CE 0197 PRODUCT IN COMPLIANCE WITH MEDICAL DEVICE DIRECTIVE 93/42/EEC (CLASS IIa).

Thank you for choosing **Somnibel**!

This product has been designed by the RDI department of SIBEL S.A.U. in cooperation with the sleep units of the University Hospital Araba / Osakidetza (Vitoria, SPAIN) and of the University Hospital Arnau de Vilanova (Lleida, SPAIN). **Somnibel** is manufactured according to the European Medical Device Directive and with the best quality standards.

Revised
Date: 2018-09
Technical Director

Approved
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Sales Director

INDEX

1. SAFETY

Somnibel is a new system for the treatment of patients with Sleep-Related Breathing Disorders (SRBD), mainly the Sleep Apnea-Hypopnea Syndrome (SAHS) or habitual snoring during sleep. It has been developed by the RDI Department of SIBEL S.A.U. with the collaboration of reference Health Centers and doctors specialized in Sleep Disorders.

Somnibel has been designed for maximum safety. The complete instructions for use should be read before proceeding with the device use. Failure to do so may result in injuries to the user and damage to the device and/or accessories.

1.1 INTENDED USE

The Somnibel device is intended for the treatment of positional Sleep Apnea Hypopnea Syndrome (SAHS) or positional snoring by applying a gentle vibrating stimulus when the patient sleeps in the supine position to induce a change in the body position, thus reducing the incidence of sleep respiratory events.

The following conditions must be taken into account:

- Body-worn device
- Use into the patient's home or similar indoor use (not for outdoor use).
- Not intended for use in moving transport vehicles

1.2 INDICATIONS FOR USE

It is well known that more than 50% of SAHS patients experience a worsening in the frequency and severity of respiratory events when sleeping in the supine position, compared to other body positions[1, 2, 3, 4]. This positional dependency is more prevalent in mild to moderate, younger and less obese patients, which are the majority of the total population of SAHS patients[5, 6, 7]. Positional SAHS is defined as an abnormal Apnea-Hyponea Index (AHI) that is double in supine position compared to other positions[5, 7]. Additionally, the severity and frequency of snoring is also positional dependant in the majority of habitual snoring subjects[8]. When the supine position is avoided, the frequency of respiratory events is reduced in patients with positional Obstructive Sleep Apnea (OSA)[9] and positional therapy is considered an effective treatment for OSA in selected patients[10].

Somnibel is a body-worn, active device able to detect the position of the patient during sleep and to generate a gentle vibration, depending on the detected position, that induces the patient to change his/her position. Somnibel has been designed to be used by the patient at home and can be placed at the forehead or chest. In both placements, the device vibration is able to induce a position change and, consequently, a reduction of respiratory events. Somnibel includes several compliance enhancement features for favoring the patient's sleep and making it more comfortable and easy to use.

Somnibel is indicated for patients older than 18 years, weighing over 40 kg and a height over of 145 cm. Although not required, it is recommended to use the device under the supervision of a sleep physician for obtaining better treatment results.

Somnibel uses a rechargeable Lithium-polymer battery and includes USB connection for battery charge. It is recommended to fully charge the battery before the first use of the device.

Somnibel must be adhered to the patient's body, at the forehead or chest, by means of a specifically designed disposable fastening adhesive. The fastening adhesive should not be placed onto injured skin. The patient should adopt a lying sleeping position (trunk inclination < 30º) while using the device.

Although Somnibel can be used within conventional environmental conditions (see section TECHNICAL SPECIFICATIONS), it is recommended to sleep with a room temperature between 18ºC and 26ºC. A hot environment may induce excessive sweating that can deteriorate the adherence of the adhesive.

1.3 ⚠ WARNINGS

Somnibel is not intended to be used with other energy sources that are not covered in this manual.

Use only Somnibel with accessories provided by the manufacturer or dealer, or those that meet the specifications of this manual. The use of other accessories with Somnibel can cause damage to the device or affect the measurements.

The battery charger connector includes a protecting cover for avoiding penetration of liquids into the device and for avoiding electrostatic discharges during their use. Do not use this accessory without this cover.

