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REPORT ON MEASUREMENTS CONDUCTED FOR

REPORT NUMBER: 565T

Free Air Thermal Testing
Per IEC 60601-2-37,
Excessive Temperatures
Sect 42.3, a1-2

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PREPARED ON: February 9, 2005

TEST METHODOLOGY REPORT

The following is the test methodology information required by IEC Standard 60601-2-37 [1]. The test methodology used to measure the A-Scan and Pachymeter probes for the Senstech ultrasound system is explained in the following sections.

All measurements were conducted in accordance with IEC Standard 60601-2-37 (International Electrotechnical Commission "Requirements for the Declaration of the Acoustic Output of Medical Diagnostic Ultrasonic Equipment") [1].

This report is not to be construed as either an actual or implicit endorsement of the device measured or as an indication of the suitability or safety of the device.

James Gessert

1.0 MEASUREMENT INSTRUMENTATION

The ambient temperature measurements were made with a Cole-Parmer Thermistor Thermometer model 8402-20, s/n 2292. One thermistor, model 8430-00 s/n 2292-1 was used. The system has a stated resolution of 0.1°C, and an accuracy of +/-0.3°C. The instrumentation has calibration traceable to the NIST. The Probe tip temperature measurements were made with a Cole Parmer thermocouple (0.005" Diameter) and a Thermocouple Data Acquisition interface (National Instruments, TBX-68T). This system has a resolution of .001°C.

2.0 MEASUREMENT SET UP AND PROCEDURE

IEC 60601-2-37 specifies that the device is to be tested in two test conditions; one is simulated use and the other is free air as specified 42.3 of the standard [1]. Because of extremely low acoustic power output test results, it was decided to evaluate the free air test for any temperature increases before proceeding with the Simulated Use testing.

The Thermocouple Set up for both the Free Air and Simulated Use Condition tests are as follows: The National Instruments Thermocouple sensor was attached directly to the face of the probe. A computer was used to collect the data from this device. A second Cole Parmer Thermistor was suspended in the air to track the ambient air temperature.

2.1 Free Air Test Procedure

1. Record Probe Serial Number: _____
2. Attach the Thermocouple to the probe tip.
3. Record Ambient Temperature: _____ °C (Verify Ambient Temperature is 23°C ± 3°C)
4. Turn on the unit under test and begin the probe operation using the standard operational settings.
5. Lower the probe and Thermocouple into a large cardboard box.
6. Run the Thermocouple Data acquisition system (Use Lab View Program: Temp_Test 9_Readout and Save.exe)
7. Conduct Test for 30 minutes.
8. Record Final Probe Tip Temperature: _____°C
9. Collect Data for 30 minutes.
10. Record tip temperature after 30 minutes.

3.0 RESULTS

3.1 Free Air Test

A-Mode Probe s/n	*Ambient Air Temp*	*Final Tip Temp*
04I402	23.1 °C	23.0 °C
04I403	21.9 °C	22.0 °C
04I446	22.3 °C	22.1 °C

20 MHz Pachymeter Probe s/n	*Ambient Air Temp*	*Final Tip Temp*
22276	22.0 °C	22.0 °C
22277	22.7 °C	22.4 °C
22346	22.1 °C	22.0 °C

4.0 CONCLUSIONS

The Free Air tests performed were conclusive. All probes performed well within the requirements; the device very clearly does not exceed the worst-case condition limits specified in the standard. The temperature trend was actually down for all probes since the test location was a few degrees cooler than the probe storage location and there was no measureable heating of the probes when driven by the ultrasound system. Since the TI values measured were exceptionally low (average value 0.00018 for Pachymetry probes and 0.00002 for A-Mode probes, Sonora Medical Systems Test Report #565) and the free air tests demonstrated no temperature rise at all, simulated use tests were not run. A TI value of 1.0 is predicted to raise the temperature of a specific tissue model 1 degree C. The measured values being nearly zero, predict a tissue temperature rise very near zero.

