LEVEL 1®

OPERATOR'S MANUAL

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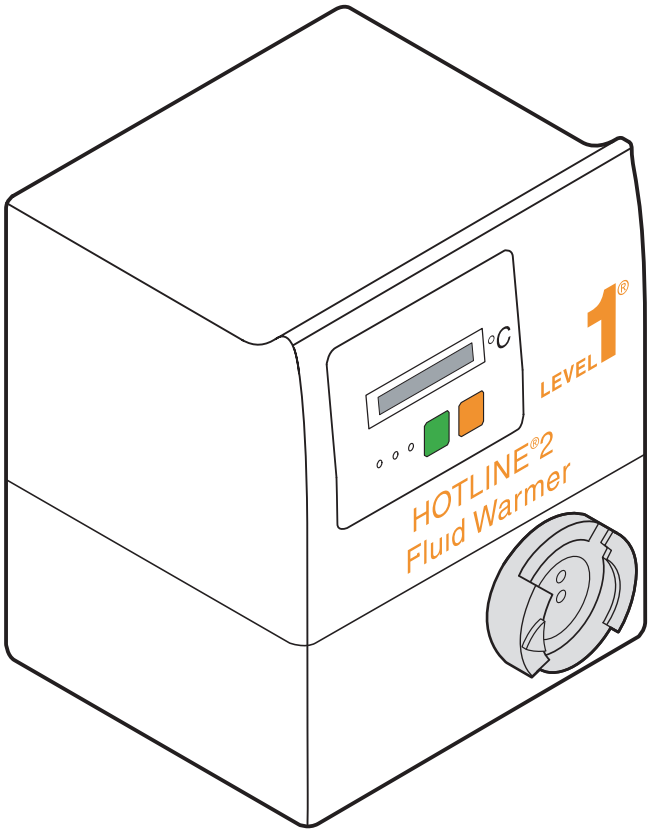
HOTLINE®2 Fluid Warmer

REF HL-290



Manufacturer:
Smiths Medical ASD, Inc.
160 Weymouth Street
Rockland, MA 02370, USA
Tel: 1-800-258-5361 (US/CA)
Tel: +1-781-878-8011

Made in USA

Australian Representative:
Smiths Medical Australasia Pty. Ltd.
61 Brandl Street, Eight Mile Plains
Brisbane, QLD 4113, Australia
Tel: +61 (0) 7 3340 1300

EC REP European Representative:
Smiths Medical International Ltd.
1500 Eureka Park, Lower Pemberton
Ashford, Kent, TN25 4BF, UK
Tel: +44 (0) 1233 722100

www.smiths-medical.com

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4533099EN Rev. 006 (05/12)

smiths medical

INSTRUCTIONS FOR USE

HOTLINE®2 FLUID WARMER (REF HL-290)

Table of Contents

NOTE: A revision date for these instructions is included for the user's information. In the event two years elapse between this date and product use, the user should contact Smiths Medical ASD, Inc. (Smiths Medical) to see if additional product information is available.

4533099EN Rev. 006 (05/12)

ABOUT THIS MANUAL

WARNING: These instructions contain important information for safe use of the product. Read the entire contents of these Instructions for Use, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient.

REFERENCES:

The L-Series Fluid Warming Set will be referred to as the **HOTLINE®2** Fluid Warming Set and Disposable Set.
The **HOTLINE®2** Fluid Warmer will be referred to as the **HOTLINE®2** Warmer.

INDICATIONS

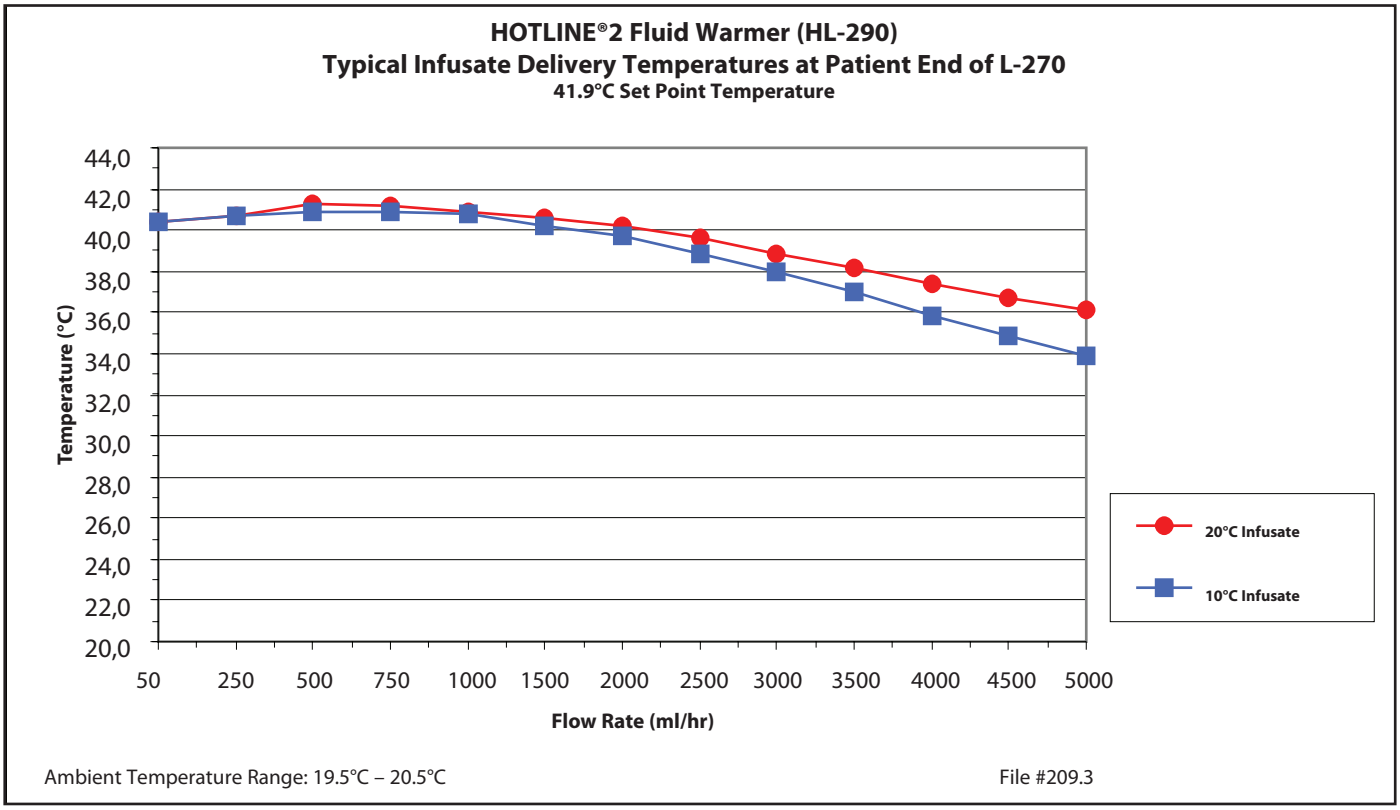
The **HOTLINE®2** Fluid Warmer is indicated for the warming of blood products and intravenous solutions prior to patient administration under gravity flow conditions. It is intended for use by appropriately trained healthcare professionals in clinical environments.

