

High Speed Blood and Fluid Transfusion Equipment

Final Report

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CONTENTS

INTRODUCTION	1
APPLIANCE OVERVIEW	2
Principles of Operation	2
APPLIANCE DESIGN	6
Component Information	6
Sorber	6
Air Coil	7
Liquid-Vapor Separator	7
Electrical Components	6
Single-Patient Cartridge	7
Miscellaneous Components	9
OPERATION	10
Preheat and Wait	10
Active Control Mode	10
PERFORMANCE	11
Fluid Warmer Equipment Optimization and Refinement Testing	11
Comparison to Existing Military Devices	16
Total Volume Threshold	20
Flow Rate Analysis and Optimization	21
REFERENCES	22

APPENDICES

APPENDIX A OPERATING INSTRUCTIONS	A1
APPENDIX B ADDITIONAL TEST RESULTS	B1

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INTRODUCTION

Hypothermia occurs as the core temperature decreases below 35 °C. Many patients become hypothermic after severe injury due to environmental exposure during transportation, infusion of cold fluids, and decreased ability to maintain normal core body temperature (37 °C). Patients with severe trauma die because of hypothermia, metabolic acidosis and coagulopathy, this phenomenon is known as the lethal triangle (Beekley et al and Gill et al.). Studies have shown the outcome of trauma patients with hypothermia are far worse than those with either trauma or hypothermia alone. It has also been shown resuscitation requirements are increased with trauma patients who become hypothermic (Jurkovich et al and Mizushima et al.). Internal warming has been considered the most effective for rewarming severely hypothermic patients which involve infusion of warm fluids. In combat settings, a fluid warmer with portability and minimal power requirement capabilities would greatly improve the treatment of injured who are in need of fluid replacement and return core body temperature as quickly as possible to normal and prevent further complications associated with hypothermia.

The University of Nevada School of Medicine (UNSOM) and Rocky Research have developed a new temperature conditioning blood and fluid infusion/transfusion technology which can be operated with electrical power, but incorporates high power density thermal battery technology to allow for rapid fluid heating without any electric energy demand. This will allow for fast blood infusion and transfusion during electric power loss periods as well as in battle field locations without access to electrical power and will thereby dramatically increase the response capability of medical personnel in the battlefield. The thermal battery technology was based on a sorption process that can be charged intermittently and used completely independent of electric power. The same electrical heater also provides energy for heating infusion fluid when the appliance was connected to external electrical power.

UNSOM and Rocky Research have successfully completed their efforts under Task 4 as outlined in the original application. Task 4 involved refinement and optimization of an engineering prototype. The proof-of-concept laboratory prototype was designed and built. It has undergone extensive performance testing and critical analysis to enable later engineering prototype refinement and optimization. The final refinement and optimization of portable infusion fluid warmer for FDA approval will occur under a new contract.

The plan for demonstrating operational effectiveness was completed with three fluid warmers and several single patient cartridges (SPC) being built during the development effort. A matrix of applicable test conditions was created to test multiple conditions simulating real world implementation. Test results have demonstrated that the fluid warmers are able to control temperature at an acceptable degree over a range of conditions while having an acceptable flow rate. The portable infusion fluid warmer was tested under a variety of clinically relevant and technically challenging simulations to confirm applicable performance achievements.

The purpose of this project was to develop an appliance to heat infusion fluid that:

1. Supports infusion rates up to 500 ml/min,
2. Can operate indefinitely when attached to an external power source, and
3. Can also operate for a limited time without any external source of energy.

Without external power, up to two units (500 ml each) of fluid can be heated. Design heating rate for the first unit is up to 500 ml/min, with lower rates acceptable for the second unit.

The objective of Task 4 in the original application was to design, fabricate and test field-ready prototypes that can be used in field test experiments. The task culminated with three operational prototypes and several prototypes of the cartridges that contact infusion fluid. These cartridges can be reused during system development, but for human use each cartridge is intended only for use with a single patient.

This report provides an overview of the appliance design and operational philosophy, details of actual design, and appliance performance testing. Operating instructions are included in an appendix.

APPLIANCE OVERVIEW

The infusion fluid warmer is a fully portable appliance that can be operated remotely from electrical power and can also be operated when connected to an external source of electrical power. Remote non-powered heating of two full units (1000 ml total) of fluid is possible. The amount of fluid that can be heated when attached to external power is unlimited.

Fluids being warmed for infusion into human patients only contact a disposable cartridge. Each cartridge is intended for use only with a single patient. Cartridges are easily installed and removed by slipping them over an aluminum cylinder that serves as the heat source.

Figure 1 comprises photographs showing the appliance, the single-use cartridge, and the cartridge being installed.

Principles of Operation

The distinguishing characteristics of this infusion fluid warmer are (1) that it stores energy for heating fluid when not attached to an external power source, (2) that it provides for high heating and infusion rates, up to 500 ml per minute, and (3) that it is portable.



Single-Patient Cartridge



Cartridge being installed

Figure 1. Rapid infusion warmer appliance.

An absorption reaction is the mechanism used for energy storage. Heat is released for remote operation by an exothermic reaction between an absorbent and an absorbate. The absorbate or working fluid is ammonia, and the absorbent is a metal inorganic salt that covalently bonds with ammonia to form a complex compound. Complex compounds (also known as coordination compounds) are unique absorbents in that the bonding reaction releases a large amount of energy, and several molecules of absorbate are held at the same energy level, meaning a great deal of heat is released at constant temperature.

Absorption of ammonia to form a complex compound is fully reversible. The absorbent is heated to reverse the reaction and remove ammonia vapor from salt. This process is known as desorption.

Hardware for practical application of absorption and desorption of ammonia for heat storage requires few parts. A flow schematic of the ammonia circuit of the appliance is shown in Figure 2. An air coil serves as an ammonia evaporator and condenser, and also stores liquid ammonia. A solenoid valve controls flow of ammonia vapor between the air coil and absorber. A liquid-vapor separator is provided at the air coil outlet to avoid liquid carryover to the absorber. When infusion fluid is being heated, ammonia vapor flows from the evaporator to the absorber. Absorption of ammonia vapor releases heat, and the absorber transfers heat to infusion fluid via a removable cartridge in thermal contact with the absorber.

The appliance is recharged for subsequent cycles of fluid heating by increasing the temperature of the absorber to drive ammonia back to the air coil. Vapor entering the air coil is condensed, and liquid collects in the bottom tubes where it is stored. The absorber is heated using an electrical heater embedded in the core of the absorber. This same electrical heater also provides energy for heating infusion fluid when the appliance is connected to external electrical power.

The air coil is equipped with a fan to facilitate heat transfer with the ambient environment for evaporating and condensing ammonia.

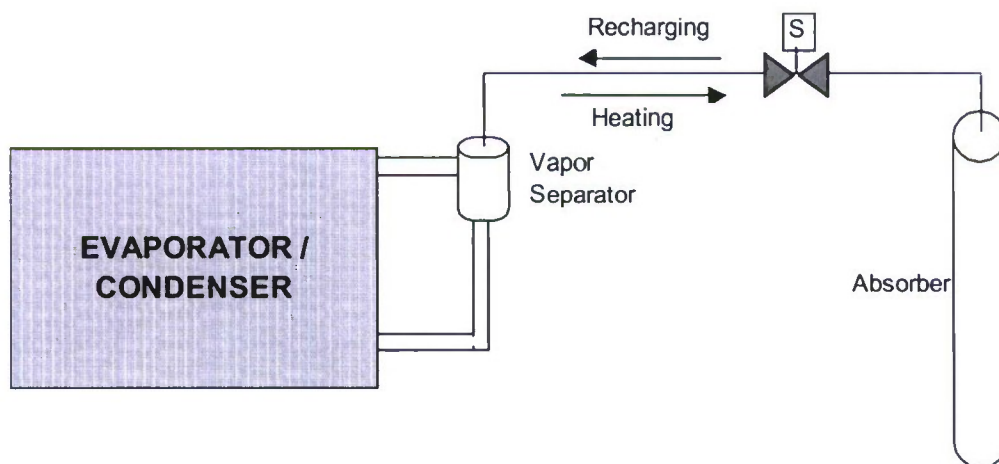


Figure 2. Rapid infusion warmer ammonia flow schematic

Figure 3 is a photograph of the appliance with the front cover removed. Major components, including those corresponding to items shown in the flow schematic, are identified.

