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87280-12 09/03

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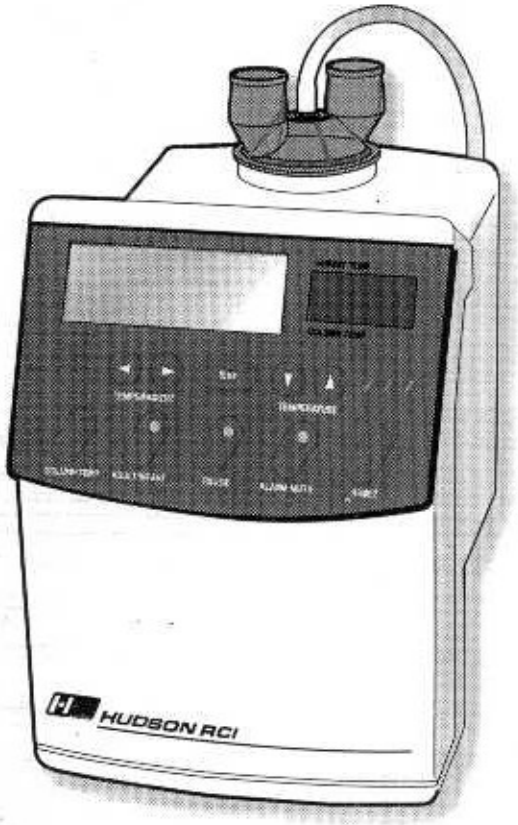

ConchaTherm® IV Plus

Heated Humidifier

Cat. No. 400-50

Contents

Introduction

Intended Use

The CONCHATHERM® IV PLUS heated humidifier is part of a complete system, designed to heat and humidify respiratory gases delivered to adult, pediatric and infant 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 IV PLUS can be used with ventilators, continuous flow systems, oxygen diluters and blenders, adjustable nebulizer adapters for aerosol therapy (using a conventional circuit), or nonflammable anesthesia gases to help maintain patient body temperature.

Features

- Selection of adult or infant operation modes
- May be used with either heated-wire or non-heated wire circuits
- Digital temperature display
- User defined proximal airway temperature with adjustable heater-to-patient temperature gradient for control of condensation
- User definable default settings for proximal airway temperature, temperature gradient and for adult and infant modes
- Responsive membrane front panel
- LCD prompters and audio-visual alarms permit rapid detection and correction of problems
- High and low temperature tracking alarms at 2.0 °C above and below the selected proximal airway temperature
- Fixed high-temperature alarm at 41.0 °C
- Disconnected/dislodged probe indicator
- Heated-wire disconnect alarm when in heated-wire mode
- Adjustable pause or hibernation mode from 5 to 60 minutes, which automatically resets
- Continuous self-diagnostic evaluation of hardware and software functions
- Microprocessor controlled

Symbols

The following symbols are used in this manual and/or on the device itself:

Symbol	Description
	**WARNING:** Indicates a condition which, if not followed exactly, may cause harm to the patient or user.
	**CAUTION:** Indicates a condition which, if not followed exactly, may cause harm to the equipment.
I	Power ON
O	Power OFF
A	Ampere
Hz	Hertz

General Warnings and Cautions

Warning: Fire Hazard. Do not use the CONCHATHERM IV Plus in the presence of flammable anesthetic gases.

Warning: Burn Hazard. The heating element of the CONCHATHERM IV PLUS is hot (as high as 140 °C). Allow the HEATER 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 CONCHA-COLUMN to cool before handling.

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

Warning: This unit requires 115 VAC (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 and secure before operating the CONCHATHERM IV PLUS. Failure to do so will cause the unit to alarm and shut down.

Warning: Always verify gas flow and airway temperature before connecting the CONCHATHERM IV PLUS to the patient.

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

Warning: Use only Hudson RCI 21-volt Heated-Wire Circuits with this HEATER.

Warning: When using Hudson RCI Heated-Wire Circuits:

1) Observe the minimum minute volumes recommended in this manual;
2) Do not cover the circuit with sheets, blankets, towels, clothing or other materials;
3) Do not apply excessive tension to the heated-wire harness - DO NOT "MILK" TUBING and;
4) 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 HEATER ON, do not turn the HEATER 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 HEATER power switch OFF, or place the unit in pause and allow the system to cool before stopping gas flow.

Warning: The check 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: Be sure to select the proper operating mode to assure proper humidification of the patient by the 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. See Low-Compliance Column product insert.

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

Warning: Do not remove the protective cover from the service connector. This is **not** a telephone plug. Use of this connector by anyone other than qualified, factory-trained personnel may damage the instrument and result in harm to the patient.

Caution: Always operate the CONCHATHERM IV PLUS heater in a vertical position with the water reservoir properly mounted.

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

Caution: Temperature patterns within the system associated with normal operation will be disrupted if there is an insufficient water level to pass through the system, causing the HEATER to alarm. Be sure the reservoir is properly installed.

Caution: Do not operate the CONCHATHERM IV PLUS with a dry reservoir. Severe damage may result.

Caution: Do not operate the CONCHATHERM IV PLUS without a CONCHA-COLUMN humidifier cartridge. Severe damage may result.

Caution: Do not autoclave, gas sterilize, pasteurize or immerse the CONCHATHERM IV PLUS in any liquid. Severe damage will result.

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

Caution: Use water traps to collect rainout when using any heater with non-heated wire breathing circuits.

Principles of Operation

The CONCHA® system of heated humidification consists of the CONCHATHERM IV PLUS heated humidifier, the CONCHA-COLUMN® humidifier cartridge, CONCHA sterile water reservoir, a Hudson RCI dual temperature probe and either a non-heated wire breathing circuit or a Hudson RCI 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 CONCHA-COLUMN where it picks up the moisture in molecular form. The heated, humidified gas is delivered to the patient through a breathing circuit, (non-heated wire or heated-wire) attached to the top of the CONCHA-COLUMN.

CONCHA-COLUMNS are available in standard and low-compliance configurations and are labeled for easy identification. Both operate on a reliable, gravity-feed system for uninterrupted water flow.

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 CONCHA-COLUMN drops as water is consumed. As the water level in the CONCHA-COLUMN drops, the compressible volume of the system increases and the system compliance changes.

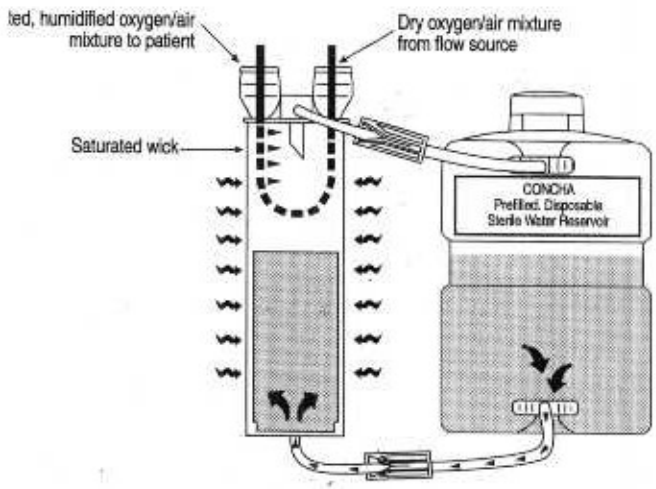

Figure 1: Standard CONCHA-COLUMN Flow Diagram

For applications requiring a more constant compressible volume and compliance, a **low-compliance CONCHA-COLUMN** (*see Figure 2*) should be used. 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 CONCHA-COLUMN's compliance plus the amount of fluid transferred to the reservoir during each inspiratory phase. Some fluid, in the form of either air or water, always transfers during each cycle[1]. 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.

The CONCHATHERM IV PLUS has been designed and tested to be used with Hudson RCI conventional (non-heated wire) circuits and compatible (21-volt) Hudson RCI heated-wire circuits. The CONCHATHERM IV PLUS requires the use of a dual temperature probe at all times.

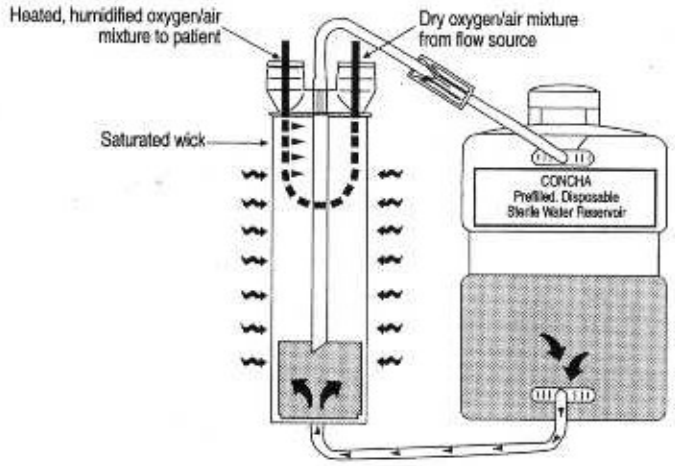

Figure 2: Low-Compliance CONCHA-COLUMN Flow Diagram

[1] 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.

