ThermaSolutions

ThermoChem™ HT-1000 System

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ThermoChem™ is a trademark of ThermaSolutions

The ThermoChem™ HT-1000 System is protected under the U.S. and International patents pending.

CAUTION:

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

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General Warnings and Precautions

Read the entire Operator's Manual before trying to operate the unit. Failure to read the manual could result in harmful effects to the user, patient, and/or machine.

This manual includes **NOTES**, which emphasize special cases involving the procedure at hand.

This Manual includes **CAUTIONS**, which emphasize special cases that could result in serious damage to equipment.

This Manual includes **WARNINGS**, which emphasize special cases that could result in serious injury and/or death.

CAUTION: If using a physiological compatible sterile solution other than Lactated Ringer's Solution, please follow that manufacturers recommended labeling regarding handling and disposal.

The ThermoChem HT-1000 is rated "Type B" in accordance with IEC60601-1, 2nd edition 1988 and Amendments 1 and 2.

WARNING: Do not use an electrocautery or other electrosurgical devices in the patient when connected to the ThermoChem HT-1000.

This Manual contains a System Specifications section which will alert operators to the environmental conditions under which the ThermoChem™ HT-1000 System is used and stored.

Do not fog or humidify the ThermoChem HT-1000 under any circumstances. If disinfection of the device needs to occur, please refer to the appropriate section of the Cleaning and Disinfection Manual.

Do not fog or humidify the operating room while the ThermoChem HT-1000 is inside the room. If the operating room is to be fogged or humidified, remove the ThermoChem HT-1000 from the room before and during the procedure.

Symbols for General Warnings

Attention, see instructions for use

Method of sterilization, ethylene oxide

Type B applied part complying with the specific requirements of the standard IEC60601-1 to provide protection against electrical shock, particularly regarding allowable leakage current. Not suitable for direct cardiac application.

Do not reuse

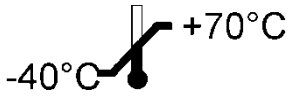
Date of manufacture

YYYY-MM

SN

Serial number

Alternating current



Storage temperature range

Protective earth (grounded)

The ThermoChem™ HT-1000 System

Indications for Use

The intended use of the ThermoChem™ HT-1000 System is to raise the core temperature of the peritoneum to a desired target temperature by continuously lavaging the peritoneum with circulating and warmed Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution.

Contraindications

Patient selection for intraperitoneal hyperthermia is based on medical judgment and is at the discretion of the attending physician.

Shipping Crate Contents

The following components are contained in the shipping crate:

- ThermoChem™ Unit
- Touchscreen Monitor
- I.V. Hanger Assembly
- Operators Manual
- ThermoChem Cleaning and Disinfection Manual
- Accessories:
  - Fluid Reservoir holder
  - Heat Exchanger holder
  - 5/32", 3/16" Allen wrench
  - #2 Phillips Screwdriver
  - Three (3) Non-disposable temperature probe extension cables
  - AC power cord
  - Two (2) Heat Exchanger probes
  - Two (2) Water lines

Preparing the ThermoChem™ HT-1000 System

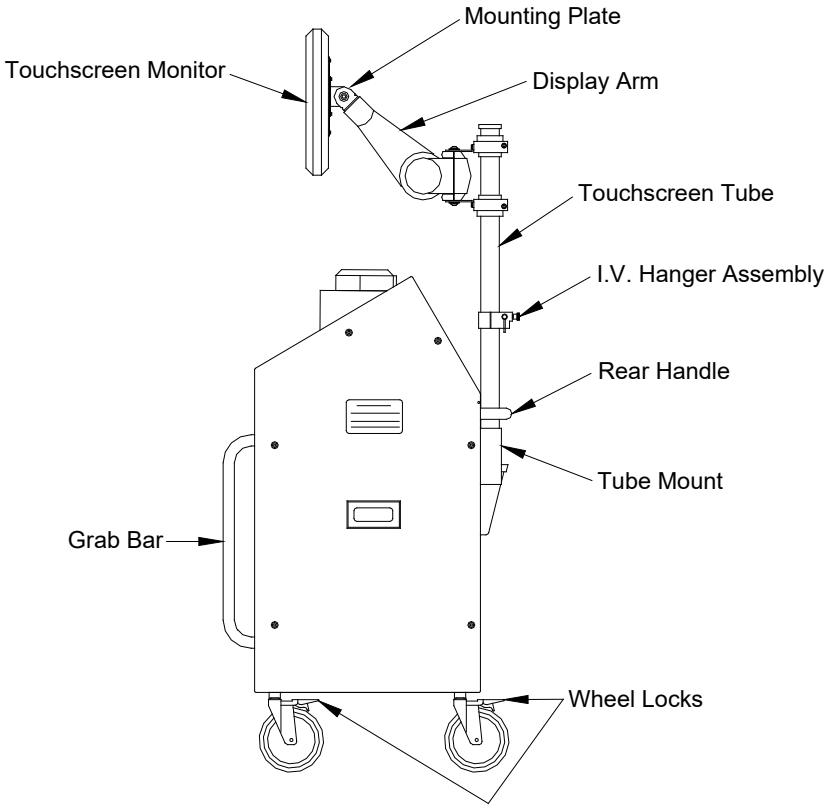


Figure 1: Right view of the ThermoChem™ Unit

Assembly Procedure

1. Remove the unit, accessories, and packing list from the shipping crate.

2. Using foot, engage the locking device on each wheel. Do not use your hands to engage the locking device.

   NOTE: *Keep wheels locked while assembling unit.*

3. Lift the touchscreen tube from its current position so that it is flush with the bottom of the tube mount and rotate the display arm so that the mounting plate faces forward. Secure the touchscreen tube using 5/32" Allen wrench to tighten the screws.

