ThermaSolutions

ThermoChem™ HT-2000 System Operator's Manual

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

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The ThermoChem HT-2000 System is protected under United States and international patents pending.

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Symbols for General Warnings

Attention, see instructions for use

Method of sterilization, ethylene oxide

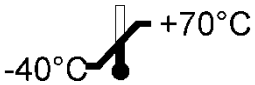
Type B applied part complying with the specific requirements of the standard IEC60601-1 to provide protection against electrical shock, particularly regarding allowable leakage current. Not suitable for direct cardiac application.

Do not reuse

Date of manufacture (YYYY-MM)

Serial number

Alternating current



Storage temperature range

Protective earth ground

CE Mark

Symbols for General Warnings, cont.

Do Not Push

Not made with natural latex rubber

Do Not Use if Package Damaged

Manufactured By

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

Type CF applied part complying with the specific requirements of the standard IEC60601-1 to provide protection against electrical shock, particularly regarding allowable leakage current.

USB Connection

Temperature Probe Connection

Equipotentiality

Symbols for General Warnings, cont.

	Caution
	Pressure Sensor Connection
IPX0	Ingress Protection Rating: No protection against ingress of water
	Operating Instructions-refer to instructions before use

Warnings, Precautions and Notes

This manual includes the following:

- **WARNINGS** emphasize situations that could result in serious injury and/or death.
- **CAUTIONS** emphasize situations that could result in serious damage to equipment.
- **NOTES** provide additional, important information regarding a specific procedure.
- **System Specifications** alert operators to the environmental conditions under which the ThermoChem™ HT-2000 System is used and stored.

Warnings

- Read this Operator's Manual in its entirety before operating the ThermoChem system. Failure to read the manual could result in harmful effects to the user, patient, and/or ThermoChem system.
- Hyperthermic perfusion at high temperatures for extended periods of time may result in acute or chronic thermal injury locally and/or systemically. Use caution when perfusing liquids at temperatures above 43°C for more than 60 minutes. Time-temperature combinations exceeding either or both of these parameters could result in serious injury.
- Do not use electrocautery or other electrosurgical devices when the Disposable tubing has been placed in the patient and the ThermoChem unit is operating.
- The Disposable kit is for single use only. Disposable components not used during the procedure, MUST be discarded and disposed of properly.
- If the Disposable kit package is damaged, DO NOT use. Damaged packaging could compromise the sterility of the components. Replace with a new Disposable kit package and notify customer service at the number listed on the back of this manual.
- Only Disposable kits supplied by ThermaSolutions are to be used with the ThermoChem unit.
- Use aseptic technique when connecting patient catheters to the Disposable inflow tube and return tube. Failure to use aseptic technique could contaminate the sterile field.
- The ThermoChem system is designed to work with disposable patient temperature probes supplied by ThermaSolutions. Use of other temperature probes could result in harm to the patient.
- If a ThermoChem system malfunction occurs or the patient needs immediate attention, turn off the roller pump by pressing 'Stop Pump' on the touchscreen monitor.
- After treatment has been initiated, the non-disposable heat exchanger water lines and connectors will be hot and may present a scald hazard. Do not disconnect water lines while the ThermoChem unit is at operating temperature or is powered on and the water bath is circulating.
- To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth ground.

Warnings (Continued)

- No modification of this equipment is allowed.
- Do not modify this equipment without authorization of the manufacturer.
- Unauthorized modification of this equipment could cause it to be unsafe to operate.
- If this equipment is modified, appropriate inspection and testing must be conducted to ensure continued safe use of equipment.
- This device is not defibrillator proof and should not be connected to a patient when using a defibrillator.
- The IPH procedure kit (disposable) is a single use only kit and should not be re-sterilized.
- The ThermoChem unit was not intended to be used in an oxygen rich environment or around flammable agents.
- The ThermoChem HT-2000 should be used only by Medical Professionals who are trained in the use of the device and who have an understanding of the English language.
- Do not fog or humidify the ThermoChem HT-2000 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-2000 is inside the room. If the operating room is to be fogged or humidified, remove the ThermoChem HT-2000 from the room before and during the procedure.

Precautions

- If using a physiological, compatible, sterile solution other than Lactated Ringer's solution, follow the alternate solution's manufacturer labeling regarding handling and disposal.
- Prior to plugging the ThermoChem unit in, the POWER switch must be in the OFF position and the power cord properly connected to the back of the unit. This will prevent any power surges to the unit.
- After mounting the Disposable on the ThermoChem unit, starting circulation of the water bath, starting the heat exchanger, and before starting the patient pump, inspect the heat exchanger and Disposable tubing for fluid. If fluid is visible anywhere in the Disposable, the heat exchanger is faulty and the Disposable must be replaced. Notify Customer Service at the number listed on the back of this manual.
- Connection of the Disposable to the ThermoChem unit, Disposable priming, and temperature probe setup must be completed prior to initiating patient treatment. Failure to thoroughly follow the setup instructions will prevent the ThermoChem system from operating properly.
- When moving the ThermoChem unit, make sure to use handles provided on the device to avoid tipping.

- Make sure when operating the ThermoChem unit that it is placed in a location and position that will allow easy access to the power cord and switch.
- When Power cycling the ThermoChem unit wait 10 seconds before turning back on.

Notes

- The Patient pump will stop if the top cover or door on the pump is opened.

Indications for Use

The ThermoChem™ HT-2000 Units are indicated for the treatment of peritoneal carcinomatosis, pseudomyxoma peritonei, mesothelioma, or mucinous carcinoma originating from colorectal, thoracic and ovarian cancers in patients whose treatment options have been exhausted.

ThermoChem HT-2000 System Overview

The ThermoChem HT-2000 System consists of the ThermoChem unit, an Intraperitoneal Hyperthermia (IPH) Kit or Disposable, and a touchscreen monitor.

The ThermoChem unit houses an internal heating unit that warms distilled or sterile water to a desired temperature. This water is circulated to a heat exchanger where it warms Lactated Ringer's (or another physiologically compatible sterile solution) for infusion into the patient's peritoneal cavity. The ThermoChem unit also has hardware and software safety circuits to help protect against patient organ damage due to overheating.

The Disposable consists of the heat exchanger, a fluid reservoir, and tubing. The warmed Lactated Ringer's (or another physiologically compatible sterile solution) is pumped through the tubing to the patient and then returns to the fluid reservoir.

The touchscreen monitor (Figure 1) provides for the user interface with the ThermoChem system. From the touchscreen monitor, these main functions are controlled:

- Set the water bath temperature
- Start and stop the water bath
- Start and stop the heat exchanger
- Start and stop the roller pump
- Set the roller pump speed
- Temperature of the internal water bath
- Temperature of the patient fluid at the heat exchanger
- Pressure of fluid in the Disposable measured at the heat exchanger
- Temperature(s) from patient temperature sensor(s), if connected
- Length of treatment, if desired
- Roller pump speed
- Alarm condition

