

 **Celsius**
Performance

TELEMETRIC SYSTEM FOR CONTINUOUS
GASTROINTESTINAL TEMPERATURE
DATA COLLECTION

SYSTEM DEDICATED TO NON-MEDICAL USES

USER GUIDE



BodyCAP
Your e-health partner

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To our customers,

we thank you for purchasing the *eCelsius Performance* system. This solution is manufactured by BodyCAP. This user guide aims to present the characteristics and the way of working of the solution and to support you in the installation and the use of the device. A proper use of the solution does not imply specific training or skills; however please read carefully this user guide and keep it on hand for review if needed.

Failure to follow these instructions may result in measurement error and personal injury or material damages. The responsibility of the manufacturer and its distributors can not be engaged in case of misuse of the system. The inspection and repair operation must be carried out by approved persons who have undergone appropriate training.

This system is composed of:

- **eViewer Performance monitor**, allowing data temperature recovering from 1 to 3 electronic capsules simultaneously.
- **Activator**, and its power supply cable allowing turn on the electronic capsule before ingestion.
- **USB key**, including the *ePerformance Manager* software to install and user documentation.
- **A (or several) disposable eCelsius Performance electronic capsule(s)** to monitor core temperature through gastrointestinal tractus.
- **Signaletic bracelet** provided for each electronic capsule delivered.
- **2 micro-USB / USB cables** and a power supply module (in option).

Destination and use case:

The *eCelsius Performance* system is designed to continuously measure gastrointestinal temperature in **non-medical use cases**. The *eCelsius Performance* electronic capsule must be swallowed. It is delivered in its original packaging and intended for a single use. It has to be woken up thanks to the activator and associated with the monitor which records the data and can return them to a PC/MAC via the interface delivered with the system.

Declaration of conformity:

BodyCAP declares that the *eCelsius Performance* solution is compliant with current directives and regulations:

- 2011/65 / EU, on the restriction of use of certain dangerous substances in electrical and electronic equipment
- 2014/53 / EU on the release of radio equipment
- 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH).

The system is designed for Non-Medical uses only. The applications fields of medical diagnosis and therapeutics in patients are excluded.

1. PRECAUTIONS OF USE

The following safety instructions ensure proper operation and will optimize the use of the *eCelsius Performance* system. Follow them carefully. For any questions that have not been answered in the manual, please ask for assistance from your distributor or manufacturer (contact information at the end of this user guide).

The *eCelsius Performance* electronic capsule is not claimed MRI compatible: It is imperative that the subject ingesting an electronic capsule does not undergo any MRI. The subject should wear the signalitic bracelet supplied with the system and indicating that he is wearing a device non-compatible with high magnetic fields exposure. The bracelet is fixed just before the ingestion and should only be removed after removal of the last electronic capsule in case of successive ingestion.

PRECAUTIONS FOR USE OF THE *eCELSIUS PERFORMANCE* SYSTEM:

Do not place or drop any object on the device, do not introduce foreign objects.

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

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

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

Do not use the device if it is damaged.

In order 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 in the presence of flammable substances.

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

The complete *eCelsius Performance* system should be kept out of the children. Particular attention must be paid with the cables to avoid any risk of strangulation or suffocation.

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

Do not expose the monitor or the activator to rain or humidity; keep them away from liquids or sprayed water.

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

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

Do not touch or press the screen.

Do not use during a gaz leak.

Do not throw into fire.

Do not disassemble or short circuit any part of the system.

PRECAUTIONS FOR USE OF THE *eCELSIUS PERFORMANCE* ELECTRONIC CAPSULE:

Do not use the electronic capsule if the packaging is damaged.

The complete *eCelsius Performance* system should be kept out of the children. Particular attention must be paid with the electronic capsules, to avoid any risk of suffocation.

Do not throw into fire.

Do not reuse the electronic capsule.

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



Do not put the device as unsorted municipal waste.

The monitor and the activator have been designed to allow a reuse and a suitable recycling of some components.

The symbol representing a waste container with a cross indicates that the product (electrical equipment, electronic and electronic capsule and / or battery) should not be put in municipal waste.

Check local regulations for disposal of electronic products.

Cleaning

The electronic capsule is delivered cleaned in an individual blister; it is not designed to be cleaned using hydro alcoholic solutions.

Any element of the solution should not, in any case, be introduced in an autoclave. It may cause permanent damage for the element concerned. The monitor and the activator may be cleaned using a hydroalcoholic wipe taking care to the external connectors.

REACH European Regulation 1907/2006/EC

Under the requirement of the Article 33.1 of the REACH European regulation, we inform users that the SVHC “Octyl Tin Stabiliser” substance is present in electronic capsule compounds in a concentration upper than 0.1% weigh/weight (SVHC/ electronic capsule). This substance was issued under CAS number 15571-58-1 on the ECHA candidate list published on June 15th 2015 (<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 phthalate level in the *eCelsius Performance* electronic capsule; acceptable level without toxicological risk for the subject:

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

WARNING TO USERS IN THE UNITED STATES

Federal Communication Commission Interference Statement 47 CFR Section 15.105(b):

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 Performance* 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: 2AENH017 – eCelsius Performance electronic capsule

FCC ID: 2AENH033 – eViewer Monitor

FCC ID: 2AENH043 – Activator

and will void the BodyCAP warranty.

2. USE CLAIMS AND CONTRAINDICATIONS

USE CLAIMS

The *eCelsius Performance* system is an electronic device for non-medical uses only. The device is **NOT intended for use in diagnosis, treatment, prevention or management of any diseases**. The device is designed for continuous human gastrointestinal temperature measurement.

The device is made of these main elements:

- A disposable electronic capsule (*eCelsius Performance*) intended to be swallowed.
- A monitor (*eViewer Performance*) to collect, display and record the data.
- An activator (*Activator*) to set the electronic capsules in operation before ingestion.
- A software (*ePerformance Manager*) allows you to set the monitor and display the data recorded by the monitor on a computer screen.
- Two USB-Micro USB cables
- A signal bracelet per electronic capsule supplied
- USB memory stick with *ePerformance Manager* software and manuals.

The accuracy of the temperature sensor is $\pm 0.1^{\circ}\text{C}$ for subject physiological range $36\text{-}41^{\circ}\text{C}$, $\pm 0.13^{\circ}\text{C}$ outside of the physiological range.



The system is designed for non-medical uses. It is designed for temperature data collection in order to optimize sport performances, to improve knowledge of subjects or for research purposes.

The device is NOT intended for use in diagnosis, treatment, prevention or management of any diseases.

CONTRAINDICATIONS AND WARNINGS

The *eCelsius Performance* system is designed for the measurement of core temperature of the subjects; it is contraindicated in a number of situations:

- For people weighting less than 40 kg.
- For people with known intestinal disorders that can lead to obstruction of the digestive tract, including diverticula and people suffering gastroparesis.
- For people with known motility disorders of the gastrointestinal tract.
- For people who have undergone surgical procedures in the gastrointestinal tract or having such medical history (esophagus, stomach, intestines).
- For people with known swallowing disorders (especially gag reflex disorders).
- For people suffering Chron's disease.
- For people with pacemaker or electro-medical implant.
- For people who have to undergo strong electromagnetic field during the period of use of the system (MRI in particular).
- For pregnant women.

Warnings

Because of the mode of administration of the system and its way of functioning, the use of the device must consider the precautions described below.

- The measure being carried out in the digestive system, the collected data may be influenced by factors such as food or water intake (hot or cold) during the first hours following the ingestion of the electronic capsule.
- The device is intended for single use, any reuse of the electronic capsule could induce an infectious risk.
- The loss of communication between the *eCelsius Performance* electronic capsule and the monitor *eViewer*, causing a stop of the subject's temperature data collection.
- The equipments are designed to properly work at an altitude between 0 and 2000m.

Risks

Risks with the equipment (monitor & activator):

Electrocution.

Burns.

