SANSA™

BY HUXLEY™

Instructions for Use

Contact Information

Huxley Medical, Inc.
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Atlanta, GA 30318
1-(888)-726-7239
huxleymed.com

For assistance, if needed, in setting up, using or maintaining the Sansa™ device, or to report unexpected operation or events, please contact Huxley Medical's Customer Service team at 1-(888)-726-7239 or visit huxleymed.com for online support.

Terms & Conditions

This License Agreement represents the complete and exclusive understanding between you and Huxley Medical, Inc. The document can be viewed at:
https://huxleymed.com/terms-and-conditions/
This product and/or method of use is covered by one or more of the U.S. patents listed at:
https://huxleymed.com/patents/

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General Information

Indications for Use

The Huxley Home Sleep Apnea Test (Sansa™) is a wearable device intended for use in the recording, analysis, and storage of biophysical parameters to aid in the evaluation of sleep-related breathing disorders of adults suspected of sleep apnea.
The device is intended for the clinical and home use setting under the direction of a Healthcare Professional (HCP).

Precautions

1. Do not use the Sansa™ device if package appears damaged or tampered with, or if the device appears damaged.
2. Safety and effectiveness of the Sansa™ device has not been established on patients receiving permanent pacing therapy.
3. Do not touch the terminals on the Patch or Sensor Pod, and do not let them touch other conductive parts or earth. This may damage the device.
4. Avoid using the Sansa™ device under bright light sources to minimize interference that may result in no or inaccurate readings.
5. Avoid using the Sansa™ device over a tattoo, as the pigment may result in no or inaccurate readings.
6. Proper skin preparation and device placement is critical. Presence of makeup, oils, dirt, or hair under the Sansa™ device may result in no or inaccurate readings. The skin preparation and device placement instructions must be followed.

Contraindications for Use

1. Known allergic reaction to medical adhesives or hydrogels or a history of adhesive skin allergies
2. Use in critical care settings
3. Use in a magnetic resonance (MR) environment
4. Use in an electrosurgery environment
5. Use in an explosive atmosphere or in the presence of flammable anesthetics or gases
6. Use on broken or injured skin
7. Use with a pacemaker that is permanently paced
8. Use with Defibrillators
9. Use with RFID equipment
10. Severe chronic obstructive pulmonary disease (COPD)
11. Respiratory muscle weakness
12. Awake or sleep-related hypoventilation
13. Significant non-respiratory sleep disorders

Notes

1. The Sansa™ Charger is used in a non-patient environment only.
2. The Sansa™ device can only connect to the charger after being removed from the patient.
3. The Sansa™ equipment is not affected by exposure to dust or lint normally found in household environments.
4. Exposure of sunlight to the Sansa™ equipment during use does not affect the use of the device.
5. The Sansa™ device is designed to contact intact patient skin for a period of less than 24 hours. The device has been tested and found to be biocompatible for cytotoxicity, sensitization, and irritation. Therefore, it is safe for use on all individuals, after considering the contraindications, restrictions, and precautions listed.

Warnings

1. Prior to use, read all package insert instructions and precautions.
2. Do not use the Sansa™ device if you have a known allergic reaction to medical adhesives, silicone, or hydrogels or a history of adhesive skin allergies.
3. Do not reuse the adhesive Patch or use the device on anyone other than the intended patient. Single patient use only. Reuse or unintended use will cause incorrect patient data and may cause skin irritation.
4. Do not apply the Patch without completing the skin preparation step.
5. Misapplication of the Sansa™ device with excessive pressure for prolonged periods can induce pressure injury.
6. The Sansa™ device is MR Unsafe! Do not expose the Sansa™ device to a magnetic resonance (MR) environment.
7. Do not open the foil pouch until you are ready to conduct the study.
8. Do not use if package is damaged.
9. Do not tamper with or disassemble the device.
10. No modification of this equipment is allowed. Significant patient hazards could result from modification.
11. Do not shower while wearing the device.
12. Use only manufacturer approved equipment. Do not use any cables, power cords, or other accessories other than the ones provided.
13. Only connect the components as described in the manual. Never connect the Patch to any external electrical item other than the supplied Sensor Pod.
14. Keep device, accessories, and packaging away from young children or pets. There is a danger of choking if the device and/or accessories are swallowed. There is a danger of strangulation if the Sansa™ Charger's cable is misused.
15. Do not use a heated blanket while wearing the Sansa™ device.
16. Use the UL listed power supply provided with the Sansa™ Charger or an equivalent UL-62368-1 certified USB A power supply providing 5V and at least 500mA current. Only authorized personnel may charge the Sansa™ device. Failure to heed this warning may cause permanent damage to the equipment.

