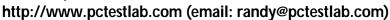
PCTEST ENGINEERING LABORATORY, INC.



6660 - B Dobbin Road Columbia, MD 21045 USA Telephone 410.290.6652 / Fax 410.290.6654





CERTIFICATE OF COMPLIANCE (SAR EVALUATION)

APPLICANT NAME & ADDRESS:

Cardiac Pacemakers Inc. (d/b/a/ "Guidant") 4100 Harmine Avenue North St. Paul, MN 55112 USA **DATE & LOCATION OF TESTING:**

Dates of Tests: September 18-19, 2003 Test Report S/N: SAR.230917459.ESC Test Site: PCTEST Lab, Columbia, MD USA

FCC ID: ESCCRMH21004

APPLICANT NAME: Cardiac Pacemakers Inc. (d/b/a "Guidant")

EUT Type: Cardiac Resynchronization Therapy Defibrillator (CRT-D)

Tx/Rx Frequency: 914 MHz

Max. RF Output Power:

Max. SAR Measurement:

Trade Name/Model(s):

-0.8 dBm (0.8 mW) Conducted
0.08 W/kg averaged over 1 gm
H215, CONTAK RENEWAL 3 RF

FCC Rule Part(s): §2.1093; FCC/OET Bulletin 65 Supplement C (July 01)

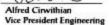
Application Type: Certification

Test Device Serial No.: Identical Prototype [S/N: 926302, 926303, 926304]
Additional Models: H210, H217, H219, H250, H255, H257, H259

This wireless portable device has been shown to be capable of compliance for localized specific absorption rate (SAR) for uncontrolled environment/general population exposure limits specified in ANSI/IEEE Std. C95.1-1992 and has predominantly followed the measurement procedures specified in FCC/OET Bulletin 65 Supplement C (2001) and IEEE Std. P1528 D1.2 (April 2003).

I attest to the accuracy of data. All measurements reported herein were performed by me or were made under my supervision and are correct to the best of my knowledge and belief. I assume full responsibility for the completeness of these measurements and vouch for the qualifications of all persons taking them.

PCTEST certifies that no party to this application has been denied the FCC benefits pursuant to Section 5301 of the Anti-Drug Abuse Act of 1988, 21 U.S.C. 862.





PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		GUIDANT	Reviewed by: Quality Manager
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	FCC ID:	Page 1 of 22
SAR.230917459.ESC	September 18-19, 2003	Therapy Defibrillator (CRT-D)	ESCCRMH21004	



TABLE OF CONTENTS

1.	INTRODUCTION / SAR DEFINITION
2.	SAR MEASUREMENT SETUP4
3.	ALIDX-500 E-FIELD PROBE SYSTEM
4.	PROBE CALIBRATION PROCESS
5.	PHANTOM & EQUIVALENT TISSUES
6.	TEST SYSTEM SPECIFICATIONS8
7.	DOSIMETRIC ASSESSMENT & PHANTOM SPECS9
8.	TEST CONFIGURATION POSITION
9.	ANSI/IEEE C95.1 - 1992 RF EXPOSURE LIMITS
10.	MEASUREMENT UNCERTAINTIES
11.	SAR TEST DATA SUMMARY
12.	SAR TEST EQUIPMENT
13.	CONCLUSION
14.	REFERENCES
EXH	HIBIT A. SYSTEM VERIFICATION17
EXH	IIBIT A. SAR DATA SUMMARY

PCTESTÔ SAR TEST REPORT	BBIBANI		Reviewed by: Quality Manager	
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	FCC ID:	Page 2 of 22
SAR.230917459.ESC	September 18-19, 2003	Therapy Defibrillator (CRT-D)	ESCCRMH21004	



INTRODUCTION / SAR DEFINITION

The FCC has adopted the guidelines for evaluating the environmental effects of radiofrequency radiation in ET Docket 93-62 on Aug. 6, 1996 to protect the public and workers from the potential hazards of RF emissions due to FCC-regulated portable devices.[1]

The safety limits used for the environmental evaluation measurements are based on the criteria published by the American National Standards Institute (ANSI) for localized specific absorption rate (SAR) in *IEEE/ANSI C95.1-1992 Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3 kHz to 300 GHz.* (c) 1992 by the Institute of Electrical and Electronics Engineers, Inc., New York, New York 10017.[2] The measurement procedure described in *IEEE/ANSI C95.3-1992 Recommended Practice for the Measurement of Potentially Hazardous Electromagnetic Fields - RF and Microwave*[3] is used for guidance in measuring SAR due to the RF radiation exposure from the Equipment Under Test (EUT). These criteria for SAR evaluation are similar to those recommended by the National Council on Radiation Protection and Measurements (NCRP) in *Biological Effects and Exposure Criteria for Radiofrequency Electromagnetic Fields*," NCRP Report No. 86 (c) NCRP, 1986, Bethesda, MD 20814.[6] SAR is a measure of the rate of energy absorption due to exposure to an RF transmitting source. SAR values have been related to threshold levels for potential biological hazards.

SAR Definition

Specific Absorption Rate (SAR) is defined as the time derivative (rate) of the incremental energy (dU) absorbed by (dissipated in) an incremental mass (dm) contained in a volume element (dV) of a given density (r). It is also defined as the rate of RF energy absorption per unit mass at a point in an absorbing body (see Fig. 1.1).

Figure 1.1 SAR Mathematical Equation

SAR is expressed in units of Watts per Kilogram (W/kg).

SAR = $s E^2/r$ where: s = conductivity of the tissue-simulant material (S/m) r = mass density of the tissue-simulant material (kg/m³) E = Total RMS electric field strength (V/m)

NOTE: The primary factors that control rate of energy absorption were found to be the wavelength of the incident field in relations to the dimensions and geometry of the irradiated organism, the orientation of the organism in relation to the polarity of field vectors, the presence of reflecting surfaces, and whether conductive contact is made by the organism with a ground plane.[6]

PCTESTÔ SAR TEST REPORT	BBIBANI		Reviewed by: Quality Manager	
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	FCC ID:	Page 3 of 22
SAR.230917459.ESC	September 18-19, 2003	Therapy Defibrillator (CRT-D)	ESCCRMH21004	



2. SAR MEASUREMENT SETUP

Robotic System

Measurements are performed using the ALIDX-500 automated dosimetric assessment system. The ALIDX-500 is made by IDX Robotics, Inc. (IDX) in the United States and consists of high precision robotics system (CRS), robot controller, Pentium 4 computer, near-field probe, probe alignment sensor, and the Left and Right SAM phantoms containing the head/brain equivalent tissue, and the flat phantoms for body/muscle equivalent. The robot is a six-axis industrial robot performing precise movements to position the probe to the location (points) of maximum electromagnetic field (EMF) (see Fig. 2.1).

System Hardware

The Robot table consists of the power supply, robot controller, safety computer, teach pendant (Joystick), six-axis robot arm, and the probe. The cell controller consists of DELL Dimension 4300 Pentium-4 1.6 GHz computer with Windows 2000 system and SAR Measurement software, National Instruments analog card, monitor, keyboard, and mouse. The robot controller is connected to the cell controller to communicate between the two computers. The probe data is connected to the cell controller via data acquisition cables.

System Electronics

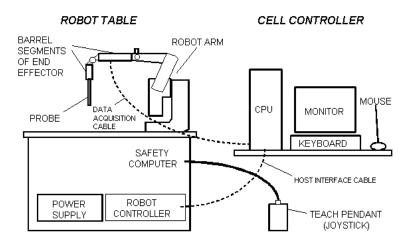


Figure 2.1 SAR Measurement System Setup

When the Robot is in the home position, the Y-axis of the coordinate system parallels the line of intersection between the tabletop and the long axis of the Robot's Large Shoulder. The Teach Pendant may be used to establish the X,Y coordinate directions by depressing the 0-X and 0-Y MOTOR/AXIS switches while in axis mode.

The robot is first taught to position the probe sensor following a specific pattern of points. In the first sweep the sensor enclosure touches the inside of the phantom head. The SAR is measured on a defined grid of points that are concentrated on the surface of the head closest to the antenna of the transmitting device (EUT).

