HUDSON RCI®

NEPTUNE

Powered by ConchaTherm Technology

ConchaTherm® Neptune™ Heated Humidifier
User's Manual

CE 0120 **Rx Only**

Teleflex MEDICAL

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English (EN)

REF NO.	DESCRIPTION
425-00	ConchaTherm Neptune Heated Humidifier
425-10	ConchaTherm Neptune Heated Humidifier - EMEA
425-20*	ConchaTherm Neptune Heated Humidifier – ACLA*
425-30	ConchaTherm Neptune Heated Humidifier - UK
425-40	ConchaTherm Neptune Heated Humidifier - Japan
425-90	ConchaTherm Neptune Power Cord: Australia
425-91	ConchaTherm Neptune Power Cord: Europe, Brazil, South Korea, Chile
425-92	ConchaTherm Neptune Power Cord: US, Mexico, Canada, Brazil
425-93	ConchaTherm Neptune Power Cord: India
425-94	ConchaTherm Neptune Power Cord: Japan, Taiwan
425-95	ConchaTherm Neptune Power Cord: China
425-96	ConchaTherm Neptune Power Cord: Argentina
395-90	ConchaTherm Neptune Temperature Probe, Adult
395-99	ConchaTherm Neptune Temperature Probe, Pediatric
386-81	ConchaTherm Neptune Reservoir Bracket
Various	ConchaTherm Neptune Mounting Brackets

**Power cord not included. Order power cord separately.*

Table of Contents

1. Introduction

Intended Use

The ConchaTherm® Neptune™ (also referred to herein as 'humidifier') is a respiratory humidifier designed to heat and humidify respiratory gases delivered via endotracheal tubes, nasal cannula or face masks to adult, pediatric and infant/neonatal patients. This system may be used with either conventional (non-heated wire) breathing circuits or compatible (21-volt) Hudson RCI heated-wire circuits.

The ConchaTherm Neptune can be used with ventilators, continuous flow systems, oxygen diluters and blenders, adjustable nebulizer adapters for aerosol therapy, or non-flammable anesthesia gases to help maintain patient body temperature.

Product Features

- Automatic operation with factory defaults or previous use selections for mode, proximal airway temperature, temperature gradient and pause time, or fully adjustable, if desired.
- User selectable Supra- and Sub-Glottic airway modes
- May be used with heated-wire or non-heated wire circuits
- Automatic detection of adult, pediatric and infant heated-wire circuits
- Digital temperature display
- Heater-to-patient temperature gradient for control of condensation
- Enhanced temperature gradient to accommodate higher inlet gas temperatures
- Responsive membrane front panel
- Internationally accepted Graphic Icon Front Panel
- LED prompts and audio-visual alarms permit rapid detection and correction of problems
- Temperature tracking alarms at 2°C above or below the selected airway temperature.
- Low Airway tracking alarm not activated until system reaches Airway Set-Point (within 2°C)
- Fixed high-temperature alarm at 41.0°C
- Disconnected/dislodged probe indicators
- Heated-wire disconnect alarm when using heated-wire circuits
- User adjustable pause time from 5 to 60 minutes.
- Continuous self-diagnostic evaluation of hardware and software
- Low Humidity Advisory

Setup Diagrams

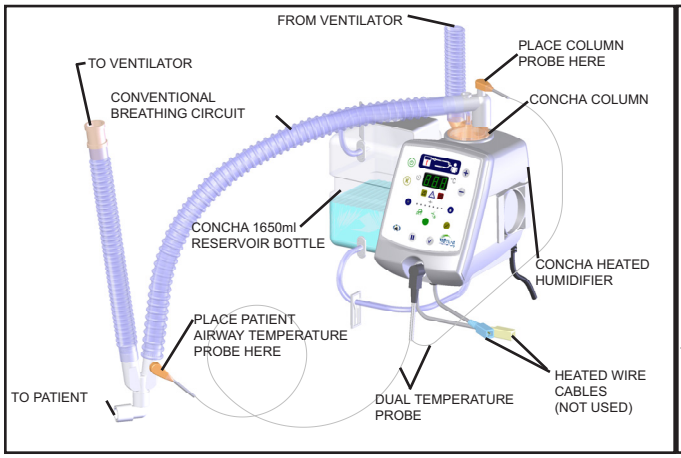


Figure 1: The CochaTherm Neptune Using a Conventional Circuit

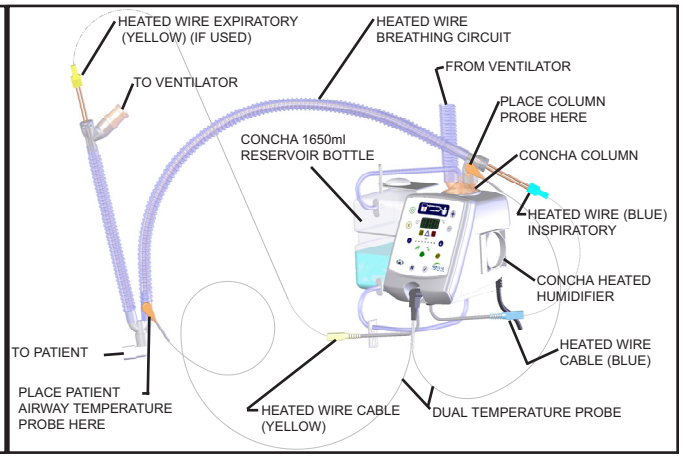


Figure 2: The CochaTherm Neptune Using a Heated-Wire Circuit

2. Symbols

The following symbols are noted on the device labeling. (See Controls and Indicators section of this manual for descriptions of Front Panel and other Icons used in this manual)

Symbol	Description
	Manfacturer Name and Address
	Do Not Dispose in Landfill, Return to Manufacturer for Recycling
 IPX1	DRIP-PROOF, a higher than ORDINARY level of protection from drips, leaks, and spills for Medical Devices.
	Type BF Device per IEC 60601-1 Patient current Leakage not to exceed 0.01mA for Applied Parts
	Caution, Hot Surfaces
	Refer to User's Manual
A	Amperes
Hz	Hertz
V~	Voltage, Alternating Current

3. General Warnings and Cautions

Warning: For safe operation, only use Hudson RCI Branded Concha Columns, Water Reservoirs, Temperature Probes and 21-Volt Heated Wire Circuits, as listed in the Hudson RCI Product Catalog.

Warning: Fire Hazard. Do not use the humidifier in the presence of flammable anesthetic gases.

Warning: Burn Hazard. The heating element of the humidifier is hot (as high as 140°C). Allow the humidifier to cool before handling.

Warning: Burn Hazard. The Concha-Column is hot (as high as 140°C) and may contain liquid at temperatures up to 80°C. Allow the column to cool before handling.

Warning: Electrical Shock Hazard. Refer all servicing to qualified, trained personnel only.

Warning: This humidifier requires 100-120V ~, (nominal) 60 Hz sine wave output. If used in a transport vehicle requiring an inverter, do not use square or pulse width modulated sine wave output. To do so may result in overheating.

Warning: The temperature probes must be properly placed in the breathing circuit before operating the humidifier. Failure to properly connect the temperature probes will cause the unit to alarm and shut down.

Warning: Always verify gas flow and airway temperature before connecting the humidifier to the patient.

Warning: Maintain adequate gas flow through the column and breathing circuit. This will prevent overheating the column and breathing circuit.

Warning: When using Hudson RCI Heated-Wire Circuits:

- Observe the minimum minute volumes recommended in this manual.
- Do not cover the circuit with sheets, blankets, towels, clothing or other materials.
- Do not apply excessive tension to the heated-wire harness - DO NOT "MILK" TUBING.
- Do not allow the circuit to rest on the patient's bare skin.

Warning: Always monitor tidal volume, minute volume, respiratory rate and all pressures and ensure that all monitoring alarms are appropriately set and functioning before connecting patient to the gas delivery system (ventilator, humidifier and circuit).

Warning: Do not leave the humidifier ON, do not turn the humidifier ON and do not exit the pause mode until there is regulated gas flow through the system. To do so may result in heat buildup, causing a bolus of hot air to be delivered to the patient. Circuit tubing may significantly soften under these conditions. Turn the humidifier OFF or place the unit in pause and allow the system to cool before stopping gas flow.

Warning: The probe alarm is not intended to replace routine physical inspection of the temperature probe placement. Be sure both probes are in place during operation of heater.

Warning: Do not use a Low-Compliance Concha-Column in continuous flow CPAP applications with gas flows greater than 50 LPM. There is potential for flooding of the breathing circuit and airway.

Warning: Only use the Comfort-Flo Concha-Column in continuous High Flow Oxygen applications. Do not exceed 40 LPM in this mode. There is potential for flooding of the breathing circuit and airway.

Warning: Sudden changes in circuit pressure may cause the water in the column to rise temporarily and may affect compressible volume.

Warning: Use of the RS-232 service connector by anyone other than qualified, factory-trained personnel may damage the instrument and result in harm to the patient. No connection to this port is to be made when device is operational and connected to a patient. Patient injury may occur.

Warning: The humidifier has been designed and tested for use with Hudson RCI Branded accessories and breathing circuits. Use of non-approved circuits or accessories with this unit may cause an unsafe condition. See the current issue of the Hudson RCI Catalog or go to the Hudson RCI Website at www.hudsonrci.com for compatible circuits and accessories validated for use with the CONCHATHERM Heated Humidifiers.

Warning: Electrical Short Hazard: Do not immerse this device in water or other fluids for cleaning. Do not autoclave, gas sterilize or pasteurize. Severe damage will result.

Warning: Only connect this device to a Hospital Grade Grounded 120 V ~ outlet, with the power cord supplied in the original packaging. This device has been developed to operate over the voltage ranges noted on the name plate label for use in foreign countries. If device is used in areas outside the United States, ensure a Hospital Grade, grounded compatible power cord is utilized. Please call Teleflex Medical's customer service to obtain Foreign Country power cord specification for your application.

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.

Caution: Always operate the humidifier in a vertical position with the water reservoir properly mounted.

Caution: Temperature patterns within the system associated with normal operation will be disrupted if there is insufficient water to pass through the system, causing a high temperature alarm.

Caution: Do not operate the humidifier with a dry or disconnected reservoir or without a column installed. Severe damage may result.

Caution: Hudson RCI Branded circuits and accessories are Single Patient Use only. With the exception of the Temperature Probes, they are not cleanable or re-useable. Accessories should be changed after a maximum of 14 days of use, or when noticeably contaminated by the patient or excessive leakage is observed.

Caution: Replace the power fuse only with one of the same rating.

Caution: Monitor the Inspiratory and Expiratory Circuits periodically for excessive condensation (rainout).

Caution: In the Invasive, or Sub-glottic Mode, the humidifier is designed to deliver a minimum fluid output of 30 mg H_2O/L at 30º C, for the proximal airway temperatures at zero gradient and with the recommended Flow Rates listed in the Specification Section of this manual.

