eCelsius Medical system

USER MANUAL P072

TELEMETRIC SYSTEM FOR CONTINUOUS MONITORING OF CORE BODY TEMPERATURE

Caution: This device is not intended for patients with BMI greater than 44.6.

Warning: Do not use device if security label on device appears to be tampered with.

P072GUI004 – User manual eCelsius Medical System.CE.1 2023-10-25

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BodyCAP
Your e-health partner

Indications for Use:

The indications for the eCelsius Medical System will depend on the specific needs of each patient and the clinical situation for which precise, continuous body temperatures are required. It can only be used on the order of a physician who has clinically assessed the contraindications and warnings associated with the use of an ingestible thermometric sensor (eCelsius Medical pill).

eCelsius Medical System is indicated for patients of 18 years or older as long as their body weight is above 40Kg.

eCelsius Medical System is not indicated for patients with special needs, esophageal or swallowing disorders, who are psychologically unsound, or have disabilities which may make the patient unable to swallow the device for any reason, these patients should be deemed ineligible for this device.

eCelsius Medical System is a prescription use device primarily (e.g., initial setup, final data assessment, reprocessing.) indicated for use in clinical environments (e.g., hospitals, hospice, clinics).

Warning:

Failure to follow these instructions may result in measurement failure, personal injuries, and property damage. The manufacturer or distributor cannot be responsible if device is misused for errors in measurement, physical injury, and material damage. Inspection and repair operations must be conducted by approved persons who have undergone proper training.

The performance of the device may be jeopardized should one or more of the following occur:

- Operation outside the manufacturer's stated temperature and humidity range.
- Storage outside the manufacturer's stated temperature and humidity range.
- Mechanical shock (for example, dropping).

This eCelsius Medical System is composed of:

- eCelsius Manager software (could be named "Manager" in this document)
- eViewer Medical monitor (could be named "monitor" in this document)
- eCelsius Medical pill (could be named "pill" in this document)
- Secured USB stick with passcode for user manual and eCelsius Manager software
- MRI ID bracelet (could be named "bracelet" in this document)
- Activator Medical (could be named "activator" in this document)
- eViewer Medical Monitor Transport Pocket
- 2 USB/micro-USB cables and a power supply

Destination and use case:

eCelsius Medical System must be used in hospitals, clinics and exclusively by health care providers. Nursing Home, EHPAD, home health are excluded.

eCelsius Medical System is designed for the measurement of core body temperature in patients, for diagnostic or therapeutic monitoring purposes. The eCelsius Medical pill is supplied sterile in its original packaging and intended for single use. It is then “activated” using the Activator Medical and with the eViewer Medical monitor records data and can send the data to a PC / MAC via the eCelsius Manager software interface supplied with the eCelsius Medical System. The eCelsius Medical pill should be ingested with a glass of water.

Declaration of conformity:

The BodyCAP manufacturer states that the eCelsius Medical System complies with the following current directives and regulations:

- 2011/65/EU and 2015/863/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)
- 2021/2226 concerning instructions for the electronic use of medical devices.
- Federal Communication Commission (FCC) Title 47 Code Federal Regulations Part 15 Radio Frequency Devices

1. TABLE OF CONTENT

1.1 - TABLE OF CONTENT

1.2 - FIGURES INDEX

2. CAUTIONS

The following safety instructions ensure proper operation and will optimize the use of the eCelsius 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 manual).

MR Safety:

eCelsius Medical System has not been evaluated for safety and compatibility in the MR environment (MR Unsafe). 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 eCelsius Medical System is not claimed to be MRI compatible, it is imperative that the patient ingesting a pill does not undergo any MRI. The patient must wear MRI ID bracelet supplied with the system, indicating that he has ingested a system that is not compatible with exposure to strong magnetic fields.

The MRI ID 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 not place or drop items on the device, do not introduce foreign objects.

Do not expose the system to dust or dirt.

Do not use it during a gas leakage.

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

Do not touch or press the screen of the eViewer Medical monitor.

Do not place the eViewer Medical monitor or the activator around small objects which may scratch them or enter inside.

Do not expose the eViewer Medical monitor 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 location of the cables, so they are not an obstruction and become a tripping hazard.

Take care not to shake or strike the eViewer Medical monitor and the activator. This could affect their normal way of working.

Do not use the eCelsius Medical 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.

Do not use the eViewer Medical monitor or Activator Medical if the security label is removed or altered.

Do not use the secure USB stick unless you are authorized to use it and have received the passcode via a separate communication.

Safety instructions:

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

Do not put the device in municipal waste. The eViewer Medical monitor and the activator have been designed to allow reuse and suitable recycling of some components. The symbol representing a waste container with a cross indicates that the product (electrical equipment, electronic 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 eViewer Medical monitor, the activator and the cables must be used in an environment where the relative humidity is > 5 % in an environment where the atmospheric pressure is between 700hPa and 1060hPa and in ambient temperature conditions between 0 and 40°C. It is also recommended to avoid spraying water.
- The eCelsius Medical pill should not be exposed to temperatures outside the range 25 – 45°C.
- The device is designed to operate at an altitude between 0 and 2000m.

Conditions and duration of storage and / or transport:

- The eViewer Medical monitor, the activator and the cables must be stored in an environment where the relative humidity is between 20 and 80%, in an environment where the atmospheric pressure is between 700hPa and 1060hPa. The eViewer Medical monitor must be stored in ambient temperature conditions between 0 and 35°C. The activator should be stored at temperatures between 0 and 45°C. It is also recommended to avoid sprayed water and protect it from exposure to sunlight.
- During the period preceding the use of the eCelsius Medical pill, it must be kept in an environment with relative humidity ranging from 20 to 80%, in an environment where the atmospheric pressure is between 700hPa and 1060hPa and in ambient temperature conditions between 5 and 35°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 eCelsius Medical pill is indicated by an expiration date on its blister. Beyond that date, device performance and safety are not guaranteed.

Sterilization:

The eCelsius Medical pill is delivered sterile in individual packaging. It is not designed to be cleaned or disinfected before use. 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).

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 eCelsius Medical pill.

- Bis(2-ethylhexyl) phthalate under the number CAS 117-81-7
- Diisobutyl phthalate under the number CAS 84-69-5
- Dinonyl phthalate under the number CAS 84-76-4

Warning to users:

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 eCelsius 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.

NOTE: "Harmful interference" is defined by the FCC as follows: Interference that endangers the functioning of a radio navigation service or of other safety services or seriously degrades, obstructs, or repeatedly interrupts a radio communication service operating in accordance with FCC rules.

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: 2AENH016 – eCelsius Medical pill

FCC ID: 2AENH033 – eViewer Medical monitor

FCC ID: 2AENH043 – Activator Medical

and will void the BodyCAP warranty.

3. USE CLAIMS AND CONTRAINDICATIONS

3.1 - USE CLAIMS

eCelsius Medical System must be used in hospitals, clinics and exclusively health care providers. Nursing Home, EHPAD, home health are excluded.

The indications for the eCelsius Medical System will depend on the specific needs of each patient and the clinical situation for which precise, continuous body temperatures are required. It can only be used on the order of a physician who has clinically assessed the contraindications and warnings associated with the use of an ingestible thermometric sensor (eCelsius Medical pill).

Components	Product #	Description
eCelsius Medical pill 	P024-M	eCelsius Medical pill which transmits core body temperature.
Activator Medical 	P030-M	The Activator Medical allows to activate the eCelsius Medical pill prior to its ingestion.
eViewer Medical monitor 	P040-M	Receives signal from eCelsius Medical pill, displays and saves data.

eCelsius Manager software 	P070-M	eCelsius Manager software allows you to set up the monitor and view the data recorded by the monitor, on a computer (PC or MAC)
Secure USB stick with passcode for user manual and eCelsius Manager software  	N/A	The secured USB stick with passcode contains the user manual, the instructions for the use, and eCelsius Manager software install.
eViewer Medical Monitor Transport Pocket 	N/A	Allows transport and eViewer Medical monitor protection from water projection.
USB eViewer Medical Monitor Cable 	N/A	Allows communication between eViewer Medical monitor and a PC / MAC
USB Activator Medical Cable 	N/A	Allows the Activator Medical to be powered by a PC/MAC or power supply.

Power supply USB adapter 	N/A	The power supply is responsible for converting the electrical voltage of sector in different DC voltages TBT, compatible with electronic circuits eViewer Medical monitor
MRI ID bracelet 	N/A	Patient identification bracelet (MRI).

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

Packaging	Product #	Description
Secondary Packaging Box 	N/A	A rigid cardboard packaging box containing a holding stall.
Stalling foam 	N/A	Cushioning system of the device eCelsius Medical System.

3.1.1 Claimed Performance Characteristics of the Device

As communicated by BodyCAP, the claimed performance characteristics of the eCelsius Medical System are:

- Continuous measurement of core temperature.
- Instantaneous detection of temperature changes.

3.1.2 Specified Clinical Benefits

Safety claims:
• Limited cases of incorrect measurement of body temperature potentially resulting in misdiagnosis or misinterpretation of the clinical state of the patient.
• Limited adverse events associated with the use of the eCelsius Medical System, such as biological hazards, chemical hazards, energy hazards, or cybersecurity risks.
• Safe ingestion of the eCelsius Medical capsule without choking or occlusion.

Performance claims:
• Continuous measurement of core temperature.
• Ability to detect rapid changes in temperature.
• Provides an accurate measurement of the core temperature:
- ±0.1°C for the human physiological range 36-41°C
- ±0.13°C outside the physiological range

Clinical benefit claims:
• Limited patient discomfort, pain, or device-related injuries.
• Avoid repeated measurement by reducing data loss occurrences.