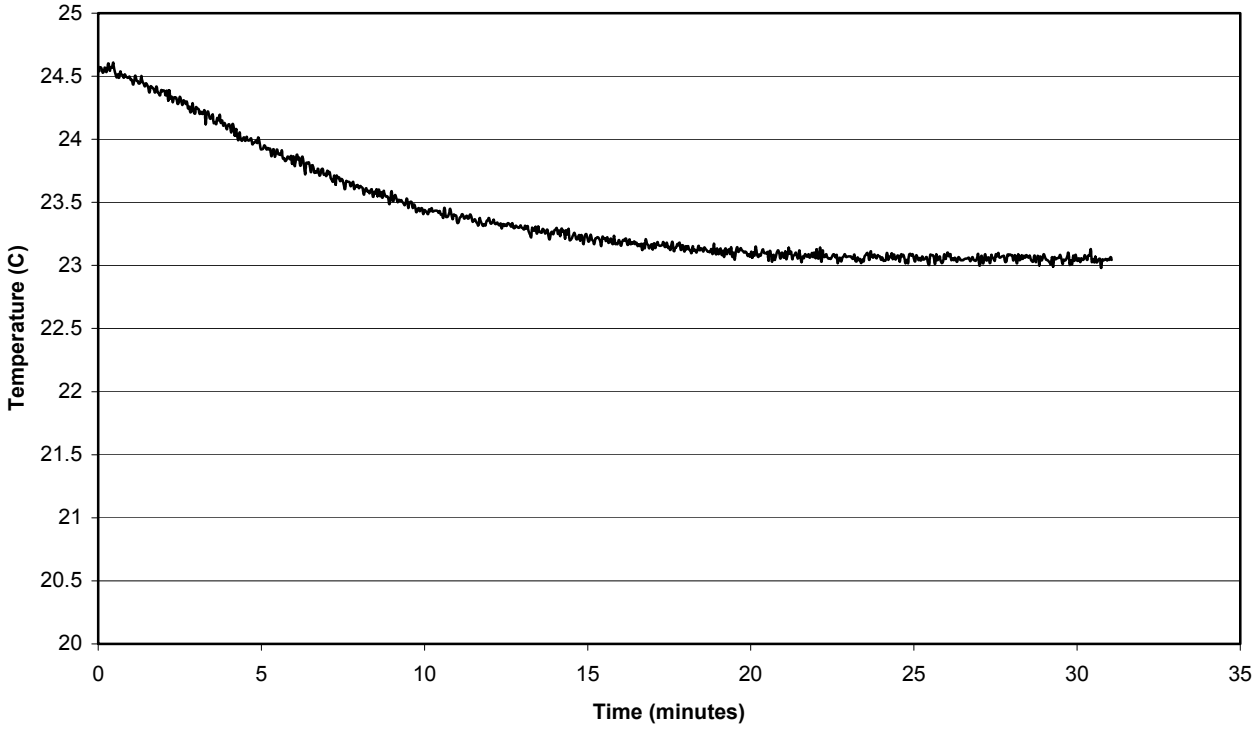
5.0 REFERENCES

1. "Medical electrical equipment-Part 2-37: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment", International Electrotechnical Commission (IEC) Reference number IEC 60601-2-37:2001(E).