Risks with *eCelsius Performance* electronic capsule:

- The *eCelsius Performance* electronic capsule has to be swallowed by the subject with a glass of water, special attention must be paid to the risk of taking a "wrong way", especially in people who have or have had swallowing disorders. This phenomenon of taking the "wrong way" may cause a blockage in the airways requiring extraction.
- Exposure to a strong electromagnetic field (MRI), which may lead to a risk of mobilization with possible trauma to the digestive tract, or a disturbance of capsule electronics and risk of erroneous data.

Potential complications:

- Swallowing the "wrong way" the *eCelsius Performance* electronic capsule, may induce partial or total airway obstruction,
- Blockage of the electronic capsule within the digestive tract, which may require recovery by endoscopy or surgery.

3. FIRST USE

INSTALLATION OF *ePerformance Manager* SOFTWARE

Minimal configuration Requirement:

- Processor 1GHz
- 500Mo RAM
- 200Mo disk space required for the installation
- Windows® 7 or operating systems Microsoft® compatibles (32 or 64 bits), Mac OS X (10.9 Lion) or ulterior
- The screen resolution has to be at minima 1024x768.

Note: an OS update may be required to properly install the software.



Picture 1:
USB Stick
BodyCAP

To install *ePerformance Manager* software and the drivers of *eViewer Performance* monitor, please:

- Launch the installer **ePerformance_Manager** or **MAC-ePerformance_Manager** according to your operating system. These installers are present on the USB memory stick provided (Picture 1) with your *eCelsius Performance* system,
- Follow the instructions step by step,
- Install the driver.

During the software installation, you have to 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 to ensure the communication between the monitor and the MAC.

Note: If the driver install does not launch automatically after a double click on the file, remember to look in the navigation panel on the left of the screen if a new disk appears **Silicon Labs VCP Driver Install Disk**.

IMPLEMENTATION OF THE DEVICE

POWER UP OF THE *eViewer Performance* MONITOR

The monitor *eViewer Performance* is delivered switched off. To exit the storage mode, you must turn on the system by a pressure on the button  (on the right side).

This procedure turns on the monitor. If the screen does not light, put the monitor in charge and repeat few minutes after.

Before using the *eViewer Performance* monitor in battery-run, you have to ensure that its charge level is sufficient.

To use the *eViewer Performance* monitor with the PC / MAC *ePerformance Manager* software, you have to install the PC / MAC *ePerformance 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 automatically interface.

To allow communication between the monitor and the PC / Mac software, please connect the powered-up monitor to a USB port of the PC / MAC.

Remark: The first connexion may take time, please let enough time for the PC to recognize the monitor and to properly install the related driver.

SUPPLY THE BATTERY

If you consider using the monitor in battery-run, ensure previously that you have enough recharged the battery.

The cable micro-USB - USB allows charging the battery of the monitor when it is connected to a power supply (wall socket with the supply provided in option or computer switched on).

CONFIGURATION OF THE *eViewer Performance* MONITOR

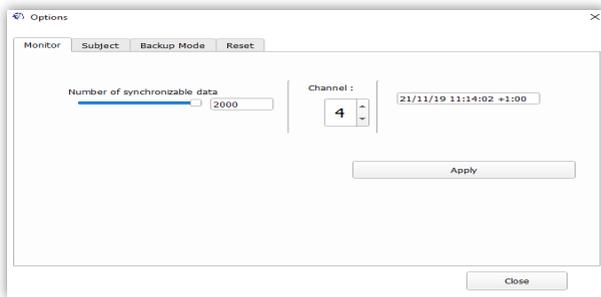
Connect the monitor to a computer having the installed *ePerformance Manager* software and launch it. At the opening of the first window, select **Configuration** (Picture 2). Logos at the bottom right allows you to select the language.



Picture 2:
Start screen of
*ePerformance
Manager*

At the opening of the second window (Picture 3), several tabs allow to configure the monitor before using.

THE TAB MONITOR



Picture 3: Tabs
to configure the
monitor

The tab "Monitor" (Picture 3) allows selecting:

- Number of data to synchronize:

By default, each electronic capsule has an internal memory allowing to store the last 2000 collected measurements. In some case, you may not need to sync all data stored in the memory.

The slide Bar "**Number of synchronized data**" allows to set the number of data to recover into memory of the associated electronic capsules, after a communication disruption. The monitor will automatically synchronize the missing data, into the range of the setting value, the process will start a soon as the monitor will be close to the subject (about 1m). The synchronization always starts with the oldest missing data and finishes with the most recent.

Set up this function is available only when no sensors are associated. The number of synchronized values will be applied to all the associated sensors.

- Communication channel:

It is required to take care that the monitor is sufficiently supplied, and to put it on an available channel. It is possible to select one of the seven channels (1 to 7) available in the monitor.



In order to reduce interferences, the selected channel has to be different from those of the other monitors working in the same environment.

You can select one of the 7 channels (1 to 7) available on the monitor. By default, the channel use is the channel 4. If you use 2 systems in the same environment, it is highly recommended to select 2 different channels.

- Date and time:

The date and time of the computer on which is installed the *ePerformance Manager* software will be send to the monitor by clicking on the **“Apply”** button. This timeline will be used to timestamp the data collected. Be careful with the PC/MAC timezone set in case your project is planned in different time zone than your computer.

Click on the button “Apply” to send the data to the monitor and go to the next step.

THE TAB SUBJECT



Picture 4: Tab for subject's data configuration

The tab **“Subject”** (Picture 4) allows configuring a monitor for a subject. The four items are free. The contents of the item 1 will be displayed at the bottom of each screen (Picture 5). All other elements (field 2/3/4) will be displayed in the subject menu of the monitor. All the information filled will be also displayed in the .CSV file after data export.



Picture 5:
Screen of eViewer
Performance monitor

After the configuration of each item, click on **“Apply”**. The activation of the electronic capsules can start (cf. *eViewer Performance Monitor* > Main functions > Activate a capsule).

4. THE *eCelsius Performance* ELECTRONIC CAPSULE



Picture 6: *eCelsius Performance* electronic capsule



Picture 7: Signalitic bracelet

The electronic capsule (Picture 6) is intended to be swallowed to measure gastrointestinal temperature, for non-medical uses only. It is delivered in deep sleep mode and has to be woken up by the activator and associated to a monitor to measure temperature periodically.

The signalitic bracelet (Picture 7) is worn to the wrist before the ingestion of the electronic capsule and should only be removed after removal of the last electronic capsule, in case of successive ingestion. A signalitic bracelet is provided with each electronic capsule delivered. These bracelets are in the same package than the electronic capsules. They allow to inform the researches that the subject swallowed a electronic capsule and thus that is forbidden to perform an MRI exam.

5. THE ACTIVATOR

The activator is intended to activate the electronic capsule *eCelsius Performance* before a recording session.



Button OK

Green LED

Micro-USB connector

Hole to place the electronic capsule

Picture 8: Description of the activator

THE BUTTONS

The button "OK" is used to launch the activation process.

The activation process is detailed in *eViewer Performance Monitor* > Main functions > Activate a capsule.

