

# SOMNO-ART DEVICE USER MANUAL



# SUMMARY

Safety measures —	-p7
Indication and intended use	-р8
Contraindications —	-p9
Safety precautions	-p9
Conditions of storage and use	-p11
Shelf life	-p12
Contact assistance —	-p12
Manufacturer — — — — — — — — — — — — — — — — — —	-p12
Explanation of the symbols	-p13
Chapter 1: About the Somno-Art Device	-p15
The recorder	-р19
The textile armband —————	-p20
Other accessories —	-p22
Companion software —	-p23
- Minimal system configuration —	-p23
- Companion software installation and identification	-p24
- General interface introduction —	-p25
Chapter 2: Connection and configuration of Somno-Art Device	p26
Connection of the recorder to the Companion —	-p28
- USB connection ————————————————————	-p28
- Bluetooth connection	-p30
Configuration of Somno-Art Device	-p33
Chapter 3: Use of Somno-Art Device	-p39
Start-up, calibration and recording	-p44
Exiting discreet mode —	-p46
Marking an event —	-p47
Stopping a recording	p48
Charging the recorder —	-p48



Chapter 4: Import and processing	-p51
Chapter 5: LEDs meaningp60 - Calibration and recording	- -p62 -p63
<ul> <li>Memory —</li> <li>Battery and recharge —</li> <li>Device connection —</li> </ul>	-p63 -p64 -p64
Chapter 6: Cleaning the device	-p68
Chapter 7: Return of the Somno-Art Device ———	-p72
<b>Chapter 8: Technical characteristics</b> Information on the components — Emissions and immunity —	– <b>p78</b> –p80 –p82

# 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.

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 use and storage**

The maximal temperature of the measurement LEDs (green LED located under the device) is +41.3 °C.

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
- (I) 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 with the Companion software
- USB cable
- Disinfectant wipes
- Resealable storage 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
  - MACOS 10.14, 10.15 and 11
- 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 and on MacOS 11, on a computer 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.

🕖 Somno-Art Device Companion v1.5.0		-		×
Somno			EN	FR
	Please identify			
	Identifier * Example: user@sonno-art.com			
	Establishment Profile * v			
	I accept the end user licence agreement			
	(@Login			
	* Mandatory fields			

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:

Somno-Art Device Comp	panion v1.5.0			- <u>-</u>	×
	USER@pprs-research.com CRA at PPRS	← Change user		The Import folder EN	FF
	ch for by devices 3 devi	es connected		Disconnect devices Selected (3)	
Devices	Number of recordings	Memory free	Battery	How do I connect a device	2
✓ 412000029P	2 recordings O Consult	518 h	100%	ô Configure	
✓ 182000015P	3 recordings  Consult	536 h	90%	ô Configure	
✓ 442000072P	5 recordings  Consult	499 h	79%	ô Configure	
	lings				
from selected d	levices (3)			Limport and process data (3)	

- (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





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.

Connect a device with Bluetooth as follows:

# 1 - Turn on the Bluetooth on the computer

Confirm that the Bluetooth is activated on your computer.

## 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.

Somno(ART

# **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.

free	Battery	(
nected		🛱 Configure

free	Battery		(
36 h	100%	Onfigure	

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.

32 | Somno-Art Device - User manual

# Somno (ART

## **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.

0	Somno-Art Device Comp	anion v1.5.0					-		×
So		user@pprs-res CRA at PPRS	earch.com	Change user			<ul> <li>Import folder</li> <li>Help</li> </ul>	EN	FR
		ch for by devices	3 devices	connected		ジン Disconnect devices ディ selected	Connect device selected		
	Devices	Number of reco	ordings	Memory free	Battery		() How do I conn	ect a devic	<u>e?</u>
	182000015P	2 recordings	Consult	536 h	100%	லි Configure			
	442000072P	5 recordings	Consult	499 h	70%	ද්ටූදි Configure			
	412000029P	2 recordings	Consult	518 h	100%	හි Configure			
	Erase all recording from selected de	ings evices					Import and pro	ocess dat	а

