eCelsius Performance Connect

TELEMETRIC SYSTEM FOR
CONTINUOUS CORE TEMPERATURE MONITORING

USER GUIDE

BodyCAP
Your e-health partner

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To our customers,

we thank you for purchasing the eCelsius Performance Connect system. This solution is manufactured by BodyCAP. This user guide aims to present the caracteristics 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 or material injury damages. The responsibility of the manufacturer and its distributors can not be engaged in case of misuse of the equipment. The inspection and repair operation must be carried out by approved persons who have undergone appropriate training.

The system is composed of:

- **A (or several) disposable eCelsius Performance capsule(s)** to monitor core tempe rature through gastrointestinal tractus.
- **A signaletic bracelet** provided with each capsule.
- **An activator and its power supply cable** allowing turn on the capsule before inges tion.
- **An ePerf Connect gateway and its power supply cable** allowing data temperature recovering from 1 to 3 capsules simultaneously.
- **An ePerf Mobile Android Application** for Android Smartphone or Tablet (available on Play Store) allowing to set up the ePerf Connect device and to visualize the data retrieved from the device.
- **An USB stick** including user documentation.

Destination and use cases:

The eCelsius performance Connect system is designed to continuously measure core temperature through gastrointestinal tractus in non-medical use cases. The eCelsius Performance 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 ePerf Connect device which records the data and can return them to an Android Smartphone or Tablet through the ePerf Mobile Application.

Declaration of conformity:

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

- 2011/65/UE, relative à la limitation de l'utilisation de certaines substances dangereuses dans les équipements électriques et électroniques

- 2014/53/UE relative à la mise sur le marché d'équipements radioélectriques

- 1907/2006 concernant l'enregistrement, l'évaluation et l'autorisation des substances chimiques, ainsi que les restrictions applicables à ces substances (REACH)

The system is designed for Non-Medical uses only. The application 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 Connect system. Follow them carefully. For any questions that have not been answered in the user guide, please ask for assistance from your distributor or manufacturer (contact information at the end of this leaflet).

The eCelsius Performance capsule is not claimed MRI compatible: It is imperative that the subject ingesting a capsule does not undergo any MRI. The subject should wear the 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 capsule in case of succesive ingestion.

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

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

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

Do not touch or press the ePerf Connect screen.

Do not use the capsule if the packaging is damaged.

Do not expose the Activator to rain or humidity; keep it 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 during a gaz leak.

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 ePerf Connect device and the activator. This could affect their normal way of working.

Do not place the ePerf Connect device or the activator around small objects that may scratch then or enter inside.

Do not use the device if it is damaged.

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

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

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

Do not throw into fire.

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

Do not put the device as unsorted municipal waste.
The ePerf Connect device 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 pill and / or battery) should not be put in municipal waste.
Check local regulations for disposal of electronic products.

Cleaning

The 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 on pain. It may cause permanent damage for the element concerned.
The other elements of the system (ePerf Connect & activator) may be cleaned using a hydroalcoholic wet wipe.

Règlement européen REACH 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 capsule compounds in a concentration upper than 0.1% weigh/weigh (SVHC/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 phtalates

Based on the toxicological evaluation, we inform users of the presence of an acceptable phthalate level in the e-Celsius performance pill; 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

2. USE CLAIMS AND CONTRAINDICATIONS

USE CLAIMS

The *eCelsius Performance Connect system* **is an electronic device for non-medical uses only.**
The device is designed for continuous human gastrointestinal temperature measurement.
The level of accuracy of the system, in comparison with the absolute temperature value, is ±0.2°C.
The temperature data resolution is 0.01°C.

eCelsius Performance Connect system **is not designed for medical use cases.**
It is designed for physiological monitoring in order to optimize sports performances, to improve knowledge of human physiology or to follow physiological parameter in research study on healthy people.
The *eCelsius Performance Connect* device must not be used for diagnosis or therapeutic uses in patients.

CONTRAINDICATIONS AND WARNINGS

Contraindications:

The *eCelsius Performance Connect system* is contraindicated in a number of situations:

- Individuals under the age of 18 years
- For people weighting less than 40Kg.
- For Pregnant women.
- For people with pacemaker or electrico-medical implant
- For people with or presenting risk of intestinal disorders that can lead to obstruction of the digestive tract, including people suffering gastroparesis.
- For people suffering history of diverticula
- For people who have undergone surgical procedures in the gastrointestinal tract or having such medical history (esophageus, stomach, instestines).
- For people with known swallowing disorders (gag reflex expecially)
- For people who have to undergo strong electromagnetic field during the period of use of the system (MRI in particular)
- For people suffering Chron's disease

Risks:

• The eCelsius Performance capsule has to be swallowed by the subject with a drink 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 route can cause a blockage in the airways requiring extraction.

• Electrocution.

• Burns.

• Intoxication.

• Gastrointestinal disorders.

• Infections.

• Waste of time for the user / Extension of support time.

• Loss of traceability (subject / capsule).

• The loss of communication between the eCelsius Performance capsule and the ePerf Connect device, causing a stop of the subject’s temperature monitoring

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

• 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:

• A “wrong way” when ingesting the eCelsius Performance capsule, which may induce partial or total airway obstruction.

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

• Lesions or injury to the gastrointestinal system requiring surgery.

3. SYSTEM INTRODUCTION

eCelsius Performance capsule

Figure 1: eCelsius Performance capsule

Figure 2: Signaletic bracelet

The capsule *eCelsius Performance* (Fig. 1) is intented to be swallowed, with a glass of water. It has to be woken up by the activator and associated to the ePerf Connect device to monitor core temperature.

The signaletic bracelet (Fig. 2) is worn to the wrist before the ingestion of the first capsule and is removed only after expulsion of the last one. A signaletic bracelet is provided with each capsule delivered. These bracelets are in the same package than the capsules. They allow to inform the caregivers that the subject swallowed a capsule and thus that it is forbiddden to perform an MRI exam.

In case of successive ingestion, the bracelet has to be removed after the expulsion of the last capsule.

THE ACTIVATOR

The activator is intented to activate the eCelsius Performance capsule before a recording session.

