

SCREEN&GO

SCREENING POLYGRAPH

USER'S MANUAL



Screen&GO Manual
Revisión: 534-70S-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 system 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 SCREEN&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. SCREEN&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

SAFETY	6
INTENDED USE	6
INTENDED USER	6
INDICATIONS FOR USE	7
SLEEP APNEA AND HYPOPNEA SYNDROME (SAHS).....	7
INDICATIONS FOR USE OF SCREEN&GO	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	13
1. INSTRUCTIONS OF INSTALLATION AND USE.....	14
1.1. OPTIONS	14
1.2 PACKING LIST	15
1.3 LAYOUT OF CONTROLS, INDICATORS AND CONNECTORS.....	18
1.3.1 FRONT/TOP/RIGHT PANELS.....	18
1.3.2 LEFT PANNEL	18
1.3.3 REAR PANNEL.....	19
1.4 INSTALLATION AND START-UP	19
1.4.1 BATTERY PLACEMENT.....	19
1.4.3 PLACEMENT OF SENSORS.....	20
1.4.3.1 PLACEMENT OF THE SCREEN&GO POLYGRAPH	20
1.4.3.2 NASAL CANNULA.....	21
1.4.3.3 THERMOCOUPLE AIRFLOW SENSOR.....	22
1.4.3.4 RESPIRATORY EFFORT BAND	23
1.4.3.5 PULSE OXIMETER.....	24
1.4.3.6 BODY POSITION AND ACTIVITY	
1.4.3.7 EVENT MARKER.....	27
2. OPERATION	28
2.1 WORKING MODES	
2.2 SYSTEM CONFIGURATION	29
2.3 INITIAL DEVICE SETUP.....	30
2.3.1 SETTING THE DATE AND TIME.....	30
2.3.2 SETTING THE LANGUAGE	30
2.3.3 SETTING THE TYPE OF BATTERIES	31
2.4 MAKING POLYGRAPHY TESTS.....	31
2.4.1 STARTING AND ENDING A TEST MANUALLY	31
2.4.2 SCHEDULED TESTS.....	32
2.4.2.1 SCHEDULING A TEST IN THE SCREEN&GO	32
2.4.2.2 DISPLAYING THE SCHEDULED TESTS.....	34

2.4.2.3 CHANNEL CONFIGURATIONS	35
2.5 TRANSFER AND REVIEW OF THE TESTS	36
2.6 FIRMWARE UPDATE	36
2.7 DEVICE OPTIONS UPDATE	37
3. TECHNICAL SPECIFICATIONS	38
3.1 GENERAL DATA.....	38
3.2 PULSE OXIMETER TECHNICAL SPECIFICATIONS	41
3.3 CONDITIONS OF OPERATION AND STORAGE OF ACCESSORIES	42
3.4 APPLICABLE STANDARDS	42
4. SYMBOLOGY	45
4.1 SYMBOLOGY OF THE SCREEN&GO.....	45
4.2 SYMBOLOGY OF THE ACCESORIES AND PACKAGING	46
4.3 VALIDATED ACCESSORIES	48
5 CLEANING AND MAINTENANCE	49
5.1 CLEANING.....	49
5.2 PREVENTIVE MAINTENANCE	49
5.2.1 ACTIONS TO BE TAKEN BY THE USER	49
5.2.2 ACTIONS TO BE TAKEN BY QUALIFIED PERSONNEL.....	50
5.3 CORRECTIVE MAINTENANCE	51
ANNEX 1. ELECTROMAGNETIC COMPATIBILITY	52
ANNEX 2. TROUBLESHOOTING GUIDE	56
ANNEX 3. BIBLIOGRAPHY	57

SAFETY

The Screen&Go device is a respiratory polygraph designed to be used with the BitmedLab software, the XPOD module 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 Screen&Go and XPOD Module. Please refer to the BitmedLab software and sensor user manuals when necessary.

Screen&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, snore, thoracic effort, body position, body activity, and the oxygen saturation and beats per minute signals with the XPOD 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.

INTENDED USERS

Health personnel:

The Screen&Go and the XPOD module are designed for use in a healthcare facility by a physician or technician trained in SRBD

and SAHS. Training in the acquisition of respiratory signals and subsequent downloading of these signals to 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 Screen&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 Screen&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 device 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 an sleep related breathing disorder with a high prevalence^{1, 2} and is associated with significant morbidity and mortality³⁻⁷. The standard laboratory polysomnography (PSG) for the diagnosis of SAHS is expensive, requires technical expertise and is of limited availability in many areas⁸. Respiratory polygraphy, based on recording the same biological signals as PSG except de neurological ones, is a valid method for the diagnosis of SAHS⁹.

