

Surrodis device – User manual (USA)
W71-1734783 (27 OCT 2024)

Symbol description

The following symbols are used on the Surrodis device. Please read the related descriptions carefully.

	Consult the user manual
	The device must not be thrown in with the other household waste
	Keep the device away from water
	Permissible temperature range for storage
	Type B1 apical part
	The device has an ingress rating of IP67 in accordance with IEC 60529
	Catalog number
	Serial number
	Manufacturer
	Date of manufacture
	Prescription only
	The device is a medical device
	Unique device identifier
	Shielding electromagnetic interference
	Do not use if package is damaged
	Electrical current

Intended use and device description

The Surrodis device is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 18 years and older with symptoms of sleep breathing disorders.

The Surrodis device is a software-based device that analyzes data from a sensor placed on the patient's chin. The device records respiratory events, identifies sleep stages and position. The device generates sleep parameters, e.g. apnea-hypopnea index (Surrodis AH²), and position

diabetes status. Data collected by the device is integrated in a report for further interpretation by the healthcare provider.

The device is not intended as a substitute for full polyannemography nor intended to be used as an apnea monitor.

Expected clinical benefits

Use of the Sanitas device makes it possible to quickly and effectively determine if you need to be treated by a healthcare professional for sleep-related disorders. An early medical diagnosis can help improve quality of life and reduce the risk of developing potentially lethal cardiovascular and metabolic comorbidities such as hypertension, congestive heart failure, stroke as well as psychological disorders such as impaired attention and executive functioning or an increased risk of developing Alzheimer's disease.

Contra-indications



- Patients with conditions affecting the relation of the mandible to the maxilla, mandibular joint cannot use the device since it is not compatible with detection of mandibular movements.
 - Unsuitable below 18 years old.
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Warnings, safety and cybersecurity precautions

To ensure user and operational safety, please read the following precautions before using the Sanitas device.

Warnings

- The sensor is only to be placed on the chin. If the sensor is not placed on the chin, that affect the accuracy of test results.
- Beards can impair the effect of the sensor. If you are bearded, please shave beforehand.
- The device is intended to be used with intact skin. Do not use the device if the skin is not intact (redness, after shaving for example) and discontinue use if you experience itching, rashness, pain, or swelling.
- The sensor may cause allergies in persons sensitive to the following materials: acrylic and polyacrylate adhesives. Do not use the sensor in patients with known allergies to these materials.
- To prevent the sensor from radio frequency sources such as electromagnetic security systems, cellular telephones, RFID or

either in hand transmitters. Some RF emitters (e.g., RF functions of a smartphone) might be accessed and disturbed the device without user's awareness. Electromagnetic disturbances could result in loss or degradation of performance and could lead to an absence of results.

- Use of this device adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.
- Nearby RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 60 cm (18 inches) to any part of the device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- Do not modify the device or use the device if modified. Changes or modifications not approved by Sumko may result in the loss or decreasing level of compliance and could void the user's authority to operate the equipment.
- Do not expose the device to fire or excessive temperatures to ensure the safety of the battery. In the event the internal battery is exposed, do not crush or smoke it if it is.
- Do not use the sensor if the battery leaks. In case a leaked liquid has come in contact with eyes or skin, rinse with clean water immediately, for at least 15 minutes, and consult a doctor. Do not also any contaminated clothes.
- The device is not intended to continuously display SpO₂ and pulse rate through time like a standard pulse oximeter routinely used in the monitoring room, in the transfer care unit, or during emergency transport (and therefore is not intended to trigger the initiation of oxygen therapy following reference documentation). The Sumko device is a non-invasive home care aid in the evaluation of oxygen saturation (OS₄) in patients 15 years and older with exclusion of sleep breathing disorders. The SpO₂ and pulse rate values are only displayed after the sleep study, being reported to the physician with all other parameters.

Charging warning

- Use of only an USB charger certified for your country of use, suitable for an input 100-240 VAC, 50-60 Hz.

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- Improper placement of the sensor on its docking station may result in excessive heating of the device and battery not charging. Always position the sensor in the designated area on the docking station.
 - If the device becomes too hot and stops charging, remove it from the docking station to allow it to cool down before attempting to charge it again. Place the docking station further away from heat sources.
 - If the sensor becomes hot, allow it to cool down for at least 20 minutes before use.
 - Maintain a distance of at least 20 cm between the docking station and the patient when sleeping.
 - Do not use a 3.5Ample charger to power the docking station.