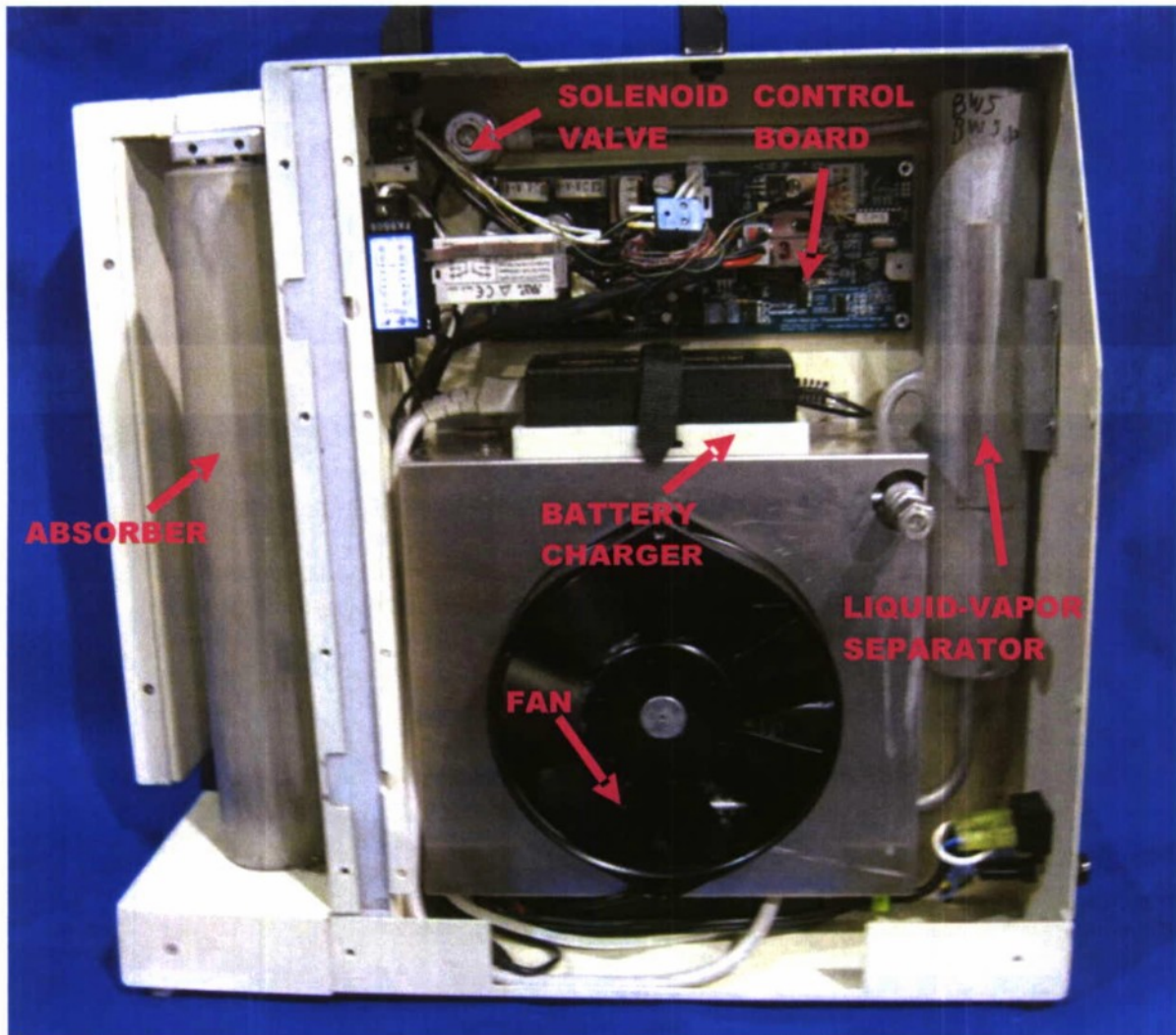


Figure 3. Major Rapid Infusion Warmer Components.

APPLIANCE DESIGN

The rapid infusion warmer (RIW) comprises an ammonia-containing subsystem, sheet metal enclosure, and supporting peripherals such as control board, fan, and battery. The ammonia-containing subsystem consists of an air coil, liquid-vapor separator, solenoid valve, absorber, charge valve, and connecting tubing. Figure 4 shows this assembly.

Component Information

Sorber

The heart of the RIW is the sorber. The sorber internals include impregnated disks with complex-compound forming metal inorganic salt and aluminum fins. They are stacked to give a sorber core length of 12”.

Holes in the fins and disks are provided for both vapor passage and a heater tube. The heater used is a cartridge heater 1/4” OD x 12.65” long. Nominal rated heater power is 648 W at 120 VAC.

The sorber shell is 6061 aluminum with 1.93” inside diameter. The outside of the sorber is tapered. The outside diameter is nominally 2.046” on the small end and 2.18” on the large end. The purpose of the taper on the sorber shell is to provide a simple means of installing a single-patient cartridge for fluid heating, while providing good thermal contact between the cartridge

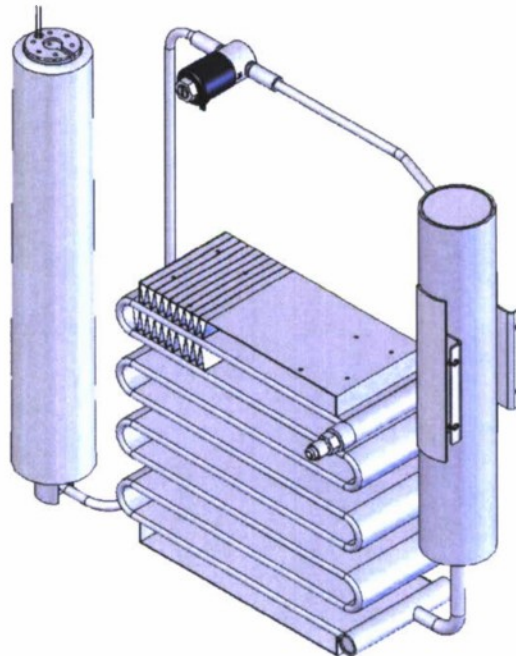


Figure 4. Sealed ammonia-containing subsystem of the Rapid Infusion Warmer

and sorber. The single-patient cartridge has a matching taper and slides over the sorber.

Air coil

The air coil used in the RIW is an automotive air conditioner type evaporator. The evaporator is a brazed aluminum assembly with serpentine multi-port tube and aluminum fins. Overall dimensions are 8.8" x 8.1" x 3.6". Evaporating and condensing rate of ammonia in the RIW maximizes at about 500 W. A coil with large capacity is used to permit close temperature approach to ambient air.

Liquid-vapor separator

A vertical cylindrical vessel is used to provide separation of liquid and vapor during fluid heating when ammonia is rapidly boiling. The reservoir is 2" diameter by 9" tall.

Electrical components

The RIW has AC and DC electrical components. Recharge is performed when the unit is connected to 120 VAC power. The electrical heater in the sorber operates on 120 volts.

The DC circuit is 24 volts nominal. A battery pack provides DC power when the unit is not connected to external power. The battery pack has 7 cells and nominal working voltage of 25.9 volts. Capacity is 2.6 Ah. The battery is used to drive control circuits, power a 24 VDC fan and operate the solenoid valve that controls flow of ammonia vapor. Battery charging is done with a charge controller obtained from the battery supplier. Control components and power supply reside on a custom printed circuit board.

Single-Patient Cartridge

The SPC is the only component of the RIW system that contacts infusion fluid. This cartridge can be used for an extended period of time¹ and for multiple infusions, but will only be used with one patient. Allowed duration of usage of a single cartridge will likely be on the order of a few days. Allowed duration depends on the volume of stagnation areas inside the heat exchanger and time required for hemolysis of human blood cells. Actual allowed duration of use will be determined during certification tests.

The cartridge has an internal taper that matches a taper on the absorber, and is installed by simply slipping it over the sorber. A slot on one side of the cartridge provides clearance for a bracket on the top of the sorber. Figure 5 shows the sorber and heat exchanger. The tapered interface between the sorber and cartridge was chosen because this contacting method resulted in very easy removal and installation of the cartridge, and because it provided the lowest thermal contact resistance between the sorber and cartridge of all the designs investigated.

¹ Allowed duration of usage of a single cartridge will likely be on the order of a few days. Allowed duration depends on the volume of stagnation areas inside the heat exchanger and time required for hemolysis of human blood cells. Actual allowed duration of use will be determined during certification tests.



Figure 5. Tapered cartridge and sorber.

The cartridge assembly has internal temperature sensors. Electrical contact to the appliance for the temperature sensors is made as the cartridge is inserted over the sorber. A plastic cover on one side covers fluid tubes and wires connected to temperature sensors. A connector at the bottom of the plastic cover inserts into a matching connector in the appliance to connect temperature signal wires to the control board.

The cartridge is fabricated from an aluminum extrusion which also forms the passage for fluid flow. A thin aluminum cover and saddles for fluid tube connections are adhesive bonded to the extruded core to complete the assembly. Biocompatible epoxy that is in compliance with ISO 10993 for use in medical appliances is used for assembly.

Miscellaneous components

Other components include sheet metal parts, support brackets, a handle, hinges, and door latches. A time delay relay is used to connect the battery to the charger. The charger requires that 120 VAC power be connected for a finite amount of time before the battery is connected to the charger. This delay function will be included on the control PCB in future systems.

A spring-loaded connector is used for making connections with the removable cartridge for temperature probes. A Schrader valve is used for the charge port. Stainless steel valve cores are used for compatibility with ammonia.

OPERATION

Operating instructions are included in the appendix. The appliance is designed to be as simple to operate as possible. The controller detects presence or absence of a SPC. It detects when fluid flow has started and controls delivery temperature accordingly. Battery charging is automatically performed when the appliance is connected to electrical power.

The controller automatically sequences through two modes of operation when fluid heating is called for, whether the function is heat battery heating or electrical power heating. These modes are (1) preheat and wait, and (2) active control.

Preheat and Wait

Preheat and wait is designed to heat the blood warmer as rapidly as possible. Temperature of the cartridge is used to calculate the amount of energy required to warm the sorber and cartridge to 37°C. This amount of energy is then. In electrical heating mode the heater is turned on full power for the proper period of time to deliver the calculated energy. In heat battery mode, the solenoid valve is pulsed open multiple times to result in the proper amount of absorption heating. The amount of ammonia delivered each pulse is known, as is the absorption energy released by the ammonia. Mass of ammonia delivered per pulse is a function of temperature of the evaporator coil, which is close to ambient temperature. An ambient temperature adjustment is made to the calculated number of pulses.

Warmup could also be accomplished with standard PID control algorithms. PID control, by nature, requires somewhat of a cautious approach to set point temperature. The preheat strategy used enables the appliance to reach operating temperature in the least possible amount of time.

After the preheat energy is delivered to the sorber, the appliance simply waits until start of flow is detected. The user can wait several minutes, if necessary, as long as fluid flow is initiated before the sorber and cartridge have cooled excessively.

Active Control Mode

After preheat, the appliance waits until flow is detected and then PID-type control of the fluid outlet temperature is initiated. Indication of flow start is a sudden rapid drop in temperature of fluid at the inlet port to the cartridge. When fluid is flowing, rate-of-change of various temperatures and integrated deviation from setpoint are input to the control algorithm. The controller then delivers energy to the sorber as required to maintain fluid delivery temperature. The appliance will continue to warm fluid as long as flow continues and the appliance has sufficient power to heat the fluid to the setpoint. The temperature setpoint is nominally 37°C. Delivery temperatures between 35 and 40°C are considered acceptable.

