ThermoStat™ 900
BLOOD AND FLUID WARMER

FAST, CLEAN, AND SAFE
MICROWAVE TECHNOLOGY

Operator's and Service Manuals
OPERATOR'S AND SERVICE MANUALS

SECTION I:
ThermoStat™ 900
BLOOD AND FLUID WARMER

SECTION II:
Empty Cartridge/
Fluid Warming Rate Module
Model WRM25
OPERATOR’S and SERVICE MANUAL

ThermoStat™ 900
BLOOD AND FLUID WARMER

CAUTION: The Paladin Biomedical Corporation ThermoStat™900 should not be operated by persons who have not read this manual and its Warnings and Cautions.

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# OPERATOR’S AND SERVICE MANUAL

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UNPACKING AND SETUP INFORMATION

See page 10 for illustration and description of parts

The ThermoStat™900 has been secured to the shipping pallet to ensure safe transport to your facility. Verify the box contains 1 each: ThermoStat™900, IV Pole Assembly, IV Bag Hook Rack, Operator’s & Service Manuals.

1. Carefully remove the shipping container’s upper carton by removing the strapping that secures it to the pallet. Do not discard this carton until the IV pole has been removed.

2. Remove the IV Pole Assembly from the carton. Place this pole assembly aside for installation at a later point.

3. Remove the packing material from the upper portion of the ThermoStat™900.

4. The base of the ThermoStat™900 is secured to the shipping pallet in several locations. Carefully cut the strapping material in these locations.

5. Grasp the ThermoStat™900 by the base and lift from the shipping pallet. The ThermoStat™900 weighs 80 pounds (31.6 Kg). Caution should be used when lifting.

**NOTE: Do not lift the ThermoStat™900 by the upper portion of the unit or the upper pole as physical damage to the unit may result.**

1. Remove the IV Bag Hook Rack from the shipping pallet. Connect the IV Bag Hook Rack to the IV pole by sliding it onto the end of the IV pole not containing an end cap. Push in the spring-loaded locking tabs on the IV pole and orient the hook rack until the locking tabs protrude from the holes in the sleeve of the hook rack.

2. Loosen the knurled knob on the IV pole mount located at the back of the upper console and insert the IV pole assembly. Set the IV pole at the desired height and tighten the knob.

3. Remove any packing material around the AC power cord.

4. Carefully remove the packing containing the Empty Cartridge and Fluid Warming Rate Module (Model WRM25) mounted to the heating cavity support. Attach the WRM25 Module to the IV Pole Assembly by snapping the IV pole clip at the rear of the module onto the IV Pole Assembly.

5. Inspect the unit for any signs of physical damage. Report any damage to your Paladin Biomedical Corporation authorized service representative by calling 1-888-927-4069.

6. Inspect for any evidence of foreign matter inside the heating chamber. This chamber must be free of any objects to enable insertion of the cartridge and proper operation of the ThermoStat™900.

See the cleaning section of this manual for details on accessing the chamber.
OPTIONAL PRESSURE INFUSOR SETUP INSTRUCTIONS

The ThermoStat™900 is equipped with a built-in air compressor for use with pressure infusors. The air-compressor is capable of supplying a maximum of 5.69 P.S.I.G. (pounds per square inch gauge pressure). Connection to the air compressor is provided via the 1/8" female CPC quick disconnect located on the top surface of the ThermoStat™900 Base Cover. Infusors may be connected using a pneumatic line with a 1/8" male quick disconnect (CPC 1/8" Flow MC series, or equivalent). The air compressor operates continuously with no additional electrical connections necessary.

HOW TO OBTAIN THERMOSTAT™900 AUTHORIZED SERVICE

Call 1-888-927-4069

• Please review the troubleshooting section of this manual.

• Be prepared to describe problems including any lights or alarms activated and the serial number of unit.

• It may be necessary for Paladin to ship a temporary replacement unit: Please have the address for the hospital shipping area available when calling for service.

• If a unit is to be shipped back to Paladin for repair, the customer is responsible for cleaning and disinfecting the unit before returning. The Customer should wait for the replacement machine to be delivered, and use that carton/pallet to return the machine in need of service. Instructions for repacking will be provided with replacement machine.

GENERAL WARNINGS AND CAUTIONS

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

Messages headed by "CAUTION" require that you alert the practitioner to exercise special care to ensure the safe and effective use of this device.

Messages headed by "WARNING" indicate information or procedures that if not followed correctly can cause serious outcomes (death, injury, or serious adverse events) to the patient, the user, or the environment.

