



**Nebulizer Heater,  
115V**



**301-P2001**



(01)00612223200114

Pegasus Research Corporation, 1518 E Edinger Ave., Unit A, Santa Ana, CA  
92705

Distributed by Sarnova, HC, LLC's family of companies:  
Bound Tree Medical, LLC, DXE Medical, Inc.  
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Dublin, Ohio 43016  
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[www.Tri-anim.com](http://www.Tri-anim.com)

## **Instructions for Use**



## **Nebulizer Heater 301-P2001**

Manufactured by:  
Pegasus Research Corporation  
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Santa Ana, CA 92705

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## **Warranty**

The Curaplex® Nebulizer Heater, 301-P2001 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. Defective units under warranty are repaired or replaced at Pegasus' discretion, pending an in-house evaluation. End users must first obtain an RGA (Returned Goods Authorization) and return product freight prepaid.

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.

## Important Safety Information

This section contains information for prescribers and guidelines for safe use of Heater.

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### WARNINGS

Death or serious injury to the patient or practitioner may occur if these warnings are not followed.

- Read and follow all instructions, labeling, and accompanying documents supplied with this medical device. Failure to follow instructions, including warnings and cautions could result in misuse of the device or device malfunction.
- Grounding reliability can only be achieved when the supply cord is connected to a properly grounded receptacle. Risk of electric shock exists if the equipment is not connected to a properly grounded receptacle.
- Exposed conductor on the power supply cord can cause is an electric shock hazard. Remove device from service if the power supply cord has exposed wires.
- Do not operate the Heater in the presence of a flammable anesthetic mixture with air, oxygen or nitrous oxide. An explosion risk exists if the Heater is operated in a volatile environment.
- Burn Hazard: During normal operation, the internal platen temperature is 135°C.
- Do not use chemicals to disinfect disposable adapters/nebulizers. Chemicals can damage and/or contaminate the aerosol delivered to the patient.
- Discontinue use and remove the device from service immediately if water leaks into the power outlet. Water incursion through the power outlet is an electric shock hazard.

### CAUTIONS

- **Do not immerse the Heater in a liquid for any reason.**
- Always check the patient-end temperature of the aerosol before connecting to the patient. Run the system for approximately 20 to 30 minutes, or in accordance with accessory Instructions for Use. Allow for temperature stabilization.
- When using pressurized systems, a gasket seal on the shoulder of the bottle is essential to maintaining system pressure without leakage. Heater adapter must be tightened firmly to avoid leakage.
- Rx Only. Federal law (U.S.A.) restricts this device to sale by or on the order of a physician.

**WARNING:** These instructions contain important information for safe use of the product. Read the entire contents of these Instructions for Use, including Warnings and Cautions, before using this product. Failure to properly follow Warnings, Cautions and Instructions could result in serious injury or death to the patient.

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## General Information

The Curaplex® System is designed to provide economical economical continuous heated and unheated aerosol (nebulization) for respiratory applications. This versatility, combined with superior performance, results in unparalleled convenience.

### Principles of Operation

The 301-P2001 Curaplex® Heater warms the aerosol produced by any of the Curaplex® Nebulizer Series, when placed between the nebulizer top and bottle. The nebulizer pickup tube passes through the heater opening and draws water from the bottle. The aerosol produced by the nebulizer gathers in the lid and is warmed as it contacts the heater plate surface prior to exiting through the nebulizer venturi. Rainout within the nebulizer returns to the bottle through the pickup tube opening and warms the bottle contents, contributing to the overall heat output of the device.

An electronic temperature control circuit provides consistent heating across a wide range of adjustment. A non reversing thermal-fuse prevents overheating should the control circuit fail.

The instructions enclosed refer to the following components of the Curaplex® System.