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		Reviewed by: Quality Manager	
SAR Filename: SAR.230917459.ESC	Test Dates: September 18-19, 2003	EUT Type: Cardiac Resynchronization Therapy Defibrillator (CRT-D)	FCC ID: ESCCRMH21004	Page 4 of 22



ALIDX-500 E-FIELD PROBE SYSTEM

Probe Measurement System



Fig 3.1 IDX System

The near-field probe is an implantable isotropic E-field probe that measures the voltages proportional to the $|E|^2$ (electric) or $|H|^2$ (magnetic) fields. The probe is enclosed in a hollow glass protective cylinder 9-mm. outer diameter, 0.5 mm. thickness and 30 cm. in length. The E-probe contains three electrically small array of orthogonal dipoles strategically placed to provide greater accuracy and to compensate for near-field spatial gradients. The probe contains diodes that are placed over the gap of the dipoles to improve RF detection. The electrical signal detected by each diode is amplified by three DC amplifiers and are contained in a shielded container in the robot end effector so its performance is not affected by the presence of incident electromagnetic fields (see Fig. 3.1).

Probe Specifications

Frequency Range: 10 kHz - 6.0 GHz

Calibration: In air from 10 MHz to 6.0 GHz

In brain and muscle simulating tissue at Frequencies from 835

up to 5800MHz

Sensitivity: 3.5 mV/mW/cm² (air – typical)

DC Resistance: 300 kohm Isotropic Response: 0.25 dB

Dynamic Range: 10 mW/kg – 100 W/kg

Resistance to Pull: 25 N
Probe Length: 290 mm
Probe Tip Material: Glass
Probe Tip Length: 40 mm
Probe Tip Diameter: 7 ± 0.2 mm

Application: SAR Dosimetry Testing

HAC (Hearing Aid Compatibility)
Compliance tests of mobile phones

Str. Et o

Figure 3.2 Triangular Probe Configuration

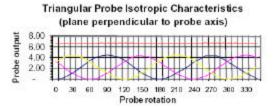


Figure 3.3
Probe Characteristics

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		BUIDANT	Reviewed by: Quality Manager
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	FCC ID:	Page 5 of 22
SAR.230917459.ESC	September 18-19, 2003	Therapy Defibrillator (CRT-D)	ESCCRMH21004	



4. PROBE CALIBRATION PROCESS

Dosimetric Assessment Procedure

Each E-Probe/Probe amplifier combination has unique calibration parameters. A TEM calibration procedure is conducted to determine the proper amplifier settings to enter in the probe parameters. The amplifier settings are determined for a given frequency by subjecting the Probe to a known E-field density (1mW/cm²) using an RF Signal generator, TEM cell, and RF Power Meter. The SAR measurement software is used for Probe calibration.

Free Space Assessment

The free space E-field from amplified probe outputs is determined in a test chamber. This calibration can be performed in a TEM cell if the frequency is below 1 GHz and in a waveguide or some other methodologies above 1 GHz for free space. For the free space calibration, we place the probe in the volumetric center of the cavity and at the proper orientation with the field. We then rotate the probe 360 degrees until the three channels show the maximum reading. The power density readings equates to 1mW/cm².

Temperature Assessment

E-field temperature correlation calibration is performed in a flat phantom filled with the appropriate simulated brain tissue. The measured free space E-field in the medium correlates to temperature rise in a dielectric medium. For temperature correlation calibration a RF transparent thermistor-based temperature probe is used in conjunction with the E-field probe.

$$\mathsf{SAR} = C \frac{\Delta T}{\Delta t}$$

where:

 Δt = exposure time (30 seconds),

C = heat capacity of tissue (brain or muscle),

 ΔT = temperature increase due to RF exposure.

SAR is proportional to $\Delta T/\Delta t$, the initial rate of tissue heating, before thermal diffusion takes place. Now it's possible to quantify the electric field in the simulated tissue by equating the thermally derived SAR to the E- field;

$$SAR = \frac{\left|E\right|^2 \cdot \mathbf{s}}{r}$$

where:

 σ = simulated tissue conductivity,

 ρ = Tissue density (1.25 g/cm³ for brain tissue)

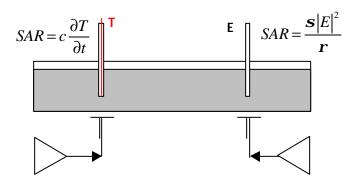


Figure 4.1 Temperature Assessment Test Configuration

PCTESTÔ SAR TEST REPORT	BBIBANI		Reviewed by: Quality Manager	
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	FCC ID:	Page 6 of 22
SAR.230917459.ESC	September 18-19, 2003	Therapy Defibrillator (CRT-D)	ESCCRMH21004	



PHANTOM & EQUIVALENT TISSUES



5.1 MICS Torso Phantom

The phantom for SAR assessment testing for medical implants is a low-loss dielectric shell, with shape and dimensions derived from CFR 47 Part 95.635. This consists of a cylinder with a size of 30 cm by 76 cm with a sidewall thickness of 0.635 cm (see Fig. 7.1). The liquid depth is maintained at a minimum depth of 15cm to minimize reflections from the upper surface.

Brain & Muscle Simulating Mixture Characterization

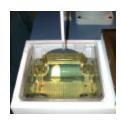


Figure 5.3 Body/Muscle Simulated Tissue

The brain and muscle mixtures consist of a viscous gel using hydroxyethylcellullose (HEC) gelling agent and saline solution (see Table 5.1). Preservation with a bactericide is added and visual inspection is made to make sure air bubbles are not trapped during the mixing process. The mixture is calibrated to obtain proper dielectric constant (permittivity) and conductivity of the desired tissue. The head tissue dielectric parameters recommended by the IEEE SCC-34/SC-2 have been incorporated in the following table. Other head and body tissue parameters that have not been specified in P1528 are derived from the issue dielectric parameters computed from the 4-Cole-Cole equations. The mixture characterizations used for the brain and muscle tissue simulating liquids are according to the data by C. Gabriel and G. Hartsgrove [9].(see Table 5.1)

Ingredients		Frequency (MHz)									
(% by weight)	4	450		835		915		1900		2450	
Tissue Type	Head	Body	Head	Body	Head	Body	Head	Body	Head	Body	
Water	38.56	51.16	41.45	52.4	41.05	56.0	54.9	40.4	62.7	73.2	
Salt (NaCl)	3.95	1.49	1.45	1.4	1.35	0.76	0.18	0.5	0.5	0.04	
Sugar	56.32	46.78	56.0	45.0	56.5	41.76	0.0	58.0	0.0	0,0	
HEC	0.98	0.52	1.0	1.0	1.0	1.21	0.0	1.0	0,0	0.0	
Bactericide	0.19	0.05	0.1	0.1	0.1	0.27	0.0	0.1	0.0	0.0	
Triton X-100	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	36.8	0.0	
DGBE	0.0	0.0	0.0	0.0	0.0	0.0	44.92	0,0	0.0	26.7	

Table 5.1
Composition of the Brain & Muscle Tissue Equivalent Matter

Device Holder



Figure 5.4
Device

In combination with the SAM Phantom, the EUT Holder (see Fig. 5.4) enables the rotation of the mounted transmitter in spherical coordinates whereby the rotation point is the ear opening. Device positioning is accurate and repeatable according to the FCC and CENELEC specifications. The device holder can be locked at different phantom locations (left head, right head, flat phantom).

* Note: A simulating human hand is not used due to the complex anatomical and geometrical structure of the hand that may produce infinite number of configurations [8]. To produce the worst-case condition (the hand absorbs antenna output power), the hand is omitted during the tests.

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		BUIDANT	Reviewed by: Quality Manager
SAR Filename: SAR.230917459.ESC	Test Dates: September 18-19, 2003	EUT Type: Cardiac Resynchronization Therapy Defibrillator (CRT-D)	FCC ID: ESCCRMH21004	Page 7 of 22



6. TEST SYSTEM SPECIFICATIONS

Automated Test System Specifications

Positioner

Robot: CRS Robotics, Inc. Robot Model: F3

Repeatability: ± 0.05 mm (0.002 in.)