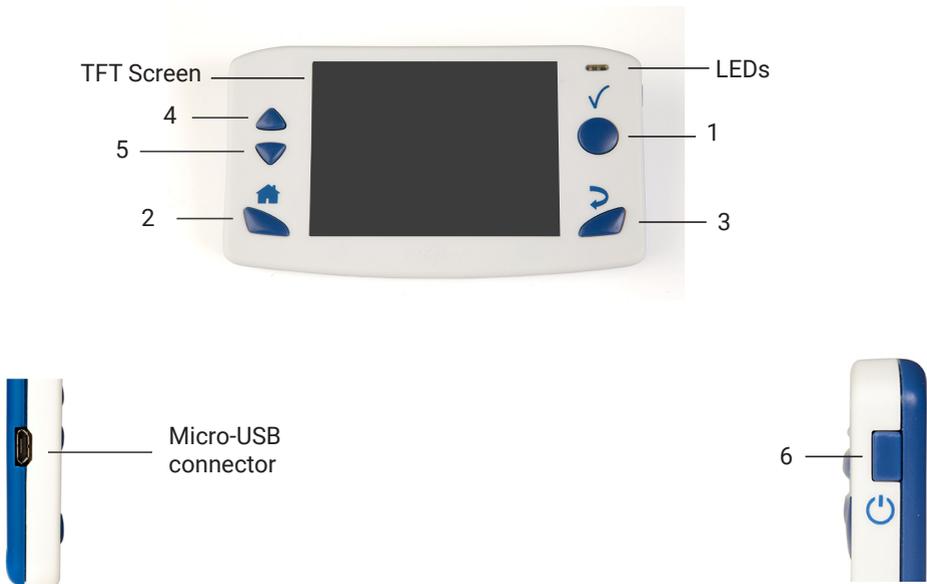
LED

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 electronic capsule placed in the hole. **In order to optimize the activation process, please rotate the electronic capsule into the hole during the activation process.**

6. eViewer Performance MONITOR

The monitor is intended to communicate in RF with the *eCelsius Performance* electronic capsule to retrieve and store temperature data.



Picture 9: Description of the monitor

THE BUTTONS

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

- **Confirm** (n°1 - Picture 9) :

The button Confirm is used to confirm the information and to go to the menu.

- **Home** (n°2 - Picture 9) :

The button Home allows to come back to the main screen of temperature data.

- **Back** (n°3 - Picture 9) :

The button Back allows to come back to the previous submenu or cancel a procedure.

- **Arrow up** (n°4 - Picture 9) :

This button allows to navigate in the menu.

- **Arrow down** (n°5 - Picture 9) :

This button allows to navigate in the menu.

- **Sleep / Wake-up** (n°6 - Picture 9) :

A long pressure on the side button allows to switch on or off the monitor if no electronic capsule are associated. A short pressure allows to switch on or off the screen.

THE LEDs

An **orange LED** and a **green LED** are positioned on the front of the monitor; in the upper right corner.

When **the orange LED flashes**, it means that the battery level is low; the monitor has to be plugged, quickly, to a power source. When you switch on the monitor, the orange LED flashes while you press the side button, indicating that the command is taken into account. If not, it is necessary to connect the monitor to a power source and try again few minutes later.

When **the green LED is lit**, it means that the monitor is connected to a power source. Its battery is charging.

BATTERY

Information

When it is not plugged to the main supply, a rechargeable lithium-ion battery powers the monitor. It is strictly FORBIDDEN to disassemble the monitor and to replace the rechargeable battery under penalty to irreparable damage on the system and security failures.

Charging cycle

In order to recharge the battery, simply plug the monitor to a power source and switch off the screen. Few hours are necessary to charge the battery (around 3h). The battery life of the monitor in battery operation is around 36h (screen regularly used but not continuously). In the context of an intensive use of the monitor (screen used continuously), the battery life will be shorter.



Please do not forget to charge eViewer Performance monitor at the end of those 36h. If the battery reaches a critical level, the system will turn into an energy saving mode. The communication with the electronic capsule will be retrieved after supply; date and time resynchronization through ePerformance Manager may be required.

In order to leverage the risk to lose the connection between the electronic capsules and the monitor, the device automatically goes into a power-saving configuration (extinction of the screen and of the RF communication with the electronic capsules) before the total discharge of the battery. Use of LEDS is described in following table:

Table 1: Battery status

Battery status	LED	Functions
Normal	-	Normal way of working
Critical	Orange led lits	Normal way of working, battery gauge is red
Energy saving mode	-	Monitor is automatically put in storage mode due to the battery critical state. After supply, it will be necessary to turn on again the monitor.

It is highly recommended, especially in the context of extended use of the material, to regularly connect the monitor to a power source during operation.

CONNECTION

Female Micro USB port

This connector is located on the left side of the monitor. It is possible to use the micro-USB port to connect the monitor to a power source via the cable and adapter (in option) provided by the manufacturer. Use of connector are:

- to set up the monitor (date, time, channel, number of data to synchronize, subject data).
- to download the data from the monitor to *ePerformance Manager Software*.
- to visualize the results of measurements.
- to export them to PDF or spreadsheet format.
- to recharge the battery of the monitor.

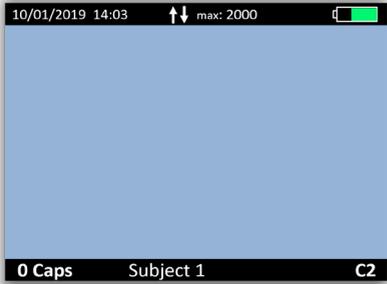
RF COMMUNICATION

In operation, it is **strongly recommended** to avoid putting the device on a metal table or other metal surface that could reduce the RF emissions.

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

In the "Data View" menu, a logo  indicated, for each electronic capsule, that the monitor has to synchronize some data with the electronic capsule. If this logo turns orange, it means that no communication occurred with the electronic capsule during the last 10 attempts.

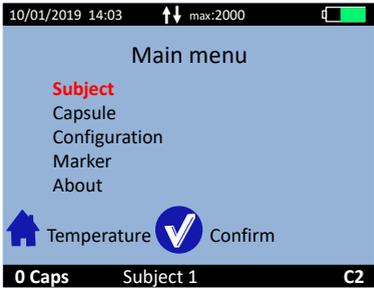
MONITOR INTERFACE MENU



Picture 10:
Screen of the eViewer
Performance monitor

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

- Date (e.g. 18/04/2018 => DD/MM/YYYY).
- Time (e.g. 14:03 => HH: MM).
- The maximal number of data to synchronize (e.g. Max: 2000, item configured through the *ePerformance Manager* software in the monitor tab).
- The battery level of the monitor (e.g. Top right of the screen).
- The operating channel of the monitor (e.g. C2).
- A field corresponding to a subject identification (e.g. Subject 1).
- The number of electronic capsules associated (e.g. 0 Caps).



Picture 11:
Main menu of
the eViewer Performance
monitor

To validate a menu and to move to a submenu, press the button **“OK”** (cf. *eViewer Performance Monitor* > The Buttons).

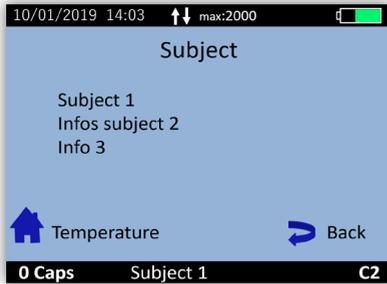
To come back, press the button **“Back”** (cf. *eViewer Performance Monitor* > The buttons).

To return directly to the temperature display, press the button **“Home”** (cf. *eViewer Performance Monitor* > The buttons).

Navigation between the menu items is possible by using the **“Up & “Down”** buttons (cf. *eViewer Performance Monitor* > The buttons).

The Subject menu

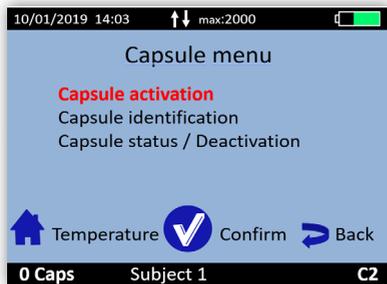
The Subject menu displays user data. The four fields are configurable from the *ePerformance Manager* software. Then Field 1 is visible on all monitor screens, in the lower band. A limitation of the size of each field is indicated in the *ePerformance Manager* software.



Picture 12: Subject menu

Capsule Menu

The menu “CAPSULE” (Picture 13) brings together the different control functions of the electronic capsules.



Picture 13: Capsule menu

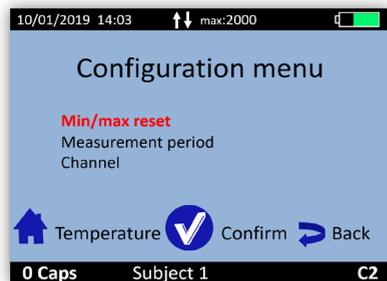
Capsule Activation: Starts the activation process of the electronic capsule.

