

Symbol description

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

	Consult the user manual
	The device must not be thrown out with the other household waste
	Keep the device away from water
	Permissible temperature range for storage
	Type BF applied part
IP22	This device has an ingress rating of IP22 in accordance with IEC 60529
	Catalog number
	Serial number
	Manufacturer
	Date of manufacture
Rx Only	Prescription only
	The device is a medical device
	Unique device identifier
	Non-ionizing electromagnetic radiation
	Do not use if package is damaged
	Direct current

Intended use and device description

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

The Sunrise device is a cloud-based software device that analyzes data from a sensor placed on the patient’s chin. The device detects respiratory events, identifies sleep stages and position. The device generates sleep parameters, e.g. apnea hypopnea index “Sunrise AHI”, and position

discrete states. 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 polysomnography nor intended to be used as an apnea monitor.

Expected clinical benefits

Use of the Sunrise 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 consequences such as impaired attentional and executive functioning or an increased risk of developing Alzheimer's disease.

Contra-indications



- Patients with conditions affecting the rotation of the condyle in the temporo-mandibular joint cannot use the device since it is not compatible with detection of mandibular movements.
 - Not suited 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 Sunrise device.

Warnings

- The sensor is only to be placed on the chin. If the sensor is not placed on the chin, it will affect the accuracy of test results.
- Beards can impact the fit 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, redness, rash, 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.
- Do not use the sensor close to radio frequency sources such as electromagnetic security systems, cellular telephones, RFID or

other in-band transmitters. Some RF emitters (e.g. RFID function of a smartphone) might be concealed and disturbed the device without user's awareness. Electromagnetic disturbances could result in loss or degradation of performances and would 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.
- Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 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 unapproved by Sunrise may results in the device operating out 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 short-circuit it.
- Do not use the sensor if the battery leaks. In case a leaked liquid has been in contact with eyes or skin, rinse with clear water immediately, for at least 15 minutes, and consult a doctor – clean also any contaminated clothes.
- The device is not intended to continuously display SpO2 and pulse rate in real time like a standard pulse oximeter routinely used in the operating room, in the intensive care unit, or during emergency transport (and therefore is not intended to trigger the initiation of oxygen therapy following detected desaturation). The Sunrise device is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 18 years and older with suspicions of sleep breathing disorders. The SpO2 and pulse rate values are only displayed, after the sleep study, in the report to the physician with all other parameters.

Charging warning

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

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- Improper placement of the sensor on its docking station may result in excessive heating of the device and inefficient charging. Always position the sensor in the designated slot 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 2 minutes before use.
 - Maintain a distance of at least 20 cm between the docking station and the patient when sleeping.
 - Do not use a USB cable longer than 3 meters to power the docking station.

Storage warning

- Between use, always store the sensor inside its docking station with its closed 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 inhalation or degradation. Always store the sensor inside its closed docking station.
- Store away from sunlight and dust, especially when charging.
- Follow 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 Sunrise support.
- Do not share or write down your app password as it could enable unwanted access to your medical records.
- Only use the Sunrise app available on the App Store or on Google Play. Apps available from other sources are not provided by Sunrise and could cause a cybersecurity threat.

Notes

- The patient is the intended operator.
- Provide accurate answers to the questions in the app, since it could affect the outcomes of the test.
- Once the user data have been entered, only the person named in the user data 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 to prevent skin irritation and to ensure good adhesion.
- The adhesives are single use: use a new 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.

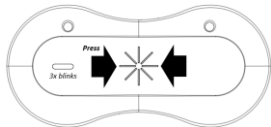
Step-by-step instruction

Please keep the smartphone used to run the Sunrise mobile app at least 1 meter away from the Sunrise Air sensor.

Step 1 - Before going to bed, download the “Sunrise.sleep” app and complete the medical questionnaire (10 minutes).

Step 2 - When you go to bed, press the “+” button on the app home screen and scan the QR code inside the packaging. This allows to pair sensor to the smartphone.

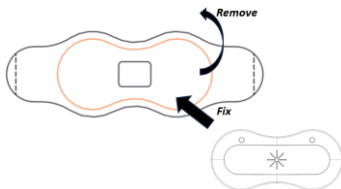
Step 3 – Remove the sensor of its docking station and press the “*” button on the sensor to start the recording. The LED will blink 3x to indicate recording stat-up.



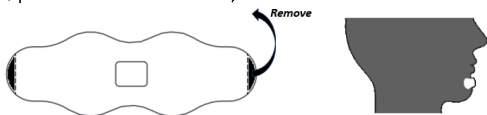
Starting a recording is not possible in the following situation:

- 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 Sunrise App.

Step 4 - Remove the central protective layer of the skin adhesive. Affix the sensor onto this area, ensuring that the small window at the back of the sensor aligns with the designated opening in the adhesive.



Step 5 – Remove the protective layer from the other side of the skin adhesive. Attach the sensor horizontally to the center of your chin, positioning the thermistors (black dots) 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 inside until next use.

