PEGASUS
Nebulizer Heater
P2001

Instructions for Use

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WARRANTY

The Pegasus Nebulizer Heater, P200l is warranted by Pegasus Research Corporation against defects in materials and workmanship for a period of one (1) year from the date of original purchase. During the warranty period, we will, at our discretion, repair or replace any heater that proves to be defective, provided that it is returned to Pegasus Research, freight prepaid. An RGA (Returned Goods Authorization) number is required on all returned product.

This warranty does not apply if the device has been damaged by accident, misuse, or as a result of service or modification by someone other than Pegasus Research.

No other express warranty is given.

5.1 Cost is determined by the value of replacement parts plus the following:

- Labor 1 – complete tear down and rebuild*
  OR
- Labor 2 – accessible components work (i.e. switch, circuit board)*
  AND
- Recertification /packaging*

** Call Pegasus Research for current labor rates.*

5.2 Warranty repairs are returned at Pegasus' cost

5.3 Units out of warranty are shipped ups prepaid. Shipping charges are end user's responsibility.

6 The end user or distributor must approve the repair estimate with a signature, date, and Purchase Order (if desired), and FAX the copy to 714-241-7177 (or email). Credit Card may be used to pay for repair charges.

7 Warranty units are repaired and returned ASAP (under highest priority)

Standard repairs are returned in approximately 10-20 days from receipt of estimate approval

Table of Contents

SYMBOLS

	**Catalogue Number**
	**Serial Number**
	**Device Manufacturer**
	**The product is certified to the Canadian and US Electrical Safety standards**
	**Consult Instructions for Use**
	**Reusable Device. Not for General Waste**
	**Electrical and Shock Hazard**
	**Temperature Hazard, Hot Surface**
	**General Warning**

Return and Servicing Policy

1. Contact distributor to report a problem.

1.1 Provide the following information:

- Date of Purchase
- Model# (ie. P2001) and serial number(s)
- Description of problem/ defect
- Contact person, ship to/ bill to address, phone, fax#

1.2 Distributor will contract Pegasus for evaluation/repair of unit.

2. Warranty status, barring abuse, is determined by the following:

- Defect/ problem appeared within 1-year of the shipping date from our facility unless the warranty card (packaged with unit) is returned indicating the date an end user received the unit.
- Warranty card date is cross-checked with tracking/ shipping records.

- Defect/ problem appeared within 90 days of a previously repaired heater according to Pegasus' device history file

3. If unable to contact distributor, end user (s) request an RGA# and sends the unit directly to Pegasus for evaluation, upon completion of step 1.1 in writing

4. Pegasus evaluates the cause of the defect/ problem free of charge.

4.1 A written evaluation is prepared that indicates cause of failure/ defect
4.2 Warranty status is honored in accordance with # 2

OR

4.3 Warranty status is void under the following typical, but not limited conditions

- Unit case was opened by end user
- Crack(s) in upper or lower housing indicates customer dropped or abused the unit, a condition that typically leads to fluid leakage inside the housing where more parts are damaged. cracked units must not be used and should be returned immediately for repair.
- Complete corrosion of inner components indicates partial or complete immersion of heater for sterilization.

5 A written estimate/ cost for repair is sent to the distributor or customer if the unit is found out of warranty.

Heater Field Check-Out

NOTE: **If heater unit shows any sign of damage, or does not pass the functional tests below, heater unit should be returned to distributor or manufacturer for repair.**

