

UNITED STATES AIR FORCE RESEARCH LABORATORY

TESTING AND EVALUATION OF THE SEABROOK MEDICAL SYSTEMS, INC. ECMO-TEMP BLOOD WARMING UNIT, MODEL SMS-3000

Allen E. Jones, TSgt, USAF

HUMAN EFFECTIVENESS DIRECTORATE
FLIGHT STRESS PROTECTION DIVISION
SYSTEMS RESEARCH BRANCH
2504 Gillingham Drive, Suite 25
Brooks AFB, Texas 78235-5104

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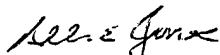
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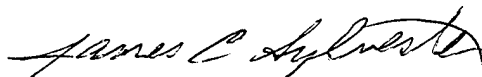
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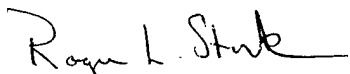
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ALLEN E. JONES, TSgt, USAF
Aeromedical Research Craftsman



JAMES C. SYLVESTER, Major, USAF, NC
Chief, Aeromedical Research



ROGER L. STORK, Colonel, USAF, BSC
Chief, Crew Technology Division

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Mr Douglas Townsend:	Electronics Engineer

**TESTING AND EVALUATION OF THE
SEABROOK MEDICAL SYSTEMS, INC.
ECMO-TEMP BLOOD WARMING UNIT,
MODEL SMS-3000**

BACKGROUND

HSD/YAM requested on behalf of the of Wilford Hall Medical Center's Extracorporeal Membrane Oxygenation (ECMO) team to evaluate the Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit for use on board USAF aeromedical evacuation aircraft. This device is one of the components of the Neonatal/Pediatric ECMO system. Specific components of the Seabrook Model SMS-3000 that underwent the evaluation process included the Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit, water inlet/outlet tubing, and heat exchanger. All components of the Seabrook Model SMS-3000 were tested for airworthiness. Throughout this report the term Equipment Under Test (EUT) refers to the Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit.

DESCRIPTION

The EUT provides a flow of temperature controlled water to a heat exchanger. This heat exchanger is connected in the blood flow path in series between the oxygenator and the patient during an ECMO procedure. The EUT provides a means for warming and controlling blood temperature prior to and during perfusion. The EUT consists of a plastic reservoir for holding distilled water; a float switch to indicate low water level; a pump for circulating water through an external heat exchanger; a heating element to warm the water; a microprocessor-based electronic control to regulate water temperature; two independent back-up high limit devices to protect the patient and the unit; a water flow indicator to provide visual assurance of proper water flow; two connecting hoses for attachment of the heat exchanger; and a fan for removing heat generated within the unit enclosure. A phone jack marked "Blood Probe" allows connection of a 400 series-type thermistor probe for monitoring and/or controlling blood temperature. The control panel offers two modes of operation: "Water Temp" and "Blood Temp". In the "Water Temp" mode, the operator selects the desired water temperature setpoint and the EUT maintains the water at that temperature. In the "Blood Temp" mode, the operator selects the desired blood temperature as measured by the remote probe, and the EUT regulates the water temperature to maintain the blood temperature at the setpoint. The "Blood Temp" mode was not evaluated because ECMO team did not require this mode. Audible and visual alarms indicate "Add Water", "Under Setpoint", "Over Setpoint", and "High Limit". Digital displays indicate water temperature, setpoint, and blood temperature (when a probe is connected), in degrees centigrade. The EUT (Figure 1) operates from 115 VAC / 60 Hz power and weighs 24 lbs (dry). The dimensions are 9.75 in. W. X 14 in. H. X 11 in. D.



Figure 1. Seabrook Model SMS-3000

PROCEDURES

Test methods and performance criteria were derived from nationally recognized performance guidelines (1 & 5), various military standards (2-4 & 6-8), and manufacturer's literature (9). The Aeromedical Research Procedures Guide describes additional safety and human interface issues to be considered during equipment testing (10). A test setup and performance check were developed specific to this EUT to verify its proper functioning under various testing conditions. Unless otherwise noted, all testing is conducted and monitored by Aeromedical Research personnel assigned to the Flight Stress Protection Division, Human Effectiveness Directorate, Air Force Research Laboratory, Brooks AFB, Texas.

The EUT was subjected to various laboratory and inflight tests to observe and evaluate its performance under anticipated operational conditions.