No. Of axes: 6

Data Acquisition Electronic (DAE) System

Cell Controller

Processor: Pentium 4

Clock Speed: 1.6 GHz

Operating System: Windows 2000TM Professional

Data Card: NI DAQ Card (in CPU)

Data Converter

Software: IDX Flexware

Connecting Lines: Data Acquisition Cable

RS-232 Host Interface Cable

Sampling Rate: 6000 samples/sec



Figure 6.1 ALIDX-500 Test System

E-Field Probes

Model: E-010 S/N: PCT003

Construction: Triangular core absolute encoder system

Frequency: 10 MHz to 6.0 GHz

Phantom

Phantom: MICS Torso Simulator

Shell Material:CC PlexiglassThickness:0.635 cmHeight:76 cmDiameter:30 cm

PCTESTÔ SAR TEST REPORT	BBIBANI		Reviewed by: Quality Manager	
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	FCC ID:	Page 8 of 22
SAR.230917459.ESC	September 18-19, 2003	Therapy Defibrillator (CRT-D)	ESCCRMH21004	



7. DOSIMETRIC ASSESSMENT & PHANTOM SPECS

Measurement Procedure

The measurement procedure consists of the process parameters, probe parameters, EUT product data, and measurement scans (teach points). The measurement procedure is a set of predefined points to be scanned and measured by the probe, DC amplified and processed by the cell controller. The corresponding voltages determined by the electric and magnetic fields are extrapolated to determine peak SAR value.

The SAR Measurement System measures field strength by employing two different types of systematic measurement scans; a coarse scan and a fine scan. Coarse and fine scans measure field strength in a rectangular area within the XY plane (a plane parallel to the top of the Robot Table). The measurement area is divided into a grid of small squares defined by equally spaced grid lines. During an actual measurement process, the probe moves along grid lines systematically recording the field strength at grid line intersections. Typically, after a coarse scan is completed, a fine scan is conducted at the peak field strength value (hot spot) that was measured in the coarse scan. The fine scan has a greater resolution (smaller grid squares) than the coarse scan, and covers only a fraction of the measurement area in the coarse scan.

Medical Implant Communication Service (MICS) Torso Specifications

The phantom for SAR assessment testing for medical implants is a low-loss dielectric shell, with shape and dimensions derived from CFR 47 Part 95.635. This consists of a cylinder with a size of 30 cm by 76 cm with a sidewall thickness of 0.635 cm (see Fig. 7.1). The liquid depth is maintained at a minimum depth of 15cm to minimize reflections from the upper surface.



Figure 7.1 MICS Torso Simulator

PCTESTÔ SAR TEST REPORT	GOIDAIN		Reviewed by: Quality Manager	
SAR Filename: SAR.230917459.ESC	Test Dates: September 18-19, 2003	EUT Type: Cardiac Resynchronization Therapy Defibrillator (CRT-D)	FCC ID: ESCCRMH21004	Page 9 of 22



8. TEST CONFIGURATION POSITION

Medical Implant Test Configurations

Implantable operating configurations are tested inside the MICS torso in a normal use configuration (see Figure 8.1). Body dielectric parameters are used.

In all cases SAR measurements are performed to investigate the worst-case positioning. Worst-case positioning is then documented and used to perform Body SAR testing.

In order for users to be aware of the body-implanted operating requirements for meeting RF exposure compliance, operating instructions and cautions statements must be included in the user's manual.

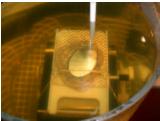


Figure 8.1 Implant Configuration

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		Reviewed by: Quality Manager	
SAR Filename: SAR.230917459.ESC	Test Dates: September 18-19, 2003	EUT Type: Cardiac Resynchronization Therapy Defibrillator (CRT-D)	FCC ID: ESCCRMH21004	Page 10 of 22



9. ANSI/IEEE C95.1 - 1992 RF EXPOSURE LIMITS

Uncontrolled Environment

UNCONTROLLED ENVIRONMENTS are defined as locations where there is the exposure of individuals who have no knowledge or control of their exposure. The general population/uncontrolled exposure limits are applicable to situations in which the general public may be exposed or in which persons who are exposed as a consequence of their employment may not be made fully aware of the potential for exposure or cannot exercise control over their exposure. Members of the general public would come under this category when exposure is not employment-related; for example, in the case of a wireless transmitter that exposes persons in its vicinity.

Controlled Environment

CONTROLLED ENVIRONMENTS are defined as locations where there is exposure that may be incurred by persons who are aware of the potential for exposure, (i.e. as a result of employment or occupation). In general, occupational/controlled exposure limits are applicable to situations in which persons are exposed as a consequence of their employment, who have been made fully aware of the potential for exposure and can exercise control over their exposure. This exposure category is also applicable when the exposure is of a transient nature due to incidental passage through a location where the exposure levels may be higher than the general population/uncontrolled limits, but the exposed person is fully aware of the potential for exposure and can exercise control over his or her exposure by leaving the area or by some other appropriate means.

Table 9.1. Safety Limits for Partial Body Exposure [2]

	HUMAN EXPOSURE LIMITS	
	UNCONTROLLED ENVIRONMENT General Population (W/kg) or (mW/g)	CONTROLLED ENVIRONMENT General Population (W/kg) or (mW/g)
SPATIAL PEAK SAR 1 Brain	1.60	8.00
SPATIAL AVERAGE SAR 2 Whole Body	0.08	0.40
SPATIAL PEAK SAR 3 Hands, Feet, Ankles, Wrists	4.00	20.00

³ The Spatial Peak value of the SAR averaged over any 10 grams of tissue (defined as a tissue volume in the shape of a cube) and over the appropriate averaging time.

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		THADIUS	Reviewed by: Quality Manager
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	FCC ID:	Page 11 of 22
SAR.230917459.ESC	September 18-19, 2003	Therapy Defibrillator (CRT-D)	ESCCRMH21004	

¹ The Spatial Peak value of the SAR averaged over any 1 gram of tissue (defined as a tissue volume in the shape of a cube) and over the appropriate averaging time.

² The Spatial Average value of the SAR averaged over the whole body.



10. MEASUREMENT UNCERTAINTIES

a	b	С	d	e=	f	g	h =	i =	k
				f(d,k)			cxf/e	cxg/e	
Uncertainty		Tol.	Prob.		Ci	Ci	1 - g	10 - g	
Component	Sec.	(± %)	Dist.	Div.	(1 - g)	(10 - g)	u _i	u _i	V _i
							(± %)	(± %)	
Measurement System									
Probe Calibration	E1.1	11.4	R	1.73	1	1	6.6	6.6	¥
Axial Isotropy	E1.2	3.4	R	1.73	0.7	0.7	1.4	1.4	¥
Hemispherical Isotropy	E1.2	5.2	R	1.73	1	1	3.0	3.0	¥
Boundary Effect	E1.3	4.7	R	1.73	1	1	2.7	2.7	¥
Linearity	E1.4	5.9	R	1.73	1	1	3.4	3.4	¥
System Detection Limits	E1.5	1.0	R	1.73	1	1	0.6	0.6	¥
Readout Electronics	E1.6	1.0	N	1	1	1	1.0	1.0	¥
Response Time	E1.7	8.0	R	1.73	1	1	0.5	0.5	¥
Integration Time	E1.8	1.7	R	1.73	1	1	1.0	1.0	¥
RF Ambient Conditions	E5.1	1.2	R	1.73	1	1	0.7	0.7	¥
Probe Positioner Mechanical Tolerance	E5.2	0.4	R	1.73	1	1	0.2	0.2	¥
Probe Positioning w/ respect to Phantom	E5.3	2.9	R	1.73	1	1	1.7	1.7	¥
Shell									
Extrapolation, Interpolation & Integration	E4.2	3.9	R	1.73	1	1	2.3	2.3	
Algorithms for Max. SAR Evaluation									¥
Test Sample Related									
Test Sample Positioning	E3.2.1	10.6	R	1.73	1	1	6.1	6.1	11
Device Holder Uncertainty	E3.1.1	8.7	R	1.73	1	1	5.0	5.0	8
Output Power Variation - SAR drift	5.6.2	5.0	R	1.73	1	1	2.9	2.9	
measurement									¥
Phantom & Tissue Parameters									
Phantom Uncertainty (Shape & Thickness	E2.1	4.0	R	1.73	1	1	2.3	2.3	
tolerances)									¥
Liquid Conductivity - deviation from	E2.2	5.0	R	1.73	0.7	0.5	2.0	1.4	
target values									¥
Liquid Conductivity - measurement	E2.2	5.0	R	1.73	0.7	0.5	2.0	1.4	
uncertainty									¥
Liquid Permittivity - deviation from	E2.2	5.0	R	1.73	0.6	0.5	1.7	1.4	
target values									¥
Liquid Permittivity - measurement	E2.2	5.0	R	1.73	0.6	0.5	1.7	1.4	
uncertainty									¥
Combined Standard Uncertainty (k=1)			RSS				13.2	13.0	
Expanded Uncertainty (k=2)							26.6	26.2	
(95% CONFIDENCE LEVEL)									

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		BUIDANT	Reviewed by: Quality Manager
SAR Filename: SAR.230917459.ESC	Test Dates: September 18-19, 2003	EUT Type : Cardiac Resynchronization Therapy Defibrillator (CRT-D)	FCC ID: ESCCRMH21004	Page 12 of 22



11. SAR TEST DATA SUMMARY

See Measurement Result Data Pages

Procedures Used To Establish Test Signal

The implant was placed into continuous transmit mode using a telemetry-programmed inductive wand. Before induction, this wand was programmed using a manufacturer software program to run the custom telemetry board. The implant was programmed to maintain maximum power.

