

HUDSON RCI®

REF: 5705
OPERATING MANUAL



Rx ONLY

ThermoGard™
Electronically Controlled Nebulizer Heater

Distributed by:
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Introduction

Intended Use

The Teleflex Medical ThermoGard Nebulizer Heater is designed for use with the Teleflex Medical REF: 1770 Variable Concentration Large Volume Nebulizer (*not supplied*) to provide continuous heated aerosol for respiratory applications.

Principles of Operation








The Teleflex Medical ThermoGard Nebulizer Heater warms the aerosol produced by the REF: 1770 Large Volume Nebulizer when placed between the nebulizer lid and jar. The nebulizer pickup tube passes through an opening in the heater and draws water from the jar. The aerosol produced by the nebulizer gathers in the lid and is warmed as it contacts the heater plate surface prior to exiting the nebulizer.

Rainout within the nebulizer returns to the jar through the pickup tube opening and gradually warms the jar 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 nonreversing thermal fuse prevents overheating should the control circuit fail.

Features

- Illuminated power switch
- Push-to-turn temperature adjustment knob
- Adjustable temperature range
- Corrosion resistant metal components

Warnings and Cautions

-  **Warning: Fire Hazard.** Do not use the ThermaGard in the presence of flammable anesthetic gases.
-  **Warning: Burn Hazard.** Internal components are hot (135 °C) and may contain liquid at temperatures up to 100 °C. Allow the heater to cool before handling.
-  **Warning: Electrical Shock Hazard.** Refer all servicing to qualified, trained personnel only.
-  **Warning:** Always verify aerosol temperature before connecting to the patient.
-  **Warning:** Never fill the nebulizer jar with water hotter than 37 °C as this may pose a patient hazard.
-  **Warning:** Always verify oxygen concentration before connecting to the patient.
-  **Warning:** Using an aerosol delivery tube less than 180 cm (6 ft.) in length may result in aerosol delivery exceeding 41 °C at the patient connection.
- ➔ **Caution:** Do not autoclave, gas sterilize, pasteurize or immerse this device in any liquid. Severe equipment damage will result.
- ➔ **Caution:** Do not operate the ThermaGard heater with a dry nebulizer, nor leave the heater operating during refilling.
- ➔ **Caution:** Always operate the ThermaGard heater in a vertical position for best performance.
- ➔ **Caution:** Replace fuses only with those of the same rating (indicated internally).

Specifications

Temperature output	Adjustable from 0 to 41 °C
Temperature control	Dual thermistor
Voltage	115 VAC, 50/60 Hz
Power consumption	200 Watts
Current	1.7 Amperes
Power fuses	4 A, two (2) required (live and neutral circuits independently fused)
Thermal fuse	117 °C nonreversing
Weight	750 g (approximately 1.65 lb.)
Height	90 mm (approximately 3½ in.), including adaptor ring
Diameter	100 mm (approximately 4 in.)
Power cord	3 m (approximately 10 ft.)
Storage temperature	-40 °C to + 70 °C
Nebulizer	Use only the Teleflex Medical REF: 1770 Large Volume Nebulizer

Performance Data

O ₂ Flow	Entrainment Setting	Output Temperature
10 LPM	98%	40 °C
10 LPM	80%	40 °C
10 LPM	60%	39 °C
10 LPM	40%	37 °C
8 LPM	35%	36 °C
5 LPM	28%	33 °C

Table 1: Nominal Output Temperatures at Various Flow and Entrainment Settings
Variation of ± 2 °C typical

NOTE: The above measurements were achieved under the following conditions: Line voltage at nominal (115 VAC); room temperature 24 °C; measured at the patient end of a 180 cm (6 ft.) x 22 mm dia. aerosol delivery tube; temperature control knob set at maximum (fully clockwise). Variation from the stated conditions will affect the output temperature of this device.

