BodyCAP

Your e-health partner

User Guide
e-CELSIUS® Performance

Telemetric system for gastrointestinal temperature monitoring

Jan. 2017

Before use, please read
entirely theses instructions

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To our customers, we thank you for purchasing the e-CELSIUS® performance system. The system includes an activator and a monitor "e-Viewer® performance" respectively dedicated to the activation and reception of data sent from e-Celsius® performance capsules. Furthermore, a PC / Mac software allows to set the monitor and to export the data stored in the monitor. The Activator, e-Viewer® performance Monitor and e-Celsius® performance capsules are manufactured by the company BodyCap. This manual is designed to introduce the features and operation of your system and to support you installing and using this product. The use of this device does not require training or specific skills; however, please read these instructions carefully and keep it handy in order to refer to it whenever you need.

Destination and use case:

e-CELSIUS® performance system is designed to continuously measure the gastrointestinal temperature. The e-Celsius® performance capsule should be swallowed. It is supplied in its original packaging and intended for a single use. It has to be activated with the Activator then associated with the monitor that stores the data collected by the capsule. Data transfer from Monitor to a PC / Mac is enabled via an interface provided with the system.

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

1 Precautions for use

The following safety instructions ensure proper operation and will optimize the use of the e-CELSIUS® 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 leaflet).

The e-CELSIUS® performance system is not claimed MRI compatible: It is imperative that the patient ingesting a capsule does not undergo any MRI. The patient should wear the wrist band supplied with the system.
The bracelet is fixed just before the ingestion and should only be removed after removal of the capsule.

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

Do not expose the e-CELSIUS® performance system to dust or dirt (clean up the system into its packaging).

Do not use in the presence of flammable substances.

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

Do not touch or press the screen of the monitor.

Do not place the monitor or the Activator around small objects that may scratch then or enter inside.

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

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 a damaged micro-USB cable or power adapter.

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

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

Do not use the capsule 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 device.

Safety instructions:

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

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 pile and / or battery) should not be put in municipal waste. Check local regulations for disposal of electronic products.

Cleaning

It is not recommended to clean the device using hydro alcoholic solutions.
The system should not, in any case, be introduced in an autoclave on pain of permanent damage for capsules concerned.

2 Use claims and contraindications

2.1 Use claims

The e-CELSIUS® performance system is an electronic device for non-medical uses.

The device is designed for continuous human gastrointestinal temperature measurement. The device is made of four elements:

- A disposable electronic capsule (e-Celsius® performance), intended to be swallowed.
- A monitor (e-Viewer® performance) to collect, display and record the data.
- An activator (Activator) to set the capsules in operation before ingestion.
- A software (e-Performance Manager) allows you to set the monitor and display the data recorded by the monitor on a computer screen.

The accuracy of the system compared to the absolute temperature value is ±0.2°C, variability level, 0.1°C.

⚠ **The system is designed for non-medicals uses.** It is designed for physiological monitoring in order to optimise sports performances or to improve knowledge of human physiology. The device must not be used for diagnosis or therapeutic uses in patients.

2.2 Contraindications and Warnings

Contraindications:

The e-CELSIUS® performance system is designed for the measurement of core temperature in humans; it is contraindicated in a number of situations:

- For people weighing less than 40 kg.
- For people with or presenting a risk of intestinal disorders that can lead to obstruction of the digestive tract, including diverticula.
- For people with motility disorders of the gastrointestinal tract.
- For people who have undergone surgical procedures in the gastrointestinal tract.
- For people with known swallowing disorders.
- For people who have to undergo strong electromagnetic field during the period of use of the system (MRI particular).

Warnings:

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 two hours following the ingestion of the capsule.

If users are overweight people, communication issues between the capsule and the monitor may be encountered due to the system operating mode. The communication between the capsule and the monitor being performed by radio-frequency at 433 MHz - 434 MHz, the signal may be attenuated by the presence of adipose tissue. Thus, communication distance between the capsule and the monitor could be reduced or even void.

3 First use

3.1 Installation of e-Performance Manager Software

Computer installation

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.

Picture 1: USB stick BodyCap

To install e-Performance Manager software and the drivers of e-Viewer® performance monitor, please:

- Launch the installer "e-Performance_Manager" or "MAC-e-Performance_Manager" according to your operating system. These installers are present on the USB memory stick provided (Picture 1: USB stick BodyCap) with your system e-CELSIUS® performance;
- 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".

3.2 Implementation of the device

3.2.1 Power up of the e-Viewer® performance monitor

The monitor e-Viewer Performance is delivered switched off. To exit the storage mode, you must turn on the system by a short simultaneous pressure on the buttons (on the front) and (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.

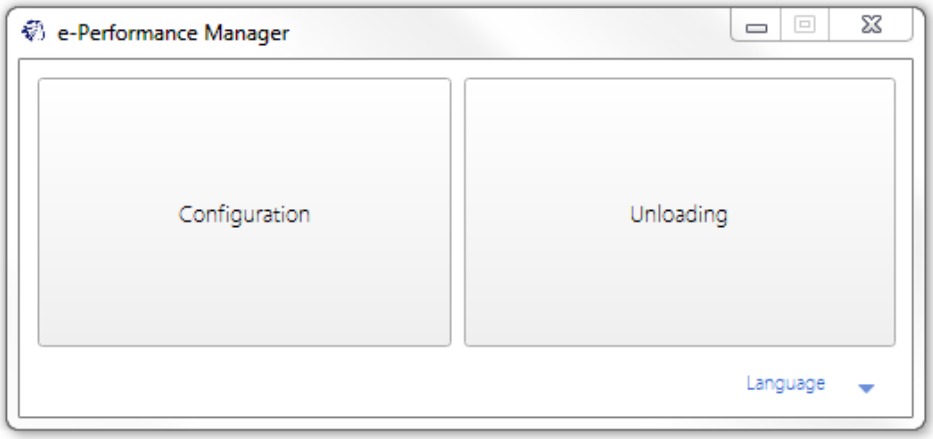
Before using the e-Viewer® performance monitor in battery-run, you have to ensure that its charge level is sufficient.
To use the e-Viewer® performance monitor with the PC / MAC e-Performance Manager software, you have to install the PC / MAC e-Performance Manager software and the BodyCap drivers (provided 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 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.

3.2.2 Supply the batteries

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 or computer switched on).

3.2.3 Configuration of the monitor

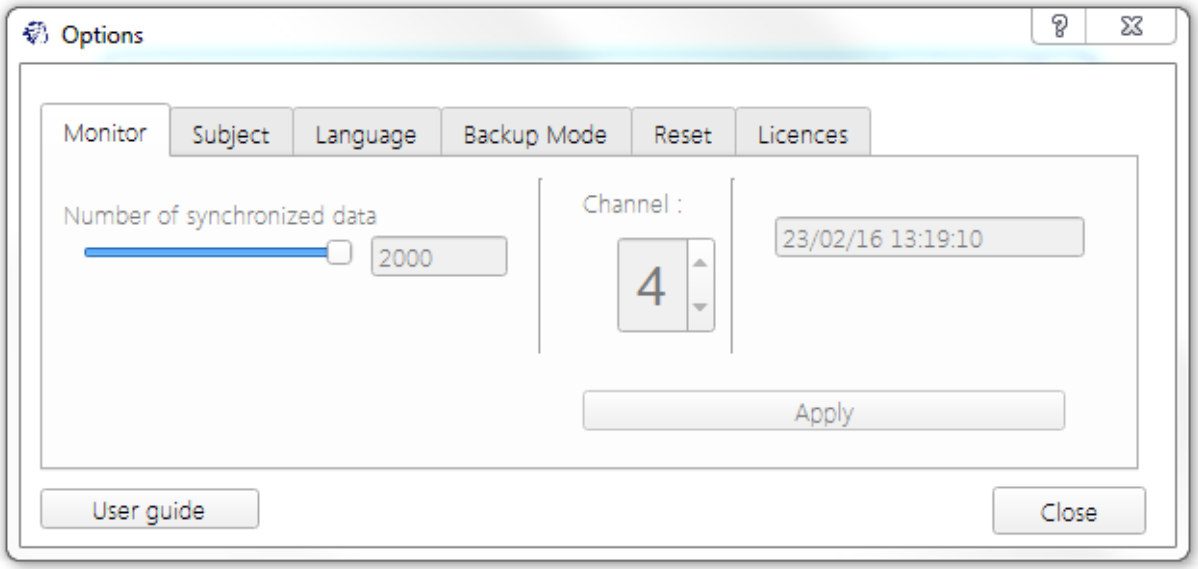
Connect the monitor to a computer having the installed e-Performance Manager software and launch it. At the opening of the first window, select "Configuration" (Picture 2: Start screen of e-Performance® Manager). A menu at the bottom right allows you to select the language.