Device Test Conditions

The device was powered through the battery. In order to verify that the device was tested at full power, conducted output power measurements were performed previous to the tests to confirm the output power.

If a power deviation of more than 5% occurred, the test was repeated.

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		BUIDANT	Reviewed by: Quality Manager
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	FCC ID:	Page 13 of 22
SAR.230917459.ESC	September 18-19, 2003	Therapy Defibrillator (CRT-D)	ESCCRMH21004	



12. SAR TEST EQUIPMENT

Equipment Calibration

Table 12.1 Test Equipment Calibration

EQUIPMENT SPECIFICATIONS							
Туре	Calibration Date	Serial Number					
CRS Robot F3	February 2003	RAF0134133					
CRS C500C Motion Controller	February 2003	RCB0003303					
CRS Teach Pendant (Joystick)	February 2003	STP0132231					
DELL Computer, Pentium 4 1.6 GHz, Windows 2000™	February 2003	4PJZ111					
E-Field Probe E-010	January 2003	PCT003					
MICS Torso Simulating Phantom (P-MICS)	September 2003	PCT700					
IDX Robot End Effector (EE-103-C)	February 2003	07111223					
IDX Probe Amplifier	February 2003	07111113					
Validation Dipole D-835S	October 2002	PCT640					
Brain Equivalent Matter	September 2003	PCTBEM101					
Muscle Equivalent Matter	September 2003	PCTMEM201					
Amplifier Research 5S1G4 Power Amp	January 2003	PCT540					
Agilent E8241A (250kHz ~ 20GHz) Signal Generator	November 2002	US42110432					
HP-8753E (30kHz ~ 6GHz) Network Analyzer	January 2003	PCT552					
HP85070B Dielectric Probe Kit	January 2003	PCT501					
Ambient Noise/Reflection, etc. <12mW/kg/<3%of SAR	January 2003	Anechoic Room PCT01					

NOTE:

The simulating material is calibrated by PCTEST using the dielectric probe system and network analyzer to determine the conductivity and permittivity (dielectric constant) of the brain and muscle-equivalent material.

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		FCC SAR MEASUREMENT REPORT		Reviewed by: Quality Manager
SAR Filename: SAR.230917459.ESC	Test Dates: September 18-19, 2003	EUT Type: Cardiac Resynchronization Therapy Defibrillator (CRT-D)	FCC ID: ESCCRMH21004	Page 14 of 22	



13. CONCLUSION

Measurement Conclusion

The SAR measurement indicates that the EUT complies with the RF radiation exposure limits of the FCC. These measurements are taken to simulate the RF effects exposure under worst-case conditions. Precise laboratory measures were taken to assure repeatability of the tests. The tested device complies with the requirements in respect to all parameters subject to the test. The test results and statements relate only to the item(s) tested. Please note that the absorption and distribution of electromagnetic energy in the body are very complex phenomena that depend on the mass, shape, and size of the body, the orientation of the body with respect to the field vectors, and the electrical properties of both the body and the environment. Other variables that may play a substantial role in possible biological effects are those that characterize the environment (e.g. ambient temperature, air velocity, relative humidity, and body insulation) and those that characterize the individual (e.g. age, gender, activity level, debilitation, or disease). Because innumerable factors may interact to determine the specific biological outcome of an exposure to electromagnetic fields, any protection guide shall consider maximal amplification of biological effects as a result of field-body interactions, environmental conditions, and physiological variables.[3]

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		BUIDANT	Reviewed by: Quality Manager
SAR Filename: SAR.230917459.ESC	Test Dates: September 18-19, 2003	EUT Type: Cardiac Resynchronization Therapy Defibrillator (CRT-D)	FCC ID: ESCCRMH21004	Page 15 of 22



14. REFERENCES

- [1] Federal Communications Commission, ET Docket 93-62, Guidelines for Evaluating the Environmental Effects of Radiofrequency Radiation, Aug. 1996.
- [2] ANSI/IEEE C95.1 1991, American National Standard safety levels with respect to human exposure to radio frequency electromagnetic fields, 300kHz to 100GHz, New York: IEEE, Aug. 1992.
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- [4] Federal Communications Commission, OET Bulletin 65 (Edition 97-01), Supplement C (Edition 01-01), Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields, July 2001.
- [5] IEEE Standards Coordinating Committee 34 IEEE Std. P1528 D1.2 (April 2003), *Draft Recommended Practice for Determining the Peak Spatial-Average Specific Absorption Rate (SAR) in the Human Body Due to Wireless Communications Devices: Experimental Techniques.*
- [6] NCRP, National Council on Radiation Protection and Measurements, *Biological Effects and Exposure Criteria for RadioFrequency Electromagnetic Fields*, NCRP Report No. 86, 1986. Reprinted Feb. 1995.
- [7] V. Hombach, K. Meier, M. Burkhardt, E. Kuhn, N. Kuster, *The Dependence of EM Energy Absorption upon Human Head Modeling at 900 MHz*, IEEE Transaction on Microwave Theory and Techniques, vol. 44 no. 10, Oct. 1996, pp. 1865-1873.
- [8] N. Kuster and Q. Balzano, *Energy absorption mechanism by biological bodies in the near field of dipole antennas above 300MHz*, IEEE Transaction on Vehicular Technology, vol. 41, no. 1, Feb. 1992, pp. 17-23.
- [9] G. Hartsgrove, A. Kraszewski, A. Surowiec, *Simulated Biological Materials for Electromagnetic Radiation Absorption Studies*, University of Ottawa, Bioelectromagnetics, Canada: 1987, pp. 29-36.
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- [12] Federal Communications Commission, OET Bulletin 65, Evaluating Compliance with FCC Guidelines for Human Exposure to Radiofrequency Electromagnetic Fields. Supplement C, Dec. 1997.
- [13] CENELEC CLC/SC111B, European Prestandard (prENV 50166-2), Human Exposure to Electromagnetic Fields High-frequency: 10kHz-300GHz, Jan. 1995.

