ThermaSolutions

Cleaning and Disinfection Manual: ThermoChem™ HT-1000 and HT-2000 Systems

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

Information in this document is subject to change without notice.

The ThermoChem™ HT-1000 and HT-2000 Systems are protected under United States and international patents pending.

ThermoChem™ is a trademark of ThermaSolutions

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Symbols for General Warnings

Attention, see instructions for use

Method of sterilization, ethylene oxide

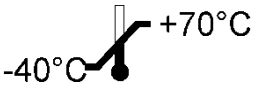
Type B applied part complying with the specific requirements of the standard IEC60601-1 to provide protection against electrical shock, particularly regarding allowable leakage current. Not suitable for direct cardiac application.

Do not reuse

Date of manufacture (YYYY-MM)

Serial number

Alternating current



Storage temperature range

Protective earth ground

CE Mark

1639

Operating Instructions-refer to instructions before use

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
	Caution
	Pressure Sensor Connection
IPX0	Ingress Protection Rating: No protection against ingress of water

Warnings, Precautions and Notes

This manual includes the following:

- **WARNINGS** emphasize situations that could result in serious injury and/or death.
- **PRECAUTIONS** 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.
- Only Disposable kits supplied by ThermaSolutions are to be used with the ThermoChem™ unit.
- 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.
- 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.
- 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 Perfusionists and Nurses who are trained in the use of the device and who have an understanding of the English language.

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

Notes

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

Surface Disinfection Procedure, HT-1000 & HT-2000

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.

Water Bath Disinfection Procedure, HT-2000

To be completed on the yearly PM/Recertification

- The following decontamination procedure was developed to decontaminate the water system of microbiological growth without damaging system components. All steps should be followed as closely as possible. This decontamination procedure should be conducted as needed or at a minimum yearly basis. Assembly of components and operation of the device should follow the instructions listed in the operator's manual.

Draining the Water Bath Reservoir:

- Follow the procedure as described in the operator's manual to drain the water bath.

WARNING:

To avoid personal injury, appropriate eye protection and personal safety protection must be worn when handling and using sodium hypochlorite (bleach). Wearing an apron is also suggested to protect clothing.

Disinfection of the Water Bath Reservoir:

- Attach a pressure sensor and a dual heat exchanger probe to the connector panel on the HT-2000.
- Attach the two supplied heat exchanger water lines to the correct fittings on the HT-2000 device.
- Attach a quick connect fitting or a non-sterile heat exchanger to the water lines, thereby ensuring a complete closed loop water circuit. (Water can flow through the water lines and back to the device).
- Fill one liter (1L) of distilled or sterile water to the empty water bath reservoir using the water access door on the side of the HT-2000. Note: Do not use de-ionized water.
- Add 12 ml of Clorox bleach or equivalent to the water reservoir. The bleach should contain sodium hypochlorite at a 5.25% solution.
- Fill an additional one liter (1L) of distilled or sterile water to the water bath reservoir.
- Turn the unit on (default water bath temperature is 42 C).
- Touch **START WATER BATH** and **START HEAT EXCH** to begin full circulation.
- Circulate for five minutes.
- Touch **STOP WATER BATH** to stop full circulation.
- Drain the unit into container capable of holding at least three liters (3L) of fluid. Refer to Draining the water bath in the operator's manual. The Water Bath Low alarm will appear on screen, along with an audible sound. Discard the water in accordance with facility policy.

Rinsing the Water Bath Reservoir:

- Fill two liters (2L) of distilled or sterile water to the empty water reservoir using the water bath access door on the side of the HT-2000.
- Clear any Water Bath alarms.
- Touch **START WATER BATH** and **START HEAT EXCH** to begin circulation
- Circulate for five minutes.
- Touch **STOP WATER BATH** to stop circulation.
- Drain the unit into container capable of holding at least three liters (3L) of fluid. The WATER BATH LOW alarm will appear on screen, along with an audible sound. Discard the water in accordance with facility policy.
- Repeat the procedure two (2) additional times, for a total of three (3) rinses.

Draining the Water Bath Reservoir:

- Touch OFF and follow on-screen instructions to power off the device.
- Drain the unit into container capable of holding at least three liters (3L) of fluid. Discard the water in accordance with facility policy.
- Disconnect the connection fitting or non-sterile heat exchanger from the water lines.
- Remove and store heat exchanger water lines, pressure sensor, and dual heat exchanger probe.
- Document the work on the unit.
- Note: The two heat exchanger hoses can also be submerged in a similar solution of 12 ml of Clorox bleach or equivalent (sodium hypochlorite at a 5.25% solution) to 2L of sterile or distilled water. The hoses should be rinsed with sterile/distilled water three times following submersion.

The unit is now ready to be returned to service.

Microbiological Inhibition Procedure, HT-2000

The following procedure was developed to inhibit microbiological growth without damaging system components. All steps should be followed as closely as possible. This procedure can be conducted as needed or after each use.

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

Microbiological Inhibition of the water bath using hydrogen peroxide:

Scenario One: The water bath of the HT-2000 is properly filled with two liters (2L) of sterile or distilled water. Drain one liter (1L) of water from the water bath. The Water Bath Low visual and audible alarm may be active. Proceed to Step #1.

