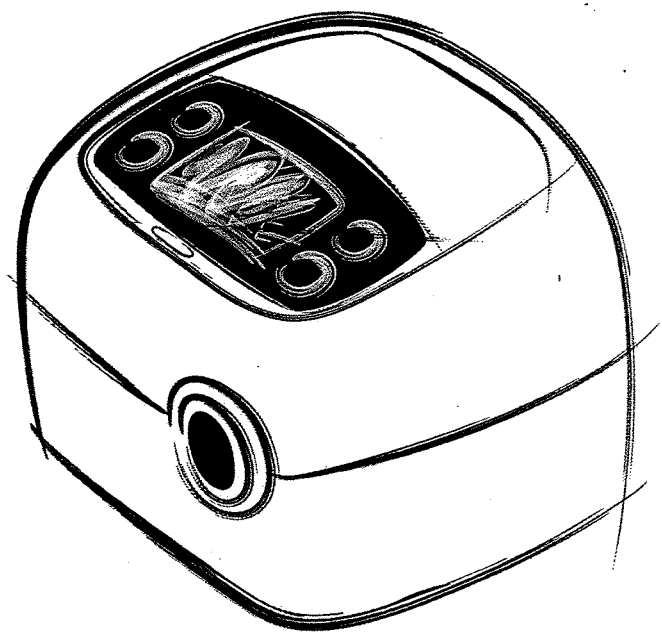
PureSom CPAP

Instruction Manual



Model No.: 9S-005500

Please read the instruction manual before use

Contents

IMPORTANT SAFEGUARDS
SAVE THESE INSTRUCTIONS
READ ALL INSTRUCTIONS BEFORE USING

WARNING –

1. THIS DEVICE IS NOT INTENDED FOR LIFE SUPPORT. It may stop operating due to power interruption but no hazards to patient.
2. If oxygen is used with the device, the oxygen flow must be turned off when the device is not in use. **Explanation of the Warning:** When the device is not in operation and the oxygen flow is left on, oxygen delivered into the tubing may accumulate within the device's enclosure and create a risk of fire.
3. Oxygen supports combustion. Oxygen **should not** be used while smoking or in the presence of an open flame.
4. Always ensure the device is generating airflow before the oxygen supply is turned on. Always turn off the oxygen supply before stopping the airflow from the device.
5. This device **should not** be used in the vicinity of a flammable anesthetic mixture in combination with oxygen or air and nitrous oxide.

   ⚠ NOTE : L'équipment ne peut être utilisé s'il y a risque de mélange d'un anesthésique inflammable avec l'air ou l'oxygène ou oxyde nitreux.

6. The airflow for breathing generated by this device may be as much as 7°C (44.6°F) higher than the room temperature. This device **should not** be used if the room temperature is warmer than 35°C (95°F) to prevent the airflow temperature from exceeding 40°C (104°F) and causing irritation to your airway.
7. If this device overheats, it will stop operating and show message "Error 002" on the display. After cooling down to proper temperature, the device can restart again.
8. This machine should be used only with masks (and connectors) recommended by the manufacturer, or by your physician or respiratory therapist. A mask should not be used unless the CPAP machine is turned on and operating properly. The vent holes associated with the mask should never be blocked for proper exhaling purpose. If the vent hole is blocked, the CPAP machine will stop and show message "**Error 002**". Unplug the power cord and allow unit to cool down. After unit has cooled, please re-connect the power cord to reset the machine.
9. At low CPAP pressure, some exhaled gas may remain in the mask and be re-breathed.

CAUTION –

1. Make sure the environment around the machine is dry and clean. Dust and foreign particles may affect the treatment. Keep the air inlet on the back of the machine clear to prevent overheating and damage of the device. Do not place the machine near a source of hot or cold air. Extreme cold or hot environment may damage user's respiratory airway.
2. If there is a possibility of electro-magnetic interference with mobile phones, please increase the distance between devices or turn off the mobile phone.
3. U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

ANGER -To reduce the risk of electrocution:
Always unplug this product immediately after using.
Do not use while bathing.
Do not place or store product where it can fall or be pulled into a tub or sink.
Do not place in or drop into water or other liquid.
Do not reach for a product that has fallen into water. Unplug immediately.