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		FCC SAR MEASUREMENT REPORT	
SAR Filename: SAR.230917459.ESC	Test Dates: September 18-19, 2003	EUT Type: Cardiac Resynchronization Therapy Defibrillator (CRT-D)	FCC ID: ESCCRMH21004	Page 16 of 22



EXHIBIT A. SYSTEM VERIFICATION

Tissue Verification

Table A.1 Simulated Tissue Verification

MEASURED TISSUE PARAMETERS						
Date(s)	09/19/2003 835MHz Brain 900MH		835MHz Brain		Hz Muscle	
Liquid Temperature (°C)	21.1	Target	Measured	Target	Measured	
Dielectric Constant: ε		41.50	40.66	55.00	52.95	
Conductivity: σ		0.900	0.91	1.050	1.00	

Test System Validation

Prior to assessment, the system is verified to the $\pm 10\%$ of the specifications at 835 MHz by using the system validation kits. (Graphic Plots Attached)

Table A.2 System Verification

System Verification TARGET & MEASURED							
Date:	Amb. Temp (℃)	Liquid Temp(℃)	Input Power (W)	Tissue	Targeted SAR _{1g} (mW/g)	Measured SAR _{1g} (mW/g)	Deviation (%)
09/19/03	22.5	21.1	0.250	835MHz Brain	2.375	2.47	3.98





Figure A.0 Dipole Verification Test Setup

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		BUIDANT	Reviewed by: Quality Manager
SAR Filename: SAR.230917459.ESC	Test Dates: September 18-19, 2003	EUT Type: Cardiac Resynchronization Therapy Defibrillator (CRT-D)	FCC ID: ESCCRMH21004	Page 17 of 22



EXHIBIT A. SAR DATA SUMMARY

Mixture Type: 900 MHz Muscle

A.1 MEASUREMENT RESULTS							
FREQUENCY	Serial No.	POWER [‡]		Device Test	Antenna	1 g SAR	
MHz		Modulation	Power (dl	3m)	Position	Position	(W/kg)
914	926302	ASK	-0.80		Implanted	Fixed	0.03
914	926303	ASK	-0.80		Implanted	Fixed	0.08
914	926304	ASK	-0.80		Implanted	Fixed	0.05
ANSI / IEEE C95.1 1992 - SAFETY LIMIT Spatial Peak Uncontrolled Exposure/General Population					Brain W/kg (mW/g) aged over 1 gram		

NOTES:

- 1. The test data reported are the worst-case SAR value with the antenna-head position set in a typical configuration. Test procedures used are according to FCC/OET Bulletin 65, Supp.C [July 2001].
- 2. All modes of operation were investigated, and worst-case results are reported.
- 3. Battery is fully charged for all readings.
- 4. SAR Measurement System ? DASY4 ⊠ IDX
 - Phantom Configuration

 MICS Torso Simulator
- 5. SAR Configuration ? Head 🗵 Body ? Hand
- 6. Test Signal Call Mode ? Manu. Test Codes ☒ Software & Magnetic Induction
 - [‡]Maximum Power is maintained by software. Power drift indicated on SAR Plots.
- 7. Tissue parameters and temperatures are listed on the SAR plots.
- 8. Liquid tissue depth is more than 15 cm

Alfred Cirwithian
Vice President Engineering



Figure A.1 SAR Test Setup

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		BUIDANT	Reviewed by: Quality Manager
SAR Filename: SAR.230917459.ESC	Test Dates: September 18-19, 2003	EUT Type: Cardiac Resynchronization Therapy Defibrillator (CRT-D)	FCC ID: ESCCRMH21004	Page 18 of 22



APPENDIX A. SAR TEST DATA

PCTESTÔ SAR TEST REPORT	FCC SAR MEASUREMENT REPORT		BUIDANT	Reviewed by: Quality Manager
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	FCC ID:	Page 19 of 22
SAR.230917459.ESC	September 18-19, 2003	Therapy Defibrillator (CRT-D)	ESCCRMH21004	

SAR Data Report 03091904

Start : 19-Sep-03 11:49:29 am End : 19-Sep-03 12:39:50 pm

Code Version: 4.08
Robot Version: 4.08

Product Data:

Type : GUIDANT
Model Number : H215
Serial Number : 926303
Frequency : 914 MHz
Transmit Pwr : 0.001 W
Antenna Posn. : Fixed

Measurement Data:

Phantom Name : Guidant1
Phantom Type : Other
Tissue Type : Muscle
Tissue Dielectric : 52.950
Tissue Conductivity : 0.980
Tissue Density : 1.000
Robot Name : CRS

Probe Data:

Probe Name : PCT003

Probe Type : E Fld Triangle

Frequency : 835 MHz
Tissue Type : Muscle
Calibrated Dielectric : 55.700
Calibrated Conductivity : 0.980
Calibrated Density : 1.000
Probe Offset : 2.400 mm
Conversion Factor : 7.700

Probe Sensitivity: 2.439 2.7.6 2.822 mV/(mW/cm^2)

Amplifier Gains : 20.00 20.00 20.00

Sample:

Rate: 6000 Samples/Sec Count: 1000 Samples

NIDAQ Gain: 5

Comments:

ASK Mode Body

CF=1; Amb. Temp= 22.5 'C; Liq. Temp=21.1 'C

Power Drop Test:

Reading @ start = 0.041 Reading @ End = 0.041 Power at End = 99.0%

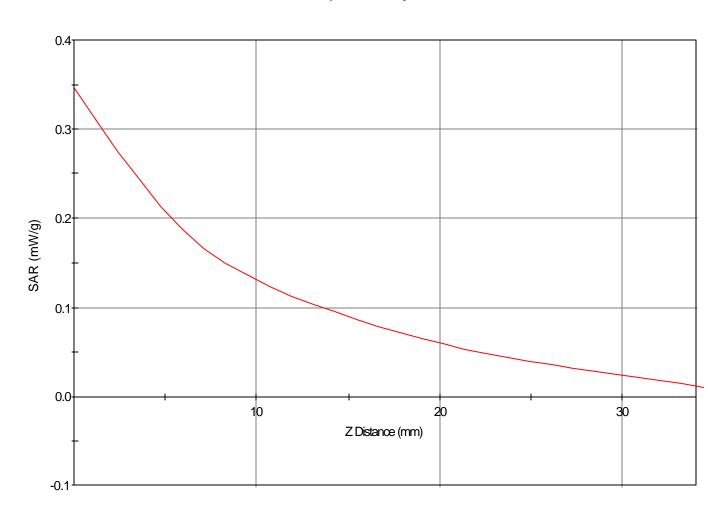
Area Scan - Max Peak SAR Value at x=5.0 y=19.0 = 0.04 W/kg

Zoom Scan - Max Peak SAR Value at x=-3.0 y=19.0 z=0.0 = 0.35 W/kg

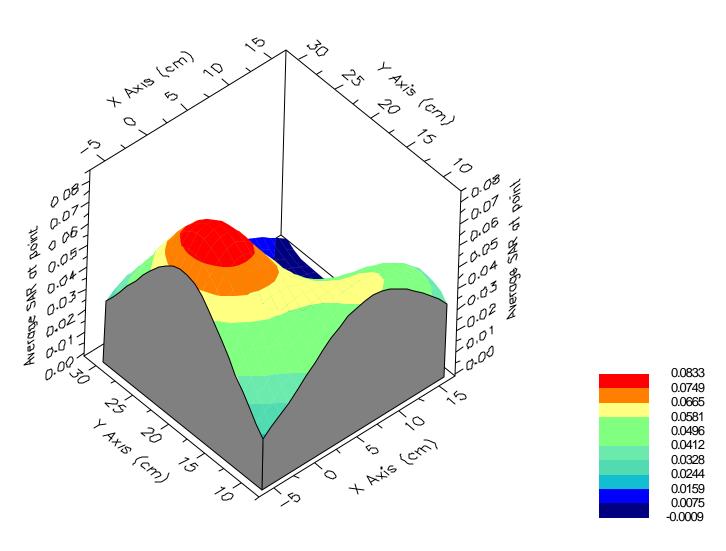
Max 1g SAR at x=-3.0 y=19.0 z=0.0 = 0.08 W/kg

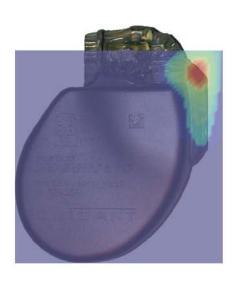
Max 10g SAR at x=3.0 y=15.0 z=0.0 = 0.03 W/kg

