LBL-10009 Rev. 08

SANSA™

BY HUXLEY™

User Manual

For assistance, please contact Huxley Medical's 24/7 Customer Service team at **1-(888)-726-7239**.

SCAN QR CODE FOR ADDITIONAL LANGUAGES AND STEP-BY-STEP VIDEO.

Rx Only

Caution: Federal law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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REF 1000-00

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REF 1000-01

2

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1 Patch

3

4

Disposable Razor

Exfoliating Pad

Alcohol Wipe

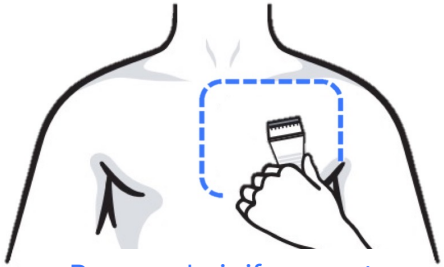
Do not throw the kit box away! You will need to use it to return the device.

2. GETTING STARTED

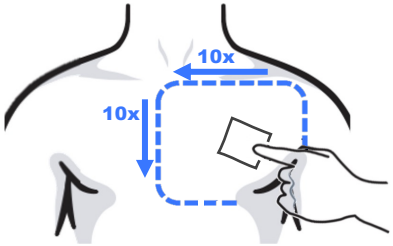
Skin Preparation

It is important to properly prepare your skin before applying the Patch to your body.

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.

3. POWERING ON AND USING THE DEVICE

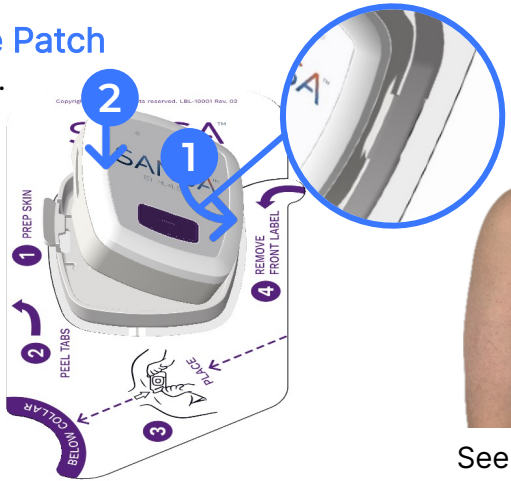
WARNING: Prepare Skin First!

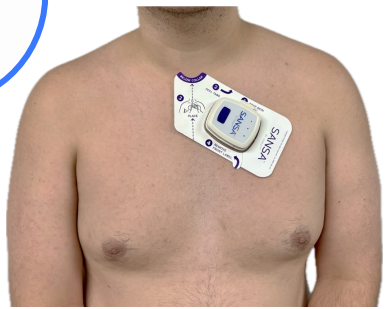
Do NOT place the Patch without following the skin preparation steps listed on the previous page!
Do NOT open the foil pouch until you are ready to conduct the study.

Connect the Sensor Pod to the Patch

Latch the Sensor Pod onto the Patch.

1. Tilt the sensor pod into the cradle.
2. Push sensor pod down to latch it in place. You should hear an audible click.

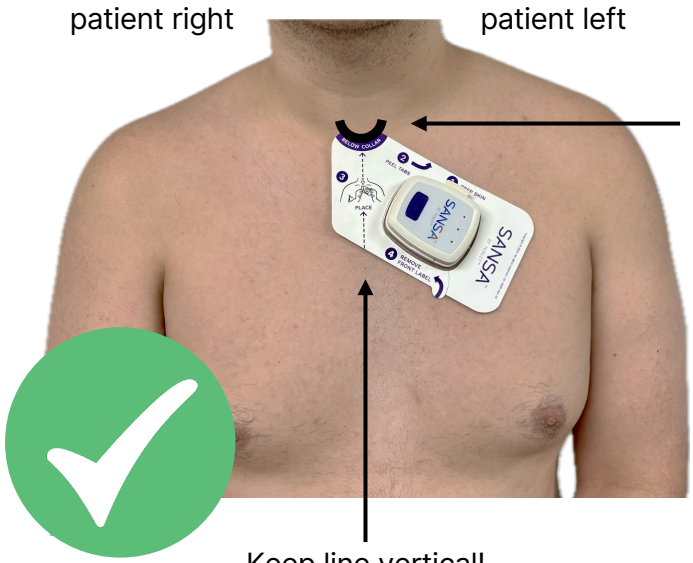




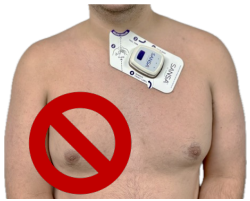
See next page for placement

3. POWERING ON AND USING THE DEVICE

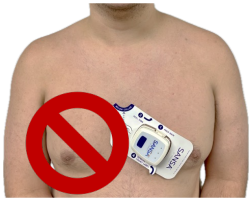
Review CORRECT Patch placement before removing liners and applying to chest.