Picture 2: Start screen of e-Performance® Manager

At the opening of the second window (Picture 3: Tabs to configure the monitor), several tabs allow to configure the monitor before using. At any instant of the configuration, you may consult the instructions by clicking on the tab "User guide" at the bottom left of the window.

3.2.3.1 The tab monitor



Picture 3: Tabs to configure the monitor

The tab "Monitor" (Picture 3: Tabs to configure the monitor) allows selecting the operation channel for the next recording session. It is required to take care that the monitor is sufficiently supplied, and to put it on an available channel.

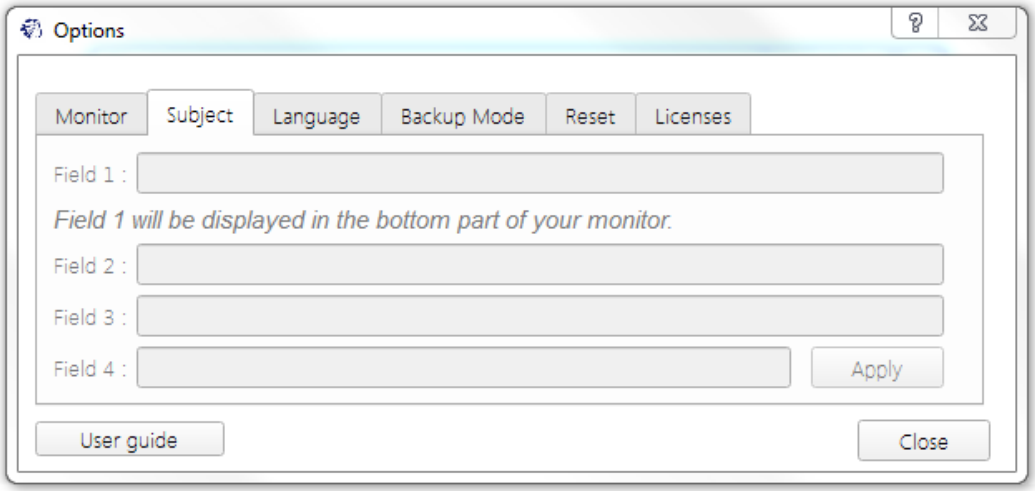
In order to reduce interferences, the selected channel has to be different from those of the other monitors working in the same environment.

It is possible to select one of the seven channels (1 to 7) available in the monitor. The date and time of the computer on which is installed the e-Performance Manager software will be send to the monitor by clicking on the “Apply” button. This timeline is associated with stored data.

The slide Bar “Number of synchronized data” (or number setting zone) allows to set the number of data to recover into memory of the associated pills, after a communication disruption. The monitor will automatically synchronize the missing data, into the range of the setting value. The synchronization always starts with the oldest missing data and finish with the most recent.
This function is available only when no sensors is associated. The number of synchronized values will be applied to all the associated sensors.

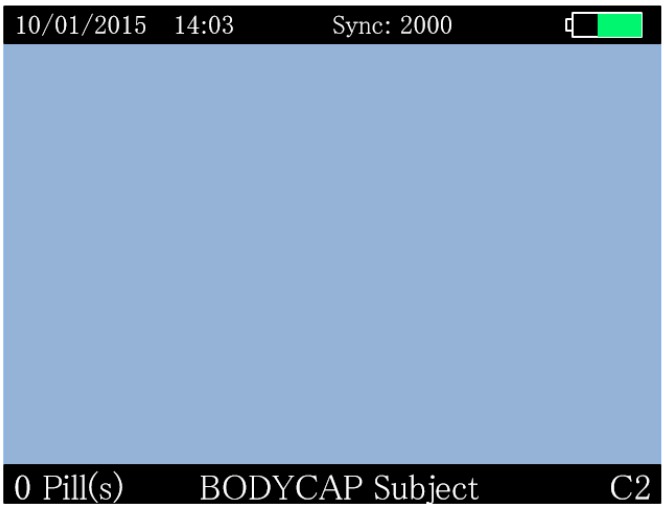
Click on the button “Apply” to send the data to the monitor and go to the next step.

3.2.3.2 The tab Subject



Picture 4: Tab for subject’s data configuration

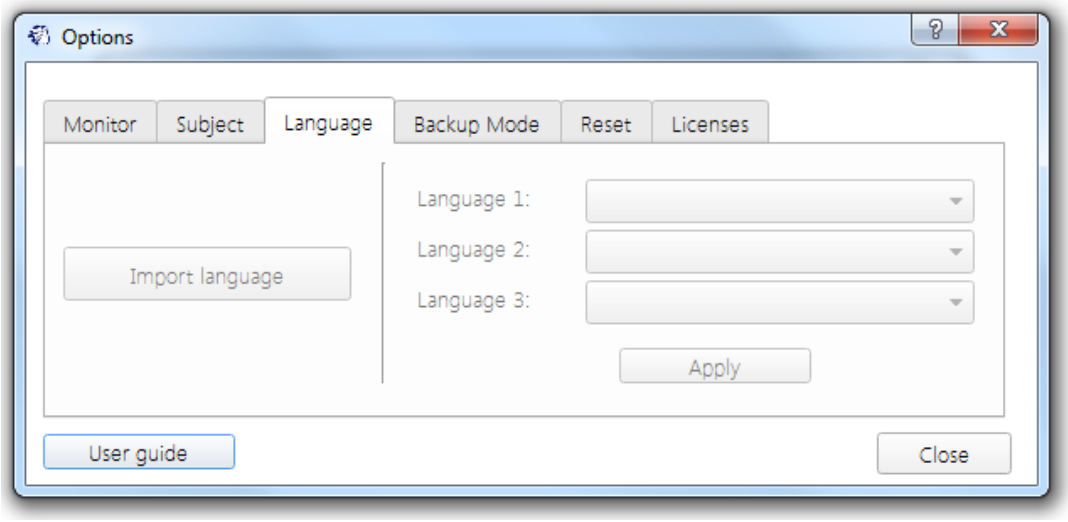
The tab "Subject" (Picture 4: Tab for subject’s data configuration) allows configuring a monitor for a subject. The four items may thus be completed at the discretion of each. The contents of the item 1 will be displayed at the bottom of each screen (Picture 5: Screen of e-Viewer® performance monitor).



Picture 5: Screen of e-Viewer® performance monitor

After the configuration of each item, click “Apply”. The activation of the capsules can begin (cf. §6.7.3).

3.2.3.3 The tab language



Picture 6: Item to configure the language of the monitor and the e-Performance Manager

The tab "Language" (Picture 6: Item to configure the language of the monitor and the e-Performance Manager) allows to import from one to three translation files on the monitor. User can choose its preferred language on the monitor by clicking on "Apply". Different language files are available on the website www.bodycap-medical.com. (This list is regularly updated).
To replace the selected language among the three options stored on the monitor, please visit the menu "Monitor" and "Language" and select the language you want to use.

3.2.3.4 The tab Backup mode

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

3.2.3.5 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 capsule is associated with the monitor AND THEN if all data have been downloaded.

3.2.3.6 The tab licenses

The tab "Licenses", allows to consult information related to used licenses and the release of the e-Performance Manager.

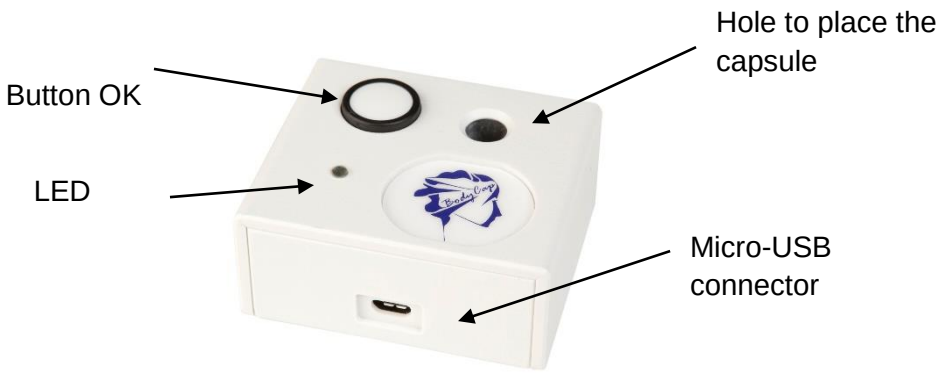
4 The e-Celsius® performance capsule

Picture 7: e-Celsius® performance capsule

The capsule (Picture 7: e-Celsius® performance capsule) is intended to be swallowed to measure gastrointestinal temperature, for non-medical uses. 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.

