snap® diagnostics

SAM® Model 9-10000

Patient Testing Instructions

Snap Diagnostics
616 Atrium Drive, Ste 100
Vernon Hills, IL, 60061

Customer Support: 847-777-0000
https://snapdiagnostics.com

FCC ID: 2BDPB910000

Warnings

- Snap Diagnostics Sleep Apnea Monitor 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). This device is a non-invasive home care aid in the evaluation of obstructive sleep apnea (OSA) in patients 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.
- To reduce the possibility of entanglement, strangulation or choking, children, elderly, or any individual who could possibly become entangled in a cable or choke on sensors should be continuously observed by an adult or monitored.
- Inspect the sensor application sites at least every 6 to 8 hours to ensure correct sensor alignment and skin integrity. Sensitivity to sensors may vary due to medical status or skin condition. Patients with poor peripheral blood circulation or sensitive skin should inspect the site more frequently. Prolonged continuous SpO2 monitoring may increase the risk of undesirable changes in skin characteristics, such as irritation, reddening, blistering, or burning.
- Discontinue use with any sign of allergic reaction to any part of the device or sensors.
- Do not use damaged equipment or sensors. If the equipment or any sensor appears to be damaged in any way, discontinue use immediately and replace.
- This device may give inaccurate readings in the presence of strong electromagnetic sources, such as electrosurgery equipment.

Warnings (continued)

- Do not use this device in the presence of magnetic resonance imaging (MR or MRI) equipment or in the presence of computer tomography (CT) equipment.
- Do not use this device in the presence of flammable anesthetics.
- Do not connect any unauthorized external devices to the device USB-C port.
- No modification of this equipment is allowed.
- Do not mix chemicals while cleaning an item. Mixed chemicals can produce toxic gases that are dangerous to inhale.

Cautions

- Rx only: U.S. Federal law restricts this recorder to sale by or on the order of a licensed healthcare practitioner. Use of this device must be under the direct supervision of a qualified adult (parent or guardian) or health care practitioner trained in the use of the SAM Model 9-10000.
- Use only Snap Diagnostics supplied sensors and cables with this device. Using other accessories may result in increased electromagnetic emission or decreased electromagnetic immunity of the equipment.
- The nasal cannula is intended for single patient use only and should be disposed of after use.
- There are no serviceable parts, and the device should not be opened. The battery in the SAM device is not removable or replaceable by the user.
- Do not allow the device or sensors to get wet.
- Avoid placing food or liquid on any part of the system.
- Do not introduce any foreign object into the device.

Indications for Use

The Snap Diagnostics SAM Model 9-10000 device is intended to record airflow, breathing effort and body position and is indicated for use and an aid for diagnostic evaluation of patients for apnea and snoring and to provide quantitative and qualitative analysis of apnea and snoring.

The Snap Diagnostics SAM Model 9-10000 is not intended as a substitute for full polysomnography when additional parameters such as sleep stages or EEG activity are required.

The target population consists of patients who are suspected of apnea and/or complain about snoring. The majority of the test procedures will take place at the patient's home, although some may take place in a sleep laboratory. Both pediatric and adult patients may be tested.

Use of this device must be under the direct supervision of a qualified adult (parent or guardian) or health care practitioner trained in the use of the Snap Diagnostics SAM Model 9-10000 device.

Introduction

This booklet provides instructions for taking your Snap Diagnostics home sleep test with the SAM Model 9-10000 device. These instructions may refer to the SAM Model 9-10000 as "SAM".

The testing equipment will be applied as instructed below, prior to the start of recording. For best results, the testing equipment should be worn for the entire recording. If you need to get up during the recording, the equipment can remain on. Re-apply equipment if removed during the recording time.

An instructional video is available on our website:
https://snapdiagnostics.com/ snap-instructional-video/

Storage
The recording device and accessories should not be stored in extreme heat or cold environments.

Temperature Range: -13 to 158 F (-25 to 70C)

Relative Humidity Range: 15% to 90% non-condensing

Operating Conditions
If stored at temperature extremes, allow 15 minutes for device to reach room temperature prior to use.

