

## About the present user manual
















This user manual is applicable to the Sunrise sleep disorders diagnostic aid (Sunrise SDDA - version 1.13.01 and above) and the Sunrise sensor, an accessory of the Sunrise SDDA. Other company names and product names mentioned in this manual are trademarks or registered trademarks of their respective companies. The TM and ® symbols are omitted in this manual. Revision notes: addition of US metrics and minor wording edits.

## Important notice

Please read the user manual carefully before using Sunrise SDDA and sensor and make sure to use them according to the instructions. Keep this manual for future reference and keep it always together with Sunrise sensor. To ensure user's safety and operations' safety, please read the safety precautions before using Sunrise sensor. In case the present user manual, the accompanying documentation or the warning labels on the equipment are lost or damaged, please contact promptly Sunrise for their replacement.

## Warning labels on the sensor

For user's safety and operations' safety, Sunrise sensor exhibits the following warning labels. The general warning labels are located at the back of the packaging.

	Consult the user manual
	Caution, read carefully the safety precautions of this user manual
	The device must not be thrown with the other household waste
	Keep the device away from water
	Single use
	Permissible temperature range for storage
	Applied part
IP22	Device has ingress rating of IP22 in accordance with IEC 60529 Protection Ingress of solid foreign objects bigger than 12.5 mm / 0.49 in Protection against harmful ingress of dripping liquid when tilted at 15 °
	Catalogue number
	Serial number
	Manufacturer
	Expiry date
	Prescription only
	The device is a medical device
	Unique device identifier
	Non-ionizing electromagnetic radiation

## Intended use and device description

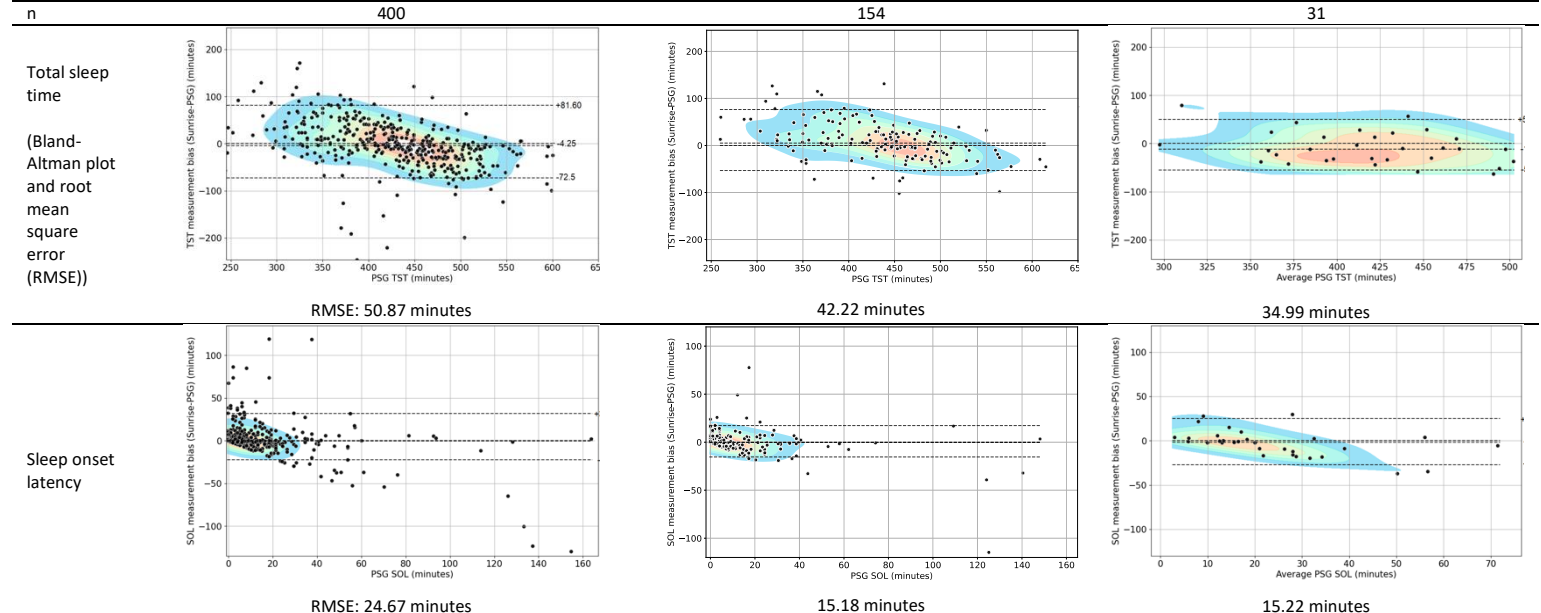
The Sunrise SDDA device is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 18 years and older with suspicions of sleep breathing disorders. The Sunrise SDDA device is a cloud-based software device that analyzes data from the Sunrise sensor placed on the patient's mandible. The device acts by recording patient's responses to questions about their sleep quality. By analyzing patient's mandibular movements, the device also detects obstructive respiratory disturbances, identifies sleep states, notifies about the OSA severity in a categorical format (non-OSA, mild-OSA, moderate-OSA, severe-OSA), generates sleep structure information (namely, total sleep time, sleep onset latency, wake after sleep onset, sleep efficiency, arousal index) and head position discrete states. Data collected by the device is integrated in a report for further interpretation by the healthcare provider.

