the e-Celsius® Manager software to install)
- One (or more) Pill(s) e-Celsius® Medical
- An information bracelet provided for each pill delivered
- 2 USB/micro-USB cables and a power supply

Destination and use case:

e-Celsius® Medical System is designed for the measurement of core body temperature in individuals, for diagnostic or therapeutic monitoring purposes. The e-Celsius® Medical pill is supplied sterile in its original packaging and intended for single use. She is then woken up using the activator and associated with the e-Viewer® Medical monitor which records data and can restore them to a PC / MAC via the e-Celsius® Manager interface supplied with the e-Celsius device medical system. The capsule should be ingested with a glass of water.

Declaration of conformity

The BodyCAP Company states that the device e-Celsius® Medical System complies with the following current directives and regulations:

- 93/42 / EEC, related to medical devices,
- 2011/65/EU, related to the limitation of the use of certain hazardous substances in electrical and electronic equipment,
- 2014/53/EU related to market release of radioelectric equipment
- 1907/2006 on the Registration, Evaluation, Authorization and Restriction of Chemicals, as well as the restrictions applicable to these substances (REACH)
- 207/2012 concerning instructions for the electronic use of medical devices.

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1 Precautions for use

The following safety instructions ensure proper operation and will optimize the use of the e-Celsius® Medical system. Follow them carefully. For questions which have not been answered in the manual, request assistance from your distributor or manufacturer (contact information at the end of this leaflet).

MR Safety:
e-Celsius® Medical System has not been evaluated for safety and compatibility in the MR environment. It has not been tested for heating, migration, or image artifact in the MR environment. The safety of device in the MR environment is unknown. Scanning a patient who has this device may result in patient injury.
The e-Celsius® Medical system is not claimed MRI compatible, it is imperative that the patient ingesting a pill does not undergo any MRI. The patient must wear wrist bracelet supplied with the system, indicating that has ingested a system that is not compatible with exposure to strong magnetic fields.

The bracelet is fixed just before the ingestion and should only be removed after expulsion of the pill. In case of successive ingestions, the bracelet should be removed after expulsion of the last pill.

Do no place or drop items on the device, do not introduce foreign objects.

Do not expose the system to dust or dirt (clean up the system into its packaging).

Do not use during a gas leakage.

Do not expose the system to strong magnetic or electrical fields.

Do not touch or press the screen of the monitor e-Viewer® Medical.

Do not place the monitor e-Viewer® Medical or the Activator around small objects which may scratch them or enter inside.

Do not expose the monitor e-Viewer® Medical or the Activator to rain or moisture, keep them away from liquids or sprayed water.

To reduce the risk of fire, electric shock and interference, only use the micro-USB cable and the adapter supplied with the system.

Do not use a damaged micro-USB cable or power adapter.

It is highly recommended to pay attention to the localisation of the cables, so they are not in the passage and do not constitute a risk of falling.

Take care to not shake or strike the monitor e-Viewer Medical and the Activator. This could affect their normal way of working.

Do not use the Pill if the packaging is damaged.

Do not use the system if it is damaged.

Connect only units which have been identified such as parts of or compatible with the electrical medical device.

Safety instructions:

DO NOT THROW IN FIRE
DO NOT SHORT-CIRCUIT
DO NOT DISASSEMBLE

Do not put the device as unsorted municipal waste. The monitor e-Viewer® Medical and the Activator have been designed to allow a reuse and a suitable recycling of some components. The symbol representing a waste container with a cross indicates that the product (electrical equipment, electronic and pile and / or battery) should not be put in municipal waste. Check local regulations for disposal of electronic products.

Temperature, humidity, and atmospheric pressure in operation

- The monitor e-Viewer® Medical, the Activator and the cables must be used in an environment where the relative humidity is between 30 and 80% in an environment where the atmospheric pressure is between 800hPa and 1060hPa and in ambient temperature conditions between 0 and 40°C. It is also recommended to avoid sprayed water.
- The Pill e-Celsius® should not be exposed to temperatures outside the range 0 - 50°C.
- The device is designed to operate at an altitude between 0 and 2000m.

Conditions and duration of storage and / or transport

- The monitor e-Viewer® Medical, the Activator and the cables must be kept in an environment where the relative humidity is between 30 and 80%, in an environment where the atmospheric pressure is between 800hPa and 1060hPa. The e-Viewer® Medical Monitor must be stored in ambient temperature conditions between 0 and 35°C. The activator should be stored at temperatures between 0 and 40 °C. It is also recommended to avoid sprayed water and protect it from exposure to sunlight.
- During the period preceding the use of the Pill e-Celsius® Medical, it must be kept in an environment with relative humidity ranging from 30 to 80%, in an environment where the atmospheric pressure is between 800hPa and 1060hPa and in ambient temperature conditions between 0 and 40°C. It is also recommended to avoid sprayed water and protect it from exposure to sunlight. Storage at lower or higher temperatures may affect the autonomy of the Pills and their performances.
- The shelf life of the Pill-Celsius® Medical is indicated by an expiration date on its blister. Beyond that date, device performances and autonomy are not guaranteed.

Cleaning

The Pill is delivered clean in an individual packaging. It is not designed to be cleaned with hydro-alcoholic solutions. Under no circumstances should the system be autoclaved, otherwise the Pills concerned will be permanently damaged.

European REACH Regulation 1907/2006 / EC

In response to the requirement of Article 33.1 of the REACH Regulation, we inform users of the presence of the substance SVHC "Octyl Tin Stabilizer" in concentrations greater than 0.1% mass / mass in the Pills. This substance is entered on the

candidate list published on 15 June 2015 under the number CAS 15571-58-1 (http://echa.europa.eu/fr/candidate-list-table).

e-Celsius® Medical must be used in hospitals, clinics and exclusively by caring staff (doctors, nurses ...) HAD, EPAHD, home health are excluded

Presence of phthalates

Based on the toxicological evaluation, we inform users of the presence of an acceptable recovered phthalate level without toxicological risk to the patient in the e-Celsius® Medical Pill.

- di-- (2--ethylhexyl) DEHP under the number CAS 117-81-7
- diisobutyl DIBP under the number CAS 84-69-5
- dinonyl under the number CAS 84-76-4

Warning to users in the united states

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This device e-Celsius Medical System complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

NO UNAUTHORIZED MODIFICATIONS

47 CFR Section 15.21

CAUTION: This equipment may not be modified, altered, or changed in any way without signed written permission from BodyCAP. Unauthorized modification may void the equipment authorization from the FCC ID : 2AENH014 and will void the BodyCAP warranty

2 Use claims and contraindications

2.1 Use claims

The e-Celsius® Medical system is designed for the measurement of core body temperature in individuals. The indications of the e-Celsius® Medical System include all clinical cases for whom accurate, continuous core body temperatures are required and may be used only on

the order of a physician who has clinically evaluated the contraindications and warnings associated with the use of an ingestible thermometer sensor (e-Celsius® Medical pill).
The e-Celsius® Medical System consists of the following components:

Components	Product #	Destination
e-Celsius® Medical pill 	P022-M	*e-Celsius® Medical* pill which transmits core body temperature.
Activator 	P030-M	The activator allows to activate the *e-Celsius® Medical* pill in advance of its ingestion.
e-Viewer ® Monitor 	P040-M	Receives signal from *e-Celsius® Medical pill*. Displays and saves data.
Built-in e-Celsius® Manager software on USB stick 	P070-M	*e-Celsius® Manager* software allows you to set up the monitor and view the data recorded by the monitor, on a computer (PC or MAC)
USB key for user manual 	NA	The USB stick containing the user manual, the instructions for the use of the Pill and the software *e-Celsius® Manager.*
E-Viewer Monitor Transport Pocket 	NA	Allows transport and eViewer® Medical monitor protection
Quick start paper guide	NA	
USB Monitor Cable 	NA	Allows communication between *e-Viewer ® Monitor* and a PC / MAC
USB Activator Cable 	NA	Allows the activator to be powered by a PC/MAC.
Power supply USB adapter 	NA	The power supply is responsible for converting the electrical voltage of sector in different DC voltages TBT, compatible with electronic circuits e-Viewer® monitor Medical
Sign bracelet per pill 	NA	Patient identification bracelet (MRI).
Secondary Packaging Box 	NA	A rigid cardboard packaging box containing a holding stall.
Stalling foam 	NA	Calage maintenance of the device *e-Celsius® Medical System*.

The level of accuracy of the system compared to the absolute temperature value is ±0.2°C. The resolution of the temperature is given at 0.01°C.

The device is intended to be implemented by the nursing staff (nurse and / or practitioners).

2.1.1 Claimed Performance Characteristics of the Device

As communicated by BodyCAP, the claimed performance characteristics of the e-Celsius® Medical system are:

- Continuous measurement of central temperature.
- Instant detection of temperature changes.

2.1.2 Specified Clinical Benefits

As communicated by BodyCAP, the clinical benefits of the e-Celsius® Medical system are:

- Allow patients to avoid discomfort from using the more invasive and painful esophageal probe and rectal probe.
- Allow patients to avoid the cable connection from using the esophageal probe and rectal probe.
- Allow patients to avoid the lost core temperature and the need of repeated measurement.
- Better acceptability of temperature monitoring by the patient compared to the systems constituting the clinical gold standard: Esophageal probe; Rectal probe.

2.2 Contraindications and Warnings

Contraindications:

The *e-Celsius® Medical System* is designed for the measurement of core body temperature in humans, it is contraindicated in a number of situations:

- For people whose body weight is less than eighty (80) pounds.
- For people with or presenting a risk of intestinal disorders that can lead to obstruction of the digestive tract, including diverticula.
- For people with known swallowing disorders, including gag reflex troubles.
- For people who have undergone surgical procedures in the gastrointestinal tract.
- In the context of a surgical operation in the gastrointestinal tract (esophagus, stomach, intestines).
- For people who must be subject to strong electromagnetic field during the period of use of the system (MRI particular).
- For people with motility disorders of the gastrointestinal tract.
- For people equipped with pacemaker or other electro-medical device.
- Minors under the age of 18
- For Pregnant women.
- For people with Crohn’s diseases.
- People unconscious before ingestion of the pill

Warnings:

Due to the mode of administration of the system and its mode of operation, the use of the device must be done considering the precautions described below:

- The e-Celsius® Medical pill (Fig. 6) is intended to be ingested, with a glass of water to measure the gastrointestinal temperature. It is delivered in deep standby. It must be awakened by the activator and associated with a monitor to operate. The fitting of the identification bracelet (Fig. 7) is followed by ingestion of the pill.

- Ingestion of the e-Celsius® Medical pill involves contact of the PVC envelope of the pill with the mucous membranes of the digestive tract, for an average duration of 2 +/- 1.5 days up to 6 days depending on the individual characteristics of gastrointestinal motility(*Validation of a new telemetric core temperature monitor* McKenzie et Osgood, 2004).

- If the temperature monitoring must be prolonged beyond the transit time of the patient concerned, then the ingestion of a new e-Celsius® Medical pill may be repeated to extend the monitoring, within the limit of 30 days. BodyCAP has carried out the necessary biocompatibility tests according to standard NF EN ISO 10993-1, taking into account the contact time of the e-Celsius® Medical pill with the mucous membranes of the digestive system, i.e. with a prolonged exposure or medical devices where the cumulative sum of the single, multiple or repeated contact time is likely to exceed 24 hours, while remaining less than 30 days. The results of these biocompatibility tests comply with the requirements of the standards claimed by BodyCAP.

The impact of the patient's intestinal transit should also be taken into account during repeated follow-up in order not to exceed the 30 days of contact validated by biocompatibility tests. If the pill is not expelled beyond this period, refer to point 8. End of user manual monitoring.

- The use of the capsule in people prone to gastrointestinal disturbances, nausea and vomiting involves increased monitoring of people.

- As the measurement is taken within the digestive system, the measured data is likely to be influenced by certain factors, in particular the artifact of food or water intake (hot or cold) for the first few hours after swallowing the pill. The impact is limited in the first 3 hours following ingestion of the e-Celsius Medical pill and is characterized by a decrease important, non-physiological temperature values collected. It is recommended that you, during these first 3 hours following ingestion of the pill to guarantee the reliability of the data, to limit water or food intakes at ambient temperatures.

- The pill is delivered sterile, must be activated through the blister pack to maintain its sterile state, and is not intended to be disinfected or cleaned after use on the person. Dispose of the pill after use by the person. The system must under no circumstances be introduced into an autoclave, otherwise permanently damage the capsules concerned.

- The device is intended for single use; any reuse of the pill is likely to induce a infectious risk.

- In the case of using the system in obese people, communication difficulties between the pill and the monitor may be encountered due to the mode of operation of the system.

The communication between the pill and the monitor being carried out in radiofrequency at 433 MHz - 434 MHz, the signal strength is attenuated by the presence of fatty tissue. Thus, communication between the pill and monitor could be reduced if not impossible.

- After use, precautions must be taken to ensure safe disposal of the pill. Each practitioner must ensure that the requirements referred to by local regulations and regulations regarding the disposal of contaminated healthcare waste are well respected.