PRINCIPLES OF OPERATION

The **HOTLINE®2** Warmer delivers fluids and blood at normothermic temperatures at routine, gravity flow rates. Conventional fluid warming systems suffer from cool-down between the warmer and the patient connection. **HOTLINE®2** Warmer overcomes this problem by providing active warming of the patient line all the way to the patient connection, protecting the patient line against exposure to cold and eliminating patient line cool-down. Active warming is achieved by jacketing the sterile patient I.V. line with a layer of precisely temperature-controlled recirculating solution. A 2.4 m (8') **HOTLINE®2** Fluid Warming Set allows blood and intravenous fluid to be delivered to the patient at normothermic temperature (37°C) at gravity flow rates from 50 to 4,250 ml per hour (0.8 – 71 ml per minute).

The **HOTLINE®2** Warmer and Fluid Warming Set are an integrated, highly effective design with unparalleled ease of use. Properly trained users can confidently and safely have the **HOTLINE®2** Warmer set up and operating within seconds.

NOTE: *The* HOTLINE®2 *Warmer must be used only with* HOTLINE®2 *Fluid Warming Sets.*



DESCRIPTION

HOTLINE®2 WARMER:

An on-board water supply is heated to 41.5°C and circulated through the **HOTLINE®2** Fluid Warming Set. Electronic circuitry continuously monitors the water temperature. Recirculating solution temperature and visual alarms are indicated on the Display Panel on the front of the **HOTLINE®2** Warmer. A green LED illuminates and the "WARMING" message is displayed on this panel when the **HOTLINE®2** Warmer is set up and operating correctly.

HOTLINE®2 FLUID WARMING SET:

Single Use **HOTLINE®2** Fluid Warming Sets are provided in single packaging with Sterile Fluid Path. The connector on the **HOTLINE®2** Fluid Warming Set engages a socket on the **HOTLINE®2** Warmer. This is the only connection necessary to provide the warming function. The **HOTLINE®2** Fluid Warming Set is easily disengaged from the **HOTLINE®2** Warmer and discarded, or it may be used to continue subsequent unwarmed infusion.

SAFETY

The **HOTLINE®2** Warmer employs a safe, recirculating solution heating system, inherently free of "hot spots" to actively warm the patient line. The primary temperature control circuit limits the recirculating solution to a 41.5°C (± 0.5°C) set-point maximum. In the unlikely event of a malfunction of this circuit, a second "watch-dog" circuit will visually and audibly alarm and stop the recirculating solution pump if the temperature reaches 1.2°C above the set point. Fluid in the **HOTLINE®2** Fluid Warming Set is never exposed to any damaging or dangerous temperatures while the **HOTLINE®2** Warmer is operating.

The **HOTLINE®2** Warmer is manufactured and certified to be in compliance with IEC 60601-1:2005.

MESSAGES:

Messages that are headed by **"CONTRAINDICATION"** indicate information that alerts the user to conditions when the device should not be used.

Messages that are headed by **"WARNING"** indicate information that alerts the user to conditions that may cause death or serious injury to the patient or user.

Messages that are headed by **"CAUTION"** indicate information that alerts the user to conditions that may cause malfunction, failure, or damage to the device.

Messages that are headed by **"NOTE"** indicate information or procedures that if not followed correctly can cause improper results.

IMPORTANT SAFETY INFORMATION

This section covers information for prescribers and guidelines for safe use of the **HOTLINE®2** Warmer.

CONTRAINDICATIONS

- Not for use in warming platelets, cryo-precipitates, or granulocyte suspensions.

WARNINGS

Death or serious injury may occur to the patient or user if these warnings are not followed.