PERFORMANCE

Fluid Warmer Equipment Optimization and Refinement Testing

Three fluid warmers and several single-patient cartridges were built during this development effort. Performance of all three appliances has been measured. Tests on at least one appliance have been made on various operating modes and conditions. Tests are normally conducted with one liter of fluid (water) from an IV bag in a pressure infuser. Test conditions are set by pressure of the infuser and temperature of the fluid to be warmed. Pressures used in the infuser were 300 mm Hg and 150 mm Hg. These pressures, with a standard infusion set with 3 mm inside diameter tubing and a 16 gauge catheter, give nominally 230 and 130 cc/min flow. Flow rate varies with fluid temperature and is not exactly identical for all cartridges. One high-flow test was also conducted with an infusion set having 3/16" (4.8 mm) inside diameter tubing, a 14 gauge catheter, and 300 mm Hg infuser pressure. Average flow for this test condition was 450 cc/min.

A matrix of applicable test conditions is shown in Table I. Except as noted all tests shown in Table I use a standard infusion set and 16 gauge catheter. With three RIW appliances and a test matrix comprising 14 test conditions, the number of tests required to fully prove each prototype becomes prohibitive. In addition, multiple single-patient cartridges were built. Testing various combinations of cartridge and appliance and condition increases the test load. For the effort reported here, all prototypes were tested with cold fluid with 300 mm of infuser pressure, in heat battery mode of operation. Fewer tests were conducted at other conditions. Most of the test effort was devoted to tuning the control algorithm. Each appliance was operated with the final control code in heat battery mode of operation, with cold fluid and 300 mm Hg infuser pressure. One appliance was tested at other conditions, with earlier versions of the code.

Table 1 Rapid Infusion Warmer Test Conditions				
	Heat Source	Infuser Pressure	Fluid Temperature	Ambient Temperature
1	Heat Battery	300 mm Hg	warm (~22°C)	warm (~22°C)
2	Heat Battery	150 mm Hg	warm (~22°C)	warm (~22°C)
3	Heat Battery	300 mm Hg	cold (4 to 7°C)	warm (~22°C)
4	Heat Battery	150 mm Hg	cold (4 to 7°C)	warm (~22°C)
5	Heat Battery	300 mm Hg	cold (4 to 7°C)	cold (~0°C)
6	Heat Battery	150 mm Hg	cold (4 to 7°C)	cold (~0°C)
7	Electricity	300 mm Hg	warm (~22°C)	warm (~22°C)
8	Electricity	150 mm Hg	warm (~22°C)	warm (~22°C)
9	Electricity	300 mm Hg	cold (4 to 7°C)	warm (~22°C)
10	Electricity	150 mm Hg	cold (4 to 7°C)	warm (~22°C)
11	Electricity	300 mm Hg	cold (4 to 7°C)	cold (~0°C)
12	Electricity	150 mm Hg	cold (4 to 7°C)	cold (~0°C)
13	Heat Battery	Large infusion set, 14 gauge catheter, cold fluid, warm ambient		
14	Electricity	Electrical tests are normally done with the heat battery absorbed, that is, in the discharged condition. At least one electrical test is done with the heat battery charged.		

Figure 6 shows fluid temperatures during operation of all three prototypes with cold fluid and 300 mm Hg infuser pressure. Temperatures within the cartridge and sorber begin rising when the preheat mode is activated. With the exception of the test on BW5, preheat is not clearly shown in the graphs. A sharp drop in fluid inlet temperature indicates the start of infusion fluid flow. It is at this point that the controller begins active control of temperature. The rise in all temperatures toward the end of each test occurs when fluid flow is stopped. Each of these tests encompasses one liter of fluid.

With the exception of BW4, the controller was able to maintain fluid supply temperature between 35 and 40°C for the entire test. Temperature of fluid delivered by BW4 slightly exceeded 40°C for approximately 24 seconds.

Results of tests with room-temperature fluid and lower infusion pressure and correspondingly lower flow rates are shown in Figure 7. At these conditions BW4 also slightly exceeded 40 for a short period of time.

Results of electrical heating tests on BW4 are shown in Figure 8. Tests at 300 mm Hg pressure with warm fluid, and 150 mm Hg pressure with warm and cold fluid are shown. The heater power of 600 W is not quite sufficient to heat cold fluid with 300 mm Hg infuser pressure. Temperature control was very good in these tests.

Test results presented in Figures 6, 7, and 8 demonstrate that the fluid warmers are able to control temperature to an acceptable degree over a range of conditions. Test results at other conditions are presented in Appendix B.

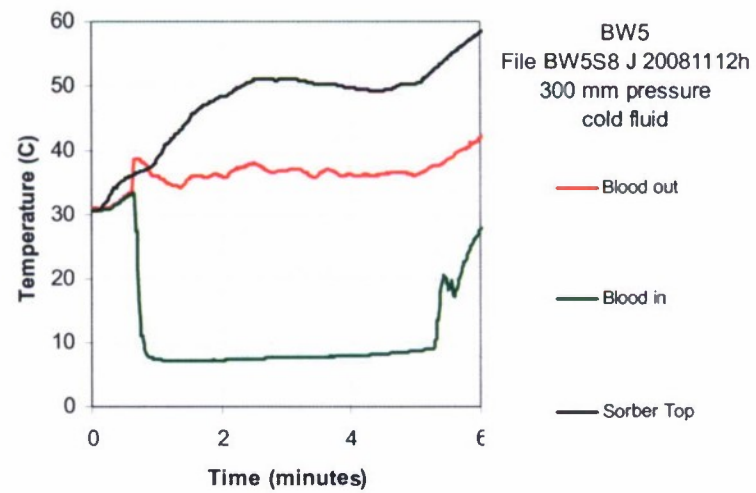
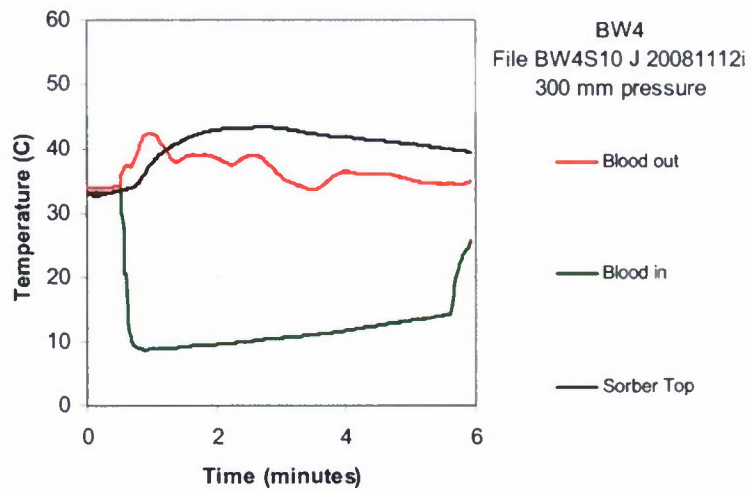
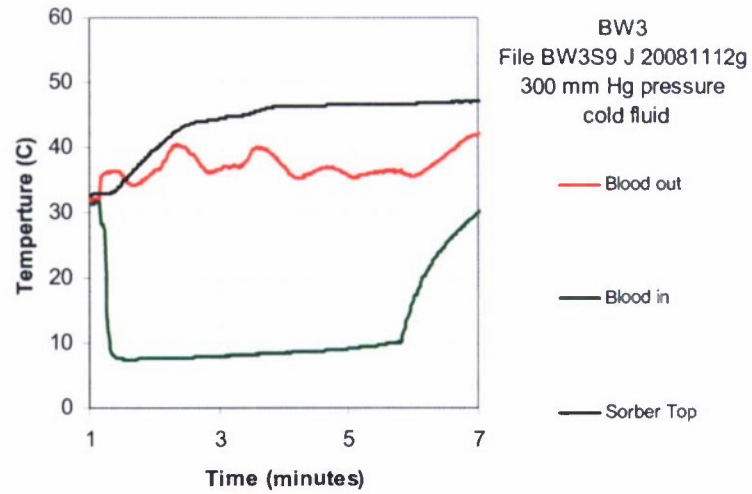


Figure 6. Performance of three prototypes with 300 mm Hg infuser pressure and cold fluid.

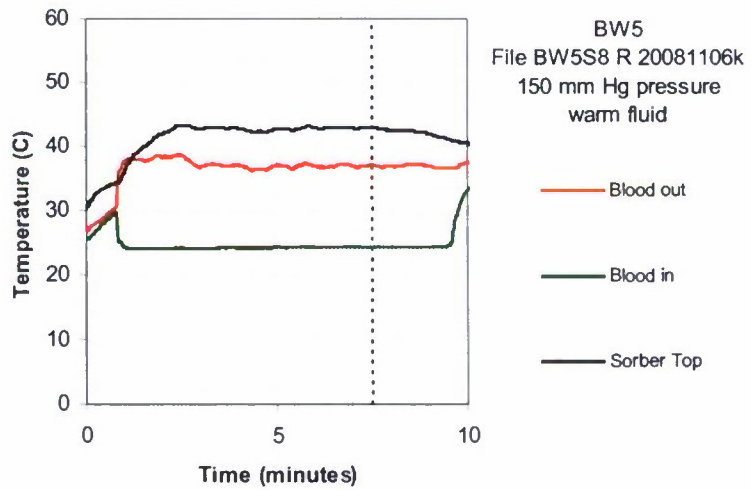
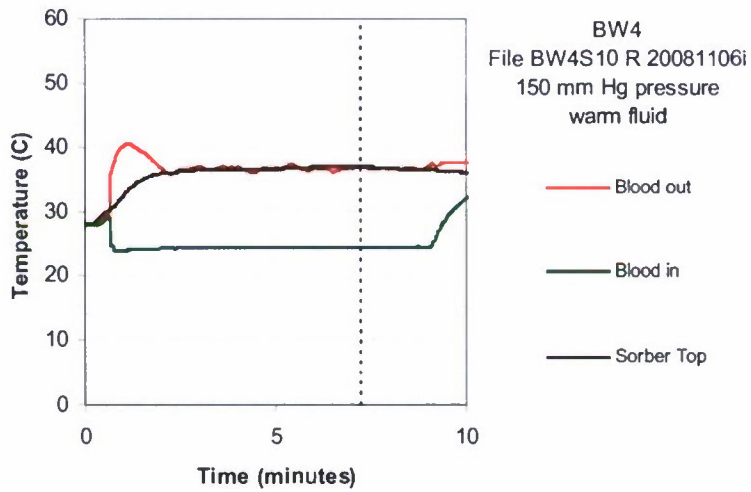
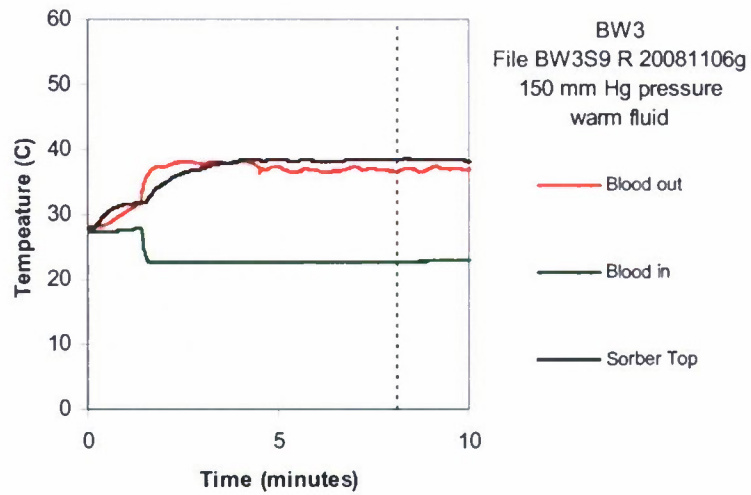


