

Thermal Angel®

Blood and IV Fluid Infusion Warmer



TA-200 Instructions

Package Contents:

The package contains one Thermal Angel TA-200 Blood and IV Fluid Infusion Warmer. The fluid path is sterile and non-pyrogenic in an unopened and undamaged package. Federal law restricts this device to sale by or on the order of a physician.

Indication for Use:

For use when normothermic fluid is indicated.

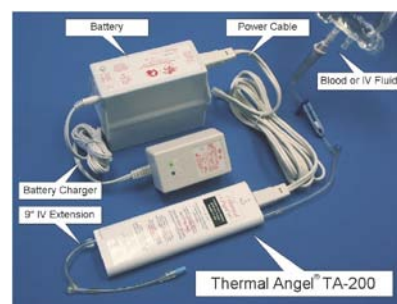
Description:

The Thermal Angel is an in-line, battery-powered disposable, lightweight and completely portable blood and IV fluid infusion warming device, capable of intravenous application and irrigation warming. The Thermal Angel can be used to help prevent fluid-induced hypothermia. The Thermal Angel TA-200 will strive to achieve 38°C (100.4°F) \pm 3°C at a flow rate of 2 to 150 ml/min given a fluid input temperature of 20°C (68°F) with a fully charged TA-BCE Battery.

With changes in flow rate or input fluid temperature, the Thermal Angel TA-200 will require an adjustment period of approximately 15-30 seconds. An internal sensor measures temperature at a rate of approximately 5000 times per second and adjusts power to the heaters accordingly.

Gather the Following:

- Thermal Angel (TA-200)
- 9 inch IV Extension Set (TA-9EXT) or similar
- Battery (TA-BCE)
- Battery Bag (TA-CC)
- Power Cable (TA-CDC)
- Battery Charger (TA-CAC)
- IV Administration Set (end user provided)
- Fluid (end user provided)



Preparation of Battery:

The Thermal Angel TA-200 is powered by a fully charged reusable Battery (TA-BCE). The Battery is charged by the Battery Charger (TA-CAC) which requires 120 Volts AC. When not in use, the Battery should remain connected to the Battery Charger to maintain the optimum charge level.

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Step 1:

- Plug Battery into Battery Charger.
- Plug Battery Charger into AC electrical outlet.
- Allow Battery to charge for 14 hours if fully discharged.

**Step 2:**

- Verify charge status of Battery by pressing red button on Battery.
- Green LED indicates a full charge.
- Yellow LED indicates a moderate charge.
- Red LED indicates an insufficient charge.

**Important:**

The LED indicators on the Battery are designed to display the charge condition when the Battery is not being charged and not being used to power the Thermal Angel. A false indication may be displayed during Battery charging or Thermal Angel operation. Check the charge status of the Battery when disconnected from the Battery Charger and Thermal Angel.

Charging the Battery and powering the Thermal Angel are two separate operations. Do not charge the Battery while the Thermal Angel is in operation.

The Battery should be fully charged prior to first use. The Battery should be recharged after each use. The Battery does not have a memory effect and may be recharged even though it has not been fully discharged.

The Battery has a life expectancy of about 150 charge cycles.

With a fluid input temperature of 20°C (68°F), a fully charged TA-BCE Battery will last through approximately 2 to 4 liters of IV fluid at various flow rates. With a fluid input temperature of 10°C (50°F), a fully charged TA-BCE Battery will last through approximately 1 to 3 units of blood at various flow rates.

Preparation of the Thermal Angel TA-200:

- Visually inspect the Thermal Angel and 9 Inch IV Extension Set to insure there is no damage to the packaging or unit.
- Use aseptic technique to open the Thermal Angel and 9 Inch IV Extension Set.



Step 1:

- Remove the female luer cap from the inlet end of the Thermal Angel.
- Connect IV tubing to the female luer. Tighten until resistance is met. Do not over tighten!



Step 2:

- Remove the male luer cap from the outlet end of the Thermal Angel.
- Connect 9 Inch IV Extension Set to the male luer. Tighten until resistance is met. Do not over tighten!



Step 3:

- Connect assembled IV line to fluid source and prime the line.



