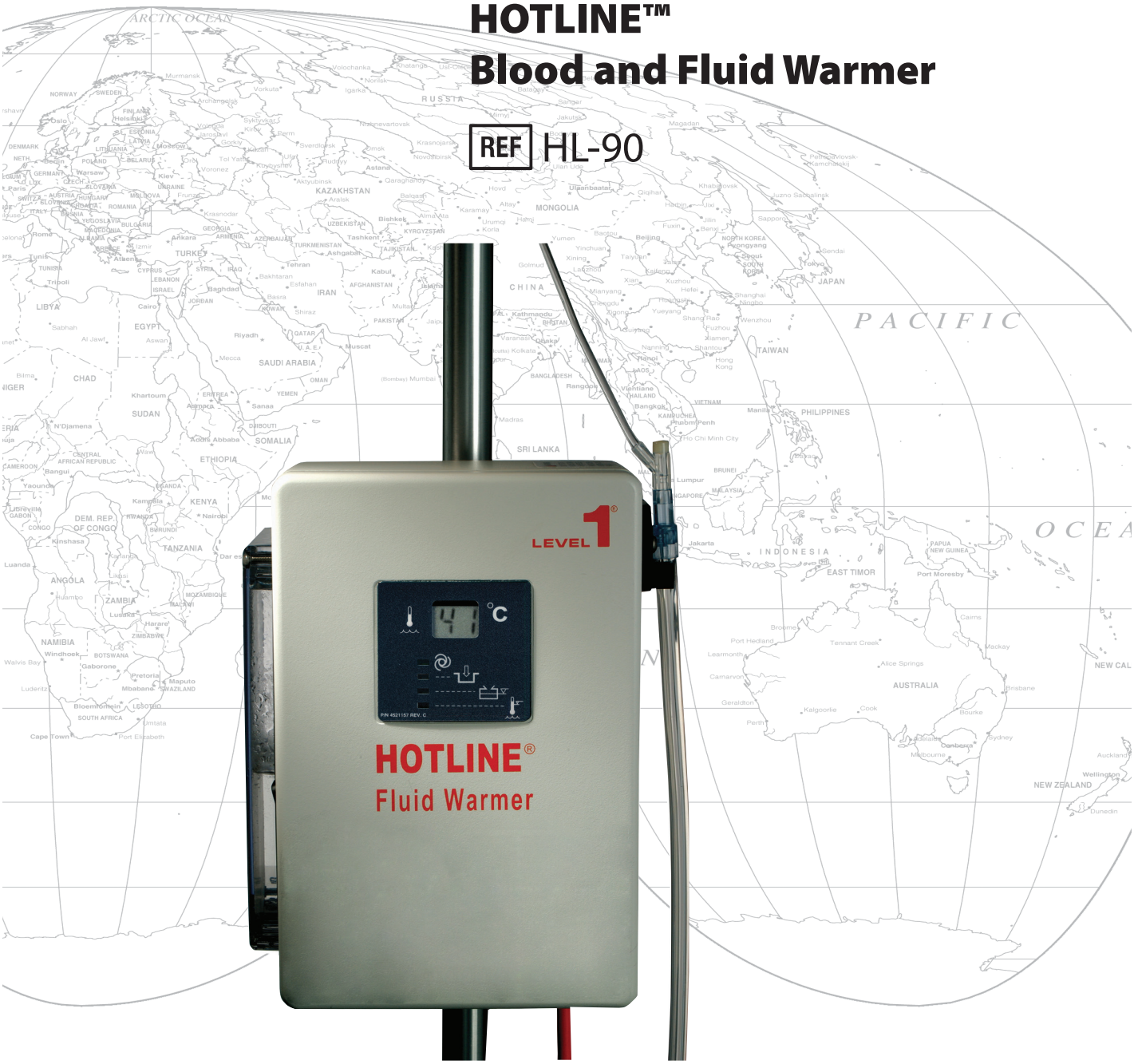
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OPERATOR'S MANUAL

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Blood and Fluid Warmer

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Blood and Fluid Warmer

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OPERATOR'S MANUAL

PN IFU0000836 (01)

HOTLINE™ Blood and Fluid Warmer

Part Number: IFU0000836 (01)

This revision supercedes all previous revisions.

Every effort has been made to ensure that the information in this manual is accurate and details provided are correct at the time of printing. The company, however, reserves the right to improve the equipment shown. Mention of third-party products is for informational purposes only and constitutes neither an endorsement nor a recommendation. ICU Medical ASD, Inc. ("ICU Medical") assumes no responsibility with regard to the performance or use of these products.

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SECTION 1

About this Manual

This operator's manual describes the assembly, use, and maintenance of the HOTLINE™ Blood and Fluid Warmer. This manual is intended for use by individuals trained in the healthcare and biomedical professions.

WARNING: These instructions contain important information for safe use of the product. Read the entire contents of this operator's manual, 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.

Indications for Use

The HOTLINE™ Blood and Fluid Warmer is designed for use with the HOTLINE™ Fluid Warming Set to warm blood and intravenous (I.V.) fluids and deliver them to the patient's intravenous access site at normothermic temperatures under gravity flow conditions. The HOTLINE™ Warmer is intended for use by trained medical personnel to provide routine flow of warmed I.V. fluid.

Conventions Used in this Manual

- The HOTLINE™ Blood and Fluid Warmer will be referred to as the HOTLINE™ Warmer.
- The L Series Fluid Warming Sets (L-70, L-70NI, L-80) will be referred to as the HOTLINE™ Fluid Warming Set or Disposable Set.

Convention	Description
CONTRAINDICATION	A Contraindication statement alerts the operator to conditions when the device should not be used.
CAUTION	A Caution statement alerts the operator to conditions that may cause malfunction, failure, or damage to the device.
WARNING	A Warning statement alerts the operator to conditions that may cause death or serious injury to the patient or operator.

SECTION 2

Description

The HOTLINE™ Warmer delivers blood and intravenous fluid at normothermic temperatures by surrounding the sterile intravenous line with a layer of warmed recirculating solution. An onboard recirculating solution supply is heated to 41.5°C ± 0.5 and circulated through the outer lumen of the HOTLINE™ Fluid Warming Set, which surrounds the intravenous line.

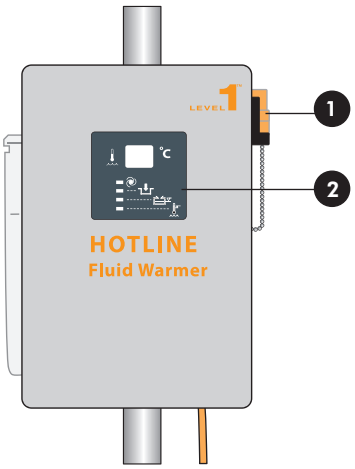
The HOTLINE™ Warmer employs a safe, recirculating solution heating system, inherently free of "hot spots," to actively warm the patient line. Electronic circuitry continuously monitors the recirculating solution temperature. The primary temperature control circuit limits the recirculating solution to 42°C maximum. In the unlikely event of a malfunction of this circuit, a second "watchdog" circuit will visually and audibly alarm and stop the recirculating solution pump if the temperature reaches 43.1°C. Fluid in the HOTLINE™ Fluid Warming Set is never exposed to any damaging or dangerous temperatures while the HOTLINE™ Warmer is operating.

The recirculating solution temperature and visual alarms are indicated on the Display Panel on the front of the HOTLINE™ Warmer. A green Operating light illuminates on this panel when the HOTLINE™ Warmer is set up and operating correctly.

Components

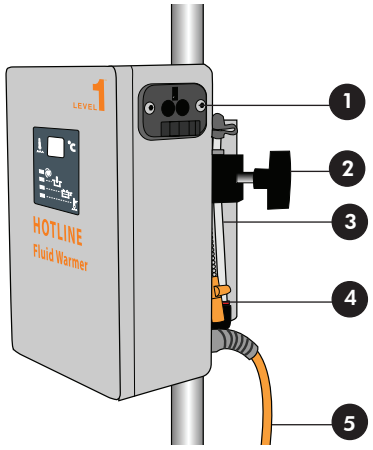
The HOTLINE™ components are called-out in the following series of figures.

Front View



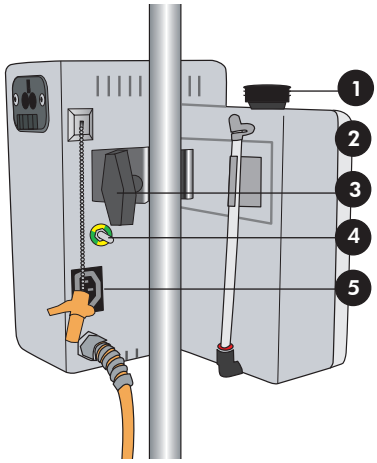
1 Socket for HOTLINE™ Fluid Warming Set with the reflux plug in place

2 Display Panel



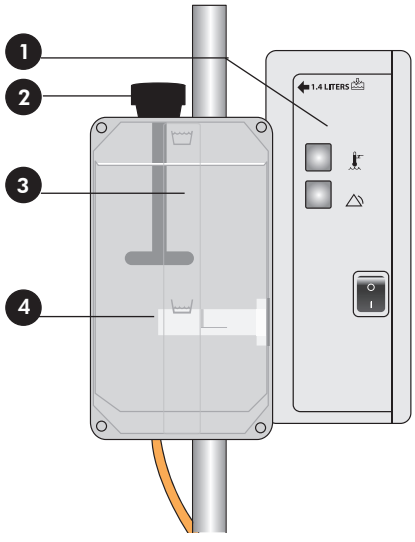
Right Side View

1. Socket with the reflux plug removed
2. Clamp for I.V. pole
3. Drain tube in tube holder
4. Reflux plug
5. Power cord



Rear View

1. Fill-port plug
2. Drain tube in tube holder
3. Clamp for I.V. pole
4. Protective earth terminal
5. Auxiliary electrical outlet (uncovered)



Left Side View

1. Power and Alarm Test Panel
2. Fill-port plug
3. Reservoir, contains recirculating solution
4. Float switch (inside reservoir)

HOTLINE™ Fluid Warming Set

HOTLINE™ Fluid Warming Sets (L-70, L-70NI, L-80) are individually packed, single-use disposables with a Sterile Fluid Path. The priming volume is 20 ml for the L-70 and L-70NI, and 21 ml for the L-80. The HOTLINE™ Fluid Warming Set has a Twin-Tube Connector that plugs into the socket on the right side of the HOTLINE™ Warmer. This is the only connection necessary to provide the warming function. The HOTLINE™ Fluid Warming Set is easily unplugged from the HOTLINE™ Warmer and discarded.

SECTION 3

Important Safety Information

This section covers information for prescribers and guidelines for safe use of the HOTLINE™ Warmer.

CONTRAINDICATION

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

WARNINGS

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

- **These instructions contain important information for safe use of the product. Read the entire contents of this operator's manual, 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™ Fluid Warming Set, L-10, PC-8, and YC-8 are single-use devices and are not intended for re-sterilization.**
- **Do not use HOTLINE™ Fluid Warming Set, L-10, 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™ Warmer is for use only with ICU 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.**

WARNINGS *[continued]*

- **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 intravenouspath. If fluid exits the patient end of the HOTLINE™ Fluid Warming Set before connecting to the intravenous administration set, remove and replace HOTLINE™ Fluid Warming Set.**

- **Remove all air from the HOTLINE™ Fluid Warming Set, L-10, 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™ 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™ Fluid Warming Set.**

- **To prevent a breach between the recirculating solution path and intravenous path, do not use needles greater than 38 mm (1.5”) in length when accessing the injection port. If there is a breach between the recirculating solution path and intravenous path, patient illness may occur because of the HOTLINE™ Warmer’s recirculating solution entering the patient’s bloodstream.**

- **Do not stick the HOTLINE™ 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™ 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™ Warmer. Remove the device from service immediately.**

- **Do not operate the HOTLINE™ Warmer in the presence of a flammable anesthetic mixture with air, oxygen, or nitrous oxide. The risk of explosion exists if the HOTLINE™ Warmer is operated in a potentially explosive environment.**

WARNINGS *[continued]*

- **Do not use the HOTLINE™ Warmer in high-energy fields such as: MRI, X-RAY, portable and mobile RF communications equipment, and other such devices. The HOTLINE™ 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.**
- **Do not mount the HOTLINE™ Warmer more than 107 cm (42") above the floor. For convenience, 107 cm (42") is indicated on the HOTLINE™ Warmer power cord by a black mark. Mounting the HOTLINE™ Warmer above 107 cm (42") may result in instability of the pole and tipping.**
- **Ensure that the HOTLINE™ Warmer clamp is screwed tightly onto the I.V. pole. Failure to securely mount the HOTLINE™ Warmer onto the I.V. pole may cause the HOTLINE™ Warmer to slide down the I.V. pole.**
- **Do not use the HOTLINE™ Warmer if equipment or Disposable Set malfunction is evident.**
- **No operator-serviceable parts. All service must be performed by ICU Medical or competent personnel.**
- **No modification of this equipment is allowed.**
- **The HOTLINE™ Warmer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you should verify normal operation of the HOTLINE™ Warmer in the configuration in which it is to be used.**
- **Common portable and mobile consumer electronic devices may cause interference with the HOTLINE™ Warmer. Observe the HOTLINE™ Warmer to verify normal operation.**
- **Facility wiring must comply with all applicable electrical codes. Do not bypass power cord connections. Do not remove a prong from the power cord.**

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™ 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™ Warmer.**
- **Do not place the HOTLINE™ Warmer directly under a faucet or use a faucet sprayer to rinse. Never spray cleaning or other fluids into openings on the HOTLINE™ 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.**
- **Do not fill the HOTLINE™ Warmer reservoir with a HOTLINE™ Fluid Warming Set in place. Failure to remove the HOTLINE™ Fluid Warming Set before the fill procedure may result in an air lock in the HOTLINE™ Warmer.**
- **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.**

Additional WARNINGS and CAUTIONS for Accessories

WARNINGS for the L-10 Gas Vent and L-80 Fluid Warming Set

- Do not tape over vents, else air will not be vented.
- Not for use with volumetric infusion pumps, hand pumps, or syringes. These may compromise the integrity of the L-10 Gas Vent or HOTLINE™ Fluid Warming Set.
- When the L-10 Gas Vent is in use, it should be placed at or below the heart level. Do not raise the gas vent above the patient's heart level. If the gas vent is raised above heart level, air may be entrained into the infusion line, possibly causing air embolism, resulting in serious injury or death.

CAUTIONS for the L-10 Gas Vent and L-80 Fluid Warming Set

- This product contains natural rubber latex, which may cause allergic reactions.

SECTION 4

Assembly Instructions

Read through the instructions completely prior to setting up the HOTLINE™ Warmer.

Step 1 - Unpack the HOTLINE™ Warmer

1. Open the shipping carton and remove the HOTLINE™ Warmer.
2. Check the contents of the package to verify the following components are present:
   - HOTLINE™ Warmer
   - Operator's Manual
   - HOTLINE™ Inspection/Test Form
3. Examine the HOTLINE™ Warmer for damage. If any components appear damaged, do not use the HOTLINE™ Warmer. Contact ICU Medical for a replacement.

Note: *After unpacking the HOTLINE™ Warmer, recycle packaging material according to hospital policy for recyclable materials.*

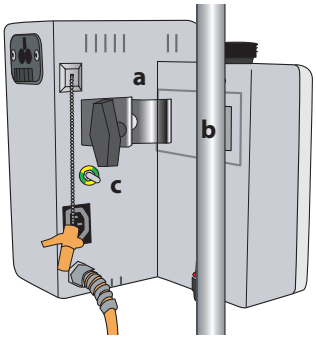
Step 2 - Clamp the HOTLINE™ Warmer to the I.V. Pole

WARNINGS

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

CAUTION

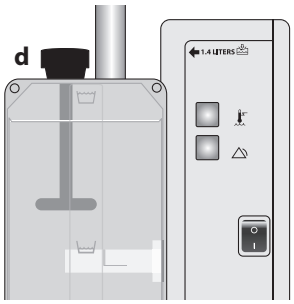
This device is cooled by convection. Be sure the air vents on the bottom and the back of the device are kept clear.



1 Slide the clamp **(a)** on the HOTLINE™ Warmer over the I.V. pole **(b)** and tighten the clamp screw **(c)** firmly.

2 Check the tightness of the HOTLINE™ Warmer to ensure it is securely clamped to the pole.

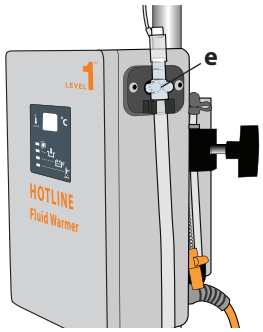
Step 3 - Disinfect the Reservoir



1 Prepare a 0.3% hydrogen peroxide solution by mixing 140 ml of 3% hydrogen peroxide solution and 1,260 ml of distilled water.

2 Remove the reflux plug from the socket if required, and then remove the fill-port plug **(d)** and fill the reservoir with 1.4 liters of 0.3% hydrogen peroxide solution.

3 Replace the fill-port plug **(d)**.

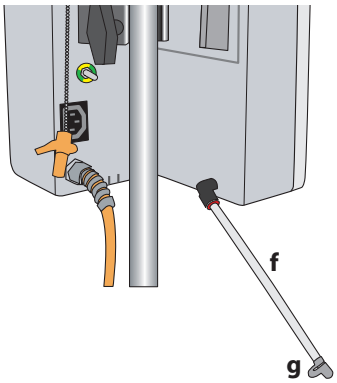


4 Insert a HOTLINE™ Fluid Warming Set **(e)** (L-70, L-70 NI, L-80) into the socket.

5 Plug the HOTLINE™ Warmer into properly grounded power outlet.

6 Turn the HOTLINE™ Warmer ON and let the solution circulate for a 30-minute disinfection period.

7 Turn the HOTLINE™ Warmer OFF.



8 Invert the drain tube **(f)** and place a container under the end of the tube. Remove the end cap **(g)** and drain the recirculating solution into the container.

