SLEEP&GO

CARDIORESPIRATORY POLYGRAPH

USER'S MANUAL



534-7AB-MU2 • REV. 2.03 • 2026-04

CE 0318

Sleep&GO Manual
Revision: 534-7AB-MU2 Rev. 2.03
All rights reserved.

Please refer to the device's Service Manual for additional information.

This manual can be purchased through the After Sales Service.

SIBEL S.A.U.
Raimon Casellas, 6-8. 08205-Sabadell (Barcelona). Spain.
National Sales: Tel. 93 436 00 08 e-mail: comercial@sibelmed.com
International Sales: Tel. +34 93 436 00 07 E-mail: export@sibelmed.com
Technical service: Tel. +34 93 433 54 50 E-mail: sat@sibelmed.com
Website: www.sibelmed.com

COPYRIGHT
No part of this publication may be reproduced, transmitted, transcribed, stored in a back-up system or translated into any language or computer language in any form or by any means, electronic, mechanical, optical, chemical or manual without the express written consent from SIBEL S.A.U.

DISCLAIMER
SIBEL S.A.U. is responsible for the security, reliability and performance of this equipment only if:
• The place where the systrem is installed or used meets the requirements for electrical installations IEC and other applicable regulations.
• All repairs, revisions or modifications, both in and out of the warranty period, are made by technical staff of SIBEL S.A.U.
• The system is used by qualified staff in accordance with the recommendations stated in this User's Manual.

PRODUCT IN COMPLIANCE WITH MEDICAL DEVICE REGULATION (EU) 2017/745. CLASS IIa.

CE 0318

Thank you for choosing **SLEEP&GO**!

This product has been developed by the RDI Department of SIBEL S.A.U. with the collaboration of reference Health Centers and doctors specialized in the area of Sleep Disorders. **SLEEP&GO** is manufactured according to the European Medical Device Regulation and with the best quality standards.

Revised
Date: 2026-04
Technical Director

Approved
Date: 2026-04
Sales Director

Index

ÍNDICE

SAFETY 6
INTENDED USE 6
INTENDED USERS 7
INDICATIONS FOR USE 7
INTENDED PATIENT POPULATION 8
LIMITATIONS FOR USE 8
CONTRAINDICATIONS AND SIDE EFFECTS 9
ESSENTIAL OPERATION 9
RESIDUAL RISKS 9
WARNINGS 9
DISPOSAL OF ELECTRICAL AND ELECTRONIC DEVICES BY DOMESTIC USERS IN THE EUROPEAN UNION 14
1. INSTRUCTIONS OF INSTALLATION AND USE 15
1.1 MODELS 15
1.2 PACKING LIST 16
1.3 LAYOUT OF CONTROLS, INDICATORS AND CONNECTORS 19
1.3.1 FRONT/TOP/RIGHT PANNEL 19
1.3.2 LEFT PANNEL 19
1.3.3 REAR PANNEL 20
1.4 INSTALLATION AND START-UP 20
1.4.1 BATTERY PLACEMENT 20
1.4.2 POWER SAVING MODE 21
1.4.3 WIRELESS MODULE INSTALLATION 21
1.4.4 PLACEMENT OF SENSORS AND ELECTRODES 21
1.4.4.1 PLACEMENT OF THE SLEEP&GO POLYGRAPH 21
1.4.4.2 NASAL CANNULA 22
1.4.4.3 THERMOCOUPLE AIRFLOW SENSOR 23
1.4.4.4 THORACIC AND ABDOMINAL EFFORT BANDS 24
1.4.4.5 PULSE OXIMETER 25
1.4.4.6 BODY POSITION AND ACTIVITY 28
1.4.4.7 SNORING SENSOR 28
1.4.4.8 LIMB MOVEMENT SENSOR 29
1.4.4.9 EKG ELECTRODES 29
1.4.4.10 EMG, EOG AND EEG ELECTRODES 30
1.4.4.11 EVENT MARKER 32
2. OPERATION 32
2.1 WORKING MODES 33
2.2 SYSTEM CONFIGURATION 33
2.3 INITIAL DEVICE SETUP 34
2.3.1 SETTING THE DATE AND TIME 34
2.3.2 SETTING THE LANGUAGE 35
2.3.3 SETTING THE TYPE OF BATTERIES 35
2.3.4 SETING THE UNITS OF THE CPAP CHANNEL 35
2.4 SWITCHING ON/OFF THE WIRELESS MODULE 36
2.5 MAKING POLYGRAPHY TESTS IN ONLINE MODE 37
2.6 MAKING POLYGRAPHY TESTS IN HOLTER MODE 37
2.6.1 STARTING AND ENDING A TEST MANUALLY 37
2.6.2 SCHEDULED TESTS 38
2.6.2.1 SCHEDULING A TEST IN THE SLEEP&GO 38
2.6.2.2 DISPLAYING THE SCHEDULED TESTS 40
2.6.2.3 CHANNEL CONFIGURATIONS 41
2.7 TRANSFER AND REVIEW OF THE TESTS 41
2.8 FIRMWARE UPDATE 42

2.9 DEVICE OPTIONS UPDATE 42
3. TECHNICAL SPECIFICATIONS 44
3.1 GENERAL DATA 44
3.2 PULSE OXIMETER TECHNICAL SPECIFICATIONS 49
3.3 CONDITIONS OF OPERATION AND STORAGE OF ACCESSORIES 50
3.4 APPLICABLE STANDARDS 51
4. SYMBOLOGY 54
4.1 SYMBOLOGY OF THE SLEEP&GO 54
4.2 SYMBOLOGY OF THE ACCESORIES AND PACKAGING 55
4.3 VALIDATED ACCESSORIES 57
5. CLEANING AND MAINTENANCE 59
5.1 CLEANING 59
5.2 PREVENTIVE MAINTENANCE 59
5.2.1 ACTIONS TO BE TAKEN BY THE USER 60
5.2.2 ACTIONS TO BE TAKEN BY QUALIFIED PERSONNEL 60
5.3 CORRECTIVE MAINTENANCE 61
ANNEX 1. ELECTROMAGNETIC COMPATIBILITY 62
ANNEX 2. TROUBLESHOOTING GUIDE 66
ANNEX 3. BIBLIOGRAPHY 68

SAFETY

The Sleep&Go device is a cardiorespiratory polygraph designed to be used with the BitmedLab software, the XPOD module, the EXG modules and other sensors, for the diagnosis and control of sleep related breathing disorders, mainly the Sleep Apnea Hypopnea Syndrome (SAHS).

This user's manual includes information on the use of the Sleep&Go (A and B), XPOD Module and EXG Module. Please refer to the BitmedLab software and sensor user manuals when necessary.
Sleep&Go has been designed for maximum safety. The complete operating instructions should be read before proceeding to operate with the system. Failure to do so may result in injuries to the user or patient and damage to the device and/or accessories.

Report any serious incident to the manufacturer and competent authority.

INTENDED USE

Acquisition, storage and display of biomedical signals for the simplified diagnosis and control of Sleep Apnea and Hypopnea Syndrome, being anyone or any combination of the following signals: respiratory airflow; snoring; CPAP pressure measurement; thoracic effort; abdominal effort; limb movement; body position; activity; oxygen saturation, beats per minute and plethysmographic wave signals with the XPOD Module; and EEG-EMG-ECG signals with the EXG Module.

Next conditions must be taken into account:

- Use in a health center, patient's home or similar indoor use (not for outdoor use).
- Not designed for use in moving transport vehicles.
- Not intended for monitoring vital signals.
- ECG signal can not be used for heart diagnosis purpose. It's only intended for bradycardia and tachycardia detection during sleep analysis.

INTENDED USERS

Health personnel:

The Screen&Go and the XPOD and EXG modules are designed for use in a healthcare facility by a physician or technician trained in SRBD and SAHS. Training in the acquisition of cardiorespiratory signals, data transmission and visualization on a PC is also required. It is not recommended that the configuration of the device is changed without understanding the principles of signal digitalizing. Healthcare personnel can contact SIBEL S.A.U. for additional training.

The medical staff must train the patient on how to perform the Sleep&Go test at home, how to avoid interferences and how to place the sensors in their correct location in case they move. The patient cannot modify the configuration of the device.

Patient:

The Sleep&Go and the XPOD module are also designed for unsupervised use by the patient themselves at home, but only when provided by a sleep technician or physician. The patient must have received appropriate training before using the polygraph. The actions to be performed by the patient for correct use of the device include putting on the devicee and sensors according to the instructions of the healthcare personnel and turning on the device. The next morning the patient must turn off the equipment and remove the device and sensors.

INDICATIONS FOR USE

SLEEP APNEA AND HYPOPNEA SYNDROME (SAHS)

The Sleep Apnea and Hypopnea Syndrome (SAHS) is a sleep related breathing disorder with a high prevalence[1,2] and is associated with significant morbidity and mortality[3-7]. The standard laboratory polysomnography (PSG) for the diagnosis of SAHS is expensive, requires technical expertise and is of limited availability in many areas[8]. Cardiorespiratory polygraphy, based on recording the same biological signals as PSG except the neurological ones, is a valid method for the diagnosis of SAHS[9].

INDICATIONS FOR USE OF SLEEP&GO

Sleep&Go is a portable monitor device designed to be used in conjunction with the BitmedLab software application, the XPOD module, the EXG module and other sensors. It is indicated, together with a comprehensive sleep evaluation, for the diagnosis and control of SAHS. It can be used as an alternative to PSG in patients with both high and low pre-test probability and with or without comorbidities[10], or in patients for whom in-laboratory PSG is not possible.

Sleep&Go is a useful tool for an accessible and accurate diagnosis of SAHS. It allows the acquisition, storage and visualization of biological signals, which can then be analyzed with BitmedLab software.

Sleep&Go can be used both in supervised (hospitals, sleep units or similar)[11] or in unsupervised environments such as the patient's home[10,12,13]. It can be used for the general screening of asymptomatic population,provided that appropriate clinical assessment is used to address potential false positives and false negatives[12, 13, 14]. **Sleep&Go** can also be used to monitor response to SAHS treatments and, in selected cases, for Positive Airway Pressure (PAP) titration.

The diagnostic and therapeutic decisions taken when using **Screen&Go** have proved to be equivalent to decisions taken from PSG studies[10, 14].

The automatic analysis implemented in BitmedLab for the detection of respiratory events from the signals recorded with the **Screen&Go** is useful for the diagnosis and monitoring of SAHS[12,13,14].

INTENDED PATIENT POPULATION

Minimum age of patients is 5 years, weighing over 15 kg and a minimum height of 95 cm. Patients must have a physiscal and mental condition that allow them to perform the poligraphic test.

LIMITATIONS FOR USE

The interpretation of the tests and any subsequent treatment must be carried out by a physician. The acceptability of a test is the responsibility of the health personnel.

When used at home, the patient is only authorized to start and stop the test, and must be instructed by the physician in this regard. The recording of ExG signals (EEG, EMG, EOG and ECG) cannot be used at home. ECG) cannot be used at home.

Screen&Go is not suitable for the diagnosis of neurological sleep disorders such as insomnia, parasomnias, circadian rhythm disorders or narcolepsy.

CONTRAINDICATIONS AND SIDE EFFECTS

No contraindication or side effect has been identified for Sleep&Go, the XPOD module and the EXG module.

ESSENTIAL OPERATION

The acquisition and representation of all physiological signals is considered an essential operation (so that the specified accuracy can be met and / or the technician is able to distinguish the artifacts), and the storage and integrity of the data on the card of memory. Communication with the computer is not considered essential as long as the integrity of the data in memory is guaranteed.

RESIDUAL RISKS

According to the application of the EN ISO 14971 standard, all risks related to the use of the **Sleep&Go** equipment have been reduced to maximum, as much as possible. It is important to read carefully all indications of use, contraindications, warnings and recommendations provided in this manual.

WARNINGS

The **Sleep&Go** IS NOT CERTIFIED FOR USE IN CONTINUOUS MONITORING, where a failure in operation may cause injuries or the death of the patient. This product does not maintain nor does it help to maintain the life of the patient. The term CONTINUOUS MONITORING is specified in regulation EN60601-1. The **Sleep&Go** is classified as Class IIa device in accordance with Medical Device Regulation (EU) 2017/745.
The pulse oximeter is not provided with physiological-type alarms.

The **Sleep&Go** is not intended for monitoring vital signals.

There are no applicable parts to the patient which produce stimulation.