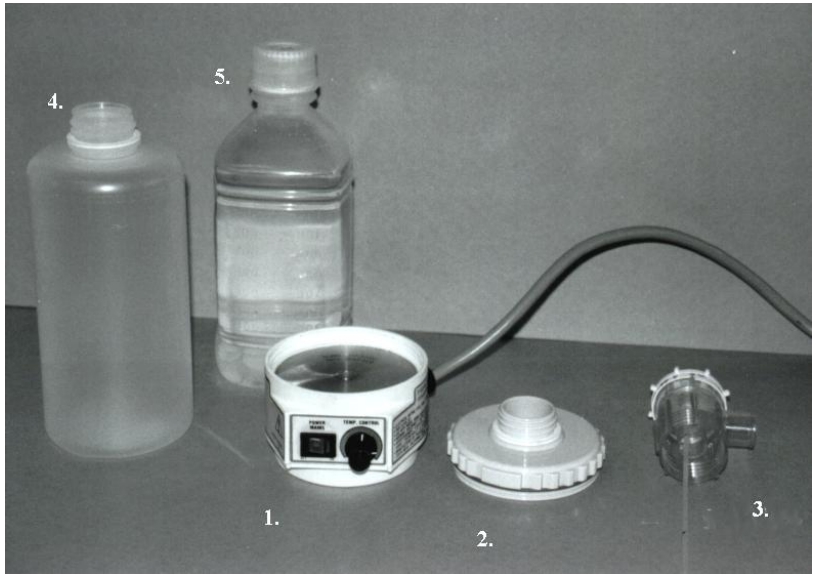
1. Remove P26100 Adapter from heater unit.
2. Inspect Heater housing for cracks or other evidence of damage. Do not continue with checkout if the housing has been damaged.
3. Inspect power cord for evidence of damage to insulation. As in step one, do not continue with checkout if power cord has been damaged.
4. Inspect for evidence of moisture incursion into heater, such as condensation on lens of switch, or drops of moisture exiting at power cord or housing joint. Do not continue with checkout if moisture is present.
5. Using an ohmmeter, check for continuity from Ground pin on electrical plug to heater plate. Remove residues or contaminates on the heater platen to ensure a solid electrical connection between ohmmeter pin and platen. Continuity is present if resistance from ground pin to platen is less than 10 ohms. Do not continue with checkout if resistance is greater than 10 ohms.
6. Place power switch in OFF position, and plug heater unit into 120-volt AC power supply. (If outlet power is less than 120-volts, a transformer power supply should be used and adjusted to 120-volts). Do not continue with checkout if the POWER ON light comes on with switch in OFF position.
7. Press POWER switch to ON position. Switch light should come on when switch is depressed.
8. Adjust temperature to maximum (fully clock-wise), and heater temperature to stabilize for sixty minutes.
9. Warning: Burn Hazard: Do not touch heater plate surface. Using a thermocouple probe for surface temperatures, measure and record heater plate surface temperature in at least four places.
10. Determine the average of the four or more temperatures measured. The average temperature should be 103 degrees C, plus or minus 5 degrees C.
11. Turn Power Switch Off and unplug Heater Unit.
12. Replace P26100 Heater Adapter, if desired, after Heater has cooled for at least 15 minutes.
13. Heater can now be placed back in service. It is suggested that this procedure be signed, dated, and filed, as evidence of completion of checkout.

General Information

The Pegasus Mistic™ System is designed to provide economical heated and unheated aerosol (nebulization). This versatility, combined with superior performance, results in unparalleled convenience.

The instructions enclosed refer to the following components of the Pegasus Mistic™ System. These components are illustrated in the photo below**.**

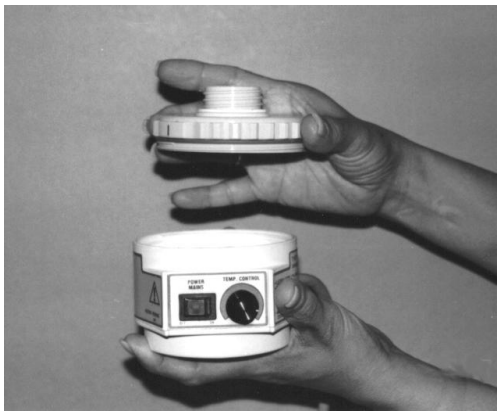
1. **P2001 Pegasus Nebulizer Heater**
2. **P26100 Pegasus Heater Adaptor Top**
3. **(P3000N, H) Mistic™ Nebulizer**
4. **P70000 Pegasus Reusable Dry Bottle**
5. **Standard Sterile Water Pour Bottle**



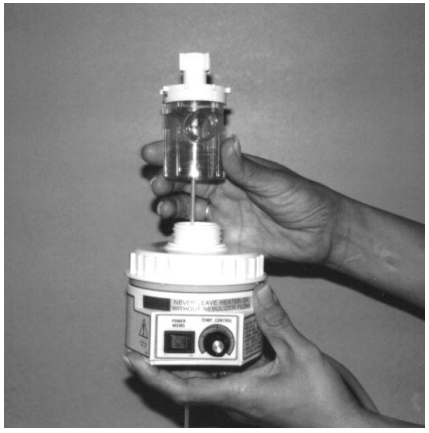
.Mistic™ Nebulizer Set-Up
P3000N and P3000H