Restrictions for Use

1. The Sansa™ device shall only be used in accordance with physician's instructions.
2. Only qualified medical personnel shall authorize the use of the Sansa™ device.
3. In the event of equipment malfunction, all repairs shall be executed by authorized Huxley Medical personnel or licensed service agents.
4. The Sansa™ device in whole, or in part, shall not be modified in any way.
5. The Sansa™ device is used as an aid for sleep diagnostic purposes only and shall not be used for monitoring. The ECG waveform output is not intended for diagnostic use for cardiac conditions.
6. Only suitably trained and qualified personnel shall be authorized to prepare the Sansa™ equipment prior to use.
7. The patient is an intended operator. The patient shall use the Sansa™ device in accordance with the User Manual. The patient shall not perform any servicing or maintenance.

Kit Contents

The Sansa™ device comes packaged in a kit with the following components:

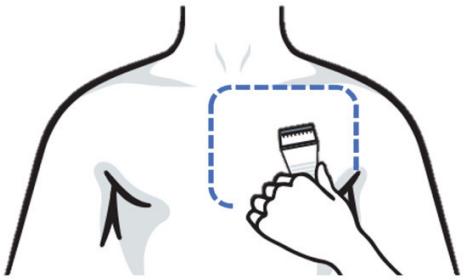
Additionally, the Sansa™ system has a custom charger and a preferred UL-certified power block. The Sansa™ Charger can be used with any UL-62368-1 certified USB A power supply providing 5V and at least 500mA current. When charging, do not position the Sansa™ device and charger such that it is difficult to disconnect from power.

Using the Sansa™ device

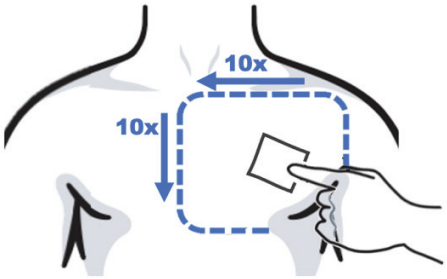
1 Skin Preparation

It is critical to prepare the skin prior to applying the Patch.

1. Wash the area outlined in blue below with soap and water, then dry thoroughly. Do not apply any lotions, oils, or perfumes.
2. If hair is present, remove the hair from the area. A razor is provided but personal hair removal products may be used. After shaving, wash and dry the area.



Remove hair if present.



Exfoliate cleaned area.

3. Exfoliate the cleaned area with the provided pad by wiping 10 times vertically and horizontally to remove any loose skin cells.
4. Clean the area with the provided alcohol wipe. Allow the area to dry completely.

It is normal for the skin to look more red than usual after cleaning.

2 Connect the Sensor Pod to the Patch

Latch the Sensor Pod onto the Patch.

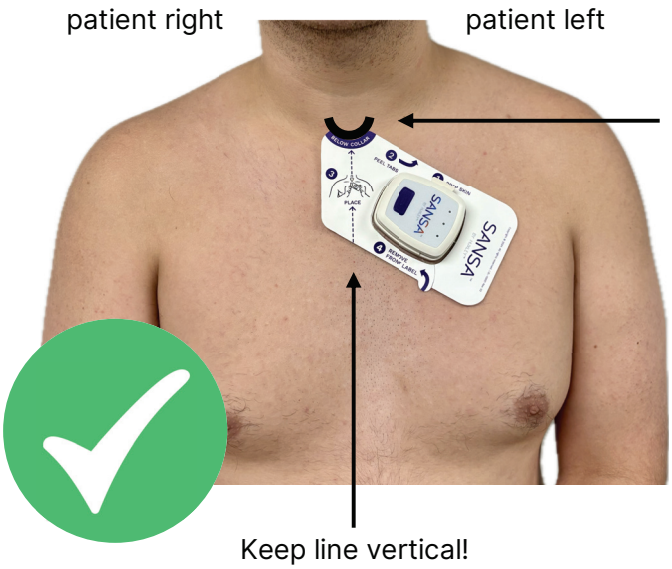
Using the Sansa™ device

WARNING: Prepare Skin First!