Capsule Identification: Allows to visualize the ID number of associated electronic capsules.

Capsule Status / Deactivation: Allows to check the status of each slot and to prepare the release of a location (after data unloading).

Configuration menu

Monitor menu is used to manage the monitor configuration (Picture 14).



Picture 14:
Configuration menu

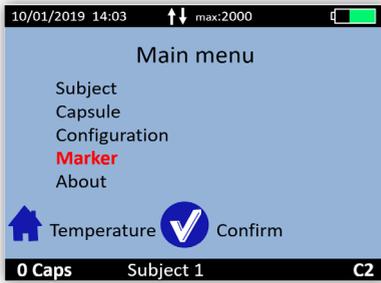
Min/max reset: Allows to reinitialize the data display for min and max value on the detailed data visualization screen.

Measurement period: Allows to change the measurement period of the electronic capsule.

Channel: Allows to set the channel.

Marker menu

The Marker menu allows to add an event marker all along the data collection; these markers will be displayed following the data export through the *ePerformance Manager* software and will be in the .CSV file.



Picture 15:
Marker menu of the monitor

About menu

The About menu allows to visualize the software serial number of the monitor, the software version of the monitor and the working mode (CE or FCC).

MAIN FUNCTIONS

SET THE MONITOR

Monitor settings are made via the *ePerformance Manager* software installed on your PC or MAC. To set the monitor, please connect it to the computer via USB to use the *ePerformance Manager* software.

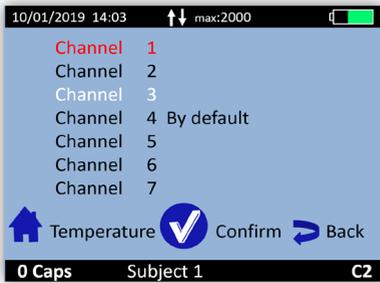
You may thus configure:

- Date and time,
- The number of data to synchronize (corresponding to the maximum amount of data you wish to synchronize from the electronic capsule memory),
- Operating channel,
- Data related to the subject.

CHANGING THE CHANNEL USED BY THE MONITOR

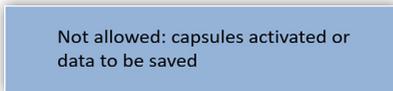
Up to 7 monitors can operate in parallel, in the same environment, thanks to the choice between 7 different communication frequency channels.

This choice can be performed through the *ePerformance Manager* software or manually on the monitor. To set the operating channel on the monitor, go to the menu **'CONFIGURATION'** and the submenu **'CHANNEL'**. Select a channel not used by monitors located in the same environment.



Picture 16:
eViewer Performance monitor
menu to set the operating
channel

This command is not possible when *eCelsius Performance* electronic capsules are associated with the monitor. The following message appears on the screen:



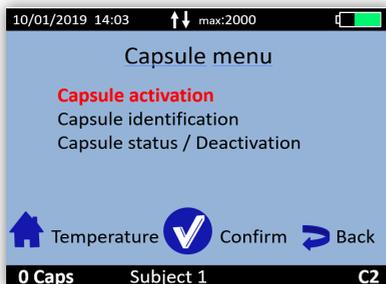
Picture 17:
Setting channel error message

Think about recording the working channel of each monitor; in case of breakage or failure, this information will be needed to launch the monitor replacement procedure (cf. *ePerformance Manager* software > Secondary functions > Back up mode).

ACTIVATE AN ELECTRONIC CAPSULE

Note: Before *eCelsius Performance* electronic capsule activation, please check the monitor's operating channel, the date and time and the number of data to synchronize. **No modification of these four parameters will be authorized after activation of an electronic capsule.**

In order to activate an electronic capsule, please go to the "Capsule menu" and then the submenu "Capsule Activation" of the monitor (Picture 18).



Picture 18:
Capsule activation menu

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

- First, the message "Plug the activator" appears on the monitor screen. Please power the activator and place it close to the monitor (<1m). Then press the button "Confirm" on the monitor.

- The message **“Place the capsule, red part down”** appears. The electronic capsule to activate has to be placed in the hole of the activator. Then press the button **“Confirm”** on the monitor.

- Finally, the message **“Push the activator button, activation in progress”** 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 electronic capsule into the hole of the activator to facilitate the activation and wait until you see the message **“Capsule activated, ID number: XX.XX.XX.XX”** on the monitor screen. It is recommended to note this ID number. **To facilitate the activation process, it is required to rotate the electronic capsule into the hole of the activator after pushing the activator button.**

Therefore, the electronic capsule is activated and associated with the monitor. Press **“Confirm”** to confirm the announcement and come back to the **Capsule menu**.

Monitor assigns to the electronic capsule a number between 1 and 3, the reference for data display. By default, the assigned number will always be the lowest available between 1 and 3 (available mean that there are no associated electronic capsule or stored data associated with this number).



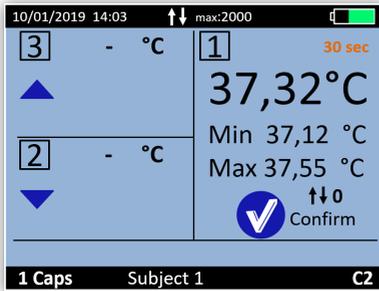
If the LED of the activator stops flashing and the message **“Error! Would you like to restart an activation”** appears on the monitor screen, please check the positioning of the *eCelsius Performance* electronic capsule in the hole of the Activator and / or slightly rotate it into the hole. Press then again the button **“Confirm”** on the monitor to restart the association process and re-press then the button on the activator. **It is clearly advice to rotate the electronic capsule inside the hole during activation progression in order to optimize the process.**

Warning: It is highly recommended to check the environment table used for activation. If the environment is metallic, it could be difficult or even impossible to activate electronic capsules properly.

For the activation of an additional electronic capsule, repeat the procedure. It is possible to connect up to 3 electronic capsules in parallel with a single monitor.

CONSULT TEMPERATURE DATA IN REAL TIME

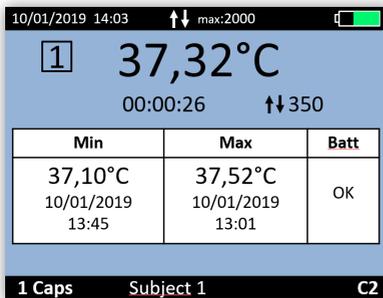
In order to visualize the collected temperature data, go to the menu **“DATA”** and the submenu **“Data view”** or directly by pressing the button Home . The screen will then allow you to visualize the latest temperature data collected for each activated electronic capsule and the minimum and maximum values collected by each associated electronic capsule.



Picture 19:
Home screen menu
of data view

Temperature data (real time temperature data, min and max) of 1 to 3 electronic capsules may be displayed on the screen. The symbol \updownarrow indicates the number of data to synchronize for each of the associated electronic capsule (the number of data stored into the memory of the electronic capsule but not yet received by the monitor) between the monitor and each of the three electronic capsules.

DETAILED TEMPERATURE DATA VISUALIZATION



Picture 20:
Detailed visualization screen
of the electronic capsule

To access to a detailed visualization, select the electronic capsule by positioning it in the right of the screen. Then press the button “**Confirm**”, a new screen appears with the following information:

- Number of the selected electronic capsule (from 1 to 3).
- The last temperature data collected (°C).
- The delay since the last temperature data collected (hh:mm:ss).
- The minimal and maximal value and the battery status of the selected electronic capsule.
- Synchronization indicator \updownarrow link to the relative electronic capsules.
- If the logo \updownarrow turns orange, that means that no communication was received from the electronic capsule during the 10 last attempts.

SYNCHRONIZATION OF THE DATA IN THE MEMROY OF THE ELECTRONIC CASPULE

It is recommended to regularly check that the real time communication is not disrupted, especially in constraining metallic environments.