Scenario Two: The water bath of the HT-2000 is empty, the water level is unknown, or user cannot confirm the water is sterile or distilled. Drain all remaining water from the water bath. With water bath empty, add one liter (1L) of sterile or distilled to the water bath access door on the side of the HT-2000. The Water Bath Low visual and audible alarm may be active. Proceed to Step #1.

1. Add 65 ml of 3% hydrogen peroxide to the water reservoir using the water bath access door.
2. Add an additional one liter (1L) of sterile or distilled water to the water bath. The water bath now contains 2L of sterile or distilled water and 65ml of 3% hydrogen peroxide solution.
3. Ensure both water hoses have been disconnected from the HT-2000. Attach a pressure sensor and a dual heat exchanger probe to the connector panel on the HT-2000.
4. If not already running, power on the HT-2000.
5. Clear any Water Bath Low alarms.
6. Touch **START WATER BATH** and **START HEAT EXCH** to begin circulation.
7. Circulate for five minutes.
8. Touch **STOP WATER BATH** to stop circulation.
9. Touch **POWER** and follow onscreen instructions to shut off the device.

10. Drain the unit into container capable of holding at least three liters (3L) of fluid. Refer to Draining the water bath in the Operator's Manual. Discard the water in accordance with facility policy.
11. Remove and store pressure sensor and dual heat exchanger probe.
12. Note: The two heat exchanger hoses can also be submerged for five minutes in a similar solution of 65ml of 3% hydrogen peroxide to 2L of sterile or distilled water.

The unit is now ready to be returned to service

Hydrogen Peroxide System Cleaning, HT-2000

The following procedure was developed to inhibit microbiological growth without damaging syst em components. All steps should be followed as closely as possible. This procedure can be cond ucted as needed or after each use. Assembly of components and operation of the device should fo llow the instructions listed in the operator's manual.

WARNING:

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

Before Starting the Hydrogen Peroxide System Cleaning:
Drain all water from the water bath of the HT-2000. Attach a dual heat exchanger probe and a pressure sensor to the connector panel. Ensure both water hoses have been disconnected, and then proceed to Step #1.

1. Add one liter (1L) of sterile or distilled water using the water bath access door on the side of the HT-2000.
2. Add 60 ml of 30% hydrogen peroxide to the water reservoir using the water bath access door .
3. Add an additional one liter (1L) of sterile or distilled water using the water bath access door.
4. Power on the ThermoChem™, if the device is not already running. Clear any Water Bath Lo w alarms.
5. Touch START WATER BATH to begin circulation.
6. Touch START HEAT EXCH.
7. Circulate for five minutes.
8. Touch STOP WATER BATH to stop circulation.
9. Touch POWER and follow onscreen instructions to shut off the device.
10. Drain the unit into container capable of holding at least three liters (3L) of fluid. Refer to Dr aining the Reservoir procedure in the operator's manual. Discard the water in accordance wi th facility policy.
11. Remove and store pressure sensor and dual heat exchanger probe.

The unit is now ready to be returned to service

Recommended Water Bath Disinfecting Procedure, HT-1000

To be completed on the yearly PM/Recertification

- The following decontamination procedure was developed to decontaminate the water system of microbiological growth without damaging system components. All steps should be followed as closely as possible. This decontamination procedure should be conducted as needed or at a minimum yearly basis. Assembly of components and operation of the device should follow the instructions listed in the operator's manual.

Draining the Water Bath Reservoir:

- Follow the procedure as described in the operator's manual to drain the water bath.

WARNING:

To avoid personal injury, appropriate eye protection and personal safety protection must be worn when handling and using sodium hypochlorite (bleach). Wearing an apron is also suggested to protect clothing.

Step 1. Disinfection of the Water Bath Reservoir:

- Attach a heat exchanger probe to the connector on the front of the HT-1000 device.
- Attach the two supplied water lines to the correct fittings on the HT-1000 device.
- Attach a quick connect fitting or a non-sterile heat exchanger to the water lines, thereby ensuring a complete closed loop water circuit. (Water can flow through the water lines and back to the device).
- Fill three liters (3L) of distilled or sterile water to the empty water bath reservoir using the water bath access door on the back of the HT-1000. Note: Do not use de-ionized water.
- Add 36 ml of Clorox bleach or equivalent to the water reservoir. The bleach should contain sodium hypochlorite at a 5.25% solution.
- Fill three additional liters (3L) of distilled or sterile water to the water bath reservoir.
- Turn the unit on and press the screen of the monitor to move to "Main" screen.
- Ensure water bath temperature is set to 42C.
- Circulate for five minutes.
- Power off the device using the On/Off switch on the back of the device.

Step 2. Draining the Reservoir during Disinfection Procedure:

- Disconnect the water lines from the front of the device.
- Separate the quick connect fitting or non-sterile heat exchanger from the water lines.
- Attach one water line to the heat exchanger inlet connection, designated by red color, on the front panel.
- Direct the water line discharge into an empty container capable of holding at least eight liters (8L) of fluid. Discard the water in accordance with facility policy.
- Turn the unit on.
- Touch the monitor to move to the "Main" screen.