Specifications

Performance Characteristics[2]

CONCHATHERM IV PLUS Heated Humidifier

SettableTemperature Range[3]:	Adult mode–Adjustable from 30.0 to 39.0 °C Infant mode–Adjustable from 30.0 to 39.0 °C
Output Voltage (Heated Wire):	21 volts AC
Temperature Display:	Three-digit, seven-segment LED
High-Temperature Alarm Limit:	41.0 ± 0.5 °C typical
Tracking Alarm:	
Heated-Wire Circuit	± 2.0 °C of the selected airway temperature
Non-Heated Wire (Conventional) Circuit	± 2.0 °C of the selected airway temperature
Warm-up Time:	20 minutes maximum with heated wire 30 minutes maximum non-heated wire
Recommended Flow Rates[4]:	Adult mode, heated-wire circuit–3 LPM min. Adult mode, non-heated wire circuit–5 LPM min. Infant mode, heated-wire circuit–2 LPM min. Infant mode, non-heated wire circuit–2 LPM min.

CONCHA-COLUMN Humidifier Cartridge

Water Capacity:	
Standard[5]	193 ± 10 mL with full reservoir
Low compliance	52 ± 10 mL with full reservoir
Compliance:	
Standard[5]	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
Compressible Volume:	
Standard[5]	103 mL with full reservoir 268 mL with reservoir at "replace" mark
Low compliance	248 mL ± 12 mL

[2] An accumulation of extreme conditions will affect the stated performance of the device.
[3] Measured at the patient end of a 153 cm (60") breathing circuit.
[4] Using a continuous flow gas source.
[5] Amount of water in CONCHA-COLUMN decreases as water is used, increasing the compressible volume as water is consumed.

Electrical Characteristics

Input Voltage and Power:	103-127 VAC, 60 Hz, 1.8 A
Power Consumption:	200 W
Leakage Current:	Less than 100 microamps
Dielectric Withstand:	1,250 volts minimum for one (1) minute
Temperature Control:	Dual thermistor
Power Fuse:	One (1) 4 amp, 125 VAC 5 x 20mm time delayed
Thermal Fuse:	140 °C nonresettable

Operating Environment Temperature

Operating Temperature:	20 to 29 °C (68 to 85°C)[6]

Physical Characteristics

Size:	21.6 cm (H*) x 15.2 cm (W) x 19.0 cm (D) 8 1/2" (H*) x 6" (W) x 7 1/2" (D) **NOTE: Allow 33 cm (13") when circuit is installed.*
Weight:	8 pounds (approximate) 3.6 Kg (approximate)

Transportation and Storage

Temperature:	-20 to +50 °C (-4 to +122 °F)
Relative Humidity:	10-100%

[6] Operating the HEATER at the extremes of the operating temperature may affect the temperature output of the device and/or cause nuisance alarms. The HEATER works ideally at a room temperature of 22 to 26 °C (72 to 78 °F).

Controls and Indicators

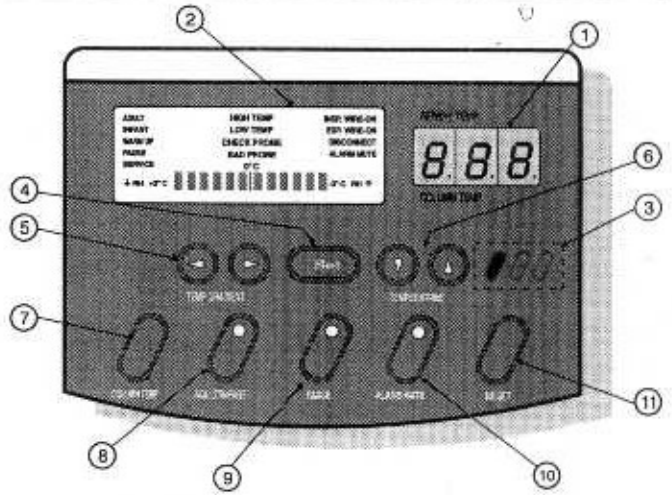

Figure 3: CONCHATHERM IV PLUS Front Panel Controls and Indicators

Indicators

(see Figure 3)

1. **LED DISPLAY**—Displays the gas temperature in whole degrees centigrade and tenths of a degree. The LED illuminates AIRWAY TEMP or COLUMN TEMP as appropriate to the temperature being displayed. During normal operation, the LED displays actual proximal patient airway temperature.
2. **LCD DISPLAY**—Displays status messages (described below) singly or in combination. In addition, this LCD displays a temperature gradient bar graph when the CONCHATHERM IV PLUS is used with a heated-wire circuit.

   ADULT—Illuminates when the CONCHATHERM IV PLUS is in the adult mode.

   INFANT—Illuminates when the CONCHATHERM IV PLUS is in the infant mode.

   WARM-UP—Flashes while the CONCHATHERM IV PLUS is warming up.

   PAUSE—Flashes when the pause mode is active.

   SERVICE—Flashes in the event of the failure of the CONCHATHERM IV PLUS. Immediately remove the unit from service should this message come on.

   HIGH TEMP—Flashes when the proximal patient airway temperature (also referred to as airway temperature) is 41.0 °C or higher, or if the airway temperature is 2.0 °C above the temperature selected by the clinician.

LOW TEMP—Flashes when the airway temperature is 2.0 °C below the temperature selected by the clinician or when the column temperature fails to reach 31 °C.

NOTE: This alarm is deactivated during the warm-up period.

CHECK PROBE—Flashes when the CONCHATHERM IV PLUS senses a dislodged or disconnected temperature probe.

Warning: The check probe alarm is not intended to replace routine physical inspection of the temperature probe placement. Be sure both temperature probes are in place at all times during the operation of the CONCHATHERM IV PLUS.

BAD PROBE—Flashes when the CONCHATHERM IV PLUS senses an abnormality that it interprets as a failed temperature probe. Replace the probe if this message comes on.

INSP. WIRE—Illuminates when the inspiratory wire of a heated-wire circuit is connected to the CONCHATHERM IV PLUS. This message will flash when the inspiratory wire is disconnected during operation.

INSP. WIRE-ON—Illuminates when power is applied by the CONCHATHERM IV PLUS to the inspiratory heated-wire.

EXP. WIRE—Illuminates when the expiratory wire of a heated-wire circuit is connected to the CONCHATHERM IV PLUS. This message will flash when the expiratory wire is disconnected during operation.

EXP. WIRE-ON—Illuminates when power is applied by the CONCHATHERM IV PLUS to the expiratory heated-wire.

DISCONNECT—Flashes when either the inspiratory or expiratory wire of the heated-wire circuit is disconnected during operation. In addition, INSP. WIRE or EXP. WIRE will flash to indicate which wire is disconnected.

ALARM MUTE—Flashes when the audible alarm has been silenced.

NOTE: The mute period ends after approximately one minute.

BAR GRAPH—Displays the difference in gas temperature, the temperature gradient, between the column temperature and the airway temperature when the CONCHATHERM IV PLUS is used with a heated-wire circuit. Each segment of the bar graph represents 0.5 °C. During operation, the bar graph displays the actual temperature gradient in the heated-wire circuit. When the SET key is pressed, the bar graph displays the temperature gradient selected by the clinician for as long as the key is pressed.

3. **STATUS INDICATORS**—These three LEDs display the operating status of the CONCHATHERM IV PLUS.

GREEN—Illuminates when the device is turned on and remains on to indicate normal operation.

YELLOW—Illuminates in conjunction with a slow-pulsing audio signal to indicate a cautionary condition (also see "Alarm Conditions" in the "Troubleshooting" section of this manual).

RED—Illuminates in conjunction with a fast-pulsing audio signal to indicate an emergency condition requiring immediate action by the clinician (also see "Alarm Conditions" in the "Troubleshooting" section of this manual).

Front Panel Controls

(see Figure 3)

4. **SET**—This key is used in conjunction with other function keys to activate or deactivate system functions. In this way, the SET key provides a safety feature to prevent inadvertent alteration of a system function. If pressed without simultaneously pressing another key, the set airway temperature is displayed on the LED; and if using a heated-wire circuit, the set column-to-airway temperature gradient is displayed on the LCD bar graph.

5. **TEMP GRADIENT**—Used simultaneously with the SET key. These keys increase or decrease the temperature gradient between the column temperature and the patient end of the heated-wire circuit. The temperature gradient is displayed on the LCD bar graph.

