Home Care Provider Setup Instructions

REMstar® | pro 2 with C-Flex™ CPAP System

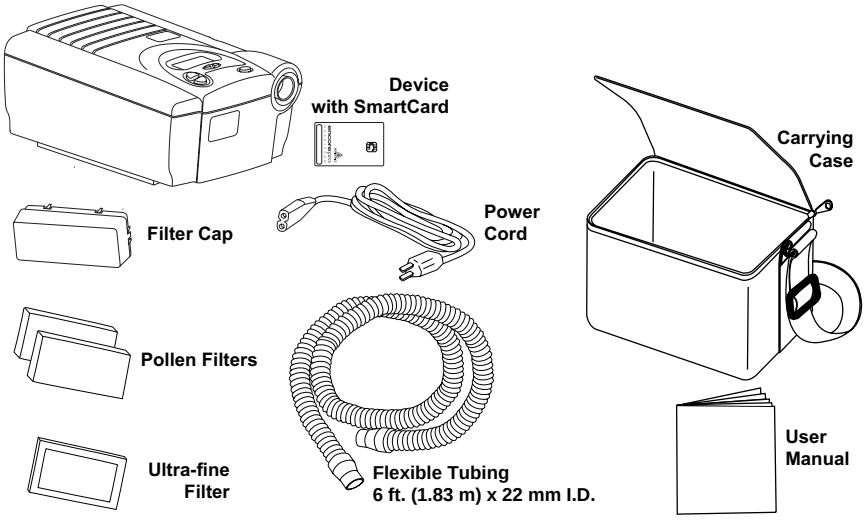
RESPIRONICS®
www.respironics.com

Always use these instructions along with the User Manual when assembling or adjusting this equipment.

For clinical systems, refer to the setup guide entitled Respironics Products in the Sleep Lab (part #1009751) for equipment setup assistance.

This CPAP system is intended for the treatment of adult obstructive Sleep Apnea only.
NOTE: The C-Flex mark is used under license.

System Contents



The FOSQ "Quality of Life" questionnaire is included with this system.

Your patients can periodically complete this questionnaire by recording their answers on the SmartCard or they can circle their answers on the enclosed FOSQ brochure. Either the SmartCard or the brochure can then be mailed to you or their medical professional for evaluation.

Symbols

Device Label

- Attention, consult accompanying documents
- AC Power
- DC Power
- Type BF Applied Part
- Class II (Double Insulated)
- **IPX0** Ordinary Equipment Rating
- Notified Body Approval for Standards Compliance
- Canadian/US Certification

Specifications

Mode of Operation: Continuous

AC Power Consumption: 100 - 240 VAC, 50/60 Hz, 1.0 A max.

Type of Protection Against Electric Shock: Class II Equipment

Degree of Protection Against Electric Shock: Type BF Applied Part

Degree of Protection Against Ingress of Water: IPX0 - Ordinary Equipment

Pressure Range: 4 to 20 cm H_2O (in 0.5 cm increments)

Pressure Stability: 4 to 10 cm H_2O (±0.5 cm H_2O)
>10 to 20 cm H_2O (±1.0 cm H_2O)
Measured in accordance with EN 17510 @ 6.6, 13.2, & 20 cm H_2O @ 500 ml with BPM set to 10, 15, & 20 BPM performed at 23° C (±2° C), 50% RH (±5%), and an atmospheric pressure of 101.54 kPascals.

Sound Pressure Level: <30 dB(A)
Measured in accordance with EN 17510 @ 10 cm H_2O at the patient circuit. This measurement applies to the REMstar Pro 2 with C-Flex with or without the optional REMstar Heated Humidifier.

Maximum Flow: 34 LPM
Measured in accordance with EN 17510 @ 6.6, 13.2, & 20 cm H_2O @ 500 ml with BPM set to 10, 15, & 20 BPM @ 23° C (±2° C), 50% RH (±5%), and an atmospheric pressure of 101.54 kPascals.

Warnings & Cautions

CAUTION!
Indicates the possibility of damage to the device.