The system has no user-serviceable parts. Use only authorized service and spare parts supplied by the manufacturer.

Contact of liquids with the internal parts of the device and the connectors must always be avoided.

The system is only resistant to moderate splashing and dripping (Protection level IP22: protection against access to hazardous parts with a finger; 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 of the envelope).

Do not submerge the parts of the device in any liquid. MAY CAUSE ELECTRIC DISCHARGE.

No parts are allowed for temporary immersion.

The cleaning instructions in this manual and also in the instructions of use of any sensor supplied but not manufactured by SIBEL S.A.U. must be carefully followed.

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

Do not use the system in and MRI environment.

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

This product is intended for indoor use (e.g. at the patient's home or hospital) and is not suitable for use during patient transportation.

Use of Sleep&Go in unattended settings may occasionally provide unconclusive tests in some patients. In this case, the test must be repeated.

The polygraph is not intended to be used outdoors or with other conditions or energy sources that are not covered in this manual.

The **Sleep&Go** is not protected against defibrillation shocks. Disconnect all cables and electrodes from the patient and the EXG module before defibrillation. During defibrillation the measurements could be incorrect, but no damage would be caused to the device. Remove the device and its applicable parts from the patient's chest if they prevent you from performing defibrillation.

Do not use an electric scalpel or a high frequency surgical device while the patient is connected to any sensors or electrodes of the **Sleep&Go**.

The use of mobile phones, transmitters and similar equipment generating radio frequency emissions and placed next to the system is not allowed during the tests. Therefore, do not use the system in the presence of radio equipment (mobile phones, walkie-talkie ...). Follow the recommendations regarding the separation distance specified in the manufacturer's declaration for EMC in this manual.

Remember that when multiple devices are connected to a patient there is a risk of accumulation of leakage current. Minimize the number of devices.

Do not remove the device cover. The service and repair of the device should be carried out only by trained personnel.

The **Sleep&Go** system is prepared to work at room temperature. Avoid exposing any part of the system to heat sources. Also avoid direct exposure to sunlight. Temperature changes cause condensation and moisture. Before using the system, allow the device to acclimate to ambient temperature. For reference, if the temperature difference between the system and the environment is above 10º C a 20 minutes wait time in an intermediate temperature is recommended.

The polygraph should not be placed adjacent to or stacked with other equipment.

The system shall be stored and used within the temperature ranges, pressure and humidity specified in section number 3.

Artefacts in the signal may be produced as a result of ESD. A trained operator should be able to recognize these artefacts easily.

The operator must be trained to be able to recognize the differences between a biological signal and signal artifacts caused by patient movements, RF interference or poor placement of the electrodes or sensors. The presence of ESD or RF devices will not lead to wrong conclusions. Unusable data is not considered a risk to the patient safety.

Cables or sensors should not surround the patient's neck, especially when the patient is a child.

The **Sleep&Go** system does not increase the safety risk for patients with pacemakers in accordance with the EN50061 standard (Medical electrical equipment – Safety of implantable cardiac pacemakers). Before using the system in patients with pacemakers, the operator should check the documents accompanying the pacemaker with respect to its certification and requirements of use and, if necessary, contact the manufacturer.

Patients must be insistently warned that they must not open the **Sleep&Go** or attempt to adjust it.
Sensors or accessories in bad condition should not be used.

Use only the **Sleep&Go** with accessories, sensors and electrodes provided by the manufacturer or dealer, or those that meet the specifications of this manual. The use of other sensors with the **Sleep&Go** can cause damage to the device or the quality of the signals.

Sensors should be handled by their strongest parts, which are the connectors. Also, they should not get wet or exposed to very abrupt changes of temperature. To clean the sensors, do not use abrasive chemicals. Do not apply excessive stress to the sensors. In particular, avoid bending any part of the sensors. This means that the material should not bend more than necessary in normal use.

The polygraph is designed to be used exclusively by medical staff, who should be supervised and instructed by a physician.

Medical personnel should inform the patient about precautions to be found in the WARNINGS AND PRECAUTIONS section and to be taken when using the equipment.

Use the provided carrying case when transporting the device and

its accessories.

Do not reuse single-use accessories as there is risk of infection to the patient.

In case of doubt or unexpected event contact the manufacturer. You can find contact details on page 2 of this manual.

Do not leave the batteries inside the device if it won't be used for a long period of time.

Ensure to perform the adquisition of signals in an acustic and light environment that allows the patient to sleeping normally.

The system cannot be used for DIRECT CARDIAC APPLICATION.

The system is not an electrocardiograph, and therefore can not be used to generate a separable ELECTROCARDIOGRAM for diagnostic purposes, electrocardiographic monitoring or for ambulatory electrocardiography. The EKG signal is only intended for bradycardia and tachycardia detection during sleep analysis.

As for the electrodes, a proper contact of the skin with the electrodes must be achieved by using conductive paste. Otherwise, there is a risk of inaccurate measurements. Avoid contact with the eyes or mucus membranes of gels, collodion, alcohol, acetone or any substance used in the placement or removal of electrodes. Be especially careful in the usage of collodion. Always follow the recommendations for use provided by your collodion manufacturer.

The conductive part of the electrodes and connectors, including the ground electrode must not touch other conductive parts, including the ground.



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

Never dispose of the **Sleep&Go**, its accessories and its batteries in the household trash. It must be disposed of properly and may need to be recycled in accordance with the statutory requirements in your country.

The device uses a lithium alkaline and could use an optional NiMh battery.

- Materials according to the RoHS Directive 2011/65/EU.
- Materials according to the Medical Device Regulation: the device and the accessories recommended in this manual do not contain phtalates. The device and all the accesories are latex free.
- Materials according to the REACH regulation: neither the device nor its accessories use any hazardous substance according to REACH regulation.
- In the event that the device or its accessories are infected at the time of recycling, it must be disinfected or disposed by following the national regulations regarding the disposal of infected products.

Information on proper disposal is available from your dealer or from Technical Support at SIBEL S.A.U.

1. INSTRUCTIONS OF INSTALLATION AND USE

1.1 MODELS

The **Sleep&Go** cardiorespiratory polygraph is available in two different models (A and B) with the following features:

Channels		Sleep&Go	
		A model	B model
Nasal cannula	Airflow		
	Snore		
	CPAP		
Thermocouple			
Inductive plethysmography band (thoracic)			
Inductive plethysmography band (abdominal)			
Auxiliary channel	External snore		
	Limb movements		
External EXG module	EXG 1		
	EXG 2		
	EXG 3		
External Xpod	SpO_2		
	BPM		
	Pulse wave		
Position			
Activity			
Marks			
Wireless (real time tests)			

Default Option

1.2 PACKING LIST

RELACIÓN DE CONTENIDO / PACKING LIST **534-708-120 REV. 11**

SCREEN&GO/SLEEP&GO CE0318

2023-11

MODELOS/ *MODELS*

CÓDIGO *CODE*	CANT. *QTY.*	DESCRIPCIÓN *DESCRIPTION*		SCREEN&GO	SLEEP&GO A	SLEEP&GO B
		POLÍGRAFO / *POLYGRAPH*				
_____(*)	1	**SCREEN&GO / SLEEP&GO SN: 347 - _____(*)**				
	1	Manual de uso SLEEP&GO / SLEEP&GO user's manual 534-7AB-MU_____(*) Rev__ ------ o -------- Manual de uso SCREEN&GO / SCREEN&GO user's manual 534-70S-MU_____(*) Rev__				
	1	Guía rápida SCREEN&GO-SLEEP&GO / SCREEN&GO-SLEEP&GO quick guide: 534-7AB-GR_____(*) Rev__				
		Productos, accesorios y componentes incluidos / *Products, accessories and components included*				
06312	1	BANDA DE SUJECIÓN TAMAÑO GRANDE (L) / *FASTENING BELT LARGE SIZE (L)*	Class I CE			
08049	1	CÁNULA DESECHABLE NASAL / *DISPOSABLE NASSAL CANNULA*	Class I CE			
06309	1	SENSOR TERMOPAR / *THERMOCOUPLE SENSOR*	Class I CE			
06314	1	INTERFAZ DE AMPLIFICACIÓN BANDA INDUCTIVA ESFUERZO TORÁCICO / *THORAX EFFORT INDUCTIVE BAND AMPLIFICATION INTERFACE*	Class I CE			
01420	1	BANDA INDUCTIVA ELÁSTICA EXTRA GRANDE (XL) / *ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)*	Class I CE			
06308	1	INTERFAZ DE AMPLIFICACIÓN BANDA INDUCTIVA ESFUERZO ABDOMINAL / *ABDOMINAL EFFORT INDUCTIVE BAND AMPLIFICATION INTERFACE*	Class I CE	---		
01420 (**)	1 (**)	BANDA INDUCTIVA ELÁSTICA EXTRA GRANDE (XL) / *ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)*	Class I CE			
06310	1	SENSOR MOVIMIENTO EXTREMIDADES / *LIMB MOVEMENT SENSOR KIT*	Class I CE	---		
09898	**1**	**MODULO PULSIOXIMETRIA XPOD / *XPOD PULSE OXIMETRY MODULE***	Class IIa CE0318			
08955	1	SENSOR PULSIOXIMETRIA SOFT (ADULTO) / *SOFT PULSE OXIMETRY SPO_2 SENSOR (ADULT)*				
08556	1	SOPORTE MÓDULO XPOD / *XPOD MODULE SUPPORT*				
08060	1	TARJETA MEMORIA MICRO SD CON ADAPTADOR SD / *MICROSD MEMORY CARD WITH SD ADAPTER*				
08094	1	LECTOR TARJETAS MEMORIA USB PARA PC/ *USB MEMORY CARD READER FOR PC*				
03673	2	PILAS ALCALINAS AA 1.5V / *AA 1.5V ALKALINE BATTERY*				
08010	1	MALETÍN TRANSPORTE SCREEN&GO / SLEEP&GO *CARRYING CASE SCREEN&GO / SLEEP&GO*				
09900	**1**	**SOFTWARE BITMEDLAB /*BITMEDLAB SOFTWARE*** MANUAL DE USO / *USER'S MANUAL* (incluido en la memoria USB / *included in the USB memory*)	Class IIa CE0318			

(**) CON LA REFERENCIA 08089 ENTREGADA CON UN SLEEP&GO NO SE INCLUYE LA REFERENCIA 01420. SOLO SE INCLUYE CON EL CONJUNTO POR SEPARADO.
WITH THE REFERENCE 08089 SUPPLIED WITH A SLEEP&GO REFERENCE 01420 IS NOT INCLUDED. ONLY INCLUDED WHEN 08089 IS DELIVERED SEPARATELY.