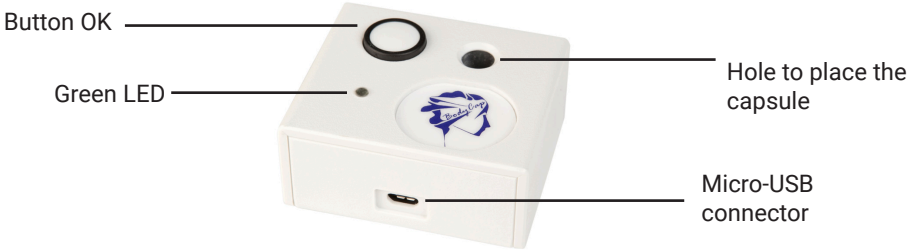


Figure 3: Description of the activator

THE BUTTON

The button “OK” is used to launch the activation process.
The activation process is detailed in ePerf Connect > Main functions > Activate a pill - *page 17.*

WARNING: Modification of the device forbidden

THE LED

A green LED is positioned on the upper side of the activator. This LED is continuously switched on when the activator is powered and flashes throughout the activation process.
When the LED is flashing, the activation process is running. During this period, it is important to not remove the capsule placed in the hole. In order to optimize the activation process, you may rotate the pill into the hole of the activator during the activation process.

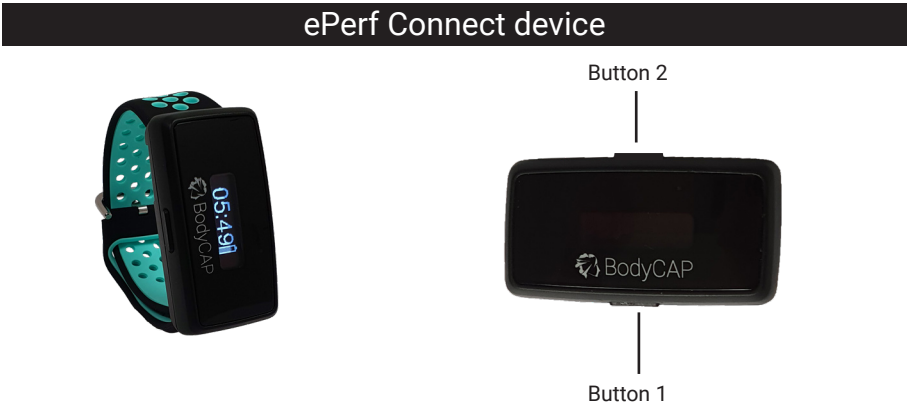


Figure 4: ePerf Connect device

ePerf Connect device is intented to communicate in RF with the e*Celsius Performance* capsule to retrieve the temperature data.

WARNING: Modification of the device forbidden

THE BUTTONS

The device has 2 buttons with differents functionalities.

Button 1 :

Long press:	- Turn on the device if it is switched off - Add a marker if the device is switched on
Short press:	- Switch on or switch off the screen - Confirm a message to come back to the main screen (Time)

Button 2 :

Long press:	-Launch BLE peering process if the device is not yet connected

THE LED

A cyan LED is on the screen side of the device.
When the LED flashes, it indicates an alert status:

- fast flashing: a new alert is ongoing (turn on the screen to identify the type of alert)
- slow flashing: alert is still on but already visualized.

THE BATTERY

Information

The device integrates a Lithium-ion rechargeable batttery. It is strictly **FORBIDDEN** to disassemble the device 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, please plug the power cable of the ePerf Connect device and connect the USB connector to a wall charger or to a USB connector. Few hours are necessary to charge the battery. The battery life of the ePerf Connect device in battery operation is around 5 days in normal use, and 3 days with continuous alert status (Led flashing).

Please do not forget to charge the battery of the device before the end of these 5 days under penalty to lost the communication with the associated capsules.

During the battery charging, the logo “battery” indicates that the device is charging, the symbol of an outlet is displayed, its level is flat (do not indicate the level of battery). Once the cable disconnected, the logo “battery” indicates the level of battery; it represents the real percentage of battery and changes along use.

If the ePerf connect device turn in energy saving mode, you just have to charge the system before turning it on pressing the button 1 (long press). If this state lasts several days, the device will lost the date/time information. You will have to set again the date and time through the ePerf Mobile application; that will take effect from the connexion to the application.

THE CHARGE CABLE

The device has a recharge clip-like connexion. The mettalic contacts of the clip have to be in contact with the 4 metallic contacts of the ePerf Connect device.
The recharge cable is only useful for the recharge.
No USB communication is possible with the ePerf Connect device.

Warning, once the cable is connected to the device:

*** the synchronisation with the capsule is automatically deactivated**
*** capsule activation is impossible**

THE RF COMMUNICATION

In operation, it is **strongly recommanded** to wear the ePerf Connect device to the wrist if possible. Lay down the device should result to a reduction of the RF communication performances with the capsule.
It is also strongly recommanded to be vigilant in the environment with a high metallic constraints (reinforced concrete wall, …) and to **check on the screen of the device that the RF communication with the capsule is not interrupted**.
In case of communication interruption, between the capsule and the device, the data are stored into the capsule internal memory to be synchronized later.
Warning: the synchronization with the capsule is automatically deactivated when the cable is connected.

ePERF CONNECT SCREEN INFORMATION

The informations available on the screen of the device are the following:

Pause mode activated with at least 1 capsule (the symbol disappears when the Pause mode is deactivated)

Loss of communication of more than 5 minutes on at least 1 capsule (the symbol disappears when the communication est restored for all the capsules)

Time view (24h or 12h format)
If the symbol --:-- appears instead of the time, it is necessary to reconnect the device to the ePerf Mobile Application to set again the date and time.
The application should send to the device the time in the 12h or 24h format depending on the parameters set on the ePerf Mobile Application.

Battery level: the gauge provides the indication of the ePerf Connect battery level.
An exclamation mark appears if the level is low and the corresponding alert is triggered.
An outlet symbol appears if the system is on charge.

BLE connexion activated: the ePerf Connect device is connected to an Android device in real time
The symbol disapears if the device is not connected anymore in real time to a BLE device.

Errors messages may appear before the time is displayed. It is recommanded to contact the after sales service if an internal error code is displayed (Int. err.).

Specific messages related to ongoing actions may also appear:

* **Associat. BLE + code:** cf BLE peering process (long press on button 2)
* **BLE associated:** Message displayed if BLE peering has worked
* **Echec BLE:** Message displayed in case of BLE peering failed
* **Add marker:** in case of manual marker add-on (long press bouton 1)
* **Good bye! :** in cas of device turned off (through ePerf Mobile App)
* **Update:** if you update the ePerf Connect device software (through ePerf Mobile App)

e-PERF MOBILE APPLICATION

The ePerf Mobile Application may be installed on an Android smartphone or tablet (cf. § ePerf Mobile installation page 14).

