

Thermal Angel®

Blood and IV Fluid Infusion Warmer



Summary of Safety and Effectiveness for TA-200 07/13/2004

Purpose:

This report provides a summary of the efforts taken to assure the safety and effectiveness of the Thermal Angel TA-200.

Background:

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 TA-200 is designed to accommodate prehospital and out-patient environments. For portability, convenience, and patient safety, the TA-200 is designed to operate from a 12VDC power source and is disposable after single patient use. The Battery Sets (TA-BCE, TA-CC, TA-CAC and TA-CDC) are reusable.

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 with a fully charged TA-BCE Battery.

The TA-200 is designed by Estill Medical Technologies, Inc, Dallas, TX, and manufactured at OptoCircuits, Ltd., Bangalore, India, under 21 CFR part 820 *Current Good Manufacturing Practices* (Quality System Requirements) and BSR/ISO/ASQ Q9001-2000 regulations.

Summary:

The efforts taken to assure safety and effectiveness fall into two major categories, Design and Manufacturing. The following paragraphs detail each category.

Design Related Summary:

- **Independent Failsafe**
The TA-200 temperature control circuitry employs an independent failsafe circuit, which has the capability to completely disable the unit in the event of an over-temperature condition.
- **Biocompatibility**
The TA-200 fluid path is constructed of 316L grade stainless steel. A polycarbonate coupling attaches two pieces of stainless steel, cemented with biocompatible, M-121HP adhesive from Loctite.ⁱ The polycarbonate coupling is the same material found in readily available luer fittings. A glass encased sensor is mounted through the polycarbonate coupling. These components have been evaluated by a clinical toxicologist.ⁱⁱ
- **Hematology**
The TA-200 has been evaluated for degree of hemolysis using pre and post device plasma free hemoglobin levels and hematocrits on separate occasions and at various flow rates.ⁱⁱⁱ
- **Electromagnetic compatibility**
The TA-200 has been tested and found to comply with EN60601-1-2: 1993, *Electromagnetic Compatibility for Medical Electrical Equipment* and 47 CFR, Part 15, Subpart B, Class A.
- **Environmental and Mechanical**
Environmental and mechanical testing was performed at Environmental Test Lab, Raytheon Systems Company, McKinney, TX. The following tests were conducted.
 - Temperature soak: Three hours temperature saturation with various temperature intervals from 0°C to 50°C.
 - Sine and Vibration: 5G peak sine sweep from 10-2000-10Hz at 1 Octave/min. 6 grms random vibration per NavMat P9492 spectrum, 10 minutes/axis.

Estill Medical Technologies, Inc.
4144 N. Central Expwy. Suite 260 Dallas, Texas 75204
(214) 561-6001 Fax: (214) 561-1930 Toll Free: (877) 354-0286 www.thermalangel.com

- Thermal Shock: Precondition at cold temperature, move to preconditioned hot chamber, stabilize hot, move to preconditioned cold chamber, and stabilize cold. Range 0°C-50°C.
- Transportation/Handling: Bounce test of packaged unit, 1 hour/axis, 3 axis.^{iv}

Manufacturing Related Summary:

- **Sterile and Nonpyrogenic Fluid Path**

Thermal Angel (TA-200) 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 on random samples from each lot.

- **Electrical Safety**

Each TA-200 undergoes an electrical isolation test as part of the manufacturing process. The isolation must be greater than $1 \times 10^9 \Omega$ measured from the heater circuit to the stainless steel tube with an applied voltage of 500VDC. This test process meets the isolation test requirements for the UL 2601-1 Standard for Medical Electric Equipment. Additionally, the battery charger is listed with UL as meeting the 2601-1 Standard for Medical Electric Equipment.

- **Effectivity**

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, 3 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.

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Hemoglobin: Thermal Angel TA-200 Hemolysis Test Data (May 7, 2002):

Four separate TA-200 devices were submitted for testing at the JPS Health Network Laboratory within John Peter Smith Hospital in Ft. Worth, Texas. For the first three TA-200 devices, four units of blood were run consecutively and continuously through the operating devices. For the fourth device, only three units of blood were run consecutively and continuously. For each unit of blood, hemoglobin was tested at flow rates near each end of the Thermal Angel TA-200 specification. Low flow was set at 4 ml/min and high flow was set at 150 ml/min minimum.