3.2 - CONTRAINDICATIONS AND WARNINGS

3.2.1 Contraindications:

The eCelsius Medical System is designed for the measurement of core body temperature in humans, it is contraindicated in several situations:
- For people whose body weight is less than 40Kg.
- 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).
- Subject with hypomotility disorders of the gastrointestinal tract, including, but not limited to ileus.
- The use of the eCelsius Medical System is prohibited if a patient has an Implantable Pulse Generator or Implantable electro-medical device of any kind. Among the devices that may be included are Pacemakers (or Implantable Pulse Generators), Implantable Cardioverter Defibrillators (ICDs), Deep brain stimulation (DBS) devices, and Left Ventricular Assist Devices (LVADs). In addition, patients with an implanted or temporarily implanted device that uses an external power-source should also be contraindicated for use of the eCelsius Medical System.
- Patients under the age of 18.
- Patients with special needs, esophageal or swallowing disorders, who are psychologically unsound, or have disabilities which may make the patient unable to swallow the device for any reason.
- For Pregnant women.
- For people with Crohn's disease.

- People unconscious before ingestion of the pill.
- Subject with previous gastrointestinal surgery.
- Ulcerative colitis, diverticulitis, and felinization of the esophagus.
- Zenker's diverticulum.
- This device is not intended for patients with BMI greater than 44.6.

3.2.2 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 eCelsius Medical pill (Fig. 6) is intended to be ingested, with a glass of water, to measure the core body temperature. It is delivered in standby mode. It must be activated by the Activator Medical and used with an eViewer Medical monitor to operate. The fitting of the MRI ID bracelet (Fig. 7) is followed by ingestion of the pill.

• Ingestion of the eCelsius 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 eCelsius 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 EN ISO 10993-1, considering the contact time of the eCelsius 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 considered 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 § 10. End of the follow up.

• Also, the eCelsius Medical pill should be used with caution in any individual exhibiting gastrointestinal disturbances, nausea and/or vomiting.

• 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 mainly observed in the first 3 hours following the ingestion of the eCelsius Medical pill but can be extended to longer period in some individuals (up to 12 hours) and is characterized by a sudden and important and non-physiological decrease or increase of the temperature values collected. The temperature collected values can be impacted for 10 to 30 minutes. It is recommended, during the follow-up period to guarantee the reliability of the data, to limit water or food intakes at ambient temperatures. In case of ingestion of hot/cold drinks/food during the monitoring period, especially during the first 12 hours, after pill ingestion, do not consider collected values during the following 30 minutes, for diagnosis or medical decision.

• 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 eCelsius Medical pill after use by the patient. The system must under no circumstances be introduced into an autoclave, otherwise permanently damage the pills concerned.

• The device is intended for single use; any reuse of the pill is likely to induce an infectious risk.
The system has been tested to be robust to interference from immunity or coexistence and to store the data in the pill. An automatic synchronization process is available in the system to get back up to 2000 data stored in the pill and sent to the monitor (cf. §8.10.9. Synchronization of the data in the memory of the pill).
• 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.

3.3 - RISKS AND COMPLICATIONS

Risks and complications:

• The eCelsius Medical pill is intended to be ingested by a person with a glass of water, special attention must be brought to the risk of misdirection, especially in people who have or had swallowing disorders. This false route phenomenon can cause a blockage in the respiratory tract requiring extraction.
• Injury to the gastrointestinal system requiring surgery.
• Careful consideration should be given before using the eCelsius Medical pill for temperature monitoring during abdominal or other surgery that might expose the sensor to ambient air and cause inaccurate temperature readings.
• A false route at the time of ingestion of the eCelsius 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 such as blockage of the pill within the digestive tract, which may require the use of laxatives. If not effective recovery by endoscopy or by surgery could be required.
• Infections due to handling before pill ingestion
• Waste of time for the user / Extension of the care time
• The loss of communication between the eCelsius Medical pill and the eViewer Medical monitor, inducing a stop of the patient's temperature monitoring
• 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 eCelsius Medical pill and the eViewer Medical monitor, 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.
• Cold/hot food/drink ingestion during the first 12 hours, after pill ingestion, may impact the collected value. It is recommended to limit water or food intakes at ambient temperatures during the monitoring period. In case of hot/cold ingestion, to avoid incorrect interpretation of the data, do not consider collected values during the subsequent 30 minutes, for diagnosis or medical decision.

3.4 - FUNCTIONS OF eCELSIUS MEDICAL SYSTEM

The operating mode of the device is summarized below:

Table 1: Mode of action

No.	Operating Principle
0.	IT department use the secured USB stick and the given passcode to access content and install the eCelsius Manager software on the authorized HCP computer account.
1.	Settings of eViewer Medical monitor thanks to eCelsius Manager software. And check on the monitor the validated parameters (Alarm levels).
2.	The association of an eCelsius Medical pill to an eViewer Medical monitor through the activator.
3.	The bracelet is worn on wrist of the patient.
4.	The ingestion of the eCelsius Medical pill.
5.	The data transmission from the eCelsius Medical pill to an eViewer Medical monitor.
6.	Real time display of Temperature data and physiological alarms.
7.	The display of the temperature graph on the computer screen via the eCelsius 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 eCelsius Medical pill is performed via an electromagnetic pulse emitted by the activator.
2.	The eCelsius Medical pill measures the temperature through a thermistor.
3.	The eCelsius Medical pill stores the last 2000 temperature collected data.
4.	The communication between the eCelsius Medical pill and the e-Viewer Medical monitor is performed through the radio frequency band of 433-434 MHz using a proprietary protocol.
5.	The eViewer Medical monitor receives, displays, and stores the data.
6.	The eViewer Medical monitor automatically asks the eCelsius Medical pill again data not received in real time.
7.	Visualization of the data through eCelsius Manager software application.
8.	The export of the data to CSV and PDF via eCelsius Manager software.

The functions frequently used are listed in Table 3.

Table 3: Frequently used functions

Frequently used functions	Main (M) / Secondary (S)
Activation of the eCelsius Medical pill	M
Temperature measurement with the eCelsius Medical pill	M
Setting the time and date of the eViewer Medical monitor with the eCelsius Manager software	M
Setting patient's information, displayed on the eViewer Medical monitor screen, with the eCelsius Manager software.	S
Setting alarms (thresholds) with the eCelsius Manager software or directly with the menus of the eViewer Medical monitor	M
Setting the RF channel used by the eViewer Medical monitor	S
Automatic data recovery from the eCelsius Medical pill with the eViewer Medical monitor	M
Storage of the data in the eCelsius Medical pill	M
Real time visualization of the data on the eViewer Medical monitor	M
Real time visualization of the alarm triggered (technical or physiological)	M
Integration of automatic technical markers with the eViewer Medical monitor	S
Integration of a manual marker with the eViewer Medical monitor	S
Extinction of the eCelsius Medical pill at the end of the measurement cycle	S
Visualization of data on the eCelsius Manager software	M

Frequently used functions	Main (M) / Secondary (S)
Export of data from eCelsius Manager software to a spreadsheet (CSV) or PDF curves	M
Management of the battery of the monitor	M
Update the monitor with eCelsius Manager software application	S

4. FIRST USE

4.0 - CYBER SECURITY

General:

User should strictly follow the instructions and technical notes listed in this section to reduce any cyber security risk to the system.
Strong password policy should be used for computer logging. Recommended password rules are:

I. Use 14 characters minimum.
II. Use at least one uppercase, one lowercase, one number, and one special character.
III. Do not include username in password.
IV. Prevent using the last 3 passwords.

Warning: Always use the most up-to-date anti-virus software to protect your device from malicious software.

Warning: Always upgrade your computer operation system where a new version of security patch is release by the manufacturer.

Warning: Please contact BodyCAP in case cybersecurity is compromised or suspected to be compromised in your product.

Software installation and upgrades:

In order to respect cyber security guidelines, eCelsius Manager software must be installed only by authorized users' accounts with cybersecurity awareness respecting IT good practices of user logging on the computers used.

eCelsius Manager software and eViewer Medical monitor shall be installed or upgraded only by the IT technical staff of the Hospital. A passcode to access secured USB stick and a password to update eViewer Medical monitor are given by BodyCAP to authorized installers.

Prior to any installation/upgrade, in order to respect Cyber Security matters, IT services must verify the eCelsius Manager software certificate is official from BodyCAP team. To verify the certificate, it is necessary to go to "digital signatures" in the "properties" of the installer icon. BodyCAP must be the certificate signer.

The PC/MAC account used for the eCelsius Medical System records should be secured by password and includes IT rules of the environment protection in order to protect information at rest (reports) like:

- Physical perimeter security
- Physical access control
- PC/Mac logging
- Secured access to network storage.

For cybersecurity matters, it is impossible to communicate with eViewer Medical monitor without using the eCelsius Manager software.

4.1 - INSTALLATION OF eCELSIUS MANAGER SOFTWARE

4.1.1 Configuration

CAUTION: Do not use USB stick unless you are authorized and have received the passcode via separate delivery in order to unlock stick and install software.
CAUTION: This section is reserved to IT department, which have the right privilege to install and update the system.

Minimal configuration Required:
Processor 1GHz. 500Mo RAM.
200Mo disk space required for the installation.

- a Windows version 10 or Windows 11, or
- a minimum version MAC OS X 10.15.

The screen resolution must be at minima 1024x768.

