

Innovative Technology

Thermal Angel® Blood and IV Fluid Infusion Warmer

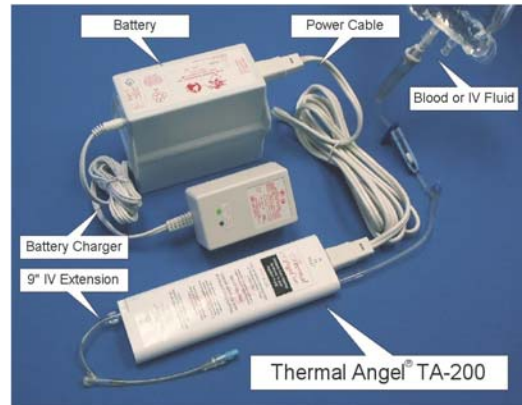


Table of Contents:

Thermal Angel TA-200 Description	2
Thermal Angel Features	2
Smart Disposable	2
Low Mass Heater	3
Temperature Regulation in Fluid Path	3
Warming Near Infusion Site	3
Compatibility	4
Portability	4
Single Disposable for Range of Flow Rates	4
Patients Can Arrive Normothermic Due to Field Use	4
Quick Training	4
Quick Set Up	5
Quick Warm Up	5
Warm Fluid for Multiple Patients Concurrently	5
Disposables and Movement of Patients Between Departments	5
Low Capital Equipment Expenditures and No Contract Requirements	6
No Sterilization Required	6
No Recalibration Required	6
No Service Calls Required	6
Comparison Matrix	8
Normothermic Fluid Delivery Comparison	13
Initial Heating Performance	14
Stop Flow Conditions and Rapid Response	14
Changing Flow Rates and Rapid Response	15

Thermal Angel TA-200 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 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.



Thermal Angel Features

- Lightweight (9 oz), in-line, disposable, portable battery-powered blood and IV fluid infusion warmer
- 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
- Quick setup within 30 seconds, warms in approximately 45 seconds
- Placed at or near the infusion site for minimal heat loss through tubing
- The unit uses standard luer fittings and will accept all standard IV line sets
- Heaters adjust automatically in response to changes in flow rate
- Disposable (single patient use), no cartridges or cleaning
- Serves as a standard of care in the pre-hospital, hospital and outpatient markets
- Single point of heated infusion from first contact through the entire continuum of care
- Meets AABB standards for blood warming devices

Smart Disposable

Many other fluid warmers require the use of a separate medical instrument that only accepts a proprietary disposable fluid path, either a custom tubing set or a custom cassette. The Thermal Angel is a smart disposable that combines the required features of a sterile fluid path with the intelligence of an advanced technology medical instrument, thus requiring no custom delivery sets. Inside each Thermal Angel is a calibrated microprocessor that directly controls all heating of the integrated fluid path. This design advantage eliminates clinical setup errors.

The Thermal Angel mechanical design consists of a heat exchanger and integral heater control board, contained within a flame resistant Lexan plastic housing. The fluid path of the heat exchanger is manufactured from passivated 316L medical grade stainless steel tubing, shaped into a serpentine coil within the housing. To complete the heat exchanger, a lightweight heater flex circuit is tightly bonded to the fluid path by a sonic welding process. This design provides a total fluid volume of approximately 9 ml. Standard luer fittings at each end of the tubing allow the Thermal Angel to be matched with all standard IV administration sets and IV extension sets. Two highly accurate temperature sensors are installed into the fluid stream for direct fluid temperature measurement and control, increasing clinical confidence in patient outcomes.

Many other fluid warmers heat either plastic tubing sets or plastic cassettes using circulating water baths or warming plates, respectively. Any heat intended for the infused fluid must first be propagated through the walls of these plastic fluid paths. After this delay, the heat can then begin warming the infusate. Unfortunately, medical device plastics have an extremely low ability to transmit heat as defined by their respective thermal conductivity (between 0.12 and 0.42 W/m °K).¹ Many other fluid warmers must overheat to compensate for the low thermal conductivity of their plastic fluid paths.

¹ ASM Engineered Materials Handbook, Desk Edition, 2002.

Significantly different, the Thermal Angel fluid path is made from medical grade stainless steel with a much higher thermal conductivity (9.42 W/m °K).² This design advantage means the Thermal Angel is able to transmit heat to the infusate substantially better than older style fluid warmers. Better heat transfer means faster initial warming and faster response to changing flow conditions. Notably safer in a clinical regard, the Thermal Angel does not overheat to obtain normothermic infusate.

