OPERATORS MANUAL FOR ACCUSOM

Applicable to reference 1017-10001-US

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1 Foreword

AccuSom is a medical device used to determine if you have sleep apnea**.**

Warning

United States Federal law restricts this device to sale by or on the order of a physician.

If any pieces are missing or if you feel the unit is not working properly, immediately call BioSerenity Customer Service: 1-877-753-3776.

The AccuSom is a non-sterile device. The AccuSom patient module is a reusable device that can be cleaned and reprocessed by BioSerenity after each patient use.

1.1 Intended use

The AccuSom is a sleep apnea diagnostic device intended to be used at-home by the patient.

1.2 Indications for use

The AccuSom device is indicated for use in the diagnostic evaluation of adults with possible sleep apnea. The AccuSom can score obstructive apneas, which includes mixed apneas.

The AccuSom device is intended for use in the home and clinic setting.

1.3 Scope

This manual explains the features of the AccuSom sleep diagnosis system to the user.

1.4 Document History

Version	Date	Description
A	05-Jul-2022	Creation
A	29-Dec-2022	Initial release

1.5 Glossary

Abbreviations	Term
APP	Mobile Phone Application
DC	Direct Current
FAQ	Frequently Asked Questions
LED	Light-Emitting Diode
RF	Radio Frequency

1.6 Symbology

Warning

Draws attention to important information and/or action: damage to the equipment is possible.

Note

Gives additional information for optimal use of the product.

2 Introduction

2.1 Prerequisites

Using the AccuSom requires:

- Using an Android Smartphone with software version Android 10 or higher, OR an iPhone with software version iOS 14.0 or higher.
- Having access to a Bluetooth connection on Android/iPhone Smartphone.
- Having access to an Internet connection (Wi-Fi / 4G) (optional).

2.2 Cautions and Warning

- AccuSom Finger sensor cannot be used with any fingernail polish or artificial nails.
- AccuSom cannot be used simultaneously with a CPAP machine or other oxygen delivery systems.
- AccuSom should not be used in a noisy environment.
- AccuSom is not intended for use with infants on 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 a monitor.
- Do not use an extension cord to plug the device while on patient.
- Do not use near, place, or drop water or other liquid on unit.
- Should be used in operating temperature range: 32 to 104 °F (0 to 40˚C).

2.3 Contraindications

There are no contraindications for the AccuSom other than those listed in the chapter “Cautions and Warning” above.

3 System Overview

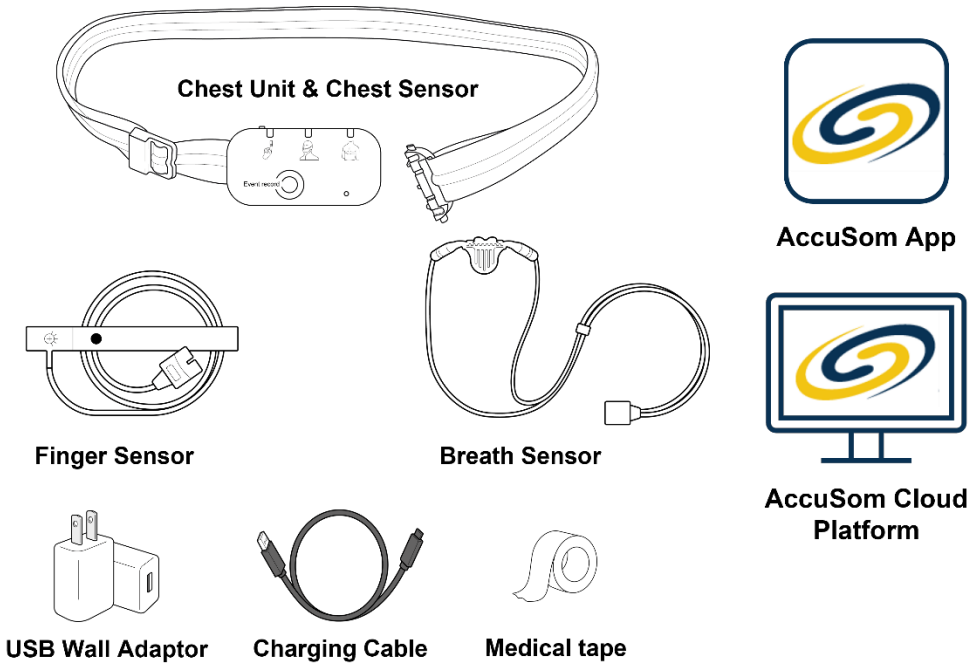
The AccuSom is composed of the following elements:

- Chest unit that includes:
  - Chest sensor
  - Breath sensor
  - Finger sensor
- Mobile Application

The AccuSom is compatible with the existing AccuSom Software Platform.