4. Using the 3/16” Allen wrench, adjust the I.V. Hanger Assembly on the touchscreen tube, as needed.

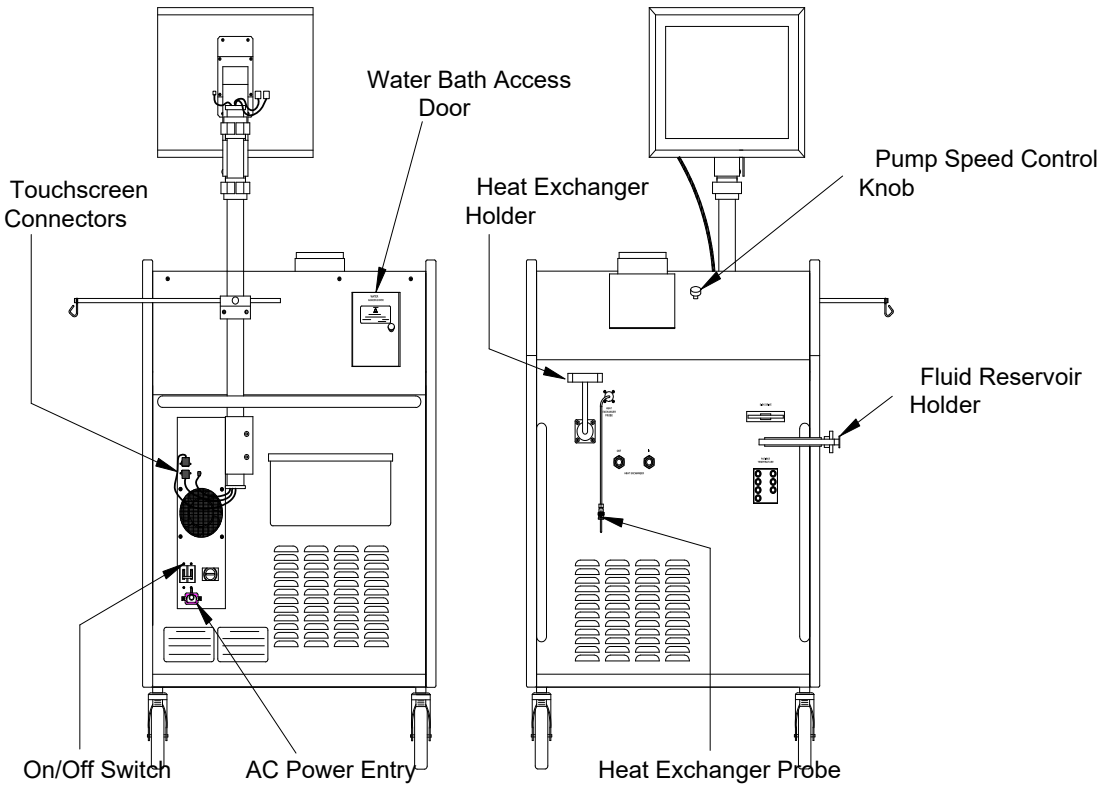


Figure 2: Rear and Front views of the ThermoChem™ Unit

5. Attach the touchscreen to the mounting plate located on the front of the display arm. Use a #2 Phillips Screwdriver to tighten the screws.

6. Connect the touchscreen cables to the appropriate connectors on both the touchscreen, and the rear of the unit.

7. Using a Phillips screwdriver, loosen the strain relief top adjustment screw of the AC power entry.

8. Insert the AC power cord into the unit and tighten the adjustment screw.

9. Facing the device, attach the fluid reservoir holder to the right-side grab bar and tighten the knob.

   NOTE: *The fluid reservoir holder may be placed anywhere on the grab bar. A lower position on the grab bar will increase the speed of drainage.*

10. Attach the heat exchanger holder to the unit positioning it up and to the left, and then tighten the knob.

    NOTE: *The proper location for the heat exchanger holder is labeled on the front of the unit.*

11. Attach the heat exchanger probe to the unit.

    NOTE: *The proper location for the heat exchanger probe is labeled on the front of the unit.*

CAUTION:

Use only distilled or sterile water. Do not use deionized water. The majority of deionizers do not maintain a neutral pH of 7. Using deionized water may damage the refrigeration system.

12. Open the water bath access door on the rear of the unit.

13. Fill the Heater/Cooler unit with 6 liters distilled or sterile water.

14. Set up roller pump occlusion. See Roller Pump Occlusion Adjustment Procedure on page 28.

15. The unit is now ready for use.

Powering and System Start-UP

1. Using foot, engage the locking device on each wheel. Do not use your hands to engage the locking device.

   NOTE: *Keep wheels locked during treatment to eliminate any movement of the unit.*

> **CAUTION:**
>
> Before plugging in, the POWER switch must be in the OFF position and the power cord properly connected to the back of the machine. This will prevent any power surges to the unit.

2. Plug the power cord into an approved power source:

   US – 120V/60Hz 20A.

   EU – 230V/50Hz 10A.

3. Rotate the roller pump speed control knob fully counterclockwise to ensure that the roller pump is off.

4. Apply power by setting the ON/OFF switch on the back of the unit to the ON position.

   NOTE: *For approximately 60 seconds the machine will perform a start-up system test. Diagnostic testing is performed internally on all electronic monitors and controllers to verify correct function.*

5. If desired and or available, a blank 3.5", 1.44 MB, IBM compatible floppy disk may be inserted into the disk drive.

6. The unit is now ready for disposable installation.

Procedure Kit and Contents

IPH Perfusion Kit (herein referred to as Disposables)

A typical disposable kit may contain:

- One (1) IPH circuit
- One (1) recirculation line with stopcock.
- One (1) IPH Table Pack or sterile components for patient connection
  - Inflow Catheters/Outflow Catheters
  - Inflow Tube assembly
  - Return Tube assembly
- Return Guards (Suction Guards)
- Temperature Probes (Myocardial or General)
- One (1) Pressure Sensor (for HT-2000 model)
- One (1) Instruction for Use

WARNING:

Disposables not used during the procedure MUST be discarded.