Low Mass Heater

The Thermal Angel was designed to have fluid path heaters with little mass, to minimize the temperature impact in a stop flow condition. In many other fluid warming products, the heater mass consists of either large area hot warming plates or large volume hot circulating water. If the infusate is stopped, any residual heat contained in the heater mass continues to be transferred to the infusate. This residual heat transfer may cause a spike in the infusate temperature. On the other hand, the Thermal Angel heater mass is extremely small (0.25 oz). In a stop flow condition, the Thermal Angel heater mass does not contribute to infusate temperature since there is insignificant thermal energy stored in such a small mass. The lightweight flex heater circuits used exclusively in the Thermal Angel are able to attain normothermic infusate because the stainless steel fluid path has such a high thermal conductivity. This design choice ensures clinical safety by avoiding any source of stored excess residual heat.

Temperature Regulation in Fluid Path

The Thermal Angel electrical design consists of a microprocessor-based temperature controller circuit and an independent analog temperature failsafe circuit, located on the heater control board. In turn, the heater control board is mated to the heater flex circuit bonded to the fluid path. The first primary function of the processor is to sample the fluid temperature, via two high accuracy temperature sensors that are directly embedded into the stainless steel fluid path. The second primary function of the processor is to adjust the heater power to maintain an output temperature of 38°C, via calibrated control software capable of responding to all clinical conditions. The microprocessor is an 8-bit device running at 8 MHz, to enable fast sampling of temperatures and efficient execution of Thermal Angel system control software. In addition to the control function, the microprocessor also performs continuous integrity tests of the temperature sensors and the heater flex circuits. The green status LED is included to provide the user with a simple indication of operational status. The analog failsafe circuit is completely independent from the microprocessor based control circuitry, adding another level of clinical safety.

With one sensor located in the fluid path near the output luer, the Thermal Angel directly measures the temperature of the fluid delivered to the patient. Based on this actual temperature, the control software then modifies the output of the heater flex circuit nearly 5000 times per second to attain normothermic temperature. Many other products indirectly measure the infusate temperature through plastic, water, or warming plates. Uniquely, the fast Thermal Angel direct temperature measurement allows quick and automatic reactions to clinical conditions such as stopped flow, flow rate change, bolus delivery, and change out of IV or blood bag.

Warming Near Infusion Site

The proprietary sets used with many other fluid warmers require the instrument to be placed anywhere from several feet up to 8 feet from the patient. As a smart disposable, the Thermal Angel distance to the patient is limited only by the length of the standard extension set chosen by the user. Using the 9 inch IV Extension Set (TA-9EXTNF) sold as an accessory, the Thermal Angel can be placed very close to the infusion site, in contrast to many other fluid warming devices. This design choice allows for the least amount of ambient cooling of normothermic fluids among all fluid warmers.

² ASM Engineering Properties of Steel, 1982.

Compatibility

The Thermal Angel was designed to be compatible with any standard IV or blood administration/extension set. For customer convenience, a 9 Inch IV Extension Set (TA-9EXTNF) is sold as an accessory to the Thermal Angel. However, standard luer connections at the proximal and distal ends allow universal use of the Thermal Angel in any clinical setting. Unlike many other fluid warmers, the Thermal Angel requires neither proprietary tubing sets nor proprietary cassettes. In addition, the Thermal Angel was designed to be compatible with any clinical infusion pump, up to the maximum flow rate specification of 150 ml/min.

Portability

Due to their size and AC power requirement, many other fluid warming devices are clearly not intended as portable fluid warming solutions.

Uniquely, the Thermal Angel allows for a continuum of care with no interruption of the infusion of warm blood or intravenous fluids. The Thermal Angel can be used at first contact with the patient, whether at a trauma scene, in transport to a healthcare facility, or inside a hospital, clinic or surgery center.

Single Disposable for Range of Flow Rates

Unlike many other fluid warmers, the Thermal Angel does not require a different disposable for different flow rates. The smart disposable design makes the Thermal Angel the simplest logistical solution to fluid warming requirements, as only one disposable product needs to be inventoried and tracked within the facility. A wide range of patients, from neonatal to trauma to geriatric to pediatric to surgical, all use the same smart disposable Thermal Angel.

Patients Can Arrive Normothermic Due to Field Use

Historically, there has never been a competing fluid warmer that is capable of working in field environments such as EMS, Flight Service or Military. Because many competing fluid warmers require AC power and a stationary environment, they are useless in the early echelons of care, and thus incapable of helping to proactively preventing hypothermia in the field before evacuation.

