

NUWAVE[®]

Plus

CPAP SANITIZER



USER MANUAL

The user manual provides the operation and safety information and contains warranty registration information. Read the user manual carefully before you use and save it for future reference.

The NUWAVE[®] manual will help show you how to properly clean and sanitize your CPAP equipment using the NUWAVE[®] device. It will also answer frequently asked questions.

To register your device for the warranty coverage, we are providing you with a warranty registration card. Fill out the enclosed registration card and return it to Spirit Medical at the address on the card.

Indications For Use

NUWAVE® is a germicide intended to disinfect non-critical medical devices and equipment surfaces including CPAP masks, tubing and water chambers.

Contraindications

Discontinue use of NUWAVE® if the user develops skin irritation such as acne or a rash around the mask contact area.

WARNINGS:



Do NOT inhale emitted ozone directly from the NUWAVE® device as this may be harmful to one's health.



Use in a well ventilated area. Do not use in a confined space.



Do NOT attempt to open or repair the device as this may result in personal injury. Opening the device will compromise the functionality of the device and void the warranty.



Do NOT leave NUWAVE® unattended near children or pets.



Do NOT block any part of the NUWAVE® generator during operation.



Use ONLY the charger and USB cable provided with your NUWAVE® device. Use of other chargers may compromise the functionality of the device and may result in personal injury.

NUWAVE® Box Contents:

- NUWAVE® Sanitizing Chamber
- NUWAVE® Generator
- NUWAVE® charging and USB power cord
- NUWAVE® Activated Carbon Filter

Important! To ensure the proper charging of your NUWAVE® generator use the approved and enclosed charger and USB cable.

Ozone Generator Characteristics:

Dimensions	Length = 4 7/8" Width = 2 3/8" Height = 2"
Weight	0.45 lbs
Electrical	Rechargeable Lithium-ion battery 2600mAh, 3.7v
Power Supply	Input: 120VAC +/-10%; Output: 1000mA, 5 VDC
Environmental	Storage Temperature: -20° to 25° C , 35% - 85% RH
	Operating Temperature: 0° to 45° C , 35% - 85% RH
	IP (Ingress protection): IPX1

NUWAVE® Sanitizer Operation Cycle Time:

NUWAVE® runs its sanitization cycle for a total of 35 minutes. NUWAVE® generates ozone for 30 minutes and provides 5 minutes of fresh air through the operation of the fan only (this provides fresh air to the bag to assist in the conversion of O₃ back to O₂ within the sanitizing chamber).

Instructions for Use:

The NUWAVE® is compatible with all CPAP masks, humidifiers and tubes and does not require adapter fittings. NUWAVE® is an easy three-step process to disinfect and sanitize your CPAP equipment.

Step One: Connecting the system.

Connect one end of your CPAP tube to the NUWAVE® ozone generator and the other end to the exterior NUWAVE® sanitizing chamber's universal adapter fitting.



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Instructions for Use (continued)

Step Two: Place components inside the NUWAVE® sanitization chamber as shown in the picture below.

If your CPAP mask has an extension tube with a 22 mm male connector, lightly insert the 22 mm male connector into the fitting on the inside of the sanitization chamber as shown in the picture below. See page 6 for detailed instructions on connecting specific heated tubes to the NUWAVE® sanitizing system.

Place your mask, headgear and water chamber into the NUWAVE® sanitization chamber. Make sure the water chamber is empty of water and dry (if possible) before placing in NUWAVE® sanitization chamber. Then zip the NUWAVE® sanitization chamber closed.

To minimize the introduction of ozone into the nearby environment, ensure that the NUWAVE® sanitization chamber is completely zipped and closed.