⚠️ WARNING:
- Grounding reliability can only be achieved by connection to a dedicated 20 ampere, hospital grade receptacle.
- Electrical shock hazard. Do not open case. THIS DEVICE CONTAINS NO USER SERVICEABLE PARTS. This device should only be serviced by Paladin Biomedical Corporation authorized service personnel.
- Proper service procedures must be followed to ensure continued compliance with federal (USA) performance standards for microwave ovens (CFR 21 section 1030), and to avoid possible exposure to excessive microwave energy. This device contains no user serviceable parts. This device should only be served by Paladin Biomedical Corporation authorized service personnel.
- Remove all air from the fluid lines and IV bags prior to connection to the patient. Failure to do so could result in the introduction of air into the patient resulting in serious injury or death. Monitor fluid lines to ensure that they remain free of air.
- When changing IV bags or while infusing liquids, the drip chambers and filter vent MUST REMAIN UPRIGHT. Laying them flat could allow air to enter the patient line causing serious injury or death.

DANGER: Explosion hazard. Do not use in the presence of flammable anesthetics.

CAUTION:
- The ThermoStat™900 device is intended for use only with the Paladin Biomedical Corporation ThermoStat™900 Cartridge. Do not attempt to operate the ThermoStat™900 without the ThermoStat™900 Cartridge properly in place.
- Do not block the air intake or air outlet vents in the base of the ThermoStat™900. Blocking the air vents may result in overheating and disabling of the device.
- Read all instructions prior to use.
- Treat all blood products as hazardous.
- Aseptic technique should be used when making all connections.
- Actual performance may vary depending on operating conditions.
- Federal law (USA) restricts this device to sale by, or on the order of a physician. The physician is solely responsible for the use of this device.
- Safe and effective use of this device requires proper set-up and operation by trained personnel.

Carefully read all WARNINGS and CAUTIONS throughout this manual.

PURPOSE

The ThermoStat™900 is intended for the warming of blood and physiologic fluids for intravenous administration.

The ThermoStat™900 provides safe and effective warming of blood and physiologic intravenous fluids at various flow rates including the high flow rates needed for trauma resuscitation and major surgical procedures. This helps prevent the hypothermia which often accompanies the administration of large volumes of cold fluids.

This device is designed for simple operation and low maintenance. A single switch engages the power and initiates a self-test. The display panel provides step by step instructions for correct installation of the cartridge and initiation of the heating process.

ABBREVIATED OPERATING GUIDE

CAUTION: This ThermoStat™900 should not be operated by persons who have not read this manual and its WARNINGS and CAUTIONS. This abbreviated guide is for use only by persons already familiar with this device and high flow administration of intravenous fluids.

1. Examine device for damage.
2. Connect to AC power.
3. Depress power switch.
4. Open heating chamber cover.
5. Place cartridge on shelf in heating chamber.
7. Close heating chamber cover.
8. Secure chamber cover latch.
9. Prime the administration set.
10. Remove cartridge and inspect for air (Repeat steps 5, 6, 7, & 8).
11. Watch and listen for indicators.
12. Monitor the warming process.
FEATURES AND BENEFITS

THE ThermoStat™900 HIGH TECHNOLOGY SYSTEM PROVIDES MANY TECHNICAL FEATURES THAT ARE NOT FOUND IN CONVENTIONAL WARMERS.

Low Priming Volume: Administration Set cartridge requires only a 5cc priming volume.

Displays Actual Outlet Fluid Temperature: Uses unique non-invasive radiometric sensing to control in-line warming and measure fluid temperature.

Air-in Cartridge Indicator: Indicator illuminates and an audible tone beeps when the minimum volume in cartridge void of blood or IV fluids is more than 2cc. Uses include indication of unprimed cartridge and empty IV bag (no fluid in-line).

Flow Rate Indicator: WRM25 Fluid Warming Rate Module indicates flow rate of fluid being warmed.

No Water Bath: No risk of water-borne contaminants. Eliminates turbulence required with many water based heat exchangers. Reduces maintenance.

Improved Portability: Patient can be separated from system without removal of the cartridge from the administration set.

Easy-to-use: Pre-assembled cartridge and administration set, is interchangeable with all ThermoStat™900 Systems.
PARTS AND INDICATORS