SAR - Z Axis at Hotspot x:-3.0 y:19.0



1g SAR Values





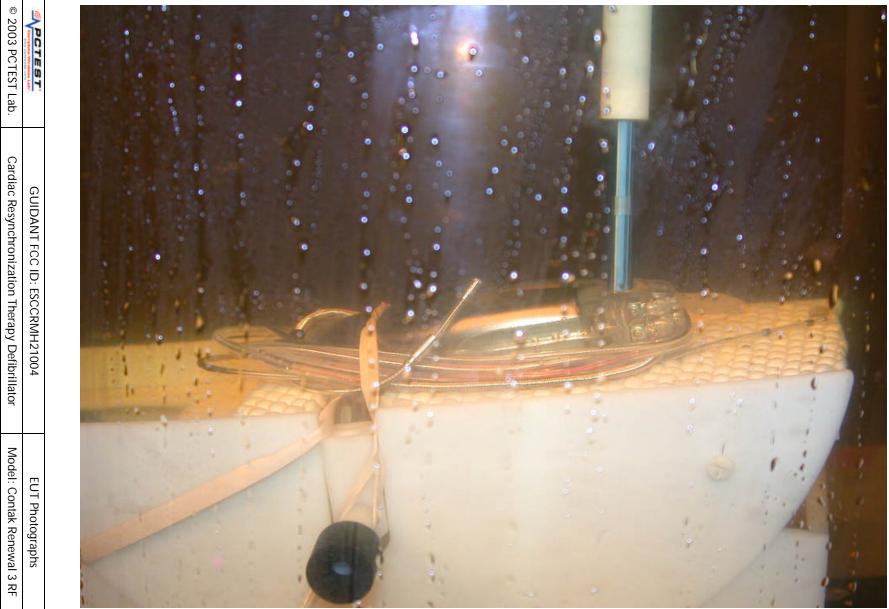


APPENDIX B. SAR TEST SETUP PHOTOGRAPHS

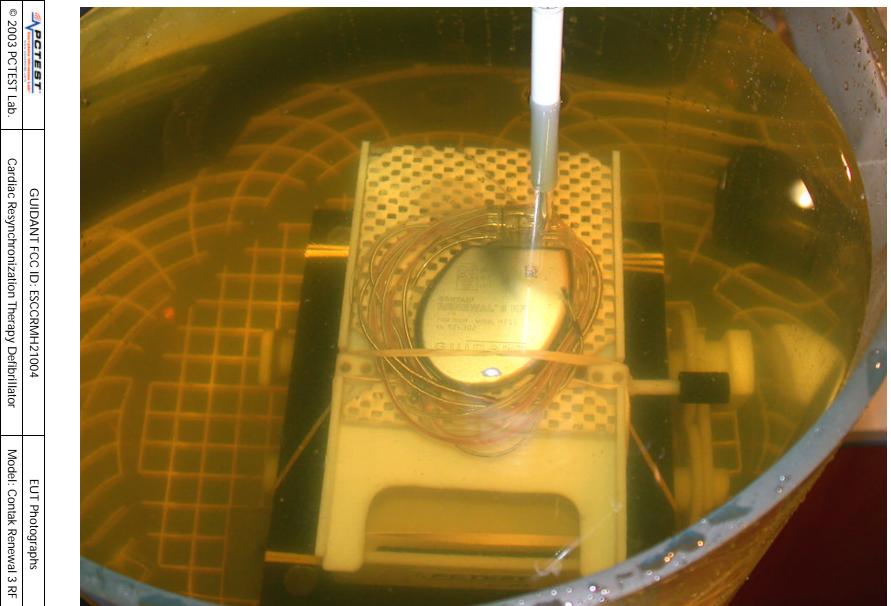
PCTESTÔ SAR TEST REPORT	EUROPEAN MEASUREMENT REPORT			Reviewed by: Quality Manager
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	Model:	Page 20 of 22
SAR.230917459.ESC	September 16-17, 2003	Therapy Difrillator	H239	













Model: Contak Renewal 3 RF



APPENDIX C. DIPOLE VALIDATION

PCTESTÔ SAR TEST REPORT	EUROPEAN MEASUREMENT REPORT			Reviewed by: Quality Manager
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	Model:	Page 21 of 22
SAR.230917459.ESC	September 16-17, 2003	Therapy Difrillator	H239	

: 19-Sep-03 08:18:35 am End : 19-Sep-03 08:24:11 am

Code Version: 4.08 Robot Version: 4.08

Product Data:

: Verification Type

Model Number : E-010 Serial Number : PCT003 Frequency : 835 MHz
Transmit Pwr : 0.250 W
Antenna Type : Dipole Antenna Posn. : Validation

Measurement Data:

Phantom Name : SAM-FLAT-B Phantom Type : Uniphantom Tissue Type : Brain Tissue Dielectric : 40.660 Tissue Conductivity: 0.910 Tissue Density : 1.000 Robot Name : CRS

Probe Data:

Probe Name : PCT003

Probe Type : E Fld Triangle

Frequency : 835 MHz : Brain Tissue Type Calibrated Dielectric : 40.000 Calibrated Conductivity: 0.910 Calibrated Density : 1.300 Probe Offset : 2.400 mm Conversion Factor : 7.200

Probe Sensitivity: 2.439 2.706 2.822 mV/(mW/cm^2)

Amplifier Gains : 20.00 20.00 20.00

Sample:

6000 Samples/Sec Rate: Count: 1000 Samples

NIDAQ Gain: 5

Comments:

835 MHz Verification

CF=1; Amb. Temp= 22.5 'C; Liq. Temp=21.1 'C

Area Scan - Max Peak SAR Value at x=8.0 y=0.0 = 2.19 W/kg

Zoom Scan - Max Peak SAR Value at x=-8.0 y=-1.0 z=0.0 = 3.84 W/kg

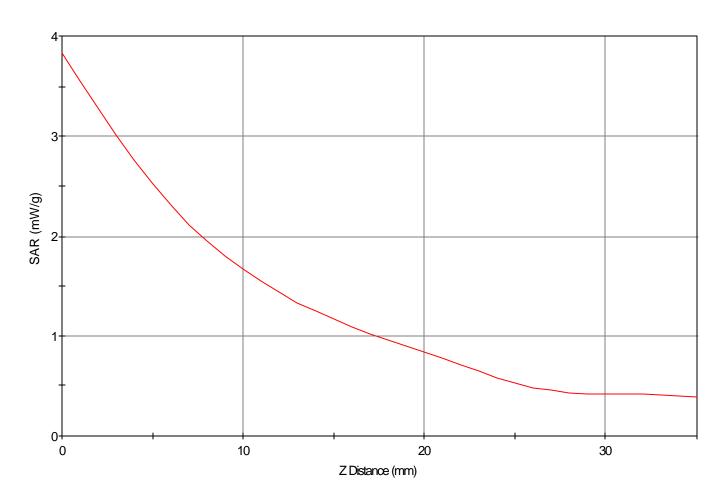
Max 1g SAR at x=-3.0 y=1.0 z=0.0 = 2.47 W/kg

Max 10g SAR at x=3.0 y=-1.0 z=0.0 = 1.56 W/kg

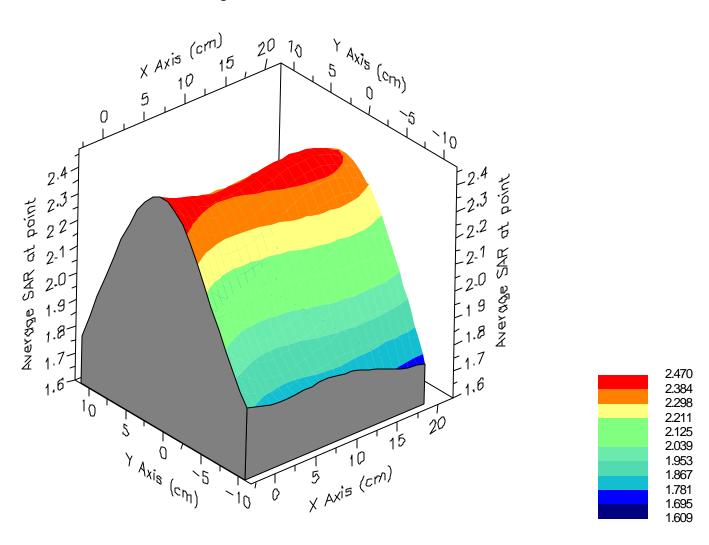
Validation Results at 0.25 W:

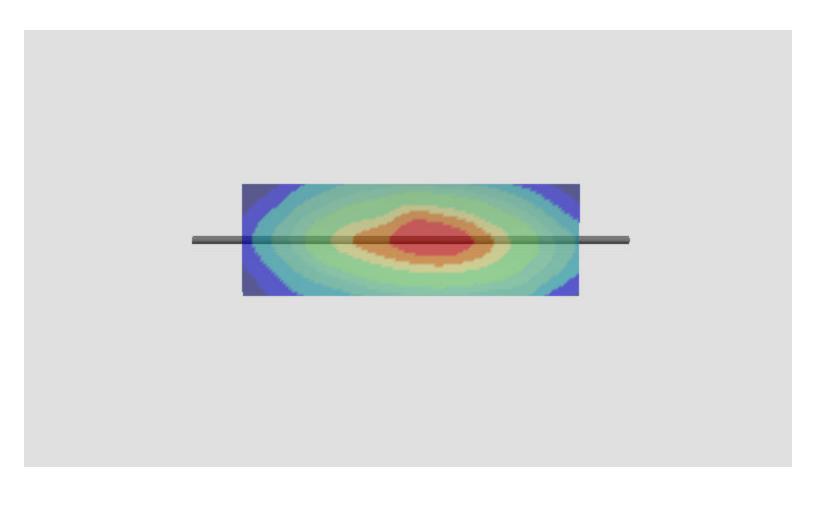
Peak Nominal = 3.5, Error: 8.85 % 1g Nominal = 2.4, Error: 3.98 % 10g Nominal = 1.6, Error: 0.49 %

SAR - Z Axis at Hotspot x:-8.0 y:-1.0



1g SAR Values

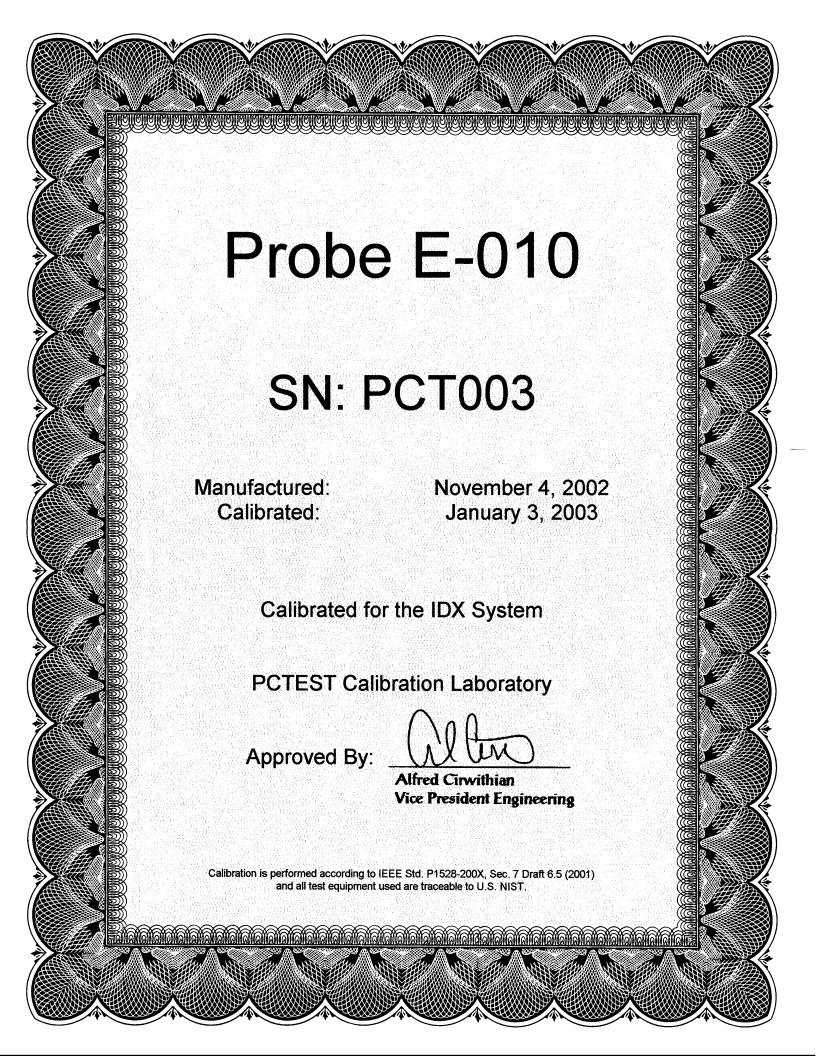






APPENDIX D. PROBE CALIBRATION

PCTESTÔ SAR TEST REPORT	EUROPEAN MEASUREMENT REPORT			Reviewed by: Quality Manager
SAR Filename:	Test Dates:	EUT Type: Cardiac Resynchronization	Model:	Page 22 of 22
SAR.230917459.ESC	September 16-17, 2003	Therapy Difrillator	H239	





6660-B Dobbin Road Columbia, Maryland 21045 USA

Calibration Summary

Model: E-010 S/N: PCT003

OFFSET	ANGLE
(cm)	(deg)
0.24	54.73

Tissue Type	Frequency (MHz)	Dielectric Constant	Conductivity (S/m)	Conversion Factor
		$arepsilon_r$	σ	$\gamma_x, \gamma_y, \gamma_z$
Brain	835	40.00	0.91	7.20
Brain	1880	40.20	1.41	4.05
Brain	2440	39.34	1.77	8.80
Brain	5300	37.10	4.84	3.20
Brain	5800	36.00	5.28	2.30
Muscle	835	55.70	0.98	7.70
Muscle	1900	53.90	1.48	4.40
Muscle	2440	52.30	1.99	9.90
Muscle	5300	48.80	5.43	3.45
Muscle	5800	48.50	6.05	2.50

Frequency	Isotropy			
(MHz)	%	dB		
835	3.49	0.15		
1880	5.35	0.23		
2440	4.02	0.17		
5300	4.85	0.21		
5800	4.93	0.21		

Boundary Effect < 2%, 2.6 mm from probe tip to phantom

Diode Compression Point: 76 mV

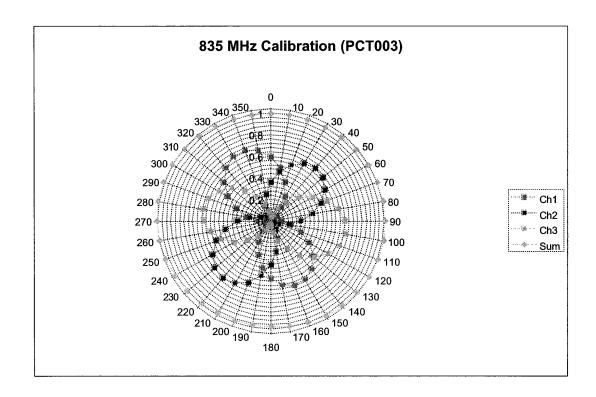
Environmental Conditions:

Temperature: 23.34 °C Relative Humidity: 34% Barometer: 100.1 kPa

This probe was calibrated under the IEEE Std 1309-1966, *IEEE Standard for Calibration of Electromagnetic Field Sensors and Probes, Exluding Antennas, from 9 kHz to 40 GHz.*

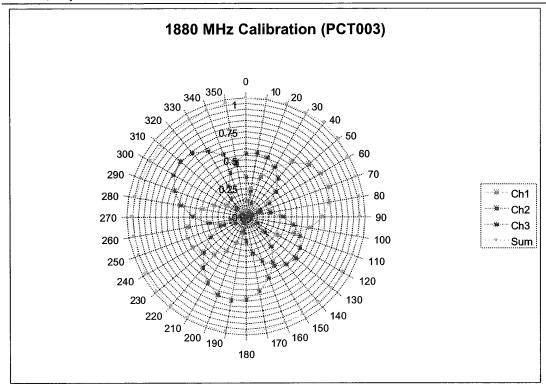


6660-B Dobbin Road Columbia, Maryland 21045 USA



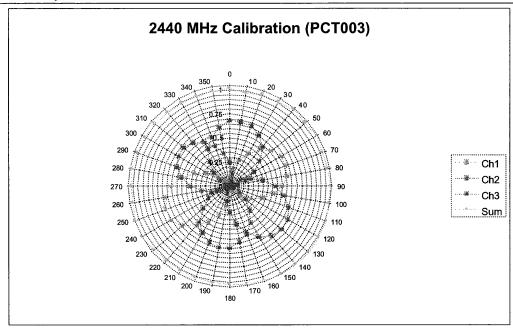


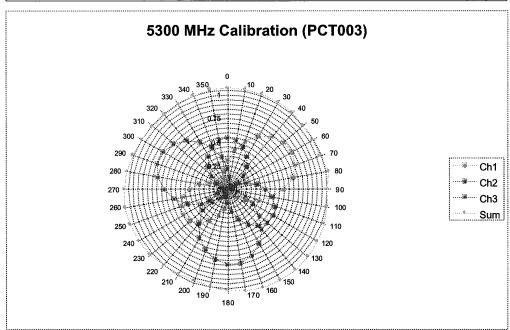
6660-B Dobbin Road Columbia, Maryland 21045 USA