Figure 7. Performance of three prototypes with 150 mm Hg infuser pressure and warm fluid.

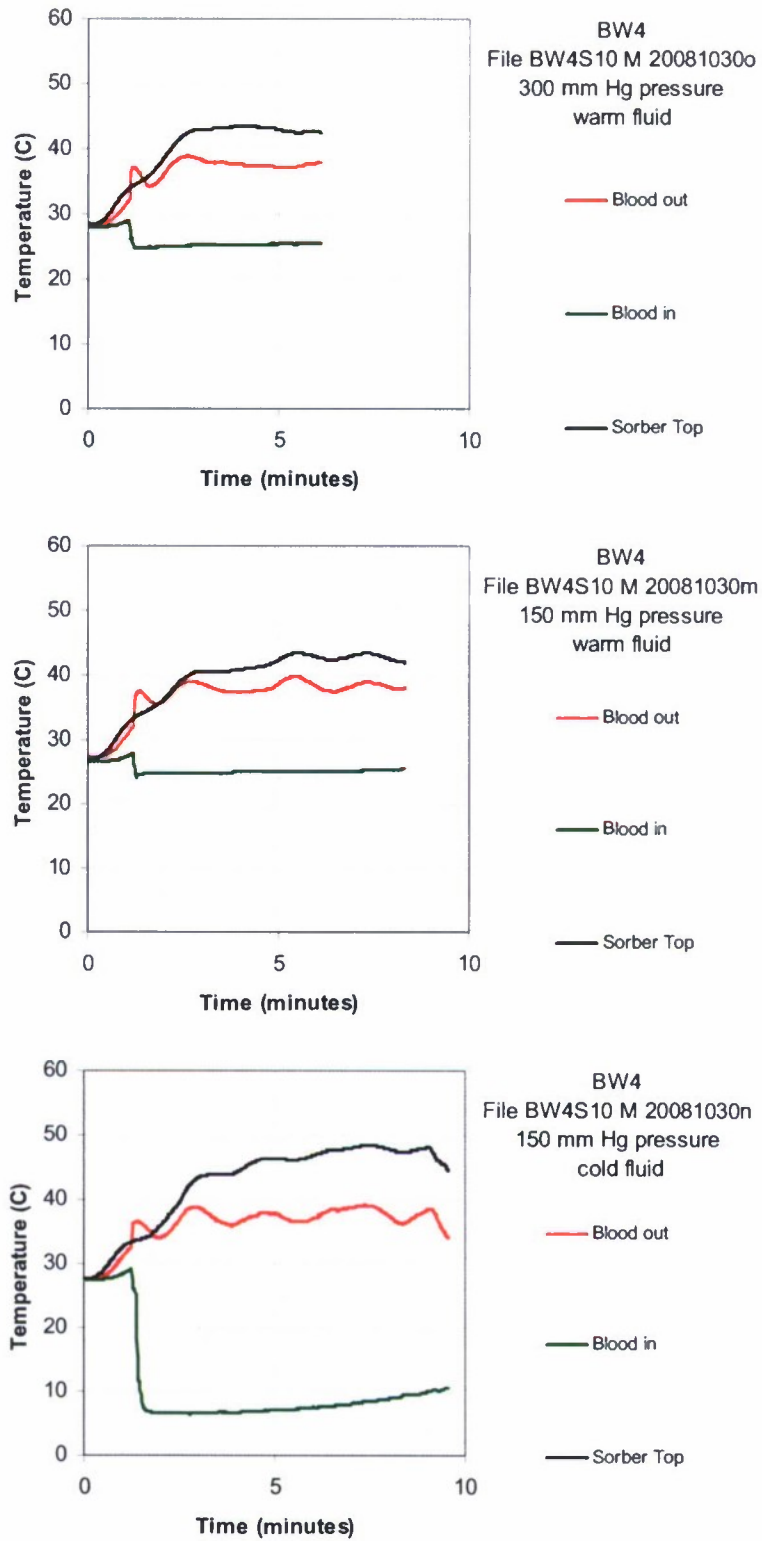


Figure 8. Performance of one prototype with electrical heating.

Comparison to Existing Military Devices

Bench testing was done on the prototype to compare performance with existing portable and non portable fluid warmers used by the military (Thermal Angel [Estill Medical Technologies], Ranger [Arizant Healthcare], The Level 1 model 1000 [Level 1 Technologies], and FMS 2000 [Belmont Instruments]). The primary objective was to compare the performance of this new fluid warmer to currently available warmers used by the military. Lactated ringers solution was used at two different temperatures: room temperature and 4° Celsius. Those fluids were run through the warmer at two different pressures (150mm/Hg and 300mm/Hg) using a hand operated pressure bag and connections were made using standard IV tubing and 18 gauge catheter. Measurements were recorded of input and output temperatures throughout the duration of time to expend one liter of fluid. Flow rate measurements were taken during each test run. Data was collected for three runs at each temperature and pressure combination. The mean and standard error of the mean was determined for each group. These data were then compared to the data in a study published in Military Medicine (Dubick et. al).

UNSOM fluid warmer flow rates achieved for high and low flow were 167 ± 3.08 and 119 ± 1.32 ml/min (See Figures 9 and 10). Average output temperatures for high flow were $37.78^{\circ}\text{C} \pm 0.05$ for 20°C and $37.32^{\circ}\text{C} \pm 0.05$ for 4°C input temperatures (See Figure 11). Average output temperatures for low flow were $38.45^{\circ}\text{C} \pm 0.07$ for 20°C and $38.28^{\circ}\text{C} \pm 0.05$ for 4°C input temperatures (See Figure 12). Time to reach average temperature for high flow was less than one second. Time to reach average temperature for low flow was 5.3 ± 0.11 seconds for room temperature and 16.3 ± 0.08 seconds for 4°C input temperatures (See Table 2). Percentage of time at $\geq 35^{\circ}\text{C}$ ranged from 96 to 100% (See Figures 13 and 14) and percentage of time $\geq 32^{\circ}\text{C}$ was 100% for all tests.

UNSOM prototype was unable to reach the flow rates achieved by the other units. For average output temperature and percentage of time $\geq 32^{\circ}$ and 35°C the prototype performed better than or equal to the other units. The prototype performed better than all other units in time to reach average temperature.

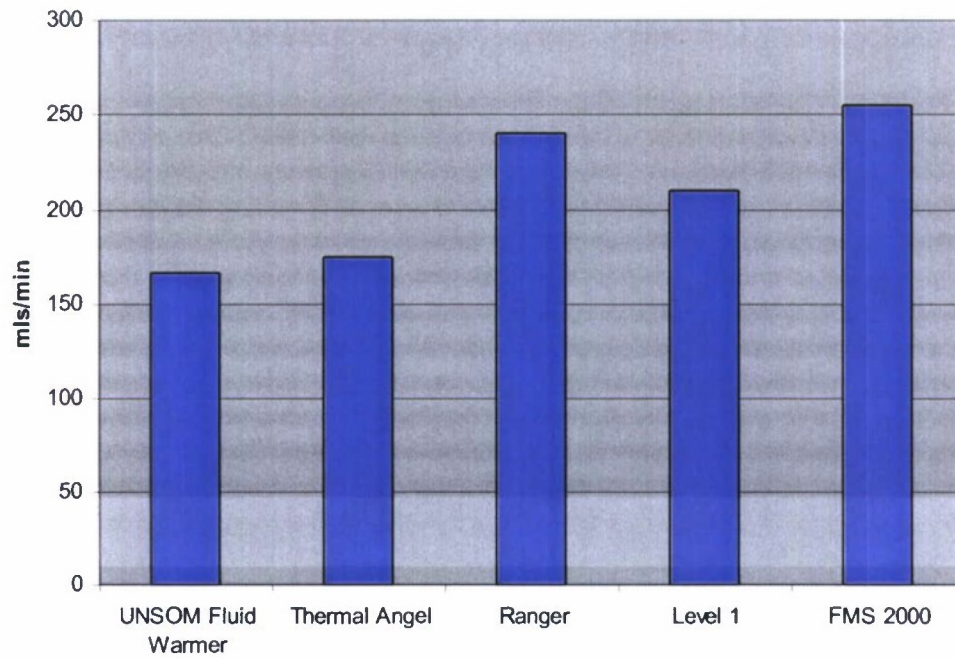


Figure 9. Comparison to Existing Military Devices High Flow Rates (300 mm Hg)