9 When all the recirculating solution has drained from the reservoir, replace the end cap and insert the drain tube back in the holder.

10 Remove the HOTLINE™ Fluid Warming Set and discard according to established hospital procedures.

Step 4 - Fill the Reservoir With Recirculating Solution

WARNING

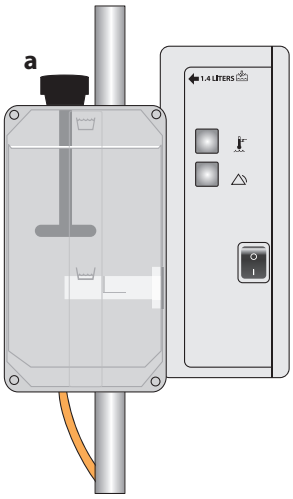
Do not fill the HOTLINE™ Warmer reservoir with a HOTLINE™ Fluid Warming Set in place. Failure to remove the HOTLINE™ Fluid Warming Set before the fill procedure may result in an air lock in the HOTLINE™ Warmer.

Recirculating Solution Protocols

Use one of the following solutions for the reservoir.

Recirculating Solution	Preparation	Maintenance
0.3% Hydrogen Peroxide Solution	Mix 140 ml of 3% hydrogen peroxide with 1,260 ml of distilled water.	Replace solution and disinfect reservoir every 12 months.
Distilled Water	Use distilled water.	Replace solution and disinfect reservoir every 30 days.
35% Isopropyl Alcohol Solution	Mix 700 ml of 70% isopropyl alcohol with 700 ml of distilled water.	Replace solution and disinfect reservoir every 30 days.

Note: *Use distilled water only, not tap water. Failure to do so may cause build-up of mineral deposits in the recirculating solution path, which may impair heater performance.*



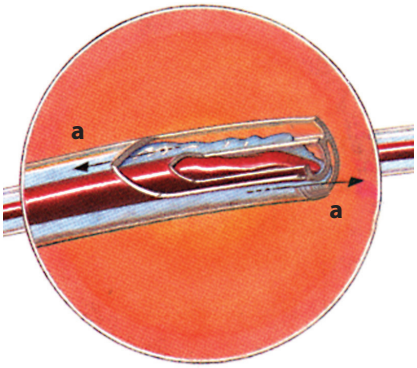
1. Prepare the recirculating solution.
2. Remove the fill-port plug **(a)**.
3. Fill the reservoir with 1.4 liters of recirculating solution.
4. Replace the fill-port plug.

Step 5 - Perform the Electrical Safety Tests

Perform all applicable electrical safety tests as required per institutional procedure. Refer to Section 9, *"Testing"*, for more information about electrical safety testing.

SECTION 5

Principle of Operation



HOTLINE™ Warmer delivers blood and intravenous fluid at normothermic temperatures under routine, gravity flow rates. Conventional fluid warming systems suffer from cool-down between the warmer and the patient connection. HOTLINE™ Warmer overcomes this problem by providing active warming of the patient line all the way to the patient connection.

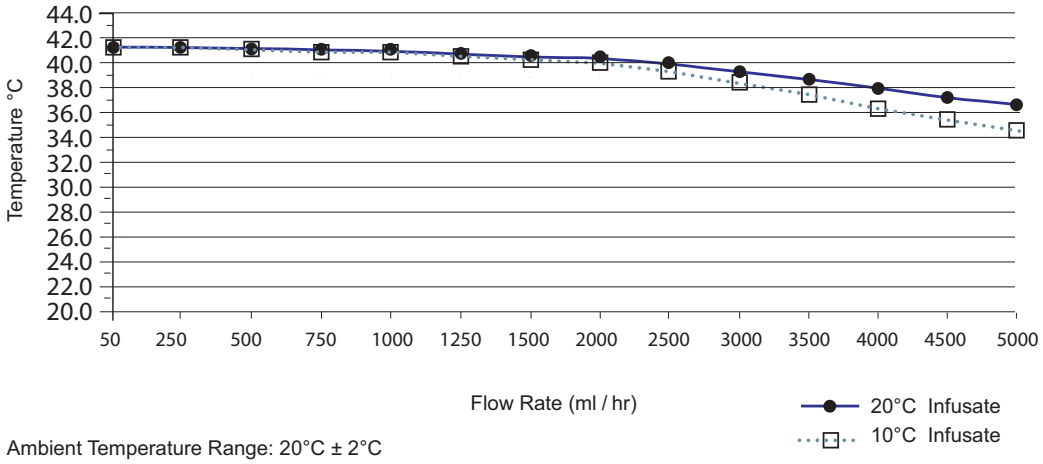
Active warming is achieved by surrounding the sterile intravenous line with a layer of precisely controlled warm recirculating solution **(a)**, thereby protecting the patient line against exposure to cold and eliminating patient line cool-down.

The unique design of the HOTLINE™ Fluid Warming Set allows blood and intravenous fluid to be delivered to the patient at normothermic temperature at gravity flow rates to 50-5,000 ml/hr.

Infusate Delivery Temperatures

The following table shows the typical infusate delivery temperatures at the patient end of an L-70 HOTLINE™ Fluid Warming Set.

Note: *The setpoint temperature of the recirculating solution is 41.9°C.*



Ambient Temperature Range: 20°C ± 2°C

SECTION 6

Operation

This section describes the controls and displays that monitor and control the HOTLINE™ Warmer, and the modes of operation.

Controls and Displays

- Display Panel
- Power and Alarm Test Buttons
- Reservoir Level Display

Display Panel

The Display Panel is located on the front of the HOTLINE™ Warmer and provides continuous information about the operation of the HOTLINE™ Warmer. A liquid crystal display (LCD) indicates recirculating solution temperature. Just below the LCD, four light-emitting diodes (LEDs) indicate operation modes for the HOTLINE™ Warmer.

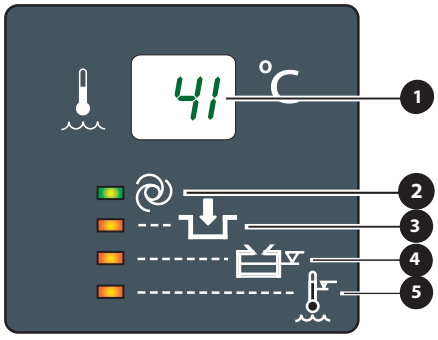
1 **Recirculating Solution Temperature -** The temperature is displayed in degrees Celsius.

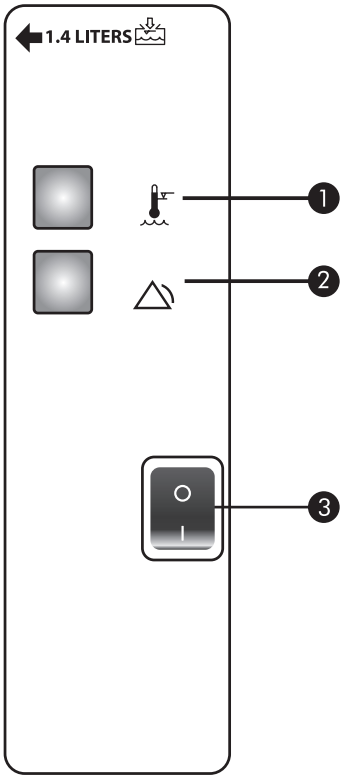
2 **ON/Operation -** The green LED illuminates when the power is turned on and the HOTLINE™ Fluid Warming set is properly installed.

3 **Check Disposables -** The red LED illuminates and an audible attention signal beeps when the HOTLINE™ Fluid Warming Set is not properly installed.

4 **Add Recirculating Solution -** The red LED illuminates and an audible attention signal beeps when the level in the reservoir is low and additional recirculating solution must be added.

5 **Over Temperature -** The red LED illuminates and an audible warning signal beeps when the recirculating solution is over the acceptable temperature for safe use.





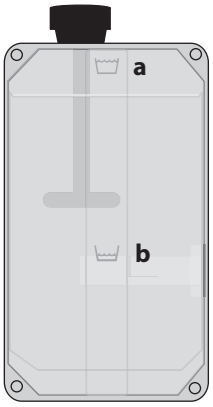
Power and Alarm Test Panel

The Power and Alarm Test Panel is located on the left side of the HOTLINE™ Warmer next to the reservoir. This panel contains two pressure-sensitive buttons that are activated when pressed, and the ON/OFF switch.

1 **Over Temperature Alarm Test Button -** The Over Temperature Alarm Test is used to confirm the proper operation of the Over Temperature circuitry.

2 **Alarm Test Button -** The Alarm Signal Test is used to confirm proper operation of the visual and audible alarms.

3 **Power ON/OFF Switch -** The black switch toggles to turn power ON and OFF.



Reservoir Level Display

The reservoir for the recirculating solution is located on the left side of the HOTLINE™ Warmer, next to the Power and Alarm Test Panel. The level of the recirculating solution is visible in the reservoir. Two symbols indicate the maximum **(a)** and minimum **(b)** solution level requirements.

Modes of Operation

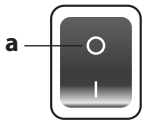
The HOTLINE™ Warmer operation is defined in the following modes:

- OFF Mode
- ON/Operating Mode
- Check Disposables Mode
- Add Recirculating Solution Mode
- Over Temperature Alarm Mode

The description of each mode includes a definition of the mode, activation and/or monitoring of the mode, mode characteristics, and method to clear the mode state.

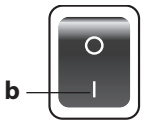
OFF Mode

The power switch is in the OFF position **(a)** and the HOTLINE™ Warmer is turned off.



ON/Operating Mode

The power switch is in the ON position **(b)** and the HOTLINE™ Fluid Warming Set has been properly installed.



Mode characteristics

- The green Operating LED **(c)** illuminates.
- The reservoir temperature display will begin to increase.
- The recirculating solution path in the HOTLINE™ Fluid Warming Set will automatically prime.



Check Disposables Mode

The Check Disposables mode indicates a missing or improperly installed HOTLINE™ Fluid Warming Set.

Mode characteristics

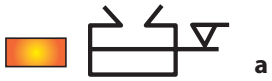
- The green Operating LED on the Display Panel turns off.
- The red Check Disposables LED **(d)** on the Display Panel illuminates.
- The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.
- The recirculating solution stops circulating.



To clear this mode, check that the Twin-Tube Connector on the HOTLINE™ Fluid Warming Set is firmly inserted in the socket.

Add Recirculating Solution Mode

The Add Recirculating Solution mode indicates that the solution level in the reservoir is below its minimum level.



Mode characteristics

- The green Operating LED on the Display Panel turns off.
- The red Add Solution LED **(a)** on the Display Panel illuminates.
- The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.
- The recirculating solution stops circulating.

To clear this mode, add recirculating solution to the reservoir.

Over Temperature Alarm Mode

The Over Temperature Alarm mode indicates that the temperature of the recirculating solution is at or above 43.1°C.



Mode characteristics

- The green Operating LED on the Display Panel turns off.
- The red Over Temperature LED **(b)** on the Display Panel illuminates.
- The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.
- The recirculating solution stops circulating.

For instructions to clear this mode, see Section 8, *"Troubleshooting"*.

SECTION 7

Operating Instructions

The Operating Instructions are grouped into five segments. Read through each segment BEFORE performing a procedure.

WARNINGS

- **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 operator if this warning is not followed.**
- **Grounding reliability can only be achieved when MAINS power cords are connected to a properly grounded receptacle. Risk of electrical shock exists if the equipment is not connected to a properly grounded receptacle.**
- **Do not fill the HOTLINE™ reservoir with a HOTLINE™ Fluid Warming Set in place. Failure to remove the HOTLINE™ Fluid Warming Set before the fill procedure may result in an air lock in the HOTLINE™ Warmer.**

Step 1 - Set Up the HOTLINE™ Warmer



1. Check that the level is above the minimum level mark **(a)** on the reservoir. Add recirculating solution to the reservoir through the fill-port if required.
2. Check the condition of the HOTLINE™ Warmer with a visual inspection before using. Remove from service any HOTLINE™ Warmer that shows physical damage.
3. Plug the HOTLINE™ Warmer into properly grounded power outlet.

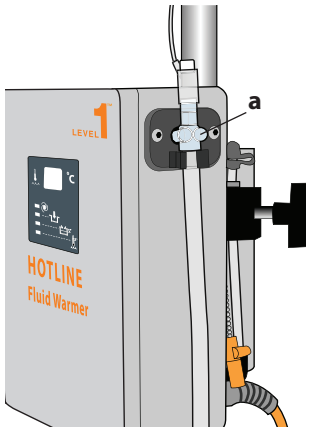
Step 2 - Set Up the HOTLINE™ Fluid Warming Set

WARNINGS

- **The HOTLINE™ Fluid Warming Set is a single-use device and is not intended for re-sterilization. Death or serious injury may occur to the patient or operator if this warning is not followed.**
- **Do not use HOTLINE™ Fluid Warming Set, L-10, PC-8, and YC-8 if the caps are not securely in place, else flow path may not be sterile and may cause death or serious injury.**
- **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™ Fluid Warming Set before connecting to the intravenous extension set, remove and replace HOTLINE™ Fluid Warming Set. Death or serious injury may occur to the patient or operator if this warning is not followed.**

To set up the HOTLINE™ Fluid Warming Set, you will need the following:

- HOTLINE™ Warmer
- Intravenous administration set
- Intravenous fluid or blood
- Extension Set, 20 cm (8") or less in length (optional)



1. Remove the reflux plug (if present) from the socket on the right side of the HOTLINE™ Warmer.
2. Plug the Twin-Tube Connector on the HOTLINE™ Fluid Warming Set **(a)** into the socket.
3. Turn ON the power switch.
   - The green Operating LED on the Display Panel illuminates.
   - The recirculating solution temperature display will begin to increase.
   - The recirculating solution path in the HOTLINE™ Fluid Warming Set will automatically prime.
4. Remove the end cap and inspect the patient end of the HOTLINE™ Fluid Warming Set for leaks to confirm the integrity of the intravenous pathway.

Step 3 - Connect the Intravenous Administration Set

WARNINGS

- **Remove all air from the HOTLINE™ Fluid Warming Set, L-10, PC-8, and YC-8 before connecting to the patient. Failure to do so may result in introduction of air to the patient, which may contribute to serious patient injury or death.**

- **To prevent a breach between the recirculating solution path and intravenous path, do not use needles greater than 38 mm (1.5") in length when accessing the injection port. If there is a breach between the recirculating solution path and intravenous path, patient illness may occur because of the HOTLINE™ Warmer's recirculating solution entering the patient's bloodstream.**

- **Do not stick the HOTLINE™ 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™ Warmer's recirculating solution entering the patient's blood stream.**

1. Connect the I.V. fluid and the intravenous administration set to the HOTLINE™ Fluid Warming Set.
2. Fully prime the intravenous administration set, the HOTLINE™ Fluid Warming Set, and patient extension set (if used).
3. Connect the distal end of the HOTLINE™ Fluid Warming Set to the patient's intravenous access site without entrapping air.

Step 4 - Using the HOTLINE™ Warmer

WARNINGS

- **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. Death or serious injury may occur to the patient or operator if this warning is not followed.**

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

WARNINGS *[continued]*

- **Not for use with pressure devices generating over 300 mmHg. Pressure greater than 300 mmHg may compromise the integrity of the HOTLINE™ Fluid Warming Set.**

1 Wait until the recirculating solution temperature display reaches 41°C, which indicates the HOTLINE™ Warmer is ready for use.

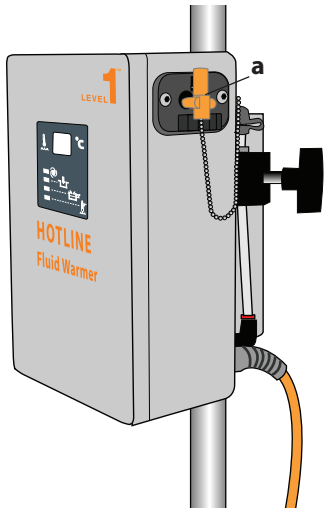
2 Adjust the rate of I.V. flow using the clamp on the intravenous administration set.

Note: *Do not kink the Disposable Set. Do not restrict the circulation of the solution through the tubing.*

Step 5 - 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 Turn OFF the power switch.

2 Remove the HOTLINE™ Fluid Warming Set, and insert the reflux plug **(a)** into the socket.

3 After use, handle and dispose of the HOTLINE™ Fluid Warming Set in a safe manner according to local guidelines for disposal of contaminated medical waste.

4 Wipe down the external surfaces of the HOTLINE™ Warmer with mild liquid detergent soap and warm tap water mixture and a soft cloth or sponge. See Section 10, *"Maintenance"*, for more details about cleaning and external disinfection.

Storage

Store the HOTLINE™ Warmer in a cool, dry place. Do not expose to extreme temperatures. See Section 13, *"Specifications and Accessories"*, for more details.

SECTION 8

Troubleshooting

Only competent personnel should perform any routine maintenance and repairs to the HOTLINE™ Warmer.

