e Celsius

Medical Connect System

P073

MEASURING SYSTEM
RELIABLE AND ACCURATE CONTINUOUS
GASTROINTESTINAL CORE TEMPERATURE
RECORDING BY TELEMETRY

USER MANUAL

Year of affixing the CE mark: XXXX

CE nnnn

Please read this manual carefully before using the medical device as it contains important information for you.

BodyCAP
Your e-health partner

TABLE OF CONTENTS

To our customers,

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

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

This system (Ref: P073-M) is composed of:

- An activator (Ref P030-M) and its power cable: allows to activate the capsules and to put them in operation before ingestion
- A Gateway e-Med Connect watch (Ref P110-M) and its charging cable: allows the collection of temperature data from 1 to 3 capsules simultaneously.
- An Android application e-Celsius Mobile (Ref P111-M) for Android Smartphone or Tablet (available on the Play Store): allows you to set up the watch and view the data recorded by the watch.
- A USB key (including the user manual)
- One (or more) e-Celsius Medical capsule(s) (Ref P022-M) delivered sterile for single use for central temperature measurement.
- An identification bracelet provided for each delivered capsule.

Purpose and use cases:

e-Celsius® Medical Connect System is intended for continuous, reliable and accurate measurement of core temperature via the gastrointestinal tract in humans for diagnostic or therapeutic monitoring purposes.

Declaration of conformity:

BodyCAP declares that the e-Celsius® Medical Connect System complies with the following current guidelines and regulations:

- 2017/745, relating to medical devices,

- 2011/65/EU, on the restriction of the use of certain hazardous substances in electrical and electronic equipment

- 2014/53/EU on the placing of radio equipment on the market

- 1907/2006 concerning the registration, evaluation and authorization of chemicals, and the restrictions applicable to these substances (REACH)

- 207/2012 on electronic instructions for use of medical devices.

WARNING TO USERS IN THE UNITED STATES

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

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

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

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

NO UNAUTHORIZED MODIFICATIONS
47 CFR Section 15.21

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

This device complies with FCC RF radiation exposure limits set forth for general population (uncontrolled exposure). This device must be installed to provide a separation distance of at least 20cm from all persons and must not be collocated or operating in conjunction with any other antenna or transmitter.

Warning to users in the CANADA

This device complies with Industry Canada licence-exempt RSS standard(s). Operation is subject to the following two conditions:
(1) this device may not cause interference, and (2) this device must accept any interference, including interference that may cause undesired operation of the device.
Under Industry Canada regulations, this radio transmitter may only operate using an antenna of a type and maximum (or lesser) gain approved for the transmitter by Industry Canada. To reduce potential radio interference to other users, the antenna type and its gain should be so chosen that the equivalent isotropically radiated power (e.i.r.p.) is not more than that necessary for successful communication.

This device complies with Industry Canada RF radiation exposure limits set forth for general population (uncontrolled exposure). This device must be installed to provide a separation distance of at least 20cm from all persons and must not be collocated or operating in conjunction with any other antenna or transmitter.

Attention pour les utilisateurs au CANADA

Le présent appareil est conforme aux CNR d'Industrie Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes : (1) il ne doit pas produire de brouillage, et (2) l'utilisateur du dispositif doit être prêt à accepter tout brouillage radioélectrique reçu, même si ce brouillage est susceptible de compromettre le fonctionnement du dispositif.
Conformément à la réglementation d'Industrie Canada, le présent émetteur radio peut fonctionner avec une antenne d'un type et d'un gain maximal (ou inférieur) approuvé pour l'émetteur par Industrie Canada.
Dans le but de réduire les risques de brouillage radioélectrique à l'intention d'autres utilisateurs, il faut choisir le type d'antenne et son gain de sorte que la puissance isotrope rayonnée équivalente (p.i.r.e.) ne dépasse pas l'intensité nécessaire à l'établissement d'une communication satisfaisante.

Le présent appareil est conforme aux niveaux limites d'exigences d'exposition RF aux personnes définies par Industrie Canada. Cet appareil doit être installé afin d'offrir une distance de séparation d'au moins 20cm avec l'utilisateur, et ne doit pas être installé à proximité ou être utilisé en conjonction avec une autre antenne ou un autre émetteur.

1. PRECAUTIONS FOR USE

The following safety instructions will ensure proper operation and optimal use of the *e-Celsius® Medical Connect System*. For questions not answered in the manual, please contact your distributor or the manufacturer (see the contact information at the end of the document).

Since the *e-Celsius®* Medical capsule is not claimed to be MRI compatible, it is imperative that the patient ingesting the capsule does not undergo any MRI examination. The person who has ingested a capsule should wear the wristband provided with the *e-Celsius® Medical* system, indicating that he or she is wearing a system that is not compatible with exposure to strong magnetic fields.

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

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

Do not touch or press the screen of the e-Med Connect watch.

Do not use the capsule if the packaging is damaged.

Do not expose activator to rain or moisture, keep away from liquids and splashing water.

To reduce the risk of fire, electric shock, and interference, use only the cables supplied with the system.

Do not use during a gas leak.

It is strongly recommended to pay attention to the location of the cables, so that they are not in a passage and do not constitute a fall hazard.

Be careful not to shake or bump the e-Med Connect watch and activator. This may affect their normal operation.

Do not place the e-Med Connect watch or activator in the middle of small objects that could scratch it or get inside.

Do not use the device if it is damaged. Do not use damaged cables.

Connect only units that have been specified as part of the electromedical system or compatible with the electromedical system.

The complete e-Celsius Medical system should be kept out of reach of children. Particular attention should be paid to the capsules and cables to prevent strangulation or choking.

Do not throw into fire.

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

Do not dispose of the device with your municipal waste. The e-Med Connect watch and activator have been designed to a reuse and a suitable recycling of some components. The crossed-out wheeled bin symbol indicates that the product (electrical, electronic and battery equipment) should not be placed with municipal waste. Check local regulations for disposal of electronic products.

Environmental conditions

The environmental conditions of transport, storage and use are summarized in the table below.

	Storage/Transport			Use		
	Temp °C	**Humidity %**	**Pressure HPa**	**Temp °C**	**Humidity %**	**Pressure HPa**
P022 Capsules	5-35°C	30%-80%	700-1060hPa	25-45°C	100	700-1060hPa
P110 Watch	5-35°C	30%-80%	700-1060hPa	5-40°C	15% - 90%	700-1060hPa
P030 Activator	0-45°C	30%-80%	700-1060hPa	5-40°C	30%-80%	700-1060hPa
P073 System	5-35°C	30%-80%	700-1060hPa	5-40°C	30%-80%	700-1060hPa

Table 1: Environmental conditions

- It is also recommended to avoid splashing water on the blister pack and exposure to sunlight. Storage at lower or higher temperatures may affect the operating time and performance of the system.

- The shelf life of the *e-Celsius® Medical* capsule is indicated by an expiration date on the blister pack. After this date, the sterility, performance and autonomy of the device are no longer guaranteed.

- The device is designed to operate in an altitude range of 0 to 2000m.

Cleaning

The capsule is delivered sterile (ethylene oxide) in an individual packaging. It is not designed to be cleaned with hydroalcoholic solutions.

The *e-Celsius capsule® Medical* must not be autoclaved under any circumstances, otherwise it will be permanently damaged.

The other elements of the system (Watch & Activator) can be cleaned with a hydro-alcoholic gel wipe.

European regulation REACH 1907/2006/EC

In response to the requirement of Article 33.1 of the REACH Regulation, we inform users of the presence of the SVHC substance «Octyl Tin Stabiliser» in a concentration greater than 0.1% mass / mass in the capsules. This substance is included in the candidate list published on June 15, 2015 under the CAS number 15571-58-1
(http://echa.europa.eu/fr/candidate-list-table).

The *e-Celsius® Medical Connect System* must be used in hospitals, clinics and exclusively by health care personnel (doctors, nurses...). This includes HAD, EHPAD, home health...

Presence of phthalates

Based on the toxicological evaluation, we inform users that there is an acceptable level of recovered phthalate without toxicological risk to the individual in the e-Celsius® Medical capsule.

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

Presence of Bisphenol A: Material of the e-Med Connect watch case (ABS-PC)

2. CLAIMS FOR USE AND CONTRAINDICATIONS

CLAIMS OF USE

The *e-Celsius® Medical Connect System* is an electronic device for the continuous, reliable and accurate measurement of core temperature via the gastrointestinal tract in humans for diagnostic or therapeutic monitoring purposes.
The device is designed for people who need continuous, reliable and accurate temperature monitoring.