- These instructions contain important information for safe use of the product. Read the entire contents of these Instructions for Use, including Warnings and Cautions, before using this product. Failure to properly follow warnings, cautions, and instructions could result in death or serious injury to the patient.
- The **HOTLINE®2** Fluid Warming Set, PC-8, and YC-8 are single-use devices and are not intended for re-sterilization.
- Do not use **HOTLINE®2** Fluid Warming Set, PC-8, and YC-8 if the caps are not securely in place, else the I.V. flow path may not be sterile.
- The **HOTLINE®2** Warmer is for use only with Smiths Medical supplied or approved parts, accessories, and Disposable Sets. The device may not function as intended with the use of unapproved parts, accessories, or Disposable Sets.
- Blood and blood products could contain pathogenic organisms. Failure to follow institutional policy and procedures for biomedical-hazardous materials could lead to exposure to harmful pathogens.
- Set-up, priming, and use require aseptic technique as per applicable institutional policies and procedures.
- Prime the recirculating solution path before connecting to the intravenous extension set. This is to confirm that there is not a breach between the recirculating solution path and intravenous path. If fluid exits the patient end of the **HOTLINE®2** Fluid Warming Set before connecting to the intravenous administration set, remove and replace **HOTLINE®2** Fluid Warming Set.
- Remove all air from the **HOTLINE®2** Fluid Warming Set, PC-8, and YC-8 before connecting to the patient. Failure to do so may result in introduction of air to the patient.
- To reduce the risk of outgassed microbubbles entering patient vasculature, an L-10 Gas Vent may be used with the **HOTLINE®2** Fluid Warming Set.
- Not for use with pressure devices generating over 300 mmHg. Pressure greater than 300 mmHg may compromise the integrity of the **HOTLINE®2** Fluid Warming Set.
  NOTE: Hand pumps can generate over 1000 mmHg.
- Do not stick the **HOTLINE®2** Fluid Warming Set with needles, as this will breach the I.V. path and compromise the integrity of the patient intravenous line. If a Disposable Set with a breached recirculating solution path/intravenous path is used, then patient illness may occur because of the **HOTLINE®2** Warmer's recirculating solution entering the patient's bloodstream.
- Activation of the Over Temperature warning signal indicates that warming has stopped and immediate operator intervention is required to clear the over temperature condition or to remove the device from service.
- If any visual indicator does not illuminate or the audible signal does not sound, do not use the **HOTLINE®2** Warmer. Remove the device from service immediately.
- Do not operate the **HOTLINE®2** Warmer in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. The risk of explosion exists if the **HOTLINE®2** Warmer is operated in a potentially explosive environment.
- Do not use the **HOTLINE®2** Warmer in high-energy fields such as: MRI, X-RAY, portable and mobile RF communications equipment, and other such devices. The **HOTLINE®2** Warmer may act as a projectile in a strong magnetic field, cause image artifacts, or not function as intended.
- Exposed conductor on MAINS power cord can cause an electrocution hazard. Remove device from service if the MAINS power cord has exposed wires.
- Grounding reliability can only be achieved when the MAINS power cord is connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.

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- Do not mount the **HOTLINE®2** Warmer more than 107 cm (42″) above the floor. For convenience, 107 cm (42″) is indicated on the **HOTLINE®2** Warmer power cord by a black mark. Mounting the **HOTLINE®2** Warmer above 107cm (42″) may result in instability of the pole and tipping.
- Ensure that the **HOTLINE®2** Warmer clamp is screwed tightly onto the I.V. pole. Failure to securely mount the **HOTLINE®2** Warmer onto the I.V. pole may cause the **HOTLINE®2** Warmer to slide down the I.V. pole.
- Do not use the **HOTLINE®2** Warmer if equipment or Disposable Set malfunction is evident.
- No user-serviceable parts. All service must be performed by Smiths Medical or competent personnel.
- **HOTLINE®2** Warmer should be tested by hospital biomedical personnel prior to placing it in service. All testing and maintenance should be performed by competent personnel.
- No modification of this equipment is allowed.

CAUTIONS

Malfunction, failure, or damage to the device may occur if these cautions are not followed:

- Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.
- Do not autoclave or immerse any part of the **HOTLINE®2** Warmer in liquids, which may cause damage and improper functioning.
- Never use organic solvents (e.g., acetone), strong acids, or bases to clean any portion of the **HOTLINE®2** Warmer.
- Do not place the **HOTLINE®2** Warmer directly under a faucet or use a faucet sprayer to rinse. Never spray cleaning or other fluids into openings on the **HOTLINE®2** Warmer or into the external connectors.
- This device is cooled by convection. Be sure the air vents on the bottom and the back of the device are kept clear.
- Medical devices require specific material characteristics to perform as intended. These characteristics have been verified for single use only. Any attempt to re-process the device for subsequent re-use may adversely affect the integrity of the device or lead to deterioration in performance.

ELECTRICAL SAFETY:

POWER REQUIREMENT

Most of the current drawn by the **HOTLINE®2** Warmer is for the 300-Watt immersion heater. When the device is first turned on and the digital display shows rapidly rising temperatures below 41°C, the 300-Watt heater is in a full ON condition. Beyond approximately 40°C, the proportional controller cycles the heater ON/OFF with proportionally shorter ON times as the recirculating solution nears the 41.5°C set point.

ELECTRICAL SAFETY TESTING:

All testing and maintenance should be performed by competent personnel. Safety testing is to be conducted on an annual basis. This involves earth leakage and ground continuity, which must be tested according to UL 2601-1 and EN 60601-1.

NOTE: **This device is equipped with disposable sensing interlocks. A HOTLINE®2 Fluid Warming Set is required to correctly operate the device and perform leakage current testing. Do not defeat the disposable sensing interlocks or try to operate the HOTLINE®2 Warmer without a Fluid Warming Set in place.**

Earth leakage must be tested according to UL 2601-1 and EN 60601-1. Earth leakage current test should be performed with the immersion heater circuit in the full ON condition. For this reason, leakage current test should be performed on a **HOTLINE®2** Warmer that has room temperature solution in the reservoir tank.

Ground continuity must be tested according to UL 2601-1 and EN 60601-1.

HOTLINE®2 Warmer is certified that it is in compliance with the European Communities Council Directive relating to Electromagnetic Compatibility (EMC): (89/336/EEC). Test methods and acceptance criteria as specified in EN 60601-1-2 demonstrate conformance.