   NOTE: Once adjusted, the HEATER will begin to heat to the new parameter. To record this parameter into the unit's memory, the HEATER requires 10 seconds of keypad inactivity, after the last parameter has been entered, before storing the parameter.

   NOTE: This control is inactive when a non-heated wire circuit is used.

6. **TEMPERATURE**—Used simultaneously with the SET key. These keys increase or decrease the set proximal patient airway temperature. Each time the key is pressed, the LED will increment in the units displayed (whole degrees or tenths of a degree). If the tenths of a degree is displayed, holding the keys will advance the display rapidly. NOTE: Once adjusted, the HEATER will begin to heat to the new parameter. To record this parameter into the unit's memory, the HEATER requires 10 seconds of keypad inactivity, after the last parameter has been entered, before storing the parameter.

7. **COLUMN TEMP**—When pressed, allows the LED display to show the temperature of gas at the outlet of the CONCHA-COLUMN. This will remain displayed for as long as the key is pressed.

8. **ADULT/INFANT**—Used simultaneously with the SET key, this key selects the operating mode of the CONCHATHERM IV PLUS.

9. **PAUSE**—Used simultaneously with the SET key to reduce power to the heater and wires, and hibernate the activity of the unit for a user definable time period of 5-60 minutes. During the pause or hibernation mode, proximal airway temperature, temperature gradient, and pause time may not be adjusted. The CONCHATHERM IV PLUS will arrive with a Hudson RCI preset pause interval of 30 minutes. When CONCHATHERM IV PLUS is in pause, a green LED will flash on the PAUSE key, and pause flashes on the LCD display. See the "Other Operating Features" section for adjusting the pause time. To terminate the pause mode, press the SET and PAUSE keys simultaneously.

10. **ALARM MUTE**—Silences the audible alarm for approximately one-minute. During the mute period, ALARM MUTE flashes on the LCD display and the LED on the ALARM MUTE key flashes. Pressing the ALARM MUTE key anytime during the mute period will reactivate the audible alarm.

11. **RESET**—This key, when pressed simultaneously with the SET key:
    - clears operating alarm conditions, if active (also see "Operating Conditions" in the "Troubleshooting" section of this manual).
    - terminates the pause mode
    - terminates the alarm mute mode
    - restarts the warm-up period

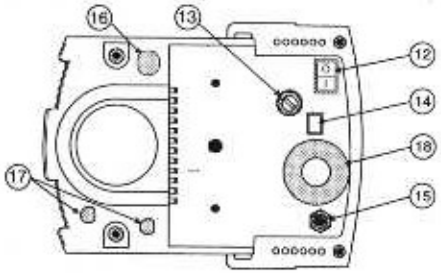

Figure 4: CONCHATHERM IV PLUS Bottom Panel

Bottom Panel

(see Figure 4)

12. **POWER ON/OFF**—This switch controls power to the CONCHA-THERM IV PLUS.

    NOTE: If the power has been turned off and then turned on in a period of less than one minute, the device will return to the control settings in effect prior to being turned off.

13. **POWER FUSE**—Slotted fuse holder containing one 4-amp fuse.

14. **SERVICE CONNECTOR**—This port is used only for test and calibration during manufacturing at the factory.

Warning: Do not remove the protective cover from the service connector. This is **not** a telephone plug. Use of this connector by anyone other than qualified, factory-trained personnel may damage the instrument and result in harm to the patient.

15. **TEMPERATURE PROBE JACK**—Connects the temperature probes to the CONCHATHERM IV PLUS.

16. **POWER CORD**—Three-conductor cable (with ground) with a hospital grade plug.

17. **HEATED-WIRE CABLE**—Color-coded connectors to match the color of the inspiratory heated-wire (blue) and the expiratory heated-wire (yellow) connectors on the Hudson RCI heated-wire circuit.

18. **AUDIBLE ALARM**—Sounds when an alarm condition exists. A slow-pulsing alarm indicates a cautionary condition and is accompanied by a slow-flashing, yellow status indicator LED. A fast-pulsing alarm indicates an emergency condition requiring immediate action by the clinician and is accompanied by a fast-flashing, red status indicator LED.

Directions for Use

Read this entire section, including all warnings and cautions, before operating the CONCHATHERM IV PLUS. Also see "Applications" later in this manual for use of the CONCHATHERM IV PLUS in particular clinical situations.

System Setup

1. CONCHATHERM IV PLUS installation.

   Mount the HEATER to a pole, ventilator or rail system using the appropriate Hudson RCI mounting bracket. Contact your Hudson RCI representative for available mounting brackets. Mounting instructions are supplied with the bracket.

Warning: Fire Hazard: Do not use CONCHATHERM IV PLUS in the presence of flammable anesthetic gases.

2. Connect the CONCHATHERM IV PLUS to power.

   Plug the HEATER into an appropriate 115 VAC (nominal) 60 Hz three-prong, grounded electrical outlet. Be sure there is power at the outlet.

Warning: This unit requires 115 VAC (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.

Warning: Do not leave the HEATER ON, do not turn the HEATER 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 HEATER power switch OFF, or place the unit in pause and allow the system to cool before stopping gas flow.

3. Install the CONCHA-COLUMN.

   Insert the CONCHA-COLUMN into the CONCHATHERM IV PLUS, passing the bottom puncture pin and tubing through the cylindrical heating element. Be sure that the tubing clamp(s) are in place.

Warning: Burn Hazard. The heating element of the CONCHATHERM IV PLUS is hot (as high as 140 °C). Allow the HEATER 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 CONCHA-COLUMN to cool before handling.

4. Install the water reservoir.

   Place the CONCHA sterile water reservoir into the reservoir holder on the mounting bracket.

5. Connect the breathing circuit to the CONCHA-COLUMN.

   - Remove the protective caps from the ports at the top of the CONCHA-COLUMN.
   - Connect the tubing from the ventilator or gas source to one of the ports on the column.
   - Connect the inspiratory circuit tubing to the remaining port. If using a column with a right-angle port, attach the tubing from the ventilator or gas source to the vertical port and the inspiratory tubing to the horizontal port.
   - Connect the expiratory circuit tubing to the expiratory port on the ventilator.

6. Connect the water reservoir to the CONCHA-COLUMN.
   - Remove the protective sheath from the bottom puncture pin on the CONCHA-COLUMN tubing. Using a twisting motion, push the pin through the puncture site at the bottom of the reservoir. Push the pin in all the way. Repeat this procedure for the top puncture pin and puncture site.
   - Open all of the tubing clamps on the CONCHA-COLUMN. Gently squeeze the reservoir to initiate water flow into the column.
7. Install the dual temperature probe.

   Insert the temperature probe plug into the jack at the bottom-of the heater. Be certain that the plug is FULLY seated. Place the long-cabled probe into the inspiratory side of the patient wye and the short-cabled probe at the CONCHA-COLUMN outlet.

Warning: The temperature probes must be properly placed and secure before operating the CONCHATHERM IV PLUS. Failure to do so will cause the unit to alarm and shut down. If using a heated-wire circuit, connect the inspiratory and expiratory wires to the appropriate color-coded connectors on the HEATER (inspiratory-blue; expiratory-yellow).

Warning: Use only Hudson RCI 21-volt Heated-Wire Circuits with this HEATER.

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 and;
   - Do not allow the circuit to rest on the patient's bare skin.
8. Set the ventilator or gas source as required

   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).

Warning: Do not leave the HEATER ON, do not turn the HEATER 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 HEATER power switch OFF, or place the unit in pause and allow the system to cool before stopping gas flow.

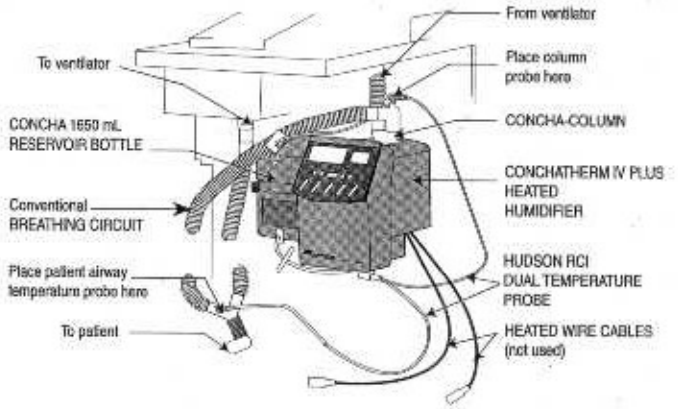

Figure 5: The CONCHA System Using a Non-Heated Wire (Conventional) Circuit

Operating the CONCHATHERM IV PLUS

Using a Non-Heated Wire (Conventional) Circuit

(see Figure 5)

1. Turn on the gas flow.

   When using the CONCHATHERM IV PLUS with a non-heated wire breathing circuit, a minimum flow rate of 5 LPM is required in the adult mode and a minimum of 2 LPM is required in the infant mode. Also refer to the "Applications" section of this manual.