Controls & Indicators

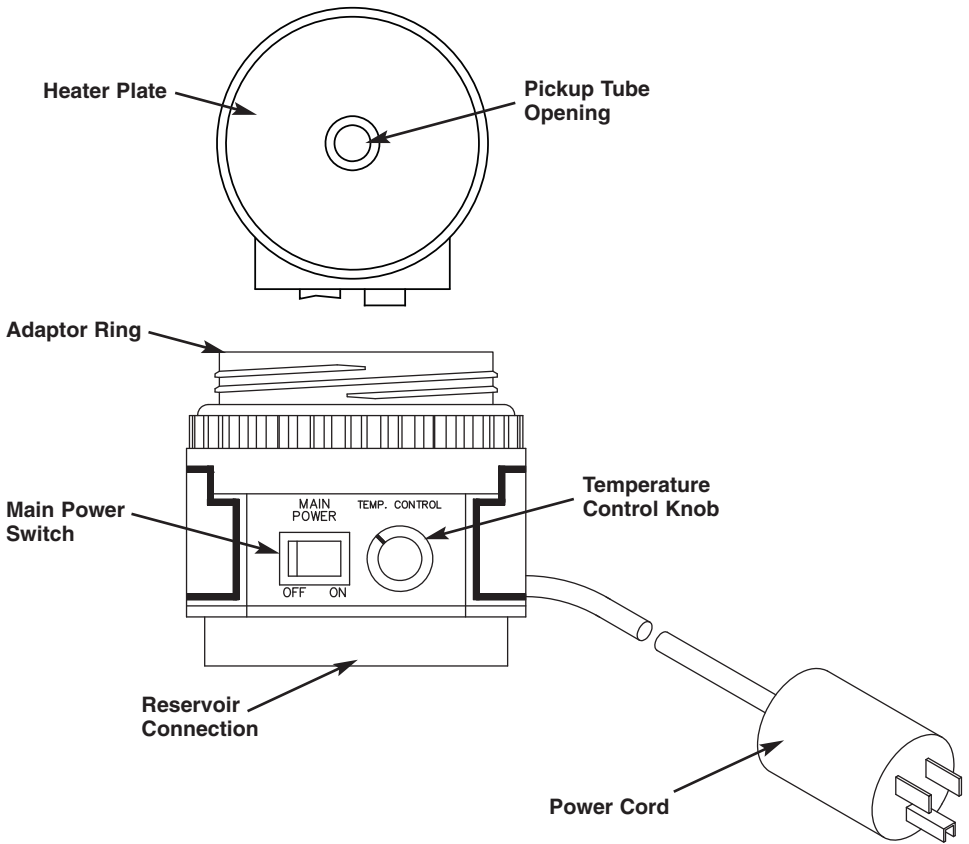


Figure 1: ThermaGard Heater, Top and Front Views

Main power switch—Illuminates when heater is turned on.

Temperature control knob—Push-to-turn knob allows adjustment of the temperature output of the heater.

Power cord—Three-conductor cable with a hospital-grade plug.

Reservoir connection—Mates with the nebulizer jar.

Adaptor ring—Allows the lid of the Teleflex Medical REF: 1770 to attach to the heater.

Heater plate—Heats to 135 °C to warm aerosol produced by the nebulizer.

Warning: Burn Hazard. Internal components are hot and may contain liquid at temperatures up to 100 °C. Allow the heater to cool before handling.

Pickup tube opening—Allows the nebulizer pickup tube to pass through the heater and into the jar.

Directions For Use

Installing the Heater

NOTE: Thoroughly clean the heater prior to use.


1. Check the heater to be sure that all surfaces are clean and intact.
2. Turn the main power switch to OFF.
3. Turn the temperature control knob fully counterclockwise (cold).
4. Attach a clean, unused REF: 1770 Large Volume Nebulizer lid to the threaded adaptor ring on the top of the heater. Feed the nebulizer pickup tube through the opening in the center of the heater plate.
5. Fill the nebulizer jar with sterile water. Attach the jar securely to the bottom of the heater.

➔➔ **Caution:** Always operate the ThermoGard heater in a vertical position for best performance.

6. Connect the nebulizer to an oxygen source and set the oxygen source to the desired flow. Adjust the nebulizer for the desired oxygen concentration as stated in the instructions supplied with the nebulizer.
7. Plug the heater power cord into a hospital-grade outlet. Turn the heater main power switch ON.
8. Push and turn the temperature control knob clockwise to the desired setting. For all flow/entrainment settings, it is recommended to start midway on dial rotation, with the knob indicator straight up.
9. Allow approximately 25 minutes for the outlet temperature to stabilize. Adjust the temperature in small increments and allow approximately 20 minutes between adjustments for the outlet temperature to stabilize.

