



**BodyCAP**  
Your e-health partner

## **User Manual**

**eTact<sup>®</sup>**

### **Memory Mode**

Activity monitoring device and temperature indication



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Dear Customer. Thank you for purchasing the eTact® monitoring system designed by BodyCAP. The system is dedicated to activity monitoring and temperature indication. The system is composed of a patch and a dedicated cable used for data communication and battery charging. A PC/MAC software is available to configure the patch and download the data stored into the patch memory, after a monitoring period; as well as “eTact Analysis” for processing and analyzing data from the patch. eTact Analysis is described in a dedicated user guide. The device is easy to use, no specific training is required. No specific skills are needed. Nevertheless, please read carefully the instructions presented in this user manual and use it whenever necessary.

#### **Destination and use case:**

eTact® is a device intended to measure the activity level as well as the raw acceleration data and give an indication of the skin temperature.

## **1. Important Safety Warnings**

The safety procedure presented in this document must be carefully followed. It does ensure a proper way of working for the patch as well as getting the optimum performances for the device.

For any question which the answer is not available in this manual, please ask for assistance to your distributor or to the manufacturer (contact details at the end of this manual).

eTact® is not compatible with MRI systems. A person wearing the patch must remove the patch before an MRI exam.

**The eTact® device is very sensitive to humidity (sweat or water projection). When the device is worn on the body, we strongly recommend using the specific bandages supplied in the starter kit to protect electronics and connector.**

Do not drop objects on the device. Do not introduce foreign objects.

Do not shoot the patch, normal operating conditions could be affected.

Keep eTact® device clear of dust and residues (store it in the package when unused for a long period).

Do not use the device if it is damaged.

Do not use with dangerous liquids or gas.

Only use recommended parts compatible with the system.

Do not use the device in presence of strong magnetic or electric fields.

It is strictly forbidden to open/modify the patch.

Be careful with the cable location when connected to the patch to avoid fall.

It is impossible to change the battery.

**Device modification strictly forbidden**

Safety recommendations:

- DO NOT THROW eTact® INTO FIRE
- DO NOT SHORT-CIRCUIT
- DO NOT OPEN
- DO NOT CHANGE THE BATTERY
- DO NOT CLEAN IN WATER/LIQUID (IMMERSION)



Do not dispose of eTact® with household waste. The patch and the cable have been designed to be recycled. The crossed-out wheeled-bin waste symbol indicates that the device (electrical equipment, electronic primary battery or rechargeable battery) must be disposed separately from ordinary household waste. Please contact your local electronic devices waste management to find the closest collection facility.

This device contains a Lithium polymer rechargeable battery.



**If the following recommendations are not properly followed, the safety conditions and functionalities of the device are no more guaranteed.**

## 2. Use cases & contraindications

### 2.1. Use Cases

eTact® is an electronic device intended for non-medical uses.

eTact® is an electronic device designed for activity monitoring and skin temperature indication for humans.

The device is composed of:

- A rechargeable electronic patch (eTact®)
- A cable used to recharge the patch battery and allow communication between the patch and a computer PC/MAC (patch configuration programming and data download)
- A software (eTact® Watcher) is associated to the system and allows to set the patch parameters as well as visualize the recorded data on a computer PC/Mac.
- A software (eTact® Analysis) for processing and analyzing the data

### 2.2. Contraindications

eTact® is an electronic device designed for activity monitoring and skin temperature indicator for humans, with contraindications in the following cases:

- Users with heart pacemaker or defibrillator
- Users exposed to a high magnetic field (MRI for instance) must be unequipped before being exposed.

## 3. Getting started

### 3.1. eTact® Watcher software installation

System requirements for optimum performances:

1GHz Processor.

500Mo of system RAM.

200Mo of hard disk space available.

Microsoft Windows® 7 OS or newer (32 or 64 bits) / Mac OS X (min 10.9 Lion).

Minimum graphic resolution: 1027x768 pixels.

To install eTact® Watcher and the cable drivers, do the following steps:

- Run the “eTact® Watcher” installer. The software package is available on the BodyCAP USB key provided in the package.
- Follow the instructions step by step including the driver install.

### 3.2. Getting started

#### 3.2.1. eTact® wake-up

eTact® is set in deep sleep mode as a default factory setting. To get the device active, you simply need to connect the cable on the patch and connect it to a USB plug or to a computer USB port. The blinking LEDs indicate the patch is active.

#### 3.2.2. Battery charging

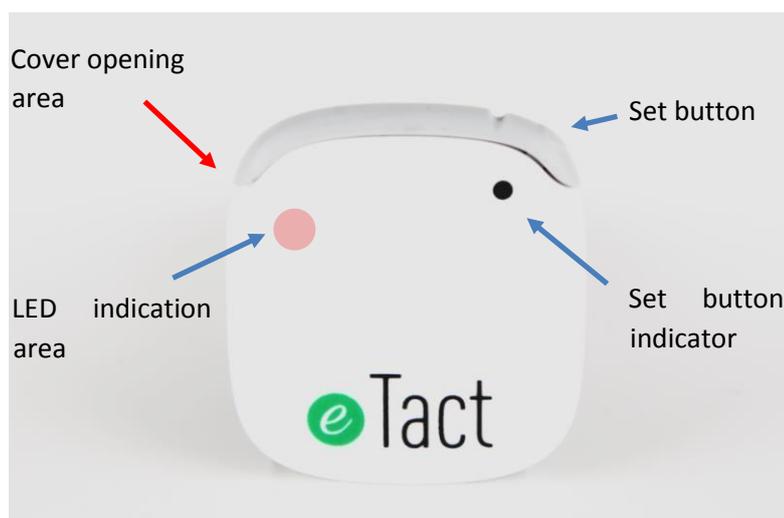
It is recommended to fully charge the battery for the first use. Keep the patch connected with the dedicated cable to a USB plug or a USB computer port for a least 2 hours.

