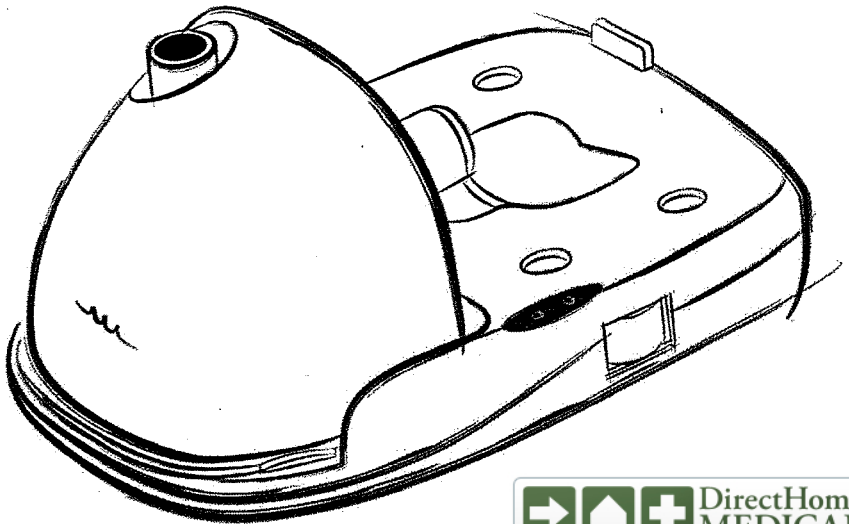


PureSom CPAP PLUS

Heated Humidifier

Instruction Manual



Presented With Compliments From
www.DirectHomeMedical.com

Model No.: 9S-006500

Please read the instruction manual before use.



CareFusion

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IMPORTANT SAFEGUARDS SAVE THESE INSTRUCTIONS. READ ALL INSTRUCTIONS BEFORE USING.

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.
- Do not reach into the water or other liquids, if product falls into water or other liquids. Unplug it immediately.

WARNING -- To reduce the risk of burns, electrocution, fire, or injury to persons:

- Do not operate CPAP (Continuous Positive Airway Pressure, which is used for Obstructive Sleep Apnea treatment) before mask and humidifier installed.
- Disconnect the humidifier from CPAP unit when not in use, water entering the CPAP unit may result in electric shock hazard or damage to the CPAP unit.
- Do not use if water comes in contact with the CPAP unit or enters the tubing.
- PureSom Heated Humidifier is not for use with patients whose supraglottic airways have been bypassed.
- Do not use PureSom Heated Humidifier(9S-006) on the floor.
- The Appliance outlet of PureSom Heated Humidifier is only applicable for 9S-005 PureSom CPAP Plus. Otherwise, it may result in electric shock hazard or damage to the PureSom Heated Humidifier unit.
- Do not cover blanket or clothes on the humidifier.
- Do not remove water chamber while humidifier is heating. Do not touch the heater plate for 30 minutes after the device is disconnected from the mains.
- 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 individuals.
- Use this product only for its intended use as described in this manual. Use this product only under physician's direction. Do not use the equipment with accessories other than those supplied with this set. Contact your local dealer/EU representative for additional information.
- Never operate this product if a) it has a damaged cord or plug, b) it is not working properly, c) it has been dropped or damaged, d) it has been dropped into water. Return the product to a specified service center or distributor or EU representative for examination and repair.
- Keep the cord away from heated or hot surfaces.
- Never block the air openings of this product or allow objects to fall or be inserted into the air vent openings or place it on a soft surface such as bed or couch, where the air openings may be blocked.
- This device SHALL NOT be used if the room temperature is warmer than 35°C (95°F) to prevent the temperature of air delivered to nasal mask over 41°C (104°F).

AUTION -- Use humidifier accompanied with PureSom CPAP Plus system and CE certified or 510(k) cleared accessories

NOTE -- U.S. Federal law restricts this device to sale by, or on the order of, a licensed physician.

