curaplex®

Humidifier Heater, 115V

REF 301-P2000

(01)00612223020002

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.
Emergency Medical Products, Inc. &
Tri-anim Health Services Inc.
5000 Tuttle Crossing Boulevard
Dublin, Ohio 43016
800-TRI-ANIM (874-2646)
www.Tri-anim.com

Instructions for Use

curaplex®

Humidifier Heater
301-P2000

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

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WARRANTY

The Curaplex® ™ Nebulizer Heater 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.

Important Safety Information

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

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.

Table of Contents

General Information 2

Curaplex® Nebulizer 301-P3000N

Nebulizer Set-Up 3
Nebulizer Performance 4
Nebulizer System 5
Disassembly and Cleaning

Curaplex® Humidifier – 301-0131

Humidifier Set-Up 6
Humidifier System 7
Disassembly and Cleaning
Humidifier Performance 7

Curaplex® Heater - 301-P2000

Heater Field Check-Out 8
Return and Servicing Policy 9
Heater Specifications 10

Symbols 11

Safety Information 12

Warranty 13

General Information

The Curaplex® System provides both humidity (humidification) and heated aerosol (nebulization) depending upon the choice of adapter used with the Curaplex® heater. This versatility combined with total aseptic isolation of the heater and superior performance, results in unparalleled convenience.

The instructions enclosed refer to the following components of the Curaplex® System. These components are illustrated in the photo below.

301-P2000	Curaplex® Heater
708-P23000	Heater Bracket
708-P23001	Vision®/Phillips™ Heater Bracket
301-P26000	Heater Core
301-P3000N	Curaplex® Standard Flow Nebulizer
301-P3100N	Curaplex® Closed Dilution Nebulizer
301-0131	Curaplex® Humidifier
P70000	Refillable Reservoir, 1000 ml

Symbols

REF	**Catalogue Number**
SN	**Serial Number**
	Device Manufacturer
c PS us CERTIFIED ELECTRICAL SAFETY	**The product is certified to the Canadian and US Electrical Safety standards**
	Consult Instructions for Use
	Reusable Device. Not for General Waste
	Warning: Electrical Shock Hazard
	Warning: Burn Hazard
	Warnings and Cautions
	Class 1 – Type B, Medical Equipment

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

- Labor 1 – complete tear down and rebuild, $75.00

OR

- Labor 2 – accessible components work (ie. switch, circuit board), $45.00

AND

- Recertification / packaging, $15.00

5.2 Warranty repairs are returned at Pegasus' cost

5.3 Units out of warranty are shipped 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

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

Curaplex® Nebulizer Set-Up

Set-Up and performance of the Curaplex® Nebulizer are described on the following pages. Use of the 301-P26000 Re-Usable and Autoclavable Heater Core is necessary for heated nebulization.

1. Inspect heater to be certain that all surfaces are clean and intact.
1. Turn Heater switch to OFF.
2. Turn temperature control knob to full counter clockwise position.
3. Using care to avoid touching inside of 301-P26000 Heater Core, screw core **firmly** into the top of the 301-P2000 Heater. (See Fig 1 and Fig 2)
4. Attach new Curaplex® Nebulizer to Heater Core. (Fig. 3)