1. Initial Inspection
2. Vibration

3. Electromagnetic Interference (EMI)
4. Thermal/Humidity Environmental Conditions, encompassing:
 - a. Hot Operation
 - b. Cold Operation
 - c. Humidity Operation
5. Hypobaric Conditions
 - a. Cabin Pressure/Altitude
 - b. Rapid Decompression to Ambient Pressure
6. Airborne Performance

INITIAL INSPECTION AND TEST PREPARATION

- a. The EUT was inspected for quality of workmanship, production techniques and pre-existing damage.
- b. The EUT was checked to ensure it met safety requirements and operating characteristics established in National Fire Protection Agency (NFPA) 99 (1); AFI 41-203, Electrical Shock Hazards (2); AFI 41-201, Equipment Management in Hospitals (3). Ground resistance and leakage current measurements were made at 115 VAC/60 Hz.
- c. The EUT was examined to ensure it met basic requirements for human factors design as outlined in MIL-STD 1472 (4).
- d. A test setup and performance check were developed to evaluate the EUT's operation in accordance with manufacturer/customer specifications throughout the various testing conditions.

TEST SETUP

The EUT was placed on a level surface, water reservoir filled, and hoses/heat exchanger connected as stated in the operation manual. When the power switch was turned to the "ON" position the following sequence of "self test" events occurred: power switch illuminated and fan energized, all visual indicators flashed four times, audible alarm sounded, and the setpoint/mode of operation to which the unit was last set flashed four times. The purpose of the "self test" was to allow the operator to check for proper operation of all indicators. The proper water flow was checked by observing the flow indicator on the front of the unit. The mode of operation was selected by pressing the "Water Temp" switch on the control panel. The setpoint temperature was adjusted to 37° C by pressing the "Setpoint" switch and simultaneously pressing either the up or down arrows.

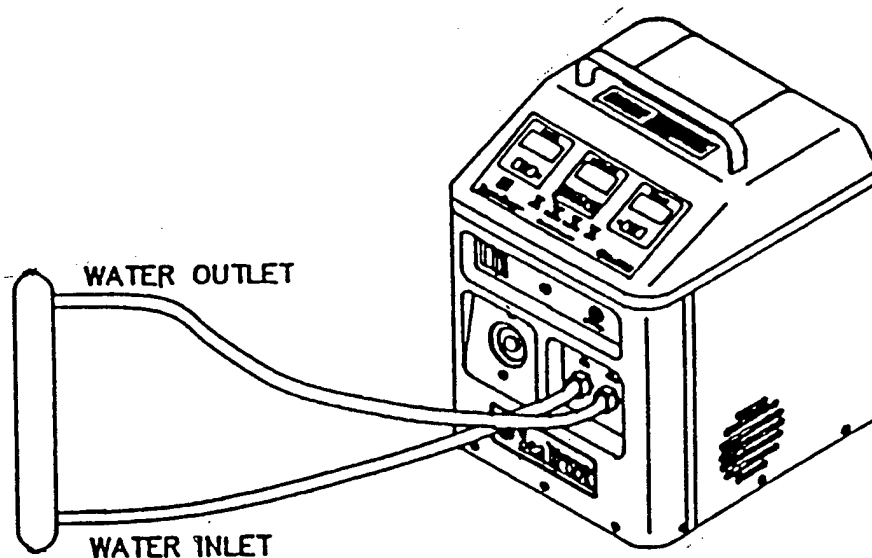


Figure 2. Test Setup

PERFORMANCE CHECK

The following performance check was used to validate the function of the EUT during each of the following test conditions. The proper water flow was checked by observing the flow indicator, the paddle wheel was spinning rapidly indicating proper flow. The reservoir water temperature was checked every 15 minutes and documented.

VIBRATION

Vibration testing is critical to determine "the resistance of equipment to vibrational stresses expected in its shipment and application environments" (6). Testing was conducted using a calibrated Unholtz-Dickie Vibration System, controller model UD-VWIN and shaker model R16W. This testing involved a set of operational tests performed along each of three axes - X, Y, and Z. The EUT was secured directly to the vibration system adapter/mounting plate. It was subjected to vibration curves with similar intensities and durations as those derived from MIL-STD-810E, Category 10, Figures 514.4-16 and 514.4-17 (Figure 4).