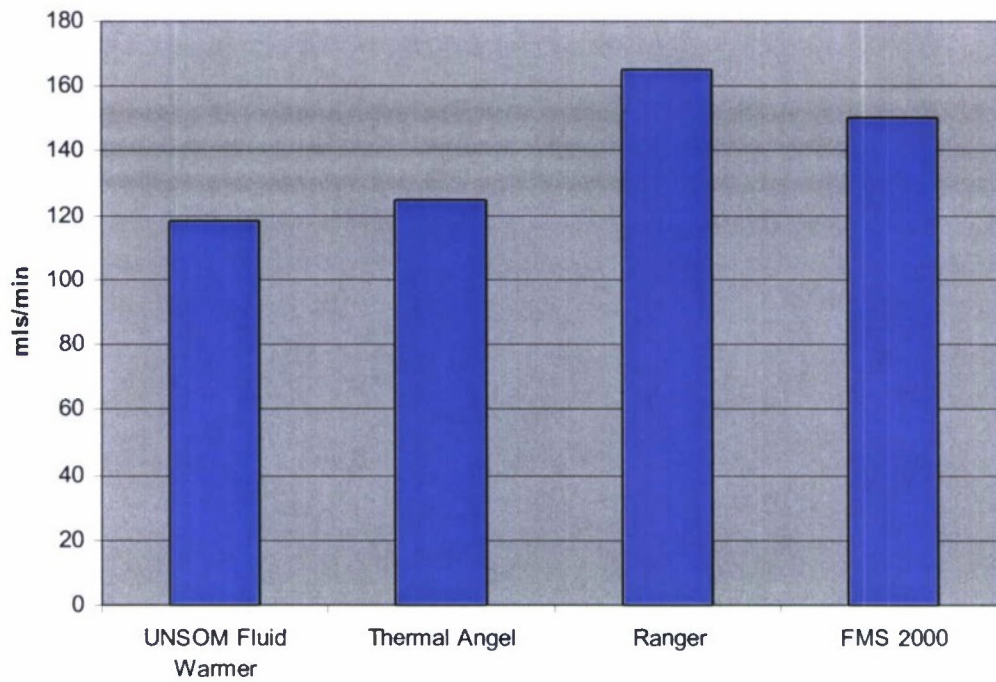


Figure 10. Comparison to Existing Military Devices Low Flow Rates (150 mm Hg)

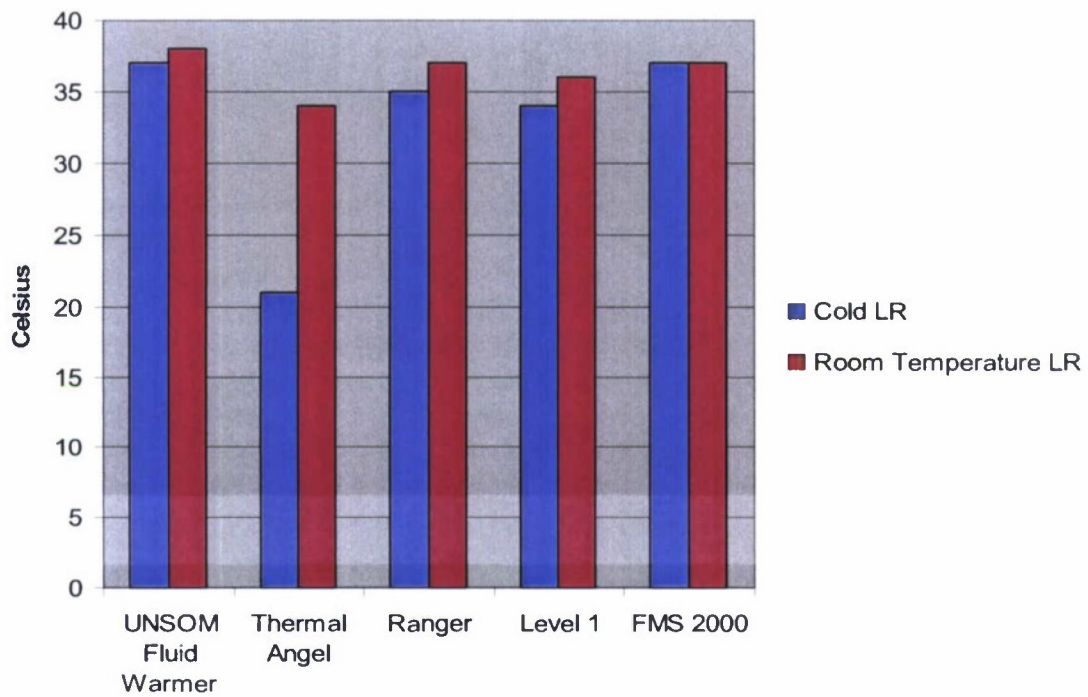


Figure 11. Comparison to Existing Military Devices Average Temperature at High Flow Rate (300 mm Hg)

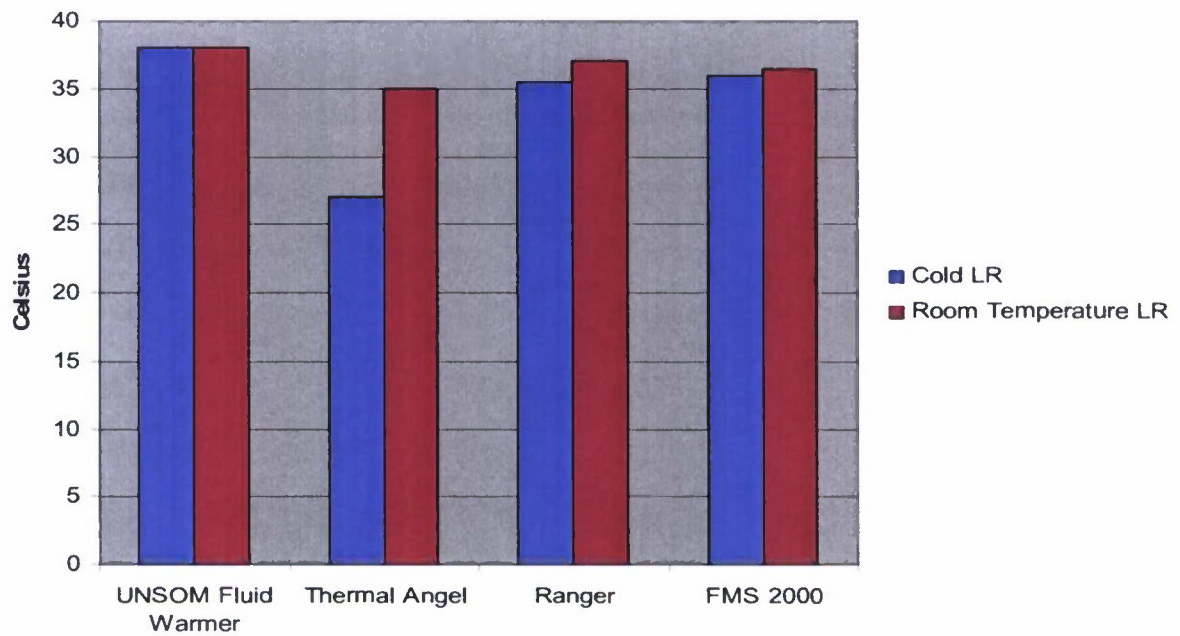


Figure 12. Comparison of Existing Military Devices Average Temperature at Low Flow Rate (150 mm Hg)

Table 2. Comparison to Existing Military Devices Time to Reach Average Temperature at Outlet (seconds)

Medical Device	High Flow Rate (300 mm Hg)		Low Flow Rate (150 mm Hg)	
	Cold LR	Room Temperature LR	Cold LR	Room Temperature LR
UNSOM Fluid Warmer	0	0	5.33 ± 0.11	16.33 ± 0.08
Thermal Angel	320 ± 6	287 ± 17.6	337 ± 26	163 ± 71
Ranger	173 ± 18	177 ± 18	213 ± 33	173 ± 33
Level 1	247 ± 20	93 ± 28	NA	NA
FMS 2000	80 ± 15	60 ± 0	73 ± 9	97 ± 14.5

NA = Not Applicable

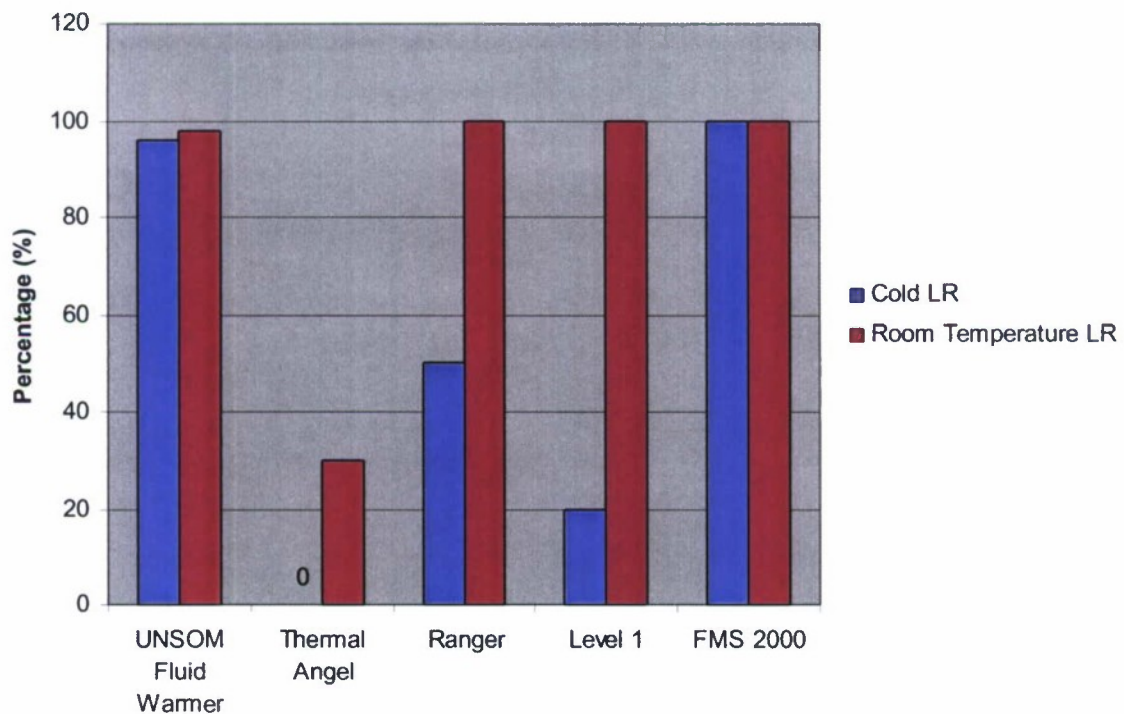


Figure 13. Comparison to Existing Military Devices Percentage of Time at $\geq 35^{\circ}\text{C}$ ran on High Flow Rate.