5 The Activator

The Activator is intended to activate the capsule e-Celsius® before a recording session.



Picture 8: Description of the Activator

5.1 The buttons

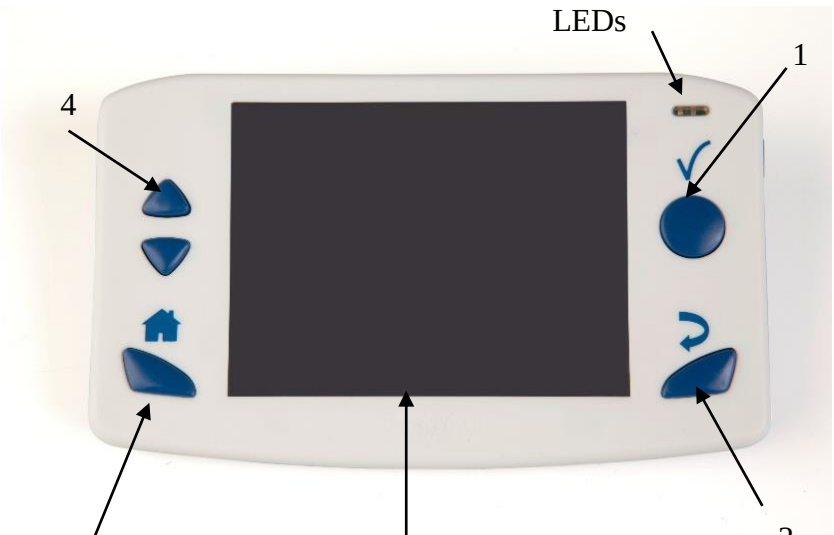
The button OK is used to launch the activation process.
The activation process is detailed in §6.7.3.

5.2 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 capsule placed in the hole. In order to optimize the activation process, you can turn round the pill into the home during the process.

6 e-Viewer® performance monitor

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



Picture 9: Description of the e-Viewer® performance monitor

6.1 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:

Validate (ref. 1 Picture 9: Description of the e-Viewer® performance monitor**)**

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

Home (ref. 2 Picture 9: Description of the e-Viewer® performance monitor**)**

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

Back (ref. 3 Picture 9: Description of the e-Viewer® performance monitor**)**

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

Arrow up (ref. 4 Picture 9: Description of the e-Viewer® performance monitor

Picture 9: Description of the e-Viewer® performance monitor**)**

This button allows navigate in the menu.

Arrow down (ref. 5 Picture 9: Description of the e-Viewer® performance monitor**)**

This button allows to navigate in the menu.

Sleep/wake-up (ref. 6 Picture 9: Description of the e-Viewer® performance monitor)

The button sleep-wake of the screen allows to switch on or off the screen.

The simultaneous use of the button sleep-wake (ref. 6 Picture 9: Description of the e-Viewer® performance monitor) and the button Home (ref. 2 Picture 9: Description of the e-Viewer® performance monitor) allows to switch on or off the monitor if no capsule are associated.

This mode is recommanded for the shelf storage of the monitor. The simultaneous use of the buttons : Home / Sleep-Wake allows to turn off the monitor. This same procedure has to be repeated to turn on the monitor.

6.2 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 the monitor is charging for the first time after a complete discharge of the battery, the orange LED may be blinking in order to inform of the very low level of battery. In this case, the screen is kept switched off for few minutes in order to get minimum level of charge.
When the green LED is lit, it means that the monitor is connected to a power source. Its battery is charging.

6.3 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 power supply of the monitor on the mains supply and switch off the screen. Few hours are necessary to charge the battery. The battery life of the monitor in battery operation is around 36h (screen regularly used but not continuously).

Please do not forget to charge e-Viewer® performance monitor at the end of those 36h under penalty. If the battery reaches a critical level, the system will turn into an energy saving mode. After charging, press simultaneously the buttons "Home" and "Sleep-Wake" and the monitor will automatically recover the associated capsules as soon as the date & time are set correctly on the monitor.

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

Table 1 : Batteries status

Battery status	LED	Functions
Normal	-	Normal operation
Critical	Orange LED flashes	The screen is switched off The RF communication is still enabled but synchronization is disabled
Energy saving mode	-	The screen is switched off The RF communication is stopped. After charging, press simultaneously the buttons "Home" and "Sleep-Wake.

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.

6.4 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 the mains supply via the cable and adapter provided by the manufacturer or directly to a computer. Use of connector are**:**

(i) to set up the monitor (**date, time,** channel**,** number of data to synchronize, patient data)
(ii) to download data from the monitor to e-Performance Manager Software
(iii) to visualize the results of measurements**,**
(iv) to export them to PDF or spreadsheet format
(v) to recharge the battery monitor.

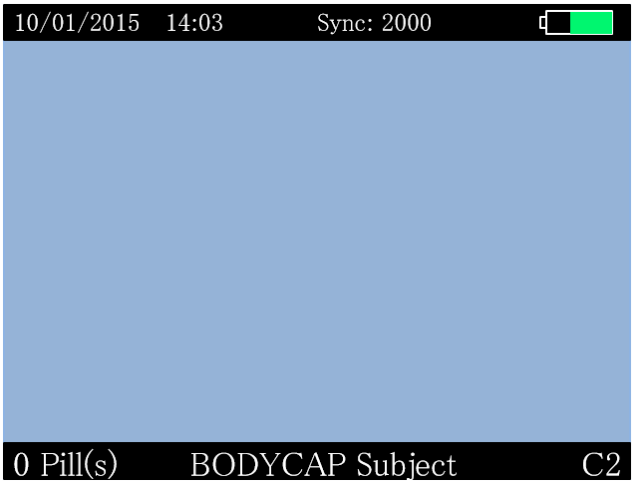
6.5 RF Communication

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 capsule is not interrupted. In the Data View menu, a star (*) associated with a capsule number

indicates that the monitor must be synchronized with the capsule. If this star turns orange, it means that the last data has been collected more than 5 minutes ago. The storage capacity of each capsule is limited to 2000 data, the communication between the capsule and the associated monitor must be restored within a maximum period of 15 hours under penalty to definitively lose some data (the automatic synchronization capsule / monitor can take time, from several minutes to several hours depending on the number of data to be recovered).

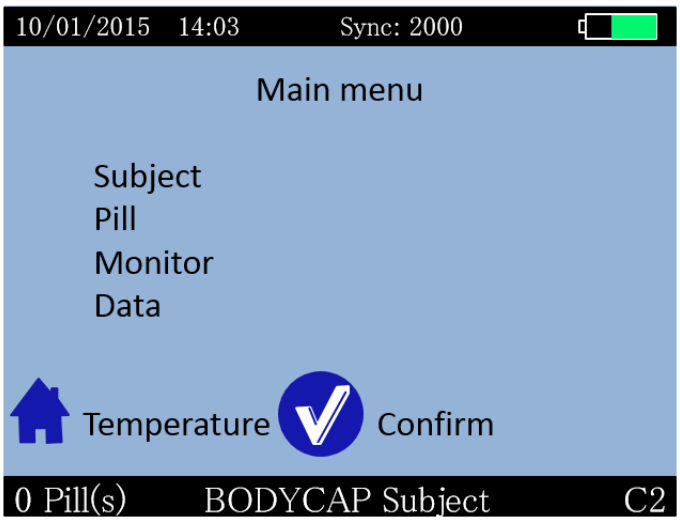
6.6 Monitor interface menu



Picture 10: Screen of the e-Viewer® performance monitor including general information

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

- Date (e.g. 10/01/2015 => DD/MM/YYYY)
- Time (e.g. 14:03 ➔ HH: MM)
- The number of data to synchronize (e.g. Sync: 2000)
- The battery level of the monitor (e.g. the top right of the screen)
- The operating channel of the monitor (e.g. C2)
- A field corresponding to a patient identification (e.g. BODYCAP Subject)
- The number of capsules associated (e.g. Caps 0)

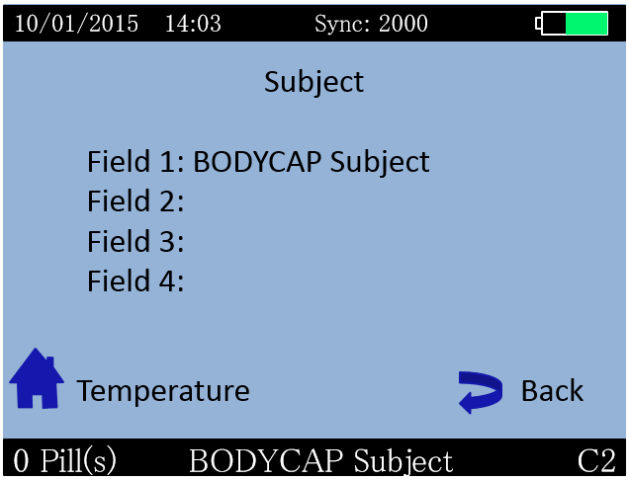


Picture 11: Main menu of e-Viewer® performance monitor

To validate a menu and to move to a submenu, press the button OK (§ 6.1).
To come back, press the button Back (§ 6.1).
To return directly to the temperature display, press the button Home (§ 6.1).
Navigation between the menu items is possible by using the up - & down buttons (§ 6.1).