In the “**Data view**” menu, a logo \updownarrow associated to an electronic capsule number indicates that the monitor needs to synchronize some data with the related electronic capsules. When the logo turns orange, that means that no communication has been possible between the electronic capsule and the monitor during the last 10 attempts.

The electronic capsule has an internal memory that automatically records the last 2000 measurements collected. Once 2000 data have been collected and stored in the electronic capsule memory, the 1st is deleted and replaced by the 2001th, ... When the communication between the monitor and electronic capsule(s) is disrupted, the monitor is not receiving real time data.

Nevertheless, there is a feature in the monitor that automatically recovers the missing data as soon as **real time communication** is restored.

The monitor synchronizes thus automatically its data with the data available in the electronic capsule memory. The maximum number of data to be synchronized must be set when configuring the monitor via *ePerformance Manager* and before associating any electronic capsules. The number of data to synchronize between the monitor and the electronic capsules can be set between 0 and 2000. This number of data to synchronize can't exceed 2000 since the memory of the electronic capsule is limited to the last 2000 data.

With a 30sec measurement period, the communication between the electronic capsule and the associated monitor has thus to be restored within a maximum range of 15 hours (6h for 15sec. sampling period, 30h for a 1min sampling period, etc.). If not, you might definitely loose some of the collected data (automatic synchronization electronic capsule / monitor can take time, from several minutes to several hours depending on the number of data to recover and sampling period settings).

Warning: The first data which will be synchronized will always be the earliest data available in the electronic capsule memory in the limit of the synchronization number set on the monitor. The most recent data are always the latest synchronized data.

To synchronize data from electronic capsule, the monitor has to be in real time communication (1m max) with the electronic capsule during several minutes. As soon as the process is disrupted, the monitor has to wait for the next real time communication of the electronic capsule to start again the synchronization process.

Synchronization indicators  gives the amount of data missing in the monitor to complete the memory in the range of the sync number set in the monitor.

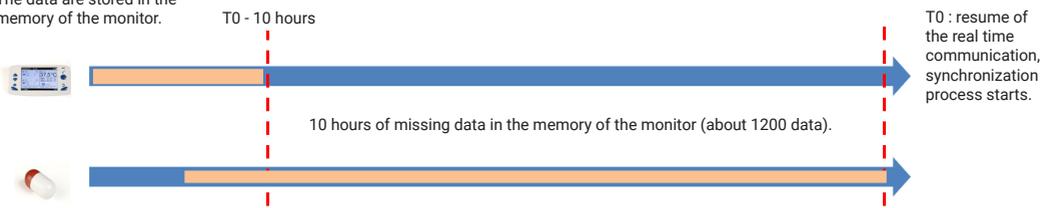
Note: the monitor always optimizes the synchronization process. It waits to have enough consecutive data (around 8 data) before ordering the electronic capsule to synchronize.

To facilitate the data synchronisation, it is important that the real time communication between the monitor and the electronic capsule is good enough.

Illustration of the synchronization process

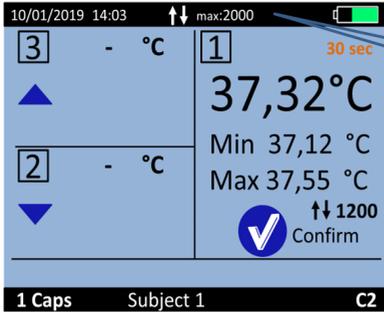
Use case: electronic capsule temperature data collection with a sampling rate of 30s. The monitor is placed close to the electronic capsule after 10 hours of missing data (lack of real time communication).

Data collected in real time.
The data are stored in the memory of the monitor.



The electronic capsule saves the last 2000 data collected in its memory (about 16h30 of recording)

Configuration 1 :

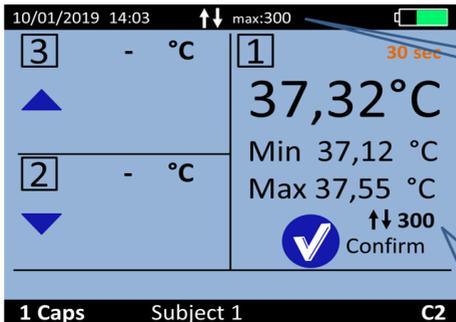


Synchronisation set up to 2000 data.

The 1200 missing datat will be synchronized.



Configuration 2 :



Synchronisation set up to 300 data.

Only the last 300 data will be synchronized.

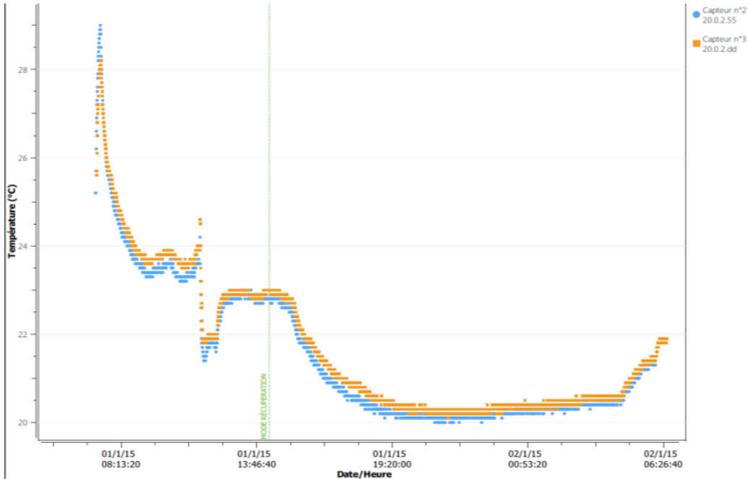


Complementary information for Backup mode:

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

A marker “**Backup mode**” green on the chart of the *ePerformance Manager* software indicates the beginning of the Backup mode. All the data before this marker are synchronized data.

This reestimation is evolutive, more is the number of data synchronized through the Back up mode, more the reestimation regarding the data preceding the marker will be fine.



Picture 21:
Backup mode marker

VISUALIZATION OF THE END-OF-LIFE OF THE ELECTRONIC CAPSULE

On the monitor, when an electronic capsule reaches the end of life, the message ‘**Low**’ appears in the column Batt (Picture 20) of the detailed visualization screen.

The electronic capsule will stop around 500 steps after the appearance of the first message “**Low**” (if the monitor and the electronic capsule are in continuous RF communication).

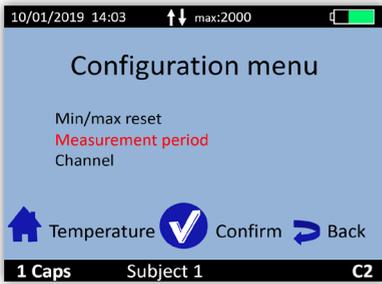
MIN / MAX RESET

In order to reset the alarms and the Min / Max values shown in the data visualization screen, go to the menu “**Configuration**” and select the function “**Min/Max reset**”.

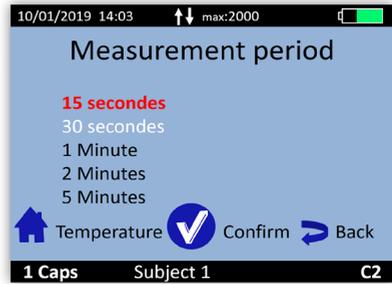
These proceedings will involve all the electronic capsules associated with the monitor.

MEASUREMENT PERIOD

It is possible to change the period between two temperature measurements. To perform the modification, please go to “**Configuration**” and then “**Measurement period**”.



Picture 22: Configuration menu for period configuration



Picture 23: Measurement period menu

A list of five periods is proposed. By default the selected value is 30s. You need to be careful with this choice. Indeed, if you select 15s, you will be able to synchronize much faster, but the amount of data can increase dramatically. A large period will extend the autonomy of the electronic capsule away from the monitor, but the synchronization process could take more time.

As a reminder:

Indeed, to synchronize data, the monitor has to be in real time RF communication with the electronic capsule during several measurements. As soon as the RF communication is disrupted, the monitor needs to wait for the next electronic capsule real time communication to start again the synchronization process. If the period is short, the waiting time is shorter.