Do NOT place the Patch without following the skin preparation steps listed on the previous page!

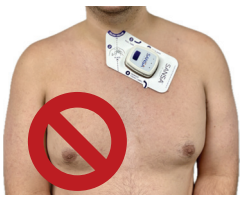
Do NOT open the foil pouch until you are ready to conduct the study.

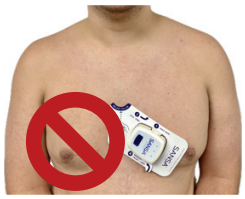
Review CORRECT Patch placement before removing liners and applying to chest.



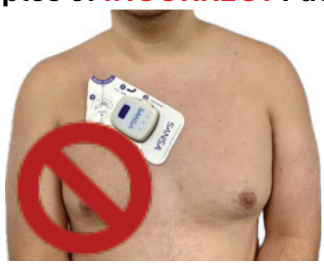
Align the device to the bone at the base of the neck at the intersection of the collar bone.

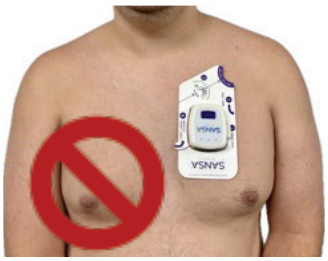
The device must be placed with the "keep vertical" arrow within ±15° of vertical and the "align to base of neck" arc within ±1-inch left-right and within ±1-inch up-down of the bone at the base of the neck.

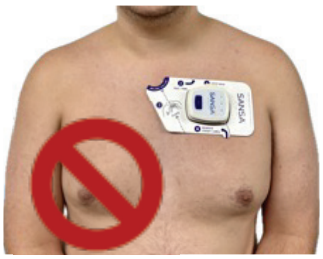

Too high!

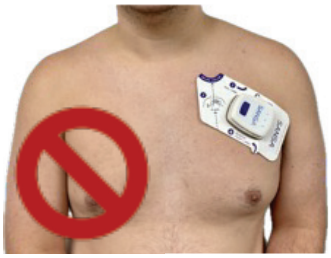

Too low!

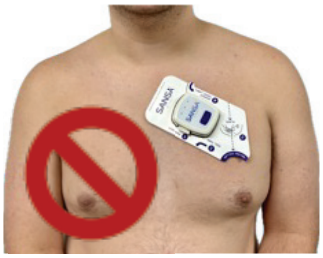
Examples of INCORRECT Patch placement.

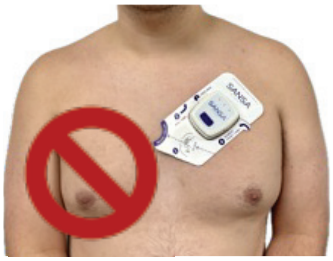

Wrong side of chest!


Rotated!


Rotated!


Too far from center!


Upside down!

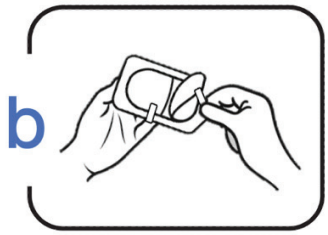

Rotated!

Using the Sansa™ device

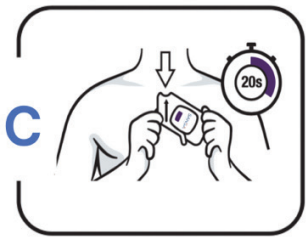
3 Apply the Patch to the Chest

Note: IMPORTANT – Once the Patch is on your skin, DO NOT adjust its position.

a Familiarize yourself with the placement images on the previous page and the instructions on the Patch itself. You may find it easier if you use a mirror to help you with the placement, or if someone assists you.