**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

🕖 Somno-Art Device Companion v1.5.0		- 0	×
Somno ART O user@pprs-research.com	<ul> <li>Import folder</li> <li>Help</li> </ul>	EN	FR
Device list > $\{ c_{ij}^{n} \}$ Configuration of the device			
Device N°182000015P Battery: 100% Device date/time: vendredi 29 octobre 2021 15:49:01	Internal so	ftware version: 1.3.0	[1.8.0]
2 recording(s) in memory, there are 536 hours of recording left 0.01 %		© Consult d	ata
Current configuration of the device (No configuration)			
How to configure a device?			
Study:* Please select a recording mode			
Subject:* Select *			
Visit:			
Birthdate: 01/01/1900 🚖			
Sex:* Select •			
	< Cancel 🖉 Valida	te the configura	tion



**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:

Please select a recording mode						
Recording mode: *	Automatic 👻					
Configure a recording period						
The device will recor	d according to the defined period.					
Start date:* Fror	n 29/10/2021 🔻 at 15:42 🗘					
Stop date:* To	29/10/2021 🔻 at 23:42 🌲					
O Configure a recording cycle						

Recording mode: * Automatic •         Configure a recording period         • Configure a recording cycle         The device will record at the defined time every day from the defined start date to the stop date (last day included).         Recording cycle:* From the 29/10/2021 •         to be 30/10/2021 •	Please select a recording mode	1	
Configure a recording period Configure a recording cycle The device will record at the defined time every day from the defined start date to the stop date (last day included). Recording cycle:* From the 29/10/2021  to the 30/10/2021	Recording mode: * Automatic	•	
Configure a recording cycle The device will record at the defined time every day from the defined start date to the stop date (last day included). Recording cycle:* From the 29/10/2021      to the 30/10/2021	Configure a recording per	iod	
The device will record at the defined time every day from the defined start date to the stop date (last day included). Recording cycle:* From the 29/10/2021 * to the 30/10/2021 *	Configure a recording cycle	le	
Recording cycle:* From the 29/10/2021 • to the 30/10/2021 •	The device will record at the d date to the stop date (last day	efined time every day from included).	the defined start
	Recording cycle:* From the	29/10/2021 💌 to the	30/10/2021 💌
Hours of recording:" From 15:42 - to 23:42 -	Hours of recording:* From	15:42 🗘 to	23:42 🗘
The device will record: 2 times, for 8 hours each time.	The device will record: 2 times, f	or 8 hours each time.	

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":

< Cancel	⊘Validate the 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.

The device N°182000015P will be configured. Once configured, the device will automatically disconnect from the software.			
Reminder of	f the configuration		
Study: PPRS Subject: S01 Visit: 1 Birthdate: 02/03/1994 Sex: Other	Recording mode: Recording cycle: Hours of recording:	Automatic mode Recording cycle from the 29/10/2021 to the 29/10/2021 from 15:46 to 23:46	
	< Cancel	⊘ Validate the configuration	

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.

Start-up, calibration and recording

### 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:

G Memory level

▲ Battery level



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).

### 3 - Calibration phase

### 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:





# 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.







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.

0	Somno-Art Device Comp	anion v1.5.0					-	- 🗆	×
So		USER@pprs-reso CRA at PPRS	earch.com	Change user			➢ Import folder ⑦ Help	EN	FR
	Q <sup>*</sup> Search neart	ch for by devices	3 devices	Disconnect devices	Connect devi selected				
	Devices	Number of reco	rdings	Memory free	Battery		How do I cor	nnect a devic	<u>e?</u>
	✔ 412000029P	2 recordings	Consult	518 h	100%	දිලි Configure			_
	✔ 182000015P	3 recordings	© Consult	536 h	90%	နင့်နဲ့ Configure			
	✓ 442000072P	5 recordings		499 h	79%	နိုင္ပ်ိနဲ Configure			
	A A Frace all recordi	ings							
	from selected de	evices (3)					L Import and proce	ess data (3	