Set-Up and performance of the Mistic™ Nebulizer are described on the following pages. Use of the P26100 Re-Usable and Autoclavable Heater Adaptor Top is necessary for heated nebulization. Instructions are as follows:

1. Inspect heater to be certain that all surfaces are clean and intact.
2. Turn Heater switch to OFF.
3. Turn temperature control knob to full counterclockwise position.
4. Using care to avoid touching inside of P26100 Heater Adaptor Top, thread top **firmly** onto the top of the P2001 Pegasus Heater.



5. Attach a new Mistic™ Nebulizer to Pegasus Heater Adapter Top.



Oxygen Flow (LPM)	Oxygen Setting (Entrainment)	Output Temperature +/- 2°C Typical
44 (FLUSH)	95%	31˚C (87.8˚F)
44 (FLUSH)	80%	31.5˚C (88.7˚F)
15	60%	33˚C (91.4˚F)
15	50%	35˚C (95˚F)
15	40%	30˚C (86˚F)
14	35%	29˚C (84.2˚F)

Pegasus Nebulizer Heater Specifications

Voltage	115 VAC +- 10 Volts
Power	200 WATTS
Current	1.7 AMPS
Surface Temperature	135 Degrees C
Power Cord	Hospital Grade, 10 Ft.

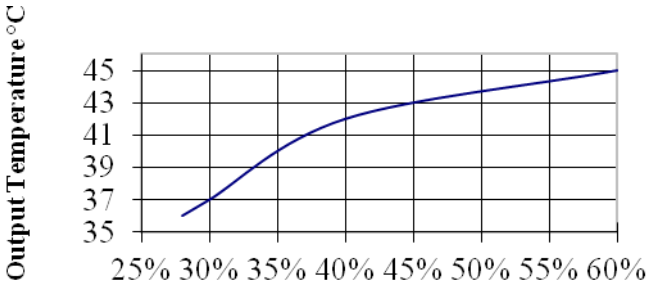
Transport and Storage Conditions

Temperature	-40 ˚C to + 70 ˚C
Relative Humidity	10% to 100% (including condensate)
Atmospheric Pressure	500 hPa to 1060 hPa

Operating Conditions

Temperature	10 ˚C to 40 ˚C
Relative Humidity	30% to 75% (noncondensing)
Atmospheric Pressure	700 hPa to 1060 hPa

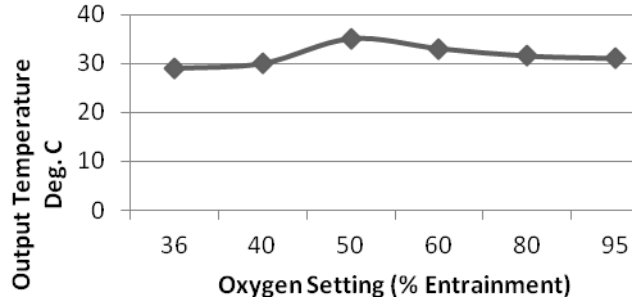
Maximum Output Temperature Using Mistic™ Standard Flow Nebulizer and Nebulizer Heater



Oxygen Flow	Oxygen Setting	Output Temperature
(LPM)	(Entrainment)	+/- 2°C Typical
12*	60%	45°C - (113°F)
10	40%	42°C - (107°F)
6	30%	37°C - (99°F)
6	28%	36°C - (97°F)

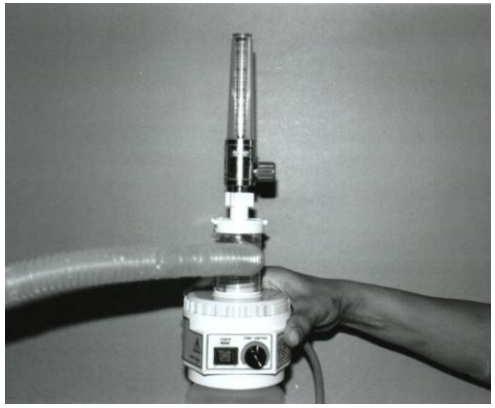
*Note: It is recommended that the heater **not** be run above midpoint at this flow rate.