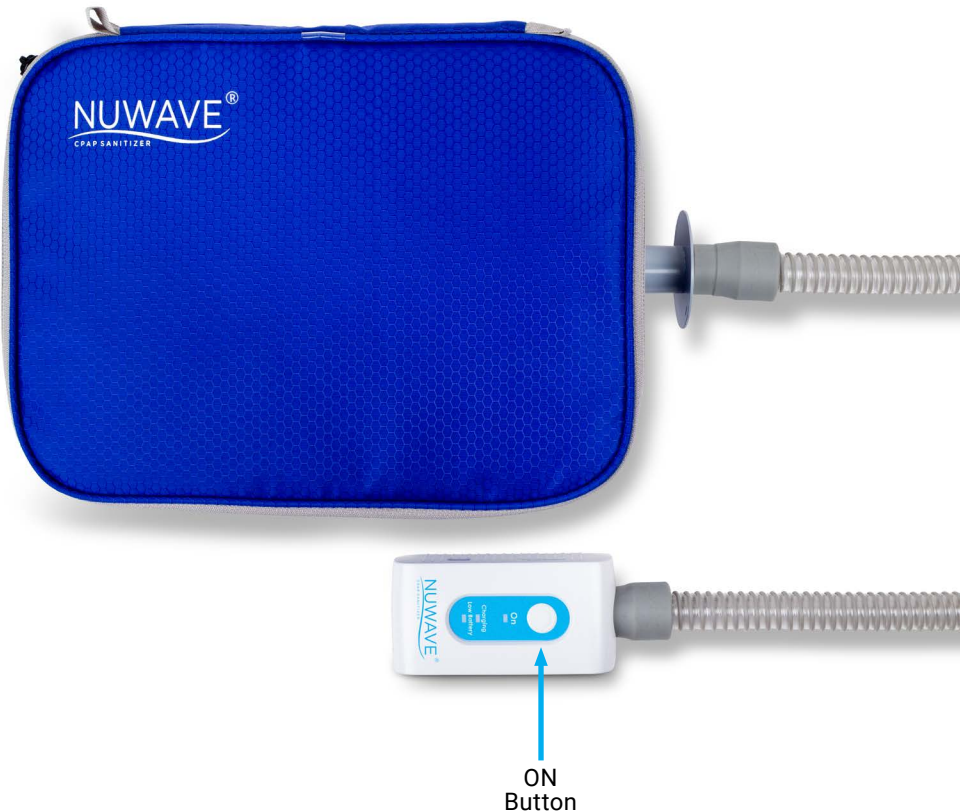


Step Three: Start the CPAP sanitization process.

To run the NUWAVE® CPAP sanitization system, simply press the ON button for approximately 2 seconds. You will then hear a beep and see the blue "On" light indicator turn on. When the blue light illuminates, the NUWAVE® will start and complete its sanitization cycle. The unit will automatically power off when complete. If you need to stop the NUWAVE® operation at any point during its cycle, press and hold the power down for approximately 2 seconds until the unit shuts off. If you turn the unit off, the blue light will go out and you will hear a beep lasting approximately 2 seconds.

NOTE: Allow NUWAVE® to run its full 30-minute sanitizing and disinfecting cycle. When the cycle is complete, it will continue to operate a 5-minute fresh air flush cycle which will help convert ozone within the sanitization chamber to active oxygen.

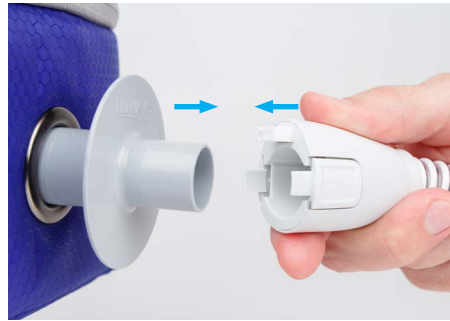
IMPORTANT: Keep the NUWAVE® closed for 2 hours after the cleaning cycle is complete.



Heated Tubes:

Connecting the Dream Station Heated Tube

Connect the soft rubber end of the DreamStation® heated tube to the fitting of the NUWAVE® ozone generator. Slide the hard, plastic end of the DreamStation® tube to the NUWAVE® universal fitting until you feel a snug fit. To operate unit, refer to page 5.



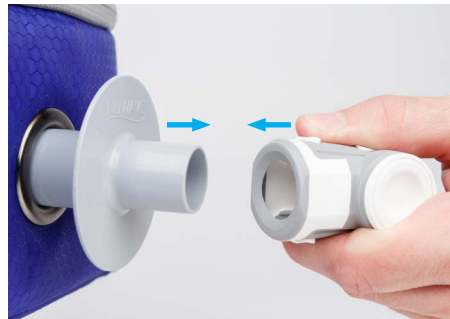
Connecting the Fisher and Paykel Heated Tubing

Connect the hard, round fitting that you would normally connect to your CPAP mask, to the NUWAVE® ozone generator. Slide the oblong end of the F&P heated tube that you would normally connect directly to the CPAP machine, to the NUWAVE® sanitizing chamber's universal fitting until the fit is snug. To operate unit, refer to page 5.