#### 3.2.3. Configuring the patch

First, connect the patch to a computer after having installed the eTact® Watcher application. Execute the application, the patch automatically updates internal timestamp. Select the “Configuration” icon (refer to section 6.2)

Please proceed with the configuration setting to choose the measurement parameters.

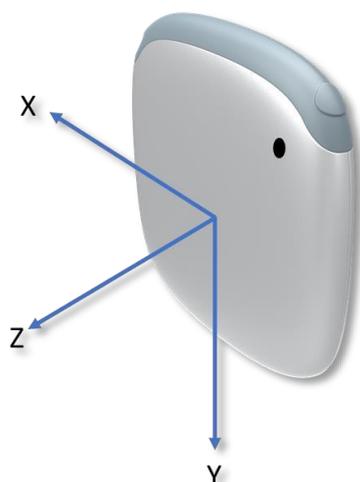
## 4. eTact® Patch



Picture 1: The eTact® patch

It should be noticed that the plastic grey cover opens from the left side of eTact® when this one is held in front of you.

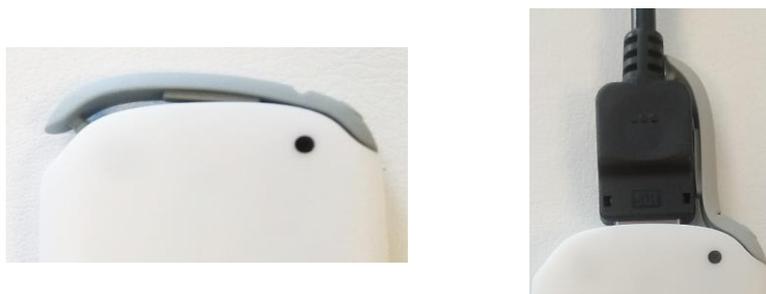
When using the X, Y, Z raw data, it is important to know the device orientation.



Picture 2: X Y Z orientation

### 4.1. Battery charging and data transfer

The patch battery can be recharged using the dedicated cable provided in the kit, either using a USB main plug or a USB PC/MAC port. The cover needs to be opened (from the left side when the patch is on the front face as indicated in Picture 3). A connector becomes visible (Figure 3). Plug the cable in this connector. Data transfer and patch programming are performed through the cable with the eTact® Watcher.



Picture 3: Cover opening and cable insertion for battery charging and data transfer

 It is recommended to close properly the cover after unplugging the cable to protect the patch and the connector.

During a recording session, the patch can be charged at any time by the user. The recording stops during charging period, then resumes recording based on initial settings as soon as the patch is unplugged.

**Be careful, in memory mode when the patch is switched off due to lack of battery during the acquisition phase, it is essential to recharge the patch AND use the eTact® Watcher interface, in order to update the time & date. This step is necessary to allow the patch to store new timestamped data properly. Initial recording parameters will remain active.**

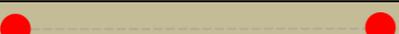
**A web page is available on BodyCAP website allowing to update time & date without eTact® watcher access. The cable and a USB connection to the computer are required. To use the web page, the used internet navigator must be Opera or Chrome.**

<https://www.bodycap-medical.com/eTact/eTact.html>

**When updating Date & Time using this web page, please ensure that eTact Watcher is not open.**

## 4.2. LED indications on eTact®

Three LEDs (Magenta, yellow, cyan) are used as indicators. The different configurations are listed in the table below (both color and relative duration are represented).

Color indication and lighting duration	Description
	Patch activated
	Patch switch off (deep sleep)
	USB cable connected
	Low battery level indication (<15% battery)
	Battery fully Charged
	Memory full alarm indication
	Time not reliable (date & date update required)
...	Please refer to button section

### 4.3. Functions associated to the push button

The patch is equipped with a button. Features associated with this button are grouped in 2 types, available during the recording session:

- Short press (until first LED indicator) shows the battery level (X):
  - Green LED:  $X > 66\%$
  - Yellow:  $33\% < X < 66\%$
  - Red:  $X < 33\%$
- Long press is used to set an event marker:
  - During long press, the 1<sup>st</sup> LED indicates battery level (like short press)
  - Keep the pressure on the button until a Blue LED flash and release the button
  - A green LED flash confirms the user marker position
  - This marker will be graphically represented in eTact® watcher by a black vertical line and in the .CSV file with a specific line and the term “user” in the column marker.

## 5. Cable and main plug characteristics

A cable is provided with the system in order to transfer the stored data and to recharge the battery. To retrieve the stored data, to charge battery or to set-up the patch, the cable must be connected to the patch and to the PC/MAC USB port.

The cable provided by the manufacturer is the only one compatible with eTact®, providing an optimum functionality and safe operating conditions.

In case of battery charging using a main plug, this one should be compatible with the following characteristics:

Input voltage: 220-240V ~ 50/60Hz

Output voltage: 5V

Output current: 1A

BodyCAP can also provide a compact main plug that perfectly fits with the device.

In case of battery charging through a PC/MAC USB port, this one should be compatible with the following characteristics:

USB 2 or USB 3

Output voltage: 5V

Driving capability: 0.5A

Remark: When using a computer to charge eTact battery, no need to open eTact® Watcher software.