Problem	Check the following
No power	1 Confirm that the HOTLINE™ Warmer is plugged in properly. 2 Confirm that the power switch is in the ON position. **Note:** *If the HOTLINE™ Warmer is plugged in and the power switch is turned ON, the green or red LED will illuminate.*
Check Disposables alarm	Confirm that the HOTLINE™ Fluid Warming Set is properly installed. 1 Push the Twin-Tube Connector firmly into the socket on the right side of the HOTLINE™ Warmer. **Note:** *Turn OFF the power switch before replacing the HOTLINE™ Fluid Warming Set.* 2 If the alarm is not cleared, replace the HOTLINE™ Fluid Warming Set. Turn ON the power switch and verify that the alarm has cleared. 3 If the alarm is not cleared, remove the HOTLINE™ Warmer from service.
Add Recirculating Solution alarm	Check the level in the reservoir • Turn OFF the power switch, remove the HOTLINE™ Fluid Warming Set if installed, and add recirculating solution to the maximum level.
Over Temperature alarm	1 Check the HOTLINE™ Fluid Warming Set for kinks or other restrictions. 2 Check for air lock: a Turn the power switch OFF, remove the HOTLINE™ Fluid Warming Set, and gently shake HOTLINE™ Warmer to dislodge air. b Plug in the HOTLINE™ Fluid Warming Set and turn power switch ON. c If the alarm is not cleared, remove the HOTLINE™ Warmer from service and return it for repair or replacement.
Hot cabinet	Check for blocked air vents on the bottom or the back of the HOTLINE™ Warmer. **Note:** *Room temperature above 42°C may cause the HOTLINE™ Warmer to shut down and the Over Temperature alarm to activate. In this situation, turn the power switch OFF and allow the HOTLINE™ Warmer to cool down before returning it to service.*

Problem	Check the following
Difficult to install the HOTLINE™ Fluid Warming Set	Lubricate O-rings in the socket. Refer to Section 10, *"Maintenance"*, for the procedure.
Recirculating solution leaks at the socket where the HOTLINE™ Fluid Warming Set plugs into the HOTLINE™ Warmer	Replace O-rings. Use the O-ring Replacement Kit: P/N 80-04-001. Refer to Section 10, *"Maintenance"*, for the procedure.
Electrical interference - receiving or transmitting	1 Move the HOTLINE™ Warmer away from the device in question. 2 Plug the HOTLINE™ Warmer into a separate electrical circuit. • If the problem continues, notify ICU Medical or your local ICU Medical distributor.

SECTION 9

Testing

The HOTLINE™ Warmer should be tested by hospital biomedical personnel prior to placing it in service. All testing and maintenance should be performed by competent personnel. If competent personnel are not available, contact ICU Medical or your local ICU Medical distributor.

If the HOTLINE™ Warmer and any installed accessories do not pass any of the listed tests, discontinue use of the HOTLINE™ Warmer and remove from service. Contact ICU Medical or your local ICU Medical distributor.

WARNING

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

Note: *Alarm testing requires a HOTLINE™ Fluid Warming Set to be installed and that the HOTLINE™ Warmer be turned ON and in the Operating mode.*

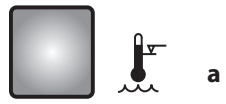
Alarm Signal Test

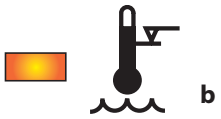
The Alarm Signal Test is used to confirm proper operation of the visual and audible alarm indicators.

1. Press and hold the Alarm Test button **(a)**.
2. Observe the following:
   - The green Operating LED turns off.
   - Three red LEDs (Check Disposables, Add Solution, and Over Temperature) illuminate.
   - The audible alarm sounds (54-59dB) and repeats approximately every two seconds.



Over Temperature Alarm Test



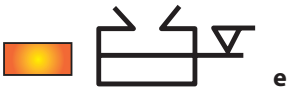


The HOTLINE™ Warmer should be running at an operating temperature of approximately 41°C to 42°C.

1. Press and hold the Over Temperature Alarm Test button **(a)**.
2. Observe the following:
   - The recirculating solution Over Temperature Alarm activates at 43°C.
   - The green Operating LED turns off.
   - The red Over Temperature LED **(b)** illuminates.
   - The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.
3. Stop pressing the Over Temperature Alarm Test button to stop the test.

Add Recirculating Solution Test



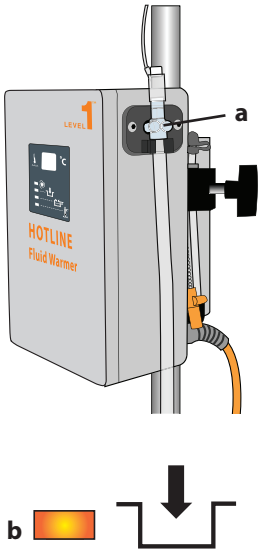


The HOTLINE™ Warmer is equipped with a float switch, which senses the recirculating solution level in the reservoir. When the recirculating solution is too low, the Add Recirculating Solution Alarm will activate.

1. Remove the fill-port plug **(c)** on the reservoir.
2. Gently depress the float switch **(d)**. (This action will simulate the low solution condition.)

   Note: *Use a non-metal tool to depress the float switch because the float switch contains a magnet.*
3. Observe the following:
   - The green Operating LED turns off.
   - The red Add Recirculating Solution LED **(e)** illuminates.
   - The audible alarm sounds (54-59 dB) and repeats approximately every two seconds.

Check Disposables Test

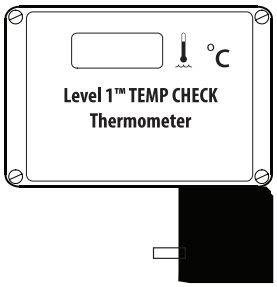


An interlock switch/sensor, located in the socket on the right side of the HOTLINE™ Warmer, senses a properly installed HOTLINE™ Fluid Warming Set. When the switch does not sense a HOTLINE™ Fluid Warming Set, the Check Disposables alarm activates.

1. Slowly remove the HOTLINE™ Fluid Warming Set **(a)** from the HOTLINE™ Warmer socket.
2. Observe the following actions:
   - The green Operating LED turns off.
   - The red Check Disposables LED **(b)** illuminates.
   - The audible alarm sounds (54-59dB) and repeats approximately every two seconds.

Note: *In any alarm condition, the pump should not be running. A small amount of solution dripping from the disconnection is normal and should stop in a few seconds.*

Temperature Verification of the Recirculating Solution



Use the Level 1™ TEMP CHECK Thermometer (HLTA-40) to verify the displayed recirculating solution temperature. Other methods of temperature verification may be inaccurate.

TEMP CHECK provides an accurate reading of the highest temperature of the recirculating solution. Because the temperature of the reservoir is typically 0.5°C to 2.0°C lower than the temperature from the heater, and the temperature of the recirculating solution begins to drop due to the effect of ambient temperature on the HOTLINE™ Fluid Warming Set, the highest temperature of the solution is just after it leaves the heater. During the temperature verification test, the TEMP CHECK is positioned on the right side of the HOTLINE™ Warmer attached to the socket and senses the solution just after it leaves the heater and before it enters the HOTLINE™ Fluid Warming Set.

Refer to the TEMP CHECK HLTA-40 Thermometer Operator's Manual for complete Temperature Verification and Calibration Instructions.

To verify the recirculating solution temperature, you will need the following:

- TEMP CHECK (HLTA-40)
- HOTLINE™ Warmer
- HOTLINE™ Fluid Warming Set

To Verify the Recirculating Solution Temperature:

1. Plug the HOTLINE™ Warmer into a power outlet.
2. Place the TEMP CHECK on the top right corner of the HOTLINE™ Warmer and plug it into the socket on the right side of the HOTLINE™ Warmer.
3. Plug the Twin-Tube Connector on the HOTLINE™ Fluid Warming Set into the socket on the right side of the TEMP CHECK.
4. Remove the black label from the auxiliary outlet on the back of the HOTLINE™ and plug in the TEMP CHECK power cord.

   Note: *The auxiliary outlet is for use only with ICU Medical accessories.*
5. Turn ON the HOTLINE™ Warmer. Allow 15 minutes for the temperature to stabilize.
6. If the TEMP CHECK display indicates a temperature between 41°C and 42°C, and the HOTLINE™ Warmer display equals the TEMP CHECK display, recirculating solution verification is complete. Refer to the TEMP CHECK Manual for OVERTEMP ALARM verification.
7. If the TEMP CHECK display does not indicate a temperature between 41°C and 42°C, refer to the TEMP CHECK Manual for calibration instructions.

Periodic Electrical Testing

Electrical Safety Tests must be performed by competent personnel authorized by the institution to perform such testing. The Safety Tests must be performed and documented at least once per year, or according to institutional policy. These tests include but are not limited to:

- Leakage current
- Ground bond test

Note: *All equipment connecting to the device must conform to IEC or ISO standards for requirements for medical electrical systems (e.g., IEC 60601-1 or clause 16 of IEC 60601-1 3Ed.). Any persons connecting additional equipment to the device, is responsible that the device system created as a result complies with the standard requirements for medical electrical systems.*

Leakage Current

Leakage current must be tested according to methods and pass/fail criteria described in IEC 60601-1. Leakage current must be performed with the heater circuit in the full ON condition. To achieve this condition, perform the test when the reservoir is at room temperature. When the HOTLINE™ Warmer is first turned on and the temperature is rapidly rising, but still below 41°C, the heater circuit is in a full ON condition.

Note: *The HOTLINE™ Warmer is equipped with sensing interlocks. A HOTLINE™ Fluid Warming Set is required to correctly operate the HOTLINE™ Warmer and perform leakage current testing. Do not defeat the sensing interlocks or try to operate the HOTLINE™ without a HOTLINE™ Fluid Warming Set in place.*

Ground Bond Test

Ground bond test must be tested according to methods and pass/fail criteria described in IEC 60601-1.

SECTION 10

Maintenance

Only competent personnel should perform any routine maintenance and repairs to the HOTLINE™ Warmer. Maintenance is scheduled with each use, every 30 days, and every 12 months. The tasks are described below.

Maintenance Performed with Every Use

CAUTION

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

Clean and inspect the HOTLINE™ Warmer.

Clean the Exterior

Clean the entire HOTLINE™ Warmer after every use.

CAUTIONS

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

1. To isolate equipment from MAINS, unplug the HOTLINE™ Warmer before servicing.
2. Visually inspect the HOTLINE™ 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 ICU Medical or your local ICU 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™ Warmer and its components to insure that they have been thoroughly cleaned. Repeat cleaning procedure if necessary.

7 After thoroughly cleaning the HOTLINE™ 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

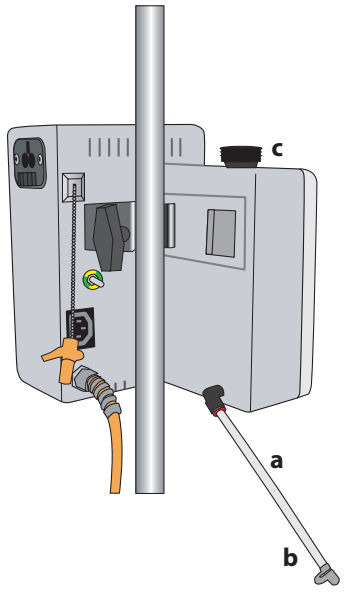
- Check the condition of the HOTLINE™ Warmer with a visual inspection before using. Remove from service any HOTLINE™ Warmer that shows physical damage.
- If the HOTLINE™ Fluid Warming Set does not install easily, lubricate the O-Rings as directed in the following section.

Disinfect the Reservoir and Change the Recirculating Solution

Disinfect the reservoir and change the recirculating solution every 30 days or every 12 months based on the recirculating solution used for the HOTLINE™ Warmer. Refer to the following table for the maintenance schedule.

Recirculating Solution	Preparation	Maintenance
0.3% Hydrogen Peroxide Solution	Mix 140 ml of 3% hydrogen peroxide with 1,260 ml of distilled water.	Replace solution and disinfect reservoir every 12 months.
Distilled Water	Use distilled water.	Replace solution and disinfect reservoir every 30 days.
35% Isopropyl Alcohol Solution	Mix 700 ml of 70% isopropyl alcohol with 700 ml of distilled water.	Replace solution and disinfect reservoir every 30 days.

Note: *Use distilled water only, not tap water. Failure to do so may cause build-up of mineral deposits in the recirculating solution path, which may impair heater performance.*



Disinfect the Reservoir

1. To isolate equipment from MAINS, unplug the HOTLINE™ Warmer before servicing.
2. Remove the drain tube from the holder on the rear of the HOTLINE™ Warmer.
3. Invert the drain tube **(a)** and place a container under the end of the tube. Remove the end cap **(b)** and drain the recirculating solution into the container.
4. When all the recirculating solution has drained from the reservoir, replace the end cap and insert the drain tube back in the holder.
5. Prepare a 0.3% hydrogen peroxide solution by mixing 140 ml of

3% hydrogen peroxide solution and 1,260 ml of distilled water.

6 Remove the fill-port plug **(c)**, fill the reservoir with the hydrogen peroxide solution, and replace the fill-port plug.

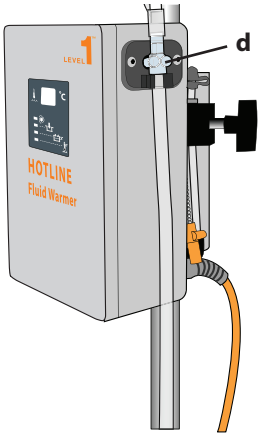
7 Remove the reflux plug from the socket if required, and insert a HOTLINE™ Fluid Warming Set **(d)** (L-70, L-70NI, L-80) into the socket.

8 Turn the HOTLINE™ Warmer ON, and let the recirculating solution circulate for a 30-minute disinfection period.

9 Turn the HOTLINE™ Warmer OFF and to isolate equipment from MAINS, unplug the power cord.

10 Empty the reservoir.

11 Remove the HOTLINE™ Fluid Warming Set and discard according to established hospital procedures.



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

Add Recirculating Solution

CAUTION

Do not fill the HOTLINE™ Warmer reservoir with a HOTLINE™ Fluid Warming Set or a TEMP CHECK in place. Failure to remove the HOTLINE™ Fluid Warming Set before the fill procedure may result in an air lock in the HOTLINE™ Warmer.

1 Prepare the recirculating solution.

2 Remove the fill-port plug.

3 Fill the reservoir with 1.4 liters of recirculating solution.

4 Replace the fill-port plug.

Maintenance Performed Every 30 Days

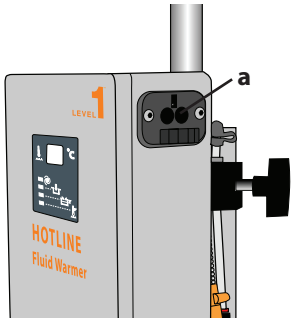
Disinfect the Reservoir and Change Recirculating Solution for Distilled Water and 35% Isopropyl Alcohol Solution

Refer to *Disinfect the Reservoir and Change the Recirculating Solution* procedure in this section.

Lubricate O-Ring Seals

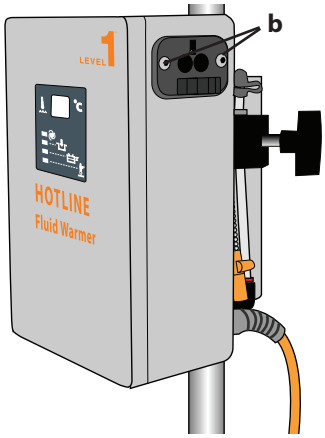
1 Place a small amount of silicone lubricant on a cotton swab.

2 Apply silicone lubricant along the O-Rings inside the socket **(a)** located on the right side of the HOTLINE™ Warmer.



Silicone lubricant is available from ICU Medical, (Silicone lubricant P/N 80-04-002).

Maintenance Performed Every 12 Months



Disinfect the Reservoir and Change Recirculating Solution for 0.3% Hydrogen Peroxide Solution

Refer to *Disinfect the Reservoir and Change the Recirculating Solution* procedure in this section.

Replace O-Rings (O-Ring Kit: P/N 80-04-001)

1. To isolate equipment from MAINS, unplug the HOTLINE™ Warmer before servicing.
2. Remove the socket head screws **(b)** with a 0.31 cm (1/8") hex wrench.
3. Remove the face plate, being careful not to damage the micro-switch lever.
4. Remove the old O-rings and clean the sockets with a cotton swab.
5. Apply silicone lubricant to two new O-rings and install into the sockets.
6. Reassemble in reverse order, being careful not to damage the micro-switch lever.
7. Insert HOTLINE™ Fluid Warming Set and power on HOTLINE™ Warmer to verify that there are no leaks around the face plate.

Testing HOTLINE™ Warmer Operation

Perform all the tests described in the testing section of this manual. See Section 9, *"Testing"*. The Scheduled Maintenance Checklist below also lists the tests.

Maintenance Log

All maintenance and testing should be done by competent personnel. Regularly scheduled maintenance ensures proper functioning of the equipment. Refer to the table below for required tasks and frequency of routine maintenance.

Maintenance Checklist

Task	Every Use	Every 30 Days	Every 12 Months
Clean the Exterior	☐		
General Inspection	☐		
Disinfect the Reservoir and Change Distilled Water or Isopropyl Alcohol solution		☐	
Lubricate the O-Rings		☐	☐
Disinfect the Reservoir and Change the Hydrogen Peroxide Solution			☐
Replace the O-Rings			☐
Alarm Signal Test			☐
Add Recirculating Solution Test			☐
Check Disposables Test			☐
Over Temperature Alarm Test			☐
Verify Temperature Calibration			☐
Electrical Safety Tests			☐

SECTION 11

Limited Warranty

ICU Medical, Inc. (the "Manufacturer") warrants to the Original Purchaser that the HOTLINE™ Blood and Fluid Warmer (the "HOTLINE™ 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™ 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™ 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™ Warmer. This warranty does not extend to subsequent purchasers. The Original Purchaser may be medical personnel, a hospital, or institution which purchases HOTLINE™ 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, ICU Medical, Inc., 6000 Nathan Lane North, Minneapolis, MN 55442, (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™ WARMER. If authorized, the HOTLINE™ 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™ 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™ Warmer's serial number will invalidate this warranty.