- Use of Positive or "Sun" gradient settings in some conditions can result in humidity outputs at the patient of less than 30mg H_2O/L at 30º C.
- Visually inspect for condensation droplets in the inspiratory circuit after one hour of operation, and periodically thereafter.

Caution: Some Ventilators produce elevated gas temperatures at the patient inhalation port which can reduce the amount of relative humidity in the circuit. Visually inspect for condensation droplets in the inspiratory circuit after one hour of operation, and periodically thereafter.

Caution: Monitor the Inspiratory and Expiratory Circuits periodically for excessive condensation (rainout). Use water traps to collect rainout when using non-heated wire breathing circuits.

4. Principles of Operation

ConchaTherm Basics

The Concha® heated humidification system consists of:

- ConchaTherm Neptune heated humidifier
- Concha-Column® humidifier cartridge (also referred to as ‘column’)
- Concha sterile water reservoir
- ConchaTherm Neptune dual thermistor probe
- Hudson RCI Breathing circuit (non-heated wire breathing circuit or 21-volt heated-wire breathing circuit.)

The servo-controlled heated humidifier continuously monitors the proximal airway temperature and regulates the heat supplied to the column by the heating element, and if used, the heated-wire circuit.

The Concha-Column humidification cartridge is inserted into the heater where it is surrounded by a heating element. Sterile water flows via a gravity-feed system from the reservoir into the Concha-Column, wetting an internal absorbent wick. The heating element conducts heat through the column's metal wall, heating the wick and vaporizing the sterile water. Ventilatory gas passes through the column where it picks up the moisture in molecular form. The heated, humidified gas is delivered to the patient through a breathing circuit attached to the top of the column. Concha-Columns are available in four configurations: Standard, Low-Compliance, Minimal Compliance and Comfort-Flo. All columns are labeled for easy identification and operate on a reliable, gravity-feed system for uninterrupted water flow.

Concha-Column Description

The Standard Concha-Column (see Figure 1) is designed for use with ventilatory parameters most commonly used with adults. The water in the column will be at the same level as that in the reservoir. The water level in both the reservoir and the column drops as water is consumed. As the water level in the column drops, the compressible volume of the system increases and the system compliance changes.

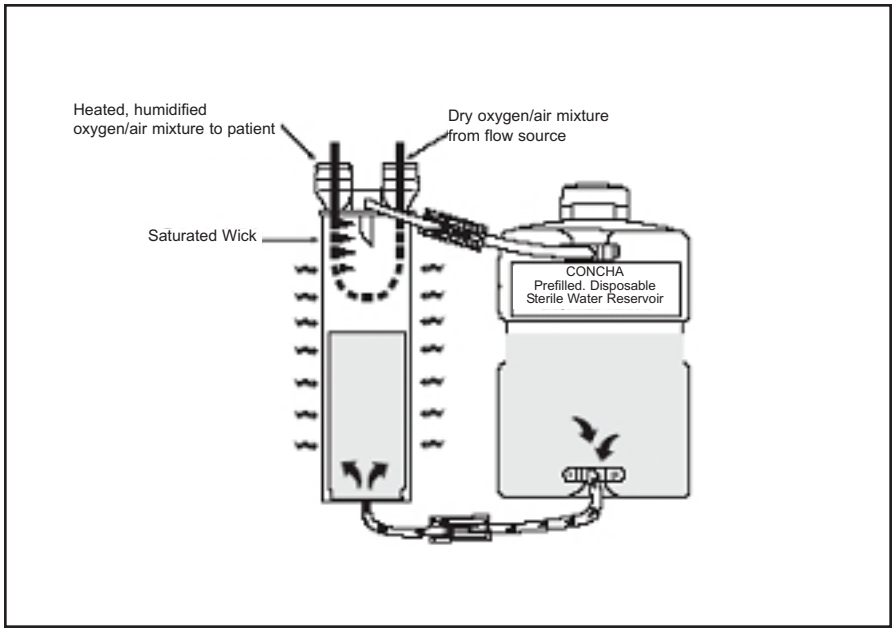


Figure 1: Standard CONCHA-COLUMN Flow Diagram

The Low-Compliance Concha-Column is recommended for applications requiring a more constant compressible volume and compliance, (see Figure 2). The Low-Compliance Concha-Column maintains a constant water level in the column resulting in a more stable compressible volume. The system's compliance equals the column's compliance plus the amount of fluid transferred to the reservoir during each inspiratory phase. Some fluid, in the form of either water vapor or water, always transfers during each cycle. In addition, because of the smaller mass of water contained inside the column, the Low-Compliance Column will heat and cool faster as compared to the Standard Concha-Column.

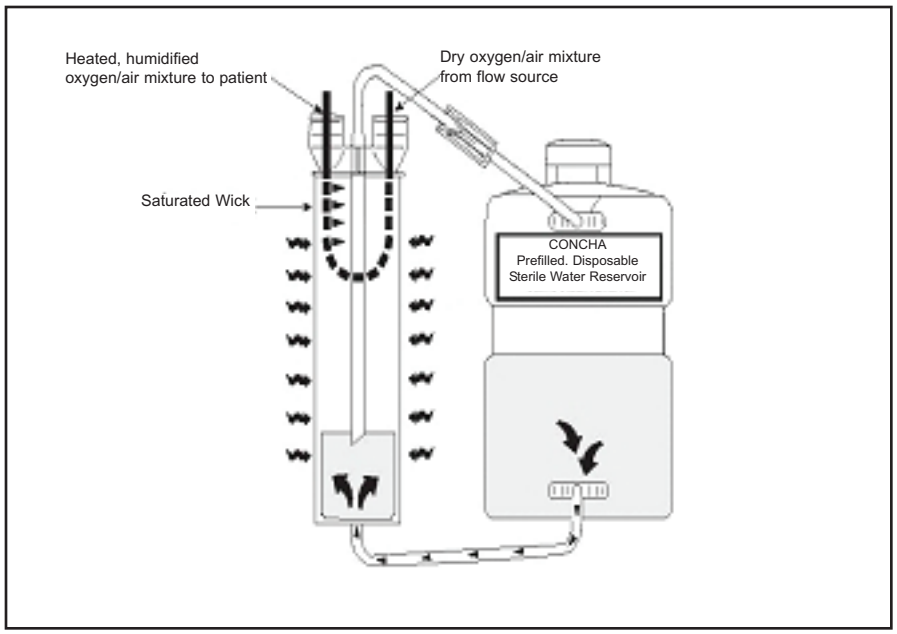


Figure 2: Low-Compliance CONCHA-COLUMN Flow Diagram

The Minimal-Compliance Concha-Column is recommended for applications requiring a low constant compressible volume and compliance,. This column maintains a constant compressible volume at 109 ml with compliance at 0.2 ml/cm H_2O. The Minimal-Compliance Concha-Column has an internal baffle and maintains a constant water level in the column resulting in a stable compressible volume. As with the Low-Compliance column, the system's compliance equals the Concha-Column's compliance plus the amount of fluid transferred to the reservoir during each inspiratory phase. Some fluid, in the form of either water vapor or water, always transfers during each cycle. This column will heat and cool slightly faster as compared to the Low-Compliance Concha-Column.

The Comfort Flo Concha-Column is for use with continuous high flow oxygen applications. This column is specially designed to maintain a constant water level in the column under high flow oxygen applications.

> **Caution:** The Comfort-Flo Column should be used exclusively with continuous high flow oxygen applications. Use of any other column during high flow oxygen applications may cause flooding of the circuit.
>
> **Note:** The amount of fluid transferred to the reservoir varies slightly depending on ventilator settings. Several factors increase the amount of fluid transfer: high peak pressure, lower breath rates, reduced water volume in reservoir, I/E ratios approaching 1:1.4, and square pressure waveforms.
>
> **Note:** The ConchaTherm Neptune requires the use of a dual temperature probe at all times.

5. Specifications

ConchaTherm Neptune Performance Characteristics:

Patient Airway Temperature Ranges (Adjustable):

Invasive Mode 	Heated-Wire Circuit: 32-39 ºC Non-heated Wire Circuit: 30-37 ºC
Non-Invasive Mode 	Heated-Wire Circuit: 30-37 ºC Non-Heated-Wire Circuit: 30-37 ºC

Temperature Display: Three-digit, seven-segment LED

High-Temperature Alarm Limit: 41.0°C typical

Tracking Alarm: ± 2.0°C of the selected airway temperature, after the set temperature has been reached.

Warm-up time: (Warm up is defined as patient temperature within 2°C of set point)

Heated-Wire	10 minutes
Non-Heated Wire	35 minutes

Recommended Flow Rates*:

Adult (22mm Circuits)	Heated-Wire Circuit	3 to 40 LPM
Adult (22mm Circuits)	Non-heated Wire Circuit	6 to 20 LPM
Pediatric (15mm Circuits)	Heated-Wire Circuit	1 to 40 LPM
Pediatric (15mm Circuits)	Non-heated-Wire Circuit	5 to 20 LPM
Infant/Neonatal (10mm Circuits)	Heated-Wire Circuit	1 to 20 LPM
Infant/Neonatal (10mm Circuits)	Non-heated Wire Circuit	3 to 20 LPM
Continuous Flow Oxygen:	Comfort-Flo System	1 to 40 LPM

**The Invasive Mode of the Concha Neptune was designed to provide 100% RH , as evidenced by moisture condensation, or "rainout" in the circuit at the recommended flow rates over the settable proximal airway temperature settings at zero gradient. In some cases, the use of positive gradient settings " ☀ " or flow rates outside the recommended ranges may result in increased warm-up times or lower than recommended humidity outputs. Additionally, some environmental conditions, such as warm ventilator outlet gas temperatures and/or high ambient temperatures, may require the use of the negative gradient setting " 💧 " to reach 100% RH, or visible moisture droplets in the circuit.*

Humidity Output:

Invasive Mode > 33 mg H_2O/L at 32º C proximal airway temperatures when set at zero gradient at the recommended Flow Rates listed above.

- Use of Positive or "Sun" gradient settings in some conditions can result in humidity outputs at the patient of less than 33mg H_2O/L at 32º C. Visually inspect for condensation droplets in the inspiratory circuit after one hour of operation, and periodically thereafter.

Non-Invasive Mode > 10 mg/L at 32º C proximal airway temperatures when set at zero gradient at the recommended Flow Rates listed above.

- This mode should only be used when the patient airways ARE NOT bypassed.

Concha-Column Performance Characteristics

Water Capacity:

Standard	193 ± 10 ml with full reservoir
Low Compliance	40 ± 5 ml
Comfort-Flo Low-Compliance:	40 ± 5 ml
Minimal Compliance column:	40 ± 5 ml

Column Compliance:

Standard:	1.12 ml/cm H_2O with full reservoir
	2.51 ml/cm H_2O with reservoir at “replace” mark
Low-Compliance:	0.25 ml/cm H_2O
Comfort-Flo Low-Compliance:	0.25 ml/cm H_2O
Minimal Compliance:	0.2 ml/cm H_2O

Column Compressible Volume:

Standard:	103 ml with full reservoir
	268 ml with reservoir at “replace” mark
Low-Compliance:	248 ml ± 12 ml
Comfort-Flo Low-Compliance:	248 ml ± 12 ml
Minimal Compliance:	109 ml

Note: The amount of water in a Standard Concha-Column decreases as water is used, increasing the compressible volume as water is consumed.