CAUTION:

Do not use if sterile packaging is damaged or appears damaged. Damaged packaging could compromise the sterility of the materials.

Installation Procedure

1. Remove IPH Procedure Kit from outside container and visually inspect that it is sealed and that there is no visible or apparent damage.

WARNING:

If package is damaged, DO NOT use. Replace with new pack and notify customer service.

2. Follow the Instructions for Use contained in your specific IPH Procedure Kit to mount the kit to the device.

3. Check that all connections and caps are tight.

4. Check that the clamp on drain line has been closed.

5. Touch the **SCREEN** to move to the "Main" screen.

NOTE: *At this time the heater/cooler will begin to circulate fluid.*

6. Visually inspect the heat exchanger and tubing to ensure that no fluid is present.

CAUTION:

If fluid is visible anywhere in the disposable, the heat exchanger is faulty, and the pack must be replaced. Notify Customer Service.

WARNING:

Only IPH Procedure kits supplied by ThermaSolutions are to be used with the ThermoChem™ HT-1000.

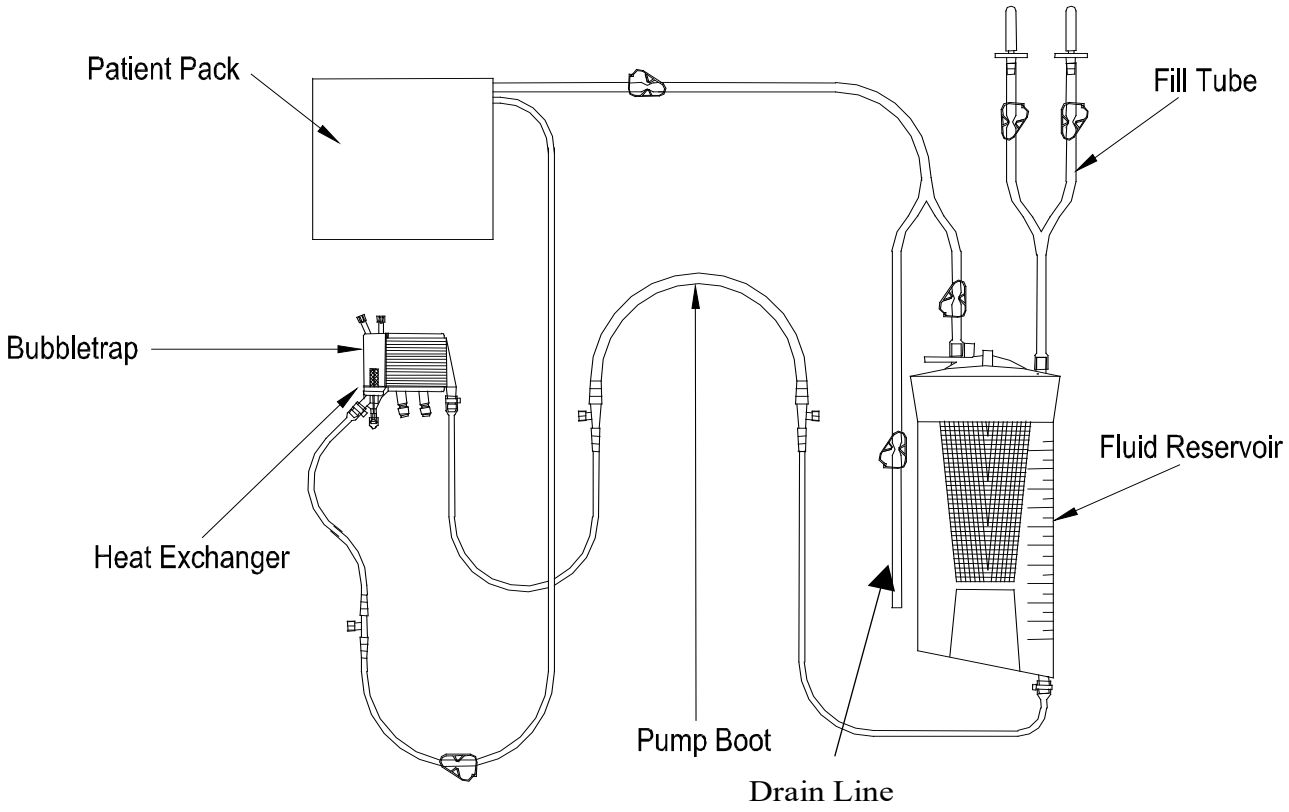


Figure 3: IPH Disposable Kit

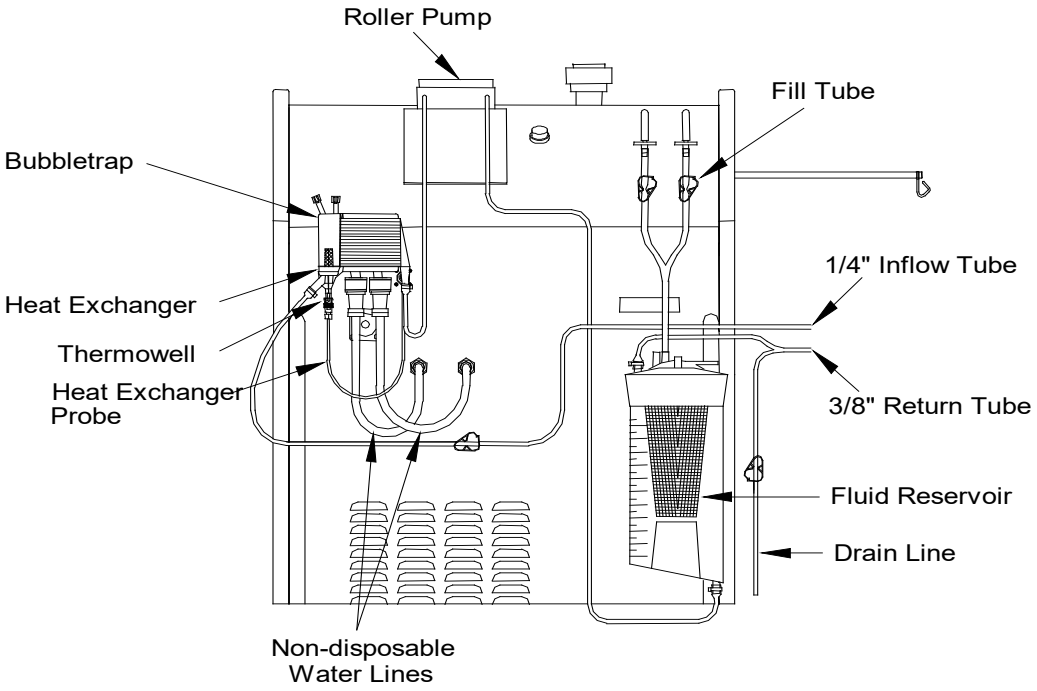


Figure 4: IPH Disposable Kit on Unit

7. **Circuit Priming**

1. If not already completed, prime the Disposable.

2. Hang Lactated Ringers U.S.P. or another physiologically compatible sterile solution from the I.V. hanger.