D. Limitations and Exclusions: Repair or replacement of the HOTLINE™ 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™ WARMER FOR ANY PARTICULAR PURPOSE.
3. The HOTLINE™ Warmer can only be used under the supervision of medical personnel whose skill and judgment determine the suitability of the HOTLINE™ 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™ Warmer for any particular medical treatment or for any medical complications resulting from the use of the HOTLINE™ 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™ 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.

SECTION 12

Service

WARNING

No operator-serviceable parts. All service must be performed by ICU Medical or competent personnel. Death or serious injury may occur if this warning is not followed.

All service must be performed by ICU Medical or competent personnel. Service by any other person or organization 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™ Warmer for service, contact ICU Medical for Returned Goods Authorization. Be sure that ALL recirculating solution is drained from the device before packing the HOTLINE™ Warmer for shipment.

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

Additional Documentation

Upon request ICU Medical will provide the following documentation:

- Circuit diagrams
- Components parts list(s)
- Description of function
- Service and calibration instructions

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

Contact your ICU Medical Technical Service Department or ICU Medical distributor at:

USA/Canada

ICU Medical, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442 USA
Tel: 1 800 258 5361 (US/CA)
Tel: +1 614 210 7300

European Representative

EC REP ICU Medical B.V.
Hofspoor 3
3994 VZ Houten
The Netherlands

www.icumed.com

SECTION 13

Specifications and Accessories

System Specifications

Standard Compliance	**Guidelines**		
Product Safety	IEC 60601-1		
EMC	EN 60601-1-2, FCC 47 CFR Part 15, Class A		
Enclosure Protection	IEC 60529 IP Code: IPX1		
Fluid Warmers	ASTM F2172-02		
Physical	**Dimensions**		
Height, Overall	24.1 cm	(9.5 inches)	
Width, Overall	21.0 cm	(8.3 inches)	
Depth, Overall	17.8 cm	(7.0 inches)	
Weight, Dry	3.5 Kg	(7.6 lbs)	
Weight, Wet (with recirculating solution)	5.0 Kg	(11.0 lbs)	
Weight, Shipping	3.6 Kg	(7.95 lbs)	
Recirculating Solution Capacity	1.4 L	(0.37 gallons)	
Maximum Height on I.V. Pole	107 cm	(42 inches)	
Environmental	**Temperature**	**Humidity [%]**	**Atmospheric Pressure**
Operation	10°C to 40°C	10 to 95	70kPa to 106kPa
Transportation	-18°C to 60°C	5 to 90	70kPa to 106kPa
Storage	-18°C to 60°C	5 to 90	70kPa to 106kPa
Thermal	**Temperature**		
Temperature Set Point	41.9°C ± 0.1°C		
Over Temperature Set Point	43.1°C		
Electrical	**Type**		
MAINS Power Input:			
100V	100VAC, 50/60 Hz, 3.8 Amps		
115V	115VAC, 50/60 Hz, 3.0 Amps		
230V	230VAC, 50/60 Hz, 1.5 Amps		

Electrical	**Type**
MAINS Auxiliary Supply Power Output:	
100V	100VAC, 50/60 Hz, 1.0 Amps
115V	115VAC, 50/60 Hz, 1.0 Amps
230V	230VAC, 50/60 Hz, 0.6 Amps
Protection Against Electrical Shock	Class 1 Equipment, Type BF Applied Part (Disposable set)
Mode of Operation	Continuous
Type of Current	Alternating
Ingress Protection Rating	IPX1
Performance	
Recirculating Solution Temperature	Recirculating solution temperature reaches 37°C from ambient in about 4 minutes
Normothermic Flow Rates	At gravity flow rates to 5,000 ml per hour

Electromagnetic Compliance

HOTLINE™ Warmer is certified to be 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.

Guidance and Manufacturer's Declaration – Electromagnetic Emissions		
Emissions test	Compliance	Electromagnetic environment - guidance
RF emissions CISPR 11	Group 1	The HOTLINE™ Warmer uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	Note: The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A). If it is used in a residential environment (for which CISPR 11 class B is normally required) this equipment might not offer adequate protection to radio-frequency communication services. The operator might need to take mitigation measures, such as relocating or re-orienting the equipment.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	
Note: Compliance using 100-240V 50/60Hz with AC power cord of 3.8 m (12.5 ft.).		

WARNINGS:

- **The HOTLINE™ Warmer should not be used adjacent to or stacked with other equipment. If adjacent or stacked use is necessary, you should verify normal operation of the HOTLINE™ Warmer in the configuration in which it is to be used.**
- **Common portable and mobile consumer electronic devices may cause interference with the HOTLINE™ Warmer. Observe the HOTLINE™ Warmer to verify normal operation.**
- **Facility wiring must comply with all applicable electrical codes. Do not bypass power cord connections. Do not remove a prong from the power cord.**

Guidance and Manufacturer's Declaration – Electromagnetic Immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 15 kV air	± 8 kV contact ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines No input/output lines tested	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ±1 kV for line to line ± 0.5 kV, ±1 kV, ±2 kV for line to ground	± 1 kV line to line ± 2 kV line to ground	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	100% drop, 0.5 periods, 0^o, 45^o, 90^o, 135^o, 180^o, 225^o, 270^o, 315^o 100% dip, 250/300 period 30% dip, 25/30 periods	100% drop, 0.5 periods, 0^o, 45^o, 90^o, 135^o, 180^o, 225^o, 270^o, 315^o 100% dip, 250/300 period 30% dip, 25/30 periods	Mains power quality should be that of a typical commercial or hospital environment. If the operator of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.
Power frequency (60 Hz) magnetic field IEC 61000-4-8	30 A/m	30 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Guidance and Manufacturer's Declaration – Radiofrequency Electromagnetic Immunity			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms 150 kHz to 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the system, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance:** $d = [1.2]\sqrt{P}$
	6 Vrms ISM bands 150 kHz to 80 MHz	6 Vrms 150 kHz to 80 MHz	$d = [0.58]\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	$d = [0.35]\sqrt{P}$ 80 MHz to 800 MHz $d = [0.7]\sqrt{P}$ 800 MHz to 2.5 GHz
Radiated RF Proximity Fields	Per 60601-1-2:2014 section 8.10 Table 9.	Per 60601-1-2:2014 section 8.10 Table 9.	$d = [6/E]\sqrt{P}$ *E is the immunity test level in V/m. Where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strength from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol:

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.

Note 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflected from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the system is used exceeds the applicable RF compliance level above, the system should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the system.

[b] Over the frequency range 150 KHz to 80 MHz, field strengths should be less than 3 V/m.

Electromagnetic Environmental Recommendations

Recommended separation distances between portable and mobile RF communications equipment and the HOTLINE™ Warmer

The HOTLINE™ Warmer is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the operator of the HOTLINE™ Warmer can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the HOTLINE™ Warmer as recommended below, according to the maximum output power of the communications equipment.

Rated Maximum output power or transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=[3.5/V1]\sqrt{P}$	80 MHz to 800 MHz $d=[3.5/E1]\sqrt{P}$	800 MHz to 2.5 GHz $d=[7/E1]\sqrt{P}$
0.01	0.12	0.12	0.23
0.10	0.37	0.37	0.74
1	1.16	1.16	2.33
10	3.69	3.69	7.38
100	11.66	11.66	23.33

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

Note 1 *At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.*

Note 2 *The ISM (industrial, scientific, and medical) bands between 150 kHz and 80 MHz are 6.765 MHz to 6.795 MHz; 13.553 MHz to 13.567 MHz; 26.957 MHz to 27.283 MHz; and 40.66 MHz to 40.70 MHz.*

Note 3 *An additional factor of 10/3 is used in calculating the recommended separation distance for transmitters in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2.5 GHz to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas.*

Note 4 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people.

Accessories

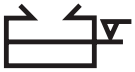
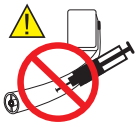
REF	**Product Description**
L-70	HOTLINE™ Fluid Warming Set with Injection Port
L-70NI	HOTLINE™ Fluid Warming Set without Injection Port
L-80	HOTLINE™ Warming Set with L-10 Gas Vent
L-10	Gas Vent
PC-8	T-Connector, 20.3 cm (8") Patient Lead with Injection Port
YC-8	Y-Connector, 20.3 cm (8") Patient Lead with Injection Port

SECTION 14

Symbols

Symbol	Meaning
	**Caution**
	Follow Instructions for Use
	Do not re-use
	Catalog Number
	Serial Number
	Batch Code
	Part Number
	Date of Manufacture
	Use by
	Manufacturer
	Authorized Representative in the European Community
	Contains or Presence of Natural Rubber Latex
	Not made with natural rubber latex
	Contains or Presence of Phthalate: bis(2-ethylhexyl) phthalate (DEHP)
	Sterile Fluid Path, Ethylene oxide gas sterilized
	Type BF Applied Part (Disposable Sets)
	Alternating Current
	Protective earth; protective ground
	Equipotentiality
	Temperature Limitation

Symbol	Meaning
	Humidity Limitiation
	Atmospheric pressure limitation
	Quantity
	Do not use if package is damaged
	Keep dry
	Keep away from sunlight
	Collect separately
Rx ONLY	**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician
	Electrical Shock Hazard
IPX1	Protected Against Dripping Water
CLASS 1	Device is a class type 1 equipment
	Protective earth terminal, for maintenance only
	Recyclable Product
	Alarm Test
	Power switch in the ON position
	Power switch in the OFF position.
	Reservoir Temperature Display
	Automatic Operation
	Recirculating Solution Temperature

Symbol	Meaning
	Over Temperature Test (Recirculating Solution Over Temperature)
	Add Recirculating Solution
	Check Disposables, Check Tubing
	Maximum Reservoir Level
	Minimum Reservoir Level
	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 recognised technical lab, to meet U.S. requirements for safety.
	Warning: Do not stick HOTLINE™ tubing wiht needles. Patient injury or death result.

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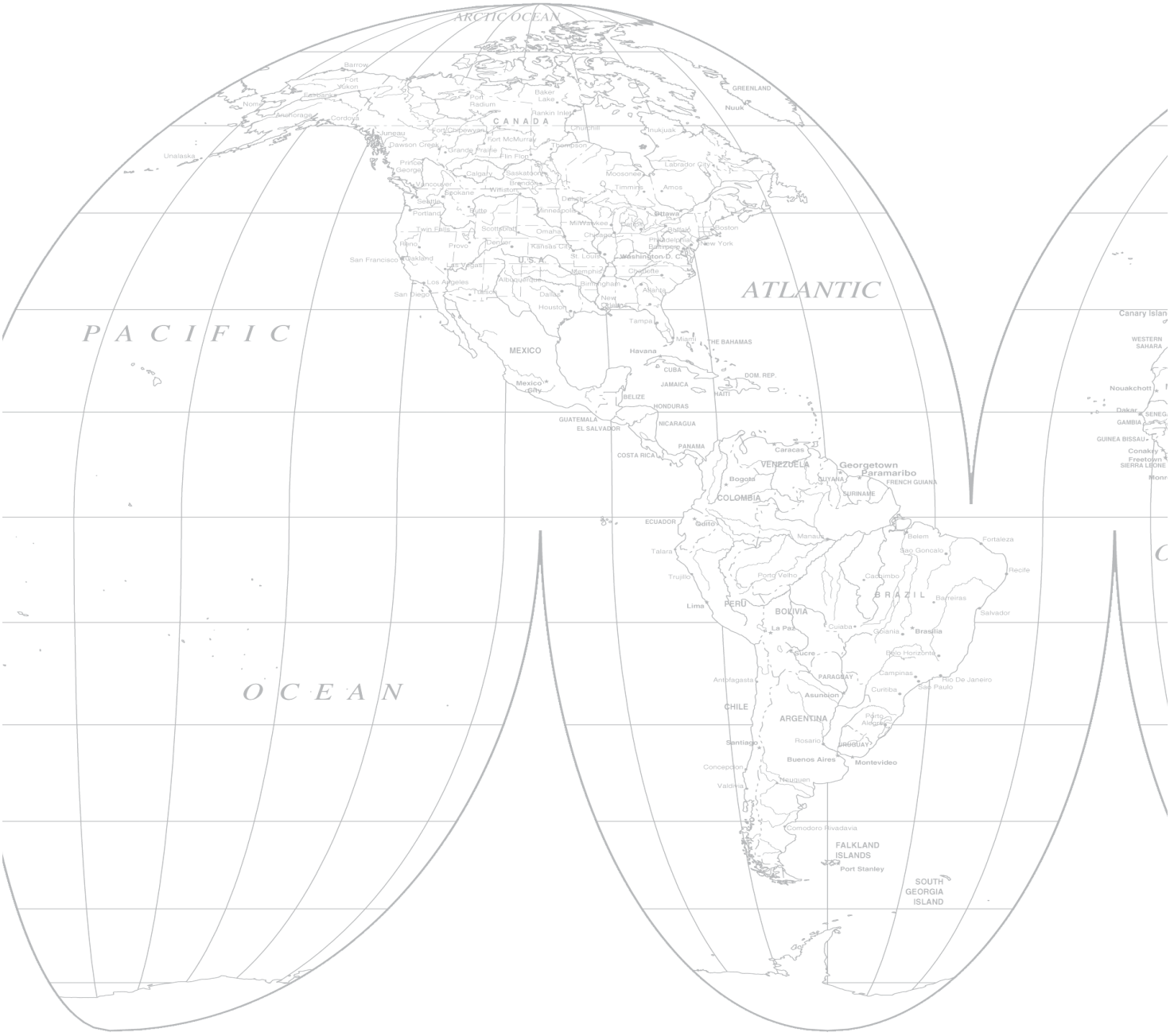
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icumedical
level 1™



ICU Medical, Inc.
6000 Nathan Lane North
Minneapolis, MN 55442 USA
Tel: 1 800 258 5361 (US/CA)
Tel: +1 614 210 7300
www.icumed.com

EC REP ICU Medical B.V.
Hofspoor 3
3994 VZ Houten
The Netherlands

Rx CE
ONLY 2797

en ENGLISH — Instructions for Use

REF **L-70 NI**

HOTLINE™ Fluid Warming Set

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 the product. Failure to properly follow warnings, cautions and instructions could result in death or serious injury to the patient.

Indications:
The **HOTLINE™** Warming Set is a single use device, designed to warm blood and intravenous fluids and deliver them to the patient's intravenous access site at normothermic temperatures under gravity flow conditions.
NOTE: The **HOTLINE™** Fluid Warming Set must only be used with the **HOTLINE™** Warmer.

Principles of Operation:
The **HOTLINE™** Warming Set employs a temperature controlled recirculating solution heating system to warm blood or intravenous fluid actively in the patient line. The recirculating solution flows through separate channels which surround the intravenous pathway. Fluid is warmed to normothermic temperatures at gravity flow rates between 50–5,000 ml/hr.

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.
- Read and follow all instructions, labeling, and accompanying documents supplied with this medical device. Failure to follow instructions, including all warnings and cautions, could lead to misuse of the device or device malfunction.
- The HOTLINE™ Fluid Warming Set, L-10, PC-8, and YC-8 are single-use devices and are not intended for re-sterilization.
- Do not use HOTLINE™ Fluid Warming Set, L-10, 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 fill the HOTLINE™ Warmer reservoir with a HOTLINE™ Fluid Warming Set in place. Failure to remove the HOTLINE™ Fluid Warming Set before the fill procedure may result in an air lock in the HOTLINE™ Warmer.
- 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™ Fluid Warming Set before connecting to the intravenous administration set, remove and replace HOTLINE™ Fluid Warming Set.
- Remove all air from the HOTLINE™ Fluid Warming Set, L-10, 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™ Fluid Warming Set.
- Do not stick the HOTLINE™ 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™ 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™ Fluid Warming Set.
- Do not use the HOTLINE™ Warmer if equipment or Disposable Set malfunction is evident.
- This product contains DEHP – data derived from animal and epidemiological studies outline the following risks, but are not limited to: Adverse effects on fetal development, kidney and liver toxicity, negative impact on fertility. Special attention on the application of phthalate products should be given for the following patient populations: pediatrics, pregnant and nursing women.

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.
- 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 use may adversely affect the integrity of the device or lead to deterioration in performance.

Storage:
Store in a cool, dry place. Do not expose to extreme temperatures.

Preparation:
Refer to the illustration on this page.
To set up the **HOTLINE™** Warming Set you will need the following:
- **HOTLINE™** Warmer
- Intravenous fluid or blood
- Intravenous administration set
- Extension Set (**B**), 20 cm (8") or less in length (optional)

Instructions for Use:
Refer to HOTLINE™ Blood and Fluid Warmer Operator's Manual for complete instructions.

Step 1 - Set Up the HOTLINE™ Warmer
1. Check that the level is above the minimum level mark on the reservoir. Add recirculating solution to the reservoir through the fill-port if required.
2. Check the condition of the HOTLINE™ Warmer with a visual inspection before using. Remove from service any HOTLINE™ Warmer that shows physical damage.
3. Plug the HOTLINE™ Warmer into properly grounded power outlet.