The system incorporates a sensor with an accuracy of absolute temperature value ±0.1°C over the physiological range. The resolution of the temperature is given as 0.01°C.

The device is designed to be managed by the nursing staff (nurses or doctors). The patient is not responsible for the actions to be performed. The e-Celsius Medical capsule is for single use only. The nursing staff is responsible for the implementation of the device, its installation and its proper functioning.

CONTRAINDICATIONS AND WARNINGS

Contraindications:

The e-Celsius® Medical Connect System is contraindicated in a number of situations:
- Minors under the age of 18
- People weighing less than 40 kg
- Pregnant women
- People with a pacemaker or an electro-medical implant
- People with or at risk of intestinal disorders that may lead to obstruction of the digestive tract, including people with gastroparesis
- People with a history of diverticulitis
- For individuals with a history of gastrointestinal pathology or surgery, the capsule should only be used when prescribed by a physician after an assessment of the risk of bowel obstruction
- People with swallowing disorders, including disorders of the gag reflex, leading to the risk of a false route
- People who must be subjected to a strong electromagnetic field during the use of the system (MRI in particular)

People who need undergoing surgery on the gastrointestinal tract (esophagus, stomach, intestine) during the intended use of the device
- People with Crohn's disease
- People who are unconscious before ingesting the capsule

Warnings

Since the e-capsule Celsius Medical must be ingested by the patient, special attention should be paid to, as described below:

- The *e-Celsius® Medical* capsule (Fig.1) is intended to be ingested with a glass of water to measure the temperature. It is delivered in deep sleep mode. It must be activated by the activator and associated with a watch to operate. The installation of the signaling bracelet (Fig.2) is followed by the ingestion of the capsule.
- Ingestion of the *e-Celsius® Medical* capsule involves contact of the PVC capsule shell with the mucous membranes of the gastrointestinal tract, for an average duration of 2 +/-1.5 days, which may be up to 6 days depending on individual gastrointestinal motility characteristics. After expulsion of the *e-Celsius® Medical* capsule, the temperature monitoring can be continued by the consecutive ingestion of new capsules up to a limit of 6 capsules. If the capsule is not expelled after this period, please refer to paragraph 5. End of monitoring.
- The use of the capsule in people prone to gastrointestinal disorders, nausea and vomiting implies an increased monitoring of the persons.
- As the measurement is taken within the digestive system, the measured data are likely to be influenced by certain factors, in particular the artefact of food or water intake (hot or cold) during the first few hours following ingestion of the capsule. The impact is limited to the first 3 hours following ingestion of the *e-Celsius® Medical* capsule and is characterized by a significant, non-physiological drop in the temperature values collected. It is recommended that during the first 3 hours following ingestion of the capsule, in order to guarantee the reliability of the data, you limit the intake of water or food at room temperature.
- The capsule is delivered sterile, must be activated through the blister to maintain its sterile condition, and is not intended to be disinfected or cleaned after use on the person. Dispose of the capsule after use by the person. Under no circumstances should the capsule be autoclaved as this may cause permanent damage.
- The device is intended for single use only, any reuse of the capsule is likely to induce an infectious risk.
- In the case of the use of the system in obese persons, communication difficulties between the capsule and the watch may be encountered due to the system's operating mode. As the communication between the capsule and the watch is carried out in radio frequency at 433 Mhz - 434 MHz, the signal strength is attenuated by the presence of fatty tissue. Thus, the communication between the capsule and the watch could be reduced or even impossible.
- After use, precautions should be taken to ensure safe disposal of the capsule. Each practitioner should ensure that the requirements of local and national regulations for the disposal of contaminated health care waste are met.

RISKS AND COMPLICATIONS

Risks

- Since the *e-Celsius® Medical* capsule must be ingested with a glass of water, particular attention must be paid to the risk of a false route, especially for people who have or have had swallowing problems. This phenomenon of false route can cause a blockage in the airways requiring an extraction.
- Electrocution
- Burns
- Intoxication
- Gastrointestinal disorders
- Infections
- Loss of time for the user / Increase in the time of care

- Loss of traceability (patient/capsule)
- Loss of sterility of the device induces an infectious risk.
- Loss of communication between the *e-Celsius® Medical* capsule and the e-Med Connect receiver watch, resulting in the interruption of the patient's temperature monitoring.
- The collection of temperature data affected by the ingestion of cold or hot beverages, which can lead to misinterpretation of the data.
- Exposure to a strong electromagnetic field (MRI), which may induce a risk of mobilization with possible trauma to the digestive tract, or a disturbance of the capsule electronics and risk of erroneous data

Possible complications

- A false route at the moment of ingestion of the *e-Celsius® Medical* capsule, which can lead to partial or total obstruction of the airways.
- Blockage of the capsule within the digestive tract, which may require endoscopic or surgical recovery.
- Injury or damage to the gastrointestinal tract requiring surgery.

FUNCTIONS OF THE e-Celsius Medical System

The mode of action of the device is summarized below:

N°	Mode of action
1	Setting up e-Med Connect using the Android application e-Celsius Mobile
2	Pairing the e-Celsius® Medical capsule with an e-Med Connect watch via an activator and using the e-Celsius Mobile application
3	The installation of the bracelet on the person's wrist
4	The ingestion of the e-Celsius® Medical capsule
5	Data transmission from the e-Celsius® Medical capsule to the e-Med Connect watch
6	Transfer and display of data collected from the watch to the e-Celsius Mobile application

Table 2 : Mode of action

The system is based on the principles listed in Table 3.

N°	Operating principle
1	The e-Celsius® Medical capsule is activated by an electromagnetic pulse emitted by the activator
2	The e-Celsius® Medical capsule measures temperature using a Silicon Bandgap temperature sensor
3	The e-Celsius® Medical capsule automatically stores the last 2,000 collected data
4	The communication between the e-Celsius® Medical capsule and the e-Med Connect watch is realized by radio frequency on the 433MHz band via a proprietary protocol
5	The e-Med Connect watch receives and stores real time data at a period of 30s
6	The e-Med Connect watch automatically re-requests any unreceived data from the e-Celsius® Medical capsule in real time
7	Viewing data on the e-Celsius® Mobile application
8	Data export to CSV and PDF formats via the e-Celsius® Mobile application
9	Physiological alarm function for data exceeding high or low temperature thresholds.

Table 3: Operating principle

Frequently used functions are listed in Table 4.

Frequently used functions	Primary (P) / Secondary (S)
Installation of the e-Celsius Mobile application on the smartphone or Android tablet	P
Turning on the e-Med Connect watch	P
Creation of a profile to associate the watch data with this profile	P
Pairing of the e-Med Connect watch by BLE with the support of e-Celsius Mobile (smartphone or tablet)	P
Setting the time and date of the e-Med Connect watch via the e-Celsius application® Mobile	P
Setting of alarms (thresholds) by the e-Celsius software® Mobile then transmitted to the e-Med connect watch	P
Setting the RF channel used by the e-Med Connect watch	S
Activation of the e-Celsius capsule® Medical	P
Ingestion of the e-Celsius Medical capsule with a glass of water	P
Temperature measurement with the e-Celsius capsule® Medical every 30s.	P
Storage of the last 2000 data in the e-Celsius capsule® Medical	P
Automatic transfer of real time data at a period of 30s by 433MHz RF from the e-Celsius Medical capsule to the e-Med Connect watch	P
Automatic synchronization of data from the e-Celsius® Medical capsule by the e-Med Connect watch of the last 2000 data	P

Instant visualization of triggered alarms (technical or physiological) through the LED and the screen for the watch and on the application	P
Automatic data transfer via BLE from the e-Med Connect watch to the Android device via the e-Celsius Mobile application	P
Visualization of data on the e-Celsius Mobile application in real time and its history	P
Integration of a manual marker via the e-Med Connect watch	S
Integration of automatic markers by the e-Med Connect watch	S
Switching off the e-Celsius capsule® Medical at the end of a measurement cycle	S
Sending data from the e-Celsius Mobile application (spreadsheet (CSV) or PDF curves)	S
Battery management of the e-Med connect watch	P
Updating the e-Med Connect watch with the e-Celsius Mobile application	S

Table 4: Frequently used functions

3. PRESENTATION OF THE MATERIAL

THE e-CELSIUS MEDICAL CAPSULE

Figure 1: e-Celsius® Medical capsule

Figure 2: Wristband

The *e-Celsius® Medical* capsule (Fig. 1) is intended to be ingested with a glass of water. It is delivered in deep sleep mode. It must be activated by the activator and associated with an e-Med Connect watch to operate. The application of the signal bracelet (Fig. 2) is followed by the ingestion of the capsule.