1. IV pole extension control knob

2. IV bag hook rack

3. Empty Cartridge/ Fluid Warming Rate Module (Model WRM25)

4. Power cord holder

5. Test procedure label

6. Pneumatic connection

7. Control console interface plug

8. 4 inch casters

9. Locking lever
10. Indicator lights with audible signal

a. Fluid temperature

b. Heating

c. Install cartridge

d. Close cover

e. Secure latch

f. Fault

g. Audible tone

11. Spill cup
12. Heating chamber cover

13. Heating chamber latch

14. Latch handle

15. Inlet tubing guide

16. Inlet tubing retainer

17. Outlet tubing guide

18. Outlet tubing retainer

19. Heating chamber shelf

20. Temperature transducers

21. Warning label

22. ThermoStat™900 cartridge
23. Power switch

24. Air inlet filter guard

25. Air inlet filter

26. Manufacturing label

27. Warning label

28. Power cord

29. Circuit breaker reset button

30. Air exhaust vent
PARTS AND INDICATORS DESCRIPTION

IV POLE

1. IV pole extension control knob - Used to raise and lower the height of the IV pole.
2. IV bag hook rack - IV bags and bottles can be held on this rack.
3. Empty Cartridge and Fluid Warming Rate Module - Displays Light and audible when cartridge is empty (~ 2 ml air). Shows Fluid Warming Rate from 25-700 ml/min (see Operator’s Manual for WRM25).
4. Power cord holder - “J” shaped extension used to hold the power cord when not in use.

BASE COVER

5. Test procedure label
6. Pneumatic connection - can be attached to pneumatic air line and pressure infusor if desired.
7. Control console interface plug - this is not a user serviceable part. Disconnections should be referred to a Paladin Biomedical Corporation authorized service representative.

WHEELS

8. 4 inch casters - allows adequate clearance for most portable IV poles to roll underneath the base during device operation.
9. Locking lever - (front wheels only) - depressing lever downward locks wheel preventing it from rolling or swiveling. Wheel is unlocked by lifting lever up (or depressing back of lever) allowing wheel to roll and swivel.

CONTROL CONSOLE

10. Light indicators, audible signal
   a. Fluid temperature - red 2-digit display with 1C (1.8F) resolution, which shows fluid temperature at the outlet port of the heating chamber when the device is operating. NOTE: This display is also used to display a fault code ranging from 00 to 99 in conjunction with the FAULT indicator light for a Device Malfunction event.
   b. Heating - green indicator is on or flickering when device is warming.
   c. Install cartridge - amber indicator is on when cartridge is absent or improperly installed.
   d. Close cover - amber indicator is on when cartridge is properly installed and cover is open.
PARTS AND INDICATORS DESCRIPTION

CONTROL CONSOLE (CONTINUED)

10. Light indicators, audible signal (continued)
   e. Secure latch - amber indicator is on when cartridge is properly installed, cover is closed and latch is not secure.
   f. Fault - red indicator alarm lights when there is failure within the warmer. Fluid warming will not take place.
   g. Audible tone - tone sounds during self-test, when latch is released during warming and when the fault indicator is on.

11. Heating chamber spill cup - the plastic funnel whose upper edge rest on the inner edge of the heating chamber shelf and protects the heating chamber from foreign material.

12. Heating chamber cover - opens for installation of ThermoStat™900 cartridge. The cover secures cartridge placement when closed and must be secured with the latch for the device to operate.

13. Heating chamber latch - secures the heating chamber cover for operation of the device.

14. Latch handle - used to secure or release the heating chamber cover latch.

15. Inlet tubing guide - channel that maintains position of cartridge tubing prior to entry into the heating chamber.

16. Inlet tubing retainer - "U" shaped projection of the inlet tubing guide that holds the cartridge tubing in position.

17. Outlet tubing guide - Channel that maintains position of cartridge tubing after it exits the heating chamber.

18. Outlet tubing retainer - "U" shaped projection of the outlet tubing guide that holds the cartridge tubing in position.

19. Heating chamber shelf - The recessed ledge between the tubing guides that supports the metal portion of the administration cartridge.

20. Temperature transducers - The rectangular white areas located along the tubing path.

21. Warning label
SYSTEM OPERATION: Instructions for Use of the ThermoStat™900

1. EXAMINE DEVICE FOR DAMAGE

Perform a visual examination of the ThermoStat™900 for any signs of physical damage. WARNING: If you observe or suspect that the warmer has been damaged, do not attempt to use the ThermoStat™900 device. Contact a Paladin Biomedical Corporation authorized service representative.

2. CONNECTION TO AC POWER

Plug the AC power cable of the ThermoStat™900 into a grounded wall receptacle with dedicated 20 ampere service.

⚠️ WARNING: Ground reliability can only be achieved by connection to a hospital Grade receptacle.

3. DEPRESS POWER SWITCH

Turn on the power to the device by depressing the power switch. The switch will illuminate to indicate the on condition. Self-test will begin immediately and consists of the following: The Fluid Temperature Display will count down from 99 to 00. All indicators on the display panel will blink three times with a short audible tone corresponding to each blink. Successful completion of the self-test is indicated by a display of the Install Cartridge Indicator. All other indicators will be off.

⚠️ WARNING: If you do not hear these indicators, or if the Fault indicator should come on, and/or the audible tone sounds continuously during this or any other of the following steps, turn the Power Switch off and remove the Cartridge from the heating chamber. Do not attempt to use the ThermoStat™900 device. Contact a Paladin Biomedical Corporation authorized service representative.