 **Warning:** Always verify aerosol temperature before connecting to the patient.

 **Warning:** Always verify oxygen concentration before connecting to the patient.

 **Warning:** Using an aerosol delivery tube less than 180 cm (6 ft.) in length may result in aerosol delivery exceeding 41 °C at the patient connection.

10. Connect aerosol tubing between the nebulizer outlet and the patient.

To Refill the Nebulizer


1. Turn the heater OFF and shut off the oxygen supply. There is no need to alter the temperature control knob unless a setting change is desired.

➔➔ **Caution:** Do not operate the ThermaGard heater with a dry nebulizer, nor leave the heater operating during refilling.

2. Carefully remove the nebulizer jar from the heater and gently tap the heater to catch any condensate in the reservoir.

 **Warning: Burn Hazard.** Internal components are hot (135 °C) and may contain liquid at temperatures up to 100 °C.

3. Fill the nebulizer jar with sterile water.

 **Warning:** Never fill the nebulizer jar with water hotter than 37 °C as this may pose a patient hazard.

4. Thread the nebulizer jar securely to the heater.

5. Turn the heater ON and open the oxygen source.

Cleaning & Maintenance

To Clean and Disinfect the Heater

1. Turn the heater OFF, unplug the power cord and allow the system to cool for at least 10 minutes.

 **Warning: Burn Hazard.** Internal components are hot (135 °C) and may contain liquid at temperatures up to 100 °C. Allow the Heater to cool before handling.

2. Remove and discard the used nebulizer lid and jar. NOTE: Do not discard the adaptor ring and O-ring seal; these parts are intended to be cleaned and reused.

3. Remove the adaptor ring and O-ring seal. Inspect and replace the seal if any damage, wear or cracking is evident.

4. Clean the heater with a mild detergent and a damp cloth, or spray or wipe the heater with a cold sterilization solution such as Cidex or Sporocidin. Rinse the heater thoroughly and dry completely.

NOTE: The adaptor ring and O-ring seal may be immersed in liquid, but do not immerse the heater.


➔➔ **Caution:** Do not autoclave, gas sterilize, pasteurize or immerse this device in any liquid. Severe equipment damage will result.

5. After cleaning, reassemble the adaptor ring and O-ring seal.

Troubleshooting

Symptom	Cause	Action
Heater leaks water	Poor seal between the heater body and adaptor ring.	<ol style="list-style-type: none"> 1. Tighten adaptor ring. 2. Inspect adaptor ring and O-ring seal for damage. Replace as needed.
Aerosol temperature cold	<ol style="list-style-type: none"> 1. Loose, broken or disconnected wire. 2. Defective power switch. 3. Main power fuse(s) open. 4. Thermal fuse open. 5. Defective thermistor circuit. 6. Defective heating element. 7. Defective circuit board. 	<ol style="list-style-type: none"> 1. Repair or replace wire. 2. Replace switch. 3. Replace fuse(s). Investigate cause for fuse failure. 4. Replace heater body assembly. 5. Replace heater body assembly. 6. Replace heater body assembly. 7. Replace circuit board.
Aerosol temperature will not adjust	<ol style="list-style-type: none"> 1. Loose adjustment knob. 2. Loose, broken or disconnected wire. 3. Defective control potentiometer. 	<ol style="list-style-type: none"> 1. Tighten or replace adjustment knob. 2. Repair or replace wire. 3. Replace potentiometer.
Maximum aerosol temperature too high or too low	<ol style="list-style-type: none"> 1. Ambient conditions, including room temperature and supply voltage, not optimum. 2. Heater out of calibration. 3. Defective thermistor circuit. 4. Defective heater body assembly. 	<ol style="list-style-type: none"> 1. Retest heater under proper conditions. 2. Calibrate heater. 3. Replace heater body assembly. 4. Replace heater body assembly.