The Subject menu

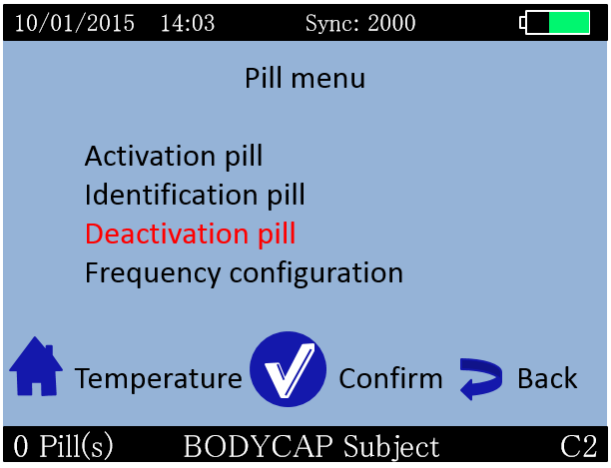
The Subject menu displays user data. The four fields are configurable from the e-Performance Manager software. Then Field 1 is visible on all monitor screens, in the lower band. A limitation of the size of each field is indicated in the e-Performance Manager software.



Picture 12: Subject menu

Pill Menu

The menu PILL (Picture 13: Pill menu) brings together the different control functions of the capsules.



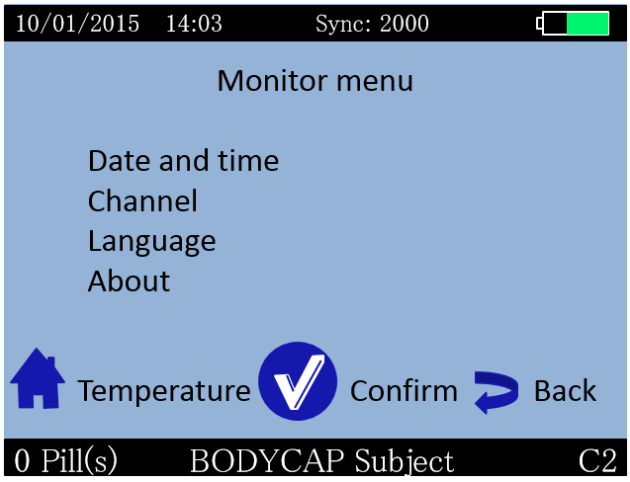
Picture 13: Pill menu

Activation pill:	Starts the activation process of the capsule.
Identification pill:	Allows to visualize the ID number of associated capsules.
Deactivation pill:	Allows to prepare the release of a location (after data unloading) and switch off the capsule.

Frequency configuration:	Allows to modify the measurement period of the associated pills

Monitor menu

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

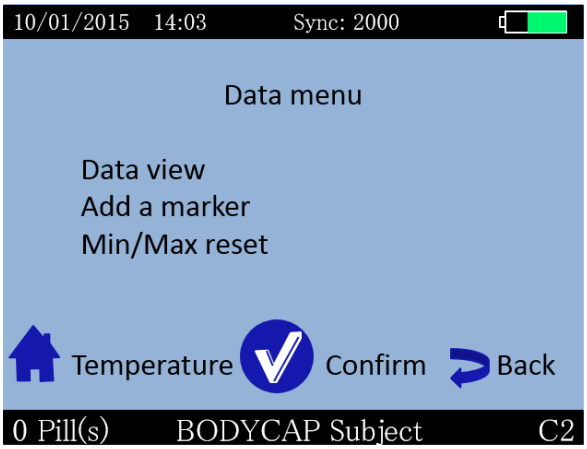


Picture 14: Monitor menu

Date and Time:	Allows to set time zone, date and time
Channel:	Allows to set the channel.
Language:	Allows to change language
About:	Allows to visualize the software release number, the serial number of the monitor and to see if the monitor is in CE or FCC mode

Data menu

The Data menu is used to visualize the latest temperature data from the associated capsules. (Picture 15: Data menu of e-Viewer performance monitor).



Picture 15: Data menu of e-Viewer performance monitor

Data view:	Allows to visualize the last collected data as well as the minimum and maximum values collected by each associated capsule.

Add a marker:	Allows to add an event marker which will appear in the graph available on e-Performance Manager software and the data file when exporting.
Min/max reset:	Allows to reinitialize the data display for min and max value on the detailed data visualization screen

6.7 Main functions

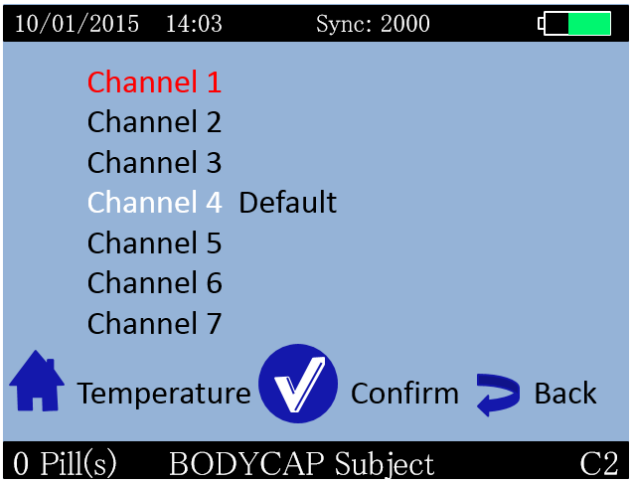
6.7.1 Set the monitor

To set the monitor, please connect it to the computer via USB to use the e-Performance Manager software.
You may also configure:

- date and time,
- the number of data to synchronize,
- operating channel and,
- data related to the subject.

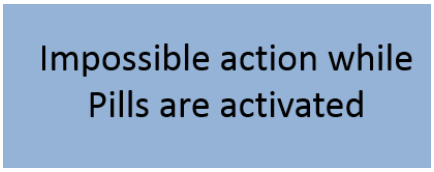
6.7.2 Changing the channel used by the monitor

Up to 7 monitors can operate in parallel, in the same environment, thanks the choice between 7 different communication frequency channels.
This choice can be performed through the e-Performance Manager software or manually on the monitor. To set the operating channel on the monitor, go to the menu "MONITOR" and the submenu "Channel". Select a channel not used by monitors located in the same environment.



Picture 16: e-Viewer® performance monitor menu to set the working channel

This command is not possible when e-Celsius® Performance capsules are associated with the monitor.
The following message appears on the screen:



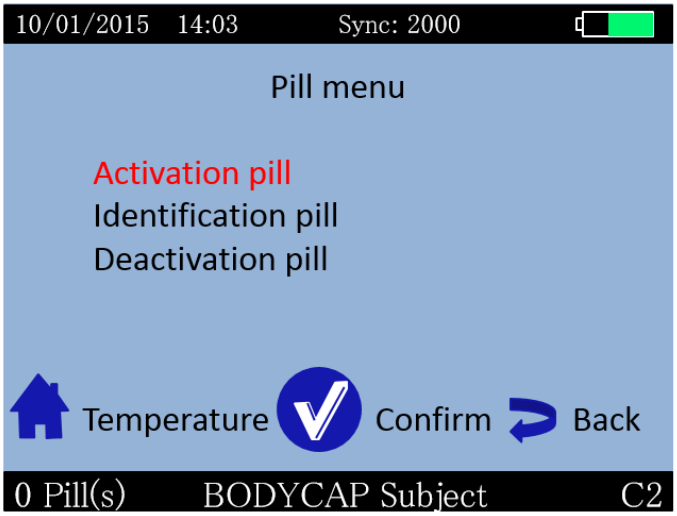
Picture 17: Setting channel error message

Think about recording the working channel of each monitor; in case of breakage or failure, this information will be needed to launch the monitor replace procedure (cf. §7.2.1).

6.7.3 Activate a pill

Note: Before pill 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 a capsule.**

In order to activate a capsule, please go to the "Capsule" menu and then the submenu "*Activation pill*" of the monitor (Picture 18: Capsule activation menu).