**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.

🕖 Somno-Art Device Companion v1.5.0		-		×
Somno (ART OC CRA at PPRS	🗁 Import folder ⑦ Help		EN	FR
Device list > 💿 Consult data				
N°182000015P Study: DefaultStudy Subject: DefaultSubject	Internal so	oftware ver	sion: 1.3.0[1	8.0]
Current configuration of the device (no configuration     Recordings on the device	ı)	⊕ C	onfigur	
() How to process my recordings? 2 recordings in memory, 536 hours of recording remain	0.01 %			-
Importing recordings				
30%				
<b>X</b> Erase all recordings	Fin	alize p	orocessi	ng

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

ion v1.5.0		_					🗁 Import folder	- 0	×	
ISER@pprs-research.com IRA at PPRS	n 🗧 Change u	ier					③ Help	EN	F	
Consult data										
Device date/time: Internal information version										
<ul> <li>Current config</li> </ul>	uration of the	levice					6	Configure	1	
Recordings on	the device									
(i) How to process my recordings?           2 recordings in memory, 536 hours of recording remain           0.01 %										
Select all		Study	Subject	Visit	Birthdate	Sex				
29/10/2021	13:21 to 13:22	PPRS	S01	1	02/03/1994	I ~	①Data to pr	ocess	_	
	13:35 to 13:37	DDDc	501		02/02/1004	 	Data to pro	ata	-	
29/10/2021	Manual	PRO	301	1	02/03/1994	<b>^</b>	i≡Process d	ata	_	
	Invit-30 Seergaps-research.cor Suit #55 Consult data  Consult data  Consult data  Consult config Recordings on Trecordings in memor Select al  25/10/2021  25/10/2021	ionv1.50 seer@pays-research.com kat #MS Consult data Con	ionv130 sectionary - research.com sectionary - research.com sectionary - research.com Period data Consult dat	ionv1.50  seret@pury=research.com k at #95  Consult data  Consult data	ionv130 sectopers-research.com EConsult data Consult data	ionv1.50 Sectoper-sesarch.com EConsult data Consult data	ionv130 sectoper-research.com EConsult data Consult data	ion v1.5.0  see Consult data  Consult data	ion v1.50 C seer@paper.sessarch.com Kat MMS Consult data Consult	



**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.

Select all		Stud	ly	Sul	oject		Visit	Birtho	late	Se	×	
	13:21 to 13:	.22	[			[	[			[.		Data to process
Manual		PPRS		501		1		02/03/:	1994	1	Ť	i≡Process data
	13:35 to 13:	37	[			[	[	02/02/		[.		① Data to process
Manual Manual		PPRS		501				02/03/	1994	1	Ť	I≡Process data
							7					
Select all		Study	Sul	bject	Vis	it	Birthdate	Sex	(			
29/10/2021	13:21 to 13:22	PPRS	S01		1		02/03/1994	I	*	_	Ø Pr	ocessing data
	Manuai											Cancel
												+ -
Recording length:	Lights Off 13:21:50						User eve 13:22:20	nt				Lights On 13:22:40
	T						•					V
00:00:51	•						•					
	13:21											13:22
+ New Event						29/10	2021					
< Prev. Next >												
							ØEr	ase all m	odificat	ions	Ø١	/alidate the recording
	13:35 to 13:37	0000					00/00/4004				() D	ata to process
29/10/2021	Manual	PPKS	501		1		02/03/1994		-			Process data

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

29/10/2021	13:21 to 13:22 Manual	PPRS	501	1	02/03/1994	Processing data
Recording length:	Lights Off 13:21:50				User event 13:22:20	+ - Lights On 13;22:40
00:00:51	-					
+ New Event < Prev. Next >	13:21			29/	10/2021	13:22
					ØErase all modificat	ions 🞯 Validate the recording

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

+ New Event	1			
< Prev. Next >		29/1	0/2021	
< Cancel	Name:	Date: 29/10/2021	Time: 00:00:00 💠	Add 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.