IMPORTANT INFORMATION AND SAFETY INSTRUCTIONS

The capsule is an applied part of the BF system. It is not intended to provide heat. Since *e-Celsius® Medical Connect System* **is not claimed to be MRI compatible, it is imperative that the person ingesting a capsule does not undergo an MRI examination. The person should wear the wristband provided with the device. The bracelet is attached before ingestion and should only be removed after the ingested capsule has been expelled. In case of consecutive ingestion, the bracelet is removed when the last capsule is expelled. If it is necessary to prolong the temperature monitoring after the expulsion of the eCelsius Medical capsule, the monitoring can be prolonged by ingesting another capsule until the end of the monitoring period within the limit of 6 consecutive capsules. In this case, the bracelet attached to the wrist must be removed only after expulsion of the last remaining capsule.**

The battery

The *e-Celsius® Medical* capsule includes 4 batteries (zinc oxide - silver).
In fact, the capsules should not be thrown away with the household waste.

Cleaning

The capsule is delivered sterile (ethylene oxide sterilization) and must be activated through the blister to maintain its sterile state. It is not designed to be cleaned with hydroalcoholic solutions or resterilized.
Under no circumstances should the capsule be put in an autoclave, otherwise it will be permanently damaged.
The capsules are exclusively intended for single use, any reuse of the capsules could induce an infectious risk.

The label

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

"Sterile Barrier System"


"Do not reuse"


"Use until deadline"

"Batch code"

"Sterilized with ethylene oxide"

"Catalogue reference"


"Manufacturer"


"Storage temperature limit"


"Keep dry"

"Do not resterilize"


"Do not use if packaging is damaged"

"Presence of phthalates"


"Prohibited to pregnant women"

The label contains an IEC 60601-1-2 symbol:

"Radiated RF disturbances"

The label contains a symbol of linked to regulation 2017/745, relating to medical devices,

"Medical Device according to Regulation 2017/745"

The label contains an IEC 60601-1 symbol:

"Follow the using instructions"

"Applied part type BF"

In addition, the label specifies the following mentions:

"It's not a drug"

"Index of protection"

"Medical device CE marked by the notified body NNNN"

"Do not dispose of the device with municipal waste"
(> Precautions for use - page 6)

"Keep out of reach of children"

"Prohibited to minors"

FEATURES

Dimensions: Length: 17.7 mm
Diameter: 8.9 mm
Weight: ≈ 1,7 g.

Operating temperature range: 25°C - 45°C

Temperature accuracy of the integrated sensor: ± 0.1°C in the range 36-41°C (physiological range), ± 0.13°C outside the physiological range

Temperature resolution: 0,01°C

Heating response time: <150s (for +2°C)

Cooling response time: <100s (for -2°C)

Sampling frequency: 30s ± 2%

Data storage in the capsule: The last 2000 temperature values are stored in the capsule

Maximum transmission distance with the watch: approx. 1 m (environment dependent)

Protection Index (IP): X8 (Matériel supportant l'immersion prolongée)

Alimentation: X8 (Material supporting prolonged immersion)

Power supply: Autonomous system containing zinc-silver oxide batteries.

Autonomy: 20 days

Contact time with the person: 2±1.5 days on average, up to 6 days depending on individual gastrointestinal motility characteristics. If the capsule is not expelled after this period, please refer to point 8. End of follow-up of the user manual.

Communication frequency: ISM band 433MHz - 434MHz

Radiated power: -22 dBm

Plastic: PVC free

Shelf life: Refer to the expiration date indicated on the blister pack

Transport and storage conditions: refer to table 1

THE SIGNAL BRACELET

The wristband is attached to the wrist before ingestion of a capsule and is removed after expulsion of the capsule (Fig. 1). A wristband is provided for each delivered capsule. These wristbands are located in the box with the capsules. They are used to inform the health care personnel that the person has ingested a capsule and is therefore not allowed to undergo an MRI examination.

It should be noted that in case of consecutive ingestion, the bracelet is removed when the last capsule is expelled.

THE ACTIVATOR

Figure 3: Activator

The Activator (Fig. 3) is designed to activate an *e-Celsius® Medical* capsule before a measurement cycle.

The battery

The activator does not include a battery. Each time it is used, the activator is powered from the mains supply (IEC60601-1 or IEC62368-1 compliant power supply required) or from a switched-on PC/ MAC. The connection between the activator and the mains power and/or the computer must only be made using the cable supplied by the manufacturer.

Cleaning

Some applications will require to clean the activator. This is possible while respecting certain rules. It is possible to clean your activator with a hydro-alcoholic gel wipe. However, it is essential to pay attention to the outer connectors as they are the most sensitive to moisture.

The system must not be autoclaved under any circumstances, otherwise it will be permanently damaged.

Maintenance

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

The label

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

"Serial number"

"Catalog reference"

"Manufacturer» + Year of manufacture (YYYY)"

"Storage temperature limit"

"Keep dry"

"Keep out of sunlight"

The label contains an IEC 60601-1 symbol:

"Follow directions for use" In addition, the label states:

"Medical device CE marked by the notified body NNNN"

"Do not dispose of the device with municipal waste" (> Precautions for use - page 6)

"Humidity level"

"Atmospheric pressure"

"Medical Device according to Regulation 2017/745"

"FCC ID"

"Do not use if packaging is damaged"

"Electronic manual"

FEATURES

Figure 4: Description of the activator

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

Power supply: via USB (5 V)

Power consumption: ≈ 115 mW only plugged in (non-operating) and 500mW during activation (during 2s).

Communication: No communication - emission of a series of electromagnetic pulses

Transport and storage conditions: refer to table 1

Lifetime: 2 years

Means of disconnecting the power supply: Disconnect the power cable

Communication: No communication - emission of a series of electromagnetic pulses

Means of disconnecting the power supply: Disconnect the power cable

WARNING : Modification of the electromedical device is prohibited

THE BOUTON

The OK button is used to start the activation procedure.
The activation procedure is detailed in the *Main functions menu > Associate a capsule - page 27*.

THE LED

A green LED is positioned on the top of the activator. This LED is continuously switched on when the activator is powered and flashes throughout the activation process.
During this period, the capsule must remain positioned in the activator's hole.

THE e-MED CONNECT WATCH

Figure 5: e-Med Connect

The e-Med Connect watch is designed to communicate via RF with the e-Celsius® Medical capsule to recover and store temperature data.

IMPORTANT INFORMATION AND SAFETY INSTRUCTIONS

The battery
The e-Med Connect watch (Fig. 5) includes a Lithium-ion battery.
The watch must not be disassembled under any circumstances; the battery must not be disconnected or thrown into a fire.
To charge the watch, please use only the dedicated cable provided by the manufacturer.

Cleaning
The cleaning of the watch must be done according to certain instructions. It is possible to clean your *e-Med Connect* watch with a hydro-alcoholic wipe in order to control the moisture content. Under no circumstances should the e-Med Connect watch be autoclaved, otherwise it may be permanently damaged.

Maintenance
It is strictly forbidden to open the e-Med Connect watch. If a malfunction or defect is found, please contact your distributor or BodyCAP (contact details at the end of the user manual).

RF (Radio Frequency) communication
In operation, the watch should be worn on the wrist of the patient who has ingested an e-Celsius Medical. IIt is recommended to be vigilant in environments with high metallic stress (reinforced concrete wall...)

and to regularly check on the watch display that the communication with the capsule is not interrupted. An indicator (see symbols CF) may be displayed indicating that the last data collected from this capsule is more than 15 minutes old (i.e. 30 communication attempts).
As the storage capacity of each capsule is limited to 2000 data, communication between the capsule and the associated watch must be re-established within a maximum of 15 hours, otherwise part of the collected data will be lost definitively (the automatic synchronization between capsule and watch may take several minutes depending on the number of data to be recovered).

