Sibelmed®



Your solution for positional apneas and snoring

Positional Therapy

somnibel®

USB

CE 0318

Clase IIa



Somnibel · positional device

What is Somnibel?

Somnibel is a Class IIa medical device that **reduces the impact of positional sleep apnea and/or snoring**.

It consists of a small, light device that is attached to the forehead and vibrates gently whenever your patient is sleeping in a supine position, encouraging him or her to change position and thus reducing the impact of respiratory events in sleep, such as positional apnea or snoring.

Many different clinical studies believe positional therapy to be an effective solution for positional OSA, obtaining similar results to CPAP treatment.

Somnibel has been developed by **SIBELMED** with the collaboration of the sleep units at the **Araba/Osakidetza University Hospital** (Vitoria, SPAIN) and the **Arnau de Vilanova University Hospital** (Lleida, SPAIN).

Obstructive sleep apnea (OSA) is a common disorder affecting at least 2% to 4% of the adult population.

Clinical Guideline for the Evaluation, Management and Long-term Care of OSA in Adults, the AASM. Lawrence J. Epstein and al.

An estimated 54% of patients with OSA are positional.

Sabil J Clin Sleep Med. 2020

35% of the adult population snores, of whom 75 % of simple snorers are positional.

Nakano Sleep 2003



Fast



Easy



No adjustment required



Restorative sleep

Benefits

Somnibel is a great step forward in comfort for patients with positional OSA.

- It is comfortable, silent and painless.
- No adaptation period.
- Does not affect or fragment the sleep structure.
- Suitable for travel, because it is light, small and easy to carry.
- Hygienic and non-invasive.



Clinical studies conducted with **Somnibel** show that:

Reduces apnea index

Increases blood oxygen saturation

Help reduce snoring index

Improves sleep quality

Improves daytime sleepiness

Hidalgo-Armas Respir Med 2019
Hidalgo-Armas Thorax 2021
Hidalgo-Armas BMJ Open Respir Res. 2023

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Devices

Positional Therapy somnibel®

Use by patients

Somnibel is aimed at patients with OSA and/or positional snoring.

Among other functions, it is activated 15 minutes after lying down to sleep and detects the sitting position, waiting a few minutes before re-applying the stimulus so that the patient can fall asleep after having gotten up.

Positional Therapy somnibel® Pro

Use by specialists

SomnibelPro is aimed at sleep units and prescribing centers.

It monitors, assesses the effectiveness and tracks the therapy.
Its configuration means that the signals can be recorded, viewed and analyzed using SomniLab software.

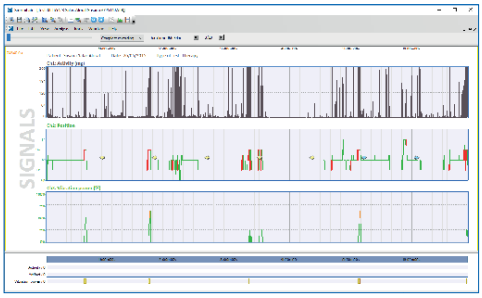


SomniLab Software

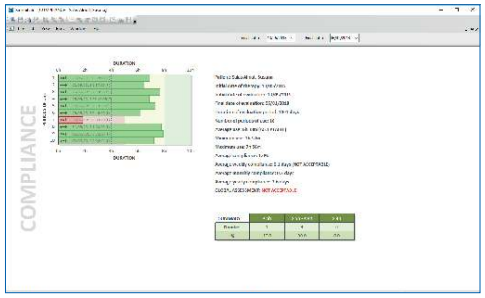
SomniLab is an intuitive software developed to download and analyze the signals recorded by your **SomnibelPro** device.

It is used to save and view:
- Body position
- Actigraphy
- Stimulus intensity

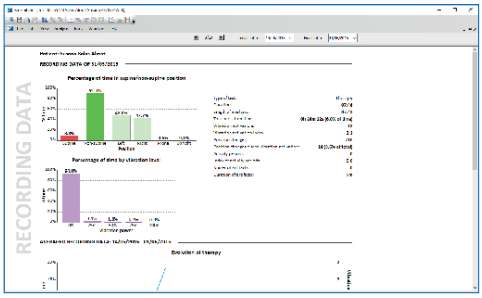
SomniLab will allow you to easily validate and track your patients thanks to its analysis of positional treatment compliance. You can use it to configure **SomnibelPro** and adapt it to each of your patients' needs. It also offers personalization options, such as initial delay times for sleep, vibration delay in supine position or increased vibration, as well as modification of therapy or placebo mode for possible clinical studies.



Signals



Compliance



Trends

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Somnibel · positional device

Main specifications

	Somnibel	SomnibelPro
Patient	>18 years old >40 Kg >145 cm	
Measurements	52 x 32 x 14 mm.	
Weight	17g.	
Operating mode	Therapy mode	
	-	Placebo mode
Monitored signals	Body position	
	-	Actigraphy
	-	Stimulus intensity
Recorded signals	-	Body position
	-	Actigraphy
	-	Stimulus intensity
Memory	-	365 recordings
Software	-	SomniLab
Battery	Rechargeable battery	
Connectivity	USB	
Adhesives	30	

Somnibel
Cód. 09892*

SomnibelPro
Cód. 09893*



*Includes 1 box of adhesives

Somnibel Adhesives
Cód. 08753



Product developed by **SIBELMED** in collaboration with

hospital universitari arnau de vilanova

Osakidetza

Screen&Go

1 to 8-channel screening polygraph*



. Respiratory flow
. SpO_2
. Pulse (BPM)
. Snoring
. Thoracic effort
. **Position**

* Activity and Thermocouple (optional)
* Thermocouple cannot be used at the same time as the thoracic effort

Sleep&Go

8 to 16-channel cardiorespiratory polygraph*



. Respiratory flow
. SpO_2
. Pulse (BPM)
. Snoring
. Thoracic effort
. **Position**
. Activity
. Abdominal effort
. Thermocouple
. Bluetooth
. CPAP level
. Limb movement
. Pulse wave

* External EXG module for EEG, EMG, EOG, ECG tests (optional)
* External snoring cannot be used at the same time as the movement sensor

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Product in compliance with:
Medical Device Regulation (EU) 2017/745
EN ISO 9001:2015 EN ISO 13485:2016+A11:2021

SIBEL S.A.U. reserves the right to modify the technical specifications without prior notice.

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FG SIB 1801_EN - Somnibel - V.2.0- 05/2024