STORAGE

Store in a cool dry place. Do not expose to extreme temperature. See Environmental Specifications for more details.

PREPARATION AND SET-UP

HARDWARE:

WARNING

HOTLINE®2 Warmer should be tested by hospital biomedical personnel prior to placing it in service. All testing and maintenance should be performed by competent personnel.

Step 1: CLAMP THE HOTLINE®2 WARMER SECURELY TO AN I.V. POLE.

WARNING

- Do not mount the **HOTLINE®2** Warmer more than 107 cm (42") above the floor. For convenience, 107cm (42") is indicated on the **HOTLINE®2** Warmer line cord by a black mark. Mounting the **HOTLINE®2** Warmer above 107cm (42") may result in instability of the pole and tipping.
- Ensure that the **HOTLINE®2** Warmer pole clamp is screwed tightly onto the I. V. Pole. Failure to securely mount the **HOTLINE®2** Warmer onto the I.V. Pole may cause the **HOTLINE®2** Warmer to slide down the I.V. Pole.

CAUTION

- This device is cooled by convection. Be sure the air vents on the bottom and the back of the **HOTLINE®2** Warmer are kept clear.

Step 2: FILL THE RESERVOIR TANK.

1. The reservoir tank is located under the **HOTLINE®2** Warmer. Remove the reservoir tank by twisting it 1/4 turn clockwise.
2. Fill the reservoir tank with 500 ml of distilled water or the 35% alcohol maintenance solution (refer to the MAINTENANCE Section for mixing instructions).
3. Replace the reservoir tank and twist counterclockwise to secure in place.

WARNING

- Grounding reliability can only be achieved when the MAINS power cord is connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.

4. Plug the **HOTLINE®2** into the applicable outlet (115V~ or 230V~).

NOTE: ***Use Distilled Water only.*** *Failure to use distilled water may cause mineral build-up in the recirculating solution path, which may impair heater performance.*

NOTE: ***If the unit does not heat to its set point temperature within *10 minutes remove unit from service.*** *(* 10 minutes of operation without Infusate being heated.)*

PREPARATION

To set up the **HOTLINE®2** Fluid Warming Set you will need the following:

- **HOTLINE®2** Warmer
- **HOTLINE®2** Fluid Warming Set (L-270)
- Intravenous fluid or blood
- Intravenous administration set

INSTRUCTIONS FOR USE:

NOTE: ***Figure 1 is a graphical representation of the following steps.***

Step 1: Set-up the HOTLINE®2 Fluid Warming Set

WARNING

- Set-up, priming, and use require aseptic technique as per applicable institutional policies and procedures. Death or serious injury may occur to the patient or user if this warning is not followed.
- The **HOTLINE®2** Fluid Warming Set, PC-8, and YC-8 are single-use devices and are not intended for re-sterilization.
- Do not use **HOTLINE®2** Fluid Warming Set, PC-8, and YC-8 if the caps are not securely in place, else the I.V. flow path may not be sterile.
- Do not stick the **HOTLINE®2** Fluid Warming Set with needles, as this will breach the I.V. path and compromise the integrity of the patient intravenous line. If a Disposable Set with a breached recirculating solution path/intravenous path is used, then patient illness may occur because of the **HOTLINE®2** Warmer's recirculating solution entering the patient's bloodstream.
- Not for use with pressure devices generating over 300 mmHg. Pressure greater than 300 mmHg may compromise the integrity of the **HOTLINE®2** Fluid Warming Set.

  NOTE: Hand pumps can generate over 1000 mmHg.
- Do not use the **HOTLINE®2** Warmer if equipment or Disposable Set malfunction is evident.

1. Insert the Fluid Warming Set Connector into the socket on the front of the **HOTLINE®2** Warmer, lining up the arrow on the connector with the arrow on the **HOTLINE®2** Warmer. Turn the connector to the right to lock into place.

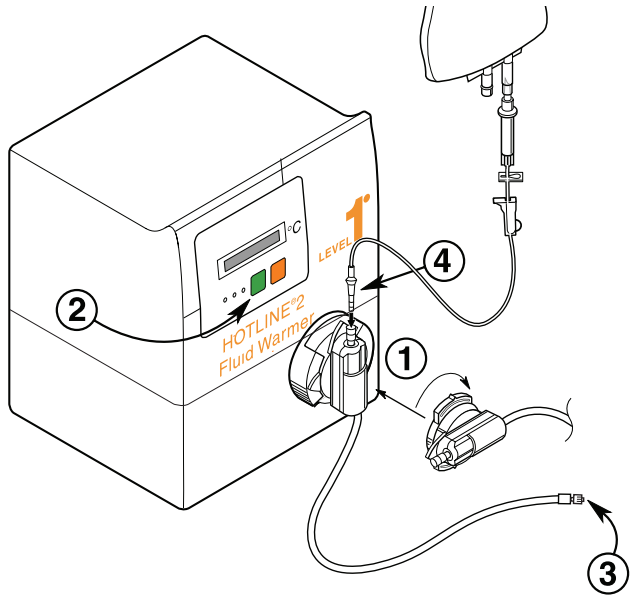

Figure 1

Step 2: Activate the Power "ON" switch.

WARNING

- Activation of the Over Temperature warning signal indicates that warming has stopped and immediate operator intervention is required to clear the over temperature condition or to remove the device from service.
- If any visual indicator does not illuminate or the audible signal does not sound, do not use the **HOTLINE®2** Warmer. Remove the device from service immediately. Death or serious injury may occur to the patient or user if this warning is not followed.