- *US federal law restricts this device to sale by or on the order of a physician.*

WARNING!
Indicates the possibility for injury to the user or the operator.

- *This device is intended for adult use only.*
- *This device is not intended for life support.*
- *CPAP devices have the potential to allow rebreathing of exhaled air. To reduce this potential, observe the following:*
  - *Use Respironics circuit accessories.*
  - *Do not wear the mask and headgear for more than a few minutes while the unit is not operating.*
  - *Do not block or try to seal the vent holes in the exhalation port.*

  As with most CPAP devices: *At low CPAP pressures, some exhaled gas (CO_2) may remain in the mask and be rebreathed.*
- *Do not use this device if the room temperature is warmer than 95° F (35° C). If this device is used at room temperatures warmer than 95° F (35° C), the temperature of the airflow may exceed 106° F (41° C). This could cause irritation to the patient's airway.*
- *This equipment is not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.*
- *If you notice any unexplained changes in the performance of the REMstar Pro 2 with C-Flex, if it is making unusual or harsh sounds, if it has been dropped or mishandled, or if the enclosure is broken, discontinue use. Contact Respironics Customer Service Department and replace any damaged parts before continuing use.*
- *To avoid electrical shock, disconnect the power cord before cleaning. DO NOT immerse the REMstar Pro 2 with C-Flex in any fluids.*
- *Pins of connectors identified with the ESD warning symbol should not be touched. Connections should not be made to these connectors unless ESD precautionary procedures are used. Precautionary procedures include methods to prevent build-up of electrostatic discharge (e.g., air conditioning, humidification, conductive floor coverings, non-synthetic clothing), discharging one's body to the frame of the equipment or system or to earth or a large metal object, and bonding oneself by means of a wrist strap to the equipment or system or to earth.*

CAUTION!

- *Tobacco smoke may cause tar build-up within the REMstar Pro 2 with C-Flex that may result in the device malfunctioning.*
- *The use of accessories other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.*

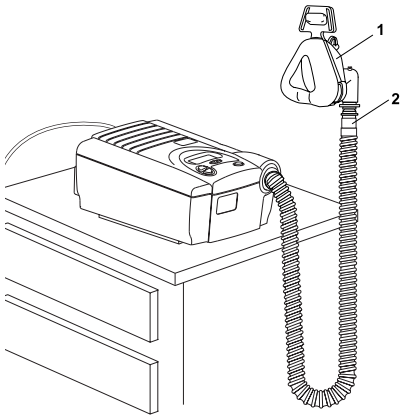
Contraindications

When assessing the relative risks and benefits of using this equipment, the clinician should understand that the REMstar Pro 2 with C-Flex can deliver pressures up to 20 cm H_2O. In the event of certain fault conditions, a maximum pressure of 30 cm H_2O is possible. Studies have shown that the following pre-existing conditions may contraindicate the use of CPAP therapy for some patients:

- Bullous Lung Disease
- Pathologically Low Blood Pressure
- Pneumothorax
- Bypassed Upper Airway
- Pneumocephalus has been reported in a patient using nasal Continuous Positive Airway Pressure. Caution should be used when prescribing CPAP for susceptible patients such as those with: cerebral spinal fluid (CSF) leaks, abnormalities of the cribriform plate, prior history of head trauma, and/or pneumocephalus. (Chest 1989; 96:1425-1426)

The use of positive airway pressure therapy may be temporarily contraindicated if the patient exhibits signs of a sinus or middle ear infection. Should the patient have any of these conditions, a health care professional will determine if CPAP therapy is appropriate.

WARNING! ***Do not connect any equipment to the REMstar Pro 2 with C-Flex unless recommended by Respironics or the health care professional. Verify that an exhalation port is present to exhaust CO_2 from the circuit. If circuit accessories, other than those recommended by Respironics, are connected to the REMstar Pro 2 with C-Flex, pressures must be verified. Use of these accessories may alter the pressure received, reducing the effectiveness of treatment.***



Respironics Accessories

When using accessories, always follow the instructions enclosed with the accessories.