2.3 Risks and complications

Risks and complications:

• The e-Celsius® Medical pill intended to be ingested by the person with a glass of water, special attention must be brought to the risk of misdirection, especially in people who have or have had swallowing disorders. This false route phenomenon can cause a blockage in the respiratory tract requiring extraction.

• Injury or injury to the gastrointestinal system requiring surgery

• A false route at the time of ingestion of the e-Celsius® Medical pill, which can induce partial or total obstruction of the airways.

• False route with blockage in the respiratory tract requiring extraction

• Electric shock

• Burns

• Intoxication

• Gastrointestinal disorders Blockage of the pill within the digestive tract, which may require recovery by endoscopy or by surgery.

• Infections

• Waste of time for the user / Extension of the care time

• The loss of communication between the e-Celsius® Medical pill and the e-Viewer Reception Monitor, inducing a stop of the patient's temperature monitoring Incorrect measurement

• Loss of traceability (patient / pill)

• Device failure / Device malfunction / Inability to use the device

• The loss of sterility of the device, inducing an infectious risk.

• The loss of communication between the Medical pill and the e-Viewer Reception Monitor Medical, inducing a cessation of the patient's temperature monitoring.

• The collection of temperature data affected by the ingestion of cold or hot drinks, which could lead to an incorrect interpretation of the data.

• Exposure to a strong electromagnetic field (MRI), which can induce a risk of mobilization with possible trauma to the digestive tract, or a disruption in the electronics of the pill and risk of incorrect data

2.4 Functions of e-Celsius® system

The operating mode of the device is summarized below:

Table 1: Mode of action

No.	Operating principle
1.	Settings of e-Viewer Medical thanks to e-Celsius® Manager software.
2.	The association of an e-Celsius® Medical pill to an e-Viewer® Medical monitor through the activator
3.	The bracelet is worn on wrist of the patient
4.	The ingestion of the e-Celsius® Medical pill
5.	The data transmission from the e-Celsius® Medical pill to an e-Viewer® monitor
6.	The display of the temperature graph on the computer screen via the e-Celsius® Manager software

The device is based on the principles listed in Table 2.

Table 2: Operating principle

No.	Operating principle
1.	The activation of the Pill e-Celsius® Medical is performed via an electromagnetic pulse emitted by the Activator.
2.	The pill e-Celsius® Medical measures the temperature through a thermistor.
3.	The pill e-Celsius® Medical stores the last 2000 temperature collected data.
4.	The communication between the e-Celsius® Medical pill and the monitor e-Viewer® Medical is performed through the radio frequency band of 433 MHz using a proprietary protocol.
5.	The monitor e-Viewer® Medical receives and stores the data.
6.	The e-Viewer® Medical monitor automatically asks the e-Celsius® Medical pill again data not received in real time
7.	Visualisation of the data through e-Celsius® Manager application.
8.	The export of the data to CSV and PDF via e-Celsius® Manager.

The functions frequently used are listed in Table 3.

Table 3: Frequently used functions

Frequently used functions	Main (M) / Secondary (S)
Activation of the pill e-Celsius® Medical	M
Temperature measurement with the pill e-Celsius® Medical	M

Setting the time and date of the monitor e-Viewer® Medical with the e-Celsius® manager software	S
Setting patient's information, displayed on the e-Viewer® Medical monitor screen, with the e-Celsius® manager software.	S
Setting alarms (thresholds) with the e-Celsius® manager software or directly with the menus of the monitor e-Viewer® Medical	M
Setting the RF channel used by the monitor e-Viewer® Medical	S
Automatic data recovery from the pill e-Celsius® Medical with the monitor e-Viewer® Medical	M
Storage of the data in the pill e-Celsius® Medical	M
Visualization of data on the monitor e-Viewer® Medical in real time	M
Real time visualization of the alarm triggered (technical or physiological)	M
Integration of automatic technical markers with the Monitor e-Viewer medical	S
Integration of a manual marker with the monitor e-Viewer® Medical	S
Extinction of the Pill e-Celsius® Medical at the end of the measurement cycle	S
Visualization of data on the e-Celsius® manager software	M
Export of data from e- Celsius® manager software to a spreadsheet (CSV) or PDF curves	M
Management of the battery of the monitor	M
Update the monitor with e-Celsius® Manager application	S

3 First use

3.1 Installation of e-Celsius® Manager

Software installation on a computer

Minimal configuration Required:
Processor 1GHz.
500Mo de RAM.
200Mo disk space required for the installation
Windows® 7 or operating systems Microsoft® compatibles (32 or 64 bits), Mac OS X (10.9 Lion) or ulterior. The screen resolution has to be at minima 1024x768.
Note: the update of the operating system may be necessary in some cases to recognize the driver.

Figure 1: USB stick BodyCAP

To install e-Celsius® Manager Software and the drivers of e-Viewer® monitor, please:

- launch the installer "e-Celsius® _setup_Windows" or "e-Celsius® _setup_Mac" according to your operating system. These installers are present on the USB key provided (Fig. 1) with e-Celsius® Medical System.
- follow the instructions step by step.

During the installation of the 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.
Note: If the launch is not done automatically by double clicking on the file, consider looking in the navigation pane on the left of the screen if a new disk has appeared "Silicon Labs VCP Driver Install Disk".

The language of the interface can be changed after opening the application e-Celsius® Manager. Select "File> Language" menu.

3.2 Implementation of the device

3.2.1 Power up the monitor e-Viewer® Medical

To turn on the monitor e-Viewer® Medical, press the button on the side of the monitor.
This process switches on the monitor. If the screen does not light, put the monitor in charge.
An LED indicates that the pressure on the button has been considered.
Before using the e-Viewer® Medical monitor in battery-run, you have to ensure that its charge level is sufficient.
To use the monitor e-Viewer with the PC / MAC e-Celsius® Manager software, you have to install e-Celsius® Manager software and the BodyCAP drivers (provided on the USB stick). At the end of the installation, the monitor and the PC / Mac software will interface automatically.
In order for the monitor to communicate with the PC / Mac software, please connect the monitor to a USB port of the PC / MAC that is turned on.

Note: The first connection may take some time, please allow the computer time to recognize the monitor and install the associated driver correctly.

3.2.2 Supply the batteries

If you plan to use the monitor e-Viewer® Medical in battery-run, make sure you have charged the battery beforehand.
The cable micro-USB - USB allows to recharge the battery of the monitor when it is connected to a power supply (wall socket or computer switched on).

3.2.3 Configuration of the monitor

The configuration of the monitor through the e-Celsius® Manager software is only allowed when no Pill is yet associated. Connect the e-Viewer® Medical monitor to a computer with the e-Celsius® Manager software and launch it. When opening of the first window, select "Configuration" (Fig. 2).

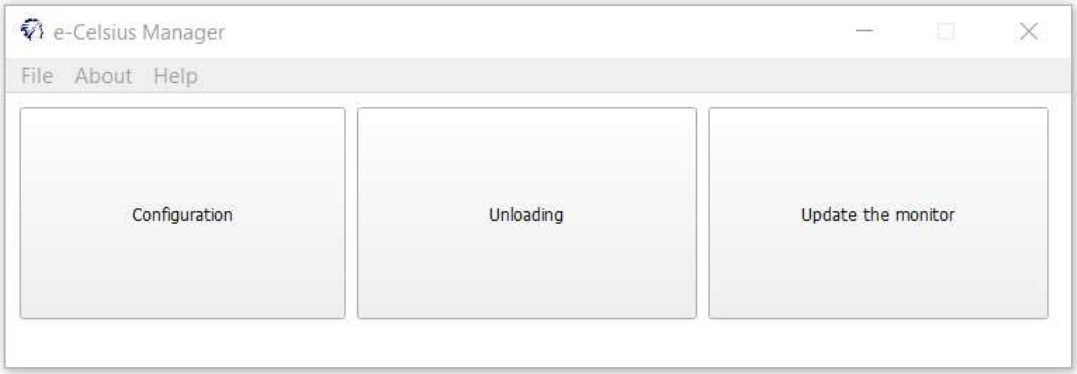

Figure 2: Start screen of e-Celsius Manager software

At the opening of the second window (Fig. 3) several tabs allow to configure the monitor before using. At any time during the configuration, you can consult this User Guide in the “Help” menu at the top of the Start Screen (Fig 2).

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3.2.3.1 The tab monitor

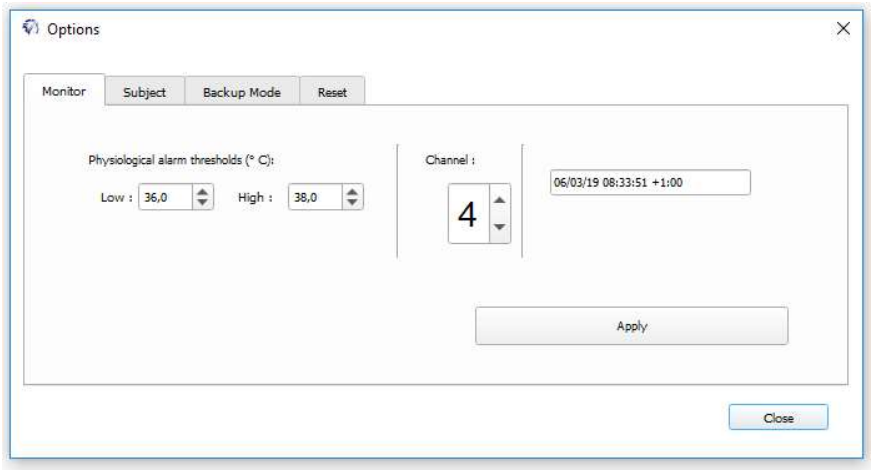

Figure 3: Tabs to configure the monitor

- **Operating channel**

The "Monitor" tab (Fig. 3) is used to select the desired operating channel for the next recording. It is necessary to choose an available channel.

The selected channel should not be the same as other monitors in the environment of use.
It is possible to select one of the 7 channels (1 to 7) available on the monitor.

- **Date and hour**

The date and time of the computer on which the e-Celsius® Manager application is installed will be sent to the monitor when using the "Apply" button. This time will date the upcoming recordings. Be sure to check that the time of your PC / MAC fit with the desired time zone.

- **Setting thresholds**

The "Thresholds" setting is used to configure the Low and High temperature thresholds for which a Visual Alert is triggered (The temperature value of the sensor affected by the alarm alternates between the colors White and Orange and the display remains lit continuously) (cf. §6.10.5).

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3.2.3.2 The tab Subject

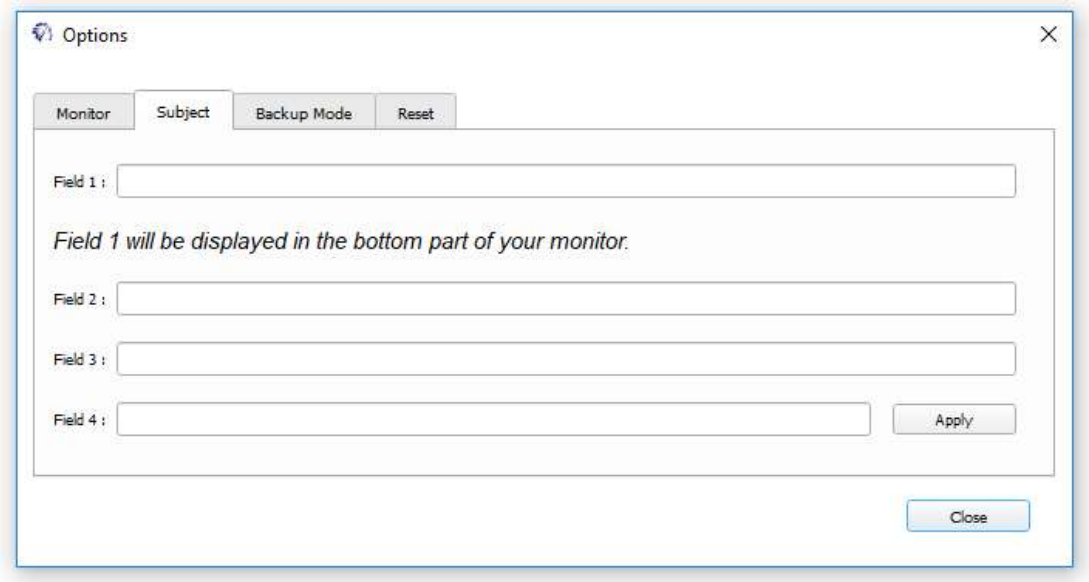

Figure 4: Tab for Subjects' data configuration

The tab "Subject" (Fig. 4) allows to configure a monitor for a patient. Thus, the four fields can be filled according to the choice of each. The contents of field 1 will be displayed on each bottom of the monitor (Fig. 5). Items entered in Fields 1, 2, 3, and 4 will be visible in the monitor's "Subject" menu as well as in the data files collected from the monitor.

After configuring the different items, click Apply to validate. This step is required before starting the association of the Pills (cf §6.10.3).