1. 301-P2001 Curaplex® Nebulizer Heater
2. P26100 Heater Adaptor Top
3. Curaplex® Nebulizer Line: 301-P3000N, 301-P3000N-S, 301-P3000N-L, 301-P3000H, 301-P3000H-S, 301-P3000H-L, 301-P3100N, 301-P3100H
4. Water Reservoir, Refillable
5. Equivalent Sterile Water source

### Curaplex® Heater Features










- Illuminated power switch
- Adjustable temperature range
- Temperature adjustment knob
- Corrosion resistant metal components

5.3 Units out of warranty are shipped UPS prepaid. Shipping charges are the 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**

## SYMBOLS

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

## Return and Servicing Policy

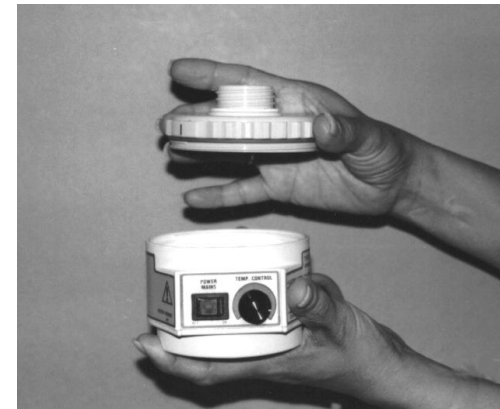
1. Contact distributor (Tri-anim) to report a problem.
  - 1.1. Provide the following information:
    - Date of purchase
    - Model# (P2001) and serial number(s)
    - Description of problem/defect
    - Contact person, ship to/bill to address, phone, fax#
  - 1.2. Distributor will contract Pegasus for evaluation/repair of unit.
2. Warranty status, barring abuse, is determined by the following:
  - Defect/ problem appeared within one (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 number 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 to indicate the 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.
    - Immersion.
5. A written estimate/cost for repair is sent to the distributor or customer if the unit is found out of warranty.
  - 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.

## Nebulizer Adapter & Curaplex® Heater Set-Up Curaplex Nebulizer line & P2001

Set-up and performance of the Curaplex® nebulizers are described on the following pages. Use of the P26100 reusable and autoclavable heater adapter 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. Use care to avoid touching inside of P26100 heater adapter top and thread top **firmly** onto the top of the P2001 Curaplex® heater.



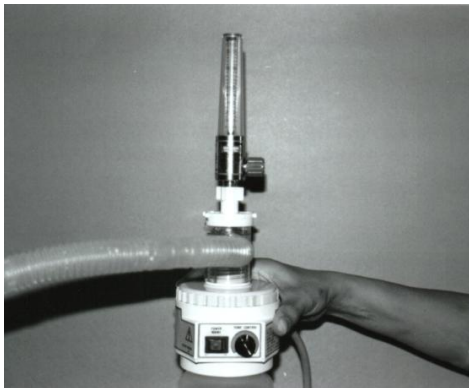
5. Attach a new Curaplex® nebulizer to heater adapter top.



- Attach Curaplex® sterile water for inhalation bottle to lower threads of heater (or nebulizer head, if unheated).



- Connect nebulizer head to oxygen flow meter and adjust flow.



- Set nebulizer head following flow rates recommended on the label for Curaplex® nebulizer line. Nebulizer and heater must be set up in a vertical position for best results.
- Plug Curaplex® nebulizer heater into hospital grade outlet.
- Turn power switch to ON. Switch light indicates proper connection.
- Turn knob clockwise to desired setting. Midway (12 o'clock position) is a good starting point.

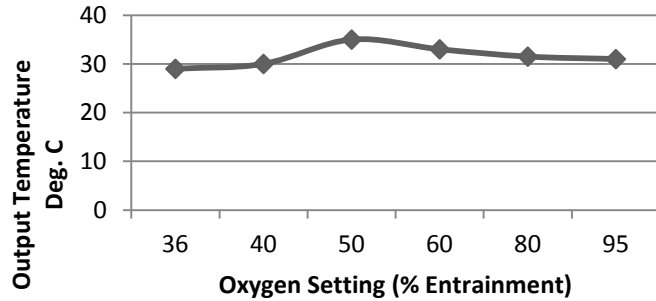
## Heater Field Check-Out

**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.**

- Remove P26100 Adapter from heater unit.
- Inspect Heater housing for cracks or other evidence of damage. Do not continue with checkout if the housing has been damaged.
- Inspect power cord for evidence of damage to insulation. As in step one, do not continue with checkout if power cord has been damaged.
- 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.
- Using an ohmmeter, check for continuity from Ground pin on electrical plug to heater plate. Remove residues or contaminants 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.
- 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.
- Press POWER switch to ON position. Switch light should come on when switch is depressed.
- Adjust temperature to maximum (fully clock-wise), and heater temperature to stabilize for sixty minutes.
- 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.
- Determine the average of the four or more temperatures measured. The average temperature should be 103 degrees C, plus or minus 5 degrees C.
- Turn power switch OFF and unplug heater unit.
- Replace P26100 Heater Adapter, if desired, after heater has cooled for at least 15 minutes.