Temperature: 41 to 104 F (+5 to +40 C)

Relative Humidity: 15% to 90% non-condensing

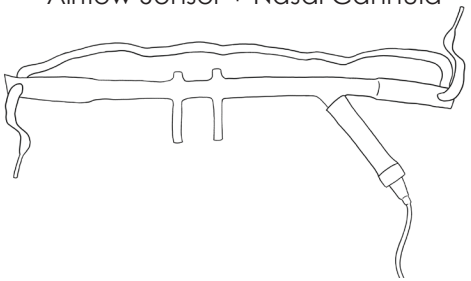
Atmospheric Pressure Range: 700 hPa to 1060 hPa

Snap Testing Kit

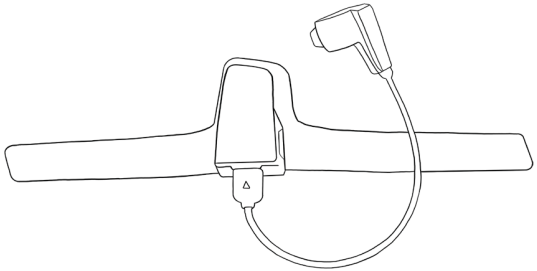
To complete your sleep test, the following equipment will be used:

Snap Sleep Apnea Monitor (SAM) + Belt

Airflow Sensor + Nasal Cannula

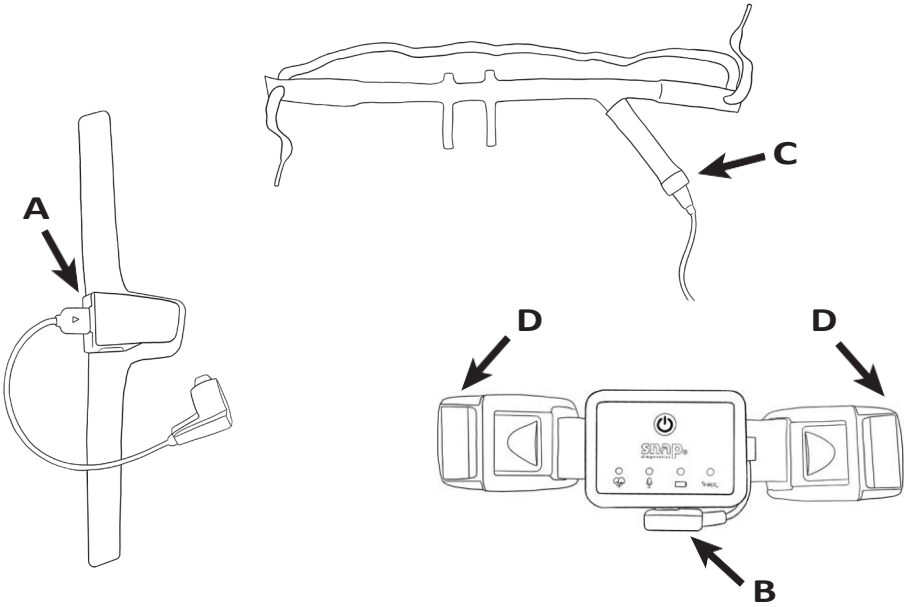


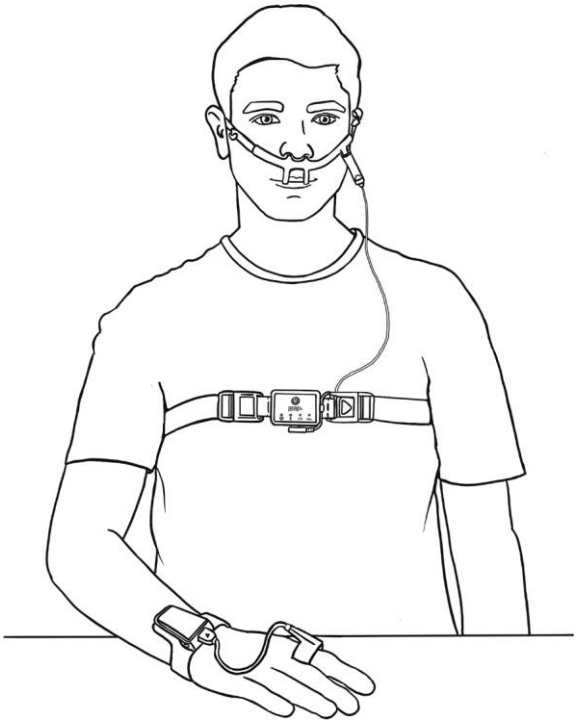
Oximetry Watch Monitor + Ring Sensor



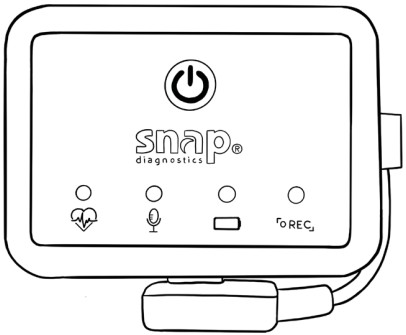
Connection Locations

A – Oximeter Monitor Connection