General System Characteristics

Pressure Drop or Resistance to Flow:

System Circuits, Concha Column and Water Reservoir shall be in compliance to ISO 8835-2 for Pressure Drop (Resistance to Flow). See individual circuit “Instructions For Use” for Resistance to Flow data.

System Pressures:

The ConchaTherm circuits are designed to exceed the ISO/CD 5367 standard of 60 cm/H_2O (6 +/- 0.3 kPa), and are tested to perform at 90 cm/H_2O.

System Leakage:

System leakage (Circuit, Concha-Column and Water Reservoir) will have a combined leakage of less than 25 ml/minute at 60 cm/H_2O (6 +/- 0.3 kPa) per ISO 5367, Annex D.

Noise Levels:

The humidifier noise level under normal operation conditions shall be less than 50 dB measured 1 meter from the device, except while audible alarms are active.

Electrical Characteristics:

Input Voltage and Power:	100-120 V ~, 50-60 Hz, 2.6 A (MAX)
	200-240 V ~, 50-60 Hz, 1.9 A (MAX)
Leakage Current:	Less than 100 micro-amps
Dielectric Withstand:	1,250 volts minimum for one (1) minute
Temperature Control:	Dual thermistor
Power Fuses:	Two 4 amp, 5 x 20mm time delayed, 250 V ~
Thermal Fuse:	152 °C non-re-settable
	140 °C re-settable

Operating Environment Temperature:

Operating Temperature:	18 to 29 °C (68 to 85°C)

Note: Operating the humidifier at the extremes of the operating temperature may affect the temperature output of the device and/or cause nuisance alarms. The humidifier works ideally at a room temperature of 22 to 26 °C (72 to 79 °F).

Physical Characteristics:

Size:	17.3 cm (H*) x 14.0 cm (W) x 20.6 cm (D) 6.8” (H*) x 5.5” (W) x 8.1” (D)
Weight:	2.8 pounds/1.3 Kg (approximate)

Note: Allow 33 cm (13”) total height allowance for column installation

Transportation and Storage:

Temperature:	-20 to +50 °C (-4 to +122 °F)
Relative Humidity:	95% max (non-condensing, Transportation) 85% max (non-condensing, Storage)

Electromagnetic Compatibility (EMC):

This device meets the requirements of IEC and UL 60601-1 Standards for Medical Electrical Devices with respect to Electromagnetic Emissions and Compatibility. This device can be placed in close proximity to other Medical Devices approved to the same standards. Communication devices or other equipment emitting RF signals may cause erratic operation of this device. (See Tables, Appendix I)

Standards:

The ConchaTherm Neptune Heated Humidifier will be tested to and will comply with the following standards:

UL 60601-1,	Medical Electrical Equipment, Part 1: General Requirements for Safety
IEC 60601-1	Medical Electrical Equipment
ISO 8185	2nd Edition; Humidifiers for Medical Use – General Requirements or Humidification Systems

IEC 60601-1 Clause 5 Classifications:

- Class I
- Type BF
- IPX1
- Rated of Continuous Operations

6. Controls and Indicators

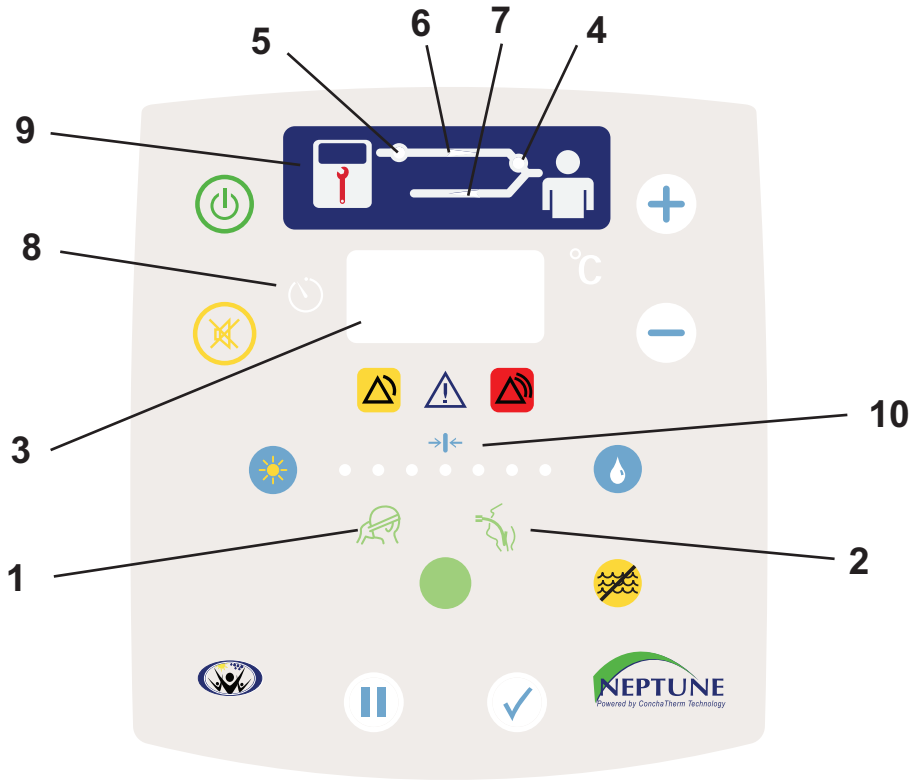


Figure 3: CONCHATHERM NEPTUNE Front Panel Indicators

Front Panel Indicators

1. **Non-Invasive Mode -** Icon illuminates when the humidifier is in the SUPRA-GLOTTIC or Non-Invasive Ventilation mode.

2. **Invasive Mode -** Icon illuminates when the humidifier is in the SUB-GLOTTIC or Invasive or Intubated mode.

3. **LED Display -** 37.0 °C Displays the temperature within tenths of a degree centigrade resolution. During normal operation, the LED displays actual proximal patient airway temperature. To display the column temperature, press and hold the column button. The column temperature will be displayed as long as the key is pressed.

4. **Airway Temperature -** Icon illuminates green during normal operation. This indicator flashes red when there is a temperature probe problem or an over temperature condition at the patient airway.

5. **Column Temperature -** Icon illuminates green when the column button is pressed and the column temperature is displayed on the temperature display LED. This indicator flashes red when there is a temperature probe problem or high temperature condition at the column.

6. **Inspiratory Wire Indicator -** Arrow icon illuminates green when the inspiratory wire of a heated-wire circuit is connected to the humidifier. This arrow will flash red when the inspiratory wire status has changed (connected or disconnected) during operation. This arrow will flash green if the status (connected/disconnected) is changed during “Confirmation of Settings or Set-up”.

7. **Expiratory Wire Indicator -** Arrow icon illuminates green when the expiratory wire of a heated-wire circuit is connected to the heater. This arrow will flash red when the expiratory wire status has changed (connected or disconnected) during operation. This arrow will flash green if the status (connected/disconnected) is changed during “Confirmation of Settings or Set-up”.

8. **Pause Indicator -** When the humidifier has been placed in pause mode, the icon will illuminate and the LED display will count down the remaining pause time.

9. **Service Indicator -** If the heater detects an internal problem during operation, the icon and the Emergency Alarm Indicator will flash and an audible alarm will sound. If this happens, turn the heater off and let it cool. If the condition persists, take the unit out of service and return to Teleflex Medical for servicing.

10. **Temperature Gradient Indicator -** Indicates the temperature gradient set point. Indicator is active when using a heated wire circuit and will be illuminated during “Set-up” and “Check Settings” modes.

STATUS INDICATORS

1. **GREEN -** Green icons indicate the device is functioning normally.

2. **YELLOW -** A Yellow flashing icon in conjunction with a low volume, 3-tone audio signal indicates a cautionary alarm condition (also see “Alarm Conditions” in the “Troubleshooting” section of this manual).

3. **RED -** A red flashing icon in conjunction with a high volume, 5-tone audio signal indicates an emergency alarm condition requiring immediate action by the clinician (see “Alarm Conditions” in the “Troubleshooting” section of this manual).

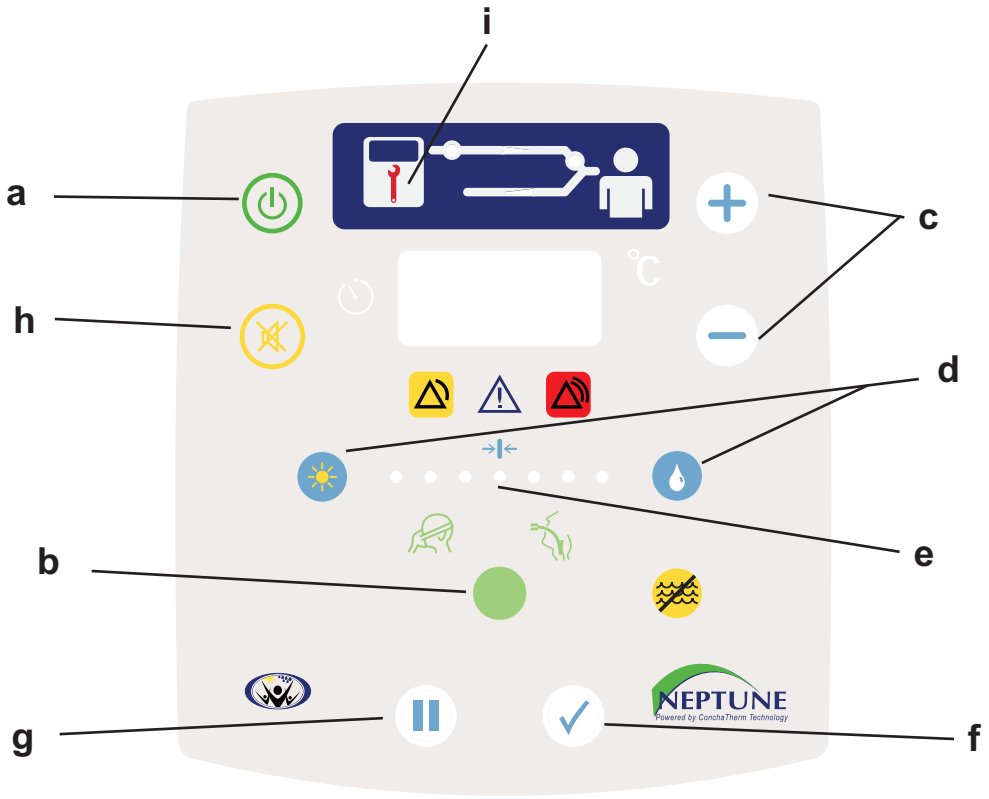


Figure 4: CONCHATHERM NEPTUNE Front Panel Controls

Front Panel Controls

a. **Power ON/OFF -** The button controls power to the humidifier. Press and hold to turn unit ON. Press and hold to turn unit OFF.