Patient Circuit

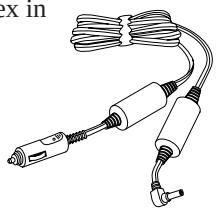
Recommended Patient Circuit

1. **Respironics nasal mask with integrated exhalation port (or Respironics mask with separate exhalation port such as the Whisper Swivel® II)**
2. **Respironics 6 ft. (1.83 m) x 22 mm I.D. flexible tubing**
3. **Respironics headgear** (not shown)

WARNING! ***If the REMstar Pro 2 with C-Flex is used for multiple persons (e.g., rental devices) a low-resistance, main flow bacteria filter should be installed in-line between the REMstar Pro 2 with C-Flex and the circuit tubing. Pressures must be verified when alternate or optional accessories are in place.***

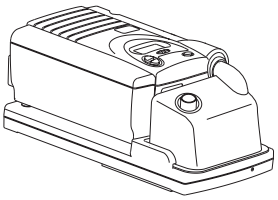
DC Power

The Respironics DC Power Cord can be used to operate the REMstar Pro 2 with C-Flex in a stationary recreational vehicle, boat, or motor home. **The Respironics DC Battery Adapter Cable** (when used with the Respironics DC Power Cord) enables the device to be operated from a 12 VDC free-standing battery.



Humidifier

The Respironics REMstar Heated Humidifier is available for use with the REMstar Pro 2 with C-Flex. The humidifier may reduce nasal dryness and irritation by adding moisture (and heat if applicable) to the airflow. When using other humidifiers, verify that the delivered pressure is correct and that proper therapy is being delivered. The humidifier cannot be operated with DC power.



Adding Oxygen

Oxygen may be added at the mask connection. Please note the warnings listed below when using oxygen with the REMstar Pro 2 with C-Flex.

WARNING! ***The oxygen supply must comply with the local regulations for medical oxygen.***

WARNING! ***A Respironics Pressure Valve (Part number 302418) must be placed in-line with the patient circuit.***

WARNING! ***Turn the REMstar Pro 2 with C-Flex on before turning the oxygen on. Turn the oxygen off before turning the REMstar Pro 2 with C-Flex off. This will prevent oxygen accumulation in the device.***

WARNING! ***If oxygen is used with this CPAP machine, the oxygen flow must be turned off when the CPAP machine is not operating.***
Explanation of warning: When the CPAP device is not in operation and the oxygen flow is left on, oxygen delivered into the ventilator tubing may accumulate within the CPAP machine enclosure. Oxygen accumulated in the CPAP machine enclosure will create a risk of fire. This warning applies to most types of CPAP machines.

WARNING! ***Oxygen accelerates fires. Keep the REMstar Pro 2 with C-Flex and the oxygen container away from heat, open flames, any oily substance, or other sources of ignition. DO NOT smoke in the area near the REMstar Pro 2 with C-Flex or the oxygen container.***

System Setup - Display Screens

WARNING! ***At a fixed flow rate of supplemental oxygen flow, the inhaled oxygen concentration will vary depending on the pressure settings, patient breathing pattern, mask selection, and leak rate. This warning applies to most types of CPAP machines.***

CAUTION! ***If the REMstar Pro 2 with C-Flex has been exposed to either very hot or very cold temperatures, allow it to adjust to room temperature (approximately 2 hours) before beginning the following setup procedures.***

Control Panel

This section provides detailed instructions for the Therapy Menu Display Screens.

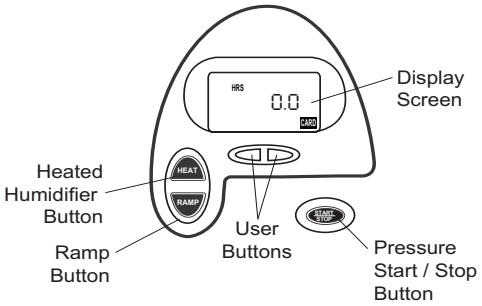
Display Screen: All device settings appear here.