Figure 1: Touchscreen Monitor Display

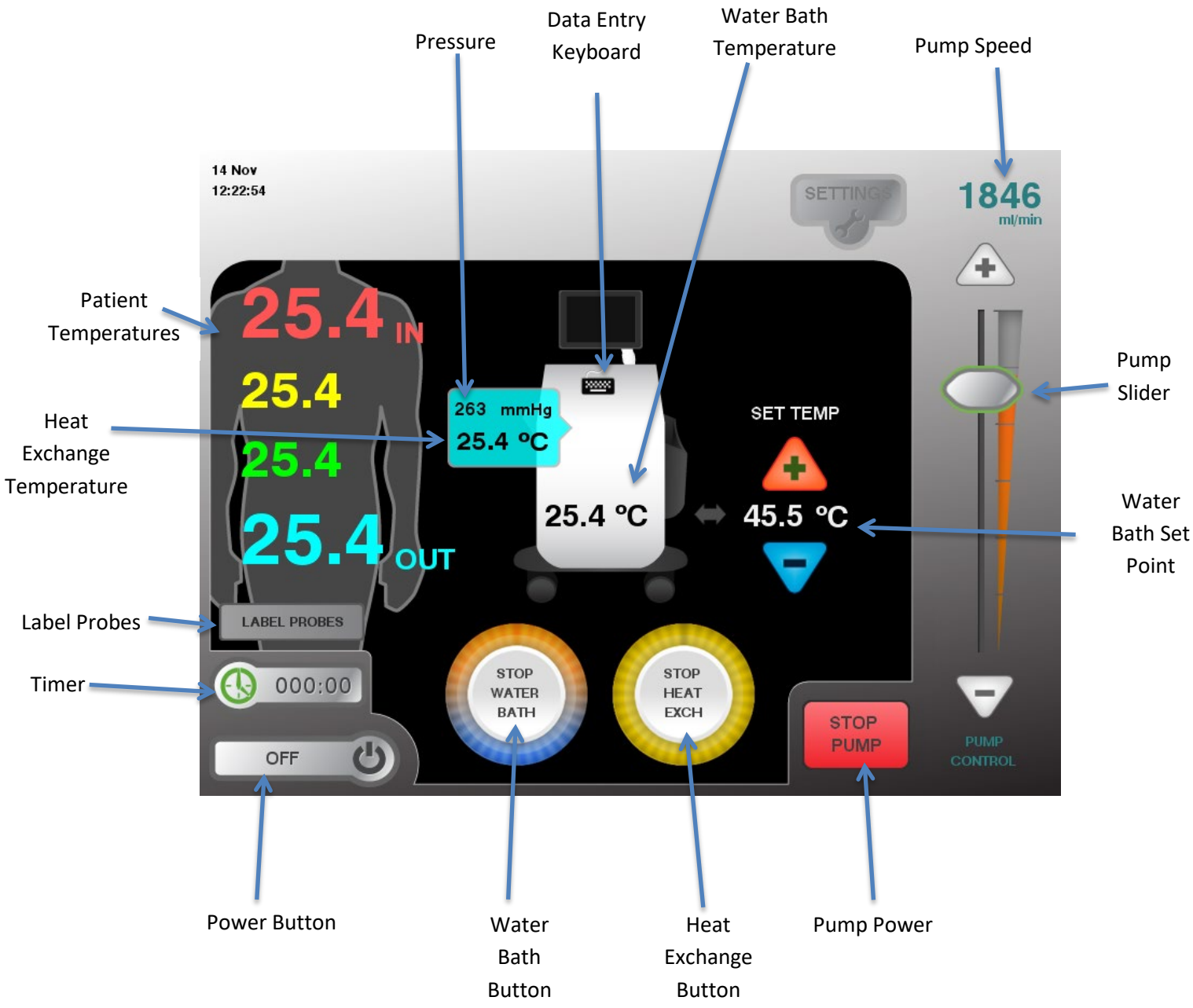
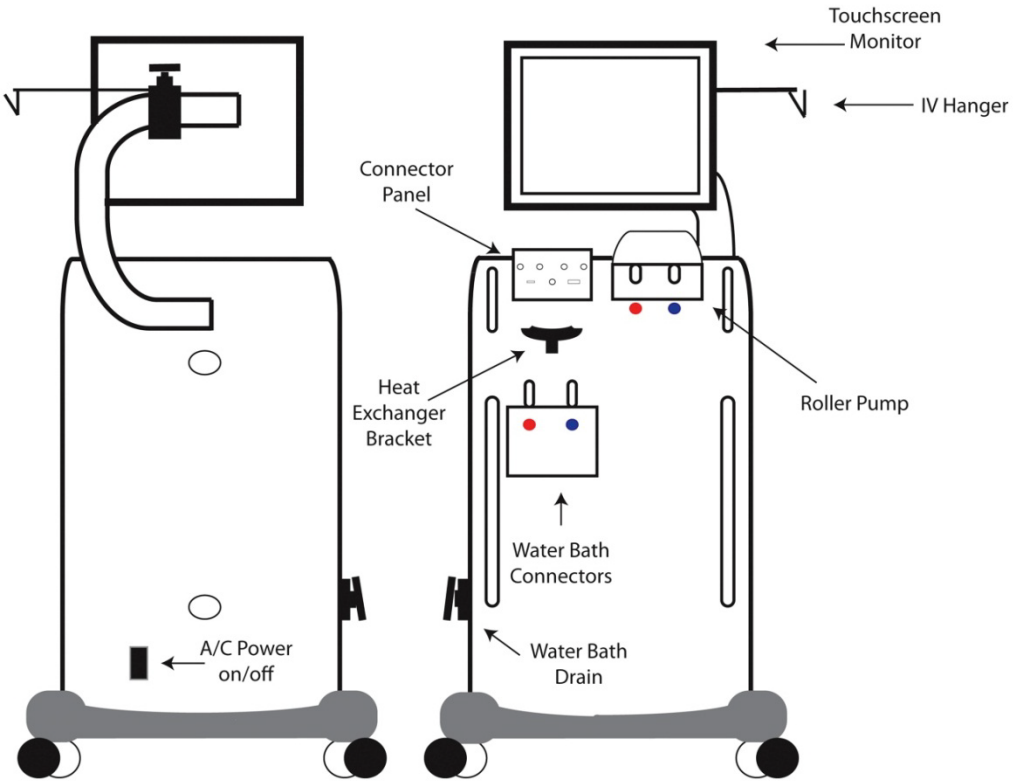


Figure 2: Rear and Front views of the ThermoChem Unit



ThermoChem HT-2000 System Components

The ThermoChem HT-2000 consists of the following components:

HT-2000	ThermoChem unit
25541-03 or 25541-04	AC Power Cord (USA-03, Europe-04)
CM-0003-10-5	IV Hanger Rod
17095-01	Fluid reservoir bracket
25540-03	Four (4) non-disposable temperature probe extension cables, three (3) in the US.
26035-02	Two (2) non-disposable heat exchanger temperature probes
038-0001	Two (2) non-disposable heat exchanger water lines
MNL-2000	Operator's Manual
MNL-2020	ThermoChem Cleaning and Disinfection Manual
MNL-2010	Quick Start Guide
101-9005	6mm Allen Wrench

Ordered separately to make up the complete system:

Intraperitoneal Hyperthermia (IPH) Procedure Kit or
Disposable

Preparing the ThermoChem Unit HT-2000 System

1. Lock each wheel of the ThermoChem unit. Press down on the wheel locks with your foot.

   NOTE: Lock wheels while setting up and using the ThermoChem unit.

2. Verify the water bath is empty and the drain valve is shut off. (Figure 2)
3. Open the water bath access door on the left side of the ThermoChem unit and fill the water bath with 2 liters (0.528 gallons) of distilled or sterile water.

   NOTE: If water backs up into the water bath access door, the water bath is full. Do not attempt to add additional water.

4. Power up the ThermoChem unit:
   a. Insert power cord into a standard electrical outlet.
      - United States – 120V/60Hz 12A
      - European Union – 240V/50Hz 6A
   b. Using the On/Off switch, turn power on.
5. Adjust the touchscreen monitor to the desired angle for proper viewing.
6. Insert the IV hanger into the hole on the touchscreen monitor support and secure by tightening the screw.
7. Secure the fluid reservoir bracket to the right lower handle on the front of the ThermoChem unit by tightening the bracket screw.

   NOTE: The fluid reservoir bracket may be placed anywhere on the handle. A lower position on the handle will increase the speed of drainage from the patient.

Procedure Kit and Installation

The Intraperitoneal Hyperthermia **(IPH) Procedure Kit** or Disposable may include the following:

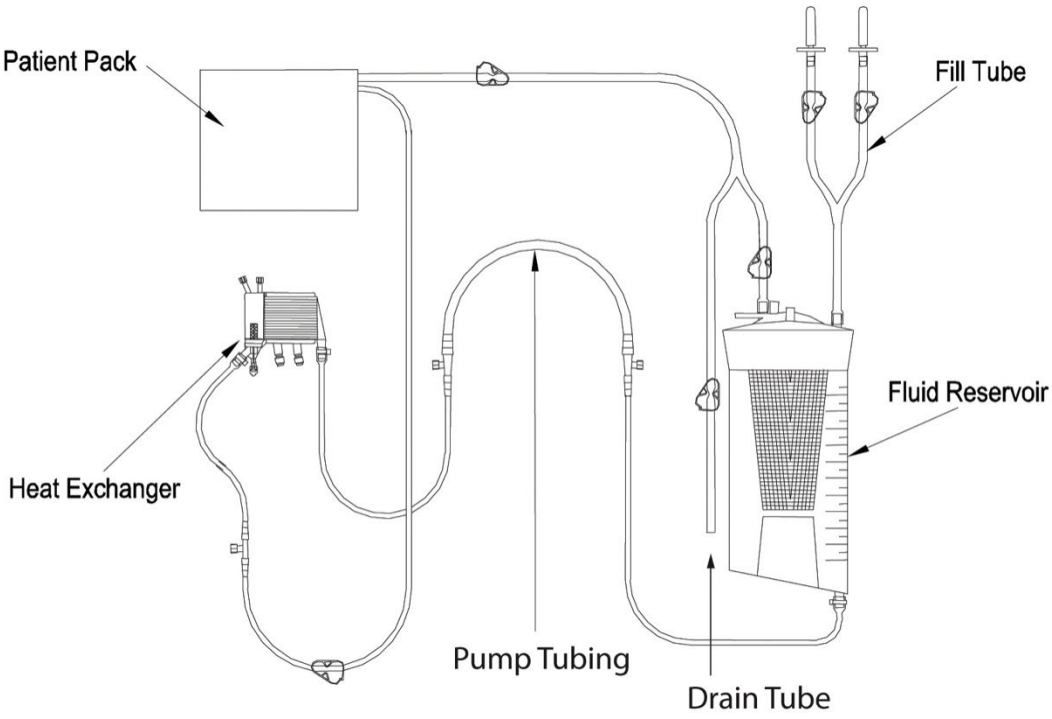
One (1) IPH circulation loop with:
- One (1) Heat Exchanger
- One (1) Fluid Reservoir (4 L)
- PVC Tubing

One (1) Pressure Sensor
Patient Connection tubing line(s) with quick connects

IPH Table Pack or sterile patient connection tubing:
- Inflow and Outflow Catheters
- Patient connection tubing, inflow and outflow
- Patient temperature probes (Myocardial or General)
- Inline filters

Note: Contents may vary slightly depending on the kit version.

Figure 3: Example: Intraperitoneal Hyperthermia (IPH) Procedure Kit or Disposable



Connecting the Disposable to the ThermoChem Unit

NOTE: Ensure that the fluid reservoir bracket is in place prior to opening the IPH disposable package.

Handle the Disposable tubing carefully as it is removed from the packaging. Ensure that the sterility of appropriate components is maintained and that the tubing does not come in contact with the floor.

1. Remove the IPH Procedure Kit (Disposable) package from the outer shipping box, if not already done.
2. Inspect the packaging to ensure it is sealed and that there is no visible or apparent damage.
3. Open the sterile package.

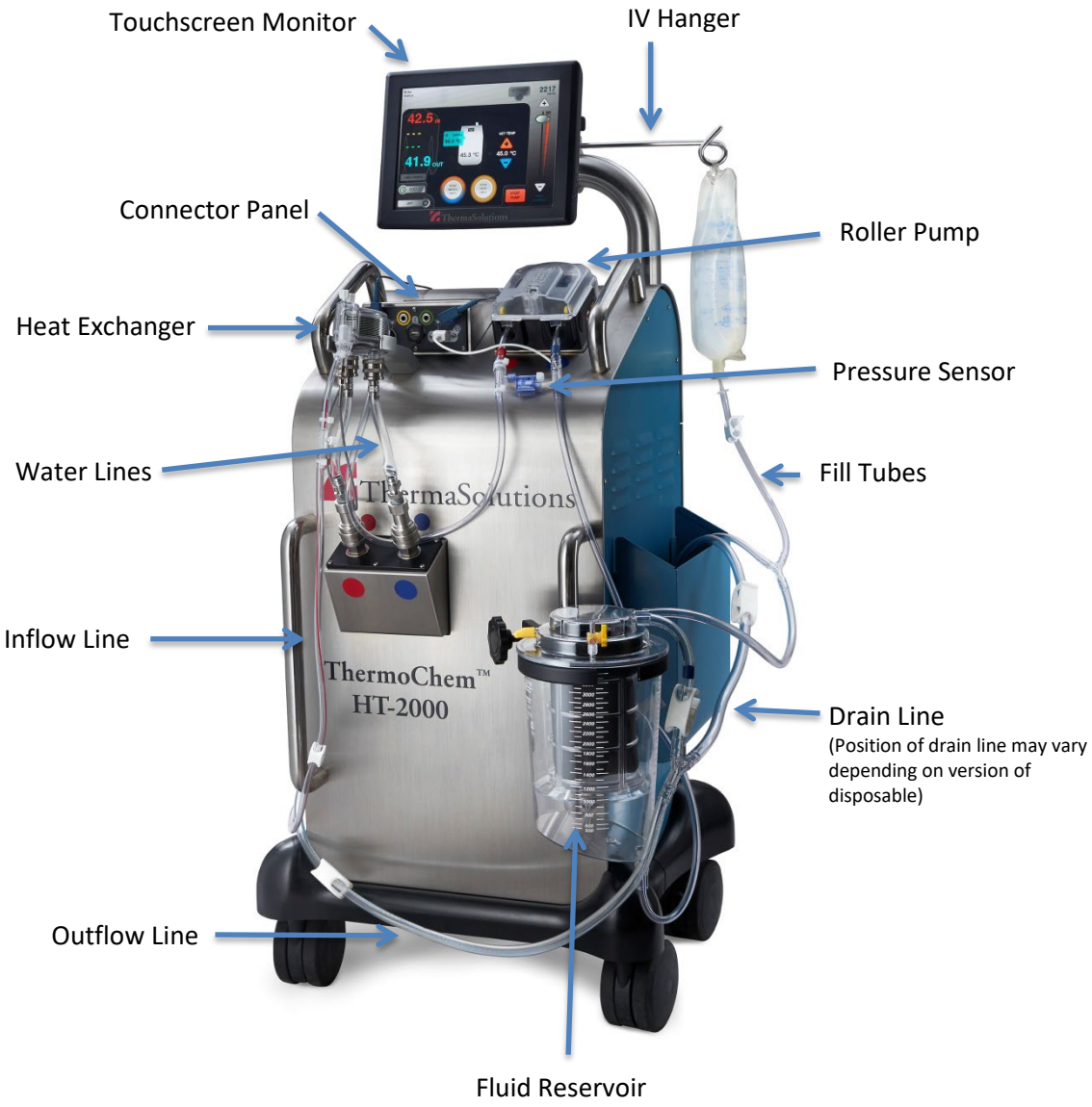
   NOTE: The Disposable is packaged sterile. Following appropriate hospital policies and procedures ensure that sterility is maintained for components coming in contact with the patient.
4. Remove the Table Pack and/or any sterile patient connection tubing and place in a secure location (e.g. pocket on right side of ThermoChem unit, table).

   NOTE: Additional components may be secured to the outside of the sterile package. Remove any additional items for assembly to the device or for the sterile field.
5. Remove the Disposable tubing set from the now open sterile packing.

   NOTE: Maintain cleanliness of the Disposable components during setup on the ThermoChem unit.
6. Check that all Disposable connections and caps are tight.
7. Set the fluid reservoir in the fluid reservoir bracket.
   a. Ensure tubing is not twisted.
   b. Clamp the drain line.
8. While holding the saline lines (if pre-attached), slide the heat exchanger into the heat exchanger bracket.
   a. Align the bottom of the heat exchanger with the bracket grove.
   b. Ensure filter and patient line are facing out.
9. Insert the pump tubing into the roller pump head matching red-to-red and blue-to-blue.

   NOTE: The portion of the tubing that is inserted into the roller pump is located between the red and blue bands on the tubing.
10. Manually rotate roller pump head to ensure tubing is seated properly in the pump head.

