Somno ART

SOMNO-ART DEVICE USER MANUAL



PPRS

THE STRATEGIC PARTNERING ORGANIZATION

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Safety measures



Caution: read this manual thoroughly and carefully before using the device.



WARNING

This danger level indicates a potentially hazardous situation that can cause physical injuries or death. Accidents may result from the incapacity to avoid the hazardous situation. This is why it is important to follow the instructions given in this warning, in order to avoid bodily harm.



INFORMATION

Informative note allowing access to additional information leading to a better use of the device.

Indication and intended use

Somno-Art Device records synchronously an estimation of the heart rate alongside the quantification of forearm movements (actimetry) during sleep allocated time. Heart rate information is derived from pulse signal and averaged every second while the quantification of movements is accumulated every second.

Somno-Art Device ambulatory recordings are intended to be used for sleep structure characterization and as an aid for diagnosis or treatment follow-up of sleep disturbances and disorders (eg. insomnia, hypersomnia).

Somno-Art Device records forearm movements (actimetry) continuously for more than 24h.

The recordings are intended to be used for the characterization of circadian rhythms.

Somno-Art Device can be worn on a forearm with a circumference between 22 cm and 32.5 cm.

Contraindications

- Do NOT open, tamper with nor modify the device
- Do NOT under any circumstance charge the device while it is being worn
- Do NOT use the device in case of allergy to one of its components
- Do NOT wear the device over a wounded or unclean skin
- Do NOT place the device in contact with water under any circumstance, be it cleaning or otherwise
- Do NOT tighten the textile armband too much

Safety precautions

USE OF SOMNO-ART DEVICE:

- Somno-Art Device must be placed on a clean, unwounded skin
- Configuration, installation and delivery of the device must be done by trained professionals
- Do not use Somno-Art Device in case of allergy to the following materials :
  - Polyamide (PA), Elasthanne (EA), Polyurethane (PU) and Polyester for the textile armband
  - Acrylonitrile Butadiene Styrene Polycarbonate (ABS PC), Polycarbonates (PC) and thermoplastic elastomers (TPE) for the recorder

- Somno-Art Device should be cleaned between every user
- Somno-Art Device must be stored in its packaging between every use, placed in its plastic bag
- Do not look directly at the green LED located under the device



RECHARGING AND POWER SUPPLY OF THE DEVICE:

- Recharge the device before first use
- The device must be recharged exclusively using the USB cable provided with the product and plugged on a computer compliant with norm EM 60950 (cf. page 23)
- Do not clean the device while it is recharging



EXPOSURE TO CONTRAINDICATED CONDITIONS:

- Do not expose the device to water or projections of water



MISCELLANEOUS:

- A shock or a fall of the device can cause malfunctions. In that case, get in touch with Somno-Art support team (cf. contact page 12)
- The device is compliant with norms EN 60601-1-2 for electromagnetic compatibility and EN 60601-1 electrical safety

- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the Somno-Art Device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The use of this equipment adjacent to or stacked with another equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be monitored to verify that they are operating normally.
- In case of device malfunction or deterioration, get in touch with Somno-Art support team (cf. contact page 12)

Conditions of storage and use

The device must be used and stored in dry, enclosed premises at room temperature:

- Room temperature between +10°C (+50°F) and +40°C (+104°F)
- Relative humidity between 30% and 75%
- Atmospheric pressure between 700 hPA and 1060 hPA

Do not expose the device to water or projections of water.
Any storage or use outside these conditions may result in malfunction or premature wear of the device.

Shelf life

The shelf life of Somno-Art Device is 3 years under normal use.

Contact assistance

For any issue or information, contact us at:

support@somno-art.com

Manufacturer

PPRS
4E, Avenue du Général de Gaulle
68000 Colmar
France

+33 (0)3 89 20 19 51
support@somno-art.com

Explanation of the symbols



European Conformity



Do not expose to liquid projections



Do not throw away in the trash. Requires a distinct disposal process



Refer to the manual



Serial number



Manufacturer



Compliant with the requirements of the norm IEC 60601-1 to ensure protection against electric shocks



Supplied only with DC power

IP22

International Protection marking IP22, protection against intrusion of solid foreign objects superior to 12.5 mm and protection against dripping water when tilted at 15

CHAPTER 1
About the Somno-Art Device

CHAPTER 1

About the Somno-Art Device

The Somno-Art Device is a Class IIa medical device intended to be used in clinical studies: at a sleep clinic or at the user's home. It is composed of a recorder that measures the wearer's heart rate from their pulse as well as their arm movements during the night. The device is designed to put the sensor window (cf. (a) diagram page 19) in contact with the subject's forearm, thanks to an armband that holds the device.
The companion software allows the configuration of the recorder and the recorded data management.

The recorder



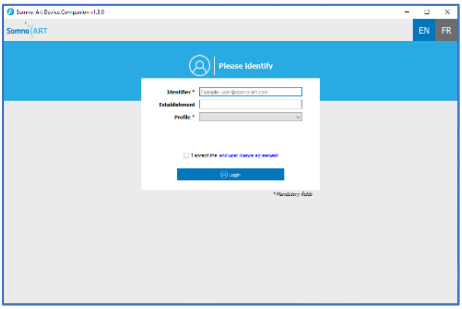
It allows to record the heart rate in beats per minute (BPM) at a frequency of 1Hz. Movements are recorded over the three axes and accumulated every second.

The textile armband



It allows the user to wear the device on their forearm.

The Companion software



It allows configuring and managing the recordings from the device.