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.



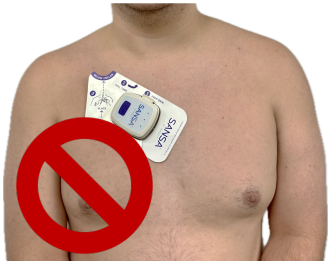
Too high!



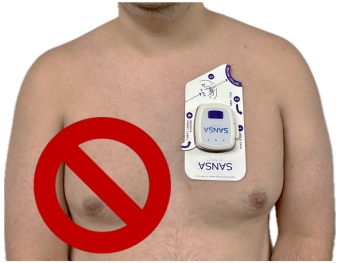
Too low!

3. POWERING ON AND USING THE DEVICE

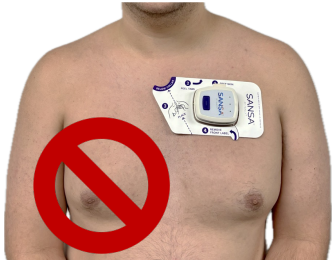
Examples of INCORRECT Patch placement.



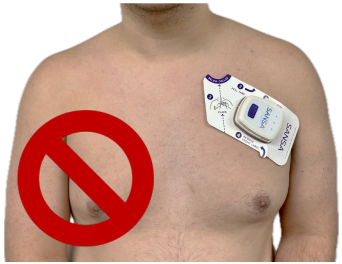
Wrong side of chest!



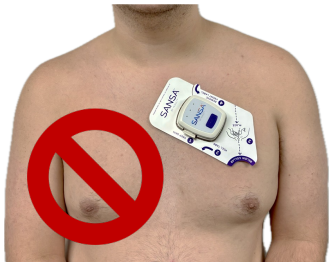
Rotated!



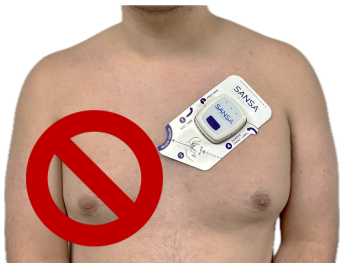
Rotated!



Too far from center!



Upside down!



Rotated!

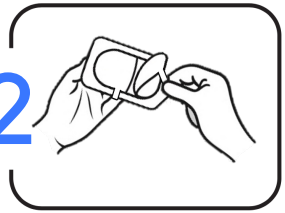
3. POWERING ON AND USING THE DEVICE

Apply the Patch to the Chest

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

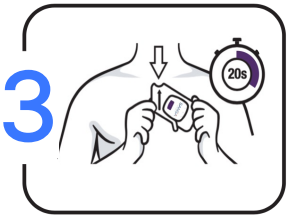
1 Familiarize yourself with the placement images on the previous pages and the instructions on the Patch itself.
It is **recommended to use a mirror** to help with the placement, or if someone assists you.

2



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

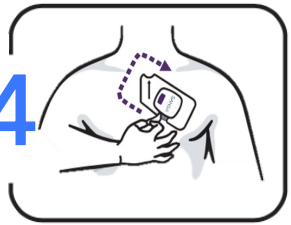
3



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.

4



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.

3. POWERING ON AND USING THE DEVICE

Turn on the Sensor Pod

The device contains 3 lights and a button. Once you have properly placed the device, you can power it on by pressing the button. When first powering on, the leftmost light will first be white and then turn green when the recording has started (as shown on the right).

After 5 minutes, the lights will turn off but the device will continue recording. Do not be concerned if the lights turn off.

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.

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.

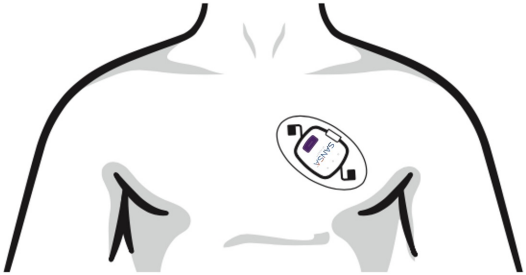
3. POWERING ON AND USING THE DEVICE

Ready to Test

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.

Wear the device for at least **7 hours**, unless directed otherwise by your physician.



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

⚠ **The device is not waterproof!**
⚠ 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.