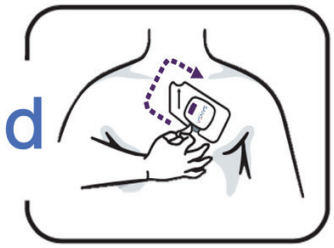


Remove **both** backings from the Patch using the two tabs.



Align notch on template to base of neck. Press on Patch edges, and firmly press on the device for 20 seconds.

NOTE: Patch adheres to skin at an angle.



Use tab to peel off template in a circular motion. Press on device for 10 seconds. Use fingers to smooth out any wrinkles.

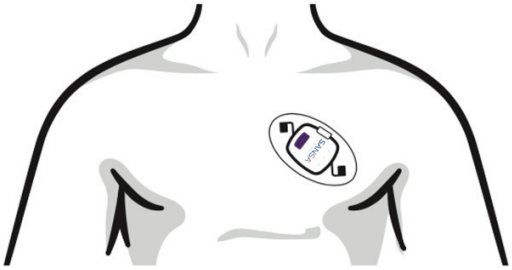
Minor discomfort may occur when the Patch is attached to the skin. If you have sensitive skin, this device may not be appropriate for use.

4 Using the Device

Understanding the User Interface
The device contains 3 lights and a button.

Turn on the Sensor Pod
Power on the device by pressing the button. When first powering on, the leftmost light will first be white and then turn green when the recording has started. After the first 5 minutes, the lights will turn off, but the device will continue recording.

If there are any errors, one or more of the lights on the device will illuminate orange. For more details on possible errors or to troubleshoot a particular error, see the Troubleshooting section.



The patch should be on the left side of the chest with the template removed.

Once the device is correctly adhered to the body and powered on, you are ready to begin your sleep test. The device will be recording data throughout your entire sleep.

If you wake up in the middle of your sleep, but plan to continue sleeping, do not remove the device.

NOTE: The Sansa™ device is not equipped with a physiological alarm system. Therefore, there shall be no alarms for low SpO_2 or other physiological states.

5 Guidance on Daily Activities

The device is not waterproof!

Showering:

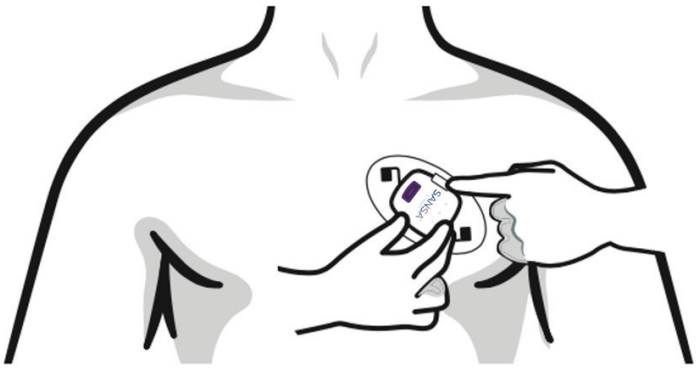
Do not shower while wearing the device.

Do not immerse the device in water (bathtub, pool, jacuzzi, etc.).

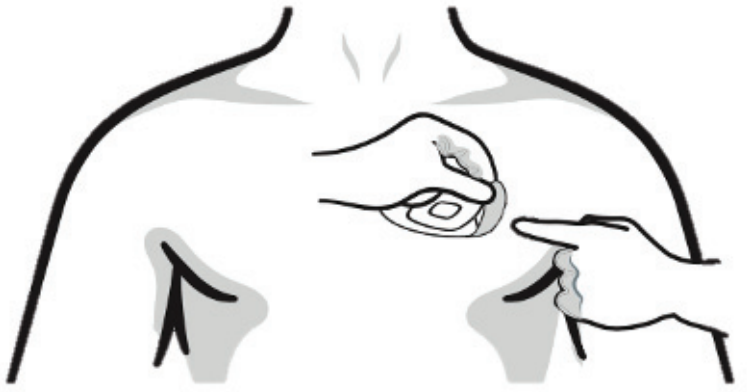
Cleaning the Device:
The device does not require cleaning during routine use. If the surface becomes dirty, the outer surface of the Sensor Pod may be gently wiped with a damp cloth or an isopropyl alcohol wipe. Allow it to dry before use.