ARNING -To reduce the risk of burns, electrocution, fire or injury to persons:
This product should never be left unattended when plugged in.
Close supervision is necessary when this product is used by, on, or near children or invalids.
Use this product only for its intended use as described in this manual, do not use attachments not recommended by the manufacturer.
Never operate this product if it has a damaged cord or plug, if it is not working properly, if it has been dropped or damaged, or dropped into water. Return the product to a service center for examination and repair.
Keep the cord away from heated surfaces.
Never block the air openings of this product or place it on a soft surface, such as a bed or couch, where their openings may be blocked. Keep the air opening free of lint, hair, and other similar particles.
Never drop or insert any object into any opening or hose.
Follow the national requirement to dispose unit.

1. Introduction

This manual should be used for initial set up of the system and saved for reference purpose.

1.1 General Information

Obstructive Sleep Apnea (OSA) is a condition that an intermitted and repetitive obstruction of the upper respiratory tract causes a complete (apnea) or partial (hypopnea) block of breathing airflow during sleep. The syndrome varies depending on the degree of relaxation of the tongue and soft palate muscle.

The most common treatment for OSA is Continuous Positive Airway Pressure (CPAP). CPAP devices can deliver a constant air pressure into your upper airway via a nasal mask. This constant air pressure can keep your airway open during sleep, therefore prevents the OSA.

This device is a micro-processor controlled continuous positive airway pressure device. It features the illuminated, menu-driven LCD display, universal power supply, and ramp time adjustment. The ramp time adjustment and ultra quiet operation ensure you to fall asleep comfortably while air pressures slowly build up to treatment level. The user compliance meter records the total system's operating time for physician's reference.

The system has been tested and successfully approved to the following standards:

CE 0197

EN 60601-1
EN 60601-1-2
EN 61000-3-2 Class A
EN 61000-3-3

EMC Warning Statement

This equipment has been tested and found to comply with the limits for medical devices to the EN 60601-1-2:2007. These limits are designed to provide reasonable protection against harmful interference in a typical medical 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 other devices in the vicinity. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to other devices, 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 device.
- Increase the separation between the equipment.
- Connect the equipment into an outlet on a circuit different from that to which the other device(s) are connected.
- Consult the manufacturer or field service technician for help.

This system has been tested and compliance to the following volunteer standards:
FDA

2 Intended Use

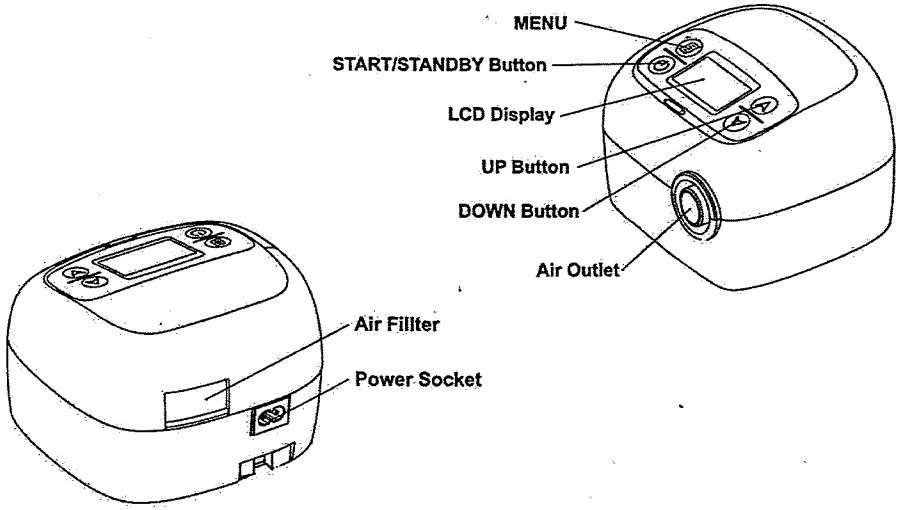
This device is intended to provide continuous positive airway pressure (CPAP) for the treatment of adult Obstructive Sleep Apnea (OSA).