The AccuSom device is delivered with a charging cable and a USB wall adaptor to be used when charging the device, as well as a roll of medical tape for additional fixation of the system when needed.

Warning The use of any unit not recommended in this document could have an unwanted effect on the system. Refer to the list of consumables listed in this document.

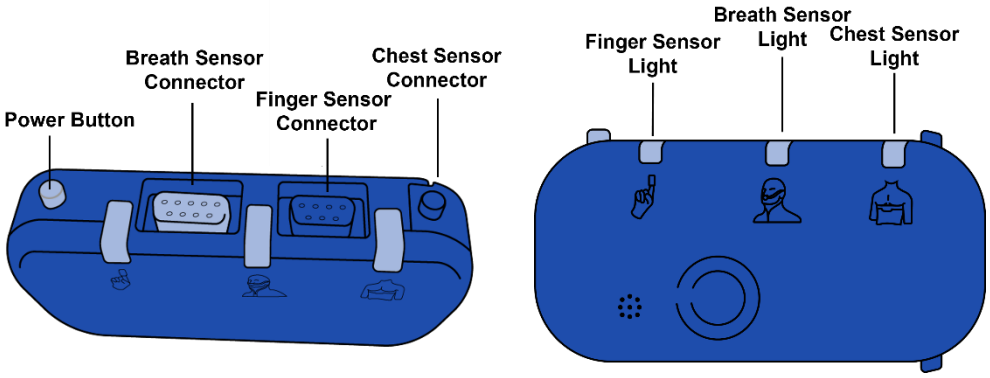


3.1 Chest Unit

The AccuSom allows up to 8.5 hours of recording.

The Chest Unit has the following features:

- Power Button with light. To turn system on, push for 2 seconds. To turn system off, push for 6 seconds.
- Connectors for: Finger sensor (white), Breath sensor (blue) and Chest sensor.
- Light indicators for Finger sensor, Breath Sensor, and Chest Sensor.
- Charging port (behind connector for chest sensor).

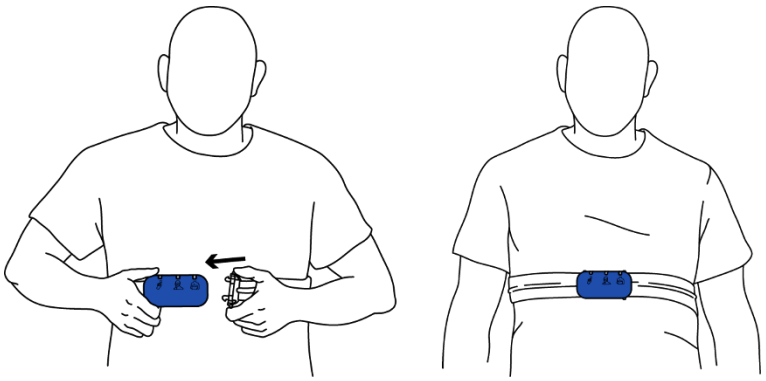


3.2 Chest Sensor

The AccuSom Chest sensor measures the breathing movements of the chest.

- Place Chest Unit below the breasts, wrap Chest sensor around your back and close the buckle.
- Adjust the length of the Chest sensor band so it fits snuggly around chest.

- The Chest Unit and Chest sensor can be worn under or over a thin nightshirt.



