Snap Diagnostics

SAM Model 9-10000

Device Instructions

Snap Diagnostics
616 Atrium Drive, Ste 100
Vernon Hills, IL, 60061
Customer Support: 847-777-0000
www.snapdiagnostics.com

FCC ID: 2BDPB910000

	**WARNINGS** • 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. • 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** • ℞ only: U.S. Federal law restricts this recorder to sale by or on the order of a licensed healthcare practitioner. • Use only Snap Diagnostics supplied sensors and cables with this device. Using other accessories may result in increased electromagnetics 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 indicated for use in the 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 device 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.

CAUTION: US Federal law restricts this device to sale by or on the order of a physician. 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 Model 9 device.

These instructions may refer to the SAM Model 9-10000 as SAM throughout this document.

Introduction

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

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 the patient needs 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/

Snap Testing Kit

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

Snap Sleep Apnea Monitor (SAM) + Belt

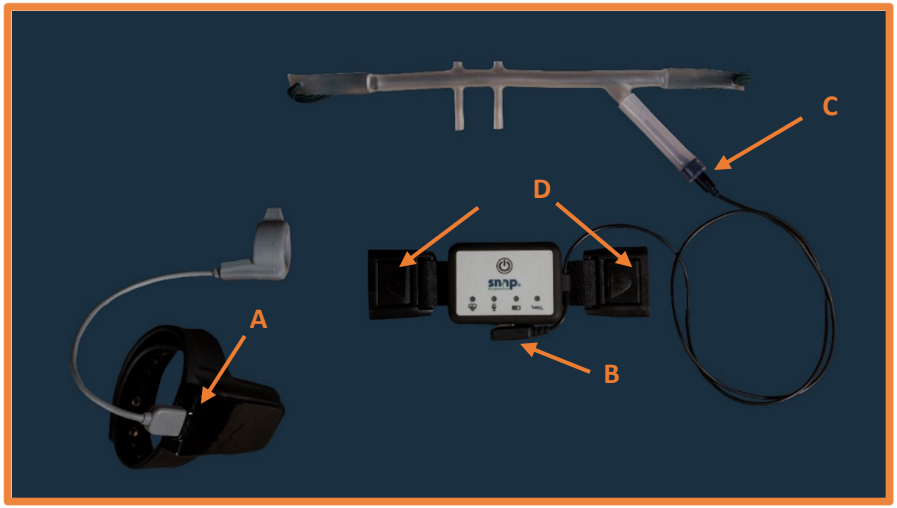
Airflow Sensor + Nasal Cannula

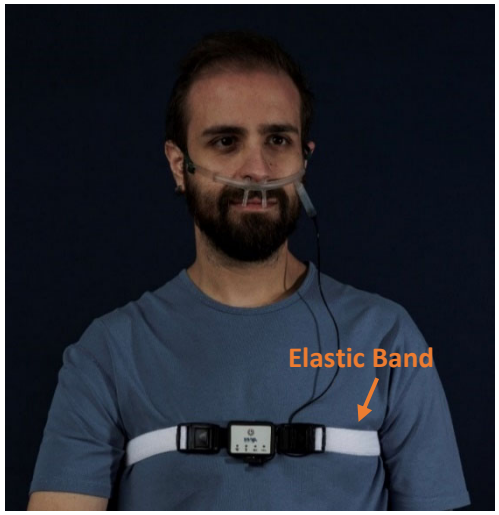
Oximetry Watch Monitor + Ring Sensor

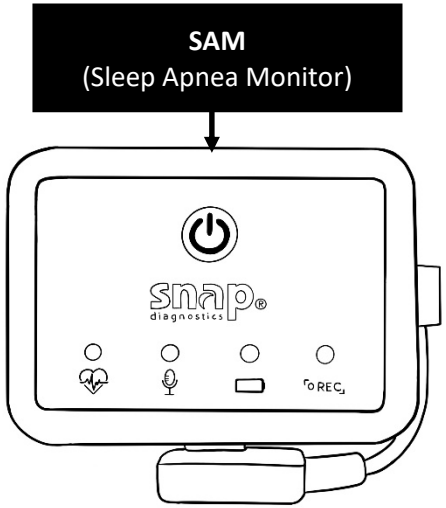
Ensure that the sensors are securely connected to the recorder before use.