END OF DATA COLLECTION

Once continuous core temperature data collection is no longer necessary, you have to ensure the evacuation of the electronic capsule by the subject.

3 solutions allow to perform this verification:

- The subject is able to attest to the evacuation of the electronic capsule,
- The temperature data collected by the monitor has a non-physiological variation physiological associated to a bowel movement,
- If none of the first 2 solutions is valid, it is possible to check if the electronic capsule is still present in the subject's gastrointestinal tract. Bring the monitor used close to the subject and check the detailed menu (*eViewer Performance* Monitor Main functions > Detailed View of Capsule Data).

The real-time capture of new data informs you that the *eCelsius Performance* electronic capsule is always present and active. This verification procedure can be repeated later.

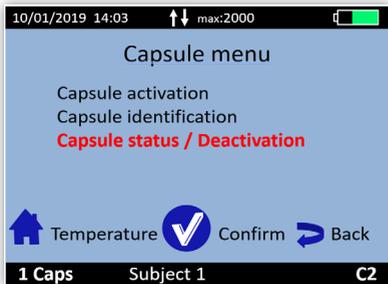
If the original monitor used for subject tracking is no longer available, another *eViewer Performance* monitor can be used to complete the procedure. In this case, go to the "*ePerformance Manager*> Secondary Functions> Back up mode menu" to activate this replacement mode.



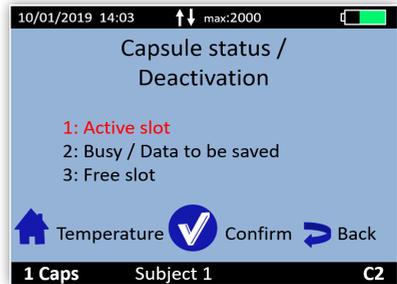
The life duration of the electronic capsule is limited to 20 days, beyond this period, the method described above is no longer usable. The electronic capsule being radiopaque, an X-ray exam will allow the removal of doubt.

DEACTIVATION OF AN ELECTRONIC CAPSULE

When use is finished, the electronic capsule can be switched off, just go to the menu **“Capsule”** (Picture 13) of the monitor and in the submenu **“Capsule Status / Deactivation”** (Picture 25) select the electronic capsule to stop and press **“Confirm”**.



Picture 24 : Menu of the monitor to deactivate an electronic capsule



Picture 25 : Selection of an electronic capsule to deactivate



A confirmation message has to be validated before the deactivation of the electronic capsule. This action is definitive, the electronic capsule disappears from the monitor database. The data file corresponding to the electronic capsule is stored until the data downloading to a computer and activation of a new electronic capsule on this location.

Three cases may be displayed:

“Busy / data to be saved”: The data of the electronic capsule remains on the monitor, but the electronic capsule is no longer associated. Data can be downloaded through the *ePerformance Manager* software. As long as unloading did not take place, a new electronic capsule cannot be activated on this location.

“Active slot”: An electronic capsule is associated.

“Free slot”: This location is available for the activation of a new electronic capsule.

Warning: If the electronic capsule to deactivate is not in the range of communication of the monitor at this moment, it will be disassociated from the monitor but not deactivated. The monitor and the electronic capsule have to communicate to turn off the electronic capsule.

USE OF THE MONITOR SCREEN

In order to save battery, the monitor screen will switch off automatically after 3 minutes of inactivity when the monitor is in battery operation. This action is cancelled when the monitor is in power supply mode.

In any case, to go or to come back to standby mode, you may simply press the side button of the monitor, represented by the following logo: . In this standby mode, the monitor is still working and communicates with the associated electronic capsules.

LOW BATTERY

The monitor has a limited autonomy depending on usage (screen on / off, number of electronic capsules associated, etc ...).

Therefore, it is important to always check the battery level of the monitor when using the monitor in battery mode. The orange LED allows you to be notified when the battery of the monitor is in a critical state while you need to plug it in USB as soon as possible.

If the monitor is switched off without being recharged on time, you simply have to put the monitor in charge (you may have to wait a few minutes before you can use the screen again), and reset immediately the time on the monitor if required.

Indeed, the radiofrequency part will restart only when the date & time of the monitor has been reset.

Warning: if an invalid time is entered, the data may be corrupted.

This action of setting the time is only available through the *ePerformance Manager* software. If electronic capsules are associated, the time setting will only be possible from the monitor interface on specific request of the monitor. It will be necessary to connect the monitor to a PC/MAC, to open the *eCelsius Performance Manager* software and click on the menu “**Files**” on the top of the left of the main window and then click on “Update monitor Date/Time”.

While the battery is in charge, the battery logo turns purple and always filled (indicating the state of charge and not the battery level). Once the cable is disconnected, the logo becomes green and shows the real percentage of the battery.

7. *ePerformance Manager* SOFTWARE

ePerformance Manager software is designed to visualize and export temperature data from a measurement cycle.

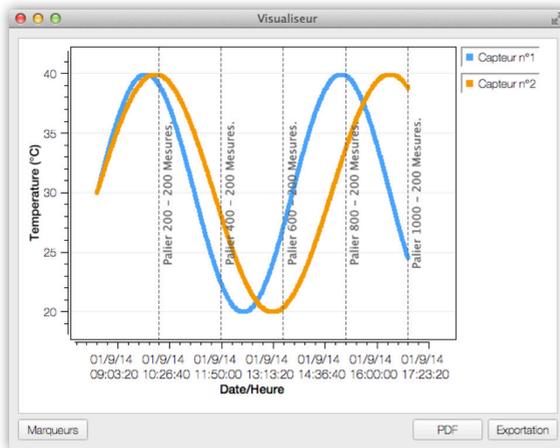
MAIN FUNCTIONS

To use the *eViewer Performance* monitor with *ePerformance Manager* software, you must install the application and the drivers (provided on the USB key BodyCAP). When the installation is completed, the monitor and the application may automatically interface.

UNLOAD AND CONSULT THE TEMPERATURE DATA ON THE *ePerformance Manager* SOFTWARE

On the main screen of the *ePerformance Manager* software, select the menu “**Unloading**” (Picture 2).

An unloading progress window appears. At the end of the process, the temperature data appear graphically (Picture 26).

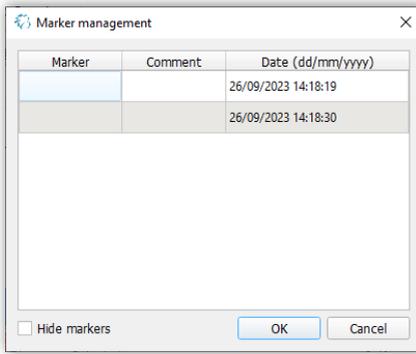


Picture 26:
Picture of the curves
obtained on the
ePerformance Manager
software after the data
unloading

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.

MARKERS FROM THE *eViewer Performance* MONITOR

The data unload includes markers added during the measurement period and displayed by a vertical black line. These markers may be named by clicking on the box “**Markers**”, a window appears to name them. For this purpose, just select the line for the desired marker, fill the corresponding fields and confirm by clicking “**OK**”. They are displayed with corresponding names.



Picture 27:
Screen of marker management

AUTOMATIC MARKERS ON *ePerformance Manager* SOFTWARE

Once automatic alarm is triggered on the monitor, an alarm marker is stored in the monitor. Then these markers are visible on *ePerformance Manager* software by vertical red dashed lines. The reason for the trigger is indicated at the bottom of the marker.

A green marker "**Back up mode**" appears at the beginning of the replacement period. The data before this marker are all synchronized and may have a dating inaccuracy. This is the case when the synchronization starts on a monitor without data (e.g. when using Backup mode).

When the function "**Min/max reset**" is performed, a corresponding marker is stored in the graph.

A marker "**Low battery**" will be stored when the monitor starts to be in low battery during data collection. It is at this time that the LED flashes and the screen switches off.