Connecting the Resmed S9/ S10 Airsense™ Heated Tube

Connect the soft, round end of the RESMED tubing that you would normally connect to your mask, to the NUWAVE® ozone generator fitting. Take the elbow-type end of tubing which normally connects to the CPAP machine and slide it over the universal NUWAVE® sanitizer chamber's universal fitting. To operate unit, refer to page 5.



Activated Carbon Filter

Your NUWAVE® CPAP Sanitizer comes with an activated carbon filter which aids in converting ozone back into active oxygen after the ozone sanitization cycle has completed. To use the filter, remove it from the enclosed plastic bag. Remove the white labels from the top and bottom of the filter and place the filter in the side pouch of your NUWAVE® sanitizing chamber. Replace filter every 6 months.



Charging your NUWAVE® Ozone Generator:

The NUWAVE® is equipped with a long life lithium ion battery. The NUWAVE® when fully charged should last almost 2 full weeks (based on 3-4 sanitization cycles per week) and will operate approximately 6-8 cycles on a full charge. We have provided charging instructions below.

Charging Instructions:

The NUWAVE® as you received it, will contain a partial battery charge. Prior to operating your NUWAVE® for the first time, we recommend that you connect the NUWAVE® to the enclosed provided charger and power cord and connect this to a wall outlet and charge the NUWAVE® for 4 hours or until the green light turns off (the green light will be lit the whole time NUWAVE® is charging and will turn off when the unit is fully charged).

If you unplug the unit and plug it in again to attempt to charge the NUWAVE® right after it is fully charged, the green light will momentarily blink and shut off. This means the unit is fully charged.



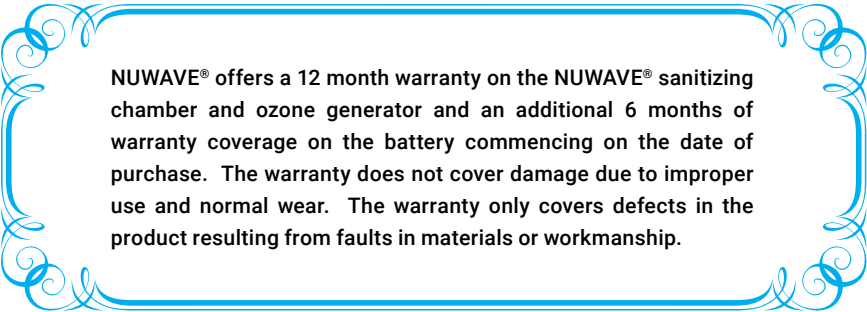
Low Battery Mode

On a full charge, your NUWAVE® ozone generator will run approximately 6-8 cycles. When the battery reaches the end of its charge, and you attempt to power up the unit again after pressing the power button for approximately 2 seconds, the red light will flash and you will hear 3 beeps. At this point it's time to charge the unit. You may operate the unit once the power cord is plugged in and you see a green light.

Using Your CPAP Equipment After the NUWAVE® Sanitizing Cycle

- After the 2 hour post sanitizing cycle has been completed, remove contents from the NUWAVE® sanitization chamber and disconnect the tubing from the NUWAVE®. You can install your water chamber and reconnect your CPAP mask and tubing to your machine and use immediately. Your CPAP mask and tubing will have a fresh smell to it.
- Any residual odor present in the mask and tubing may be flushed from the system by connecting to the CPAP machine and running the CPAP machine for 30-60 seconds.
- The 2600 mAh rechargeable battery meets UN 38.3 transportation specifications for lithium ion batteries.
- The warranty becomes VOID if repairs are undertaken by unauthorized persons and if original parts are not used. To obtain service within the warranty period, please contact your distributor.
- It is recommended to sanitize the CPAP tubing, mask, headgear and tubing weekly.

Limited Warranty



NUWAVE® offers a 12 month warranty on the NUWAVE® sanitizing chamber and ozone generator and an additional 6 months of warranty coverage on the battery commencing on the date of purchase. The warranty does not cover damage due to improper use and normal wear. The warranty only covers defects in the product resulting from faults in materials or workmanship.

