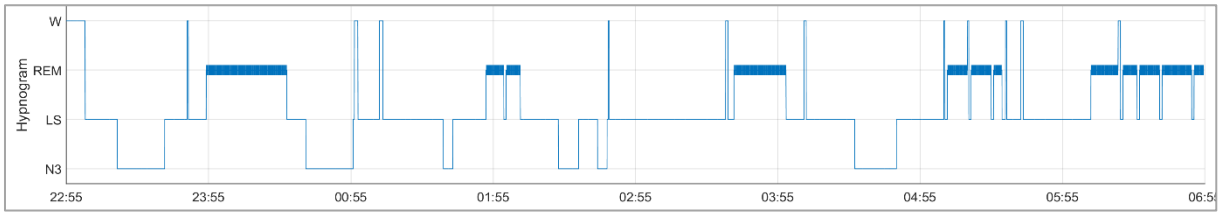
DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

Somno-Art Software
Healthcare Professional Manual



Somno-Art Software version 2.7.0[3.2.0]

Release date: 2022-01

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

Approval

Author	Review	Approval
Débora Kirscher Software development and signal processing engineer DocuSigned by: Débora Kirscher 46E970ED9928401...	Gil Fuchs Chief product officer DocuSigned by: Gil Fuchs 2D2A9AB5C2F7438...	Baptiste Planat QMR DocuSigned by: Baptiste Planat 80892845B28E454...
Date: 2022-01-04	Date: 2022-01-04	Date: 2022-01-04

Revision History

Date	Version	Description	Author
2016-01-13	S1.0.0	Software version 1.0.0	G. Fuchs
2016-02-10	s1.1.0	Software version 1.1.0	G. Fuchs
2017-01-31	s1.2.0	Software version 1.2.0	G. Fuchs
2018-06-15	s2.0.0	Software version 2.0.0[1.4.0]	G. Fuchs V. Dehouck
2018-07-03	s2.0.0-2	Approval box	G. Fuchs
2018-07-26	s2.1.0	Software version 2.1.0[2.0.0]	V. Dehouck
2018-10-16	s2.1.1	Software version 2.1.1[2.1.0]	V. Dehouck
2018-02-27	s2.2.0	Software version 2.2.0[2.3.0]	V. Dehouck
2019-08-05	s2.3.0	Software version 2.3.0[2.4.0]	D. Kirscher V. Dehouck
2019-10-16	s2.4.0	Software version 2.4.0[2.4.1]	V. Dehouck
2020-01-30	s2.5.0	Software version 2.5.0[3.0.0]	V. Dehouck
2020-02-04	s2.5.1	Software version 2.5.1[3.0.0]	V. Dehouck
2020-10-27	s2.6.0	Software version 2.6.0[3.1.0] Intended use update Split between TP and HCP manuals	D. Kirscher
2022-01-04	S2.7.0	Software version 2.7.0[3.2.0]	D. Kirscher

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

Table of content

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

1 Introduction

1.1 Medical Indications

Somno-Art Software is a standalone software, which analyses physiological signals of heart rate and movements of adults in order to assess subject's sleep parameters, including sleep continuity, latencies and architecture.

Somno-Art Software results are intended to be used for sleep structure characterization and as an aid for diagnosis and treatment follow-up of sleep disturbances and disorders by a healthcare professional.

Analysed sleep periods must be periods of sleep allocated time lasting at least 5 hours, starting when subject is still awake and recorded in a non-moving sleep environment. Signals of heart rate and movements must be synchronized together, heart rate must have a beat-to-beat resolution and movements a 1-sec resolution.

1.2 Patient Population

Somno-Art Software is intended to be used on adults only.

Sleep recordings from patients suffering from heart rate disorders cannot be analysed with Somno-Art Software.