Maximum Output Temperature Using Mistic™ High Flow Nebulizer and Nebulizer Heater



6. Attach sterile water bottle to lower threads of Heater (or nebulizer, if unheated).

7. Connect Nebulizer to oxygen flow meter and adjust flowr. Follow Flow Rates recommended on the label for P3000N and P3000H models. Nebulizer and Heater should be positioned nearly vertical for best results.



8. Set Nebulizer air entrainment collar to desired oxygen concentration.
9. Plug Pegasus Nebulizer Heater into Hospital Grade Outlet.
10. Turn power switch to ON. Switch light indicates proper connection.
11. Turn knob clockwise to desired setting. Midway (12:00) is a good starting point.

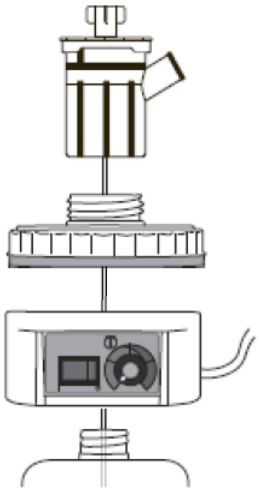
12. Run unit approximately 20 minutes to allow stabilization. Check for desired temperature at the patient end of aerosol hose.

CAUTION:

Always measure temperature of aerosol <u>before</u> connecting to patient.

13. Connect patient hose from nebulizer outlet to patient mask or tee.

P3000N and P3000H



P3000N, P3000H Mistic™ Nebulizer

P26100 Pegasus Adapter Top

P2001 Pegasus Heater

P70000 Reusable Dry Bottle

Nebulizer System Disassembly and Cleaning

1. Turn heater OFF, unplug power cord, and allow five (5) minutes to cool. Always turn heater off before shutting off nebulizer.

CAUTION

<u>Burn hazard: During normal operation internal platen temperature is 135 °C.</u>

2. Turn off oxygen flow meter and remove nebulizer from flow meter along with heater and water bottle.
3. Unscrew the nebulizer from heater adapter top and discard.
4. Unscrew P26100 Pegasus Reusable Heater Adapter Top and re-process (see step 9).
5. Remove water bottle from bottom and discard.

6. Dry off external surfaces of heater.
7. If disinfecting or cleaning is desired, the Pegasus heater can be sprayed or wiped down with Sporicidin or Cidex cold disinfecting solutions,
   OR
   If cold sterilants are not available or permited, wipe down the heater unit with a multipurpose cleaner (i.e. Formula 409).
8. Remove sterilants/ cleaner from heater platen with a disposable, lint-free cloth, moistened with sterile water or alcohol. Please note that the heater platen surface temperature operates above pasteurization temperature, and aids in the sterilization process.

CAUTION

<u>Do not immerse the Pegasus Nebulizer Heater</u>
<u>Do not reprocess Mistic™ Nebulizer with liquid sterilants or steam</u>

9. The P26100 Pegasus Reusable Heater Adapter Top should be sterilized by Steam Autoclave at 130 - 140 degrees C or by Pasteurmatic or Sporicidin cold sterilant. If cold sterilant is used, be sure to rinse adapter thoroughly.

Nebulizer Performance

Standard Flow Nebulizer
Nominal oxygen flow to the Mistic™ Standard Flow Nebulizer is 6-12 lpm oxygen. At that flow rate, oxygen concentration is controlled via the entrainment dial between 28% and 95%.

High Flow Nebulizer
Nominal oxygen flow to the Mistic™ High Flow Nebulizer is 14 – 44 (flush) lpm oxygen. At that flow rate, oxygen concentration is controlled via entrainment dial between 35% and 95%.

Temperatures within 2˚ max. are typically reached at one hour of operation. During use, overflow water from nebulizer re-circulates back into the reservoir bottle. The output temperatures are based on sufficient warming of the reservoir water. A 1000ml bottle requires 1.5 to 2 hours to warm fully from room temperature. A low water condition (50ml or less) can cause approximately a 2˚ increase over the maximums listed for short periods prior to empty water condition, when output temperatures will drop. The temperature output given below is at the maximum heater setting end of a 6 foot hose (patient end) and a room temperature of 22˚C.

NOTE: ***Output temperature at patient end should be continuously monitored.***