A marker "**Period configuration**" appears when period of measurement is changed.

A marker "**Monitor Shutdown**" appears when the monitor is completely out of battery. RF communication is then broken.

After an event "**Monitor switch off/extinction**" please put the monitor in charge and set a correct date and time. After validation of the date and time on the monitor, the radio communication with the electronic capsules will get back and the data synchronization will start. To indicate this event, a marker "**Monitor wake-up**" will be stored and displayed on the download window and the CSV file. If you voluntarily choose to not reconfigure the date and time, a marker "**Date and Time not configured**" will be stored and displayed.

A marker "**Slot full**" indicates that the memory capacity of the slot is 100% full (150 000 data per electronic capsule).

HIDE MARKERS

If you do not want to see all the markers, you can check the "**Hide Markers**" box at the bottom left of Picture 27.

EXPORT TEMPERATURE'S DATA UNLOADED ON ePerformance Manager SOFTWARE

To export temperature data, one curve or more may be selected from the icons at the top right of the screen, shown in Picture 26.

To export curves as displayed on the screen of the software, a PDF file may be generated with the “**PDF button**” (Picture 26). The graph exported in PDF is the same than the graph displayed (with the same zoom and the same number of curves).

A data file in spreadsheet format can be generated from the “**Export**” button. Various parameters (decimal separator, data separator, ...) may be set to generate a file fully compatible with the spreadsheet software used on your PC/MAC. A spreadsheet including the temperature data, the date and time of recording and the markers will be generated automatically.

In the CSV file you will find the complete data table as shown on Picture 28.

The status column provides important information:

- **Case 1: you have a temperature in column D and the box column E is empty:** These data were received by the monitor in real time.
- **Case 2 : you have a temperature in column D and the info “Synchronized” in the box column E:** these data were asked by the monitor afterwards during synchronization process.
- **Case 3 : you have no data in column D and you have the info “Missing data” in the box column 2:** these data were not synchronized yet OR this data are out of the range of synchronization number set on the monitor.

Test P060PVES001				
Field 1	Data001			
Time Zone	UTC+1			
Pill n°1	22.FF.FF.11			
Sample numb	Date(mm/dc	Hour	Temperat	Status
1	11/07/2019	14:49:07	26.03	
2	11/07/2019	14:49:38	26.63	Synchronized
3	11/07/2019	14:50:09	26.73	
4	11/07/2019	14:50:40	26.8	
5	11/07/2019	14:51:11	26.92	
6	11/07/2019	14:51:42	27.05	
7	11/07/2019	14:52:13	27.09	
8	11/07/2019	14:52:44	27.18	
9	11/07/2019	14:53:15	27.19	
10	11/07/2019	14:53:46	27.19	
11	11/07/2019	14:54:17	27.22	
12	11/07/2019	14:54:48	27.09	
13	11/07/2019	14:55:19	26.94	
14	11/07/2019	14:55:50	26.86	

Picture 28: CSV information

At the end of the file, you can find the list of automatic and manual markers.

SECONDARY FUNCTIONS

BACKUP MODE

When the operation of the monitor is disturbed (failure, broken, ...), it is possible to recover the communication with electronic capsule which was associated first; via **an another monitor**. This allows to ensure the continuity of the cycle of measurement.

It is necessary to start the backup operation with an operational monitor. This mode will allow to retrieve data from all the *eCelsius Performance* electronic capsules communicating on the selected channel, in the communication range of the monitor and whose ID number is known.

Important: the electronic capsules to be recovered have to all come from the same monitor and be recovered with the same other monitor. The monitor broken has to not be switched on in the same environment after backup beginning under penalty of data corruption or electronic capsules extinction.

First, it is necessary to bring a new functional and charged monitor. Then, check that no electronic capsule is associated with this monitor. Connect it to the *ePerformance Manager* software. After you have started the *ePerformance Manager* software, connect the monitor to a functional PC/Mac with the cable provided by the manufacturer.

Connect it to the *ePerformance Manager* software and set the date and time ("Configuration" tab). Select "Backup mode" on the *ePerformance Manager* software and set the monitor operating channel to the same channel as the faulty monitor; to the operating channel of the electronic capsules you wish to recover.



Picture 29:
Tab "backup mode"

Validate the start of the backup mode by clicking "Enable backup mode".

The following window appears:



Picture 30:
Research activated
electronic capsules

Enter the ID number of the electronic capsules you want to recover. These IDs are obtained at the end of the activation process (cf. *eViewer Performance Monitor* > Main functions> Activate a capsule). The order of electronic capsules does not really matter.

Warning: all the electronic capsules must have been first activated with the same original monitor. Select **“Apply”**. You will see the banners of the monitor switch from black to white, indicating the use of the Backup mode.

Place the monitor close to the environment of the electronic capsules to recover. The monitor will automatically resynchronize with the electronic capsules that are still close and will match the entered ID number in the *ePerformance Manager* software.

To exit the replace mode, you have to disassociate the electronic capsules of the monitor (**cf. eViewer Performance monitor > Main functions > Capsule status/Deactivation**) and download the data via the *ePerformance Manager* software.

Note: To exit the recovery mode, connect the monitor to a PC with the cable provided by the manufacturer and go again to the tab **“Backup mode”** on the *ePerformance Manager* software. Click then on **“Disable the Backup mode”**. Banners on the monitor switch then again in black, indicating that the Backup mode is stopped.

THE RESET TAB

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

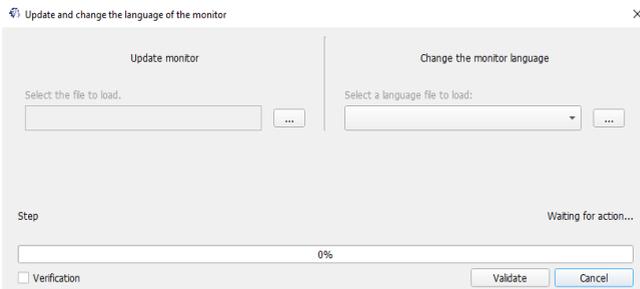
Reset is possible only if no electronic capsule is associated with the monitor AND if all data have been downloaded.

ABOUT TAB

The button **“About”** on the main window of the *ePerformance Manager* software allows to consult information concerning the licences used and the software version.

UPDATE THE MONITOR TAB

On the main window of the *ePerformance Manager* software, the «Update Monitor» tab allows you to remotely update the software version of the monitor as well as the language files associated to a new software version release. If necessary, a specific procedure will be sent to you.



**Picture 31:
Tab “Update the
monitor”**

8. CABLES AND POWER SUPPLY



Two cables are supplied with the system: two USB - micro-USB cables which allow to connect the monitor to a computer to download data or power the monitor and/or the activator by connecting them to a computer on or sector through the adapter (in option). The cable with ferrite is intended to be used with the activator; the cable without ferrite with the monitor.



Picture 32:
Cable and mains supply
adaptor (in option)

Only cables and power supply provided by the manufacturer should be used to ensure proper operation and to not deteriorate the system.

The power supply module (provided in option) is the external isolation mean of the device.

9. EQUIPMENT SPECIFICATIONS

MANUFACTURER INFORMATION

BodyCAP
3, rue du Dr Laënnec
14200 Hérouville St Clair
FRANCE
+33 (0)2.61.53.08.14
<http://www.bodycap-medical.com>



BodyCAP
Your e-health partner

ePerformance Manager REQUIRED CONFIGURATION

Minimal configuration Requirement:

- Processor 1GHz.
- 500Mo de RAM.
- 200Mo disk space required for the installation.
- Windows® 7 or operating systems Microsoft® compatibles (32 or 64 bits).
Mac OS X (10.9 Lion) or ulterior.
- The screen resolution has to be at minima 1024x768.

eCelsius Performance ELECTRONIC CAPSULE TECHNICAL DATA

CHARACTERISTICS

Dimensions: Lenght: 17.7 mm Diameter: 8.9 mm Weight: ≈ 1.7 g.