INDICATIONS FOR USE OF SCREEN&GO

Screen&Go is a portable monitor device designed to be used in conjunction with the BitmedLab software application, the XPOD 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 comorbidities¹⁰, or in patients for whom in-laboratory PSG is not possible.

Screen&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.

Screen&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}. Screen&Go can also be used to monitor response to SAHS treatments.

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 physical 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.

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 Screen&Go and the XPOD 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, provided 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 Screen&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 Screen&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 EN 60601-1. The Screen&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 Screen&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 Screen&Go in unattended settings may occasionally provide inconclusive 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 Screen&Go is not protected against defibrillation shocks. 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 of the Screen&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.

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

The Screen&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 10° 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.

Artifacts in the signal may be produced as a result of ESD. A trained operator should be able to recognize these artifacts 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 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 Screen&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 Screen&Go or attempt to adjust it.

Sensors or accessories in bad condition should not be used.

Use only the Screen&Go with accessories and sensors provided by the manufacturer or dealer, or those that meet the specifications of this manual. The use of other sensors with the Screen&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 acquisition of signals in an acoustic and light environment that allows the patient to sleeping normally.

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



Never dispose of the Screen&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 alkaline battery 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 accesories 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. OPTIONS

The Screen&Go screening polygraph is available with the the following features:

Channels		Screen&Go
Nasal cannula	Airflow	
	Snore	
Auxiliary		
External Xpod	SpO ₂	
	BPM	
Body position		
Activity		
Marks		



Default



Option

1.2 PACKING LIST

RELACIÓN DE CONTENIDO / PACKING LIST
SCREEN&GO/SLEEP&GO C€0318

534-708-120 REV. 11

2023-11

MODELOS/ MODELS

CÓDIGO CODE	CANT. QTY.	DESCRIPCIÓN DESCRIPTION	SCREEN&GO	SLEEP&GO	
				A	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 ____ 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 SUJECCIÓN TAMAÑO GRANDE (L) / FASTENING BELT LARGE SIZE (L)	Class I C€		
08049	1	CÁNULA DESECHABLE NASAL / DISPOSABLE NASAL CANNULA	Class I C€		
06309	1	SENSOR TERMOPAR / THERMOCOUPLE SENSOR	Class I C€		
06314	1	INTERFAZ DE AMPLIFICACIÓN BANDA INDUCTIVA ESFUERZO TORÁCICO / THORAX EFFORT INDUCTIVE BAND AMPLIFICATION INTERFACE	Class I C€		
01420	1	BANDA INDUCTIVA ELÁSTICA EXTRA GRANDE (XL) / ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)	Class I C€		
06308	1	INTERFAZ DE AMPLIFICACIÓN BANDA INDUCTIVA ESFUERZO ABDOMINAL / ABDOMINAL EFFORT INDUCTIVE BAND AMPLIFICATION INTERFACE	Class I C€		
01420 (**)	1 (**)	BANDA INDUCTIVA ELÁSTICA EXTRA GRANDE (XL) / ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)	Class I C€	---	
06310	1	SENSOR MOVIMIENTO EXTREMIDADES / LIMB MOVEMENT SENSOR KIT	Class I C€	---	
09898	1	MODULO PULSIOXIMETRIA XP0D / XP0D PULSE OXIMETRY MODULE	Class IIa C€0318		
08955	1	SENSOR PULSIOXIMETRIA SOFT (ADULTO) / SOFT PULSE OXIMETRY SPO ₂ SENSOR (ADULT)			
08556	1	SOPORTE MÓDULO XP0D / XP0D 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 C€0318		

(**) 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.