1. The “SELF-TEST” message will appear in the display. All LEDs will light (green, yellow, and red) and the audible alarm will sound briefly.
2. Once the **HOTLINE®2** Warmer has completed the start-up test procedure, the “PASSED SELF-TEST” message will display, followed by the “SET POINT” message which indicates the recirculating solution temperature. The “WARMING” message displays while in use. The green “OPERATING” LED will illuminate. The recirculating solution temperature, displayed in degrees Celsius, will begin to increase. The recirculating solution temperature display will reach 37°C in approximately 4 minutes. When **HOTLINE®2** Warmer reaches it set point temperature it is ready to warm fluids.

Step 3: Confirm Integrity of Tubing Set

1. The recirculating solution path will automatically prime when the **HOTLINE®2** Warmer is turned on. Inspect the patient end of the tubing for leaks to confirm the integrity of the intravenous pathway.

Step 4: Connect the Intravenous Administration Set

WARNING

- Prime the recirculating solution path before connecting to the intravenous extension set. This is to confirm that there is not a breach between the recirculating solution path and intravenous path. If fluid exits the patient end of the **HOTLINE®2** Fluid Warming Set before connecting to the intravenous administration set, remove and replace **HOTLINE®2** Fluid Warming Set. Death or serious injury may occur to the patient or user if this warning is not followed.
- Remove all air from the **HOTLINE®2** Fluid Warming Set, PC-8, and YC-8 before connecting to the patient. Failure to do so may result in introduction of air to the patient.

1. Using aseptic technique, connect the intravenous administration set to the **HOTLINE®2** Fluid Warming Set.
2. Fully prime the intravenous administration set and the **HOTLINE®2** Fluid Warming Set.
3. Aseptically, connect to the patient’s intravenous access site without entrapping air.
4. Adjust the rate of flow using the clamp on the intravenous administration set.

After Use

WARNING

- Blood and blood products could contain pathogenic organisms. Failure to follow institutional policy and procedures for biomedical-hazardous materials could lead to exposure to harmful pathogens.

1. Depress the Power “OFF” switch.
2. The “WAIT DRAINING” message will appear in the display while the **HOTLINE®2** Warmer recaptures recirculating solution from the **HOTLINE®2** Fluid Warming Set tubing.
3. When recirculating solution recapture is complete the “REMOVE DISPOSABLE” message will display for 15 seconds and the **HOTLINE®2** Warmer will shut down.
4. Disconnect the **HOTLINE®2** Fluid Warming Set by turning the connector to the left.
5. After use, this product may be a potential biohazard. Handle and dispose of in accordance with accepted medical practice and applicable local, state and federal regulations.

TROUBLESHOOTING

1. Alarms: Visual (red indicator LED) and Audible (pulsed alarm)

- **Display reads "OVER TEMPERATURE":** Indicates a malfunction of the temperature control system. No fluid warming is taking place. Depress the Power "OFF" switch and remove from service for repair or replacement.

2. Indicator: Visual (LCD)

- **Display reads "WATER TANK LOW":** Blinking message indicates that additional distilled water or 35% alcohol maintenance solution should be added to the **HOTLINE®2** Warmer reservoir tank. Failure to use distilled water or 35% alcohol maintenance solution may impair heater performance.

3. Indicator: Visual (yellow indicator LED) and Audible (pulsed alarm)

- **Display reads "FAILED SELF-TEST":** Indicates that the **HOTLINE®2** Warmer has failed the Self-Test procedure. Depress the Power "OFF" switch and remove the **HOTLINE®2** Warmer from service.
- **Display reads "DISPOSABLE":** Indicates that the **HOTLINE®2** Fluid Warming Set is not properly installed and fluid warming is not taking place. Check **HOTLINE®2** Fluid Warming Set connector insertion.
- **Display reads "ADD WATER":** Indicates that additional distilled water or 35% alcohol maintenance solution must be added to the **HOTLINE®2** Warmer reservoir tank. No fluid warming is taking place. Depress the Power "OFF" switch, remove the reservoir tank, fill with distilled water or 35% alcohol maintenance solution, replace and activate the Power "ON" switch. Failure to use distilled water or 35% alcohol maintenance solution may cause mineral build-up in the recirculating solution path, which may impair heater performance.
- **Display reads "NOT WARMING":** Indicates that warming is not taking place. Check for kinks in the tubing. If the problem persists, depress the Power "OFF" switch and remove the **HOTLINE®2** Warmer from service.

REMOVAL FROM SERVICE:

If any of the following conditions occur the HOTLINE®2 Warmer must be removed from service.

- Failed Self-Test
- Over Temperature Alarm is activated
- IV Pole Clamp does not function correctly
- Missing, misaligned, incorrect or incomprehensible characters on the LCD
- Does not circulate or recapture solution
- Pumping solution without disposable connected
- Does not reach maximum set point temperature within 10 minutes (when not administering Infusate)
- Does not power up or power down
- Audible and Visual Indicators do not function
- LCD characters do not change with respect to the **HOTLINE®2** Warmer function or display wrong language.

MAINTENANCE

All testing and maintenance should be performed by competent personnel.

EXTERNAL CLEANING: EVERY USE

CAUTION

- Do not autoclave or immerse any part of the **HOTLINE®2** Warmer in liquids, which may cause damage and improper functioning.

Clean and inspect the **HOTLINE®2** Warmer.

Clean the Exterior

Clean the entire **HOTLINE®2** Warmer after every use.

CAUTION

- Never use organic solvents (e.g., acetone), strong acids, or bases to clean any portion of the **HOTLINE®2** Warmer.
- Do not place the **HOTLINE®2** Warmer directly under a faucet or use a faucet sprayer to rinse. Never spray cleaning or other fluids into openings on the **HOTLINE®2** Warmer or into the external connectors.