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)

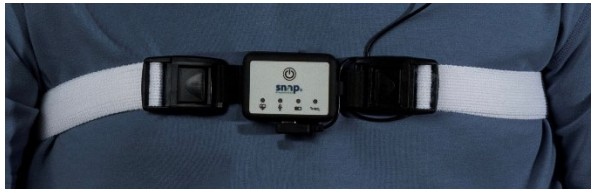



Elastic Band


SAM
(Sleep Apnea Monitor)
snap
diagnostics
REC

Connect to the SAM + Belt

Patient Instruction 1: The Sleep Apnea Monitor (SAM) is connected to an elastic belt which will be worn over the patients clothing. The patient will fasten the Belt around their chest, placing the SAM device 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 the chest with the airflow sensor (microphone) 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

Patient Instruction 2: The wire of the SAM Airflow Sensor (microphone) is connected to a nasal cannula. The patient will place the nasal cannula underneath their nose with the shorter pair of prongs, resting under their nostrils and the longer pair of prongs pointing down towards their mouth. The elastic headband fits over the ears, pulling 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 (microphone) LED will display in green.

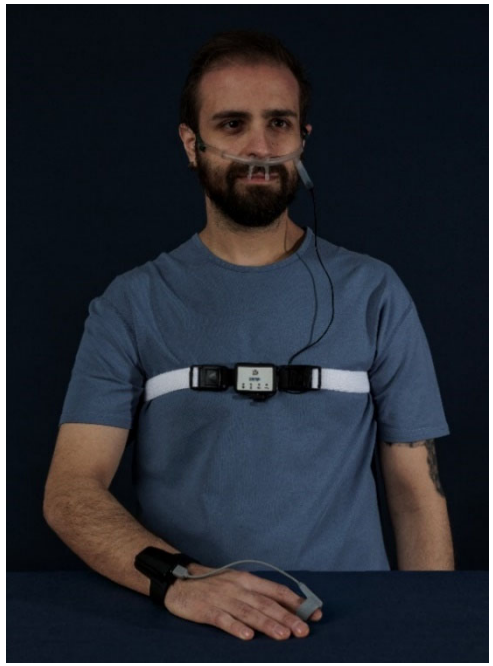
Tip: The longer prongs should rest just in front of your upper lip and can be slightly trimmed with scissors if necessary.

Connect to the Oximetry Watch Monitor + Ring Sensor

Patient Instruction 3: The Oximetry Watch Monitor is worn around the wrist. The patient will strap the watch to their non-dominant hand. The fit should feel secure, and not too loose or too tight.

Patient Instruction 4: We recommend placing the Ring Sensor on the thumb. If the thumb is too tight, the patient may use a different finger. The ring can be placed on the bony part of the finger between the knuckles and may be secured with medical tape as needed.

Tip: If it feels comfortable, we recommend using a different hand for each night of testing and wearing the ring sensor on the thumb. The patient should be instructed to check the skin on their finger and wrist for irritation during and after use. Prolonged continuous SpO2 monitoring may increase the risk of undesirable changes in skin characteristics such as irritation, reddening, blistering, or burning. If any symptoms occur, the patient should 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, it should be adjusted before starting the recording. For further guidance, testing support is available at (847)777-0000.

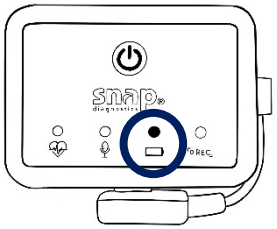
Once the patient has comfortably applied the monitors and sensors, they can turn them on to begin recording.

Rotate the SAM device up to see the face of the device and LED’s

Start Recording

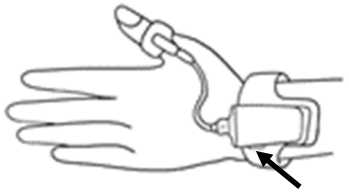
Patient Instruction 5: Turn on the SAM Recorder.

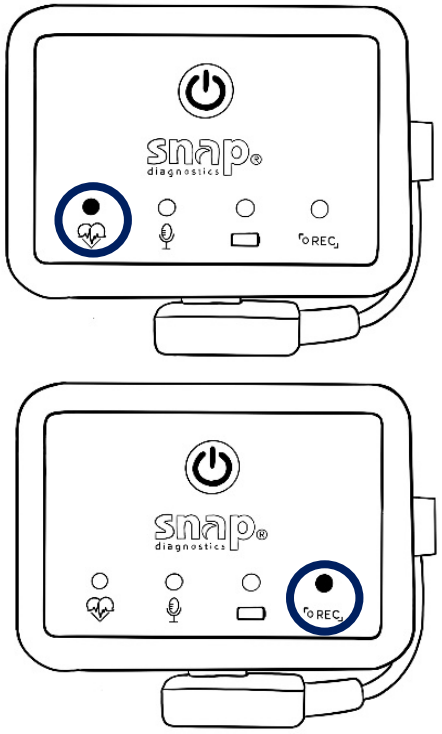
- Press the power/record button to turn on the SAM Recorder and start the recording. The light above the battery symbol will illuminate.



Patient Instruction 6: Turn on the Oximetry Watch Monitor.

- The patient will 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.