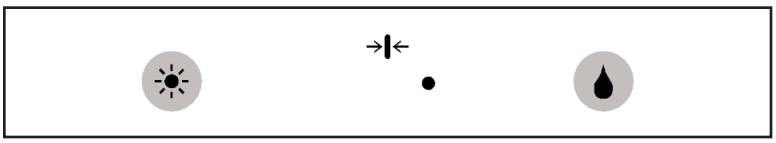
b. **Mode Selector -** This key selects the operating mode (Invasive or Non-Invasive).

c. **Temperature and Pause Time Control -** The Increase and Decrease Buttons allow the user to adjust the proximal patient airway temperature and pause time settings.

d. **Temperature Gradient -** Sun and Raindrop - These keys increase or decrease the temperature gradient between the column and the patient end of the heated-wire circuit.

e. **Gradient Display -** Blue LED between the Sun and Raindrop indicates the actual temperature gradient setting. The example below shows a setting of one degree towards the raindrop. This setting would increase humidity in the circuit.

Example:



f. **Accept Button -** Used to check settings, access adjustable settings and accept the displayed parameters and store settings into memory.

g. **Pause Button -** Used to enter the Pause Mode for a user adjustable period of 5-60 minutes.

h. **Alarm Mute Button -** Used to silence a Cautionary Alarm for two minutes.

i. **Column Button -** When pressed, the LED displays the temperature of the gas at the outlet of the column. The column temperature will remain displayed as long as the key is pressed.

7. Directions for Use

Read this entire section, including all warnings and cautions, before operating the ConchaTherm Neptune. See the “Applications” section for tips on using the ConchaTherm Neptune in specific clinical situations.

System Setup

1. Installation:
   Mount the humidifier to a pole, ventilator or rail system using the appropriate mounting bracket. Contact your Teleflex Medical representative for available mounting brackets. Mounting instructions are supplied with the bracket.

   Warning: Fire Hazard: Do not use humidifier in the presence of flammable anesthetic gases.

2. Connect the humidifier to power.
   - Connect the supplied hospital grade power cord to the rear of the unit.
   - Plug the humidifier into an appropriate 120 V ~ three-prong, grounded electrical outlet. Verify power at the outlet.

   Warning: This unit requires 120 V ~ (nominal) 60 Hz sine wave output. If used in a transport vehicle requiring an inverter, do not use square wave or pulse width modulated sine wave output. To do so may result in overheating.

3. Install the Concha-Column and Concha Water Reservoir.
   - Insert the column into the humidifier. Be sure that the tubing clamp(s) are closed.
   - Place the water reservoir into the reservoir holder.

4. Connect the ventilator circuit to the Concha-Column.
   - Remove the yellow cap from the top of the column.
   - Connect the humidifier line from the ventilator to one of the ports on the column.
   - Connect the inspiratory tubing elbow to the remaining port on the column.
   - Connect the expiratory tubing elbow to the expiratory port on the ventilator.

5. Connect the dual thermistor probe.
   - Insert the temperature probe plug into the jack at the lower front of the humidifier.
   - Place the short-cabled probe at the column outlet and the long-cabled probe into the inspiratory side of the patient wye.

   Warning: The temperature probes must be properly placed in the breathing circuit before operating the humidifier. Failure to properly connect the temperature probes may cause the unit to alarm and shut down.

6. Connect the heated-wire pigtails (not applicable when using conventional circuits).
   - Connect the inspiratory limb heated-wire (blue) pigtail to the blue heated-wire connector on the humidifier cable. Connect the expiratory limb heated-wire (yellow) pigtail to the yellow heated-wire connector on the humidifier cable.
   - Verify heated-wires are connected to the humidifier before turning the unit on.

   Note: The humidifier will automatically enter heated-wire operation when it senses the inspiratory heated-wire from a Hudson RCI circuit.

   Warning: If using a heated-wire circuit with this humidifier, use only Hudson RCI 21-volt-circuits.

Warning: When using Hudson RCI Heated-Wire Circuits:

- Observe the minimum minute volumes recommended in this manual.
- Do not cover the circuit with sheets, blankets, towels, clothing or other materials.
- Do not apply excessive tension to the heated-wire harness — DO NOT "MILK" TUBING.
- Do not allow the circuit to rest on the patient's bare skin.

7. Connect the water reservoir to the column.
   - Remove the cap from the column's bottom puncture pin. Push and twist the pin through the puncture site at the bottom of the reservoir. Insert the pin all the way. Repeat this procedure for the top puncture pin and puncture site.
   - Open the tubing clamp(s) and gently squeeze the reservoir bottle.

8. For next steps proceed to the Automatic Operation and/or User Adjustable Operation sections of this manual.

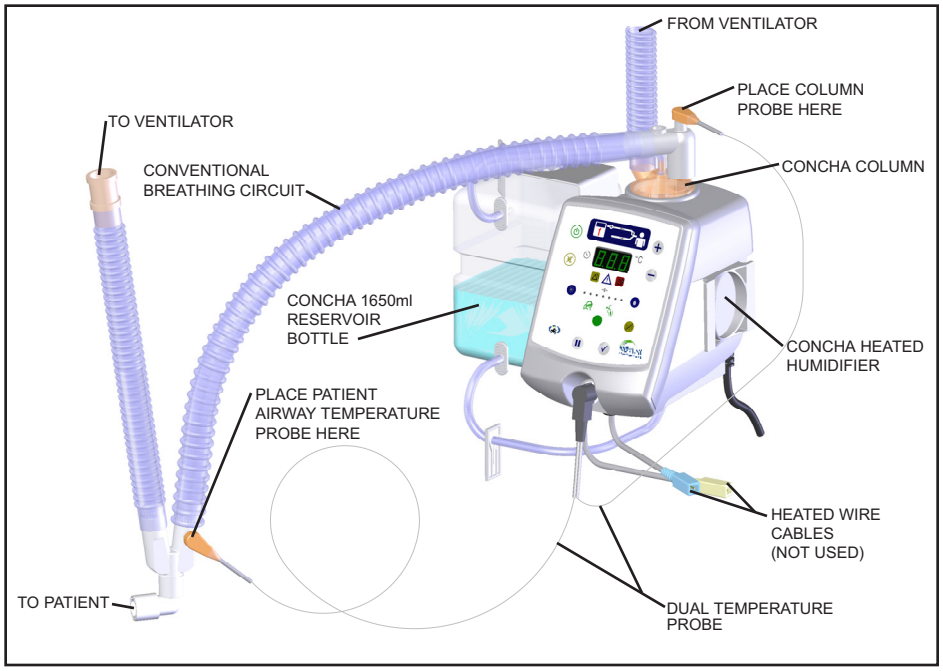


Figure 5: The COCHATHERM NEPTUNE System using a Non-Heated Wire (Conventional) Circuit

Automatic Operation

1. Set up and turn ON the ventilator or gas source (see the Ventilator Manufacturer Instructions for Use to determine ventilator operation and monitoring requirements).

   Warning: Always monitor tidal volume, minute volume, respiratory rate and all pressures and ensure that all monitoring alarms are appropriately set and functioning before connecting patient to the gas delivery system (ventilator, humidifier and circuit).

2. Turn the humidifier's power ON .

   Once activated, the humidifier will perform a self-check (a scrolling dash will be seen on the LED display). When the self-check is complete, the unit will issue an audible alert. This indicates the humidifier is ready for operation. At this point the user can choose to confirm or change the settings.

   Warning: If the heater detects a fault during the self-check, the icon will flash and an audible alarm will sound. If this happens, take the unit out of service and return to Teleflex Medical for servicing.

   Warning: Do not leave the humidifier on, do not turn the humidifier on and do not exit the pause mode until there is regulated gas flow through the system. To do so may result in heat buildup, causing a bolus of hot air to be delivered to the patient. Circuit tubing may significantly soften under these conditions. Turn the humidifier power switch OFF, or place the unit in pause and allow the system to cool before stopping gas flow.

   Warning: Always verify gas flow and airway temperature before connecting the humidifer to the patient.

   Note: The humidifier will not begin to heat until the settings have been confirmed.

   Note: The humidifier will automatically detect Hudson RCI adult, pediatric and neonatal heated-wire circuits.

   Note: Confirm the heated-wire icons illuminate green when the appropriate heated-wires are connected to the unit.

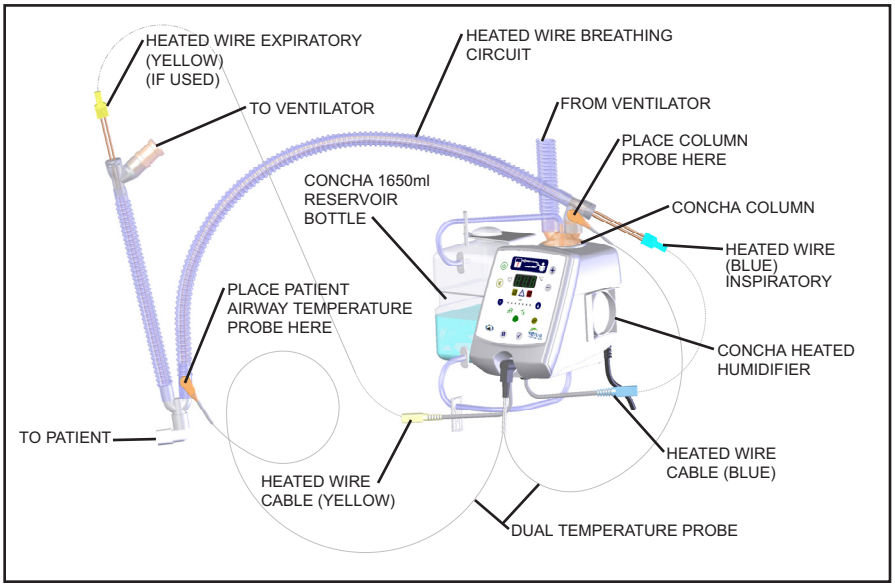


Figure 6: The CONCHATHERM NEPTUNE System Using a Heated-wire Circuit

3. Confirm Settings.

The accept button ✓ will flash and the humidifier will automatically display the stored settings for mode (invasive or non-invasive) and patient airway temperature. When using a heated-wire circuit, the heated-wire and temperature gradient indicators will illuminate. Patient airway temperature and temperature gradient will default to the last used values for the present configuration (mode and breathing circuit type). If the configuration has not been used previously, factory default settings will apply.

To begin operation using the displayed settings, press and release the accept ✓ button. The heater will begin warm-up and then normal operation.

Note: To adjust the displayed settings, see User Adjustable Operation.

Note: Power is not applied to the heater or heated-wires until the settings have been confirmed.

Note: If the user does not press the accept button to confirm these settings or press and hold the accept button to enter the User Adjustable Operation within 5 minutes, the unit will alarm. To clear this alarm, press the accept button ✓ .