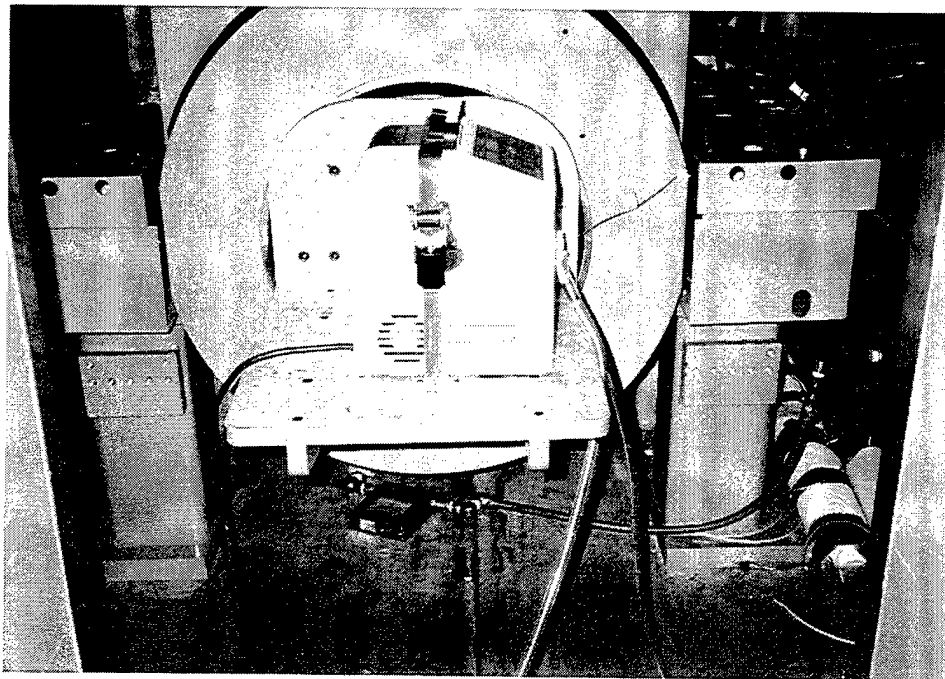


Figure 3. Vibration Table Mounting

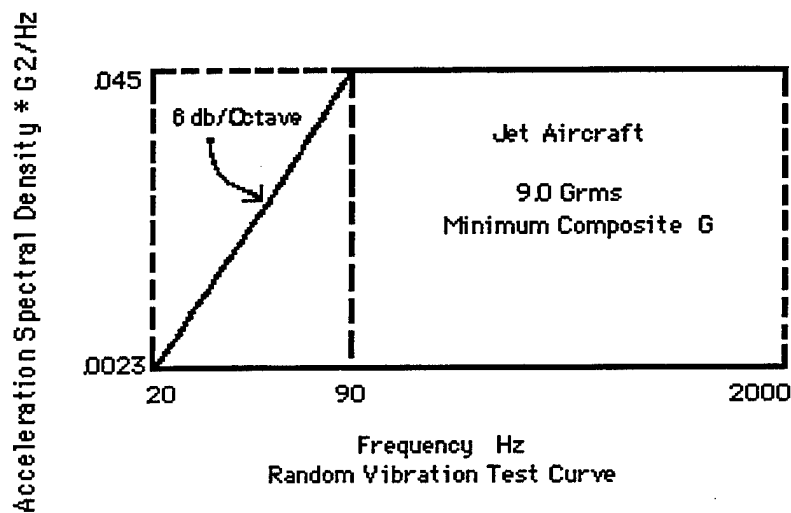
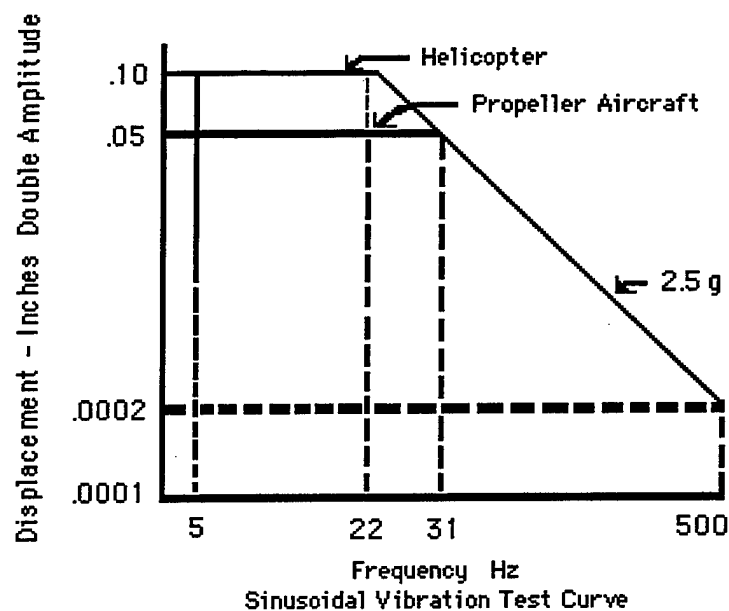