Step 2 - Set Up the HOTLINE™ Fluid Wwarming Set
1. Remove the reflux plug (if present) from the socket on the right side of the HOTLINE™ Warmer.
2. Plug the Twin-Tube Connector on the HOTLINE™ Fluid Warming Set (**A**) into the socket.
3. Turn ON the power switch.
   - The green Operating LED on the Display Panel illuminates.
   - The recirculating solution temperature display will begin to increase.
   - The recirculating solution path in the HOTLINE™ Fluid Warming Set will automatically prime.
4. Remove the end cap and inspect the patient end of the HOTLINE™ Fluid Warming Set for leaks to confirm the integrity of the intravenous pathway.

Step 3 - Connect the Intravenous Administration Set
1. Connect the I.V. fluid and the intravenous administration set to the HOTLINE™ Fluid Warming Set.
2. Fully prime the intravenous administration set, the HOTLINE™ Fluid Warming Set, and patient extension set (if used).
3. Connect the distal end of the HOTLINE™ Fluid Warming Set to the patient's intravenous access site without entrapping air.

Step 4 - Using the HOTLINE™ Warmer
1. The recirculating solution temperature display will reach 37°C from ambient in about 4 minutes.
2. Adjust the rate of I.V. flow using the clamp on the intravenous administration set. **NOTE:** Do not kink the Fluid Warming Set. Do not restrict the circulation of the solution through the tubing.

Step 5 - After Use
1. Turn OFF the power switch.
2. Remove the HOTLINE™ Fluid Warming Set, and insert the reflux plug into the socket.
3. After use, handle and dispose of the HOTLINE™ Fluid Warming Set as a potential biohazard. **NOTE:** Dispose of the HOTLINE™ Fluid Warming Set in a safe manner according to local guidelines for disposal of contaminated medical waste.

Troubleshooting:
1. **Alarms:** Visual (red indicator light) and Audible (pulsed alarm).

ALARM	SYMBOL	CHECK THE FOLLOWING
Check Disposables	⇩	Confirm that the HOTLINE™ Fluid Warming Set is properly installed. Push the Twin-Tube Connector firmly into the socket on the right side of the HOTLINE™ Warmer.

2. **Difficult Insertion of HOTLINE™ Warming Set into Warmer:** Lubricate the O-Rings in the socket. Refer to Section 10 of the Operator's Manual for the procedure.
3. **Recirculating solution leaks at the Socket:** Replace the O-Rings. Refer to Section 10 of the Operator's Manual for the procedure.

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fr FRANÇAIS — Mode d'emploi

REF **L-70 NI**

Kit de réchauffage de solutés HOTLINE™

AVERTISSEMENT : Ce mode d'emploi contient des informations importantes pour l'utilisation sans danger du produit. Lire l'intégralité du contenu de ce mode d'emploi, y compris les avertissements et précautions, avant d'utiliser le produit. Le non respect des avertissements, des mises en garde et du mode d'emploi risque d'entrainer la mort ou des lésions graves au patient.

Indications :
Le kit de réchauffage **HOTLINE™** est un dispositif à usage unique destiné à réchauffer le sang et les solutés I.V. et à les délivrer au point d'accès intraveineux à des températures normothermiques dans des conditions d'écoulement par gravité.
REMARQUE : Utiliser exclusivement le kit de réchauffage de solutés **HOTLINE™** avec le réchauffeur **HOTLINE™**.

Principes de fonctionnement :
Le kit de réchauffage **HOTLINE™** utilise un système de chauffage à solution recirculante à température contrôlée pour réchauffer activement le sang ou le soluté I.V. dans la ligne patient. La solution recirculante s'écoule dans des canalisations distinctes entourant la tubulure intraveineuse. Le soluté est porté à des températures normothermiques à des taux d'écoulement par gravité de 50 à 5 000 ml/h.

CONTRE-INDICATIONS
Ne pas utiliser pour le réchauffage de plaquettes, de cryoprécipités ou de suspensions de granulocytes.

AVERTISSEMENTS
Le non respect de ces avertissements risque d'entrainer la mort ou des lésions graves au patient ou à l'utilisateur.
- Lire attentivement toutes les instructions, l'étiquetage et les documents d'accompagnement fournis avec cet appareil médical. Le non respect des instructions, y compris tous les avertissements et mises en garde, peut aboutir à une utilisation incorrecte ou une défaillance de l'appareil.
- Le kit de réchauffage de solutés HOTLINE™ et les accessoires L-10, PC-8 et YC-8 sont à usage unique et ne doivent pas être restérilisés.
- Ne pas utiliser le kit de réchauffage de solutés HOTLINE™ ni les accessoires L-10, PC-8 et YC-8 si les capuchons ne sont pas fermement en place, sous risque de compromettre la stérilité du circuit I.V.
- Ne pas remplir le réservoir du réchauffeur HOTLINE™ si un kit de réchauffage de solutés HOTLINE™ est installé. Si le kit de réchauffage de solutés HOTLINE™ n'est pas retiré avant le remplissage, cela peut entrainer blocage à l'air dans le réchauffeur HOTLINE™.
- Le sang et les produits sanguins peuvent contenir des organismes pathogènes. Le non respect de la réglementation et des procédures de l'établissement relatives au matériel présentant un danger biologique peut entrainer une exposition à des agents pathogènes nocifs.
- L'installation, l'amorçage et l'utilisation doivent être effectués sous asepsie, selon la réglementation et les procédures de l'établissement.
- Amorcer le trajet de la solution recirculante avant le raccordement au kit prolongateur de perfusion. Cette mesure sert à confirmer l'absence de communication entre la solution recirculante et le trajet de perfusion. Si du liquide s'écoule de l'extrémité patient du kit de réchauffage de solutés HOTLINE™ avant la connexion au kit de perfusion, retirer et remplacer le kit de réchauffage de solutés HOTLINE™.
- Débuller complètement le kit de réchauffage de solutés HOTLINE™ et les accessoires L-10, PC-8 et YC-8 avant le raccordement au patient. On risque sinon d'introduire de l'air dans l'organisme du patient.
- Afin de limiter le risque d'entrée de microbulles libérées dans la vasculature du patient, un dégazeur L-10 peut être utilisé avec le kit de réchauffage de solutés HOTLINE™.
- Ne pas perforer le kit de réchauffage de solutés HOTLINE™ avec des aiguilles, sous risque de percer le trajet de perfusion et de compromettre l'intégrité de la ligne de perfusion patient. Si l'on utilise un kit jetable dont le trajet de solution recirculante/perfusion est percé, le patient risque de tomber malade suite à une pénétration de la solution recirculante du réchauffeur HOTLINE™ dans sa circulation sanguine.
- Ne pas utiliser avec des dispositifs produisant des pressions supérieures à 300 mm Hg. Une pression supérieure à 300 mm Hg peut compromettre l'intégrité du kit de réchauffage de solutés HOTLINE™.
- Ne pas utiliser le réchauffeur HOTLINE™ en cas de défaillance manifeste du matériel ou d'un kit jetable.
- Ce produit contient du DEHP. Les données provenant d'études réalisées chez l'animal et d'études épidémiologiques soulignent notamment les risques suivants : effets indésirables sur le développement fœtal, néphrotoxicité et hépatotoxicité, impact négatif sur la fertilité. Une attention particulière doit être portée à l'utilisation de produits contenant des phtalates chez les populations de patients suivantes : enfants, femmes enceintes et allaitantes.

MISES EN GARDE
Un mauvais fonctionnement, une défaillance ou l'endommagement du dispositif peuvent survenir si ces mises en garde ne sont pas observées :
- La législation fédérale américaine n'autorise la vente de ce produit que sur prescription médicale.
- Les dispositifs médicaux requièrent des caractéristiques matérielles spécifiques pour être utilisés comme prévu. Ces caractéristiques ont été avérées uniquement en cas d'usage unique. Toute tentative de retraitement du dispositif en vue d'une réutilisation peut gravement compromettre son intégrité ou ses performances.

Entreposage :
Entreposer dans un lieu frais et sec. Ne pas exposer à des températures extrêmes.

Préparation :
Consulter l'illustration sur cette page.
Matériel nécessaire pour installer le kit de réchauffage **HOTLINE™** :
- Réchauffeur **HOTLINE™**
- Sang ou soluté I.V.
- Kit de perfusion
- Kit prolongateur (**B**) de 20 cm ou moins (facultatif)

Mode d'emploi :
Consulter le manuel d'utilisation du réchauffeur de sang et de solutés HOTLINE™ pour des instructions détaillées.

Étape 1 – Préparation du réchauffeur HOTLINE™
1. Vérifier que le niveau est au dessus du repère minimum du réservoir. Ajouter le cas échéant de la solution recirculante au réservoir par l'orifice de remplissage.
2. Vérifier visuellement l'état du réchauffeur HOTLINE™ avant de l'utiliser. Mettre hors service tout réchauffeur HOTLINE™ visiblement endommagé.
3. Brancher le réchauffeur HOTLINE™ à une prise électrique correctement mise à la terre.

Étape 2 – Installer le kit de réchauffage de solutés HOTLINE™
1. Retirer le cas échéant le bouchon antireflux du réceptacle sur le côté droit du réchauffeur HOTLINE™.
2. Introduire le raccord à double tubulure du kit de réchauffage de solutés HOTLINE™ (**A**) dans le réceptacle.
3. Mettre l'interrupteur d'alimentation sur marche.
   - La DEL verte Opérationnel du panneau d'affichage s'allume.
   - La température affichée pour la solution recirculante commence à augmenter.
   - Le trajet de la solution recirculante dans le kit de réchauffage de solutés HOTLINE™ s'amorce automatiquement.
4. Retirer le capuchon terminal et inspecter l'extrémité patient du kit de réchauffage de solutés HOTLINE™ pour la présence de fuites et pour confirmer l'intégrité du trajet de perfusion.

Étape 3 – Raccorder le kit de perfusion
1. Raccorder le kit de perfusion et le soluté I.V. au kit de réchauffage de solutés HOTLINE™.
2. Amorcer complètement le kit de perfusion, le kit de réchauffage de solutés HOTLINE™, et, le cas échéant, le kit de prolongateur patient.
3. Raccorder l'extrémité distale du kit de réchauffage de solutés HOTLINE™ au site d'accès de perfusion du patient, sans piéger d'air.

Étape 4 – Utilisation du réchauffeur HOTLINE™
1. L'affichage de température de la solution recirculante prend 4 minutes environ pour atteindre 37 °C à partir de la température ambiante.
2. Régler le débit de la perfusion au moyen du clamp du kit de perfusion. **REMARQUE :** Ne pas tordre le kit de réchauffage de solutés. Ne pas entraver la circulation de la solution dans la tubulure.

Étape 5 – Après l'utilisation
1. Mettre l'interrupteur d'alimentation sur arrêt.
2. Retirer le kit de réchauffage de solutés HOTLINE™ et insérer le bouchon antireflux dans le réceptacle.
3. Après l'utilisation, manipuler et éliminer le kit de réchauffage de solutés HOTLINE™ comme du matériel présentant un risque biologique. **REMARQUE :** Le kit de réchauffage de solutés HOTLINE™ doit être éliminé avec beaucoup de soin et conformément aux directives locales sur les déchets médicaux contaminés.

Dépannage :
1. **Alarmes :** Visuelle (voyant rouge) et auditive (signal sonore pulsé).

ALARME	SYMBOLE	VÉRIFIER CE QUI SUIT
Vérifier les tubulures	⇩	Confirmer que le kit de réchauffage de solutés HOTLINE™ est correctement installé. Introduire fermement le raccord à double tubulure dans le réceptacle situé sur le côté droit du réchauffeur HOTLINE™ .

2. **Difficulté de raccordement du kit de réchauffage HOTLINE™ au réchauffeur :** Lubrifier les joints toriques du réceptacle. Consulter la section 10 du manuel d'utilisation pour la procédure à suivre.
3. **Fuite de solution recirculante au niveau du réceptacle :** Remplacer les joints toriques. Consulter la section 10 du manuel d'utilisation pour la procédure à suivre.

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de DEUTSCH — Gebrauchsanleitung

REF **L-70 NI**

HOTLINE™-Flüssigkeitswärmeset

WARNHINWEIS: Diese Anleitung enthält wichtige Informationen zur sicheren Anwendung des Produkts. Die Gebrauchsanleitung einschließlich aller Warn- und Vorsichtshinweise vollständig durchlesen, bevor das Produkt verwendet wird. Nichtbeachtung der Anleitungen und der Warn- und Vorsichtshinweise kann zu schweren Verletzungen und zum Tod des Patienten führen.

Indikationen:
Das **HOTLINE™**-Flüssigkeitswärmeset ist ein zum Einmalgebrauch vorgesehenes System, mit dem Blut und Infusionsflüssigkeiten gewärmt und bei normothermen Temperaturen unter Schwerkraftbedingungen in den Patienten infundiert werden können.
HINWEIS: Das **HOTLINE™**-Flüssigkeitswärmeset darf nur mit dem **HOTLINE™**-Wärmesystem verwendet werden.

Funktionsprinzip:
Das **HOTLINE™**-Flüssigkeitswärmeset verwendet ein temperaturgesteuertes Heizwasserumlaufsystem zur aktiven Erwärmung von Blut oder Infusionsflüssigkeit in der Patientenleitung. Die Umlauflösung fließt durch separate, einen Mantel um die Infusionsflüssigkeitsleitung bildende Schläuche. Die Flüssigkeit wird bei schwerkraftabhängigen Flussraten zwischen 50-5000 ml/h auf normotherme Temperatur erwärmt.

KONTRAINDIKATIONEN
Nicht zum Erwärmen von Thrombozyten, Kryopräzipitaten oder Granulozyten-Suspensionen verwenden.

WARNUNGEN
Nichtbeachten dieser Warnhinweise kann zum Tod oder zu schweren Verletzungen des Patienten oder Benutzers führen.
- Sämtliche Anweisungen, Etikettierungen und Begleitunterlagen für dieses medizinische Gerät sind durchzulesen und zu befolgen. Nichtbeachten der Anweisungen einschließlich aller Warn- und Vorsichtshinweise, kann zur Fehlbedienung oder zum Versagen des Gerätes führen.
- Das HOTLINE™-Flüssigkeitswärmeset, der L-10, die PC-8 und die YC- 8 sind Einmalprodukte, die nicht resterilisiert werden dürfen.
- Das HOTLINE™-Flüssigkeitswärmeset, der L-10, die PC-8 und die YC-8 nicht verwenden, wenn die Kappen nicht sicher befestigt sind, da der Flüssigkeitsweg in diesem Fall eventuell nicht steril ist.
- Den Tank des HOTLINE™-Wärmesystems nur bei abgenommenem HOTLINE™-Flüssigkeitswärmeset auffüllen. Wenn das HOTLINE™-Flüssigkeitswärmeset nicht vor dem Einfüllen entfernt wird, kann Luft im HOTLINE™-Wärmesystem eingeschlossen werden.
- Blut und Blutprodukte können pathogene Organismen enthalten. Nichtbeachtung der Richtlinien und Verfahrensvorschriften der Klinik für biologisch gefährliche Materialien kann zum Kontakt mit gesundheitsschädlichen Pathogenen führen.
- Bei Aufbau, Vorfüllen und Verwendung sind aseptische Techniken gemäß den jeweiligen Klinikvorschriften anzuwenden.
- Das Wasserumlaufsystem vor Anschließen an die Patientenanschlussleitung vorfüllen. Dadurch wird sichergestellt, dass zwischen dem Wasserumlaufsystem und dem Infusionssystem keine Verbindung besteht. Sollte Flüssigkeit aus dem Patientenende des HOTLINE™-Flüssigkeitswärmesets austreten, bevor es an das Infusionsset angeschlossen wurde, das HOTLINE™-Flüssigkeitswärmeset entfernen und auswechseln.
- Vor dem Anschluss an den Patienten muss alle Luft aus dem HOTLINE™-Flüssigkeitswärmeset, dem L-10, der PC-8 und der YC-8 entfernt werden. Nichtbeachtung dieser Anforderung kann zur Infusion von Luftblasen beim Patienten führen.
- Um das Risiko des Eintritts entgaster Mikrobläsen in das Gefäßsystem des Patienten zu verringern, kann der L-10 Gasabzug mit dem HOTLINE™ Flüssigkeitswärmeset verwendet werden.
- Keine Kanülen in das HOTLINE™-Flüssigkeitswärmeset stecken, da dies den Infusionsweg durchbricht und die Patientenleitung beschädigt. Bei Verwendung eines Einmalsets mit Verbindung zwischen Wasserumlaufsystem und Infusionsleitung kann die Umlauflösung des HOTLINE™-Wärmesystems in den Kreislauf des Patienten gelangen und zur Erkrankung des Patienten führen.
- Nicht mit druckerzeugenden Geräten, die mehr als 300 mmHg aufbauen, verwenden. Drücke über 300 mmHg können das HOTLINE™-Flüssigkeitswärmeset beschädigen.
- Das HOTLINE™-Wärmesystem nicht verwenden, wenn eine offensichtliche Fehlfunktion des Gerätes oder des Einmalsets vorliegt.
- Dieses Produkt enthält DEHP – Laut Daten aus Tier- und epidemiologischen Studien bestehen bei DEHP folgende Risiken, sind aber nicht beschränkt auf: Nachteilige Auswirkungen auf die fetale Entwicklung, Nieren und Leberunverträglichkeit, negative Auswirkungen auf die Fruchtbarkeit. Besondere Vorsicht ist bei der Anwendung von Phthalat-Produkten für die folgenden Patientengruppen geboten: Kinder, schwangere und stillende Frauen.