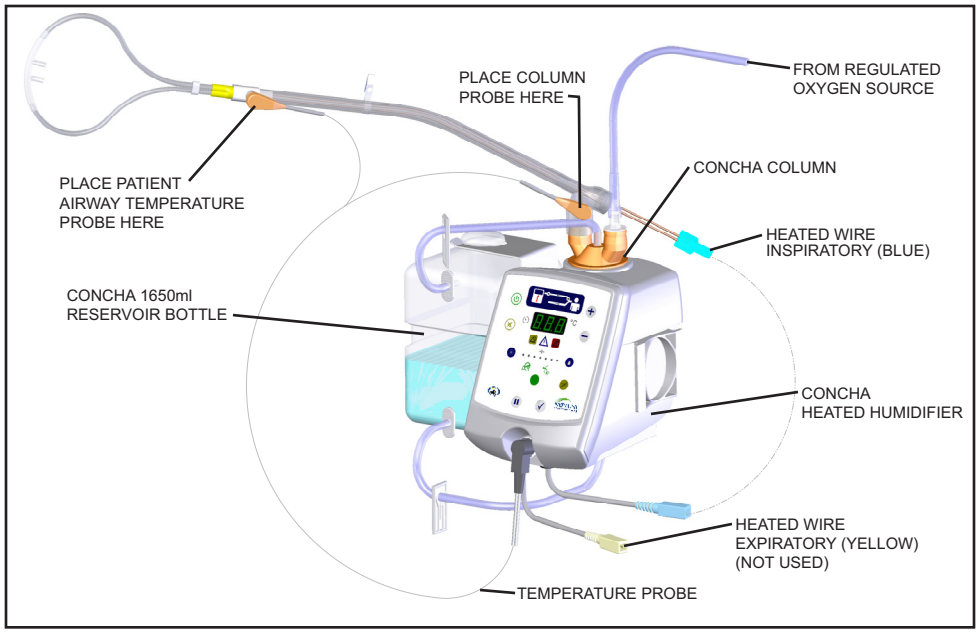


Figure 7: The CONCHATHERM NEPTUNE System for the Comfort-Flo Cannula

4. Warm-Up.

During warm-up, the °C will flash and the LED display will show the actual proximal patient airway temperature. Warm-Up ends when the patient airway temperature reaches within 2°C of the set airway temperature. Once warm-up is complete the °C will stop flashing.

Note: During warm-up, the low temperature alarm is deactivated.

Warm-up Time: 10 minutes (heated-wire circuits)
35 minutes (conventional circuits)

Note: Warm-up times consider that warm-up is achieved when the patient airway temperature is within 2°C of the patient airway set temperature.

5. Normal Operation.

After warm-up, the humidifier will convert to normal operation. Figure 8 shows a typical display for the ConchaTherm Neptune during normal operation.

Figure 8: CONCHATHERM NEPTUNE - Normal Operation Using a Dual Heated-Wire Circuit

Warning: Maintain adequate gas flow through the column and breathing circuit. This will prevent overheating the column and circuit.

Warning: Do not leave the humidifier on, do not turn the humidifier on and do not exit the pause mode until there is regulated gas flow through the system. To do so may result in heat buildup, causing a bolus of hot air to be delivered to the patient. Circuit tubing may significantly soften under these conditions.

6. Pause Mode

To facilitate activities such as circuit changes and nebulizer treatments, the ConchaTherm Neptune features a pause mode. During this period, humidifier settings are maintained and automatically re-activated when the designated pause time ends.

To activate the PAUSE Mode, press and hold the pause button . The timer icon will illuminate and the LED display will count down the remaining time in pause. The factory default pause time is 30 minutes.

During pause mode:

- Power to the heater is reduced and the power to heated-wires is turned off.
- The humidifier will not allow adjustment of the mode, airway temperature, temperature gradient or pause interval.

To exit PAUSE, press the flashing pause button or allow the pause time to expire. Both exit methods will return the humidifier to warm-up and normal operation.

Warning: Do not exit the pause mode until there is regulated gas flow through the system. To do so may result in heat buildup, causing a bolus of hot air to be delivered to the patient. Circuit tubing may significantly soften under these conditions.

7. Changing the breathing circuit.

When replacing the breathing circuit with the same type of breathing circuit (heated-wire being replaced with heated-wire), place the heater in pause mode before changing the circuit. If replacing the breathing circuit with a different type of breathing circuit (Infant/Adult or Heated-wire/Non-Heated wire), turn the humidifier OFF before changing the circuit. This will allow the heater to auto-detect the new circuit without alarming.

Note: The humidifier will give a heated-wire change alarm if PAUSE is exited and the heated-wire configuration has been changed.

Note: If the circuit type is changed the humidifier will revert to the remembered settings the last time that circuit was used.

Warning: Do not leave the humidifier ON, do not turn the humidifier ON and do not exit the pause mode until there is regulated gas flow through the system. To do so may result in heat buildup, causing a bolus of hot air to be delivered to the patient. Circuit tubing may significantly soften under these conditions. Turn the humidifier power switch OFF, or place the unit in pause and allow the system to cool before stopping gas flow.

8. Removing From Service.

To turn the humidifier OFF, press and hold the  button until the display goes blank. Allow the unit to cool before stopping gas flow.

Warning: If the humidifier detects an internal problem during operation, the service icon  and the Priority Alarm Indicator will flash and an audible alarm will sound. If this happens, turn the humidifier OFF and let it cool. If the condition persists, take the unit out of service and return to Teleflex Medical for servicing.

User Adjustable Operation

The ConchaTherm Neptune will arrive with the following factory default settings: invasive mode, patient airway temperature 37.0° C, temperature gradient 0° C, and pause interval 30 minutes. **All of these parameters may be adjusted by the clinician.**

To change the displayed settings, press and hold the accept button ✓. Once desired settings are entered, press the ✓ button to accept changes. The heater will begin Warm-Up and then normal operation.

While the heater is operating you can view the "set" parameters by pressing and releasing the accept button ✓. The humidifier will display the set mode, airway temperature, and the temperature gradient, if applicable, for 5 seconds.

Adjustable Parameters

1. Invasive or Non-Invasive Mode:

To change the patient airway mode, press and hold the ✓ accept button. The currently selected patient airway mode icon and the mode selector button will be illuminated.

To adjust the mode, press the mode selector button.

✓ **To accept the new mode**, press the accept button. The unit will return to warm-up and then normal operation. The selected mode will be retained in memory and the appropriate mode icon will remain illuminated during warm-up and normal operation.

Note: When the mode is changed, the humidifier will remember the last settings used with that mode and circuit type, or will default to factory settings if used for the first time.

2. Proximal Patient Airway Temperature.

To access the temperature for adjustment, press and hold the accept button ✓. The LED display will show the set Proximal Patient Airway Temperature and the increase ⊕ and decrease ⊖ buttons will be illuminated.

⊕ **To increase the airway temperature**, press the increase button once for each degree desired.

⊖ **To decrease the airway temperature**, press the decrease button once for each degree desired.

✓ **To accept the new temperature**, press the accept button. The unit will return to Warm-Up and normal operation.

Note: With each adjustment, allow adequate time for the humidifier to reach the selected temperature. This will vary and is dependent on flow rate, type and length of tubing, ventilating volume, respiratory rates and Concha-Column.

3. **Temperature Gradient** (only active if using heated-wire circuits)

When using the ConchaTherm Neptune with heated-wire circuits, the temperature gradient may be adjusted to allow for the proximal patient airway temperature to be up to 3.0 ºC warmer or cooler than the temperature at the column outlet. Adjustment of the temperature gradient allows for better control of condensation or “rainout” within the circuit. A positive temperature gradient results in an airway temperature that is warmer than the temperature of the gas at the column. A negative temperature gradient results in an airway temperature that is cooler than the temperature of the gas at the column. This column-to-patient temperature gradient is displayed as a blue LED when viewing the “set” parameters.

The ConchaTherm Neptune will arrive from the factory with the column-to-patient temperature gradient set at 0 ºC. A temperature gradient of 0 ºC allows the temperature of the gas, and therefore, the relative humidity (RH) of the gas, to be constant throughout the length of the heated-wire circuit. Figure 9 shows a typical circuit response and LED display when the airway temperature is set at 37 ºC and the temperature gradient is set at 0 ºC.

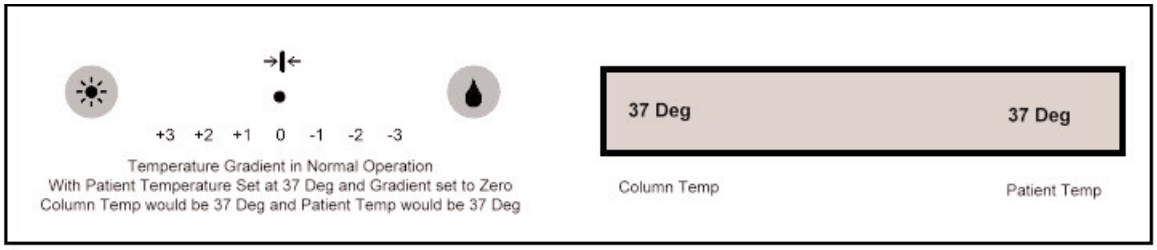


Figure 9: Zero Temperature Gradient, Display at 0°C.

- **To view the set temperature gradient**, quickly press and release the accept button. The temperature gradient the will be displayed for five seconds and will be represented by a the blue LED between the Sun and Raindrop.

- **To adjust the temperature qradient**, press and hold the accept button. The zero temperature gradient icon →|← , the blue temperature gradient LED, and the sun and rain icons will be illuminated.

- **To set a more positive temperature gradient**, press the sun button for each additional positive degree desired.

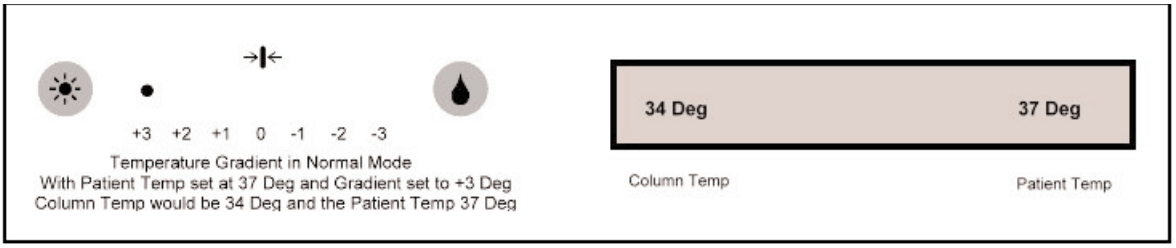


Figure 10: Positive Temperature Gradient, Display at +3.0°C.

Note: A positive or increased temperature gradient results in a lower relative humidity (↓RH) at the proximal patient airway and potentially less rainout in the circuit tubing.

Important: A positive temperature gradient may result in a humidity deficit to the patient, depending on the temperatures and ventilator parameters used.

To set a more negative temperature gradient, press the rain button for each additional negative degree desired.