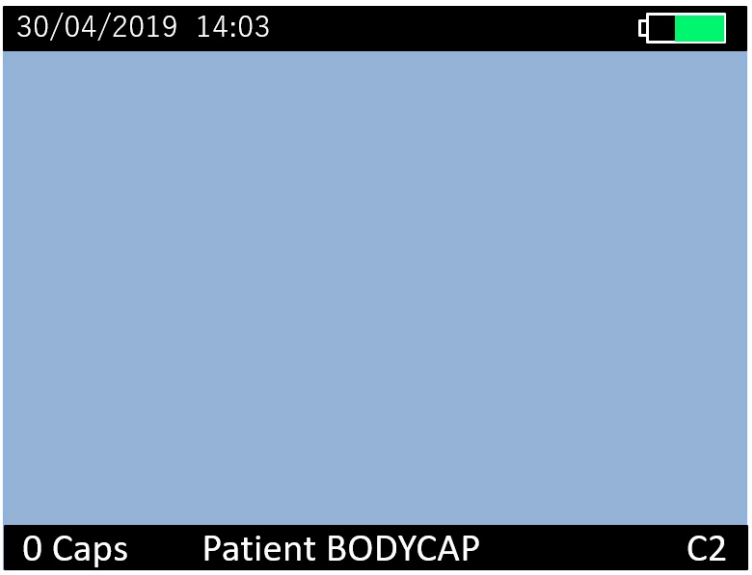

Figure 5: Screen of the monitor

3.2.3.3 The Backup Mode

The "Backup Mode" tab is used to replace a failed monitor. The use of the "Backup mode" is presented in §7.2.1.

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3.2.3.4 The reset tab

The "Reset" tab is used to restore the original configuration of the monitor and delete all data stored in the monitor. The reset is only possible if no Pill is associated with the monitor and if the last data collected has been downloaded to a PC / MAC.

4 The Pill e-Celsius® Medical

Figure 6: Pill e-Celsius® Medical

Figure 7: Warning bracelet

The e-Celsius® Medical pill (Fig. 6) is intended to be ingested with a glass of water to measure gastrointestinal temperature. It is delivered in deep sleep. It must be woken up by the activator and associated with a monitor to work. Attach the identification bracelet to the wrist of the patient before swallowing the pill (Fig. 7).

4.1 Important information and safety recommendation

The pill is an applied part of the system type BF. It is not intended to provide heat.

e-Celsius® Medical System is not claimed to be compatible with MRI, it is imperative that the person ingesting a pill does not have an MRI scan. The person must wear the bracelet supplied with the device The bracelet is attached before ingestion and should only be removed after expulsion of the ingested pill. In the event of consecutive ingestion, the bracelet is removed upon expulsion from the last pill. If it is necessary to prolong the temperature monitoring after the expulsion of the pill

Temperature monitoring can be extended by ingesting another pill until the end of the monitoring period without exceeding the 30 contact days validated by biocompatibility tests. . In this case, the bracelet attached to the wrist should not be removed after expelling the last remaining pill.

The battery
The pill e-Celsius® Medical includes 4 batteries (Zinc–Silver Oxide).
In fact, the pill should not be disposed with the household waste.

Cleaning
The pill is supplied sterile (sterilization with ethylene oxide) and must be activated through the blister to maintain its sterility. It is not designed to be cleaned using hydro alcoholic solutions or re-sterilized.
The system should not, in any case, be introduced in an autoclave on pain of permanent damage for Pills concerned.
The pills are intended for single use only, any reuse of the pills could lead to an infectious risk.

The label
The label contains the following symbols of the NF EN ISO 15223-1:


"Do not reuse"


"Use until"

"Batch Code"

"Sterilised with ethylene oxide"

"Catalogue number»


"Manufacturer"


"Storage temperature limit"


"Keep dry"


"Do not re-sterilize"


"Do not use if the packaging is damaged"

"Presence of phthalates"


Do not use in pregnant women

The label contains a symbol from IEC 60601-1-2:


« Radiated RF disturbances »

The label contains a symbol from the IEC 60601-1:

"Follow the using instructions"

"Applied part type BF"

Also, the label precise the following mentions:

"This is not a drug"

"Protection Index"

"Medical device CE marked by the notified body LNE-GMED"

Do not put the e-Celsius® ® device in municipal waste (refer to §1).

" This device complies with Part 15 of the FCC Rules "

4.2 Characteristics

Dimensions:	Length: 17.7 mm. Diameter: 8.9 mm. Weight: ≈ 1.7 g.
Operating temperature Range:	0°C - 50°C
Accuracy:	±0.2°C in the range 25 - 45°C.
Temperature resolution:	0.01°C
Heating Transient time:	< 150s (+2°C)
Cooling transient time:	< 100s (-2°C)
Sampling frequency:	30 s ±20%.
Storage capacity in the Pill:	The 2000 last temperature data are stored in the pill.

Transmission distance with the monitor:	around 1m (depending from environment).
Ingress Protection (IP):	X8 (Material supporting prolonged immersion)
Power:	autonomous system including zinc-silver oxide piles.
Battery life:	20 days.
Contact time with the patient:	2 ± 1.5 days on average, up to 6 days depending individual characteristics of gastrointestinal motility. If the pill is not expelled beyond this period, refer to point 8. End of user manual monitoring
Communication Frequency:	ISM Band 433MHz - 434MHz
Radiated Power:	-22 dBm
Plastic:	Biocompatible PVC.
Storage life:	Refer to the limit date printed on the blister.
Condition of carriage And storage:	Temperature (0 to 40°C), humidity (30 to 80%)

WARNING: Modification of the electro-medical device forbidden

5 The Activator

Figure 8: Activator

The Activator (Fig. 8) is intended to activate the pill e-Celsius® Medical before a measurement cycle.

5.1 Important information and safety instructions

The battery

The system does not include any battery. For each use, the power supply of the Activator is performed by mains supply or a PC / MAC switched on. The connexion between the Activator and the mains supply and/or the computer has to be done only with the cables and the power supply provided by the manufacturer.

Cleaning

Some applications wil require to clean the Activator. This is possible while respecting certain rules. You can clean your Activator with a damp cloth or a wipe to control the humidity. Nevertheless, it is essential to pay attention to external connectors because they will be the most sensitive to humidity.
The system should not, in any way, be introduced in an autoclave under penalty of permanent damage.

Maintenance

It is strictly forbidden to open the activator. If a fault or malfunction is found, contact **your distributor or the manufacturer (**contact details **at the end of the user manual).**

The label
The label contains the symbols of the NF EN 980:

SN : XXX	"Serial Number"
REF	"Catalogue reference"
AAAA	"Manufacturer + Production date"
	"Temperature storage limit"
	"Keep dry"
	"Keep away from light and sun"

The label contains the following symbols of the NF EN ISO 15223-1:

	"Follow the using instruction"

The label also mentions:

	"Do not dispose the device with municipal waste" (refer to §**1**)
CE 0459	"Device marked CE medical by the notified body LNE-GMED"
FC	" This device complies with Part 15 of the FCC Rules "

5.2 Characteristics

Figure 9: Description of the Activator

Dimensions:	Length: 690 mm. Width: 590 mm. Height: 310 mm. Weight: ≈ 62 g.
Power supply:	Main power supply unit (100 ~ 240 V) or PC via USB (5 V).
Power consumption:	≈ 115 mW only connected (out of operation) and 500mW during activation (for 2s).
Communication:	No communication – emission of a series of electromagnetic pulses.
Life duration:	2 Years
Way to disconnect from the mains supply:	Unplug the power cable.
Condition of carriage and storage:	Temperature (0 to 40°C), humidity (30 to 80%)

Warning: Modification of the electro-medical device is forbidden

5.3 The buttons

The button OK is used to launch the activation process.
The activation process is detailed in §6.10.3.

5.4 The LED

A green LED is positioned on the upper side of the Activator. This LED is continuously switched on when the Activator is powered and flashes throughout the activation process.
When the LED is flashing, the activation process is running. During this period, it is important to not remove/move the pill placed in the hole.

6 The monitor e-Viewer Medical

Figure 10: Monitor e-Viewer Medical

The monitor is intended to communicate in RF with the pill e-Celsius® Medical to recover and store temperature data.

6.1 Important information and safety instructions

The battery
The monitor e-Viewer Medical contains a Lithium-ion battery.
The monitor should not, in any case, be disassembled; the battery should not be disconnected, or disposed of by fire.
To recharge the monitor e-Viewer Medical, please only use the cable and the adapter provided by the manufacturer.

Cleaning
Cleaning the monitor e-Viewer Medical should be done within certain limits. It is possible to clean your monitor with a damp cloth or a wipe to control the humidity. Nevertheless, it is essential to pay attention to external connectors because these are the most sensitive to humidity.
The system should not, under any circumstances be autoclaved. This would cause permanent damage.

Maintenance
It is strictly forbidden to open the monitor e-Viewer Medical. If a fault or a malfunction if found, please contact your distributor or the manufacturer (Contact details at the end of this user manual).

RF Communication
In operation, it is not advisable to put the monitor e-Viewer Medical on a metal table or other metal surface which could reduce the RF emissions.
It is also recommended to be vigilant in environments with high metal stress (reinforced concrete wall ...) and to regularly check on the monitor screen that the communication with the pill is not interrupted. In the data view screen, the symbol ↑↓ associated to a number indicates that the monitor must be synchronized with the pill. If this symbol turns to orange, it means that the last data collected from the pill come from more than 5 minutes. The storage capacity of

each pill is limited to 2000 data, the communication between the pill and the associated monitor must be restored within a maximum period of 15 hours under penalty to definitively lose some data (the automatic synchronization pill / monitor can last several minutes depending on the number of data to be recovered).

The label

The label contains the following symbols from the standard NF EN ISO 15223-1:

SN : XXX	"Serial Number"
REF	"Catalogue reference"
 AAAA	"Manufacturer + Production date"
	"Temperature storage limit"
	"Keep dry"
	"Keep away from light and sun"

The label contains a symbol from IEC 60601-1-2:

	« Radiated RF disturbances »

The label contains a symbol from IEC 60601-1:

	"Follow the using instruction"

The label also mentions:

	"Do not dispose the device with municipal waste" (refer to §1)
CE 0459	"Device marked CE medical by the notified body LNE-GMED"
FC	" This device complies with Part 15 of the FCC Rules "

6.2 Description of the Monitor

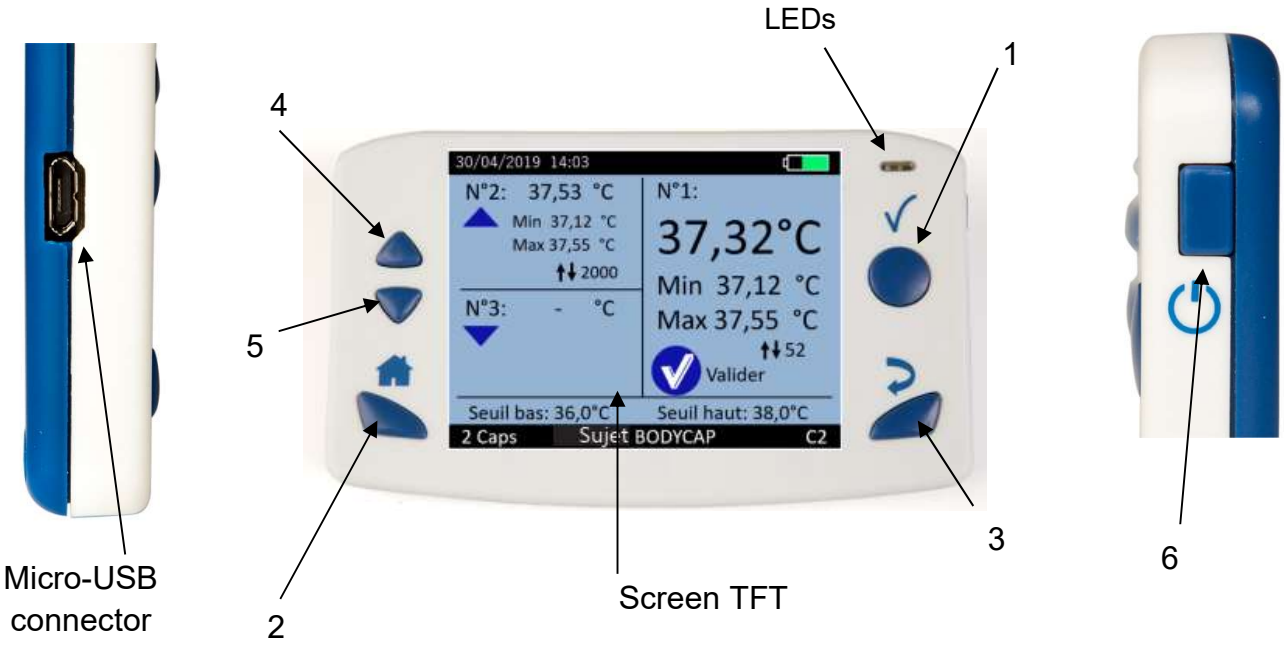


Figure 11: Description of the monitor e-Viewer Medical

6.3 Features

Dimensions:	Length: 120 mm. Width: 70 mm. Thickness: 15 mm. Weight: ≈ 120 g.
Screen:	320 x 240 pixels.
Operating temperature:	0 to + 35 °C.
Storage capacity:	150 185 data per activated pill.
Connector:	Female micro-USB.
Power supply:	Battery Lithium-ion rechargeable with a mains supply adapter (100 ~ 240 V) and a cable micro-USB – USB provided with the system. To charge the system, with USB, via a computer, please install the e-Celsius® Manager Software following the process described in this user manual.
Time to charge:	≈3 h.
Battery life:	≈ 36 h.
Band of communication:	ISM 433MHz → 434MHz.
Life duration:	2 years (or around 500 recharge cycle).