The recorder



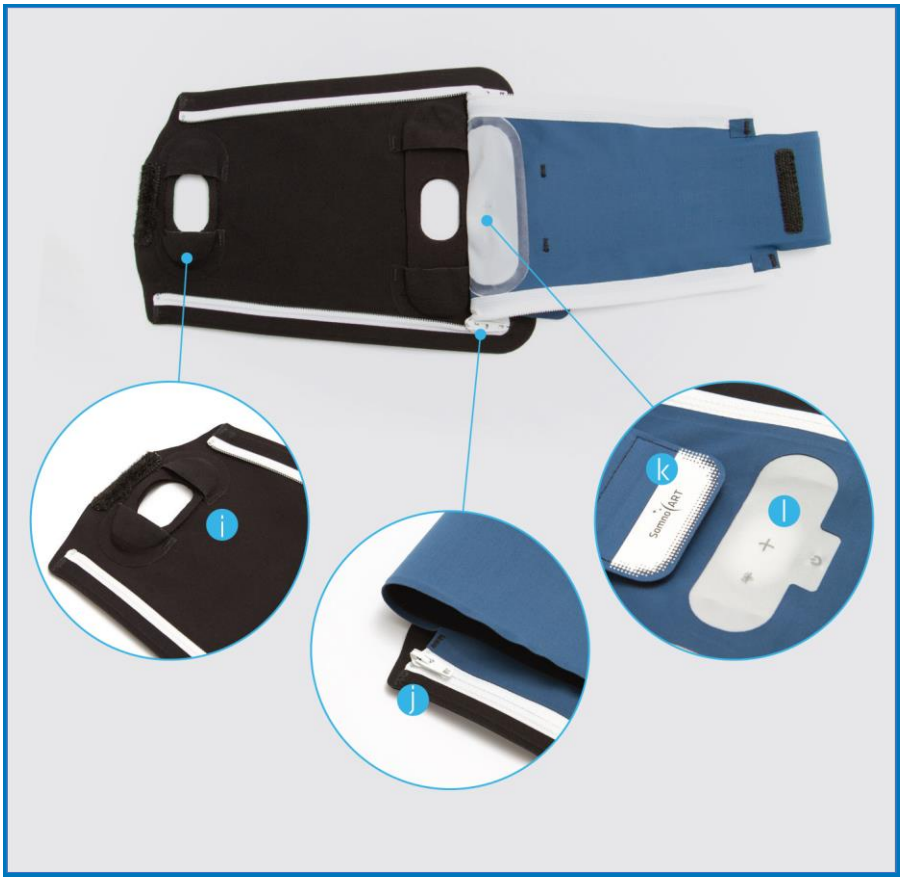
(a) Sensors
(b) Memory LED
(c) Recording LED
(d) Battery LED
(e) Bluetooth button
(f) Event button
(g) USB connection
(h) ON/OFF button

The armband





Once the device is in place in the armband and turned on, the LEDs from the device are visible through the fabric.



(i) Recorder fixation strap
(j) Zipper
(k) Scratch strip
(l) See-through textile window to visualize the LEDs and press the buttons

Other accessories

The Somno-Art Device is supplied with different accessories:

- USB key to install the Companion software
- USB cable
- Disinfectant wipes
- Resealable plastic bags

Companion software

The Companion software has been specifically designed to be used in clinical or experimental research. Patients will never have access to this software; it must only be used in dedicated facilities such as hospitals or clinical sites. It allows the configuration and the management of data from the recorder.

The Companion software must be used by a qualified and trained person. Unqualified persons (study participants, caregiver, etc.) must not have access to the software.

Minimal system configuration

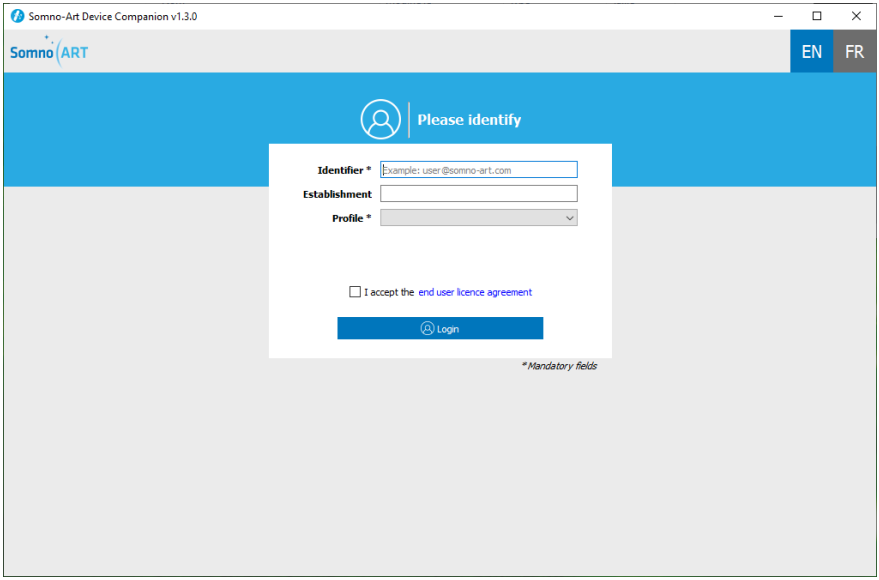
- OS : WINDOWS 7, 8, 8.1 and 10
- Port : USB or Bluetooth*
- Program size: ~ 20 Mo
- File size: < 4 Mo per full night
  Anticipate at least 64 Mo per device
- RAM : > 1Go
- Processor : 1.6 GHZ
- Monitor: minimal resolution 1 024x768

* Only on Windows 10 version 1607 or superior, on a PC with Bluetooth capabilities.

Companion software installation and identification



The Companion software does not require prior installation. It is enough to double-click on the executable provided to start the application. The complete executable folder is required for the software to run.



Once the Companion software opened, the identification window will appear, where a username and profile are required to be entered. Filling in the establishment is optional but recommended in order to improve the data traceability.

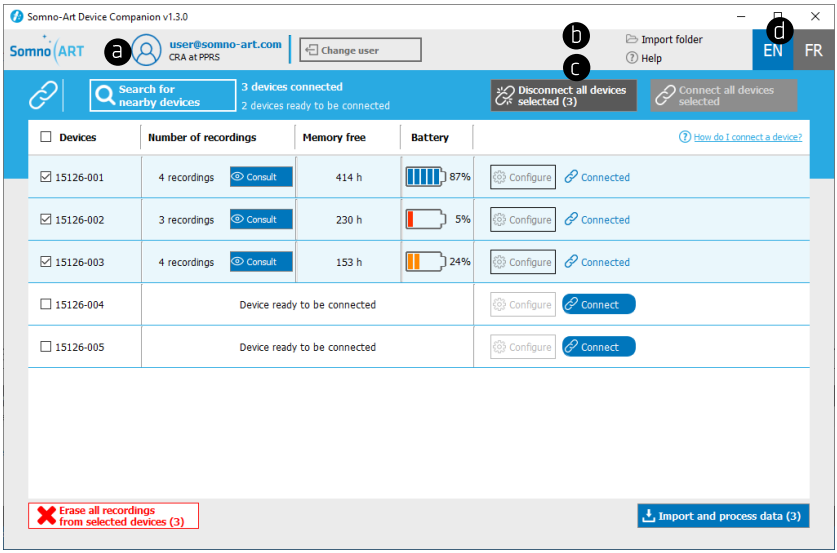
The user must also accept the End-User License Agreement in order to proceed.