VORSICHTSHINWEISE
Wenn diese Vorsichtshinweise nicht befolgt werden, kann es zu Fehlfunktion, Ausfall oder Beschädigung des Geräts kommen:
- In den USA darf dieses Produkt nach den gesetzlichen Vorschriften nur durch einen Arzt oder auf ärztliche Verschreibung abgegeben werden.
- Medizinische Produkte erfordern bestimmte Materialeigenschaften, um ihre vorgesehene Funktion erfüllen zu können. Diese Eigenschaften wurden nur für eine einmalige Anwendung validiert. Jeder Versuch der Wiederaufbereitung für weitere Anwendungen kann die Integrität des Produktes beeinträchtigen oder zu einer schlechteren Funktion führen.

Lagerung:
Kühl und trocken lagern. Keinen extremen Temperaturschwankungen aussetzen.

Vorbereitung:
Siehe Abbildungen auf dieser Seite.
Zur Vorbereitung des **HOTLINE™**-Wärmesets sind folgende Artikel erforderlich:
- **HOTLINE™**-Wärmesystem
- Infusionsflüssigkeit oder Blut
- Infusionsset
- Verlängerungsset (**B**), Länge 20 cm oder weniger (optional)

Gebrauchsanleitung:
Vollständige Anleitungen entnehmen Sie bitte dem Bedienungshandbuch für den HOTLINE™ -Blut- und Flüssigkeitswärmer.

Schritt 1 – Vorbereitung des HOTLINE™-Wärmesystems
1. Der Flüssigkeitsstand im Tank muss über der Mindestmarkierung liegen. Ggf. Umlauflösung durch die Einfüllöffnung nachfüllen.
2. Den Zustand des HOTLINE™-Wärmesystems vor der Inbetriebnahme visuell überprüfen. HOTLINE™-Wärmesysteme, die Beschädigungen aufweisen, sind außer Betrieb zu nehmen.
3. Das HOTLINE™-Wärmesystem an eine ordnungsgemäß geerdete Steckdose anschließen.

Schritt 2 – Vorbereitung des HOTLINE™-Flüssigkeitswärmesets
1. Ggf. den Rückflussstopfen aus dem Anschluss an der rechten Seite des HOTLINE™-Wärmesystems entfernen.
2. Den Doppelschlauch-Verbinder des HOTLINE™-Flüssigkeitswärme (**A**) sets in den Anschluss stecken.
3. Hauptschalter einschalten.
   - Die grüne Betriebs-LED im Anzeigefeld leuchtet auf.
   - Die angezeigte Temperatur der Umlauflösung beginnt zu steigen.
   - Das Wasserumlaufsystem des HOTLINE™-Flüssigkeitswärmesets wird automatisch vorgefüllt.
4. Den Endstöpsel entfernen und das Patientenende des HOTLINE™-Flüssigkeitswärmesets auf Leckstellen überprüfen, um die Integrität des Infusionslösungswegs zu bestätigen.

Schritt 3 – Anschluss des Infusionssets
1. Infusionsbeutel und Infusionsset an das HOTLINE™-Flüssigkeitswärmeset anschließen.
2. Das Infusionsset, das HOTLINE™-Flüssigkeitswärmeset und die Patientenanschlussleitung (sofern verwendet) ganz vorfüllen.
3. Das distale Ende des HOTLINE™-Flüssigkeitswärmesets an die intravenöse Zugangsstelle des Patienten anschließen, ohne dabei Luft einzuschließen.

Schritt 4 – Verwendung des HOTLINE™-Wärmesystems
1. Die angezeigte Temperatur der Umlauflösung erreicht 37 °C (von Umgebungstemperatur) in etwa 4 Minuten.
2. Mit Hilfe der Klemme am Infusionsset die Flussrate einstellen. **HINWEIS:** Die Schläuche des Flüssigkeitswärmesets nicht abknicken. Den Fluss der Lösung durch den Schlauch nicht behindern.

Schritt 5 – Nach dem Gebrauch
1. Hauptschalter ausschalten.
2. Das HOTLINE™-Flüssigkeitswärmeset entfernen und den Rückflussstopfen in den Anschluss einsetzen.
3. Das HOTLINE™-Flüssigkeitswärmeset nach dem Gebrauch als potenzielle biologische Gefahrenquelle handhaben und entsorgen. **HINWEIS:** Das HOTLINE™-Flüssigkeitswärmeset muss mit großer Sorgfalt und entsprechend den lokalen Vorschriften für kontaminierten medizinischen Abfall entsorgt warden.

Fehlersuche:
1. **Alarme:** Optische Alarme (rotes Lämpchen) und Tonalarme (unterbrochener Alarmton).

ALARM	SYMBOL	FOLGENDES ÜBERPRÜFEN
Einwegsets prüfen	⇩	Sicherstellen, dass das HOTLINE™-Flüssigkeitswärmeset richtig eingesetzt ist. Den Doppelschlauch-Verbinder fest in den Anschluss rechts am HOTLINE™-Wärmesystem anschließen.

2. **Schwierigkeiten beim Anschließen des HOTLINE™-Wärmesets an das Wärmesystem:** Die O-Ringe in der Anschlussbuchse schmieren. Anleitungen sind dem Kapitel 10 der Bedienungshandbuchs zu entnehmen.
3. **Umlauflösung tritt am Anschluss aus:** Die O-Ringe auswechseln. Anleitungen sind dem Kapitel 10 der Bedienungshandbuchs zu entnehmen.

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es ESPAÑOL — Instrucciones de uso

REF **L-70 NI**

Equipo de calentamiento de fluidos HOTLINE™

ADVERTENCIA: Estas instrucciones contienen información importante para el uso seguro del producto. Lea todas estas instrucciones de uso, incluidas las advertencias y precauciones, antes de utilizar este producto. Si no se siguen correctamente las advertencias, las precauciones y las instrucciones, podrían provocarse la muerte o lesiones graves al paciente.

Indicaciones:
El equipo de calentamiento **HOTLINE™** es un dispositivo para un solo uso, diseñado para calentar la sangre y los fluidos intravenosos, y suministrarlos en el sitio de acceso intravenoso del paciente, a temperaturas normotérmicas, en condiciones de flujo por gravedad.
NOTA: El equipo de calentamiento de fluidos **HOTLINE™** solo debe ser utilizado con el calentador **HOTLINE™**.

Principios de funcionamiento:
El equipo de calentamiento **HOTLINE™** emplea un sistema de calentamiento de la solución recirculante a temperatura controlada para calentar activamente la sangre o el fluido intravenoso en la línea del paciente. La solución recirculante fluye a través de canales independientes que rodean el canal de fluido intravenoso. El fluido se calienta hasta que alcanza una temperatura normotérmica a velocidades de flujo por gravedad de 50 a 5000 ml/hora.

CONTRAINDICACIONES
No debe utilizarse para calentar plaquetas, crioprecipitados ni suspensiones de granulocitos.

ADVERTENCIAS
Si no se siguen estas advertencias, puede ocasionarse la muerte o lesiones graves al paciente o al usuario.
- Lea y siga todas las instrucciones, etiquetas y documentos adjuntos que se suministran con este dispositivo médico. Si no se siguen las instrucciones, incluidas todas las advertencias y precauciones, el dispositivo podría utilizarse o funcionar incorrectamente.
- El equipo de calentamiento de fluidos HOTLINE™, al igual que los dispositivos L-10, PC-8 e YC-8, son para un solo uso y no deben resterilizarse.
- No utilice el equipo de calentamiento de fluidos HOTLINE™ ni los dispositivos L-10, PC-8 o YC-8 si las tapas no están colocadas de forma segura; de lo contrario, la vía del flujo intravenoso podría no ser estéril.
- No llene el depósito del calentador HOTLINE™ con el equipo de calentamiento de fluidos HOTLINE™ instalado. Si no quita el equipo de calentamiento de fluidos HOTLINE™ antes del procedimiento de llenado, puede quedar aire atrapado en el calentador HOTLINE™.
- La sangre y los hemoderivados podrían contener organismos patógenos. Si no se siguen las normas y procedimientos del centro para materiales biológicos peligrosos, podría producirse la exposición a patógenos peligrosos.
- Utilice una técnica aséptica para la configuración, cebado y el uso, de acuerdo con las normas y procedimientos aplicables del centro.
- Cebe la vía de solución recirculante antes de conectarla al equipo de extensión intravenoso. Esto se hace para confirmar que no existen roturas que comuniquen la vía de la solución recirculante y la vía intravenosa. Si sale líquido por el extremo del paciente del equipo de calentamiento de fluidos HOTLINE™ antes de conectarlo al equipo de administración intravenoso, retire y sustituya el equipo de calentamiento de fluidos HOTLINE™.
- Extraiga todo el aire del equipo de calentamiento de fluidos HOTLINE™ y de los dispositivos L-10, PC-8 y YC-8 antes de conectarlos al paciente. Si no se toma esta medida puede ocurrir que se introduzca aire en el paciente.
- Para reducir el riesgo de que entren microburbujas de gas en la vasculatura del paciente, se debe usar una línea de descarga de gases L-10 con el equipo de calentamiento de fluidos HOTLINE™.
- No perfore el equipo de calentamiento de fluidos HOTLINE™ con agujas, ya que ocasionaría una rotura que afectaría a la integridad de la vía intravenosa del paciente. Si se utiliza un equipo desechable que tenga roturas que permitan que el contenido de la vía de solución recirculante se mezcle con el de la vía intravenosa o viceversa, el paciente podría enfermar debido a la entrada de solución recirculante del calentador HOTLINE™ en el torrente sanguíneo.
- No lo utilice con dispositivos a presión que generen más de 300 mmHg. Una presión superior a 300 mmHg puede poner en peligro la integridad del equipo de calentamiento de fluidos HOTLINE™.
- No utilice el calentador HOTLINE™ si es evidente el mal funcionamiento del equipo o de algún elemento desechable.
- Este producto contiene DEHP. Los datos derivados de los estudios en animales y epidemiológicos detallan los siguientes riesgos, entre otros: efectos adversos sobre el desarrollo fetal, toxicidad renal y hepática, impacto negativo sobre la fertilidad. Debe prestarse especial atención al realizar la aplicación de productos con ftalatos en los siguientes grupos de pacientes: pacientes pediátricos, mujeres embarazadas y mujeres lactantes.

PRECAUCIONES
Si no se siguen estas precauciones, el dispositivo puede funcionar incorrectamente y presentar averías o daños:
- Las leyes federales de EE.UU. restringen la venta de este dispositivo a un médico o por prescripción facultativa.
- El material de los dispositivos médicos debe reunir características específicas para funcionar como es debido. Dichas características únicamente se han verificado para un solo uso. Cualquier intento de reprocesar el dispositivo para su ulterior reutilización puede afectar negativamente a la integridad del mismo o dar lugar a fallos en su funcionamiento.

Almacenamiento:
Almacene el dispositivo en un lugar fresco y seco. No lo exponga a temperaturas extremas.

Preparación:
Consulte la ilustración de esta página.
Para montar el equipo de calentamiento de fluidos **HOTLINE™** se necesita lo siguiente:
- Calentador **HOTLINE™**
- Fluido intravenoso o sangre
- Equipo de administración intravenosa
- Equipo de extensión (**B**) de 20 cm o menos de longitud (opcional)

Instrucciones de uso:
Consulte las instrucciones completas en el Manual del usuario del calentador de sangre y fluidos HOTLINE™.

Paso 1. Preparación del calentador HOTLINE™
1. Compruebe que el nivel esté por encima de la marca de nivel mínimo del depósito. Si es necesario, añada solución recirculante al depósito a través del orificio de llenado.
2. Compruebe visualmente el estado del calentador HOTLINE™ antes de utilizarlo. Ponga fuera de servicio cualquier calentador HOTLINE™ que muestre daños físicos.
3. Enchufe el calentador HOTLINE™ a una toma de corriente con una puesta a tierra adecuada.

Paso 2. Preparación del equipo de calentamiento de fluidos HOTLINE™
1. Quite la tapa de reflujo (si está instalada) del receptáculo del lado derecho del calentador HOTLINE™.
2. Conecte el conector de dos tubos del equipo de calentamiento de fluidos HOTLINE™ (**A**) al receptáculo.
3. Encienda el equipo.
   - Se ilumina el LED verde de funcionamiento en el panel de visualización.
   - La temperatura de la solución recirculante que se indica en la pantalla comenzará a aumentar.
   - La vía de solución recirculante del equipo de calentamiento de fluidos HOTLINE™ se cebará automáticamente.
4. Quite la tapa del extremo e inspeccione el extremo del paciente del equipo de calentamiento de fluidos HOTLINE™ para detectar cualquier fuga y confirmar la integridad de la vía intravenosa.

Paso 3. Conexión del equipo de administración intravenosa
1. Conecte la bolsa de fluido intravenoso y el equipo de administración intravenosa al equipo de calentamiento de fluidos HOTLINE™.
2. Cebe completamente el equipo de administración intravenosa, el equipo de calentamiento de fluidos HOTLINE™ y el equipo de extensión al paciente (si se usa).
3. Conecte el extremo distal del equipo de calentamiento de fluidos HOTLINE™ al sitio de acceso intravenoso del paciente, con cuidado de no introducir aire.

Paso 4. Uso del calentador HOTLINE™
1. La temperatura de la solución recirculante que se indica en la pantalla tarda aproximadamente 4 minutos en alcanzar los 37 °C a partir de la temperatura ambiente.
2. Ajuste la velocidad del flujo intravenoso con la pinza del equipo de administración intravenosa. **NOTA:** No retuerza el equipo de calentamiento de fluidos. No restrinja la circulación de la solución a través de los tubos.

Paso 5. Después del uso
1. Apague el equipo.
2. Retire el equipo de calentamiento de fluidos HOTLINE™ e introduzca la tapa de reflujo en el receptáculo.
3. Después del uso, manipule y deseche el equipo de calentamiento de fluidos HOTLINE™ como material potencialmente biopeligroso. **NOTA:** Deseche de modo seguro el equipo de calentamiento de fluidos HOTLINE™, respetando la normativa local sobre eliminación de residuos médicos contaminados.

Solución de problemas:
1. **Alarmas:** Visuales (luz roja indicadora) y sonoras (alarma pulsátil).

ALARMA	SÍMBOLO	COMPRUEBE LO SIGUIENTE
Comprobar el equipo desechable	⇩	Compruebe que el equipo de calentamiento de fluidos HOTLINE™ está instalado correctamente. Introduzca firmemente el conector de dos tubos en el receptáculo situado en el lado derecho del calentador HOTLINE™.

2. **Inserción difícil del equipo de calentamiento HOTLINE™ en el calentador:** Lubricar las juntas tóricas en el receptáculo. Consulte el procedimiento en el apartado 10 del Manual del usuario.
3. **Fuga de solución recirculante en el receptáculo:** Cambie las juntas tóricas. Consulte el procedimiento en el apartado 10 del Manual del usuario.

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it ITALIANO — Istruzioni per l'uso

REF **L-70 NI**

Set scaldafluidi HOTLINE™

AVVERTENZA - Le presenti istruzioni contengono importanti informazioni per l'uso del prodotto in sicurezza. Prima dell'uso del presente prodotto, leggere per intero le presenti istruzioni per l'uso, incluse le avvertenze e le precauzioni. La mancata osservanza delle avvertenze, delle precauzioni e delle istruzioni può provocare gravi lesioni o il decesso del paziente.

**

- Niet voor gebruik met druktoestellen die meer dan 300 mmHg genereren. Bij een druk van meer dan 300 mmHg kan de integriteit van de HOTLINE™ vloeistofverwarmingsset worden aangetast.
- Gebruik de HOTLINE™ verwarmer niet als de apparatuur of de disposable duidelijk defect is.
- Dit product bevat DEHP – gegevens afkomstig uit dier- en epidemiologisch onderzoek wijzen op onder de volgende risico's: Nadelige effecten op de foetale ontwikkeling, nier- en levertoxiciteit en negatieve invloed op de vruchtbaarheid. Er moet speciale aandacht worden besteed aan de toepassing van flatalduundende producten bij de volgende patiëntenpopulaties: kinderen, zwangere vrouwen en vrouwen die borstvoeding geven.

LET OP

Er kan defect, storing of beschadiging van het apparaat optreden als deze voorzorgen niet in acht worden genomen:

- Krachtens de nationale wetgeving (van de VS) mag dit product uitsluitend door of op voorschrift van een arts worden verkocht.
- Voor een beoogde werking moeten medische hulpmiddelen over specifieke materiaaleigenschappen beschikken. Deze eigenschappen zijn na verificatie alleen voor eenmalig gebruik geschikt verklaard. Probeer niet het hulpmiddel opnieuw te bewerken met hergebruik als doel. Zulke pogingen kunnen een ongunstige invloed op de integriteit van het hulpmiddel hebben of kunnen een verslechterde werking van het hulpmiddel veroorzaken.

Opslag:
Op een koele, droge plaats bewaren. Niet aan extreme temperatuur blootstellen.

Voorbereiding:
Zie de afbeelding op deze pagina.
Om de **HOTLINE™** verwarmingsset op te stellen, hebt u het volgende nodig:

- **HOTLINE™** verwarmer
- Infuusvloeistof of blood
- Intraveneus toedieningssysteem
- Verlenging (**B**), 20 cm of minder in lengte (optioneel)

Gebruiksaanwijzing:
Zie de HOTLINE™ bloed- en vloeistofverwarmer Bedieningshandleiding voor complete instructies.

Stap 1 – De HOTLINE™ verwarmer opstellen

1. Controleer of het niveau zich boven de markering voor het minimumniveau op het reservoir bevindt. Voeg zo nodig circulatievloeistof toe via de vulopening aan het reservoir toe.
2. Controleer de toestand van de HOTLINE™ verwarmer aan de hand van een visuele inspectie alvorens deze te gebruiken. Een HOTLINE™ verwarmer die fysieke beschadiging vertoont, moet buiten gebruik worden gesteld.
3. Steek de stekker van de HOTLINE™ verwarmer in een naar behoren geaard stopcontact.