## 6. The patch management software « eTact® Watcher »

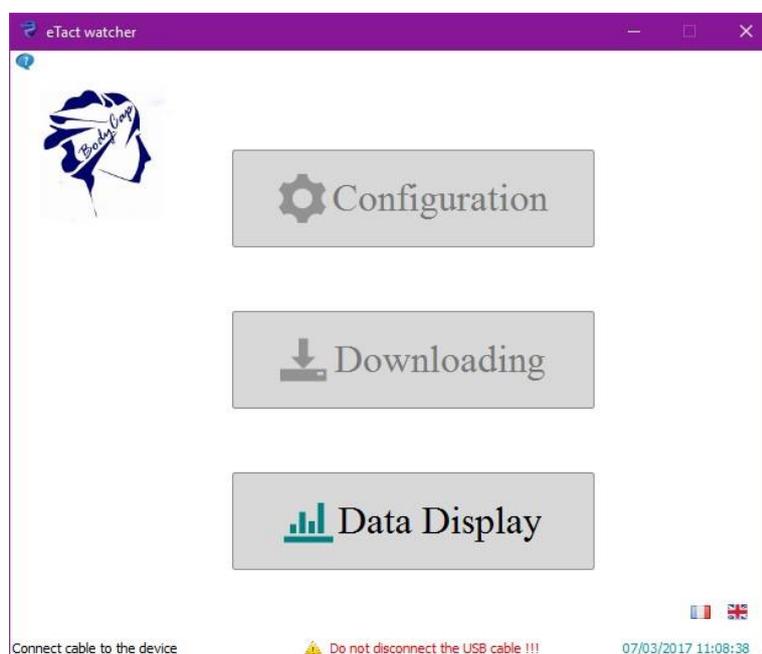
### 6.1. Start screen

eTact® Watcher is the computer software to:

- Set-up the configuration: This option allows to choose the period of each measurement parameters to store into the patch.
- Retrieve the data on a computer: The software allows to unload the data stored in the patch's memory to a PC/Mac through USB port
- Visualize the data: the software can display temperature & activity data day per day.

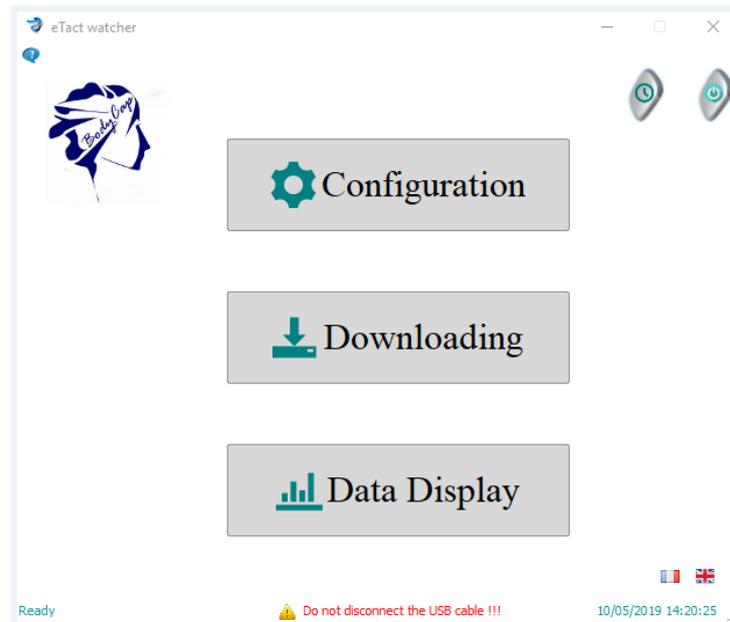
If you want to get access to all option, eTact® Watcher requests to connect the cable to the PC/MAC and then to the eTact®.

If the cable or eTact® are not connected, the data display action will be the only possibility.



Picture 4: Main menu when eTact® is unconnected

Once the patch is fully connected to the PC/MAC, the main window gives access to the full functionalities.



Picture 5: Main menu when the device is operational

Some buttons are available and allow different actions:

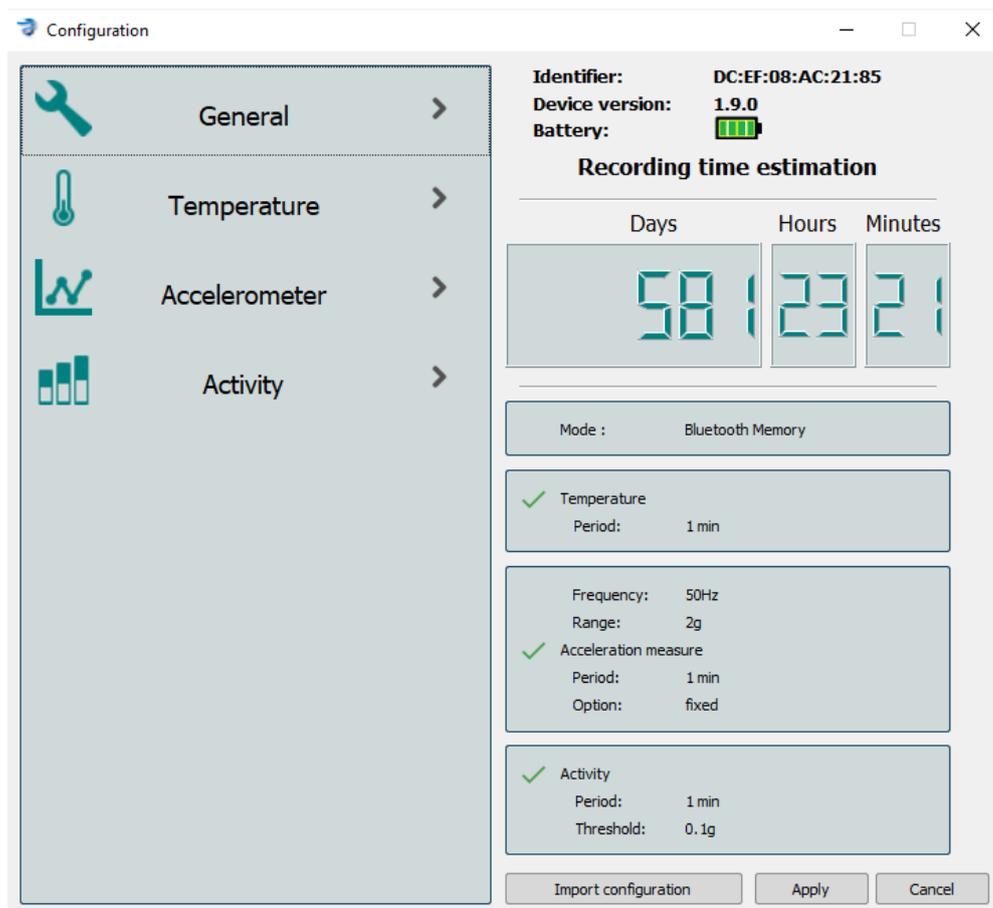
	Select language: French / English
	Setting eTact® internal clock
	Switch off the device (stops ongoing recording and sets the patch in shelf mode)