RELACIÓN DE CONTENIDO / PACKING LIST **534-708-120 REV. 11**

SCREEN&GO/SLEEP&GO CE0318

2023-11

Opciones firmware (canales internos) / *Firmware options (internal channels)*						
08078	1	OPCIÓN FIRMWARE CANAL DE RONQUIDO POR PRESIÓN / *PRESSURE SNORING CHANNEL FIRMWARE*				
08079	1	OPCIÓN FIRMWARE CANAL DE POSICIÓN CORPORAL / *BODY POSITION CHANNEL FIRMWARE OPTION*				
08080	1	OPCIÓN FIRMWARE CANAL DE ACTIGRAFÍA / *ACTIGRAPHY CHANNEL FIRMWARE OPTION*				
08081	1	OPCIÓN FIRMWARE CANAL DE MARCAS DEL PACIENTE / *PATIENT'S MARKS CHANNEL FIRMWARE OPTION*				
08082	1	OPCIÓN FIRMWARE CANAL DE PRESIÓN CPAP / *CPAP PRESSURE CHANNEL FIRMWARE OPTION*		---		
08083	1	OPCIÓN FIRMWARE CANAL DE ONDA DE PULSO / *PULSE WAVE CHANNEL FIRMWARE OPTION*		---		
08084	1	OPCIÓN FIRMWARE MÓDULO INALÁMBRICO / *WIRELESS MODULE FIRMWARE OPTION*		---		
Productos y accesorios Opcionales / *Optional Products and Accessories*						
08956	1	SENSOR PULSIOXIMETRIA SOFT (PEDIÁTRICO)/ *SOFT PULSE OXIMETRY SPO_2 SENSOR (PEDIATRIC)*	Class IIa CE0123			
09899	**1**	**MÓDULO EXG / *EXG MODULE***	Class IIa CE0318	---		
06346	1	SENSOR RONQUIDO PIEZOELÉCTRICO / *PIEZOELECTRIC SNORE SENSOR*	Class I CE	---		
07681	1	CÁNULA ORO-NASAL DESECHABLE SLEEPSENSE (PAQUETE DE 5u) / *DISPOSABLE SLEEPSENSE ORO-NASAL CANNULA* 60cm *(PACK OF 5u)*	Class I CE			
06311	1	BANDA DE SUJECIÓN TAMAÑO PEQUEÑO (S) / *FASTENING BELT SMALL SIZE (S)*	Class I CE			
06313	1	BANDA DE SUJECIÓN TAMAÑO EXTRA GRANDE (XL) / *FASTENING BELT XTRA LARGE SIZE (XL)*	Class I CE			
01425	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO PEQUEÑA (S) / *ELASTIC INDUCTIVE BAND SMALL SIZE (S)*	Class I CE			
01424	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO MEDIANA (M) / *ELASTIC INDUCTIVE BAND MEDIUM SIZE (M)*	Class I CE			
01421	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO GRANDE (L) / *ELASTIC INDUCTIVE BAND LARGE SIZE (L)*	Class I CE			
01420	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO EXTRA GRANDE (XL) / *ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)*	Class I CE			
01417	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO EXTRA EXTRA GRANDE (XXL) / *ELASTIC INDUCTIVE BAND XTRA XTRA LARGE SIZE (XXL)*	Class I CE			
01644	1	CABLE ADAPTADOR 1MM A 1.5MM / *CABLE ADAPTER 1MM TO 1.5MM*	Class I CE	---		
02741	1	PUENTE DE INTERCONEXIÓN / INTERCONNECTION BRIDGE	Class I CE	---		
08701	1	ELECTRODO CUCHARA ORO EXG (PAQUETE 10u) / *EXG GOLD CUP ELECTRODES (PACK OF 10u)*	Class I CE	---		
08093	1	CABLES PARA ELECTRODOS DE CORCHETE (PAQUETE DE 10u) / *CABLES FOR BUTTON STUD TYPE ELECTRODES (PACK OF 10u)*	Class I CE	---		
01027	1	ELECTRODO DE ECG (PAQUETE DE 50u) / *ECG ELECTRODE (PACK OF 50u)*	Class I CE	---		

RELACIÓN DE CONTENIDO / PACKING LIST **534-708-120 REV. 11**

SCREEN&GO/SLEEP&GO CE0318

2023-11

Opciones firmware (ligadas a sensores extenos) / *Firmware options (bond to external sensors)*					
09980 (06309)	1	OPCIÓN FIRMWARE CANAL TERMOPAR / *THERMOCOUPLE CHANNEL FIRMWARE OPTION*			---
09981 (06314)	1	OPCIÓN FIRMWARE CANAL ESFUERZO TORÁCICO / *THORACIC EFFORT CHANNEL FIRMWARE OPTION*		---	---
09982 (06308)	1	OPCIÓN FIRMWARE CANAL ESFUERZO ABDOMINAL / *ABDOMINAL EFFORT CHANNEL FIRMWARE OPTION*	---		---
09983 (06310, 06346)	1	OPCIÓN FIRMWARE CANAL AUXILIAR / *AUXILIARY CHANNEL FIRMWARE OPTION*	---		---

■ **ESTÁNDAR** ***STANDARD*** □ **OPCIONAL** ***OPTIONAL*** --- **NO DISPONIBLE** ***NOT AVAILABLE***

ADVERTENCIA:

- LOS ARTÍCULOS Y CANTIDADES RELACIONADAS ANTERIORMENTE HAN SIDO CUIDADOSAMENTE COMPROBADAS. EN CASO DE FALTAS O DESPERFECTOS PROCEDAN A COMUNICÁRNOSLO LO MAS PRONTO POSIBLE.
- SÍ DETECTA CUALQUIER DAÑO EN EL EMBALAJE, CONTACTE CON SU DISTRIBUIDOR ANTES DE PROCEDER A LA INSTALACIÓN DEL EQUIPO.
- NO SE DEBE DESPRENDER DE LOS EMBALAJES, BOLSAS, ETC. HASTA QUE VERIFIQUE TOTALMENTE EL CORRECTO FUNCIONAMIENTO DEL EQUIPO.
- EN CASO DE DEVOLUCIÓN DE MATERIAL O EQUIPO EN DEPOSITO, ROGAMOS NOS LO ENVÍEN EN PERFECTO ESTADO, COMPLETO DE ACCESORIOS Y DEBIDAMENTE EMBALADO. CUALQUIER DESPERFECTO OCASIONADO PROVOCARÍA UN CARGO CORRESPONDIENTE EN LA REPARACIÓN O EN LA REPOSICIÓN.

WARNING:

- *THE ITEMS AND QUANTITIES RELATED BEFORE HAVE BEEN CAREFULLY CHECKED. IN CASE OF ANY PART IS MISSING OR IS DAMAGED, NOTIFY US AS QUICKLY AS YOU CAN.*
- *IF YOU DETECT ANY DAMAGE IN THE PACKAGING, CONTACT WITH YOUR DISTRIBUTOR BEFORE PROCEEDING TO INSTALL IT.*
- *DO NOT THROW AWAY THE PACKAGING, BAGS, ETC. UNTIL THE CORRECT FUNCTIONING OF THE DEVICE IS VERIFIED*
- *IN THE CASE OF RETURNING THE GOODS, IT WILL BE APPRECIATED THAT YOU SEND THE DEVICE IN PERFECT ORDER, WITH ALL THE ACCESSORIES AND PROPERLY PACKAGED. ANY DAMAGE SUFFERED WILL MAKE A CHARGE CORRESPONDING TO REPAIR OR NEW PARTS.*

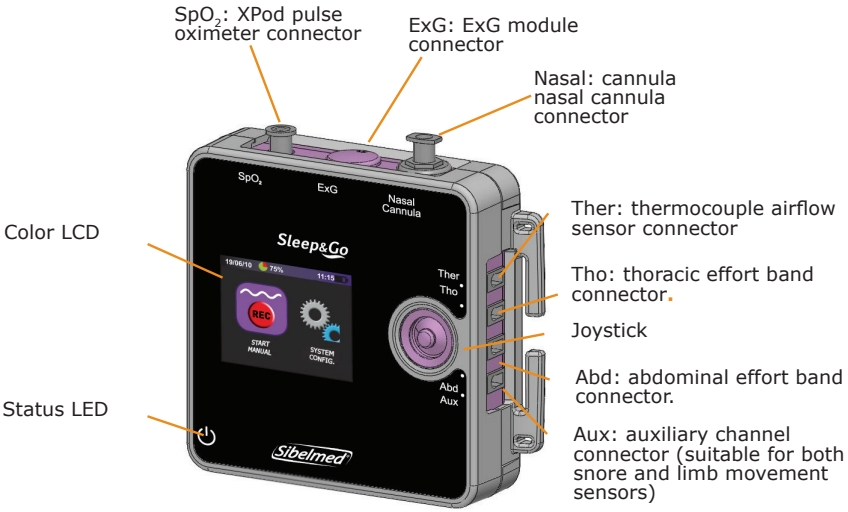
PREPARADO/*PREPARED BY:* ..... **FECHA/*DATE*:** .....

(*) Ver datos en etiqueta / *View data in the following label* :

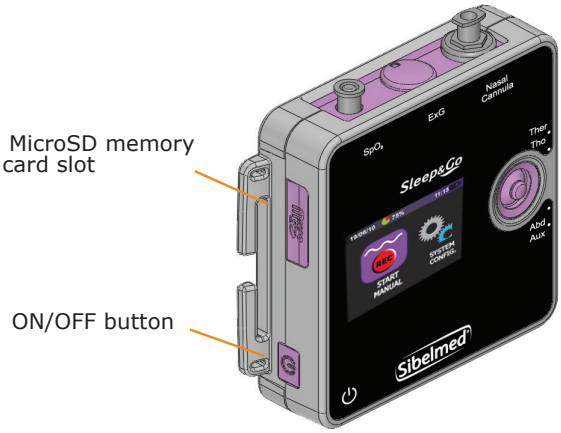
(Pegar etiqueta embalaje)

1.3 LAYOUT OF CONTROLS, INDICATORS AND CONNECTORS

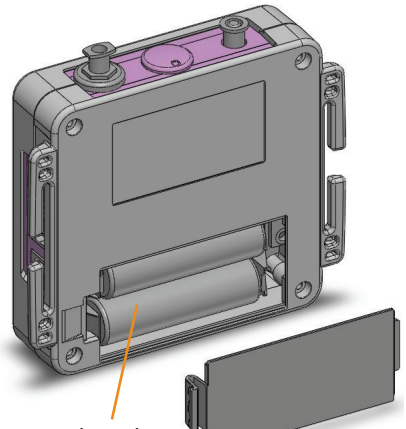
1.3.1 FRONT/TOP/RIGHT PANNEL



1.3.2 LEFT PANNEL



1.3.3 REAR PANNEL



Battery compartment
(2x AA alkaline or
rechargeable batteries).

1.4 INSTALLATION AND START-UP

This system is made of solid-state professional components manufactured under stringent quality controls. However, accidents may occur during the transportation or storage, being convenient an initial checking of the device and accessories prior to installation. If you detect a deterioration in the package, please contact the transport company and your supplier immediately, prior to installation. Do not dispose the packaging until completely verifying the proper functioning of the system.
Use only accessories described in this manual. The use of not recommended accessories could adversely affect both the patient safety and the equipment.

1.4.1 BATTERY PLACEMENT

The **Sleep&Go** system uses two 1.5V AA batteries. You can use alkaline or rechargeable batteries with, at least, 2450mA/h. Using smaller capacity batteries diminishes the autonomy. The autonomy in normal use is about 12 hours operating in online mode and 24 hours in holter mode.

The battery compartment is located on the rear panel, protected by a cap that needs to be removed to proceed to change the batteries



Before opening the battery compartment to replace the batteries please switch off the Sleep & Go.

1.4.2 POWER SAVING MODE

To save power, the device switches off the display after 50 seconds of inactivity (even if it is running a test) and the whole device after 5 minutes if the user does not start a test nor interacts with the joystick.

1.4.3 WIRELESS MODULE INSTALLATION

The PC must have enabled and available this type of communication in order to use the wireless link with the **Sleep&Go** (optional module). Install the driver and software for the PC wireless module, as detailed in the module user's manual. You must then search the **Sleep&Go** from the wireless software in Windows and pair the PC with the **Sleep&Go**. The pairing code corresponds to the last three digits of the **Sleep&Go** serial number. You will find the serial number on the label on the back of the **Sleep&Go** device.

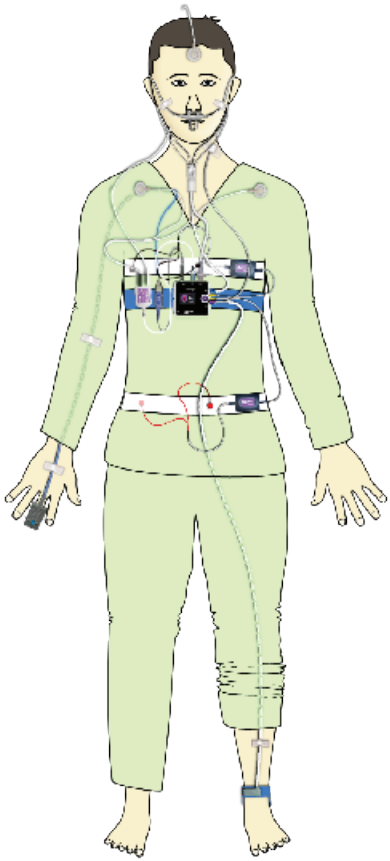
1.4.4 PLACEMENT OF SENSORS AND ELECTRODES

1.4.4.1 PLACEMENT OF THE SLEEP&GO POLYGRAPH

The small size and weight of the **Sleep&Go** system allows the patient to wear it comfortably fastened with a strap. Follow these steps to fasten the device to the patient:

- Insert the strap between the two guides in the rear side of the **Sleep&Go**.
- Place the device on the patient's chest, in a comfortable position midway between the thoracic effort band (which should be on top) and the abdominal effort band (which should be below).
- Secure the strap by means of the Velcro so that the device stands firm.