Stap 2 – De HOTLINE™ vloeistofverwarmingsset opstellen

1. Verwijder (indien aanwezig) de reflux-plug van de aansluiting aan de rechterkant van de HOTLINE™ verwarmer.
2. Steek de dubbele slangconnector op de HOTLINE™ vloeistofverwarmingset (**A**) in de aansluiting.
3. Zet de stroomschakelaar aan.
   - De groene led 'In bedrijf' op het afleesvenster licht op.
   - Het temperatuurdisplay van de circulatieopstelling begint te stijgen.
   - Het circulatieopstelling pad in de HOTLINE™ vloeistofverwarmingsset wordt automatisch gevuld.
4. Verwijder de eindstop en inspecteer het patiëntuiteinde van de HOTLINE™ vloeistofverwarmingsset op lekken om te bevestigen dat het infuuspad intact is.

Stap 3 – Het intraveneuze toedieningssysteem aansluiten

1. Sluit de infuusvloeistof en het intraveneuze toedieningssysteem aan op de HOTLINE™ vloeistofverwarmingsset.
2. Zorg dat het intraveneuze toedieningssysteem, de HOTLINE™ vloeistofverwarmingsset en de patiëntverlenging (indien gebruikt) volledig worden gevuld.
3. Sluit het distale uiteinde van de HOTLINE™ vloeistofverwarmingsset aan op de intraveneuze toegangspluats van de patiënt zonder dat er luchtbellen worden gevormd.

Stap 4 – De HOTLINE™ verwarmer gebruiken

1. Het temperatuurdisplay van de circulatieopstelling stijgt in ongeveer 4 minuten van omgevingstemperatuur tot 37 °C
2. Stel de infuusstroomsnelheid af met gebruik van de klem op het intraveneuze toedieningssysteem.
   NB: De slangen van de vloeistofverwarmingsset niet knikken. De circulatie van de oplossing door de slang niet verhinderen.

Stap 5 – Na gebruik

1. Zet de stroomschakelaar uit.
2. Verwijder de HOTLINE™ vloeistofverwarmingsset en steek de reflux-plug in de aansluiting.
3. Na gebruik moet de HOTLINE™ vloeistofverwarmingsset als mogelijk biologisch gevaarlijk materiaal worden gehanteerd en afgevoerd.
   NB: Het de HOTLINE™ vloeistofverwarmingsset moet op veilige wijze en in overeenstemming met de plaatselijke voorschriften voor gecontamineerd medisch afval worden afgevoerd.

Storingzoeken:

1. **Alarmen:** Visueel (rood waarschuwingslampje) en akoestisch (pulserend alarm).

ALARM	SYMBOOL	CONTROLEER HET VOLGENDE
Controleer disposable		Controleer of de HOTLINE™ vloeistofverwarmingsset naar behoren is aangebracht. Duw de dubbele slangconnector stevig in de aansluiting aan de rechterkant van de HOTLINE™ verwarmer.

2. **Het insteken van de HOTLINE™ vloeistofverwarmingsset in de verwarmer verloopt moeizaam:** Smeer de O-ringen in de aansluiting. Zie voor de procedure hoofdstuk 10 van de Bedieningshandleiding.
3. **Circulatieopstelling lekt bij de aansluiting:** Vervang de O-ringen. Zie voor de procedure hoofdstuk 10 van de Bedieningshandleiding.

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pt PORTUGUÊS — Instruções de utilização

REF **L-70 NI**

Sistema de aquecimento de fluidos HOTLINE™

ADVERTÊNCIA: Estas instruções contêm informações importantes para uma utilização segura do produto. Leia na íntegra estas instruções de utilização, incluindo as advertências e as precauções, antes de utilizar este produto. O não cumprimento das advertências, precauções e instruções pode originar lesões graves ou mesmo a morte do doente.

Indicações:
O sistema de aquecimento **HOTLINE™** é um dispositivo para uma única utilização, concebido para aquecer sangue e fluidos intravenosos e administrá-los através do local de acesso intravenoso do doente em temperaturas normotérmicas sob condições de fluxo de gravidade.
OBSERVAÇÃO: O sistema de aquecimento de fluidos HOTLINE™ deve ser utilizado apenas com o aquecedor **HOTLINE™**.

Princípios de funcionamento:
O sistema de aquecimento **HOTLINE™** emprega um sistema de aquecimento de solução recirculante em temperatura controlada para aquecer o sangue e os fluidos intravenosos na linha do doente. A solução recirculante flui através de canais separados que circundam a via intravenosa. O fluido é aquecido a temperaturas normotérmicas em índices de fluxo de gravidade entre 50-5,000 ml/h.

CONTRA-INDICAÇÕES

Não deve ser usado para aquecimento de plaquetas, crioprecipitados e suspensões de granulócitos.

ADVERTÊNCIAS

Se estas advertências não forem seguidas, poderão ocorrer lesões graves ou mesmo a sua morte.

- Leia e cumpra todas as instruções, rotulagem e documentos anexos fornecidos com este aparelho médico. O não cumprimento das instruções, incluindo todas as advertências e precauções, poderá conduzir à utilização incorrecta do aparelho ou à sua avaria.
- O sistema de aquecimento de fluidos HOTLINE™, da saída de gases L-10 e das extensões PC-8 e YC-8 são dispositivos para uma única utilização e não se recomenda a reesterilização.
- Não utilize o sistema de aquecimento de fluidos HOTLINE™, L-10, PC-8 e YC-8 se as tampas não estiverem bem fixas, caso contrário, a via do fluxo I.V. pode não ficar estéril.
- Não encha o reservatório do aquecedor HOTLINE™ com um sistema de aquecimento de fluidos HOTLINE™ instalado. Se não remover o sistema de aquecimento de fluidos HOTLINE™ antes do procedimento de enchimento, pode provocar o aprisionamento de ar no aquecedor HOTLINE™.
- O sangue e os derivados do sangue podem conter microrganismos patogénicos. O não cumprimento dos procedimentos e normas da instituição relativos a materiais perigosos do ponto de vista biológico poderá originar a exposição a agentes patogénicos nocivos.
- A preparação, a purga e a utilização requerem uma técnica asséptica conforme as directrizes e os procedimentos institucionais aplicáveis.
- Purgue a via da solução recirculante antes de a ligar ao conjunto de extensão intravenosa. Isto deverá ser efectuado para confirmar que não existe uma interrupção entre a via da solução recirculante e a via intravenosa. Se sair fluido pela extremidade do sistema de aquecimento de fluidos HOTLINE™ ligada ao doente antes da ligação ao conjunto de administração intravenosa, remova e substitua o sistema de aquecimento de fluidos HOTLINE™.
- Elimine todo o ar do sistema de aquecimento de fluidos HOTLINE™, da saída de gases L-10 e das extensões PC-8 e YC-8 antes de estabelecer a ligação ao doente. O não cumprimento desta instrução poderá resultar na introdução de ar no doente.
- Para reduzir o risco de que microbolhas desgaseificadas entrem na vascularização do paciente, uma saída de gases L-10 pode ser utilizada com o sistema de aquecimento de fluidos HOTLINE™.
- Não perfure o sistema de aquecimento de fluidos HOTLINE™ com agulhas, já que assim provocaria a interrupção da via I.V., comprometendo a integridade da linha intravenosa do doente. Se utilizar um conjunto descartável com uma via de solução recirculante/via intravenosa interconectada, poderão ocorrer problemas no doente devido à entrada da solução recirculante do aquecedor HOTLINE™ na corrente sanguínea.
- Não deve ser utilizado com aparelhos de pressão que gerem uma pressão acima de 300 mmHg. Uma pressão superior a 300 mmHg poderá comprometer a integridade do sistema de aquecimento de fluidos HOTLINE™.
- Não utilize o aquecedor HOTLINE™ se houver um mau funcionamento evidente do equipamento ou do conjunto descartável.
- Este produto contém DEHP – os dados obtidos a partir de estudos com animais e epidemiológicos destacam os seguintes riscos, embora não sejam exaustivos: efeitos adversos no desenvolvimento do feto, toxicidade renal e hepática, impacto negativo na fertilidade. Deverá prestar-se especial atenção à aplicação de produtos à base de ftalatos nas seguintes populações de doentes: pediátrica, grávidas e mulheres em período de amamentação.

PRECAUÇÕES

Se estas precauções não forem cumpridas, poderão ocorrer avarias, falhas ou danos no aparelho:

- A lei federal dos E.U.A. restringe a venda deste dispositivo a médicos ou mediante receita médica.
- É necessário que determinadas características do material de dispositivos médicos tenham o desempenho pretendido. Estas características foram validadas para uma utilização única. Qualquer tentativa de reprocessar o dispositivo para subsequente reutilização pode afectar adversamente a integridade do dispositivo ou levar à alteração do seu desempenho.

Armazenamento:
Armazene em área seca e fresca. Não o exponha a temperaturas extremas.

Preparação:
Consulte a ilustração nesta página.
Para ligar o sistema de aquecimento **HOTLINE™**, é necessário o seguinte:

- Aquecedor **HOTLINE™**
- Fluido intravenoso ou sangue
- Conjunto de administração intravenosa
- Conjunto de extensão (**B**) de 20 cm ou mais curto (opcional)

Instruções de utilização:
Consulte o manual do operador do aquecedor de sangue e fluidos HOTLINE™ para obter instruções completas.

Passo 1 - Preparar o aquecedor HOTLINE™

1. Verifique se o nível está acima da marca mínima no reservatório. Se necessário, adicione solução recirculante ao reservatório através da porta de enchimento.
2. Antes de utilizar, inspeccione visualmente o estado do aquecedor HOTLINE™. Coloque fora de serviço qualquer aquecedor HOTLINE™ que esteja danificado.
3. Ligue o aquecedor HOTLINE™ a uma tomada eléctrica com ligação à terra adequada.

Passo 2 - Preparar o conjunto de aquecimento de fluidos HOTLINE™

1. Remova a tampa de retenção (se existente) do orifício de encaixe no lado direito do aquecedor HOTLINE™.
2. Ligue o conector duplo do sistema de aquecimento de fluidos HOTLINE™ (**A**) ao orifício de encaixe.
3. Ligue o interruptor de alimentação.
   - O LED verde de funcionamento existente no painel com ecrã acende-se.
   - Os valores da temperatura da solução recirculante apresentados no visor começam a aumentar.
   - A via da solução recirculante no sistema de aquecimento de fluidos HOTLINE™ será purgada automaticamente.
4. Remova a tampa da extremidade e verifique se a extremidade do sistema de aquecimento de fluidos HOTLINE™ ligada ao doente apresenta fugas para confirmar a integridade da via intravenosa.

Passo 3 - Ligar o conjunto de administração intravenosa

1. Ligue o saco de fluido I.V. e o conjunto de administração intravenosa ao sistema de aquecimento de fluidos HOTLINE™.
2. Purgue completamente o conjunto de administração intravenosa, o sistema de aquecimento de fluidos HOTLINE™ e o conjunto de extensão do doente (se utilizado).
3. Ligue a extremidade distal do sistema de aquecimento de fluidos HOTLINE™ ao local de acesso intravenoso do doente sem que fique a aprisionado.

Passo 4 - Utilizar o aquecedor HOTLINE™

1. A temperatura da solução recirculante atinge os 37 °C em cerca de 4 minutos a partir da temperatura ambiente.
2. Ajuste o débito do fluido I.V. utilizando o acessório de fixação do conjunto de administração intravenosa.
   OBSERVAÇÃO: Não dobre o sistema de aquecimento de fluidos. Não obstrua a circulação da solução através da tubagem.

Passo 5 - Após a utilização

1. Desligue o interruptor de alimentação.
2. Remova o sistema de aquecimento de fluidos HOTLINE™ e insira a tampa de retenção no orifício de encaixe.
3. Após o uso, manuseie e elimine o sistema de aquecimento de fluidos HOTLINE™ lacka mellan banan för den cirkulerande lösningen och infusionslangen. Om det kommer ut vätska från patientänden av HOTLINE™ vätskevärmarsett innan det kopplas till infusionsaggregatet, ska HOTLINE™ vätskevärmaret tas bort och bytas ut.
- Tränga ut all luft från HOTLINE™ vätskevärmaret, L-10, PC-8 och YC-8 före anslutning till patienten. Underlåtenhet att göra detta kan resultera i att luft kommer in i patienten.
- För att minska risken för att gasmikrobubblor förs in i patientens kärl kan en L-10 gasventil användas tillsammans med HOTLINE™ vätskevärmaret.
- Stick inte HOTLINE™ vätskevärmaret med nålar eftersom det bryter infusionsbanan och skadar patientens infusionsslang. Om ett engångsset med en trasig bana för cirkulerande lösning/infusionsslang används, kan patienten bli sjuk på grund av att HOTLINE™ värmarens cirkulerande lösning kommer in i patientens blodomlopp.
- Denna produkt är ej avsedd att användas tillsammans med tryckanordningar som genererar tryck på över 300 mmHg. Tryck som överstiger 300 mmHg kan skada HOTLINE™ vätskevärmaret.
- Använd inte HOTLINE™ värmaren om det är uppenbart att utrustningen eller engångssetet inte fungerar på rätt sätt.
- Denna produkt innehåller DEHP – data som härletts från djurstudier och epidemiologiska studier visar på, men begränsas inte till, följande risker: Negativa effekter på fosterutvecklingen, toxicitet för njurar och lever, negativ inverkan på fertiliteten. Särskild uppmärksamhet vid användning av flatalprodukter bör iaktttas för följande patientgrupper: barn, gravida och ammande kvinnor.

FÖRSIKTIGHETSTÄGARDER

Underlåtenhet att följa försiktighetsåtgärderna kan leda till funktionsstörningar, funktionsavbrott eller skada på anordningen.

- Enligt amerikansk federal lagstiftning får denna produkt endast säljas av eller på ord av läkare.
- Medicintekniska utrustningar kräver specifika egenskaper hos materialet för att de ska fungera såsom avsett. Dessa egenskaper har endast verifierats för engångsbruk. Varje försök att upparbeta utrustningen för efterföljande återanvändning kan förorsaka skador på utrustningen eller leda till försämrad funktion.

Förvaring:
Förvaras svalt och torrt. Får ej utsättas för extrema temperaturer.

Förberedelse:
Se bilden på denna sida.
Följande krävs för att installera **HOTLINE™** värmarset:

- **HOTLINE™** värmare
- Infusionsvätska eller blod
- Infusionsset
- Förlängningsset (**B**), 20 cm eller kortare (tillval)

Bruksanvisning:
Se användarhandboken för HOTLINE™ blod- och vätskevärmare för fullständiga instruktioner.

Steg 1 – Installera HOTLINE™ värmaren

1. Kontrollera att vätskenivån är över behållarens markering för lägsta nivå. Tillsätt cirkulerande lösning i behållaren genom påfyllningsporten om det behövs.
2. Kontrollera HOTLINE™ värmarens skick genom en visuell inspektion före användning. Ta varje HOTLINE™ värmare som visar tecken på fysisk skada ur drift.
3. Anslut HOTLINE™ värmaren till ett ordentligt jordat uttag.

Steg 2 – Förbered HOTLINE™ vätskevärmaret

1. Ta bort återflödespluggen (om den finns) från uttaget på högra sidan av HOTLINE™ värmaren.
2. Anslut dubbelslangskopplingen på HOTLINE™ vätskevärmaret (**A**) till uttaget.
3. Slå på strömbrytaren.
   - Den gröna lysdioden för drift på displayanen tänds.
   - Den cirkulerande lösningens temperaturdisplay visar temperatur.
   - Banan för den cirkulerande lösningen i HOTLINE™ vätskevärmaret fylls automatiskt.
4. Ta bort ändlocket och undersök patientänden av HOTLINE™ vätskevärmaret för läckage för att bekräfta att infusionslangen är hel.

Steg 3 – Anslut infusionsaggregatet

1. Anslut påsen med infusionsvätska och infusionsaggregatet till HOTLINE™ vätskevärmaret.
2. Fyll infusionsaggregatet, HOTLINE™ vätskevärmaret och patientens förlängningsset (om sådant används) fullständigt.
3. Koppla den distala änden av HOTLINE™ vätskevärmaret till patientens intravenösa ingångsställe utan att innesluta någon luft.

Steg 4 – Använd HOTLINE™ värmaren

1. Den cirkulerande lösningens temperaturdisplay går från rumstemperatur till 37 °C på ungefär 4 minuter.
2. Justera flödeshastigheten för infusionsvätskan med hjälp av infusionsaggregatets klämma.
   OBS! Vik inte vätskevärmaret. Stryp inte lösningens cirkulation genom slangen.

Steg 5 – Efter användning

1. Slå av strömbrytaren.
2. Ta bort HOTLINE™ vätskevärmaret och sätt i återflödespluggen i uttaget.
3. Efter användning ska HOTLINE™ vätskevärmaret hanteras och bortskaffas som biologiskt riskavfall.
   OBS! HOTLINE™ vätskevärmaret måste avfallshanteras med största försiktighet och i enlighet med lokala föreskrifter för kontaminerat medicinskt avfall.

Felsökning:

1. **Larm:** Visuella (rött indikatorlampa lyser) och ljudlarm (pulserande ton).

LARM	SYMBOL	KONTROLLERA FÖLJANDE
Kontrollera engångsseten		Kontrollera att HOTLINE™ vätskevärmaret installerats på rätt sätt. Tryck in dubbelslangskopplingen stadigt i uttaget på högra sidan av HOTLINE™ värmaren.