Heater can now be placed back in service. It is suggested that this procedure be signed, dated, and filed, as evidence of completion of check-out.

**Maximum Output Temperature Using Curaplex High Flow Nebulizer and Nebulizer Heater**



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	36%	29°C (84.2°F)

**Curaplex® Nebulizer Heater Specifications**

Class 1 – Type B  Medical Equipment

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**

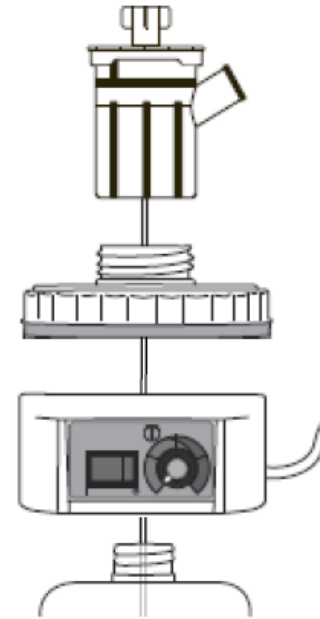
Temperature	10 °C to 40 °C
Relative Humidity	30% to 75% (noncondensing)
Atmospheric Pressure	700 hPa to 1060 hPa

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

**CAUTION**

**Always measure temperature of aerosol before connecting to patient.**

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



**Curaplex® Nebulizer Line:**  
 301-P3000N, 301-P3000N-S,  
 301-P3000N-L  
 301-P3000H, 301-P3000H-S,  
 301-P3000H-L  
 301-P3100N, 301-P3100H

**P26100 Heater Adapter Top**

**P2001 Curaplex® Nebulizer Heater**

**Sterile Water for Inhalation**

**Nebulizer System Disassembly and Cleaning**

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

**CAUTION**

**Burn hazard: During normal operation internal platen temperature is 135° C**

- 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 reusable heater adapter top and re-process (see step 9).
5. Remove water bottle from heater housing and discard or reprocess where applicable.
6. Dry off external surfaces of heater.
7. If disinfecting or cleaning is desired, the Curaplex® Nebulizer Heater can be sprayed or wiped down with Sporidicin® or Cidex® cold disinfecting solutions.  
**OR**  
If cold sterilants are not available or permitted, 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**

**Do not immerse the Curaplex® Nebulizer heater**  
**Do not reprocess the Curaplex® nebulizer with liquid sterilants or steam**

9. The P26100 reusable heater adapter top should be sterilized by steam autoclave at 130 - 140 degrees C or by Pasteurmatic™ or Sporidicin® cold sterilant. If cold sterilant is used, be sure to rinse adapter thoroughly.

**Nebulizer Performance**

**Standard Flow Nebulizer**

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

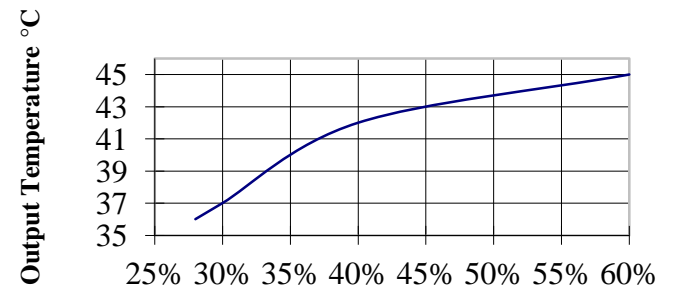
**High Flow Nebulizer**

Nominal oxygen flow to the Curaplex® High Flow Nebulizer is 14 – 44 (flush) lpm oxygen. At that flow rate, oxygen concentration is controlled via entrainment dial between 36% 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.**

**Maximum Output Temperature Using Curaplex Standard Flow Nebulizer and Nebulizer Heater**



**Oxygen Setting (Entrainment)**

Oxygen Flow (LPM)	Oxygen Setting (Entrainment)	Output Temperature +/- 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.