Somno-Art Software is not intended for subjects wearing cardiac devices (i.e. defibrillator, stimulator…), under a beta receptor blocking agent treatment, or with active cardiovascular disease (including but not limited to: atrial fibrillation or flutter, second and third-degree atrioventricular heart block, resting supraventricular tachycardia > 100 beats per minute, unstable ischemic heart disease, valvular abnormality, sick sinus syndrome or other condition requiring pacemaker) or diastolic blood pressure > 110 mmHg.

Pathological motor activity cannot be considered in the use of the Somno-Art Software analysis and have to be considered as an exclusion criterion.

1.3 Intended User

Somno-Art Software is intended for use by trained professionals only.

Patients and healthcare professionals do not have access to Somno-Art Software.

Results are used by healthcare professionals with sleep expertise.

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

1.4 Manufacturer

PPRS
4E Avenue du Général de Gaulle
68000 Colmar
FRANCE

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

www.somno-art.com

Please contact us for a paper version of this manual

1.5 Lifetime of the device

The last version of this software will be supported by PPRS for 3 years after its release date.

2 Input Data

The software reads night recordings of beat-to-beat cardiac intervals and movements stored in Somno-Art Recording (SAR) or Extensible Markup Language (XML) file formats.

Somno-Art Software performances have been established for time in bed lasting more than 5 hours.

In order to be analysable by the software, the period between Lights Off and Lights On events described in recordings must be strictly superior to 5 minutes.

This input data must be transferred to Somno-Art Trained Professionals in a secure manner for being analysed by Somno-Art Software.

2.1 Somno-Art Recording (SAR)

The software reads night recordings stored in SAR files (Somno-Art Recording), produced by the Somno-Art Device. These files noticeably contain:

- Actimetry signals and beat-to-beat cardiac intervals
- Lights Off, Lights On and event times
- Information about the subject

SAR files are supported since version “V1.1.1[1.7.0]” of Somno-Art Device.

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

2.2 Extensible Markup Language (XML)

The software also reads night recordings stored in XML files respecting a specific schema. These files contain among others:

- Actimetry signal and beat-to-beat cardiac intervals
- Lights Off, Lights On and event times
- Information about the subject

Lights Off and On events indicate from which point in the recording the software will start its sleep analysis and at which point it will stop.

2.3 All formats

All input files must respect the following naming convention:

<recording identifier>.<ext>

Or, if a visit code is provided,

<recording identifier>_<visit code>.<ext>

For complete specification of input files, see the document “Input files specification“.

2.4 Data quality review

The signals of the recording will be reviewed according to specific criteria by the Somno-Art Trained Professional, which will allow determining their quality. Recordings with major issues, which makes analysis impossible, will be excluded from analysis.

3 Outputs

The produced outputs are of two types:

- Recording related output: Covers one particular recording analysis
- Global output: Describes several recordings analysed.

Outputs can be CE-marking or FDA-marking compliant. As only one type of outputs is produced, outputs type has to be decided with PPRS at the beginning of the study.

3.1 Recording related outputs

For each night recording analysed, a sleep stage classification is automatically performed by the software. Sleep parameters are then computed based on classification, alongside with some other metrics. This generated information is exported in both exploitable file formats (text files, Microsoft Excel) and rendered file format (pdf).

3.1.1 Sleep stage classification

Sleep stages classifications are exported in a text file format, which gives the determined sleep stage for each 30-second page of the record. The 1-s epoch classification is down sampled into 30-s epochs. To do so, the dominant stage (or the first occurring stage, if they were equally represented) is selected.

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

Classification start 2021-03-30 23:13:51 Page duration 00:00:30 Scorer Somno-Art Software 2.7.0[3.2.0]

Time	Page	Stage
23:13:51	1	0
23:14:21	2	0
23:14:51	3	0
23:15:21	4	0
23:15:51	5	0
23:16:21	6	0
23:16:51	7	0
23:17:21	8	0
23:17:51	9	0
23:18:21	10	0
23:18:51	11	0
23:19:21	12	0
23:19:51	13	0

Figure 1 Sleep stages classification text output (extract)

Filename: Somno-Art_**<input filename>**_HYPNO.txt

Note: if outputs are CE-marking compliant, the classification is a 4-stages classification (W, N1+N2, N3, REM). If outputs FDA-marking compliant, it is a 3 stages classification (W, NREM, REM).