During the Self Test observe that the WRM25 Module successfully completes its testing sequence as follows:

WRM25 Module Panel:

Four (4) of the 30 individual indicator elements that are evenly distributed on the display panel will illuminate initially for approximately 2 seconds, then each of the thirty (30) display elements will illuminate individually from top to bottom followed by 3 flashes of all 30 display elements together with the “Empty Cartridge” and “Ready” Indicators in synchrony with 3 audible tones. The “Ready” (green) indicator light will then remain continuously illuminated.

Refer to the separate Operator’s Manual for proper operation of the WRM25 Empty Cartridge and Fluid Warming Rate Module.
4. OPEN HEATING CHAMBER COVER

Grasp the handle on the right side of the heating chamber and pull up. Refer to Figure 1. Raise the cover until it rests in the open position. Refer to Figure 2.

CAUTION: Remove any foreign objects from the heating chamber spill cup. Remove any foreign material from the shelf surface which mates with the cartridge. Failure to do so may result in improper warmer operation, damage to the warmer and inadequate fluid warming.

![Figure 1](image1)
![Figure 2](image2)

5. PLACE CARTRIDGE ON SHELF IN THE HEATING CHAMBER

Position the cartridge so that they key on the right side of the cartridge mates with the notch on the right side of the shelf. Press down firmly and the cartridge will snap into place. Correct position is confirmed when the installed cartridge indicator disappears and the close cover indicator illuminates. Refer to Figure 3.

![Figure 3](image3)

CAUTION: If you are unable to install the cartridge easily, check the heating chamber spill cup for the presence of foreign objects. If no foreign objects are visible, and you still cannot easily install cartridge, do not attempt to use the ThermoStat™900 device. Contact a Paladin Biomedical Corporation authorized representative.

6. SECURE CARTRIDGE TUBING

Place the tubing from the inlet port of the cartridge into the upper tubing guide and press into place. Push the tubing firmly into the "U" shaped tubing retainer at the upper edge of the tubing guide. Refer to Figure 4a.

![Figure 4a]

**WARNING:** All air must be removed from the fluid lines and IV bag prior to connection to the patient. Failure to do so could result in the introduction of air to the patient. Monitor fluid lines to ensure that they are free of air. When changing IV bags or while infusing liquids, the drip chambers and filter vent **MUST REMAIN UPRIGHT.** Laying them flat could allow air to enter the patient line causing serious injury or death. Follow instructions which accompany ThermoStat™900 cartridge and/or administration set.

Place the tubing from the outlet port of the cartridge into the lower tubing guide and press into place. Push the tubing firmly into the "U" shaped tubing retainer at the lower edge of the tubing guide. Refer to Figure 4b.

![Figure 4b]

**CAUTION:** Failure to ensure that the inlet and outlet tubing is properly positioned in the tubing guides and retainers may lead to damage to the tubing, possible warmer malfunction and inadequate fluid warming.
SYSTEM OPERATION: Instructions for Use of the ThermoStat™900

7. CLOSE CHAMBER COVER

With the latch handle in the open position refer to Figure 5. Lower the heating chamber cover. Proper position is confirmed when the close cover indicator disappears and the secure latch indicator appears.

![Figure 5](image)

8. SECURE LATCH

Push the handle down to secure latch. Proper position is confirmed when the secure latch indicator disappears. The Empty Cartridge Indicator Light on the WRM25 Module will flash and an audible will sound until the administration set cartridge has been successfully primed.

9. PRIME THE ADMINISTRATION SET

Use the instructions supplied with the ThermoStat™900 Cartridge and/or Administration Set to prime the tubing and cartridge, using sterile technique.
10. INSPECT FLUID LINES FOR AIR

After priming remove the cartridge from the heating chamber and inspect the cartridge and tubing for air. Replace the cartridge on shelf in heating chamber and repeat steps 5, 6, 7, & 8.

\[\text{WARNING! When changing IV bags or while infusing liquids, the drip chambers and filter vent MUST REMAIN UPRIGHT. Laying them flat could allow air to enter the patient line causing serious injury or death.}\]

11. WATCH AND LISTEN FOR INDICATORS

The heating indicators will come on or flicker and the fluid temperature display will indicate the temperature of the warm fluid.

\[\text{WARNING: If the fault indicator should come on and/or the audible tone sound continuously, turn the main power switch off and remove the cartridge from the heating cavity chamber. Do not attempt to use the ThermoStat™900. Contact your Paladin Biomedical Corporation authorized service representative.}\]

12. MONITOR THE WARMING PROCESS

Monitor the warming process. The heating indicator will be on or flicker while fluid warming is in progress and the fluid temperature display will indicate the temperature of the warm fluid. If the fluid temperature at the outlet port falls below 34°C (93.2°F), the fluid temperature display will blink and the fluid warming will continue.

\[\text{CAUTION: In the event that the heating chamber door is unlatched or open while warming is in progress, the audible tone will sound once and warming will stop.}\]
SYSTEM OPERATION: Discontinue Use

1. OPEN COVER

When warming process is complete, open the heating cavity chamber cover by grasping the latch handle and pulling up.