As the U.S. Military has discovered, warming fluids in the most forward echelons of care has profound effects on the health of the patients during transport and recovery. Due to its diminutive size and weight, the Thermal Angel can be used at first contact with the patient, either outside of the hospital, or inside. The Thermal Angel can also travel with the patient between vehicles or departments. We find that many hospitals coordinate with the EMS providers to accept patients already receiving the benefit of a Thermal Angel that had been administered at the scene. The hospital simply unhooks the Battery, hooks up their own Battery, and provides a new Thermal Angel unit to the EMS provider in exchange. The patient never stops receiving warm fluids.

Quick Training

Many competing fluid warming products require extensive training by a qualified instructor. Issues include proper set up procedures, calibration procedures, choice of proper disposables for each particular application, an understanding of flow rate limitations, and sterilization. Their complex nature requires cumbersome training to use them effectively.

Because the logistics of training users is so difficult, especially in an austere environment, the Thermal Angel was designed to require minimal training. The 5 Steps are printed on the Thermal Angel label, bag, and instruction insert. Furthermore, there is an instructional video available on the Thermal Angel website which can be viewed in less than 3 minutes. By providing multiple avenues for training, the end user

chooses the approach most appropriate for them and their time schedule. Most hospitals and EMS facilities train themselves on the Thermal Angel and do not require an in-house training session.

Quick Set Up

Studies have shown that competing fluid warmers take critical minutes to set up. Issues include ensuring sterilization of key components, selection of proper disposables given the infusion situation, configuration and setting of switches and knobs, and power up procedures to start the warming process.

Because the Thermal Angel is elegantly simple, there are no knobs, settings or switches. An experienced user can set up the Thermal Angel in a matter of seconds. The U.S. Army Ranger Medics are trained to set up and use the Thermal Angel in complete darkness in less than one minute in battlefield conditions. The Thermal Angel can meet these stringent military specifications.

Quick Warm Up

The Hotline requires 6 to 8 minutes to warm up to proper fluid delivery temperature. Because of this delay, compounded by the long set up time, the Hotline often goes unused due to time constraints.

In comparison, the Thermal Angel is warming within 45 seconds, more than 6 times faster.

Warm Fluid for Multiple Patients Concurrently

Historically, hospitals only purchase a few fluid warming machines to service specific areas of the hospital. If the hospital is constrained in their capital budget and has one or two expensive fluid warmers, the hospital is limited in its ability to concurrently provide warm fluids to multiple patients.

The Thermal Angel was designed to be small, disposable and inexpensive, so that dozens of patients can be receiving warm fluids concurrently at any point in the day. For the same price as a Bair Hugger Ranger fluid warmer that would serve one patient at a time, the hospital could instead buy enough Thermal Angel Battery Sets to service multiple patients concurrently. This paradigm shift allows the hospital to enhance protocols and serve patients like never before, opening up the possibility of warming fluids anywhere inside or outside the walls of the hospital.

Disposables and Movement of Patients Between Departments

Many other fluid warming devices have an initial expense for the warming unit and more charges for the disposables. Extreme scenarios may even add the cost of a clinician to monitor the equipment. When a patient is to receive warm fluids, the hospital must account for the cost of the warming unit and the disposables. If the patient requires continuous warming and is moved between departments, the hospital must also be willing to move the large AC-powered equipment to another room, leaving the disposables attached to the patient and machinery. This causes logistical issues with equipment that has been removed from its primary location. Instead, if the hospital has the budget to purchase multiple warming stations in various departments, they may then be forced to open another disposable after the move, and accept the time constraints of starting up another piece of warming equipment. In either situation, the hospital must incur substantial costs.

Since the Thermal Angel is a portable, battery-powered single patient device, there are no additional costs due to movement. The Thermal Angel stays with the patient throughout the continuum of care to virtually any department the patient visits, untethered by the requirements of AC power. There are no new disposable costs from OR, to Recovery, to ICU, and finally, to the patient room.

Low Capital Equipment Expenditures and No Contract Requirements

Other fluid warmers may require volume commitments by the hospitals in order to offset the expensive capital equipment costs. As has been shown, many of those competing fluid warmers go unused for various reasons, leading to wasted capital tied up in both hardware and disposables.

No Sterilization Required

Some competing fluid warmers such as the Hotline require a labor intensive sterilization procedure. The Hotline uses a water bath for heat transfer, and this bath must be maintained and sterilized. Failure to follow the proper sterilization procedures may have detrimental effects. This is a time consuming task that must be managed and documented, often dissuading the caregiver from using the Hotline fluid warmer.