General interface introduction

The Companion software has five key functions:

- User profile identification
- Connection and disconnection of one or more devices
- Configuration of a device
- Import and processing of recordings from one or more devices
- Erasure of all recordings from one or more devices.

The main navigation menu at the top of the screen is composed of different elements:



(a) Reminder of the identified user and an option to change the user
(b) Option to change the output folder for the recordings
(c) Access to the built-in software help
(d) Option to change the language (English or French)

CHAPTER 2

Connection and configuration of Somno-Art Device

CHAPTER 2

Connection and configuration of Somno-Art Device

Connection of the recorder to the Companion

Once identified, the page of device connection is shown. There are two possibilities to connect to the Companion software:

- USB connection
- Bluetooth connection

USB connection

Connect a device with USB as follows:

1 - Plug in the USB cable



Connect the USB cable to the device then to the computer. The device briefly vibrates twice and automatically displays the operating state of the device.

2 - Connect to the Companion software



Once plugged in, the device will be automatically recognized by the Companion software and connected.

Once the device is connected, the event and memory LEDs light up and remain lit.

The battery LED will either flash green or stay green depending on the level of charge.

Bluetooth connection

Connect a device with Bluetooth as follows:

1 - Turn on the Bluetooth on the computer

To turn on the Bluetooth on the computer:

1. Go to the Start Menu
2. Click on Settings > Devices
3. In the following window, verify that the Bluetooth is set to "Active"

2 - Turn on the device



To turn the device on, press the ON/OFF button for 2 seconds.
The device briefly vibrates twice and automatically displays the operating state of the device for 5 seconds.

It is necessary to press on the Bluetooth button within the 5 seconds after turning on the device, as explained below. Otherwise, start again.

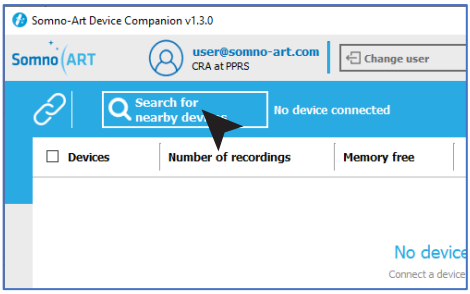
3 - Turn on the Bluetooth on the device



Press the button for 2 seconds to turn on the Bluetooth.

Once turned on, the device will try to pair with the Companion software and therefore with your computer. The 3 LEDs of the device will flash blue successively.

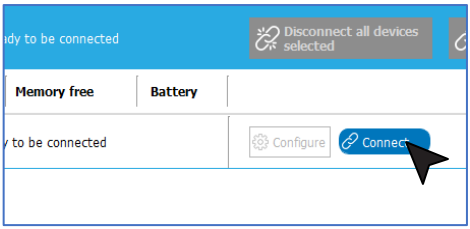
4 – Display the device on the Companion software



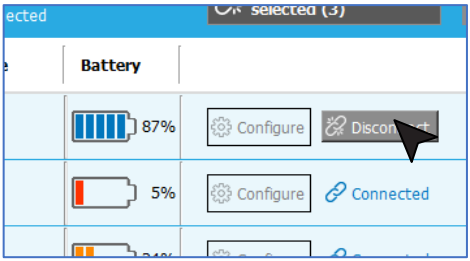
Click on "Search for nearby devices" on the Companion software.

It is necessary to press on the "Search for nearby devices" button in the following minute after turning on the device. Otherwise, start again.

Once the device has been detected by the Companion software, it will appear in the list of nearby devices ready to be paired with.



Click on "Connect" to connect the device.



Simply click on the button again to disconnect the device.

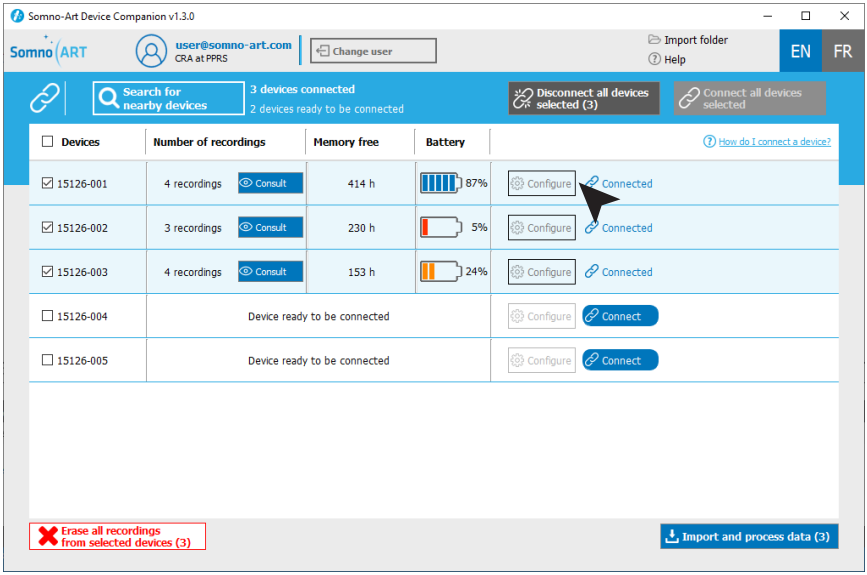


Once the device is connected, the LEDs will light up and remain blue.

Configuration of Somno-Art Device

1 - In order to configure a device, connect the device to the Companion software. Then, go to the device configuration page:

- either by clicking on the "Configure" button in the list of devices
- or by clicking on "Consult" then "Configure" once you are on the device import page.