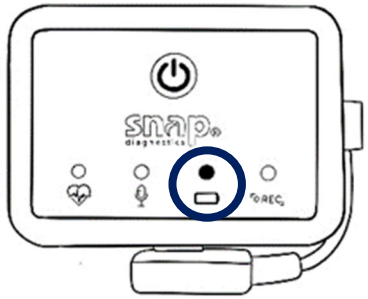
After the device completes its self-test a green REC light indicates all functions are operable and recording will start automatically. Once recording has started, only the REC light will display blinking green approximately every 5 seconds. The device will record for 6 hours and automatically turn off.

If LEDs display magenta or amber, refer to the table on page 14 for troubleshooting or contact Snap Customer Support at (847)777-0000.

Battery Life

To conserve battery, the device is programmed to 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.



The SAM and Oximetry Watch Sensor must be charged before each patient use. Please use only cables provided by Snap Diagnostics to charge the batteries.

LED Communications

The LEDs on the SAM device will communicate the device status. During the start-up process a self-test will run for approximately 40 seconds. The LEDs 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 Record/Power LED will remain green for the duration of the recording unless a sensor becomes disconnected, changing the LED to amber. All other LEDs will remain unlit while the recording is in progress.

To check the status of the SAM device during the recording, pressing the power button 1 time will illuminate the LED's for 5 seconds. *Do not double press the power button as this will stop the recording.*

If the Battery or Record LED displays a constant magenta color, contact Snap Customer Support at (847)777-0000.

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

Upload the Data

Once your patient has completed the test and returned it to you, upload the data for analysis. [Upload Instructions to be inserted when available]

Results

Sleep data is analyzed by our laboratory at Snap, and once ready, will be sent directly to the ordering medical provider.

To inquire about the status of a 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 registration and other inquiries, our in-house Support team is available during business hours. Please see our website for hours of operation, https://snapdiagnostics.com/contact/.

Patients may find answers to frequently asked questions (FAQs) on our website, https://snapdiagnostics.com/patient-faq/.

Patients may visit our website to read their privacy rights under the Health Insurance Portability and Accountability Act (HIPAA), 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/tbd.

To view the IDTF Performance Standards on a smartphone, scan this QR code using your phone's camera. [QR Code]

In addition to the instructions provided in this booklet, a patient instruction booklet and instructional video are available on our website, https://snapdiagnostics.com.

Cleaning Instructions

Reusable parts shall be thoroughly cleaned between patients. Disposable parts shall be discarded after patient use. A visual inspection of the device, sensors and accessories shall be conducted between patient use for visual contaminants and damage. Inspection of the device, sensors, and accessories after cleaning for the presence of visual contaminants shall be conducted. If there is a presence of visual contaminants, the cleaning process shall be repeated. If the cleaning process is unable to remove visual contaminants, the device shall be returned to Snap. Any damaged parts shall be returned to Snap.

SAM Device (reusable) – Clean with 10% bleach, or wipe using an ammonium chloride disinfecting wipe.

Airflow Sensor Wire/Microphone (reusable) – Clean with 10% bleach or wipe with 70% isopropyl alcohol.

Cannula (disposable) – This item is intended for single patient use and must be discarded in trash after patient use.

Elastics Band (belt) – The reusable belt (dark band) may be washed in warm water with mild detergent. The disposable belt (white band) must be discarded in trash after each patient use.

Nonin Oximetry Watch and Ring Sensor (reusable) - Do NOT use isopropyl alcohol or Ammonium Chloride. Use 10% bleach on the device and sensor. Use mild detergent on the wrist band.

CheckME Oximetry Watch and Ring Sensor (reusable) – Wipe with 70% isopropyl alcohol.

Warning: Do not mix chemicals while cleaning an item. Mixed chemicals can produce toxic gases that are dangerous to inhale.

Maintenance

Servicing and Calibration
There are no user serviceable parts, and no calibration is required. For problems with the device, contact Snap Diagnostics Support at (847)777-0000.
If any sign of damage appears on the recorder or sensors, please call Snap Diagnostics to arrange a return or exchange.

Battery Information
Battery Type: 3.7V Lithium-Ion rechargeable
Charge Input: DC 5V+/-10%

Expected Service Life
5 years

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

Avoid spilling liquids on the recording device. Do not immerse in water.
Temperature Range: -13 to 158 F (-25 to 70 C) Relative Humidity: 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

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.*

EMC Interference

Snap SAM Model 9-10000 has been tested and found to comply with the electromagnetic compliance limits for EN 60601-1-2:2020 Ed 4.1.

These limits are designed to provide reasonable protection against harmful interference in a typical use environment. The equipment generates radio-frequency energy and, if not installed and used in accordance with the instructions, may cause interference to other devices in the vicinity. If this equipment does interfere with other devices, which can be determined by turning the equipment off and on, try to correct the interference by one or more of the following measures:

- *Reorient or relocate the receiving device.*
- *Increase the separation between the equipment.*

Model 9-10000 must be put into service according to the electromagnetic compliance (EMC) guidelines and declarations provided here.