1/3

RELACIÓN DE CONTENIDO / PACKING LIST**534-708-120 REV. 11****SCREEN&GO/SLEEP&GO C€0318**

2023-11

Opciones firmware (canales internos) / Firmware options (internal channels)						
08078	1	OPCIÓN FIRMWARE CANAL DE RONQUIDO POR PRESIÓN / <i>PRESSURE SNORING CHANNEL FIRMWARE</i>				
08079	1	OPCIÓN FIRMWARE CANAL DE POSICIÓN CORPORAL / <i>BODY POSITION CHANNEL FIRMWARE OPTION</i>				
08080	1	OPCIÓN FIRMWARE CANAL DE ACTIGRAFÍA / <i>ACTIGRAPHY CHANNEL FIRMWARE OPTION</i>				
08081	1	OPCIÓN FIRMWARE CANAL DE MARCAS DEL PACIENTE / <i>PATIENT'S MARKS CHANNEL FIRMWARE OPTION</i>				
08082	1	OPCIÓN FIRMWARE CANAL DE PRESIÓN CPAP / <i>CPAP PRESSURE CHANNEL FIRMWARE OPTION</i>	---			
08083	1	OPCIÓN FIRMWARE CANAL DE ONDA DE PULSO / <i>PULSE WAVE CHANNEL FIRMWARE OPTION</i>	---			
08084	1	OPCIÓN FIRMWARE MÓDULO BLUETOOTH / <i>BLUETOOTH MODULE FIRMWARE OPTION</i>	---			
Productos y accesorios Opcionales / Optional Products and Accessories						
08956	1	SENSOR PULSIOXIMETRIA SOFT (PEDIÁTRICO) / <i>SOFT PULSE OXIMETRY SPO₂ SENSOR (PEDIATRIC)</i>	Class IIa C€0123			
09899	1	MÓDULO EXG / EXG MODULE	Class IIa C€0318	---		
06346	1	SENSOR RONQUIDO PIEZOELECTRICO / <i>PIEZOELECTRIC SNORE SENSOR</i>	Class I C€	---		
07681	1	CÁNULA ORO-NASAL DESECHABLE SLEEPSENSE (PAQUETE DE 5u) / <i>DISPOSABLE SLEEPSENSE ORO-NASAL CANNULA 60cm (PACK OF 5u)</i>	Class I C€			
06311	1	BANDA DE SUJECIÓN TAMAÑO PEQUEÑO (S) / <i>FASTENING BELT SMALL SIZE (S)</i>	Class I C€			
06313	1	BANDA DE SUJECIÓN TAMAÑO EXTRA GRANDE (XL) / <i>FASTENING BELT XTRA LARGE SIZE (XL)</i>	Class I C€			
01425	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO PEQUEÑA (S) / <i>ELASTIC INDUCTIVE BAND SMALL SIZE (S)</i>	Class I C€			
01424	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO MEDIANA (M) / <i>ELASTIC INDUCTIVE BAND MEDIUM SIZE (M)</i>	Class I C€			
01421	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO GRANDE (L) / <i>ELASTIC INDUCTIVE BAND LARGE SIZE (L)</i>	Class I C€			
01420	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO EXTRA GRANDE (XL) / <i>ELASTIC INDUCTIVE BAND XTRA LARGE SIZE (XL)</i>	Class I C€			
01417	1	BANDA INDUCTIVA ELÁSTICA TAMAÑO EXTRA GRANDE (XXL) / <i>ELASTIC INDUCTIVE BAND XTRA XTRA LARGE SIZE (XXL)</i>	Class I C€			
01644	1	CABLE ADAPTADOR 1MM A 1.5MM / <i>CABLE ADAPTER 1MM TO 1.5MM</i>	Class I C€	---		
02741	1	PUENTE DE INTERCONEXIÓN / <i>INTERCONNECTION BRIDGE</i>	Class I C€	---		
08701	1	ELECTRODO CUCHARA ORO EXG (PAQUETE 10u) / <i>EXG GOLD CUP ELECTRODES (PACK OF 10u)</i>	Class I C€	---		
08093	1	CABLES PARA ELECTRODOS DE CORCHETE (PAQUETE DE 10u) / <i>CABLES FOR BUTTON STUD TYPE ELECTRODES (PACK OF 10u)</i>	Class I C€	---		
01027	1	ELECTRODO DE ECG (PAQUETE DE 50u) / <i>ECG ELECTRODE (PACK OF 50u)</i>	Class I C€	---		

RELACIÓN DE CONTENIDO / PACKING LIST

534-708-120 REV. 11

SCREEN&GO/SLEEP&GO C€0318

2023-11

Opciones firmware (ligadas a sensores externos) / 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	---		---

**ESTANDAR**
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 COMUNICARNOSLO LO MAS PRONTO POSIBLE.
- SI 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:

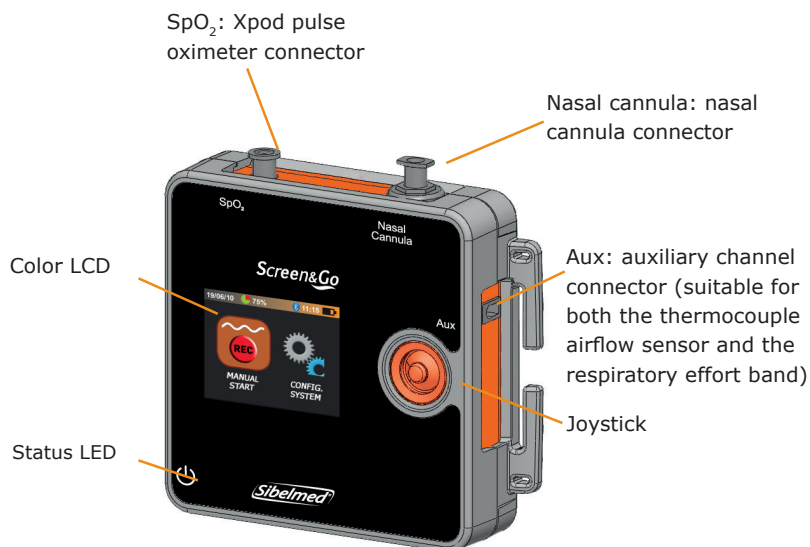
- THE ITEMS AND QUANTITIES RELATED BEFORE HAVE BEEN CAREFULLY CHECKED. IN CASE OF ANY PART IS MISSING OR IS DAMAGED, NOTIFY US AS QUICKLY AS YOU CAN.
- IF YOU DETECT ANY DAMAGE IN THE PACKAGING, CONTACT WITH YOUR DISTRIBUTOR BEFORE PROCEEDING TO INSTALL IT.
- DO NOT THROW AWAY THE PACKAGING, BAGS, ETC. 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 :**

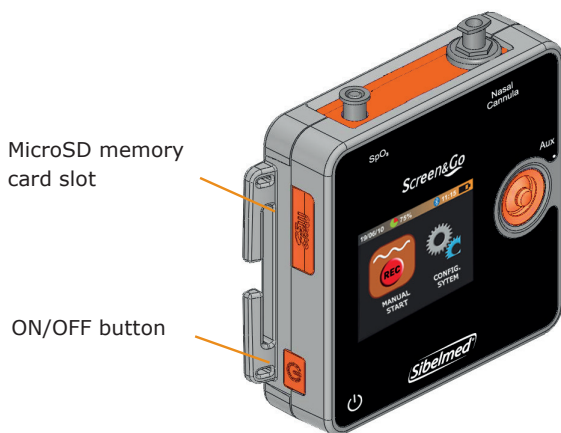
(Pegar etiqueta embalaje)

1.3 LAYOUT OF CONTROLS, INDICATORS AND CONNECTORS

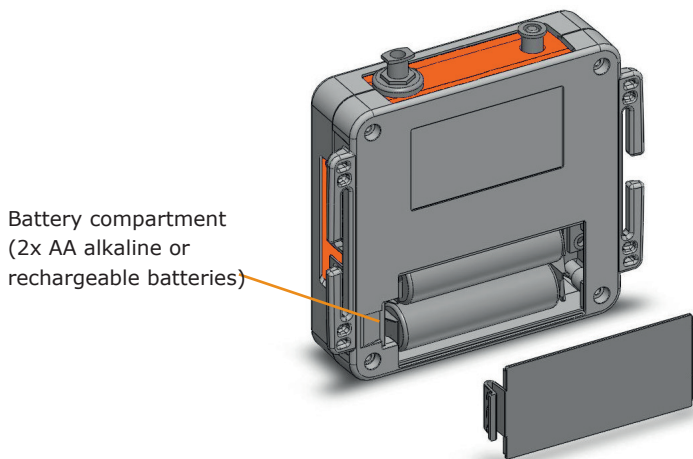
1.3.1 FRONT/TOP/RIGHT PANNELS



1.3.2 LEFT PANNEL



1.3.3 REAR PANNEL



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 Screen&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 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 Screen & 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.