The indications available on the watch
The rear shell contains the following symbols of the NF EN ISO 15223-1 standard:

SN XXXX Serial number"

"CE marked medical device"

Do not dispose of the device with municipal waste (> Precautions for use - page 6)

A QR code with the following information:
BodyCAP Gateway
Ref: P110
SN: XXXX
Year of manufacture: AAAA
https://www.bodycap-medical.com/

The label on the box contains the following symbols:

REF "Catalog reference"

AAAA "Manufacturer" + Year of manufacture (YYYY)

"Storage temperature limit"

"Keep dry"

"Keep out of sunlight"

"Radiated RF disturbances"

"Applied part type BF"

5V "Input: 5V"

"Follow the instructions for use"

"Humidity level"

"Atmospheric pressure"

"Medical Device according to Regulation 2017/745"

"FCC ID"

"Do not use if packaging is damaged"

"Electronic manual"

"Keep out of reach of children"

DESCRIPTION OF THE EQUIPMENT

Figure 6 - eMed Connect Box Description

THE CHARACTERISTICS

Dimensions : Length: 52 mm
Width: 25 mm
Thickness: 15 mm
Weight: ≈ 33g (boiter & bracelet)

Screen: 128 x 32pixels

Operating temperature: 5-40°C

Data storage: 152,916 measurements per activated capsule

Power supply: Lithium-ion battery rechargeable with a dedicated micro-USB cable supplied with the system.

It is required to use a power supply conforming to IEC 60601-1 or IEC 62368-1 (5V / 1A).

Charge time: ≈ 3 h.

Autonomy: ≈ 5j

IP rating: 67

Communication frequency:

ISM 433MHz ›› 434MHz.

Bluetooth Low Energy 4.x ou 5.x

Lifetime: 2 years (or about 500 recharge cycles).

Transport and storage conditions: refer to table 1

Means of disconnecting the power supply: Disconnect the power cable

Power Input: 100-240V~ 50/60Hz

WARNING: Modification of the electromagnetic device is prohibited

THE BUTTONS

The watch has 2 buttons with different functions.

Button 1:

Long press:	- turns on the watch if it is off
	- sets a marker if the watch is already turned on
Short press:	- turns the screen on or off
	- Confirm a message to return to the main screen (time)

Bouton 2:

Long press:	Starts the Bluetooth pairing (BLE) if the watch is not already connected.

THE LED

A Cyan LED is present on the upper face of the watch.
When the LED flashes, it indicates either:

- rapid flashing: a new alert is present (turning on the display allows to identify the type)
- slow flashing: the alert is still present but already displayed.

THE BATTERY OF THE e-MED CONNECT WATCH

Information

The watch is equipped with a rechargeable battery of the Lithium-Polymer type. It is strictly **forbidden** to disassemble the watch and replace the rechargeable battery, as this may cause irreparable damage to the system and safety defects.

Recharge cycle

To charge the battery, you will just have to plug the power cable of the watch and connect the USB to a suitable power supply or a computer USB socket. It takes a few hours to charge the battery. The autonomy of the e-Med Connect watch in battery operation is about 5 days in normal operation and 3 days in continuous alarm.

Please do not forget to charge the battery at the end of those 5 days to avoid the risk of losing the connection and configuration to all capsules in operation.

While the battery is charging, the battery logo on the watch changes to a plug symbol and a fixed level (indicating the state of charge, not the battery level). Once the cable is disconnected, the logo returns to normal and represents the actual percentage of the battery.

If the watch is in standby mode following the power save mode, simply recharge the system before turning it on by pressing button 1. If this state lasts several days, then the system will lose its date/time references. It will be mandatory to go back to the *eCelsius® Mobile* application to reset the time. This will be done automatically upon connection to the application.

THE RECHARGE CABLE

The watch has a charging system in the form of a clip. The metal contacts of the clip must be in contact with the 4 metal contacts of the watch.
The cable is only used for charging.
No USB communication is possible with the watch.
Be careful when the cable is plugged in:
*** synchronization with the capsule is automatically deactivated**
*** the activation of the capsule is impossible**

Figure 7 - eMed Connect cable

THE COMMUNICATION RF

During operation, it is **strongly recommended** that the e-Med Connect watch be worn on the patient's wrist. Putting the watch down would result in reduced RF communication performance with the capsule.

It is also recommended to be vigilant in environments with strong metallic stress (reinforced concrete wall...) and t**o check on the watch screen that the communication with the capsule is not interrupted.**
In case of a communication breakdown between the capsule and the watch, the data is stored in the internal memory of the capsule so that it can be synchronized later.

Warning: the synchronization with the capsule is automatically disabled when the cable is connected.

DISPLAY INFORMATION ON e-MED CONNECT

Figure 8 - eMed Connect Watch Screen

The information available on the screen is as follows:

°F °C **Physiological alarm** triggered for at least 1 capsule. It is imperative to consult the e-Celsius Mobile application in order to identify the cause (the symbol disappears only if the alarm is acknowledged on the e-Celsius Mobile application). The choice of °C /°F is made on the e-Celsius Mobile application.

Pause mode activated for at least 1 capsule (the symbol disappears if the pause mode is deactivated)

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

Time display (24h or 12h format)
If the symbol --- appears instead of the time, it is necessary to reconnect to the e-Celsius Mobile to send a date and time reference.
The application will send to the watch the 12 or 24h format according to the settings applied on the mobile object.

Battery level: the gauge gives an idea of the battery level of the watch. An exclamation mark appears if the level becomes low and the corresponding alarm is triggered.
A plug symbol appears if the system is being charged.

BLE connection activated: the watch is connected to an Android device in real time. The symbol disappears if the watch has no more active real time BLE connection.

Error messages may appear before the time is displayed. It is recommended to contact the service if an internal error (Err int.) is mentioned.

Specific messages related to the current action may also appear:
* Associat. BLE + code: see BLE pairing process (long press on button 2)
    * Associated BLE: Message displayed if the BLE pairing was successful
    * BLE failure: Message displayed if the BLE pairing fails
* Add marker: Message displayed when adding a marker manually (long press on button 1)
* Goodbye! Message displayed in case the watch is turned off (via e-Celsius Mobile)
* Update: Message displayed if you are updating your watch software (via e-Celsius Mobile)

The e-CELSIUS MOBILE APPLICATION

The e-Celsius Mobile application can be installed on a tablet or Android mobile device (see § Installation P24). The application is used for:

* Set up the watch (time, information, channel etc...)
* Guide the user through the steps of activation, deactivation and pausing the capsules
* Collect real-time and synchronized data available in the watch's memory
* Display data in real time (numeric or graphical)
* Visualize technical or physiological alarms (symbols, notifications)
* Store & Visualize former capsule data

4. PRINCIPLES OF OPERATION

FIRST USE

THE IMPLEMENTATION OF THE DEVICE

POWERING UP THE e-MED CONNECT WATCH

The e-Med Connect watch is delivered turned off. **To take it out of shelf mode, you must turn on the system by pressing and holding button 1 (on the edge of the BodyCAP side)**. This procedure turns on the screen of the watch. If the screen does not light up, put the watch on charge and repeat the operation after a few minutes. An LED indicates that the button has been pressed. Before using the e-Med Connect watch on battery, you must ensure that its charge level is sufficient. A symbol on the display shows the battery level.

CHARGING THE BATTERIES

If you plan to use the watch on battery power, please check its charge status. The USB cable compatible with the e-Med Connect watch allows charging of the watch's internal battery when it is connected to a power source (mains power supply or a switched-on computer). The watch charges even when it is turned off.