The application is used to:

* Set the ePerf Connect device (Time, Information, Canal etc...)
* Guide the user in the activation process, deactivation process and pause mode
* Collect the real time temperature data and synchronize the data available in the ePerf Connect memory
* Display the data in real time (numerically or graphically)
* Store, Display or export the data collected or from old capsules

4. OPERATING PRINCIPLES

FIRST USE

ePerf Connect DEVICE IMPLEMENTATION

TURN ON ePerf Connect

ePerf Connect device is provided turn off. **To turn on the device, please make a long pression on the button 1 (on the side of the device - BodyCAP side).** This process turn on the screen of the device. If the screen does not turn on, connect the ePerf Connect device to a power source and try again few minutes later.
A LED confirms the pression on the button.
Before use of the ePerf Connect on battery mode, please ensure that the charge level is sufficient. A symbol on the screen of the ePerf Connect device indicates the level of battery.

BATTERY CHARGING

If you intend to use the ePerf Connect device on battery mode, please ensure that the charge level is sufficient. The USB Cable compatible with the device allows to charge the internal battery when it is connected to a power source (main outlet or laptop switch on). The ePerf Connect device charge even if it is turn off.

ePerf Mobile INSTALLATION

The ePerf Mobile Application allows to retrieve and to display the data collected by the *eCelsius Performance Connect system*. To do so, please use an Android device with this minimal configuration:

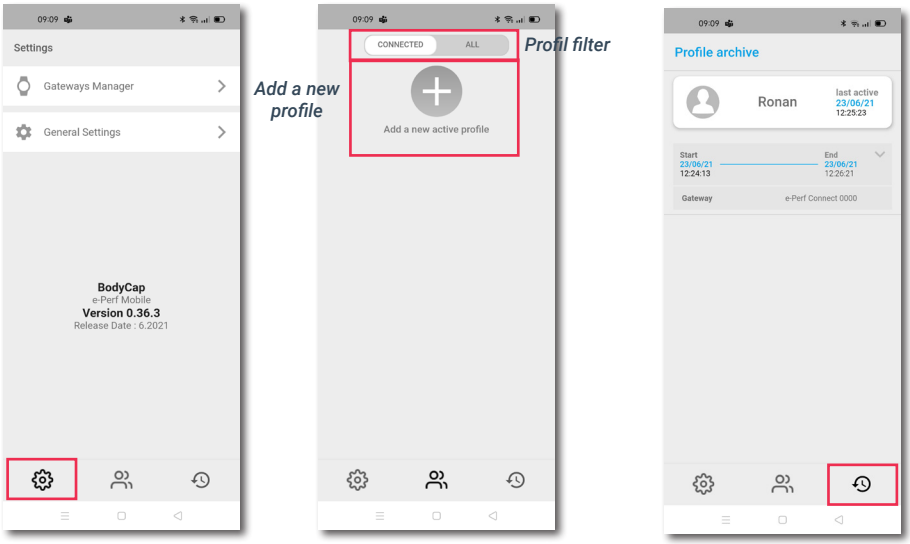
- Android 8 or superior
- Bluetooth Low Energy 4.x or 5.x
- Play Store access
- 100Mo available for installation of the application

To install ePerf Mobile, please:

- Launch the Android Play Store
- Search the **ePerf Mobile** application from BodyCAP Company
- Before to launch ePerf Mobile application, please ensure that the options **Bluetooth & Localization** are activated
- During the first use of the application you have to authorize the application **to access to the position of the device.**

MAIN VIEW OF THE APPLICATION

The application is based on 3 functionalities reprensented at the bottom of the screen with logos.



Display the parameters

Display active profiles
Main page for data visualization

Archives
Old data visualization

Figure 5: Main screen of the ePerf Mobile Application

ePerf Connect & ePerf Mobile peering

To communicate, the ePerf Connect device and the ePerf Mobile application have to be paired. To do so, the application will guide you in the sucessive actions.

1- Creation / profile use: A profile corresponds to a subject that intend to use an ePerf Connect device. You have to create a new profile (+) or to use an existing profile in the available list, allowing to identify the couple ePerf Connect device/subject. For a new profile, you may fill up to 16 characters (figures, letters, lowercase, uppercase, special characters).

Note: 2 profiles can not have the same name to avoid any confusion.

2- **Association of an available ePerf Connect:** You may then select an existing ePerf Connect device or pair a new device to the ePerf Mobile application. To pair a new device, you have to make a long press on the up button (bouton 2) until the message “Associat. BLE” appears on the screen of the ePerf Connect device.
On ePerf Mobile, a green reference “ePerf Connect XX.XX” should appear that indicates the ePerf Connect device is available for a BLE association. Once selected, please validate the peering by entering in ePerf Mobile Application the code displayed on the screen of the ePerf Connect device. The ePerf Connect device will appear in the list of available paired devices. In case of error, please try again the whole process.

Note: the BLE name of the ePerf Connect corresponds to the serial number at the back of the device (SN: XXX).

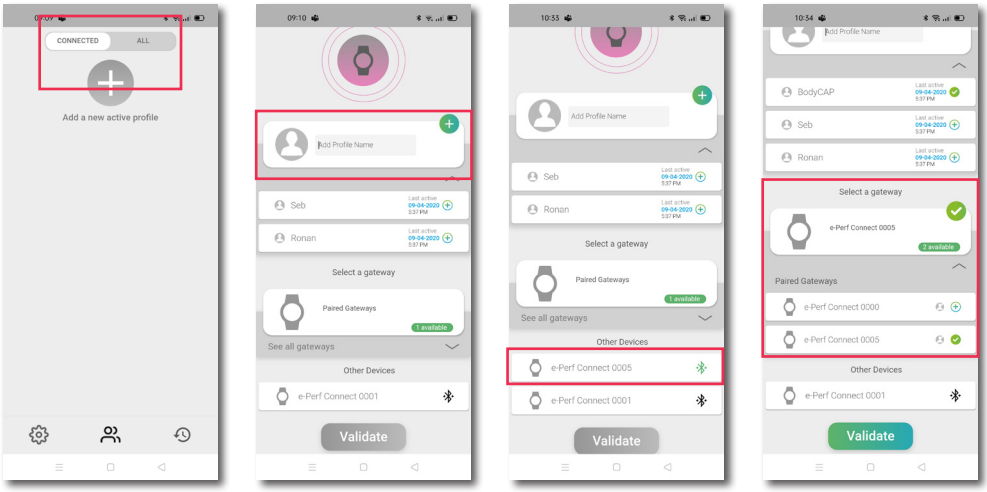
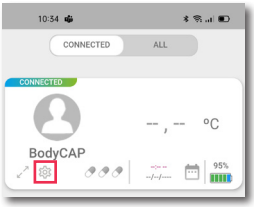