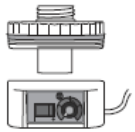


Figure 1

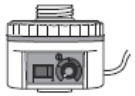


Figure 2

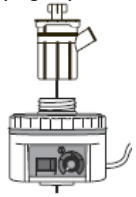


Figure 3

5. Attach sterile water bottle to lower threads of Heater core, or Nebulizer, if unheated (Fig 4).

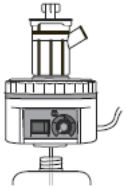


Figure 4


Figure 5

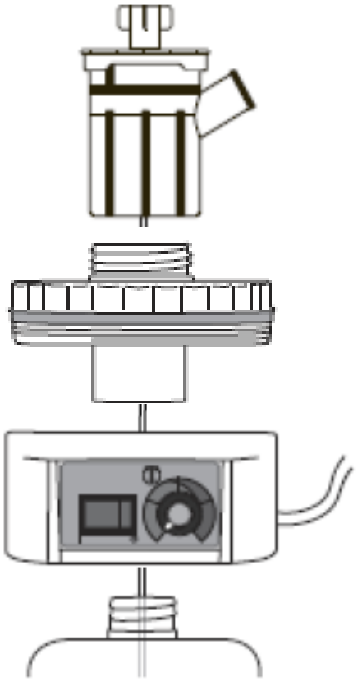
6. Connect Nebulizer to oxygen **flowmeter** and adjust flowmeter (Fig 5). Follow Flow Rates recommended on the label or insert. Nebulizer and Heater should be very nearly vertical for best results.
7. Set Nebulizer air entrainment collar to desired oxygen concentration.
8. Plug Curaplex® Heater into Hospital Grade Outlet.
9. Turn power switch to On. Switch light indicates proper connection.
10. Turn knob clockwise to desired setting. Midway (12:00) is a good starting point.
11. 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 before connecting to patient.
The 301-P2000 is NOT recommended for use with High Flow Nebulizers.

12. Connect patient hose from Nebulizer outlet to patient mask or tee.

Curaplex® Nebulizer Performance



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

301-P26000 Heater Core

**301-P2000 Curaplex®
Humidifier/Nebulizer Heater**

Sterile Water for Inhalation

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

(Temperatures within 2° of max are typically reached at one hour of operation)
During use, overflow water from the 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 (50 ml or less) can cause approximately a 2° increase over the maximums listed for short periods prior to water empty condition when output temperatures will drop.

The temperature output given on the next page is at the maximum heater setting at the end of a 6 foot hose (patient end) and a room temperature of 22° C.

Return and Servicing Policy

1. Contact distributor (Tri-Anim, etc.) to report a problem.

1.1 Provide the following information:
- Date of Purchase
- Model# (ie. 301-P2000) 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, request an RGA# directly from Pegasus and send the unit directly to Pegasus facility 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.

CAUTION

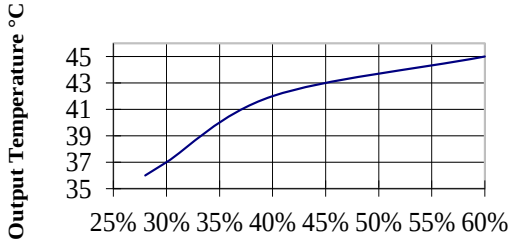
Do not immerse the Curaplex® Heater.
Do not reprocess Curaplex® 301-0131 Humidifier with liquid sterilants or steam.

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 301-0131 Humidifier 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 aluminum heater plate. Scratch surface of platen with ohmmeter pin, if necessary, to establish electrical contact. Continuity is present if resistance from ground pin to platen is less than 1.0 ohms. Do not continue with checkout if resistance is greater than 1.0 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***.
10. Use IR thermometer **or** place hand (DO NOT TOUCH) above platen surface to verify significant heat output and heater functionality.
11. Turn Power Switch Off and unplug Heater Unit.
12. 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.

Output temperature at patient end should be continuously monitored.



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)

Nebulizer System Disassembly and Cleaning

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

CAUTION

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

2. Turn off oxygen flowmeter and remove Nebulizer from flowmeter along with heater and water bottle.
3. Unscrew disposable Nebulizer from heater core top and discard.
4. Unscrew 301-P26000 Heater Core and re-process as per step 9.
5. Remove water bottle from bottom and discard.
6. Dry off external surfaces of heater.
7. Because the heater is aseptically isolated from the patient system, it is not necessary to routinely disinfect the heater itself. If, however, disinfecting or cleaning is desired, the Curaplex® heater can be sprayed or wiped down with Sporicidin or Cidex cold disinfecting solutions.