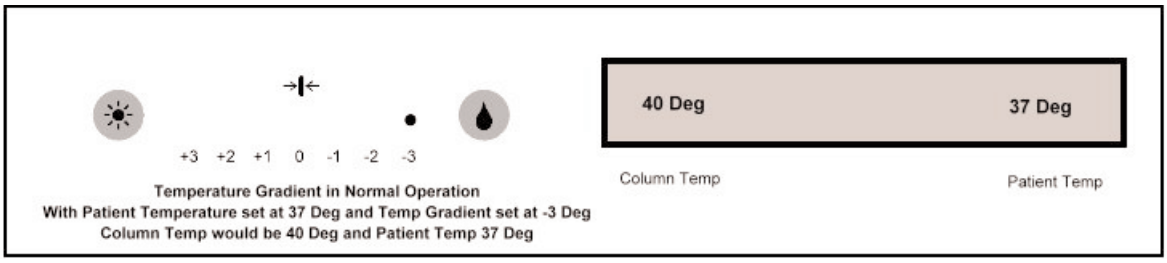


Figure 11: Negative Temperature Gradient, Display at -3.0°C.

Note: A negative or decreased temperature gradient results in a higher relative humidity (↑RH) at the proximal patient airway.

Note: A negative temperature gradient increases the potential for rainout within the heated-wire circuit.

Caution: The ConchaTherm Neptune is designed to deliver a minimum fluid output of 30 mg H_2O/L at 30º C, under normal operating conditions. (See recommended Flow Rates on Page 8). Use of positive or "sun" gradient settings in some conditions can result in humidity outputs at the patient of less than 30mg H_2O/L at 30º C. Visually inspect for condensation droplets in the inspiratory circuit after one hour of operation.

To accept the new temperature gradient settings, press the accept button. The unit will return to warm-up and normal operation. The temperature gradient selected will be retained in memory.

Note: During normal operation, the temperature gradient LED and buttons are not displayed.

4. Low Humidity Advisory:

The AARC Clinical Practice Guideline[1] for Humidification during Mechanical Ventilation states that the humidification method chosen should provide a minimum of 30 mg H_2O/L of delivered gas at 30 ºC. The ConchaTherm Neptune is designed to advise the user of low-humidity conditions (when the humidifier is in the Invasive mode and the set airway temperature and gradient result in a column temperature equal to or less than 31 ºC). The humidifier will advise the user of this condition by displaying a flashing proximal patient airway temperature in the “Set-Up” or “Confirm Settings” Mode. An audible alarm will not sound. In order to address this low humidity situation, the user should either increase the patient airway temperature or move the gradient closer to the Raindrop.
(See instructions in the User Adjustable Operation section.)

Note: Setting a positive gradient may invoke this advisory condition. For example, a selected airway temperature of 33 ºC and a Gradient setting of +3 ºC would result in a column temperature of 30 ºC causing the humidifier to invoke the low-humidity advisory.

Note: The Low Humidity Advisory function is not active in the Non-Invasive mode.

5. Pause Time

To view or adjust the set pause time, press and hold the accept button. The pause button will illuminate.

1 Branson, RD, Campbell SC, Chatburn RL, Covington J. AARC Clinical Practice Guideline: Humidification during Mechanical Ventilation. Respiratory Care 1992; 37:887-890.

Press the pause button. The set pause time will be shown on the LED Display and the increase and decrease buttons and the pause indicator icon will illuminate. The pause time can now be adjusted from 5 to 60 minutes, in 5-minute increments.

To increase the pause time, press the increase button once for each 5-minute increase desired.

To decrease the pause time, press the decrease button once for each 5-minute decrease desired.

To accept the new pause time, press the accept button. The unit will return to warm-up and normal operation.

6. High Output Mode: (Compensates for Hot Inlet Gas Temperature)

Some ventilators generate high internal temperatures during operation, therefore heating the gas that is delivered to the humidifier. A humidifier responds to this high incoming gas temperature by assuming that less heat is required. As a result less water vapor is created. To compensate for this situation, the ConchaTherm Neptune features a High Output Mode (see figure 12). This mode allows the humidifier to respond to high incoming gas temperatures by increasing the column-to-patient temperature gradient. By increasing this gradient, the column will generate more heat and therefore produce more water vapor.

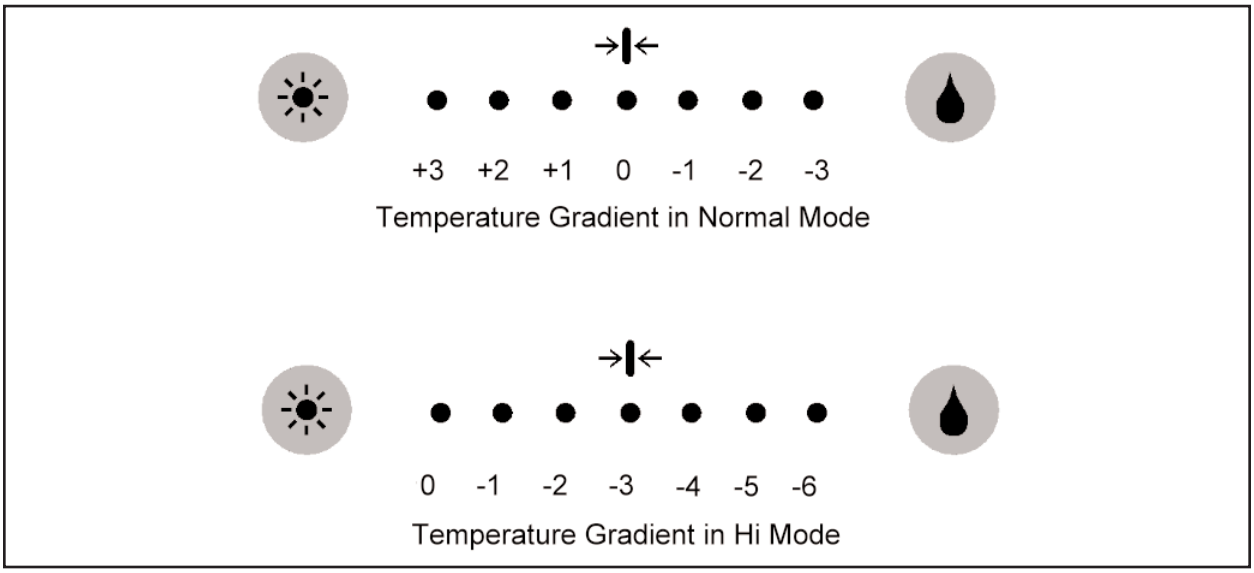


Figure 12: Normal and High Output Gradient Ranges

Caution: When using the High Output Mode to compensate for high inlet gas temperatures from the ventilator, visually inspect for condensation droplets in the inspiratory circuit after one hour of operation, and periodically thereafter to ensure adequate humidity to the patient.

To access and display the High Output mode, press and hold the **accept** button to enter the set-up mode,

& **To check the current gradient mode,** press the sun and rain buttons simultaneously. If normal gradient mode is active, the LED display will show three dashes (---). If High Output Mode is active, the LED display will read “HI.”

& **To change the gradient mode**, press and hold the sun and the rain buttons simultaneously for 3 seconds. The LED display will indicate the mode selected (--- for Normal and HI for High).

To set a positive temperature gradient, press the sun icon for each positive degree desired.

To set a negative temperature gradient, press the rain icon for each negative degree desired.

Note: Adjust the gradient until adequate humidity is visible in the breathing circuit.

To accept the Temperature Gradient selection, press the accept button. The humidifier will return to warm-up and normal operation. (See Figure 13 for examples of high gradient settings)

To check the Temperature Gradient Mode while the humidifier is operating, press the accept button:

→|← When High Output Mode is active, the gradient icon will flash.

→|← When normal temperature gradient is active, the gradient icon will be continuously illuminated.

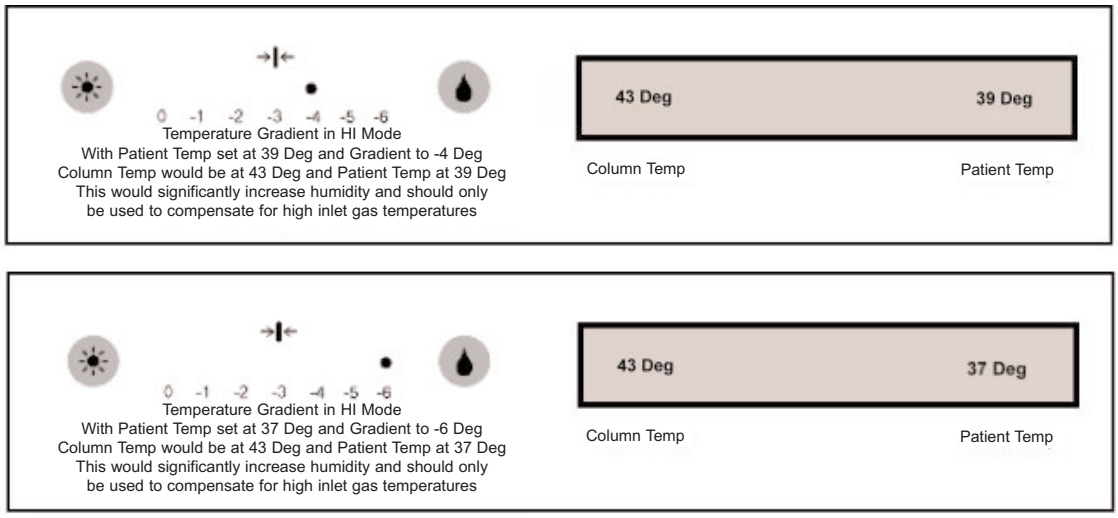


Figure 13: High Output Examples

Automatic Gradient Adjustment

The ConchaTherm Neptune is intended to heat and humidify respiratory gases at a proximal patient airway temperature selected by the clinician. In addition, the ConchaTherm Neptune will allow the use of heated-wire circuits to minimize the condensation or "rainout" within the circuit. Please note that certain environmental conditions will not allow the humidifier to maintain both the proximal patient airway temperature and the temperature gradient at the levels entered by the user. Under these conditions, the humidifier will automatically adjust the temperature gradient in order to maintain the proximal patient airway temperature within 2°C of the selected temperature. Once the environmental conditions allow, the humidifier will automatically return to utilizing the selected temperature gradient.

Note: In some conditions, the use of sun (or positive) gradient settings can result in humidity outputs at the patient of less than 33mg H_2O/L. Visually inspect for condensation droplets in the inspiratory circuit after one hour of operation.

Other Operating Features

Display Settings

During operation, the humidifier displays the mode, actual proximal patient airway temperature and the airway temperature and heated-wire icon(s), if applicable.

To display the airway temperature and temperature gradient settings, press and release the accept button. The humidifier will display the set parameters for 5 seconds (the temperature gradient settings are only applicable when using heated wire circuits).

Column Temperature

During operation, the humidifier displays actual proximal patient airway temperature. To display the temperature of the gas at the column, press the column button. The temperature probe LED will move to the column location and the column temperature will be displayed as long as the button is pressed. Once the key is released, the display will resume showing the actual patient airway temperature.