NOTE, CAUTION AND WARNING STATEMENTS

- DANGER:** Danger indicates an immediately hazardous situation which will result in death or serious injury if not avoided.
- WARNING:** Warning indicates a potential hazardous situation which will result in death or serious injury if not avoided.
- CAUTION:** Caution indicates a potential hazardous situation which will result in property damage or destruction of equipment if not avoided.
- NOTE:** Note indicate some tips that user should pay attention to.

SYMBOLS



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



Attention, should read the instructions before use.



Attention, should read the instructions.



Class II



Fill line



Air flow direction



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.



Authorized representative in the European community



Manufacturer

Introduction

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

1.1 General Information

This system has been tested and successfully approved to the following standards.



EN60601-1
EN60601-1-2
EN 61000-3-2 Class A
EN 61000-3-3

 For US and CANADA only

E228589
53DG



Medical Equipment- Heated Humidifier
with respect to electrical shock, fire and
mechanical hazards only in accordance with
UL60601-1 and CAN/CSA C22.2 No. 601.1

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.

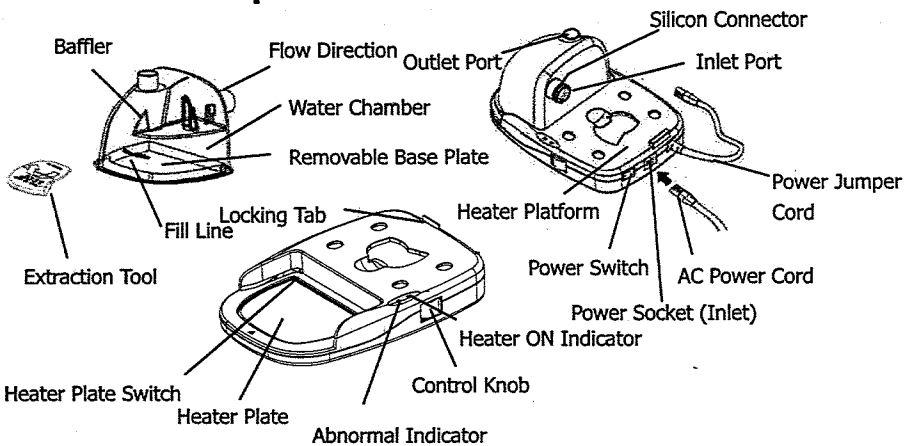
- FDA

1.2 Intended use

PureSom Heated Humidifier is for use with PureSom CPAP Plus system. It had been designed to increase the humidity of the air from the CPAP thereby relieving the symptoms of a dry nose and throat that some people may experience.

NOTE: Equipment not suitable for use in the presence of a flammable anesthetic mixture with air or with oxygen or nitrous oxide.

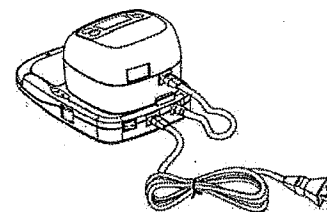
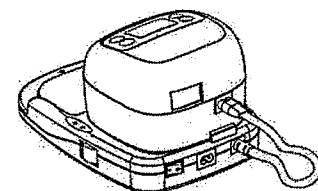
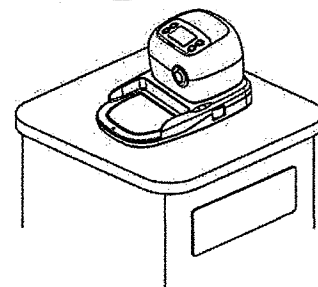
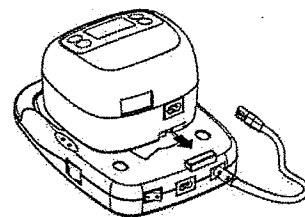
2. Product description