B – Airflow Sensor (microphone) to SAM Connection
C – Airflow Sensor (microphone) to Cannula Connection
D – Elastic Band Connection (band not shown below)





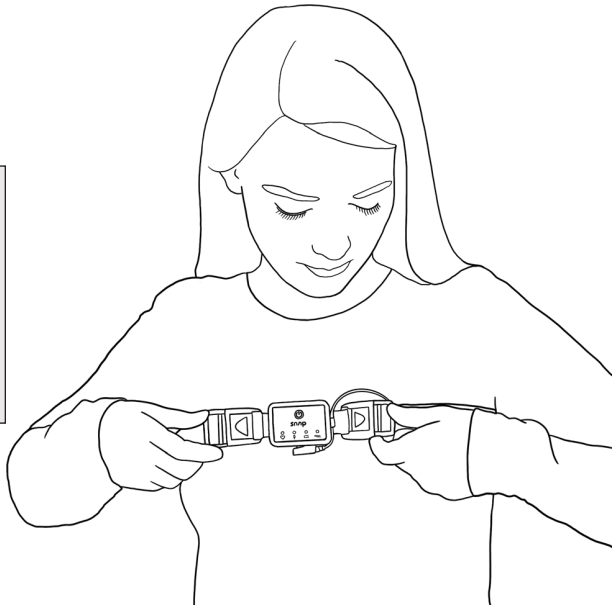
SAM
(Sleep Apnea Monitor)



Connect to the SAM + Belt

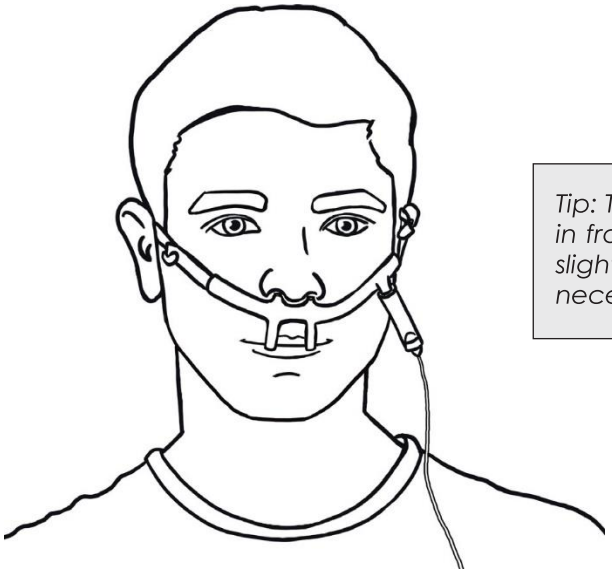
Step 1: Fasten the Belt around your upper chest, over your bed clothes, placing the Sleep Apnea Monitor (SAM) in front. The belt size can be adjusted. It should fit snug and not cause a restriction in breathing. The SAM should be placed on your chest with the airflow sensor connection facing down.