3. Spike the bag utilizing spikes on the fill tube and allow fluid to drain into the fluid reservoir. If using only one spike, clamp unused spike tube.

4. Clamp spike on fill tube after all fluid is drained into reservoir.

5. Touch the **H_2O SET POINT** icon on the touchscreen monitor.

6. Set the water bath temperature by selecting 45°C.

7. Touch the **ACCEPT** icon.

8. Slowly rotate roller pump speed control knob clockwise and begin circuit priming.

9. Start the roller pump and adjust speed to approximately 800 ml/min.

10. Gently hand-tap the heat exchanger to ensure all air has escaped.

11. Allow fluid to recirculate within the disposable tubing set.

NOTE: *Heat exchanger temperature should not exceed 43°C.*

Entering Patient Information

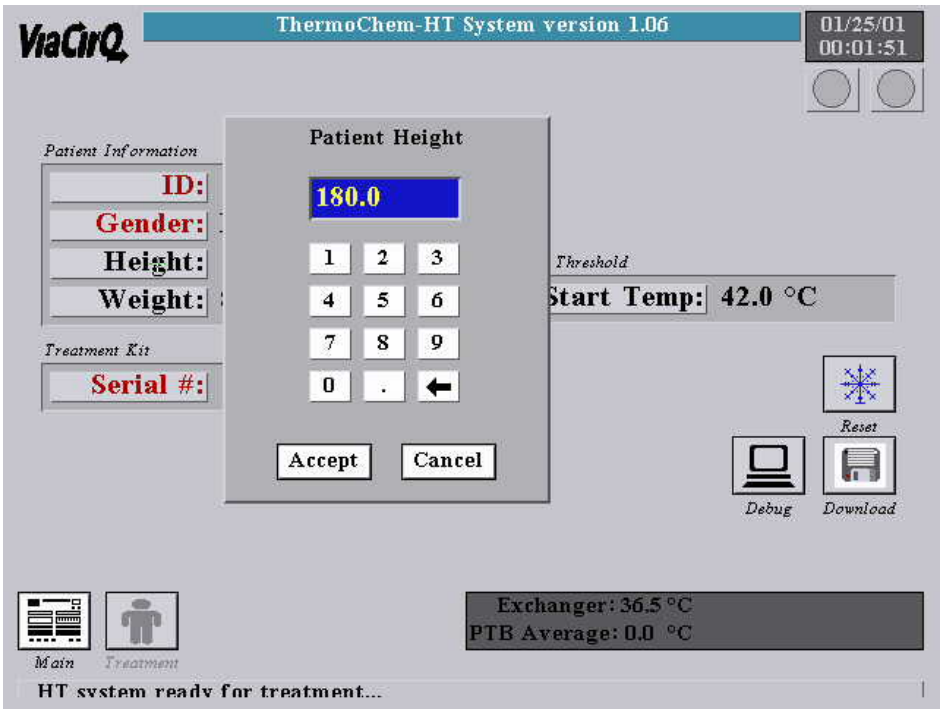


Figure 5: Patient Data Screen

1. Touch the **TREATMENT** icon to enter the patient data. Touch icons for **ID**, **GENDER**, **HEIGHT**, **WEIGHT**, and **START TEMP** to supply patient data.

2. Touch the **SERIAL #** icon and enter in the serial or lot # from IPH Disposable Treatment Kit.

3. Touch the **MAIN** icon to return to the previous screen.

Patient Connection

WARNING:

The following steps must be performed using an aseptic technique. Failure to do so can contaminate the sterile field.

1. Follow the Instructions For Use for your specific Disposable to ensure proper connection of the inflow and outflow tubing to the patient.

2. Follow the Instructions For Use for you specific Disposable to properly and safely place the patient temperature probes.