Contact of liquids with the internal parts of the device and the connectors must always be avoided. The system is resistant to moderate splashing and dripping (Protection level IP22: protected against solid objects with a diameter of 12.5 mm and above; protected against water drops falling vertically with a maximum inclination of 15 degrees).

Accessories should be handled by their strongest parts, which are the connectors. They should also not get wet or exposed to very abrupt changes of temperature. Do not apply excessive stress to the accessories. In particular, avoid pulling or bending any part of the cables.

Do not disconnect the accessories from the device by pulling the cable. You can damage the product or accessories reducing the product's safety. Hold always the connectors when disconnecting the device.

Deteriorated accessories (battery charger with broken case, cable or connector) should not be used since there is risk of cramps. Contact SIBEL S.A.U. or your provider for acquiring new ones.

Deteriorated fastening adhesives (excessively wrinkled or partially removed from the protecting cover) should not be used since their adhesiveness may be reduced. Dispose defective adhesives and use a new one.

In case of device overheating during battery charge or during use, immediately disconnect it from the mains and stop using the device. Contact SIBEL's After Sales Service or your dealer.

Fastening adhesives are intended for single-use. Do not reuse the adhesives since their adhesiveness is considerably reduced after the first use. Use always a new adhesive for each treatment session.
The cleaning instructions in this manual must be carefully followed.

No parts are allowed for temporary immersion. IT MAY CAUSE ELECTRIC DISCHARGE.

The Somnibel device is prepared to work at room temperature. Avoid exposing any part of the device or accessories to heat sources. Also avoid direct exposure to sunlight. Temperature changes cause condensation and moisture. Before using the device, allow the it to acclimate to ambient temperature.

The device is not designed to work in an explosive environment or in the presence of flammable anesthetics or gases of any kind. MAY CAUSE EXPLOSION.

The device should be used in an acoustic environment that allows the patient to sleep normally.

Keep your device protected from shock and vibration. During transportation, place all the items in the original packaging. The material provides enough protection against small accidental impact.

Do not throw the packaging after using the device. It can be used for device transportation.

Do not use Somnibel or the fastening adhesive continuously for a period longer than 10h. Prolonged use of the product can induce adverse effects such as headache, skin marks or redness after adhesive removal. If you detect any of these effects, stop using the device and contact your physician.

Do not try to open the device. In case of malfunction or unexpected operation, please contact SIBEL's After Sales Service or your dealer.

In case of receiving Somnibel with a deteriorated packaging, do not use the device and contact your courier agency or SIBEL's After Sales Service.

Do not use the device in and MRI environment.
The use of mobile phones, transmitters and similar equipment generating radio frequency emissions and placed next to the device is not allowed during treatment with Somnibel. Therefore, do not use the device in the presence of radio equipment (e.g. mobile phones). Follow the recommendations regarding the separation distance specified in the manufacturer's declaration for EMC in this manual (Annex 1).

1.4  DISPOSAL OF ELECTRICAL AND ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION

Never dispose Somnibel in the household trash, since it contains a Lithium-Polymer battery and electronic components. It must be disposed properly and may need to be recycled in accordance with the statutory requirements in your country.

- Waste of batteries Directive: the lithium-polymer battery contained into the device must be extracted and disposed appropriately before disposing the device.
- Materials according to the RoHS Directive: the device and its accessories are RoHS compliant.
- Materials according to the Medical Device Directive: none of the components or accessories that may be used in combination with the device contain phtalates. The device and all the accessories are latex free.
- Materials according to the REACH regulation: neither the device nor its accessories use any hazardous substance according to REACH regulation.

Fastening adhesives for Somnibel can be disposed in the household trash, unless local legal requirements are applicable. See the fastening adhesive User's Manual for additional information on disposal. Information on proper disposal Information on proper disposal is available from SIBEL's After Sales Service or your dealer.

2. INSTALLATION INSTRUCTIONS

2.1 MAIN FEATURES

- Automatic ON/OFF
- Internal rechargeable battery: > 3 nights (10h/night)
- Visual indicator of battery status
- Initial self-test

2.2 PACKING LIST

CODE 08768 QTY. 1 SOMNIBEL POSITIONAL THERAPY DEVICE

CODE 08741 o 08742 QTY. 1 USB CHARGER

CODE 08741 TRUMPower TMW7-5-E-UB
CODE 08742 GLOBTEK GTM41134-0606-1.0

CODE 08753 QTY. 1 30u. FASTENING ADHESIVES BOX, includes:

- 30 FASTENING ADHESIVE

- ADHESIVE USER'S MANUAL

CODE 08754 QTY. 1 Somnibel **USER'S MANUAL**

3. INSTRUCTIONS FOR USE

1 Clip one fastening adhesive to a **Somnibel** device until you hear a "click" (the light blinks 3 times in green and the device vibrates).