## Performance summary

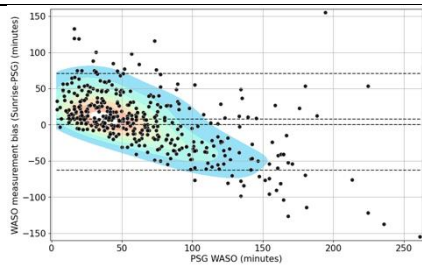
For obstructive respiratory disturbances, diagnostic performance against the gold standard polysomnography has been validated on 154 patients and on 31 patients over 18 years old.

n		154		31	
ORDI	>=5	>=15	>=30	>=5	>=30
Sensitivity	0.91	0.88	0.76	0.96	0.71
Specificity	1.00	0.98	0.83	0.50	0.73
F1 score	0.95	0.93	0.69	0.92	0.53
BAC	0.96	0.93	0.80	0.73	0.71
PPV	1.00	0.99	0.63	0.89	0.80
NPV	0.61	0.85	0.90	0.75	1.00
LR+	Infinite	54.59	4.49	1.92	2.45
LR-	0.09	0.12	0.29	0.08	0.40

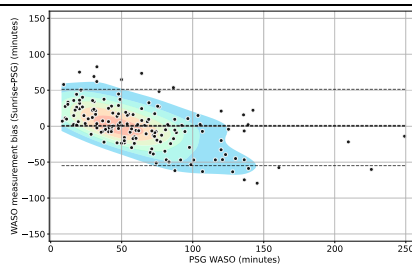
For sleep structure information, agreement against the gold standard polysomnography has been validated on 400 patients, 154 patients and on 31 patients over 18 years old.