- *Electromagnetic emissions (see Table A-1) on page 21.*
- *Electromagnetic immunity (see Table A-2) on pages 22-25.*
- *Recommended separation distances between radiofrequency (RF) communications equipment and Model 9-10000 (see Table A-2) on page 22-25.*

NOTE: Portable and mobile RF communications equipment can affect device operation

Electromagnetic Emissions

Table A-1. *Electromagnetic compatibility (EMC) emissions guidelines and declarations for SAM Model 9-10000*

SAM Model 9-10000 is intended for use in the electromagnetic environment specified below. Users should ensure that it is used in such an environment.		
Emissions Test	***Compliance***	***Electromagnetic Environment—Guidance***
RF emissions CISPR 11	*Group 1*	*Model 9-10000 uses RF energy only for its internal functions. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.*
RF emissions CISPR 11	*Class B*	*Model 9-10000 is suitable for use in in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.*

Electromagnetic Immunity

Table A-2. *Electromagnetic compatibility (EMC) immunity guidelines and declarations for SAM Model 9-10000*

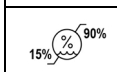
Model 9-10000 is intended for use in the electromagnetic environment specified below. The customer or user of Model 9-10000 should ensure that it is used in such an environment.			
Immunity Test	***IEC 60601 Test Level***	***Compliance Level***	***Electromagnetic Environment—Guidance***
Electrostatic discharge (ESD) IEC 61000-4-2	*±8 kV contact* *±15 kV air*	*±8 kV contact* *±15 kV air*	*Floors should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.*
Radiated Immunity IEC 61000-4-3	*10 V/m 80 MHz to 1GHz* *3V/m 1GHz to 2.7 GHz*	*10V/m* *3V/m*	*Portable and mobile RF communications equipment should be used no closer to any part of the SAM, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.* *d = 1.2 √P 80 MHz to 800 MHz* *d = 2.3 √P 800 MHz to 2.7 GHz*

Model 9-10000 is intended for use in the electromagnetic environment specified below. The customer or user of Model 9-10000 should ensure that it is used in such an environment.			
Immunity Test	***IEC 60601 Test Level***	***Compliance Level***	***Electromagnetic Environment—Guidance***
Conducted Immunity *IEC 61000-4-6*	*150kHz to 80MHz* *ISM[a] and AR Bands*	*3Vrms, 1kHz AM @80%* *6Vrms, 1kHz AM @80%*	*d = 1.2 √P*
Radiated RF IEC 60601-1-2 (wireless communications)	*28 V/m for GSM, TETRA 800, iDEN 820, CDMA 850, or LTE Band 5 services (0.3 m separation)* *27 V/m for TETRA 400 service* *28 V/m for GMRS 460, FRS 460, GSM 1800, CDMA 1900, GSM 1900, DECT, LTE Band 1, 3, 4, and 25,*	*28V/m* *27V/m* *28V/m*	*d = 0.3 minimum* *d = 0.3 minimum* *d = 0.3 minimum*

Model 9-10000 is intended for use in the electromagnetic environment specified below. The customer or user of Model 9-10000 should ensure that it is used in such an environment.			
Immunity Test	***IEC 60601 Test Level***	***Compliance Level***	***Electromagnetic Environment—Guidance***
	UMTS, Bluetooth, WLAN, 802.11 b/g/ n, RFID 2450, and LTE Band 7 services 9 V/m for LTE Band 13 and 17, and WLAN 802.11 a/n services	*9V/m*	*d = 0.3 minimum* *where P is the maximum output power rating of the transmitter in watts according to the transmitter manufacturer and d is the recommended separation distance in meters.* *b Field strengths from fixed RF transmitters, as determined by electromagnetic site survey,* *c should be less than the compliance level in each frequency range.* *d Interference may occur in the vicinity of equipment marked with the following symbol:*
Not Applicable: Harmonic Emissions (IEC 61000-3-2), Voltage Flicker Emissions (IEC 61000-3-3), Electrical Fast Transients (IEC 61000-4-4), Surge (IEC 61000-4-5), Voltage dips (IEC 61000-4-11)			

The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz
Amateur Radio Bands: 1.8MHz – 2.0MHz, 3.5MHz – 4.0MHz, 5.3MHz – 5.4MHz, 7MHz – 7.3MHz, 10.1MHz 10.15MHz, 14MHz – 14.2MHz, 18.07MHz – 18.17MHz, 21.0MHz – 24.1MHz, 24.89MHz – 24.99MHz, 28.0MHz -29.7MHz, and 50.0MHz – 54.0MHz.

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
SN	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%

Good Night!

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