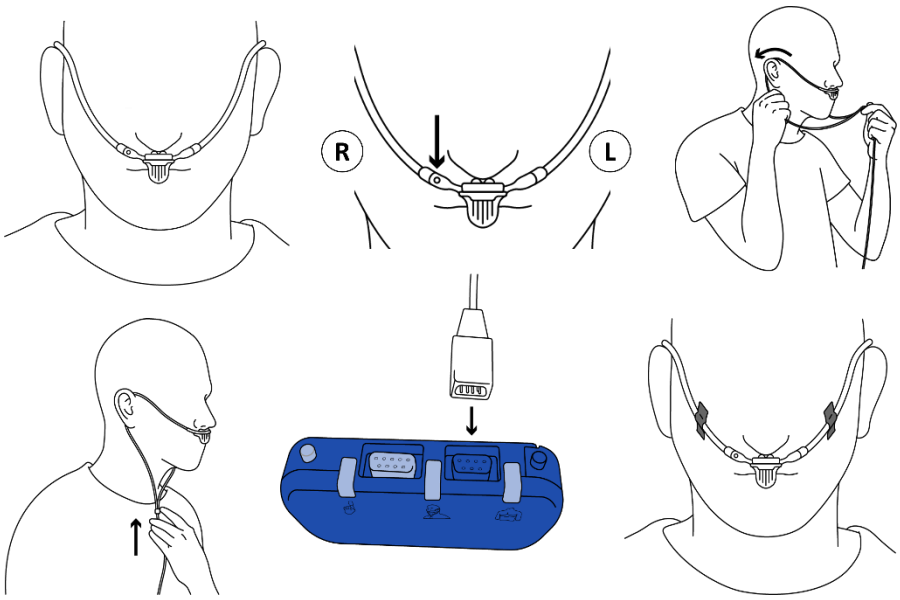
3.3 Breath Sensor

The AccuSom Breath sensor measures the flow of air from nose and mouth.

- Place the two humps of the Breath Sensor between your nose and upper lip. The 5 small holes in the large hump should face your lip.
- Run the sensor cables over and behind your ears.
- Tighten the slide ring upwards to fit snuggly under your chin.
- Connect the Breath Sensor to the **BLUE** port on top of the device

OPTIONAL: Attach the sensor to your cheeks with enclosed tape. This may be helpful if you move a lot during your sleep.

Note
The large hole should be on the right side and face forward.

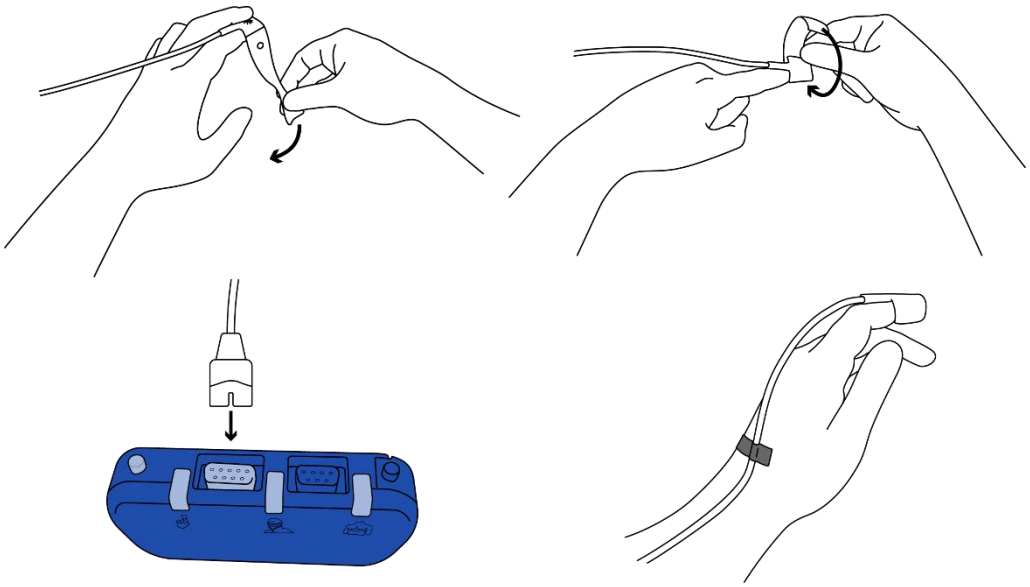


3.4 Finger sensor

The AccuSom Finger Sensor measures the saturation of oxygen in the blood.

- Peel off the clear sheet.
- Lay Finger Sensor flat on your finger with the + symbol on top of your nail.
- Wrap the adhesive around your finger like a band-aid.
- Connect the sensor to the **WHITE** port on the top of device.

OPTIONAL: Attach the sensor cable to the back of your arm with a piece of tape. This may be helpful if you move a lot.