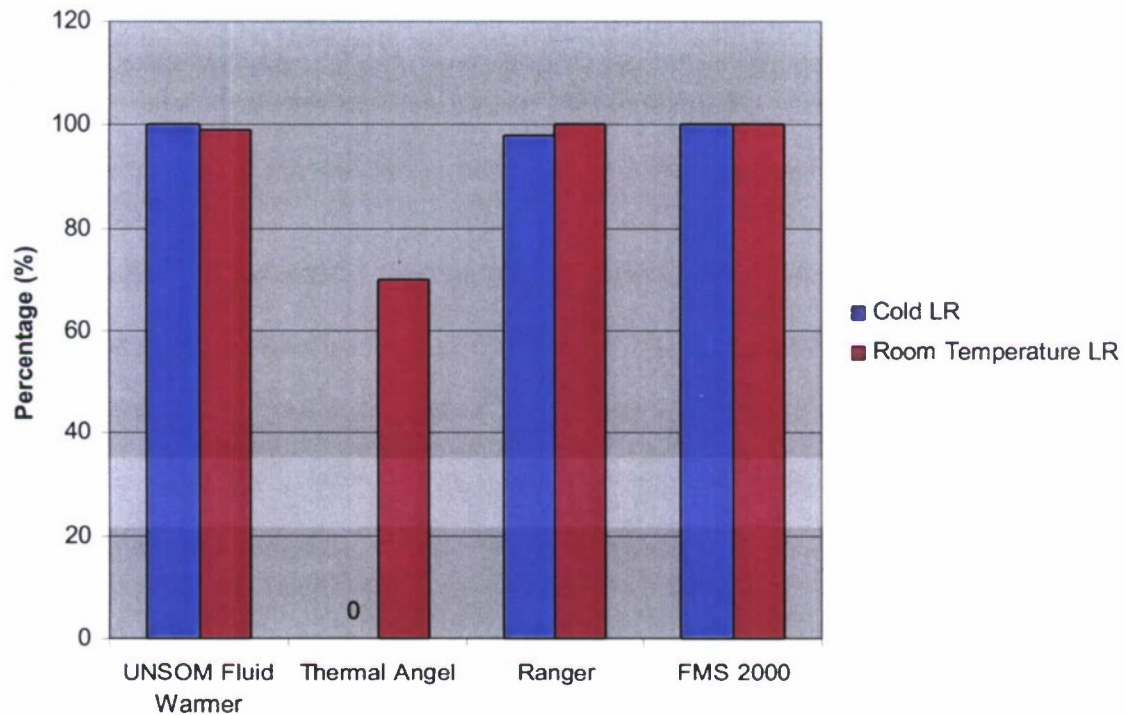


Figure 14. Comparison to Existing Military Devices Percentage of Time at $\geq 35^{\circ}\text{C}$ ran on Low Flow Rate.

Total Volume Threshold

Total infusion volume represents the total volume that can be administered to the patient on one battery charge. This volume, in the field, would represent the total resuscitation bolus the warmer could deliver on battery power without external power supply. Of note, the device is capable of running indefinite volumes while on external power. First, different fluid temperatures were tested to determine if temperature of fluid sent into the system will affect the total volume threshold.

Starting Fluid Temperature (degrees Celsius)	Total Volume Threshold (ml)
30 degrees C	3400 ml
10 degrees C	1200 ml

Next, a variety of different tubing/pressure/catheter configurations were tested for total volume threshold.

<u>Tubing Type</u>	<u>Infusion Pressure</u>	<u>Catheter Gauge</u>	<u>Total Volume (ml)</u>
24" Standard	300 mmHg	18 Ga	2700 ml
	150 mmHg	18 Ga	2400 ml
100" Standard	450 mmHg	16 Ga	2000 ml
	300 mmHg	14 Ga	2100 ml
		16 Ga	2200 ml
		18 Ga	2200 ml

Flow Rate Analysis and Optimization

The fluid warmer was initially tested using Lactated Ringer's that was at room temperature on a pressure bag inflated to pressures varying from 150mm Hg to 450mmHg. Standard IV bag spikes were connected to the fluid bags and then to the fluid warmer. The infusions tubing setup was twenty-four (24) inches in length from the warmer to the catheter initially and later refit with standard length patient tubing measuring 100 inches. Later, the tubing was replaced with larger diameter "Level 1" tubing to attain max flow rates. The catheter tip attached to the end of tubing ranged from 14 to 18 gauge in size and affixed firmly to the tubing. All thermocouples (temperature sensing probes) were confirmed for absence of fluid leak. The runs were all started according to Rocky Research operating instructions. Results on maximum flow rate in ml/min were calculated over battery powered full runs until the output temperature dropped below 35 degrees Celsius.

<u>Tubing Type</u>	<u>Infusion Pressure</u>	<u>Catheter Gauge</u>	<u>Flow Rate (ml/min)</u>
24" Standard	300 mmHg	18 Ga	171 ml/min
	150 mmHg	18 Ga	120 ml/min
100" Standard	450 mmHg	16 Ga	136 ml/min
	300 mmHg	14 Ga	118 ml/min
		16 Ga	111 ml/min
		18 Ga	113 ml/min
Level 1	450 mmHg	14 Ga	596 ml/min
		16 Ga	504 ml/min
		18 Ga	277 ml/min
	300 mmHg	14 Ga	538 ml/min
		16 Ga	345 ml/min

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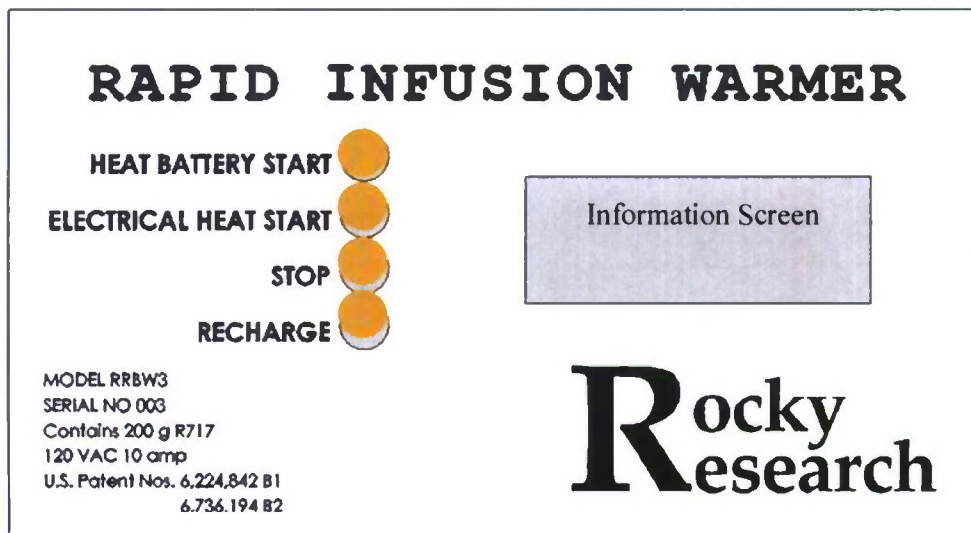
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RAPID INFUSION WARMER

APPENDIX A

OPERATING INSTRUCTIONS



GENERAL

The control panel for the blood warmer is as shown above. There is no power-off button. The LCD information panel tells status of the system. When the appliance is connected to external power, the back light is continuously illuminated. On battery power, the back light is on for 20 seconds following any user input.

Normally the display indicates standby mode as shown to the right. The 2nd line cycles through display of five temperatures, channels 0 through 4.

Identification of these is as follows:

- | | |
|--|--|
| <p>Channel 0 Fluid temperature at the cartridge inlet (meaningless if no cartridge is installed.)</p> <p>Channel 1 Temperature of fluid at the cartridge midpoint.</p> <p>Channel 2 Temperature of fluid at the cartridge outlet.</p> <p>Channel 3 Temperature of the cold junction on the control board inside the appliance.</p> <p>Channel 4 Temperature at the top of the sorber. This temperature is only accurate above approximately 70°C.</p> | <p>STANDBY: SYS INACTIVE
Channel 0 Temp = 28.7</p> <p>Battery: Charge Required</p> |
|--|--|

During most modes of operation, a “clicking” sound will be heard inside the appliance. This noise is from operation of the solenoid valve that controls flow of ammonia to and from the sorber.

The internal electrical battery will charge anytime the unit is connected to 120 VAC external power. The internal heat battery will charge only when “RECHARGE” is pressed. The fourth line of the display indicating recharge status is not fully functional. The system should be recharged anytime the solenoid valve has been opened, even once, since the last recharge.

Instructions for each mode of operation follow. A list of fault codes and additional button functions are also presented.

To heat fluid using stored energy

This mode of operation can be used with or without the appliance connected to external power.