## 6.2. eTact® configuration

A synthetic window is displayed, providing all important parameters that could be set-up. The ultimate used configuration is displayed for each parameter: temperature, activity, accelerometer. The configuration of each parameter is possible from the left part of the window. The right part displays a sum-up of the chosen parameters. The active configuration of the patch is provided in the right part of the screen at window opening.

A battery level indicator and the MAC address & software version of the patch are given at the right top of the screen.

The maximum estimated recording time (full memory) depends on the chosen parameters and is displayed on the right part of the screen. The calculation is done whenever a parameter is changed.



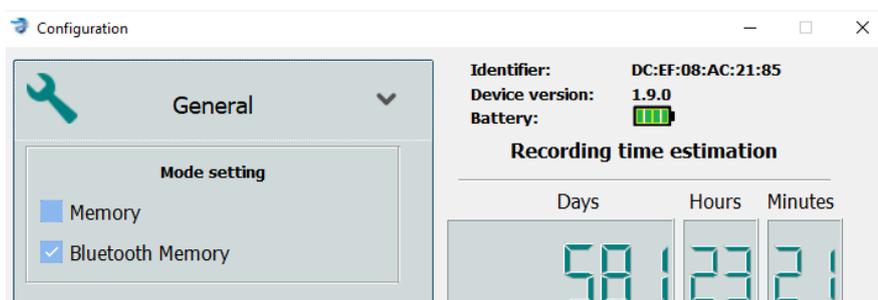
Picture 6: eTact® settings control panel

**Warning:** Once the configuration is validated, the data stored into the patch will be automatically erased.

### 6.2.1. General settings

User has the choice to set eTact® patch in two different modes:

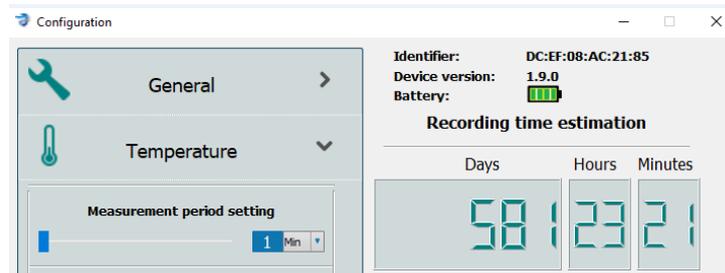
- Memory mode: all the data are stored in the memory and available on eTact® Watcher through the cable.
- Bluetooth/memory mode: advanced mode which require the creation of an Android application to save and display the data. It must include an integration of a BodyCAP library for BLE communication.



Picture 7: General setting

## 6.2.2. Temperature measurement settings

It is possible to select the temperature measurement period setting with a value in min or s. (from 30s to 30min)



Picture 8: Temperature acquisition setting

## 6.2.3. Accelerometer settings

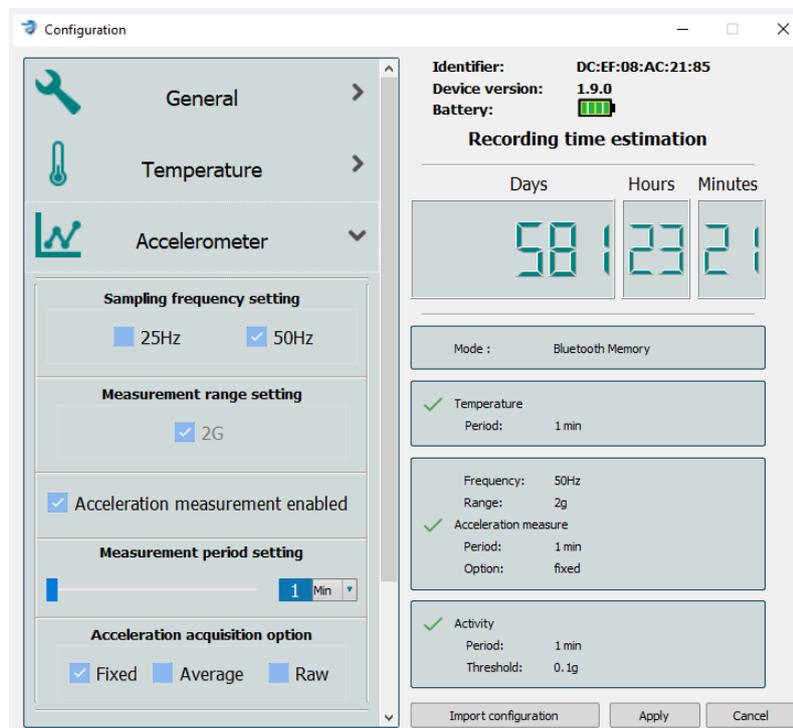
The accelerometer range is  $\pm 2G$ .