Temperature Probe Setup

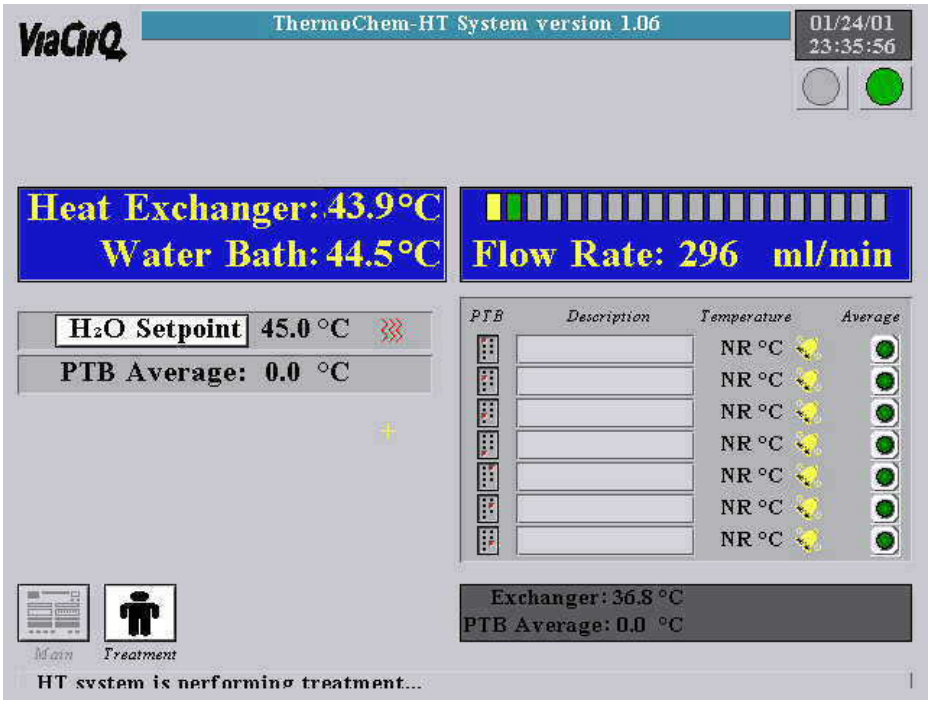


Figure 6: Main Screen

1. Ensure that temperature probes are correctly placed to monitor inflow/outflow or patient temperatures.

Caution:

If the temperature probe is contained with a sharp (ex. Myocardial temperature probe), use caution when handling and when placing in/near patient.

WARNING:

The use of the unit is designed to work with disposable temperature probes supplied by ThermaSolutions Use of others could result in harm to the patient.

2. Have sterile personnel pass the temperature probe connection end out of the sterile field.

3. Attach the temperature probe cable to the non-disposable temperature probe extension cable.

4. Plug the non-disposable temperature probe extension cable into the ThermoChem™ HT-1000 temperature block located on front of device.

NOTE: *If probe temp is > 37°C when probe is connected to the unit, a "Patient Temperature Probe Notice" message will appear along with the display of the probe temperature.*

5. Touch probe **DESCRIPTION** box on main screen to set probe identification information.

6. Identify the appropriate temperature probe location by touching the **PROBE IDENTIFICATION** label icon on the screen.

NOTE: *A window will appear containing a list of predefined labels.*

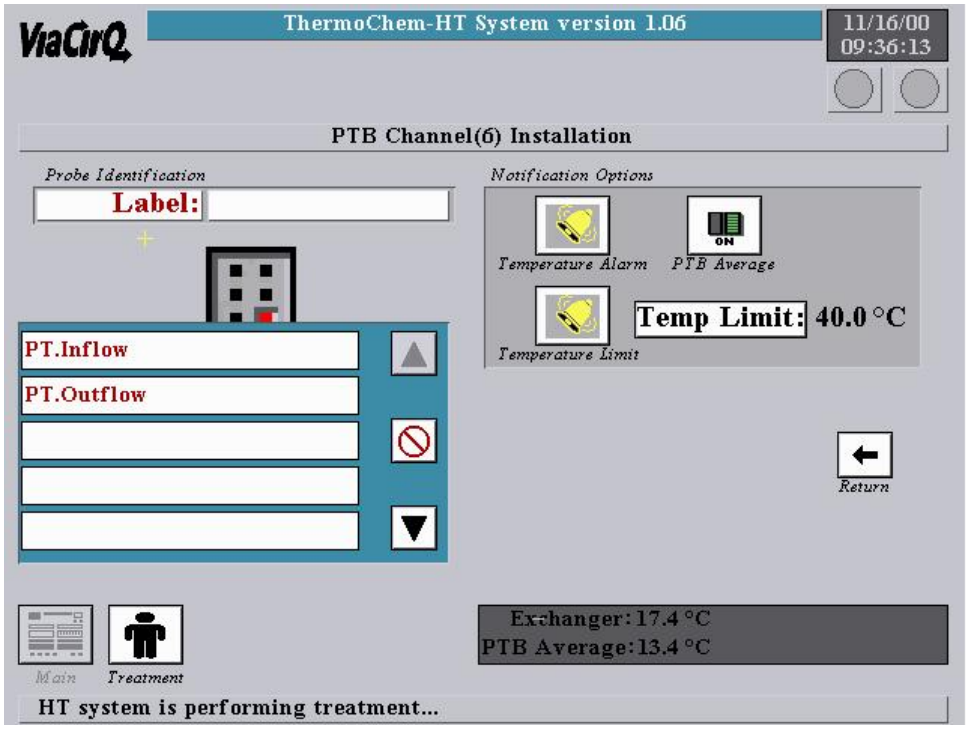


Figure 7: Label Selection Screen.