Tip: The SAM + Belt will be worn over your clothing. The length of the belt may be adjusted by releasing the Velcro® and pulling on the end of the belt. The fit should feel snug, but comfortable.



Connect to the Airflow Sensor + Nasal Cannula

Step 2: Place the nasal cannula underneath your nose with the shorter pair of prongs resting under your nostrils and the longer pair of prongs pointing down toward your mouth. The elastic headband fits over the ears. You can pull on the ends of the band to adjust the cannula for a comfortable fit. Prior to the start of recording, when you speak or blow into the cannula the airflow sensor (microphone) LED will display in green.

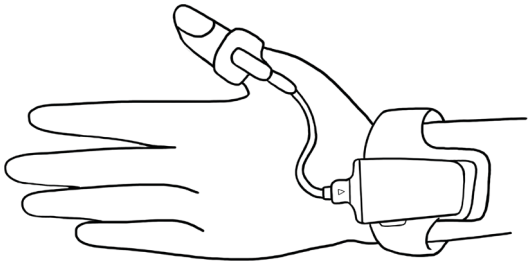


Tip: The longer prongs should rest just in front of your upper lip and can be slightly trimmed with scissors if necessary.

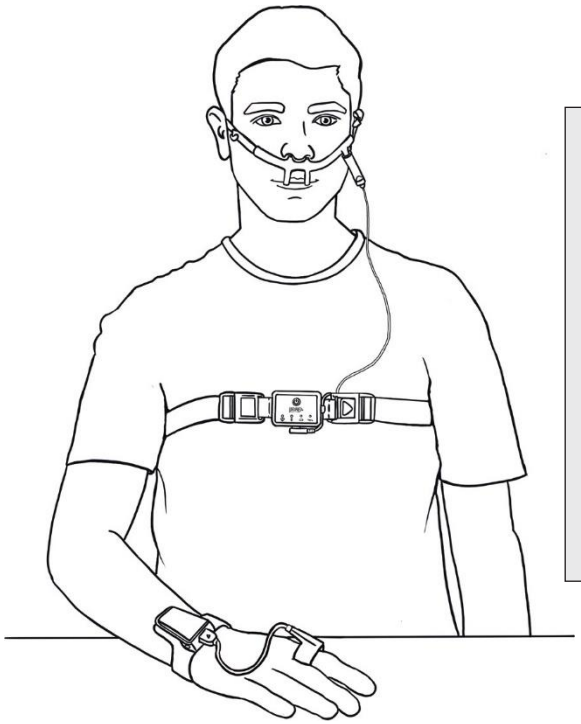
Connect to the Oximetry Watch Monitor + Ring Sensor

Step 3: The Oximetry Watch Monitor is worn around the wrist. Strap the watch to your non-dominant hand. Do not close the wrist strap too tightly. The fit should feel secure, and not too loose or too tight.

Step 4: Place the ring sensor on your thumb. If the thumb is too tight, you may use a different finger. The ring can be placed on the bony part of the finger between the knuckles, preferably at the base of the finger or thumb, and may be secured with medical tape as needed. Do not place on fingernail or directly over knuckle.



Tip: If it feels comfortable, we recommend using a different hand for each night of testing and wearing the ring sensor on your thumb. If you have any conditions that cause loss of feeling or poor circulation, or if you use medications that may cause you to be less alert, be sure to check the skin on your finger for irritation during and after use. If you experience any irritation, discontinue use and call Snap at ***(847) 777-0000*** *for assistance.*



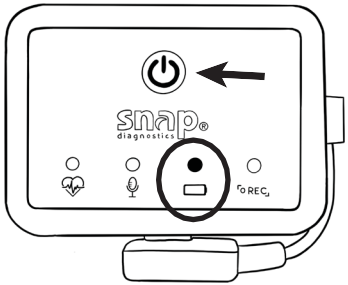
Important: The testing equipment should feel secure yet comfortable. If any part feels too tight, be sure to adjust it before starting the recording. For further guidance, testing support is available at ***(847) 777-0000****.*

Once you have comfortably applied the monitors and sensors, you can turn them on to begin recording.