Water Chamber:	The water chamber contains the water for humidification. Its removable base plate allows itself ease for cleaning.
Fill Line:	Symbol indicates the maximum level of water that water chamber can contain.
Flow Direction:	Symbol Indicates the air flow direction
Baffle:	The baffle can prevent water spillage due to improper shaking.
Extraction Tool:	Open the water chamber for cleaning.
Heater Plate:	Warms the water in the water chamber.
Locking Tab:	Holds the CPAP in place.
Heater Plate Switch:	When the switch is pressed against the water chamber, the heater plate will start to work.
Control Knob:	This control knob, graduated from 1 to 6, is used to adjust the humidity. 1 is minimum humidity, 6 is maximum humidity.
Heater On Indicator (Green LED):	When lit, this indicates that the heater is turned on.
Abnormal Indicator (Orange LED):	When lit, this indicates that the fuse blows off.
Inlet Port with Silicon Connector:	Connect to the outlet port of the CPAP device.
Outlet port:	Connect the flexible tubing here.
AC Power Cord:	Connect to an AC outlet providing main power to the heated humidifier.
Power Socket (Inlet):	Connect the AC power cord here.
Power Jumper Cord:	Connect the heated humidifier and the CPAP device.
Power Switch:	Turn the heated humidifier ON or OFF.

3. Installation

3.1 Set Up



1. Place the CPAP device on the heater platform. Position the CPAP device so that the four feet match up with the four recessed areas in the platform and the rubber tab at the back of the platform slips into the slot in the rear of the CPAP unit (beneath the power socket) locking the device securely into place.

2. Place the CPAP and heater platform on a flat surface and at a lower level than your sleeping position.

3. Connect the power jumper cord to the AC inlet on the back of the CPAP device.

4. Connect the AC power cord to the power socket (inlet) on the back of the heater, and plug it into main outlet.

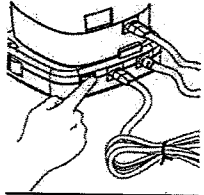


NOTE: 1. Make sure the heated humidifier unit is suitable for the local power voltage.
2. The plug is also served as the disconnect device.

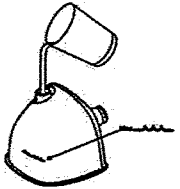
4 Operation


4.1 Operating instruction

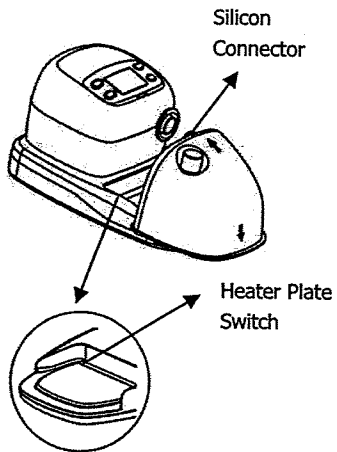
Daily Use



1. Turn on the heater by pressing On/Off switch on the back of the heater platform. The heater power on indicator will be lit (green light)



2. Fill the chamber to the fill line  with distilled water (approx. 450 ml).



3. Press down and slide the chamber into place. Make sure the silicon connector on the inlet connector fit securely over the CPAP device air outlet.

Note: Make sure the water chamber is pushed to the end to press against the heater plate switch. At the same time, the heater on indicator will be lit to indicate the heater plate starts to warm.

Note: The heater will be automatically turned off while the water chamber is removed from the heater platform.

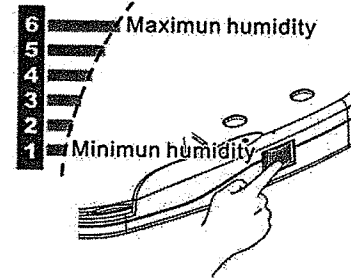
4. Connect the flexible tubing to the outlet connector on the water chamber.



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5. Connect the other end of the flexible tubing to your mask.



6. Adjust the control knob to increase the humidity in the range of 1 to 6 (refer to diagram). 1 is minimum humidity, 6 is maximum humidity. The optimum setting is dependent on the ambient temperature and humidity of your room.

The system is ready for use. Consult the CPAP user's manual for operating instructions.