The Thermal Angel is sterilized by Ethylene Oxide according to ANSI/AAMI/ISO, 11135 and EN 550 Medical Devices—Validation and Routine Control of Ethylene Oxide Sterilization. Additionally, a Limulus Amebocyte Lysate Endotoxin test is performed per USP and FDA Standards. After sterilization, the Thermal Angel is delivered to the end user in a sterile package ready for use. Because the Thermal Angel is a disposable, single patient fluid warmer, it is discarded after use. There are no sterilization procedures required by the user.

No Recalibration Required

Many competing fluid warmers are based on a reusable hardware component that provides the warming technology and temperature management. Because the reusable component is so active, the end user must be concerned with changes in the equipment over time which may necessitate recalibration to remain within specification. This creates an extra cost to use the equipment represented by downtime and labor.

In order to assure that the Thermal Angel performs within the design specifications, each production unit undergoes calibration and performance testing as part of the manufacturing process. The calibration process consists of operating the Thermal Angel while connected to a fluid delivery system. The fluid delivery system is set to deliver water at a flow rate of 50 ml/min and input temperature of 20°C. The temperature of the fluid exiting the unit is measured after a stabilization time of 3 minutes. Adjustments to the output temperature are made electronically by placing the Thermal Angel into a special test mode. After each adjustment, the output temperature is rechecked. The stable output temperature must be $38.0^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ in order to pass calibration. After calibration, three individual performance tests are executed. As with the calibration process, the performance tests also consist of operating the Thermal Angel while connected to the water based fluid delivery system. For the first test, the fluid flow rate is set to 50 ml/min. For the second test, the fluid flow rate is set to 100 ml/min. For the third test, the fluid flow rate is set to 20 ml/min. For all of the tests, the fluid input temperature is set to 20°C. In order to pass each test, the Thermal Angel must maintain an output temperature of $38.0^{\circ}\text{C} \pm 1.5^{\circ}\text{C}$ after a 3 minute stabilization period.

Because of the extensive calibration of every Thermal Angel produced and its disposable nature, the end user will never have to recalibrate the Thermal Angel. It is simply discarded and replaced for the next patient.

No Service Calls Required

Our research has shown that while hospitals may carry some competing fluid warmers, they often go unused because of a repair situation that has never been remedied due to time constraints or capital equipment expenditure issues. One hospital spoke of a \$20,000 capital equipment machine that has gone unused, even though they have a contract for disposables, because they cannot afford to repair the machine. Beyond the actual cost of the repairs, the hospital must also consider the loss of time due to coordination of repairs by hospital technicians. Ultimately, the patients are losing the benefit of warm fluids.

The Thermal Angel was designed as a disposable product to help avoid downtime due to service calls.

If by chance a Thermal Angel is damaged, another inexpensive Thermal Angel is used in its place. There is nothing to repair, no time lost waiting for a service call, and no single point of failure that cannot be replaced within a minute. This feature is extremely beneficial, especially in a fast-paced environment such as an ER, EMS setting or battlefield.

[See Comparison Matrix on next page.]

Comparison Matrix

	Sims Hotline*	Arizant Bair Hugger Ranger**	Thermal Angel TA-200***
Heating Technology	Circulating Water	Warming Plates	Smart Dry Heat
Fluid Path Delivery	<p>Indirect</p> <p>Proprietary tubing connected to circulating water.</p> <p>Promotes significant source of heat loss from water bath to infusion site (8 feet distance).</p> <p>If proprietary tubing is unavailable then warmer can not be utilized.</p>	<p>Indirect</p> <p>Proprietary cassette is placed between warming plates.</p> <p>Promotes significant source of heat loss from warming plates to infusion site (3 feet distance).</p> <p>If proprietary cassette is unavailable or if cassette flow rate capacity is different than required, warmer can not be utilized.</p>	<p>Direct</p> <p>Smart Design: The Thermal Angel combines both the heating technology and fluid path into a single disposable unit.</p> <p>No proprietary tubing.</p> <p>Thermal Angel extension set minimizes heat loss from warmer to infusion site (9 inches).</p> <p>Thermal Angel may be utilized with any IV tubing that has a standard luer fitting.</p>
Measurement and Control of Fluid Temperature	<p>Indirect</p> <p>Temperature sensors are placed within the circulating water. The sensors measure the temperature of the water but fail to measure the temperature of the output fluid.</p> <p>Output fluid temperature is controlled 8 feet from infusion site.</p> <p>Unit must overheat fluid temperature (42°C), recognizing that its fluid path and distance from the infusion site are major factors for heat loss.</p>	<p>Indirect</p> <p>Temperature sensors are placed within the warming plates. The sensors measure the temperature of the warming plates but fail to measure the temperature of the output fluid.</p> <p>Output fluid temperature is controlled 3 feet from infusion site.</p> <p>Unit must overheat fluid temperature (41°C), recognizing that its fluid path and the distance from the infusion site are major factors for heat loss.</p>	<p>Direct</p> <p>Temperature thermistors are placed directly inside the fluid path. The thermistors directly measure the temperature of the output fluid nearly 5000 times per second, and automatically adjust the heaters based on flow rate or input fluid temperature.</p> <p>Output fluid temperature is controlled 9 inches from infusion site.</p> <p>No need to purposely overheat fluid temperature. Direct temperature measurement and ability to warm close to infusion site allows the Thermal Angel to minimize common heat loss factors.</p>