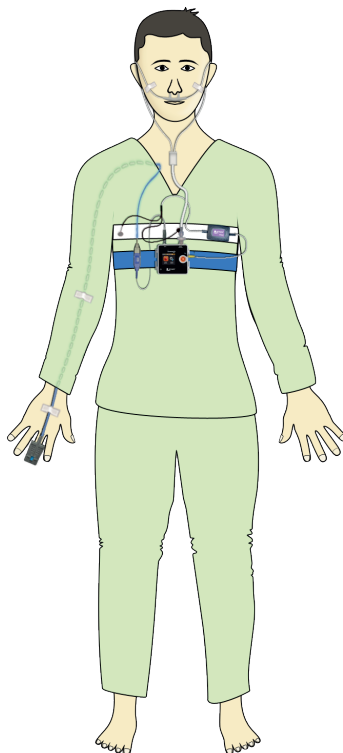
1.4.3 PLACEMENT OF SENSORS

1.4.3.1 PLACEMENT OF THE SCREEN&GO POLYGRAPH

The small size and weight of the Screen&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 Screen&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

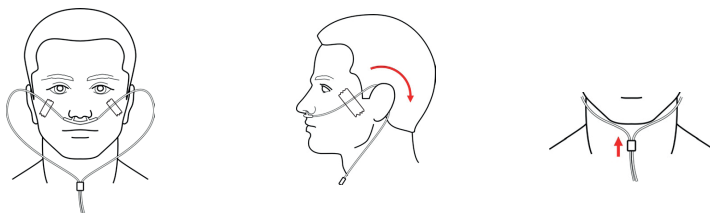


1.4.3.2 NASAL CANNULA

The nasal airflow cannula (refs. 07681, 08049) is used to acquire the airflow and snoring 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 Screen&Go (labeled as "Nassal cannula") and turn it until secured.



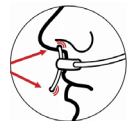
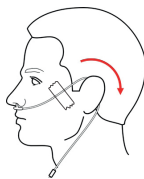
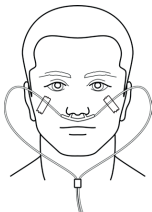
1.4.3.3 THERMOCOUPLE AIRFLOW SENSOR

In addition to the nasal cannula, the Screen&Go may also use the thermocouple sensor (ref. 06309) in order to measure the respiratory airflow. Both the thermocouple airflow sensor and the effort band are to be connected to the connector labeled as "Aux" and therefore both can not be used at the same time.

The quality of the registered signal depends on variables such as the filters selected in the software, the sensor placement, the patient's respiration and room temperature. 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 Screen&Go labeled as "Ther".

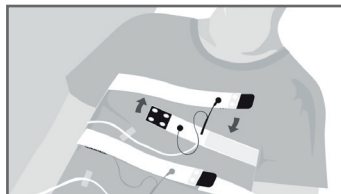
The ambient temperature affects the magnitude of the signal. If the temperature is similar to the patient's temperature, the signal level may be very low. On the other side, if the ambient temperature is very different from the patient's temperature, the signal level will be higher.

1.4.3.4 RESPIRATORY EFFORT BAND

The inductive plethysmography belt (refs. 01425, 01424, 01421, 01420, 01417) supplied with the Screen&Go is based in the RIP technology (Respiratory Inductive Plethysmography).

- Strap the sensor band around the patient's chest or abdomen, over any clothing.
- Attach the first wire of the interfaze box (ref. 06314) 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 snaps with the interface disconnected from equipment.

- Both the thermocouple airflow sensor and the effort band are to be connected to the connector labeled as "Aux" and therefore both can not be used at the same time.
- Fix each of the little boxes to the corresponding belt with the aid of the provided strips.

1.4.3.5 PULSE OXIMETER

The system allows to measure the pulse rate and the functional oxygen saturation, based on the technology developed by Nonin Medical Inc. The pulse oximeter is calibrated to measure the 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 SpO₂ 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.

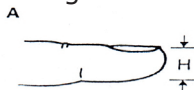
In adults, the ideal point for the application of the oximeter sensor is the index finger. However, it may also be placed in other fingers when the thickness is between 5mm and 21mm (0.2" and 0.8"), (dimension "H" in the figure).

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 "SpO₂" 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 Screen&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.

- 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.
- 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 above 42°.
- Read the instructions for use before use. Strictly follow the manufacturer's safety instructions, as well as those specified in this manual.
- For long-term measurements, it is recommended to use flexible or disposable sensors.
- The adult sensor is for people over 12 years of age (>40Kg). 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 standardized.
- 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, place the batteries and/or turn on the device again, and the device will be ready to operate again in any mode.