6 Removing the Device

Remove the Sensor Pod from the Patch
When your monitoring period is complete, remove the Sensor Pod from the Patch and place it back in the shipping box to return.
Gently press latch on Patch to release Sensor Pod.
The Sensor Pod will automatically power off after 10 hours.



Remove the Adhesive Patch
Gently peel at one end of the Patch to lift an edge. Pull the edge with one hand and use your other hand to support the underlying skin.
Some adhesive residue may remain after the Patch is removed. Wash the skin with soap and water, then pat dry.



7 Returning the Device

Do not dispose of the Sensor Pod. It is critical that you return the Sensor Pod back to Huxley.
Dispose of the Patch in accordance with local regulations.

Place the Sensor Pod back into the kit box that it arrived in, ensuring it goes back into the corresponding pocket that it arrived in.

Once the box has been repacked, seal the kit by removing the liner on the tape on the box and fold the lid down over the exposed tape. Apply pressure to ensure good contact.

The box contains a prepaid shipping label. Drop it off at the nearest shipping carrier indicated on the return label located on the back of the box.

Charging the Device

The Sansa™ device must be charged every time the Sansa™ device is prepared for use. The Sansa™ device must be charged using the Sansa™ Charger provided. The Sansa™ Charger can be used with the AC adapter provided or an equivalent UL-62368-1 certified USB A power supply providing 5V and at least 500mA current.

Only authorized personnel may charge the Sansa™ device. Failure to heed this warning may cause permanent damage to the equipment.

To charge the Sansa™ device:

1. Latch the Sansa™ device into the Sansa™ Charger.
2. Connect the Sansa™ Charger to the power supply.

The battery level will be indicat

ge Level:

- Actively charging
- Less than 50% charge

Visual Cue:

- Left light is solid white
- Middle light is blinking blue
- Right light is off

Charge Level:

- Actively charging
- Greater than 50% charge

Visual Cue:

- Left light is solid white
- Middle light is solid blue
- Right light is blinking blue

Charge Level:

- Fully charged

Visual Cue:

- Left light is solid white
- Middle light is solid blue
- Right light is solid blue

Charging takes approximately 1.5 hours.

Troubleshooting

Verifying Equipment Operation

The Sansa™ device contains a built-in self-diagnostic procedure that runs whenever the device is first powered on. This test is used to verify equipment operation prior to use. If the device fails any checks, an error message will be displayed.

Error Messages

The device may experience the following errors:

Error Description:
Low Battery
Visual Cue:
Left light flashes orange
Solution:
The device does not have sufficient battery life to support a study. Contact Customer Service at **1-(888)-726-7239** to get a replacement kit mailed to you.

Error Description:
Poor device contact
Visual Cue:
The left and right lights are orange.
Solution:
Revisit the previous steps to ensure the Patch is well adhered to the body, properly placed, and the Sensor Pod is fully latched. For more assistance, contact Customer Service at **1-(888)-726-7239**.

Error Description:
Critical Error
Visual Cue:
At least one light is orange in a configuration other than the two error configurations detailed previously.
Solution:
Contact Customer Service at **1-(888)-726-7239**.

Symbols Used on the Product Labels

Symbol	Description
	Type BF Applied Part The entire Sansa™ device is considered a BF type applied part.
	Do not re-use
IP24	Ingress Protection rating of 24 The device is protected against solid objects greater than 12.5mm (10N of force) and protected against water splashes from any direction.
	Manufacturer
	Catalogue Number
	Serial Number
	Lot Number
	Follow Instructions for Use
	Consult Instructions for Use
	Prescription Use Only. Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.
	Use-by Date
	Temperature Limitations
	Humidity Limitations
	Do not use if package is damaged and consult Instructions for Use
	Keep dry
	RF Transmitter
	Device is registered with the United States Federal Communications Commission under the unique identified referenced. For legal sale of wireless devices in the United States, manufacturers must have the device evaluated by an independent lab to ensure it conforms to FCC standards.