	Sims Hotline*	Arizant Bair Hugger Ranger**	Thermal Angel TA-200***
Ability to Handle Flow Rate Variations (Mass of Heater Technology)	<p>Slow response to variations in flow rates. Significant mass is present in water bath.</p> <p>Stop flow situation: Sudden decrease in flow rate means additional heat is absorbed into the fluid path. Unit must regulate temperature spike by waiting for heat to dissipate through ambient surroundings.</p> <p>Low to high flow situation: Sudden increase in flow rate requires that additional heat must be generated through large mass of circulating water. Fluid output temperature is not normothermic until these drastic changes have stabilized and been transferred to the fluid.</p>	<p>Slow response to variations in flow rates. Significant mass is present in warming plates.</p> <p>Stop flow situation: Sudden decrease in flow rate means additional heat is absorbed into the fluid path. Unit must regulate temperature spike by waiting for warming plates to dissipate heat through ambient surroundings.</p> <p>Low to high flow situation: Sudden increase in flow rate requires that additional heat must be generated through large mass of metal warming plates. Fluid output temperature is not normothermic until these drastic changes have stabilized and been transferred to the fluid.</p>	<p>Thermal Angel responds quickly to variations in flow rates. Minimal mass is present in the flex heaters.</p> <p>Stop flow situation: Heaters immediately shut off under stop flow conditions. The Thermal Angel was designed with minimal mass in the heating technology to help avoid adding extra heat into the fluid path in a stop flow. The Thermal Angel directly regulates the fluid output temperature nearly 5000 times per second and can adjust to significant changes in flow rates because of the minimal mass.</p> <p>Low to high flow rates: Heaters immediately increase temperature upon increased flow rates. The Thermal Angel heat flex circuit is tightly bonded to the fluid path via a sonic weld process, ensuring a rapid warm up for any flow rate adjustment. The unit checks its output temperature nearly 5000 times per second and can adjust to significant changes in flow rates by directly affecting the heat applied to the small mass of the heater technology, resulting in very rapid changes to the controlled output fluid temperature.</p>
Portable	<p>No</p> <p>Constrained to AC power outlet. One more piece of equipment to add into limited power plug space.</p>	<p>No</p> <p>Constrained to AC power outlet. One more piece of equipment to add into limited power plug space</p>	<p>Yes</p> <p>Its small size (9 inches) and weight (9 ounces) allows warm fluids to be infused in locations, departments and environments never serviced before.</p>

	Sims Hotline*	Arizant Bair Hugger Ranger**	Thermal Angel TA-200***
Portable (Cont.)	<p>Constrained to IV pole mount.</p> <p>Bulky size reduces available work area.</p> <p>Physically adds additional barrier between caregiver and patient.</p>	<p>Constrained to IV pole mount.</p> <p>Bulky size reduces available work area.</p> <p>Physically adds additional barrier between caregiver and patient.</p>	<p>Not constrained to IV pole mount.</p> <p>No AC power constraint. No more fighting over limited plug space.</p> <p>Small size and weight ensures minimal obstruction between caregiver and patient.</p>
Power Requirement	AC Power	AC Power	Rechargeable Battery
Weight	11 lbs.	8 lbs.	9 oz.
Size	Mounted to standard 6 ft. IV Pole	Mounted to standard 6 ft. IV Pole	9 inches
Flow Rate	1-83 ml/min	KVO-150 ml/min (standard flow cassette) 150-500 ml/min (high flow cassette)	2-150 ml/min
Calibration Required	<p>Yes</p> <p>Annual calibration of fluid tank, electronics and sensors is required.</p> <p>Calibration equipment must be purchased from manufacturer at additional cost.</p> <p>Requires Biomedical technician to perform calibration.</p>	<p>Yes</p> <p>Annual calibration of warming plates and sensors is required.</p> <p>Single use calibration cassette must be purchased at additional cost.</p> <p>Requires Biomedical technician to perform calibration.</p>	<p>No</p> <p>At the factory, every Thermal Angel undergoes a three stage calibration process involving actual fluid administration at various flow rates.</p> <p>Calibration and flow rate testing procedures must achieve and maintain manufacturing specifications before the unit is released for sterilization.</p> <p>Since the Thermal Angel is disposable, it is discarded after single patient use, negating any need for further calibration.</p>
Maintenance Required	<p>Yes</p> <p>Daily maintenance check for contamination of water supply and external connections.</p> <p>Quarterly sterilization.</p>	<p>Yes</p> <p>Daily maintenance check for build up on plates.</p> <p>Daily external cleaning of unit connections.</p> <p>Monthly sterilization.</p>	<p>No</p> <p>No maintenance.</p> <p>No cleaning.</p> <p>Discard after each use.</p>