Figure 6: BLE peering ePerf Connect with ePerf Mobile

MAIN FUNCTIONS

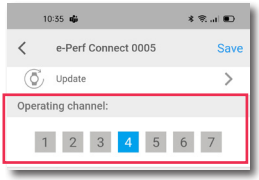
EPERF CONNECT CONFIGURATION ON EPERF MOBILE

Before use of ePerf Connect, it is necessary to configure few parameters.
To do so, please go to the ePerf Connect setting options thanks to the “Nut” symbol on the main screen below the profile concerned.
The parameters available are:



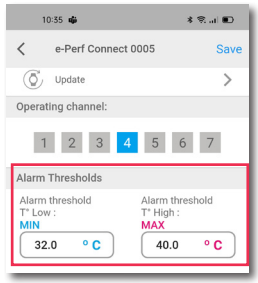
• **The date and time (automatic)**
The date and time of the Android support (Smartphone or tablet) on which the ePerf Mobile Application is installed will be sent to the ePerf Connect device.
This information will allow data timestamp for the coming recording session and is also displayed on the screen of the ePerf Connect device.

• Operational canal



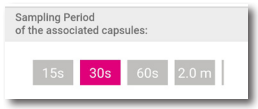
It allows to select the operational canal that aims to be used for the coming recording session. This is an advanced parameter, limiting the interferences between several ePerf Connect device operating in the same environment.
This parameter is not modifiable anymore once capsules are associated to the ePerf Connect device.

• Temperature thresholds setting



The setting of "**Thresholds**" allows to configure the up and down thresholds with which the color of the temperature data displayed changes.
Minimum and maximum temperature thresholds may be used to have a visual alert (color code) on the subject temperature data through the ePerf Mobile App.
The values by default are 36.0°C and 40°C. The minimum and maximum values are limited to 5°C and 45°C. The thresholds values used may be consulted at anytime, on the temperature visualization screen though the ePerf Mobile App.

• Measurement period setting



The measurement periods setting of the capsules allows to configure the frequency of the temperature data measurement for all the caspules associated to the ePerf Connect device.

• Comment addition

The application allows to add a comment to a profile. In the profile settings, select comment and enter a note, up to 64 characters.

Remark: A new setting has to be saved to be applied.

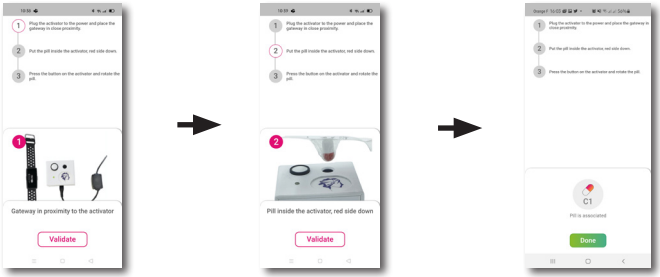
CAPSULE ASSOCIATION

To associate an *eCelsius Performance capsule*, please have:

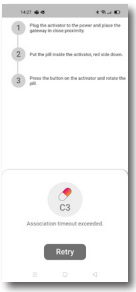
* the activator and its cable
* the ePerf Connect device turned on and with the charge cable removed
* the ePerf Mobile application launched and paired to the ePerf Connect device
* An eCelsius Performance capsule

Note: the application and the ePerf Connect device have to be paired to launch an association.

Please go then to the ePerf Mobile Application and select the profile associated to the ePerf Connect device used. Extend the profile by clicking on the capsules. The detail of each capsule appears then. Select the slot of the capsule to associate by clicking on the corresponding "+" and follow the instructions of the application.



The capsule to associate has to be placed into the hole of the activator, red part down. Once the capsule is activated and associated to the ePerf Connect device, the data collected are displayed on the ePerf Mobile Application.



If the LED of the Activator stops flashing and that the message "Retry" appears on the screen of the ePerf Mobile application, please check the right positioning of the eCelsius Performance capsule in the hole of the Activator and/or slightly rotate the capsule into the hole, click on the "Retry" button of the application to launch again the activation process and press again the button of the activator.

To activate an additional capsule, run again the activation process with a new capsule. It is possible to associate up to 3 capsules in parallel with the same ePerf Connect device.

CAPSULE INGESTION

The *eCelsius Performance* capsule is now ready to be swallowed by the subject, with a glass of water, to measure gastrointestinal temperature.
Please follow the use claims and contraindications introduced on the page 8. The signaletic bracelet (Fig. 2) has to be worn just after capsule ingestion. The ePerf Connect device has to be worn by the subject in order to collect and transmit the temperature to the Application.

If the ePerf Connect device is worn as a wristwatch, the sense is not relevant but to have more comfort to read the time, we may recommand to place the BodyCap logo on the arm side and not on the hand side.

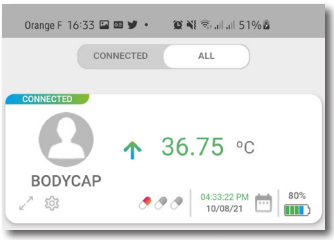
CONSULT TEMPERATURE DATA IN REAL TIME

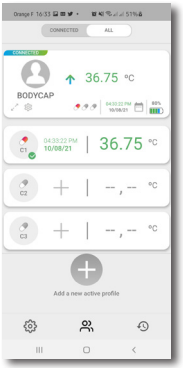
To consult the temperature data collected, the ePerf Connect device and the Android device have to be able to communicate through BLE. Select the profile that you want to visualize.