The accelerometer acquisition frequency can be set to 25Hz or 50Hz.

Options are suggested giving the possibility to provide complementary acceleration data:

- Fixed option: takes the instantaneous acceleration value just at the end of the chosen sampling period (from 30s to 30min)
- Average option: Return the average of signal magnitude vector calculated 25 or 50 times per second (depending on settings) during the selected period (from 30s to 30min).
- Raw option: All acceleration samples are stored into memory with a frequency of 25 or 50Hz.

**Note: This option is not compatible with actimetry measurement. Setting this option will automatically deactivate activity measurement.**

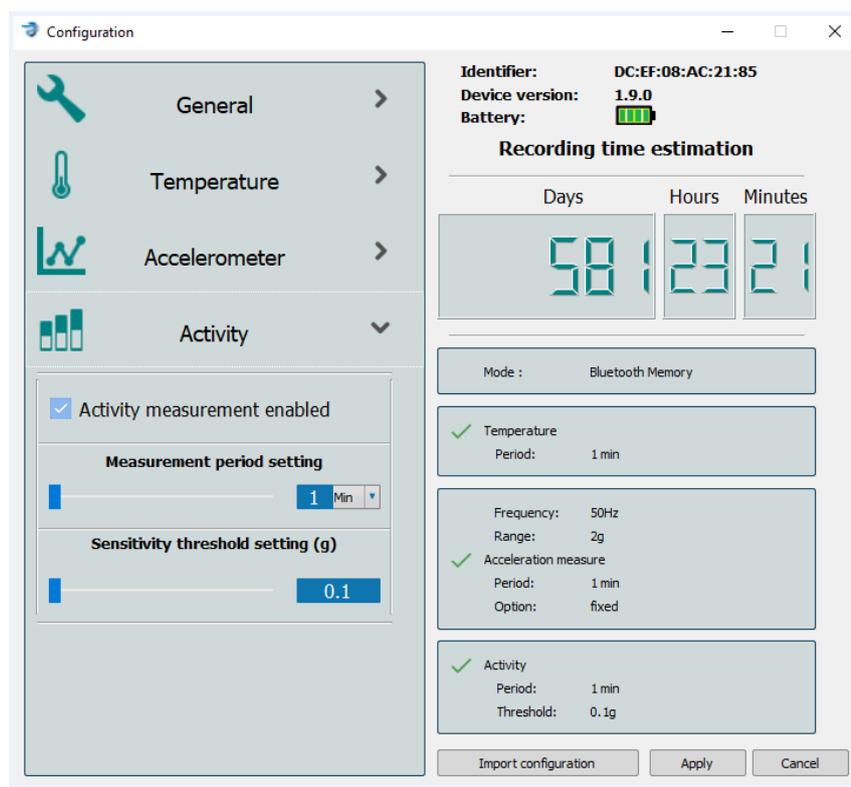


Picture 9: Accelerometer settings

### 6.2.4. Activity tracker settings

The activity measurement configuration is accessible after a click on the arrow > is done. It is then possible to:

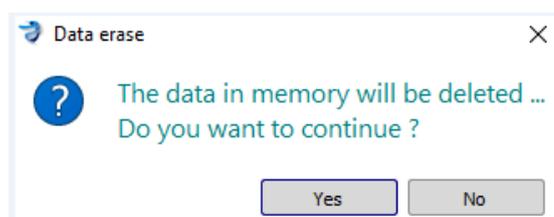
- Enable/disable the activity algorithm (TAT based algorithm)
- Adjust the algorithm computing period in min or s (from 30s to 30min). The TAT value recorded for each period corresponds to the number of times the selected acceleration threshold was reached or exceeded. Thus, for a configuration of 25Hz associated with a period of 1 minute, the recorded TAT values will be between 0 (no activity) and 1500 (system saturation corresponding to a maximum activity:  $25\text{Hz} * 60\text{s}$ )
- Adjust the acceleration threshold to compute the activity level (a 0.1G threshold correspond to an acceleration value of 1.1G).



Picture 10: Activity settings

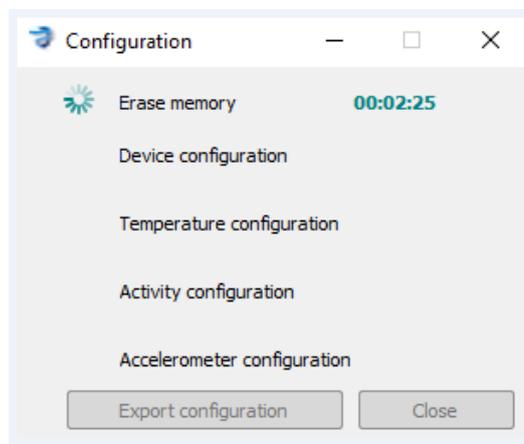
### 6.2.5. eTact® programming

After the « Apply » icon has been pushed (Configuration window), a new window opens and indicates the programming status.