INSTALLATION OF e-CELSIUS MOBILE

The e-Celsius Mobile application allows you to retrieve and display the data collected by the capsule/ watch system. To do this, you need a device with a minimum required configuration:

Tablet or smartphone with the following configuration:

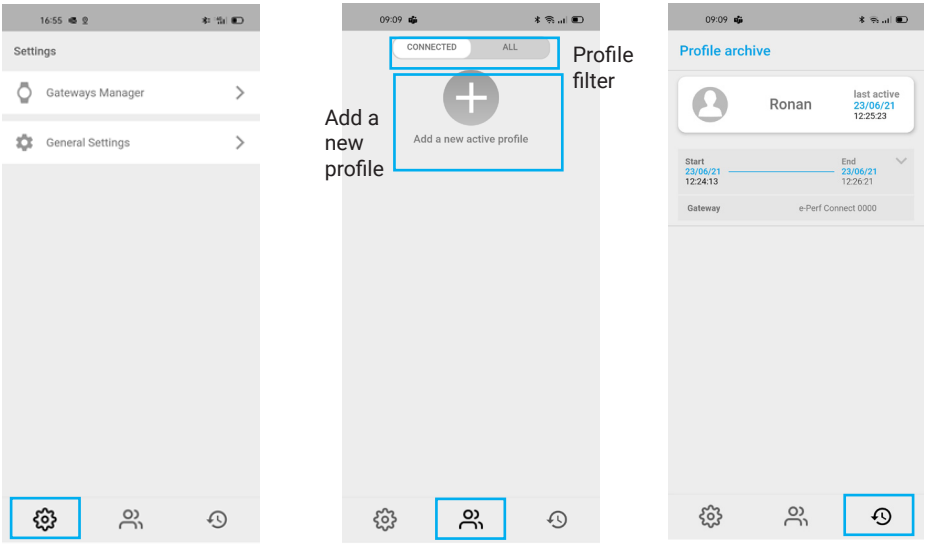
- Android 8 or higher
- Bluetooth Low Energy 4.x or 5.x
- Access to the "Play Store
- 100MB available for the installation of the application

To install e-Celsius® Mobile please:

- launch the Android play store
- Search for the "e-Celsius Mobile" application from the "BodyCAP" company
- Before launching the application, please make sure that the options "bluetooth" & "location" are activated
- When using the application for the first time you must allow the application to "access the position of the device".

THE MAIN DISPLAY OF THE APPLICATION

The application is based on 3 features represented at the bottom of the pages by logos.



Display of the parameters

Viewing active profiles
Main page

Archives
for former data visualization

Figure 9: e-Celsius Mobile - Main Display

APPAIRAGE e-MED CONNECT & e-CELSIUS MOBILE

In order to communicate with each other, the e-Med Connect watch and the e-Celsius Mobile application must be paired. To do this, the application guides you through the various actions. **Bluetooth and phone/ tablet location must be activated.**

* Creating/using a profile: You must create a new profile (+) or use an existing profile from the available list, allowing the wearer of the watch to be identified. For a new profile, it is possible to enter a set of 16 characters (numbers, letters, lower case, upper case and special characters). Note: two profiles cannot have the same name to avoid confusion.

* Association of an available watch: you must then select an existing watch or pair a new watch with the system. To pair a new watch, you must press and hold the top button of the watch (button 2) until the message "associat. BLE" appears on the watch screen. On e-Celsius Mobile, you should see a green e-Med Connect XXXX reference appear, indicating that this watch is available for association via Bluetooth. Once selected, you must validate the pairing by entering in the e-Celsius Mobile application, the code written on the e-Med Connect screen. The watch will appear in the list of available paired watches. In case of error, you will have to repeat all the actions.

Note: the BLE name of the watch corresponds to its serial number on the back of the case SN:XXXX

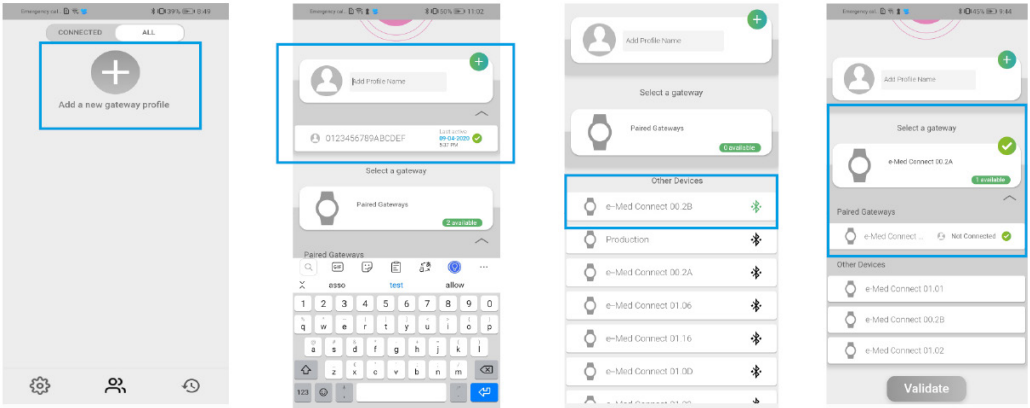


Figure 10: e-Med Connect BLE pairing with e-Celsius Mobile

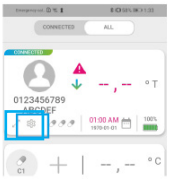
MAIN FUNCTIONS

e-MED CONNECT CONFIGURATION ON e-CELSIUS MOBILE

Before using the watch with a capsule, it is necessary to configure some parameters.
To do this, please go to the watch settings options using the nut located on the main screen below the concerned profile.
The available parameters are:

- **Date and time (automatic)**

The date and time of the device (smartphone or tablet) on which the e-Celsius® Mobile application is installed will be sent to the watch. This time will be used to date future recordings. It is also displayed on the watch screen.



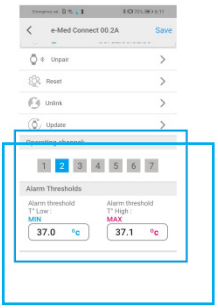
- **The operating channel**

This allows you to select the desired operating channel for the next recording. This is an advanced setting, limiting interference if several watches are in the same environment.

This setting can no longer be changed once the watch has associated capsules.

- **The setting of physiological alarm thresholds**

The **"Thresholds"** setting allows you to configure the Low and High temperature thresholds for which a visual physiological alert is triggered (LED on the watch & alarm on the support)



- **Add a comment**

The application allows you to record a comment for a given profile. In the profile settings, select comment and enter a note, 64 characters maximum.

Note: All new settings must be saved to be applied.

Figure 11 - eMed Connect Configuration

COMBINATION OF A CAPSULE

In order to associate an *e-Celsius® Medical* capsule, please have all the system elements ready:
* the activator and its cable
* the e-Med Connect watch which is turned on without the watch cable removed
* the e-Celsius Mobile application which is launched and paired with the watch
* a new e-Celsius Medical capsule

Note: the application and the watch must be connected to launch an association.

The operator (nursing staff) is responsible for this action, before giving the capsule to the patient.

Then go to the e-Celsius Mobile application and select the created profile which is associated with the dedicated watch. Unfold the profile by clicking on the capsules. The details of each capsule appear. Choose the location of the capsule to associate by pressing the corresponding + and follow the instructions of the application.

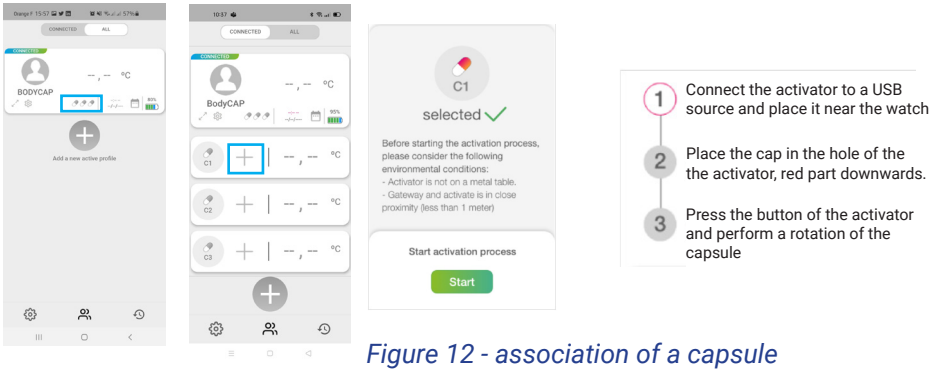


Figure 12 - association of a capsule

The capsule to be activated should be placed in the dedicated hole of the activator, white end up. If you wish to maintain the sterility of the capsule, this operation must be performed while preserving the integrity of the blister. To activate a capsule through the blister, it is necessary to position it vertically in the blister and it is advisable to hold it by exerting pressure and rotating the capsule. Once the capsule is activated and associated with the watch, the data can be viewed on the e-Celsius Mobile application.

If the activator LED stops flashing and the message "Error! Wish you to restart an association" appears on the e-Celsius Mobile application screen, please check that the *e-Celsius® Medical* capsule is correctly positioned in the activator and/ or move the *e-Celsius® Medical* capsule slightly in the hole, press the "restart" button on the e-Celsius Mobile application to restart the association process and then press the activator button again.