The information related to the main screen are the following:

- The profile name (*BODYCAP*)
- BLE connexion status active/inactive (*connected*)

- The last data collected (*36.75°C*) with the capsules associated
- The date and time for this data (04:33 PM 10/08/2021)
- The battery level of the ePerf Connect device (80%)
- The number of capsule associated (1 red)=> click on the capsules allows to display the status for each capsule (extend/fold up the status)





The temperature of the profile is the last temperature received for all the capsule associated to the ePerf Connect device. If the detail of the capsules is displayed, each capsule will displayed its own data and its status. The capsule symbol may be accompanied by one of this icon:

Free slot

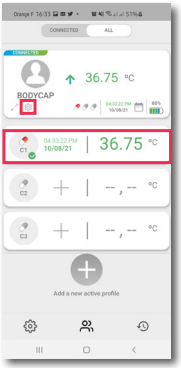
Capsule activated on the slot

Slot busy with a capsule in “Pause” mode

Slot busy with an active capsule but presenting a RF communication issue between the ePerf Connect device and the capsule

CONSULT TEMPERATURE GRAPHICS

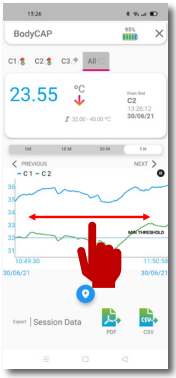
The capsules temperature data may be displayed graphically. To do so, please click on one of the capsule temperature data displayed to visualize the corresponding graph or click on the double arrows below the profile name to display the graphic including all the capsules associated.
It is possible to navigate on the screen by sweeping the finger on the active plage (to the right or to the left)



Display the graph with all the capsule associated to the ePerf Connect device (C1/C2/C3)

Display the graph only for C1

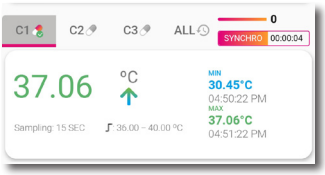
Graphic exemple for the pill C1



Graphic exemple for all the pills associated to the ePerf Connect device (Pill C1 + C2

On the upper side of the screen, you may visualize several information related to each capsule:

- The minimum temperature value for the capsule (since the last reset)
- The maximum temperature value for the capsule (since the last reset)
- The number of missing data between the capsule and the ePerf Connect device
- The time elapse (hh:mm:ss) since the last real time data communication
- The configurable temperature thresholds are also reminded.



The temperature displayed respect a color code allowing to immediately identify the current condition of the subject:

- Red: temperature in real time above the high threshold
- Green: temperature in real time between the high and down thresholds
- Blue: temperature in real time below the high threshold

AUTOMATIC SYNCHRONIZATION OF THE DATA STORED IN THE CAPSULE MEMORY

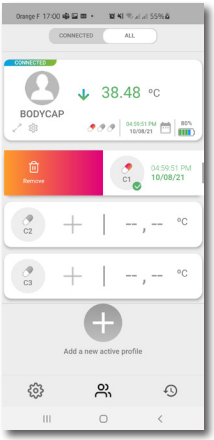
The ePerf Connect device, worn by the subject, will automatically seek to synchronize the data not received in real time. If the ePerf Connect device has been put away from the subject, it will synchronized the data once it will come back close to the capsules concerned. The numeric indication displayed on the ePerf Mobile Application should alert of any issue regarding the communication between the capsule and the ePerf Connect device.

CAPSULE END OF LIFE VISUALIZATION

When a capsule reaches its end of life, an alert is triggered on the ePerf Connect device (LED flashing) and the information is then sent to the ePerf Mobile Application as a notification.
The capsule will stopped around 500 measurements after the notification appears. A marker will be automatically added in the raw data file.

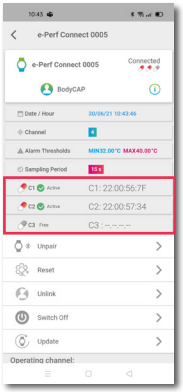
CAPSULE DEASSOCIATION

When the use of the capsule is over, (capsules released, end of the monitoring period, ...) the desassociation with the ePerf Connect device is performed through the ePerf Mobile Application. On the profile concerned, select the capsule to deassociate, put your finger on the slot and swipe your finger on the right. Click then on the red trash icon to finalize the operation.
To ensure the sucess of the operation, the capsule and the ePerf Connect device have to be close each other to be able to communicate.



An acknowledge has to be confirmed before the deassociation of the capsule. This is a definitive action, the capsule disappears from the ePerf Connect device data base. The corresponding capsule data file is archived in the ePerf Mobile application.

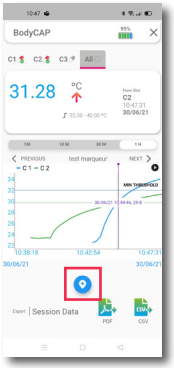
SECONDARY FUNCTIONS



ID CAPSULES VISUALIZATION

It is possible to access to the unique ID of the capsule going on ePerf Mobile application and then access to the ePerf Connect parameters (“Nut” logo at the bottom of the android device).
The capsule ID are in an hexadecimal format: XX.XX.XX.XX in wich X may be from 0 to 9 and from A to F.
Once the capsule is deactivaed, it disappears of this list and is transfered to the Archives (Cf. page 22).

MARKERS



The system give the opportunity to record specific events through automatic or manual markers.
The automatic markers are triggered and recorded once the condition observed. They may thus appeared *a posteriori* in case of data synchronization.

The manual markers may be directly added:
- by pushing the button 1 of the ePerf Connect device (long press)
- through the ePerf Mobile application by double-clicking on the graph of the capsule concerned.
- by pressing the marker button

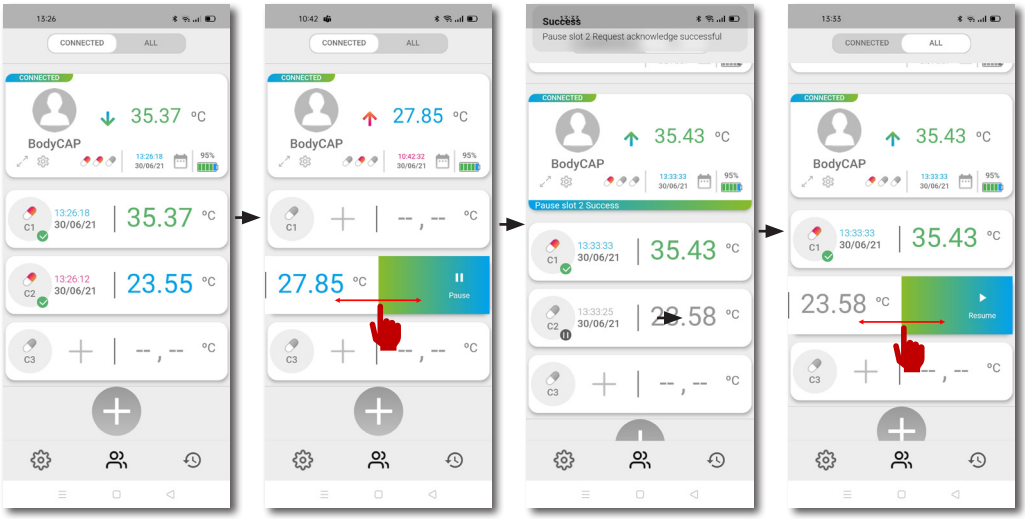
The markers are then diplayed ont the graphic through a vertical line and in the raw data file after data export.The buttons “Next” and “Previous” on the graph allow to navigate from one marker to another.