1. Install single-patient cartridge on the appliance. The cartridge can be connected to tubes and primed before or after installing on the appliance.
1. Push button labeled "HEAT BATTERY START"
2. A series of clicks will follow. The display will be as shown to the right. The numeral "1" on the left side of the first line indicates preheat mode.
3. The temperature display on line 2 shows fluid temperature inside the cartridge. During preheat mode, the temperature displayed is at the middle of the cartridge. Ideally, wait until this temperature reaches 35°C before starting fluid flow. In critical situations, flow can be started at lower temperature at the discretion of medical personnel involved.
4. Once flow starts, the appliance will recognize that flow has started and will control delivery temperature. The numeral on the left side of line 1 will change to "2" to indicate that the unit is in active control mode. In the unlikely event that the appliance fails to recognize that flow has started, pressing "HEAT BATTERY START" once more will force it to go to active control.
5. The appliance will automatically control infusion fluid delivery temperature. Continue to infuse the patient until medical reasons dictate otherwise, or until the warmer can no longer maintain sufficient delivery temperature. The HEX numeral (0-F) on the right side of display line 1 indicates what fraction of the time the control valve is open. Normally this information is not important to the operator. In critical situations, operation of the automatic controller can be overridden by pressing and holding the "RECHARGE" button. This will open the solenoid valve for maximum flow of ammonia vapor to the sorber, giving maximum heating.
6. When infusion is complete, press the "STOP" button on the controller. This display will return to standby mode. The system must be recharged before again being used in heat battery mode.

I HEAT BATTERY OPERATION 0 Temperature = 28.7°C
--

Battery: Charged

If the system detects faults, it will not start preheat and will display "Fault Warning" on line 1 and the fault code on line 2. The most probable fault code for this mode of operation is "1" and indicates that the cartridge is not making electrical contact with the appliance. Press the cartridge down further onto the sorber.

SUMMARY

1. INSTALL PRIMED CARTRIDGE
2. PRESS "HEAT BATTERY START"
3. START FLUID FLOW WHEN TEMPERATURE $\geq 35^{\circ}\text{C}$
4. STOP FLUID FLOW WHEN TEMPERATURE STAYS BELOW 35°C
5. PRESS "STOP"
6. RECHARGE THE APPLIANCE BEFORE THE NEXT USE.

To heat fluid using external electrical power

This mode of operation requires that the appliance be connected to external power.

1. Install single-patient cartridge on appliance.
The cartridge can be connected to tubes and primed before or after installing on the appliance.
2. Push button labeled "ELECTRICAL HEAT START"
3. The display will be as shown to the right. The numeral "3" on the left side of the first line indicates preheat mode.
4. The temperature display on line 2 shows fluid temperature inside the cartridge. During preheat mode, the temperature displayed is at the middle of the cartridge. Ideally, wait until this temperature reaches 35°C before starting fluid flow. In critical situations, flow can be started at lower temperature at the discretion of medical personnel involved.
5. Once flow starts, the appliance will recognize that flow has started and will control delivery temperature. The numeral on the left side of line 1 will change to "4" to indicate that the unit is in active control mode. In the unlikely event that the appliance fails to recognize that flow has started, pressing "ELECTRICAL HEAT START" once more will force it to go to active control.
6. The appliance will automatically control infusion fluid delivery temperature. Continue to infuse the patient until the medical reasons dictate otherwise. Heating power available is 600W, which is sufficient to heat 260 cc/min of fluid from 4°C to 37°C. The HEX numeral (0-F) on the right side of display line 1 indicates what fraction of available power being used. If this number is high (>9) and fluid delivery temperature is not above 35°C, it is necessary to decrease infusion rate. In critical situations, operation of the automatic controller can be overridden by pressing and holding the "RECHARGE" button. This will cause the heater to operate at maximum power.
7. When infusion is complete, press the "STOP" button on the controller. The display will return to standby mode.

3	Electrical Heat	0
	Temperature = 28.7°C	
	Battery: Charged	

If the system detects faults, it will not start preheat and will display a fault code on line 2. Highest probability fault codes for this mode of operation are "1", cartridge not connected, and "7" indicating the appliance is not connected to external 120 VAC electrical power.

SUMMARY

1. CONNECT APPLIANCE TO 120 VAC POWER SOURCE
2. INSTALL PRIMED CARTRIDGE
3. PRESS "ELECTRICAL HEAT START"
4. START FLUID FLOW WHEN TEMPERATURE $\geq 35^{\circ}\text{C}$
5. PRESS "STOP" WHEN INFUSION IS COMPLETE

To recharge the system

This mode of operation requires that the appliance be connected to external power.

1. Remove single-patient cartridge from the unit.
2. Close and latch the door that covers the sorber.
3. Push button labeled "RECHARGE"
4. A click will be heard from inside the appliance indicating that the solenoid valve has opened and recharge has started. The display will be as shown to the right. The HEX digit to the right of the first line indicates portion of available heater power being used for recharge. This will display 100% (HEX digit "F") until temperature nears the setpoint of 185°C and the controller modulates heater power.
5. The temperature display on line 2 shows sorber temperature as recharge proceeds. This value only has meaning above about 70°C².
6. Recharge requires about 20 minutes. When recharge is complete, the fan will shut down and the display will return to standby mode. The sorber will slowly cool. Channel 4 temperature on the second line of the display indicates sorber temperature.
7. After recharge is complete, the sorber door can be opened to facilitate more rapid cooling of the sorber. METAL PARTS WILL BE VERY HOT. These include the sorber and inside walls surrounding the sorber. It is best to let the sorber cool without opening the door if time permits. If the need exists for immediate use, a fan can be used to further enhance sorber cooling. Let the sorber cool to 37°C before attempting to heat infusion fluid.

RECHARGE UNDERWAY	0
Temperature = 182.7°C	
Battery: Charged	

Highest probability fault codes for this mode of operation are "1", "2", "3" meaning recharge is being attempted with a cartridge in place, "6" if the door is not securely closed, and "7" indicating the appliance is not connected to external 120 VAC electrical power.

SUMMARY

1. INSURE NO CARTRIDGE
2. CLOSE AND LATCH THE SORBER DOOR
3. PRESS "RECHARGE"
4. LET RECHARGE RUN TO COMPLETION
5. LET SORBER COOL TO 37°C OR BELOW BEFORE HEATING INFUSION FLUID

² Cost and performance optimization of the controller precluded accurate temperature measurement near ambient temperature. The control circuit only has need for accurate temperature measurement as the recharge setpoint temperature is approached.

FAULT CODES

CODE	HEAT BATTERY OPERATION	ELECTRIC HEATING	RECHARGE
1	No cartridge in place, or failed temperature sensor at cartridge inlet port.		A cartridge is in place. Remove before recharging
2	Failed temperature sensor at cartridge mid point.		
3	Failed temperature sensor at cartridge outlet port.		
4	bad thermocouple cold junction – no user fix possible		
5	bad sorber thermocouple – no user fix possible		
6	na	na	Sorber cover door not securely closed
7	na	External 120 VAC electrical power not connected	

ADDITIONAL BUTTON FUNCTIONS

1. Push **“HEAT BATTERY START”** button or **“ELECTRICAL HEAT START”** after initiation of heating, either heat battery or electrical.
Forces the appliance into active control mode. Usually used only if the system fails to detect start of infusion fluid flow
2. Push and hold **“RECHARGE”** during heating, either heat battery or electrical
Forces the appliance to maximize heating. In **“ELECTRICAL HEATING”** heater power is set to 100%. In **“HEAT BATTERY”** the solenoid is opened. This condition is maintained as long as the button is held. Releasing the button returns to active control.
3. Push **“STOP”** during standby for display reset
If at anytime the display appears to have stopped updating, is blank, is garbled, or shows other evidence of failure, hold the start button for at least one second. The display will briefly show reboot information and then return to standby mode.

If the display remains blank and the unit is not connected to external power, the battery is discharged. Connect to 120 VAC for battery charging.

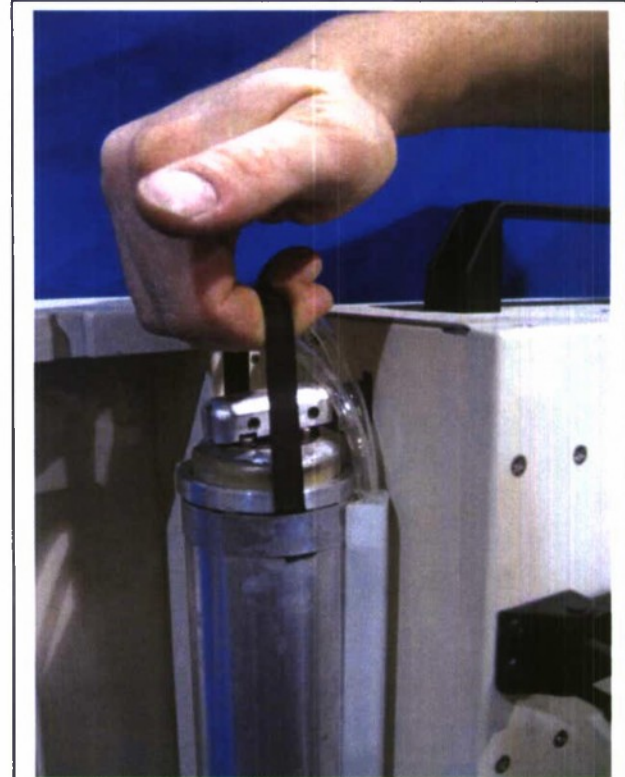
INSTALLATION AND REMOVAL OF THE SINGLE PATIENT CARTRIDGE

The cartridge should be inserted snugly over the sorber without pushing down with excessive force. When inserting, be careful not to squeeze it closed, as this will make it difficult to slide over the sorber. Often the cartridge can be simply dropped after it is lined up over the sorber and inserted far enough that the top bracket has entered the slot on the side of the cartridge. When inserted properly, the top of the cartridge will be 1/4" to 1" below the top rim of the sorber. The protrusion on the bottom of the plastic cover must extend into the contactor recess in the appliance. If it does not, press the cartridge down a little further on the sorber. If proper electrical connection between the appliance and cartridge is not made, fault code 1,2, or 3 will be displayed when fluid heating is called for. If this happens press the cartridge on slightly further. If the fault code repeats, remove the cartridge and reinstall it.