Alarm Mute

Press the alarm mute button to silence the cautionary audio alarm. The alarm will be silenced for approximately two minutes, or until the alarm deactivates. When muted, the alarm remains activated and the alarm mute and cautionary alarm icons are illuminated. The alarm will deactivate if the alarm condition self-corrects. Pressing the alarm mute button before the end of the mute period, or before the condition self-corrects, will reactivate the audible alarm.

Power Interruption

If the electrical power is interrupted while the unit is in operation the humidifier will restore the settings that were in effect prior to the interruption.

Incompatible Heated-Wire Circuits

The ConchaTherm Neptune was designed to detect incompatible heated-wire resistance. If an incompatible resistance heated-wire is detected, the heated-wire arrows will flash red, a priority alarm will be activated and the unit will not warm-up.

Warning: For safe operation, only use Hudson RCI labeled Concha Columns, Water Reservoirs, Temperature Probes and 21-Volt Heated Wire Circuits, as listed in the Hudson RCI Product Catalog.

8. Applications

The ConchaTherm Neptune heated humidification system is designed to heat and humidify respiratory gases delivered to adult, pediatric, and infant patients. The following information is offered regarding the use of the humidifier in specific applications.

The ConchaTherm Neptune has been tested to operate with ventilators designed to support neonatal, pediatric, and adult patients using commonly applied ventilation modalities. These ventilators may incorporate some or all of the following performance characteristics:

- Machine or patient cycled delivery of breath
- Control of pressure, volume, flow or time

Anesthesia

The ConchaTherm Neptune may be used with non-flammable anesthetic gases with either non-heated wire or heated-wire breathing circuits at the minimum recommended flows for adults and infants (see Specifications). As flow through the circuit nears the lower limits, the use of a heated-wire circuit and a Low-Compliance Concha-Column is recommended in order to maintain circuit temperature and avoid a tracking alarm. The humidifier is NOT RECOMMENDED in anesthesia applications requiring flows of less than those stated in the "Specifications". For additional information, see "Low-Flow Applications" later in this section.

Incubators and Warmers

When setting up the humidifier for use with a radiant warmer or incubator, place the proximal patient airway temperature probe away from lamps or other sources of heat so as not to affect the temperature reading.

Warning: Placing a temperature probe in an environment which is at or near the temperature of the gas, such as an incubator or radiant warmer, may mask a dislodged probe or cause the heater to shut off, thus reducing the humidity and temperature to the patient.

Low-Flow Applications

The ConchaTherm Neptune may be used with a heated-wire breathing circuit at the following minimum continuous flows:

- Adult: Heated-Wire Circuit - 3 LPM minimum
- Infant/Pediatric: Heated-Wire Circuit - 1 LPM minimum
- Continuous Flow Oxygen: Comfort Flo System - 1 LPM minimum

For example, with the humidifier in the adult mode, a volume of three liters of gas must pass the proximal patient airway temperature probe every minute while the unit is operating. In low-flow applications, the use of a Low-Compliance Concha-Column is recommended in order to maintain circuit temperature and avoid a tracking alarm. When using the humidifier in low-flow applications, the warm-up period may be longer due to the slower heat transfer through the breathing circuit.

For non-heated wire applications in low flow conditions, the following minimum flows must be observed to ensure maintenance of the patient airway temperatures. If lower flows are desired, please use a heated-wire breathing circuit:

- Adult: Non-Heated-Wire Circuit - 6 LPM minimum
- Pediatric: Non-Heated-Wire Circuit - 5 LPM minimum
- Neonatal Non Heated Wire Circuit – 3 LPM minimum

Transport Vehicles

Electromagnetic fields generated by communications and emergency equipment found on most medical transport vehicles may affect the performance of the humidifier. Furthermore, extreme environmental conditions may result in nuisance alarms or extended warm-up times. The interior temperature of the vehicle should be within the recommended operating environment temperature range. The user should confirm the performance of the humidifier in the particular transport vehicle prior to use.

Warning: This unit requires 120 V ~ (nominal) 60 Hz sine wave output. If used in a transport vehicle requiring an inverter, do not use square wave or pulse width modulated sine wave output. Overheating could result.

Warm or Cool Environments

Operating the humidifier in environments near the extremes of its operating environment temperature range may result in alarms as the unit attempts to control the airway temperature as it is affected by heat transfers along the circuit path.

The ConchaTherm Neptune works best at a room temperature of 22 to 26 °C (72 to 78 °F). Evaluate the circuit, circuit length, room temperature and other factors before placing the humidifier into service.

9. Troubleshooting and Maintenance

ALARMS

The ConchaTherm Neptune has two alarms conditions: priority and cautionary. Priority alarms are indicated by a red status light and an audible alarm. Clinician involvement is required to reset a priority alarm. To reset a priority alarm, turn the unit's power OFF, correct the alarm condition and turn the unit's power ON. Cautionary alarms are indicated by yellow status light and an audible alarm. The cautionary audible alarm can be silenced by pressing the alarm mute button. The alarm will deactivate if the alarm condition self-corrects.

PRIORITY ALARMS (Red Status Indicator Light and Audible Alarm)
Note: To reset a Priority Alarm, turn power OFF, correct the alarm condition and turn power ON.

A. HIGH TEMP:

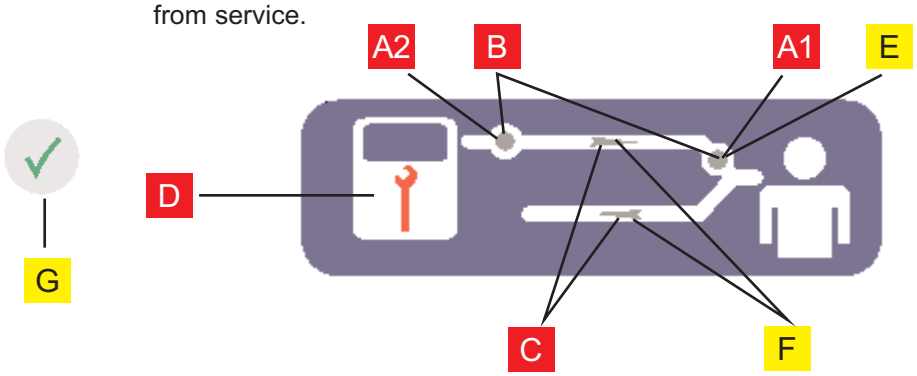
A1. Patient temp >43°C (Patient Temp Indicator Flashes Red):
- Airway temperature improperly set for ambient and ventilatory conditions. Reconfirm setings are appropriate for ventilation and ambient conditions.

A2. High temperature at column outlet (Column Temp Indicator Flashes Red):
- Low/no flow through column or reservoir, correct low/no flow condition.
- Low water level in column or reservoir, replace water reservoir and/or column.

B. CHECK PROBE (Patient and Column Temp Indicators Flash Red)
- Temp probe dislodged or disconnected from the ventilator circuit, insert probe securely into circuit.
- Temp probe not properly connected at the heater, properly connect probe.
- Temp probe/cable failure, replace temp probe.
- Low/no flow through column or reservoir, correct low/no flow condition.

C. HEATED-WIRE CIRCUIT (Heated Wire Indicators flash red)
- Inspiratory and/or expiratory wire is disconnected during warm-up period or normal operation.
- Breathing circuit may be incompatible or defective, replace the breathing circuit with a new compatible circuit.

D. SERVICE
- Unit failed self-diagnostic check. Turn power OFF, let the humidifier cool and turn the power back ON. If the condition persists, remove the unit from service.



CAUTIONARY ALARMS (Yellow Status Indicator Light and Audible Alarm):

Note: Press the alarm mute button to silence the Cautionary Audio Alarms for approximately two minutes. When muted, the alarm remains activated, and the ALARM MUTE button and Cautionary Alarm Icon are illuminated. The alarm will automatically reset if the alarm condition "self-corrects."

E. AIRWAY TEMP (Patient Temp Indicator Flashes Green):

- Airway temperature >41ºC, power is disconnected to humidifier and wires, power returns when temp falls back below 40.5ºC and alarm will deactivate, check temperature setting for ambient and/or ventilator conditions
- Patient Temp > +/- 2ºC from set point after warm-up is complete (°C stops flashing), check for proper usage for current ambient and ventilatory conditions.

F. HEATED-WIRE DISCONNECT (Heated-Wire Indicators Flash green)

- Heated-wire pigtail has been disconnected and not reconnected during setup or confirm settings. Reconnect pigtails and confirm green arrows are illuminated.

G. CONFIRM SETTINGS TIMEOUT (✓ Button Flashes):

- Finish confirming or changing settings, then press the accept button.

SYMPTOMS AND CORRECTIVE ACTIONS

Should the humidifier exhibit any of the symptoms listed below, perform the indicated corrective action before removing the unit from service.

Note: These conditions may not necessarily be accompanied by an alarm.

All displays on the unit are blank.

- Power cord not connected to power
  Connect cord to power outlet. Verify power outlet to outlet.

- Power not turned ON
  Press Power ON/OFF Button.

- Blown power fuse
  Replace power fuse located on back panel.

- Blown internal fuse
  Return the unit for service.

Unit not heating.

- Operator failed to accept current settings. Press the accept button.

- Internal malfunction, usually accompanied by a service alarm. Return the unit for service.

Proximal patient airway temperature will not set below 32 °C or above 39 °C in the Invasive mode or with Heated-Wire circuit in use.

- Settings outside the humidifier operating range, select a temperature within the operating range (see Specifications)

Proximal patient airway temperature will not set below 30 °C or above 37 °C in the Non-Invasive mode with a Non-Heated Wire circuit in use.

- Settings outside the humidifier operating range, select a temperature within the operating range (see Specifications)

Temperature probe not properly connected to humidifier.

- Turn unit off for 60 seconds. Properly connect the temperature probe to the humidifier and turn unit back on.

Unit displaying "Service" icon and alarm condition.

- Remove the humidifier from use.

Humidifier does not retain user defined settings.

- Program desired settings for proximal airway, gradient and pause time. Press accept ✓ button to return unit to warm-up and normal operation. If problem persists after reprogramming, return to factory for service.

Sudden power failure.

- Power button inadvertently pushed, causing loss of power, or power cord inadvertently removed from humidifier.

- Replace cord if necessary, press power ON/OFF button and the humidifier will display user defined settings for mode, proximal patient airway temperature, temperature gradient, and pause time. Press accept button to return to warm-up and program memory with displayed settings.

Note: If the humidifier was in the pause mode prior to the power failure, restart the system as noted above. Unit cannot be placed in pause until completion of the Warm-up cycle.

Routine Checks

1. Observe the condensation levels in the breathing circuit with every ventilator check. Drain as necessary.

2. Replace the Concha-Column with each ventilator circuit change.

- Avoid skin contact with HOT metal surfaces.

- NEVER reprocess the Concha-Column. Columns are designed for single-patient use.

Warning: Burn Hazard: The metal surfaces of the column and heater may be HOT (as high as 140 °C). Allow the column and heater to cool before handling.