Marker button	Auto	Signification
User marker	no	Marker added through a long press on button 1 or through the ePerf Mobille App
Power ON	yes	ePerf Connect turned on
Power OFF	yes	ePerf Connect volontary turned off (through the ePerf Mobile App)
Critical battery	yes	The ePerf Connect is turned off due to a too low battery level
Pause activated (1/2/3)	yes	A capsule (1/2/3) is put in Pause mode
Pause deactivated (1/2/3)	yes	A capsule (1/2/3) previsously in Pause mode is “on” again
Date and time update	yes	Date and time updated through the ePerf Mobile App
Capsule activated (1/2/3)	yes	A capsule (1/2/3) is associated
Capsule deactivated (1/2/3)	yes	A capsule (1/2/3) is deactivated
Internal alert XX	yes	The ePerf Connect device triggered a technical alert that requires an intervention of the support service team
Slot memory 1/2/3 full	yes	Memory of the ePerf Connect device full
Measurement period	yes	New measurement period applied

CAPSULE PAUSE MODE

It is possible that one or several capsules have been activated at the same time to cover consecutive ingestion. It exists, for this case, a specific mode that consists to put the capsule that is not of immediate interest in Pause mode. The temperature data collected by the capsule will thus not be retrieved and stored into the ePerf Connect device. Once this mode will be deactivated, the ePerf Connect device will communicate again with the capsule concerned to retrieve the last 2000 data stored into the capsule memory and to restore a classic real time communication.

To activate or deactive the Pause mode, you just have to select an active capsule, to click on it and to swipe your finger to the left. That will make appear the option “Activate the Pause” if the capsule is active or “Deactivate the Pause” is the capsule is already in Pause mode.



Attention, the Pause mode may lead to data loss if the capsule is swallowed and the Pause mode is not removed. It is strongly recommanded to check on the ePerf Mobile application that you have access to the real time data before ingestion.
The Pause mode may also allow to save battery of the ePerf Connect device (cf p23)

OLD CAPSULE VISUALIZATION - ARCHIVES

A deactivated capsule will automatically be placed in the “Archives’ menu of the Application’, in the corresponding profile folder.
A capsule is always linked to the profile with which it has been activated. It will be stored under the name of the profile it was associated with and then sorted by session (Profile/ePerf Connect device), activation date and serial number.
It is possible to select, in Archive menu, the capsule(s) of interest for:

* view again the temperature data through the application (Max 3 capsules),
* export them in CSV or PDF,
* erase definitively the corresponding data from the Android device memory.

The selection of several capsules can only be made if all the capsules come from the same session (profile + ePerf Connect device).
The data are stored in the Application as long as the user does not delete them.

DATA EXPORTATION

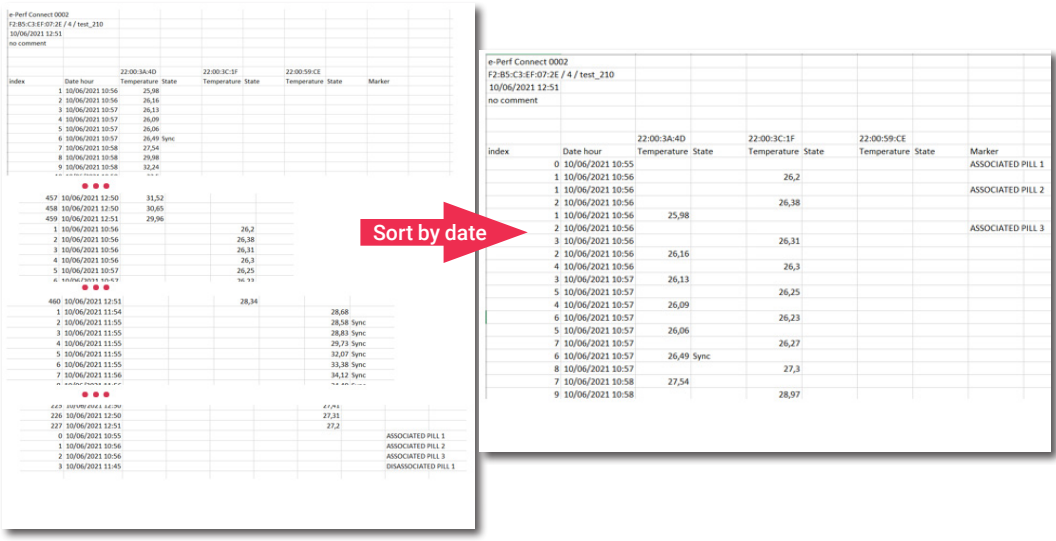
It is possible to export the data:

- **During acquisition:** simply go to the graphic visualization screen of the capsule concerned or the "All" tab of the application and click on the export button.

-**A posteriori in the archive area:** in the archives, select the capsules of interest and click on the export button.

The possible data export formats are PDF (full graphical representation of temperature data) or CSV (raw data). The file is stored in the Android device memory (documents / profile) and available for transfer by email.

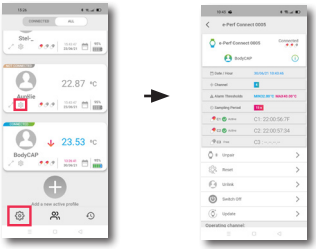
The CSV file presents the data of each capsule in different columns but the date / time column is common. The data are initially sorted by capsules. However, it is possible to sort them in chronological order. To do so, please select all the dates of the capsules concerned, then "Sort by date" and "Extend the selection" to the columns of data.



ePerf Connect BATTERY MANAGEMENT OPTIMIZATION

The ePerf Connect device is optimized for an RF communication with 1 to 3 capsules simultaneously. However, if a capsule is removed or stay away from the ePerf Connect device (capsule not swallowed for instance), a visual alert (LED) will trigger and the ePerf Connect device will try to restore the RF communication with the capsule(s) concerned by activating more regularly the radio functionnalities.
That is why, it is recommended to deactivate a capsule for which the removal has been observed and to put in "Pause mode" a capsule that has not been yet swallowed. That will allow to limit the power consumption and improve the automy of the ePerf Connect device.