Raise the cover until it rests in the open position.

The secure latch indicator will come on, then go off as the cover is raised.

The close cover indicator will come on, the heating indicator will go off and the fluid temperature display will go blank.

2. REMOVE CARTRIDGE

Remove the cartridge from the heating chamber by grasping the inlet and outlet tubing beyond the tubing retainers.

Pull upward until the tubing is released from the tubing retainers and the tubing guides.

Continue to pull upward until the cartridge lifts out of the heating chamber.

The install cartridge indicator will come on and the close cover indicator will go off.

3. CLOSE AND LATCH COVER

Lower the heating chamber cover.

When the cover is closed, latch it by pressing the latch handle in toward the heating chamber.

The install cartridge indicator will remain on.

4. TURN THE DEVICE OFF

Depress the power switch.

When the lighted switch is dark, the device is off.

Unplug the power cord from the wall receptacle and wrap the cord on the cord holder.

5. CLEAN THE DEVICE

Clean after every use by the following instructions on page 24 of this manual.
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<th>POSSIBLE CAUSES</th>
<th>ACTION</th>
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| FAULT indicator lights continuously at any time after the initial self-test. OR AUDIBLE STEADY TONE sounds continuously at any time. | Device malfunction | Stop fluid flow to Patient.  
Record the fault code number displayed on the heating chamber fluid temperature display.  
Depress the power switch—the light should go off.  
Remove the cartridge from the heating chamber.  
Take the device out of service and call a Paladin Biomedical Corporation authorized service representative. |
| Fluid temperature shown on temperature display is less than 40°C OR Fluid temperature Indication is Flashing | A very high flow rate, especially with very cold inlet temperature, can lead to an under heating condition. | The physician may choose to lower the flow rate until the outlet temperature returns to an acceptable level.  
OR  
The physician may choose to monitor the amount of fluid administered at less than normothermic temperature.  
**NOTE: The unit will continue to heat fluid and attempt to reach target temperature.** |
| Low Flow Rate                   | The fluid flow is stopped or restricted.     | Open the cover and reposition inlet and outlet tubing, if necessary.  
OR  
Replace the blood filter/vent if it is excessively clotted.  
OR  
Open cricket clamps and roller clamps along the fluid path until desired flow is established.  
OR  
Straighten any bends or kinks along administration line. |
# TROUBLESHOOTING

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<th>PROBLEM/ CONDITION</th>
<th>POSSIBLE CAUSES</th>
<th>ACTION</th>
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<tr>
<td>No temperature display AND No Heating Indicator AND Power Switch is illuminated.</td>
<td>Sequence of internal cartridge, close cover, secure latch not completed.</td>
<td>If install cartridge indicator is on, follow steps 5 thru 11 in the Instructions for Use. OR If the close cover indicator is on, follow steps 8 through 11 in the Instructions for Use. OR If secure latch indicator is on, follow steps 9 through 11 in the Instructions for Use.</td>
</tr>
<tr>
<td>No &quot;Fluid Warming Rate&quot; display AND No &quot;Temperature&quot; indicator AND Power switch is NOT illuminated.</td>
<td>Unit not turned on. OR Circuit breaker is tripped.</td>
<td>Press power switch until illuminated. Reset circuit breaker by pressing reset button at rear of unit. If button can be depressed, check to see that power is on by pressing power switch until it becomes illuminated. Pressing more than twice without illumination indicates problem still remains. Check that the unit is properly plugged into 20 amp 120 volt receptacle.</td>
</tr>
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⚠️ **WARNING:** If the corrective actions above do not correct the problem, do not attempt to use the ThermoStat™900. Contact an Paladin Biomedical Corporation authorized service representative.
CLEANING: Cleaning the ThermoStat™900

The ThermoStat™900 device should be cleaned after every use, and whenever contaminated, consistent with your facilities practices.