Figure 1: Secured USB stick

4.1.2 Secured USB stick operating mode

Action	Result
0. Key is not connected to USB	-
1. Press the KEY button	 LEDs blink together
2. Within 10s enter Passcode sent by BodyCAP services and press KEY Button	 will illuminate together for approximately 4s. and then change to blinking 
3. Connect the USB stick into USB port within 30s	 illuminate and remain solid (blue LED can flicker)
4. Get access to USB stick content	You can access to user manual and/or e- Celsius Manager installer
5. When finish, unplug the drive	All indicators will turn off. Drive is lock again

Remark: by security, in case of 10 wrong passcode attempts, the content of the key is deleted.
Remark: The USB stick may need to be charged 30min before being used. In this case, connect to USB. Access is not possible.

4.1.3 Install of eCelsius Manager software

Note: the update of the operating system (OS) may be necessary in some cases to recognize the USB driver.
To install eCelsius Manager software and the drivers of the eViewer Medical monitor, please:
• Get the passcode to access the content of the secured USB stick
• Verify the certificate as described in § 4.0. 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. These installers are present on the USB stick provided (Fig. 1) with the eCelsius Medical 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.
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 to see if a new disk has appeared “Silicon Labs VCP Driver Install Disk”.

The language of the interface can be changed after opening the application eCelsius Manager. Click on one of the flags in bottom right of the window.

4.2 - IMPLEMENTATION OF THE DEVICE

4.2.1 Power up the eViewer Medical monitor

To turn on the eViewer Medical monitor, 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.
A LED indicates that the pressure on the button has been considered.

Before using the eViewer Medical monitor in battery mode, you must ensure that its charge level is sufficient.
To use the eViewer Medical monitor with the PC / MAC eCelsius Manager software, you must install the eCelsius 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.
For the monitor to communicate with the PC / MAC software, please connect the monitor to an 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 properly.

4.2.2 Supply the batteries

If you plan to use the eViewer Medical monitor in battery mode, 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 USB port). The battery can charge even if the monitor is switched off.

4.2.3 Configuration of the monitor

The configuration of the monitor through the eCelsius Manager software is only allowed when no pill has yet been paired. Connect the eViewer Medical monitor to a computer with the eCelsius Manager software and launch it. When opening the first window, select “Configuration” (Fig. 2).

Figure 2: Start screen of eCelsius Manager software.

At the opening of the second window (Fig. 3) several tabs allow you 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).

4.2.3.1 The tab monitor

Figure 3: Tabs to configure the monitor.

Working channel

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

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

Date and time

The date and time of the computer on which the eCelsius Manager software 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 fits with the desired time zone.

Note: The time is displayed with the format dd/mm/YYYY.

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. §8.10.5). Medical staff need to verify thresholds values before patient ingestion.

4.2.3.2 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 your needs. The contents of field 1 will be displayed on the 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.

These fields are used to identify to which patient the eViewer Medical monitor is related to, but for patient information security matters, you should never use direct Patient's name.

After configuring the different items, click Apply to validate. This step is required before starting the association of the pills (cf. §8.10.3).

Figure 5: Screen of the monitor

4.2.3.3 The Backup Mode

The "Backup Mode" tab is used to replace a failed monitor. The use of the "Backup mode" is presented in §9.2.1.

4.2.3.4 The reset tab

The "Reset" tab is used to restore the original configuration of the monitor and delete all data stored in the monitor. 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.

5. eCELSIUS MEDICAL SYSTEM LABEL INFORMATION

Symbols Glossary:

SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT
	EN ISO 15223- 1:2021 Reference no. 5.1.1. (ISO 7000- 3082)	Manufacturer	Indicates the medical device manufacturer.
	EN ISO 15223- 1:2021 Reference no. 5.1.3. (ISO 7000- 2497)	Manufacturing Date	Indicates the medical device manufacturing date.
	EN ISO 15223-1:2021 Reference no. 5.1.4. (ISO 7000- 2607)	Use by date	Indicates the date after which the medical device do not be used.
	N/A	Do not use with pregnant women	Indicates that women who are pregnant should not take the pill or use the device.
	ISO 11607-1:2019 + A1:2023	Sterile Barrier System	Indicates the presence of a unique sterile barrier system.
	EN ISO 15223- 1:2021 Reference no. 5.1.6. (ISO 7000- 2493)	Catalog number	Indicates the manufacturer's catalog number so that the medical device can be identified.
	EN ISO 15223- 1:2021 Reference no. 5.1.5.	Batch code	Indicates the manufacturer's batch code so that the batch can be formally identified.
	EN ISO 15223- 1:2021 Reference no. 5.1.7. (ISO 7000- 2498)	Serial number	Indicates the manufacturer's serial number so that a specific medical device can be identified.
	EN ISO 15223-1:2021 Reference no. 5.2.3. (ISO 7000- 2501)	Sterilized using ethylene oxide	Indicates a medical device that has been sterilized using ethylene oxide.
	EN ISO 15223-1:2021 Reference no. 5.2.6. (ISO 7000-2608)	Do not resterilize	Indicates a medical device that is not to be resterilized.
	EN ISO 15223- 1:2021 Reference no. 5.3.2. (ISO 7000- 0624)	Keep away from sunlight	Indicates a medical device that needs protection from light sources.

SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT
	EN ISO 15223- 1:2021 Reference no. 5.3.4. (ISO 7000- 0626)	Keep dry. Keep away from rain	Indicates a medical device that needs protection from moisture.
	EN ISO 15223- 1:2021 Reference no. 5.3.7. (ISO 7000- 0632)	Temperature limit	Indicates the temperature limits to which the medical device can be safely exposed.
	EN ISO 15223- 1:2021 Reference no. 5.3.8. (ISO 7000- 2620)	Humidity limi-tation	Indicates the range of humidity to which the medical device can be safely exposed.
	EN ISO15223- 1:2021 Reference no. 5.3.9 (ISO 7000- 2621)	Atmospheric pressure limi-tation	To indicate the acceptable upper and lower limits of atmospheric pressure for transport and storage.
	EN ISO 15223- 1:2021 Reference no. 5.2.8. (ISO 7000- 2606)	Do not use if package is damaged	Indicates a medical device that should not be used if the package has been damaged or opened and that the user should consult the instructions for use for additional information.
	EN ISO 15223-1:2021 Reference no. 5.4.2. (ISO 7000- 1051)	Do not re-use	Indicates a medical device that is intended for one single use only NOTE: Synonyms for “Do not reuse” are “single use” and “use only once.”
	IEC 60601-1, Symbol 20 (ICE 60417- 5333)	Type BF applied part	To identify a type BF applied part complying with IEC 60601- 1.
	EC 60601-1, Reference no.10 (ISO 7010- M002)	Refer to instruc-tion manual/ booklet	To signify that the instruction ma-nual/booklet must be read.
IPX8	IEC 60601-1 (IEC 60529)	Degree of pro-tection	Protection against moisture entry of ENCLOSURE during long periods of immersion under pressure.
	EN 15986:2011 Reference no. A.4	Contains or presence of phthalate: bis (2-ethylhexyl) phthalate (DEHP)	Medical device is derived from or manufactured from products containing phthalate: bis (2- ethyl-hexyl) phthalate (DEHP).
	IEC 62133:2017 IEC 60086-4:2019	Battery, li-Ion	On battery powered equipment.

SYMBOL	STANDARD REFERENCE	SYMBOL TITLE	EXPLANATORY TEXT
	IEC 60601-1- IEC 60601-1-2	Non-ionizing electromagnetic radiation	N/A
	EN ISO15223-1:2021 Reference no. 5.7.7.	Medical Device	Indicating a medical device.
	ASTM F2503 Reference no. Table 2, Symbol 7.3.3; 7.4.9.1; Fig.9	(MR) Unsafe	3.1.14: An item which poses unacceptable risks to the patient, medical staff, or other persons within the MR environment.
	Regulation (EC) n° 765/2008 of July 9, 2008, sets the general principles of the “CE” marking MDR 2017/745	“CE” marking	It materializes the commitment of the product manufacturer to its compliance with the requirements set by Community regulations.
	EN 50419:2006 + 2022	Collect separately	Separate collection for waste of electrical and electronic equipment. Do not dispose of battery in municipal waste. The symbol indicates separate collection for battery is required.
	N/A	Min. body weight Limit	Body weight minimum limit to swallow the eCelsius Medical pill.
	N/A	Not suitable for child. Keep away from child	The eCelsius Medical pill is small and can be accidentally swallowed by children, please keep the system away from children.

A QR code is also implemented in the label with (GTIN number/Batch number/Manufacturing date).

6. THE CORE BODY TEMPERATURE SENSOR eCELSIUS MEDICAL PILL

Figure 6: eCelsius Medical pill

Figure 7: MRI ID bracelet

The eCelsius Medical pill (Fig. 6) is intended to be ingested with a glass of water to measure Core Body temperature. It is delivered in deep sleep. It must be woken up by the activator and associated with a monitor to work. Attach the MRI ID bracelet to the wrist of the patient before swallowing the pill (Fig. 7).

6.1 - IMPORTANT INFORMATION AND SAFETY RECOMMENDATION

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

eCelsius 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 eCelsius Medical pill includes 4 batteries Ag-Zn Oxide. In fact, the pill should not be disposed of with household waste.

Sterility

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, disinfected, or re- sterilized.
The system should not, in any case, be introduced in an autoclave due to risk of permanent damage.
The pills are intended for single use only, any reuse of the pills could lead to an infection risk.