⚠ **Cautions: Some patients might have pre-existing contraindications for CPAP therapy, or might experience some potential side effects of using CPAP device, please consult your physician if you have any questions concerning your therapy.**

2 Product Description

Components including:

(1) Main CPAP device
(2) Detachable power cord
(3) User manual
(4) Flexible air tubing with 1.8 m length
(5) Full face or nasal mask and headgear straps (Optional, Always use CE certified and 510(k) cleared mask for CPAP)
(6) Carrying bag (optional)

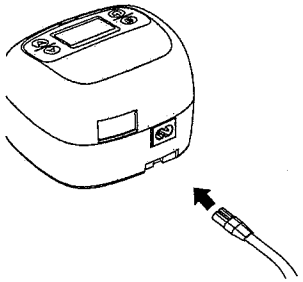


Installation

1 Unpacking

To secure its contents inside, the CPAP device and accessories are bundled in a paper packaged box. Unpack this box by removing the CPAP and its accessory and checking for any damage, which may have occurred during shipping. If there are damages, please contact your dealer immediately.

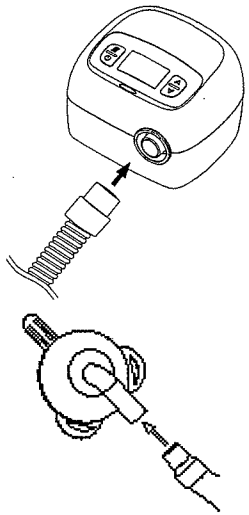
2 Setting Up



1) Connect the power cord to CPAP device and plug into main electrical outlet.

   Once the power cord is plugged into the electrical outlet, the device is in ready to operate position ("**STANDBY**" sign appears in LCD display)

⚠ **NOTE: The plug can also be used to disconnect the device.**



2) Connect one end of the air tubing firmly onto the air outlet of the CPAP.

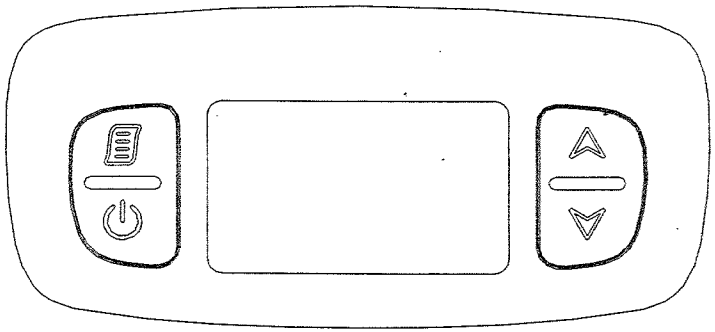
3) Connect the other end of the air tubing to the mask system. Putting on the mask and headgear according to the mask instruction manual.

4 Operation

⚠ **NOTE:** Always read the operating instruction before use.

4.1 Control Panel Description

Button arrangement on control panel and main use of the buttons:



START/STANDBY
To start the treatment, simply press the ***"START/STANDBY"*** button. To stop the treatment, press the ***"START/STANDBY"*** button again. The display will switch between ***[STANDBY]*** and Therapy Pressure ***[XX.X cmH$_2$O]*** in cmH$_2$O unit.

MENU
Press the ***"MENU"*** button to enter the setting mode when device is in standby mode. The adjustment setting includes ramp time selection, therapy pressure adjustment, altitude compensation, and total operating meter. When each setting's value has been changed, press ***"MENU"*** for confirmation and press ***"MENU"*** again for next setting selection. Please refer to 4.2 Function Description section for detailed information.

UP
Press the ***"UP"*** button to select the increasing value.

DOWN
Press the ***"DOWN"*** button to select the decreasing value.

2 Function Description

1) Ramp Time

Ramp time function allows user to fall into sleep with a lower, comfortable pressure and helps users gradually accustomed to increasing treatment pressure. The first selection of pressing ***"MENU"*** is ***[Ramp XX MIN]***. When the ***"MENU"*** setting is in ***[Ramp XX MIN]*** mode, press ***"UP"*** or ***"DOWN"*** button to set the preferred ramp time and press ***"MENU"*** for confirmation. There are 10 adjustable levels, 0, 5, 10, 15, 20, 25, 30, 35, 40 and 45 minutes.