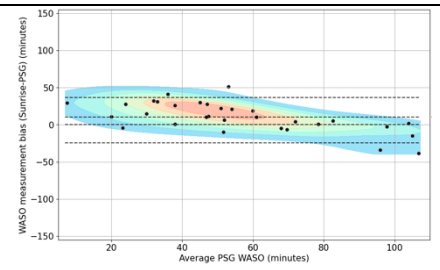
Wake after sleep onset



RMSE: 44.35 minutes

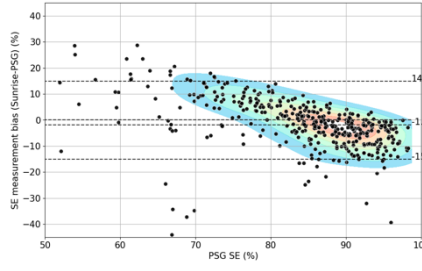


31.14 minutes

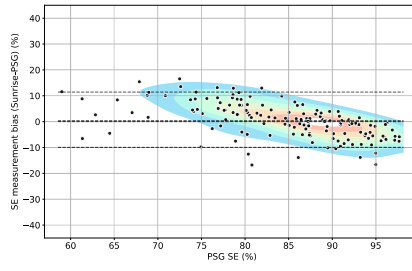


22.30 minutes

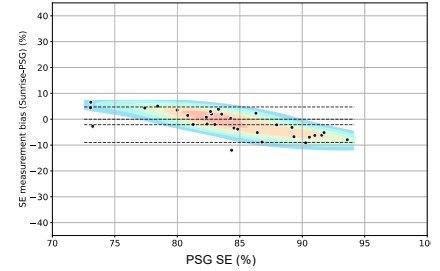
Sleep efficiency



RMSE: 9.84%

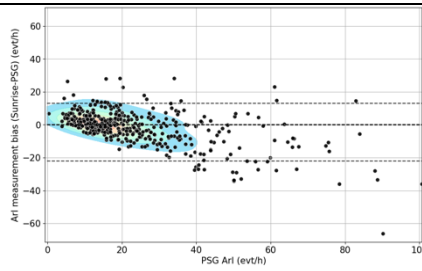


6.65%

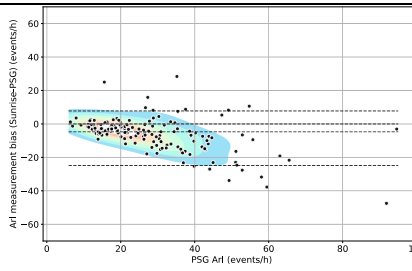


5.13%

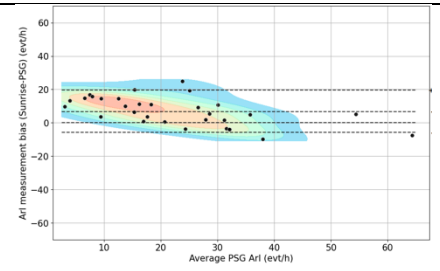
Arousal index



RMSE: 10.79 events/h



13.17 events/h



10.98 events/h

## Expected clinical benefits

The use of the Sunrise SDDA system will allow to quickly and effectively determine if a patient needs to be taken in charge by a healthcare professional in order to treat obstructive sleep apnea. An early medical diagnosis can help to improve the quality of life and to reduce the risk to develop 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, increased risk of developing Alzheimer's disease.

## Contra-indications



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

## Sunrise platform

The Sunrise platform can be accessed by healthcare professionals to consult the data collected by Sunrise SDDA during sleep. Data is accessible once the user has recorded a night and shared his results with the HCP.

Setting up your account: please go on [practitioner.hellosunrise.com](https://practitioner.hellosunrise.com) to sign up.

Viewing user results: the list of Sunrise users who are linked to the HCP account is displayed. If a user wants to share his results with an HCP (by entering the HCP email address in the mobile application) but HCP is not registered, HCP will receive an email to sign up. Please click on the magnifying glass icon to the right of a user name to access the night list of the corresponding user. Detailed results of a particular night are available when clicking on the magnifying glass icon to the right of that particular night. After each night spent with Sunrise sensor for one of the users linked to HCP account, HCP will receive an email notifying him that results are available.

Supported web browsers: Google Chrome, Safari, Microsoft Edge, Firefox. It is recommended to use one of these browsers. Should you observe a problem on any other browsers or browser versions, please report this problem to [support@hellosunrise.com](mailto:support@hellosunrise.com).