	Sims Hotline*	Arizant Bair Hugger Ranger**	Thermal Angel TA-200***
Training Procedures	<p>Unintuitive Design.</p> <p>Must learn pre-operational procedures.</p> <p>Must learn operational procedures.</p> <p>Must learn post-operational procedures.</p> <p>Must learn calibration procedures.</p> <p>Must learn sterilization procedures.</p> <p>Must learn maintenance procedures.</p> <p>Difficult to find reference material for each of the training procedures.</p>	<p>Unintuitive Design.</p> <p>Must learn pre-operational procedures.</p> <p>Must learn operational procedures.</p> <p>Must learn post-operational procedures.</p> <p>Must learn calibration procedures.</p> <p>Must learn sterilization procedures.</p> <p>Must learn maintenance procedures.</p> <p>Difficult to find reference material for each of the training procedures.</p>	<p>Intuitive Design.</p> <p>No pre-operational procedures.</p> <p>5 quick operational steps.</p> <p>No post-operational procedures.</p> <p>No calibration procedures.</p> <p>No sterilization procedures.</p> <p>No maintenance procedures.</p> <p>Easy to understand instructions printed on label, packaging and insert; available for web download.</p> <p>One-line Video based training manual.</p>
Set Up Time	2-4 minutes	2-4 minutes	30 seconds
Warm Up Time	6-8 minutes	2-3 minutes	45 seconds
Priming Volume	20 ml	<p>44 ml (standard flow cassette)</p> <p>90 ml (high flow cassette)</p>	9 ml
Mounting Options	<p>IV pole</p> <p>Must be near power outlet.</p>	<p>IV pole</p> <p>Must be near power outlet.</p>	<p>Thermal Angel can double as an arm board near the infusion site (minimal heat loss) or may be placed away from the infusion site (increases heat loss).</p> <p>Additional attachment options include: IV pole, gurney, wheel chair, supply carrying case.</p> <p>No limits.</p>

	Sims Hotline*	Arizant Bair Hugger Ranger**	Thermal Angel TA-200***
Disposable Cost	The disposable cost will double for each area of care the patient passes through; new disposable tubing must be opened at each location.	The disposable cost doubles for each area of care the patient passes through; new disposable cassette must be opened at each location.	Single disposable travels with patient through entire continuum of care (provides up to 72 hrs of normothermic fluid delivery).
Reusable Equipment Cost	The reusable equipment cost will double for each area of care needed to infuse warm fluids; one machine warms one patient at a time.	The reusable equipment cost will double for each area of care needed to infuse warm fluids; one machine warms one patient at a time.	Both the disposable (TA-200) and the reusable equipment (Battery set) travels with patient; The Thermal Angel is the most effective warmer with the highest return on investment (ROI). Hospitals purchase multiple Battery sets in order to provide warm fluids to dozens of patients concurrently, rather than just one.

* Specifications Source: ECRI's "Healthcare Product Comparison System", December 2002; Brochures
** Specifications Source: ECRI's "Healthcare Product Comparison System", December 2002; Brochures
*** Specifications Source: Estill Medical Technologies, June 29, 2004