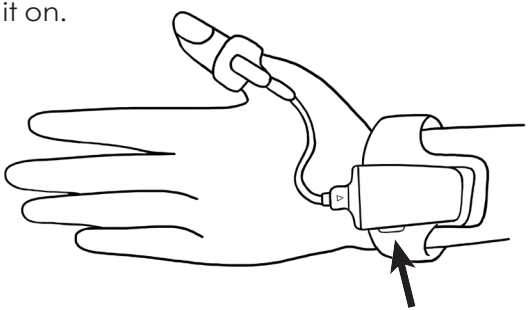
Rotate the SAM device up to better see the front of the device and the LED lights.

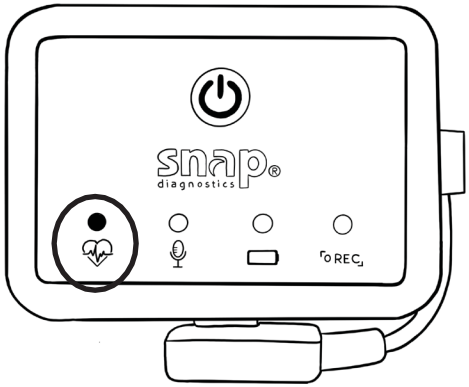
Start Recording

Step 5: Turn on the SAM Recorder. Press the power/record button ⏻ to turn on the SAM recorder and start the recording. The light above the battery symbol will illuminate.

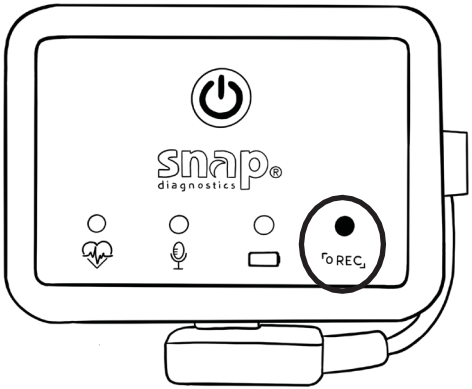


Step 6: Turn on the Oximetry Watch Monitor. Press the power button on the side of the watch to turn it on.





When powered on, the Oximetry Watch Monitor will automatically pair with the SAM recorder. Once successfully paired, a blue light will illuminate on the SAM recorder. Note: A blinking blue light indicates that the device is searching for connection. A solid blue light indicates that the device is connected.



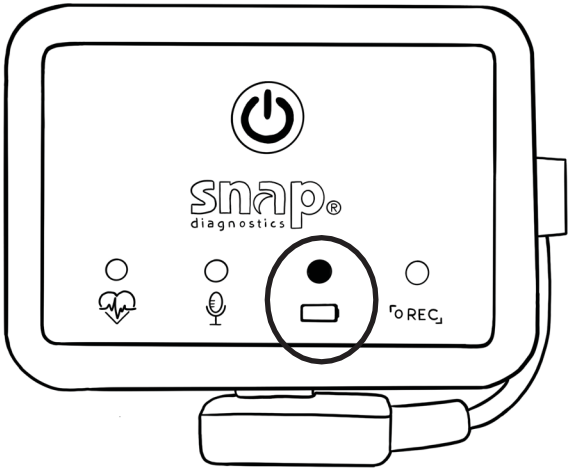
After the device completes its self-test a green REC light indicates all functions are operable and recording will start automatically. Once recording has started, only the REC light will display blinking green approximately every 5 seconds. The device will record for 6 hours and automatically turn off.

If the lights display magenta or amber, refer to the table on page 16 for troubleshooting or contact Snap Customer Support at ***(847) 777-0000****.*

Battery Life

The recorder will turn off automatically after 6 hours of use. If you need to turn off the device for any reason, press the power button twice.

A fully charged battery, indicated by a green light, can record 3 nights of sleep. A half full battery, indicated by an amber light, can record a full night of sleep. A magenta light indicates that the battery must be charged before use.