Sansa™ Specifications

FDA Classification	
Regulatory Class	Class II
Product Code	MNR (Ventilatory Effort Recorder)
Regulation Number	21 CFR 868.2375
IEC 60601 Classification	
Type of Protection	Internally Powered
Degree of Protection	Type BF Applied Part (not defibrillation-proof) Transit-Operable Body-Worn
Physical - Patch	
Length	131 mm
Width	74 mm
Thickness	11 mm
Weight	13 g including liners
Use Duration	Single-use disposable
Physical – Sensor Pod	
Length	60 mm
Width	51 mm
Thickness	16 mm
Weight	45 g
Typical Operation Time	One (approximately 10 hours) sleep study
Expected Service Life	Three years
Servicing, Maintenance, and Reprocessing	The Sansa™ Sensor Pod is reprocessed for multiple uses. Servicing, maintenance, and reprocessing is to be conducted only by Huxley Medical, Inc.
Physical – Charger and Power Supply	
Expected Service Life	Three years
Power	
Type	Rechargeable lithium-ion polymer battery not user serviceable
Charger Isolation	Class II double isolation provided via external power supply
External Power Supply	5V DC adapter, at least 500mA current with USB-A Connector; UL-62368 certified
Environmental Conditions	
Operating Temperature	5° to 40° C
Operating Humidity	15-90% (non-condensing)
Operating Pressure	700 to 1060 hPa
Transport Temperature	-20° to 60° C
Transport Humidity	Up to 95% (non-condensing)
Storage Temperature	10° to 27° C
Storage Humidity	Up to 95% (non-condensing)

Shelf Life – Patch	12 months
Ingress Protection	IP24
Method of Sterilization	Device provided non-sterile
Warm up / Cool down Period	There is no time required to wait before using the device when transported or stored at the extremes of the temperature ranges listed above.
Data Acquisition	
Channels	Oxygen Saturation (SpO_2) ECG Heart Rate (ECG-Derived) Respiratory Effort Chest Movement Actigraphy Body Position Snoring Sleep Staging
Performance	
SpO_2 Accuracy	$A_{rms} \leq 3\%$ (in range 70%-100%)
SpO_2 Resolution	1%
Body Position Classification	5 discrete states: Left, Right, Prone, Supine, Upright
Sleep Staging Classification	2 discrete states: Wake, Sleep
ECG Sample Rate	250Hz
Heart Rate Accuracy	$A_{rms} \leq 3$ BPM (in range 30-250 BPM)
Heart Rate Resolution	1 BPM
Heart Rate Calculation Method	QRS detection is performed by applying two moving averages to pre-processed ECG signal. Pre-processing utilizes Stationary Wavelet Transform and a wavelet-based denoising method. Additionally, segments of the signal are identified as having low quality for accurate QRS detection by comparing the power of clean QRS complexes to the overall signal power. Heart rate is calculated by averaging the time intervals between consecutive QRS complexes within a moving window. In cases where the ECG quality is deemed poor based on the previously mentioned Signal Quality Index (SQI), the heart rate measurement is flagged.

Essential Performance

Essential Performance of the Sansa™ device is defined as accurate collection of ECG and PPG data. In the event that the device cannot collect data, an indication will be provided notifying the patient that the device is not collecting data.

PPG Sensor Hardware Specifications

The emitted wavelengths range from 600 to 1000 nm and the peak optical power is less than 25 mW. Information about the wavelength range can be especially useful to clinicians.

NOTE: A functional tester cannot be used to assess the accuracy of the internal pulse oximeter.

SpO_2 Accuracy

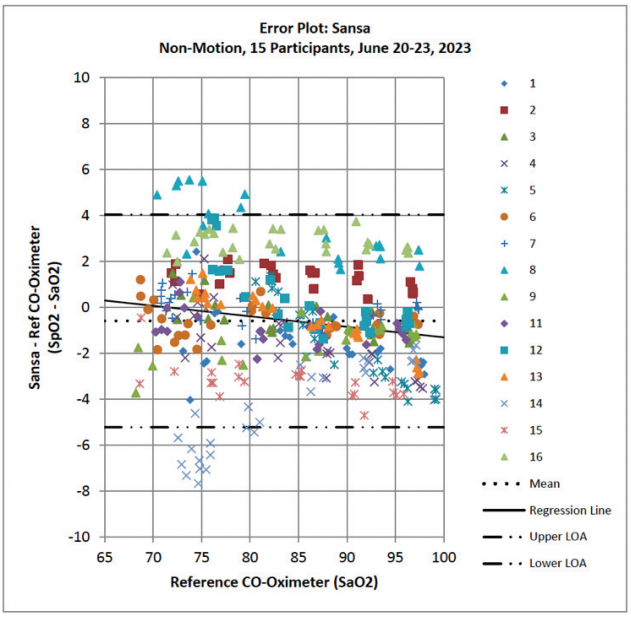
The Sansa™ device is calibrated to measure functional oxygen saturation of arterial hemoglobin (SpO_2). The SpO_2 accuracy of the Sansa™ device was characterized under a controlled desaturation study per ISO 80601-2-61, comparing Sansa™ performance to SaO2 derived from arterial blood draws across the range of 70% to 100%. The Sansa™ device met the required $A_{rms} \leq 3.5\%$ across the range of 70% to 100%.