Cartridge removal is best done by using the thumb pad at the top of the sorber for reaction force. This can easily be done by grasping the handle with your fingers while pressing your thumb against the thumb pad on the top of the sorber. Proper and improper cartridge removal techniques are illustrated in the figures to the right.



Correct removal technique

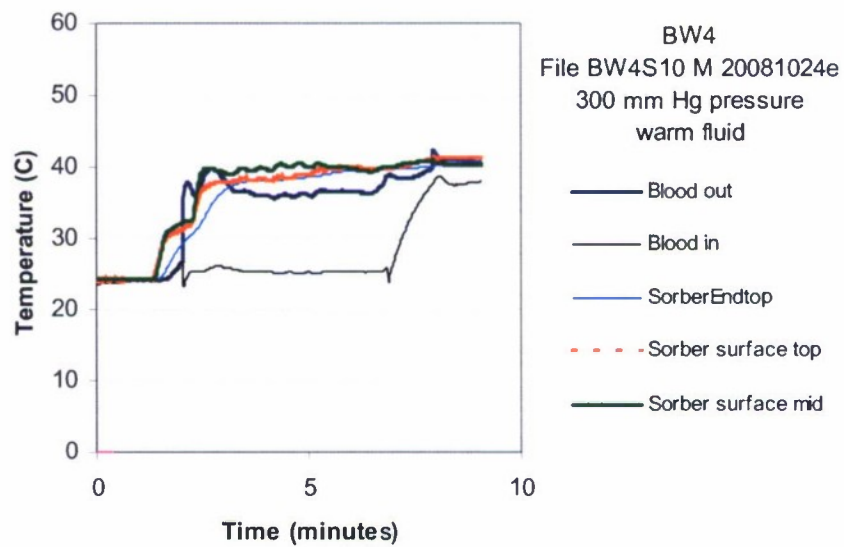
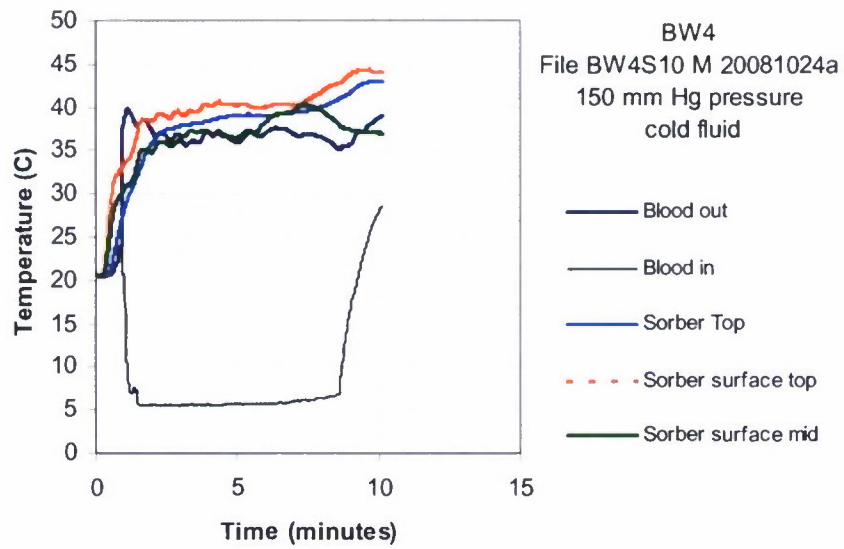


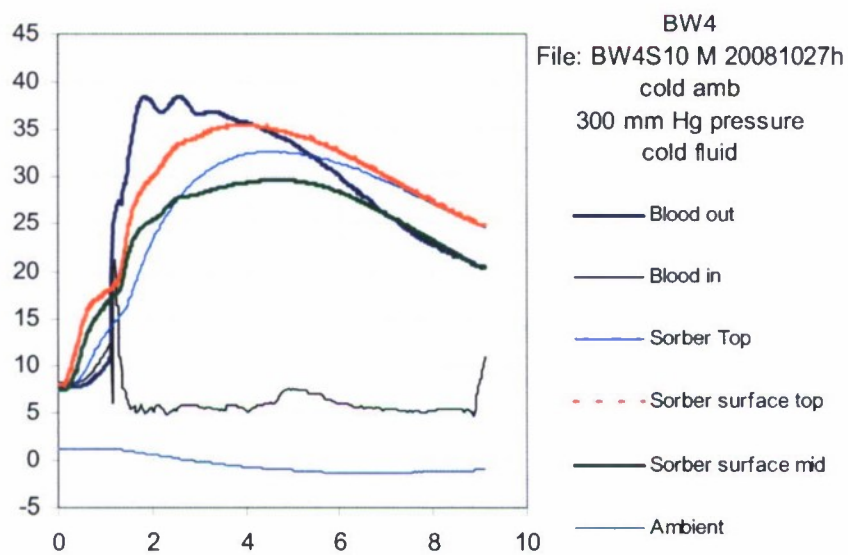
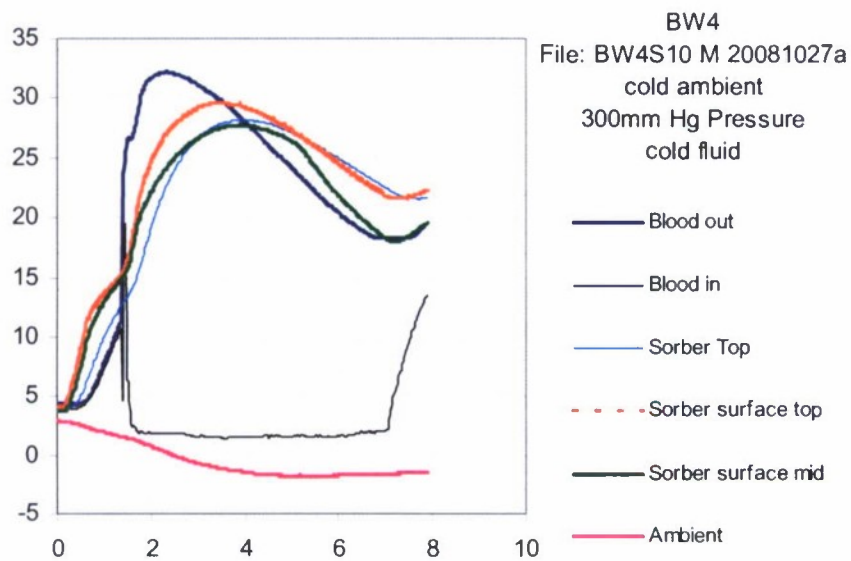
Incorrect removal technique

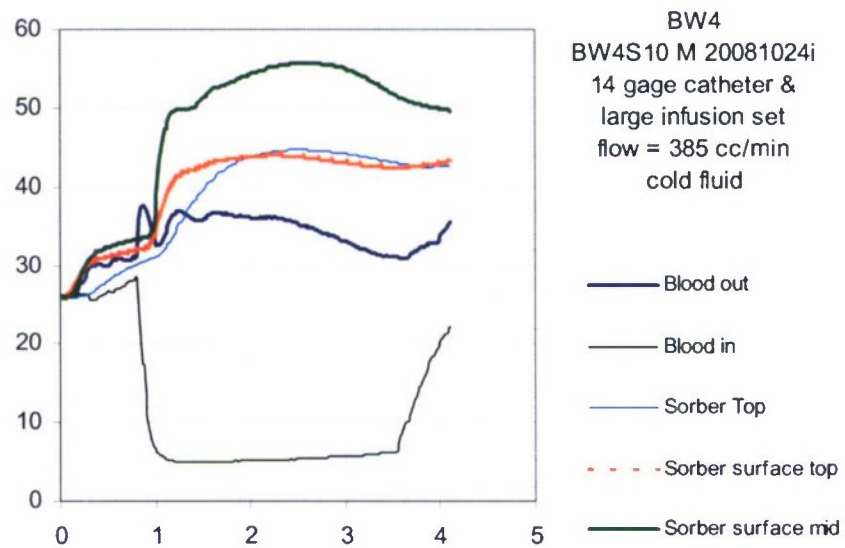
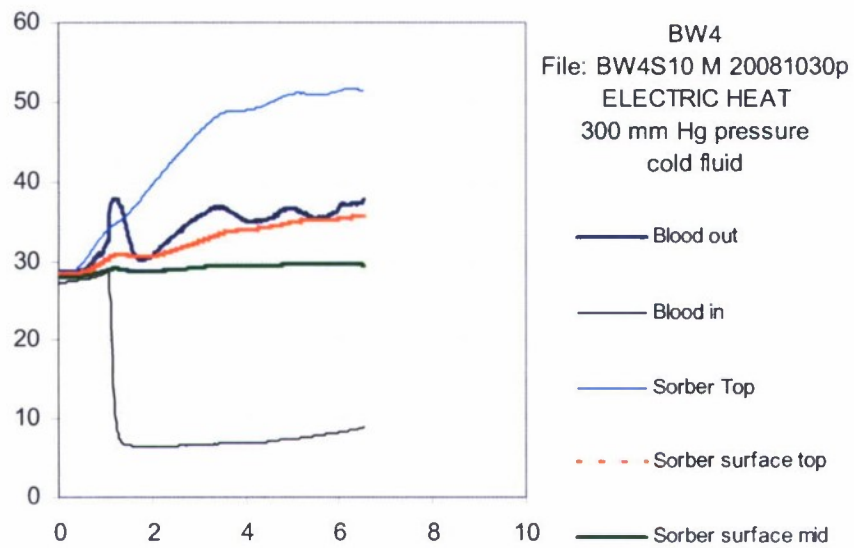
RAPID INFUSION WARMER

APPENDIX B

ADDITIONAL TEST RESULTS







REPORT DOCUMENTATION PAGE					Form Approved OMB No. 0704-0188	
The public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing the burden, to Department of Defense, Washington Headquarters Services, Directorate for Information Operations and Reports (0704-0188), 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302. Respondents should be aware that notwithstanding any other provision of law, no person shall be subject to any penalty for failing to comply with a collection of information if it does not display a currently valid OMB control number. PLEASE DO NOT RETURN YOUR FORM TO THE ABOVE ADDRESS.						
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