2)Ramp Starting Pressure

Press ***"MENU"*** button to select ***[Ramp P XX.X]*** menu, press ***"UP"*** or ***"DOWN"*** button to set the preferred ramp starting pressure and press ***"MENU"*** for confirmation. The ramp starting pressure can be changed from 3 cmH_2O to "Therapy Pressure – 1" cmH_2O. For example, if your therapy pressure is 10 cmH_2O, the maximum ramp starting pressure you can select is 9 cmH_2O.

3) Therapy Pressure

Press ***"MENU"*** button to select ***[P XX.XcmH₂O]*** menu, you can view the current pressure setting displayed in cmH_2O unit. Therapy pressure is adjustable only by the physician.

NOTE: The therapy pressure is adjustable only by the physician.

4) Altitude Compensation

Press ***"MENU"*** button to select ***[Alt X]*** menu, press ***"UP"*** or ***"DOWN"*** button to set the preferred altitude compensation level from 1 to 8. The level should be set depending on your elevation above sea level. Once the preferred level has been selected, press ***"MENU"*** for confirmation.

⚠ NOTE: Users can operate the Probasics Zzz-PAP at wide range of altitude within 0~8000 ft (limit to 5000 ft if the pressure is set at 18.5-20 cmH2O). The altitude function provides a method of accuracy pressure output at high altitude. Users must follow the below table to select correct altitude setting depending on your elevation above sea level, the device will automatically regulate airflow output to achieve targeted pressure at high altitude. Otherwise, wrong altitude setting will cause inaccuracy pressure output.

There are eight altitude compensation levels. The level should be set depending on your elevation above sea level. Below table is the comparison of altitude setting and altitude.

Altitude Setting	Altitude (Imperial)	Altitude (Metric)
1	0 ~ 1000 ft	0 ~ 304 m
2	1001 ~ 2000 ft	305 ~ 609 m
3	2001 ~ 3000 ft	610 m ~914m
4	3001 ~ 4000 ft	915 m ~1219m
5	4001 ~ 5000 ft	1220 m ~1524m
6	5001 ~ 6000 ft	1525 m ~1829m
7	6001 ~ 7000 ft	1830 m ~2134m
8	7001 ~ 8000 ft	2135 m ~2438m

(4) Total Meter

Press ***"MENU"*** button to select ***[TM XXXX.X hr]*** menu, the total meter records the total number of hours that the device has been active. The meter can be re-set only by the physician.

NOTE: The total meter can be re-set only by the physician.

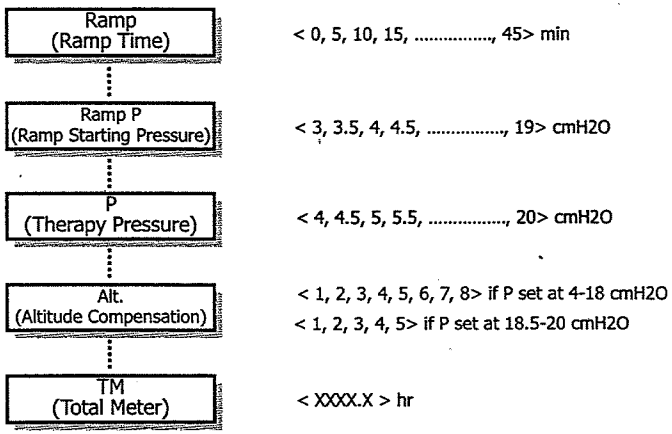
(5) Turn off the Device

Remove the power cord from the electrical outlet, and disconnect power cord from the power socket on the back of device.

⚠ NOTE: **Once the setting is confirmed, press *"MENU"* button. Otherwise, the device will automatically go back to standby without saving the modification if no action is taken in 5 seconds.**

4.3 Flowchart of Menu settings

Enter the user's menu mode by pressing the "***MENU***" button.



In each setting, when the preferred value has been selected, press ***"MENU"*** for confirmation and press ***"MENU"*** again to enter next selection.

NOTE: For physicians, please refer to a separated "Physician's Additional Instruction" page.

Adding a Humidifier

PureSom CPAP device can be used with Heated Humidifier which is available from the home care provider. The heated humidifier may reduce nasal dryness and irritation by providing adequate moisture and heat to the airflow. Please refer to the heated humidifier instruction manual for complete setup information

NOTE: When PureSom CPAP device is used with the heated humidifier, its power supply is from the power socket outlet of the heated humidifier. Do not connect the power cord to CPAP device and plug into main electrical outlet.