1. Unplug the **HOTLINE®2** Warmer before servicing.
2. Visually inspect the **HOTLINE®2** Warmer to ensure there is no visible damage or deterioration of the enclosure such as cracks, or deterioration of the labels and power cord. Do not clean if there is a defect. Contact Smiths Medical or your local Smiths Medical distributor.
3. Immerse a soft cloth or sponge as an applicator into the cleaning solution consisting of mild liquid detergent soap and warm tap water mixture. Squeeze out excess solution so that the applicator is not dripping. Wipe or scrub the entire surface of the enclosure and control panels. Use a soft brush to clean the power cord if necessary.
4. Rinse a separate soft cloth or sponge in room temperature running potable water. Squeeze out excess water so that the applicator is not dripping. Wipe all of the aforementioned surfaces. Repeat rinsing the cloth or sponge several times with fresh running water during this process to insure all visible residue is removed.
5. Dry the item with a hand towel or soft cloth.
6. Visually inspect the **HOTLINE®2** Warmer and its components to insure that they have been thoroughly cleaned. Repeat cleaning procedure if necessary.
7. After thoroughly cleaning the **HOTLINE®2** Warmer, perform disinfection if required.
8. If it is hospital policy to perform disinfection as part of reprocessing, then follow your institution's guidelines for disinfecting of the surfaces of non-critical medical devices. The list below includes low-level disinfectants that are commonly used in the medical community and high-level disinfectants that are claimed by the manufacturer. The effectiveness of these listed disinfectants should be validated using the hospital procedures.

   The following disinfectant agents can be used without causing damage to the enclosure:

   Low Level Disinfectants:

   - fantastik® All Purpose Cleaner

   High Level Disinfectants:

   - 1.56% Phenol (e.g., Sporicidin®)
   - 3.4% Glutaraldehyde (e.g., CIDEX® Plus)
   - 10% Bleach solution
   - 1% Ammonia solution
   - Surface disinfectants compatible with plastic materials.
9. Rinsing of the disinfectant residue should be done using a soft cloth or sponge as the applicator.

GENERAL INSPECTION: EVERY USE

Visually check the condition of the **HOTLINE®2** Warmer. Remove from service any **HOTLINE®2** Warmer which shows physical damage or one in which the **HOTLINE®2** Fluid Warming Set does not install easily.

CHANGE DISTILLED WATER: EVERY 30 DAYS

1. Unplug the **HOTLINE®2** Warmer before servicing.
2. The reservoir tank is located under the **HOTLINE®2** Warmer. Remove the reservoir tank by twisting it 1/4 turn clockwise.
3. Empty the reservoir tank.
4. Fill the reservoir tank with 500 ml of distilled water or 35% alcohol maintenance solution; directions follow.
   Maintenance solution:
   - 35% isopropyl alcohol / distilled water solution: mix 250 ml of 70% isopropyl alcohol and 250 ml of distilled water (this will equal 500 ml of fluid)
5. Replace the reservoir tank and twist counterclockwise to secure in place.

DISINFECTION: EVERY 30 DAYS

To disinfect the reservoir tank and recirculating solution path, the following procedure should be employed:

1. Unplug the **HOTLINE®2** Warmer before servicing.
2. The reservoir tank is located under the **HOTLINE®2** Warmer. Remove the reservoir tank by twisting it 1/4 turn clockwise.
3. Empty the reservoir tank.
4. Fill the reservoir tank with 500 ml of:
   - A 35% isopropyl alcohol / distilled water solution: mix 250 ml of 70% isopropyl alcohol and 250 ml of distilled water (this will equal 500 ml of fluid)

These suggested instructions are designed to be used in conjunction with established hospital procedures.

NOTE: ***Use Distilled Water only. Failure to use distilled water may cause mineral build-up in the recirculating solution path, which may impair heater performance.***

5. Replace the reservoir tank and twist counterclockwise to secure in place.
6. Insert a **HOTLINE®2** Fluid Warming Set into the **HOTLINE®2** Warmer.
7. Activate the Power "ON" switch and let the solution circulate for 30 minutes.
8. Depress the Power "OFF" switch, remove the reservoir tank and empty.
9. Refill the reservoir tank with 500 ml of distilled water or 35% alcohol maintenance solution.
10. Replace the reservoir tank and twisting it 1/4 turn counterclockwise to secure in place.

TESTING

All testing and maintenance should be performed by competent personnel.

All testing should be performed annually or following hospital protocol.

NOTE: ***Indicator testing requires a* HOTLINE®2 *Fluid Warming Set to be installed and the* HOTLINE®2 *Warmer operating.***

WARNING

- If any visual indicator does not illuminate or the audible signal does not sound, do not use the **HOTLINE®2** Warmer. Remove the device from service immediately. Death or serious injury may occur to the patient or user if this warning is not followed.

INDICATOR TESTING

Add Water Indicator: The **HOTLINE®2** Warmer is equipped with a float switch, which senses the recirculating solution level in the reservoir tank. When the recirculating solution is too low, the ADD WATER Indicator will activate.

To test the Add Water Indicator circuit:

1. Unplug the **HOTLINE®2** Warmer before servicing.
2. The reservoir tank is located under the **HOTLINE®2** Warmer. Remove the reservoir tank by twisting it 1/4 turn clockwise.
3. Empty the reservoir tank, then refill the reservoir tank with approximately 200 ml of water and replace it.
4. Turn the unit on and observe the LCD, it will display the words "ADD WATER".
5. Observe that the green LED goes out.
6. The yellow ADD WATER LED will light.
7. The audible alarm will sound.
8. Water will stop circulating.
9. Remove the reservoir tank; add approximately 75 ml of water.
10. Replace the reservoir tank, turn the unit on and observe the LCD, it will intermittently display the words "LOW WATER LEVEL".