Figure 4. MIL-STD-810E, Category 10, figures 514.4-16 and 514.4-17

ELECTROMAGNETIC COMPATIBILITY

Electromagnetic compatibility testing is a primary concern on USAF aeromedical evacuation aircraft. Safety is the driving factor to assessing the effects of excessive electromagnetic emissions, a source of potential influence on aircraft navigation and communications equipment. Medical devices may be susceptible to fields generated by aircraft equipment and malfunction in their presence.

The EUT was evaluated for compliance with MIL-STD-461D & MIL-STD-462D (7 & 8). ASC/ENAI engineers at Wright-Patterson AFB evaluated the electromagnetic compatibility data and determined the airworthiness of the medical device. Specific tests conducted were as follows:

a. Radiated Emissions (RE-102), "Radiated Emissions, Electric Field, 10 kHz to 18 GHz.": For Air Force aircraft applications, radiated emissions were tested in a narrower range of frequencies from 2 MHz - 1 GHz. This test measured the amount of EMI emitted by the equipment during operation. It verifies the device's potential to affect other equipment susceptible to electromagnetic emissions (i.e., aircraft navigation and communications equipment).

b. Conducted Emissions (CE-102), "Conducted Emissions, Power Leads, 10 kHz to 10 MHz.": For Air Force aircraft applications, conducted emissions were tested throughout the entire band of 10 kHz - 10 MHz. This test measured emissions generated by the medical device along its power supply lines. It was performed to assess the device's potential to affect other items connected to the same power source, particularly aircraft systems.

c. Radiated Susceptibility (RS-103), "Radiated Susceptibility, Electric Field, 10 kHz to 40 GHz.": For Air Force aircraft applications, radiated susceptibility was tested in a narrower frequency range from 30 MHz - 12.4 GHz at the following field strength levels: 20 V/M below 1 GHz and 60 V/M above 1 GHz (MIL-STD-461D field strength values from Table IV, Category Aircraft Internal). This test evaluated the device's resistance to predefined levels of EMI generated by antennas both internal and external to the aircraft.

d. Conducted Susceptibility (CS-101), "Conducted Susceptibility, Power Leads, 30 Hz to 50 kHz.": For Air Force aeromedical aircraft applications, conducted susceptibility was tested throughout the entire frequency band, from 30 Hz to 50 kHz. This test evaluated the EUT's ability to "withstand ripple voltages associated with allowable distortion of power source voltage wave forms."

e. Conducted Susceptibility (CS-114), "Conducted Susceptibility, Bulk Cable Injection, 10 kHz to 400 MHz.": For Air Force aeromedical aircraft applications conducted susceptibility was tested throughout the frequency band from 10 kHz to 200 MHz. This test determined whether "simulated currents that will be developed on platform cabling from electromagnetic fields generated by antenna transmission would affect the equipment under test."

f. Conducted Susceptibility (CS-115), "Conducted Susceptibility, Bulk Cable Injection, Impulse Excitation": This test was performed to ensure the EUT could withstand the "fast rise and fall time that may be present due to platform switching operations and external transient environments such as lightning and electromagnetic pulse."

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

Extreme temperature and humidity testing determines if aeromedical equipment can be stored and operated during severe environmental conditions without experiencing physical damage or deterioration in performance(6). Extreme environmental conditions can have incapacitating effects on medical equipment including the following: changes in material characteristics and material dimensions, overheating, changes in lubricant viscosity, changes in electronic components, and electronic or mechanical failures due to rapid water or frost formation.