## Sample report

### Sleep structure ∨

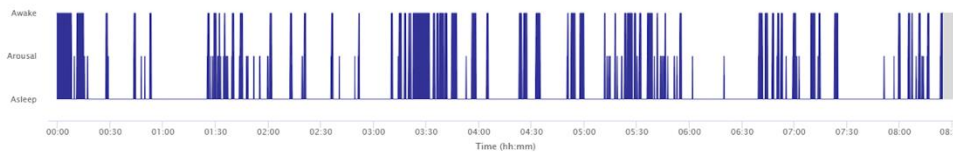
Total sleep time 6 hours 49 minutes

Arousal index 22.1 per hour

Sleep onset latency 15 minutes

Wake after sleep onset 83 minutes

Sleep efficiency 80%



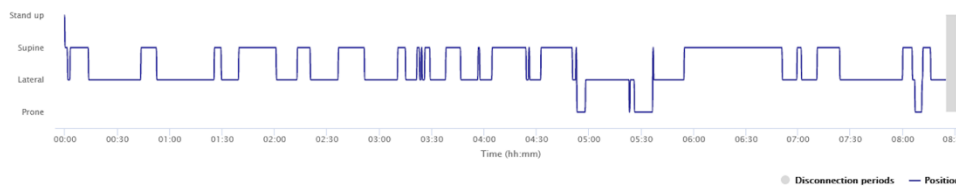
Disconnection periods Sleep states

### Obstructive respiratory disturbances ∨

Obstructive respiratory disturbances

Non-OSA Mid-OSA Moderate-OSA Severe-OSA

Position changes	5.3 per hour
Sleep time in supine position (% of TST)	40%
Sleep time in non supine position (% of TST)	60%



## What's in the box?

The Sunrise box contains the sensor, a quick start guide, a measuring tape, adhesive bandages and this user manual.

## Functional description

In order to measure the physiological parameters during sleep, movements are recorded via the sensor placed on the chin. These data, associated with the user data introduced in the mobile application downloaded by the user on a smartphone, are analyzed by a proprietary and dedicated software. The healthcare professional can access the cloud platform in order to consult the measured physiological parameters. The app on the smartphone allows: the introduction of the user data, the data acquisition and the encrypted data transfer to the cloud server. A wireless connection (Bluetooth low energy) is established between the sensor and the smartphone. At the end of your night, a wireless connection (Wi-Fi or 3G/4G connection) allows communication between the smartphone and the cloud server.

## Warnings, safety and cybersecurity precautions

To ensure user's safety and operations' safety, please read the safety precautions before using Sunrise SDDA and Sunrise sensor. The following signs are used in the present user manual:



Indicates a potentially hazardous situation which, if not avoided, could result in serious injury or possibly death



Indicates a potentially hazardous situation which, if not avoided, may result in minor to moderate injury or equipment damage



Emphasizes additional information that is provided to ensure the proper use of Sunrise

Sunrise recommends not to use the sensor close to electrical and magnetic fields (e.g. magnetic resonance imaging, microwaves), as it may affect measurements. The sensor may affect other electronic and medical devices. The sensor contains a lithium battery. As with any other battery, if the internal elements of the battery are damaged, it can sink, overheat or result in a fire. Please make sure to follow these instructions carefully: replacing the battery requires the intervention of a specialized staff who is approved by Sunrise; do not expose the device to the fire or to temperatures exceeding 40°C; do not leave the sensor in a vehicle or directly exposed to sun; do not expose the sensor to water or humidity, nor handle it with wet hands - if a liquid enters the sensor, do not use it; do not submit the sensor to important shocks; do not use a damaged device, as the battery protective casing could be damaged or drilled; do not use the device if the battery leaks - in case leaked liquid has been in contact with your eyes or your skin, rinse with clear water immediately, for at least during 15 minutes, and consult a practitioner - clean also any contaminated clothes. If water gets in contact with the sensor, wipe the water away immediately to avoid any rust.



Sunrise SDDA and sensor are exclusively designed as an aid for the diagnosis of sleep disorders. Any other use of Sunrise SDDA or sensor has neither been tested nor approved. The use for any other purpose could cause incidents.



Do not use on patient below 18 years old



Do not use accessories, detachable part and materials not described in this instruction for use as it could be unsafe



Do not interconnect the sensor to other equipment not described in this instruction for use as it could be unsafe



Sunrise 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.



Do not place the sensor in your mouth or swallow it as you could suffocate



Provide accurate answers to questions in the app since it could affect the outcomes of the test



Once the user data have been introduced, only the person designated in the data is allowed to perform the test



Do not use the sensor with a pacemaker or similar implanted device since it could impair its functioning



Do not use the sensor close from radio frequency sources such as electromagnetic security systems, cellular telephones, RFID or other in-band transmitters. Electromagnetic disturbances could result in loss or degradation of essential performances and would lead to an absence of results.



Sunrise sensor has to be transported in its dedicated box. The sensor is fragile, it is recommended to carry it carefully.



Make sure that Sunrise sensor is at no risk of falling in the event of a natural disaster (e.g. earthquake). If the sensor falls over, it may result in malfunctioning. In such case, stop using the sensor and please contact Sunrise immediately.