To activate an additional capsule, repeat the procedure. Up to 3 capsules can be associated in parallel with the same e-Med Connect watch.

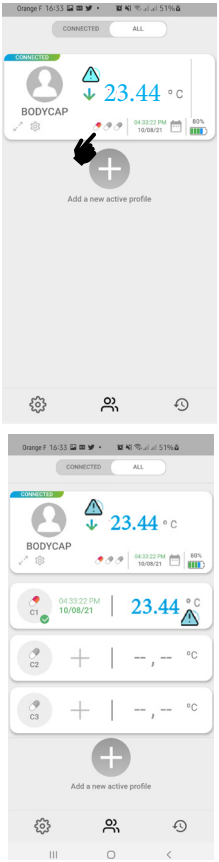
If you wish to maintain the sterile state, the capsule must be removed from its blister as late as possible before ingestion.

INGESTION OF THE CAPSULE

The *e-Celsius® Medical* capsule is now ready to be ingested by the patient, with a glass of water, for gastrointestinal core temperature measurement. Please observe the claims of use and contraindications presented on page 8. The application of the signal bracelet (Fig. 2) is followed by the ingestion of the capsule. The e-Med Connect watch must also be installed on the patient's wrist in order to collect and transmit all data to the application. The direction of the watch does not matter, but for the wearer's comfort, it is recommended to position the BodyCAP logo on the arm side and not on the hand side.

CONSULT THE TEMPERATURE DATA IN REAL TIME

In order to consult the collected temperature data, the watch and the application must be able to communicate via BLE. Select the profile you wish to view.



The information on the main page is as follows:

* The profile name (0123456789ABCDEF)
* The BLE connection active/inactive (connected CONNECTED)
* The last data collected (23.44°C) by the associated capsules
* The date and time of this data (03:04 PM 2021-02-11)
* Watch battery level (90%)
* The presence of a physiological alarm if applicable (⚠) for at least one of the active capsules
* The number of activated capsules (1 red)=> click on the capsules allows a status display by capsule (unfold/unfold the status)

The profile temperature is the last temperature received for all capsules associated with the watch at the same time. In the case where capsule details are displayed, each capsule will display its own data and status. The capsule symbol can be accompanied by one of the following icons:

Free space

Location occupied by an active capsule

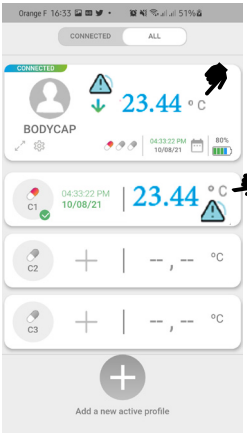
Location occupied by a capsule in pause mode

Location occupied by an active capsule but with radio connection (Capsule/Watch) issue

Figure 13 - Consultation of temperature data

CONSULT THE TEMPERATURE GRAPHS

The temperature data of the capsules can also be visualized in graphic form.
To do this, simply click on a capsule temperature to display the corresponding graph or on the generic temperature of the profile to display the graph of all the associated capsules.

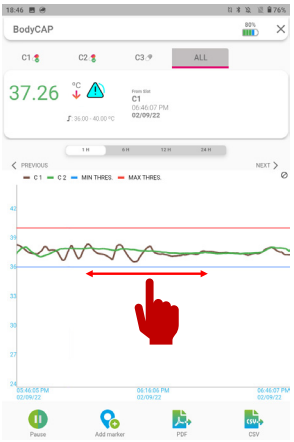


Displays the graph with all the capsules active of the watch (C1/C2/C3)

Display the graph of C1 only

Figure 14 - Viewing the temperature graphs

Example of a C1 graph



Exemple de graphique C1 + C2

It is possible to navigate in the graph by dragging your finger on the active range. (to the left or to the right)

On the upper part of the screen you will be able to see several information related to this capsule:
* The minimum temperature seen by the capsule (since the last reset)
* The maximum temperature seen by the capsule (since the last reset)
* The triggering of the alarm if the thresholds are reached or exceeded

* the number of missing data between the watch and the capsule (indicator that the communication with the capsule needs special attention)
* The elapsed time (hh:mm:ss) since the last real time data
* The adjustable thresholds of physiological alarms are also recalled. ∫: 33.00 – 36.50 °C

The temperature display is color coded to identify immediately the current condition of the patient:

* Red: real time temperature above the high threshold
* Green: real time temperature between thresholds
* Blue: real time temperature below the low threshold

AUTOMATIC SYNCHRONIZATION OF THE DATA IN THE CAPSULE'S MEMORY

The watch worn on the patient's wrist will automatically synchronize the no received data in real time. If the watch is set down, it will synchronize the data when it returns back to the dedicated capsules. The indication on the e-Celsius Mobile application should warn you of a possible communication problem between the watch and the capsule.

CONFIGURATION OF THE TRIP POINTS OF THE PHYSIOLOGICAL ALARM

Minimum and maximum temperature thresholds can be used to trigger a visual physio-logical alarm both on the e-Med Connect watch (via the LED) and on e-Celisus Mobile via a notification and an alarm symbol. To set them up, you have to go directly to the watch settings (Nut) on the e-Celsius® Mobile interface.

The default values are 36.0°C and 38°C. The minimum and maximum threshold values are set between 33°C and 41°C. Note that it is important to always check the consistency between the set thresholds and the values for which you think an alarm is necessary. The used threshold values are available at any time on the temperature display screen of the e-Celsius Mobile application.

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

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

WARNING SIGNAL FOR EXCEEDING THE THRESHOLD = PHYSIOLOGICAL ALARM

Minimum and maximum temperature thresholds can be used to trigger a visual alarm. These thresholds then concern all the associated or coming capsules. The change from the current temperature below the low threshold or above the high threshold constitutes a physiological alarm.
This alarm signal is manifested by

* the flashing LED on the watch

* the display of the °C! symbol at the top left of the watch's display
* the symbol on the profile and on the concerned capsule
* the min or max associated with the cap in Red or Blue color
* a notification on the phone/tablet if it is connected in real time BLE to the watch

The delay inherent in the determination of an alarm condition is a maximum of 30 seconds in the case of real-time communication between the capsule and the watch.

This physiological alarm has a lock. These different signals will remain visible until the alarms are reset. When the current temperature stabilizes between the two thresholds, the alarm signals remain visible until the alarms are reset.

The alarm system is divided between the watch and the mobile application. The two elements of the system must allow a BLE communication. For this, they must be within 10m of each other and the watch worn on the patient's wrist.

Note that the alarm may be triggered by synchronized data (received afterwards) that has previously exceeded one of the two temperature thresholds. In this case, the minimum or maximum values are time-stamped at the time the data was received (date of synchronization).

VISUALIZATION OF THE END OF LIFE OF THE CAPSULE

When a capsule reaches the end of its life, an alarm is triggered on the watch (flashing LED) and the information is then transmitted to the e-Celsius Mobile application as a notification.
The capsule will stop about 500 measurements after the notification appears. A marker is automatically placed in the data file.

RESET ALARMS

In order to reset the alarms and the Min/Max values shown in the data display window, click and hold your finger on the alarm symbol. A window will appear offering you a "Reset alarms". This action will then concern all the capsules associated with the watch. A confirmation message will be asked to validate the reset.

DESASSOCIATION OF THE CAPSULE

When the use is finished and you want to stop the capsule, to do so, simply go to the e-Celsius Mobile application, on the concerned profile and choose the capsule you want to stop.
Hold your finger on the cap and slide it to the right.
In order to ensure the success of the procedure, the capsule and the watch must be close enough to communicate.

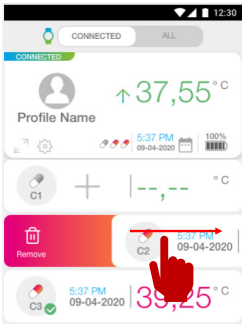
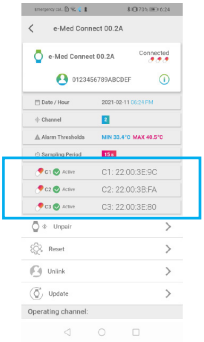


Figure 15 - capsule disassociation

A confirmation request must be validated before the actual disassociation of the capsule. This action is definitive, the capsule disappears from the database of the watch. The data file corresponding to the capsule is archived in the application e-Celsius Mobile.