3.1.2 Sleep report

A sleep report for each recording analysed is generated. This report can be classic or simplified (for CE outputs), depending on healthcare professionals needs.

As only one type of report is produced, report type has to be decided with PPRS at the beginning of the study.

3.1.2.1 Classic sleep report

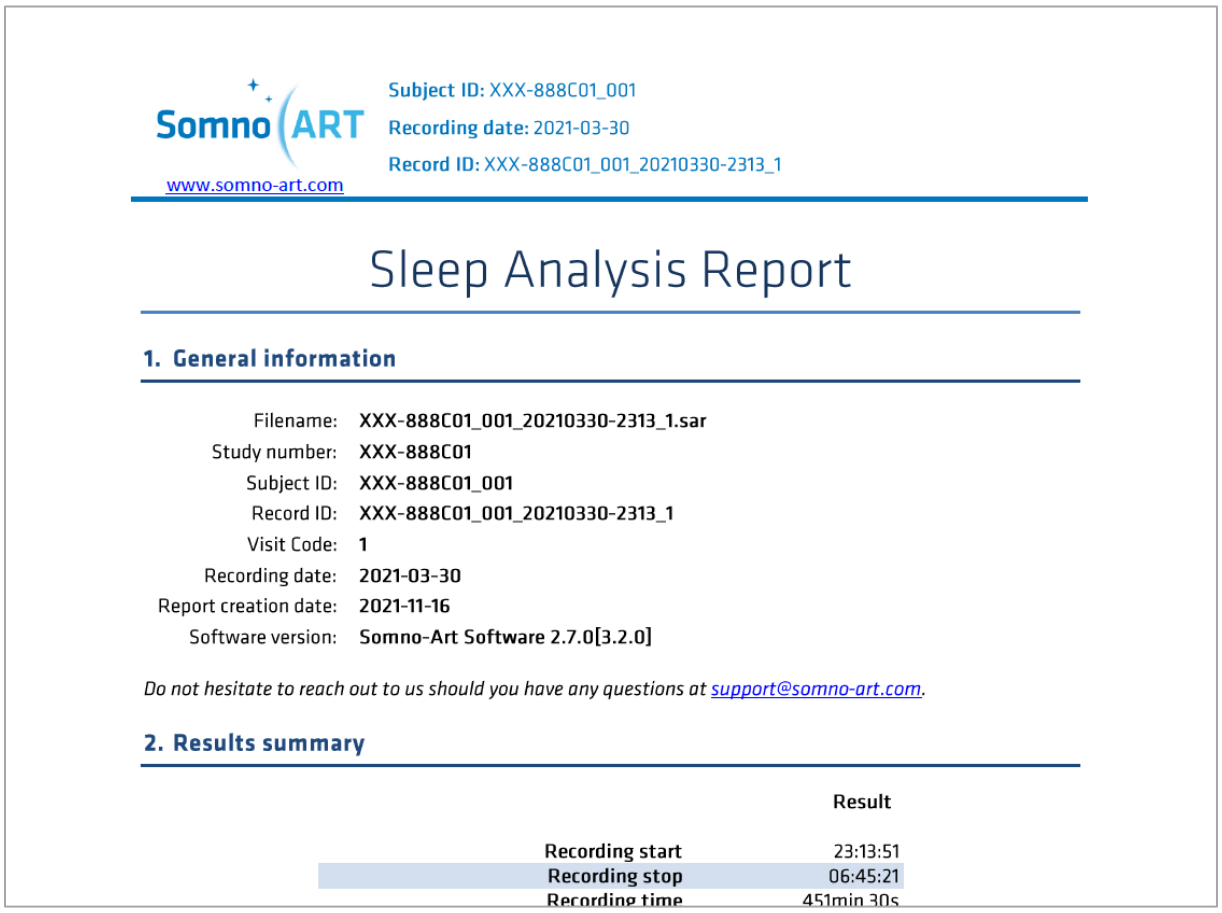
CE outputs

This document includes general information about the recording, an image of the determined hypnogram, the computed sleep architecture parameters besides their normative values, the matrix of sleep stages transitions, some measures performed on the recording and a guide about how to read the report. This report is in PDF file format.