4. REMOVING THE DEVICE

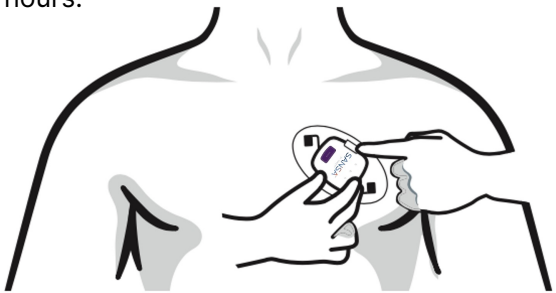
Remove the Sensor Pod from the Patch

When your monitoring period is complete, remove the Sensor Pod from the Patch and place it back in shipping box to return.

Gently press latch on Patch to release Sensor Pod.

When you remove the Sensor Pod, do not be alarmed if lights flash and the Pod vibrates. This is normal.

The Sensor Pod will automatically power off after 10 hours.

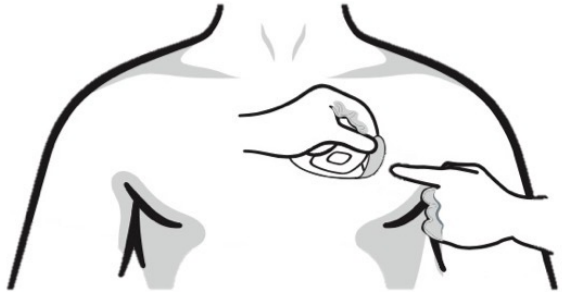


Remove the Patch from the Chest

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.

Dispose of the Patch in accordance with local regulations.



5. RETURNING THE DEVICE

⚠ Do not dispose of the Sensor Pod. It is critical that you return the Sensor Pod back to Huxley.

1. 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.
2. 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.
3. Drop the box in your mailbox or your closest US Postal Service mailbox. No need to add postage. The box already has a prepaid return label.

6. 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.

When the device is initially turned on, the leftmost light will display green for ~5 minutes then turn off. The device will continue to record after the lights turn off. This is normal.

Error Messages

If the device fails any checks an error message will be displayed, indicated by different light patterns:

1. Poor device contact

Cue:
The left and right lights are orange.

Solution:
Press firmly on the Patch and Pod for ~20 seconds and revisit the previous steps to ensure the patch is well adhered to the body, placed in the right position, and the Pod is fully latched.

If the lights continue, contact Customer Service at **1-(888)-726-7239**.

2. Low Battery

Cue:
Left light flashes or is solid orange

3. Critical Error

Cue:
All 3 lights are orange, or lights do not match any of the examples shown here.

Solution:
Contact Customer Service at **1-(888)-726-7239**.

Appendix A: Sansa™ Specifications

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 setting use under the direction of a Healthcare Professional (HCP).
The SANSA™ device records and stores ECG recording for up to 10 hours of wear time which can be displayed in the software portal for manual annotation and analysis. The SANSA™ does not provide automated analysis of the ECG and is not intended to be used with a 3rd party automated algorithm and is not intended for pacemaker analysis.

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 in this document must be followed.

Notes

1. The Sansa™ equipment is not affected by exposure to dust or lint normally found in household environments.
2. Exposure of sunlight to the Sansa™ equipment during use does not affect the use of the device.
3. 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.
4. The Sansa™ device will record for 10 hours after initialized. The Sensor Pod will automatically power off after 10 hours and does not require any powering off.

Contraindications for Use

1. Do not use if you have a known allergic reaction to medical adhesives or hydrogels or a history of adhesive skin allergies
2. Do not use in critical care settings
3. Do not use in a magnetic resonance (MR) environment
4. Do not use in an electrosurgery environment
5. Do not use in an explosive atmosphere or in the presence of flammable anesthetics or gases
6. Do not use on broken or injured skin
7. Do not use with a pacemaker that is permanently paced
8. Do not use with Defibrillators
9. Do not use with RFID equipment
10. Do not use if you have severe chronic obstructive pulmonary disease (COPD)
11. Do not use if you have respiratory muscle weakness
12. Do not use if you have awake or sleep-related hypoventilation
13. Do not use if you have significant non-respiratory sleep disorders

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.
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 this User Manual. The patient shall not perform any servicing or maintenance.

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 this 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.

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

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
REF	Catalogue Number
SN	Serial Number
LOT	Lot Number
	Follow Instructions for Use
	Consult Instructions for Use
Rx Only	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
	RF Transmitter
FC	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.

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.

Electromagnetic Compatibility

Turn off or relocate all transmitting devices in the room, such as smart phones, smart watches and headphones, at least 30 cm (12 inches) away from the Sansa™ device, as they could interfere with the test.

HUXLEY™

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