SECONDARY FUNCTIONS

VIEWING OF CAPSULE IDENTIFIERS



It is possible to know the unique identifier of the capsules by going to e-Celsius Mobile and viewing the watch parameters (Nut). Capsule identifiers are given in hexadecimal form: XX.XX.XX.XX where X can go from 0 to 9 and A to F. As soon as the capsule is deactivated, it disappears from this list and is transferred to the archive. (See page 34)

Figure 16 - capsule identifiers

THE MARKERS

The system gives the possibility to record specific events by the use of markers.

Automatic markers are stored and manual markers can be placed directly by pressing button 1 (long press) or via the e-Celsius Mobile application by double clicking on the graphic area.

The markers are then materialized on the graph by a vertical line and in the data during the CSV export.

On the graph it is possible to visualize the markers by clicking on the left and right arrows just above the graph.

In the case of automatic markers, this is triggered when the condition is discovered. In the case of synchronized data, it can therefore be triggered afterwards.

Figure 17 - Markers

Type of marker	Auto	Meaning
User marker	no	Marker placed by long press on button 1 or via e-Celsius Mobile
Power ON	yes	Switching on the watch
Power OFF	yes	Voluntary switch-off of the watch (via the e-Celsius Mobile application)
Critical battery	yes	The watch turns off due to a low battery level
Pause activated (1/2/3)	yes	A capsule (1/2/3) is paused
Pause disabled (1/2/3)	yes	A previously paused capsule (1/2/3) is considered again
Date and time updated	yes	Update of the date and time of the watch by e-Celsius Mobile
Capsule activated (1/2/3)	yes	A capsule (1/2/3) is associated
Capsule disabled (1/2/3)	yes	One capsule (1/2/3) is disassociated
Internal alarm XX	yes	The watch has triggered a technical alarm requiring an intervention of the after-sales team

Low battery alarm	yes	The watch triggers its low battery alarm
Threshold slot alarm (1/2/3)	yes	Physiological alarm triggered
Alarm reset	yes	The physiological alarm is reset for all capsules of this watch
Change of thresholds	yes	Modification of the alarm thresholds
Change of thresholds	yes	Watch memory full

THE PAUSE MODE OF A CAPSULE

It is possible that one or more capsules have been activated at the same time to anticipate a consequent ingestion. In this case, the non-ingested capsules will trigger the physiological temperature alarm. In this case, there is a special mode that consists in pausing the capsule that we are not immediately interested in. The temperature data will not be recorded in the watch and the alarms will not be triggered on this data. As soon as this mode is deactivated, the watch will communicate with the capsule again to ask for the last 2000 data before resuming the classic real time communication.

To activate or deactivate the pause mode, simply select an active capsule, click and drag your finger to the left. This will bring up the option "enable pause" if the capsule is active or "disable pause" if the capsule is lready in pause mode.
A pause symbol also appears on the watch display as a reminder that at least one capsule is in a pause state.

Figure 18 - Pausing a capsule

Be careful, the pause mode can cause the lost of data if the capsule is swallowed and the pause is not removed. It is necessary to check on the e-Celsius Mobile application that you still have access to the data of the capsules in progress.

ARCHIVE MANAGEMENT - FORMER CAPSULES

A deactivated capsule will automatically be placed in the corresponding folder in the application's archives. It will be filed under the name of the profile to which it was associated and sorted by activation date and serial number.
It is then possible to select the capsule(s) of interest for:
* view them again through the application (Max 3 capsules)
* export them in CSV or PDF
* delete the corresponding data from the phone's memory
The selection can only be made if the capsules are from the same session (profile + watch).

DATA EXPORT

It is possible to export the data:

* During acquisition: simply place in the graphic display window of the desired capsule or the "all" tab of the application and click on the export button
* A posteriori in the archive area: in the archive, select the capsules of interest and click on the export button.

The possible export formats of the data are PDF or CSV.

OPTIMIZATION OF THE e-MED CONNECT BATTERY

The e-Med Connect watch is optimized for radio communication with 1 to 3 capsules in parallel. However, if a capsule is evacuated or if it stays away from the watch (e.g. not swallowed), an alarm light (LED) will be triggered and the watch will try to re-establish communication with the capsule(s) by activating the radio functionality more often.
For this reason, it is recommended to deactivate a capsule that has been visualized to be emptied and to pause a capsule that has not yet been swallowed. This will limit consumption and improve the battery life of the watch.

END OF FOLLOW-UP - APPLICATION

When your tracking on e-Celsius Mobile is complete and your capsules are deactivated from the profile, you have several options to finalize your session by going to the watch settings:

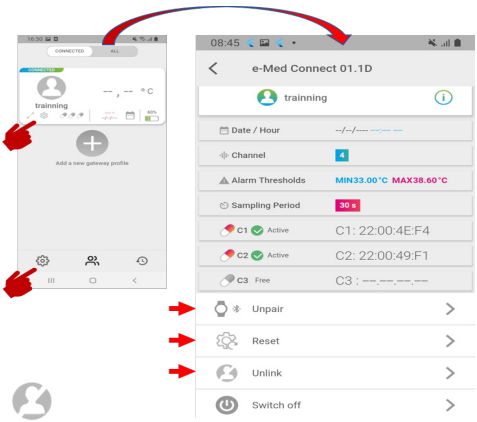


Figure 19 - end of follow-up options

* **separate the profile and the watch:**
This action can be carried out:
- at the end of the monitoring to archive the data and allow a new use of the watch with another profile.
- during the monitoring, if you are no longer required to follow the watch and to allow the monitorind by an other mobile object .

*** dissociate the mobile object and the watch (Bluetooth):**

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

*** Reset the watch:**

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

TURNING OFF THE e-MED CONNECT PRODUCT

It is possible to turn off the watch using the e-Celsius Mobile application. To do this, simply go to the parameters of the watch (see paragraph above) and press the corresponding button.
The watch must be connected to the application. Once the order is sent, the watch displays a message of extinction and it will shut down after a few seconds.

UPDATING THE WATCH

It is possible to update your e-Med Connect watch if a new software version has been provided by BodyCAP. To do so, please go to the available settings on e-Celsius Mobile for the concerned e-Med Connect watch. The e-Celsius Mobile application must recognize the BLE connection with e-Med Connect. Select "Update watch" and follow the steps.

VISUALIZATION OF THE e-CELSIUS MEDICAL ALARM SYSTEM

Caregivers should regularly check the temperature displayed on the application screen e-*Celsius Mobile and the LED on the watch to identify alarms*.
The watch associates 6 categories of alarms, 5 of them relate to the state of the electro-medical system and 1 relating to the physiological state of the person.

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

Controlled function	Alarm conditions	Delay due to the alarm condition	e-Med Connect alarm mode	e-Celsius Mobile alarm mode	Priority
Temperature of the person	The measured temperature exceeds the preset physiological thresholds	30 seconds max. in case of real time communication 10 min after activation (goal: avoid alarm due to collected temperature before ingestion)	Flashing LED + "°C!" symbol	Notification + symbol + min/max	Low (delayed)
Capsule battery	The remaining autonomy of the capsule will allow a maximum of 500 measurements	30 seconds maximum in the case of real-time communication	Flashing LED	Notification & display in parameters of the watch	Low
Watch battery	The battery of the watch is low or critical	Immediate	Flashing LED and symbol on the watch display	Low battery notification, % returned to the general display if the watch is connected	Low
Loss of communication between the watch and the capsule	The watch does not receive any real time data from the capsule since 5min	15 minutes	Flashing LED and symbol on the display of the watch	Notification and display of the number of missing data. Symbol on the status of the capsule	Low
Memory full	The watch has no memory for data recording	immediate	Flashing LED	Notification & display in parameters of the watch	Low (improbable)
Internal error alarm	The watch is faulty	Immediate, the use of the watch is limited	Flashing LED + message displayed on the screen		Average

Table 5: Alarm systems

5. END OF FOLLOW-UP

When continuous temperature monitoring is no longer necessary, it must be ensured that the patient ejected the capsule.
There are 3 solutions to achieve this verification:
- The person is able to attest to the evacuation of the capsule
- The temperature data collected by the system shows a non-physiological variation during a passage to the saddle.
- If none of the first 2 solutions is valid, it is possible to check if the capsule is still present in the person's digestive tract. Approach the e-Med Connect watch connected in real time to the e-Celsius Mobile application, used for close tracking of the person and check the reception of real time data. The real-time capture of new data informs you that the *e-Celsius® Medical* capsule is still present and active. This verification procedure can be repeated.