 **Warning: Burn Hazard.** Internal components are hot (135 °C) and may contain liquid at temperatures up to 100 °C. Allow the Heater to cool before handling.

 **Warning: Electrical Shock Hazard.** Service should be performed by qualified personnel experienced in the repair of medical electronic equipment.

Equipment Required

- ¾ in. socket
- Volt/ohm meter (VOM)
- Thermocouple and thermal instrument capable of 150 °C
- Screwdriver
- Soldering iron
- Silicone sealant (RTV)

Disassembly

NOTE: Also see Exploded Assembly View (*Fig. 2*) and Wiring Diagram (*Fig. 3*) included in this manual.

1. Remove and discard the used REF: 1770 Nebulizer lid and jar. Thoroughly dry the heater.
2. Inspect the heater for damage or wear.
3. Using a ¾ in. socket, remove the nut from the bottom of the heater and lift off the heater body cover.
- ➔ **Caution:** Do not loosen or remove the internal ¾ in. nut securing the backing plate and platen assembly or the water tight seal will be lost. This area of the heater is not field-serviceable.
4. Separate the power cord from the circuit board terminal block. It is not necessary to loosen or remove the strain relief from the cable.
5. Check all wiring for wear and loose, broken or disconnected terminals.
NOTE: Internal wiring utilizes PTFE insulation with a temperature rating of 200 °C.
6. The power switch may be removed and replaced without further disassembly. Compress the locking tabs on each end of the switch and press it out of the heater body. When reassembling, orient the rocker switch to match the ON/OFF designations on the front panel.
7. The temperature control potentiometer may also be replaced without further disassembly. Orient the alignment tab and center the adjustment knob when installing.
8. Separate the circuit board from the heater body by removing the two mounting nuts, unsoldering black wire T3 and disconnecting yellow wires P3 and P4.
9. No further disassembly of the heater body is required. Replace the heater body if it is defective.

Inspection

Circuit board: Inspect the circuit board for damage or defects. Do not alter any adjustments; otherwise, recalibration will be required. Fuse replacement and calibration are the only field-serviceable operations on the board. Replace the fuses only with those with the identical type and rate. NOTE: A thorough investigation should be conducted to determine the cause of any fuse failure.

Heater body assembly: If the heater body assembly is suspect, check the thermistor circuit and the heater element as follows:

Thermistor circuit: Measure the resistance across the two yellow wires connecting P3 and P4. Resistance should be 180-200 K ohms with the heater in an ambient temperature of approximately 24 °C. Replace the heater body assembly if out of this range.

Heater element: Measure the resistance across the heater element (black and red wires). Resistance should be 65 ± 8 ohms. If resistance is infinite, the thermal fuse is probably open. Replace the heater body assembly if the resistance is out of range or if the thermal fuse is open.

NOTE: Following any repair, calibrate the heater as needed and perform the test described in this manual before returning the heater to service.

Calibration

Whenever a circuit board or heater body assembly is replaced, or if the calibration is suspect, the heater should be recalibrated. NOTE: Each circuit board must be calibrated with the particular heater body to which it will be assembled.

1. Turn the temperature control knob to minimum (fully counterclockwise).
2. Turn the trim potentiometer on the circuit board fully clockwise.
3. Apply temperature conductive paste to the tip of the thermocouple and place the thermocouple onto the surface of the heater plate, approximately opposite the "burn hazard" warning imprinted on the plate.
4. Plug the heater in, turn it ON and allow the temperature to stabilize. The reading should be between 40 °C and 60 °C.
5. Turn the temperature control knob to maximum (fully clockwise) and monitor the temperature. The reading should stabilize between 60 °C and 80 °C.
6. Slowly turn the trim potentiometer on the circuit board counterclockwise in quarter-turn increments and allow the temperature to stabilize.
7. Following each adjustment, the temperature will cycle up and down about 5 °C after it stabilizes. Continue to adjust the circuit board trim potentiometer counterclockwise until the peak temperature during the cycle is between 101 °C and 103 °C.
8. To check calibration, move the thermocouple to a point on the heater plate 90° from the original test point. Record the peak temperature from three consecutive cycles; the average should be between 101 °C and 103 °C. If not, readjust the circuit board trim potentiometer and recheck.

