



SOMNOLTER

*Portable Sleep Monitor
associating
Simplicity, Comfort et Clinically Demonstrated Efficiency*

SOMNOLTER is an ambulatory sleep recorder intended for the diagnosis of Sleep Apnea Syndrome (SAS). It can also be used to assess the effectiveness of the administered treatment (by continuous positive airway pressure (CPAP), by mandibular advancement or by any other modality).

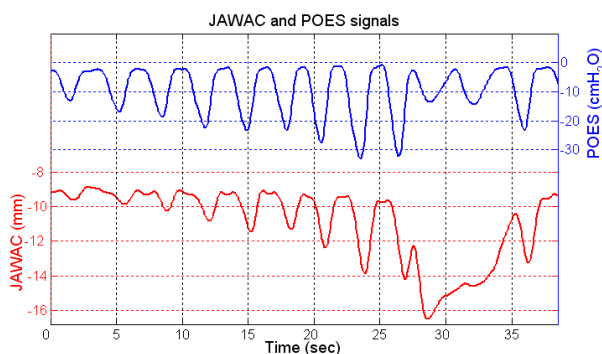
« Snoring, daytime hypersomnolence and witnessed apnoeas are symptoms frequently observed in the general population. Subjects with a combination of these abnormalities suggesting a high probability of sleep apnoea syndrome and in whom a sleep study is warranted represent 7.5% of the adult population » ^[1]



The Sleep Apnea Syndrome is serious. The unconscious struggle that a sleeper with sleep apnea leads in order to try and draw air in leaves marks. It exposes the person to repetitive nocturnal stress and puts considerable strain on the heart. Scientific studies have demonstrated that this syndrom can have severe health consequences like arterial hypertension, cardiac disease, stroke, diabetes, daytime drowsiness (responsible for many work and traffic accidents) and memory impairment.

*« An undiagnosed severe sleep apnea syndrom multiplies by 5
the risk of cardiovascular mortality »* ^[2]

SOMNOLTER, thanks to its unique characteristics, offers a simple, comfortable, and efficient solution for diagnosing sleep apnea.



Oesophageal pressure (POES – in blue), the gold standard signal for respiratory effort measurement, and movements of the mouth (JAWAC - in red) during an obstructive event. A tight correspondance between the two signals can be observed while respiratory efforts are made, until the arousal occurs.

In addition to other signals traditionally recorded during ambulatory sleep monitoring, the device records mandibular movements (the Jawac signal, where "Jawac" stands for "Jaw Activity").

Mandibular movements form an excellent marker of respiratory effort during sleep. Respiratory effort is an extremely important parameter in the diagnosis of Sleep-Disordered Breathing, but it has rarely been measured during home sleep studies due to previously unsuitable sensors.

Automatic discrimination between wake and sleep, detection of arousals, and measurement of the mouth opening are other indisputable assets provided by the Jawac technology.

[1] Prevalence of symptoms of sleep apnoea syndrome. Study in a french middle-aged population, *Meslier et al.*, Rev Mal Respir 2007; 4: 05-13.

[2] Sleep disordered breathing and mortality: eighteen-year follow-up of the Wisconsin sleep cohort, *Young et al.*, Sleep 2008;31(8):1071-8.

SOMNOLTER comes with an extremely powerful software for detection and automatic recognition of sleep-related breathing disorders such as obstructive, central, and mixed apneas, hypopneas, mouth breathing, pathological snoring, and upper airway resistance.

An automated analysis validated on more than 500 recordings*

* A clinical study comparing the use of Somnolter in automated analysis mode to polysomnography on 570 patients confirms that Somnolter provides accurate and reliable diagnoses: Sensitivity of 83% and Specificity of 96%^[3]

The software provides rapid and high-performance display and scoring, with:

1. Manual or automatic analysis, with selection of the parameters of the automatic analysis;
2. Automatic detection of all abnormal respiratory events: apneas, hypopneas, upper airway resistance and abnormal respiratory effort;
3. Recognition of the central or obstructive nature of the syndrome;
4. Detection of hypopneas followed by an arousal (with or without desaturation);
5. Automatic rejection of wake periods for the precise calculation of the indices;
6. Full analysis of oximetry signals (SpO2 desaturation/resaturation, pulse rate, ...);
7. A clear and detailed analysis report;
8. Automated transfer of raw data, analysis results and reports between colleagues;
9. Windows® XP/Vista/7 compatibility.