END OF MONITORING - APPLICATION



At the end of the monitoring period with ePerf Mobile and once your capsules are deactivated from the profile, several options are available to properly close your session. Please go to the device settings:

Separate the profile and the device:

This action can be performed:

- at the end of the monitoring period to archive the data and to allow the device to be used again with another profile.
- in use if you no longer need to track the device and to allow to be tracked by another mobile object.

Example of use: The user of the Android device no longer intends to track the ePerf Connect device but this one continues to function (it is tracked by another Android device).

Dissociate the mobile object and the device (Bluetooth):

This action will remove the automatic BLE connexion with the device. The device will no longer appear in the list of available devices. You will have to go through the pairing process again to be able to reset communication with the device.

Example of use: The device disappears completely from the user's environment. This one will no longer follow this device in the future (rental return).

Reset the device:

Resetting the device will couple profile/device separation and deletion of data and markers from the Android device memory.
This action is only possible if the device is connected to the application and no capsule is still active.

Example of use: The profile/device measurement session has ended. ePerf Connect data are deleted to return the system to shelf mode.

ePERF CONNECT DEVICE TURN OFF

It is possible to turn off the ePerf Connect device using the ePerf Mobile application. To do so, please go to the device settings (see paragraph above) and press the corresponding button.
The device has to be connected to the application. Once the command is sent, the device displays a shutdown message and will shut down after a few seconds.

ePERF CONNECT DEVICE UPDATE

It is possible to turn off the ePerf Connect device using the ePerf Mobile application. To do so, please go to the device settings (see paragraph above) and press the corresponding button.The device has to be connected to the application. Once the command is sent, the device displays a shutdown message and will shut down after a few seconds. Please finally select “Update the device” and follow the steps.

eCELSIUS PERFORMANCE CONNECT SYSTEM ALERTS SYSTEM VISUALIZATION

The ePerf Connect device shows 5 alert categories.

The triggering and displaying conditions are summarized in the table below.

Function managed	Alert condition	Delay related to the Alert	Alert mode for ePerf Connect	Alert mode for ePerf Mobile
Capsule battery	Remaining capsule autonomy should allow around 500 measurements maximum	30 secondes maximum in case of real time communication	Flashing LED	Notification & display in the ePerf connect Parameters
ePerf Connect battery	ePerf Connect battery is low or critical	Immediate	Flashing LED and symbol on the ePerf Connect screen	Notification in case of low battery, % of battery displayed on the general screen of each ePerf Connect connected
Communication loss between capsule and ePerf Connect	ePerf Connect device does not receive anymore the real tom data from the capsule since 5min.	30 periods	Flashing LED and symbol on the screen of ePerf Connect device	Notification and number of mission data displayed. Symbol on the capsule status
Full memory	The ePerf Connect device does not enough memory to ensure data storage	Immediate	Flashing LED	Notification & info displayed in the ePerf Connect device parameters
Internal error alert	The ePerf connect device is faulty	Immédiate, the usability of the device is limited	Flashing LED + message displayed on the screen	

Tableau 1: Alert system

5. TECHNICAL DATA

eCELSIUS PERFORMANCE CAPSULE CHARACTERISTICS

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

Temperature range: 25°C - 45°C

Accuracy of temperature sensor: ± 0.1°C in the range 36-41°C (physiologic range), ± 0.13°C out of the physiologic range

Température resolution: 0.01°C

Capsule memory capacity: the 2000 last temeprature values are stored into the capsule internal memory

Maximal transmission distance with ePerf Connect: around 1 to 3m (environment depending)

Power: Autonomous system inclding 4 zinc-oxide batteries

Autonomy: 20 days for a 30sec measurement period

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 pill. The shelf life of the eCelsius Performance capsule is validated for a use up to 24 months after this date. Beyond that date, device performances and autonomy are not guaranteed.

ENVIRONMENTAL CONDITIONS

In operation

- Temperatures in the range 25-45°C
- Ingress protection (IP): X8 (Material supportanting prolonged immersion)

Storage and/or transportation

- Humidity between 30 and 80% of relative humidity
- Atmospheric pressure between 700hPa and 1060hPa
- Ambiant temperature between 5 and 35°C
- Avoid sprayed water
- Avoid exposure to sunlight

ACTIVATOR CHARACTERISTICS

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

Power: 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 serie of electromagnetic pulses

Life duration: 2 years

Means to disconnect from the main supply: Disconnect the power cable

ENVIRONMENTAL CONDITIONS

In operation

- Humidity between 30 and 80% HR
- pression atmosphérique comprise entre 700hPa et 1060hPa
- température ambiante comprise entre 5 et 40°C

Storage and/or transportation

- Humidity between 30 and 80% HR
- Atmospheric pressure between 700hPa and 1060hPa
- Ambiant temperature between 0 and 45°C
- Avoid sprayed water
- Avoid unlight exposure

ePerf Connect CHARACTERISTICS

Dimensions: Lenght: 52 mm
Width: 25 mm
Height: 15 mm
Weight: ≈ 33g (Device & bracelet)

Screen: 128 x 32 pixels

Data storage : 152 916 mesures par capsule activée

Power: Lithium-ion battery rechargeable through a main supply adapter (100~240 V) and a dedicated cable provided with the device.

Time to charge: ≈ 3 h.

Autonomy: ≈ 5j

Communication frequency:

ISM band 433MHz - 434MHz.