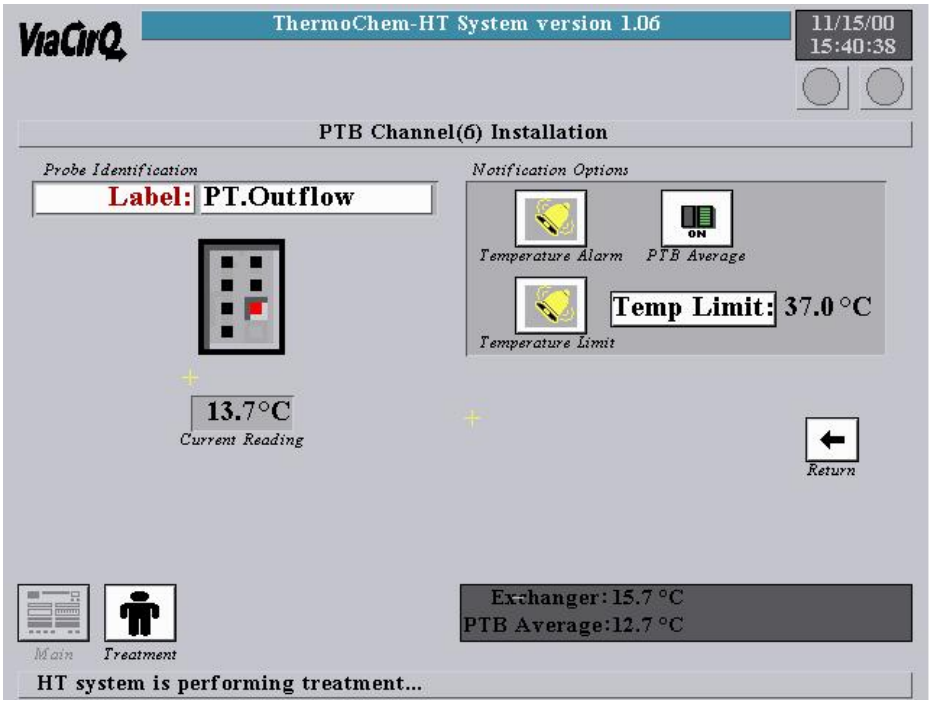


Figure 8: Temperature Probe Screen.

7. Select the appropriate corresponding label on the screen.

   NOTE: *Custom labels may be entered for monitoring locations not available on the predefined list as follows: For **USER DEFINED** labels, touch box to the right of label and enter desired label using keyboard. Touch **ACCEPT** when complete.*

8. Set the temperature alert by touching the **TEMP LIMIT** icon and set the desired temperature to alert.

9. Touch **ACCEPT**.

10. Select notification options by touching desired icons.

11. Touch **RETURN**.

12. Repeat the process steps 2 through 11 for the outflow probe and any other temperature probes in use.

13. Stop the roller pump by turning roller pump speed control knob counterclockwise and turn the stopcock OFF to the heat exchanger.

Initiating Treatment

CAUTION:

Disposable installation, circuit priming procedures, and temperature probe setup must be completed prior to initiating treatment. Failure to thoroughly follow the set-up instructions will prevent the unit from operating properly.

WARNING:

If a malfunction occurs or the patient needs immediate attention, shut off the roller pump by turning the pump speed control knob fully counter-clockwise, thereby suspending treatment.

1. Release all clamps on the inflow and outflow lines.

   NOTE: *Ensure that clamp on drain line remains closed.*

2. Turn the roller pump speed control knob clockwise and verify that fluid flows.

3. Slowly increase the roller pump speed until the target flow rate is achieved.

4. Ensure that the H2O SET POINT is set to 45°C

5. Once patient temperatures approach the temperature target, adjust **H_2O SET POINT** to maintain the target temperature.

   NOTE: *At the beginning of treatment and periodically throughout, observe the entire circuit to make sure there are no leaks, kinks, or restrictions that would interfere with fluid flow. Monitor patient and fluid temperatures and adjust accordingly to maintain the target temperature.*

6. Respond to any alerts during treatment.

7. After treatment period is complete, stop the roller pump, and clamp the 3/8” (.953cm) tube above the fluid reservoir.

8. Hang Lactated Ringers U.S.P. or other physiologically compatible sterile solution(s) from the I.V. pole.

9. Ensure the clamp on fill tube is closed then spike the bag(s) with the spikes

located on fill tube.

10. Place drain tube in proper hospital waste container.

11. Open clamp on drain tube.

12. Start the roller pump and slowly allow reservoir to drain.

13. Stop the roller pump when only a small amount of fluid remains in the reservoir.

14. Open the clamp on the fill tube and allow fluid to drain into reservoir.

15. At physician's direction start pump and allow all fluid to be pumped from the reservoir and inflow line.

16. When inflow line is empty, stop the roller pump and clamp ALL lines.

Downloading Patient Data

NOTE: *If the option to use a disk was selected, it is possible to download the patient session data to a floppy disk. Use the "Download" icon located on the Treatment screen. Be sure there is a disk in the floppy drive. Downloading must be completed prior to disposable removal.*

1. Insert a blank IBM formatted 3.5 inch, 1.44 MB floppy diskette into the floppy drive. If the 3.5 inch drive is not accessible from the front of your model, remove the right side panel to access drive.

CAUTION:

Be careful when removing the side panel to access the 3.5 inch drive. Live electrical current is present in the interior of the device, and can pose a shocking or electrocution hazard.

2. Rotate the roller pump speed control knob counter-clockwise until the roller pump stops.

3. Wait for the flow rate reading on the main screen to drop to zero.

4. Wait for the status message at the bottom of the screen to change to "HT system is ready for treatment".

5. Touch the **TREATMENT** icon.

6. The **DOWNLOAD** icon must not have a red Ø on it. If it does, repeat from step 2.

7.

CAUTION:

If the diskette contains prior treatment session data and there is insufficient memory on the disk for the new data, the data will be lost. A single diskette normally can hold data for six 6-hour treatment sessions.

Touch the **DOWNLOAD** icon.

8. Touch the **ACCEPT** icon. The status message at the bottom of the screen will change to, "Downloading Data . . .".

NOTE: *The green light on the floppy drive will illuminate.*

CAUTION:

Do not remove the disk while the green light is on.

9. Wait for the status message at the bottom of the screen to change to: "Data Download Complete" and the green light on the floppy drive to extinguish.

10. Wait for the status message at the bottom of the screen to change to: "HT system ready for treatment".

11. The unit is now ready for disposable removal.

Shutting Down the ThermoChem™ System

Disposable Removal

1. Power down the unit by setting the ON/OFF switch on the back of the unit to OFF.

2. Have sterile personnel clamp the fluid tubes near the catheters.

3. Disconnect the patient temperature probes.

4. Remove the heat exchanger probe from the heat exchanger.

5. Have sterile personnel disconnect the fluid tubes from the patient catheter and allow sterile personnel to pass tubes off the field.