Condition of carriage and storage: Temperature (0 to 35°C), humidity (30 to 80%)

Way to disconnect from the mains supply: Unplug the power cable.

Warning: Modification of the electro-medical device is forbidden

6.4 The buttons

The features of the 6 buttons of the monitor are described below. 5 are placed around the screen and 1 on the right side:

The button Validate (ref. 1 Fig. 11)
The button Validate is used to confirm the information and to enter the menus.

The button Home (ref. 2 Fig. 11)
The button Home allows to come back to the main screen of temperature data.

The button Back (ref. 3 Fig. 11)
The button Back allows to come back to the previous submenu or cancel a procedure.

The button Arrow up (ref. 4 Fig. 11).
This button Allows to get in the menus.

The button Arrow down (ref. 5 Fig. 11).
This button allows to down in the menus.

The button sleep-wake of the screen (ref. 6 Fig. 11).
A long pressure makes it possible to turn on or off the monitor when no Pill is associated. A short press makes it possible to put the screen in standby or to turn it on again.

6.5 The LEDs

An orange LED and a green LED are positioned on the front side of the monitor, in the upper right corner.
When the orange LED flashes, it means that:

- the battery level is low. The monitor should be quickly plugged, into a power supply.
- an internal error occurred. A specific message indicates that the monitor is no longer usable. The technical service of the manufacturer must be contacted.

When the Green LED is lit, it means that the monitor is connected to a power source. Its battery is therefore being loaded. When the battery is fully charged, the green LED goes out. When the monitor is off, the orange LED lights to indicate that the pressure on the side button has been considered (ref 6 fig.11).

6.6 The battery of the monitor e-Viewer Medical

Information
When it is not plugged to the mains supply, the monitor is powered by a rechargeable lithium-ion battery. It is strictly FORBIDDEN to disassemble the monitor and to replace the rechargeable battery under penalty to irreparable damage on the system and security failures.
.
Charging cycle
In order to recharge the battery, simply plug the power supply of the monitor on the mains supply and switch off the screen. Few hours are required to charge the battery. The battery life of the monitor e-Viewer Medical in battery operation is around 36h (screen regularly used but not continuously).

Please do not forget to charge the monitor e-Viewer® at the end of those 36hours to avoid the risk of losing the connection and configuration to all Pills in operation.

To lessen the risk of losing the connection and configuration between the Pills and the monitor e-Viewer Medical, the monitor automatically goes into a power-saving configuration (extinction of the screen and of the RF communication with the Pills) before the total discharge of the battery.

It is strongly recommended, for prolonged use of the equipment, to connect the monitor to a power supply during operation.
While the battery is charging, the battery logo will turn purple and still full (indicating the charge status and not the battery level). Once the cable is unplugged, the logo turns green, orange or red again and represents the actual percentage of the battery.

If the monitor is in standby mode after power saving mode, just recharge the battery before turning it on. If this state lasts for several days, then the system will lose its date / time references. It will be mandatory to return to the e-Celsius® Manager application to reset it. Connect to e-Celsius® Manager and check that the monitor is connected to the PC and turned on. Going to the "File> Update Time" menu will automatically update the monitor (Date / Time) according to the PC settings.

6.7 The connexions

Female Micro USB port
This connector is located on the left side of the monitor e-Viewer Medical**. It is possible to use the micro-USB port to connect the monitor to the mains supply throught the cable and adapter provided by the manufacturer or directly to a computer. Connection to a computer will allow**:

(i) **to set up the monitor e-**Viewer Medical **(**date, time, **channel**, **alarm thresholds, patient data)**
(ii) **to download data of the monitor to e-Celsius® Manager Software**
(iii) **to visualize the results of measurements**,
(iv) **to export them to PDF or spreadsheet format**
(v) **to recharge the battery monitor.**

6.8 RF Communication

In operation, it is **strongly discouraged** to place the e-Viewer Medical monitor **on a metal table or other metal surface** that would reduce the performance of RF transmission.
It is also recommended to be vigilant in environments with high metallic stress (reinforced concrete wall ...) and to **check regularly on the monitor screen that communication with the pill is not interrupted**.
In the event of communication failure, between the pill and the monitor, the data is stored in the internal memory of the pill so that it can be synchronized later. In the general temperature display window, **the number of data to be synchronized between the monitor and the pill is automatically displayed next to the double arrow ⇅. If this double arrow flashes in Orange, it means that no exchange with the pill has taken place during the last 10 communication attempts.**

6.9 Menus of the monitor e-Viewer Medical

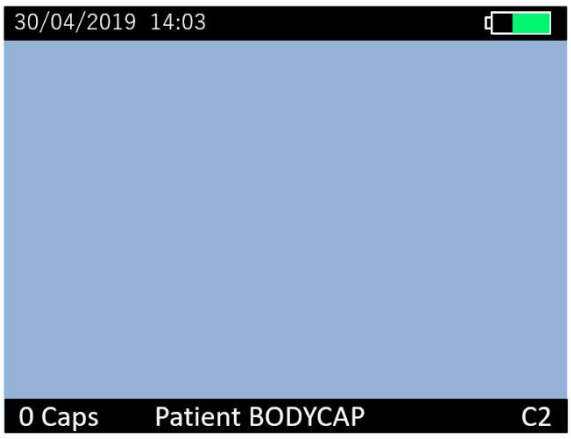


Figure 12: Screen of the monitor e-Viewer Medical with general information

Regardless the level of the menu in which the user is, the monitor screen indicates some general information including:

- The date (e.g. 30/04/2019)
- The daytime (e.g. 14:03)
- The battery level of the monitor (eg the top right of the screen)
- The operating channel of the monitor (eg C2)
- A field corresponding to a patient identification (eg Patient BODYCAP)
- The number of pills associated (eg Caps 0)
- An orange cross in the top banner of the screen indicates that the memory related to an associate pill is full.

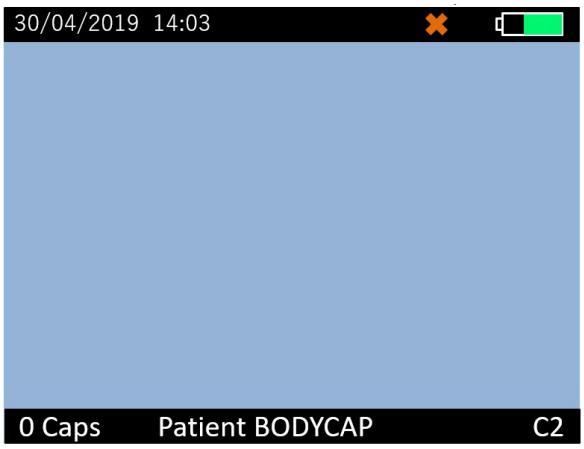


Figure 13: Screen of the monitor e-Viewer Medical with the symbol related to full memory status

- An orange triangle in the top banner of the screen indicates that a physiological alarm has been triggered and should be investigated (Fig. 14). In the event of an alarm being triggered, this indicator is visible on each monitor screen, until the concerned alarm is processed.

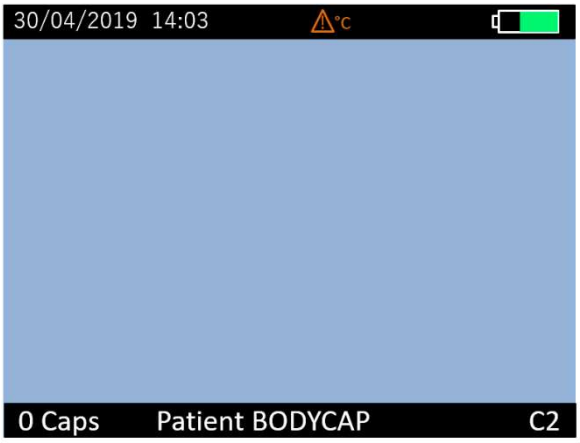


Figure 14: Monitor generic screen displaying physiological alarm

Tree view of the main menu of the monitor (Fig. 15)

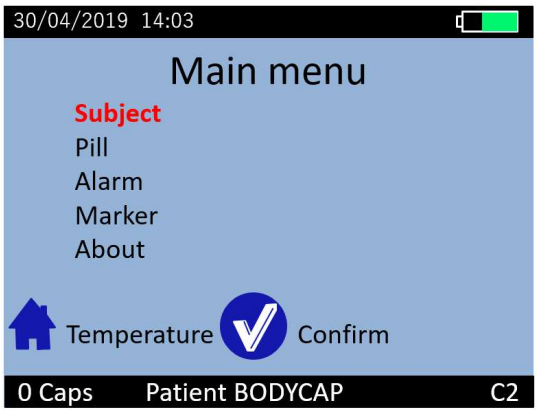


Figure 15: Main menu of the monitor e-Viewer Medical

To validate a menu and move to submenu, press the button OK (§ 6.4).
To return back, press the button Back (§ 6.4).
To return directly to the temperature display, press the button Home (§ 6.4).
Navigation between the menu items is possible by using the up-down buttons (§ 6.4).

The menu Subject
The menu Subject displays the information of the four fields filled in the “subjct” tab of e-Celsius® Manager. Field 1 is then visible on all monitor screens in the lower band.

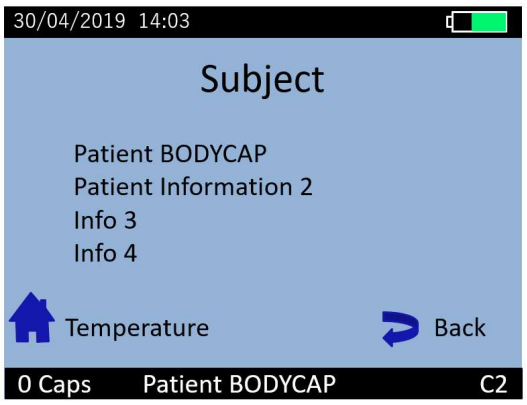


Figure 16: Menu Subject

The menu Pill
The menu pill (Fig. 17) brings together the different control functions of the pills.

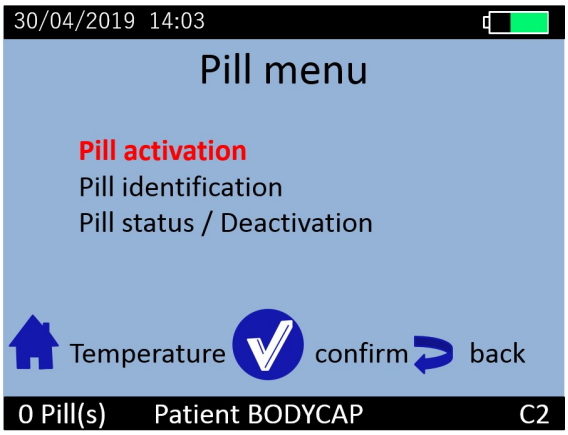


Figure 17: Menu Pill of e-Viewer Medical

Pill activation:	Starts the Association process of the pill.
Pill Identification:	View the serial number of the associated pills.
Pill status / Deactivation:	Dissociated pill from monitor (after data unloading) and switch off the pill.

Menu Alarm

The Alarm menu is used to manage physiological alarms

Alarm reset:	Allows you to reset the alarms triggered by exceeding a threshold and to update the displayed Min and Max values from all associated pills
Reset thresholds:	Allows to configure the default values of alarm thresholds, Low: 36°C; high: 38°C.
Thresholds setting:	Allows viewing and modifying alarm thresholds. The values can be selected between 33°C (Low Threshold) and 41°C (High Threshold).

Menu Marker

Allows user to add an event marker. This marker will be reported both in the graph of e-Celsius® Manager and in the CSV file after data export.

Menu About

The About menu allows you to view the software version of the e-Viewer Medical Monitor as well as identify the monitor from its unique address.

6.10 Main functions

6.10.1 Set the monitor

To set the monitor, please connect it to the computer via USB to use the e-Celsius® Manager software.

You will configure:

- the date and time,
- the high and low physiological alarm levels,
- the operating channel and,
- the data related to the patient.

6.10.2 Changing the working channel of the monitor

Up to 7 monitors can operate in parallel in the same environment. This is made possible by setting each monitor to work on a different channel so that the monitor does not interfere with each other.
Setting the operating channel is performed through e-Celsius® Manager software.
This command is not possible when Pills e-Celsius® are associated with the monitor.