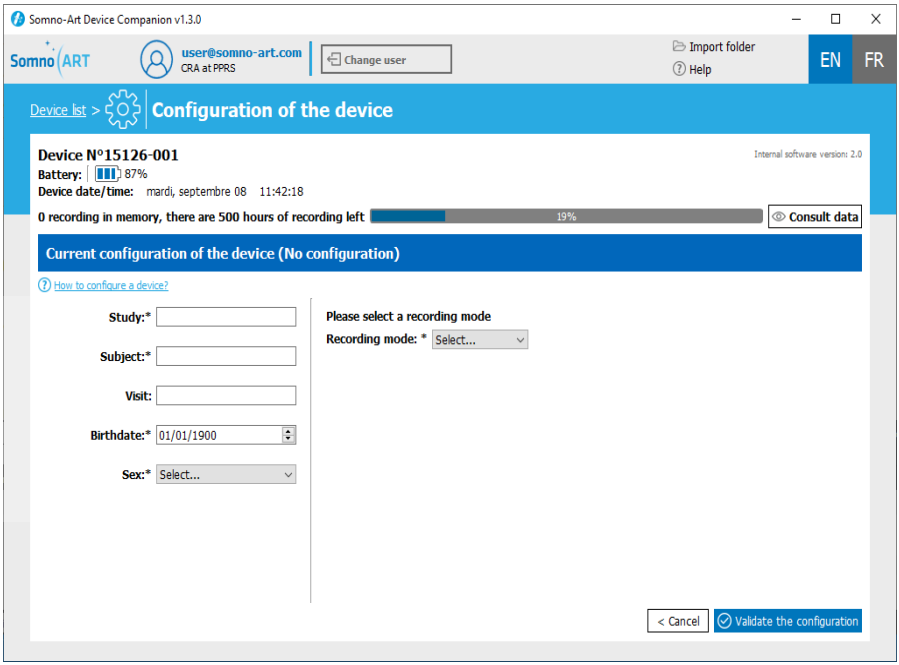


If one or more recordings are on the device, delete the data if they have already been imported and processed. Otherwise, import, process and then delete the data from the device.

2 - Once on the device configuration page, fill in the various fields with the subject details.

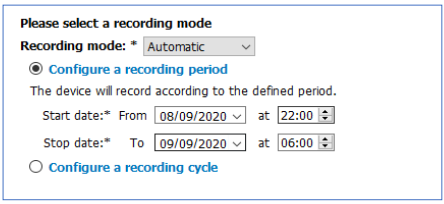
All fields must be entered. Those followed by an asterisk are mandatory:

- The study code
- The subject code. In order to ensure the anonymity of the subjects, do not use their surname and/or first name, avoid using initials and respect the format of the study code
- The visit code (optional)
- The date of birth of the subject recorded
- The sex of the subject recorded

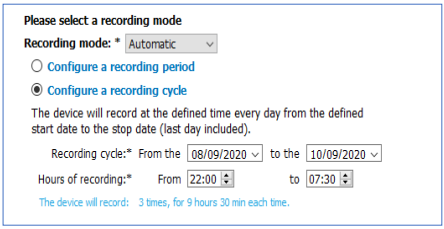


3 – Then, enter the recording mode. Select one of the two recording modes available:

- Manual mode: In manual mode, the user starts and stops the recording or turns the device on or off.
- Automatic mode: In automatic mode, the device is programmed to turn on and off at a set date and time. Recording starts and stops automatically. Two configurations are possible in automatic mode:



Configure a recording **period**: In this mode, the device turns on and records during a defined period.

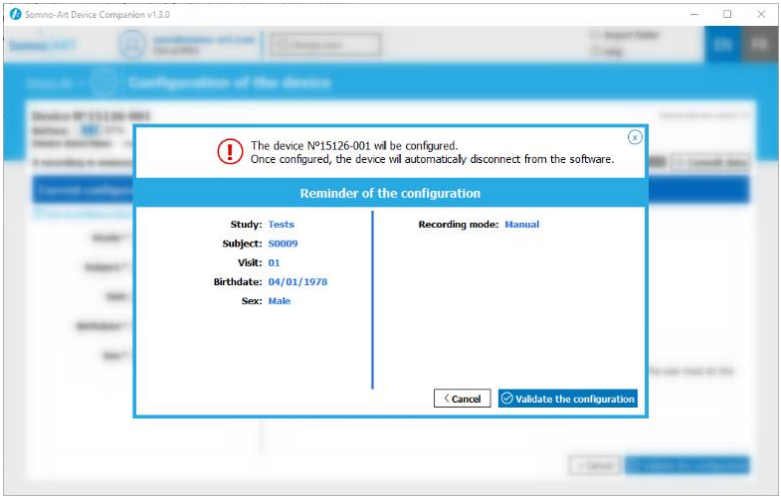


Configure a recording **cycle**: In this mode, the device records during the defined times every day from the start date until the end date.

4 - Once the recording mode has been selected, click on "Validate configuration":



5 - After confirming, a summary message will appear, reminding the chosen configuration. Check the configuration and click on "Validate configuration" if it is correct or click on "Cancel" to go back.



Once the configuration is complete, devices connected using Bluetooth will automatically disconnect from the Companion software.

CHAPTER 3
Use of Somno-Art Device

CHAPTER 3 Use of Somno-Art Device

These are the steps for wearing the device:

1 - Inserting the recorder into the textile armband





Open the armband completely to fit in the recorder.





Insert the extremities of the recorder into the fixation straps. Once the device is in place, close the armband with the zippers and secure it with the central scratch strip.



2 - Wearing the device





Choose the non-dominant arm (left arm for a right-handed person).

Start by positioning the scratch strip and insert the forearm in the armband. The device should be placed on the upper forearm.

Tighten as required using the scratch strip on the armband.



The armband must not be tightened too much, but enough so that the device will not move when the arm is pointing downwards.

Preferably, the main casing should be placed on the inside the forearm.

1 - Starting the device



To turn the device on, press the ON/OFF button for 2 seconds. It will briefly vibrate twice and automatically display the operating state of the device for 10 seconds.

In automatic mode, the device turns on automatically and cannot be turned on outside the programmed recording hours, aside from displaying the device state.