General placement schema



1.4.4.2 NASAL CANNULA

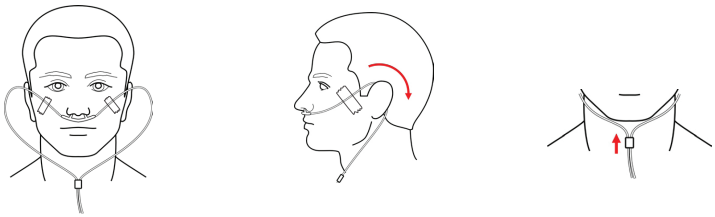
The nasal airflow cannula (refs. 07681, 08049) is used to acquire the airflow, snoring, and CPAP pressure level signals, by means of the device's internal pressure transducer.

The placement of the nasal cannula has a significant impact in obtaining high quality signals. Follow these steps to place it properly:

- Place the cannula over the upper lip. Bend the nasal probes softly until the tips are exposed to the maximum possible air flow. The tips should not get in contact with the skin or penetrate the nasal orifice.

- Wrap the tube around the ears and place it under the chin. Surgical tape can be used to fasten the tubes to the cheeks of the patient. If necessary, adjust the tubes under the chin.

- Insert the cannula connector in the Luer connector of the **Sleep&Go** (labeled as "Nassal cannula") and turn it until secured.



1.4.4.3 THERMOCOUPLE AIRFLOW SENSOR

In addition to the nasal cannula, the **Sleep&Go** may also use the thermocouple sensor (ref. 06309) in order to measure the respiratory airflow. The thermocouple sensor is to be connected to the connector labeled as "Ther".

The quality of the registered signal depends on variables such as the filters selected in the software, the sensor placement, the patient's respiration, room temperature and CPAP pressure. Filters can reduce the noise in the respiratory signal, but they can also add distortion to the signal if used in excess. Filters are applied in the **BitmedLab** software. Read that software's manual if you need to modify them.

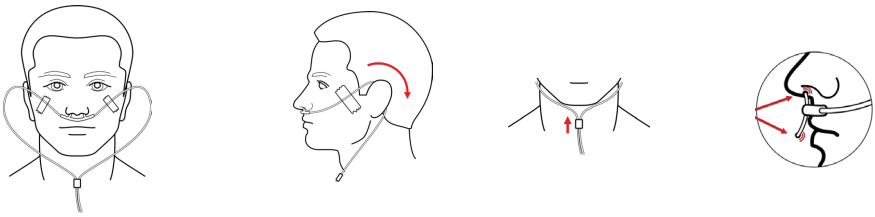
The placement of the thermocouple sensor has a significant impact in obtaining high quality signals. Follow these steps to place it

properly:

- Place the thermocouple on the upper lip. Bend the nasal tips softly until the ends of the sensor are exposed to the maximum possible air flow. The tips should not get in contact with the skin or penetrate the nasal orifice.

- Wrap the cable around the ears and place it under the chin. Surgical tape can be used to fasten the cables to the cheeks of the patient. If necessary, adjust the sensor cable on the chin.

- Bend the oral probe softly in its position in front of the mouth, so that the end of the sensor is exposed to the greatest oral flow possible, approximately 1 cm from the mouth. The probe should not touch the skin or the lips, nor penetrate the oral cavity.



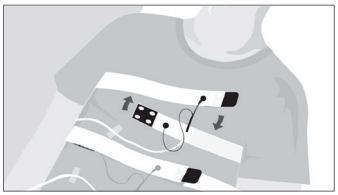
- Insert the sensor connector in the connector of the **Sleep&Go** labeled as "Ther".

The ambient temperature affects the magnitude of the signal. If the temperature is similar to the patient's temperature, the signal level may be very low. On the other side, if the ambient temperature is very different from the patient's temperature, the signal level will be higher.

The placement of a CPAP mask over the thermocouple sensor may affect the difference between the patient and the room temperature and may also affect the placement of the thermocouple sensor.

1.4.4.4 THORACIC AND ABDOMINAL EFFORT BANDS

The inductive plethysmography belts (refs. 01425, 01424, 01421, 01420, 01417) supplied with the **Sleep&Go** are based in the RIP technology (Respiratory Inductive Plethysmography).



- Strap the sensor bands around the patient's chest and abdomen, over any clothing.
- Attach the first wire to the snap that is on the same side of the band as the Velcro patch.
- While holding this end to the left of the patient's center line, wrap the band around the patient's chest or abdomen.
- Pull the other end over the first end and secure the band on the right side of the center line. The band should be snug but not too tight.
- Attach the second wire to the exposed snap.

Make the connection and disconnection of the clips of the bands with the interface box disconnected from the equipment.

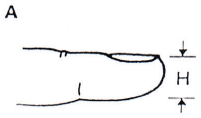
- Make sure the box in the cable that goes to the chest band is labeled as "Chest" (ref. 06314) and the one going to the abdominal band is labeled as "Abd." (ref. 06308).
- Insert the connector from each the respiratory effort belt in the corresponding input connector of the **Sleep&Go**, labeled as "Thor" for the thoracic belt and "Abd" to the abdominal belt.
- Fix each of the little boxes to the corresponding belt with the aid of the provided strips.

1.4.4.5 PULSE OXIMETER

The system is able to provide the pulse wave, as well as the measurement of the pulse rate and the functional oxygen saturation, based on the technology developed by Nonin Medical Inc. The pulse oximeter is calibrated to display functional oxygen saturation and does NOT require calibration. The external pulse-oximeter (named Xpod) (ref. 09898) is to be connected on the top side of the device. The SpO_2 sensor is to be connected on the free end. Pay special attention to the sensor being used. Please consult the manufacturer before using non-recommended sensors.

To place pulse oximeter sensor, follow these steps:

- Couple the Xpod to the clipping piece and attach it to the band, with the long cable of the sensor facing upwards.
- Connect the short cable from the Xpod to the "SpO_2" connector on the device, matching both red marks
- Insert a finger (preferably the index finger) in the sensor until the finger tip reaches the stop. It is not recommended to place this sensor in the thumb. Keep the fingernail of the patient pointing toward the top side of the sensor. Make sure that long fingernails do not interfere with the adequate positioning of the finger.
- To obtain the best results, fasten the cable to the finger, using surgical tape, preferably around the base of the finger. Make sure that the tape fastening the cable does not restrict blood circulation.

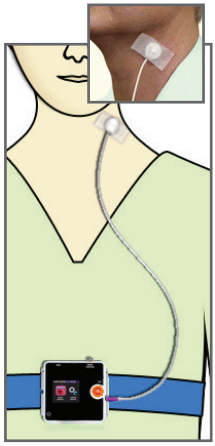


Furthermore, the following conditions of use should be observed:

- The oximeter must not be used by itself to reach important medical conclusions. Medical caution must always be taken and other means must be used, whenever possible, for confirmation.
- Incorrect use or inappropriate handling of the sensor can cause damage to the sensor or cable. This would lead to incorrect measurements and readings.
- Remove nail polish or artificial nails before applying the sensor, as they could cause incorrect readings.
- The sensors cannot be sterilized. Do not submerge the sensors in liquid. The sensors must be disconnected from the **Sleep&Go** prior to cleaning or disinfection.
- The operation of the oximeter sensor may be affected by the presence of strong room lighting. If necessary, the sensor area must be protected (e.g. with surgical tape).
- The oximeter may not be capable of detecting minimal values

of saturation with the same degree of accuracy and precision as the maximum values of saturation. It is also possible that it can not quantify the degree of existing hyperoxemia.

- Interferences such as movements, abnormal hemoglobins, intravascular contrasts, states of low perfusion and skin pigmentation may affect the operation of the pulse oximeter.
- It is unlikely that organisms are transmitted via pulse oximetry. However, we recommend washing the pulse oximetry sensor for each change of patient with soapy water or disinfectant solution as specified by the manufacturer.
- The pulse oximetry module and the pulse oximetry probe is CE marked. The temperature of the area of the probe in contact with the finger will not reach temperatures > 42 °.
- See the instructions for use before use. Strictly follow the manufacturer's safety instructions, as well as those specified in this manual.
- The maximum recommended time of application of an pulse oximeter in the same place is 24 hours. The point of placement must be checked frequently to determine the position, circulation and cutaneous sensitivity of the patient. Reaction to the sensors by the patients may be different depending on their state of health and skin condition. Adhesive material must not be used if the patient shows an allergic reaction to such material.
- For long-term measurements, it is recommended to use flexible or disposable sensors.
- The adult sensor is for people over 12 years of age (>40 kg). The pediatric sensor is for children aged between 5 and 12 years of age (15-40 kg).
- The system can measure the pulse rate and functional oxygen saturation. A functional meter can not be used to evaluate the accuracy of a pulse oximetry sensor or a pulse oximetry monitor.
- The pulse oximeter waveform is not normalized.



- Do not use blood flow restrictors because they can lead to loss of signal.
- If the power supply is interrupted for more than 30 s, insert the batteries and / or turn on the device again, and the device will be ready to work again in any mode.

1.4.4.6 BODY POSITION AND ACTIVITY

The **Sleep&Go** records information about the patient's body position and actigraphy. Both sensors are place inside the **Sleep&Go** device, so no external accessory is needed.

1.4.4.7 SNORING SENSOR

Apart from the snoring signal obtained from the nasal cannula you may also use a piezoelectric snoring sensor (ref. 06346) to detect the patient's tracheal sounds during sleep. The piezoelectric snoring sensor can be plugged into the connector labeled as "Aux", if you're not using the limb movement sensor. Also, you may connect the sensor in any of the channels provided by the ExG module (optional).

The snoring sensor is placed on the throat of the patient and it generates a signal in response to the vibration produced during snoring. The piezoelectric sensors are based on the movement produced by the vibrations and not on the sounds. Therefore they cancel artefacts related to external noise. The snoring signal is converted into analogical voltage which can be measured.

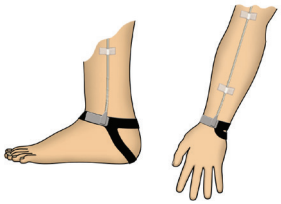
To place a piezoelectric snoring sensor, follow these steps:

- Tell the patient to imitate a snore while you place your fingers, slightly off-centre, upon the throat. Try to select a point where the greatest vibration related to the snoring sound is produced.
- Do not place the sensor directly over the larynx.
- Place the sensor with the flattest part in contact with the skin and secure it with surgical tape.
- Insert the snoring sensor connector into the corresponding input of the **Sleep&Go** ("Aux" connector or any connector in the ExG module).

1.4.4.8 LIMB MOVEMENT SENSOR

The limb movement sensor (ref. 06310) is used to detect the movements of the patient's limbs during sleep. The limb movement sensor is to be connected to the "Aux." connector. However, if you purchased the ExG module you may also connect the sensor to any of its channels.

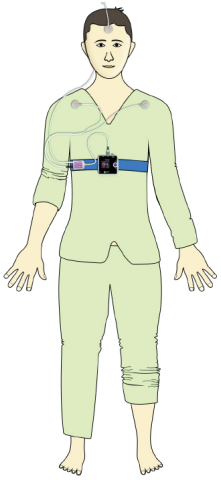
- To place a limb movement sensor, follow these steps: Place the sensor in the wrist (inner side of the wrist, over the tendons) or the patient's ankle (front side of the ankle), in an area that provides the maximum movement signal, as shown in the figure below. If you put the sensor in the ankle then fix it by using the provided strap.



- Secure the sensor cable to the patient's skin with hypoallergenic tape.

- Insert the movement sensor connector in the corresponding input of the **Sleep&Go** (connector labeled as "Aux" or any of the input channels available in the ExG module).

1.4.4.9 EKG ELECTRODES



We recommend using the electrodes (ref. 02646) provided by the manufacturer. If you are using other electrodes, carefully read the instructions before using them and make sure they are compatible with the **Sleep&Go** system.

The following steps should be taken to place these electrodes:

- Prepare the area where the electrodes are to be placed. The skin must be cleaned adequately using abrasive paste. This allows a good contact impedance (typically less than 10K).

- Attach the electrode to the patient's skin by removing the electrode film that protects the adhesive. Place one electrode on each collar bone.

- Connect the cables (ref. 08093) to the button stud connectors in the electrodes.