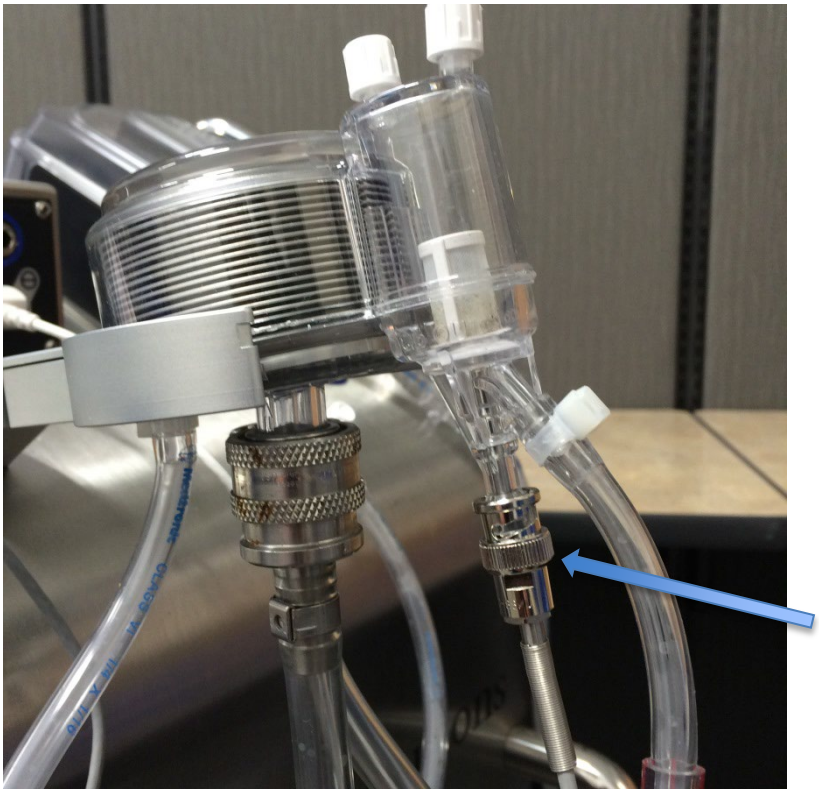
Figure 4: Disposable Connected to the ThermoChem Unit



Connect the Heat Exchanger Temperature Probe, Pressure Monitor and Water Lines.

1. Connect non-disposable heat exchanger temperature probe. (Figure 5)
    a. Insert pointed end of temperature probe into bottom of heat exchanger filter and the plug into the ThermoChem unit connector panel.

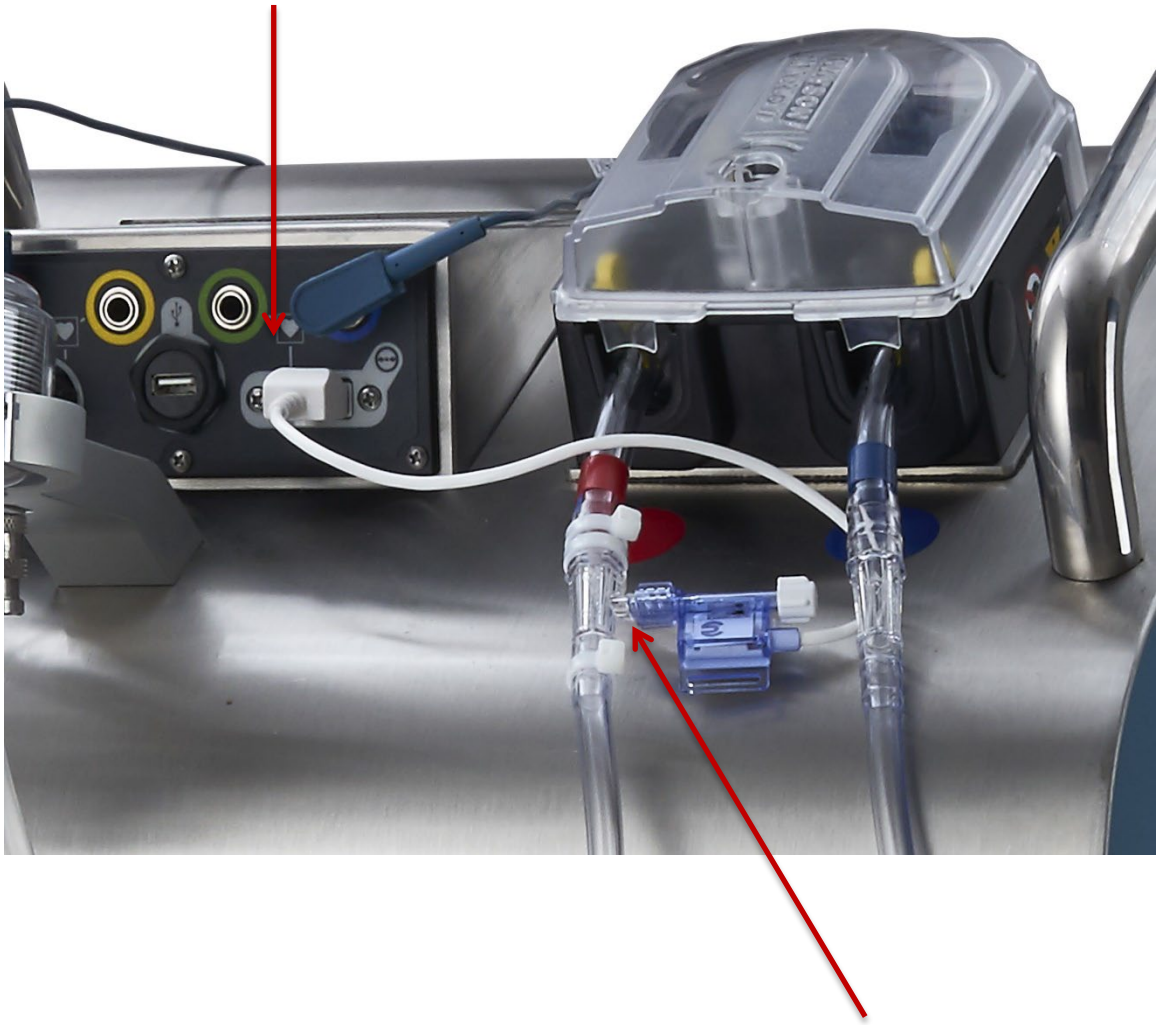
Figure 5: Temperature Probe Connections



2. Connect disposable pressure sensor to the first luer lock after the roller pump.

   Insert plug from the pressure sensor into the ThermoChem unit connector panel. (Figure 6)

Figure 6: Pressure Sensor Connections



3. Connect the non-disposable heat exchanger water lines (Figure 7).
    a. Pull collar back, push into place connecting small ends of the water lines to the heat exchanger and large ends to the ThermoChem unit.
    b. Ensure water lines are fully seated.

NOTE: When attached correctly, the water lines will be parallel to each other. If the water lines cross, the lines are attached incorrectly.

Figure 7: Water Line Connections

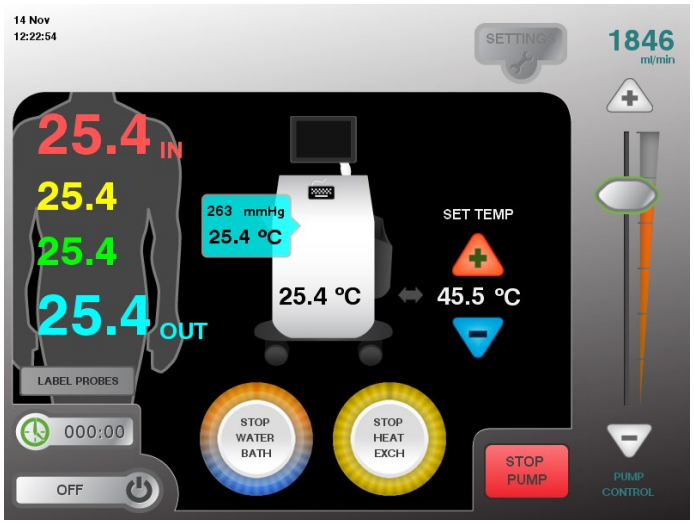
Priming the Disposable

To prime the Disposable tubing:

1. Hang two (2) 1-liter intravenous (IV) bags of Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution from the IV hanger.
2. Spike IV bags with the spikes on the fill tubes of the Disposable.
3. Fill the fluid reservoir by opening the clamps from the IV bags.
4. Clamp the fill tubes.

   NOTE: Hang additional IV solution bags as needed.
5. Start the ThermoChem system to begin circulating the fluid. On the touchscreen monitor (Figure 8):
   a. Touch 'START WATER BATH' to start heating and circulating the water bath.
   b. Touch 'START HEAT EXCH' to start the heat exchanger.
   c. Touch 'POWER PUMP' to start the roller pump.
   d. Touch + or-, or the use slider bar to increase roller pump speed.
   e. Check heat exchanger and tubing for leaks. If any are present, replace the disposable kit and notify ThermaSolutions customer service.

Figure 8: Touchscreen Monitor

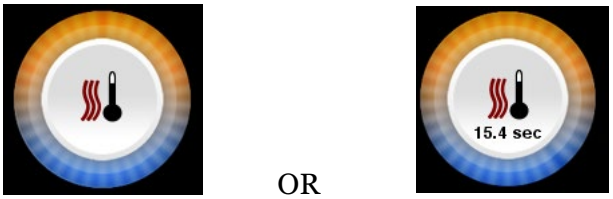


6. Gently hand-tap the heat exchanger to ensure all air has escaped.
7. Set water bath temperature 'Set Temp' to desired temperature by pressing + or –.