Overall, the Arms is estimated to be 2.4% for the range 70-100%.

	A_{rms}
70-100%	2.4
90-100%	2.2
80-<90%	1.8
70-<80%	2.9

Note: Because pulse oximeter equipment measurements are statistically distributed, only about two-thirds of pulse oximeter measurements can be expected to fall within $\pm A_{rms}$ of the value specified in the report.

Number of Participants	15
Gender	Male: 47% Female: 53%
Age	20-46 years
BMI	19.9 – 34.9
Race	Black / African American: 24% American Indian / Alaskan Native: 12% Asian: 6% White: 59%
Skin Tone (Fitzpatrick Scale)	Light (I): 53% Medium Light (II): 13% Medium (III): 7% Medium Dark (IV): 7% Dark (V): 13% Very Dark (VI): 7%



Reference: Reference CO-Oximetry	
Linear Regression (Error Plot)	y=3.2727+ -0.04580 x
Mean Bias	-0.59
# pts	369
Upper 95% Limits of Agreement	4.04
Lower 95% Limits of Agreement	-5.23

Summary of Clinical Performance

Sansa™ clinical performance was compared to the gold standard polysomnography (PSG) in a prospective multi-center clinical study in the United States. The results of the study support that Sansa™ is sufficiently accurate as an aid to diagnose moderate to severe SDB. The study was demographically representative of patients with SDB across age, sex, race, ethnicity, BMI, and skin tone.

Number of Participants	340
Gender	Male: 46.8% Female: 53.2%
Age	18 - 87 years (Mean: 55.4)
BMI	18.7 – 65.1
Race	Black / African American: 27.4% American Indian / Alaskan Native: 0.3% Asian: 1.5% White: 67.9% Other: 2.9%
Skin Tone (Fitzpatrick Scale)	Light (I): 34.4% Medium Light (II): 28.2% Medium (III): 11.5% Medium Dark (IV): 15.9% Dark (V): 8.5% Very Dark (VI): 1.5%

Below are the estimated performance specifications achieved by the Sansa™ device against PSG.

AHI (4% ≥15 events/hour)	Sensitivity: 88.2% Specificity: 87.3%
AHI (3% ≥15 events/hour)	Sensitivity: 92.6% Specificity: 74.4%
AHI (4% ≥5 events/hour)	Sensitivity: 93.7% Specificity: 71.4%
AHI (3% ≥5 events/hour)	Sensitivity: 96.4% Specificity: 54.9%
ODI 4% (number of events/hour)	Limits of Agreement: -20.7, 19.2
ODI 3% (number of events/hour)	Limits of Agreement: -21.6, 23.1
Sleep / Wake Classification Performance	Accuracy: 87% (95% CI: 87%, 88%) Sensitivity (Sleep): 95% (95% CI: 95%, 95%) Specificity (Sleep): 63% (95% CI: 62%, 64%)
Total Sleep Time (minutes)	Limits of Agreement: -81.3, 122.1
Snore*	Accuracy 66.5%
*Snore evaluated in 50 subjects on an epoch-by-epoch basis with a threshold of 0.1 in the scoring interface.	

Data Access and Interpretation

Data from the Sansa™ device is analyzed using the Huxley Sleep Portal. When a study has been completed and is ready for interpretation, the time-series data will be available for review, as well as events auto-detected by the Sansa™ algorithm. After review is complete, a diagnostic sleep report may be generated.