9. Following recalibration, test the unit as described below before returning the heater to service.

NOTE: Calibration is intended to provide a maximum heater output of 39 ± 2 °C under test conditions.

10. Reassemble the ThermaGard heater in reverse order of disassembly. Apply silicone sealant (RTV) beneath the body nut (*Item 12, page 11*) so a seal is formed between the threaded shaft, body nut and heater body cover (*Item 13, page 11*).

Testing

NOTE: Following any repair, perform the test described below.

1. Fill a REF: 1770 Large Volume Nebulizer and install it to the heater as described in this manual.
2. Set the flow to 10 LPM and adjust the nebulizer to an oxygen concentration of 60%. Turn the heater ON and set the temperature control to maximum (fully clockwise).
3. Attach 180 cm (6 ft.) of aerosol tubing to the nebulizer outlet and place a temperature indicating device at the distal end.
4. Allow the system to operate for 60 minutes or until the temperature stabilizes. The temperature at the distal end should be 39 ± 2 °C.
5. Check the connection at the adaptor and heater body for water leakage.

Refer questions to: Teleflex Medical

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Assembly View

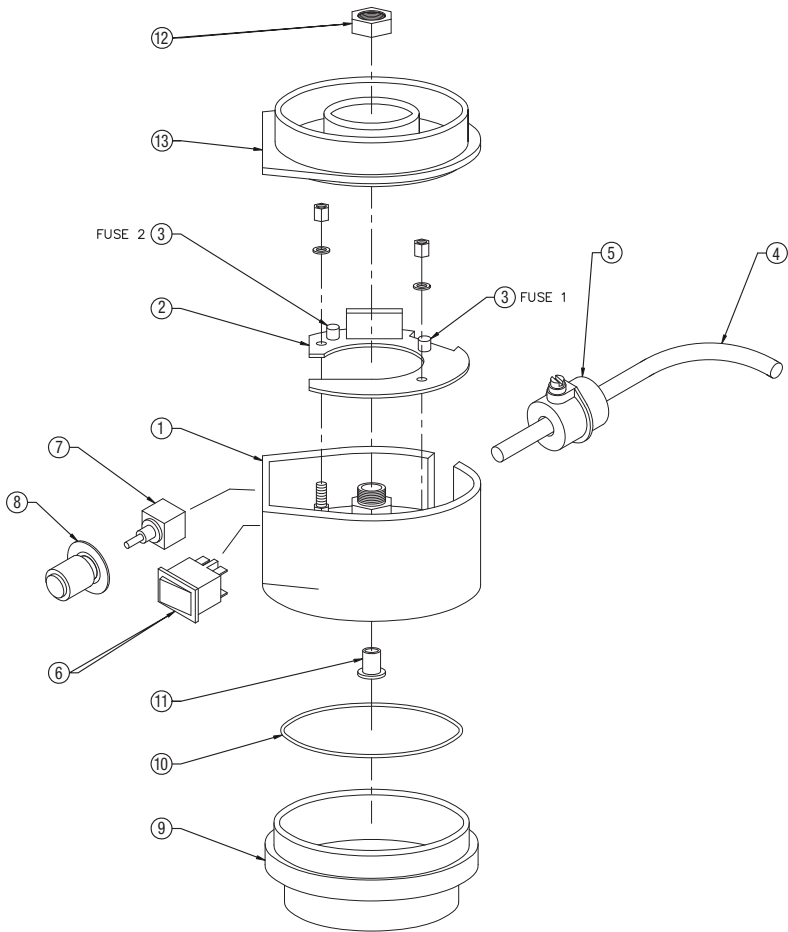


Figure 2: Exploded Assembly View

Parts List

① Heater Body Assembly	57010	⑦ Temperature Control Potentiometer	57016
② Circuit Board Assembly	57011	⑧ Temperature Control Knob	57017
③ Power Fuse (2 required)	57012	⑨ Adaptor Ring	57018
④ Power Cord	57013	⑩ O-ring Seal	57019
⑤ Strain Relief	57014	⑪ Pickup Tube Insulator	57020
⑥ Power Switch	57015	⑫ Body Nut	57021
		⑬ Heater Body Cover	57022