Step 4:

- Connect the male end of the Power Cable to the inlet end cap of the Thermal Angel.
- Connect the female end of the Power Cable to the Battery.
- The green LED on the Thermal Angel inlet end cap should display continuous illumination without blinking.



Step 5:

- Connect 9 Inch IV Extension Set to IV catheter.
- Engage roller clamp on IV tubing to adjust flow.



Blood Infusion:

Always use with approved blood administration set. When infusing blood through the Thermal Angel TA-200, follow the instructions provided with the blood administration set. The Thermal Angel TA-200 is intended to function as an extension of the IV tubing. Replace the Thermal Angel TA-200 when replacing the blood administration set. Refer to your facility/organization protocol.

Adverse events should be handled by discontinuing the use of the Thermal Angel TA-200 and immediately notifying the manufacturer or manufacturer's representative.

In circumstances where instructions are unclear about changing the blood administration set, replace the Thermal Angel TA-200 after infusion of two units of blood.

Specifications and Characteristics:

The Thermal Angel TA-200 is a single use item. When necessary, cleaning should consist of wiping the external covering of the unit with a damp cloth. Do not submerge, sterilize or autoclave the Thermal Angel TA-200.

The Thermal Angel TA-200 will strive to achieve 38°C (100.4°F) ±3°C at a flow rate of 2 to 150 ml/min given a fluid input temperature of 20°C (68°F) with a fully charged TA-BCE Battery. This temperature is set by the manufacturer and may not be altered.

With changes in flow rate or input fluid temperature, the Thermal Angel TA-200 will require an adjustment period of approximately 15-30 seconds. The Thermal Angel TA-200 is designed to operate with flow rates of 2 to 150 ml/min. Operation beyond the design specifications will result in lower output temperature.

The Thermal Angel TA-200 is compatible with any existing IV administration set that utilizes standard luer connections.

Incoming fluid temperature must be between 4°C (39.2°F) and 38°C (100.4°F).

The Thermal Angel TA-200 requires a fully charged TA-BCE Battery.

Thermal Angel TA-200 Device Life Expectancy:

The Thermal Angel TA-200 may be left in-line until the IV site or line is changed, up to 72 hours. The Thermal Angel TA-200 will perform for approximately 72 hours of accumulated use while receiving power from multiple fully charged Batteries. After approximately 72 accumulated hours of use, the Thermal Angel TA-200 will continue to operate until power is removed; however, it will not power up again and should be discarded. Dispose of the Thermal Angel TA-200 using biohazard precautions.

If the incoming fluid temperature exceeds 47°C (116.6°F) and the power is connected, the failsafe circuit will be activated. Activation of the failsafe circuit will result in permanent operational termination.

The Battery, Battery Bag, Battery Charger and Power Cable are reusable.

 **Caution!**

Entry into the product housing is not authorized and should not be attempted. Any attempt to gain entry into the internal components of the Thermal Angel will void any warranty claims. Unlawful entry into the product housing can lead to product malfunction.

Use of the Thermal Angel TA-200 inconsistent with its instructions may result in failure of the device.

Discontinue use if the green LED is off or blinking.

Store the Thermal Angel TA-200 at temperatures between 0°C (32°F) and 40°C (104°F). Exceeding these limits may cause the device to malfunction.

Testing has not yet determined maximum shelf life.

The Thermal Angel TA-200 has not been evaluated within the confines of a MRI.

Troubleshooting:

Problem	Cause	Solution
No power or green LED not illuminated on inlet end cap	Power Cable not secure to Battery and/or Thermal Angel	Secure connections
	Inadequate Battery charge	Charge Battery
	Thermal Angel, Battery or Power Cable malfunction	Replace
Blinking green LED on inlet end of cap	Thermal Angel malfunction	Disconnect Power Cable and reconnect. If LED continues to blink, replace Thermal Angel.
	Fluid input temperature too low or too high	Verify fluid input temperature is between 4°C (39.2°F) and 38°C (100.4°F)
No flow	Roller clamp or stopcock closed	Open as desired
	Kink in IV line	Straighten or replace IV line

Warranty Information:

The Thermal Angel TA-200 is warranted to be free from manufacturer defect and is covered for one year from the date of purchase.

Patent:

Assembled by OPTO CIRCUITS INDIA LTD. under U.S. Patent Nos. 6,142,974 & 6,139,528 (other patents pending) for:

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