Cleaning & Maintenance

1 Device

The device should be checked and dusted regularly (at least every 30 days). Wipe with a damp cloth and a mild detergent and keep it free from dust. If other detergent is used, choose one that will have no chemical effects on the surface of the plastic case. All parts should be air-dried thoroughly before use.

⚠ **WARNING:** Don't try to open this device. Repairs and internal servicing should only be performed by an authorized service agent and qualified technician. Don't drop any foreign object into the air tube or air outlet.

2 Tubing and Mask

The tubing and mask should be checked and cleaned regularly. Please refer to the cleaning instruction packaged with the accessories.

1. Disconnect the air tubing from the air outlet of the device.
2. Remove the air tubing and headgear straps from the mask.
3. Wash the mask system according to the instructions supplied with it.
4. Wash the tubing in warm water using mild detergent. Rinse thoroughly, hang and allow to dry.
5. Before next use, assemble the mask and headgear according to the mask user instructions.
6. All items of the mask and air tubing are subject to normal wear and tear and may eventually be replaced. Replace the mask and the air tubing if they are damaged.

⚠ **CAUTION:** Do not use blench, chlorine-, alcohol-, or aromatic-based (including all scented oils), moisturizing or antibacterial soaps to clean the cushion, mask, air tubing. These solutions may cause hardening and reduce the life of the product.

⚠ **CAUTION:** Do not wash or dry the mask or air tubing at a temperature above 70°C (160°F)

⚠ **WARNING:** Do not use any cleaner containing fragrance or conditioners as they will leave a residue.

⚠ **WARNING:** The mask must not be re-used by another person. This is to avoid the risk of cross-infection.

6.3 Air Filter

The air filter should be cleaned at least once every two weeks or more often if this device is operated in a dusty environment and replaced with a new one every six months.

⚠ **CAUTION:** Dirty air filter may cause high operating temperatures that affect device performance. Ensure the air filter is cleaned and fitted at all times.

1. Remove the dirty filter from the enclosure on the rear of the device.
2. Wash the filter in warm water with a mild detergent, and rinse with water. Allow the filter to air dry completely before reinstalling. Do not use a filter that is not completely dry. If the filter is torn, replace it.
3. Reinstall the filter.

NOTE: Please follow national requirements to dispose the unit properly.

7. Troubleshooting

The table below lists troubleshooting solutions for the problems that may happen. If the problem persists, contact your equipment provider service agent.

Problem	Possible Causes	Solutions
No display	1. The power cord is not connected to the power socket. 2. LCD failure or controlled PCB failure.	1. Ensure the power cord is connected. 2. Contact your equipment provider for repair.
Display code incorrect	LCD failure or controlled PCB failure.	Contact your equipment provider for repair.
Illuminant under LCD is not on	LED failure	Contact your equipment provider for repair.
Buttons disable	Button failure	Contact your equipment provider for repair.
Air delivered is slow	1. During ramp time. 2. Filter is too dirty. 3. Flow generator failure.	1. Check the ramp time setting 2. Change or clean the filter regularly. 3. Contact your equipment provider for repair.

Error / Warning Messages show in LCD.

Message type	Definition	Message in LCD
Error: Primary function can't execute.	Error for system's settings abnormal	Error 001
	Error for flow generator failure	Error 002
Warning:	The allowed maximum time of the meter is reached	Warn 001
	The allowed maximum time of the meter is nearly reached	Warn 002

NOTE: When the warning message appears, contact your physician or equipment provider to reset the meter.