It is advised to record the working channel of each monitor; in case of breakage or failure, this information will be needed to launch the monitor replacement procedure (cf §7.2.1).

6.10.3 Activate a pill

Note: Before e-Celsius® medical pill activation, you must fill the Subject information in the configuration interface of e-Celsius® Manager. Please also check the monitor's operating channel and the date and time.
No modification of these parameters will be possible after the activation of a pill.
In order to associate an e-Celsius® Pill, please go to the "Pill" menu and then the submenu "*Pill activation*" of the monitor e-Viewer Medical (Fig. 18).

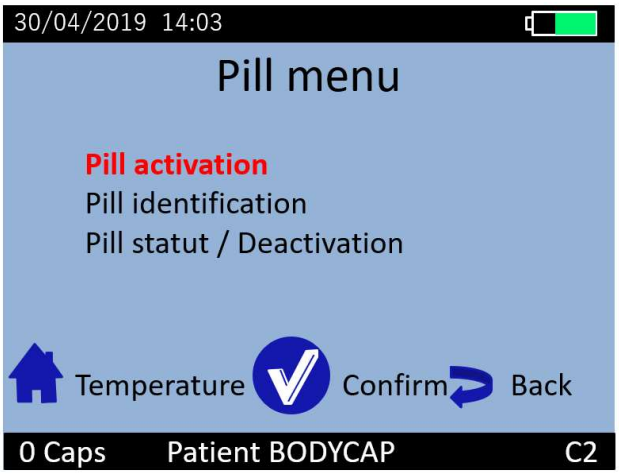


Figure 18: Menu Pill activation

After validation of the command "Pill activation", dialog boxes will guide you through the activation process:

- At first, the message "*Plug the activator, Place the pill, red part down*" appears on the monitor screen; after connecting the activator and placing it in a close environment (<1m) from the monitor, press the OK button of the monitor as soon as the message "*Please wait ...*" has disappeared.
- The pill to be activated must be placed in the dedicated hole of the activator, white tip upwards. If you wish to preserve the sterile status of the pill, this operation may be performed while the pill is still inside the unopened sterile blister packaging. To activate

a pill through the blister, it is necessary to place it vertically in the blister and it is advisable to maintain it by exerting pressure and rotation of the pill. Then press the button OK on the monitor e-Viewer Medical.

- Finally, the message "*Activation in progress ... Push the activator button*" appears. You must then make a short press on the button of the activator.
- Once the button of the Activator activated, the green LED located on it will flash; then let the cap in place and wait until you see the message "*Pill activated, Serial number: XX.XX.XX.XX*" on the monitor screen. **It is recommended to make note of this serial numbe**r; they can be helpful when analyzing the data from multiple subjects.

At any time during the recording, you will be able to find the unique identifier of the pill in the "Pill" menu then the "Pill identification" submenu (Fig 19).

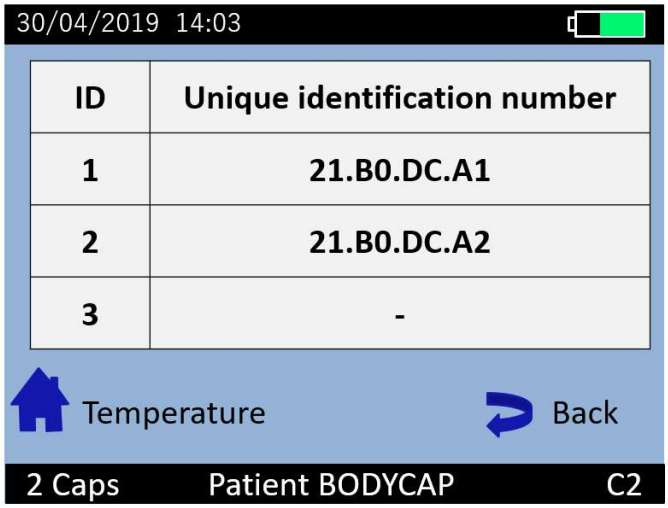


Figure 19: Identification of associated pills

This shows, the pill is activated and associated to the monitor. Press OK to confirm the announcement and come back to the menu “Pill”.
A pill number from 1 to 3 is then assigned by the monitor. It will allow you to view data on the monitor while data collection. By default, the assigned number will always be the lowest available between 1 and 3 (available mean that there are no associated pill or stored data not discharged on this issue).

If the LED of the activator stops flashing and the message "*Error! Would you like to restart an activation*" appears on the monitor screen, please check the positioning of the e-Celsius® Medical Pill in the hole of the Activator and / or slightly move the e-Celsius® Medical pill in the hole, press the button OK on the monitor e-Viewer Medical to restart the association process and re-press then the button on the Activator.

For the activation an additional pill, repeat the procedure. It is possible to connect up to 3 pills in parallel with a single monitor.

If you want to keep the pill sterile it should be activated and removed from its packaging as late as possible before ingestion.

6.10.4 Consult temperature data in real time

To visualize the collected temperature data, press the button Home . The screen will then allow you to visualize (i) the latest temperature data collected and (ii) the minimum and maximum values collected by each associated pill.

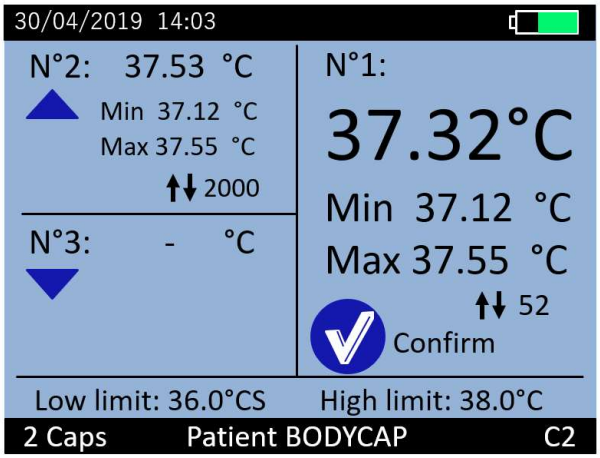


Figure 20: Screen of data visualization

Temperature data (real time temperature data, min and max) of 1 to 3 pills may be displayed on the screen. The low and high thresholds for triggering alarms are also displayed at the bottom of the screen.

The min/max values appear 10min after pill activation to avoid from alarm triggering before ingestion.

6.10.5 Configuration of triggering thresholds alarms

Minimum and maximum temperature thresholds may be used to trigger a visual alarm. To set up the thresholds, you can use e-Celsius® Manager software or the menus on the monitor. To do this, go to the menu "Alarm" and select "Threshold setting." The window (fig.21) is displayed.

The button OK 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).

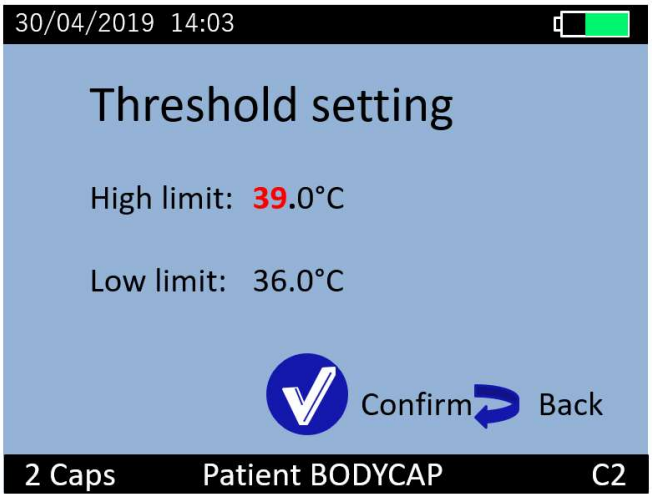


Figure 21: Configuration of triggering thresholds alarms

The values of minimum and maximum thresholds are bounded between 33°C and 41°C. Note that it is important to always check the consistency between the configured thresholds and the values for which you think that a warning is required. The threshold values used are available at any time in the temperature display (by pressing the button Home with the logo).

Note: If the visual alarm is triggered before the change of threshold, even if the new threshold values allow the current temperature value to be in the acceptable range, this visual alarm will only be deactivated by the user action "**Alarms reset**".

Note: During the 10 first minutes following the pill activation, the alarm is deactivated (only for the Pills concerned) in order to give time to swallow the pill and not being impacted by ambient temperature.

6.10.6 Resetting the triggering thresholds alarms

At any time, you can go back to default thresholds values (low = 36°C and up = 38°C) by selecting the menu **"Alarm"** and then **"Reset thresholds."** A confirmation is required before returning to the values listed above.

6.10.7 Warning signal for threshold overrun = physiological alarm

Minimum and maximum temperature thresholds can be used to trigger a visual alarm. These thresholds concern all associated or coming pills. A change of the temperature value below the lower threshold or above the upper threshold will generate a physiological alarm. This alarm signal is indicated by alternating color for the text of the current temperature value (orange and white) to attract attention (Fig. 22). The minimum or maximum values that would have exceeded these thresholds are red. The minimum and maximum values that would have exceeded these thresholds are displayed in red.

The delay inherent in the determination of an alarm condition is a maximum of 30 seconds in the case of a real-time communication between the pill and the monitor.
In addition, regardless of the screen you are on, an alert icon is permanently displayed in the top banner of the monitor screen even on a screen that does not display the triggering of the alarm. (Fig. 23).

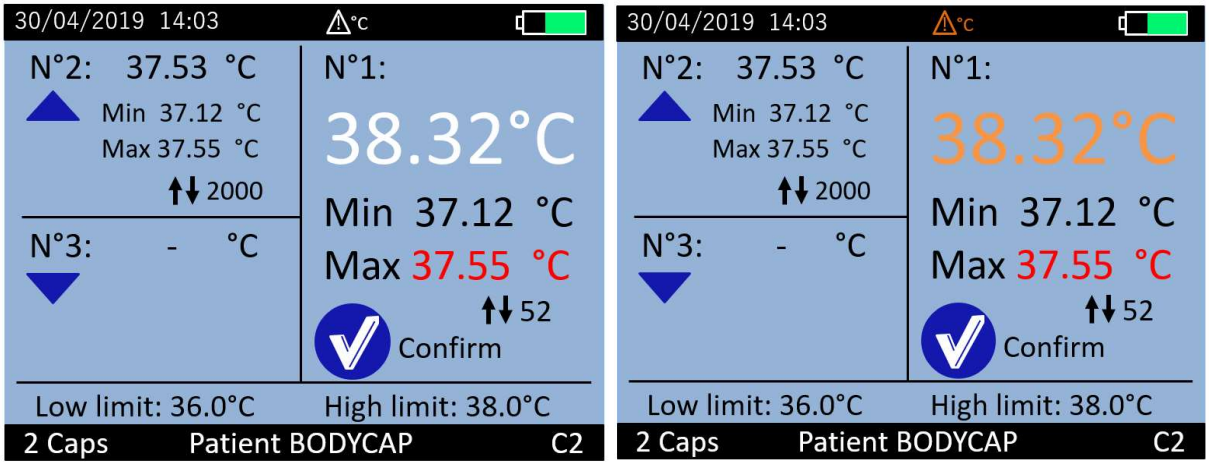


Figure 22: Triggering of temperature alarm

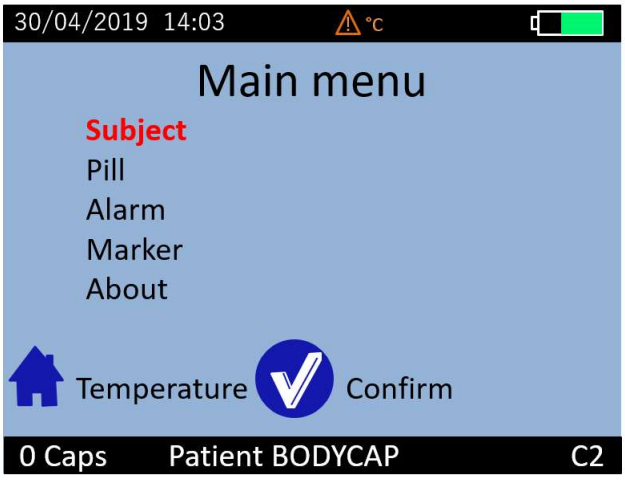


Figure 23: Triggering the alarm outside the data view window, an alert icon is displayed in the top banner of the screen.

These different signals remain visible until the alarm resetting. When actual temperature stays in the range between the two thresholds, it continues to flash until the alarm reset is performed.

In addition, when the screen is on standby and the physiological alarm occurs, the monitor will automatically come back on the data temperature screen so that the user can quickly see the threshold is exceeded.

Warning: the alarm can be triggered by synchronized data (received a posteriori) that previously exceeded one of the two temperature thresholds. In this case, the minimum or maximum values are is time stamped at the time of the reception of the data (date of the synchronization).

BodyCAP
Le compagnon santé connectée.