FDA outputs

This document includes general information about the recording, an image of the determined hypnogram, the computed sleep architecture parameters and a guide about how to read the report. This report is in PDF file format.

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06



Somno ART
www.somno-art.com

Subject ID: XXX-888C01_001
Recording date: 2021-03-30
Record ID: XXX-888C01_001_20210330-2313_1

Sleep Analysis Report

1. General information

Filename:	XXX-888C01_001_20210330-2313_1.sar
Study number:	XXX-888C01
Subject ID:	XXX-888C01_001
Record ID:	XXX-888C01_001_20210330-2313_1
Visit Code:	1
Recording date:	2021-03-30
Report creation date:	2021-11-16
Software version:	Somno-Art Software 2.7.0[3.2.0]

Do not hesitate to reach out to us should you have any questions at support@somno-art.com.

2. Results summary

	Result
Recording start	23:13:51
Recording stop	06:45:21
Recording time	451min 30s

Figure 2: Client Report output (extract)

Filename PDF: Somno-Art_**<input filename>**.pdf

If the recording device runs out of battery, a message is added to inform the user:

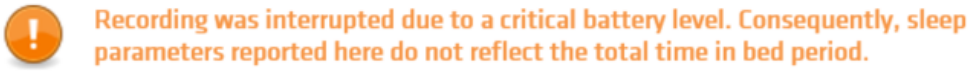


Figure 3 : Warning message in case of device out of battery

When Somno-Art Software is not able to analyse the whole recording, it gives a partial analysis and informs the user with the following warning message:

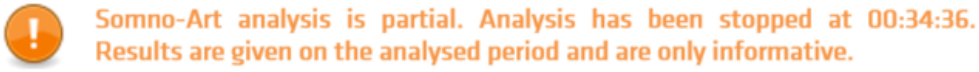


Figure 4: Warning message in case of partial analysis

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

A warning message appears if the duration is inferior to 5 hours to inform them that the results are only informative.

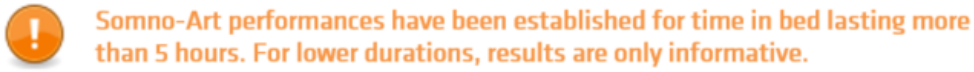


Figure 5: Warning message in case of recording duration inferior to 5 hours

Finally, a warning message appears if the filename does not correspond to study, subject, record and/or visit information stored in the file.

Figure 6: Warning in case of filename issue

3.1.2.2 Simplified report (CE outputs only)

This document includes general information about the recording, an image of the determined hypnogram, the computed sleep architecture parameters besides their normative values, some measures performed on the recording and a guide about how to read the report. This report is in PDF file format.

3.1.3 Signals export in CSV format

CSV files with content of SAR input files can be generated. These 3 files contain following information:

- Somno-Art_**<input filename>**_header+Events.csv : information from SAR file header and events from SAR file
- Somno-Art_**<input filename>**_MV.csv : actimetry from SAR file accumulated every 30 seconds
- Somno-Art_**<input filename>**_RR.csv : raw RR intervals from SAR file

3.2 Global analysis related outputs

These outputs aggregate results of several recordings.

3.2.1 Sleep parameters

These documents aggregate the sleep architecture parameters of all recordings and store them into two Microsoft Excel tables: one for standard sleep parameters and the other one for remaining parameters (CE outputs only).