   NOTE: The water bath should reach the desired temperature within 15 to 20 minutes of starting the heat exchanger.
8. Allow fluid to warm and circulate until the patient is ready for treatment.

Note: Water bath circulation may briefly restart then stop automatically if the device senses the water bath heating element is at its upper operational limit. If this situation occurs, one of the alternate water bath buttons will appear. An alternate water bath button may also appear when stopping the water bath. This is a normal condition. (Figure 9)

Figure 9: Alternate Water Bath Buttons



OR

Note: When the alternate water bath button (Figure 9) is showing on the main screen, the internal water bath circulation cannot be stopped until the normal water bath button reappears. All other functions of the device will still continue to work normally. This is a normal condition.

Moving the Prepared ThermoChem Unit

To move the prepared ThermoChem unit into the operating room:

1. Shut down the ThermoChem unit:
    a. Touch 'STOP PUMP'.
    b. Touch 'STOP HEAT EXCH'.
    c. Touch 'STOP WATER BATH'.
    d. Press 'OFF' and confirm software shutdown.
    e. When the system indicates that it is safe to do so, turn power off using the On/Off switch on the back of the device.
    f. Unplug the power cord from the electrical outlet.
2. Move the ThermoChem unit to the desired location.
3. Restart the ThermoChem unit:
    a. Insert power cord into a standard electrical outlet.
    b. Turn power on using the On/Off switch.
    c. Touch 'START WATER BATH'.
    d. Touch 'START HEAT EXCH'.
    e. Touch 'POWER PUMP'.
    f. Set water bath temperature 'SET TEMP' to desired temperature.

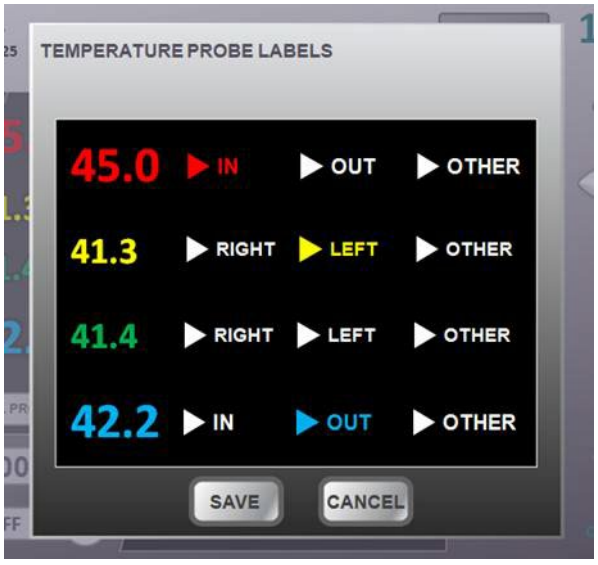
Patient Preparation and Connection of the Disposable to the Patient

The physician will configure the desired internal patient tubing setup to deliver the warmed solution to the peritoneal cavity and select the desired locations for the disposable patient temperature probes.

When the physician has placed the temperature probes:

1. Connect the patient temperature probes to the ThermoChem unit.
    a. Using aseptic technique, the physician will pass the patient temperature probe connections out of the sterile surgical field.
    b. Attach the patient temperature probe connections to the non-disposable temperature probe extension cable.
    c. Connect the non-disposable temperature probe extension cable to the ThermoChem unit connector panel.
2. Label temperature probes on the touchscreen monitor (Figure 9).
    - Red – temperature of fluid flowing into patient (default)
    - Yellow – patient temperature probe (optional)
    - Green – patient temperature probe (optional)
    - Blue – temperature of fluid out from the patient (default)
3. Touch 'SAVE' when temperature probe labels are complete.

Figure 10: Temperature Probe Labels Screen



When the physician is ready for the Disposable tubing:

1. Ensure the inflow catheters, outflow catheters, and temperature probes are correctly placed according to physician preference.
2. Using sterile technique, follow the Instructions for Use in your Disposable kit to open patient tubing and pass onto or off of the sterile surgical field.
3. Prior to the physician or operator connecting the Disposable tubing to the inflow and outflow catheters, stop the pump by pressing 'STOP PUMP' on the touchscreen monitor.
4. Clamp the patient inflow line to the sterile field and outflow line to the fluid reservoir.
5. Following the Instructions for Use in your Disposable kit:
    a. Connect the inflow line from the Disposable kit to inflow tubing at the patient.
    b. Connect the outflow tubing at the patient to the outflow tubing line(s) leading to the fluid reservoir.

Initiating Patient Treatment

To initiate patient treatment:

1. Unclamp the patient inflow line to the sterile field.

   NOTE: Ensure clamp on outflow line to the fluid reservoir remains closed.
2. Touch 'POWER PUMP' to start the roller pump.
3. Touch + or –, or use slider bar, to increase pump speed.
4. Verify fluid is flowing and peritoneal cavity is filling with fluid.
5. Slowly increase roller pump speed until the target flow rate is achieved.
    a. Use slider bar or press + or – on the touchscreen to adjust pump speed.
6. Open the clamp on the patient outflow line to the fluid reservoir. Adjust the clamp on the patient outflow line to achieve the desired fluid volume in the patient's peritoneal cavity. Maintain a reserve amount of fluid in the reservoir.

Monitor Patient Treatment

1. Maintain a constant level of fluid in the fluid reservoir.
    a. Add additional of Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution as needed.
    b. Evacuate fluid from fluid reservoir as needed.
2. Maintain fluid level in patient's peritoneal cavity as directed by the physician.
    a. Adjust roller pump speed by touching + or –, or use slider bar, on touchscreen monitor.
    b. Adjust the clamp on the patient outflow line on the fluid reservoir.

3. Start the TIMER to measure therapy time. The timer will continue counting until the timer is manually turned off. Turn off the timer by touching the timer symbol on the touchscreen monitor.
   NOTE: When the timer is restarted, it will reset to zero.

4. Monitor temperatures.
   a. As directed by the physician, adjust the water bath 'SET TEMP' to achieve desired patient temperature.
5. Monitor the Disposable tubing and heat exchanger for leaks, kinks, or other restrictions that could interfere with fluid flow.
6. Respond to any alarms during treatment.
   a. If any tubes are manually clamped, check that they are in the correct position before resuming the treatment.

Discontinuing Patient Treatment

After treatment is complete:

1. Connect drain tube into waste bag or proper hospital hazardous waste collection container.
2. Stop the roller pump by touching 'STOP PUMP' on the touchscreen monitor.
3. Stop the timer by touching the timer button.
4. Open clamp on drain line. If the drain line is directly before the reservoir, clamp the line to the reservoir. If the drain line is directly after the heat exchanger, clamp the inflow line to the patient.
5. Start the roller pump by touching 'POWER PUMP' on the touchscreen monitor and allow the fluid in the reservoir to slowly drain.
6. IF ADDITIONAL FLUSH OF FLUID IS DESIRED:
    a. When a small amount of fluid remains in the fluid reservoir, stop the roller pump by touching 'STOP PUMP' on the touchscreen monitor.
    b. Hang two (2) additional 1-liter intravenous (IV) bags of Lactated Ringer's Solution, U.S.P., or another physiologically compatible sterile solution from the IV hanger.
    c. With fill tube clamps closed, spike IV bags.
    d. Open clamps on the fill tubes and allow fluid from the IV bags to drain into the reservoir.
    e. At the physician's discretion, start the roller pump and allow fluid to be pumped from the reservoir.
7. When the reservoir and the patient outflow line is empty, stop the roller pump and clamp <u>all</u> lines.
8. Shut down the ThermoChem unit. On the touchscreen monitor:
    a. Touch 'STOP PUMP'.
    b. Touch 'STOP HEAT EXCH'.
    c. Touch 'STOP WATER BATH'.

    NOTE: The HT-2000 logs information about the operation of the device. If Operator wants to export this User Log, please follow the directions in Appendix A: Data Input and User Log Export, prior to continuing.

    d. Press 'OFF' and confirm software shutdown.
9. When the system indicates that it is safe to do so, turn power off using the On/Off switch on the back of the device.