3.4.1 Compatible finger sensors

The AccuSom is compatible with the following finger sensors:

Manufacturer	Reference	Name
Unimed	U543-01	SpO2 Disposable Sensor
Unimed	F543-01	SpO2 Disposable Sensor
Unimed	U403-01	Reusable Adult Finger clip SpO2 Sensor
Unimed	U603-01	Reusable Adult/Neonate Wrap SpO2 Sensor
Amydi-Med	AMD-DS-NM0001-1	Disposable SpO2 Sensor

3.5 Charging the AccuSom

The device charging port is located on the side of the device where the Chest Sensor snaps to it.

Note
The AccuSom cannot record data when charging.
The device should never be placed to charge while worn.

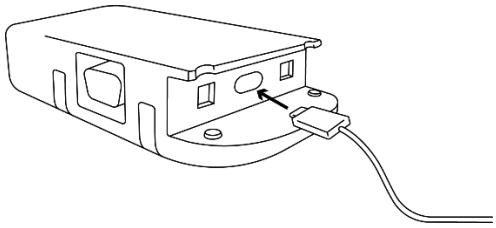
Charging prior to a study, AND after the study

- Connect the provided charging cable to the port on the right side of the device.
- Connect the charging cable to the included USB wall adapter.
- Please leave the system to charge for 5 hours.
- The Sensor lights will blink blue while the system is charging.
- Sensor lights turn fixed blue once the system is fully charged.

4 Performing a Sleep Study with AccuSom

4.1 Before you start

- Begin by charging AccuSom device for 4 hours once you remove it from its packaging using the included USB-C charging cable and USB wall adaptor.
- Sensor lights will blink blue until charging is complete.
- Your smartphone will need to be plugged into its charger before beginning test.
- Please ensure that Bluetooth is activated on your smartphone prior to starting. To do so, open settings and turn Bluetooth connection on.



To charge the AccuSom, only the USB-C cable and USB wall adaptor included with the device shall be used.

4.2 How to get the AccuSom App

Obtain the AccuSom app on your Smartphone:

- By scanning the QR code below:

Download
AccuSom Application

Download on the App Store

GET IT ON Google Play

- Or directly from the Apple App Store or Google Play store.

4.3 Starting a new study

The AccuSom has available two modes to record a study:

- Study with Smartphone application: The AccuSom application guides the setup of the system and enables the patient to send the study data to BioSerenity and the end of the recording.
- Study without Smartphone application. The System setup is guided by a paper patient manual. At the end of the last study, the patient sends the system back to BioSerenity where the study data is retrieved from the device.

4.3.1 Study with smartphone application

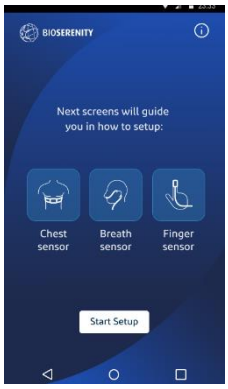
Step 1

- Open the AccuSom app on your smartphone.
- Press “Start your sleep study” on the AccuSom app.
- Bluetooth connection and location service must be enabled on the device to use the application.

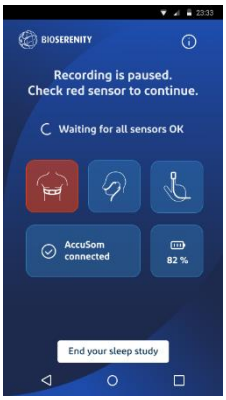
Step 2

- Turn on the AccuSom device by pushing the power button for 2 seconds.
- The power button light will blink green when the system is on.
- Wait for Bluetooth to pair with the AccuSom recorder.

Step 3



- Follow the instructions on the application on how to setup the device.
- The sensor light of each sensor turns green when the sensor is in “OK” state, meaning that the sensor is correctly placed and that the recorder is receiving signal from it.
- Once all 3 sensors are in “OK” state, the recording will start automatically.



It is not unusual for sensors to have brief disruptions and need to be adjusted.

If the sensor continues to alarm, please call customer service 24/7.

Step 4

- Once you have finished your night:
- Do not turn off the application.
- Remove the system from your body. To open the chest sensor buckle, depress the two buttons.
- Connect the device to the charger, recorded data will be sent to BioSerenity via the mobile application.
- Once data has been sent you may turn off the application.

If the mobile application has disconnected from the device during the night, restart the application and follow the steps on how to connect to the device.

If you are scheduled to do another study next night, please leave the device in charge until the battery is fully charged and the sensor lights turn fixed blue.

If no further studies are scheduled, you may disconnect the device from its charger. Please place the system in the pouch it arrived in and send it back to BioSerenity.