Pressure Start/Stop Button: Use this button to start or stop the airflow. DO NOT start the airflow until the circuit tubing is connected.

Heated Humidifier Button: Use this button when the optional REMstar Heated Humidifier has been prescribed. This button will control the optional heated humidifier's output. Follow the instructions included with the humidifier.

Ramp Button: When the airflow is turned on, use this button to lower the airflow pressure. This will allow you to fall asleep more easily. When the airflow is turned off, use this button to access the patient menu.

User Buttons: Use these buttons to change the device settings.



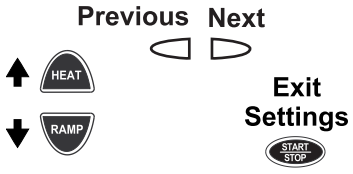
Display Screens

When in the Setup Menu, the humidifier and ramp buttons operate as up and down keys to change the settings, the left/right user buttons allow you to go to the previous/next question or setting, and the pressure start/stop button is used to exit the Setup Menu. Holding the humidifier or ramp buttons down will cause the values to change more quickly.

Enter Therapy Setup Menu

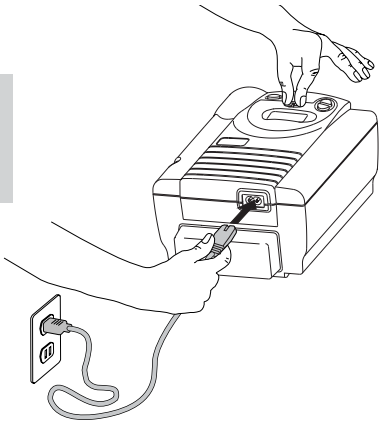
1. To enter the Therapy Setup Menu, hold the two top user buttons down while plugging in the power cord. Continue holding the buttons down until the REMstar Pro 2 with C-Flex beeps.

Note: The word "setup" will appear on all of the screens indicating that you are in the Therapy Setup Menu. ***If you press the pressure start/stop button, you will exit the Setup Menu.***



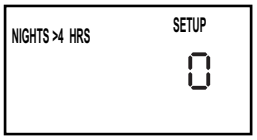
IMPORTANT!

Prescribed therapy settings can only be set using the Therapy Menu. To prevent patients from tampering with the settings, do not reveal the directions to Therapy Menu access to the patient.



Reset the Compliance Totals

a. The number of nights the REMstar Pro 2 with C-Flex was used for more than four consecutive hours will appear. Like a trip meter in a car, this total and the therapy hours (see page 7 for a description of therapy hours) can be reset to give a detailed look at patient usage. This data may be useful in tracking patient compliance. Resetting these totals will not erase the total operation time or other patient data. *The patient can view this reading but cannot reset it.*



To erase the totals and go back to zero, press and hold the ramp or humidifier button. The word "ERASE" will appear on the screen. Hold the button down until the time changes to "0" and the word "ERASE" disappears.

Press the right user button to go to the next setting.

Choose the Mode

b. The therapy mode will appear (CPAP or CFLE). The C-Flex™ mode is CPAP therapy along with the C-Flex comfort setting (step d). The CPAP mode is CPAP therapy without the C-Flex setting.

To change the mode, press the ramp or humidifier button until the correct mode appears.

Press the right user button to go to the next setting.

Set the Pressure

c. The CPAP pressure setting will appear.
Range: 4 to 20 cm H_2O (0.5 cm H_2O increments)

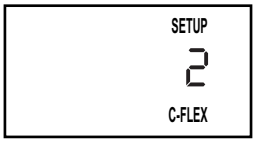
To change the pressure setting, press the ramp or humidifier button until the correct pressure appears.

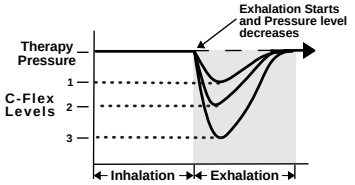
Press the right user button to go to the next setting.