1.4.3.6 BODY POSITION AND ACTIVITY

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

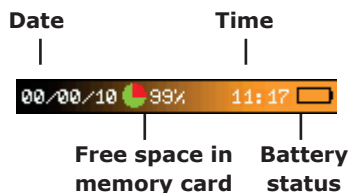
1.4.3.7 EVENT MARKER

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 Screen&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 Screen&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

The Screen&Go works always in holter mode. In this mode the Screen&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:

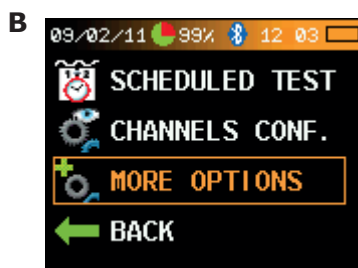
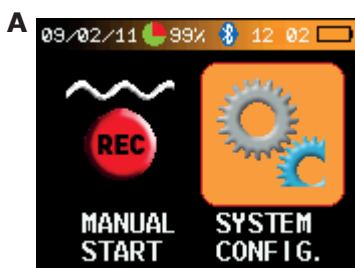
- a. Manual start and stop: the patient starts and stops manually the recording of the test, through the color screen and joystick in the Screen&Go.
- b. Automatic start and stop: health personnel program the Screen&Go to start and stop automatically the test at a certain date and time.

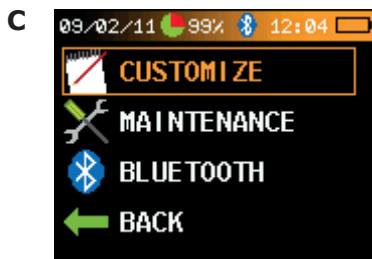
The device's batteries last up to 24 hours with a single charge.

2.2 SYSTEM CONFIGURATION

The setup mode in the Screen&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 Screen&Go do the following:

- Switch on the Screen&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).





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 Screen&Go:

- Select "DATE AND TIME".
- Use ↑ and ↓, 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 Screen&Go:

- Select "LANGUAGES".
- Use ↑ and ↓ move along the different available languages. The selected language is marked with the ✓ symbol.

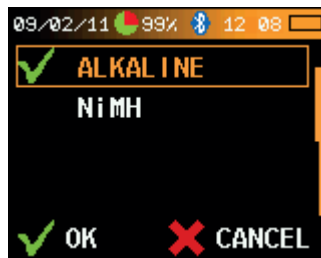


- When you have set the desired language select "OK. " If you want to cancel the language settings then select "CANCEL".

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 "BATTERIES".
- Use ↑ and ↓ to select the type of batteries used in the device. The type of batteries is marked with the ✓ mark.
- When you have set the desired language select "OK. " If you want to cancel the language settings then select "CANCEL".



2.4 MAKING POLYGRAPHY TESTS

There are two different ways to start and stop the tests, either manually or automatically (scheduled).

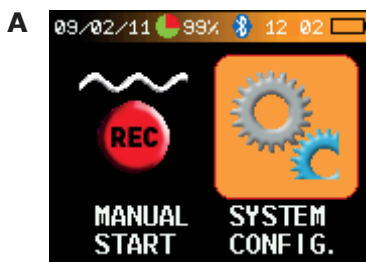
2.4.1 STARTING AND ENDING A TEST MANUALLY

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 SpO₂ and BPM channels, if there is an error, there is no finger in the sensor or if it is disconnected, the SpO₂ and BPM values are set to zero and furthermore the following messages in Red will appear: DATA ERROR, DISCONNECTED SENSOR or NO FINGER. If the pulseoximeter works correctly, the message MEDIUM 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).



2.4.2 SCHEDULED TESTS

The Screen&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 Screen&Go for starting or ending the test.

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

2.4.2.1 SCHEDULING A TEST IN THE SCREEN&GO

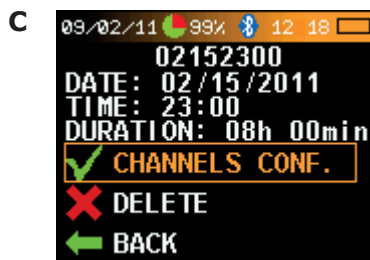
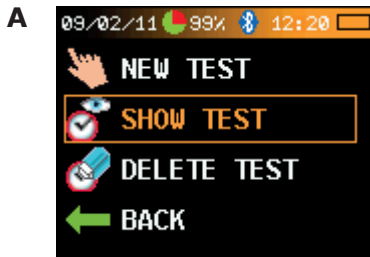
- Switch on the Screen&Go and gain access to the setup mode by making the following keystrokes on the joystick, one after another and leaving a short interval of time between each of them: ↓, ↓, ↑, ↑.
- Select the "SYSTEM CONFIG." icon and press the joystick to move to the setup screen.
- Select "SCHEDULED 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 Screen&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.