Warning: Always verify gas flow and airway temperature before connecting the CONCHATHERM IV PLUS to the patient.

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

Warning: Do not leave the HEATER ON, do not turn the HEATER 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 HEATER power switch OFF, or place the unit in pause and allow the system to cool before stopping gas flow.

2. Set the CONCHATHERM IV PLUS power switch to ON (I).

   Once activated, the CONCHATHERM IV PLUS performs a self-diagnostic routine which briefly displays all segments of both the LED and LCD displays, illuminates all discreet LEDs and sounds the audible alarm. Once the self-diagnostic routine is complete:
   - the green LED on the unit will remain lit
   - the LED on the ADULT/INFANT key will flash
   - the words Adult and Infant on the LCD display will flash

   This indicates that the CONCHATHERM IV PLUS is waiting for selection of the operating mode.

   NOTE: The CONCHATHERM IV PLUS will not begin to heat until an operating mode is selected by the clinician.

3. Select the operating mode (adult or infant).

   To select the infant mode, press and hold the SET key. Press the ADULT/INFANT key until the word Infant is displayed on the LCD, and the temperature display is illuminated. Release the SET key.

   NOTE: The ADULT/INFANT key will continue to flash for 60 seconds. During this time, you may change the operating mode to Adult, by following the instructions on selecting the adult mode. When the key stops flashing, the CONCHATHERM IV PLUS will supply heat to the system.

   To select the adult mode, press and hold the SET key. Press the ADULT/INFANT key until the word Adult is displayed on the LCD, and the temperature display is illuminated. Release the SET key.

   NOTE: The ADULT/INFANT key will continue to flash for 60 seconds. During this time, you may change the operating mode to Infant by following the instructions on selecting the infant mode. When the key stops flashing, the CONCHATHERM IV PLUS will supply heat to the system.

   To change the operating mode after the 60-second mode selection period has expired, the CONCHATHERM IV PLUS must be turned off for one minute or longer to clear the previous selection.

   NOTE: The CONCHATHERM IV PLUS must be placed into either the adult or infant operating mode before the unit begins to heat. If, **after five minutes** the operating mode has not been selected, the CONCHATHERM IV PLUS will alarm, notifying the user that additional input is required.

   NOTE: When using the CONCHATHERM IV PLUS with a 15 mm internal diameter pediatric breathing circuit, use the adult mode. Observe all minimum flow requirements associated with use of the device in the adult mode.

4. Set the proximal patient airway temperature.

   The CONCHATHERM IV PLUS will arrive from Hudson RCI with the proximal patient airway default temperature set at 35.0 °C. To select a different airway default temperature, follow the directions below for increasing or decreasing airway temperature. When the SET key is pressed, the selected airway temperature will be displayed on the LED. When the SET key is released, the LED will display the actual airway temperature.

   To increase the proximal patient airway temperature, press and hold the SET key. Press the "▲" key, located directly over the word TEMPERATURE to the desired setting; holding the "▲" key will advance the display rapidly. Release the SET key.

   To decrease proximal patient airway temperature, press and hold the SET key. Press the "▼" key, located directly over the word TEMPERATURE to the desired setting. If the tenths of a degree is displayed, holding the "▼" key will advance the display rapidly. Release the SET key.

   NOTE: With each adjustment, allow adequate time for CONCHATHERM IV PLUS to reach the selected temperature. This will vary and is dependent on flow rate, type and lengths of tubing, ventilating volume, respiratory rates and type of CONCHA-COLUMN used.

   NOTE: Should the primary memory become corrupted, the CONCHATHERM IV PLUS will revert to the Hudson RCI set temperature of 35.0 °C.

5. CONCHATHERM IV PLUS Warm-Up Period.

   Once the operating mode has been selected, the CONCHATHERM IV PLUS will enter into a "warm-up" period. The CONCHATHERM IV PLUS allows 30 minutes for the system to come up to operating

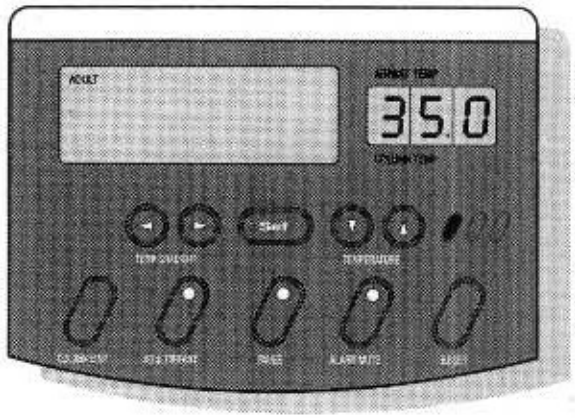

Figure 6: Typical CONCHATHERM IV PLUS Displays in Normal Non-Heated Wire Breathing Circuit Operation

temperature when using a non-heated wire circuit. The phrase WARM-UP will flash on the LCD for the duration of this period.

The warm-up period ends after 30 minutes or when the airway temperature stabilizes within 2.0 °C of the set airway temperature. During the warm-up period, the low temperature alarm is deactivated to keep the unit from giving a low temperature alarm while the system temperature stabilizes.

If the HEATER is not within 2.0 °C of the set airway temperature after a warm-up period of 30 minutes, the HEATER will display a low-temperature alarm. If additional warm-up time is required, simultaneously press the SET and RESET keys.

6. After the warm-up period, CONCHATHERM IV PLUS will convert to its operating mode. *Figure 6* shows a typical display pattern for the CONCHATHERM IV PLUS in the adult mode using a non-heated wire breathing circuit. The display shows an actual airway temperature of 35.0 °C.

7. Changing the breathing circuit.

   Place the HEATER in pause when changing the circuit. Once the pause interval ends, the HEATER will return to the warm-up mode, then normal operation.

   NOTE: If replacing a non-heated wire breathing circuit with a Hudson RCI Heated-Wire Circuit, the CONCHATHERM IV PLUS will automatically enter heated-wire operation when it senses the inspiratory heated-wire has been connected.

Warning: Do not leave the HEATER ON, do not turn the HEATER 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 HEATER power switch OFF, or place the unit in pause and allow the system to cool before stopping gas flow.

8. When removing the CONCHA-THERM IV PLUS from service, turn the HEATER power switch OFF and allow the unit to cool before stopping gas flow.

Warning: Leaving the HEATER ON without gas flow 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.

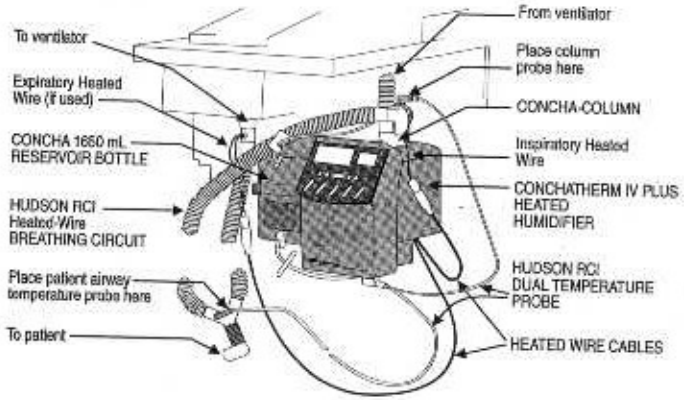

Figure 7: The CONCHA System Using a Heated-Wire Circuit

Operating the CONCHATHERM IV PLUS

Using a Heated-Wire Circuit

(see Figure 7)

1. Be sure the heated-wires from the circuit are connected to the CONCHATHERM IV PLUS before the unit is turned on. For correct heated-wire circuit connection, please see the Heated-Wire Circuit product insert.

   IMPORTANT: The CONCHATHERM IV PLUS automatically enters heated-wire operation when it senses that the inspiratory heated-wire from a Hudson RCI circuit has been connected. If using a Hudson RCI dual heated-wire circuit, be sure that both wires are connected.

Warning: Do not leave the HEATER ON, do not turn the HEATER 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 HEATER power switch OFF or place the unit in pause and allow the system to cool before stopping gas flow.

Warning: Use only Hudson RCI 21-volt Heated-Wire Circuits with this HEATER.

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 and;
- Do not allow the circuit to rest on the patient's bare skin.

2. Turn on the gas flow.

   When using the CONCHATHERM IV PLUS with a heated-wire breathing circuit, a minimum flow rate of 3 LPM or greater is required in the adult mode and a minimum of 2 LPM is required in the infant mode. Also refer to the "Applications" section of this manual.

Warning: Always verify gas flow and airway temperature before connecting the CONCHATHERM IV PLUS to the patient.