TA-200 Serial #	Blood Unit #	Pre-Test (mg/dL)	Post-Test (mg/dL)		Difference (mg/dL)		Percent Change (%)	
			Low Flow	High Flow	Low Flow	High Flow	Low Flow	High Flow
M61	0166278	16.5	16.9	17.3	0.4	0.8	2.4	4.8
M61	5458507	17.7	17.7	17.7	0.0	0.0	0.0	0.0
M61	2868260	19.4	18.8	19.6	-0.6	0.2	3.1	1.0
M61	2868504	18.6	18.3	18.4	-0.3	-0.2	1.6	1.1
M63	0166466	16.6	16.8	17.1	0.2	0.5	1.2	3.0
M63	0166258	19.1	19.1	19.0	0.0	-0.1	0.0	0.5
M63	5452841	15.3	16.6	17.1	1.3	1.8	8.5	11.8
M63	0132137	17.9	17.8	18.4	-0.1	0.5	0.6	2.8
M65	2866508	18.5	18.7	18.7	0.2	0.2	1.1	1.1
M65	2866544	17.4	18.0	18.2	0.6	0.8	3.4	4.6
M65	2866468	17.2	17.3	17.2	0.1	0.0	0.6	0.0
M65	2866822	17.6	17.2	18.0	-0.4	0.4	2.3	2.3
M67	0187749	17.4	17.5	17.5	0.1	0.1	0.6	0.6
M67	0132131	17.6	18.0	18.2	0.4	0.6	2.3	3.4
M67	2874204	19.5	19.5	19.6	0.0	0.1	0.0	0.5

**TA-200 Hemoglobin Test Results Under Continuous Blood Flow Conditions
[Low Flow = 4 ml/min, High Flow = 150 ml/min Minimum]**

The difference values in the table represent a simple subtraction of pre-test hemoglobin values from post-test hemoglobin values. The percent change values in the table represent the ratio of difference values to pre-test values. These are expressed in the table as an absolute percentage of hemoglobin change from pre-test to post-test.

These results for continuous flow conditions demonstrate only very small changes in hemoglobin.

Hematocrit: Thermal Angel TA-200 Hemolysis Test Data (May 7, 2002):

Four separate TA-200 devices were submitted for testing at the JPS Health Network Laboratory within John Peter Smith Hospital in Ft. Worth, Texas. For the first three TA-200 devices, four units of blood were run consecutively and continuously through the operating devices. For the fourth device, only three units of blood were run consecutively and continuously. For each unit of blood, hematocrit was tested at flow rates near each end of the Thermal Angel TA-200 specification. Low flow was set at 4 ml/min and high flow was set at 150 ml/min minimum.

TA-200 Serial #	Blood Unit #	Pre-Test (%)	Post-Test (%)		Difference (%)		Percent Change (%)	
			Low Flow	High Flow	Low Flow	High Flow	Low Flow	High Flow
M61	0166278	54.2	55.5	56.9	1.3	2.7	2.4	5.0
M61	5458507	59.4	58.7	59.0	-0.7	-0.4	1.2	0.7
M61	2868260	63.3	61.9	63.2	-1.4	-0.1	2.2	0.2
M61	2868504	59.3	58.4	58.9	-0.9	-0.4	1.5	0.7
M63	0166466	54.6	55.5	56.7	0.9	2.1	1.6	3.8
M63	0166258	61.2	62.2	61.5	1.0	0.3	1.6	0.5
M63	5452841	49.7	54.9	56.7	5.2	7.0	10.5	14.1
M63	0132137	58.9	58.9	60.9	0.0	2.0	0.0	3.4
M65	2866508	61.5	61.0	60.6	-0.5	-0.9	0.8	1.5
M65	2866544	54.7	56.3	56.5	1.6	1.8	2.9	3.3
M65	2866468	55.3	55.4	55.8	0.1	0.5	0.2	0.9
M65	2866822	58.7	58.8	61.4	0.1	2.7	0.2	4.6
M67	0187749	57.9	57.9	58.1	0.0	0.2	0.0	0.3
M67	0132131	56.7	58.3	59.0	1.6	2.3	2.8	4.1
M67	2874204	64.9	65.6	65.6	0.7	0.7	1.1	1.1

**TA-200 Hematocrit Test Results Under Continuous Blood Flow Conditions
[Low Flow = 4 ml/min, High Flow = 150 ml/min Minimum]**

The difference values in the table represent a simple subtraction of pre-test hematocrit values from post-test hematocrit values. The percent change values in the table represent the ratio of difference values to pre-test values. These are expressed in the table as an absolute percentage of hematocrit change from pre-test to post-test.