Source code	Subject code	Record code	Visit code	Analysis status	Lights Off Time	Lights On Time	Sleep Alloc. Time (min.)	Total Sleep Time (min.)
XXX-888C01	PX-0001	20120419-2240	1	Done				
XXX-888C01	PX-0002	20120420-2242	1	Done				
XXX-888C01	PX-0003	20120421-2050	1	Done				
XXX-888C01	PX-0004	20120421-2103	1	Done				
XXX-888C01	PX-0005	20120422-2341	1	Done				
XXX-888C01	PX-0006	20120419-2245	1	Done				

Figure 7: Sleep parameters output

Filename standard parameters: Somno-Art_SLEEP_PARAMS.xlsx

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

Filename Extra Parameters: Somno-Art_EXTRA_PARAMS.xlsx

In both files, a tab “Definitions” contains the definition of all sleep parameters given in the Excel table. A tab “Info” contains information about the date of the analysis and the software version.

CE outputs

The file Somno-Art_SLEEP_PARAMS.xlsx contains following sleep parameters:

- Lights Off Time: Lights off clock time (hr:min:sec). First epoch (included) of sleep analysis
- Lights On Time: Lights on clock time (hr:min:sec). Last epoch (excluded) of sleep analysis
- Sleep Alloc. Time (min.): Sleep allocated time. Duration from Lights Off to Lights On
- Total sleep Time (min.) (TST): Total duration of non-W stages
- Sleep Latency (min.): Or sleep onset. Time from Lights Off to any sleep stage
- WASO (min.): Wake after Sleep Onset, duration of W stages after sleep onset
- Sleep Eff. (%): Sleep efficiency. Total sleep time over sleep allocated time
- Latency R (min.): Time from Sleep Onset to first REM
- W Dur. (min.): Total duration of W, from Lights Off to Lights On
- N1+N2 Dur. (min.): Total duration of N1+N2, from Lights Off to Lights On
- N3 Dur. (min.): Total duration of N3, from Lights Off to Lights On
- R Dur. (min.): Total duration of REM, from Lights Off to Lights On
- N1+N2 Perc. (%): N1+N2 percentage. Total N1+N2 duration over total sleep time
- N3 Perc. (%): N3 percentage. Total N3 duration over total sleep time
- R Perc. (%): REM percentage. Total REM duration over total sleep time

The file Somno-Art_EXTRA_PARAMS.xlsx contains following sleep parameters and metrics:

- NREM Dur. (min.): Total duration of N1, N2 and N3, from Lights Off to Lights On
- NREM Perc. (%): NREM Sleep percentage. NREM Sleep duration over total sleep time
- WASO Perc. (%): WASO percentage. Duration of W stages after sleep onset over duration from Sleep Onset to Lights On
- Sleep Latency N1+N2 (min.): Time from Lights Off to first N1 or N2 stage
- Sleep Latency N3 (min.): Time from Lights Off to first N3
- Sleep Latency R (min.): Time from Lights Off to first REM
- Latency N1+N2 (min.): Time from Sleep Onset to first N1 or N2 stage
- Latency N3 (min.): Time from Sleep Onset to first N3
- LPS (min.): Latency to persistent sleep. Time from Lights Off to the first occurrence of continuous 10 min in any sleep stage
- WALPS (min.): Wake after latency to persistent sleep
- P R Onset (min.): Persistent REM Onset. Time from Lights Off to the first occurrence of continuous 2 min in REM
- P R Latency (min.): Persistent REM Latency. Time from Sleep Onset to the first occurrence of continuous 2 min in REM
- Latency LPS -> R (min.): Time from Latency to persistent sleep to first REM
- No. of stage changes: Number of sleep stage changes