- Use a wire adaptor with 2 1.5mm TouchProof connectors to 1mm key connector (ref. 01644) for connecting the couple of electrodes to the appropriate channel. In order to acquire the EKG signal you must have the ExG module (optional, ref. 09899). Connect the adapter to any of the three ExG channels included in the module. Hold the ExG module to the thoracic effort band.

- Interferences may be reduced by tying together the electrode wires.

- Place a third electrode on the patient's forehead and connect it to the neutral input Ⓝ in the ExG module.

- The EKG signal should not be acquired if the device is used at patient's home.

1.4.4.10 EMG, EOG AND EEG ELECTRODES

We recommend using the cup electrodes (ref. 08701) provided by the manufacturer. If you are using other electrodes, please carefully read the instructions before using them and make sure they are compatible with the **Sleep&Go** system.

The following steps should be taken to place these cup electrodes:

- Prepare the area where the electrodes are to be placed. The skin must be cleaned adequately using abrasive paste. This allows a good contact impedance (typically less than 10K).

- Fix the electrode to the patient's skin by filling the cup with conductive paste and fixing it in place with colodion. A hair dryer can be used to speed up the drying process. When the test is over the electrodes are easyly removed with acetone.

- Use a wire adaptor with 2 1.5mm TouchProof connectors to 1mm key connector (ref. 01644) for connecting the couple of electrodes to the appropriate channel. In order to acquire the EMG, EOG or EEG signals you must have the ExG module (optional, ref. 09899). Connect the adapter to any of the three ExG channels included in the module. Hold the ExG module to the thoracic effort band.

- To use a common reference for several EEG channels, each electrode must be connected to one of the connectors of the wire adaptors (ref. 01644). Use one or more interconnection bridges (ref. 02741) to interconnect the remaining pole of all referenced channels, so that every channel uses the same reference.

- Interferences may be reduced by tying together the electrode wires.

- Place a third electrode on the patient's forehead and connect it to the neutral input (N) in the ExG module.

- The EEG, EOG and EMG signals should not be acquired if the device is used at patient's home.

In addition to the aforementioned explanations, the following precautions and considerations should be taken into account while using the electrodes:



The conductive part of the electrodes and connectors, must never touch other conductive parts, including the earth connection.

When several devices are connected to a patient, there is a risk of accumulating leakage currents, which can become dangerous for the patient. Reduce to the absolute minimum the number of devices connected to the patient.

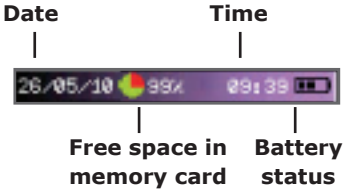
To protect the patient against the effects of electric shock, all electrodes must be removed from the patient before using a cardiac defibrillator.

1.4.4.11 EVENT MARKER

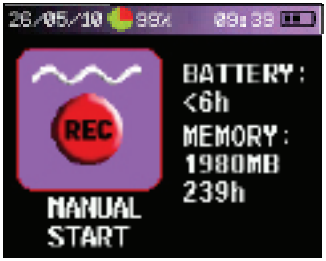
During the test (either online or in holter mode), the patient is allowed to make a mark by simply pressing the joystick for at least 3 seconds. After these 3 seconds the screen lights on and the mark is registered. These marks are used to indicate certain events, such as the patient getting up to the bathroom, taking medication and so on.

2. OPERATION

The Sleep & Go is fitted with a color screen and a joystick to interact with the options exposed by the device's software.
The top part of the screen displays an info bar with the device status at any time:



This is the screen displayed when the **Sleep&Go** is switched on:



This screen displays status information and enables starting a new test in holter mode. The icon "MANUAL START" is selected by default. The patient can not modify the device configuration.
Use the joystick to navigate through the different screens that will be introduced. The joystick supports four directions (↑, ↓, →, ←), while pressing it is used to click an option.

2.1 WORKING MODES

Two working modes are available, depending on the way tests are handled:

Holter mode: in this mode the **Sleep&Go** stores the tests in a memory card. Later, the tests are transferred to the computer for evaluation. It is designed for home use or at the hospital or clinic. There are two ways of starting a test in holter mode:

a. Manual start and stop: the patient starts and stops manually the recording of the test, through the color screen and joystick in the **Sleep&Go**.

b. Automatic start and stop: health personnel program the **Sleep&Go** to start and stop automatically the test at a certain date and time.

The device's batteries last up to 24 hours in holter mode with a single charge.

Online mode: in this mode the test data are sent in real time to the PC via wireless, the transfer from the memory card not being necessary after the test. This mode is intended for use in the clinic / hospital or the sleep lab.
The device's batteries last up to 12 hours in online mode with a single charge.

2.2 SYSTEM CONFIGURATION

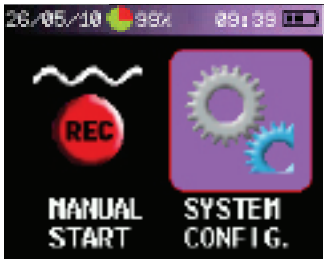
The setup mode in the **Sleep&Go** is designed to change the device configuration (date and time, language, type of batteries used) and schedule new tests. Only healthcare personnel should access the device settings. To enter to the setup menu of the **Sleep&Go** do the following:

- Switch on the **Sleep&Go** and make the following keystrokes on the joystick, one after another and leaving a short interval of time between each of them: ↓, ↓, ↑, ↑.

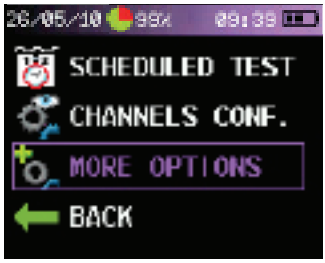
- The screen changes and a new icon is displayed: "SYSTEM CONFIG." (A). Select the "SYSTEM CONFIG." icon and press the joystick to move to the setup screen.

- Select "MORE OPTIONS" (B).
- Select "CUSTOMIZE" (C).

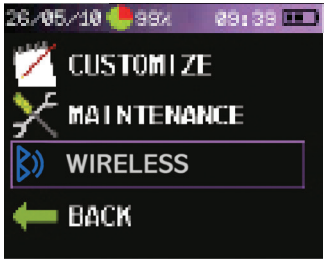
A



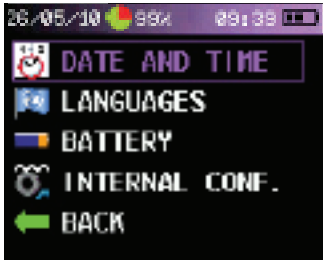
B



C



D



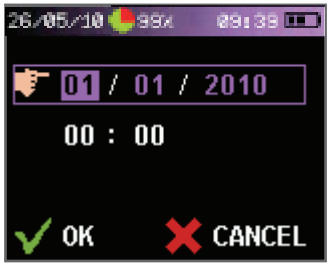
- If CPAP channel is activated, BATTERY menu changes to OTHER OPTIONS.

2.3 INITIAL DEVICE SETUP

2.3.1 SETTING THE DATE AND TIME

Once in the "CUSTOMIZE" screen, follow these steps in order to change the date and time in the **Sleep&Go**:

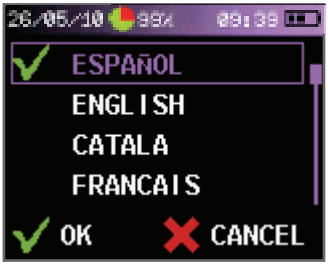
- Select "DATE AND TIME".
- Use ↑ and ↓ to access each of the options to set the date and time in the device. Use ↑ and ↓, to modify the values in each field.
- Once you have set the date and time select "OK. " To cancel setting the date and time select "CANCEL".



2.3.2 SETTING THE LANGUAGE

Once in the "CUSTOMIZE" screen follow these steps in order to change the language in the **Sleep&Go**:

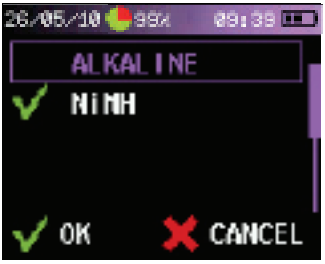
- Select "LANGUAGES".
- Use ↑ and ↓ move along the different available languages. The selected language is marked with the ✓ symbol.
- When you have set the desired language select "OK. " If you want to cancel the language settings then select "CANCEL".



2.3.3 SETTING THE TYPE OF BATTERIES

It is very important that the type of batteries is correctly configured for the remaining battery life information to be displayed properly. Alkaline or rechargeable Nickel-Metal Hydride (minimum 2450mAh) AA batteries should be used. In the "CUSTOMIZE" screen follow these steps:

- Select "BATTERY" or "MORE OPTIONS > BATTERY" in case the CPAP channel is available.
- Use ↑ and ↓ to select the type of batteries used in the device. The type of batteries is marked with the ✓ mark.
- When finished select "OK". If you want to cancel setting the type of batteries then select "CANCEL".



2.3.4 SETING THE UNITS OF THE CPAP CHANNEL

- Select "MORE OPTIONS".
- Select "BATTERY".
- Select "CPAP UNITS"
- Select cmH_2O or hPa and press OK. If you want to cancel the setting select CANCEL.

2.4 SWITCHING ON/OFF THE WIRELESS MODULE

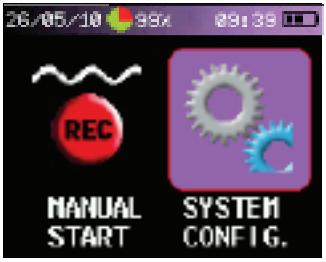
The wireless module can be turned on and off at any time, in order to reduce battery consumption and increase the battery life. You need to switch on the wireless module when making real-time tests (online mode). If you are making holter tests there is no need of keeping the module powered.

The wireless module is supplied by default in the **Sleep&Go** B Model and is optional in the A Model.

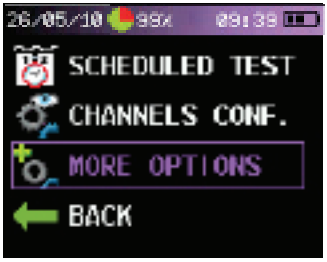
To switch on/off the wireless module follow these steps:

- With the **Sleep&Go** in the home screen make the following keystrokes with the joystick: ↓, ↓, ↑, ↑.
- The screen changes and displays a new icon: "SYSTEM CONFIG." (A). Select "SYSTEM CONFIG." and press the joystick to move to the setup screen.
- Select "MORE OPTIONS" (B).
- Select "WIRELESS" (C).
- If the wireless module is switched on you will be prompted to turn it off. If the module is switched off you will be prompted to turn it on (D). Select "OK" or "CANCEL ". When the wireless module is powered a wireless logo is displayed in the status bar. Otherwhise no icon is displayed. The blue wireless logo indicates that the module is on, while the green logo means that data is being transmitted to the PC.

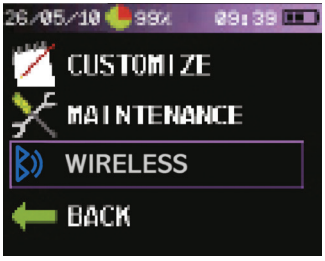
A



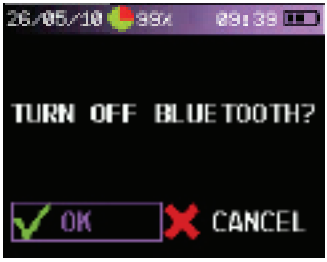
B



C



D



2.5 MAKING POLYGRAPHY TESTS IN ONLINE MODE

In this mode, the polygraph transmits the real-time data to the PC via wireless connection, displaying the signals on the computer screen. The wireless module in the **Sleep&Go** must be enabled (optional in the A model, supplied by default in the B model). Make sure the device is switched on and the wireless communication is enabled (see above).

All new online tests are to be started from the **BitmedLab** software. Please refer to the software's manual for information on how to make an online test.

2.6 MAKING POLYGRAPHY TESTS IN HOLTER MODE

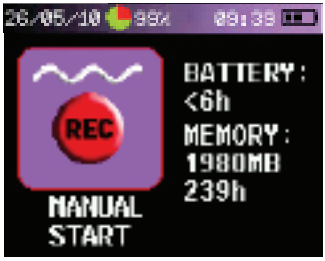
When the device operates in holter there are two different ways to start and stop the tests, either manually or automatically (scheduled).