Disposable Removal

1. Within the sterile surgical field:
    a. Disconnect the patient temperature probes from the non-disposable temperature probe extension cables.
    b. Clamp the Disposable inflow and outflow tubes near the patient inflow and return tube assemblies.
    c. If required, disconnect the Disposable inflow and outflow tubes from the patient catheters.
    d. Pass the Disposable inflow and outflow catheters and lines off the sterile surgical field.
2. From the heat exchanger:
    a. Disconnect the non-disposable heat exchanger temperature probe and place in the side pocket of the ThermoChem unit.
    b. Disconnect the non-disposable water lines.

    NOTE: Ensure a container is available to collect water as it drains from the water lines and heat exchanger.
3. Disconnect the disposable pressure sensor from the HT-2000 Connector Panel.
4. Remove the Disposable from the ThermoChem unit:
    a. Remove Disposable tubing from roller pump.
    b. Remove the heat exchanger.
    c. Remove fluid reservoir from bracket.
5. Discard all Disposable components in accordance with the hospital's disposal policy.
6. Ensure non-disposable components are stowed in the side pocket of the ThermoChem unit including:
    - reservoir bracket
    - IV hanger
    - non-disposable temperature probe extension cables
    - non-disposable heat exchanger temperature probes
    - non-disposable water lines

Draining the Water Bath

Open the water bath drain to drain the water bath. Drain into a bucket or floor drain. This should be done after every use.

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.

Cleaning the Water Bath

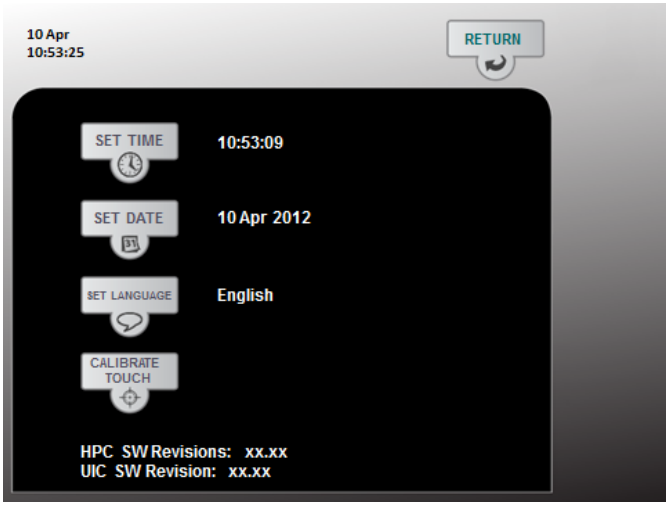
Please refer to the ThermoChem Cleaning and Disinfection Manual (#MNL-2020) for instructions on cleaning the water bath of your device.

Settings

The time, date, and language are set from the 'SETTINGS' screen. Calibration of touch is also available from this screen.

Select 'Settings' on the touchscreen monitor. The 'SETINGS' screen is displayed (Figure 11). Follow the directions below, as appropriate.

Figure 11: Settings Screen



Set Time

1. Select 'SET TIME'.
2. Touch the appropriate arrows to set the time.
3. Touch 'SAVE' to set the time.

Set Date

1. Select 'SET DATE'.
2. Touch the appropriate arrows to set the date.
3. Touch 'SAVE' to set the date.

Set Language (if necessary)

1. Select 'SET LANGUAGE.
2. Touch the appropriate arrows to set the language.
3. Touch 'SAVE' to set the language.

Touch sensitivity on the touchscreen monitor may be calibrated. Follow the directions below, as appropriate.

Calibrating Touch

1. Select ‘CALIBRATE TOUCH’.
2. Touch the targets to adjust touch positioning.
3. Touch ‘SAVE’ to set touch calibration.
4. Select ‘SETTINGS’ on the touchscreen monitor

To return to the main screen on the touchscreen monitor, select ‘RETURN’ on the Settings Screen.

Routine Service, Preventative Maintenance and Repair

Performed by ThermaSolutions

All service and maintenance other than described above should be performed by an authorized ThermaSolutions Service Representative.

On an annual basis the ThermoChem HT-2000 should receive Preventative Maintenance and certification of operation.

The annual preventative maintenance shall also include disinfecting the water bath system and inspection of labels to ensure they are legible.

Performed by user

1. Drain water bath after every use.
2. Disinfect water bath system as required by facility policy.
3. Clean exterior after every use.
4. Store reusable accessories in the ThermoChem side pocket.

No other maintenance or service should be performed by the user.

Cleaning and Disinfection

Please see ThermoChem Cleaning and Disinfection Manual, for all updated procedures on cleaning of the device, water bath reservoir and components. (Document # MNL-2020)

Preparation for Shipping

If the device is to be shipped complete these steps:

1. Drain the unit into container capable of holding at least three liters (3L) of fluid. Discard the water in accordance with facility policy.
2. Document the maintenance work on the unit.

Troubleshooting

Issue	Solution/Response
An 'Error Alert' is displayed/ Alarm is displayed on touchscreen monitor	Follow instructions listed below the alarm. Touch the 'Clear' icon to clear the alarm.
'Error Alert' message cannot be cleared.	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Touchscreen monitor is blank.	Ensure touchscreen monitor is turned on and all cords are connected. Power button for monitor is on the lower right side of monitor.

Technical Alarms

High Priority Technical Alarm Message	Solution/Response
System communications Failure	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists. The alarm notification will occur about 30 seconds after event has occurred.
Heat exchange 1 hardware fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Heat exchange 2 hardware fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Water bath 1 hardware fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Water bath 2 hardware fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Pressure hardware fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Internal heater hardware fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Safety signal hardware fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Heat exchanger is too hot	Replace heat exchanger temperature probe. Notify Customer Service at the number listed on the back of this manual if problem persists.
No water bath temperature	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.

High Priority Technical Alarm Message Cont'd	Solution/Response
Water bath is too hot	Make sure heat exchanger and water bath are off and the temperature is set to 37C. Touch Clear icon and you can continue use of the patient pump. Power Cycle Device to try getting back to full use. Notify Customer Service at the number listed on the back of this manual if problem persists.
Heat exchange measure fault	Replace heat exchanger temperature probe.
Water bath measure fault	Touch Clear icon. Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Water bath heater fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Water bath low	Ensure that water bath has at least 2 L of water and touch clear icon.
Pump control error	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists. The alarm notification will occur about 7 seconds after event has occurred.
Unspecified internal fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Watchdog fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
Pump door open	Close Patient Pump door and touch clear.
No heat exchanger temperature	Reattach or replace heat exchanger temperature probe.
Pressure is too high	Check lines before continuing. Touch clear icon.

Medium Priority Technical Alarm Message	Solution/Response
Internal board temp is too hot	Touch clear icon. Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.
High pump speed	Touch clear icon. Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists. The alarm notification will occur about 9 seconds after event has occurred.
Low pump speed	Touch clear icon. Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists. The alarm notification will occur about 9 seconds after event has occurred.
Pressure is elevated	Check lines for occlusion before continuing. Touch clear icon.
Audio failure	Touch clear icon. Audio alarm may no longer be available until device is powered cycled.
Electronics enclosure fan fault	Touch clear icon. Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists
Water bath fan fault	Power Cycle Device. Notify Customer Service at the number listed on the back of this manual if problem persists.

Electromagnetic Environment Guidance

Electromagnetic Environment Guidance	
Electromagnetic Emissions	**Compliance**
RF Emissions EN 60601-1-2:2015 (CISPR 11:2015 + A1:2016) IEC 60601-1-2:2014/ICES-003, Issue 5:2012	Group 1 Class A Class A Class A
Harmonic emissions IEC61000-3-2:2014	Class A
Voltage fluctuations/flicker emissions IEC61000-3-3:2013	AC Input
Electromagnetic Immunity	**Compliance**
Electrostatic Discharge (ESD) IEC61000-4-2:2008	Contact ±8kV Air ±2kV, ±4kV, ±8kV, ±15kV
Radiated RF Electromagnetic Fields IEC61000-4-3:2010	80 to 2700 Mhz 3 V/M AM 80% 1khz ,3 sec dwell
Electrical fast transients/burst IEC61000-4-4:2012	Test at AC Port at ±2kV and Patient Temperature Sensor at ±1kV
Surge IEC61000-4-5:2014	Test at AC Port for open circuits and short circuits at ± 0.5kV, ±1kV, ±2kV
Conducted disturbances, induced by RF fields IEC61000-4-6:2013	0.15 Mhz to 80 Mhz 3 VRMS AM 80% 1 khz 3 sec dwell
Power frequency (50 hz) magnetic field IEC61000-4-8:2009	Test at AC Port with30 A/m 60 Hz
Voltage dips, short interruptions, and voltage variations on power supply input lines, IEC61000-4-11:2004	Test at AC Port for both 220 Vac/60hz and 100 Vac/60hz input voltages

System Specifications

Weight and Dimension

Depth: 43.2 cm (17 in)
Width: 44.5 cm (17.5 in)
Depth at base casters: 58.4 cm (23 in)
Width at base casters: 61.0 cm (24 in)
Height:
    With monitor: 131 cm (51.5 in)
    Without monitor: 100 cm (39.5 in)
Weight: 106 kg (235 lbs.)
Shipping weight: 201 kg (444 lbs.)