6. Disconnect water lines from machine.

7. Remove heat exchanger from machine.

WARNING:

Water bath fluid hoses and connectors are hot and may present a scald hazard. Do not disconnect water bath hoses while unit is at operating temperature or powered on with the primary pump circulating water.

8. While holding heat exchanger and hoses over a water container, remove hoses from heat exchanger and drain into container.

9. Remove the tubing from the roller pump.

10. Remove the fluid reservoir from its holder.

11. Discard the disposables in accordance with hospital disposal policy.

Note: The water reservoir should be drained after every use.

Draining the Reservoir:

1. Attach the heat exchanger hose to the heat exchanger inlet connection, designated by red color, on the front panel.

2. Direct the hose discharge into an empty container capable of holding at least six (6) liters of fluid.

3. Turn the unit on.

4. Touch main **SCREEN** to move to the connect sequence.

   NOTE: *The unit will pump the water into the container.*

   NOTE: *The Water Bath is Too Low error message will appear.*

5. Turn the unit off when water stops flowing.

   NOTE: *The reservoir is now empty.*

6. Disconnect the heat exchanger inlet hose.

Exterior Cleanup

Monitor: Only use cleaners that are approved safe for use on touchscreen monitor. Disposable cleaning wipes, approved for use on monitors and screens are preferred. Never apply liquid or sprays directly to the screen of the device. Always utilize a clean, abrasion-free cloth when cleaning the monitor screen. Apply liquids or sprays to the cleaning cloth, not directly to the screen. Use the cloth to gently wipe the monitor screen. Any residual cleaner on the screen should be removed with a clean, dry abrasion-free cloth. Isopropyl alcohol wipes (35% to 70%) can be used if other cleaning solutions are not available.

Outer surfaces of the device: Wipe all outer surfaces of the ThermoChem unit using a surface cleaning solution listed as “compatible” for use on stainless steel. Cleaning solutions that are approved for use on blood borne pathogens should be used. Never apply cleaners directly to the device. Apply liquids or sprays to a clean, abrasion-free cloth, and gently wipe the device. Any residual cleaner should be removed with a clean, dry abrasion-free cloth. A solution of 1 part chlorine bleach to 50 parts water can be used if other compatible cleaning solutions are not available.

Troubleshooting

Clearing Alerts

Error alerts are displayed in the fault message area at the upper area of the screen along with an error message and/or the code number.

Touch the CLEAR icon displayed along with the message to clear an alert.

Any additional alert conditions, if they exist, will appear in the same manner. If alerts cannot be cleared, discontinue use and notify Customer Service.

Restarting after System Failure

CAUTION:

After performing a power-off restart, the operator must re-enter the water bath temperature, patient parameter data, patient temperature probe labels, and patient temperature probe alarm set-points.

The following power-off restart steps should be performed if the start-up system test fails and it is necessary to start over after corrective action:

1. Turn the unit OFF by setting the ON/OFF switch on the back of the machine to the OFF position.

2. Wait at least 1 minute.

3. Apply power by setting the ON/OFF switch to the ON position.

NOTE: *If there have already been three unsuccessful attempts to start-up the system, consult the Service Manual or call Customer Service at the number listed on the back of this manual.*

General Maintenance and Servicing

CAUTION:

Do not use deionized water. Using deionized water may damage the refrigeration system. Use only distilled water or sterile water.

Recommended Reservoir Disinfection Procedures

Please see **ThermoChem Cleaning and Disinfection Manual** (Document #MNL-2020) for all procedures to disinfection and clean the water bath reservoir and components of the HT-1000. Cleaning of the water bath reservoir and device should be done on a minimum of once per year or according to facility/regulatory guidelines.

WARNING:

To avoid personal injury, appropriate eye protection and gloves must be worn when handling and using sodium hypochlorite and hydrogen peroxide. Wearing an apron is also suggested to protect clothing.

Annual Maintenance Procedures

Calibration Check

> ***NOTE:*** *Only authorized maintenance personnel should perform this procedure.*

As-Needed Maintenance Procedures

Cleaning the Exterior (page Error! Bookmark not defined.**)**

Recommended Reservoir Decontamination Procedure (page 26)

Roller Pump Occlusion Adjustment Procedure:

CAUTION:

Proper occlusion setting is necessary for correct operation of this pump. Improper settings may result in damage to the pump.

NOTE: *The disposable tubing supplied by ThermaSolutions must be properly installed to follow this procedure.*

1. Place the inlet and outlet lines into a container of water.

2. Close the cover.

3. Run the pump at approximately 300 ml/min until tubing is completely filled with fluid.

NOTE: *If the pump does not self-prime, turn the power switch to the OFF position, open the cover, and rotate both occlusion adjust thumbwheels clockwise until the pump will self-prime.*

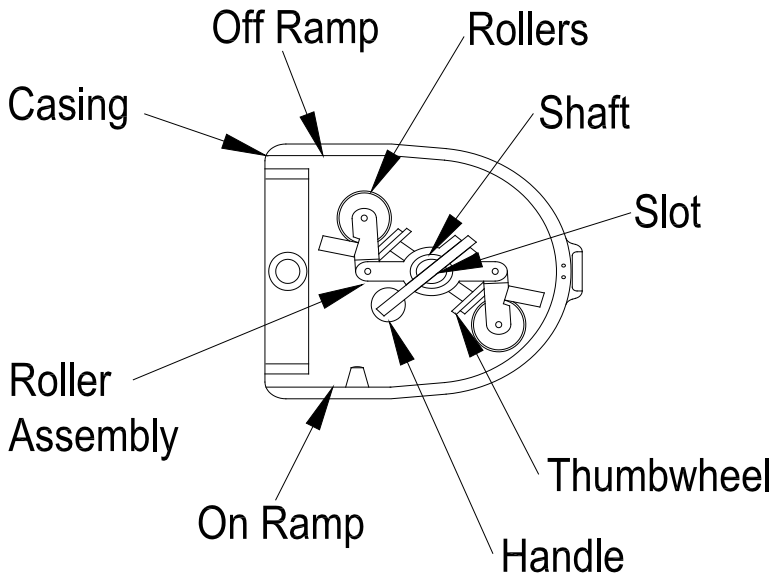


Figure 9: Roller Pump.