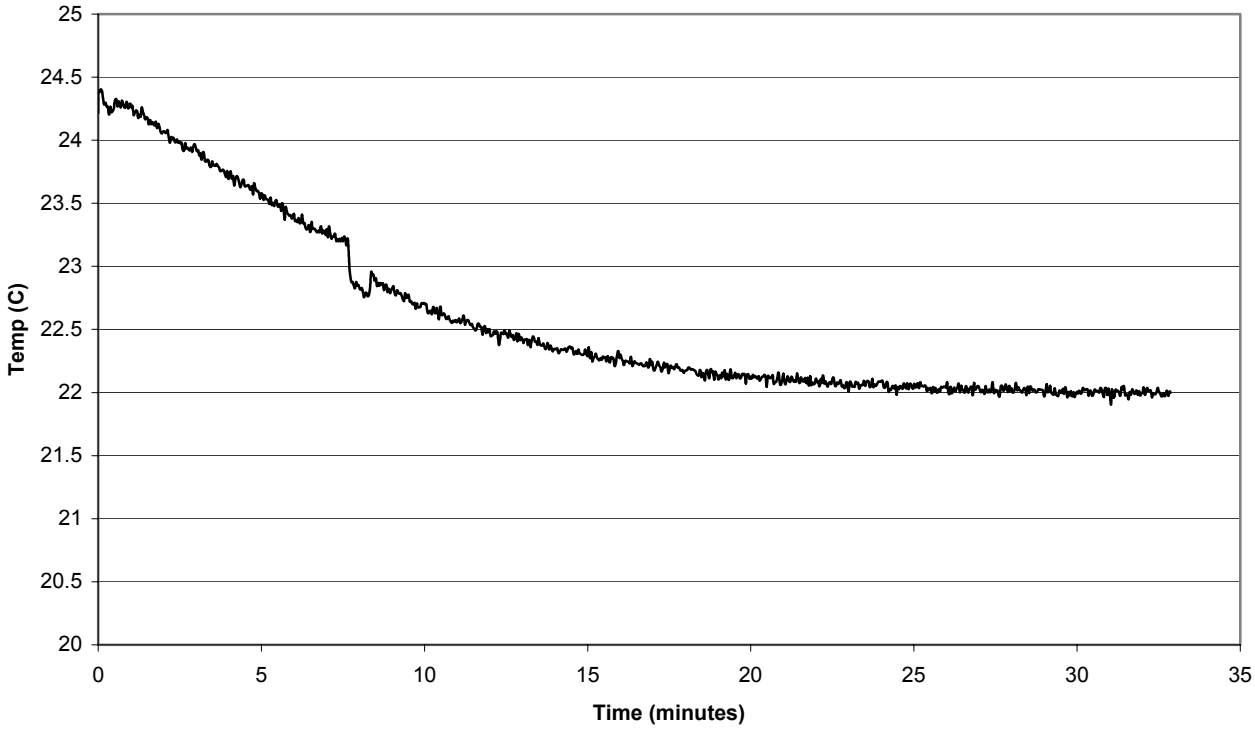
6.0 PLOTS

Free Air Test Data Plots

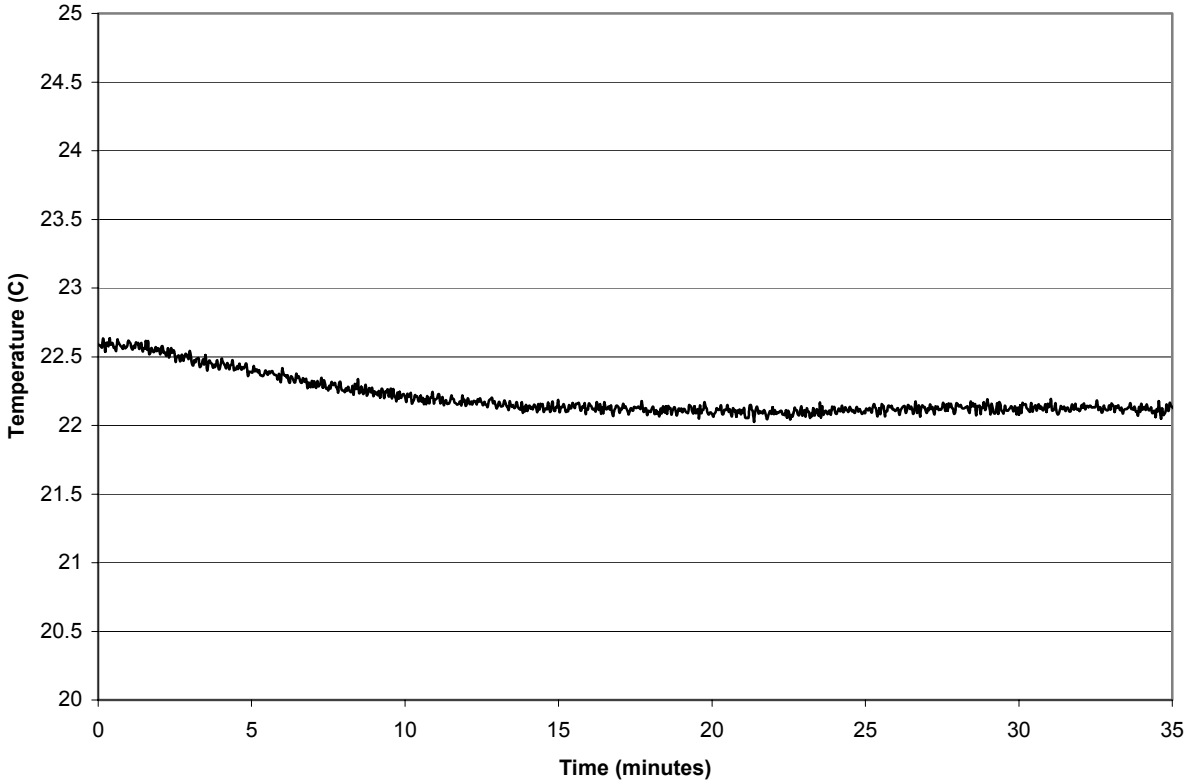