6.2 - CHARACTERISTICS

Dimensions:	Length: 17.7 mm. Diameter: 8.9 mm.Weight: ≈ 1.7 g.
Ambient Operating Range	Temperature (25-45°C),
Temperature Range:	25 - 45°C
Accuracy:	±0.1°C for human physiological range 36-41°C ±0.18°C outside of the physiological range
Functional temperature mode:	Direct mode
Temperature resolution:	0.01°C
Heating Transient time:	< 150s (+2°C)
Cooling transient time:	< 100s (-2°C)
Sampling frequency:	30s +2%
Storage capacity in Pill:	Last 2000 temperature readings
Transmission distance:	1m (depending on environment).
Ingress Protection (IP):	X8 (Material supporting prolonged immersion)
Power Pill:	4 x Ag-Zn Oxide (1.55VDC).
Cell Configuration:	2 Serial 2 Parallel
Pill Algorithm:	Embeds a firmware managing electronics to realize theintended use: • Takes temperature. • Stores data in the memory • Communicates in RF (RX & TX)
Pill battery life:	20 days.
Time:	The time for a steady state reading is 30 s ± 2%.
Pill frequency:	ISM Band 433MHz - 434MHz
Pill radiated Power:	-22 dBm
Plastic of the pill shell:	Biocompatible PVC.
Pill storage life:	Refer to the limit date printed on the blister.

Type of temperature measurement of the pill: The device takes a core body temperature as it passes through the gastro intestinal tract.

WARNING: Modification of the electro-medical device forbidden

7. ACTIVATOR MEDICAL

Figure 8: Activator Medical

The activator (Fig. 8) is intended to activate the eCelsius Medical pill before a measurement cycle.

7.1 - IMPORTANT INFORMATION AND SAFETY INSTRUCTIONS

The Battery

The system does not include a battery. For each use, the power supply of the activator is connected to a mains supply, or a PC / MAC. The connection between the activator and the mains supply and/or the computer must be done only with the cables and the power supply provided by the manufacturer.

7.1.1 Cleaning/Disinfection:

The activator is reusable, the system should be cleaned and disinfected after each use or as required.

Accessories	Area to be cleaned
Activator Medical (P030)	Button
	Upper and Lower shells

- Disinfectant surface contact time 1 to 15 minutes, depending on the desired antimicrobial effectiveness.
- Rinsing is not necessary unless the treated areas are intended to be in contact with the skin or mucous membranes.
- Repeat the application 5 times on the areas to be treated using new wipes.
- Close the wipes packaging after each opening.
- Do not reuse the wipe.

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).

A security label at the back of the activator is present to certify the integrity. It covers a screw on the bottom shell. If it is broken or removed, the activator should not be used.

7.2 - CHARACTERISTICS

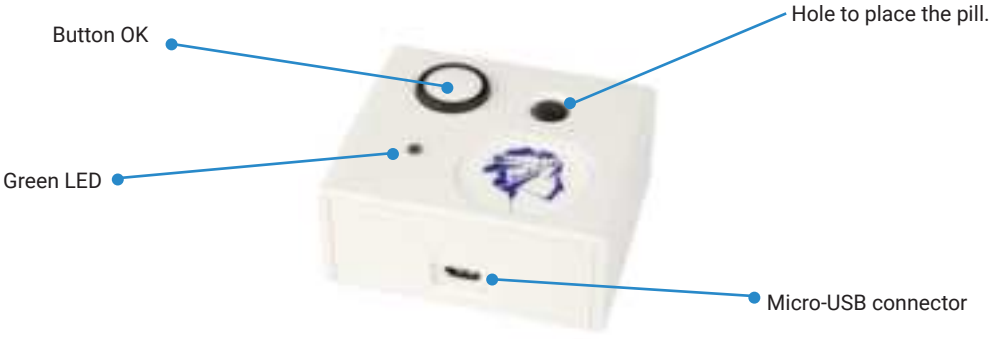

Figure 9: Description of the Activator Medical

Dimensions:	Length: 69 mm. Width: 59 mm. Height: 31 mm. Weight: ≈ 62 g
Power supply:	Main power supply unit (100 ~ 240 V) or PC via USB (5 V).
Power consumption:	125 mW only connected (out of operation) and 500mW during activation (for 10s).
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 45°C) Humidity (20 to 80%)
Activator Algorithm:	Embeds a lock algorithm firmware: If button is pressed, the LED blinks & energy goes through antennas/coils.

WARNING: Modification of the electro-medical device forbidden

7.3 - THE BUTTONS

The button OK is used to launch the activation process. The activation process is detailed in §8.10.3.

7.4 - 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.

8. THE eVIEWER MEDICAL MONITOR

Figure 10: eViewer Medical monitor

The monitor is intended to communicate in RF with the eCelsius Medical pill to recover and store temperature data.

One monitor is dedicated to one patient at a time. The use of multiple eCelsius Medical pills is possible to monitor one patient's temperature for multiple days.

8.1 - IMPORTANT INFORMATION AND SAFETY INSTRUCTIONS

The battery

The eViewer Medical monitor 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 eViewer Medical monitor, please only use the cable and the adapter provided by the manufacturer.

Cleaning/Disinfection:

The monitor is reusable, the system should be cleaned and disinfected after each use or as required. Please sue the following procedure:

Accessories	Area to be cleaned
eViewer Medical monitor (P040-M)	Buttons
	Upper and Lower shells
	Screen

- Disinfectant surface contact time 1 to 15 minutes, depending on the desired antimicrobial effectiveness.
- Rinsing is not necessary unless the treated areas are intended to be in contact with the skin or mucous membranes.

- Repeat the application 5 times on the areas to be treated using new wipes.
- Close the wipes packaging after each opening.
- Do not reuse the wipe.

Maintenance

It is strictly forbidden to open the eViewer Medical monitor. If a fault or a malfunction is found, please contact your distributor or the manufacturer (Contact details at the end of this user manual).
A security label at the back of the monitor is present to certify the integrity of the eViewer Medical monitor. It covers one screw of the bottom shell. If it is broken or removed, the monitor should not be used.

RF Communication

In operation, it is not advisable to put the eViewer Medical monitor on a metallic table or other metal surface which could reduce the RF emissions.
When synchronizing data, keep the eViewer Medical monitor within one foot of the patient. It is also recommended to be vigilant in environments with high metal content (reinforced concrete wall) and to regularly check on the monitor screen that 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 data 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 (10 communication attempts). 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).

8.2 - DESCRIPTION OF THE eVIEWER MEDICAL MONITOR

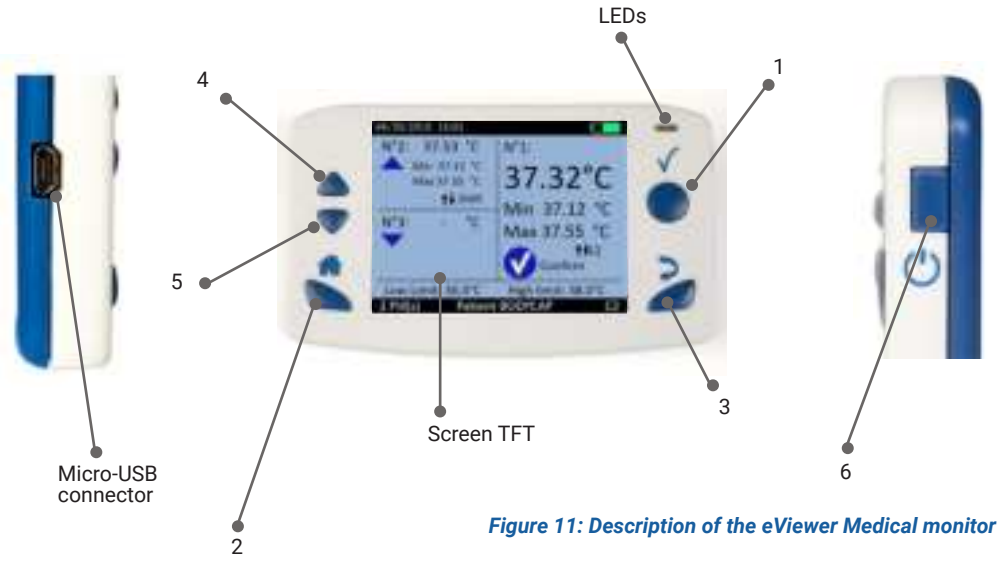

Figure 11: Description of the eViewer Medical monitor

8.3 - FEATURES

Dimensions:	Length: 120 mm. Width: 70 mm. Thickness: 15 mm. Weight: ≈ 120 g.
Screen:	320 x 240 pixels.
Operating temperature:	0 to 40 °C.
Storage capacity:	150 000 data per activated pill.
Connector:	Female micro-USB
Power supply:	Battery Lithium-ion (3.7VDC; 1400mAh) rechargeable with a mains supply adapter (100~240 V) and a cable micro-USB provided with the system.
Power Supply Input:	100-240VAC; 50-60Hz; 0.5A; Class II; type BF
Power Supply Output:	5VDC; 1.2A
Time to charge:	3 h.
Battery life:	36 h.
Band of communication:	ISM Band 433MHz → 434MHz.
Life duration:	2 years (or around 500 recharge cycle).
Condition of carriage and storage:	Temperature (0 to 35°C) Humidity (20 to 80%)
Way to disconnect from the mains supply:	Unplug the power cable.

Monitor Algorithm:

Embeds a complete firmware managing electronics to:

- Communicates in RF (TX & RX) with 1 to 3 pills simultaneously.
- Stores received data in allocated memory.
- Decides if missing data requires synchronization with 1 pill.
- Displays data & options on screen.
- Manage date & time.
- Manages alarm triggering signals (Battery, communication, physiologic)
- USB communication management (configuration, data unload, firmware update)

WARNING: Modification of the electro-medical device forbidden

8.4 - 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 you to come back to the main screen of temperature data.

The button Back (ref. 3 Fig. 11)
The button Back allows you 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.