2.4.2.2 DISPLAYING THE SCHEDULED TESTS

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

- Switch on the Screen&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).



2.4.2.3 CHANNEL CONFIGURATIONS

The Screen&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, 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.

2.5 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 Screen&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 Screen&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.

2.6 FIRMWARE UPDATE

Over time, new versions of the program managing the Screen&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 Screen&Go.

- Insert the memory card in the Screen&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 Screen&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.

2.7 DEVICE OPTIONS UPDATE

As mentioned in paragraphs 1.2 and 1.3, the Screen&Go is delivered with just the airflow channel enabled. 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 Screen&Go.
- Insert the memory card in the Screen&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 Screen&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 Screen&Go:	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) / >24h in holster 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 (respiratory airflow, snore) • Polygraphic aux. • Pulse oximeter • Actimetry • Body position • Event marker • LUER connector. • 1 mm key connector. • Specific 3-pin connector. • Internal • Internal • Joystick

Storage sampling rate (software selectable):	• Airflow (pressure transducer) • Snore (pressure transducer) • Polygraphic aux. • Pulse rate • Oxygen saturation • Actimetry • Body position • Event marker	• Selectable: 25, 50, 100 samples/s • Selectable: 50, 100, 250 samples/s • Selectable: 10, 25 samples/s • 1 sample/s • 1 sample/s • Selectable: 10, 25, 50 samples/s • 1 sample/s • 1 sample/s
Resolution:	• Resp airflow. (pressure transducer), snore (pressure transducer), polygraphic aux., actimetry • Pulse rate, oxygen saturation • Body position • Event marker	• 12 bits • 8 bits • 8 bits • 8 bits
Sample storage size:	16 bits per sample	
Input range:	• Polygraphic aux. • Airflow (pressure transducer) • Snoring (pressure transducer) • Pulse • Oxygen saturation • Actimetry • Body position	• “+/- 5 mVpp (+/- 0.5 mVpp if thermocouple sensor is used). • +/- 4 cmH₂O (3.9 hPa) over the cannula approx. • +/- 0.5 cmH₂O (0.49 hPa) over the cannula approx. • 18 – 300 BPM (1/min) • 0 – 100 % • approx. +/-30 mg (300 m/s²) • Supine, prone, left, right, seated
Linearity:	Resp. airflow (pressure transducer), snore (pressure transducer)	+/- 3%
	Polygraphic aux., actimetry	+/- 3%
Accuracy:	(See pulseoximeter table)	
Pulseoximeter		

Fixed hardware filters:	• Polygraphic aux. • Airflow (pressure transducer) • Snoring (pressure transducer) • Pulse • Oxygen saturation • Actimetry • Body position • 0.05 – 10 Hz • 0.05 – 50 Hz • 30 – 250 Hz • - • - • 0.5 – 25 Hz • -	
Environmental conditions:	In operation	Transportation and storage(*2)
	Temperature: 5°C to 40°C Relative humidity: 15-90% (without condensation) Barometric pressure: 700hPa to 1060hPa (approx. 3000 to -380m)	Temperature: -20°C to +60°C Relative humidity: <90% (without condensation)
Dimensions:	90 x 90 x 25 mm	
Weight device:	< 200 g	

(*2) The device must be left at least 30 minutes at ambient temperature (20°C) before being used when comes from the warehouse 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
Accuracy Precision ¹ SpO ₂ (70-100%) (±1DS) ² Pulse rate	No movement: Finger clip sensor: adults, paediatric: ±2 digits Flexible sensor: adults, paediatric: ±3 digits Movement ³ : Finger clip sensor: adults, paediatric: ±2 digits Flexible sensor: adults, paediatric: ±3 digits Low perfusion ⁴ : All sensors: adults, paediatric: ±2digits 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 groups.
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 ± 2 mmHg of the value measured by a CO-oximeter.