Electrical Supply

Class I
Type B Patient Protection
Type CF Patient Protection, See Label
US: 120V ± 10%/60 Hz, 12A
EU: 240V ± 10%/50Hz, 6A

Operation Temperature Range

Water bath: 36°C to 47°C
Default temperature primary fluid:
    Water bath: 42°C
Default temperature primary fluid (for alarm defaults):
    Water bath: 37°C

Water Bath Temperature Safety Limits

Software: 53°C ± 1°C
    (Roller pump shuts off)
Hardware: 55°C + 3°C, - 1.7°C
    (Heater shuts off)

Heat Exchanger Temperature Safety Limits

Software: 47°C ± 1°C
Hardware: 48°C ± 1°C

Operating Conditions

Ambient temperature range: 10°C to 40°C
Relative humidity range: 30% to 75%, Non-condensing
Pressure range: 525 mmHg to 795 mmHg
Mode of operation: Continuous

IEC60529 IPX0

Shipping and Storage

Storage Temperature: -40°C to 70°C
Storage relative humidity: 15% to 95%, non-condensing
Storage pressure: 510 mmHg to 795 mmHg

Fluid Flow Rate

User adjustable to 0 to 2400 ml/min

EMC Compliance

IEC 60601-1-2, 4th edition, 2014
CISPR 11, group 1, Class A

Alarm Signal Sound Pressure Range

50 – 70db

Appendix A

Data Input and Patient Log Export

The HT-2000 logs information about the operation of the device during the preparation and treatment phases. The patient log contains the device data displayed on the main screen. The patient log also contains the patient information and treatment events that have been entered by the user. The patient log can be retrieved using a USB drive following the instructions below.

1. When treatment is finished, plug a USB drive into the USB port on the device. **Note:** (Do not do this during a treatment procedure)
2. Wait a few seconds for the USB drive to be recognized and then press the 'OFF' button on the touchscreen.
3. The USB Shutdown Screen (Figure 12) should show on the monitor.
4. Touch the 'Export Patient Log' button. This button will display green if there is user data that can be exported.
5. All patient logs will be downloaded off the device and onto the USB drive. (Figure 13)
6. Touch the 'Shutdown' button to turn off the device (and follow the directions on the screen to power down); or touch the 'RETURN' button to go back to the main treatment screen.
7. Remove the USB drive when the device is powered off.

Note: When returning to the main screen after a user log export, the device will start a new log file. New log files are also created after a power cycle of the device. (Device being turned off then on again or an unexpected disruption of power to the device). All log files are in comma separated values format and can be opened in a compatible spreadsheet program.

Data Exporting and Shutting Down.

The data export feature of the HT-2000 allows for exporting of procedure data:

- the status of the water bath, heat exchanger and patient pump
- water bath set point
- water bath temperature
- heat exchange temperature
- up to four patient temperatures
- pressure
- alarms
- patient ID, information and treatment events

A USB drive is required (≤ 8GB in size). Exporting of data removes all treatment data from the device. The treatment data is stored using the Patient ID. If no patient ID is entered, the data is stored sequentially by date and time.

Figure 12: USB Shutdown Screen

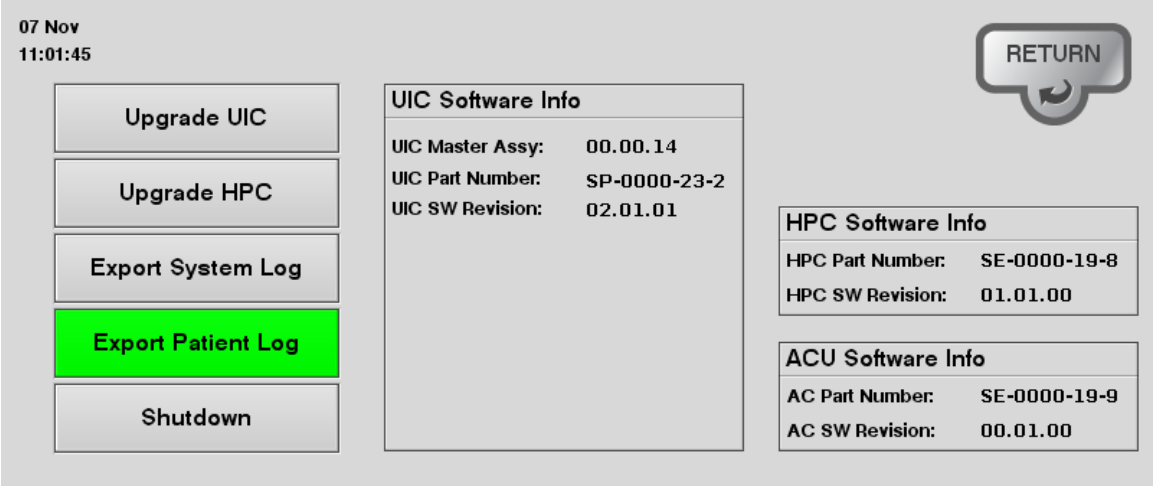
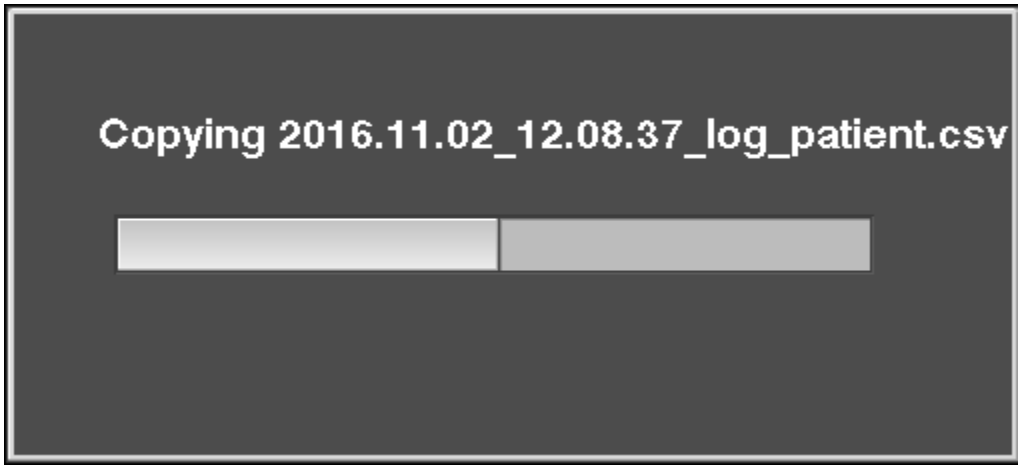


Figure 13: Patient Log Download



Patient Information and Treatment Event Data

Patient information and treatment events can be entered by the User Interface Icon on the device. The User Interface Icon appears as a keyboard on the main treatment screen of the device. When the icon is pressed, the User Interface and keyboard appears. The User Interface has two (2) screens: the Patient Information screen and the Treatment Event screen. Information entered and saved in either of these screens becomes part of the patient log and can be downloaded from the device. The following instructions explain how to enter Patient and Treatment data.

- **WARNING –** Do not enter identifying patient information such as names, addresses etc. into the user interface.

Enter Patient ID

1. Select the white box to the right of 'Patient ID'. (Figure 14)
2. Using the keyboard, type in the patient id information.
   Note: Protect private and confidential patient information according to hospital policy.
3. Save the Patient ID by selecting the save record button, labeled 'Save rec.'