8.5 - 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 indicate that the pressure on the side button has been considered (ref 6 fig.11).

8.6 - THE BATTERY OF THE eVIEWER MEDICAL MONITOR

Information

When it is not plugged into 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 in penalty to irreparable damage on the system and security failures.

Charging cycle

To recharge the battery, simply plug the power supply of the monitor into the mains supply and switch off the screen. Few hours are required to charge the battery. The battery life of the eViewer Medical monitor in battery operation is around 36h (screen used but not continuously).

Please do not forget to charge the eViewer Medical monitor at the end of those 36 hours 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 eViewer Medical monitor, 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 eCelsius Manager software application to reset it. Connect to eCelsius Manager software 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 / MAC settings.

8.7 - THE CONNECTIONS

Female Micro USB port

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

(i) to set up the eViewer Medical monitor (date, time, channel, alarm thresholds, patient data)
(ii) to download data of the eViewer Medical monitor to the eCelsius Manager software
(iii) to visualize the results of measurements,
(iv) to export them to PDF or spreadsheet format
(v) to recharge the battery of the eViewer Medical monitor.

8.8 - RF COMMUNICATION

In operation, it is **strongly discouraged** to place the e-iewer 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 metal content (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 eViewer Medical monitor, the data are stored in the internal memory of the pill so that they 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 arrows. If this double arrows flashes in Orange, it means that no exchange with the pill has occurred during the last 10 communication attempts.**

8.9 - MENUS OF THE eVIEWER MEDICAL MONITOR

Figure 12: Screen of the eViewer Medical monitor 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., 04/30/2019) in the US format (MM/DD/YYYY)
- The daytime (e.g., 14:03) on 24h format
- The battery level of the monitor (e.g., the top right of the screen)
- The working channel of the monitor (e.g., C2)
- A field corresponding to a patient identification (e.g., Patient BODYCAP)
- The number of pills associated (e.g., 0 Pill(s))
- An orange cross in the top banner of the screen indicates that the memory related to an associated pill is full.

Figure 13: Screen of the eViewer Medical monitor 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 eViewer Medical monitor

To validate a menu and move to submenu, press the button Confirm/OK (§ 8.4). To return back, press the button Back (§ 8.4).

To return directly to the temperature display, press the button Home (§ 8.4). Navigation between the menu items is possible by using the up-down buttons (§ 8.4).

The menu Subject

The menu Subject displays the information of the four fields filled in the “subject” tab of eCelsius 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 the eViewer Medical monitor

Pill activation: Starts the Association process between the pill and eViewer Monitor.

Pill Identification: View the serial number of the associated pills.

Pill status / Deactivation: Dissociates the pill from monitor (after data unloading) and switches off the pill.

Menu Alarm
The Alarm menu is used to manage physiological alarms.

Alarm reset: Allows 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 eCelsius Manager software and in the CSV file after data export.

Menu About
The About menu allows you to view the firmware version of the eViewer Medical monitor as well as identify the monitor from its unique address.

8.10 - MAIN FUNCTIONS

8.10.1 Set the monitor

To set up the eViewer Medical monitor, please connect it to the computer via USB to use the eCelsius Manager software. You will configure:

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

8.10.2 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 monitors do not interfere with each other. Setting the operating channel is performed through eCelsius Manager software.
This command is not possible once eCelsius Medical pills 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. §9.2.1 Back-up Mode).

Note: a dedicated 8th channel is reserved for activation and can never be selected by the user as a working channel.

8.10.3 Activate a pill

Note: Before eCelsius Medical pill activation, you must fill in the Subject information in the configuration interface of the eCelsius Manager software. 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.
The medical staff must also check the applicable thresholds to be sure it will be adapted to the patient situation control. To associate an eCelsius Medical pill, please go to the “Pill” menu and then the sub-menu “Pill activation” of the eViewer Medical monitor (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 eViewer Medical monitor.
- 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 rotate the pill in the hole of the activator 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 number; 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).

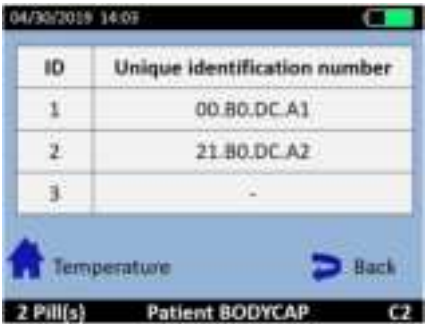

Figure 19: Identification of associated pills

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 all along data collection. By default, the assigned number will always be the lowest available between 1 and 3 (available means 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 eCelsius Medical pill in the hole of the activator and / or slightly move the eCelsius Medical pill in the hole, press the button OK on the eViewer Medical monitor to restart the association process and re-press then the button on the activator.

For the activation of 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.

8.10.4 Consult temperature data in real time

To visualize the collected temperature data, press the “Home” button. 
The screen will visualize (i) the latest temperature data collected and (ii) the minimum and maximum values collected by each associated eCelsius Medical 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 alarm triggering before ingestion.

8.10.5 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 eCelsius 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.

8.10.6 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.

8.10.7 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 eCelsius Medical 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 draw attention to it (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 real-time communication between the eCelsius Medical pill and the eViewer Medical 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 is reset. 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 eViewer Medical 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 time stamped at the time of the reception of the data (date of the synchronization).

In the event that the eCelsius Medical System device presents measurement, display, or other failures likely to limit the ability to interpret core temperature data, we remind you that the core temperature measurement can always be performed by any other tool, at the discretion of the medical staff.

8.10.8 Detailed visualization of the data of one pill.

To access a detailed visualization, select the eCelsius Medical pill by positioning it to 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 (hh:mm:ss).
- The minimal and maximal value and the battery status of the eCelsius Medical 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.

8.10.9 Synchronization of the data in the memory of the pill

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

In the “Data visualization” menu, the symbol indicates the number of data to synchronize between the eCelsius Medical pill and the eViewer Medical monitor. This symbol turns to orange and flashes when no communication occurred during the last 5 minutes.

The eCelsius Medical pill has 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 eViewer Medical monitor and / eCelsius Medical 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 eViewer Medical monitor will automatically synchronize its data with the 2000 data available in the memory of the eCelsius Medical pill.

The storage capacity of each pill is limited, the communication between the eCelsius Medical pill and the associated eViewer Medical monitor has 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 synchronizes first the oldest data available in the memory of the pill. The most recent are thus recovered last.
To synchronize data, the eViewer Medical monitor must be in real-time communication (max distance 1 meter) with the pill. If a new disturbance breaks the synchronization process, it is necessary to wait for the next real time communication of the eCelsius Medical 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 eViewer Medical monitor optimizes the synchronization and waits to have enough consecutive data (max 8 data) before giving the synchronization order to the concerned eCelsius Medical pill.
To facilitate the recovery of data stored in the memory by the monitor, it is important to have a good communication quality between the eCelsius Medical pill and the eViewer Medical monitor.

Example: Temperature monitoring with one pill. Data synchronization is performed after 10 hours of missing communication.

Data collected in real time are always stored in the monitor.

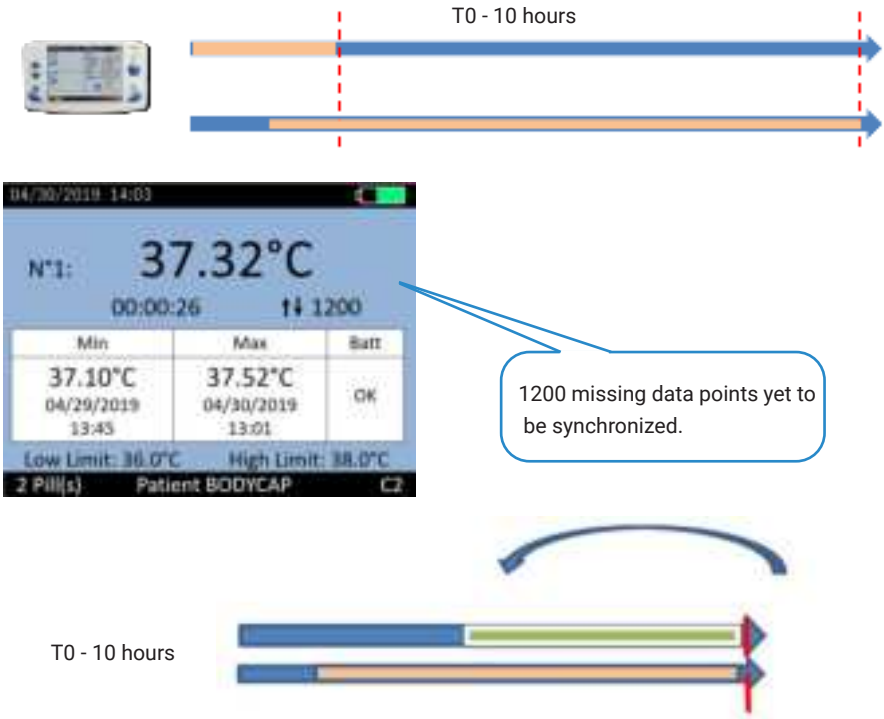

Figure 25: Illustration of the operating mode of the synchronization

10 hours of data are missing in the memory of the monitor (1200 data).

The pill always gets the last 2000 collected data in its memory, (that means 16.5 hours of recording).

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 eCelsius 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.