Picture 18: Capsule activation menu

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

- First, the message "Plug the activator" appears on the monitor screen; after connecting the activator and placing it close to the monitor (<1m), press the button OK as soon as button appears.
- Then the message "Place the pill, small part down" appears. The capsule to activate has then to be placed in the hole of the activator, big part upwards.
- Then press the button OK on the 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 leave the capsule in place 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**.

Therefore, the capsule is activated and associated with the monitor. Press OK to confirm the announcement and come back to the Menu Capsule.

Monitor assigns to the 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 capsule or stored data associated with this number).

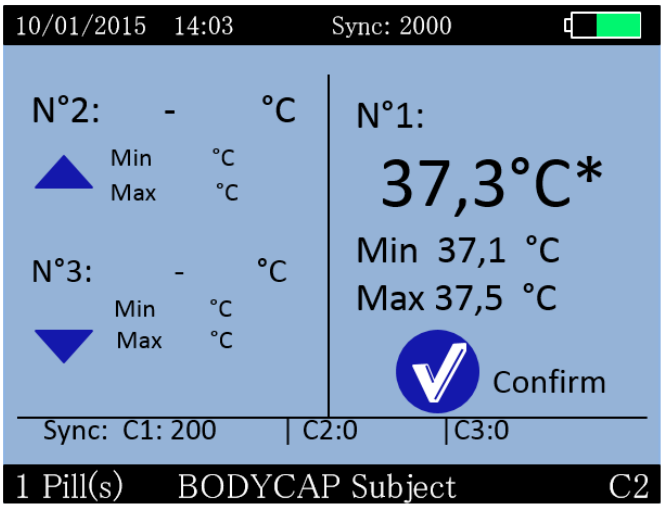
If the LED of the activator stops flashing and the message "Error! Would you like to restart an activation " appears on the monitor screen, please check the positioning of the e-Celsius® performance capsule in the hole of the Activator and / or slightly move the e-Celsius® performance capsule in the hole, press the button OK on the monitor to restart the association process and re-press then the button on the Activator. It may be wise to rotate the pill inside the hole during activation progression in order to optimize the process.

Be careful: It is highly recommended to verify the environment table used for activation. If the environment is metallic, it could be difficult or even impossible to activate pills properly.

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

6.7.4 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 capsule and the minimum and maximum values collected by each associated capsule.



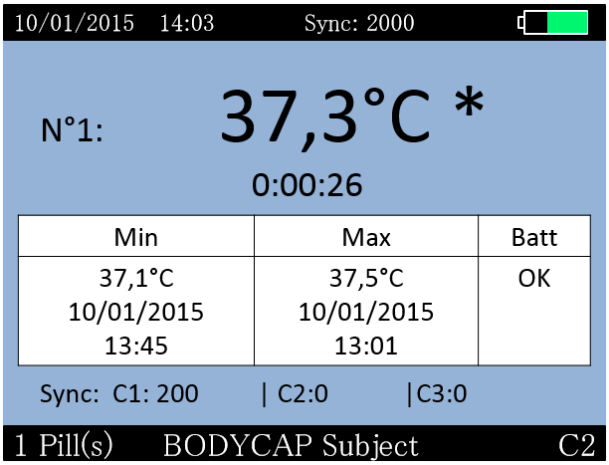
Picture 19: Home screen menu of data view

Temperature data (real time temperature data, min and max) of 1 to 3 capsules may be displayed on the screen.

When this visualization mode in used, the monitor screen never turns off to standby mode.
Please note that, when the visualization mode is used, the data synchronization between the monitor and the capsules is slowed. It is advisable to leave this screen to optimize synchronization delay.

6.7.5 Detailed temperature data visualization

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



Picture 20: Detailed visualization screen of a capsule

- The number of the selected capsule (from 1 to 3).
- The last temperature data collected (°C).
- The delay since the last temperature data collected (h:mm:ss).
- The minimal and maximal value and the battery status of the selected capsule.
- Synchronisation indicator C1, C2, C3 link to relative pills.

In this display mode, the screen never turns automatically in standby mode, thereby facilitating continuous data visualization of the capsule. This display mode slowed the synchronization of data between the monitors and associated capsules. It is recommended to leave this display mode to optimize the speed of data recovery.

6.7.6 Synchronization of the data in memory of the capsule

It is recommended to be vigilant in environments with high metal stress (reinforced concrete wall ...) and to regularly check on the monitor screen that communication with the capsule is not disturbed.
In the screen "Data View ", a star (*) associated with a capsule number indicates that the monitor has to be synchronized with the capsule. An orange star means that the last data have been collected more than 5 minutes.
The capsule has an internal memory that automatically records the last 2000 measurements collected. When the communication between the monitor and / capsule(s) is disrupted (indicated by the star on the temperature display screen), the monitor is not receiving / the data.

Nevertheless, there is a feature in the monitor that automatically recovers the missing data as soon as communication is restored.
The monitor synchronizes also automatically its data with the data available in the capsule memory. The number of data for which the synchronization will be performed has to be previously set during the configuration of the monitor. The number of data to synchronize between the monitor and the capsules can be set between 0 and 2000. This

number of data to synchronize can't exceed 2000 since the memory of the capsule is limited to 2000 data.

In the case the pill emits the data every 30s, the communication between the capsule and the associated monitor has to be restored within a maximum period of 15 hours. If not, you might permanently loose some of the collected data (automatic synchronization capsule / monitor can take time, from several minutes to several hours depending on the number of data to recover).

The first data which will be synchronized will always be the earliest data available in the pill memory in the limit of the synchronisation number set on the monitor. The most recent data are always the latest synchronised data.

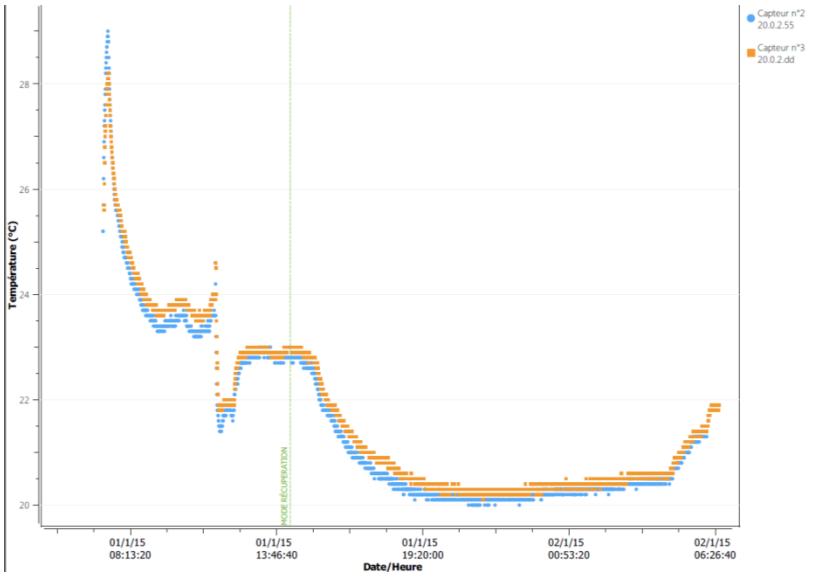
To synchronise data from pill, the monitor has to be in real time communication with the pill during several minutes. As soon as the RF link is broken, the monitor has to wait for the next pill communication to continue the synchronisation process.

Synchronisation indicators C1, C2 and C3 gives the amount of data missing in the monitor to complete the memory in the range of the sync number set in the monitor.

Remark: the monitor always optimizes the synchronisation process. It waits to have enough consecutive data (around 9 data) before ordering the pill to synchronize.

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 e-Performance Manager software indicates the beginning of the Backup mode. All the data before this marker are synchronized data.



Picture 21: "Back up mode" marker

Data synchronization is significantly slowed in two cases:

- When the display mode "Visualizing data" temperature is set (Picture 19: Home screen menu of data)
- When the display mode "Detailed Data visualization of a capsule" (Picture 20: Detailed visualization screen of a capsule) is set

In order to optimize data recovery, we recommend to leave the display mode.