4.3.2 Study without Smartphone application.

Step 1

- Setup the system as shown on pages 8-10
- Turn on the AccuSom device by pushing the power button for 2 seconds.
- The power button light will blink green when the system is on.
- The sensor light of each sensor turns green when the sensor is in “OK” state, meaning that the sensor is correctly placed, and that the recorder is receiving signal from it.
- Once all 3 sensors are in “OK” state, the recording will start automatically.

Step 2

- To end a recording, press the power button for 6 seconds. The device will turn off.
- Remove the device and all the sensors from your body. To open the chest sensor buckle, press the two buttons.
- Please place the system in the pouch it arrived in and send it back to BioSerenity.
- Your data will be uploaded immediately upon arrival.

4.4 Recorder Light status

Power button LED		Description
	Blinking Green	System powered on but not recording
	Fixed Green	System recording

Sensor LEDs		Description
	Any Fixed Green	Respective sensor OK
	Any Flashing Orange	Respective sensor not OK
	Chasing Blue/Aqua	System charging
	All Fixed Blue	System charged
	All Fixed White	Waiting for upload
	All Flashing White	Uploading
	All Fixed Orange	System error
OFF	All OFF	System OFF

5 Safety information

5.1 Operating condition

The AccuSom is designed for home use.

For safe use, the following environmental conditions must be met.

Environment	Component	Temperature	Relative humidity
Usage (Operating)	AccuSom System	0°C to +40˚C / 32°F to +104˚F	15-85% non-condensing
	Chest Unit	0°C to +40˚C / 32°F to 104˚F	10-90% non-condensing
	Breath sensor		
	Chest sensor		
	Finger sensor	0 to +40˚C / 32°F to 104˚F	15-85% non-condensing
Storage & Transportation (Non-Operating)	AccuSom System	-20°C to +55˚C / -4°F to +131˚F	15-85% non-condensing
	Chest Unit	-20°C to +55˚C / -4°F to +131˚F	<90% non-condensing
	Breath sensor		
	Chest sensor		
	Finger sensor	-25°C to +55˚C / -13°F to +131˚F	15-85% non-condensing

Altitude: -200 to 3,000 m ASL (685 hPa to 1040 hPa in the range of 0°C to +50°C).

5.2 Technical Specifications

Component	Characteristics
Chest Unit Dimensions	105 x 50 x 20 mm
Chest Unit weight	125 grams
Battery	Li-Ion Polymer 3.7V 1800 mAh
Charging cable	USB-A to USB-C
Battery Autonomy	> 9 hours
Maximum charging time	5 hours
Memory capacity	8 GB
Service life	4 night recordings
Finger Unit:	
SpO2 Range	0 – 100% SpO2 Saturation
HR Range	25 – 250 bpm
Sampling frequency	1 Hz
Output frequency	0.2 Hz
Clinical Accuracy	3%

Resolution	1%
Chest Unit: Sampling frequency	10 Hz
Breath Unit: Sampling frequency	5208 Hz

5.3 Safety information

Warning
The AccuSom is an electrical device containing type BF applied parts in contact with the patient in accordance with the standard 60601-1.

Warning
Electromedical devices require special precautions regarding EMC (Electromagnetic Compatibility) and must be installed and operated in accordance with the EMC information provided in the sections below.

Warning
The use of accessories, transducers, and cables other than those specified (except for transducers and cables sold by the manufacturer of AccuSom) such as replacement parts for internal components, may cause an increase of EMISSIONS or a reduction of IMMUNITY of the device.

Warning
The use of an AccuSom that is modified, or presenting signs of deterioration or a replacement of internal components, may cause an increase of EMISSIONS or a reduction of its IMMUNITY.

Warning
Portable and mobile RF (Radio Frequency) communication devices may affect ELECTROMEDICAL DEVICES. They must be kept away from the AccuSom.

Warning
The AccuSom is intended to be used on still patients.

Warning
Do not use the system simultaneously with any other medical device that has not been validated along with (CPAP machine, Oxygen machine).

Warning
Do not use a damaged or degraded device (packaging damaged, product damaged, corrosion....).

Warning
Do not modify the device.

Warning
Electrode conductive parts and associated connectors for applied parts, must not be in contact with other conductive parts, including ground.

Warning

Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

5.4 Information on Residual Risks

Warning

Do not use near, place, or drop water or other liquid on unit.