**With the Power Cord UNPLUGGED from the outlet:**

1. Apply cleansing solution to all exposed surfaces of the warmer and the power cord.
2. Open the heating chamber cover and remove any contamination from the tubing guides, retainers, cartridge shelf, and inside the heating chamber spill cup.
3. Check underside of the heating chamber and remove any contamination that has passed through the heating chamber spill cup.
4. Remove any foreign objects which have fallen through the heating chamber spill cup or collected in the spill cup cover according to the instructions on page 25.
5. Apply disinfectant and allow for appropriate exposure time of disinfectant according to hospital policy.
6. Replace the heating chamber spill cup if foreign materials cannot be cleaned or removed.
7. Rinse all cleaning and disinfecting solution from the warmer by wiping all surfaces with a clean, soft cloth moistened with tap water.
8. Thoroughly dry the warmer using a clean, soft cloth.

**CAUTION: DO NOT USE SOLVENTS OR ABRASIVE CLEANSERS ON ANY SURFACE OF THE ThermoStat™900.** All finishes on the device (plating, painting, and labeling), are designed to withstand normal usage. Highly caustic solvents and/or abrasive cleaners could damage the device surface if used excessively and with vigorous rubbing. Damage to plating, particularly in the area of the cartridge shelf, will adversely impact device performance.
CLEANING: Removing Foreign Material from the Heating Chamber

CAUTION: The ThermoStat™900 should not be operated with any foreign matter present in the heating chamber spill cup. Failure to observe this caution could result in permanent damage to the device.

The ThermoStat™900 is designed such that any foreign matter that may enter the heating chamber will be contained by the heating chamber spill cup or passed through the spill cup into the spill cup cover on the underside of the heating chamber. Should foreign matter become trapped within the spill cup, the spill cup cover on the underside of the heating chamber can be removed to allow for removal of the foreign materials.

**SPILL CUP COVER REMOVAL:**

1. Loosen the knurled knob located underside of the heating chamber. Do NOT try to completely remove this knob; the knob will stay attached to the spill cup cover.

2. Pull the spill cup cover down until the cover clears the two retaining pins.

3. Remove the foreign matter lodged in the spill cup cover. Remove the heating chamber spill cup and discard in accordance with hospital policy if soiled or contaminated. Do not attempt to clean heating chamber spill cup after removal. **CAUTION:** Damaged or creased foil on heating chamber spill cup can cause system malfunction.

4. Clean the inside of the spill cup cover per the Cleaning Procedure on page 24.

5. Replace the spill cup cover by sliding the cover under the two retaining pins on the underside of the heating chamber. Insert the threads of the knurled knob assembly into the hole in the underside of the heating cavity chamber.

6. Tighten the knurled knob to a snug fit.


**CAUTION:** Unit should not be operated without the spill cup or spill cup cover properly installed.

Spill cups can be obtained by contacting your Paladin Biomedical Corporation Authorized Service Center. See page 4 of this manual for instructions.

CLEANING: Cleaning the Air Inlet Filter

The Air Inlet Filter should be removed and cleaned when ever visibly dirty, or at least every six months, to ensure adequate air flow and proper warmer performance.

PROCEDURE:

1. Carefully unsnap the plastic air inlet filter guard by pulling up and out at the bottom edge.
2. Remove the foam air inlet filter from the device base.
3. Wash the air inlet filter and the air inlet filter guard in warm water with a mild detergent.
4. Thoroughly rinse the air inlet filter and air inlet filter guard with warm tap water.
5. Thoroughly dry the air inlet filter and air inlet filter guard with a clean towel.
6. Thoroughly clean the metal mesh screen found behind the air inlet filter using a vacuum cleaner with a soft bristle brush attachment. If this screen cannot be cleaned adequately by vacuuming, consult your Paladin Biomedical Corporation authorized service representative.
7. Inspect the air inlet filter and the air inlet filter guard for damage. Replace the air inlet filter or the air inlet filter guard if either is damaged.
8. Reinstall the foam air inlet filter over the metal mesh screen.
9. Carefully snap the air inlet filter guard over the filter housing.
10. Check that all four sides of the air inlet filter guard are securely fastened before returning the ThermoStat™900 to service.
MAINTENANCE: Check of the Safety Interlock Switches

CAUTION: If the ThermoStat™900 fails the safety interlock switch test, the device should not be used. Contact a Paladin Biomedical Corporation authorized service representative at 1-888-927-4069.

Safety Interlock Switches:

- The heating chamber shelf contains a switch to sense when the cartridge is installed.
- The heating chamber contains a switch to sense when the cover is closed.
- The heating chamber cover latch contains a switch to sense that the latch is secured.

All three switches must be closed (completed) in order for warming to occur. Opening any one of the switches will cause warming to stop. The proper operation of these switches should be verified every SIX (6) months or when proper performance is questioned, using the following procedure.

PROCEDURE FOR CARTRIDGE INSTALLED SWITCH OPEN:

1. Initial conditions.
   - Warmer attached to AC power source.
   - Power switch on.
   - Self test completed.
   - NO cartridge installed.