6.7.7 Visualization of the end-of-life of the capsule

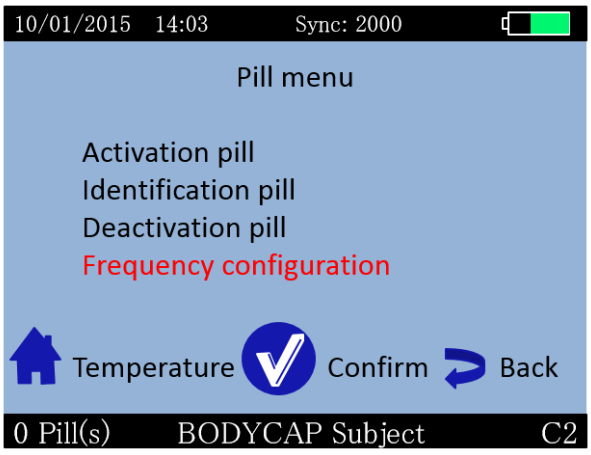
On the monitor, when a capsule reaches the end of life, the message "Low" appears in the column Batt (Picture 20: Detailed visualization screen of a capsule) of the detailed visualization screen.
The capsule will stop around 500 steps after the appearance of the first message "Low" (if the monitor and the capsule are in continuous RF communication).

6.7.8 Min/Max reset

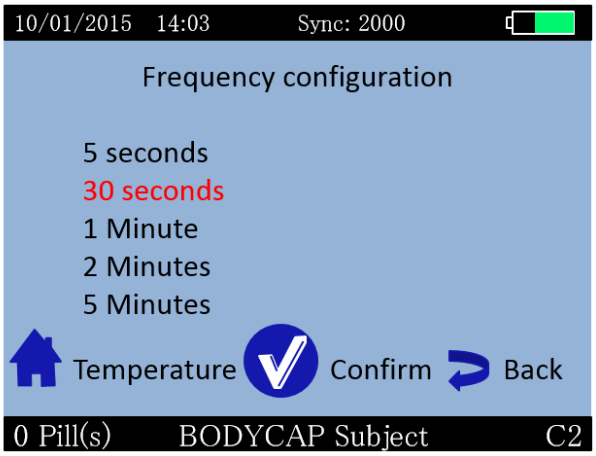
In order to reset the alarms and the Min / Max values shown in the data visualization screen, go to the menu "DATA" and select the function "Min/Max reset".
These proceedings will involve all the capsules associated with the monitor.

6.7.9 Measurement period

It is possible to change the period between two temperature measurement. To perform the modification, please go to pill menu and then Frequency configuration.



Picture 23: pill menu for frequency configuration



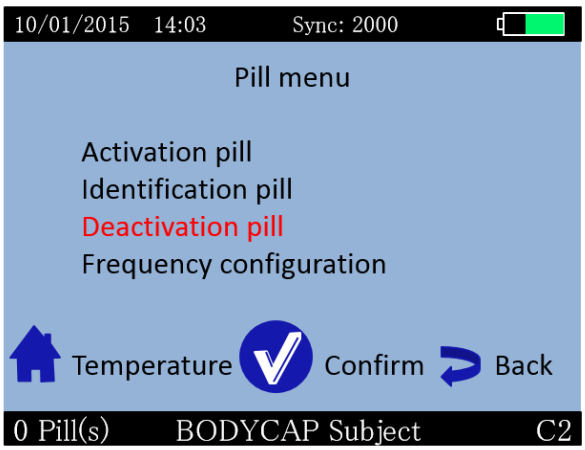
Picture 22: Measurement period

A list of five periods choice is proposed. By default the selected value is 30s. You need to be carefull with this choice. Indeed, if you select 5s, you will be able to synchronise much quickly, but the amount of data can increase dramatically. A large period will extend the autonomy of the pill away from the monitor, but the synchronisation process could take more time.

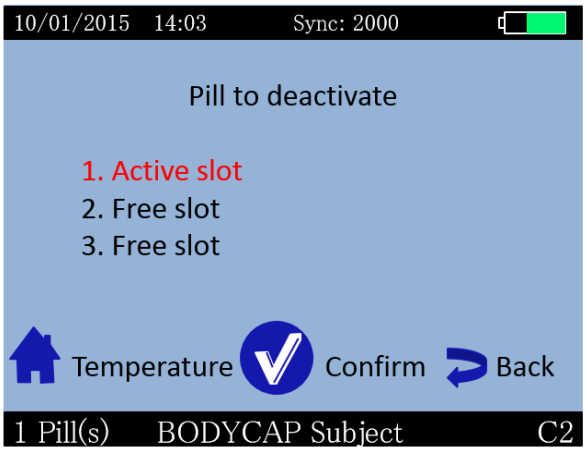
Indeed, to synchronise data, the monitor has to be in real time RF communication with the pill during several measurements. As soon as the RF communication is disrupted, the monitor needs to wait for the next pill communication to continue synchronisation process. If the period is short, the waiting time is shorter.

6.7.10 Deactivation of a pill

After usage, just go to the menu "Pill" (Picture 13: Pill menu) of the monitor and in the submenu "Deactivation pill" (Picture 24: Menu of the monitor to deactivate a) select the capsule to stop and press OK.



Picture 25: Menu of the monitor to deactivate a pill



Picture 24: Selection of a capsule to deactivate.

In order to ensure the success of the procedure, the capsule and monitor must be close enough to communicate.

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

Three cases may be displayed:

- "Busy slot ": The data of a capsule remains on the monitor, but the capsule is no longer associated. Data can be downloaded on the e-Performance Manager software. As long as unloading did not take place, a new capsule cannot be activated on this location.
- "Active slot": A capsule is associated
- "Free slot": This location is available to the activation of a new capsule.

Warning: If the capsule to deactivate is not in the range of communication of the monitor at this moment, it will not be shut down. The monitor and the capsule have to communicate to allow this operation.
When the monitor and the pills can't communicate during the deactivation, the monitor will send the order during the 4 subsequent communications with the pill. Depending on the current sampling frequency this process duration can range from 20s (Sampling rate 5s) to 20min (Sampling rate 5min). During this period do not restart the process or else, it will extend the waiting duration.

6.7.11 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 for 2 possible reasons:

- The monitor is in power supply mode. In this case, the screen is constantly switched on without user action.
- The monitor displays data temperature screen. This screen is very important for subject monitoring. In this case, the monitor does not automatically go into standby.

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 mode, the monitor is still working and communicates with the associated pills.

6.7.12 Low battery

The monitor has a limited autonomy depending on usage (screen on / off, number of 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/green 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 ASAP.
If not, however, 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.
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 may be done directly on the monitor or through the e-Performance Manager software. If capsules are associated, the time setting will only be possible from the monitor interface.
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.

6.7.13 Overview of the alarm system

The monitor combines three categories of alarms related to the state of the system.

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
Battery of the capsule	The remaining autonomy of the capsule 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 (Picture 20: Detailed visualization screen of a capsule) of detailed visualization screen (§ 6.7.5).	Low
Battery of the monitor	The battery of the monitor is low or critical	Immediate	Battery status are indicated by the LEDs on the front side of the monitor	Medium
Loss of communication	Black star if some data are missing and orange star if the communication with the pills is disrupted for	Depends on the sampling frequency previously set	Star Displayed	Medium*

	more than 5 times the sampling frequency			

Tableau 2: Alarm systems

* The punctual loss is indicated by a black star; a long loss is indicated by an orange star.

7 e-Performance Manager® software

e-Performance Manager software is designed to visualize and export temperature data from a measurement cycle.

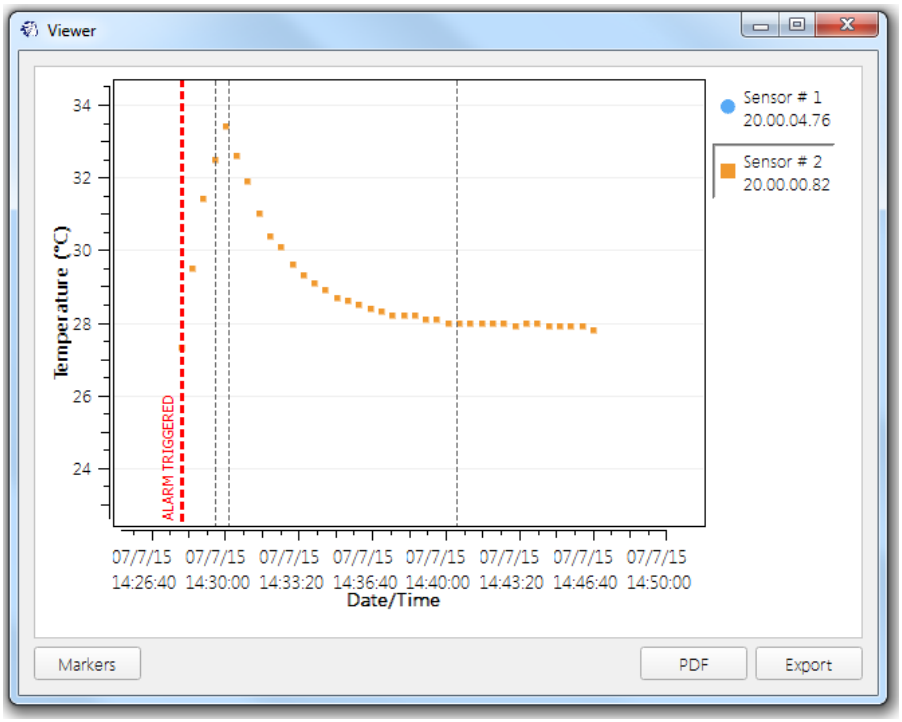
7.1 Main functions

To use the e-Viewer® performance monitor with e-Celsius® performance Manager software, you must install the application and the BodyCap drivers (provided on the USB key BodyCap). When the installation in completed, the monitor and the application may automatically interface.