Warning

Do not use the device on a patient with open wounds.

Warning

Use the system indoors in a quiet environment.

Warning

Do not use the device in case of allergy to one of the components: latex, PVC, polyester.

5.5 Information on Wireless technology

AccuSom wireless technologies:

- Bluetooth Low Energy: device and patient's mobile phone
- Mobile network (e.g. 3G, 4G or 5G): patient's mobile phone
- Wi-Fi: patient's mobile phone

AccuSom wireless functions:

- Upload data from the device to the mobile application via Bluetooth link.
- Send data from the mobile application to Bioserenity servers using internet connection provided by mobile network or Wi-Fi.

5.6 Information on Electromagnetic Compatibility

Basic EMC standard or test method	Immunity test levels (IEC60601)
Home healthcare environment	
Electrostatic discharge (ESD) (IEC61000-4-2)	± 8 kV contact ± 15 kV air
Rated power frequency magnetic fields (IEC61000-4-8)	30 A/m
Radiated RF EM fields (IEC 61000-4-3)	10 V/m 80 MHz at 2.7 GHz 80% MA at 1 kHz
Proximity fields from RF wireless communications equipment (IEC 61000-4-3)	28 V/m 450 MHz, 810 MHz 870 MHz, 930 MHz 1720 MHz, 1845 MHz 1970 MHz, 2450 MHz
Conducted disturbances induced by RF fields (IEC061000-4-6)	3 V 150 KHz at 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz 80% MA at 1 KHz
Electrical fast transients / bursts (IEC 61000-4-4)	± 2 kV 100 KHz repetition frequency
Surges Line to line (IEC 61000-4-5)	± 0,5 kV, ± 1 kV
Surges Line to ground (IEC 61000-4-5)	± 0.5 kV, ± 1 kV, ± 2 kV
Voltage dips (IEC 61000-4-11)	0% UT; 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°
	0% UT; 1 cycle 70% UT; 25/30 cycles Single phase at 0°
Voltages interruptions (IEC 61000-4-11)	0% UT. 250 cycles at 50 Hz 300 cycles at 60 Hz

Table 9 – Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment

Test frequency (MHz)	Band [a] (MHz)	Service [a]	Modulation [b]	Maximum power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
385	380 –390	TETRA 400	Pulse modulation [b] 18 Hz	1,8	0,3	27
450	430 – 470	GMRS 460, FRS 460	FM [c] ± 5 kHz deviation 1 kHz sine	2	0,3	28
710	704 – 787	LTE Band 13, 17	Pulse modulation [b] 217 Hz	0,2	0,3	9
745						
780						
810	800 – 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation [b] 18 Hz	2	0,3	28
870						
930						
1 720	1 700 – 1 990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation [b] 217 Hz	2	0,3	28
1 845						
1 970						
2 450	2 400 – 2 570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation [b] 217 Hz	2	0,3	28
5 240	5 100 – 5 800	WLAN 802.11 a/n	Pulse modulation [b] 217 Hz	0,2	0,3	9
5 500						
5 785						

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.

[a] For some services, only the uplink frequencies are included.

[b] The carrier shall be modulated using a 50 % duty cycle square wave signal.

[c] As an alternative to FM modulation, 50 % pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.

When operating, the AccuSom emits Bluetooth type radiation in the 2.4 GHz band at levels inferior to 20 mW. It may therefore perturb other devices using radio frequency in these bands. As a result, it is advisable to use it away from devices that may be perturbed by this radiation.

When operating, the AccuSom receives Bluetooth type radiation in the 2.4 GHz band. It may therefore be perturbed by' other devices using radio frequency in these bands. As a result, it is advisable to use it away from devices that may generate radio frequency in these bands.

When operating, the AccuSom emits Bluetooth type radiation in the 2.4 GHz band, modulated in GFSK. The maximum effective radiated power (WORST) is 2.08 mW.

Manufacturer's directives and declarations - electromagnetic emissions

The AccuSom is intended to be used in the electromagnetic environment specified below. It is necessary for the client or user of the AccuSom to make sure that it is used in such an environment.