These results for continuous flow conditions demonstrate only very small changes in hematocrit.

Hemoglobin and Hematocrit: Thermal Angel TA-200 Hemolysis Test Data (May 7, 2002):

Four separate TA-200 devices were submitted for testing at the JPS Health Network Laboratory within John Peter Smith Hospital in Ft. Worth, Texas. For the first three TA-200 devices, four units of blood were run consecutively and continuously through the operating devices. For the fourth device, only three units of blood were run consecutively and continuously. For each unit of blood, hemoglobin and hematocrit were tested at flow rates near each end of the Thermal Angel TA-200 specification. Low flow was set at 4 ml/min and high flow was set at 150 ml/min minimum.

The hemoglobin and hematocrit test results were then statistically examined. The standard deviation (σ) of pre-test and post-test data was used to determine a statistically valid range of hemoglobin values (i.e., mean \pm 3 σ).

TA-200 Serial No.	# Blood Units	Pre-Test Range (mg/dL)	Post-Test Range Low Flow (mg/dL)	Post-Test Range High Flow (mg/dL)
M61	4	18.1 +/- 3.7	17.9 +/- 2.5	18.3 +/- 1.3
M63	4	17.2 +/- 4.9	17.6 +/- 3.4	17.9 +/- 2.4
M65	4	17.7 +/- 1.7	17.8 +/- 2.1	18.0 +/- 1.0
M67	3	18.2 +/- 3.5	18.3 +/- 3.1	18.4 +/- 0.9

**Statistical Analysis of TA-200 Hemoglobin Test Results
(Mean \pm 3 Standard Deviations)
[Low Flow = 4 ml/min, High Flow = 150 ml/min Minimum]**

TA-200 Serial No.	# Blood Units	Pre-Test Range (%)	Post-Test Range Low Flow (%)	Post-Test Range High Flow (%)
M61	4	59.1 +/- 11.2	58.6 +/- 7.9	59.5 +/- 4.5
M63	4	56.1 +/- 15.2	57.9 +/- 10.1	59.0 +/- 8.7
M65	4	57.6 +/- 9.5	57.9 +/- 7.6	58.6 +/- 4.7
M67	3	59.8 +/- 13.3	60.6 +/- 13.0	60.9 +/- 3.3

**Statistical Analysis of TA-200 Hematocrit Test Results
(Mean \pm 3 Standard Deviations)
[Low Flow = 4 ml/min, High Flow = 150 ml/min Minimum]**

By assuming that all four TA-200 devices are essentially identical, test results for all 15 blood units were then combined for a summary analysis of hemoglobin and hematocrit.

Hemolysis Test Parameter	Pre-Test Range (mg/dL)(%)	Post-Test Range Low Flow (mg/dL)(%)	Post-Test Range High Flow (mg/dL)(%)
Hemoglobin	17.8 +/- 3.4	17.9 +/- 2.6	18.1 +/- 2.5
Hematocrit	58.0 +/- 11.8	58.6 +/- 9.1	59.4 +/- 8.4

**Summary Statistical Analysis of TA-200 Hemolysis Test Results
(Mean \pm 3 Standard Deviations)
[Low Flow = 4 ml/min, High Flow = 150 ml/min Minimum]**

Statistically insignificant changes in both hemoglobin and hematocrit demonstrate that the Thermal Angel TA-200 does not cause hemolysis under specified operating conditions.

ⁱ TA-200 Device Master Record
ⁱⁱ Greene Shepherd, RPh, PhD, "Biocompatibility of the Thermal Angel Fluid Warmer," 1998
ⁱⁱⁱ 1999, 2000, 2000, 2002; Most recent sampling included. Hemoglobin HGB (Sodium Lauryl Sulfate method). Performed using supernate of specimen after centrifugation. Hematocrit HCT (ratio of total RBC volume to whole blood utilizing cumulative pulse height detection).
^{iv} Report #8L0516EUS; #9I0301EEU with KTL Dallas, Inc, Lewisville, TX