2. **Svårt att sätta i HOTLINE™ värmarset i värmaren:** Smörj uttagets O-ringar. Läs om proceduren i avsnitt 10 av användarhandboken.
3. **Den cirkulerande lösningen läcker ut ur uttaget:** Byt ut O-ringarna. Läs om proceduren i avsnitt 10 av användarhandboken.

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da DANSK — Brugsanvisning

REF **L-70 NI**

HOTLINE™ væskevarmpningssæt

ADVARSEL: Disse instruktioner indeholder vigtige oplysninger mht. sikker anvendelse af produktet. Læs hele brugsanvisningen, inklusive advarsler og forholdsregler inden anvendelse af dette produkt. Hvis ikke advarsler, forholdsregler og instruktioner følges nøje, kan det resultere i død eller alvorlige kvæstelser for patienten.

Indikationer:
HOTLINE™ væskeopvarmningssættet er beregnet til at opvarme blod og intravenøse væsker og tilføre dem til patientens intravenøse adgangssted ved normale kropstemperaturer under tyngdekraftsflowforhold.
BEMÆRK: **HOTLINE™** væskeopvarmningssættet må kun anvendes med HOTLINE™ væskevarmeren.

Driftsprincipper:
HOTLINE™ væskeopvarmningssættet anvender et temperaturkontrolleret opvarmningssystem med recirkulationsopløsning til at opvarme blod eller intravenøse væske aktivt i patientslangen. Recirkulationsopløsningen strømmer gennem separate kanaler, der omslutter den intravenøse vej. Væsken opvarmes til normale kropstemperaturer ved tyngdekraftsflowhastigheder på 50-5000 ml/t.

KONTRAINDIKATIONER

Ikke til brug til opvarmning af trombocytter, kryoprecipitater eller granulocytsuspensioner.

ADVARSLER

Hvis ikke disse advarsler følges, kan det resultere i død eller alvorlig kvæstelse for patient eller bruger.

- Læs og følg alle instruktioner, mærkning og dokumenter, der følger med dette medicinske udstyr. Manglende efterfølgelse af instruktioner, herunder alle advarsler og forholdsregler, kan medføre forkert brug af apparatet, eller at apparatet fejlfungerer.
- HOTLINE™ væskevarmningssættet, L-10, PC-8 og YC-8 er anordninger for engangsbrug og skal ikke resteriliseres.
- Ikke brug HOTLINE™-væskevarmningssættet, L-10, PC-8 og YC-8 hvis hettene ikke sitter forsvarlig på plass, ellers kan det hende at IV-banen ikke er steril.
- Fyld ikke HOTLINE™-varmerens reservoar med en HOTLINE™-væskevarmningssett installert. Dersom HOTLINE™-væskevarmingssettet ikke fjernes før påfylling, kan det føre til at det dannes en luftlomme i HOTLINE™-varmeren.
- Blod og blodprodukter kan inneholde patogene organismer. Dersom institusjonens regler og rutiner for biomedisinsk farlig materiale ikke følges, kan dette føre til eksponering av skadelige patogener.
- Installasjon, fylling og bruk krever aseptisk teknikk i henhold til helseinstitusjonens gjeldende rutiner og prosedyrer.
- Fyll banen til den resirkulerende løsningen før den kobles til det intravenøse forlengingssettet. Dette gjøres for å bekrefte at det ikke er lekkasje mellom den resirkulerende løsningens bane og den intravenøse banen. Hvis det kommer væske ut av pasient-endestykket til HOTLINE™-væskevarmingssett før det kobles til den intravenøse administreringssettet, må HOTLINE™-væskevarmingssettet fjernes og erstattes.
- Fjern all luften fra HOTLINE™-væskevarmingssettet, L-10, PC-8 og YC-8 før tilkobling til pasienten. Dersom dette ikke gjøres, kan det føre til at det blir tilført luft inn i pasienten.
- For å redusere risikoen for at gassbobler skal komme inn i pasientens vaskulatur, kan man bruke en L-10 gassventil sammen med HOTLINE™-væskevarmingssettet. Ikke stikk i HOTLINE™-væskevarmingssettet med nåler, da dette kan føre til ødeleggelse av IV-banen og svekke integriteten til pasientens intravenøse slange. Dersom det brukes et engangssett med en resirkulerende løsning/IV-banen, kan pasienten bli syk fordi HOTLINE™-varmerens resirkulerende løsning kommer i pasientens blodomløp.
- Skal ikke brukes med trykkanordninger som genererer over 300 mmHg. Trykk over 300 mmHg kan svekke integriteten til HOTLINE™-væskevarmingssettet.
- Ikke bruk HOTLINE™-varmeren hvis det er tydelig tegn på at utstyret eller engangssettet ikke fungerer riktig.
- Dette produktet inneholder DEHP. Data avledet fra dyre- og epidemiologiske studier viser følgende potensielle risikoer, følgende risikoer: Negativ virkning på fosterutvikling, nyre- og levertoksisitet, negativ virkning på fruktbarhet. Bruken av flatalprodukter må vurderes spesielt nøye for følgende pasientpopulasjoner: pediatripasienter og gravide og ammende kvinner.

FORHOLDSREGLER

Det kan oppstå funksjonsfeil, svikt eller skader på anordningen dersom disse forholdsreglene ikke følges:

- Etter amerikansk lovgivning kan dette utstyret kun selges eller bestilles av en lege.
- Medisinsk utstyr krever særskilte materialegenskaper for å fungere etter hensikten. Disse egenskapene er kun verifisert for engangsbruk. Eventuelle forsøk på å gjenprosessere utstyret for gjentatt bruk vil kunne ha negativ effekt på utstyret eller føre til at funksjonsevnen forringes.

Oppbevaring:
Oppbevares tørt og køligt. Må ikke udsættes for ekstreme temperaturer.

Forberedelse:
Se illustrationen på denne side.
Du skal bruge følgende ved monteringen af **HOTLINE™** væskeopvarmningssættet:

- **HOTLINE™**-varmer
- Intravenøs væske eller blod
- Intravenøst administreringssæt
- Forlængersæt (**B**), 20 cm, eller mindre længde (valgfrit)

Brugsanvisning:
Se brugervejledningen til HOTLINE™ blod- og væskevarmer for komplette instruktioner.

Trin 1 – Montering af HOTLINE™ væskevarmeren

1. Check, at niveauet er over mærket for minimumniveauet på reservoiret. Tilsæt recirkulationsopløsning i reservoiret gennem påfyldningsåbningen, hvis det er påkrævet.
2. Check HOTLINE™ væskevarmerens tilstand med en visuel inspektion inden brug. Tag en HOTLINE™ væskevarmer ud af drift, hvis den viser tegn på fysisk beskadigelse.
3. Tilslut HOTLINE™ væskevarmeren til en stramkontakt med jordforbindelse.

Trin 2 – Montering af HOTLINE™ væskeopvarmningssættet

1. Fjern tilbakestrømspluggen (hvis aktuelt) fra holderen på den højre side av HOTLINE™-varmeren.
2. Plugg dobbelslangekoblingen på HOTLINE™-væskevarmingssettet (**A**) inn i holderen.
3. Slå på strømbryteren.
   - Det grønne drift-LED-lyset tennes på displaypanelet.
   - Temperaturdisplayet for den resirkulerende løsningen begynner å øke.
   - Banen til den resirkulerende løsningen til HOTLINE™-væskevarmingssettet begynner å fylles automatisk.
4. Fjern endehetten og inspiser pasient-endestykket til HOTLINE™-væskevarmingssettet for lekkasje for å bekrefte integriteten til den intravenøse væskebanen.

Trinn 3 – Tilslut det intravenøse administrationssæt

1. Tilslut IV-væsken og det intravenøse administrationssæt til HOTLINE™ væskevarmingssettet.
2. Prim det intravenøse administrationssæt, HOTLINE™ væskevarmingssettet og patientforlængersættet (hvis et sådant anvendes) helt.
3. Kobl den distale ende af HOTLINE™ væskevarmingssættet til patientens intravenøse adgangssted uden at indfange luft.

Trin 4 – Brug af HOTLINE™ væskevarmeren

1. Recirkulationsopløsningens temperaturdisplay når 37 °C fra omgivende temperatur på ca. 4 minutter.
2. Juster IV-flowhastigheden med klemmen på det intravenøse administrationssæt.
   BEMÆRK: Der må ikke være knæk på væskevarmingssættet. Cirkulation af opløsningen gennem slangen må ikke hæmmes.

Trin 5 – Efter brug

1. Sluk for stramafbryderen.
2. Fjern HOTLINE™ væskeopvarmningssættet og sæt tilbageløbspproppen i stikforbindelsen.
3. Efter brug håndteres og bortskaffes HOTLINE™ væskeopvarmningssættet som en potentiel biofare.
   BEMÆRK: HOTLINE™ væskeopvarmningssættet skal bortskaffes med største omhu i henhold til de lokale forskrifter om kontamineret medicinsk affald.

Fejlfinding:

1. **Alarmer:** Visuel (rødt indikatorlys) og akustisk (pulserende alarm).

ALARM	SYMBOL	CHECK FØLGENDE
Check engangsstarkiler		Bekræft, at HOTLINE™ væskeopvarmningssættet er korrekt sat i. Tryk konnektoren med dobbeltslange i stikforbindelsen på højre side af HOTLINE™ væskevarmeren.

2. **Vanskelig indføring af HOTLINE™ opvarmningssættet i væskevarmeren:** Smør O-ringene i stikforbindelsen. Se Afsnit 10 i brugervejledningen, der beskriver proceduren.
3. **Recirkulationsopløsning siver ud ved stikforbindelsen:** Skift O-ringene. Se Afsnit 10 i brugervejledningen, der beskriver proceduren.

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no NORSK — Bruksanvisning

REF **L-70 NI**

HOTLINE™-væskevarmingssett

ADVARSEL: Disse anvisningene inneholder viktig informasjon om hvordan produktet skal brukes på en sikker måte. Les hele denne bruksanvisningen, inkludert advarslene og forholdsregler, før produktet brukes. Unnlatelse av å følge advarsler, forholdsregler og anvisninger kan føre til død eller alvorlig skade på pasienten.

Indikasjoner:
HOTLINE™-varmingssett er en anordning for engangsbruk som er laget for å varme blod og intravenøse væsker, og tilføre dem til pasientens intravenøse tilgangssted ved normotermiske temperaturer under tyngdeforhold.
MERK: HOTLINE™-væskevarmingssettet må kun brukes med **HOTLINE™** -varmeren .

Driftsprinsipp:
HOTLINE™-varmingssettet benytter et temperaturstyrt varmesystem for den resirkulerende løsningen til å varme opp blod eller intravenøse væsker aktivt i pasientslangen. Den resirkulerende løsningen går gjennom adskilte kanaler som omgir den intravenøse væskebanen. Væsken varmes opp til normotermiske temperaturer ved tyngde-flythastigheter fra 50–5000 ml/h.

KONTRAINDIKASJONER

Skal ikke brukes til å varme blodplater, kryospresipitater eller granulocytt-suspensjoner.

ADVARSLER

Pasienten eller brukeren kan dø eller bli alvorlig skadet dersom det ikke blir tatt hensyn til disse advarslene.

- Les og følg alle instruksjoner, etiketter/merker og vedlagte dokumenter som medfølger denne medisinske anordningen. Dersom anvisningene, innbefattet alle advarsler og forholdsregler ikke følges, kan dette føre til at anordningen blir brukt på feil måte eller funksjonsfeil.
- HOTLINE™-væskevarmingssettet, L-10, PC-8 og YC-8 er anordninger for engangsbruk og skal ikke resteriliseres.
- Ikke bruk HOTLINE™-væskevarmingssettet, L-10, PC-8 og YC-8 hvis hettene ikke sitter forsvarlig på plass, ellers kan det hende at IV-banen ikke er steril.
- Fyll ikke HOTLINE™-varmerens reservoar med en HOTLINE™-væskevarmingssett installert. Dersom HOTLINE™-væskevarmingssettet ikke fjernes før påfylling, kan det føre til at det dannes en luftlomme i HOTLINE™-varmeren.
- Blod og blodprodukter kan inneholde patogene organismer. Dersom institusjonens regler og rutiner for biomedisinsk farlig materiale ikke følges, kan dette føre til eksponering av skadelige patogener.
- Installasjon, fylling og bruk krever aseptisk teknikk i henhold til helseinstitusjonens gjeldende rutiner og prosedyrer.
- Fyll banen til den resirkulerende løsningen før den kobles til det intravenøse forlengingssettet. Dette gjøres for å bekrefte at det ikke er lekkasje mellom den resirkulerende løsningens bane og den intravenøse banen. Hvis det kommer væske ut av pasient-endestykket til HOTLINE™-væskevarmingssett før det kobles til den intravenøse administreringssettet, må HOTLINE™-væskevarmingssettet fjernes og erstattes.
- Fjern all luften fra HOTLINE™-væskevarmingssettet, L-10, PC-8 og YC-8 før tilkobling til pasienten. Dersom dette ikke gjøres, kan det føre til at det blir tilført luft inn i pasienten.
- For å redusere risikoen for at gassbobler skal komme inn i pasientens vaskulatur, kan man bruke en L-10 gassventil sammen med HOTLINE™-væskevarmingssettet. Ikke stikk i HOTLINE™-væskevarmingssettet med nåler, da dette kan føre til ødeleggelse av IV-banen og svekke integriteten til pasientens intravenøse slange. Dersom det brukes et engangssett med en resirkulerende løsning/IV-banen, kan pasienten bli syk fordi HOTLINE™-varmerens resirkulerende løsning kommer i pasientens blodomløp.
- Skal ikke brukes med trykkanordninger som genererer over 300 mmHg. Trykk over 300 mmHg kan svekke integriteten til HOTLINE™-væskevarmingssettet.
- Ikke bruk HOTLINE™-varmeren hvis det er tydelig tegn på at utstyret eller engangssettet ikke fungerer riktig.
- Dette produktet inneholder DEHP. Data avledet fra dyre- og epidemiologiske studier viser følgende potensielle risikoer, følgende risikoer: Negativ virkning på fosterutvikling, nyre- og levertoksisitet, negativ virkning på fruktbarhet. Bruken av flatalprodukter må vurderes spesielt nøye for følgende pasientpopulasjoner: pediatripasienter og gravide og ammende kvinner.

FORHOLDSREGLER

Feilfunksjon, svigt eller beskadigelse af anordningen kan forekomme, hvis disse forholdsregler ikke overholdes:

- Ifølge amerikansk lov må dette produkt kun sælges af eller på ordination af en læge.
- Medicinsk udstyr kræver specifikke materialeegenskaber for at fungere som tilsigtet. Disse egenskaber er kun kontrolleret til engangsbrug. Ethvert forsøg på at behandle udstyret til efterfølgende genbrug kan påvirke perfekt tilstand af udstyret negativt eller medføre forringet funktionsevne.

Oppbevaring:
Oppbevares tørt og kaldt. Må ikke udsættes for ekstreme temperaturer.

Forberedelse:
Se illustrationen på denne side.
For å sette opp **HOTLINE™**-varmingssettet trenger du følgende:

- **HOTLINE™**-varmer
- Intravenøs væske eller blod
- Intravenøst administreringssett
- Forlengingssett (**B**), 20 cm, eller mindre lengde (valgfritt)

Bruksanvisning:
Se brugervejledningen til HOTLINE™ blod- og væskevarmer for fuldstændige anvisninger.

Trinn 1 – Sette opp HOTLINE™-varmeren

1. Kontroller at nivået er over minimumsnivåmerket på reservoaret. Fyll på resirkulerende løsning i reservoaret gjennom fyllingsporten hvis nødvendig.
2. Kontroller HOTLINE™-varmerens tilstand med en visuell inspeksjon før den tas i bruk. HOTLINE™-varmere som viser tegn på fysisk skade, skal tas ut av drift.
3. Plugg HOTLINE™-varmeren i en behørig jordet stikkontakt.

Trinn 2 – Sette opp HOTLINE™-væskevarmingssettet

1. Fjern tilbakestrømspluggen (hvis aktuelt) fra holderen på den høyre siden av HOTLINE™-varmeren.
2. Plugg dobbelslangekoblingen på HOTLINE™-væskevarmingssettet (**A**) inn i holderen.
3. Slå på strømbryteren.
   - Det grønne drift-LED-lyset tennes på displaypanelet.
   - Temperaturdisplayet for den resirkulerende løsningen begynner å øke.
   - Banen til den resirkulerende løsningen til HOTLINE™-væskevarmingssettet begynner å fylles automatisk.
4. Fjern endehetten og inspiser pasient-endestykket til HOTLINE™-væskevarmingssettet for lekkasje for å bekrefte integriteten til den intravenøse væskebanen.

Trinn 3 – Koble til det intravenøse administreringssettet

1. Koble IV-væsken og det intravenøse administreringssettet til HOTLINE™-væskevarmingssettet.
2. Fyll det intravenøse administreringssettet, HOTLINE™-væskevarmingssettet og pasientens forlengingssett (hvis aktuelt) helt opp.
3. Koble den distale enden av HOTLINE™-væskevarmingssettet til pasientens intravenøse tilgangssted uten å stenge inne luft.

Trinn 4 – Bruke HOTLINE™-varmeren

1. Temperaturdisplayet for den resirkulerende løsningen vil nå 37 °C fra omgivelsestemperaturen etter ca. 4 minutter.
2. Juster IV-flythastigheten med klemmen på det intravenøse administreringssettet.
   MERK: Det må ikke oppstå knekk på væskevarmingssettet. Det må ikke oppstå hindringer for sirkuleringen av løsningen gjennom slangen.

Trinn 5 – Etter bruk

1. Slå av strømbryteren.
2. Fjern HOTLINE™