7.1.1 Unload and consult the temperature data on the e -Performance Manager software

On the main screen of the e-Performance Manager software, select the menu "Unloading" (Picture 2: Start screen of e-Performance® Manager).

An unloading progress window appears. At the end of the process, the temperature data appear graphically (Picture 26: Picture of the curves obtained on the e-performance Manager software after the data unloading.)

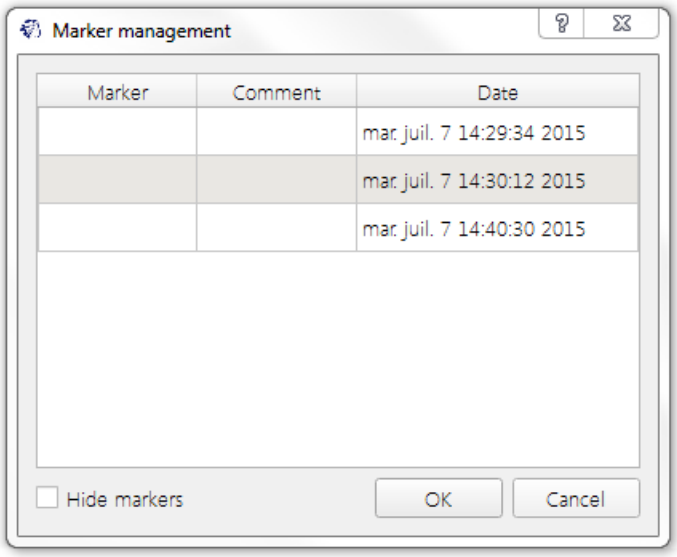


Picture 26: Picture of the curves obtained on the e-performance Manager software after the data unloading.

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.

7.1.2 Markers from the e-Viewer® performance monitor

The data unload includes markers indicated during the registration 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

7.1.3 Automatic markers on e-Performance manager software

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

A green marker "**Replace mode**" appears at the beginning of the replace phase. The data before this marker are all synchronized and may have a dating inaccuracy. This is a case where 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 begins to be in lack of battery during data collection. It is at this time that the LED flashes and the screen switches off.

A marker "**monitor Shutdown**" appears when the monitor is completely out of battery.

A marker "**Frequency Configuration**" appears when period of measurement is changed.

After an event “**monitor switch off/extinction**”, it needs to put the monitor in charge and to set a correct date and time. After validation of the date and time on the monitor, the radio communication with the capsules will get back and the data synchronization will begin. To indicate this event, a marker “monitor wake-up” will be stored and displayed on the download window and the CSV file.

7.1.4 Hide markers

If you do not want to see all the markers, you can check the "Hide Markers" at the bottom left of Picture 27: Screen of marker management.

7.1.5 Export temperature’s data unloaded on e-Performance Manager software

To export temperature’s data, one curve or more may be selected from the icons at the top right of the screen, shown in Picture 26: Picture of the curves obtained on the e-performance Manager software after the data unloading..
To export curves as displayed on the screen of the software, a PDF file may be generated with the "PDF" button (Fig. 26). The view from the graph in the exported PDF file is the display of the graph (with the same zoom and the same number of curve).
A data file in spreadsheet format can be generated from the "Export" button. A spreadsheet including the temperature data, the date and time of recording and the markers will be generated automatically.

In the CSV file you will find the complete data table as shown on picture 28.
The status column gives important information:
Case 1: you have a temperature in column D and void status: This data was received by the monitor in real time.
Case 2: you have a temperature in column D and Synchronised status: this data was asked by the monitor afterwards during synchronisation process.
Case 3: you have no data in column D and you have a “out of limit” status: this data was not synchronised yet OR this data is out of the range of synchronisation number set on the monitor.

	A	B	C	D	E	F
1	Bodycap Subject					
2	Time zone	UTC1				
3						
4						
5	Sensor n°1	00.00.2C.8D				
6	Sample number	Date	Time	Temperature (°C)	Status	
7	1	13/10/2016	17:03:57	24,1		
8	2	13/10/2016	17:04:27	24		
9	3	13/10/2016	17:04:56	23,8		
10	4	13/10/2016	17:05:26	23,8		
11	5	13/10/2016	17:05:56	23,8		
12	6	13/10/2016	17:06:26	25	Synchronised	
13	7	13/10/2016	17:06:56	25	Synchronised	
14	8	13/10/2016	17:07:25	25	Synchronised	
15	9	13/10/2016	17:07:55	25	Synchronised	
16	10	13/10/2016	17:08:25	24		
17	11	13/10/2016	17:10:23	31,8	Synchronised	
18	12	13/10/2016	17:12:20	31,8		
19	13	13/10/2016	17:14:18	28,2	Synchronised	
20	14	13/10/2016	17:16:15	28,6	Synchronised	

Picture 28: CSV information

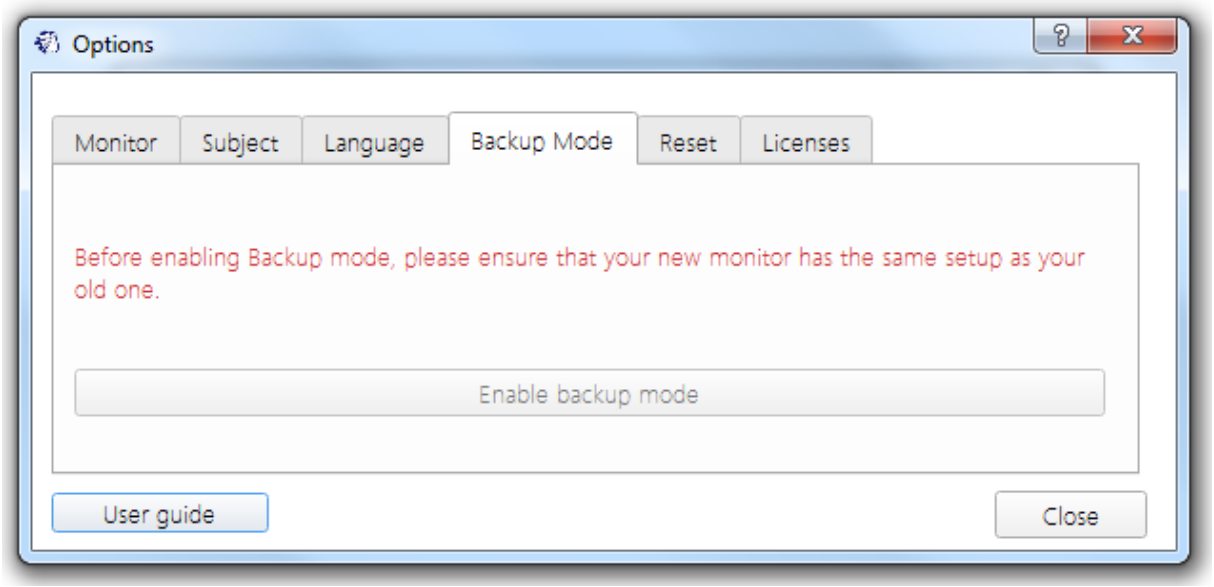
At the end of the file, you can find the list of automatic and manual markers.