If the sensor housing is damaged, the sensor cannot be used. In such case, the correct functioning, results measurement and operator safety are not guaranteed anymore. Please contact Sunrise immediately.



Store the unpacked sensor away from light since it could affect adhesive efficacy



Make sure the skin is clean, free of soap residue and lotion, allowed to dry thoroughly before applying the sensor and/or the dressing to prevent skin irritation and to ensure good adhesion



Keep Sunrise sensor away from children and pets to avoid accidental swallowing



Keep Sunrise sensor away from pest to avoid damaging the sensor



Do not remove the battery stripe of the sensor before applying it on the chin



Do not use Sunrise sensor when travelling (in a plane, train or other), as it could affect its correct functioning



Sunrise sensor may cause allergy to persons sensitive to the following materials: 3M adhesives. Do not use the sensor on patients with known allergies to these materials.



Avoid removing the sensor once it has been attached to the chin as it may affect the adherence properties of the sensor



Use a new adhesive bandage if you have to remove the previous one as this could impact adherence properties of the bandage



Do not modify the Sunrise sensor since it could make the device unsafe and lead to a degradation of its essential performances



Do not share or write down your app password as it could allow unwanted access to your medical record



Do not share or write down your platform password as it could allow unwanted access to your patient medical records



If you are working on a shared-computer, please log-off when you are done using Sunrise platform as it could allow unwanted access to your patient records



Only use Sunrise app available on the App Store or on Google Play. App available from other sources are not provided by Sunrise and could cause a cybersecurity threat.

## Residual risk and side-effect

The performance of the algorithm has been assessed as satisfactory compared to the gold standard. However, Sunrise SDDA is an aid in diagnosis. Thus, the decision to perform treatment shall not be done on the sole basis of Sunrise SDDA results.

The Sunrise sensor and film dressing are biocompatible. However, we cannot exclude that users may have allergic reaction.

## Installation

Prerequisite: Sunrise SDDA requires the user to be able to use a smartphone (Android or iOS). This smartphone must be loaded, have an internet connection (Wi-Fi or 3G/4G) to perform the test and access the results. Please check that there is enough free space on the smartphone memory to be able to install the app (at least 500 MB). Sunrise SDDA and sensor can be used in home and hospital environment. The Sunrise sensor is ready to be used. There is no treatment or handling of the device to perform.

Set-up location and environment: please use Sunrise sensor in a normal environment only. If Sunrise sensor undergo drastic environmental changes (e.g. during transport or shipment), please make sure not to operate the sensor prior to sufficient acclimatization.



Do not run the sensor in an environment with risk of explosion, as in an environment rich in oxygen or in the presence of other flammable agents.

Do not use the sensor in a scanner with magnetic resonance imaging (MRI).

Do not run the sensor in the presence of a defibrillator.

Do not plunge the sensor into water or any other liquid and do not pour liquid on the device.



Sunrise mobile app is compatible with iOS 12+ and Android 6+.

Setting up your Sunrise SDDA and sensor: before going to sleep, please connect the smartphone to the power supply for the night. After switching on the smartphone, please download the Sunrise app from the iOS or Android app store. Please create an account and enter your first name, last name, email address, password, gender, date of birth, height, weight, neck circumference (please use the provided measuring tape to measure it) and confirm. Then, please answer questions related to your sleep and please confirm. After, you will be asked to review and approve the consent form for the processing of your personal data by checking the "I consent to the processing of my data under these conditions" box and then clicking on the "Next" button. To start a new night, please pair the sensor and your smartphone by scanning the QR code on the sticker. Then, remove the battery stripe and follow the illustrated step-by-step instructions to place the sensor on your chin (horizontally in the middle of the chin, skin must be cleaned with soap before sticking). A new screen will appear with a short explanation on how to start the test. At that point, you can push the "Start recording" button. This will start the test and the "Recording started, have a good night!" confirmation text will appear on your screen within seconds. You can now go to sleep, leaving the smartphone in your bedroom.

During the next 15 minutes, you will have the possibility to cancel the recording by pushing on the return button, at the bottom of the smartphone. After 15 minutes, the "End test" button appears in red on the screen. You can stop the test by clicking it. Please note that the test can only be relaunched during the same night and if previous tests do not exceed 60 minutes.