2 Pay attention to the indications of the device after turn ON (consult section VISUAL INDICATIONS AND WARNINGS).

3 Remove the protective cover from the adhesive.

4 Pay attention to the correct orientation indicated by an arrow at the label of the device. Place the device and ahesive to the forehead or chest.

5 Lie down for sleeping.

6 On the next morning, remove the fastening adhesive from the skin and unclip it from the device (check that the green light blinks twice).

7 Dispose the fastening adhesive and its cover.

8 Connect the device to the mains by means of the battery charger. Check that the light turns on green.

9 When the light turns off, the device battery is fully charged and it can be disconnected from mains.

10 When not in use, store the device and accessories into its packaging.

Do not forget to unclip the fastening adhesive from Somnibel after each use. This will expand battery life.

If Somnibel indicates low battery after clipping the fastening adhesive, connect the device to mains before using it for assuring a complete therapy during the whole night.

3.1 SOMNIBEL FUNCTIONING

Somnibel is automatically turned ON when the fastening adhesive is clipped to the device. At the beginning, the device performs a self-test for checking its correct functioning. The visual indicator on the device will provide indications of the results of self-test and battery status (see sections VISUAL INDICATIONS AND WARNINGS).

After turning ON, Somnibel will wait for 15 minutes before starting the stimulus application so that the patient can restfully get asleep.

Somnibel device generates a gentle vibrating stimulus when the supine position is detected for inducing the patient to change his/her body position. If the patient does not change the position, the device will wait for 30 seconds and then it will increase the stimulus intensity. The intensity will be progressively increased until the patient changes the position (4 intensity levels).

3.2 COMPLIANCE ENHANCEMENT SETTINGS

The Somnibel device includes additional features for enhancing patient compliance to the positional therapy.

These features are configured with default parameters, as follows:

Settings	Default value	Description	Enhancement
EasySleep Delay	15 min	Time between device ON and activation of stimulus if patient is in supine position.	Allows the patient to fall sleep at the beginning of treatment.
Supine Delay	30 sec	Time between detection of supine position and activation of stimulus.	Allows the patient to transition between left and right positions without applying any stimulus.
Stimulus Increase Period	60 sec	Time between consecutive increases of stimulus intensity.	Modifies the rate of stimulus increase for adapting it to each patient's needs.
Time at Maximum Power	20 min	Maximum time with the stimulus at 100% of intensity if patient does not change position.	Avoids excessive application of vibration stimulus.
Back to Sleep Delay	5 min	When the device detects the upright position and returns to any other position, it waits some minutes before applying again the stimulus.	Allows the patient to fall sleep again after getting up in the middle of the night.

3.3 VISUAL INDICATIONS AND WARNINGS

	TURN ON	
	RUNNING	
	TURN OFF	
	LOW BATTERY	Connect the device to the mains with the battery charger.
	CHARGING	The light turns OFF when the device is fully charged.
	UNSTABLE CLIPPING	Adhesive incorrectly clipped to the device. Check the clipping of both snap buttons to avoid device uncoupling.
	SEFT-TEST ERROR	Internal device error. Contact SIBEL's After Sales Service or your dealer.

(vibration)

3.4 TRAVELLING WITH THE SOMNIBEL

Do not throw the packaging after using the device. It can be used for device transportation.

If you need to travel, you can bring your Somnibel with you for continuing your treatment. Somnibel can be easily and safely transported in your personal luggage by placing the device and accessories (battery charger, fastening adhesive box, etc.) into the original packaging.

4. CLEANING INSTRUCTIONS

The Somnibel device and the battery charger should be gently cleaned, with a cloth moistened with soapy (neutral) water or with 96º alcohol. Then they can be wiped dry. Particular care must be taken to ensure that no liquid enters the interior of the device or the connectors and connections. Abrasive substances or solvents must be avoided.
Fastening adhesives should not be cleaned and must be disposed after each use.