3. For determination of accuracy in movement conditions:
 SpO₂: the sensor is rotated through the index, middle, ring and pinkie fingers and rubbing motion and tapping motion is simulated at a frequency of 1 Hz.
 Pulse Rate: a pulseoximetry tester (Oxitest Plus 7) is used to introduce simulated motion artifacts (movement motion, tremor motion and spike motion).
4. For determination of accuracy in low perfusion conditions:
 SpO₂: a pulseoximetry tester (Oxitest Plus 7) is used to introduce simulated low perfusion.
 Pulse Rate: a pulseoximetry tester (Oxitest Plus 7) is used to introduce simulated low perfusion. The accuracy is verified from 18 to 300 BPM at different levels of SpO₂ values (70%, 80%, 90% and 97%)

3.3 CONDITIONS OF OPERATION AND STORAGE OF ACCESSORIES

Although the device 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 all accessories.

3.4 APPLICABLE STANDARDS

The Screen&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:

- CE marking Class II a

Safety:

- EN 60601-1:2006+AC:2010+A11:2011+A1:2013+A12:2014+A2:2021+A13:2024: Electrical safety.
- 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 at medical devices (Professional use and domicile)

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 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 and information to be supplied.

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 the restriction of 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, EN ISO 9001:2015

-

Risk Management:

- EN ISO 14971:2019 + A11:2021

The user should follow:

Data protection. Regulation (EU) 2016/679

4. SYMBOLOGY

4.1 SYMBOLOGY OF THE SCREEN&GO



SERIAL NUMBER



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



REFERENCE



CONSULT INSTRUCTIONS FOR USE



ATTENTION ADDITIONAL WARNINGS IN THE ACCOMPANYING DOCUMENTATION



ATTENTION, RISK IDENTIFIED



MEDICAL DEVICE



START UP (STANDBY)



BF APPLIED PARTS



NO SPO₂ ALARMS



IP22 (see section WARNINGS AND PRECAUTIONS)



DISPOSAL OF WASTE ELECTRICAL / ELECTRONIC ACORDING TO THE WEEE DIRECTIVE



BATTERIES



FOLLOW INSTRUCTIONS FOR USE

4.2 SYBOLGY OF THE ACCESORIES AND PACKAGING



CE MARKING



DO NOT REUSE



BATCH NUMBER



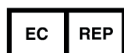
REFERENCE



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



US FEDERAL REGULATION RESTRICTS THE SALE OF THIS DEVICE UNDER MEDICAL PRESCRIPTION. ALSO MAY BE APPLICABLE IN OTHER COUNTRIES



HUMIDITY LIMITATION



USE BY



STACKING LIMITATION



THIS WAY UP



FRAGILE



KEEP AWAY FROM WATER



PRESSURE LIMITATION

4.3 VALIDATED ACCESSORIES

The Screen&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 CANNULA	S.L.P. INC.	08049	15805-2-FT
THORAX EFFORT INDUCTIVE BAND AMPLIFICATION INTERFACE	S.L.P. INC.	06314	9102S-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

5 CLEANING AND MAINTENANCE

The Screen&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 Screen&Go was developed.

5.1 CLEANING

To clean the unit and its accessories, excluding the sensors, use a damp cloth and mild (hand) soap. To disinfect the device you can use alcohol 96° 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 immediately after use. Nasal cannulas are single use and must be replaced with each patient.

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



The device can not be sterilized. For the cleaning and disinfection of sensors, 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 Screen&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		
SCREEN&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	SCREEN&GO works with batteries.
Harmonic emissions EN-IEC 61000-3-2	Not applicable	SCREEN&GO works with batteries.
Voltage fluctuations / Flicker emissions EN-IEC 61000-3-3	Not applicable	SCREEN&GO works with batteries.

Guidance and manufacturer's declaration – electromagnetic emissions

SCREEN&GO is intended for use in the electromagnetic environment specified below. The costumer or the user of **SCREEN&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 Frequency 100 kHz	Not applicable Not applicable	SCREEN&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	SCREEN&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: 0°, 45°, 90°, 135°, 180°, 225°, 270° y 315°. 0% Ut; 1 cycle 70% Ut; 25/30 cycles: 0° 0% Ut ; 250/300 cycles (5 segundos)	Not applicable	SCREEN&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

SCREEN&GO is intended for use in the electromagnetic environment specified below. The customer or the user of **SCREEN&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	10 V/m 80 MHz to 2.7 GHz 80% AM at 1kHz	10 V/m	
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 SCREEN&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 Screen&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.

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

- Check that the erroneous sensor is correctly connected.

Pulse oximetry signals are null

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