Normothermic Fluid Delivery Comparison

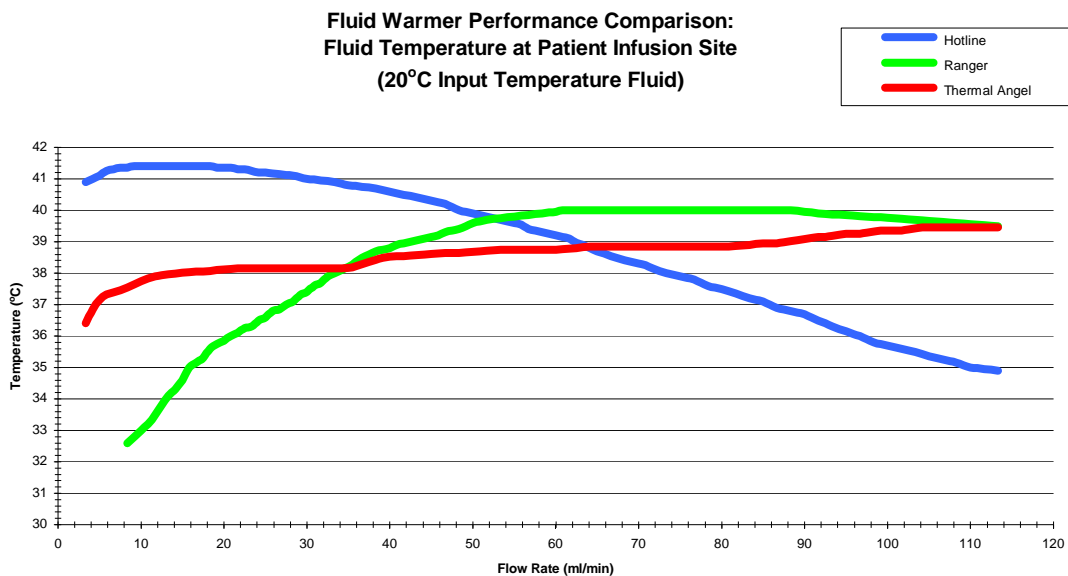
Using data published by the manufacturers of the Hotline and Ranger fluid warming systems, performance is directly compared to the innovative Thermal Angel performance, up to the highest published flow rate for the Hotline.

As illustrated below, the Thermal Angel has the most consistent normothermic performance across these flow rates. The low mass heaters, stainless steel fluid path inside the unit, short fluid delivery path and calibrated smart microprocessor control of the Thermal Angel help to provide a superior normothermic fluid delivery to the patient.

Note that at lower flow rates, the water bath of the Hotline causes unnecessary fluid overheating while the Ranger cassette technology delivers fluid well below normothermic temperatures. At higher flow rates, the water bath of the Hotline likewise causes low temperature fluid delivery. These inadequate output temperatures are the result of the technology involved in these older designs.

The Thermal Angel contains innovative technology that can deliver fluid close to the 38°C normothermic temperature across this range of flow rates.

Furthermore, these temperatures are measured at the patient infusion site, and do not accurately represent the true temperature of the fluid inside the Hotline or Ranger before it travels down the long fluid delivery path. Therefore, the temperature of the fluid inside the Hotline and Ranger is higher than shown below. Conversely, the Thermal Angel's fluid delivery path is only 9 inches (TA-9EXTNF), so the true temperature of the fluid inside the Thermal Angel is extremely close to the output temperature, thus not overheating the fluid to compensate for long tubing distance to the patient.



Data Sources:

Hotline Marketing Literature, Chart Title "HOTLINE Fluid and Blood Warmer Infusate Delivery Temperature" [42 degree Celsius HOTLINE Water Bath Temperature – measured at the patient end of the 2.4 m (8 ft.) L-70 disposable tubing set], Level 1, Inc. (Smiths Medical).

Ranger Marketing Literature, Chart Title "Ranger System Performance" [Fluid temperature at end of patient line], Augustine Medical, Inc.

Thermal Angel Test Data, Fluid temperature at patient end of standard 9" extension line (TA-9EXT), Estill Medical Technologies, Inc.

Initial Heating Performance

Unlike many other fluid warming systems, the smart microprocessor control of the Thermal Angel ensures that fluids are not overheated under initial heating or stop flow conditions. Since the Thermal Angel has temperature sensors located directly in the fluid path and is checked 5000 times per second, the microprocessor is able to make extremely quick and accurate decisions regarding fluid temperature control.