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

- No. of ascending stage changes: Number of sleep stage changes to a lighter sleep stage or to wake
- No. of descending stage changes: Number of sleep stage changes to a deeper sleep stage
- No. of Awk.: Number of Awakenings, from sleep onset to Lights On. If the last stage is W, it doesn't count
- No. of Awk. >15s: Number of Awakenings exceeding 15 seconds, from sleep onset to Lights On. If the last stage is W, it doesn't count.
- WASF (min.): Wake time after sleep offset. Total duration of W from last sleep stage to Lights On.
- No. of Cycles: Number of sleep cycles
- No. of Mov.: Number of individualised movements
- No. of Mov. before SO: Number of individualised movements before Sleep Onset
- No. of Mov. after SO: Number of individualised movements after Sleep Onset
- No. of Mov. before PSO: Number of individualised movements before Persistent Sleep Onset
- No. of Mov. after PSO: Number of individualised movements after Persistent Sleep Onset
- Mov. dur. (min): Movements total duration
- Mov dur before SO (min.): Movements duration before Sleep Onset
- Mov dur after SO (min.): Movements duration after Sleep Onset
- Mov dur before PSO (min.): Movements duration before Persistent Sleep Onset
- Mov dur after PSO (min.): Movements duration after Persistent Sleep Onset
- No. of AC: Number of Cardiac Arousals
- No. of AC before SO: Number of Cardiac Arousals before Sleep Onset
- No. of AC after SO: Number of Cardiac Arousals after Sleep Onset
- No. of AC before PSO: Number of Cardiac Arousals before Persistent Sleep Onset
- No. of AC after PSO: Number of Cardiac Arousals after Persistent Sleep Onset
- AC dur. (min): Cardiac Arousals total duration
- AC dur. before SO (min.): Cardiac Arousals total duration before Sleep Onset
- AC dur. after SO (min.): Cardiac Arousals total duration after Sleep Onset
- AC ampl. (bpm): Average amplitude of Cardiac Arousals
- AC ampl. before SO (bpm): Average amplitude of Cardiac Arousals before Sleep Onset
- AC ampl. after SO (bpm): Average amplitude of Cardiac Arousals after Sleep Onset

FDA outputs

The file Somno-Art_SLEEP_PARAMS.xlsx contains following sleep parameters:

- Lights Off Time: Lights off clock time (hr:min:sec). First epoch (included) of sleep analysis
- Lights On Time: Lights on clock time (hr:min:sec). Last epoch (excluded) of sleep analysis
- Sleep Alloc. Time (min.): Sleep allocated time. Duration from Lights Off to Lights On
- Total sleep Time (min.) (TST): Total duration of non-W stages
- Sleep Latency (min.): Or sleep onset. Time from Lights Off to any sleep stage
- WASO (min.): Wake after Sleep Onset, duration of W stages after sleep onset
- Sleep Eff. (%): Sleep efficiency. Total sleep time over sleep allocated time

DocuSign Envelope ID: C53E787F-F400-4B15-B8E2-E8E5C62DDE06

- LPS (min.): Latency to persistent sleep. Time from Lights Off to the first occurrence of continuous 10 min in any sleep stage
- W Dur. (min.): Total duration of W, from Lights Off to Lights On
- N1+N2 Dur. (min.): Total duration of N1+N2, from Lights Off to Lights On
- Non-REM Dur. (min.): Total duration of Non-REM Sleep, from Lights Off to Lights On
- R Dur. (min.): Total duration of REM, from Lights Off to Lights On

The analysis status is reminded for each recording. For some statuses, results provided are only informative or only calculated on a portion of the night.

The main analysis status can be:

- "**Done**": the analysis was performed successfully.
- "**Partial**": the analysis was stopped before Lights On, because of a major invalidity in input signals. The results are given on the analysed period (between Lights Off and analysis stop) only.

A secondary status can be added to the main status. The different cases are:

- "**out of battery**": the recording ends before given Lights On (due to a critical battery level).
- "**time in bed < 5h**": the time in bed period lasts less than 5 hours

Please note that results provided by Somno-Art Software are only informative in case of "Partial" or "time in bed < 5h" results.