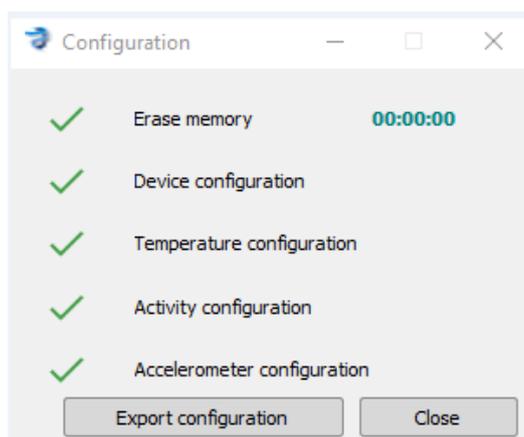
Picture 11: memory erase

Warning: the first part of the configuration is a full and automatic erase of eTact® memory. This action will take a few minutes. The remaining time before the erase completion is indicated. **It is strictly forbidden to disconnect the patch or the cable during this time, otherwise the system could be damaged.**



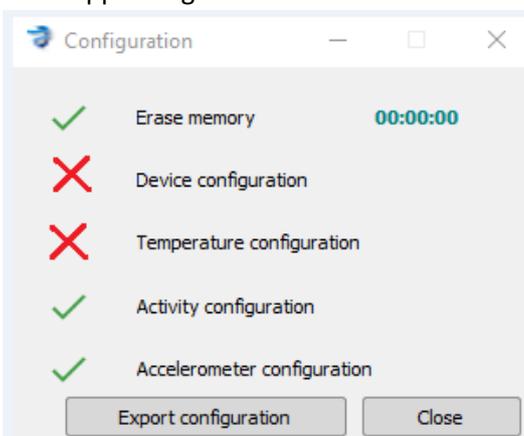
Picture 12: eTact® configuration programming

When the configuration is completed, a status is provided as followed:



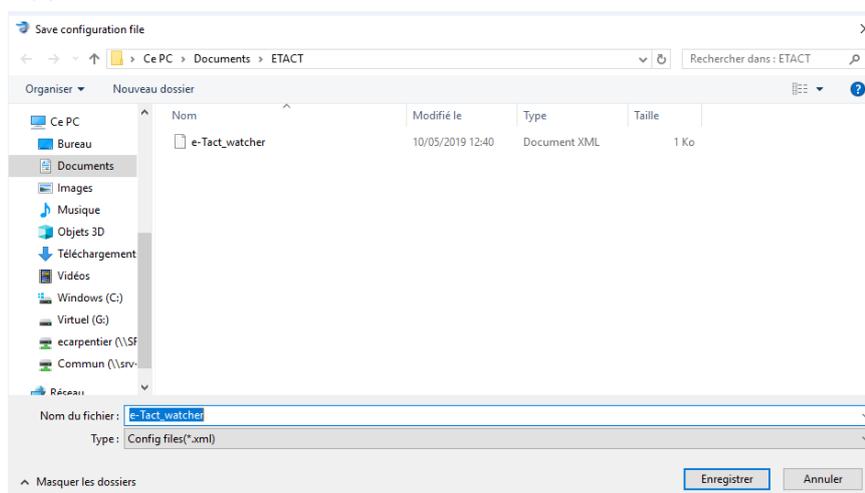
Picture 13: Configuration successful

When the configuration fails, a red cross indicates the wrong parameter. In this case, the configuration parameters should be checked and applied again.



Picture 14: Configuration failure example

The « Export configuration » button gives the user the possibility to save the patch configuration into an .XLM file. The same parameters can be applied later to multiple patches by importing this file in the configuration window.



Picture 15: eTact® configuration export window

### 6.2.6. eTact® Analysis

eTact Analysis is a tool to process and analyze data recorded by eTact.

Using eTact® Analysis software to process data from the patch eTact requires a dedicated configuration:

- Activity period: 1min
- Temperature measurement period: > 1min
- Accelerometer mode (OFF, FIXED or AVERAGE)
- Accelerometer period (Fixed or Average): > 1min
- Accelerometer frequency: 25Hz
- Activity sensitivity threshold: 0.1G

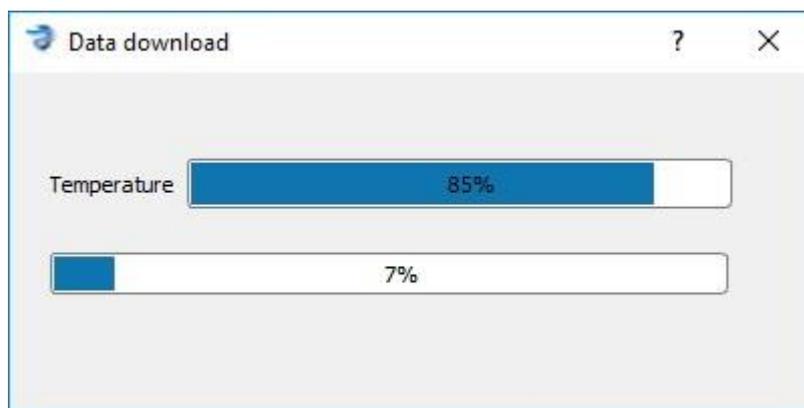
eTact Analysis software is described in a dedicated user manual. Please read it carefully before using it.

### 6.3. Data transfer (download)

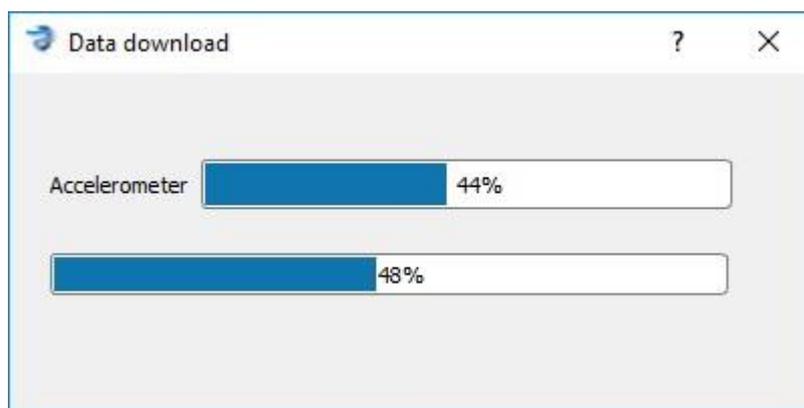
The recorded data into the internal memory of the patch can be downloaded through the cable connected to a PC/MAC. In the main eTact® Watcher window, a simple click on the “Download” button is necessary. **During data download, it is strictly forbidden to disconnect the patch or the cable from the computer otherwise the system could be damaged.**

A new window pops up, providing the status of the downloaded data:

- A progress bar on the type of transferred data (temperature, activity, accelerometer)
- A global progress bar of the full download data.