5. TECHNICAL SPECIFICATIONS

	Somnibel
Useful life	3 years
Size (L x W x H)	51.9 x 31.7 x 14.5 ± 0.5 mm
Weight	16.8 ± 1.0 gr
Power supply	Internal rechargeable Lithium-Polymer battery (> 3 nights @ 10h/night)
Enclosure protection degree:	IP22
Environmental conditions	**Use:** Temperature range: 5ºC to 40ºC **(Note 1)**/ Relative humidity range: 35% to 85%(non-condensing) / Atmospheric pressure range: 700 hPa to 1060 hPa (from 2950 m to 350 m of altitude, approximately) **Transport and storage conditions:** **Device (Note 2)**: Temperature range: -20ºC to 60ºC. /Humidity range: <93%(non-condensing). **Adhesives:** Temperature range: -25ºC to +70ºC / Humidity range: <93% (non-condensing).
Intensity Level at Maximum Stimulus	< 23 dB HL
A-weighted sound pressure level, L_{pA} A weighted sound power level, L_{WA}	DECLARED SINGLE-NUMBER NOISE EMMISSION VALUES in accordance to ISO 4871 **(Note 3)** < 36 dBA < 35 dBA
USB 2.0 connectivity	Only for battery charge
Automatic ON/OFF	X
Initial Self-Test	X
Operational modes	Therapy
Monitored signals	Sleeping position
Compliance Enhancement Settings **(Note 4)**	

	Somnibel
Auto-adjusting Stimulus Levels	0%, 25%, 50%, 75%, 100% (< 110 dB)
EasySleep Delay	15 min
Supine Delay	30 secs
Stimulus Increase Period	60 secs
Time at Maximum Power	20 min.
Supine threshold angle	45º
Visual indications **(Note 5)**	Device Turn ON / Device Turn OFF / Device running / Low battery / Charging battery / Self-Test error Incorrect Clipping

Notes:
1. Maximum temperature is restricted to 37ºC only when the device is used during the treatment (with the adhesive). Thus, the temperature on the adhesive will be below 40ºC (maximum recommended temperature for the adhesive) and below 41ºC (according to EN60601-1 standard). / **2.** Transport and storage conditions of the device are reduced with respect to the IEC 60601-1-11 standard due to the specifications of the internal lithium –polymer battery, vibration motor and switches. / **3.** Values measured at a distance of 0.25 m for the maximum intensity level with a test method equivalent to ISO 3744:2010. / **4.** See section COMPLIANCE ENHANCEMENT SETTINGS for definitions. / **5.** See section VISUAL INDICATIONS AND WARNINGS

6. APPLICABLE DIRECTIVES AND STANDARDS

- European directive concerning medical devices 93/42/EEC
- Rohs Directive: 2011/65/EU.
- Waste disposal according to WEEE Directive 2012/19/UE.
- Regulation EC 1272/2008 on classification, labeling and packaging of substances and mixtures (REACH).
- Packaging and packaging waste directive 94/62/ EC modified by 2004/12/EC
- Batteries waste directive 2006/66/EC modified by 2013/56/EU.

- Quality (EN ISO 13485:2016+AC:2016, EN ISO 9001:2015)
- Risk management (EN ISO 14971:2012)
- Safety Medical devices (EN 60601-1:2006+AC:2010+A1:2013+AC:2014)
- Safety Medical devices – Batteries (EN 62133:2013).
- Safety Medical devices – Home use (EN 60601-1-11:2010).
- Electro-magnetic Compatibility (EN 60601-1-2:2007+AC:2010)
- Biocompatibility: Biological evaluation of medical devices (EN ISO 10993-1:2009+AC:2010)
- Usability (EN 60601-1-6:2010+A1:2015 and EN 62366:2008+A1:2015)
- Software of medical devices (EN 62304:2006+AC:2008+A1:2015)
- Documentation and information (EN 1041:2008 and EN ISO 15223-1:2016)

7. SYMBOLS


MANUFACTURER (manufacture date, name and address of the manufacturer)