Step 7 – In the app, press on the “retrieve data” button to download the recorded information.

Step 8 - The night’s results should be available for your practitioner within minutes.

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

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

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

Cleaning

Only clean the Sunrise sensor after use with a damp cloth or an isopropyl alcohol wipe and allow it to dry before use.

Maintenance and repair

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

Technical specifications

Model reference	A9XX
Dimensions and weight	Sensor: 1,74 x 0,8 x 0,33 in / 44.2 x 20 x 8.6 mm 0,53 oz / 15g
	Docking station: 3,14 x 0,81 x 1,57 in / 80 x 20.6 x 40mm 2,82 oz / 80g
Docking station power supply	5V DC - 150 mA
PPG LEDs	Red (660 nm) and infrared (880 nm)
Transport and storage conditions between uses	Temperature range: -20 °C to +5 °C
	Temperature range: +5 °C to +35 °C at a non-condensing relative humidity up to 90 % Temperature range: >35 °C to 60 °C at a water vapor pressure up to 50 hPa
Operating conditions	Within temperature: +5 °C to +35 °C Relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapor partial pressure greater than 50 hPa
	An atmospheric pressure range of 700 hPa to 1060 hPa
Expected service life	4 years

Wireless specifications

Functions and technology	The mobile app allows the patient to connect to the sensor, control it and retrieve data from it. The sensor and the smartphone communicate via Bluetooth low energy (Bluetooth 4.0, 4.1, 4.2, 5.0).
Operating characteristics	Operating frequency: 2.4 GHz (min. 2360 MHz and max. 2500 MHz) Transmitted power: maximum output power of 6 dBm (with typical value of 4 dBm) Operating range: between 1 and 3 meters/ 1.1 and 3.3 yards Modulation: GFSK
Quality of Service (QoS) for safe and effective operation	Minimum transfer rate of 1.6 kB/s
Security measures	Bluetooth low energy communications are encrypted and cellular or Wi-Fi communications use the secured 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 Sunrise support. 3- Is the distance between your smartphone and the sensor between 1 and 3 meters/ 1.1 and 3.3 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. If none of these actions solved the problem, please contact the Sunrise support.
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Disconnection of the sensor	Is the distance between your smartphone and the sensor between 1 and 3 meters/ 1.1 and 3.3 yards? If not, please move it.
Wireless coexistence issues	In case of wireless coexistence issues, please keep the smartphone between 1 and 3 meters/ 1.1 and 3.3 yards from the sensor during recording and do not place Bluetooth devices within 1 meter/ 1.1 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 standards

The Sunrise Air has been tested according to IEC 60601-1 and IEC 60601-1-2.

Emission test	Standard	Compliance level
Conducted and Radiated emission	CISPR 11	Group 1 – Class B
Immunity test	Standard	Compliance level
Electrostatic discharge	IEC 61000-4-2	± 8 kV contact ±2, 4, 8, 15 kV air
Radiated immunity	IEC 61000-4-3	10 V/m 80 MHz - 2.7 GHz 27 V/m 380-390 MHz 28 V/m 430-470 MHz 800-960 MHz 1700-1990 MHz 2400-2570 MHz 9 V/m 704-787 MHz 5100-5800 MHz
Power frequency magnetic field	IEC 61000-4-8	30 A/m
Close proximity magnetic field	IEC 61000-4-39	8 A/m 30 kHz (CW) 65 A/m

			134,2 kHz (2,1 kHz PM 50%)
			7,5 A/m
			13,56 MHz (50Kz PM 50%)
Electrical transients / bursts	fast IEC 61000-4-4	± 2 kV	100 kHz repetition frequency
Voltage surge	IEC 61000-4-5	Line-to-line: ± 0.5 kV, ± 1 kV Line-to-ground: ± 0.5 kV, ± 1 kV, ± 2 kV	
Conducted disturbances	IEC 61000-4-6	3 V	0.15 MHz – 80 MHz
Voltage dips	IEC 61000-4-11	0 % UT, 0.5 cycle	
Voltage interruptions	IEC 61000-4-11	0 % UT, 0.5 cycle, angle 0°, 45, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT, 1 cycle, angle 0° 70 % UT, 25/30 cycles, angle 0°	

Based on the electromagnetic compliance test results, it can be concluded that foreseeable electromagnetic disturbances will not result in an unacceptable risk/danger to the end user.

FCC ID: 2BHAASUN300

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



CAUTION

Avoid exposure to Radio Frequency (RF) emitters (such as RFIDs (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 results from being

obtained. If you encounter problems (e.g. cannot start/stop the test, interrupted connection with the sensor), 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. concealed RFIDs).

Recycling and disposal

In accordance with the WEEE Directive and EU Regulation 2023/1542, Sunrise will take back old units and dispose of them free of charge. Sunrise 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 retiring this equipment.

Incident reporting

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

Contact

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



Email: support@hellosunrise.com

Address: Sunrise SA, Chaussée de Marche 598/02,
5101 Namur, Belgium