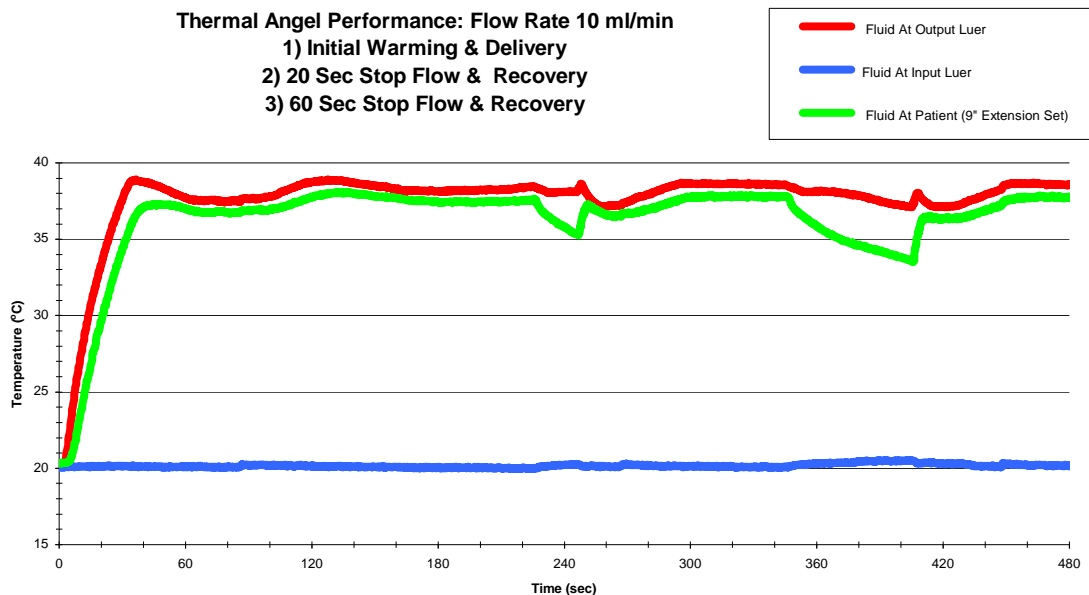
As illustrated below, the Thermal Angel's innovative technology provides conservative control of fluid temperatures during initial fluid warming. Within the nominal 45 second warm up time, normothermic temperatures have been achieved both for fluids exiting the device and for fluids entering the patient infusion site. As shown, despite the initial rapid temperature rise, the smart microprocessor avoids overheating the fluid by quickly recognizing that normothermic temperature has been achieved and responding appropriately.

Stop Flow Conditions and Rapid Response

The Thermal Angel's innovative heater and control technology ensures quick and accurate control of fluid temperature under stop flow conditions.

In the example below, fluid flow was first stopped at approximately 230 seconds for a duration of 20 seconds. Once fluid flow was resumed at the original 10 ml/min flow rate, the volume of fluid contained within the heated fluid path passed through the device. Since the heater mass is so small, there was very little residual heat transferred to the fluid path during this stop flow period. This can be seen in the very small temperature rise of the fluid at the output luer, demonstrating how the Thermal Angel heaters were immediately shut off under stop flow conditions. Also shown below is a longer stop flow scenario that begins at 350 seconds for a duration of one minute. Noteworthy in both stop flow conditions is the lack of any temperature spike for the patient, a conservative clinical result that was designed into the Thermal Angel temperature control system.

Under stop flow conditions, the patient first experiences a brief cooler fluid temperature followed by a quick rise back to normothermic temperature when flow is resumed. The innovative Thermal Angel technology clearly avoids overheating during stop flow conditions.



Changing Flow Rates and Rapid Response

The smart microprocessor control of the Thermal Angel ensures that fluids are never overheated during changes in flow rates. The innovative Thermal Angel technology provides the unique ability to quickly and accurately respond to both increases and decreases in flow rate.

Illustrated in the example below is a Thermal Angel that had already been delivering fluid at a 10 ml/min flow rate when the data collection began.

After approximately 20 seconds into collecting the performance data, the flow was decreased to 5 ml/min. Note the quick response to this slight flow rate change, and the subsequent rapid achievement of stable delivery temperature. Due to ambient cooling of the extension set, the delivery temperature at 5 ml/min was slightly lower than that at 10 ml/min.

At approximately 130 seconds, the flow rate was increased back to the original 10 ml/min. Note again the quick response and temperature adjustment.

The flow rate was further increased to 50 ml/min at approximately 240 seconds. Sensing a more drastic downward change in temperature, the control system quickly increased the fluid path heating. Within 45 seconds, the patient connected to the Thermal Angel would be experiencing stable normothermic fluid again. Note the only very slight ambient cooling of fluid due to the 9" extension set at 50 ml/min flow rate.

Downward again to 10 ml/min, the flow rate was adjusted at approximately 340 seconds. Even with this 80% reduction in flow rate, the fluid temperature at the patient infusion site varied only slightly until it was quickly stabilized again.

Finally, a further 80% decrease to the minimum specified Thermal Angel flow rate of 2 ml/min was conducted at approximately 440 seconds after data collection began. No overheating is experienced at any change in flow with the Thermal Angel, making this innovative technology a superior clinical choice for fluid warming.