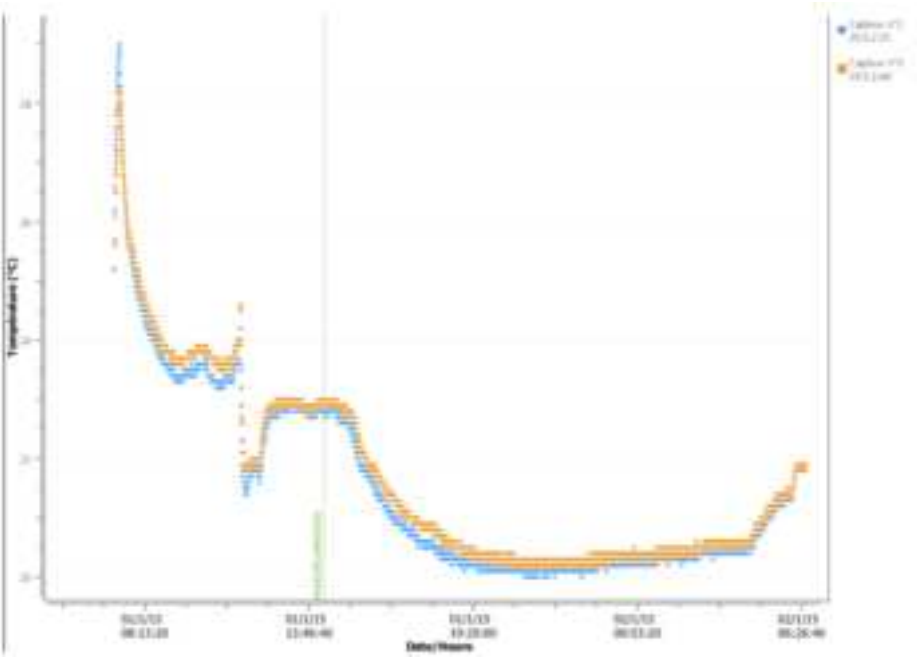

Figure 26: ‘‘Backup mode’’ marker

8.10.10 Visualization of the end-of-life of the pill

On the eViewer Medical monitor, when a pill reaches the end of life, the message “Low” appears in the column Batt (Figure 24) of the detailed visualization screen (§8.10.8). The eCelsius Medical pill will stop around 500 steps after the first message “Low” has appeared (if the monitor and the pill are in continuous RF communication).

8.10.11 Alarm Reset

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 eCelsius Medical pills associated with the eViewer Medical monitor.
A confirmation message needs to be validated by user.

8.10.12 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 eCelsius Medical pill and eViewer Medical monitor must be close enough to communicate.

Figure 27: Menu of the eViewer Medical monitor to deactivate a pill

Figure 28: Selection of pill 1 to deactivate

A confirmation must be validated before the deactivation of the eCelsius Medical pill. This action is definitive; the pill disappears from the eViewer Medical 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 an eCelsius Medical pill remains on the eViewer Medical monitor, but the pill is no longer associated. Data can be downloaded on the eCelsius Manager software. As unloading did not take place, a new pill cannot be activated on this location. The slot is locked.
- **“Active slot”:** A eCelsius Medical pill is associated.
- **“Free slot”**: This location is available for the activation of a new eCelsius Medical pill.

8.10.13 Use of the monitor screen

To save battery, the eViewer Medical monitor screen will switch off automatically after 1 minute of inactivity when the monitor is in battery operation. This action is canceled on 3 possible conditions:

- The monitor is plugged into 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 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 a physiological alarm trigger, 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:

8.10.14 Overview of the alarm system

Caregivers should regularly control the temperature data displayed on the eViewer Medical monitor screen.

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

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

Function controlled	Alarm condition	Delay due to the alarm condition	Alarm mode	Priority Following IEC 60601-1-8
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 on 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 24) of detailed visualization screen (§8.10.8).	Low
Battery of the monitor	The battery of the is low or critical	Immediate	Battery status is 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 color of the synchronization symbol changes.	Medium
The memory of the monitor if full	The monitor cannot 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

Table 4: Alarm systems

9. THE eCELSIUS MANAGER SOFTWARE

eCelsius Manager software is designed to visualize and export temperature data from a measurement cycle, it is the interface between the monitor and PC / MAC.

9.1 - MAIN FUNCTIONS

To use the eViewer Medical monitor with eCelsius Manager software, you must install the application and BodyCAP drivers (provided on the BodyCAP secured USB stick). After the installation completion, the monitor and the application will interface automatically.

PC/MAC HMI Algorithm: a computer software to:

- Manage configuration of the monitor through USB.
- Unload data from monitor through USB
- Display data historic in graphics.
- Allow exporting data in CSV or graphic in PDF.
- Manage firmware or language update of the monitor through USB.

9.1.1 Unload and consult the temperature data on the eCelsius Manager software.

On the main screen of the eCelsius 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)

Remark: Dates are given with UE format: dd/mm/yyyy

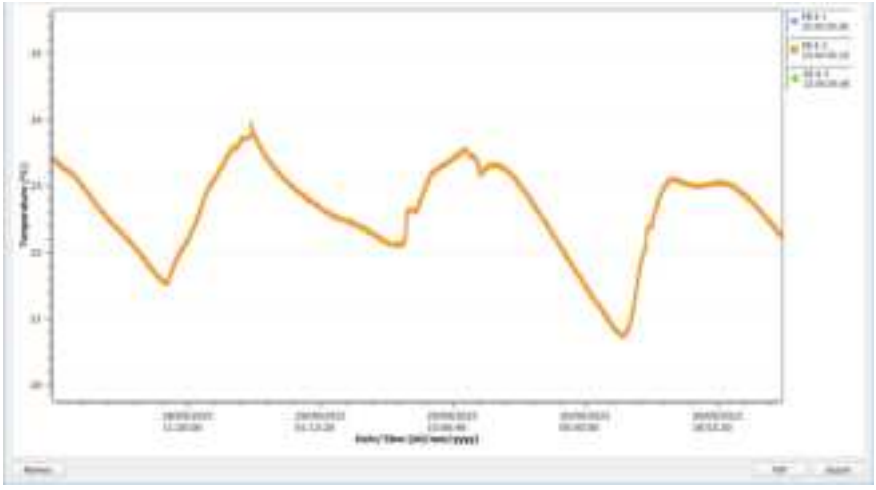

Figure 29: Picture of the curves obtained on the eCelsius Manager software after data unloading

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.

9.1.2 Visualization of markers from the eViewer Medical monitor

The data unload includes markers entered with the eViewer Medical 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 in the corresponding fields and confirm by clicking OK. They then appear on the chart and data export with the entered text.

Remark: Dates are given with EU format: dd/mm/yyyy

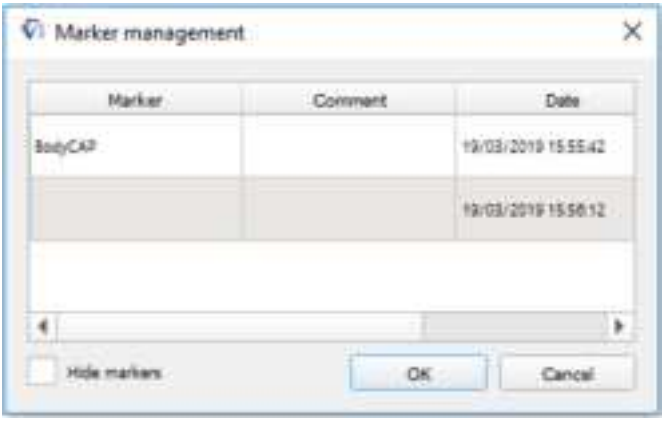

Figure 30: Screen for marker management

9.1.3 Visualization of markers

Once an alarm is triggered on the eViewer Medical monitor (technical or physiological), an alarm marker is stored in the monitor. These markers are then viewable on eCelsius 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 (e.g., 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

Table 5: Marker

9.1.4 Hide Markers

If you do not want to see all the markers, you can check the **"Hide Markers"** at the bottom left of Figure 30.

9.1.5 Export temperature data unloaded on eCelsius Manager software

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 eCelsius Manager 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 curves).

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. Some parameters can be selected during the process of export (Digit separator, Date format, °C/°F…).

9.2 - SECONDARY FUNCTIONS

9.2.1 Backup mode

If during operation a monitor fails or is broken, it is possible to recover the communication with eCelsius Medical pill(s) which were associated; via another eViewer Medical 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 eCelsius Medical pills functioning on the selected channel, in the communication range of the eViewer Medical monitor and whose serial number is known.

With the replacement monitor first, check that no pill is associated with this monitor. Connect it to the eCelsius 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 eViewer Medical monitor to the same channel as the failed monitor.

Enter the serial number of the eCelsius Medical pills you want to recover. (§ 8.10.3) 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 eViewer Medical monitor switch from black to white, indicating that the Backup mode is active.

Place the monitor close to the environment of the eCelsius Medical pills to recover. The eViewe Medical monitor will automatically resynchronize with the pills that are still close and match the serial number entered in the eCelsius Manager.

To exit the replacement mode, you must disassociate the eCelsius Medical pills of the eViewer Medical monitor (§ 8.10.12) and download the data via the eCelsius Manager software.

Note: To exit the recovery mode, connect the monitor to a PC / MAC with the cables provided by the manufacturer and go again to the tab Backup mode on the eCelsius Manager software. Click then on “Disable backup mode”. Banners on the eViewer Medical monitor switch then again in black, indicating that the replacement mode is stopped.

9.2.2 Updating eViewer Medical monitor

CAUTION: You can’t access the update option unless you are authorized and have received the password via separate delivery in order.
CAUTION: This section is reserved to IT department, which have the right privilege to install and update the system and the monitor.

It may be necessary to update the firmware. For this, the monitor must be reset before the update (§4.2.3).