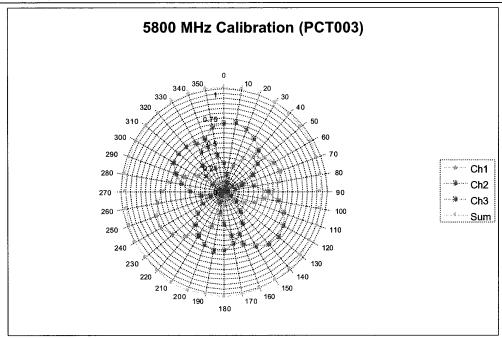
6660-B Dobbin Road Columbia, Maryland 21045 USA

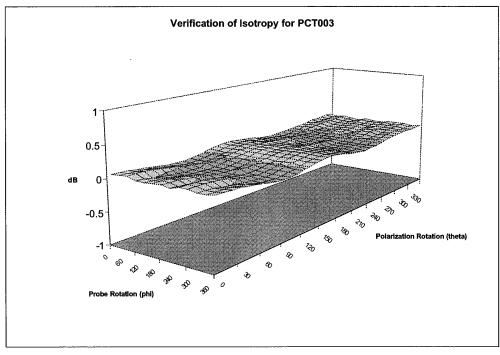






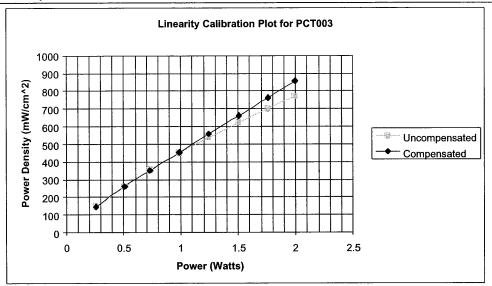
6660-B Dobbin Road Columbia, Maryland 21045 USA







6660-B Dobbin Road Columbia, Maryland 21045 USA



Probe Physical Characteristics

Serial Number:

PCT003

Sensor Offset:

Sensor Length:

Tip Enclosure:

Tip Diameter:

Tip Length:

Total Length:

PCT003

2.4 mm

2.5 mm

Glass

7 mm

40 mm

Total Length:

290 mm



6660-B Dobbin Road Columbia, Maryland 21045 USA

Test Equipment

The test equipment used during the probe calibration are listed as follows:

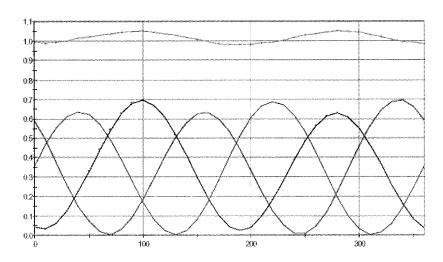
EQUIPMENT SPECIFICATIONS					
Туре	Calibration Date	Asset Number/ Serial Number			
CRS Robot F3	February 2002	RAF0134133			
CRS C500C Motion Controller	February 2002	RCB0003303			
CRS Teach Pendant (Joystick)	February 2002	STP0132231			
DELL Computer, Pentium 4 1.6 GHz, Windows 2000™	February 2002	4PJZ111			
E-Field Probe E-010	January 2003	PCT003			
Flat SAM Phantom (P-SAM-FLAT)	February 2002	94X-097			
IDX Robot End Effector (EE-103-C)	February 2002	07111223			
IDX Probe Amplifier	February 2002	07111113			
Validation Dipole D-835S	October 2002	PCT441			
Validation Dipole D-1900S	October 2002	PCT541			
Validation Dipole D-2450S	October 2002	PCT641			
Validation Dipole D-5000S	November 2002	PCT741			
HP-778D Dual-Directional Coupler (0.1 ~ 2.0 GHz)	November 2002	PCT664			
MicroCircuits Directional Coupler (4.0 ~ 8.0 GHz)	November 2002	PE2204-6			
Amplifier Research 5S1G4 Power Amp	January 2003	PCT540			
IFI T184-10 Power Amplifier (4.0 ~ 18.0 GHz)	December 2002	5957			
Agilent E8241A (250kHz ~ 20GHz) Signal Generator	November 2002	US42110432			
HP-8648D (9kHz ~ 4 GHz) Signal Generator	January 2003	PCT526			
HP-8753E (30kHz ~ 6GHz) Network Analyzer	January 2003	PCT552			
HP85070B Dielectric Probe Kit	January 2003	PCT501			
IFI CC110EXX TEM Cell (DC to 2000 MHz)	January 2003	PCT498			
EMCO 3115 Horn Antenna (2.0 ~ 18.0 GHz)	August 2002	PCT496			
Guidline 5150 Precision Dual-Thermometer	November 2002	66145			



6660-B Dobbin Road Columbia, Maryland 21045 USA

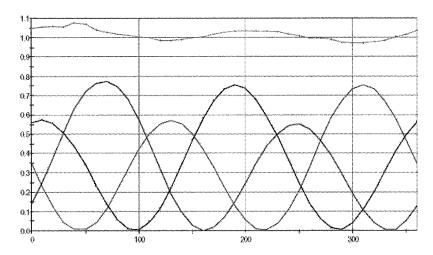
> TEM Calibration Plot Date: 3-Jan-03 05:19:17 pm Probe Name: PCT003 Frequency: 835

Sensitivity: Ch1: 2.439 Ch2: 2.706 Ch3: 2.822 mV/(mW/cm^2) isotropicity: 3.49% 0.15 db Min=0.981 Max=1.051



TEM Calibration Plot Date: 3-Jan-03 05:52:39 pm Probe Name; PCT003 Frequency: 1880

Sensitivity: Ch1: 4.794 Ch2: 5.895 Ch3: 5.327 mV/(mW/cm^2) lsotropicity: 5.35% 0.23 db Min=0.971 Max=1.078



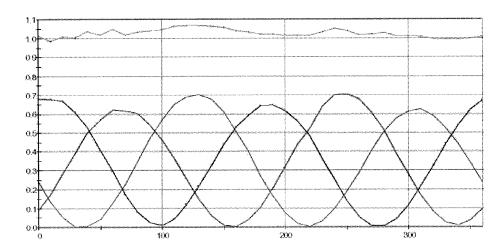
CALIBRATED BY: _____ DATE: 01/15/03



6660-B Dobbin Road Columbia, Maryland 21045 USA

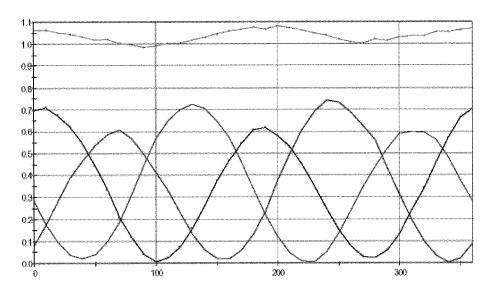
TEM Calibration Plot
Date: 3-Jan-03 10:10:11 am
Probe Name: PCT003
Erromency: 2440

Frequency: 2440
Sensitivity: Ch1: 2,075 Ch2: 2.820 Ch3: 2.456 mV/(mW/cm^2) Isotropicity: 4,02% 0.17 db Min=0.985 Max=1.066



TEM Calibration Plot
Date: 3-Jan-03 10:31:24 am
Probe Name: PCT003
Erroquency: 5300

Frequency: 5300
Sensitivity: Ch1: 1.939 Ch2: 2.177 Ch3: 2.062 mV/(mW/cm^2) | Isotropicity: 4.85% 0.21 db Min=0.984 Max=1.081





6660-B Dobbin Road Columbia, Maryland 21045 USA

TEM Calibration Plot
Date: 3-Jan-02 12:06:18 pm
Probe Name: PCT003

Frequency: 5800
Sensitivity: Ch1: 0.6759 Ch2: 0.8082 Ch3: 0.7596 mV/(mW/cm^2) Isotropicity: 4.93% 0.21 db Min=0.973 Max=1.082