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

Warning: Do not leave the HEATER ON, do not turn the HEATER 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 HEATER power switch OFF, or place the unit in pause and allow the system to cool before stopping gas flow.

3. Set the CONCHATHERM IV PLUS power switch to ON (I).

   Once activated, the CONCHATHERM IV PLUS performs a self-diagnostic routine which briefly displays all segments of both the LED and LCD displays, illuminates all discreet LEDs and sounds the audible alarm. Once the self-diagnostic routine is complete:

   - the green LED on the unit will remain lit
   - the LED on the ADULT/INFANT key will flash
   - the words Adult and Infant on the LCD display will flash

   This indicates that the CONCHATHERM IV PLUS is waiting for selection of the operating mode.

   NOTE: The CONCHATHERM IV PLUS will not begin to heat until an operating mode is selected by the clinician.

4. Select the operating mode (adult or infant).

   To select the infant mode, press and hold the SET key. Press the ADULT/INFANT key until the word Infant is displayed on the LCD, and the temperature display is illuminated. Release the SET key.

   NOTE: The ADULT/INFANT key will continue to flash for 60 seconds. During this time, you may change the operating mode to Adult, by following the instructions on selecting the adult mode. When the key stops flashing, the CONCHATHERM IV PLUS will supply heat to the system.

   To select the adult mode, press and hold the SET key. Press the ADULT/INFANT key until the word Adult is displayed on the LCD, and the temperature display is illuminated. Release the SET key.

   NOTE: The ADULT/INFANT key will continue to flash for 60 seconds. During this time, you may change the operating mode to Infant, by following the instructions on selecting the infant mode. When the key stops flashing, the CONCHATHERM IV PLUS will supply heat to the system.

   To change the operating mode after the 60-second mode selection period has expired, the CONCHATHERM IV PLUS must be turned off for one minute or longer to clear the previous selection.

   NOTE: The CONCHATHERM IV PLUS must be placed into either the adult or infant operating mode before the unit begins to heat. If, **after five minutes** the operating mode has not been selected, the CONCHATHERM IV PLUS will alarm, notifying the user that additional input is required.

   NOTE: When using the CONCHATHERM IV PLUS with a 15 mm internal diameter pediatric breathing circuit, use the adult mode. Observe all minimum flow requirements associated with use of the device in the adult mode.

5. Set the proximal patient airway temperature.

   The CONCHATHERM IV PLUS will arrive from Hudson RCI with the proximal patient airway default temperature set at 35.0°C. To select a different airway default temperature, follow the directions below for increasing or decreasing airway temperature. When the SET key is pressed, the selected airway temperature will be displayed on the LED. When the SET key is released, the LED will display the actual airway temperature.

   To increase proximal patient airway temperature, press and hold the SET key. Press the "▲" key, located directly over the word TEMPERATURE to the desired setting; holding the "▲" key will advance the display rapidly. Release the SET key.

   To decrease the proximal patient airway temperature, press and hold the SET key; press the "▼" key, located directly over the word TEMPERATURE to the desired setting; holding the "▼" key will advance the display rapidly. Release the, SET key.

   NOTE: With each adjustment, allow adequate time for CONCHATHERM IV PLUS to reach the selected temperature. This will vary and is dependent on flow rate, type and lengths of tubing, ventilating volume, respiratory rates and type of CONCHA-COLUMN used.

   NOTE: Should the primary memory become corrupted, the HEATER will revert to the Hudson RCI set temperature of 35 °C.

6. Set the column-to-patient temperature gradient.

   When using the CONCHATHERM IV PLUS with Hudson RCI Heated-Wire Circuits, the temperature gradient may be adjusted to allow for the proximal patient airway temperature to be up to 3.0 °C warmer or cooler than the temperature at the CONCHA-COLUMN outlet. Adjustment of the temperature gradient allows for better control of the relative humidity delivered to the patient and better control of rainout, condensation, within the heated-wire circuit. A positive temperature gradient results in a 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-airway temperature gradient is displayed as a bar graph on the HEATER LCD display.

   The CONCHATHERM IV PLUS will arrive from Hudson RCI with the column-to-patient temperature gradient set at 0 °C. A temperature gradient of 0 °C allows the temperature of the gas and, therefore, the relative humidity (R.H.) of the gas, to be constant throughout the length of the heated-wire circuit. *Figure 8* shows a typical circuit response and bar graph display when the airway temperature is set at 37 °C and the temperature gradient is set at 0 °C.

   To select a different temperature gradient, use the SET and TEMP GRADIENT keys as described

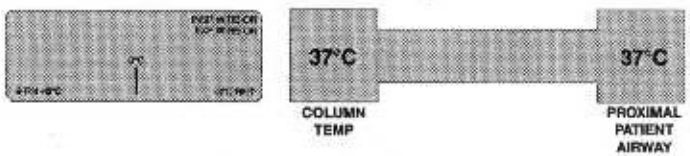

Figure 8: Zero Temperature Gradient, Display at 0 °C.

below. When the SET key is pressed, the set temperature gradient will be displayed on the LCD's bar graph. When the SET button is released, the bar graph will display the actual temperature gradient within the heated-wire circuit. Allow time for stabilization after adjustment.

To set a positive temperature gradient, press and hold the SET key. Press the "◄" key, located directly over the word TEMP GRADIENT to the desired setting. Each time the TEMP GRADIENT "◄" key is pressed, the bar graph on the LCD display will increment by a single segment. Each segment represents 0.5 °C. Release the SET key. *Figure 9* shows a typical bar graph display with the airway temperature set at 37 °C and the temperature gradient set at +3.0 °C.

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

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

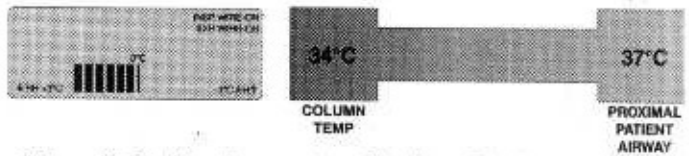

Figure 9: Positive Temperature Gradient, Display at +3.0 °C.

To set a negative temperature gradient, press and hold the SET key. Press the "►" key, located directly over the word TEMP GRADIENT to the desired setting. Each time the TEMP GRADIENT "►" key is pressed, the bar graph on the LCD display will increment by a single segment. Each segment represents 0.5 °C. Release the SET key. *Figure 10* shows a typical bar graph display with the airway temperature set at 37 °C and the temperature gradient set at -3.0 °C.

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

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

The CONCHATHERM IV PLUS is designed to deliver a minimum fluid output of 30 mg/L, requiring a minimum column temperature of approximately 31 °C. Always set the temperature gradient to allow for a column temperature of at least 31 °C; otherwise, a low-temperature alarm will activate.

NOTE: Should the primary memory become corrupted, the HEATER will revert to the Hudson RCI set temperature gradient of 0 °C.

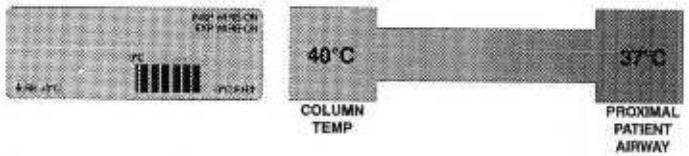

Figure 10: Negative Temperature Gradient, Display at -3.0 °C.

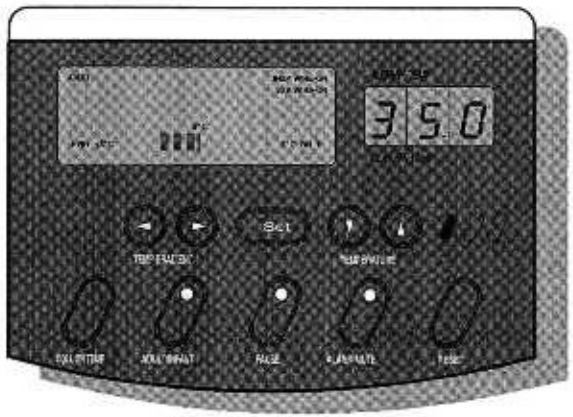

Figure 11: Typical CONCHATHERM IV PLUS Displays in Normal Heated-Wire Operation

7. CONCHATHERM IV PLUS Warm-Up Period.

   Once the operating mode has been selected, the CONCHATHERM IV PLUS will enter into a warm-up period. The CONCHATHERM IV PLUS allows 20 minutes for the system to come up to operating temperature when used with a heated-wire breathing circuit. The phrase WARM-UP will flash on the LCD for the duration of this period.

   The warm-up period ends after 20 minutes or when the airway temperature stabilizes within 2.0 °C of the set airway temperature. During the warm-up period, the low temperature alarm is deactivated to keep the unit from giving a low temperature alarm while the system temperature stabilizes.