3. Check the water reservoir for adequate sterile water. Water level at or below the replacement line may cause erratic temperature fluctuations.

To change the water reservoir:

- Close all clamps leading to the column and remove the upper puncture pin from the reservoir.
- Carefully remove the reservoir from the holder and lower the reservoir to a level below the column. Orient the reservoir so that the holes are on top. Remove the lower puncture pin from the reservoir.
- Discard the used reservoir and place a new Concha sterile water reservoir in the reservoir bracket.
- Press the lower pin through the puncture site at the bottom of the reservoir. TWIST and PUSH the pin in all the way. Repeat this procedure for the top puncture pin and puncture site.

- Open all clamps on the column and squeeze the reservoir to initiate flow into the column.

Caution: Proper operation of the humidifier requires proper installation of the water reservoir. Follow the reservoir installation instructions exactly.

4. Check the digital temperature display on the humidifier whenever making any adjustments to the setup.

5. Check the LED Icons whenever an alarm condition occurs and note the digital temperature display.

Cleaning

Use a 3% hydrogen peroxide solution or sodium hypochlorite to disinfect the outer surfaces. DO NOT use alcohol or solvent on the unit.

Caution: Never autoclave, gas sterilize (ETO), irradiate, pasteurize or submerge the unit in solution.

To clean the temperature probe, see cleaning instructions included with the probe.

Routine Maintenance

The ConchaTherm Neptune continuously performs self-diagnostic checks during operation. If a malfunction is detected during a routine check, the humidifier will shut off power and display the Service icon. (See "Troubleshooting").

- Check the power cord for damage prior to each use.

- Immediately remove from service any humidifier which shows signs of over heating or electrical malfunction.

It may be necessary to replace the power fuse should it blow. To replace the power fuse:

- Remove the fuse tray from the “Power Entry Module” at the rear of the unit. Check and replace blown fuses if detected, replace fuse tray.
- Power Fuses:
  Two, 250 V ~, 4 amp, 5 x 20mm time delayed

Service and Repairs

The ConchaTherm Neptune has no user serviceable components inside and requires no annual calibrations. Component part lists and circuit diagrams are confidential and not commercially available. Please contact the Teleflex Medical Customer Service Department at 1-866-246-6990 if you have special needs or questions with this policy.

If your humidifier requires service and repairs, contact the Teleflex Medical Customer Service Department at 1-866-246-6990.

Repair of leased heaters:
A Teleflex Medical customer service representative will assist you in obtaining a replacement heater for your ConchaTherm Neptune. User-performed repairs of leased heaters should not be attempted. Such repairs shall be considered user caused damage and may result in the cancellation of the lease.

Repair of user-owned heaters:
Customer Service shall provide instructions for the return of your heater. Upon receipt, the heater will be evaluated and an estimate of repair costs shall be made and provided to you. You may elect to receive a remanufactured or replacement heater for your unit. This option provides a substantial savings on repair costs and greatly reduces the turnaround time for the repair. User-performed repairs during the warranty period will void the warranty.

10. Limited Warranty Statement

WHAT THE WARRANTY COVERS AND FOR HOW LONG

Teleflex Medical ("Teleflex") warrants the Cat. No. 425-00 CONCHATHERM NEPTUNE ("Product") against defects in material and workmanship under normal use and service for a period of one (1) year from the date of purchase.

Teleflex Medical, at its option, will at no charge either repair the Product (with new or reconditioned parts) or replace it (with new or reconditioned Product), during the warranty period provided that it is returned in accordance with the terms of this warranty. Replaced parts or replaced Product is warranted for the balance of the original warranty period. All replaced parts or Product shall become the property of Teleflex. This expressed limited warranty is extended by Teleflex to the original end user purchaser only and is not assignable or transferable to any other party. This is the complete warranty for the Product manufactured by Teleflex. Teleflex assumes no obligations or liability for additions or modifications to this warranty unless made in writing and signed by an officer of Teleflex. Teleflex does not warrant the installation, maintenance or service of the Product. Teleflex cannot be responsible in any way for any ancillary equipment not furnished by Teleflex, which is attached to or used in connection with the Product. Because each system, which may use the Product, is unique, Teleflex disclaims liability for range, coverage, or operation of the system as a whole under this warranty.

GENERAL PROVISIONS

THIS WARRANTY IS THE EXCLUSIVE REMEDY AND SETS FORTH THE FULL EXTENT OF TELEFLEX MEDICAL'S RESPONSIBILITY. THIS WARRANTY IS IN LIEU OF ALL OTHER EXPRESS WARRANTIES. IMPLIED WARRANTIES, INCLUDING WITHOUT LIMITATION, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS FOR A PARTICULAR PURPOSE ARE LIMITED TO THE DURATION OF THIS LIMITED WARRANTY.

IN NO EVENT SHALL TELEFLEX MEDICAL BE LIABLE FOR DAMAGES IN EXCESS OF THE PURCHASE PRICE OF THE PRODUCT OR INDIRECT, SPECIAL, INCIDENTAL, OR CONSEQUENTIAL DAMAGES OF ANY KIND WHATSOEVER, INCLUDING WITHOUT LIMITATION LOST PROFITS, LOSS OF USE OR LOSS OF TIME.

STATE LAW RIGHTS

SOME STATES DO NOT ALLOW THE EXCLUSION OR LIMITATION OF INCIDENTAL OR CONSEQUENTIAL DAMAGES, OR LIMITATION ON HOW LONG AN IMPLIED WARRANTY LASTS, SO THE ABOVE LIMITATION MAY NOT APPLY TO YOU.

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

HOW TO GET WARRANTY SERVICE

You must provide proof of purchase (bearing the date of purchase and Product item serial number) in order to receive warranty service and, also, deliver or send the Product transportation and insurance prepaid, to an authorized service location. Warranty services will be provided by Teleflex Medical or through an authorized Teleflex Medical service center. If you first contact the company that sold you the Product (e.g. Teleflex Medical Distributor), they can facilitate your obtaining warranty service. You can also call Teleflex Medical at 1-866-246-6990 for warranty service information.

WHAT THIS WARRANTY DOES NOT COVER

a. Defects or damage resulting from use of the Product in other than its normal and customary manner.

b. Defects or damage from misuse, accident, or neglect.

c. Defects or damage from improper testing, operation, maintenance, installation, alteration, modification or adjustment.

d. A Product subjected to unauthorized Product modifications, disassembles or repairs (including, without limitation, the addition to the Product of non-Teleflex supplied equipment) which adversely affects performance of the Product or interferes with Teleflex Medical's normal warranty inspection and testing of the Product to verify any warranty claim.

e. Product that has the serial number removed or made illegible.

f. Freight and insurance costs to the service center.

g. Scratches or other cosmetic damage to Product surfaces that does not affect the operation of the Product.

h. Normal and customary wear and tear

Teleflex MEDICAL

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Appendix I
Electromagnetic Emissions Tables

Recommended separation distances between portable and mobile RF communications equipment and the CONCHATHERM NEPTUNE Humidifier.

The CONCHATHERM NEPTUNE Humidifier is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the CONCHATHERM NEPTUNE Humidifier can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the CONCHATHERM NEPTUNE Humidifier 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 $d = [3.5/V1]\sqrt{P}$	80 MHz to 800 MHz $d = [3.5/E1]\sqrt{P}$	800 MHz to 2.5 GHz $d = [7/E1]\sqrt{P}$
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.

Guidance and manufacturer's declaration - electromagnetic immunity			
The CONCHATHERM NEPTUNE Humidifier is intended for use in the electromagnetic environment specified below. The customer or the user of the CONCHATHERM NEPTUNE Humidifier should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance	Electromagnetic environment - guidance
Electrostatic discharge (ESD) **IEC 61000-4-2**	**±6 kV contact** **±8 kV air**	**±6 kV contact** **±8 kV 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 **IEC 61000-4-4**	**±2 kV for power supply lines** **±1 kV for input/output lines**	**±2 kV for power supply lines** **±1 kV for input/output lines**	**Mains power quality should be that of a typical commercial or hospital environment.**
Surge **IEC 61000-4-5**	**±1 kV differential mode** **±2 kV common mode**	**±1 kV differential mode** **±2 kV common mode**	**Mains power quality should be that of a typical commercial or hospital environment.**
Voltage dips, short interruptions and voltage variations on power supply input lines **IEC 61000-4-11**	**<5% U_T (>95% dip in U_T) for 0.5 cycle** **40% U_T (60% dip in U_T) for 5 cycles** **70% U_T (30% dip in U_T) for 25 cycles** **<5% U_T (> 95% dip in U_T) for 5 sec**	**<5% U_T (>95% dip in U_T) for 0.5 cycle** **40% U_T (60% dip in U_T) for 5 cycles** **70% U_T (30% dip in U_T) for 25 cycles** **<5% U_T (> 95% dip in U_T) for 5 sec**	**Mains power quality should be that of a typical commercial or hospital environment. If the user of the CONCHATHERM NEPTUNE Humidifier requires continued operation during power mains interruptions, it is recommended that the CONCHATHERM NEPTUNE Humidifier be powered from an uninterruptible power supply or a battery.**
Power frequency (50/60 Hz) magnetic field transient/burst **IEC 61000-4-6**	**3 A/m**	**3 A/m**	**Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.**
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

Guidance and manufacturer's declaration - electromagnetic immunity			
The CONCHATHERM NEPTUNE Humidifier is intended for use in the electromagnetic environment specified below. The customer or the user of the CONCHATHERM NEPTUNE Humidifier should assure that it is used in such an environment			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF **IEC 61000-4-6**	**3Vrms** **150kHz TO 80 MHz**	**3V**	**Portable and mobile RF communications equipment should be used no closer to any part of the CONCHATHERM NEPTUNE Humidifier, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.** **Recommended separation distance** $d = [3.5/V_1]\sqrt{P}$ $d = [3.5/E1]\sqrt{P}$ **80 MHz to 800 MHz** $d = [7/E1]\sqrt{P}$ **800 MHz to 2.5 GHz** **where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufactured and *d* is the recommended separation distance in meters (m).**
Radiated RF **IEC 61000-4-3**	**3V/m** **80 MHz to 2.5 GHz**	**3V/m**	**Field strengths from fixed RF transmitters, as, determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b]** **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] 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 CONCHATHERM NEPTUNE Humidifier is used exceeds the applicable RF compliance level above, the CONCHATHERM NEPTUNE Humidifier should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the CONCHATHERM NEPTUNE Humidifier.

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Guidance and manufacturer's declaration - electromagnetic emissions		
The CONCHATHERM NEPTUNE Humidifier is intended for use in the electromagnetic environment specified below. The customer or the user of the CONCHATHERM NEPTUNE Humidifier should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions **CISPR 11**	**Group 1**	**The CONCHATHERM NEPTUNE Humidifier uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.**
RF emissions **CISPR 11**	**Class B**	**The CONCHATHERM NEPTUNE Humidifier is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.**
Harmonic emissions **IEC 61000-3-2**	**Class A**	
Voltage fluctuations/ flicker emissions **IEC 61000-3-3**	**Complies**	