Retrieve a previous Patient ID

If you are continuing treatment on a previous patient or want to utilize previous Patient Information or Treatment Events:

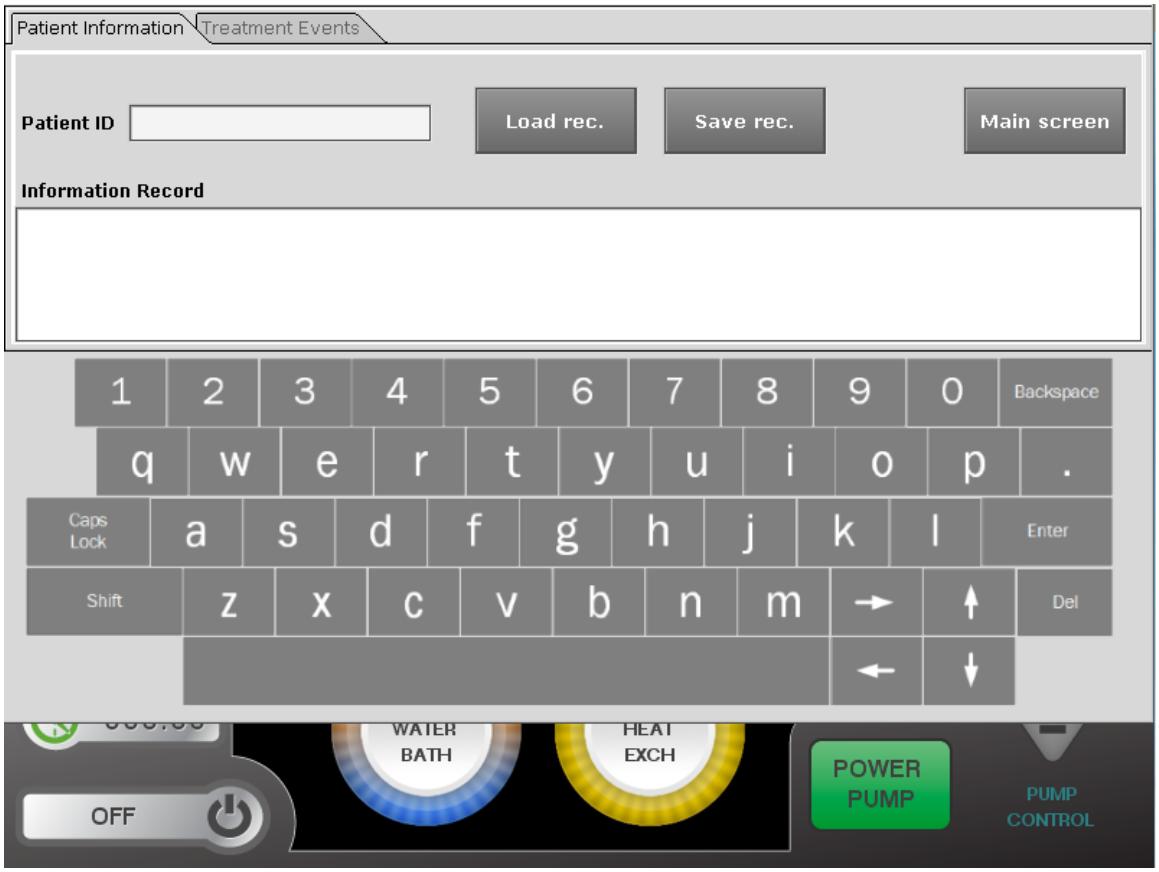
1. Select the white box to the right of 'Patient ID'.
2. Using the keyboard, type in the patient id information.
3. Retrieve the previous Patient and Treatment information by selecting the load record button, labeled 'Load rec.'
4. NOTE: only the Patient ID and Information Record data will be recalled from memory. No Treatment Events data will be recalled.

Enter Information Record

The Information Record allows for free entry of treatment specific information using the keyboard.

1. Select the white box to the beneath of 'Information Record'.
2. Using the keyboard, type in the information.
3. Save the Information Record by selecting the save record button, labeled 'Save rec.'

Figure 14: Patient Information Screen



Enter Treatment Events

This page allows the input of specific data and records that data along with the time of entry. This feature is useful for recalling time specific events and data.

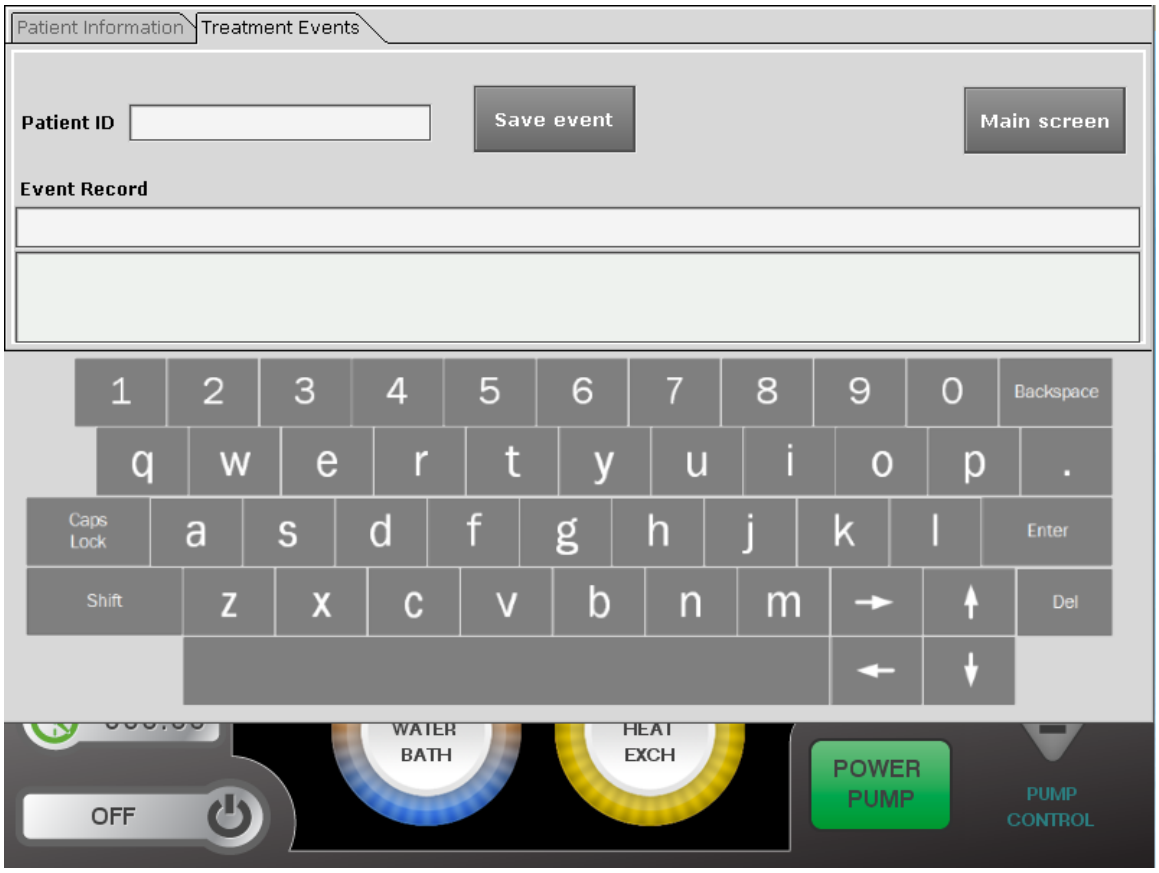
1. Select the tab labeled 'Treatment Events' to access the treatment events page.
2. Select the white box below 'Event Record'.
3. Using the keyboard, type in the event information.
4. Save the treatment event by selecting the save event button, labeled 'Save event'.

Note: After the event has been saved, the event will appear below the input box, along with a time stamp for the event. The events can be reviewed using the navigation keys on the keyboard.

Return to Main Screen

After 20 seconds of inactivity, the Patient Information and Treatment Events screen will close. However, to return to the main screen at any time, select the main screen button, labeled 'Main screen'.

Figure 15: Treatment Information Screen



Cybersecurity Warnings

⚠ The HT-2000 is equipped with a single USB port that is intended to be used only for the following operations:
- Downloading Patient Logs (See “Data Exporting and Shutting Down” Section
- Uploading software updates or patches (to be performed ONLY by an authorized ThermaSolutions Service Representative)

⚠ USB Drives that are used for the operations above MUST be 8 GB or less.

⚠ The HT-2000 does not have the access ports or capability to be connected to any other device, instrument, network, database, the internet, or anything else other than a USB drive. Doing so could render the instrument inoperable. Contact your authorized ThermaSolutions Service Representative with any USB drive questions.

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