   If the HEATER is not within 2.0 °C of the set airway temperature after a warm-up period of 20 minutes, the HEATER will display a low-temperature alarm. If additional warm-up time is required, simultaneously press the SET and RESET keys.

8. After the "warm-up" period, CONCHATHERM IV PLUS will convert to its operating mode. *Figure 11* shows a typical display pattern for the CONCHATHERM IV PLUS in the adult mode using a heated-wire breathing circuit. The display shows an actual airway temperature of 35.0 °C and a temperature gradient of +1.5 °C.

   Note: The LCD illuminates the word ON beside the INSP. WIRE or EXP. WIRE whenever power is applied to the wire. If a heated-wire is disconnected at any time during operation, the CONCHATHERM IV PLUS will flash the word DISCONNECT and flash which wire (INSP. WIRE or EXP. WIRE) is disconnected.

9. Changing the breathing circuit.

   If replacing the breathing circuit with a heated-wire breathing circuit, place the HEATER in pause during the circuit change. Once the pause interval ends, the HEATER will return to the warm-up mode, then normal operation.

   If replacing the heated-wire breathing circuit with a non-heated wire breathing circuit, turn the HEATER off during the circuit change. This will clear the heated-wire setting from the HEATER.

   IMPORTANT: The CONCHATHERM IV PLUS will give a heated-wire disconnect alarm if the HEATER is placed in pause when a heated-wire breathing circuit is replaced with a non-heated wire breathing circuit.

Warning: Do not leave the HEATER ON, do not turn the HEATER 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 HEATER power switch OFF or place the unit in pause and allow the system to cool before stopping gas flow.

10. When removing the CONCHATHERM IV PLUS from service, turn the HEATER power switch OFF and allow the unit to cool before stopping gas flow.

Warning: Leaving the HEATER in the ON position without gas flow 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.

Other Operating Features

Setting User Defined Parameters

The CONCHATHERM IV PLUS will arrive from Hudson RCI with the patient airway temperature set at 35.0° C and the temperature gradient set at 0° C for the adult and infant modes. The pause interval will be set at 30 minutes. All these parameters may be adjusted by the clinician.

Once adjusted, the HEATER will begin to heat to the new parameters. To record these parameters into the unit's memory, the HEATER requires 10 seconds of keypad inactivity, after the last parameter has been entered, before storing the parameters.

Pause

To facilitate clinical activities such as circuit changes and nebulizer treatments, the CONCHATHERM IV PLUS pause feature allows the clinician to reduce power to the heater and heated-wire breathing circuit for up to 60 minutes without turning off the main power switch. During this period, CONCHATHERM IV PLUS parameter settings are maintained and automatically activated when the pause period ends.

The CONCHATHERM IV PLUS will arrive from Hudson RCI with the pause time default set at 30 minutes. Adjustment of pause time must be done before placing the CONCHATHERM IV PLUS into the pause mode. When the pause mode is activated, the CONCHATHERM IV PLUS will not allow adjustment of the pause time, airway temperature, or temperature gradient. To adjust pause time, airway temperature and temperature gradient, CONCHATHERM IV PLUS must be removed from the pause mode.

To adjust the pause time, press and hold the PAUSE key. Press the "▲" or "▼" key, located directly over the word TEMPERATURE until the desired setting (5 to 60 minutes, in 5-minute increments) appears on the LED display. Release the PAUSE key.

NOTE: Should the primary memory become corrupted, the CONCHATHERM IV PLUS will revert to the Hudson RCI set pause time default of 30 minutes.

To view the current pause interval, press and hold the PAUSE key. The pause interval will appear on the LED display. Release the PAUSE key.

To activate the pause mode, press and hold the SET key. Press the PAUSE key one time. Release the SET key. CONCHATHERM IV PLUS enters the pause mode (indicated by PAUSE flashing on the LCD and the LED on the pause key flashing).

NOTE: The high-temperature alarm remains in effect during the pause period.

To exit the pause mode, before the designated time interval ends, press and hold the SET key. Press the PAUSE key one time. Release the SET key. CONCHATHERM IV PLUS will return to the warm-up mode, then 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.

To Display Selected Settings

While in operation, the CONCHATHERM IV PLUS displays the **actual** proximal patient airway temperature and temperature gradient readings as measured by the temperature probes. To display the airway temperature and temperature gradient selected by the clinician, press and hold the SET key.

As long as the SET key is pressed, the HEATER's LED will display the selected airway temperature and, if used with a heated-wire circuit, the selected column-to-airway temperature gradient will be displayed on the LCD bar graph. Once the key is released, the displays will resume showing the actual readings for temperature and, if applicable, temperature gradient.

Column Temperature

While in operation, the CONCHATHERM IV PLUS displays the **actual** proximal patient airway temperature as measured by the temperature probe at the circuit wye. To display the temperature of the gas at the column, press and hold the COLUMN TEMP key.

The LED will display the column temperature as long as the COLUMN TEMP key is pressed. Once the key is released, the display will resume showing the actual proximal patient airway temperature.

Alarm Mute

Pressing this key silences the audio alarm for approximately one minute while the clinician corrects the situation, which caused the alarm. During this period, the visual alarm remains activated, and the LED on the alarm mute key flashes. Pressing the ALARM MUTE key again before the end of the mute period reactivates the audible alarm. Pressing SET and RESET simultaneously will also reactivate the audible alarm.

Blank the 0.1 °C Display

The CONCHATHERM IV PLUS has been set at the factory to display temperatures to a single decimal place. To blank the tenths of a degree display, simultaneously press the COLUMN TEMP, TEMP GRADIENT "◄" and RESET keys. Repeat this sequence to restore the 0.1°C display.

When the clinician blanks the tenths of a degree display, the airway temperature will read as follows: if the tenths of a degree are .4 and lower, the temperature will be rounded down and if the tenths are .5 and greater, the temperature will be rounded up to the next degree.

Power Interrupt

In the event of power interruption, once the clinician selects the operating mode, the CONCHATHERM IV PLUS will restore the user settings that were in effect prior to the interruption.

Should the humidifier's memory become corrupted, the humidifier will revert to the Hudson RCI default airway temperature of 35.0 °C, temperature gradient of 0 °C, and pause interval of 30 minutes.

Low-Humidity Advisory

The American National Standards Institute (ANSI) standard for heated humidifiers (Z79.9) requires that units be able to deliver at least 30 mg H_2O per liter of gas. This is equivalent to gas saturated with water vapor (100% relative humidity) at 30 °C. The CONCHATHERM IV PLUS will advise the user of this low-humidity condition by displaying LOW TEMPERATURE on the LCD whenever the column temperature drops below 31°C. The audible alarm will not sound.

NOTE: Setting a positive temperature gradient may invoke this advisory condition. For example, a selected proximal patient airway temperature of

32 °C with a column-to-patient temperature gradient of +3 °C would result in a column temperature of 29 °C, causing the CONCHATHERM IV PLUS to invoke the low-humidity advisory.

Incorrect Mode Selection

The CONCHATHERM IV PLUS has the ability to detect the use of an incompatible circuit for the selected mode of operation (Adult/Infant). An "incompatible circuit" is an infant circuit used with the HEATER in adult mode.

If the clinician selects the adult mode with an infant circuit connected to the device, the CONCHATHERM IV PLUS will detect electrical characteristics or heating patterns other than those normally expected. When this happens, the CONCHATHERM IV PLUS may respond as follows:

- The CONCHATHERM IV PLUS may issue a high- or low-temperature alarm as patient temperatures fluctuate beyond the ±2 °C tracking band.
- The CONCHATHERM IV PLUS may alarm, flashing the Adult prompt on the LCD, indicating that it has detected either an incorrect warming slope within the circuit or an incorrect heated-wire.

It is possible that a non-heated wire infant circuit would appear to function properly for a time as the fluctuating patient temperature remains within the ±2 °C tracking band. Eventually, this situation may be detected with a low-temperature alarm. Throughout this episode, however, high-temperature alarms would always remain in effect.

NOTE: The CONCHATHERM IV PLUS does not attempt to detect the use of an adult circuit in infant mode, as the resulting lower power output does not pose a patient risk. However, an additional warm-up period may be needed at start-up, and heating patterns within the adult circuit during operation may result in a low-temperature alarm. It is important for the clinician to choose and install the correct circuit for the selected mode in order to assure proper humidification delivery.

Gradient Adjustment

The CONCHATHERM IV PLUS is intended to heat and humidify respiratory gases at a proximal patient airway temperature selected by the clinician. In addition, the CONCHATHERM IV PLUS will allow the use of a heated-wire circuit to minimize the condensation or "rainout" within the circuit. However, certain environmental conditions will not allow the CONCHATHERM IV PLUS to maintain both the proximal patient airway temperature and the temperature gradient at the levels entered by the user. Under these conditions, the CONCHATHERM IV PLUS will 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 CONCHATHERM IV PLUS will return to enforcing the selected temperature gradient. The actual column-to-patient gradient will be continuously displayed on the unit's LCD. To view the temperature gradient originally selected by the user press the SET key.