[3] Added value of a mandible movement automated analysis in the screening of obstructive sleep apnea, Maury *et al.*, to appear in *J. of Sleep Res* 2012.

A full analysis report in a few clicks...

Somnolter - Analysis Report

1 **Patient/Recording Information** - Patient ID: SRNRA1620819

Name:	Severe	Recording date (dd/mm/yy):	07/01/10
First name:	OSAHS	Recording duration (hh:mm:ss):	16:00:20
Gender:	M		
Birthdate (dd/mm/yy):	19/08/62	Useful Javac signal (%):	100
Weight (kg):	72	Useful nasal flow signal (%):	100
Height (cm):	171	Useful RIP signal (%):	98
BMI :	24.6	Useful SpO2 signal (%):	100

1 A summary of the data pertaining to the patient and his/her recording.

2 **Analysis Parameters**

Apnea: airflow reduction \geq 90%, duration [10-90] seconds
 Hypopnea: 90% \geq airflow reduction \geq 50%, duration [10-90] seconds, with desaturation \geq 3% or arousal
 RE : effort threshold = 0.5 mm, duration \geq 60 seconds
 Sleep : automatic detection (Multi-signals)

2 The settings of the parameters used by the automatic analysis.

3 **Analysis: multi-signal**

Apnea and hypopnea index (AHI):	44.3
Respiratory disturbance index (RDI):	59.9
Respiratory arousal index (RAI):	46.5
Arousal index (Ari):	58.3
Cumulative time in respiratory effort (CTRE):	00:42:16 8.9%
Mean mandibular lowering in mm (MML):	-12
Total analysis time (hh:mm:ss):	08:53:46
Total sleep time (hh:mm:ss):	07:52:44

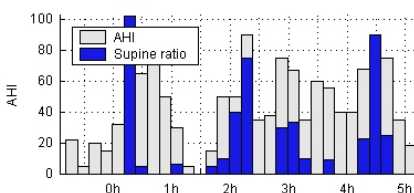
Analysis: oximetry

Oxygen desaturation index (ODI):	46.7
Oxygen resaturation index (ORI):	45.8
Cumulative time with SpO2 < 90% (CT90):	00:05:03
Cumulative time with SpO2 < 80% (CT80):	00:00:00
Cumulative time with SpO2 < 70% (CT70):	00:00:00
Minimum saturation (%):	85
Mean saturation (%):	95.7
Mean pulse rate (bpm):	74

3 The indices.

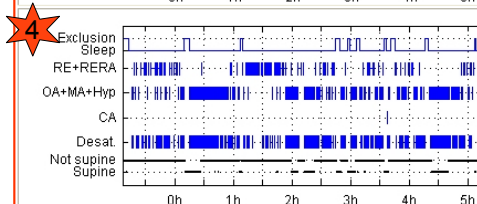
4 The distribution of events throughout the night.

Events



Respiratory Events

	OA	Hyp	MA	CA	RERA	Desat
Number:	152	189	2	6	123	368
Ratio (%):	33	40	0	1	26	
Mean duration (s):	18.2	21.4	25.5	15.3	40.6	33.7



Posture

	Supine	Left	Right	Prone	Standing
Duration (hh:mm:ss):	01:22:49	03:03:14	03:26:38	00:00:00	00:00:00
AHI:	81.1	39	34.3		
ODI:	69.6	43.9	40.1		