Disposable Indicator: An interlock switch located in the Disposable Interface Block senses a properly installed **HOTLINE®2** Fluid Warming Set. When the switch does not sense a **HOTLINE®2** Fluid Warming Set the message "DISPOSABLE" will be displayed.

To test the Disposable Indicator circuit:

1. Slowly remove the **HOTLINE®2** Fluid Warming Set from the **HOTLINE®2** Warmer.
2. Observe that the green LED goes out.
3. The message "DISPOSABLE" will be displayed.
4. The audible alarm will sound.
5. Recirculating solution will be recaptured.

TEMPERATURE VERIFICATION

All testing and maintenance should be performed by competent personnel.

Displayed Recirculating Solution Temperature: Should be verified using a Level 1® ***TEMP CHECK*** Thermometer (HLTA-20). Other methods of temperature verification may be inaccurate. **HOTLINE®2** Warmer can be returned for temperature verification.

Refer to the TEMP CHECK Thermometer (HLTA-20) Operator's Manual that accompanies the HLTA-20 for complete Temperature Verification and Calibration Instructions.

RECOMMENDED MAINTENANCE CHECK LIST

MODEL: HOTLINE®2 FLUID WARMER

REF HL-290

All testing and maintenance should be performed by competent personnel.

Write your date of purchase here _____

Write your serial number here _____

30-day maintenance tasks

Change Distilled Water or 35% alcohol maintenance Solution											

12 months maintenance tasks

Verify Temperature/ Calibrate (see Temp Check Manual)										
Alarm / Indicator Testing										
Earth Leakage Test										
Ground Continuity Test										

You may photocopy this form for your record keeping.

Notes:

LIMITED WARRANTY

HOTLINE®2 Fluid Warmer REF HL-290

Smiths Medical ASD, Inc. (the "Manufacturer") warrants to the Original Purchaser that the **HOTLINE®2** Fluid Warmer (the "**HOTLINE®2** Warmer"), not including accessories, shall be free from defects in materials and workmanship under normal use, if used in accordance with this Operator's Manual, for a period of one year from the actual date of sale to the Original Purchaser. THERE ARE NO OTHER WARRANTIES.

This warranty does not cover normal wear and tear and maintenance items, and excludes any accessory items or equipment used with the **HOTLINE®2** Warmer.

Subject to the conditions of and upon compliance with this Limited Warranty, the Manufacturer will repair or replace at its option without charge (except for a minimal charge for postage and handling) any **HOTLINE®2** Warmer (not including accessories) which is defective if a claim is made during such one-year period.

The following conditions, procedures, and limitations apply to the Manufacturer's obligation under this warranty:

A. Parties Covered by this Warranty: This warranty extends only to the Original Purchaser of the **HOTLINE®2** Warmer. This warranty does not extend to subsequent purchasers. The Original Purchaser may be medical personnel, a hospital, or institution which purchases **HOTLINE®2** Warmers for treatment of patients. The Original Purchaser should retain the invoice or sales receipt as proof as to the actual date of purchase.

B. Warranty Performance Procedure: Notice of the claimed defect must be made in writing or by telephone to the Manufacturer as follows: Customer Service Department, Smiths Medical ASD, Inc., 160 Weymouth Street, Rockland, MA 02370, (800) 258-5361. Notice to the Manufacturer must include date of purchase, model and serial number, and a description of the claimed defect in sufficient detail to allow the Manufacturer to determine and facilitate any repairs which may be necessary. AUTHORIZATION MUST BE OBTAINED PRIOR TO RETURNING THE **HOTLINE®2** WARMER. If authorized, the **HOTLINE®2** Warmer must be properly and carefully packaged and returned to the Manufacturer, postage prepaid. Any loss or damage during shipment is at the risk of the sender.

C. Conditions of Warranty: The warranty is void if the **HOTLINE®2** Warmer has been 1) repaired by someone other than the Manufacturer or its authorized agent; 2) altered so that its stability or reliability is affected; 3) misused; or 4) damaged by negligence or accident. Misuse includes, but is not limited to, use not in compliance with the Operator's Manual or use with non-approved accessories. Removal or damage to the **HOTLINE®2** Warmer's serial number will invalidate this warranty.

D. Limitations and Exclusions: Repair or replacement of the **HOTLINE®2** Warmer or any component part thereof is the EXCLUSIVE remedy offered by the Manufacturer. The following exclusions and limitations shall apply:

1. No agent, representative, or employee of the Manufacturer has authority to bind the Manufacturer to any representation or warranty, expressed or implied.
2. THERE IS NO WARRANTY OF MERCHANTABILITY OR FITNESS OR USE OF THE **HOTLINE®2** WARMER FOR ANY PARTICULAR PURPOSE.
3. The **HOTLINE®2** Warmer can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the **HOTLINE®2** Warmer for any particular medical treatment.
4. All recommendations, information, and descriptive literature supplied by the Manufacturer or its agents are believed to be accurate and reliable, but do not constitute warranties.

The Manufacturer disclaims responsibility for the suitability of the **HOTLINE®2** Warmer for any particular medical treatment or for any medical complications resulting from the use of the **HOTLINE®2** Warmer. The Manufacturer shall not be responsible for any incidental damages or consequential damages to property, loss of profits, or loss of use caused by any defect or malfunction of the **HOTLINE®2** Warmer.

This warranty gives the Original Purchaser specific legal rights, and the Original Purchaser may have other legal rights which may vary from state to state.

SERVICE

WARNING

No user-serviceable parts. All service must be performed by Smiths Medical or competent personnel.

All service must be performed and/or authorized by Smiths Medical or competent personnel. Service by others voids the warranty and transfers liability for malfunctions of the device to the servicing organization.