DATE OF MANUFACTURE

CATALOGUE NUMBER

SERIAL NUMBER

CE MARKING, NOTIFIED BODY NUMBER


BF APPLIED PARTS


CAUTION, ADDITIONAL WARNINGS IN ACCOMPANYING DOCUMENTS


WARNING, RISK IDENTIFIED


CONSULT INSTRUCTIONS FOR USE


DIRECT CURRENT

IP22 (SEE SECTION WARNINGS)


DEVICE UPRIGHT POSITION

BATCH CODE


USE BY DATE


DOES NOT CONTAIN NATURAL RUBBER LATEX


DO NOT REUSE


WASTE OF ELECTRICAL AND ELECTRONIC EQUIPMENT


TEMPERATURE LIMITS


ATMOSPHERIC PRESSURE LIMITATION


HUMIDITY LIMITATION


KEEP DRY


FRAGILE, HANDLE WITH CARE


RECYCLABLE CARDBOARD


THIS WAY UP PACKAGING

8. BIBLIOGRAPHY

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Annex 1: ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
Somnibel is intended for use in the electromagnetic environment specified below. The customer or the user should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - Guidance**
RF (Radiated) emissions CISPR 11 (EN 55011)	Group 1 Class B	Somnibel uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF (Conducted) emissions CISPR 11 (EN 55011)	Grupo 1 Clase B	Somnibel works with batteries. Applicable to the charger.
Harmonic emissions EN-IEC 61000-3-2	Not applicable	Somnibel works with batteries. Power of the charger is lower than 75W.
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-3	Yes	Somnibel works with batteries. Applicable to the charger.

Guidance and manufacturer's declaration – electromagnetic immunity

Somnibel is intended for use in the electromagnetic environment specified below. The costumer or the user of Somnibel should assure that it is used in such an environment.

Immunity test	EN-IEC 60601 test level	Compliance level	Electromagnetic environment –Guidance
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst EN-IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines Not applicable	Somnibel works with batteries. Applicable to the charger. The input/output line cables are shorter than 3 meters long.
Surge EN-IEC 61000-4-5	±1 kV differential ±2 kV common mode	±1 kV differential ±2 kV common mode	Somnibel works with batteries. Applicable to the charger.
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	<5 % Ut (>95 % dip in Ut) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	<5 % Ut (>95 % dip in Ut) for 0.5 cycle 40 % Ut (60 % dip in Ut) for 5 cycles 70 % Ut (30 % dip in Ut) for 25 cycles <95 % Ut (>5 % dip in Ut) for 5 seconds	Somnibel works with batteries. Applicable to the charger. **(Note 1)**
Power frequency (50 / 60 Hz) magnetic field EN-IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial of hospital environment.
Conducted RF EN-IEC 61000-4-6 Radiated RF EN-IEC 61000-4-3	3 Vrms 150KHz to 80 MHz 3 V/m 80 MHz to 2.5 GHz	3 Vrms 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of Somnibel, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance (Note 2)** $d = \left[\frac{3.5}{V_1}\right]\sqrt{P}$ de 80 MHz a 800 MHz $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ de 80 MHz a 800 MHz / $\left[\frac{3.5}{E_1}\right]\sqrt{P}$ de 80 MHz a 2.5 MHz **(Note 2,3,4)**

Note 1. Ut is the a.c. mains voltage prior to application of the test level. / **Note 2**. At 80 MHz and 800 MHz, the higher frequency range applies. / **Note 3**. These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. / **Note 4**. **P** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and **d** is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range[b]. Interference may occur in the vicinity of equipment marked with the following symbol: 

a. Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which Somnibel is used exceeds the applicable RF compliance level above, Somnibel. should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such reorienting or relocating Somnibel. **b.** Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and Somnibel

Somnibel is intended for use in an electronic environment in which radiated RF disturbances are controlled. The costumer or the user of Somnibel can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and Somnibel as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz 	80 MHz to 800 MHz 	800 MHz to 2.5 GHz 
0,01	0,12	0,12	0,23
0,1	0,37	0,37	0,74
1	1,17	1,17	2,33
10	3,69	3,69	7,38
100	11,67	11,67	23,33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.
Note 1. At 800 MHz, the separation distance for the higher frequency applies. / **Note 2.** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absortion and reflection from structures, objects and people.