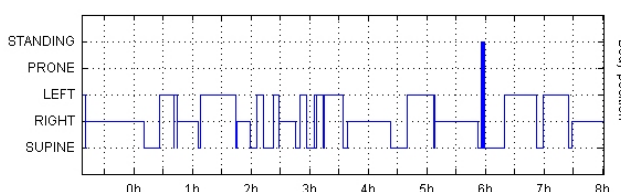
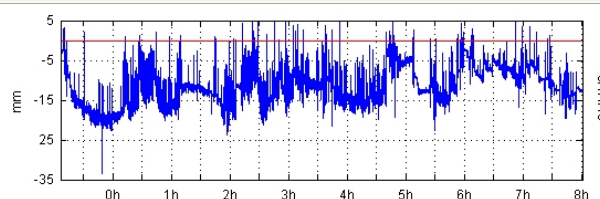
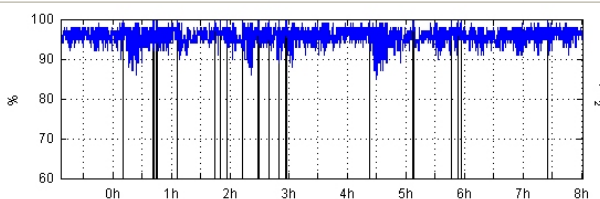
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5 Detailed information, for each type of event.

6 The influence of body position on the different indices.

Graphs



nomics

Measure without effort

RECORDER

Dimensions, weight

85mm (3.35") x 55mm (2.16") x 16mm (0.63"), 80g (2.8oz)

Power

Internal battery, rechargeable via USB

Average consumption

In recording mode: 240mW

In sleep mode: 0.4mW

Autonomy

18 hours recording time (multiple recordings allowed)

Data transfer

Via USB to a PC

RECORDED SIGNALS

Mandibular movements

« JAWAC » technology: resonant magnetic field transducer

Measurement range: 7cm (2.75") to 23.5cm (9.25")

Resolution: on the order of 0.1mm

Sampling frequency: 10Hz

Airflow

Technology: pressure transducer

Measurement range: ± 3 mbar difference with ambient pressure

Resolution: on the order of 0.006mbar

Sampling frequency: 4.000Hz, Downsampled to 10Hz for airflow and snoring.

Respiratory motion (Thorax, Abdomen, and Sum)

Technology: inductive bands

(RIP – Respiratory Inductance Plethysmography)

Sampling frequency: 10Hz

SpO2

Measurement range: 0 to 100%

Accuracy (for adults using the 8000AA Finger Clip Sensor, in the 70 to 100% range, with $\pm 1SD$): $\pm 2\%$

Sampling frequency: 3Hz

Pulse rate

Measurement range: 18 to 300bpm

Accuracy (for adults using the 8000AA Finger Clip Sensor, no motion): ± 3 bpm

Sampling frequency: 3Hz

Plethysmographic pulse waveform

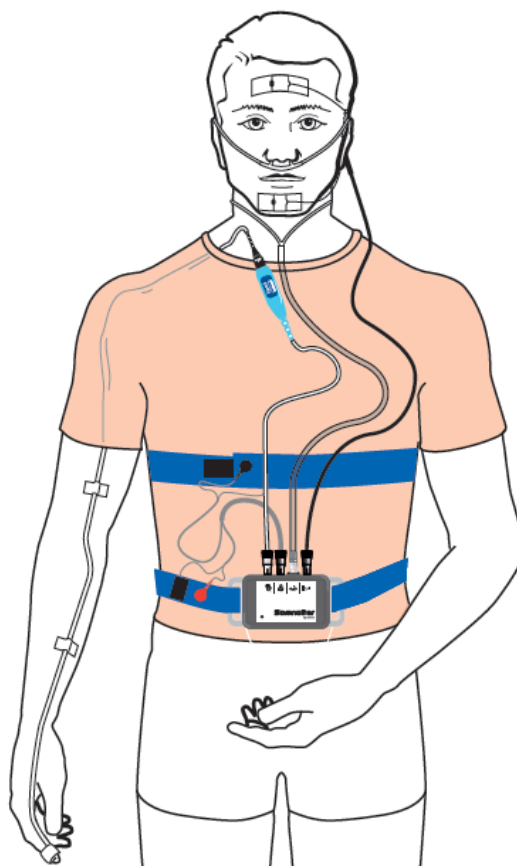
Sampling frequency: 75Hz

Body position

Technology: 3-axis accelerometer

Values: lying supine / lying on the right side / lying on the left side / lying prone / upright

Sampling frequency: 1Hz



SOMNOLTER