NON-WARRANTY WORK

Devices received that are no longer under warranty can be returned for repair at a cost. The device will be promptly inspected and a verbal estimate of the repair cost will be provided. A purchase order will be required from the original purchaser consistent with the verbal estimate. A written estimate will be provided upon request.

Before returning the **HOTLINE®2** Warmer for service, contact Smiths Medical for Returned Goods Authorization. Be sure that ALL recirculating solution is drained from the device before packing the **HOTLINE®2** Warmer for shipment.

Note: The* HOTLINE®2 *Warmer must be cleaned and disinfected for repair shipment or it will be immediately returned as received.

DISPOSAL INFORMATION

Observe national and local codes or requirements for disposal of contaminated materials and for recycling of solid waste materials that may impact the environment.

SERVICE CONTACTS:

USA/Canada
Smiths Medical ASD, Inc.
160 Weymouth Street
Rockland, MA 02370 USA
Tel: 1-800-258-5361 (US/CA)
Tel: +1-781-878-8011

European Representative
Smiths Medical International Ltd.
1500 Eureka Park, Lower Pemberton
Ashford, Kent, TN25 4BF, UK
Tel: +44 (0) 1233 722100

Australian Representative
Smiths Medical Australasia Pty. Ltd.
61 Brandl Street, Eight Mile Plains
Brisbane, QLD 4113, Australia
Tel: +61 (0) 7 3340 1300
Fax: +61 (0) 7 3340 1399

www.smiths-medical.com

ACCESSORIES

REF	Product Description
L-270	HOTLINE®2 Fluid Warming Set
PC-8	T-Connector, 20.3 cm (8") patient lead with Injection Port
YC-8	Y-Connector, 20.3 cm (8") patient lead with Injection Port

SPECIFICATIONS REF HL-290

If the **HOTLINE®2** Warmer should encounter any electrical interference, either receiving or transmitting, move the **HOTLINE®2** Warmer away from the device in question. Plug the **HOTLINE®2** Warmer into a separate electrical circuit. If problem continues, notify Smiths Medical or your local Smiths Medical Distributor for assistance.

PHYSICAL SPECIFICATIONS:

Height	24.1 cm (9.5 inches)
Length	21 cm (8.3 inches)
Width	17.8 cm (7.0 inches)
Weight dry	3.5 kg (7.6 lbs.)
Weight wet	5.0 kg (11.0 lbs.)
Weight, Shipping	3.6 kg (7.95 lbs.)

ELECTRICAL SPECIFICATIONS:

Electrical Classification: Class 1 Equipment, Type BF

Input Voltage	**115V~**	**230V~**
Operating Frequency	50-60 Hz	50-60 Hz
Operating Current	3.0A	1.5A

OPERATING SPECIFICATIONS:

The recirculating solution has a set point temperature of 41.5°C with an accuracy of ± 0.5°C. The temperature displayed has an accuracy of ± 1.0°C.

Temperature Set point Range (36.0 - 41.9°C) ±0.5°C

Max. Height on I.V. Pole 107 cm (42 inches)

This equipment was tested for compliance to UL 2601-1 and EN 60601-1.

ENVIRONMENTAL SPECIFICATIONS:

	Temperature	Humidity [%]
Operation	10°C - 30°C	10-95
Transport	-18°C - +60°C	5-90
Storage	-18°C - +60°C	5-90

SYMBOLS

CAUTION	
MAXIMUM WATER LEVEL	
ALTERNATING CURRENT	
TYPE BF APPLIED PART	
PROTECTED AGAINST THE INGRESS OF WATER	IPX 1
ELECTRICAL SHOCK HAZARD	
DATE OF MANUFACTURE	
LINE (MAINS)	L
NEUTRAL (MAINS)	N
PROTECTIVE EARTH	
ON FOR A PART OF THE EQUIPMENT	
OFF FOR A PART OF THE EQUIPMENT	
COLLECT SEPARATELY FOR ELECTRICAL AND ELECTRONIC EQUIPMENT	
CATALOG NUMBER	REF
SERIAL NUMBER	SN
BATCH CODE	LOT
CONTAINS OR PRESENCE OF PHTHALATE: bis(2-ethylhexyl) phthalate (DEHP)	PHT DEHP

AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY	EC REP
MANUFACTURER	
QUANTITY	
DO NOT REUSE	
CONSULT INSTRUCTIONS FOR USE **(The symbol appears on the device with a blue background.)**	
CONSULT INSTRUCTIONS FOR USE	
NOT MADE WITH NATURAL RUBBER LATEX	
CAUTION: FEDERAL (U.S.A.) LAW RESTRICTS THIS DEVICE TO SALE BY OR ON THE ORDER OF A PHYSICIAN.	**Rx ONLY**
DEVICE IS CLASS TYPE 1 EQUIPMENT	***CLASS 1***
DO NOT USE IF PACKAGE IS DAMAGED	
STERILE FLUID PATH, ETHYLENE OXIDE GAS STERILIZED	
TEMPERATURE LIMITATION	
HUMIDITY LIMITATION	
KEEP AWAY FROM SUNLIGHT	
KEEP DRY	
USE BY	
RECYCLABLE PRODUCT	
DEVICE HAS BEEN TESTED BY TÜV SÜD AMERICA, A NATIONALLY RECOGNIZED TECHNICAL LABORATORY, TO MEET ALL REQUIREMENTS FOR SAFETY.	
DEVICE HAS BEEN TESTED BY NATIONAL TECHNICAL SYSTEMS, A NATIONALLY RECOGNIZED TECHNICAL LABORATORY, TO MEET U.S. REQUIREMENTS FOR SAFETY.	
CE MARK AND NOTIFIED BODY NUMBER **(0473 INDICATES AMTAC)**	CE 0473