Emission testing	**Conformity**	**Electromagnetic environment - directives**
RF emissions CISPR 11	Class A	The AccuSom must emit electromagnetic energy to carry out the function for which it is intended. Neighboring electronic devices may be affected.
RF emissions CISPR 11	Class B	The AccuSom is suitable for use in any premises other than domestic premises and those directly linked to the public network for low-voltage power supply to buildings for domestic use.
Harmonic emissions CEI 61000-3-2	Not applicable	
Voltage fluctuations / Flicker CEI 61000-3-3	Not applicable	

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 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.

5.7. Risks linked to using the device

5.6.1 Risks of Electric Shock to patient

In order to mitigate any potential hazard associated with electric shock:

Root Cause	Mitigation
User contacts high voltage areas lead	The device uses a low voltage (5V DC) external power charger. The risk is the same as mobile phone's charger.

5.6.2 Risks Associated with Battery & Charger

In order to limit any potential hazard of explosion/fire/smoke/toxic emissions related to battery & charger:

Root Cause	Mitigation
Battery overheats due to short circuit or overcharging	The device shall use a IEC62133 rev B and UN38.3 compliant battery. It is thus protected against short circuits.

5.6.3 Risks Associated with RF exposure in order to limit any potential hazard of user thermal injury, tissue damage:

Root Cause	Mitigation
Excessive RF exposure during transmission of status using cellular modem	The device does not transmit record data using cellular modem while attached to patient. It only transmits status which is a very small amount of data and is not more dangerous than usual BLE device such as mobile phone or BLE smart watch.

5.6.4 Risks Associated with errors in measurement/diagnosis

In order to limit any potential hazard of incorrect diagnosis of user:

Root Cause	Mitigation
Sensor bad manufacturing or bad positioning	Software sensors are checked at start of measurement.
Removal of sensor during the night	Adhesive band provided to stick the sensor cables and prevent removal.

5.6.5 Risks associated with human errors

See risks associated to sensors

5.6.6 Risks associated with chest sensor

Root Cause	Mitigation
Tube is blocked, leads to dampened chest movement signal **Chest sensor in bad position leads to bad effort signal** **Detachment of the clip or glide of the tube adjustment buckle**	Software sensors are checked at start of recording. Manufacturing acceptance test. When incorrect sensor data is detected, a message is spoken by the device to invite the patient to check the sensor.
User injury	Cables length is as short as possible. Placement optimized so that it minimizes the risk of going around the neck.

5.6.7 Risks associated with breath sensor

Root Cause	Mitigation
User injury by entanglement	Cables length is the shortest as possible.
Breath sensor in bad position leads to bad effort signal	Placement is optimized so that the cable doesn't go around the neck. IFU and app show how to correctly place it and warn about the risk. When incorrect data is detected, a message is spoken by the device to invite patient to check the device.

6 Regulatory information

6.1 System Life Cycle

6.1.1 Product Lifetime

The components of the system lifetime are estimated in the following list:

- AccuSom Chest Unit: 10 use cycles with refurbishment. Each use cycle has up to 4 night recordings.
- AccuSom Chest Sensor: Single Patient
- AccuSom Breath Sensor: Single Patient
- AccuSom Finger Sensor: Single Patient

Once the lifetime duration of the product is reached, contact BioSerenity Customer Service: 1-877-753-3776.

Warning

In the case of storage for more than 1 year before first use, the battery must be charged once a year to maintain its functionality.

6.1.2 Recycling the AccuSom parts

Directive 2012/19/EU of the European Parliament and of the Council of 4 July 2012 on waste electrical and electronic equipment (WEEE) and Directive 2006/66/EC of the European Parliament and Council of 6 September 2006 on batteries and accumulators and waste batteries and accumulators and repealing Directive 91/157/EEC governing the recycling of batteries, electrical wire and electronic components. The electronic components cannot be discarded along with household waste.

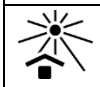
Warning

The battery contains hazardous products such as Lithium, which cannot be thrown away with household waste.

Note

Return the device to the manufacturer for recycling or recycle as a small electronic device that contains a lithium battery.