2. Close and latch the heating chamber cover.

3. Verify that heating indicator does NOT come on or flicker.

4. Verify that fluid temperature display is blank.

5. Verify that install cartridge indicator is on.
MAINTENANCE: Check of the Safety Interlock Switches

PROCEDURE FOR COVER CLOSED SWITCH OPEN:

1. Initial conditions.
   • Warmer attached to AC power source.
   • Power switch on.
   • Self test completed.
   • Cartridge installed.
2. Run 0.9% room temperature saline through the ThermoStat™900 Administration Set at a rate of 250 milliliters per minute.
3. With saline running, latch the heating chamber handle with the heating chamber cover OPEN.
4. Verify that the heating indicator does not come on or flicker.
5. Verify that the fluid temperature indicator is blank.
6. Verify that the close cover indicator is ON.
7. Verify that NO other indicator is ON.

PROCEDURE FOR LATCH SECURED SWITCH OPEN:

1. Initial conditions.
   • Warmer attached to AC power source.
   • Power switch on.
   • Self test completed.
   • Cartridge installed.
2. Run 0.9% room temperature saline through the ThermoStat™900 Administration Set at a rate of 250 milliliters per minute.
3. Close the heating chamber cover DO NOT secure the heating chamber latch.
4. Verify that the heating indicator is blank.
5. Verify that the fluid temperature indicator is blank.
6. Verify that the secure latch indicator is ON.
7. Verify that NO other indicator is ON.
MAINTENANCE: Check of Fluid Warming Performance

CAUTION: If the ThermoStat™900 fails to meet the requirements of the Fluid Warming Performance test, it should not be used. Contact a Paladin Biomedical Corporation authorized service representative at 1-888-927-4069.

The fluid warming performance should be verified every SIX (6) months or when proper fluid temperature control or operation is questioned. Follow the procedure described below.

PROCEDURE:

1. Cool a one liter bag of 0.9% normal saline solution to 10°C (50°F).
2. Connect the bag to the inlet port of a ThermoStat™900 Cartridge via a standard intravenous administration set.
3. Connect the outlet port of the above cartridge to a thermally insulated collection container appropriate to collect a warm solution volume of at least 1 liter.
4. Prime the administration set and cartridge with a cool solution.
5. Install cartridge.
6. Close and latch the heating chamber cover.
7. Start the solution flowing at a rate of approximately 400 milliliters per minute. Note that the fluid temperature indicator will rapidly rise up to 40°C (104°F).
8. Discard the priming volume from the collection container.
9. Place a calibrated thermometer in the insulated container.
10. Verify that the temperature of the collected fluid is at a normothermic temperature of 35°C to 40°C once a volume of at least 500 milliliters (approximately 75 seconds) is collected with allowance for cooling due to the container/environment and thermometer accuracy.
11. Continue to run the cool solution through the warmer until the supply bag is empty.
12. When the fluid line is empty at the outlet port of the cartridge, verify that the Heating Indicator is not on continuously and that the Empty Cartridge Indicator located on the WRM25 Module illuminates and an audible tone sounds.
13. Verify that no other indicator is on.
MAINTENANCE: Check of Over Temperature Test

WARNING: If the ThermoStat™900 fails to meet the requirements of the Over Temperature test, the device should not be used. Contact a Paladin Biomedical Corporation authorized service representative at 1-888-927-4069.

The proper operation of the Over Temperature controls should be verified every SIX (6) months or whenever there is any question of proper performance. Follow the procedure described below.

PROCEDURE:

1. Warm a bag of 0.9% saline to at least 45°C (113°F) and record the temperature.
2. Connect the bag to the inlet port of the ThermoStat™900 Cartridge via a standard intravenous administration set.
3. Connect the outlet port of the above cartridge to a thermally collection container appropriate to collect a warm solution volume of at least 1 liter.
4. Prime the administration set and cartridge with the warm solution.
5. Install the cartridge.
6. Close and latch the heating chamber cover.
7. Start the solution flowing at a rate approximately 250 milliliters per minute.
8. Verify that the temperature display rises to show the temperature of the inlet fluid.
9. Verify that the temperature display blinks when the temperature is greater than 43°C (107.6°F).
10. Verify that the heating indicator remains off and does not flicker.
11. Measure the temperature of the fluid in the collection chamber and verify that is no greater than the inlet temperature.
12. Fluid Temperatures exceeding 44°C on the outlet temperature sensor will cause an audible alarm.
MAINTENANCE: AC Leakage Current Test

The AC leakage should be checked every SIX (6) months or whenever there is any question of proper performance.

⚠️ WARNING: If the unit fails to meet the requirements of the AC leakage current test, the device should not be used. Contact a Paladin Biomedical Corporation authorized service representative at 1-888-927-4069.