2 - Display of the operating state of the device

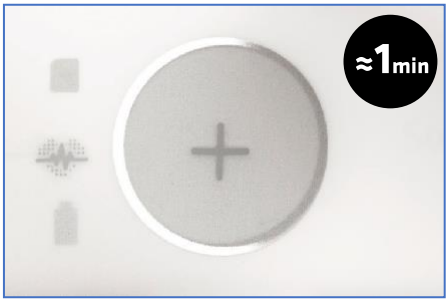


The operating state of the device is displayed for 10 seconds and shows the following information:

Memory level

Battery level

3 - Calibration phase



Once the display of the operating state is over, the device calibration phase begins automatically. During the calibration, the LEDs flash white one after the other.

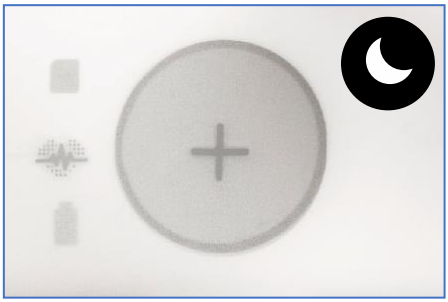
When the calibration is completed, all LEDs light up in green for 4 seconds. During this phase, it is recommended not to move the arm. The calibration phase lasts approximately 1 minute, but will take longer in case of movements.
If the LEDs light up continuously in orange, it means the calibration has failed. Turn off the device (by pressing the ON/OFF button for 5 seconds), replace it again on the forearm and turn it back on (by pressing the ON/OFF button for 2 seconds).

4 - Start of the recording



Once the calibration is complete, the recording sequence starts and the recording LED flashes according to the heart rate for 20 seconds.

5 - Switch to discreet mode



If the user does not press any button for a period of 20 consecutive seconds, the device will automatically switch to discreet mode. Even though the LEDs are not on, the device is still recording.

Exiting discreet mode



A short press on the ON/OFF button exits discreet mode during the recording. The device briefly vibrates twice, and the lights are turned on for 20 seconds, displaying the following information:

Memory level

Heart rate

Battery level

Marking an event



The user can mark an event happening during the night. For example, if the user gets up to drink some water or to go to the toilet, they can mark an event in order to report it.

During a recording, pressing the Event button for 2 seconds will allow marking an event at that moment.

To indicate that this event has been taken into account, the device will vibrate twice slowly.

Stopping a recording



In Manual functioning, the recording can be stopped by pressing the ON/OFF button for more than 5 seconds.
The device vibrates twice briefly and a third time longer, and the operating state is displayed for 5 seconds, then the device turns off.

In Automatic functioning, the device stops automatically the recording once the programmed end time is reached. The operating state will also be displayed before turning off.

Charging the recorder



The recorder is recharged by connecting it to the USB port of a computer.

When the battery is empty, the device is charged in 2 hours.

Before charging the recorder, always remove it from the arm.



When the device is charging, the battery LED flashes in green. Once fully charged, the LED stops flashing and stays green.

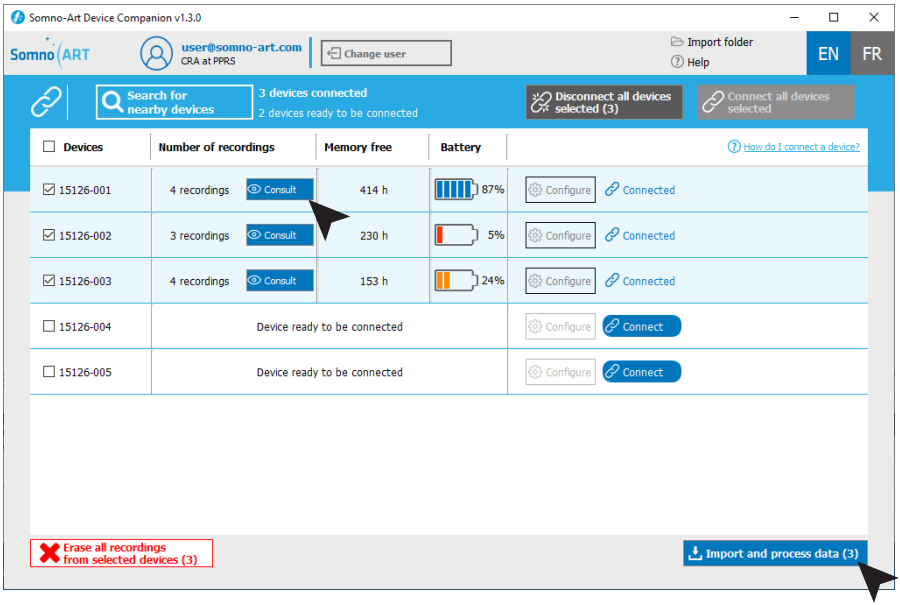
CHAPTER 4
Import and processing

CHAPTER 4

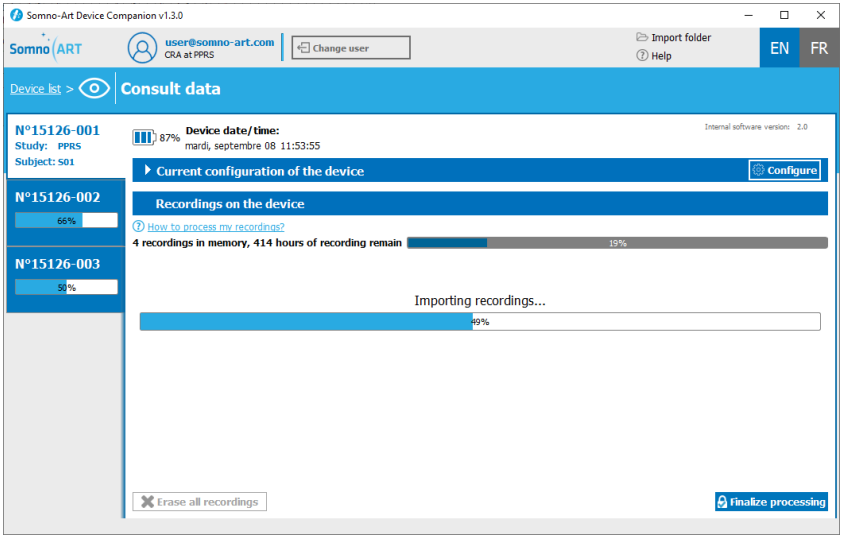
Import and processing

1 - In order to import and process the data from a device, connect the device to the Companion software. Then, go to import and data processing:

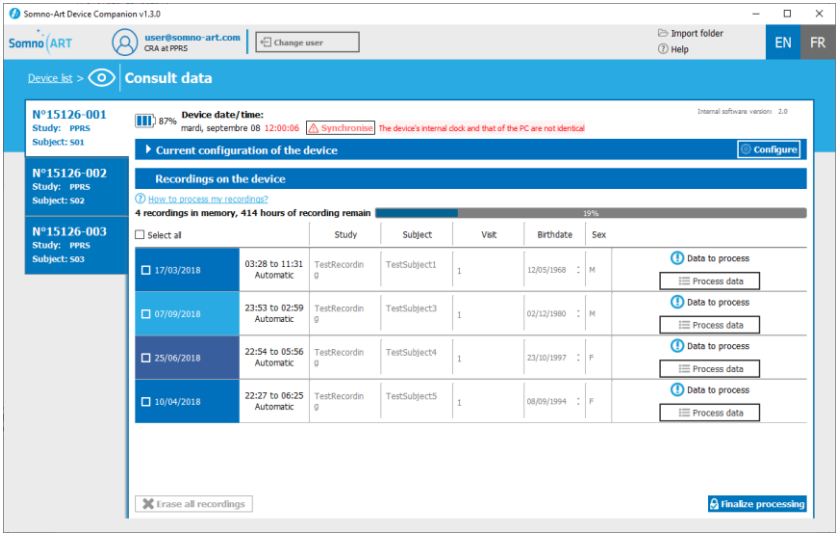
- either by clicking on the "Consult" button in the list of devices
- or by clicking on "Import and process data", having selected the corresponding device beforehand. Note that this way you can select up to 5 devices and start the import and processing of data for several devices at once.



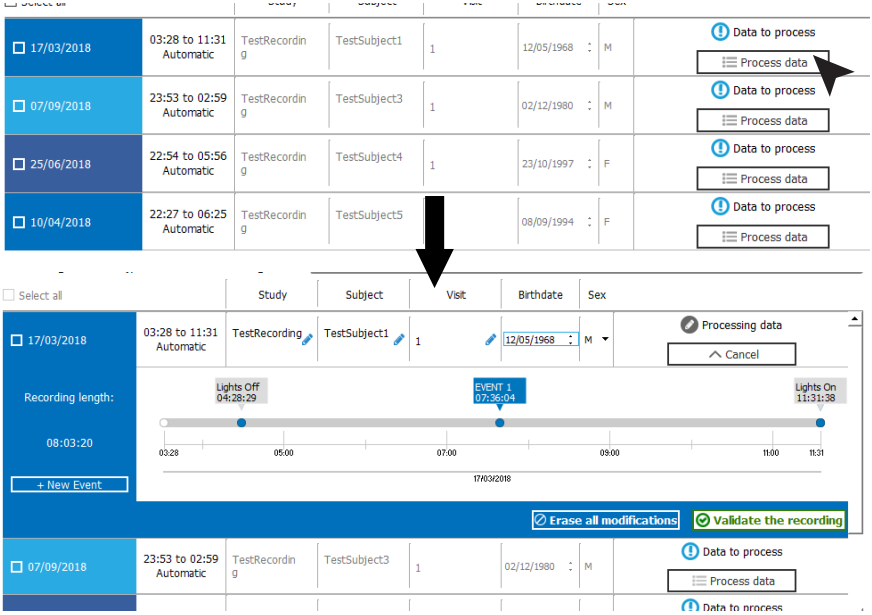
2 - Once on the data view and processing page, the progress of the import can be seen on the top left and in the middle of the screen.



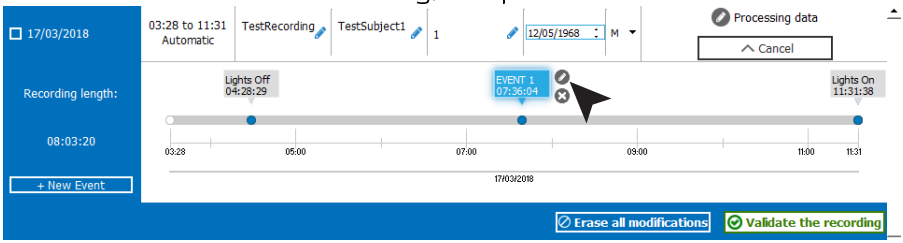
3 - After the data import is complete, all recordings for the participant appear in the second part of the screen.



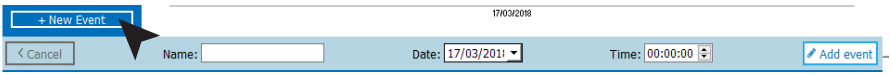
4 – Then, process the data from each recording in order to finish the data processing. To do this, click on "Process data" in order to display the details of the recording.



From the details of the recording, it is possible to:

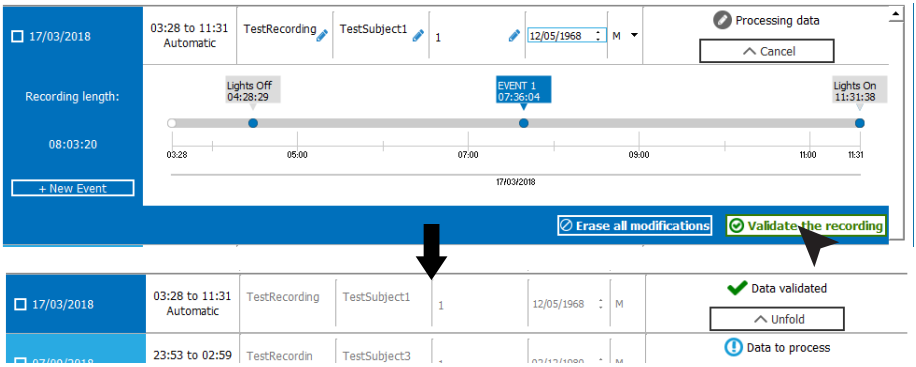


1. Modify or delete an event (options appear with a click of the mouse on the event)

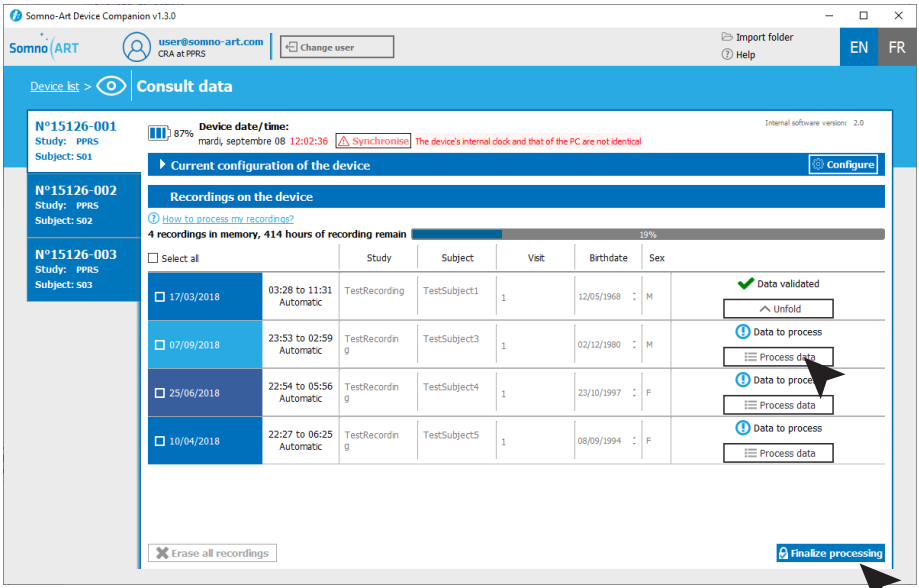


2. Add an event. Click the "New event" button to open a section where a new event can be recorded. After completing the fields, click on "Add event".

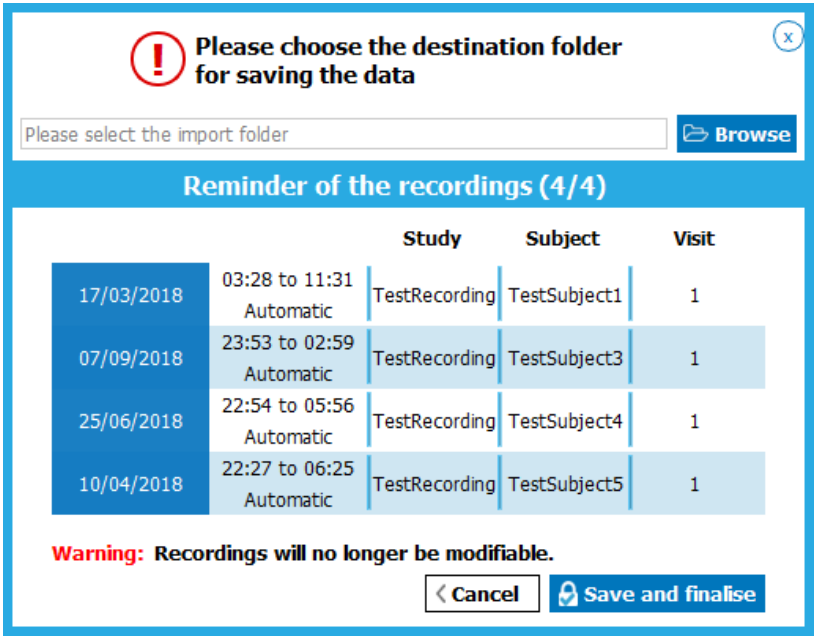
5 – Once the modifications are complete, click on "Validate modifications" to finish processing the recording.



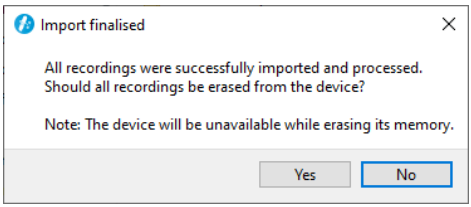
6 – Perform the same step for all recordings. Once all data have been processed, click on "Finalize processing".



7 – After confirming, a summary message will appear, reminding the processed recordings. Check the elements and click on "Save and finalize" or "Cancel" to return to processing. Note that it is also possible to select or change the destination folder for recordings.



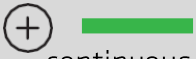
8 – After confirming, a pop-up window appears to confirm the data have been successfully processed. At this stage, it is possible to erase the data from the device or to keep them.



CHAPTER 5
LEDs meaning

CHAPTER 5 LEDs meaning

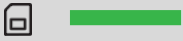
Calibration and recording

LEDS STATE	MEANING	ACTIONS
 alternating	Device calibrating	Do not move and wait for the calibration to end
 continuous	Successful calibration	
 flashing	The calibrated device is recording data	
 continuous	Unsuccessful calibration	Turn off the device (by pressing the ON/OFF button for 5 seconds), place it again on the forearm and turn it back on (by pressing the ON/OFF button for 2 seconds).

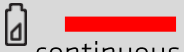
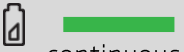
Critical failure

LEDS STATE	MEANING	ACTIONS
 continuous	Critical failure – The device cannot record anymore	Please contact Somno-Art customer service.

Memory

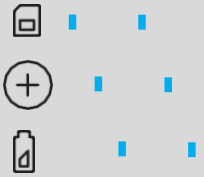
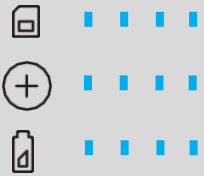
LEDS STATE	MEANING	ACTIONS
 continuous	Memory almost full less than 16 recording hours remaining	The device memory is almost full; only one night can still be recorded. Please import device data using the Companion software.
 continuous	Memory full less than 8 recording hours remaining	Please import device data using the Companion software.
 continuous	Enough memory to record	

Battery and recharge

LEDS STATE	MEANING	ACTIONS
 continuous	Battery too low no recording	Charge the device.
 continuous	Low battery (<16h)	One night can still be recorded but the device must be recharged at the end of the recording.
 Flashing slowly	Battery charging	
 continuous	Battery fully charged	The device can be unplugged.