2.6.1 STARTING AND ENDING A TEST MANUALLY

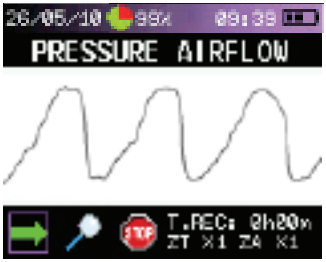
In this mode either the patient or the technician will start and end the test:

- Switch on the device by pressing for 3 seconds the ON/OFF button.
- Once in the main screen press the joystick (A) to select the "MANUAL START" icon.
- This starts the recording of the test. If all sensors are properly connected then the signals are displayed on the screen and the LED on the front panel starts flashing. If any of the sensors to be acquired is not properly connected the message "CHECK SENSOR" is displayed, giving the opportunity to test the connection. After a few seconds the screen switches off automatically.
- In the case of the SpO_2 and BPM channels, if there is an error, there is no finger on the sensor or if it is disconnected, the SpO_2 and BPM values are set to zero and, in addition, the following messages will appear in red: ERROR OF DATA, SENSOR DISCONNECTED or WITHOUT FINGER. If the pulse oximeter works correctly, the message AVERAGE QUALITY (in yellow) or GOOD QUALITY (in green) will appear.
- To stop the test just select the "STOP"  option or hold down the ON/OFF button for 3 seconds (B).

A



B



2.6.2 SCHEDULED TESTS

The **Sleep&Go** is built with an internal clock suitable for scheduling new tests in holter mode at certain dates and times, which also end at the right time as programmed by medical personnel. In this way the patient does not have to interact at all with the **Sleep&Go** for starting or ending the test.

You can schedule up to 5 consecutive tests. These tests may be scheduled right from the **Sleep&Go** device or by using the **BitmedLab** software in the PC. This manual describes the programming procedure in the **Sleep&Go**. Refer to the software manual for information on the programming process in **BitmedLab**.

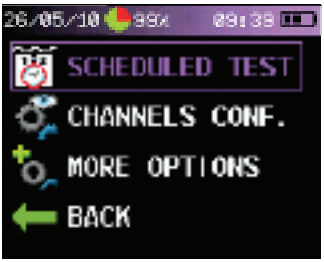
2.6.2.1 SCHEDULING A TEST IN THE SLEEP&GO

- Switch on the **Sleep&Go** and gain access to the setup mode by making the following keystrokes on the joystick, one after another and leaving a short interval of time between each of them: ↓, ↓, ↑, ↑.
- Select the "SYSTEM CONFIG." icon and press the joystick to move to the setup screen.
- Select "SCHEDULED TESTS" (A).
- Select "NEW TEST" (B).
- Select the "DATE" field and set the starting date for the test. Select "OK" when finished (C, D).
- Select the "TIME" field and set the starting time for the test.

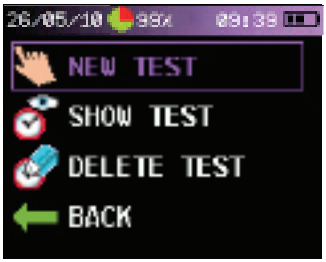
Select "OK" when finished (E).

- Move to the "DURATION" field and enter the number of hours and minutes for the test (F).
- Select the option "CHANNELS CONF.". The device displays all channel configurations stored on the memory card. A channel configuration establishes which channels are recorded during the test, as well as their sampling rates. There may be up to 10 different channel configurations. A detailed explanation on how to change these configurations is given below. Select which configuration is more suitable for the type of test you want to do (G).
- Select "SAVE" once all parameters are configured. You may switch off now the **Sleep&Go**.
- The device will start automatically the test at the designated date and time. The screen will light for 50 seconds, displaying the signals acquired by the sensors. The front panel LED will blink during the whole test.

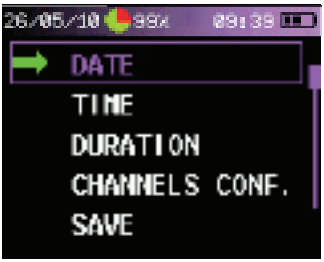
A



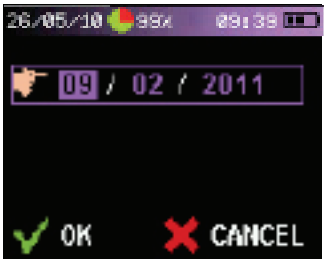
B



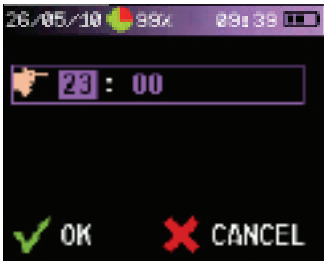
C



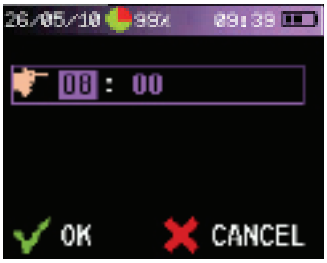
D



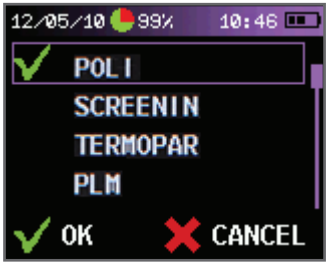
E



F



G

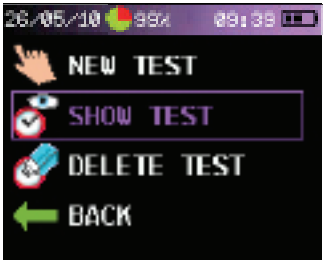


2.6.2.2 DISPLAYING THE SCHEDULED TESTS

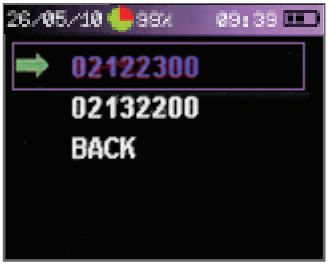
You can see the scheduled tests in the **Sleep&Go** (up to a maximum of 5 tests):

- Switch on the **Sleep&Go** and enter the setup mode by making the following keystrokes with the joystick: ↓, ↓, ↑, ↑.
- Select the "SYSTEM CONFIG." icon and press the joystick to move to the setup screen.
- Select "SCHEDULED TEST".
- Select "SHOW TEST" (A).
- All scheduled tests are displayed. For more info on any scheduled test select it (B).
- The screen shows the programming data of the test (onset date and time, duration, channel configuration) (C).
- To view the channel configuration (enabled channels and sampling frequencies) select "CHANNELS CONF." (D).

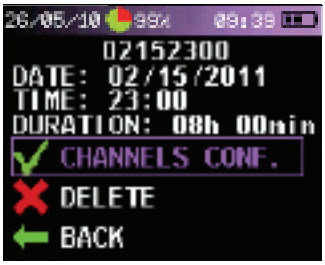
A



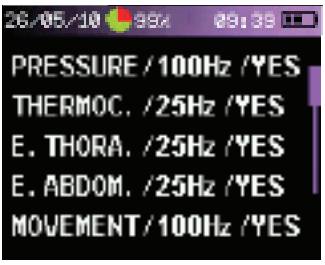
B



C



D



2.6.2.3 CHANNEL CONFIGURATIONS

he Sleep & Go may hold up to 10 channel configurations. Each configuration stores which of the available device's channels will be acquired, as well as the sampling rates for each of them. The available sample rates depend on each type of channel. Some channels, such as pulse oximetry or body position, have a fixed sampling frequency, while in others, such as the respiratory effort bands or the ExG channels, the sampling rate can be chosen among several values.

The creation and modification of channel configurations is made in the **BitmedLab** software, then they are transferred to the MicroSD memory card. See the software's manual for more information on this point.

2.7 TRANSFER AND REVIEW OF THE TESTS

Tests must be transferred to the PC prior to review. Several tests may be stored in the memory of the **Sleep&Go** before transferring

them to the PC. Transferring the test immediately after it is finished is not necessary.

In order to transfer the tests to the PC extract the MicroSD memory card from Sleep & Go and insert it into your PC's card reader. Most computers are supplied by default with a memory card reader. If your computer does not have one you can use an USB card reader. After inserting the memory card in your PC run the **BitmedLab** software and download the tests as explained in the software's manual.

The tests are automatically deleted from the memory card when they are transferred to the PC. Do not delete the files in the memory card before downloading the tests to the PC.

2.8 FIRMWARE UPDATE

Over time, new versions of the program managing the **Sleep&Go** (firmware) might be released, either to improve the operation of the equipment or to add new features.

- The Technical Service will provide one or several files to be copied to the MicroSD memory card of the **Sleep&Go**.
- Insert the memory card in the **Sleep&Go** and switch it on.
- The firmware update starts automatically. When prompted, confirm that you want to update the firmware.
- When the update is complete the **Sleep&Go** switches off automatically. Your device is already updated.
- In case you are provided with several files the process will be repeated as many times as needed.

2.9 DEVICE OPTIONS UPDATE

As mentioned in paragraphs 1.2 and 1.3, the **Sleep&Go** is available in two different models with increasing features. The available channels may be expanded, though. In case new features

are purchased please follow these steps in order to update your device:

- The Technical Service will provide one file to be copied to the MicroSD memory card of the **Sleep&Go**.
- Insert the memory card in the **Sleep&Go** and switch it on.
- The update starts automatically. When prompted, confirm that you want to update the device's features.
- When the update is complete the **Sleep&Go** switches off automatically. Your device is already updated and the new channels are available from now on.

3. TECHNICAL SPECIFICATIONS

3.1 GENERAL DATA

Useful life for **Sleep&Go** and ExG module:	7 years
Useful life for Xpod pulseoximeter module:	5 years
Battery type / battery life:	2x AA alkaline batteries or AA NiMh rechargeable batteries (2450mAh minimum) / 12h in online mode, >24h in holter mode.
Enclosure protection degree:	IP22
Memory type:	Type Micro SD, 2Gb maximum capacity Micro SD- HC type , maximum 16Gb capacity
Device classification (EN60601-1):	Class: internally powered Type BF applied parts, not protected against defibrillator
Input impedance:	>10 MΩ
CMRR (common mode rejection ratio):	>80dB

Signal input connectors:	
Pressure transducer (airflow, snoring, CPAP pressure)	LUER connector
Thermocouple, thoracic effort, abdominal effort, polygraphic auxiliary, ExG channels (x3)	1 mm key connector
Pulse oxymeter	Specific 3-pin connector
Actimetry	Internal
Body position	Internal
Event marker	Joystick

Storage sampling rate (software selectable):	
Airflow (pressure transducer)	Selectable: 25, 50, 100 samples/s
Snoring (pressure transducer)	Selectable: 50, 100, 250 samples/s
CPAP pressure	1 sample/s
Thermocouple	Selectable: 10, 25 samples/s
Thoracic effort	Selectable: 10, 25 samples/s
Abdominal effort	Selectable: 10, 25 samples/s
Polygraphic aux.	Selectable: 25, 50, 100 samples/s
ExG channels (x3)	Selectable: 100, 250 samples/s
Pulse rate	1 sample/s
Oxygen saturation	1 sample/s
Plethysmographic wave	75 samples/s
Actimetry	Selectable: 10, 25, 50 samples/s
Body position	1 sample/s
Event marker	1 sample/s
Resolution:	
Airflow. (pressure transducer), snore (pressure transducer), thermocouple, thoracic effort, abdominal effort, polygraphic aux., ExG channels (x3), actimetry	12 bits
Pulse rate, oxyen saturation, plethysmographic wave	8 bits
Body position	8 bits
Event marker	8 bits
CPAP pressure	1cm$H_2$0 or 1hPa

Sample storage size:	16 bits per sample
Input range: Thermocouple Thoracic effort, abdominal effort, polygraphic aux, ExG channels (x3) Airflow (pressure transducer) CPAP pressure Snoring (pressure transducer) Pulse rate Oxygen saturation Plethysmographic wave Actimetry Body position	 +/- 0,5 mVpp +/- 5 mVpp +/- 4 cmH_2O (3.9 hPa) over the cannula aprox. 0 - 20 cmH_2O (19,6 hPa) +/- 0.5 cmH_2O (0.49 hPa) over the cannula aprox. 18 – 300 BPM (1/min) 0 – 100 % 0 – 255 aprox. +/- 30 mg (300 m/s^2) Supine, prone, left, right, seated
Linearity: Resp. airflow (pressure transducer), snore (pressure transducer) Thermocouple, thoracic effort, abdominal effort, polygraphic aux., ExG channels (x3), actimetry	 +/- 3% +/- 3%
Precision: CPAP pressure Pulseoximeter	 +/- 2cmH_2O (1,96 hPa) (See pulseoximeter table)

Fixed hardware filters: Thermocouple, thoracic effort, abdominal effort Polygraphic aux. ExG channels (x3) Airflow (pressure transducer) CPAP pressure Snoring (pressure transducer) Pulse rate Oxygen saturation Plethysmographic wave Actimetry Body position	 0.05 – 10 Hz 0.05 – 50 Hz 0.05 – 250 Hz 0.05 – 50 Hz 0.02 Hz 30 – 250 Hz - - - 0.5 – 25 Hz -	
PC communication interface:	Wireless 2.1 (option)	
Environmental conditions:	In operation (*)	Transportation and storage (*)(*2)
	Temperature: 5ºC to 40ºC Relative humidity: 15-90% (without condensation) Barometric pressure: 700hPa to 1060hPa (approx. 3000 to -380m)	Temperature: -20ºC to +60ºC Relative humidity: <90% (without condensation)
Dimensions:	90 x 90 x 25 mm	
Weight:	< 200 g	

(*) The conditions may vary in some of the accessories (like AgCl electrodes Ref. 02646, EXG silver cup electrodes Ref. 08701 or Cable for button stud type electrodes Ref. 08093).
(* 2) The device should be left at least 30 minutes at room temperature (20ºC) before being used when it comes from the store at maximum or minimum temperatures.

