ACCUSØM Home Sleep Test User Manual

CCUSOM

DN/OFF

BREATH

6

FINGER



For assistance at any time during testing, call: 877-753-3776 and please visit www.novasom.com for the "Home Sleep Test Animated Instructions"

Two Night Test

Before You Begin

A Cautions & Warnings:

- AccuSom[™] is not intended for use with infants or children.
- AccuSom is not an apnea monitor and only records breathing sounds, blood oxygen, and respiratory effort
- AccuSom has no alarms and should not be used as an apnea monitor
- AccuSom should not be used in a noisy environment
- AccuSom Finger Sensor cannot be used with any dark color fingernail polish (blue, black, purple, deep red)
- The AccuSom test cannot be used simultaneously with your CPAP machine or other oxygen delivery system.

Charging the Unit:

The unit is fully-charged when shipped from NovaSom, however the device battery slowly discharges over time. If you have waited longer than three days to start your test, you must charge the device prior to testing.

Description & Restrictions:

The AccuSom Home Sleep Test is a medical device used in the diagnostic evaluation of adults suspected of having sleep apnea.

AccuSom is a prescription device, and therefore Federal Law restricts this device to sale or use by a physician, or as prescribed by, a physician.

Contraindications:

There are no contraindications for AccuSom

Symbols:

Battery









Non-Ionizing Electromagnetic Radiation

and Electronic Equipment

Waste of Electronic



Manufacturer



Power On/Off



Type BF Applied Part

Serial Number



Catalogue Number



Consult Accompanying Documents



Class II Equipment

2 IACCUS@M

System Components

AccuSom™	Worn on the arm with strap
Power Charger	Used to charge device and transmit data the day(s) after testing
Chest Sensor	Worn around the chest to measure breathing effort
Finger Sensor	Worn on the finger to measure oxygen levels in the blood and heart rate
Breath Sensor	Placed under the nose to measure airflow and snoring
	tus Light Finger Sensor Connector
Chest Sensor Connector	Finger Sensor Indicator
Chest Sensor Indicator	CHEST ON/OFF ON/OFF BREATH BREATH
Breath Sensor Connector (on bottom of device)	

STEP 1: Connecting Chest Sensor to Chest and AccuSom[™]

1A. Connect black clips under the breasts. The tube can be worn under or over a thin night shirt.

1B. Push black button and pull clear tubing to adjust.



STEP 2: Connecting Finger Sensor to Finger and AccuSom[™]

2A. Remove any dark fingernail polish before connecting sensor to index finger. If the sensor is too tight or loose on your index finger, you can wear it on any finger except your thumb.



of the device.

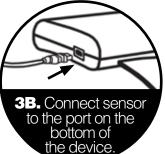
4 ∎ACCUSØMI

STEP 3: Connecting Breath Sensor to Face and AccuSom[™]



3A.

- Tighten the slide ring upwards under chin.
- Place the Breath sensor under your nose (as pictured) with the two round humps under your nose. The sensor



is positioned correctly when the single large hole is on the right side of your face.

• Attach the sensor to your face with a 2-inch piece of the enclosed tape.

System is now

recording.

STEP 4: Turning on the AccuSom™ Device

4**A**.

- Turn device on by pressing ON/OFF button firmly for 2 seconds and then let go.
- The sensor lights on the unit will flash until each sensor is placed properly.
- All sensor lights on the AccuSom unit should be GREEN. The device will announce "System is now recording".
- If there is an issue with a connector, the AccuSom will announce "Check sensor", and one or more lights on the device will flash yellow, indicating which sensor(s) needs attention.
- You may go to sleep once the device is successfully connected to your arm. Please note that device may be placed below the elbow.

STEP 5: Transmitting Test Results & Charging the AccuSom™

The morning AFTER testing, follow these instructions in this exact order:

- 1. Disconnect all wires from the device.
- 2. Plug charger into wall outlet, then connect charger to device.
- 3. Device will say "Now Charging". If not, push the on/off button firmly for 2 seconds and let go..
- 4. Leave the device in this charging position for at least 30 minutes. During this time your Sleep Test Results will be transmitting to NovaSom.



For nights 1 and 2 of testing: Continue charging up to 3 hours to fully charge the device in preparation for your next night of testing. On the morning after the final night of testing: Follow steps 1 through 4. Charging for 30 minutes will transmit your final Sleep Test results, but you do not need to fully charge the device prior to returning it to NovaSom.

STEP 6: Shipping Instructions

- 1. Place the AccuSom[™] with all sensors. User Manual and completed forms carefully back in the box as they were placed when you received the system.
- 2. Place the prepaid return shipping label on the box.
- 3. Follow the instructions included in the box on how to return the AccuSom™.

Frequently Asked Questions

What if I need to get up in the middle of the night?

There is nothing special to do if you need to get up at night. Leave the sensors in place and connected to the AccuSom on your arm. If any of the sensor loses connectivity with the AccuSom device, a voice prompt will indicate which sensor needs to be repositioned or plugged back into the device.

What if the voice prompt says "Check Chest Sensor"?

If the voice prompt says "Check Chest Sensor": Reposition and tighten the Chest Sensor. The sensor should be placed just below the breasts. Once the Chest Sensor has been correctly repositioned and tightened, and the connection to the AccuSom device has been verified, the voice prompt will say "Chest Sensor OK" and Chest Sensor light will turn green. This may take about 30 seconds. If the Chest Sensor LED light is still not green, squeeze the Chest Sensor Belt tubing between two fingers. If the LED light still does not turn green, call NovaSom, Inc. at **1-877-753-3776**.

What if the voice prompt says "Check Breath Sensor"?

If the voice prompt says "Check Breath Sensor", please reposition the Breath Sensor so that it is resting just above your upper lip and is centered below your nose. Make sure the side with the five small holes is facing your mouth. Once the sensor has been correctly positioned, and the connection from the Breath Sensor to the AccuSom has been verified, the voice prompt will say "Breath Sensor OK" and the Breath Sensor light will turn green. This may take about 30 seconds. If the LED light still does not turn green, call NovaSom, Inc. at **1-877-753-3776**. If you are a very active sleeper, this may happen several times during the night.

What if the voice prompt says "Check Finger Sensor"?

If the voice prompt says "Check Finger Sensor", check to make sure the Finger Sensor is correctly positioned on the fingertip and that the cable is connected to the device and that you have completely removed any dark nail polish. Once the Finger Sensor has been correctly repositioned, the Finger Sensor light will turn green, and the voice prompt will say "Finger Sensor OK". This may take about 30 seconds. If the LED light still does not turn green, call NovaSom, Inc. at **1-877-753-3776**.

(Frequently asked questions are continued on back cover.)

Frequently Asked Questions (continued)

What if the the Power Light is not lit?

Press ON/OFF button firmly for 2 seconds and let go to turn device on. If the LED light still does not turn green, the battery may be too low. Connect device to charger and power On device. If LED light still does not turn green, call NovaSom, Inc. at **1-877-753-3776**.

What if I also use a CPAP machine or Oxygen?

The AccuSom test cannot be used simultaneously with your CPAP machine or Oxygen.

AccuSom is manufactured and serviced by:



For 24/7 Testing Assistance Call: (877) 753-3776

Calls for All Other Questions During Business Hours:

Monday – Friday: 9:00 am - 10:00 pm EST Saturday: 9:00 am - 5:30 pm EST

NovaSom, Inc.

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