Temperature range: 25°C - 45°C.

Accuracy: temperature sensor is $\pm 0.1^{\circ}\text{C}$ for human physiological range 36-41°C, $\pm 0.13^{\circ}\text{C}$ outside of the physiological range.

Temperature resolution: 0.01°C.

Storage capacity (electronic capsule): the 2000 last temperature values are stored into the electronic capsule internal memory. The number of data to synchronize can be set from 0 to 2000 data depending on your use case. This functionality is only available from the *ePerformance Manager* software AND before any electronic capsule activation.

Transmission distance between electronic capsule and monitor: around 1m.

Power: autonomous system including 4 zinc-silver oxide batteries.

Autonomy: 20 days with measurement period at 30s.

Communication frequency: ISM Band 433MHz - 434MHz.

Measurement period available: 15s - 30s - 1min - 2 min - 5min.

Plastic: Biocompatible PVC.

The manufacturing date is indicated on the blister of the electronic capsule. The shelf life of the eCelsius Performance electronic capsule is validated for a use up to 24 months after this date. Beyond this date, device performances and autonomy are no longer guaranteed.

ENVIRONMENTAL CONDITIONS

In operation

- Temperatures in the range 25 – 45°C.
- Ingress Protection (IP): X8 (Material supporting prolonged immersion).

Storage and/or transport

eCelsius Performance electronic capsule in the blister:

- Humidity between 20 and 80% relative humidity
- Atmospheric pressure between 700hPa and 1060hPa
- Ambient temperature conditions between 5 and 35°C
- Avoid sprayed water
- Avoid exposure to sunlight

ACTIVATOR TECHNICAL DATACHARACTERISTICS

Dimensions: Lenght: 69 mm Width: 59 mm Height: 31 mm Weight: ≈ 62 g.

Power supply: Main power supply unit (100 ~ 240 V) ou PC via USB (5 V).

Power consumption: ≈ 115 mW only connected (out of operation) and 500mW during activation (for 2s).

Communication: No communication – emission of a series of electromagnetic pulses.

Life duration: 2 years.

Means to disconnect from the main supply: Unplug the power cable.

ENVIRONMENTALS CONDITIONS**In operation**

- Humidity between 20 and 80% of relative humidity
- Atmospheric pressure between 700hPa and 1060hPa
- Ambient temperature conditions between 0 and 40°C

Storage and/or transport

- Humidity between 20 and 80% of relative humidity
- Atmospheric pressure between 700hPa and 1060hPa
- Ambient temperature conditions between 0 and 45°C
- Avoid sprayed water
- Protect from exposure to sunlight

eViewer Performance TECHNICAL DATACHARACTERISTICS

Dimensions: Lenght: 120 mm Width: 70 mm Thickness: 15 mm Weight: ≈ 120 g.

Screen: 320 x 240 pixels

Storage capacity: 150 000 data per activated electronic capsule

Connector: Female micro-USB

Power supply: Battery Lithium-ion rechargeable with a main supply adapter (100 ~ 240 V) and a cable micro-USB – USB provided with the system.

Time to charge: ≈ 3 h.

Battery life: ≈ 36 h.

Band of communication: ISM 433MHz - 434MHz.

Life duration: 2 years (or around 500 recharge cycles).

Means to disconnect from the mains supply: Unplug the power cable

ENVIRONMENTAL CONDITIONS

In operation

- Humidity between 20 and 80% of relative humidity
- Atmospheric pressure between 700hPa and 1060hPa
- Ambient temperature conditions between 0 and 40°C

Storage and/or transport

- Humidity between 20 and 80% of relative humidity
- Atmospheric pressure between 700hPa and 1060hPa
- Ambient temperature conditions between 0 and 35°C
- Avoid sprayed water
- Protect from exposure to sunlight

POWER SUPPLY TECHNICAL DATA

CHARACTERISTICS

Brand: GLOBTEK (HONG KONG) LTD

Frequency range: 50/60Hz

Input voltage: 100-240V

Output voltage: 5V

Input current: 0.2A

Output current: 1A

10. FAILURES GUIDE

Issue	Probable cause	Solution
The monitor does not turn on.	Monitor standby.	Check that the monitor is not in standby or deep standby.
	The battery of the monitor is discharged.	Connect the monitor to a power source, check that the green led is on.
	The monitor is at the end of life.	The manufacturing date is on the monitor label. It is warranty for 2 years or 500 recharges cycles.
	The monitor may required maintenance.	Please ship back the monitor to your distributor or the manufacturer.
The LED on the activator does not turn on.	The activator is not properly connected to the power source.	Please ensure that the connections are correct and that the power source is on.
	The activator is at the end of life.	The manufacturing date is on the label. It is warrentee for 3 years.
	The activator may required maintenance.	Please ship back the monitor to your distributor or the manufacturer.
The RF communication monitor-electronic capsule does not work.	Metallic environment.	Do not use on a table or in a metallic environment.
	The distance is too important.	Please enure that the electronic capsule is within the communication range of the monitor, check the time/ date of the last data received.
	The electronic capsule is not associated.	Follow carrefully the activation procedure. If the association is difficult, check that the electronic capsule is within range of the monitor or turn the electronic capsule into the activator hole. The monitor shows the number of electronic capsules associated.
Inappropriate autonomy of the monitor.	Battery not charged.	Plug in the monitor and wait a few minutes before being able to interact with the monitor.
	Battery is at the end of life.	Discard the device with a certified organism.
Inappropriate autonomy.	Used batteries.	Check the date on the blister.
The communcation between monitor-PC does not work.	Improper connection.	Check that the cable is properly connected.
	The monitor may required a maintenance.	Please ship back the monitor to your distributor or the manufacturer.
The green LED of the monitor does not light or flash.	Faulty power supply.	Check the power supply or connect the monitor to a PC USB (avoiding USB hubs).
Association of the electronic capsule non-functional.	3 electronic capsules maximum per monitor.	Please check that a monitor slot is free.
Frozen screen.	The monitor may require servicing or maintenance.	Perform a hardware RESET by pressing the Reset button located on the back of the monitor, near the label. Return to the manufacturer.

Table 2: Failures guide

11. SYMBOLS



“Do not reuse”



“Batch code”



“Catalogue number”



“Manufacturer address”. This symbol is associated with the manufacturing year for the monitor and the activator (format YYYY), and the month and year of production for electronic capsules (format YYYY-MM).



“Storage temperature limit”



“Keep dry”



“Do not use if the packaging is damaged”



“Protection indice”: electronic capsule resists to a prolonged immersion



“CE marked”



“Do not put the system in municipal waste”



“Contraindicated for pregnant woman”



“Contains phtalates”



“Hygrometry level”



“Atmospheric pressure”



“Keep away from sunlight”

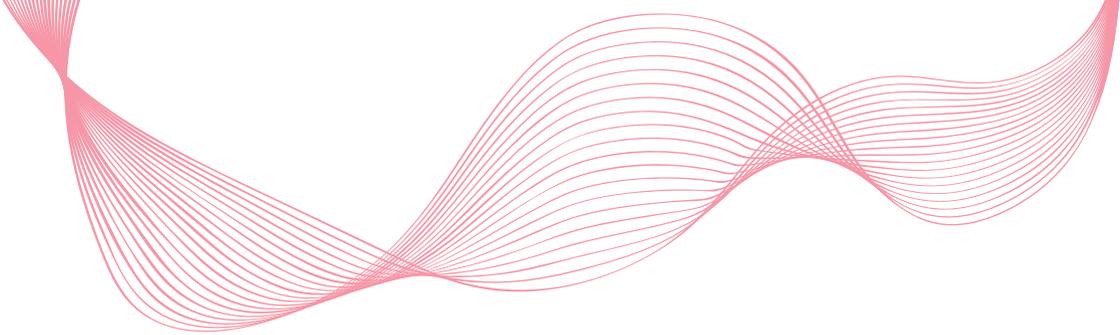


“Follow the instruction of use”



BodyCAP

Your e-health partner



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