⚠ **The duration of the capsule's operation is limited to 20 days, after which time the method described above can no longer be used. Since the capsule is radiopaque, an X-ray will allow the removal of any doubt if the capsule is found blocked, it may be removed by endoscopy, surgery or any other means at the discretion of a gastroenterologist.**

6. TECHNICAL DATA

KEY PERFORMANCE

For the *e-Celsius® Medica*l Connect System, the key performance is the continuous measurement of core temperature via the gastrointestinal tract.
There is no need for testing to maintain essential performance or basic safety because even in case of product failure there is no electrical or EMC hazard to the person.

EMC TABLES

EMC Product Reference Chart	
Applicable model	
P022	(e-Celsius® Medical)
P110	(e-Med Connect)
P030	(Activatorr)

Important: Information about electromagnetic compatibility (EMC)
Medical devices manufactured by BodyCAP comply with the IEC60601-1-2:2014 standard for immunities and emissions.
All the information given below is based on the normative requirements to which manufacturers of electro-medical devices are subject, as defined in the IEC60601-1-2 Ed4 standard. The medical device complies with the applicable electromagnetic compatibility standards, however, the user must ensure that any electromagnetic interference does not create an additional risk, such as from radio frequency transmitters or other electronic devices.

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

Cable length

Cables and accessories	Maximum length	Type of test	In compliance with:
Cables/Cords	< 3m	RF emission	CISPR 11, Classe B
		Emission of harmonic currents	IEC 61000-3-2
		Fluctuation and flickering of the voltage	IEC 61000-3-3
		Immunity to electrostatic discharges	IEC 61000-4-2
		Radiated immunity - Electromagnetic fields	IEC 61000-4-3
		Immunity to fast electrical transients in bursts	IEC 61000-4-4
		Shock wave immunity	IEC 61000-4-5
		Shock wave immunity Driving immunity - Disturbance of the radio-frequency line	IEC 61000-4-6
		Radiated immunity - Magnetic fields	IEC 61000-4-8
		Immunity to voltage dips, short interruptions and voltage variations	IEC 61000-4-11

Guidelines and manufacturer's declaration of conformity regarding electromagnetic emissions
The *e-Celsius® Medical* System is intended for use in the electromagnetic environment described in the table below. The user and installer should therefore ensure that the medical device is used in the environment described below.

Test Emission	Compliance	Electromagnetic environment Remarks
Disruption of radiation electromagnetic (Radiated Emissions) (CISPR11)	Group 1	The medical device uses RF energy for its internal functioning
RF emission (CISPR11)	Class B	The medical device is suitable for use in a health care facility environment professional.
Current emission harmonics (IEC 61000-3-2)	Class A	
Voltage variations, voltage fluctuations and flicker (IEC 61000-3-3)	Compliant	

Guidelines and manufacturer's declaration of conformity regarding electromagnetic immunity

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

Immunity test	Standards	Test level according to IEC 60601	Level of compliance	Electromagnetic environment Remarks
Electrostatic discharge (ESD)	EN 61000-4-2	±8kV to contact ±15kV to air	±8kV to contact ±15kV to air	Professional health care facility environment. We were able to observe during the indirect discharges at +15KV at the level of the power supply, a break on the USB connector of this one. This breakage does not induce any degradation of the essential performances and the basic safety of the device is not altered.
Rapid electrical transients in bursts	NF EN 61000-4-4	± 2 kV for power supply lines	± 2 kV for power supply lines ± 1 kV for signal ports	Environment of a professional health care facility.
Shock waves	NF EN 61000-4-5	± 1 kV in differential mode ± 2 kV in common mode	± 1 kV in differential mode ± 2 kV in common mode	Environment of a professional health care facility.
Magnetic field at the assigned industrial frequency	NF EN 61000-4-8	30 A/m	30 A/m	Environment of a professional health care facility.
Tension dips	NF EN 61000-4-11	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315 0% UT for 1 cycle and 70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single-phase: at 0	0% UT for 0.5 cycles A 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315 0% UT for 1 cycle and 70% UT for 25 cycles at 50 Hz For 30 cycles at 60 Hz Single-phase: at 0	Environment of a professional health care facility.
Voltage interruptions	NF EN 61000-4-11	0% UT; for 250 cycles at 50 Hz for 300 cycles at 60 Hz	0% UT; for 250 cycles at 50 Hz for 300 cycles at 60 Hz	Environment of a professional health care facility.

Electromagnetic immunity, radio frequencies:

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

Immunity test	Standards	Test level according to IEC 60601	Level of compliance	Electromagnetic environment Remarks
WARNING: Portable RF communications devices (including peripherals such as antenna cables and external antennas) should not be operated closer than 30cm (12 inches) to any part of the UNIT UNDER TEST, including cables specified by the manufacturer. Failure to do so may result in impaired performance of these devices. Interference is possible near equipment identified by the following symbol: 				
Radiated radio frequency electromagnetic fields	NF EN 61000-4-3	10 V/m 80 MHz to 2.7 GHz 80 % MA at 1 kHz	10 V/m 80 MHz to 2.7 GHz 80 % MA at 1 kHz	Environment of a professional health care facility.
Radiated radio frequency electromagnetic fields	NF EN 61000-4-3	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	9 V/m 710 MHz, 745 MHz, 780 MHZ, 5240 MHz, 5550 MHz, 5785 MHz 27 V/m 385 MHz 28 V/m 450 MHz, 810 MHz, 870 MHz, 930 MHz, 1720 MHz, 1845 MHz, 1970 MHz, 2450 MHz	Environment of a professional health care facility.
Conducted disturbances induced by RF fields	NF EN 61000-4-6	3 V 150KHz to 80MHz 6 V in ISM band and band between 0.15 MHz	3 V 150KHz to 80MHz 6 V in ISM band and band between 0.15 MHz	Environment of a professional health care facility.

7. MATERIAL-VIGILANCE DECLARATION

Users of a device and third parties who are aware of an incident or risk of incident involving a device that has resulted or may result in the death or serious deterioration of the state of health of a patient, user or third party must report it without delay to the manufacturer BodyCAP or to the "Agence nationale de sécurité du médicament et des produits de santé".

materiovigilance@ansm.sante.fr
Lien BodyCAP: www.bodycap-medical.com

8. TROUBLE SHOOTING GUIDE

Problem	Probable cause	Solution
The watch does not turn on	The battery of the watch is discharged	Connect the watch using the dedicated USB cable.
	The watch is at the end of its life	The date of manufacture is written on the label. It is guaranteed to work properly for 500 recharge cycles.
	The watch may require maintenance	Refer to your distributor or manufacturer.
The activator LED does not light up.	Activator not properly connected	Make sure that the connections are correct and that the power outlet is powered.
	The activator is at the end of its life	The date of manufacture is written on the label. It is guaranteed for 2 years of use.
	The activator may require maintenance	Refer to your distributor or manufacturer.
The RF watch-cap communication does not work.	The distance is too great	Make sure the capsule is within reach of the watch, check the date of the last data received on the application
	The capsule is not associated	Follow the activation procedure. Check that the cable of the watch is disconnected. If the association is difficult, check The application shows the number of associated capsules. The application shows the number of associated capsules.
Inappropriate autonomy of the watch.	Battery not recharged	Plug in the watch and wait a few minutes before turning it back on
	End of life battery	Dispose of at a WEEE organization.
Inappropriate autonomy of the capsule.	Used batteries	Check the date on the blister pack.
The watch-application link does not work.	Bluetooth already connected to another mobile object	The screen of the watch shows a BLE symbol showing the already active connection.
	The watch is not paired with this mobile device	Perform the BLE pairing procedure.
The Cyan LED on the watch does not light up or flashes.	Power supply failure	Check the power supply or connect the watch with its dedicated cable to a USB
Non-functional capsule association.	3 capsules maximum per watch	Verify that a location on the watch is free on the application.

If you have any questions about the operation of the system that are not answered in the user manual, contact BodyCAP:

BodyCAP
3, rue du Docteur Laënnec
14200 Hérouville Saint Clair
FRANCE

+33. (0)2 61 53 08 14
support@bodycap-medical.com
www.bodycap-medical.com

CE nnnn