6.10.8 Detailed visualization of the data of one pill.

To access to a detailed visualization, select the pill by positioning it in the right of the screen. Then press the OK button, a new screen appears with the following information:

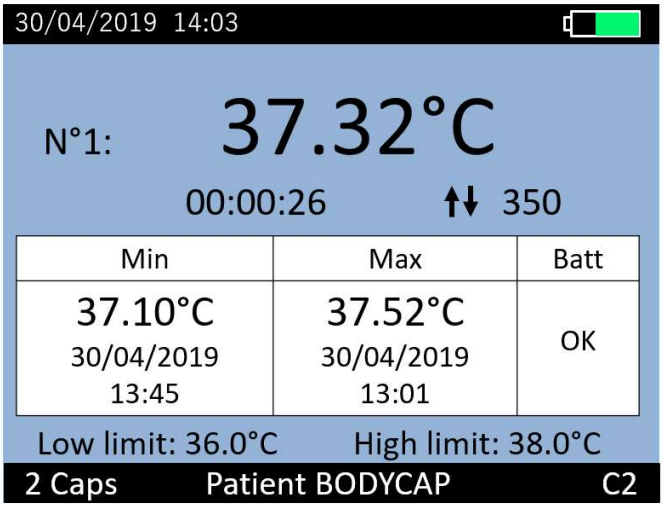


Figure 24: Detailed visualization screen of a pill

- The number of the selected pill (from 1 to 3).
- The last temperature data collected (°C).
- The time elapse since the last temperature data collected (h:mm:ss).
- The minimal and maximal value and the battery status of the Pill selected.
- The synchronization index ↑↓ related to this pill, and the number of data to synchronize.
- The thresholds used to trigger an alarm are also reminded.

6.10.9 Synchronization of the data in the memory of the pill

It is recommended to be vigilant in environments with high metal stress (reinforced concrete wall ...) and to regularly check on the monitor screen that communication with the Pill is not disturbed.

In the Data visualization menu, the symbol ↑↓ indicates the number of data to synchronize between the Pill and the monitor. This symbol turns to Orange and flashes when no communication occurred during the last 5 minutes.

The Pill has got an internal memory that automatically records the last 2000 collected data. When 2000 data have been collected and saved in the memory of the pill, the first data is deleted and replaced by the data 2001 ... When the communication between the monitor and / pill (s) is interrupted, the monitor does not receive the data.

Nevertheless, there is a feature in the monitor to automatically recover the missing data as soon as communication is restored. The monitor will automatically synchronize its data with the 2000 data available in the memory of the pill.

The storage capacity of each pill is limited, the communication between the pill and the associated monitor have to be restored within a maximum period of 15 hours under penalty to permanently lose some of the data collected (automatic synchronization pill / monitor can take

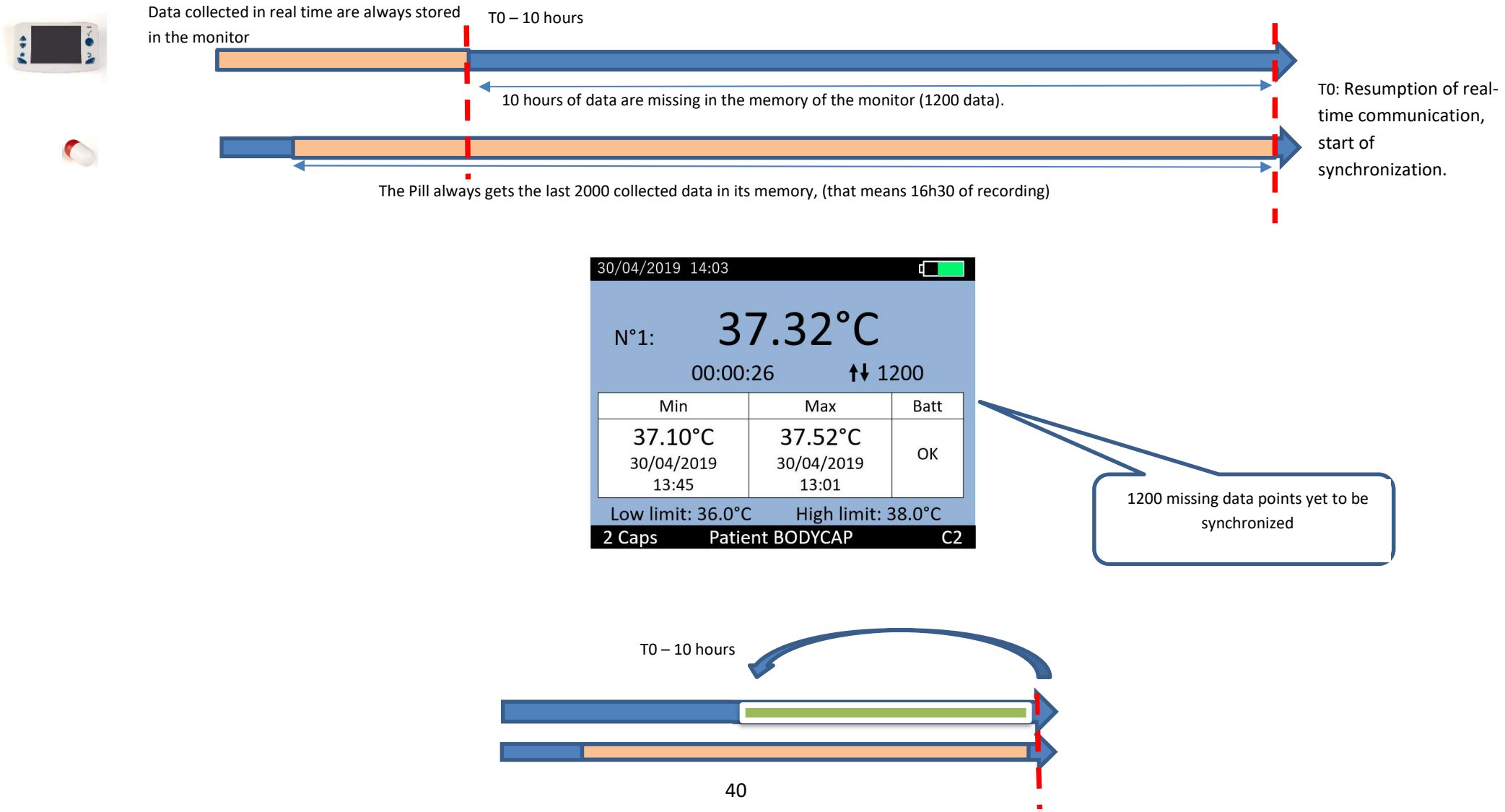
time , from several minutes to several hours depending on the number of data to recover). **Warning: The monitor synchronize first the oldest data available in the memory of the pill. The most recent are thus recovered last.**

To synchronize data, the monitor must be in real-time contact (max distance 1 meter) with the pill. If a disturbance breaks the synchronization process, it is necessary to wait for the next communication of the pill to resume the synchronization where it remained.

The indicators ↑↓, give the amount of data that remains to be synchronized for each of the associated pills.
Note: the monitor optimizes the synchronization and waits to have a sufficient amount of consecutive data (max 8 data) before giving the synchronization order to the concerned pill.
To facilitate the recovery of data stored in the memory by the monitor, it is important to have a good quality of communication between the pill and the monitor.

Figure 25: Illustration of the operating mode of the synchronization

Example: Temperature monitoring with one pill (Sampling frequency 30s). Data synchronization is performed after 10 hours of missing communication.



Additional information about the Backup mode

If data is synchronized without initial data (which is the case in replace mode), the time and date associated to the data will be estimated. It is possible to observe an inaccuracy of a few minutes for the recorded time.

A green marker "Backup mode" on the chart displayed on e-Celsius® Manager Software indicates the beginning of the Backup mode. All the data before this marker are synchronized data.

This reassessment can be improved, as you will record new real time data, the estimated time of the recovered data will be improved.

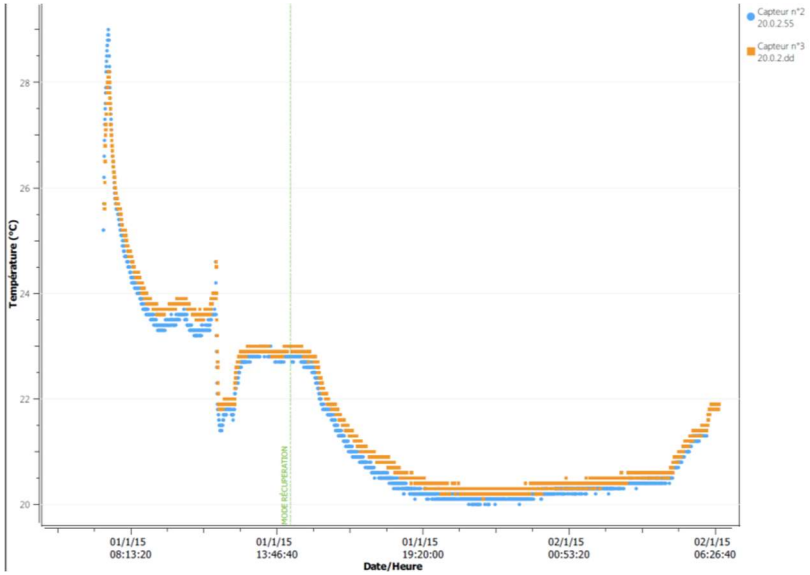


Figure 26: "Backup mode" marker

6.10.10 Visualization of the end-of-life of the pill

On the monitor, when a pill reaches the end of life, the message "Low" appears in the column Batt (Figure 25) of the detailed visualization screen (§6.10.4). The pill will stop around 500 steps after that the first message "Low" has appeared (if the monitor and the Pill are in continuous RF communication).

6.10.11 Alarm reset

In order to reset the alarms and the Min / Max values shown in the data visualization screen, go to the menu "Alarm" and select the function "Alarms reset".

These proceedings will be applied to all the pills associated with the monitor.

A confirmation message needs to be validated by user.

6.10.12 Deactivation of a pill

When use is completed and you want to stop the pill, just go to the menu "Pill" (Fig. 27) of the monitor and in the submenu "Pill status / Deactivation", select the pill to turn off and press OK. To ensure the success of the procedure, the pill and monitor must be close enough to communicate.

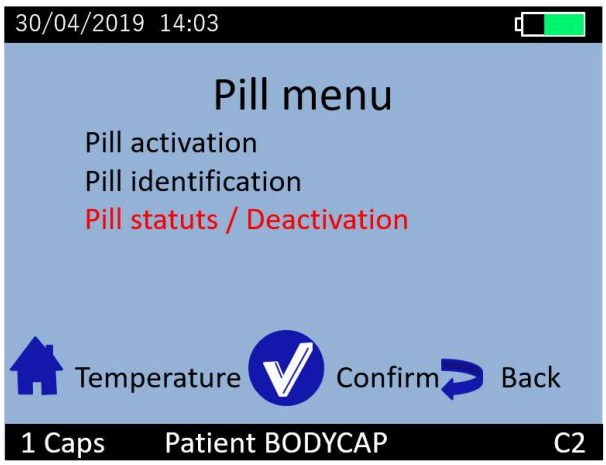


Figure 27: Menu of the monitor e-Viewer Medical to disassociate a Pill

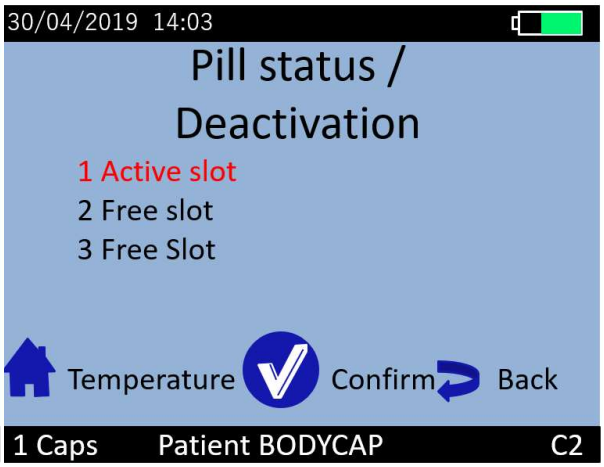


Figure 28: Selection of a Pill to disassociate.

A confirmation must be validated before the deactivation of the pill. This action is definitive; the pill disappears from the Monitor database. The data file corresponding to the pill is stored until the unloading of data to a computer and the activation of a new pill on this location.

Three cases may be displayed:

- **"Locked / Data to be saved":** The data of a pill remains on the monitor, but the pill is no longer associated. Data can be downloaded on the e-Celsius® Manager Software. As unloading did not take place, a new pill cannot be activated on this location.
- **"Active slot":** A pill is associated
- **"Free slot":** This location is available to the activation of a new pill.

6.10.13 Use of the monitor screen

To save battery, the monitor screen will switch off automatically after 1 minutes of inactivity when the monitor is in battery operation. This action is canceled for 3 possible reasons:

- The monitor is plugged to a power supply. In this case, the screen is constantly switched on without user action.
- The monitor is on the data temperature screen. This screen is very important for patient monitoring. In this case, without user action, the monitor does not automatically go into standby.
- If the monitor is in standby mode and that a physiological alarm triggers, the monitor will automatically switch on and will go on the temperature display.