The update of eViewer medical monitor is only possible through eCelsius Manager. If a new version is available for the monitor, IT department must update the eCelsius Manager first. eCelsius Manager always embed the latest version of the monitor to update.

To perform the update:

Go to the main page of eCelsius Manager software and select button: "**Update the monitor**". Enter the given password. Click on update to proceed.

Figure 33: eCelsius Manager software window allowing to update eViewer Medical monitor

10. END OF THE FOLLOW UP

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

3 solutions allow to carry out this verification:

- The patient can attest to the evacuation of the pill.
- The temperature data collected by the eViewer Medical monitor show a non-physiological variation during an obstruction.
- If neither 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 § 8.10.8). The real-time capture of new data informs you that the eCelsius 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 eViewer Medical monitor can be used to perform the procedure. In this case, refer to § 9.2.1 to activate the Backup mode.

The operating time of the eCelsius Medical pill is limited to 20 days, beyond this period, the method described above is no longer usable. As the pill is radiopaque, an X-ray will allow remove any doubts. If the eCelsius 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.

11. TECHNICAL DATA

11.1 - ESSENTIAL PERFORMANCE

For the eCelsius Medical System, the essential performance is continuous measurement of core body temperature of the patient.

Warning: eCelsius Medical System contains USB ports. Please do not insert into USB ports any unauthorized devices, including RF transmitters, and do not use the USB ports to charge other equipment.

11.2 - EMC TABLES

EMC table for products	
Applicable references	
P024-M	eCelsius Medical pill
P040-M	eViewer Medical monitor
P030-M	Activator Medical

Important: information about electromagnetic compatibility (EMC)

Medical devices manufactured by BodyCAP comply with IEC 60601-1-2:2020 (ed.4.1) standard for immunities, emissions and IEC 60601-2-2 (2017) for Particular requirements for the basic safety and essential performance of high frequency surgical equipment and high frequency surgical accessories. All the information that appears below comes from normative requirements to which manufacturers of electro-medical devices are subject, within the meaning of standard IEC 60601-1-2:2020 (ed.4.1). 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 cables of the medical device must be kept away from each other. Certain types of mobile telecommunications devices such as cell phones are susceptible 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.

Table 6: Cable Length:

Cables and accessories	Maximum Length	Test type	In accordance with:
Cables / Cords	< 3 m	RF emission	CISPR 11, Class B
		Emission of harmonic currents	IEC 61000-3-2
		Fluctuating and Flickering Voltage	IEC 61000-3-3
		Immunity to Electrostatic Discharge	IEC 61000-4-2
		Immunity Electromagnetic fields	IEC 61000-4-3
		Immunity to electrical fast transients/bursts	IEC 61000-4-4
		Surge immunity	IEC 61000-4-5
		Conducted RF immunity	IEC 61000-4-6
		Radiated Immunity - Magnetic Fields	IEC 61000-4-8
		Immunity to voltage dips, short interruptions	IEC 61000-4-11

Electromagnetic Compatibility:

The eCelsius Medical System device is intended for use in the electromagnetic environment. The user and the installer must therefore ensure that the device medical is used in the environment described below.

• Medical electrical equipment should be used with precautions according to EMC (electromagnetic compatibility) and must be installed according to the EMC notices disclosed in this manual, otherwise the fulfillment of the requirements for electromagnetic emission and electromagnetic immunity may be adversely affected.

• Since the intensity of electromagnetic energy is greatest near the source of a transmitting antenna, portable and mobile RF communications equipment can affect medical electrical equipment.

• This medical device may be used in places in which a patient lives or is generally present, and in professional healthcare facility environments excluding x-ray imaging, magnetic resonance imaging and high frequency surgical equipment environments.

• **WARNING**: Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

• **WARNING**: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the device, including cables. Otherwise, degradation in the performance of this equipment may be expected.

• **WARNING:** Use of accessories, transducers, and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

• The system has been designed to withstand the effects of EMI (Electromagnetic Interference). However, extremely high levels of electromagnetic energy (above the levels of IEC 60601-1-2:2020 (ed.4.1) may still produce interferences.

• To reduce the risk of EMI, follow these recommendations:

- Do not turn on or use hand-held personal communications devices such as mobile two-way radios or cellular phones, near the Device. If these devices need to be used, follow the recommended separation distance.

- In the case of unexplained EMI, consider the locations of nearby transmitters, such as radio or TV stations. You may have to move the DEVICE or place shielding between the transmitter and the DEVICE.

- Be aware that modifying the DEVICE or adding accessories or components not specifically authorized by manufacturer may make the DEVICE more susceptible to interference from radio waves.

• The following cables and accessories have been approved for use with the system, and comply with current EMC Standards: USB Cables

• Warning: Please do not use this device near the following common RF emitters:

- Radio frequency identification (RFID) readers could potentially be used in proximity to the subject device, particularly in the professional healthcare environment. Be aware of the potential for RFID readers to cause EMI, and take steps to mitigate such interference, e.g., increase the separation distance.

- Diathermy devices could potentially be used by the patient concurrent with peritoneal dialysis, particularly in the professional healthcare environment. Be aware of the potential for diathermy to cause EMI and take steps to mitigate such interference, e.g., avoid concurrent use of the eCelsius Medical System and diathermy equipment.

- Electronic article surveillance (EAS) systems could potentially be in proximity to the subject device, since this is a small, portable device that could potentially be used while walking or in a wheelchair. Be aware of the potential for EAS systems to cause EMI, and take steps to mitigate such interference, e.g., avoid use of the eCelsius Medical System in public spaces where EAS systems may be located or pass through the center of EAS systems without lingering or leaning against them.

Table 7: Guidance and manufacturer's declaration – electromagnetic emission:

Emission Test	Compliance	Electromagnetic environment - guidance
RF emission (CISPR11) (IEC 60601-1-2)	Group 1	The medical device uses RF energy only for its internal function. Therefore, its RF emissions are low and are not likely to cause any interference in nearby electronic equipment
RF emission (CISPR11) (IEC 60601-1-2)	Class B	The medical device is suitable for use in all establishments other than domestic and may be used in domestic establishments and those directly connected to the public low- voltage power supply network that supplies buildings used for domestic purposes, provided the following warning is heeded: **Warning**: This equipment/system is intended for use by healthcare professionals only. This equipment/ system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re- orienting or relocating the device or shielding the location.
Harmonic Emission (IEC 61000-3-2)	Class A	
Voltage fluctuation and Flicker (IEC 61000-3-3)	Complies	

Table 8: Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	Standard	Test level	Compliance level	Environment electromagnetic guidance
Electrostatic Discharge (ESD)	IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	The relative humidity should be at least 5 %.
Electric fast Transient/ bursts	IEC 61000-4-4	±2 kV AC power supply ± 1 kV for ports input/output lines	±2 kV AC power supply ± 1 kV for ports input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge	IEC 61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth ± 1 kV Signal input/ output) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth ON	Mains power quality should be that of a typical commercial or hospital environment.
RATED Power frequency magnetic fields	IEC 61000-4-8	30 A/m 50 Hz or 60 Hz	30 A/m 50 Hz or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment
Immunity to voltage dips, short interruptions, and voltage variations on power supply input lines	IEC 61000-4-11	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	0% UT; 0.5cycle at 0°, 45°, 90°, 135°,180°, 225°, 270° and 315° 0% UT; 1cycle and 70% UT; 25/30 cycles Single phase at 0° 0% UT; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. eViewer Monitor requires continued operation during power mains interruptions, it is recommended that the manufacturer device be powered from an uninterruptible power supply or a battery. Pill is battery operated and activator is does not require continuous power.
Interruptions voltage	IEC 61000-4-11	45°, 90°,135°,180°,	0% UT for 250 cycles to 50 Hz for 300 cycles to 60 Hz	Environment of a care facility professional health. NOTE UT is the a.c. mains voltage prior to application of the test level.

Table 9: Guidance and manufacturer's declaration – electromagnetic immunity

Immunity test	Standard	Test level	Compliance level	Environment electro-magnetic guidance
Conducted RF	EN 61000-4-6	Vrms 150 kHz to 80 MHz outside ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands	Vrms 150 kHz to 80 MHz outside ISM bands 6 Vrms 150 kHz to 80 MHz in ISM bands	Except as indicated in Table 10, portable and mobile RF communications equipment should be used no closer to any part of the manufacturer device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance. d = 1.2√P d = 2√P
Radiated RF (EM fields)	EN 61000-4-3	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz 10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	3 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz 10 V/m 80 MHz – 2.7 GHz 80 % AM at 1 kHz	d = 1.2√P (80 MHz to 800 MHz) d = 2.3√P (80 MHz to 2.7 GHz)
Radiated RF (Proximity fields from RF wireless communications equipment)	EN 61000-4-3	See Table 11	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	where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and (d) is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
Proximity magnetic fields	IEC 61000-4-39	See Table 10a		

Recommended separation distances between portable and mobile RF communications equipment and the manufacturer device.

eCelsius 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 except as indicated in Table 10.

Table 10: Separation Distance According to Frequency of Transmitter (m)

Rates Maximum Power Output of Transmitter (W)	Separation Distance According to Frequency of Transmitter (m)			
	150 kHz to 80 MHz outside ISM bands d = 1.2√P	150 kHz to 80 MHz in ISM bands d = 2√P	80 MHz to 800 MHz d = 1.2√P	800 MHz to 2.7 GHz d = 2.3√P
0.01	0.12	0.2	0.4	1
0.1	0.37	0.64	1.3	2.6
1	1.2	2	4	8
10	3.7	6.4	13	26
100	12	20	40	80
For transmitters rated at a maximum output power not listed above, the recommended separation distance is 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.				