Sleep Scoring Interface

The following time-series metrics are available for review:

- Oximetry (SpO_2)
- Heart Rate
- Body Position
- Chest Movement
- ECG
- Respiratory Effort
- Actigraphy
- Snoring
- Sleep/Wake

The following event types are auto-generated. Manually added or adjusted events will be denoted as such but will be used alongside the autoscored events to calculate summative metrics for the report:

- Desaturation Event
- Respiratory Event
- Excluded – SpO_2
- Excluded – Heart Rate

Diagnostic Sleep Report

Once scoring of a study is complete, a diagnostic sleep report is generated. It contains summaries of all time-series metrics, and the following summary metrics are presented:

- Sansa-derived Apnea Hypopnea Index (sAHI)
- Oxygen Desaturation Index (ODI)
- Total Sleep Time (TST)

Additionally, the following statistics are generated:

- Sleep Efficiency
- Sleep Latency
- Mean, Maximum, and Minimum SpO_2
- Mean of Desaturation Nadirs
- Number of Desaturations in the following ranges: 4-9%, 10-20%, >20%, and Total
- Mean, Maximum, and Minimum Heart Rate during Sleep and during Wake, as well as total number of beats

Signal Inadequacy

If a period of SpO_2 data is of low quality, the time-series SpO_2 signal associated with that region will be marked as excluded. SpO_2 signal exclusions are based on low perfusion or excessive noise on the underlying Infrared and Red PPG signals.

If a period of ECG data is of low quality, the time-series Heart Rate signal associated with that region will be marked as excluded. ECG exclusions are based on low signal or excessive noise, or when the device has triggered leads off due to poor or no contact with the patient.

Excluded data periods are grayed out in the scoring interface and the report to indicate low quality, but the underlying signal is still able to be seen. These areas are considered unreliable and the excluded Heart rate and SpO_2 is for reference only and should not be used in clinical evaluation of the patient's state. These regions are excluded from respiratory analysis and will not be marked with respiratory events by the automated scoring algorithm.

Exclusions may be removed to manually add an event in the case that the physician has reason to believe an event not evaluable by the algorithm should be added.

Additionally, an outcome will not be produced for a sleep study with a sleep time of less than 60 minutes.

Electromagnetic Compatibility

The Sansa™ device is suitable for the electromagnetic environment of typical homes. During the immunity testing described below, the Sansa™ device continued to record normally.
The Sansa™ device has been designed to minimize the impact of electromagnetic interference from other electrical equipment and to minimize the interference caused to other electrical equipment. The Sansa™ device has been tested and found to comply with the Medical Electrical Equipment - General Requirements for Safety-Collateral Standard: Electromagnetic Compatibility, IEC 60601-1-2 2014. Due to the growth of equipment transmitting RF and other sources of electrical noise in the health-care environment, it is possible that due to proximity or strength of the source of the interference, degradation to the performance of the Sansa™ device may result.

Warnings:

- 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 Sansa™ device, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- The Sansa™ device should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, the Sansa™ device should be observed to verify normal operation. If operation is not normal, the Sansa™ device or the other equipment should be moved.
- Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

EMISSIONS test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions: CISPR 11	Group 1	The Sansa™ device uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The Sansa™ device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions: CISPR 11	Class B	
IMMUNITY test	**Compliance**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2, 4, 8, 15 kV air	The relative humidity should be at least 5 %
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	Power frequency magnetic fields from common appliances in the home are not expected to affect the device. Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. Keep the Sansa™ device away from sources of high levels of power line magnetic fields (in excess of 30 A/m) to reduce the likelihood of interference.”
Radiated RF IEC 61000-4-3	10 V/m 80 Mhz-2.7GHz	The Sansa™ device is suitable for the electromagnetic environment of typical home use settings.

FCC Compliance

Contains FCC ID: 2BHX6-SANSALTE1000

FCC Compliance Statement:

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.

CAUTION: The grantee is not responsible for any changes or modifications not expressly approved by the party responsible for compliance. Such modifications could void the user's authority to operate the equipment.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

This equipment has been tested and meets applicable limits for radio frequency (RF) exposure.

HUXLEY

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Need help or have questions? Contact Customer Service at 1-(888)-726-7239 or visit huxleymed.com for online support.