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

  NOTE: The Water Bath is Too Low error message will appear.
- When the water stops draining, reattach the second water line and the quick connect fitting or a non-sterile heat exchanger.

Step 3. Rinsing the Water Bath Reservoir:

- Fill six liters (6L) of distilled or sterile water to the empty water reservoir using the water bath access door on the back of the HT-1000.
- Clear any Water Bath Low alarms.
- Allow the water to circulate for five minutes.
- Power off the device using the On/Off switch on the back of the device.
- Drain the unit by following step 2, **Draining the Reservoir during Disinfection Procedure.**
- Repeat the procedure two (2) additional times, for a total of three (3) rinses.

Step 4. Returning the Unit to Service:

- Allow any remaining water to drain from the water line.
- Power off the device using the On/Off switch on the back of the device.
- Remove and store water lines and heat exchanger probe.
- Document the maintenance work on the unit.
- Note: The two heat exchanger hoses can also be submerged for five minutes in a similar solution of 36 ml of Clorox bleach or equivalent (sodium hypochlorite at a 5.25% solution) to 6L of sterile or distilled water. The hoses should be rinsed with sterile/distilled water three times following submersion.

The unit is now ready to be returned to service

Recommended Microbiological Inhibition Procedure, HT-1000

The following procedure was developed to inhibit microbiological growth without damaging system components. All steps should be followed as closely as possible. This procedure can be conducted as needed or after each use.

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

Microbiological Inhibition of the water bath using hydrogen peroxide:

Scenario One: The water bath of the HT-1000 is properly filled with six liters (6L) of sterile or distilled water. Drain one liter (1L) of water from the water bath. Proceed to Step #1.

Scenario Two: The water bath of the HT-1000 is empty, the water level is unknown, or user cannot confirm the water is sterile or distilled. Drain all remaining water from the water bath following procedures in the Operator's Manual. With the water bath empty, add five liters (5L) of sterile or distilled to the water bath access door on the side of the HT-2000. Proceed to Step #1.

1. Add 200 ml of 3% hydrogen peroxide to the water reservoir using the water bath access door.
2. Add an additional one liter (1L) of sterile or distilled water to the water bath. The water bath now contains 6L of sterile or distilled water and 200 ml of 3% hydrogen peroxide solution.
3. Ensure both water hoses have been disconnected from the HT-1000. Attach a heat exchanger probe to the connector on the front of the HT-1000.
4. If not already running, power on the HT-1000 and proceed to the main screen.
5. Clear any alarms.
6. Set Water Bath to 42 C.
7. Circulate for five minutes.
8. Power off the device using the On/Off switch on the back of the device.
9. Attach one water line to the heat exchanger inlet connection, designated by red color, on the front panel.
10. Direct the water line discharge into an empty container capable of holding at least eight liters (8L) of fluid. Discard the water in accordance with facility policy.
11. Power on the unit.
12. Touch the monitor to move to the "Main" screen.

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

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

13. When the water stops flowing, power off the device using the On/Off switch on the back of the device.
14. Allow any remaining water to drain from the water line.
15. Remove and store water lines and heat exchanger probe.
16. Document the maintenance work on the unit.

Note: The two water lines can also be submerged for five minutes in a similar solution of 200ml of hydrogen peroxide at a 3% solution to 6L of sterile or distilled water.

The unit is now ready to be returned to service

Hydrogen Peroxide System Cleaning, HT-1000

The following procedure was developed to inhibit microbiological growth without damaging system components. All steps should be followed as closely as possible. This procedure can be conducted as needed or after each use.

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

Before Starting the Hydrogen Peroxide System Cleaning:
Drain all water from the water bath of the HT-1000 following the procedure in the Operator's Manual. Attach a heat exchange temperature probe connection on the front of the HT-1000. Ensure both water hoses have been disconnected, and then proceed to Step #1.

1. Add five liters (5L) of sterile or distilled water using the water bath access door on back of HT-1000.
2. Add 180 ml of 30% hydrogen peroxide to the water reservoir using the water bath access door.
12. Add an additional one liter (1L) of sterile or distilled water using the water bath access door.
13. Power on the ThermoChem™, if the device is not already running.
14. Clear any alarms
15. Circulate for five minutes.
16. Power off the device using the On/Off switch on the back of the device.
17. Attach one water line to the heat exchanger inlet connection, designated by red color, on the front panel.
18. Direct the water line discharge into an empty container capable of holding at least eight liters (8L) of fluid. Discard the water in accordance with facility policy.
19. Power on the unit.
20. Touch the monitor to move to the "Main" screen.

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

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

21. When the water stops flowing, power off the device using the On/Off switch on the back of the device.

22. Allow any remaining water to drain from the water line.

23. Remove and store water lines and heat exchanger probe.

24. Document the maintenance work on the unit.

The unit is now ready to be returned to service

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EC REP

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Reference only

Not to be used as part of printed manual