Storage warning

- Recommend not always store the sensor inside its docking station with the device cover.
- For long term storage, store the device in its packaging.
- Sensor must be transported in its packaging, as the sensor is fragile. It is recommended to carry it carefully.
- Keep away from children, pets and pests to avoid risks of choking or degradation. Always store the sensor inside its closed docking station.
- Store away from sunlight and dust especially when charging.
- To keep the recommended storing temperature, to maximize the battery life.
- To ensure optimal battery performance, it is recommended to recharge the sensor at least once every 6 months.

Cybersecurity precautions

- If a cybersecurity event is detected or suspected, please contact the Bureau & report.
- Do not share or write down your app password as it could create unwanted access to your medical records.
- Only use the Bureau app available on the App Store or on Google Play. Apps available from other sources are not protected by a filter and could represent a cybersecurity threat.

Notes

- The patient is the intended operator
- Provider will make answers to the questions in the app, since it could affect the outcomes of the test
- Once the set data has been entered, only the sensor named in that sensor is allowed to perform the test
- For people requiring assistance, the caregiver must answer the questionnaires or check the boxes and assist to the use and placement of the sensor
- Make sure the skin is clean, free of soap residue and lotion, and allowed to dry thoroughly before applying the sensor and/or the additional adhesive bandage(s) around a limb to help and to ensure good adhesion
- The adhesives are designed to be a non-skin adhesive. If you have to remove the previous one as this could impact adherence properties of the bandage
- The sensor is only compatible with its associated docking station. Do not use any other wireless chargers to attempt to charge the device.

Step-by-step instruction:

Please keep the smartphone used to run the SunBio mobile app at least 1 meter away from the SunBio Armband.

Step 1 – Before going to bed, download the “SunBio Sleep” app and enables the location permission (if enabled)

Step 2 – When you go to bed, press the “Turn On” on the app home screen and scan the QR code on the packaging. This allows to pair sensor to the smartphone.

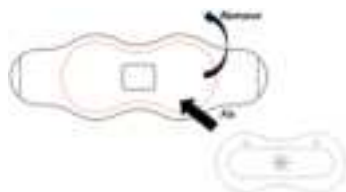
Step 3 – Remove the sensor of its docking station and press the “Turn On” button on the sensor to start the recording. The “LED” will be green to indicate recording start up.



Starting a recording is not possible in the following situation:

- Low battery, indicated by a blinking yellow LED. Place the sensor on its docking station to charge the device.
- Recording in memory, indicated by a blinking blue LED. Erase the memory with the Run to App.

Step 4: Remove the central sensor velcro of the skin adhesives. Affix the sensor onto this area, ensuring that the small window at the back of the sensor aligns with the designated opening in the adhesives.



Step 5: Remove the adhesive layer from the other side of the skin adhesive. Affix the sensor horizontally to the corner of your ear, positioning the thermistor (black dot) to face your nostrils (if you are bearded, please shave beforehand).



Step 6: When you wake up, remove the used adhesive. Place the sensor back on its docking station; the recording will cease automatically. Keep it in a cool, dry place.

Step 7: In the app, press on the "previous data" button to download the recorded information.

Step 8: The right's results should be available for your smartphone within minutes.

If the test is stopped when the first beep, the sensor will automatically delete the data and reset for a new recording.

When removed from its docking station, the front LED is steady and on, indicating the sensor is ready to record.

During recording, the blue red LED indicates the device is on.

Cleaning

Only clean the device in the sensor after use with a damp cloth or an isopropyl alcohol swab and allow to dry before use.

Maintenance and repair

Only authorized personnel from Sirona are permitted to repair or maintain the device. Unauthorized handling may result in damage and pose safety risks.

Technical specifications

Model reference	26000
Dimensions and weight	Sensor 1,74 x 0,8 x 0,32 in / 44,2 x 20 x 8,1 mm 0,63 oz / 18 g
	Tooling station 3,7 x 0,21 x 1,62 in / 94 x 53,8 x 41 mm 2,52 oz / 72,5 g
Tooling station power supply	5V DC 150 mA
RFID IDs	2nd (980 nm) and Infrared (880 nm)
Transport and storage conditions between uses	Temperature range: 00 °C to +60 °C Temperature range: -5 °C to +65 °C at a non-condensing relative humidity up to 20 % Temperature range: +35 °C to 60 °C at a water vapor pressure up to 60 hPa
Operating conditions	Water temperature: -5 °C to +35 °C Relative humidity range of 15 % to 20 % non-condensing, but including a water vapor partial pressure greater than 20 hPa Atmospheric pressure range of 700 hPa to 1010 hPa
Expected service life	2 years