CAUTION

Do not immerse the Curaplex® Heater
Do not reprocess Curaplex® Nebulizer with liquid sterilants or steam

8. Wipe the heater surface with a damp sponge to remove excess disinfectant.
9. The P26000 Core should be sterilized by steam autoclave at 130 - 140°C, or, by Pasteurmatic. **DO NOT USE CHEMICALS!**

Humidifier Set-up

1. Inspect heater to ascertain all surfaces are clean and intact.
2. Turn heater switch to OFF.
3. Turn temperature control knob to full counterclockwise position.
4. Attach a new Mistic™ Humidifier to threads on top of heater by turning on clockwise. Be sure to tighten firmly (Fig 1).
5. Attach water container to humidifier threads below heater)Fig 2)

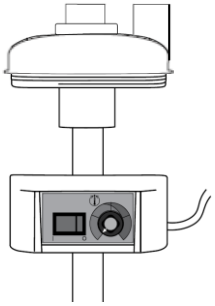


Figure 1

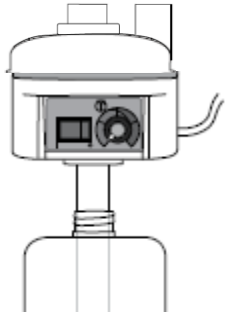


Figure 2

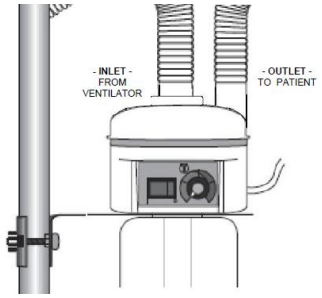


Figure 3

6. Mount the Curaples® Humidifier System on a convenient vertical surface using the P23000 bracket (Fig. 3), or the P23001 bracket when setting up the system with a Vision Ventilator.
7. Connect gas flow to an oxygen diluter or connect the pressure source with an aerosol hose to the inlet port of humidifier.
8. Connect patient hose to outlet port of humidifier and adjust the hoses to a convenient position.
9. Plug the Pegasus™ Heater into a hospital grade outlet.
10. Turn power switch ON. Switch light indicates proper connection.
11. Turn temperature control knob clockwise to desired setting. Midway on dial rotation (straight up) is a recommended position to start for all entrainment settings.
12. **IMPORTANT:** Thoroughly wet wick in humidifier chamber by inverting system after assembly, squeezing the bottle to force water into chamber or by pouring water (30ml) into upper chamber. Until primed by one of the means above, humidifier will not adequately function.

13. Run unit for approximately 20 to 30 minutes to insure temperature stabilization. Check for the desired temperature level at the patient end of the hose.
14. Connect patient hose to patient mask or tee.

CAUTION

- **Always measure temperature of gas before connecting to patient.**
- **To avoid softening of the reservoir bottle threads, the humidifier setting must never be left without flow.**
- **When humidifying pressurized systems, use water bottles with a gasket seal on the shoulder of bottle neck, which is essential to maintaining system pressure without leakage.**
- **Equipment not suitable for use in the presence of a flammable anesthetic mixture with air, or with oxygen, or with nitrous oxide.**

Humidifier Performance

Output temperature in the Curaplex® Humidifier System is naturally limited by the absorption of the water from the bottle. This absorption rate provides adequate warmth and humidity for most applications but will not allow unsafe temperatures to be achieved regardless of flow rate.

The output specification is based on continuous air flow at 24°C in a 24°C environment. Output specified is at the patient end of a 6 foot hose.

FLOW RATE (Minute Volume)	**OUTPUT TEMPERATURE**
5 LPM	35 Degrees C (95 Degrees F)
10 LPM	34 Degrees C (93 Degrees F)
15 LPM	31 Degrees C (93 Degrees F)
20 LPM	30 Degrees C (86 Degrees F)

Output is saturated (100% RH) up to 15 LPM flow. Variations of as much as 2 Degrees C may be seen due to heater/humidifier and setup variables.

Disassembly and Cleaning

1. Turn off heater, unplug power cord, and allow five (5) minutes to cool.

CAUTION

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

2. Disconnect pressure supply hose and patient hose.
3. Remove water bottle.
4. Unscrew humidifier adapter from the heater.