6.2 Product Symbology

Symbol	Description
	Manufacturer
	Date of manufacture
	Do not re-use
	Single patient, multiple use
	Use by date
	Serial number
	Catalogue number
	Batch code
	Do not use if package is damaged
	Keep away from sunlight
	Non-sterile
	Latex Free
	Lower and upper limit of temperature
	Lower and upper limit of relative humidity
	Caution – See the user manual
	Keep away from rain
	The product must be eliminated in a suitable salvage and recycling structure
IP22	IP rating
	Direct current

	Type BF applied part
	Refer to instruction manual
	Operating instructions
Rx only	Restricts this device to sale by or on the order of a physician
	Do not expose the device to magnetic resonance (MRI) environments
	Marking on the exterior of the product or on parts of the device, including RF transmitters or involving RF (Radio Frequency) electromagnetic energy for diagnosis or treatment. DEVICES and EM SYSTEMS which include RF transmitters or which intentionally apply RF electromagnetic energy for the diagnosis or treatment must bear the symbol ICE 60417-5140 (2003-04) relating to non-ionizing radiation.

6.3 Contact

6.3.1 Contact Information

Problems completing the AccuSom sleep test:

Call BioSerenity Patient and Clinical Support toll free: 1-877-753-3776, select Option 5, Clinical Assistance.

6.3.2 Additional Information

Need more information?

Go to: www.bioserenity.com/sleep-wellness

Need a copy of your AccuSom sleep test results?

Go to: www.bioserenity.com/sleep-wellness and click on button “Request Results” to download the medical release request form.

6.3.3 Maintenance

The product is limited to 4 uses by the patient. After 4 recordings, the patient shall send the device back to BioSerenity for recycling.

6.3.4 Cleaning

The device can be cleaned with disinfecting cleaning wipes.

6.3.5 FAQ

What if voice prompt says "Check Breath Sensor"?

- Move and tighter the Breath Sensor so 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
- Secure the Breath Sensor cables to your cheeks with medical tape.
- Turn off ceiling fans, all other fans should face away from test subject
- Blow into breath sensor
- If the Breath Sensor light does not turn green, call BioSerenity during normal business hours

What if voice prompt says "Check Finger Sensor"?

- Check to see if the Finger Sensor is correctly positioned on the fingertip and that the cable is connected to the device.
- Dark nail polish has been completely removed.
- Warm your fingertip.
- If the Finger Sensor light does not turn green, call BioSerenity during normal business hours.

What if voice prompt says "Check Chest Sensor"?

- Move and tighten the Chest Sensor so it is just below the breasts.
- Squeeze the Chest Sensor Belt tubing between two fingers.
- Check for any knots or holes in tubing
- If the Chest Sensor light does not turn green, call BioSerenity during normal business hours.

What if the power light is not lit?

- Press On/Off button for 5 seconds to turn device on. If the power button light does not blink green, the battery may be too low.
- Connect the device to a charger and charge for 5 hours to fully charge the device. If power button light still does not blink green when power button is pushed, call BioSerenity during normal business hours.

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

- Leave the sensors in place and connected to the Chest Unit on your chest. You can move around and return to bed.

What if I use a CPAP Machine?

- The AccuSom system cannot be used at the same time as your CPAP machine.

What if my mobile phone has turned off during the night?

- Turn your mobile device back on.
- If your mobile phone is out of battery, please put it to charge and turn it on.
- Relaunch the Mobile Application, it will guide you to finish your sleep study and upload your data.

What if the AccuSom does not connect to the mobile application?

- Please go to "Settings" on your mobile device and verify that Bluetooth connection is turned on.
- If the AccuSom still cannot connect to the Mobile Application, call BioSerenity during normal business hours.

What if the AccuSom is not able to send my data?

- Please check that your mobile device has access to internet either via WIFI or 4G and that Bluetooth connection is turned on.
- If the AccuSom still cannot connect to the Mobile Application, call BioSerenity during normal business hours.
- Please send the device back to BioSerenity, your data will be uploaded on arrival.

6.3.6 Materiovigilance

Every serious incident related to the device must be notified to the manufacturer (BIOSERENITY USA, Inc., 801 Cromwell Park Drive, Suite 108, Glen Burnie, MD 21061, USA. Phone 1-877-753-3776) and to the competent authority from the user State.

6.3.7 Manufacturer Information

AccuSom, AccuSom breath sensor and AccuSom chest sensor

BIOSERENITY USA, Inc.
801 Cromwell Park Drive, Suite 108,
Glen Burnie, MD 21061, USA.
Phone: 1-877-753-3776

AccuSom is a trademark of BioSerenity.

Finger sensors

Unimed Medical supplies Inc
Bld # 8, Nangang 3rd Industrial Park, Tangtou,
Shiyan, 518108, ShenZhen, P.R. China

Shenzhen Amydi-med Electrics Tech Co., Ltd
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