Table 10a: Immunity to Proximity magnetic fields in the frequency range 9 kHz to 13.56 MHz

Test frequency	Modulation	IMMUNITY TEST LEVEL (A/m)
30 kHz	CW	8
134.2 kHz	Pulse modulation 2.1 kHz	65
13.56 MHz	Pulse modulation 50 kHz	7.5

Table 11: Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band a) (MHz)	Service a)	IMMUNITY TEST LEVEL (V/m)	Compliance level (V/m)
385	380 –390	TETRA 400	27	27
450	430 –470	GMRS 460, FRS 460	28	28
710 745 780	704 –787	LTE Band 13, 17	9	9
810 870 930	800 –960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE-Band 5	28	28
1720 1845 1970	1 700– 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE-Band 1, 3, 4, 25; UMTS	28	28
2450	2400 –2570	Bluetooth, Wi-Fi, 802.11 b/g/n, RFID 2450, LTE Band 7	28	28
5240 5500 5785	5100 –5800	WLAN 802.11 a/n	9	9

The following frequencies are used in the device: 433-434 MHz

The preferred frequency of the device is 433 MHz

The bandwidth of the receiving section of the ME EQUIPMENT in those bands is 433-434 MHz

Each frequency of transmission: 433 MHz and 434 MHz

EFFECTIVE RADIATED POWER [ERP]: -22 dBm (6.31 µW)

Type and frequency characteristics of the modulation:

Parameter	Value
Central frequency	433.220 + channel * 0.200 (MHz) With channel in [0 ...7] The channel 4 is reserved for association procedure.
Modulation	GFSK, BT_Filter 0.5
Frequency deviation	48.125 kHz
Data rate	48004 bits/s

11.3 - CYBERSECURITY

In order to respect cyber security guidelines, eCelsius Manager software must be installed only by authorized users with cybersecurity awareness respecting IT good practices of user logging on the computers used.

Warning: Always use the most up-to-date anti-virus software to protect your device from malicious software.

Warning: Please contact BodyCAP in case cybersecurity is compromised or suspected to be compromised in your product.

eCelsius Manager software and eViewer Medical monitor shall be installed or upgraded only by the IT technical staff of the Hospital.

The PC/MAC account used for the eCelsius Medical System records should be secured by password and includes IT rules of the environment protection in order to protect information at rest (reports) like:

- Physical perimeter security
- Physical access control
- PC/Mac logging
- Secured access to network storage.

DEVICE INTERFACE

- Any changes in the device configuration should only be performed by qualified IT technicians.
- The device (monitor) does not interface with other devices using ports, connectors, or other hardware means except eCelsius Manager installed on computers (PC/MAC).
- Device may interface with pill via secured RF signal.
- Never attempt to connect the device to any other devices than recommended.

THE DEVICE IS DESIGNED TO PROVIDE SEVERAL FEATURES THAT PROTECT THE SYSTEM AGAINST CYBER THREATS:

- USB stick is secured by passcode given to authorized person only.
- Secured communication between eCelsius monitor and e-Celsius Manager provides authentication mechanism before communication initiation.
- Secured communication between the eViewer Medical monitor and eCelsius Medical pill uses mutual recognition by private IDs before communication initiation.
- Firmware's are always tested by manufacturer and signed with BodyCAP certificate.
- The pill firmware is not accessible to the user by mechanical enclosure.
- The monitor and the activator have no access permitted and a sealed security label is placed on the junction of both shells to detect physical intrusion.
- Update of the monitor firmware is possible only by authorized user having password to access the update section.
- No Personal patient information is embedded in the system.

PILL CONNECTION INSTRUCTIONS AND SYSTEM REQUIREMENTS

• Always use the most updated firmware monitor to communicate with the pill.

• The connection to the pill is achieved only when the device is connected through the RF signal during data monitoring.

• The RF signal is EU GDPR (2016/679) regulation and USA HIPAA legislation certified to provide maximal IT protection means.

• All device logs (markers) and data are stored in the locally on the device.

• The primary function of the system is constantly backupable with classic thermometers.

• The monitor configuration is maintained in case of firmware update.

• You must install anti-malware software to protect your computer against cyber security risks when it is interfacing with the Manager.

• Computer operating system should be upgraded anytime there is a new update, version, or security patch released by the manufacturer.

IN CASE SERVICING IS REQUIRED AND IN CASE YOU'VE DETECTED CYBERSECURITY VULNERABILITY OR INCIDENT, YOU SHOULD FOLLOW THE BELOW INSTRUCTIONS:

• If you face difficulties connecting to the device via your computer, please contact your local distributer for assistance.

• To protect your computer from cyber-attacks you should always follow manufacturer's instructions on how to respond in case your device was / is subjected to cybersecurity vulnerability or incidents.

12. TROUBLESHOOTING

Table 12: Troubleshooting

Problem	Probable cause	Solution
The eViewer Medical 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 pills.
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 eCelsius Medical 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.

13. CABLES AND POWER SUPPLY

Two cables are supplied with the system: two USB - micro-USB cables that allow you to connect the eViewer 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

14. THE MRI ID BRACELET

The MRI ID bracelet should be attached to the wrist before ingestion of an eCelsius Medical 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.

The bracelet states “The Patient has Ingested an Electronic Device Incompatible with MRI Exposure” in English.

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

15. MATERIALOVIGILANCE DECLARATION

Users of a device and third parties who are aware of an incident or risk of incident involving a device which has resulted or may result in the death of, or serious deterioration in the state of health of a patient, a user or a third party must report it without delay to the BodyCAP manufacturer or to the “Agence nationale de sécurité du médicament et des produits de santé” (French National Agency for the Safety of Medicines and Health Products):

- materiovigilance@ansm.sante.fr
- www.bodycap-medical.com

Table 13: Celsius to Fahrenheit Conversion Table

Celsius	Fahr.	Celsius	Fahr.	Celsius	Fahr.	Celsius	Fahr.	Celsius	Fahr.
-98	-144.4	-54	-65.2	-10	14	35	95	81	177.8
-97	-142.6	-53	-63.4	-9	15.8	36	96.8	82	179.6
-96	-140.8	-52	-61.6	-8	17.6	37	98.6	83	181.4
-95	-139	-51	-59.8	-7	19.4	38	100.4	84	183.2
-94	-137.2	-50	-58	-6	21.2	39	102.2	85	185
-93	-135.4	-49	-56.2	-5	23	40	104	86	186.8
-92	-133.6	-48	-54.4	-4	24.8	41	105.8	87	188.6
-91	-131.8	-47	-52.6	-3	26.6	42	107.6	88	190.4
-90	-130	-46	-50.8	-2	28.4	43	109.4	89	192.2
-89	-128.2	-45	-49	-1	30.2	44	111.2	90	194
-88	-126.4	-44	-47.2	0	32	45	113	91	195.8
-87	-124.6	-43	-45.4	1	33.8	46	114.8	92	197.6
-86	-122.8	-42	-43.6	2	35.6	47	116.6	93	199.4
-85	-121	-41	-41.8	3	37.4	48	118.4	94	201.2
-84	-119.2	-40	-40	4	39.2	49	120.2	95	203
-83	-117.4	-39	-38.2	5	41	50	122	96	204.8
-82	-115.6	-38	-36.4	6	42.8	51	123.8	97	206.6
-81	-113.8	-37	-34.6	7	44.6	52	125.6	98	208.4
-80	-112	-36	-32.8	8	46.4	53	127.4	99	210.2
-79	-110.2	-35	-31	9	48.2	54	129.2	100	212
-78	-108.4	-34	-29.2	10	50	55	131	101	213.8
-77	-106.6	-33	-27.4	11	51.8	56	132.8	102	215.6
-76	-104.8	-32	-25.6	12	53.6	57	134.6	103	217.4
-75	-103	-31	-23.8	13	55.4	58	136.4	104	219.2
-74	-101.2	-30	-22	14	57.2	59	138.2	105	221
-73	-99.4	-29	-20.2	15	59	60	140	106	222.8
-72	-97.6	-28	-18.4	16	60.8	61	141.8	107	224.6
-71	-95.8	-27	-16.6	17	62.6	62	143.6	108	226.4
-70	-94	-26	-14.8	18	64.4	63	145.4	109	228.2
-69	-92.2	-25	-13	19	66.2	64	147.2	110	230
-68	-90.4	-24	-11.2	20	68	65	149	111	231.8
-67	-88.6	-23	-9.4	21	69.8	66	150.8	112	233.6
-66	-86.8	-22	-7.6	22	71.6	67	152.6	113	235.4
-65	-85	-21	-5.8	23	73.4	68	154.4	114	237.2
-64	-83.2	-20	-4	24	75.2	69	156.2	115	239
-63	-81.4	-19	-2.2	25	77	70	158	116	240.8
-62	-79.6	-18	-0.4	26	78.8	71	159.8	117	242.6
-61	-77.8	-17	1.4	27	80.6	72	161.6	118	244.4
-60	-76	-16	3.2	28	82.4	73	163.4	119	246.2
-59	-74.2	-15	5	29	84.2	74	165.2	120	248
-58	-72.4	-14	6.8	30	86	75	167	121	249.8
-57	-70.6	-13	8.6	31	87.8	76	168.8	122	251.6
-56	-68.8	-12	10.4	32	89.6	77	170.6	123	253.4
-55	-67	-11	12.2	33	91.4	78	172.4	124	255.2
				34	93.2	79	174.2	125	257
						80	176	126	258.8

BodyCAP

Your e-health partner

For any questions concerning the system operation that is not included into the user guide, please contact BodyCAP Team:

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