During the night with Sunrise SDDA and sensor: data are automatically collected, there is no additional manipulations needed. Please see the section "Use of the app" for more details about the app.

When your night is over: please click on the "End test" button and confirm. You will have the opportunity to leave a comment about your night, that will be communicated with the night data. After a few seconds, the app will automatically restart, and the "Home" screen will appear. Feedback about your night will be available maximum 48 hours after data have been sent. Please see our troubleshooting section if you encounter any trouble.

## Use of the app

Settings: you can access practitioner and profile settings in the down right corner of the screen.

## Frequently asked questions

This section will answer the questions you might have regarding Sunrise SDDA and sensor. Please review also the "Troubleshooting" section for further technical questions.

What if ...	
I don't know precisely my weight and/or size.	Please make sure to indicate a value as close as possible to reality in order to guarantee the results accuracy.
I wear a beard.	The sensor may not be suited for bearded users. Close shaving or usage of the provided film dressing is advised to ensure optimal adhesion.
I wear a night cream.	Sunrise sensor is suitable for night cream application except thick creams that might leave the skin too slippery and prevent the effective sticker adherence.
I'm afraid of feeling something with Sunrise.	You won't feel anything. No wave or electric current is transmitted from the sensor to your skin. Sunrise sensor is certified compliant to the latest standards for electrical safety.
I usually sleep on my stomach.	Sleeping with Sunrise sensor does not require any specific position.
I often get up during the night (to go to the toilets, to drink, etc.).	You can get up during the night without taking the smartphone with you. Sunrise sensor will reconnect automatically.
I have forgotten to stop the recording when I woke up.	The recording will automatically stop after 15 hours. Please contact Sunrise.
The sensor came off during the night.	Please contact Sunrise.
The sensor felt on the floor.	Please contact Sunrise.

Before sleeping, I always read, watch TV, etc.

Sunrise sensor can be fixed on your chin before these activities. However, we recommend you to push the "Start recording" button after finishing these.

When will I receive the results of my night(s)?

Your complete results will be available within 48 hours.

I don't have an email account.

Please contact Sunrise.

## Cleaning and maintenance

As the device is single use there is no cleaning and maintenance operations to perform. If you notice any damage on the device, please contact Sunrise.

## Reprocessing



Reprocessed sensor by other companies than Sunrise could pose several risks: the electrical safety can't be guaranteed. Moreover, essential performances may not be achieved and could lead to an erroneous interpretation by the Sunrise SDDA. Firmware may be not up-to-date with last safety and security updates. Thus they will not be compatible with Sunrise SDDA.

## Disposal and environment

Sunrise will take old sensor back and dispose them off free of charge. The sensor should not be thrown in a general household waste bin. Please contact Sunrise for advises when retiring the equipment. Moreover, Sunrise aims at restricting the use of hazardous substances in its electronic and electrical equipment, according to the European Union's directive on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

## Warranty

If, upon delivery from Sunrise to the customer, the sensor presents a defect, Sunrise will replace it at no charge. Sunrise is not responsible for malfunctions resulting from (the following list is non exhaustive): improper handling; repairs or modifications made by any person other than Sunrise or a third party approved by Sunrise in writing; device use in combination with hardware or software other than that designated by Sunrise; factors and causes unrelated to the device itself; device use under severe conditions such as harsh environments, with high temperature, high humidity, corrosive gas, vibration, etc.; fire, earthquake or other forces of nature, or any other force majeure event, including wars, riots and crimes.

## Limitation of liability

In no event will Sunrise be liable for any lost revenue, profit or data, or for special, indirect, consequential, incidental or punitive damages, however caused regardless of the theory of liability, arising out of or related to the use of or inability to use the device, even if Sunrise has been advised of the possibility of such damage. In no event will Sunrise' liability, whether in contract, tort (including negligence) or otherwise, exceed the amount paid for the service.