Applications

The CONCHATHERM IV PLUS 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 CONCHATHERM IV PLUS in specific applications.

The CONCHATHERM IV PLUS heated humidifier system 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 IV PLUS heated humidification system 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 "Directions for Use" earlier in this manual).

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 CONCHATHERM IV PLUS is NOT RECOMMENDED in anesthesia applications requiring flows of less than those stated in the "Directions for Use". For additional information, see "Low-Flow Applications" later in this section.

Incubators and Warmers

When setting up the CONCHATHERM IV PLUS 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.

Pediatric Patients

When using the CONCHATHERM IV PLUS with a 15 mm internal diameter pediatric breathing circuit, use the adult mode of operation. Observe all minimum flow requirements associated with use of the device in the adult mode.

Low-Flow Applications

The CONCHATHERM IV PLUS heated humidification system may be used with a heated-wire breathing circuit at the following minimum continuous flows:

Adult Mode: minimum 3 LPM

Infant Mode: minimum 2 LPM

For example, with the CONCHATHERM IV PLUS 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. The CONCHATHERM IV PLUS is NOT RECOMMENDED for use at flows less than those listed above.

When using the CONCHATHERM IV PLUS in low-flow applications, an additional warm-up period may be needed due to the slower heat transfer through the breathing circuit.

Transport Vehicles

Electromagnetic fields generated by communications and emergency equipment found on most medical transport vehicles may affect the performance of the CONCHATHERM IV PLUS. 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 CONCHATHERM IV PLUS in the particular transport vehicle prior to use.

Warning: This unit requires 115 VAC (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 CONCHATHERM IV PLUS 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 IV PLUS 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 CONCHATHERM IV PLUS into service.

Troubleshooting and Maintenance

Alarm Conditions

EMERGENCY (PRIORITY RED) ALARMS: These alarms indicate an emergency condition requiring immediate action by the clinician to prevent possible patient harm. These conditions are indicated by a continuous or flashing red LED and a fast-pulsing audio signal.

Under emergency alarm conditions, the CONCHATHERM IV PLUS turns off power to the heater surrounding the CONCHA-COLUMN and turns off power to the heated-wires, if used. To reset the alarm, turn off power to the CONCHATHERM IV PLUS, correct the problem, wait 60 seconds for the microprocessor to reset and then apply power. Once the operating mode is chosen, power will return to the heating elements of the CONCHATHERM IV PLUS and the unit will begin to warm to the set parameters in effect prior to the alarm condition.

If the recommended action does not correct the problem, remove the CONCHATHERM IV PLUS from use (see "Service and Repairs" section).

LCD Alarm Display	Alarm Condition(s)	Possible Cause(s)	Recommended Action
HIGH TEMP (also see "Cautionary" HIGH TEMP Alarms)	1. High temperature at the column outlet[7]	1a. Low or no flow through the column or reservoir 1b. Low water level in the column or reservoir	1a. Correct the low or no flow condition. 1b. Replace water reservoir and/or column.
CHECK PROBE	1. Improper temperature probe input 2. Unit senses temperature patterns inconsistent with normal operation	1. Temperature probe dislodged or fallen out of breathing circuit 2. Unit turned off briefly instead of using pause mode	1. Insert probe into the breathing circuit. 2. Turn unit off, allow the unit to cool 5-10 minutes, then restart.
BAD PROBE	Open circuit or short circuit in temperature probe input	1. Temperature probe not properly connected to CONCHATHERM IV PLUS 2. Temperature probe failure	1. Turn unit off for 60 seconds. Properly connect the temperature probe to the CONCHA-THERM IV PLUS and turn unit back on. 2. Replace temperature probe.
ADULT	1. Improper temperatures from breathing circuit as it heats 2. Improper wire detected (heated-wire circuit only)	1a. Wrong breathing circuit attached, i.e., infant circuit used in adult mode 1b. Wrong mode selected for the application 2a. Wrong breathing circuit attached, i.e., infant circuit used in adult mode 2b. Incompatible circuit	1. Turn unit off for 60 seconds. Turn back on and select the proper operating mode. 2. Replace the circuit with the compatible Hudson RCI circuit.
INSP. WIRE and DISCONNECT	Interruption in the inspiratory wire signal	1. Inspiratory heated-wire has become disconnected from the CONCHATHERM IV PLUS 2. Incompatible heated-wire circuit used 3. Broken inspiratory heated-wire	1. Reconnect inspiratory wire. 2. Replace with Hudson RCI circuit. 3. Replace circuit.
SERVICE	CONCHATHERM IV PLUS failure or self diagnostic test	Equipment failure	Remove the CONCHATHERM IV PLUS from use.[8]

[7] Temperatures at which the CONCHATHERM IV PLUS will alarm vary depending upon operating mode.

[8] "Service" alarms indicate an equipment problem with the CONCHATHERM IV PLUS itself and cannot be reset using the SET and RESET keys. Should a service alarm be displayed, always remove the CONCHATHERM IV PLUS from service until the unit can be repaired or corrected.

CAUTIONARY (PRIORITY YELLOW) ALARMS: These alarms indicate a condition requiring caution or a check on the part of the clinician. These conditions are indicated by a continuous or flashing yellow LED and a slower-pulsing audio signal, when the condition is present.[9]

When Cautionary HIGH TEMP Alarms result from a proximal patient airway temperature greater than 2.0 °C above the set airway temperature, the CONCHATHERM IV PLUS will continue to have power available to control the temperature within ±2 °C. Once the proximal patient airway temperature decreases to within 2.0 °C, the audible HIGH TEMP alarm will be deactivated. The HIGH TEMP indicator and the Yellow LED light will continue to flash notifying the clinician a high temperature condition occurred. To clear the visual alarms, press SET and RESET.

When Cautionary HIGH TEMP Alarms result from a proximal patient airway temperature of greater than 41.0 °C, the CONCHATHERM IV PLUS will turn off the power and the control function to the HEATER and the heated-wires. Once the proximal patient airway temperature decreases to below 41.0 °C, the unit will return the power and the control function to the HEATER and the wires and deactivate the audible HIGH TEMP alarm. The unit will begin to warm up to the selected parameters in effect prior to the alarm condition. The HIGH TEMP indicator and the Yellow LED light will continue to flash notifying the clinician a high temperature condition occurred. To clear the visual alarms, press SET and RESET.

During cautionary LOW TEMP alarms, once the problem has been corrected, the alarm will automatically reset and the unit will return to normal operation.

The other alarms can be reset by pressing SET and RESET simultaneously.

Unless otherwise noted, under cautionary alarm conditions, the HEATER continues to control heat to the CONCHA-COLUMN and the heated-wires in the breathing circuit, if used.

If the recommended action does not correct the problem, remove the CONCHATHERM IV PLUS from service.

[9] The "low humidity" advisory is NOT accompanied by an audible alarm.

LCD Alarm Display	Alarm Condition(s)	Possible Cause(s)	Recommended Action
HIGH TEMP (also see "Emergency" HIGH TEMP Alarms)	1a. Proximal patient airway temperature over 41.0 °C 1b. Proximal airway temperature greater than 2.0 °C above the selected airway temperature 1c. Proximal airway temperature exceeded limit of backup alarm 2. Improper temperature probe input	1. Airway temperature improperly set for ambient and/or ventilatory conditions 2. Temperature probe dislodged or affected by external heat source	1a. Set the CONCHATHERM IV PLUS to the proper temperature. 1b. Set the CONCHATHERM IV PLUS to the proper temperature. 1c. Turn unit off for 60 seconds. Turn back on and set the unit to the proper temperature. 2. Reposition or reinsert probe.
ADULT INFANT	Unit has not entered an operating mode.[10]	Operator failed to select an operating mode (adult or infant) within five minutes of turning on the power	Select an operating mode using the SET and ADULT/INFANT keys.
LOW TEMP	1. Proximal airway temperature more than 2.0 °C below the selected airway temperature. 2. Improper temperature probe input 3. Improper temperatures from the breathing circuit as it heats 4. Column has dropped below the temperature at which effective levels of humidity can be delivered ("low humidity" advisory)[9]	1a. Unit has not yet warmed up to operating temperature due to unusual environmental or ventilatory conditions 1b. Low or no flow through the breathing system 1c. Environmental conditions outside the operating range of the unit 2a. Temperature probe dislodged or fallen out of breathing circuit 2b. Temperature probe placed into the breathing circuit incorrectly 3. Wrong mode selected or wrong breathing circuit attached, i.e., infant circuit used in adult mode 4. Airway temperature improperly set for ambient and/or ventilatory conditions	1a. Initiate an additional warm-up period. 1b. Correct the low or no flow condition. 1c. Correct environmental conditions if possible. 2a. Insert probe into the breathing circuit. 2b. Place the (long-cabled) patient probe in the inspiratory side of the patient wye and the (short-cabled) column probe at the column outlet. 3. Turn unit off for 60 seconds. Turn unit on and select the proper operating mode. 4. Set the CONCHATHERM IV PLUS to the proper temperature.
EXP. WIRE and DISCONNECT	Interruption in the expiratory wire signal	1. Expiratory heated-wire has become disconnected from the CONCHATHERM IV PLUS 2. Incompatible heated-wire circuit used 3. Broken expiratory heated-wire	1. Reconnect expiratory wire. 2. Replace with Hudson RCI circuit. 3. Replace circuit.