3.2 PULSE OXIMETER TECHNICAL SPECIFICATIONS

The pulse oximeter of the unit is based on the technology of NONIN MEDICAL, INC.

Range of values / resolution: Oxygen saturation Pulse rate	 0-100% / 1% 18-321 BPM/ 1 pulse, 0 = erroneous value
Precision [1] SpO_2 (70-100%) (±1DS) [2] Pulse rate	No movement: Finger clip sensor: adults, paediatric: ±2 digits: ±3 digits Flexible sensor: adults, paediatric: ±3 digits Movement[3]: Finger clip sensor: adults, paediatric: ±2 digits: ±3 digits Flexible sensor: adults, paediatric: ±3 digits: ±4 digits Low perfusion[4]: All sensors: adults, paediatric: ±2dígitos: ±3 digits No movement (18-300 BPM): Finger clip sensor/flexible sensor: adults, paediatric: ±3 digits Movement (40-240 BPM)[3]: Finger clip sensor/flexible sensor: adults, paediatric: ±5 digits Low perfusion (40-240 BPM)[4]: Finger clip sensor/flexible sensor: adults, paediatric: ±3 digits
Measuring wavelength / power	Red: 660nm. / 0.8W Infrared: 910nm. / 1.2mW
Maximum application time	Consult the operating instructions of the pulsioximetric sensor
Biocompatibility and toxicity	Consult the operating instructions of the pulsioximetric sensor

1. All precision specifications were determined from studies of hypoxia induced in healthy adult volunteers, of both sexes, from Caucasian, Indian

and African ethnic group.

2. Standard Deviation. Due to the statistic distribution of the pulse oximeter measurements , only about two-thirds of the pulse oximeter measurements can be expected to be found within ±Arms of the value measured by a CO-oximeter.
3. For the determination of the precision in the conditions of movement:
   SpO2: the sensor is rotated through the index, middle, ring and little finger and simulates rubbing and tapping at a frequency of 1 Hz.
   Pulse frequency: a pulse oximetry tester (Oxitest Plus 7) is used to introduce simulated motion artifacts (movement movement, tremor movement and peak movement).
4. For the determination of accuracy in low perfusion conditions:
   SpO2: a pulse oximetry analyzer (Oxitest Plus 7) is used to introduce low simulated perfusion.
   Pulse frequency: a pulse oximetry analyzer (Oxitest Plus 7) is used to introduce low simulated perfusion. The accuracy is verified from 18 to 300 BPM in different levels of SpO2 values (70%, 80%, 90% and 97%).

3.3 CONDITIONS OF OPERATION AND STORAGE OF ACCESSORIES

Although the device and the EXG module stands temperatures between -25 and 70 ° C, the specified temperature range is lower (-20 ° C and 60 ° C) in order to ensure the proper storage of most accessories.

Exceptionally, ECG electrodes (Ref. 02646), silver cup EXG electrodes (Ref.08701) and the cable for button-stud type electrodes (Ref 08093) support lower storage temperatures. The following table shows the conditions for these accessories:

	Temperature transportation/ storage	Humidity transportation/ storage
ECG electrodes (Ref. 02646)	10 to 40ºC	< 93% (without condensation)
EXG silver cup electrodes (Ref.08701)	10 to 50 ºC	20 - 80% (without condensation)
Cable for button stud type electrodes (Ref 08093)	10 to 50ºC	20 - 80% (without condensation)

3.4 APPLICABLE STANDARDS

The **Sleep&Go** is manufactured by SIBEL and the system (including the software) meets the following standards and regulations:

Recommendations:

- National consensus document on the apnea-hypopnea syndrome (SAHS). Spanish Sleep Group (GES), September 2005.
- The AASM Manual for the Scoring of Sleep and Associated Events: Rules, Terminology and Technical Specifications, Version 2.6.

European Regulation of Medical Devices (EU) 2017/745:

- EC marking Class II a

Safety:

- EN 60601-1:2006+AC:2010+A11:2011+A1:2013+A12:2014+A2:2021+A13:2024: Electrical safety.
- EN IEC 80601-2-26:2020 + A1:2024 Electromedical Devices. Part 2: Special Safety Requirements for Electroencephalographs.
- EN IEC 60601-2-40:2025 Safety requirements for Electromyographs.
- EN 60601-1-11:2015 + A1:2021 General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

EMC:

- EN 60601-1-2:2015 + A1:2021 EMC in medical devices. Healthcare and homecare (Without EXG module)

See **Annex 1. Electromagnetic compatibility**

Software:

- EN 62304:2006+AC:2008+A1:2015 Medical device software - Software life-cycle processes

Usability:

- EN 60601-1-6:2010 + A1:2015 + A2:2021 Medical Electrical Equipment – Part 1-6 General requirements for basic safety and essential performance - Collateral standard: Usability
- EN 62366-1:2015 + A1:2020 Medical Devices – Application of usability engineering to medical devices

Pulse oximetry:
- EN ISO 80601-2-61:2019 Special requirements for basic safety and essential operation characteristics of pulse oximeters for medical use

Biocompatibility:
- EN ISO 10993-1:2020 Biological evaluation of medical devices

Vibration:
- Levels according to EN 60601-1-11:2015 + A1:2021 (covers EN ISO 80601-2-61).

Environmental conditions:
- Levels and tests according to EN 60601-1-11:2015 + A1:2021

Symbology:
- EN ISO 15223-1:2021 + A1:2025 Symbols to be used with medical device labels, labelling andi nformation to be suplplied.

Packaging and labelling
- Packaging and packaging waste Regulation (EU) 2025/40
- Regulation (EC) 1272/2008 on classification, labelling and packaging of substances and mixtures (REACH).

Information supplied by the manufacturer:
- EN ISO 20417:2021 Information supplied by the manufacturer of medical devices

Electrical and electronic waste:
- Directive 2012/19/EU on Waste Electrical and Electronic Equipment (WEEE).

Hazardous substances:
- Directive 2011/65/EU on restrictions on the use of certain hazardous substances in electrical and electronic equipment (RoHS).

System quality:
- Manufactured according to the SIBEL S.A.U. Quality Manual, which is compliant with EN ISO 13485:2016+A11:2021 and EN ISO 9001:2015

Risk Management:
- EN ISO 14971:2019 + A11:2021

Radio equipment and communication terminals (for Sleep&Go B):

- EN 300328 v2.1.1:2016

The user should follow:

- Data protection: Regulation (EU) 2016/679.

In addition, although outside the scope and intended use of the device, some security aspects from the following standards have been applied:

- EN IEC 80601-2-49:2019 + A1:2024 (partial application) Medical electrical equipment: Particular requirements for the basic safety and essential operation of multifunction patient monitoring equipment.

4. SYMBOLOGY
4.1 SYMBOLOGY OF THE SLEEP&GO

	SERIAL NUMBER
	MANUFACTURER (manufacture date, name and address of the manufacturer)
	BATCH NUMBER
	REFERENCE
	CONSULT INSTRUCTIONS FOR USE
	ATTENTION ADDITIONAL WARNINGS IN THE ACCOMPANYING DOCUMENTATION
	ATTENTION, RISK IDENTIFIED
	START UP (STANDBY)
	BF APPLIED PARTS
	NO SpO_2 ALARMS
	IP22 (see section WARNINGS AND PRECAUTIONS)
	DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC ACORDING TO THE WEEE DIRECTIVE
	NEUTRAL CONNECTOR
	BATTERIES
	MEDICAL DEVICE
	FOLLOW THE INSTRUCTIONS FOR USE

4.2 SYMBOLOGY OF THE ACCESORIES AND PACKAGING



CE MARKING



DO NOT REUSE



BATCH NUMBER



REFERENCE



LATEX FREE



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



AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY



DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC ACORDING TO THE WEEE DIRECTIVE



TEMPERATURE LIMITATION



SERIAL NUMBER



MANUFACTURING DATE



LATEX FREE



DO NOT STERILIZE



U.S. FEDERAL REGULATION RESTRICTS THIS DEVICE TO SALE BY ORDER OF PHYSICIAN. MAY ALSO BE APPLICABLE IN OTHER COUNTRIES



HUMIDITY LIMITATION



USE BY



STACKING LIMITATION



THIS WAY UP



FRAGILE



KEEP AWAY FROM WATER



PREASURE LIMITATION

4.3 VALIDATED ACCESSORIES

The **Sleep&Go** device is used in combination with other medical accessories manufactured by SIBEL S.A.U. or by other manufactures. We only recommend the use of these accessories for proper operation of the equipment (see section 1.2 PACKING LIST).
The sensors used by other manufacturers are:

Accessory	Manufacturer	SIBEL reference	Manufacturer reference
THERMOCOUPLE SENSOR	S.L.P. INC.	06309	1401S-BI
SOFT PULSE OXIMETRY SpO_2 ADULT SENSOR	UNIMED MEDICAL SUPPLIES INC.	08955	U404NS-08
SOFT PULSE OXIMETRY SpO_2 PAEDIATRIC SENSOR	UNIMED MEDICAL SUPPLIES INC.	08956	U104NS-08
DISPOSABLE SLEEPSENSE ORO-NASAL CANNULA (PACKAGE 5PC)	S.L.P. INC.	07681	14802-2-FT
DISPOSABLE SLEEPSENSE NASAL CANNULAR	S.L.P. INC.	08049	15805-2-FT
THORAX EFFORT INDUCTIVE BAND AMPLIFICATION INTERFACE	S.L.P. INC.	06314	9102S-BI
ABDOMINAL EFFORT INDUCTIVE BAND AMPLIFICATION INTERFACE	S.L.P. INC.	06308	9101S-BI
FASTENING BELT SMALL SIZE (S)	S.L.P. INC.	06311	1348B
FASTENING BELT LARGE SIZE (L)	S.L.P. INC.	06312	1341
FASTENING BELT EXTRA LARGE SIZE (XL)	S.L.P. INC.	06313	1340
ELASTIC INDUCTIVE BAND SMALL SIZE (S)	S.L.P. INC.	01425	9002-L40
ELASTIC INDUCTIVE BAND MEDIUM SIZE (M)	S.L.P. INC.	01424	9002-L60
ELASTIC INDUCTIVE BAND LARGE SIZE (L)	S.L.P. INC.	01421	9002-L90
ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)	S.L.P. INC.	01420	9002-L120
ELASTIC INDUCTIVE BAND XTRA XTRA LARGE SIZE (XXL)	S.L.P. INC.	01417	9002-L150
LIMB MOVEMENT SENSOR KIT	S.L.P. INC.	06310	1770S-KIT-BI
PIEZOELECTRIC SNORE SENSOR	S.L.P. INC.	06346	1250S-BI

Accessory	Manufacturer	SIBEL reference	Manufacturer reference
EXG GOLD CUP ELECTRODE (PACKAGE 10PC)	GRASS TECHNOLOGIES	08701	F-E5GH-30
CABLE ADAPTER 1MM TO 1.5MM	PLASTICS ONE, INC.	01644	249497X04010XXX
INTERCONNECTION BRIDGE	PLASTICS ONE, INC.	02741	455455X01010XXX
CABLE FOR BUTTON STUD TYPE ELECTRODES (PACKAGE 10PC)	SPES MEDICA S.R.L.	08093	S2231050261
ECG ELECTRODE (PACKAGE 50PC)	TELIC	01027	LF-50

5. CLEANING AND MAINTENANCE

The **Sleep&Go** polygraph requires, like any electronic equipment, a maintenance in order to:

- Ensure the safety of the patient, the operator and its environment.
- Ensure the reliability and accuracy of the functions for which the **Sleep&Go** was developed.