Use and Care

Periodically inspect your NUWAVE® device for damage and wear:

- Check the Power Supply connections and the USB Cable for loose connectors or exposed wiring.
- Check the Chamber Bag for zipper function and ability to completely close the Chamber Bag.
- Check the NUWAVE® Ozone Generator housing for damage or loose components.

If damage or wear is suspected with your NUWAVE® device, contact Spirit Medical. For additional information, please visit <http://www.spiritmedical.net/nuwave.html>

To clean your NUWAVE® device, wipe with a damp cloth.



Do NOT submerge the NUWAVE® device in water or any other liquids. Do NOT use harsh chemical agents to clean any part of the NUWAVE® device. The NUWAVE® contains a Lithium-Ion battery and sensitive electronic components. Failure to follow this caution may compromise the functionality of the device and may result in personal injury.

Disposal

The NUWAVE device contains a Lithium-Ion battery and electronic components. Dispose of the NUWAVE® device in accordance with local / regional regulations. For additional information, contact Spirit Medical.

Troubleshooting Guide:

Problem	Possible Solution(s)
Charging indicator does not light up	Make sure the unit is plugged in properly. If the green light does not turn on, contact Spirit Medical at our toll free number.
NUWAVE® does not operate	Hold power button down until you hear a beep and see the blue light come on. If NUWAVE® still does not operate, make sure it is charged by plugging power cord into the unit and connecting to a wall circuit using supplied UL power charger. If you see a green light come on, allow it to fully charge. When unit is fully charged, the green light will turn off. Once the unit is fully charged, turn the unit on. If unit still does not turn on, contact Spirit Medical at our toll free number.

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Troubleshooting Guide (Continued)

Problem	Possible Solution(s)
The battery is charged but NUWAVE® is not working	Make sure you depress the power button for at least 2 full seconds and wait for the blue light to come on. Continue to hold down button. If unit does not turn on, contact Spirit Medical at our toll free number.
The NUWAVE® is not generating ozone	If, after you press the ON button, the fan and blue light are not on and you do not smell ozone or you suspect the unit is not generating ozone, power the unit up and hold it upside down and look into the outlet of the unit (the side opposite the fan) on the opposite side of the power button. If the unit is generating ozone, you will see a purple/blue light illuminate on the inside of the unit. This is the diode that is generating ozone and it will illuminate when it is generating ozone. If you are still not able to tell if the unit is generating ozone, contact Spirit Medical at our toll free number.


For repair or additional information, please visit <http://www.spiritmedical.net/nuwave.html>

EMC Compatibility

Guidance and Manufacturer's Declaration – Electromagnetic Emissions

The Ozone Generator (CPAP device) is intended for use in the electromagnetic environment specified below. The customer or the user of the Ozone Generator should assure that it is used in such an environment.

Emissions Test	Compliance	Electromagnetic Environment – Guidance
(EN 55011:2009)	Class A (Group 1)	The RF energy observed is only from its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.

Immunity Test	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment – Guidance
Electrostatic Discharge (ESD): IEC 61000-4-2	±15 kV Air; ±8 kV Contact	±15 kV Air; ±8 kV Contact	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic materials, the relative humidity should be at least 30%.
Power Frequency (50 / 60 Hz) Magnetic Field: IEC 61000-4-8	30 A / m	30 A / m	Power frequency magnetic field should be at levels characteristic of a typical location in a typical commercial or hospital environment.
Radiated Radio Frequency	3 V / m (80 MHz to 2.7 GHz)	3 V / m (80 MHz to 2.7 GHz)	<p>Portable and mobile RF communications equipment should be used no closer to any part of the Ozone generator, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance is given by:</p> $d = 1.2 \sqrt{P}$ <p>With</p> $d = 1.2 \sqrt{P}$ $d = 2.3 \sqrt{P}$ <p>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).</p> <p>Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.</p> <p>Interference may occur in the vicinity of equipment marked with the following symbol:</p> 

Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the Ozone Generator.

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

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Rated maximum output of transmitter (W)	Separation distance according to frequency of transmitter (m)		
	150 kHz to 80MHz $d = 1.2 \sqrt{P}$	80 MHz to 800 MHz	800 MHz to 2.7 GHz
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 to 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.

Symbols

Symbol	Symbol Description
	CAUTION: Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.
	MANUFACTURED BY: Indicates the medical device manufacturer.
	POWER

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NUWAVE-PLUS-IFU (Rev. A)