7.2 Secondary functions

7.2.1 Backup mode

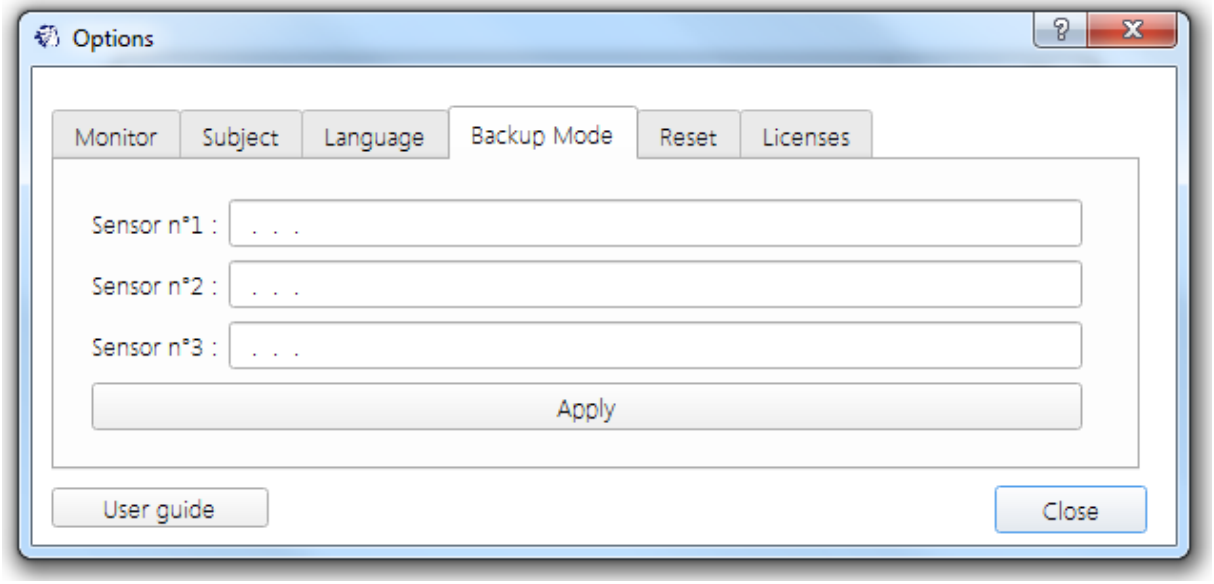
When the operation of the monitor is disturbed (failure, broken, …), it is possible to recover the communication with capsule which was associated first; via an another monitor. This allow to ensure the continuity of the cycle of measurement
It is necessary to start the replace operation with an operational monitor. This mode will allow to retrieve data from all the e-Celsius® performance capsules communicating on the selected channel, in the communication range of the monitor and whose ID number is known.
Important: the capsules to recover have to be all issues from the same monitor and recovered with another one. The monitor broken has to not be switch on in the same environment after backup beginning under penalty of data corruption or capsules extinction

First, it is necessary to bring a new functional and charged monitor. Then, check that no capsule is associated with this monitor. Connect it to the e-Performance Manager software and configure the operating channel of the monitor to the same channel as the failed monitor. In fact, on the operating channel of the capsules you want to recover [follow the procedure in § 6.7.2]. After you have started the e-Performance Manager software, connect the monitor to a functional PC/Mac with the cables provided by the manufacturer. Select "Backup mode" on the e-Performance Manager software.



Picture 29: Tab "backup mode"

Validate the start of the mode by clicking "Enable backup mode".
The following window appears:



Picture 30: Research activated capsules

Enter the ID number of the capsules you want to recover. (§ 6.7.3)
The order of capsules does not matter.
Warning: all the 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 replace mode.
Place the monitor close to the environment of the capsules to recover. The monitor will automatically resynchronize with the capsules that are still close and will match the entered ID number in the e-Performance Manager software.

To exit the replace mode, you have to disassociate the capsules of the monitor (§ 6.7.9) and download the data via the e-Performance Manager software.
Note: To exit the recovery mode, connect the monitor to a PC with the cables provided by the manufacturer and go again to the tab Backup mode on the e-Celsius® performance Manager software. Click then on "Disable the Backup mode." Banners on the monitor switch then again in black, indicating that the replace mode is stopped.

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.

Picture 31: Cable and mains supply adaptor

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

9 Equipment specifications

9.1.1 Manufacturer Information

BodyCap
6 rue de la Girafe
14000 Caen
FRANCE

+33 (0)2.61.53.08.14

http://www.bodycap-medical.com

9.1.2 e-Performance 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.

9.1.3 e-Celsius Performance pill technical data:

9.1.3.1 Characteristics

Dimensions:	Length: 17.7 mm. Diameter: 8.9 mm. Weight: ≈ 1.7 g.
Accuracy:	±0.2°C in the range 25 - 45°C.
Variability:	±0.1°C
Storage capacity (Capsule):	The 2000 last temperature data are stored in the capsule. 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 e-Performance manager software AND before any capsule activation.
Transmission distance between capsule and monitor:	around 1m (environment dependant).
Power:	autonomous system including 4 zinc-silver oxide batteries.
Battery life:	20 days.

Communication frequency:	ISM Band 433MHz - 434MHz
Plastic:	Biocompatible PVC.
Storage life:	Refer to the expiry date printed on the package.

9.1.3.2 Environmental conditions:

In operation

- temperatures in the range 0 - 50°C
- Ingress Protection (IP): X8 (Material supporting prolonged immersion)

Storage and/or transport

e-Celsius® performance pill in the blister:

- humidity between 30 and 80% relative humidity,
- atmospheric pressure between 800hPa and 1060hPa
- ambient temperature conditions between 0 and 40°C
- avoid sprayed water
- avoid exposure to sunlight

The shelf life of the e-Celsius® performance capsules is indicated by an expiration date on the packaging. Beyond that date, device performances and autonomy are not guaranteed.

9.1.4 Activator technical data:

9.1.4.1 Characteristics

Dimensions:	Length: 690 mm. Width: 590 mm. Height: 310 mm. Weight: ≈ 62 g.
Power supply:	Main power supply unit (100 ~ 240 V) or PC via USB (5 V).
Power consumption:	≈ 115 mW only connected (out of operation) and 500mW during activation (for 2s).
Communication:	No communication – emission of a series of electromagnetic pulses.
Life duration:	2 years.
Means to disconnect from the main supply:	Unplug the power cable.

9.1.4.2 Environmental conditions:

In operation

- humidity between 30 and 80% of relative humidity
- atmospheric pressure between 800hPa and 1060hPa
- ambient temperature conditions between 0 and 40°C

Storage and/or transport

- humidity between 30 and 80% of relative humidity,
- atmospheric pressure between 800hPa and 1060hPa
- ambient temperature conditions between 0 and 35°C.
- avoid sprayed water
- protect from exposure to sunlight.

9.1.5 e-Viewer Performance technical data:

9.1.5.1 Characteristics

Dimensions:	Length: 120 mm. Width: 70 mm. Thickness: 15 mm. Weight: ≈ 120 g.
Screen:	320 x 240 pixels.
Storage capacity:	100 000 data per activated 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. To charge the system, with USB, via a computer, please install the e-Performance Manager software following the described process in this user manual.
Time to charge:	≈3 h.
Battery life:	≈ 36 h.
Band of communication:	ISM 433MHz → 434MHz.
Life duration:	2 years (or around 500 recharge cycles).
Means to disconnect from the mains supply:	Unplug the power cable.

9.1.5.2 Environmental conditions:

In operation

- humidity between 30 and 80% of relative humidity
- atmospheric pressure between 800hPa and 1060hPa
- ambient temperature conditions between 0 and 40°C

Storage and/or transport

- humidity between 30 and 80% of relative humidity,
- atmospheric pressure between 800hPa and 1060hPa
- ambient temperature conditions between 0 and 35°C.
- avoid sprayed water
- protect from exposure to sunlight.

9.1.6 Power Supply technical data:

9.1.6.1 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

Tableau 3 : Failures guide

Problem	Probable cause	Solution
The monitor does not switch on.	Monitor in sleep mode	Check that the monitor is not in sleep mode or deep sleep mode
	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 capsule is not working.	The distance is too large	Ensure that the capsule is in the range of the monitor, check the date of the last temperature data received.
	The capsule is not associated	Respect the activation process. If the association is difficult, ensure that the capsule is close enough to the monitor or please turn the capsule in the hole of the activator. The monitor indicates the number of associated capsules.
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 a DEEE organism.
Inappropriate autonomy of the capsule	Old battery	Check the date printed on the label.
	Incorrect connection	Check that the cable is properly connected.

The connection between the monitor and the PC/MAC do not work.	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	
Association to the capsule does not work.	3 capsules maximum per monitor	Check that a location is free on the monitor.
Frozen screen.	The monitor may require a maintenance action	Please contact the manufacturer Perform a hardware reset. Press with a small pin into the reset button placed on the backside of the monitor. You will find it at the label place. Return to the manufacturer

11 Symbols

"Do not reuse"

"Use until"

"Batch code"

"Catalogue number"

"Manufacturer"

"Storage temperature limit"

"Keep dry"

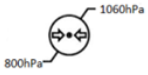
"Do not use if the packaging is damaged"

"Protection indice"

"CE marked"

“Do not put the system in municipal waste””

“Hygrometry level for storage “



“Atmospheric pressure for storage“

“Keep away from sunlight”

"Date of production"

“Follow the instruction of use”