## Technical specifications of the Sunrise sensor

Dimensions	46.5 x 20.0 x 5.6 mm / 1.8 x 0.8 x 0.2 in
Weight	3 g / 0.1 oz
Transport conditions	Temperature range: -25 °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 70 °C at a water vapor pressure up to 50 hPa
Storage conditions	Temperature range: +10 °C to +27 °C at a non-condensing relative humidity between 40 % and 60 %
Operation conditions	Within temperature: +5 °C to +40 °C Relative humidity range of 15 % to 90 %, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa

## Wireless specifications of the Sunrise sensor

Functions and technology	The Sunrise mobile app allows the patient to connect to the Sunrise sensor, control it and retrieve data from it. The Sunrise 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- Did you remove the battery strip from the sensor? If not, please remove it. 2- Did you see a flashing light when you removed the battery strip? If not, please contact the 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 no, 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.
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 / 1.1 yards meter of the sensor or smartphone. Please keep all sources of radio frequency interference away from the test location.

## Electromagnetic compatibility and telecommunications standards compliance

The Sunrise sensor has been tested according to IEC 60601-1 et IEC 60601-1-2.

Electromagnetic immunity	Phenomenon	Immunity test levels	Compliance level
	Electrostatic discharge (IEC 61000-4-2)	± 6kV contact ± 4kV air	± 6kV contact ± 4kV air
	Radiated RF EM fields (IEC 61000-4-3)	10 V/m 80 Mhz-2,7 GHz 80% AM at 1 kHz	10 V/m 80 Mhz-2,7 GHz 80% AM at 1 kHz
	Rated power magnetic field (IEC-61000-4-8)	30 A/m 50 Hz and 60 Hz	30 A/m 50 Hz and 60 Hz
	Specific conditions for Broadband data transmission systems (ETSI EN 301 489-17)	3 V/m 2.7 GHz to 6.0 Ghz	3 V/m 2.7 GHz to 6.0 Ghz

The Sunrise sensor contains the FCC ID: SH6MDBT42V.

## Warnings and cautions linked to wireless functions



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 may prevent results from being obtained. If you encounter problems (e.g. cannot start/stop the test, interrupted connection with the sensor), please discard 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).



Leave the smartphone in your sleeping room during the test, to make sure it can detect the sensor appropriately. Keep a distance of maximum 3 meters.



Do not place your smartphone closer than one meter from your sensor since it could impair its functioning



Do not place any Bluetooth device closer than one meter from your sensor since it could impair its functioning



Do not place your smartphone in plane mode, since data will be sent to your smartphone all along the test

## Error messages in the Sunrise mobile app

Please verify your connection setting and try again	The phone is not connected to Wi-Fi or 3G/4G
The action could not be completed, please try again	An internal problem has occurred
Your email does not seem to exist in our database	No account exists with the email address entered
Your password is incorrect	The password entered does not match the password of this account
Please answer all questions	One or more questions displayed on the screen are unanswered
To continue, please review and acknowledge the informed consent and privacy policy	Sunrise's consent must be accepted in order to register
No sensor was found, please try again	No sensor matches the scanned QR code
Please turn the bluetooth on	The app could not connect to the sensor because the phone's Bluetooth is disabled
You are already linked with this practitioner	The link with this practitioner is already present in the database and it is not possible to duplicate it

## Troubleshooting

Please see the table below in case of trouble with your device. If the solution is not listed below or if you remain unable to solve the problem, please contact Sunrise. In case the device must be returned to Sunrise, please make sure to include the sensor and all accessories in order to allow full understanding of the problem.

What if ...	
I cannot move forward or go back in the application	The application is not responding. Restart the application.
I cannot remember my password	Click on "I forgot my password" to receive an email and reset your password
I cannot see my past nights feedback	There is no signal where you are. Please find a place where there is signal or configure the available internet connection. The data are not available yet. The data will be available within 48 hours after you end up the test.
I didn't received my results after 48 hours	Please check the test status. If status is "sending", please check your internet connection. If status is "analyzing", please contact Sunrise.

## General usage comments

Please make sure to use the Sunrise SDDA and sensor only as instructed in the present user manual. Please do not open the sensor make any modifications that has not been authorized by Sunrise. Unauthorized handling can result in maladjustments or other damages, which in turn can lead to incorrect results.

## Contact

In case of any trouble regarding Sunrise, please contact Sunrise:



Email: [support@hellosunrise.com](mailto:support@hellosunrise.com) - phone: +32 81 26 11 26

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