Testing was conducted in the Air Force Research Laboratory's A-7 Environmental Chamber. The EUT was placed in the center of the calibrated environmental chamber. During environmental testing the EUT was monitored continuously, and a performance check was conducted every 15 minutes. The following describes the conditions of the environmental tests performed:

- a. Humidity: $94 \pm 4\%$ RH, $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 4 hours
- b. Hot Temp Operation: $120^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($49^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hours
- c. Modified Hot Temp Operation: $85^{\circ}\text{F} \pm 3.6^{\circ}\text{F}$ ($29.5^{\circ}\text{C} \pm 2^{\circ}\text{C}$) for 2 hours
- d. Cold Temp Operation: $32^{\circ}\text{F} \pm 7.2^{\circ}\text{F}$ ($0^{\circ}\text{C} \pm 4^{\circ}\text{C}$) for 2 hours

HYPOBARIC CONDITIONS

Cabin Pressure/Altitude: Altitude testing is critical for aeromedical evacuation equipment due to potential effects of barometric pressure changes on the equipment. A majority of the aircraft characterized as opportune aircraft available for use in aeromedical evacuation, pressurize their cabin atmosphere to barometric pressures equivalent to 8,000-10,000 ft above sea level. The differences in pressures affect the operation of some medical equipment. Altitude testing consisted of operating the EUT while ascending from ground level to 10,000 ft; stopping at 2,000 ft increments for performance checks; and then descending back to ground, at rates of 5,000 ft/min. Descent is stopped at 2,000 ft for performance checks.

Rapid Decompression Testing: A rapid decompression (RD) is the loss of aircraft cabin pressurization and subsequent pressure equalization with ambient atmospheric pressures. It is important to assess medical equipment functioning during and after RD so as not endanger a patient, personnel, or the aircraft itself. The EUT operated inside the rapid decompression test chamber as the chamber was pressurized to an equivalent of 8,000 ft altitude. Then the chamber altitude was brought to 40,000 ft over a period of 60 seconds, held at 40,000 ft for a few minutes, and then returned to ground at a rate of 10,000-12,000 ft/min. The test was repeated twice more; once for a 7-second RD and once for a 1-second RD. The EUT was monitored throughout the

series of decompressions; performance checks were assessed each time the unit returned to ground level.

AIRBORNE PERFORMANCE

Airborne performance evaluations are a cost-effective and invaluable means of validating clinical and operational suitability under actual operating conditions. By carefully evaluating medical equipment items in their proposed operational environment, Aeromedical Research verifies demonstration of all pertinent patient care issues are adequately addressed by the test protocols. Safe and reliable operation is the primary goal of the inflight evaluation and forms the basis for subsequent recommendations to the users.

This phase of testing was conducted by qualified aeromedical crew members from Aeromedical Research on C-9 and C-141 aeromedical evacuation missions. The EUT was positioned and secured to the neonatal/pediatric ECMO transport cart and evaluated. Human factors characteristics, securing methods, setup/tear down times and securing locations were also evaluated. Feedback from ECMO team members, and other aeromedical evacuation crew members participating in delivery of patient care was obtained concerning EUT human factor considerations.

EVALUATION RESULTS

INITIAL INSPECTION

Initial inspection revealed no manufacturing defects. The unit performed to the manufacturer's specification. Electrical safety test results showed all parameters to be within referenced guideline limits.

VIBRATION

The EUT operated satisfactorily during vibration testing.

ELECTROMAGNETIC COMPATIBILITY

The EUT had radiated emissions in excess of MIL-STD-461D limits when plugged directly into 115 VAC / 60 Hz power. However, when the EUT is plugged into a Tripplite® Isobar Model IB-4 noise filter/transient voltage surge suppresser the radiated emissions did not exceed the MIL-STD-461D limits. ASC/ENAI, Wright-Patterson AFB certified the EUT for use in aeromedical evacuation system only on large-bodied U.S. Air Force aircraft while plugged into a Tripplite® Isobar Model IB-4, and operating from 115 VAC / 60 Hz power.

THERMAL/HUMIDITY ENVIRONMENTAL CONDITIONS

The EUT operated satisfactorily only during cold and humidity operation testing. During the hot operation test, the EUT operated in excess of the 10% of the preset water temperature. Therefore, modified hot operation tests at 35.0°C (95°F), 32.2°C (90°F), and 29.5°C (85°F) were conducted. The EUT operated in excess of the 10% of the preset water temperature during the 35.0°C and 32.2°C hot operation tests. During the 29.5°C hot operation test, the EUT operated within 10% of baseline readings.

HYPOBARIC CONDITIONS

1. Cabin Pressure/Altitude: The EUT operated satisfactorily during hypobaric testing.
2. Rapid Decompression: The EUT operated satisfactorily following each decompression.