Danger: In order to avoid the destruction or damages of the CPAP equipment or even the hazard of electric shock, when the water chamber is connected to the outlet port of CPAP, DO NOT fill water from the outlet port of the water chamber. Users must fill water no more than the marking for maximum volume after the water chamber is removed from the heater device and CPAP.

5 Cleaning

5.1 Heater

1. Clean the heater by wiping it with a damp cloth. Allow the heater to air dry before connecting the power cord.
2. Inspect the heater and power cord for any damage and replace it if necessary.

5.2 Water Chamber

1. Turn the device off and allow the heater and water to cool.
2. Disconnect the flexible tubing from the water chamber. Press down on the water chamber and slide it out of the heater. Empty the remaining water.
3. Use the extraction tool to remove the chamber base. Match the indent on the extraction tool to the remark on the water chamber. Use the dotted line on the tool as the pivot and flip it over to remove the base.
4. Use a mild detergent to wash all the chamber parts. Rinse all the parts with clear water and allow them to air dry.
5. All items of the chamber are subject to normal wear and tear and may eventually be replaced. Replace the chamber parts if any damage is present.



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6 Service

If the heated humidifier malfunction or doesn't work, contact your equipment provider service agent immediately. Never try to open the enclosure of heated humidifier. The heated humidifier maintenance needs qualified maintenance personnel.

NOTE: Follow the national requirements to dispose the device.

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
Heater on indicator not light at all	1. heater plate over heated 2. PCB indicator worn out	1. Contact your local agent or EU representative for service.
Abnormal indicator lights	1. The fuse blows off	1. Contact your local agent or EU representative for service.
There is no air flow on through the mask	1. CPAP device is not turned on or working correctly 2. Flexible tubing is not connected right. 3. Flexible tube is blocking.	1. Refer to your CPAP user manual. 2. Reconnect the flexible tubing correctly. 3. Unblock the flexible tube.
Condensation in mask or flexible tube	1. The heater plate setting is too high. 2. The operating environment or position of heated humidifier is not properly. The temperature close to mask or flexible tube is low.	1. Adjust the control knob to low temperature setting. 2. Remove any air conditioner which may nearby the heated humidifier. Or keep room temperature up near 25°C.
Water Leakage	1. Assembly of water chamber is not proper or incorrectly. 2. Water chamber or removable base plate worn out.	1. Remove the water chamber from the heated humidifier, pull out the water and reassemble the water chamber again, make sure the removable base plate is right fit into water chamber, and fill the water till it reach fill line and check if it still leak or not. 2. Replace a new water chamber.

8 Technical Description

Item	Specification
Model No.:	9S-006500
Power Requirement:	AC100-240V, 50/60Hz, 0.6-1.2A
Fuse Rating:	T2A, 250 VAC
Dimensions:	Heater: 25.5 x 17.5 x 5 cm (10" x 6.9" x 1.97") Water Chamber: 13.6 x 15 x 10.5 cm (5.36" x 5.91" x 4.14")
Weight (without Water):	Heater: under 600g (1.32 lbs) Water Chamber: under 250g (0.55 lbs)
Water Capacity:	450ml
Maximum Heater Plate Temperature:	Approximate 70°C (158°F)
Pressure Drop:	0.2cmH ₂ O @ 60LPM
Humidity Output:	≥10 mgH ₂ O/L (ambient temperature of 23°C ± 2°C, ambient relative of humidity 60% ± 15%)
Operating Environment	Temperature: 5°C-35°C Humidity: 15%-95%RH Atmospheric Pressure: 609-768mmHg
Storage Environment	Temperature: -15°C-50°C Humidity: 10%-90%RH Atmospheric Pressure: 609-768mmHg
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:

1. The specification is also suitable for other areas operating with same power supply.
2. Consult the distributor or EU representative for other technical documents.

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_r 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
Conducted RF IEC 61000-4-6	3Vrms150 kHz to 80 MHz outside ISM bands ^a	3Vrms	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 $d = 1.2\sqrt{P}$ 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.