[9] The "low humidity" advisory is NOT accompanied by an audible alarm.

[10] NOTE: The HEATER will NOT begin heating until an operating mode has been selected and the 60-second mode selection period has expired.

Operating Conditions

Should the CONCHATHERM IV PLUS 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.

Symptom(s) or Problem	Possible Cause(s)	Recommended Action
All displays on the unit are blank	1. Power cord not connected to power outlet 2. Power switch not turned "ON" ("I") 3. Blown power fuse 4. Blown internal fuse	1. Connect cord to power outlet. Verify power to outlet. 2. Turn on power switch. 3. Replace power fuse located on bottom panel. 4. Return the unit for service.
Bar graph display on the LCD is blank	1. Heated wire(s) from the breathing-circuit not connected to the CONCHATHERM IV PLUS 2. Incompatible heated-wire circuit used	1. Connect heated wire(s). 2. Replace with Hudson RCI circuit.
Unit not heating	1. Operator failed to select an operating mode (adult or infant). NOTE: Unit will begin alarming within five minutes of turning on the power. 2. Internal malfunction, usually accompanied by a service alarm	1. Select an operating mode using the SET and ADULT/INFANT keys. 2. Return the unit for service.
Proximal patient airway temperature will not set below 30 °C or above 39 °C	Settings outside the CONCHATHERM-IV PLUS operating range	Select a temperature within the operating range
RESET key does not clear alarm	1. Incorrect use of SET and RESET keys 2. Proximal airway temperature exceeded limit of backup high temperature alarm 3. Temperature probe not properly connected to CONCHATHERM IV PLUS 4. Unit displaying "Service" alarm condition	1. Press both SET and RESET keys simultaneously. 2. Turn unit off for 60 seconds to clear alarm condition. Turn unit back on. 3. Turn unit off for 60 seconds. Properly connect the temperature probe to the CONCHATHERM IV PLUS and turn unit back on. 4. Remove the CONCHATHERM IV PLUS from use.
CONCHATHERM IV Plus does not retain user defined settings and Hudson RCI defaults are shown.	1. Patient mode not selected. 2. Did not allow 10 seconds of keypad inactivity for humidifier to write settings into microprocessor memory	1. Always identify patient mode upon activation of CONCHATHERM IV Plus. 2. Define settings for proximal airway temperature, temperature gradient and pause time. Allow 10 seconds of keypad activity for humidifier to write settings into microprocessor's memory.
Sudden power failure 1. Less than 60 seconds 2. Greater than 60 seconds	1. Power switch inadvertently turned off or power cord inadvertently removed from power outlet 2. Interruption of main power	1. Return power to CONCHATHERM IV PLUS. HEATER will return to user defined settings for proximal patient airway temperature, temperature gradient and pause time. 2. Return power to CONCHATHERM IV PLUS. Enter the operating mode to return to user defined settings for proximal patient airway temperature, temperature gradient, and pause time. 3. If the CONCHATHERM IV PLUS was in the pause mode prior to the power failure, return power to the HEATER. Enter the operating mode to return to user defined settings, and press SET and PAUSE to activate the pause mode.

Routine Checks

1. Observe the condensation levels in the breathing circuit with every ventilator circuit 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 CONCHA-COLUMN and heater may be HOT (as high as 140 °C). Allow the CONCHA-COLUMN and heater to cool before handling.

3. Check the water reservoir for adequate sterile water supply. A water supply at or below the replacement line on the reservoir may cause erratic temperature fluctuations.

   The reservoir can be replaced at any time without interrupting the gas flow.

   To change the water reservoir:

   a. Close all clamps leading to the CONCHA-COLUMN and remove the upper puncture pin from the reservoir.

   b. Carefully remove the reservoir from its holder and lower the reservoir to a level below the CONCHA-COLUMN. Orient the reservoir so that the holes are on top. Remove the lower puncture pin from the reservoir.

   c. Discard the used reservoir and place a new CONCHA sterile water reservoir in the reservoir bracket.

   d. 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.

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

   NOTE: These instructions are also provided with each CONCHA-COLUMN.

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

4. Check the digital temperature display on the CONCHATHERM IV PLUS heater whenever making any adjustments to the setup.
5. Check the LCD display 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 the instructions included with the probe.

Routine Maintenance

The CONCHATHERM IV PLUS continuously performs self-diagnostic checks during operation. Should the unit malfunction, the CONCHATHERM IV PLUS will shut off power and display a "Service" code on the LED display (also see "Troubleshooting"). Check the power cord regularly for damage. Immediately remove from service any CONCHATHERM IV PLUS which shows signs of overheating, smoking or electrical malfunction.

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

To replace the power fuse:

1. Using a slotted screw-driver, turn the knob on the fuse holder (located on the bottom of the CONCHATHERM IV PLUS) one-quarter turn counterclockwise.
2. Pull the fuse holder out of the unit and remove the blown fuse. Do not discard the holder.
3. Press the new fuse into the clip on the holder and replace the holder into the unit using a slotted screwdriver.

Fuse type: 4-amp 125 VAC
5 x 20 mm time-delayed

Service and Repairs

If your CONCHATHERM IV PLUS requires service and repairs, contact the Hudson RCI Customer Service Department at 1-800-848-3766 or 1-909-676-5611.

Repair of leased heaters:

Your Hudson RCI customer service representative will assist you in obtaining a Hudson RCI remanufactured or replacement heater for your CONCHATHERM IV PLUS.

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:

Hudson RCI 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 Hudson RCI remanufactured or replacement heater for your CONCHATHERM IV PLUS. 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 CONCHATHERM IV PLUS warranty.

Limited Warranty Statement

I. WHAT THE WARRANTY COVERS AND FOR HOW LONG

Hudson Respiratory Care Inc. ("HUDSON RCI") warrants the Cat. No. 400-50 CONCHATHERM IV PLUS ("Product") against defects in material and workmanship under normal use and service for a period of one (1) year from the date of purchase.

Hudson RCI, at its option, will at no charge either repair the Product (with new or reconditioned parts), 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 Hudson RCI.

This expressed limited warranty is extended by Hudson RCI 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 Hudson RCI. Hudson RCI assumes no obligations or liability for additions or modifications to this warranty unless made in writing and signed by an officer of Hudson RCI. Hudson RCI does not warrant the installation, maintenance or service of the Product.

Hudson RCI cannot be responsible in any way for any ancillary equipment not furnished by HUDSON RCI, which is attached to or used in connection with the Product. Because each system, which may use the Product, is unique, Hudson RCI disclaims liability for range, coverage, or operation of the system as a whole under this warranty.

II GENERAL PROVISIONS

This warranty sets forth the full extent of Hudson RCI'S responsibility regarding the Product, repair or replacement, at Hudson RCI's option, is the exclusive remedy. THIS WARRANTY IS GIVEN IN LIEU OF ALL OTHER EXPRESSED 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 HUDSON RCI BE LIABLE FOR DAMAGES IN EXCESS OF THE PURCHASE PRICE OF THE PRODUCT, FOR ANY LOSS OF USE, LOSS OF TIME, INCONVENIENCE, COMMERCIAL LOSS, LOST CONSEQUENTIAL DAMAGES, ARISING OUT OF THE USE OR INABILITY TO USE SUCH PRODUCT, TO THE FULL EXTENT SUCH MAY BE DISCLAIMED BY LAW.

III. 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.

IV. 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 Hudson RCI or through an authorized Hudson RCI service center. If you first contact the company, which sold you the Product (e.g. Hudson RCI Distributor), it can facilitate your obtaining warranty service. You can also call Hudson RCI at 1-800-848-3766 for warranty service information.

V. 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 audition to the Product of non-Hudson RCI supplied equipment) which adversely affects performance of the Product or interferes with Hudson RCI's normal warranty inspection and testing of the Product to verify any warranty claim.

e. Product, which 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 effect the operation of the Product.

h. Normal and customary wear and tear