Device connection

LEDS STATE	MEANING	ACTIONS
 continuous or alternatively	USB connection successful	Device successfully connected, the user can now access the data via the Companion software.

LED STATE	MEANING	ACTIONS
 alternatively	**Bluetooth is turned on and is ready to pair**	Click on “Search for nearby devices” in the Companion software.
 continuous	**Bluetooth pairing successful**	Device successfully connected, the user can now access the data via the Companion software.
 Flashing slowly or quickly	**The device is being configured or is transferring data**	Finish the configuration or wait until the data transfer is complete.

CHAPTER 6
Cleaning the device

CHAPTER 6 Cleaning the device

How to clean the recorder?

It is recommended to wear medical gloves to protect oneself against potential contamination.

Remove the recorder from the armband and clean it with a disinfectant wipe.

The wipe must comply with the hygiene requirements for the reprocessing of medical devices (bactericidal action: EN 1040 and EN1276; fungal action: EN 1275; virucidal action: EN14476).

How to clean the armband?

Used armbands can be put in the washing machine at 30°C.

Do not put the armband in the dryer.

The armband should also be changed between each user.

CHAPTER 7
Return of the Somno-Art Device

CHAPITRE 7

Return of the Somno-Art Device

Return

Somno-Art Device and its accessories must not be discarded. Please return them to PRESTOCAB at the following address:

PRESTOCAB
247, rue de la Blanche Porte
59200 TOURCOING
France

To prevent any contamination or infection of the staff, the environment or the equipment, make sure to disinfect and decontaminate the device before returning it.

Disposal of the device



Devices must not be discarded

In case of exception:



Never dispose of electrical and electronic equipment in a household bin or at a municipal waste treatment facility without a sorting station.

Handle them separately so they can be reused, or appropriately treated, recycled or recovered in total safety.

Additional information:

- The recorder is made of ABS/PC plastic
- This paper-printed user manual can be recycled
- All electronic components of the system meet Directive RoHS2

CHAPTER 8
Technical characteristics

CHAPTER 8 Technical characteristics

Information on the components

Description	Technical specification
Battery	Lithium Ion 35 hours of battery life Full charge in 2 hours
LED	Color : = 528nm (true green) Light intensity: 710 - 1800 mcd
Heart Beat detection	Resolution : 4ms
Movement detection	Accelerometer 3-Axes Digital MEMS Sample rate : 250Hz Output dynamics : +/- 4g with a 4mg resolution Values averaged every second
Flash Memory	60 nights of recording, 63.97 Mo of memory
Composition	For the recorder : Acrylonitrile Butadiene Styrene Polycarbonate (ABS/PC), Polycarbonates (PC) et thermoplastic elastomers (TPE) For the textile armband: Polyamide (PA), Elasthanne (EA), Polyurethane (PU), Polyester
Weight	Weight recorder alone: 45g +/-2g Weight textile armband alone: 55g +/- 2g Total weight: 100g +/-5g
Dimensions	Main recorder casing : 112 mm x 33 mm x 15.6 mm (max) Small recorder casing : 66 mm x 21 mm x 11 mm (max) Cable between the 2 casings: 103 mm long x 8 mm Textile armband: 152 mm x 225 mm x 120 mm x 196 mm

Emissions and immunity

The device complies with electromagnetic compatibility standard EN 606001-1-2 and electrical safety standard EN 60601-1.

Directives and declaration of the Manufacturer – Electromagnetic Emissions

Somno-Art is intended to be used in the electromagnetic environment specified thereafter.
Somno-Art clients or users should ensure that it is used in such an environment.

Emission test	Conformity	Electromagnetic environment and directives
Emissions RF CISPR11	Group 1	Somno-Art Device only uses RF energy for its internal functions.
Emissions RF CISPR11	Class B	Somno-Art Device is intended to be used at home. Therefore, its RF emissions are very weak and are not prone to interfere with nearby electronic device. The Somno-Art device implements Bluetooth Low Energy technology that operates in the spectrum range 2.4GHz - 2.4835GHz Bluetooth data is transmitted using Gaussiar frequency-shift keying (GFSK). The Effective Radiated Power is +6 dBm maximum (4mW).

Directives and declaration of the Manufacturer – Electromagnetic Immunity

Somno-Art is intended to be used in the electromagnetic environment specified thereafter.
Somno-Art clients or users should ensure that it is used in such an environment.

Immunity test	Test level CEI 60601	Conformity level	Electromagnetic environment – directives
Electrostatic discharges (ESD) CEI 61000-4-2	+ 8 kV in contact + 15 kV in the air	+ 8 kV in contact + 15 kV in the air	Floors should be wooden, concrete or ceramic tiles. Should floors be covered in synthetic materials, relative humidity should be at least 30%.
Magnetic field at the frequency of the electrical network (50/60 Hz) CEI 61000-4-8	30 A/m	30 A/m	Magnetic fields at the frequency of the electrical network should have levels characteristic of a representative location in a typical commercial or hospital environment.
Radiated RF disturbances CEI 61000-4-3	10 V/m from 80 MHz to 2,5 GHz	10 V/m	Use at home.

Radiated RF disturbances CEI 61000-4-3	380 – 390 MHz (TETRA 400) 27 V/m; PM 50% 18 Hz	27 V/m
Fields near a RF wireless equipment	430 – 470 MHz (GMRS 460, FRS 460) 28 V/m; (FM +5 kHz, 1kH sine) PM 18 Hz	28 V/m
	704 – 787 MHz (LTE Band 13, 17) 9 V/m PM; 50% 217 Hz	9 V/m
	800 – 960 MHz (GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5) 28 V/m; PM 50% 18 Hz	28 V/m
	1700 – 1990 MHz (GSM 1800, CDMA 1900, DECT, LTE Band 1, 3 ,4, 25, UMTS) 28 V/m; PM 50% 217 Hz	28 V/m
	2400 – 2570 MHz (Bluetooth, WLAN, 802.11 b/g/n RFID 2450, LTE Band 7) 28 V/m; PM 50% 217 Hz	28 V/m
	5100 – 5800 MHz (WLAN 802.11a/n) 9 V/m; PM 50% 217 Hz	9 V/m

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