8. Technical Specifications

Item		Specifications
Mode of Operation		Continuous
Pressure Range		4 –20 cmH_2O (adjustable in 0.5 cmH_2O increment)
Ramp Time		0 – 45 minutes (adjustable in 5-minute increment)
Ramp Starting Pressure		3 to therapy pressure
Altitude Compensation (Manual setting)		Level 1~8 for 0 ~ 8000 ft when the pressure is set at 4-18 cmH_2O. Level 1~5 for 0 ~ 5000 ft when the pressure is set at 18.5-20 cmH_2O
Dimensions (W x D x H)		14.5 x 13.0 x 10.0 cm or 5.7" x 5.1" x 3.9"
Weight		Approximately 800 g or 1.76 lb
Sound Level		30 dBA at 10 cmH_2O, 1 meter distance
Power Input		AC100-240V, 50/60 Hz, 0.5-0.3A
Environment	Temperature	Operating: +5°C to +35°C (+41°F to +95°F) Storage: -15°C to +50°C (+5°F to +122°F) Shipping: -15°C to +70°C (+5°F to +158°F)
	Humidity	Operating: 15%RH to 95%RH non-condensing Storage: 10%RH to 90%RH non-condensing Shipping: 10%RH to 90%RH non-condensing
Air Tubing		Flexible plastic, 1.8m (approx.)
Classification:		Class II Type BF, Applied Parts Nasal Mask Not suitable for use in the presence of a flammable anesthetic mixture IPX0: Enclosed equipment without protection against ingress of water Continuous operation.

⚠**NOTE: The manufacturer reserves the right to modify the specification without notice.**

BF symbol, which indicated this product, is according to the degree of protecting against electric shock for type BF equipment.

Attention, should read the instructions.

Class II

Disposal of Electrical & Electronic Equipment (WEEE):
This product should be handed over to an applicable collection point for the recycling of electrical and electronic equipment. For more detailed information about the recycling of this product, please contact your local city office, household waste disposal service or the retail store where you purchased this product.

9. NOTE, CAUTION, AND WARNING STATEMENTS

⚠ **NOTE:** Indicate information that you should pay special attention to.

⚠ **CAUTION:** Indicate correct operating or maintenance procedures in order to prevent damage to or destruction of the equipment or other property.

⚠ **WARNING:** Calls attention to a potential danger that requires correct procedures or practices in order to prevent personal injury.

Appendix A: EMC Information

Guidance and Manufacturer's Declaration- Electromagnetic Emissions:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment:

Emissions Test	Compliance	Electromagnetic Environment-Guidance
Harmonic emissions IEC61000-3-2	Class A	The device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Voltage fluctuations / Flicker emissions IEC61000-3-3	Complies	

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
Electrostatic Discharge(ESD) IEC61000-4-2	±6kV contact ±8kV air	±6kV contact ±8kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/ burst IEC61000-4-4	±2kV for power supply line ±1kV for input/out line	±2kV for power supply line ±1kV for input/out line	Mains power quality should be that of atypical commercial or hospital environment
Surge IEC61000-4-5	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	± 1 kV line(s) to line(s)	Mains power quality should be that of atypical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC61000-4-11	<5 % UT(>95 % dip in UT)for 0,5 cycle 40 % UT(60 % dip in UT)for 5 cycles 70 % UT(30 % dip in UT)for 25 cycles <5 % UT(>95 % dip in UT)for 5 sec	<5 % UT(>95 % dip in UT) for 0,5 cycle 40 % UT(60 % dip in UT) for 5 cycles 70 % UT(30 % dip in UT) for 25 cycles <5 % UT(>95 % dip in UT) for 5 sec	Mains power quality should be that of atypical commercial or hospital environment. If the user of this device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (50/60Hz) magnetic field IEC61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of atypical location in a typical commercial or hospital environment.
NOTE: U_T is the a.c. mains voltage prior to the application of the test level			

Guidance and Manufacturer's Declaration- Electromagnetic Immunity:

This device is intended for use in the electromagnetic environment specified below. The user of this device should make sure it is used in such an environment.

Immunity Test	IEC60601 test level	Compliance	Electromagnetic Environment-Guidance
			Portable and mobile RF communications equipment should be used no closer to any part of this device, including cables, than there commended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2\sqrt{P}$ 150kHz to 80MHz
Conducted RF IEC 61000-4-6	3Vrms150 kHz to 80 MHz outside ISM bands[a]	3Vrms	$d=1.2\sqrt{P}$ 150kHz to 80MHz $d=2.3\sqrt{P}$ 80 MHz to 2.5G MHz
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3V/m	Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m).[b] Field strengths from fixed RF transmitters, as determined by an 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:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz;13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz.
b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,5 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in these frequency ranges.
c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.
d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and this device

This device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of this device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and this device as recommended below, according to the maximum output power of the communications equipment

Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** m		
	150 kHz to 80 MHz $d = 1.2\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.2\sqrt{P}$	**800 MHz to 2,5 GHz** $d = 2.3\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.