AIRBORNE PERFORMANCE

The inflight evaluation of the EUT was performed on C-9 and C-141 aeromedical evacuation missions. The EUT was secured to the Neonatal/Pediatric ECMO Patient Transport Cart as one of the components of the Neonatal/Pediatric ECMO system. Evaluation confirmed that the unit would operate successfully during all phases of flight. The water temperature recorded was between 37.0°- 37.6° C. Evaluation confirmed that the unit would operate successfully during all phases of flight.

SUMMARY

Aeromedical Research found the Seabrook Model SMS-3000 ECMO-Temp Blood Warming Unit to be conditionally acceptable for use on large bodied U.S. Air Force aeromedical evacuation aircraft such as the C-9, C-130, C-141, etc. Its operation was within expected parameters when subjected to vibration, electromagnetic interference (EMI), cold and humid environmental extremes, simulated cabin altitudes, and did not produce a hazard to patient or crew during rapid decompression. Since the EUT operated within expected parameters during the airborne performance phases of testing it is deemed conditionally acceptable for use. The following requirements apply:

- a. Set up and operated by ECMO team members
- b. Must be plugged into a Tripplite® Isobar Model IB-4 noise filter and transient voltage surge suppresser
- c. Positioned and secured to the neonatal/pediatric ECMO transport cart
- d. The setpoint temperature must be adjusted if the ambient temperature at the enplaning or deplaning station exceeds 29.5°C (85°F).

REFERENCES

1. National Fire Protection Agency (NFPA) 99, Health Care Facilities Code
2. AFI 41-203, Electrical Shock Hazards
3. AFI 41-201, Equipment Management in Hospitals
4. MIL-STD 1472, Human Engineering Design Criteria for Military Systems, Equipment, and Facilities.
5. Emergency Care Research Institute (ECRI)
6. MIL-STD 810E, Environmental Test Methods and Engineering Guidelines.
7. MIL-STD 461D, Electromagnetic Emission and Susceptibility Requirements for the Control of Electromagnetic Interference.
8. MIL-STD-462 D, Measurement of EMI Characteristics.
9. Seabrook Medical Systems, Inc., Seabrook Model SMS-3000, Product Manual.
10. Aeromedical Research Procedures Guide, Internal Operating Instruction, Systems Research Branch, Armstrong Laboratory.

APPENDIX
MANUFACTURER'S SPECIFICATIONS OF
SEABROOK MEDICAL SYSTEMS, INC.
ECMO-TEMP BLOOD WARMING UNIT,
MODEL SMS-3000

SPECIFICATIONS

Physical

Size	9.75 in. H. x 14 in. W. x 11 in. D.
Weight	24 lbs (Dry)
Hose Length	48 inches
Couplings	Quick-Connect
Case Material	Modified Polyphenylene Oxide Plastic

Electrical System

Voltage	115V AC / 60 Hz
Current	4.25 Amp
Circuit Breaker	7 Amp
Power Cord	3 Conductor, 16 Awg, 8' Long
Leakage Current	Under 100 Microamperes

Circulating System

Reservoir Capacity	3 Quarts
Reservoir Fluid	Sterile Distilled Water
Fill Cap	Vented
Flow Rate	2 to 3 GPM (through heat exchanger)
Maximum Pressure	8.2 PSI

Control System

Type	Microprocessor-based, Digital
Accuracy	$\pm 0.1^{\circ}\text{C}$
Self-Calibrating	120 Second Intervals
Setpoint Display	7 Segment, 3 Digits
Water Temp. Display	7 Segment, 3 Digits
Blood Temp. Display	7 Segment, 3 Digits
Display Range(Water)	$5.0^{\circ} - 50.0^{\circ}\text{C}$
Display Range (Blood)	$30.0^{\circ} - 45.0^{\circ}\text{C}$

Heating System

Setpoint Range	$35.0^{\circ} - 40.0^{\circ}\text{C}$
Heating Element	300 Watts, Cartridge Type

Safety System

Over Setpoint Alarm (Blood)	0.3°C Above Setpoint
Over Setpoint Alarm (Water)	1°C Above Setpoint
Under Setpoint Alarm (Blood)	0.3°C Below Setpoint
Under Setpoint Alarm (Water)	1°C Below Setpoint
High Limit Alarm	42°C
Back-up High Limit Alarm	$43.0^{\circ} - 47^{\circ}\text{C}$
Add Water Alarm	Activates at "ADD" Mark on Reservoir

Operational Temperature

When the EUT was tested by Underwriters Laboratories, the testing conditions were at an ambient (room) temperature of 25°C (77°F).