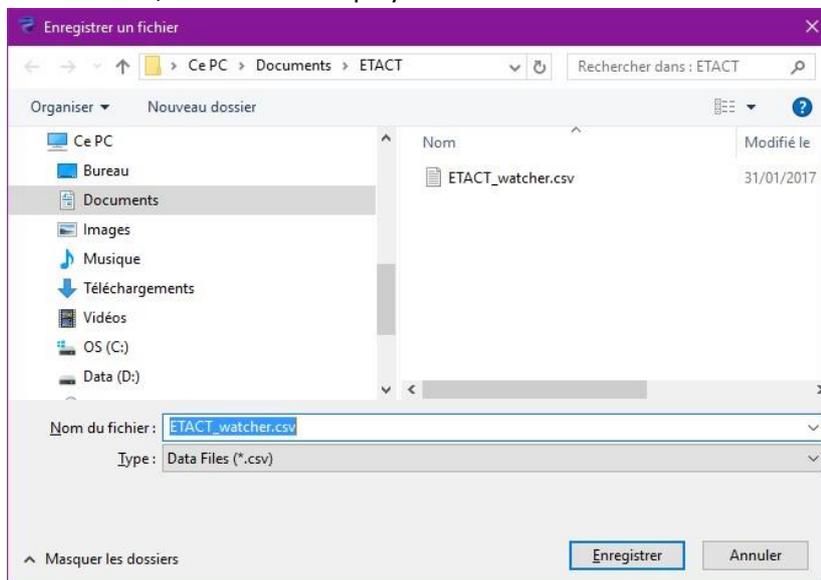


Picture 16: Data transfer (temperature)



Picture 17: Example of global data transfer at 48% (Accelerometer data transfer)

At the end of the data transfer, a window is displayed to select the root for the .CSV file generation.



Picture 18: Downloaded data file saving

After the download is finished, a confirmation is requested to keep or erase the eTact® memory. This action is definitive. However, it only concerns data, the configuration settings remain in the memory.

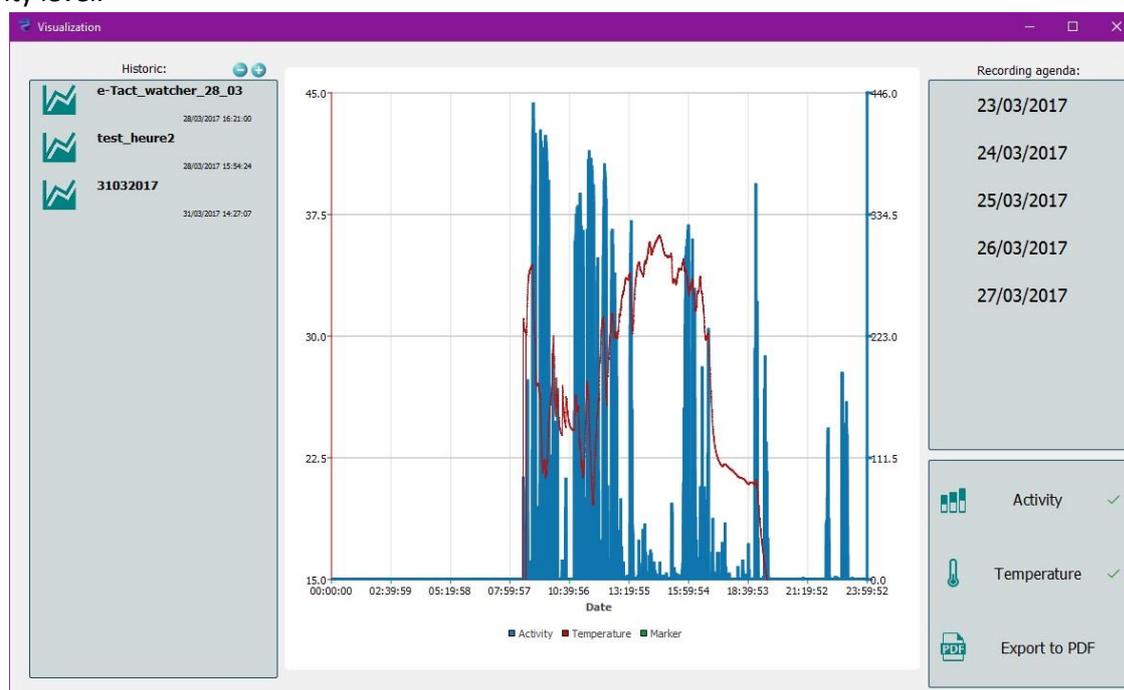


Picture 19: Memory erase confirmation

## 6.4. Data display

### 6.4.1. Graphic view with eTact Watcher

In the main eTact® Watcher window (picture 4), select the « Data Display » icon. Select then the .CSV file to display. The data are displayed in a dedicated window, providing temperature and activity data information. The left axis corresponds to the temperature in °C and the right axis corresponds to the activity level.



Picture 20: Temperature and activity display

A .CSV list is available in the left part of the window. The files previously downloaded into the eTact® directory are displayed on this section. It is possible to import additional files (pressing the (+) icon) stored in other directories. The list can be deleted (pressing the (-) icon).