29/10/2021	13:21 to 13:22 Manual	PPRS	S01	1	02/03/1994	I •	Processing data
Recording length:	Lights Off 13:21:50				+ - Lights On 13:22:40		
00:00:51	13:21				13:22		
+ New Event < Prev. Next >				:	29/10/2021		
< Cancel	Name:		Date: 29/10/2021 _		<u> </u>	Time: 00:00:00	Add event
				-	Ø Erase	e all modification	s 🛛 🛇 Validate the recording
29/10/2021	13:21 to 13:2 Manual	2 PPRS	S01	1	02/	/03/1994 I	
	13:35 to 13:3	7	[	[	[	ſ	① Data to process

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

🕜 Somno-Art Device Compa	nion v1.5.0						-		-		×
Somno (ART	user@pprs-research.com CRA at PPRS	🕂 Change us	ier					Import folder (?) Help		EN	FR
Device list > 🔘	Consult data										
N°182000015P Study: PPRS Subject: S01								ware version:	1.3.0[1.8.0	0]	
	Recordings on t	the device	levice						-gr Conn	igure	
	2 recordings in memory,	. 536 hours of rec	ording remain 📗			0.01 9	6				
	Select all		Study	Subject	Visit	Birthdate	Sex				
	29/10/2021	13:21 to 13:22 Manual	PPRS	S01	1	02/03/1994	I v	VData va	lidated old	]	-
	29/10/2021         13:35 to 13:37 Manual         PPRS         S01         1         02/03/1994         1						I -	① Data to I == Process	process s data		-
	Erase all recording	js					·	<b>∂</b> Fina	alize proc	cessing	



**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.

Please choose the destination folder $\bigotimes$ for saving the data									
/Documents/dev/Somno-Art Device Companion v1.5.0-Client/Outputs									
	Re	eminder of th	ne recordir	ngs (2/2)					
			Study	Subject	Visit				
:	29/10/2021	13:21 to 13:22 Manual	PPRS	S01	1				
	29/10/2021	13:35 to 13:37 Manual	PPRS	S01	1				
Warning: Recordings will no longer be modifiable.									
			< Cance	el 🔒 Save	and finalize				

**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.

💋 Import finalized		×						
All recordings were successfully imported and processed. Should all recordings be erased from the device?								
Note: The device will be unav	Note: The device will be unavailable while erasing its memory.							
	Yes	No						





CHAPTER 5 LEDs meaning



# LEDs meaning

### **Calibration and recording**

LEDS STATE	MEANING	ACTIONS
	Device calibrating	Do not move and wait for the calibration to end
alternating		
(+) 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).

# Somno

### **Critical failure**



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.
	Battery charging	
Flashing slowly		
continuous	Battery fully charged	The device can be unplugged.

### **Device connection**

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



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



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 7 days of battery life with 1 hour of recharge per day With 90 minutes of recharge per day, there is no limit of battery life			
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	720 hours of recording (~ 90 nights)			
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			



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

#### Directives and declaration of the Manufacturer – Electromagnetic Emissions

Somno-Art Device is intended to be used in the electromagnetic environment specified thereafter.

Somno-Art Device 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 Gaussian frequency-shift keying (GFSK).	
		The Effective Radiated Power is +6 dBm maximum (4mW).	



# Directives and declaration of the Manufacturer – Electromagnetic Immunity

Somno-Art Devcice is intended to be used in the electromagnetic environment specified thereafter.

Somno-Art Device 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	380 <u>-</u> 390 MHz	27.V/m
disturbances	(TETRA 400)	2/ V/III
	27 V/m; PM 50% 18 Hz	
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%	28 V/m
	21/ Hz 2400 – 2570 MHz ( B l u e t o o t h , 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

#### S-A GEN2

PPRS 4E Avenue du Général de Gaulle 68000 Colmar FRANCE +33 (0)3 89 20 19 51 support@somno-art.com

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