Bluetooth Low Energy 4.x or 5.x

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

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

ENVIRONMENTAL CONDITIONS

In operation

- Humidity between 30 and 80% of relative humidity
- Atmospheric pressure between 800hPa and 1060hPa
- Ambiant temperature between 5 and 40°C

Storage and/or transportation

- Humidity between 30 and 80% of relative humidity
- Atmospheric pressure between 700hPa and 1060hPa
- Ambiant temperature between 5 and 35°C
- Avoid sunlight exposure
- Avoid sprayed water

	Storage/Transport			Use		
	Temp °C	Humidity %	Pressure HPa	Temp °C	Humidity %	Pressure HPa
eCP capsules - P022	5 - 35°C	30% - 80%	700 - 1060hPa	25 - 45°C	100 %	700 - 1060hPa
ePerf Connect device- P110	5 - 35°C	30% - 80%	700 - 1060hPa	5 - 40°C	15% - 90%	700 - 1060hPa
Activator - P030	0 - 45°C	30% - 80%	700 - 1060hPa	5 - 40°C	30% - 80%	700 - 1060hPa
System P063	5 - 35°C	30% - 80%	700 - 1060hPa	5 - 40°C	30% - 80%	700 - 1060hPa

6. FAILURES GUIDE

Issue	Probable cause	Solution
ePerf Connect does not turn on	The battery of the ePerf Connect is discharged	Connect the ePerf Connect to a power source via the dedicated cable
	The ePerf Connect device is at the end-of-life	The manufacturing date is on the label.
	The ePerf Connect may require maintenance	Please ship back the device to your distributor or the manufacturer
The LED on the activator does not turn on.	L 'activateur 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 2 years
	The activator may required maintenance	Please ship back the monitor to your distributor or the manufacturer
The RF communication ePerf Connect - capsule does not work	The distance is too important	Please enure that the capsule is within the communication range of the ePerf Connect, check the time/date of the last data received
	The pill is not associated	Follow carrefully the activation procedure.If the association is difficult, check that the pill is within range of the ePerf Connect or turn the pill into the activator hole. ePerf Mobile shows the number of capsules associated
Automatic synchronization does not work	The ePerf Connect is on charge	Unplug the cable from the ePerf Connect and wear the device to the wrist. Please ensure that the capsule is close enough to the device, and check the date & time of the last received data on the ePerf Mobile
Inappropriate autonomy of the ePerf Connect	Battery not charged	Plug the ePerf Connect and wait few minutes before to try to turn it on again
	Battery is at the end-of-life	Discard the device with a certified organism.
Innappropriate capsule autonomy	Used batteries	Check the date on the blister
The communication between ePerf Connect - ePerf Mobile does not work	Bluetooth of the ePerf Connect device already connected to another Android device	The screen of the ePerf Connect display a BLE logo indicating the active connexion
	The ePerf Connect device is not paired to the Android device	Please follow the BLE peering process
The Cyan LED does not swith on or does not flash	Faulty power supply	Please check the power supply or connect the ePerf Connect with the dedicated cable
Association of the pill non-functional	3 pills maximum per ePerf Connect	Please check that a ePerf Connect slot is free

7. SYMBOLS

« Do not reuse »

« Batch code »

« Catalog reference »

« Manufacturer address ». The symbol is associated to the year of the manufacturing date for the ePerf Connect device and Activator (format AAAA), and to the month and the year of the capsule manufacturing (format AAAA-MM)

« Storage temperature limits »

« Keep dry »

« Do not use if the package is damaged »

« Protection indice » : the capsule resist to a prolonged immersion

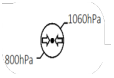
« Device CE marked »

« Contra indicated for pregnant women »

« Contain phtalates »

« Do not put the *eCelsius Performance Connect* device with the municipal waste, cf “Security warnings”

« Level of humidity between 30% and 80% »



« Amospheric pressure between 800hPa and 1060hPa »

« Dot not expose to sunlight »

« Follow the instructions of use »

« Compliant with FCC regulation »

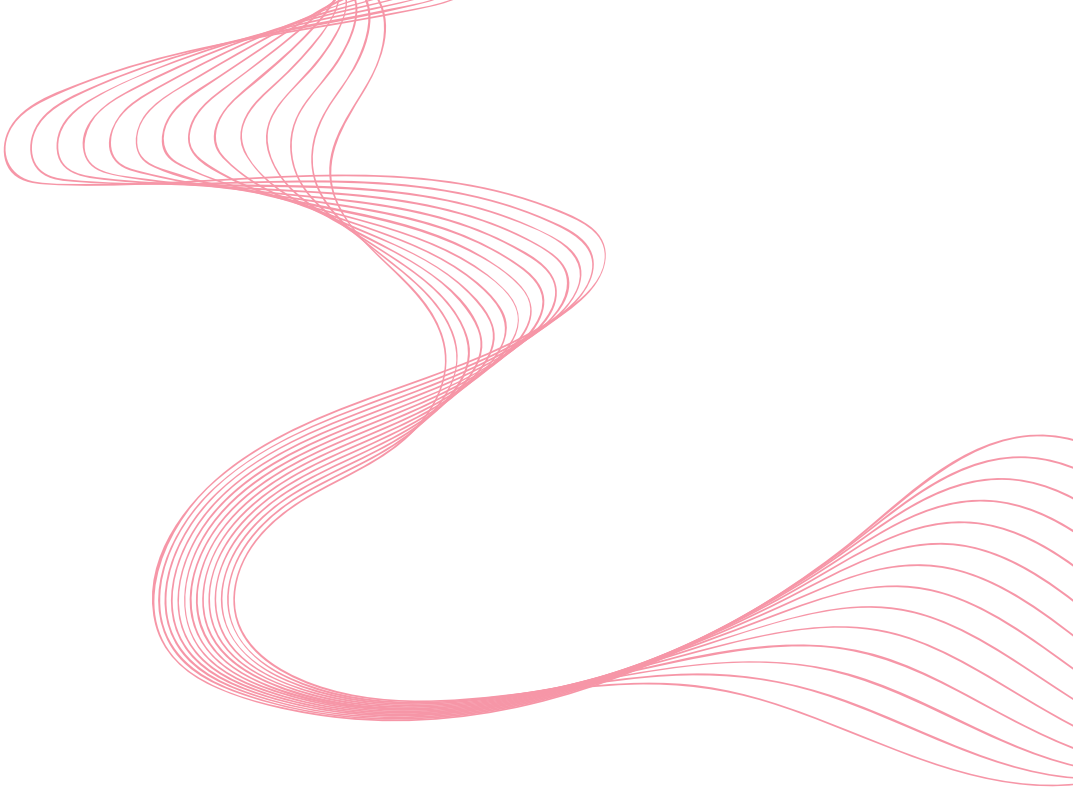
« Forbidden under 18 years old »

« Electronic user guide »

« Non-ionising electromagnetic radiation »

« Keep out of reach for children »

« Serial number »



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

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