5.1 CLEANING

To clean the unit and its accessories, excluding the sensors and electrodes, use a damp cloth and mild (hand) soap. To disinfect the device you can use alcohol 96º or 0.1% sodium hypochlorite solution (equivalent to a 1:50 dilution of bleach in water if the bleach concentration is 5%). Then, wipe dry any remaining moisture. Do not use other chemical products or detergents for domestic use. Please read carefully the SAFETY section.

Properly dispose the disposable sensors and single-use electrodes immediately after use. Nasal cannulas are single use and must be replaced with each patient.

For the cleaning and disinfection of reusable sensors and electrodes, please refer to the information provided by its manufacturer.



The device can not be sterilized. For the cleaning and disinfection of sensors and electrodes, please refer to the information provided by its manufacturer.

All sensors should be cleaned properly after each use and before use in a new patient.

5.2 PREVENTIVE MAINTENANCE

Preventive maintenance consists of all actions needed to keep the equipment in good working order.

5.2.1 ACTIONS TO BE TAKEN BY THE USER

Check periodically that all cables, external accessories and other items are in perfect condition, not broken and with no external damage. Pay special attention to the cables and connectors.

It is also advisable from time to time to start a test and check that the connected sensors respond correctly.

If you detect any problems that you can not solve, please get in contact with the customer service of SIBEL S.A.U. or your distributor for servicing and repair.

You can also check the "Known abnormalities report" (534-701-MU2) available to the user from SIBEL S.A.U.

5.2.2 ACTIONS TO BE TAKEN BY QUALIFIED PERSONNEL

The Medical Device Regulation (EU) 2017/745 recommends the regular servicing and / or calibration to ensure the reliability of the medical devices and the safety of patients, users and the environment. The general technical verification of safety systems, settings and features being part of the device, must be made according to the Procedure of Verification and Adjustment for the **Sleep&Go**, of SIBEL S.A.U.

These operations must be carried out by service personnel from the manufacturer or distributor. The latter, must be in possession of a written authorization from SIBEL S.A.U., at least during the warranty period, in order to perform such maintenance.

The manufacturer is not responsible for malfunction or damage to the equipment resulting from poor maintenance done by personnel not certified in writing or belonging to SIBEL S.A.U.

Accessories and spare parts should always be original and requested to the manufacturer or authorized dealer to ensure the proper functioning of the polygraph.

Periodic functional and metrological verification is necessary to ensure the operation of equipment over the life of the product. The manufacturer recommends annual inspections by an authorized service center, and in any case not exceeding two years, according to the verification and adjustment procedures specified by the manufacturer and applied during the manufacture of the equipment.

5.3 CORRECTIVE MAINTENANCE

Corrective maintenance is the process of leaving the device in good conditions of use when it stops working due to malfunction or misuse.

If you detect a fault in the equipment that prevents normal operation, please contact the SIBEL S.A.U. Customer Service Centre, specifying the type of problem suffered.

SIBEL, S.A.U. **Customer Service**
Tel. +34 93 433 54 50
sat@sibelmed.com

ANNEX 1. ELECTROMAGNETIC COMPATIBILITY

Guidance and manufacturer's declaration – electromagnetic emissions		
SLEEP&GO 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)	Grupo 1 Clase B	
RF (Conducted) emissions CISPR 11 (EN 55011)	Not applicable	**SLEEP&GO** works with batteries.
Harmonic emissions EN-IEC 61000-3-2	Not applicable	**SLEEP&GO** works with batteries.
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-3	Not applicable	**SLEEP&GO** works with batteries.

Guidance and manufacturer's declaration – electromagnetic emissions			
SLEEP&GO is intended for use in the electromagnetic environment specified below. The costumer or the user of **SLEEP&GO** should assure that it is used in such an environment. Tests EN-IEC 61000-4-4 y -4-5 are applicable to AC/DC power inputs, and input/output signal. Test EN-IEC 61000-4-6 additionally applies to patient connections. Test EN-IEC 61000-4-11 only applies to AC power inputs.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – Guidance**
Electrical fast transient/burst EN-IEC 61000-4-4	±2 kV for power supply lines and earth ±1 kV for input/output lines Frecuency 100 kHz	Not applicable Not applicable	**SLEEP&GO** works with batteries. The input/output line cables are shorter than 3 meters long.
Surge EN-IEC 61000-4-5	±0.5, ±1 kV differential mode (Line to line). ±0.5, ±1, ±2 kV common mode (Line to ground).	Not applicable Not applicable	**SLEEP&GO** works with batteries.
Conducted RF EN-IEC 61000-4-6	3 Vrms de 150KHz a 80 MHz 6 Vrms in ISM bands 80% AM a 1kHz	3 Vrms 6 Vrms	
Voltage dips, short interruptions and voltage variations on power supply input lines EN-IEC 61000-4-11	0% Ut ; 0.5 cycles: 0º, 45º, 90º, 135º, 180º, 225º, 270º y 315º. 0% Ut; 1 cycle 70% Ut; 25/30 cycles: 0º 0% Ut ; 250/300 cycles (5 segundos)	Not applicable	**SLEEP&GO** works with batteries.
NOTE Ut is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration – electromagnetic immunity			
SLEEP&GO is intended for use in the electromagnetic environment specified below. The costumer or the user of **SLEEP&GO** should assure that it is used in such an environment. Below mentioned tests are applicable to enclosure. Additionally, test EN-IEC 61000-4-2 is applicable to input/output signal and patient connections.			
Immunity test	**EN-IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) EN-IEC 61000-4-2	±8 kV contact ±2, ±4, ±8, ±15 kV, air	±8 kV contact ±2, ±4, ±8, ±15 kV, air	
Radiated RF EN-IEC 61000-4-3	3 V/m (With EXG) 10 V/m (Without EXG) 80 MHz to 2.7 GHz 80% AM at 1kHz	3 V/m (With EXG) 10 V/m (Without EXG)	
Proximity fields from RF communications EN-IEC 61000-4-3	(View following table).		Portable and mobile RF communications equipment should be used no closer than 30cm to any part of **SLEEP&GO** including cables. The distance is calculated according to: $d = \left[\frac{6}{E}\right]\sqrt{P}$ where P is the output power rating of the transmitter in watts (W), d is the recommended separation in meters (m) and E is the immunity level in V/m.
Power frequency (50 / 60 Hz) magnetic field EN-IEC 61000-4-8	30 A/m	30 A/m	Only applicable to devices sensitive to magnetic fields.

Proximity fields EN-IEC 61000-4-3					
Frecuency (MHz)	Band (MHz)	Modulation	Power (W)	Distance (m)	E (V/m)
385	380-390	Pulso 18Hz	1.8	0.3	27
450	430-470	FM D:+/-5kHz 1kHz sinus	2	0.3	28
710 745 780	704-787	Pulso 217Hz	0.2	0.3	9
810 870 930	800-960	Pulso 18Hz	2	0.3	28
1720 1845 1970	1700-1990	Pulso 217Hz	2	0.3	28
2450	2400-2570	Pulso 217Hz	2	0.3	28
5240 5500 5785	5100-5800	Pulso 217Hz	0.2	0.3	9

ANNEX 2. TROUBLESHOOTING GUIDE

The Sleep&Go does not start

- Make sure the batteries are placed according to the polarity in the battery compartment.
- Be sure to use AA alkaline or NiMH rechargeable batteries of at least 2450mAh.
- Make sure you press the power button for at least 3 seconds.

The PC can not communicate with the device

- Make sure you have purchased the wireless option in your **Sleep&Go**.
- Make sure the **Sleep&Go** is switched on and the LED on the front panel is lighting.
- Verify that the wireless option is activated in the **Sleep&Go**.
- Verify that the wireless module in the PC is enabled and working properly.

In a new test the message "CHECK SENSOR" is displayed on screen

- Check that the erroneous sensor is correctly connected.

The signals of the electrodes look noisy or distorted

- In the case of the electrodes, make sure that the skin-electrode impedance is good. Check the PLACEMENT OF SENSORS AND ELECTRODES section, with suggestions on the placement of the electrodes.
- Check the connection of the ground electrode. This electrode plays an important role in signal quality.
- Twist the wires of the different electrodes to reduce the environmental noise.
- In the **BitmedLab** software, check that the filters currently selected are appropriate for the type of signal being acquired.

Pulse oximetry signals are null

- Make sure the pulse oximeter sensor is correctly connected to the patient, as indicated the PLACEMENT OF SENSORS AND ELECTRODES section.
- Make sure the pulse oximetry sensor connector is properly plugged into the top panel of the **Sleep&Go**.
- Make sure the red light in the pulse oximetry sensor switches on when connected to the **Sleep&Go**.

ANNEX 3. BIBLIOGRAPHY

1. Duran J, Esnaola S, Rubio R, et al. Obstructive sleep apneahypopnea and related clinical features in a population-based sample of subjects aged 30 to 70 yr. Am J Respir Crit Care Med 2001;163:685–9.

2. Peppard PE, Young T, Barnet JH, et al. Increased prevalence of sleep disordered breathing in adults. Am J Epidemiol. 2013;177(9):1006–1014.

3. Peppard PE, Young T, Palta M, et al. Prospective study of the association between sleep-disordered breathing and hypertension. N Engl J Med. 2000; 342(19):1378–1384

4. Lévy P, Bonsignore MR, Eckel J. Sleep, sleep-disordered breathing and metabolic consequences. Eur Respir J. 2009;34(1):243–260.

5. Campos-Rodriguez F, Martinez-Garcia MA, Martinez M, et al. Association between obstructive sleep apnea and cancer incidence in a large multicenter Spanish cohort. Am J Respir Crit Care Med. 2013;187(1):99–105.

6. Young T, Finn L, Peppard PE, et al. Sleep disordered breathing and mortality: eighteen-year follow-up of the Wisconsin sleep cohort. Sleep. 2008;31(8): 1071–1078.

7. Terán-Santos J, Jiménez-Gómez A, Cordero-Guevara J. The association between sleep apnea and the risk of traffic accidents. NEngl J Med. 1999;340(11): 847–851.

8. Durán-Cantolla J, Mar J, de La Torre Muñecas G, et al. The availability in Spanish public hospitals of resources for diagnosing and treating sleep apnea-hypopnea syndrome. Arch Bronconeumol. 2004 Jun;40(6):259-67.

9. Kapur VK, Auckley DH, Chowdhuri S, et al. Clinical practice guideline for diagnostic testing for adult obstructive sleep apnea: an American Academy of Sleep Medicine clinical practice guideline. J Clin Sleep Med. 2017;13(3):479–504.

10. Guerrero A, Embid C, Isetta V et al. Management of sleep apnea without high pretest probability or with comorbiditiesby three nights of portable sleep monitoring. Sleep. 2014 Aug 1;37(8):1363-73.

11. Domínguez-Mayoral A, Sánchez-Gómez J, Guerrero P, et al. High prevalence of obstructive sleep apnea syndrome in Spain's Stroke Belt. J Int Med Res. 2021 Oct; 49(10):1-13.

12. Muñoz-Gómez R, Navarrete-Martínez E, Serrano-Merino J, et al. The usefulness of the Spanish version of the STOP-Bang questionnaire for screening for moderate or severe sleep apnea syndrome in primary care. Front. Public Health 10:975114.

13. Peñacoba P, Llauger MA, Fortuna AM, et al. A new tool to screen patients with severe obstructive sleep apnea in the primary care setting: a prospective multicenter study. BMC Pulm Med. 2022; 22: 38.

14. Peñacoba P, Llauger MA, Fortuna AM, et al. Primary care and sleep unit agreement in management decisions for sleep apnea: a prospective study in Spain. J Clin Sleep Med. 2020;16(9):1579–1589.