To enter or leave standby mode, press the side button of the monitor represented by the following logo:

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6.10.14 Overview of the alarm system

Caregivers should regularly control the temperature data displayed on the e-Viewer Medical monitor screen.

The monitor combines 7 categories of alarms with 6 related to the state of the electro-medical system and 1 on the patient's physiological status.

The conditions for triggering and warning of each are summarized in the table below.

Tableau 4: Alarm systems

Function controlled	Alarm condition	Delay due to the alarm condition	Alarm mode	Priority
Patient temperature	The temperature measured go out the physiological pre-selected thresholds	30 seconds maximum in the case of a real time communication 10 minutes after pill activation (avoid alarms due to collected temperature before ingestion)	A Warning symbol is displayed in the top banner of the screen Temperature values are flashing	Medium
Battery of the pill	The remaining autonomy of the pill will reach a maximum of 500 measures	30 seconds maximum in the case of a real time communication	The message "Low" appears in the column Batt (Figure 25) of detailed visualization screen (§ 6.10.10).	Low
Battery of the monitor	The battery of the is low or critical	Immediate	Battery status are indicated by the LEDs on the front side of the monitor	Medium
Loss of communication	The number of missing data is displayed next to the synchronization symbol ↑↓ (remains black)	30s	The number of missing data points is displayed	Low
Prolonged loss of communication	The synchronization symbol ↑↓ turn to Orange of the communication is off in the last 5 minutes	5 minutes	The number of missing data points is displayed The colour of the synchronization symbol changes.	Medium
The memory of the monitor if full	The monitor can't store more data from one of the associated Pills	After the 150 000 data (over the 20 days life duration of the pill)	Red cross in the top banner	Low

Alarm Internal Error	The monitor is faulty	Immediate, the use of the monitor is prohibited	Orange flashing LED + Warning message on the monitor	Medium

7 The e-Celsius® Manager Software

e-Celsius® Manager software is designed to visualize and export temperature data from a measurement cycle, it's the interface between the monitor and PC / MAC.

7.1 Main Functions

To use the e-Viewer Medical monitor with e-Celsius® Manager software, you must install the application and BodyCAP drivers (provided on the USB BodyCAP). After the installation completion, the monitor and the application will interface automatically.

7.1.1 Unload and consult the temperature data on the e - Celsius manager Software

On the main screen of the e-Celsius® Manager Software, select the menu "Unloading" (Fig. 2).

An unloading progress window appears. At the end of the unloading, the temperature data appear graphically (Fig. 29)

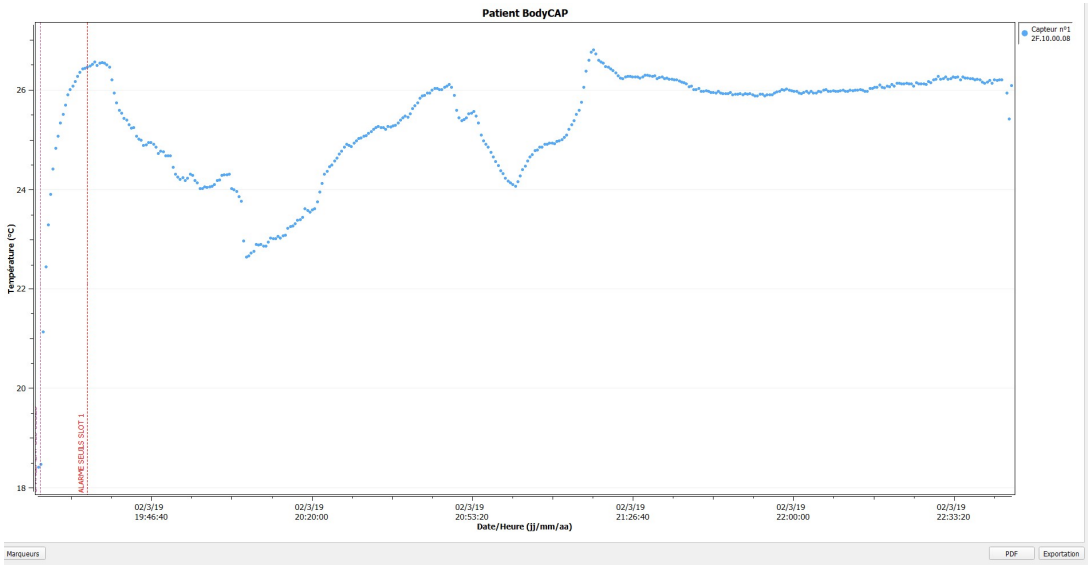

Figure 29: Picture of the curves obtained on the e-Celsius® Manager Software after data unloading.

It is possible to move on the graph by keeping key **Alt** pressed and clicking the left mouse button while sliding it from the left to the right.

7.1.2 Visualization of markers from the monitor e-Viewer®

The data unload includes markers entered with the monitor during the recording period and visualizable by a vertical black line. These markers may be named by clicking on the box

"Markers". A window then appears. Select the line for the desired marker, fill the corresponding fields and confirm by clicking **OK**. They then appear on the chart and data export with the entered text.

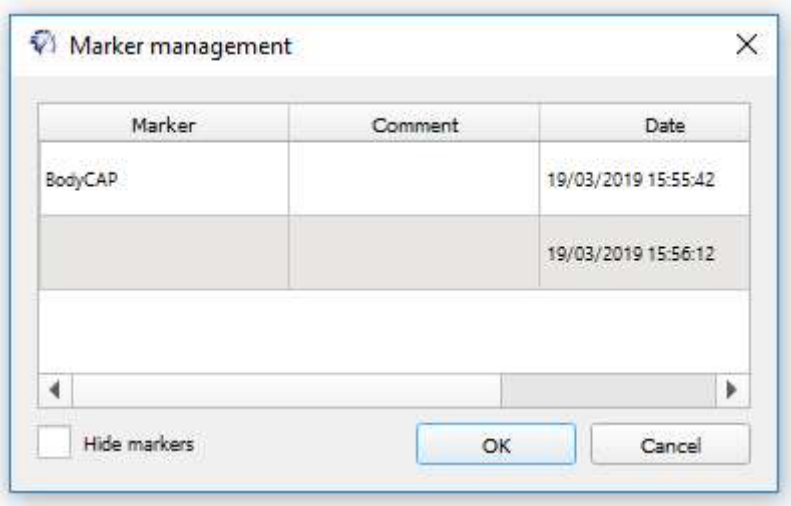

Figure 30: Screen for marker management

7.1.3 Visualization of markers

Once an alarm is triggering on the monitor (technical or physiological), an alarm marker is stored in the monitor. These markers are then viewable on e-Celsius® Manager Software by vertical red dashed lines. The reason for the alarm is indicated at the bottom of the marker.

A green marker "Backup mode" appears at the beginning of the replacement phase. The data which come previously to this marker are all synchronized and may have a dating inaccuracy. This is a case where the synchronization starts on a monitor without initial data (eg when replacing mode).

Real time data or synchronized data may trigger the alarm. On the curve, the marker is shown at a time when the monitor triggered the alarm: it may be in real time or early synchronization.

Marker type	Meaning
Critical battery	Monitor shuts down due to low battery level
Monitor shutdown	Voluntary shutdown by the monitor button
Slot threshold alarm (1/2/3)	Physiological alarm triggered
Change of thresholds	Modification of alarm thresholds
Alarm reset	-
Replacement mode enabled	-
Monitor wake-up	-
Slot memory 1/2/3 full	Monitor memory full

7.1.4 Hide markers

If you do not want to see all the markers, you can check the "**Hide Markers**" at the bottom left of the Figure 31.

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7.1.5 Export temperature data unloaded on e-Celsius® Manager

To export temperature data, one or more temperature plots may be selected from the icons at the top right of the screen shown in Fig.29.
To export graphs as displayed on the screen of the software, a PDF file may be generated with the button "**PDF**" (Fig. 29). The graph will be exported as it is displayed on the screen (with the same zoom and the same number of curve).
A data file in spreadsheet format can be generated from the "Export" button. A spreadsheet including the temperature data, the date and time of recording and the markers will be generated automatically.

7.2 Secondary functions

7.2.1 Backup mode

If during operation a monitor fails or is broken; it is possible to recover the communication with pill(s) which were associated; via another monitor. This allows the recovery of the data stored on each pill.
To do this, it is necessary to start backup Mode with another monitor. This mode enables retrieval of data from all the e-Celsius® Medical pills functioning on the selected channel, in the communication range of the monitor and whose serial number is known.

With the replacement monitor firstly, check that no pill is associated with this monitor. Connect it to the e-Celsius® Manager software, go to the configuration panel and select "Backup mode".

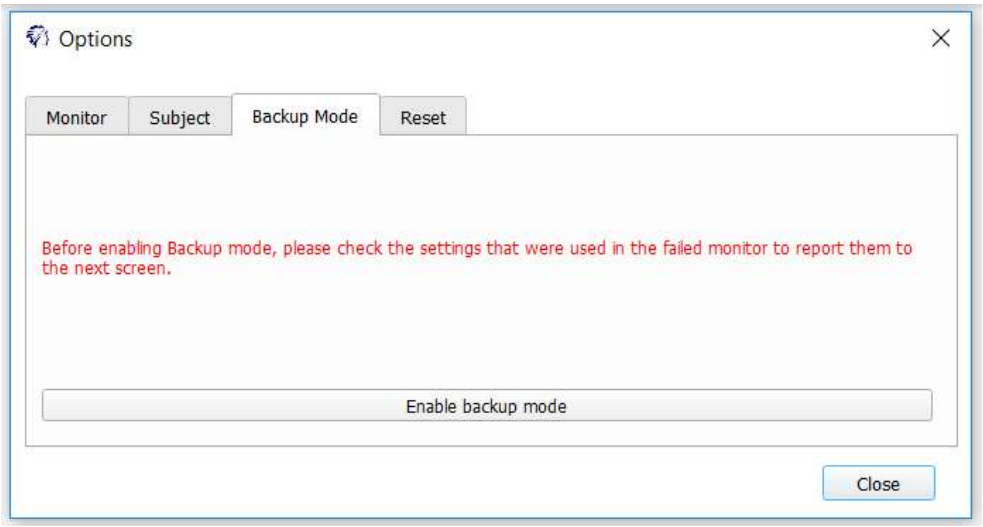

Figure 31: Tab Backup mode

The following window appears:

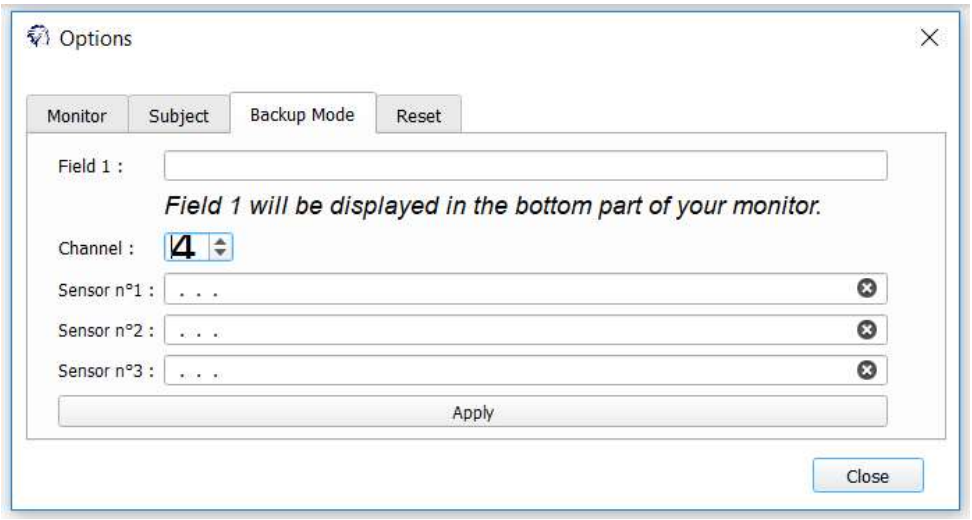

Figure 32: Research activated Pills

Fill the Field 1 and configure the operating channel of the monitor to the same channel as the failed monitor.
Enter the serial number of the pills you want to recover. (§ 6.10.3)
The order of pills does not matter.
Warning: all the Pills must have been activated with the same original monitor.

Click on **Apply**. You will see the banners of the monitor switch from black to white, indicating that the Backup mode is active.
Place the monitor close to the environment of the pills to recover. The monitor will automatically resynchronize with the pills that are still close and match the serial number entered in the e-Celsius® Manager.

To exit the replacement mode, you must disassociate the pills of the monitor (§ 6.10.12) and download the data via the e-Celsius® Manager software.
Note: To exit the recovery mode, connect the monitor to a PC with the cables provided by the manufacturer and go again to the tab Backup mode on the e-Celsius® Manager software. Click then on "Disable backup mode." Banners on the monitor switch then again in black, indicating that the replacement mode is stopped.

7.2.2 Updating and changing the language of e-Viewer Medical monitor

Periodically it may be necessary to update the firmware. For this, the monitor must be reset before the update (§3.2.3.4).

