

DRAFT

ACCUSOM

AccuSom with RFID Finger Sensor Assembly User Manual



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

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One Night Test

Before You Begin



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.

- Do not use near, place or drop water or other liquid on unit.
- Do not use an extension cord.
- Operating temperature: 32-104 degrees Fahrenheit-

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.

The unit must not be used while charging.

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.

FCC

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.

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 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 to try to correct the interference by one or more of the following measures.

- Increase the separation between the AccuSom and the receiver.

- **IMPORTANT!** Changes or modifications not expressly approved by NovaSom, Inc. could void the users's authority to operate the equipment.

Contraindications:

The AccuSom device-with RFID Finger Sensor Assembly is not intended for use by persons with pacemakers or persons with internal cardiac defibrillators (ICD).

Symbols:

	Battery		Waste of Electronic and Electronic Equipment		Catalogue Number
	Output Voltage		Non-ionizing Electromagnetic Radiation		Consult Accompanying Documents
	Manufacturer		Serial Number		Class II Equipment
	Power On/Off		Type BF Applied Part		

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

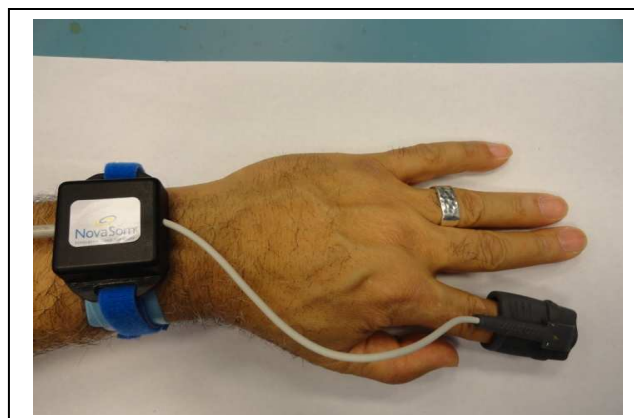
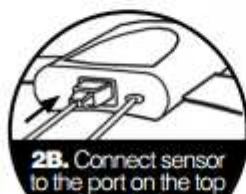


STEP 1: Connecting Chest Sensor to Chest and AccuSom™



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.



The RFID Bracelet will be secured to your wrist prior to testing by your physician's office or designated clinic.



The RFID Reader (black box) on the RFID finger sensor must be positioned over the RFID disc in the bracelet. Make sure the word "NovaSom" on the bracelet is under the RFID Reader (black box) on the Finger Sensor.

If the bracelet will not stay in place, use the tape provided with the AccuSom. Put tape over the strap and bracelet on each side to secure

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.



3B. Connect sensor to the port on the bottom of the device.

STEP 4: Turning on the AccuSom™ Device

4A.

- 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.

The device will start charging the battery automatically whenever the power supply is connected. While charging, the orange status light above the ON/OFF switch will turn on. Once fully

charged, the orange light will turn off. All other indicator lights other than the orange status light will be off during charging.



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" makes sure that the RFID bracelet is under the Finger Sensor RFID Reader (black box). Make sure that the Finger sensor is connected to the AccuSom.

The RFID finger sensor may take up to 15 minutes to acquire the finger sensor signal as it needs to read the RFID disk in the bracelet.

If the RFID bracelet is not positioned correctly under the RFID Reader on the finger sensor during testing the Finger Sensor will disconnect and data recording will stop. The Finger Sensor LED will flash yellow within 40 minutes. The device will discontinue recording unless the finger sensor signal is acquired.

Use tape provided to hold the bracelet in place if necessary. Tape over the wrist strap and bracelet on either side of your arm to secure.

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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www.novasom.com

www.apnea.com

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