The AC leakage current test should be performed with the main power on and the device operating at its maximum warming rate by the procedure below. This test should only be performed by trained, qualified personnel using the appropriate equipment. Follow the procedure described below.

PROCEDURE:

1. Inspect the AC power cord and plug for signs of wear or damage.
2. Depress the power switch.
3. Cool a one liter bag of 0.9% saline to 10°C (50°F).
4. Connect the bag to the inlet port of the cartridge via standard administration set.
5. Connect the outlet port of the cartridge to a thermally insulated collection container appropriate to collect a warm solution volume of at least one liter.
6. Prime the administration set and cartridge with the cool solution.
7. Start the solution flowing at a rate of approximately 400 milliliters per minute.
8. Verify that the fluid temperature display rapidly rises to 40°C (104°F).
9. Verify that the AC leakage current is less than 100 microamps.
10. If the AC leakage current is greater than 100 microamps, take the device out of service. Contact a Paladin Biomedical Corporation authorized service representative.
<table>
<thead>
<tr>
<th>Operating Principles:</th>
<th>Circuit Breaker:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Closed loop control of in-line microwave warming using non-invasive radiometric sensing</td>
<td>Integral, 17.5 A</td>
</tr>
<tr>
<td><strong>Dimensions:</strong></td>
<td>Electrical Leakage:</td>
</tr>
<tr>
<td>16&quot; x 18&quot; (40.7 cm x 45.8 cm) footprint. 7'7&quot; (231 cm) height, IV Pole fully extended</td>
<td>Less than 100 microamps</td>
</tr>
<tr>
<td><strong>Weight:</strong></td>
<td>Main Power Switch:</td>
</tr>
<tr>
<td>75 pounds (34 kg)</td>
<td>Illuminated push button</td>
</tr>
<tr>
<td><strong>Wheels:</strong></td>
<td>Display Panel Features:</td>
</tr>
<tr>
<td>Four. 4&quot; (10.2 cm), front two lockable</td>
<td>Fluid Temperature (2 digit readout)</td>
</tr>
<tr>
<td><strong>Ambient Operating Temperature:</strong></td>
<td>Heating Indicator</td>
</tr>
<tr>
<td>150°C (60°F) to 350°C (95°F)</td>
<td>Install Cartridge Indicator</td>
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<tr>
<td><strong>Humidity:</strong></td>
<td>Close Cover Indicator</td>
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<tr>
<td>Non-condensing</td>
<td>Secure Latch Indicator</td>
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<td><strong>Ambient Storage Temperature:</strong></td>
<td>Fault Indicator</td>
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<tr>
<td>-18°C (0°F) to 66°C (150°F) non-condensing</td>
<td>Audible Tone Signal</td>
</tr>
<tr>
<td><strong>AC Power Requirements:</strong></td>
<td><strong>Self-Test:</strong></td>
</tr>
<tr>
<td>115-125 (120 nominal) VAC, 16 A, 60 Hz, 3 wire, single phase</td>
<td>Initiated at power-on and checked continuously during device operation</td>
</tr>
<tr>
<td><strong>Cord Plug:</strong></td>
<td>Outlet Fluid Temperature:</td>
</tr>
<tr>
<td>14/3 SJT x 12', low leakage, hospital grade</td>
<td>39-41°C (102.2-105.8°F)</td>
</tr>
<tr>
<td><strong>WRM25 Module:</strong></td>
<td>Maximum Flow Rate:</td>
</tr>
<tr>
<td>Empty Cartridge Indicator</td>
<td>@ 4°C (39.2°F) inlet = 360 ml/min.</td>
</tr>
<tr>
<td>Fluid Warming Rate Indicator</td>
<td>@ 10°C (50.0°F) inlet = 430 ml/min.</td>
</tr>
<tr>
<td>See separate Operator’s Manual</td>
<td>@ 20°C (68.0°F) inlet = 645 ml/min.</td>
</tr>
<tr>
<td></td>
<td>(0.9% Saline, @ 120 VAC nominal)</td>
</tr>
<tr>
<td></td>
<td><strong>37-42°C (98.6-107.6°F) (Packed Red Blood Cells, undiluted PRBC’s, Warmer @ 120 VAC nominal)</strong></td>
</tr>
<tr>
<td></td>
<td>See ThermoStat™900 Administration Set labeling for Maximum Normothermic Fluid Delivery Ranges.</td>
</tr>
</tbody>
</table>

Paladin Biomedical Corporation reserves the right to change specifications without prior notice.

**WARNING:** Modifying the unit in any way could result in impaired performance. DO NOT REMOVE screws, brackets, or covers, OR operate system without the spill cup or the spill cup cover in place.