Note: If the CPAP pressure setting is 4 cm H_2O, the following C-Flex level settings will not appear. Go to Step e.

Set the C-Flex Level

d. If you chose the C-Flex mode, the C-Flex level will appear. This setting allows you to adjust the level of air pressure that the patient is feeling when they exhale during therapy. We recommend starting with the setting of "1" which provides the least relief. Levels 2 and 3 progressively reflect increased pressure relief.
Range: 1 - 3 (1 ea. increments) *The patient also has access to this setting in the Patient Setup Menu*





To change the setting, press the ramp or humidifier button until the correct setting appears.

Press the right user button to go to the next setting.

Set the Ramp Time

e. The ramp time will appear.
Range: 0 to 45 minutes (5 minute increments)

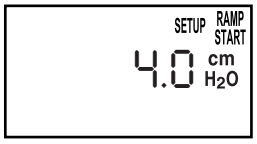
To change the ramp time, press the ramp or humidifier button until the correct time appears. ***If you do not want ramp, set the time to "0."***

Press the right user button to go to the next setting.

Note: If the ramp time is set to "0" the ramp settings are complete. Go to Step g.

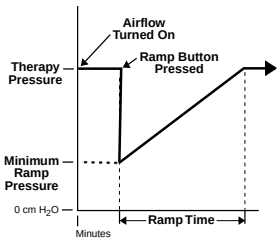
Set the Ramp Starting Pressure

f. The ramp starting pressure will appear.
Range: 4 cm H_2O - CPAP Pressure Setting (0.5 H_2O increments) *The patient also has access to this setting in the Patient Setup Menu, if prescribed.*



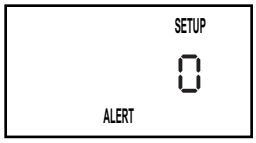
To change the ramp starting pressure, press the ramp or humidifier button until the correct pressure appears.

Press the right user button to go to the next setting.



Set the Patient Disconnect Alert

g. The patient disconnect setting will appear. This setting has two functions. When a large, continuous air leak (such as mask removal) has been detected in the circuit, it enables/disables the audible alert (a beeping sound) and the Auto-off feature which allows the REMstar Pro 2 with C-Flex to automatically turn the airflow OFF. *The patient also has access to this setting in the Patient Setup Menu.*



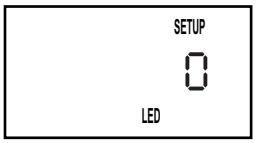
1 = on **0 = off**

To change the setting, press the ramp or humidifier button.

Press the right user button to go to the next setting.

Set the Button Lights

h. The button lights setting will appear. This setting allows you to have the lights behind the buttons turned on or off while the airflow is turned on. (The lights will always be on when the airflow is off.) *The patient also has access to this setting in the Patient Setup Menu.*



1 = on **0 = off**

To change the setting, press the ramp or humidifier button.

The settings are complete. Press the pressure start/stop button to exit the settings menu.

Prepare for Delivery

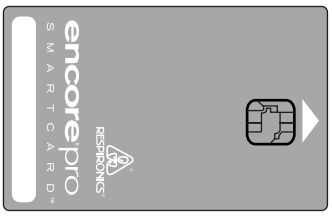
2. Prepare the REMstar Pro 2 with C-Flex for delivery.

a. Verify the settings before delivering the REMstar Pro 2 with C-Flex to the patient. Optional: Pressure Verification via Manometer - A water column manometer can be connected for additional pressure verification. When the blower is turned on, the current pressure will appear on the screen.

b. Follow the instructions in the User Manual to install the filters and connect the patient circuit.

c. Fill out the information form in the front of the User Manual. Review the User Manual with the patient.

SmartCard



The REMstar Pro 2 with C-Flex is delivered with an Encore® Pro SmartCard® installed. The SmartCard is a plastic card similar in size and shape to a normal credit card. But, instead of holding information on a magnetic stripe, it holds data in a small silicon chip embedded in the card.