If the patch was used for more than one day, the visualization will be displayed day per day. On the right part of the window shows a “Recording agenda”.

To finish, on the bottom right, some options help to filter the data (only temperature or activity). An export of the visualization in PDF file is also possible.

### 6.4.2. CSV file

Downloading data of the patch through eTact Watcher will automatically generate a .CSV file saved to the selected folder at the end of the download process. This .CSV file can be opened with a software like Excel.

	A	B	C	D	E	F	G	H	I	J	K	L	M	N	O
1	@MAC		Soft Rev	Mode	TempStatus	TempPeriod	AccStatus	AccCnfFreq	AccCnfRange	AccPeriod	AccOpt	ActStatus	ActPeriod	ActThreshold	
2	CB:81:01:16:BA:61		1.9.0	BLE_FLASH	YES	900 sec	YES	50 Hz	2 g	900 sec	AVERAGE	YES	900 sec	0.1 g	
3															
4	Index	Date	Temperature	Activity	X-axis	Y-axis	Z-axis	Average-Acc	Marker	Informations					
5	0	01/04/2019 11:55								DECONNECT					
6	1	01/04/2019 11:55								BLE / FLASH					
7	5	01/04/2019 11:55								BATTERY LOAD : 100%					
8	902	01/04/2019 12:10	24,34	252				0,998884							
9	1802	01/04/2019 12:25	24	0				0,999127							
10	2702	01/04/2019 12:40	23,94	0				0,998841							
11	3602	01/04/2019 12:55	23,89	0				0,998983							

Picture 21: CSV file header

The two first lines of the CSV file displays the chosen configuration applied on the patch:

- @MAC: Patch MAC Address
- Soft Rev: Patch software revision
- Mode: Flash or BLE\_Flash
- TempStatus: Temperature status (compulsory)
- TempPeriod: Temperature Period (from 30s to 30min)
- AccStatus: Accelerometer status (Row/Average/Fixed)
- AccCnfFreq: Accelerometer Frequency Configuration (25Hz or 50Hz)
- AccCnfRange: Accelerometer measurement range (2G)
- AccPeriod: Accelerometer period (from 30s to 30min)
- Accompt: Accelerometer option (Row/Average/Fixed)
- Act Status: TAT activity status
- Act Period: Activity period (from 30s to 30min)
- Act Threshold: Activity sensitivity threshold (from 0.1G to 1G)

The following lines are related to patch data:

- Index: not used.
- Date: Timestamp of the data (format: DD/MM/YYYY HH:mm:ss)
- Temperature: Temperature measurement in °C
- Activity: TAT count
- X-axis / Y-axis / Z-axis: Accelerometer data (fixed or raw options)
- Average-Acc: Average of Acceleration data
- Marker: Automatic & manual markers
  - Connect: Patch is connected to cable
  - Disconnect: Patch is disconnected to cable
  - Flash / BLE-Flash: selected mode
  - Battery load xx%: Battery level (automatic measurement from disconnection and every 6h)
  - Shutdown: patch shutdown (user action, low batt etc...)
  - Wake up: following shutdown
  - Timestamp updated: timestamp of the patch was updated (with eTactWatcher or webpage)
  - USER: long press on the patch button generate user marker
  - Low Battery: patch battery is running low
- Information:
  - Time is not reliable: This data is timestamp, but you can't be sure of the integrity of the date/time. You must update the patch

## 7. Warranty

BodyCAP guarantee the proper system functioning when handled correctly and in accordance with the instructions provided in this user manual.

**eTact® is under a 1-year limited warranty.**

## 8. eTact® important information.

### 8.1. Important information and safety instructions

#### Battery

eTact® embeds a Lithium polymer battery. Therefore, the device must follow the recycling procedure at the end of lifetime.

#### Cleaning

eTact® is delivered in a separate packaging. The device can be regularly cleaned using a hydro-alcoholic solution after a monitoring period. It is strictly recommended to keep the cover properly closed to avoid any cleaning solution inside eTact®. Never perform immersion on the device.

#### Using eTact® on a long period

In case the patch is worn in a permanent way, it is recommended to switch between different areas on the body to let the skin breathe properly.

#### Keeping eTact® in place on the skin

Keeping the patch properly in place is possible using a transparent film dressing frame, specifically designed for long term wear.

BodyCAP can provide the transparent film in quantities.

### 8.2. Manufacturer



#### BodyCAP

+33 (0)2.61.53.08.14

3 rue du Docteur Laennec

14200 Hérouville Saint Clair

FRANCE

<http://www.bodycap-medical.com>

### 8.3. Main characteristics

<b>Dimensions:</b>	Length: 37 mm. Height: 41 mm. Thickness: 7mm
<b>Weight:</b>	≈ 9 g
<b>Storage temperature:</b>	0°C – 28°C
<b>Operating temperature:</b>	10°C - 45°C.
<b>Temperature Sampling frequency:</b>	adjustable from 30s to 30min.
<b>Activity Sampling frequency:</b>	adjustable from 30s to 30min.
<b>Power supply:</b>	Lithium Polymer rechargeable battery 3.7V 0.14Wh typ.
<b>Autonomy:</b>	7 days typical (depending on the configuration parameters)
<b>Plastic:</b>	ABS-PC and opening in elastomer
<b>Storage duration on a shelf:</b>	7 months if the system of Off with a fully charged battery.

### 8.4. Regulatory Notices

**CE** : The eTact® product is compliant with the essential requirements and the listed European Directive in the CE declaration.

**Contains FCC ID: 2AAQS-ISP130301:** the device integrates a radio frequency module compliant with the part 15 of the FCC rules (Federal Communications Commission of the United States).