4. When the tubing set has filled with fluid, shut off the pump.

5. Position one roller at approximately the midpoint of the pump track.

6. Place the outlet tubing at or below the surface of the pump housing.

7. Remove the inlet end of the tubing from the fluid container.

8. Slowly raise the inlet end while observing the fluid level in the tubing.

   NOTE: *If the fluid level begins to drop, tighten the spring in the roller assembly by rotating the thumbwheel so that it moves toward the machine shaft, thereby increasing the spring tension.*

9. Continue raising the fluid level to a height of approximately 60 cm (23") above the surface of the pump housing.

10. Tighten the spring further (if necessary) until the fluid column stops dropping at a height of approximately 60 cm.

    NOTE: *If the fluid level does not drop, gradually decrease the spring tension by turning the thumbwheel in the opposite direction as above. Decrease the spring tension until the fluid column level is maintained.*

11. Turn the manual handle to slowly move the fluid, stopping at a number of points along the pump track.

    NOTE: *At each stopping point, observe the column of fluid. If it drops, increase the spring tension until the water level barely stops dropping.*

12. Maintain a column of fluid at approximately 60 cm at all points on the pump track, including the ON and OFF ramps. To maintain fluid column, it may be necessary to place the inlet end of tubing into the fluid container to draw in more fluid.

13. Repeat this procedure for the opposite roller.

14. The roller pump occlusion is now properly set for the tubing set.

Pump Roller Replacement

1. Turn the ThermoChem™ HT-1000 Unit off.
2. Lift the roller pump-casing lid. Refer to **Figure 9**.
3. Remove the disposable tubing from the raceway by hand-operating the roller pump.
4. Rotate the roller assembly by hand until the shaft is parallel to the slot which holds the handle.
5. Lift the handle.
6. Lift out the roller assembly and replace it with the new one.
7. Reinstall the disposable tubing in the roller pump.
8. Place the handle in its slot.
9. Close the roller pump casing lid.
10. Perform Occlusion Adjustment Procedure.

Preparation for Shipment

NOTE: *Prior to shipping contact Customer Service at the phone number listed on the back of this manual, to receive a Return Authorization Number.*

CAUTION:

If it is necessary to return the unit, the following instructions must be followed to prevent damage to the unit.

1. Attach a heat exchanger hose to the heat exchanger inlet connection on the front of the panel marked with the red colored sticker.

2. Direct the hose discharge to an empty container capable of holding six (6) liters of fluid.

3. Turn the unit on. Touch the screen after self-test to start the pump.

   NOTE: *The unit will pump water into the container. The container must be capable of holding at least eight (8) liters of fluid. Water will stop flowing when the reservoir is empty.*

4. Turn the unit off when water stops flowing.

5. Allow all remaining water to drain from the device.

6. Disconnect the hose from the heat exchanger inlet.

7. Remove the I.V. hanger assembly.

8. If required by the shipping container, disconnect the touchscreen connectors on the rear of the unit. Remove the touchscreen monitor from the mounting plate on the display arm. **Place in original packaging.**

9. If required to fit into the shipping container: Disconnect the touchscreen connectors on the rear of the unit and the monitor. Remove the touchscreen monitor from the mounting plate on the display arm. Place into padded container. Rotate the display arm parallel with the rear handle.

10. Slide the touchscreen tube down so that the arm is near the rear handle.

11. Loosen the strain relief top adjustment screw to disconnect the AC power cord.

12. Remove the AC power cord from the unit and tighten the adjustment screw.

13. The unit is now ready for shipping.

14. **NOTE:** Return all components of the shipping crate as listed on page 3. All components must be returned in *original packaging.*

System Specification

Weight and Dimension

Depth:	26 in/66 cm
Width:	29.5 in/75 cm
Height:	69 in/175 cm (w/Touchscreen Monitor) 44.5 in/113 cm (w/o Touchscreen Monitor)
Weight:	Approx. 330 lbs/150 kg
Shipping Weight:	Approx. 550 lbs/250 kg

Electrical Supply

Class I
Type B Patient Protection
US - 120V/60 Hz, 20A,
EU – 230V/50Hz, 10A

Operation Temperature Range:

- Water bath: 30°C to 47°C
- Default temperature primary fluid Water bath 37°C (for alarm defaults)
- Default temperature primary fluid Water bath 42°C

Water Bath Temperature Safety Limits:

- Software: 53°C +/-1°C (roller pump shuts off)
- Hardware: 55°C+3°C /- 1.7°C (heater/cooler shuts off)

Heat Exchanger Temperature Safety Limits:

- Software: 45°C +/-1°C (roller pump shuts off)
- Hardware: 46°C+/-1°C (roller pump shuts off)

Operating Conditions

- Temperature range: 10°C to 40°C
- Relative humidity range: 30% to 75% Non-condensing
- Pressure range: 525mm Hg to 795mm Hg

Shipping and Storage Conditions

- Storage Temperature: -40°C to 70°C
- Storage relative humidity: 15% to 95% non-condensing.
- Storage pressure: 510mm Hg to 795mm Hg.

Fluid Flow Rate

- Primary Fluid 6 to 8 L per minute
- Secondary Fluid 2400ml per minute +/-10%

EMC compliance

- IEC 60601-1-2 2nd edition, 2001 CISPR 11, group 1, Class B

Document No. MNL-1000.Ver.2

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Reference only

Not to be used as part of printed manual