Go to the configuration menu of e-Viewer Manager and select "**Update the monitor**"

Select the update file on the left by pressing the three dots ... (the file to choose is *.hex) supplied by the manufacturer and select the desired language on the right.

It is also possible to change the language file of the monitor without updating it, by pressing the three dots ... (right), choose the update folder provided by the manufacturer having the languages adapted to the software version of the monitor.

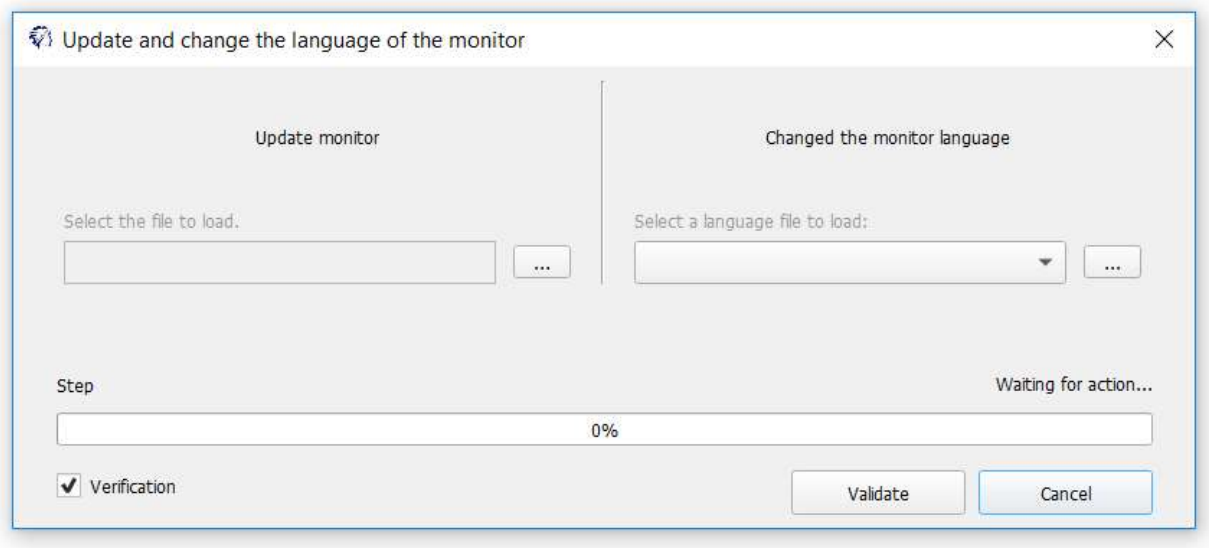

Figure 33: e-Celsius® Manager window allowing to update e-Viewer Medical monitor

8 End of the follow up

When continuous monitoring of the temperature is no longer necessary, it must be ensured that the patient ejected the pill.

3 solutions allow to carry out this verification:

- The patient is able to attest to the evacuation of the pill
- The temperature data collected by the monitor show a non-physiological variation during a passage to the saddle.
- If none of the first 2 solutions is valid, it is possible to check if the pill is still present in the patient's digestive tract. Approach the monitor used for monitoring to the nearest patient and check the detailed menu (see paragraph 6.10.8). The real-time capture of new data informs you that the e-Celsius® Medical pill is always present and active. This verification procedure can be repeated.

If the monitor used for patient tracking is no longer available, another e-Viewer Medical monitor can be used to perform the procedure. In this case, refer to Paragraph 7.2.1 to activate the Back up mode.

⚠ **The operating time of the capsule is limited to 20 days, beyond this period, the method described above is no longer usable. As the capsule is radiopaque, an X-ray will allow remove any doubts. If the e-Celsius® medical pill is found to be blocked, it may be subject to a decision to extract by endoscopy, surgery or any other means, at the discretion of a physician gastroenterologist.**

9 TECHNICAL DATA

9.1 ESSENTIAL PERFORMANCE

For the e-Celsius® Medical System device, the essential performance lies in the continuous measurement of core body temperature in individual

There is no need to perform tests to maintain the essential performance or safety because even in case of breakdown of the product there is no electrical and EMC danger for the person

9.2 EMC TABLES

EMC table for products	
Applicable references	
P022-M	(e-Celsius®)
P040-M	(e-Viewer)
P030-M	(Activator)

Important: information about electromagnetic compatibility (EMC)

Medical devices manufactured by BodyCAP comply with IEC60601-1-2: 2014 standard for immunities and emissions. All the information that appears below comes from normative requirements to which manufacturers of electro-medical devices are subject, within the meaning of standard IEC60601-1-2 Ed4. The device medical device complies with current electromagnetic compatibility standards, however, the user ensure that any electromagnetic interference does not create an additional risk, such as radio frequency transmitters or other electronic devices.

In this chapter you will find the information necessary to ensure proper installation and commissioning of your medical device under the best conditions in terms of electromagnetic compatibility. The various cords of the medical device must be kept away from each other. Certain types of mobile telecommunications devices such as cell phones are susceptible to to interfere with the medical device. The separation distances recommended in this chapter must therefore absolutely be observed. The medical device must not be used near or placed on top of another device. If that cannot be avoided, it is necessary to check its correct functioning under the conditions of use before any use. The use of accessories other than those specified or sold by BodyCAP as replacement parts, may result in increased emission or decreased immunity of the medical device.

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Cable length

Cables and accessories	Maximum Length	Test type	In accordance with:
Cables / Cords	< 3m	RF emission	CISPR 11, Class B
		Emission of harmonic currents	IEC 61000-3-2
		Fluctuating and flickering Voltage	IEC 61000-3-3
		Immunity to landfills Electrostatic	IEC 61000-4-2
		Immunity Electromagnetic fields	IEC 61000-4-3
		Immunity to transients fast electrics in salvo	IEC 61000-4-4
		Shockwave immunity	IEC 61000-4-5
		Shockwave immunity Driving immunity Radio frequency driving disturbance	IEC 61000-4-6
		Radiated Immunity - Magnetic Fields	IEC 61000-4-8
		Immunity to the hollows of tension, brief cuts, and voltage variations	IEC 61000-4-11

Guidelines and manufacturer's declaration (electromagnetic emissions)

The e-Celsius® Medical System device is intended for use in the electromagnetic environment. tick described in the table below. The user and the installer must therefore ensure that the device medical is used in the environment described below.

Emissions Test	Compliance	Electromagnetic environment Notes
Disruption of radiation electromagnetic (Radiated emissions) (CISPR11)	Group 1	The medical device uses RF energy for its internal function
RF emission (CISPR11)	Class B	The medical device is suitable for use in an environment of a health care facility professional
Harmonic Emission (IEC 61000-3-2)	Class A	
Voltage fluctuation (IEC 61000-3-3)	Complies	

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Guidance and manufacturer's declaration of conformity regarding electromagnetic immunity

The e-Celsius® Medical System device is intended for use in the magnetic environment and electromagnetic described in the table below. The user and the installer should ensure the electromagnetic environment compliance.

Immunity test	Standard	Test level according to IEC 60601	Compliance level	Environment electromagnetic Note
Immunity to electrostatic discharges	IEC 61000-4-2	±8kV to contact, ±15kV to air	±8kV to contact, ±15kV to air	Environment of a health care facility professional.
Electric fast Transient/bursts	IEC 61000-4-4	±2 kV AC power supply lines	±2 kV AC power supply ± 1 kV for ports signal Environment of a care facility professional health	Environment of a care facility professional health.
Surge	IEC 61000-4-5	± 1 kV in mode Differential ± 2 kV in mode common	± 1 kV in mode Differential ± 2 kV in mode common	Environment of a care facility professional health.
Magnetic field at the frequency industrial assigned	IEC 61000-4-8	30 A/m	30 A/m	Environment of a care facility professional health.
Immunity to voltage dips, short interruptions, and voltage variations	IEC 61000-4-11	0% UT For 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° 0% UT for 1 cycle and 70% UT for 25 cycles to 50 Hz for 30 cycles to 60 Hz Single phase: at 0	0% UT For 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° et 315° 0% UT for 1 cycle and 70% UT for 25 cycles to 50 Hz for 30 cycles to 60 Hz Single phase: at 0	Environment of a care facility professional health.
Interruptions voltage	IEC 61000-4-11	0% UT for 250 cycles to 50 Hz for 300 cycles to 60 Hz	0% UT for 250 cycles to 50 Hz for 300 cycles to 60 Hz	Environment of a care facility professional health.

Electromagnetic immunity, radiofrequencies:

The e-Celsius® Medical System device is intended for use in the magnetic environment and electromagnetic described in the table below. The user and the installer should ensure the electromagnetic environment compliance.

Immunity test	Standard	Test level according to IEC 60601	Compliance level	Environment electromagnetic Note
WARNING: Portable RF communications devices (including RFID devices) should not be used peripherals such as antenna cables and external antennas) closer to 30cm (12 pouces) from any part of the UNIT UNDER TEST, including cables specified by the manufacturer. Otherwise, the performance of these devices could be impaired. Interference is possible near equipment identified by the following symbol: 				
Fields electromagnetic radio frequency radiated	EN 61000-4-3	10 V / m 80 MHz to 2.7 GHz 80% MA at 1 kHz	10 V / m 80 MHz to 2.7 GHz 80% MA at 1 kHz	Environment of a care facility professional health.
Fields electromagnetic radio frequency radiated	EN 61000-4-3	9 V / m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V / m 385 MHz 28 V / m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V / m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V / m 385 MHz 28 V / m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Environment of a care facility professional health.
Disturbances conduits, induced by RF fields	EN 61000-4-6	3 V 150KHz to 80MHz 6 V in ISM band and band between 0.15 MHz	3 V 150KHz to 80MHz 6 V in ISM band and band between 0.15 MHz	Environment of a care facility professional health.

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Recommended Separation Distances between Portable and Mobile RF Communications Equipment and This Device

e-Celsius Medical System is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment.

Rates Maximum Power Output of Transmitter (W)	**Separation Distance According to Frequency of Transmitter (m)**		
	150 kHz to 80 MHz d = 1.2 P	80 MHz to 800 MHz d = 1.2 P	800 MHz to 2.5 GHz d = 2.3 P
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters
(m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output
power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

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10 Failures guide

Tableau 5: Failures guide

Problem	Probable cause	Solution
The monitor does not switch on.	The battery of the monitor is discharged	Connect it on the mains supply and wait few minutes before interacting the monitor (on the mains supply)
	The monitor is in end of life	The manufacturing date is printed on the label. The proper operation of the monitor is warranted for 500 recharges cycles.
	The monitor may require a maintenance action	Return to your distributor or to the manufacturer.
The LED of the activator does not switch on.	The activator is not property connected	Ensure that the connections are correct, and the power outlet has power
	The activator is in end of life	The manufacturing date is printed on the label. The proper operation of the activator is warranted for 2 years
	The activator may require maintenance action	Return to your distributor or to the manufacturer
The RF communication between monitor and pill is not working.	The distance is too large	Ensure that the pill is in the range of the monitor, check the date of the last temperature data received.
	The pill is not associated	Respect the activation process. If the association is difficult, ensure that the pill is close enough to the monitor or please turn the pill in the hole of the activator. The monitor indicates the number of associated pill.
Inappropriate autonomy of the monitor	Non-recharged battery	Connect the monitor to the mains supply and wait few minutes before interacting with the monitor (on the mains supply).
	Battery in end of life	Scrap it to an electronic waste organism for collection
Inappropriate autonomy of the pill	Old battery	Check the date printed on the label.
The connection between the monitor and the PC/MAC do not work.	Incorrect connection	Check that the cable is properly connected.
	The monitor may require a maintenance action	Return to the manufacturer
The green LED of the monitor does not switch on or blink.	Check the power supply	Check power or plug in the monitor on a USB of the PC (in avoiding USB hubs)
Association to the pill does not work.	3 pills maximum per monitor	Check that a location is free on the monitor.

11 Cables and power supply

Two cables are supplied with the system: two USB - micro-USB cables that allow you to connect the e-Viewer® Medical monitor to a computer to download the data or power the monitor and / or the activator by connecting them to a computer on or to the mains through the adapter. We could observe during indirect discharges at + 15KV at the power supply unit sector, a breakage on the USB connector thereof. This breakage does not induce any degradation of essential performance and basic security of the device is not altered.

Figure 34: Cable and mains supply adaptor

To reduce the risk of electrocution, burns, fire, or damage to equipment, do not connect only cables supplied by the manufacturer.

The power supply for this device has the following characteristics:
Brand: GLOBTEK (HONG KONG) LTD
Model: GTM41078-05-USB

The power supply is the means for external insulation of the electro-medical device.

Data plate:

Figure 35: Power supply data plate

12 The Wristband

The ‘no MRI’ wrist strap should be attached to the wrist before ingestion of a pill and removed after expulsion of the pill (Fig. 7). A wristband is provided for each pill delivered. These wristbands are in the box with the pills. They make it possible to inform the nursing staff that the patient has ingested a pill and that it is therefore forbidden to have an MRI.

It should be noted that in case of consecutive ingestion, the bracelet is removed on expulsion of the last pill.

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