A-Scan Probe s/n 04I402



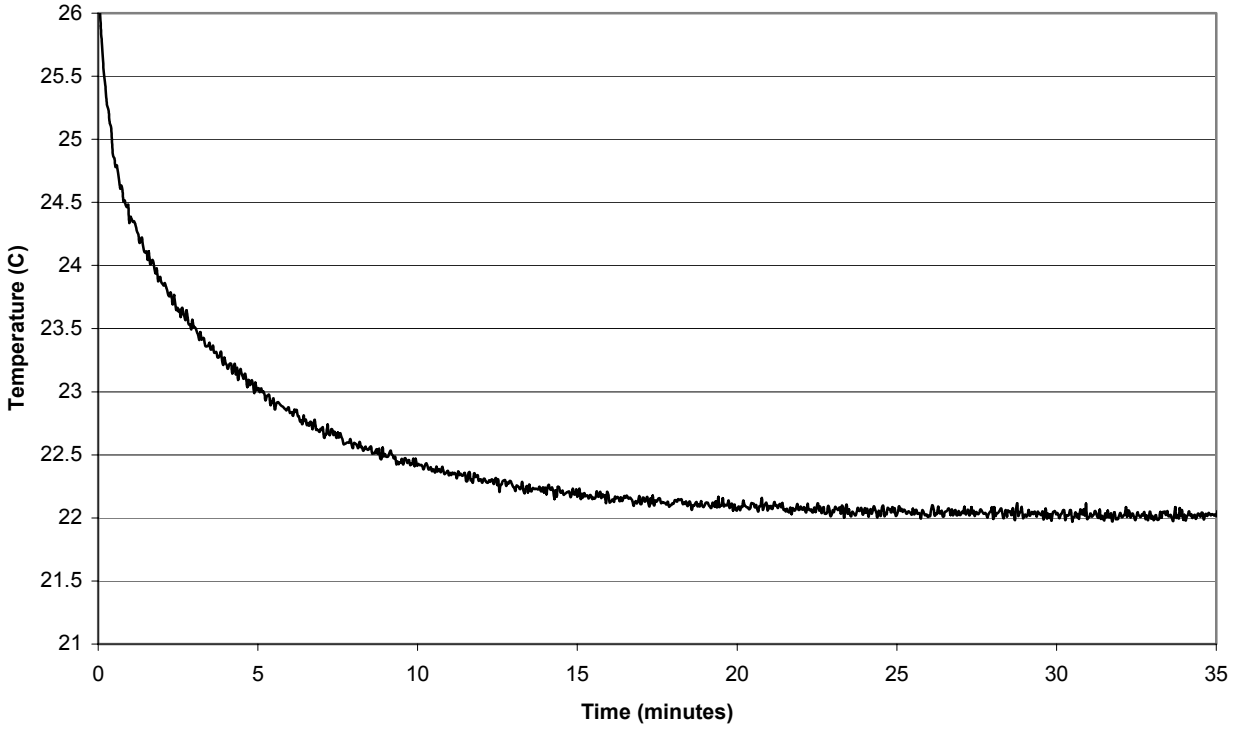
A-Scan Probe s/n 04I0403



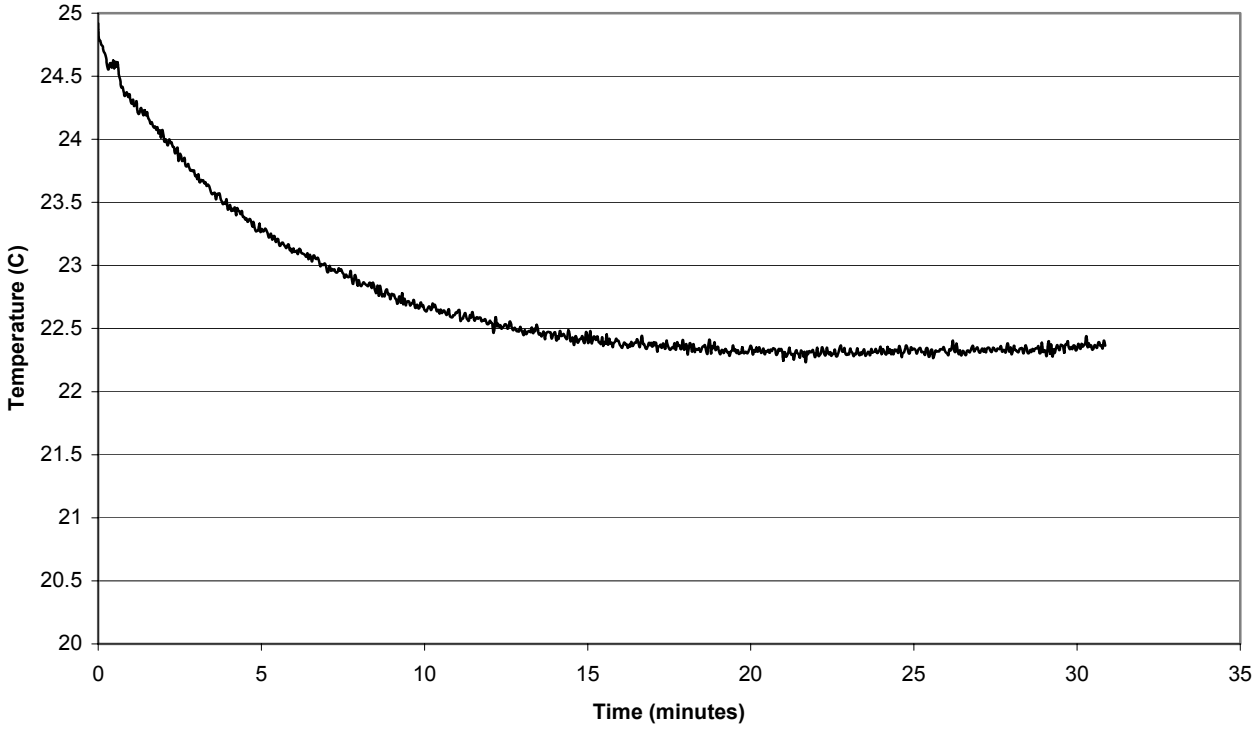
A-Scan Probe s/n04l446



Pachymetry Probe s/n22276



Pachymetry Probe s/n22277



Free Air Test
Pachymetry Probe s/n22346