Wireless specifications

Function and technology	The mobile app allows the pet owner to connect to the sensor, activate it and retrieve data from it. The sensor and the smartphone communicate via Bluetooth® energy (Bluetooth® LE 4.1, 4.2, 5.0)
Operating characteristics	Operating frequency: 2.4 GHz (min. 2380 MHz and max. 2500 MHz) Transmitted power: maximum output power of 5 dBm (with typical value of 4 dBm) Operating range: between 1 and 3 meters/ 3.3 and 9.8 yards Modulation: GFSK
Quality of Service (QoS) for safe and effective operation	Maximum transfer rate of 1.25 MB/s
Security measures	Bluetooth® low energy communications are encrypted and cellular or Wi-Fi communications use the secure HTTPS protocol

Wireless troubleshooting

Unable to pair the sensor	1. Have you placed the sensor on its docking station? If not, please do so and ensure that the docking station is powered on. 2. Is the front sensor's LED on? If not, please contact Sundin support. 3. Is the distance between your smartphone and the sensor between 1 and 3 meters/ 3.3 and 9.8 yards? If not, please move it. 4. Is the Bluetooth enabled on your smartphone? If not, please enable it. If yes, disable it and then enable it. 5. Please restart your smartphone. 6. Please use another smartphone. 7. None of these are solved the problem, please contact the Sundin support.
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Three-meter of the sensor	is the distance between your smartphone and the sensor between 1 and 8 meters/ 3.3 and 9.2 yards? If not, please move it!
Wireless coexistence Issues	In case of wireless coexistence issues, please keep the smartphone between 1 and 3 meters/ 3.3 and 9.2 yards from the sensor during recording and do not pass Bluetooth devices within 1 meter/ 3.3 yards of the sensor or smartphone. Please keep all sources of radio frequency interference away from the test location.

Electromagnetic compatibility and compliance with telecommunications from Jordan

The Smart Air has been tested according to EC 89/367 L and EC 90/269 L 2.

Emission test	Standard	Compliance level
Conducted and Radiated emission	CISPR 11	Group 1, Class B
Immunity test	Standard	Compliance level
Electrostatic discharge	EC 80000 7-2	± 2 kV contact ± 3, 4, 8, 9 kV air
Radiated Immunity	EC 80000 7-3	10 V/m 80 MHz - 2.7 GHz 20 V/m 92.5-92.9 MHz 20 V/m 193-170 MHz 80.0-96.0 MHz 1730-199.5 V/m 2400-2670 V/m 9 V/m 70-1757 MHz 5700-5800 MHz
Power frequency magnetic field	EC 80000 7-8	90 A/m
Close proximity magnetic field	EC 80000 7-32	8 A/m 90MHz (100) 25 A/m

			18.75 MHz (7.1447 MHz 50%) 7.5.6m 18.75 MHz (5.007 MHz 50%)
Function	fast	EC 61000.7.2	± 7 KHz 100 kHz repetition frequency
Voltage range		EC 61000.7.5	Interference: ± 0.5 V, 1 kHz Interference: ± 0.5 V, 1 kHz, ± 7 KHz
Conducted disturbances		EC 61000.7.8	90 0.15 V/m – 80 MHz
Voltage dips		EC 61000.7.11	0.5 V, 0.5 cycle
Voltage Interruptions		EC 61000.7.11	0.5 V, 0.5 cycle, angle 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0.5 V, 1 cycle, angle 0° 70 % V, 25/75 cycles, angle 0°

Based on the electromagnetic compatibility test results it can be concluded that foreseeable electromagnetic disturbances will not result in an unacceptable disturbance to the end user.

TCR 7.26-4443UN30.5

This device complies with part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) This device may not cause harmful interference, and (2) This device must accept any interference received, including interference that may cause undesired operation.

Warnings and cautions linked to wireless functions



Avoid exposure to Radio Frequency (RF) fields (such as RFs from radiofrequency identification systems or security systems (e.g., electromagnetic anti-theft systems and metal detectors)). This may lead to signal loss and delay and possibly prevent use of the device.

established. If you encounter problems (e.g. cannot switch up the test, interrupted connections with the server), please remove all sources of radio frequency interference from the place where you perform the test. Note that these sources of radio frequency interference may not be easily identified (e.g. wireless PDA's).

Recycling and disposal

In accordance with the WEEE Directive and E. Regulation 2006/66/EC, Kintive will take back old units and dispose of them free of charge. Kintive encourages the return of devices at the end of their life for optimal recycling of batteries and other components. This device must not be discarded in general household waste. Follow the recommendations of your local waste disposal authority.

Please ensure responsible recycling when returning this equipment

Incident reporting

Any serious incident that has occurred in relation to the Surro device should be reported to Kintive and the national competent authority in which the patient is established.

Contact

In case of any problems regarding the Kintive device, please contact Kintive:



Email: support@kintive.be

Address: Kintive, SA, Chaussees de Vervins 69/69B
2701 Hamme, Belgium