When installed in the REMstar Pro 2 with C-Flex, the SmartCard records the date, time, and duration of each use **(storage capacity: at least 6 months)**. When capacity is reached, the oldest data is overwritten. Using the Respironics SmartCard reader/writer and the Encore Pro software, you can download and view the usage data. Follow the instructions included with the Encore Pro software to download the data.

Note: If the card is not installed, this information will not be recorded. When a SmartCard is installed, the word "Card" will appear in the lower right corner of the display screen.

FOSQ

The REMstar Pro 2 with C-Flex is programmed to allow the users to take a "Functional Outcomes of Sleep Questionnaire" (FOSQ). FOSQ is a "quality of life" questionnaire designed specifically for people with sleep disorders. The results allow health care professionals to see how therapy has improved the quality of their patients' lives.

By having their patients complete the questionnaire periodically, health care professionals can collect valuable information about the effectiveness of their treatment. The FOSQ brochure (included with this package) details the questionnaire. The SmartCard will record the answers to questions displayed on the REMstar Pro 2 with C-Flex screens. The card can then be removed from the REMstar Pro 2 with C-Flex and mailed to the health care professional for evaluation using the Encore Pro software application.

Device Usage and Patient Compliance

The REMstar Pro 2 with C-Flex stores and displays device usage and patient compliance.

Therapy Hours is the total number of hours the patient has received therapy on the REMstar Pro 2 with C-Flex. This total will appear on the display screen whenever the airflow is turned off. (The power cord must be plugged in.) This total can be reset to zero. Like a trip meter in a car, this total can be reset to give a detailed look at patient usage. This data may be useful in tracking patient compliance. Resetting the total will not erase the total operation time or other patient data. *The patient can view this reading but cannot reset it.*

Nights with Greater Than Four Hours Usage is the total number of nights that REMstar Pro 2 with C-Flex therapy took place for four or more consecutive hours. This total can also be reset to zero. *This total can also be viewed in the patient setup menu.*

Total Operation Time is the total number of hours the REMstar Pro 2 with C-Flex has been in use. This total includes factory testing time. When the power cord is plugged in, this total will appear for a few seconds. This total cannot be reset to zero.

Service

The REMstar Pro 2 with C-Flex does not require routine servicing. If the REMstar Pro 2 with C-Flex begins to malfunction, refer to the "Troubleshooting" section of the User Manual or contact Respironics. Repairs and adjustments must be performed only by trained personnel fully acquainted with this equipment. Service performed by unqualified personnel or installation of unauthorized parts could cause personal injury, invalidate the warranty, or result in costly damage.

Disposal

When necessary, dispose of the REMstar Pro 2 with C-Flex and accessories in accordance with local regulations.

If you need product assistance, call

Respironics' Customer Service Department
1-800-345-6443 (USA and Canada) or 1-724-387-4000

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
RF emissions CISPR 11	Group 1	This device uses RF energy only for its internal function. 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	This device is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network.
Harmonic emissions IEC 61000-3-2	N/A	
Voltage fluctuations/ Flicker emissions IEC 61000-3-3	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	IEC 60601 Test Level	Compliance Level	Electromagnetic Environent - Guidance
Electrostatic Discharge (ESD) IEC61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 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%.
Electrical fast Transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input-output lines	±2 kV for supply mains ±1 kV for input/output lines	Mains power quality should be that of a typical home or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV for common mode	Mains power quality should be that of a typical home or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	<5% U_T (>95% dip in U_T) for 0.5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	Mains power quality should be that of a typical home or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
NOTE: U_T is the a.c. mains voltage prior to 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	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical home or hospital environment.
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.2\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.2\sqrt{P}$ 80 MHz to 800 MHz $d = 2.3\sqrt{P}$ 800 MHz to 2.5 GHz 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). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] 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] 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 re-orienting or relocating the device.

[b] Over the frequency range 150 kHz to 80 MHz, the 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 Power Output 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.

RESPIRONICS®
1001 Murry Ridge Lane
Murrysville, Pennsylvania
15668-8550 USA

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