If you have insufficient battery, please call Snap Support **(847) 777-0000**.

LED Communications

The LED lights on the SAM device will communicate the device status. During the start-up process, a self-test will run for approximately 40 seconds, where the lights will automatically cycle through a color sequence for a short period of time, ending in blue or green before the recording starts. There is no need to monitor this process.

The power/record light will remain green for the duration of the recording unless a sensor becomes disconnected. If a sensor disconnects, the light will change to amber. All other lights will remain unlit while the recording is in progress unless the status is checked.

You can rotate the SAM device up towards you to better see the front of the device and the lights.

To check the status of the SAM device during the recording, press the power/record button one time. This will illuminate the sensor lights for 5 seconds. *Do not double press the power button as this will stop the recording.*

If the battery or power/record light displays a constant magenta color, contact Snap Customer Support at **(847) 777-0000**.

LED Communications (continued)

LED Color Meaning	Green (Working)	Amber (Alert)	Magenta (Fail)	Blue (BLE)
Battery	Full Charge	1-Night Charge Available	No Charge, Call Snap	N/A
REC Record	Power/ Record	Disconnected Sensor	Errors Present, Call Snap	Startup Mode (Flashing)
Pulse Oximeter	N/A	Sensor Not Detected	N/A	Bluetooth Connected When Solid
Airflow (Microphone)	Sound Detected	Sensor Not Detected	N/A	N/A

Return the Test Kit

Once you have completed the test, return the test for analysis with all parts provided. Follow the instructions provided when you received it:

- If the test kit was sent directly to you from Snap, return it to Snap following the shipping instructions provided in the box or on our website: **https://snapdiagnostics.com/return-instructions**
- If you received the kit from your provider's office, return it to them.

Results

Your sleep data is analyzed by our laboratory at Snap, and once ready, will be sent directly to your medical provider. Your medical provider will contact you to discuss the results of the test.

To inquire about the status of your test, you may call our support team at **(847) 777-0000** or email us at **Support@SnapDiagnostics.com**.

Support

We offer 24-hour patient support to answer testing-related questions. For assistance, please call **(847) 777-0000**.

Please visit our website at **https://snapdiagnostics.com** to find answers to frequently asked questions (FAQ) and to view our instructional video.

Patient FAQ: **https://snapdiagnostics.com/patient-faq**

Instructional Video: **https://snapdiagnostics.com/snap-instructional-video**

To view the instructional video on a smartphone, scan this QR code using your phone's camera.

To read your privacy rights under the Health Insurance Portability and Accountability Act (HIPAA), please visit: **https://snapdiagnostics.com/privacy**

Snap Diagnostics is approved as an Independent Diagnostic Testing Facility (IDTF). To read about Medicare's IDTF Performance Standards, please visit: **https://snapdiagnostics.com/idtf-performance-standards**

Symbol Table

Symbol	Definition
	Type BF Applied Part applies to entire SAM Device
	Manufacturer
IP22	Protected against spraying water and against access to hazardous parts with a tool, per IEC 60529.
	Caution
	Serial Number
	Keep Away from Rain
	Consult Instructions for Use
	Prescription Use Only
	Date of Manufacture
	Device shall have a shipping/storage temperature range of -25 to +70°C
	Device shall have a shipping/storage relative humidity tolerance of at least 90%

Bluetooth Wireless Communications

This product implements Bluetooth wireless communication. Only manufacturer-supplied Bluetooth accessories should be connected to the product. If you experience difficulty in making or maintaining a Bluetooth connection, please contact Snap Customer Support at **(847) 777-0000**.

Do not connect the product's USB port to any computer, charger, or accessory other than those provided by the manufacturer.

FCC Compliance Statement

FCC ID: 2BDPB910000

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.

Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this 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 an 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.*

Good Night!

Snap Diagnostics
616 Atrium Drive, Ste 100
Vernon Hills, IL, 60061

Customer Support: 847-777-0000
https://snapdiagnostics.com

726-784636 Rev D