Wiring Diagram

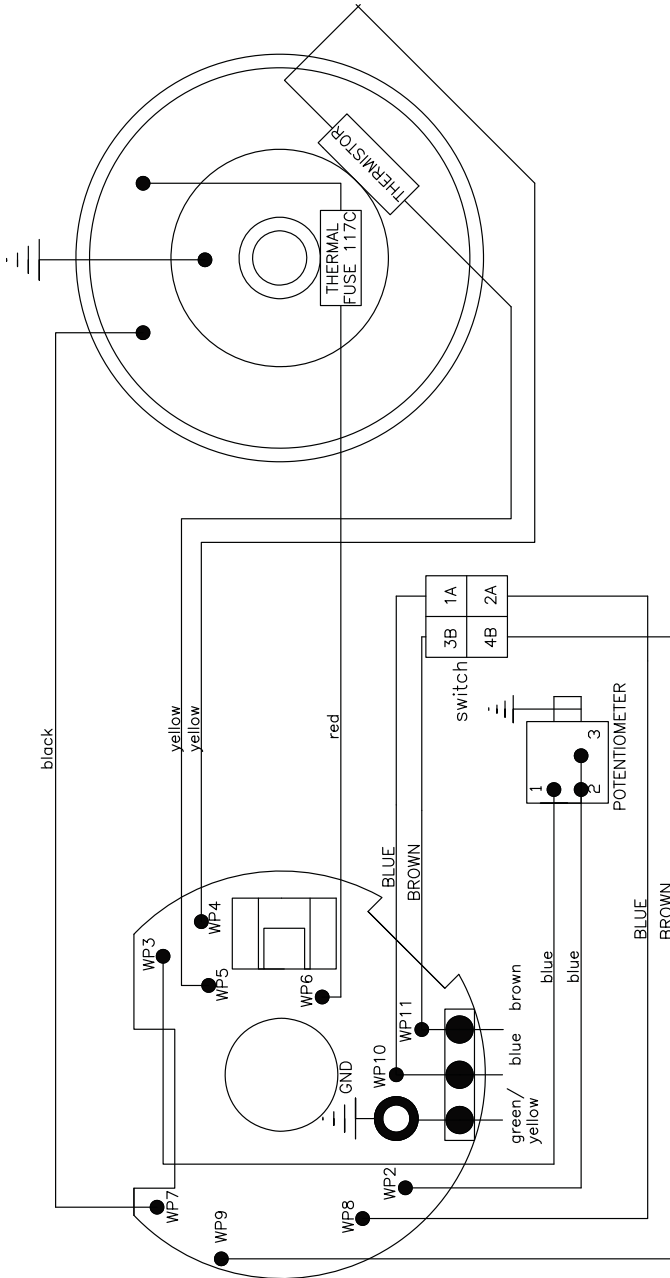


Figure 3: Wiring Diagram

Warranty

The ThermoGard Nebulizer Heater is warranted by Teleflex Medical Incorporated, hereafter called Teleflex Medical, 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 repair or, at our option, replace at no charge any heater that proves to be defective, provided you return the device, shipping prepaid, to Teleflex Medical. 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 Teleflex Medical.

No other express warranty is given. The repair or replacement of the device is your exclusive remedy. **ANY OTHER IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS IS LIMITED TO THE ONE-YEAR DURATION OF THIS WRITTEN WARRANTY.** Some states, provinces or countries do not allow limitations on how long an implied warranty lasts, so the above limitation may not apply to you. **IN NO EVENT SHALL TELEFLEX MEDICAL BE LIABLE FOR CONSEQUENTIAL DAMAGES.** Some states, provinces or countries do not allow the exclusion or limitation of incidental or consequential damages, so the above limitation may not apply to you.

This warranty gives you specific legal rights; and you may also have other rights which vary from state to state, province to province or country to country.

This device is sold on the basis of specifications applicable at the time of manufacture. Teleflex Medical shall have no obligation to modify or update this device once sold.

If you have questions concerning this warranty, please contact an authorized Teleflex Medical distributor or Teleflex Medical Incorporated.

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