

Report No. SC304990-02

EMC - TEST REPORT

EUROPEAN STANDARD EN 60601-1-2: 2001

Test Report File No. : **SC304990-02** Date of Issue: 30 December 2003

Model / Serial No. : **SC-5100-02 and SC-5210 / --**

Product Type : SCS Implant System

Applicant : ADVANCED BIONICS

Manufacturer : ADVANCED BIONICS

License holder : ADVANCED BIONICS

Address : 12740 San Fernando Road
: Sylmar, CA 91342

Test Result : ☒ **Positive*** ☐ **Negative**

Test Project Number
Reference(s) : **SC304990-02**

Total pages - Test Report : 44

(*) See General Remarks.

TÜV Product Service reports apply only to the specific sample tested under stated test conditions. It is the manufacturer's responsibility to assure the continued compliance of production units of this model. TÜV Product Service, Inc. shall have no liability for any deductions, inferences or generalizations drawn by the client or others from TÜV Product Service, Inc. issued reports.

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TEST REGULATIONS:

The tests were performed according to the following regulations:

-
- - EN 60601-1-2 / 2001
 - - EN 60601-2-24 / 1995
-

■ - EN 55011 / 1998

■ - CISPR 11 (1997)

■ - EN 61000-4-2

■ - EN 61000-4-3

■ - EN 61000-4-8

■ - Group 1

□ - Class A

■ - Group 1

□ - Class A

□ - Group 2

■ - Class B

□ - Group 2

■ - Class B

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Environmental Conditions In The Laboratory:

	<u>Actual</u>
Temperature	: 20-24 °C
Relative Humidity	: 29-43 %
Atmospheric Pressure	: 99.8-100.0 kPa

Power Supply Utilized:

Power supply system : 6 VDC / 4.5 VDC

Symbol Definitions:

- - Applicable
- - Not Applicable

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Test Conditions: CONDUCTED EMISSIONS (Interference Voltage)

The CONDUCTED EMISSIONS (Interference Voltage) measurements were performed in the following location at the San Diego Testing Facility:

☒ - Test not applicable

☐ - SR-2, Shielded Room, 12' x 24' x 10', Metal Chamber

Test Equipment Used:

Model No.	Prop. No.	Description	Manufacturer	Serial No.
FCC-LISN-50-25-2	552	Power Mains Network (LISN), 50 μ H/250 μ H/50 Ω /0.25 μ F	Fischer Custom Communications, Inc.	113
ESHS 20	459	EMI Test Receiver	Rohde & Schwarz	832354/004
CAT-20	--	20 dB Attenuator	Mini-Circuits	--
LISN 3, 50 A	262-263	LISN	Fischer Custom Communications, Inc	3-4

Result:

☒ - Pass

☐ - Fail

Remarks: _____

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Test Conditions: RADIATED EMISSIONS (Electric Field)

The RADIATED EMISSIONS (Electric Field) measurements were performed in the following location at the San Diego Testing Facility:

☐ - Test not applicable

- - Canyon #1 (10- and 30-Meter Open Area Test Site), Carroll Canyon, San Diego
(Calibration Due Date: 17 July 2002)

Testing was performed at a test distance of:

- - 10 meters

Test Equipment Used:

Model No.	Prop. No.	Description	Manufacturer	Serial No.
LPB 2520/A	739	Antenna, Bilog	Antenna Research	1169
ESVS 30	6732	EMI Test Receiver	Rohde & Schwarz	833825/003

Result:

- - Pass ☐ - Fail

Remarks: _____

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Test Conditions: ELECTROSTATIC DISCHARGE (ESD)

The immunity against ELECTROSTATIC DISCHARGE (ESD) was performed in the following location at the San Diego Testing Facility:

☐ - Test not applicable

■ - TR-1, Test Room

Test Equipment Used:

Model No.	Prop. No.	Description	Manufacturer	Serial No.
NSG435	470	ESD Simulator System	Schaffner	751
--	--	Horizontal Coupling Plane	TÜV Product Service, Inc.	--
--	--	Vertical Coupling Plane	TÜV Product Service, Inc.	--

Test Specification:

Discharge Voltage (Air): ■ - 2 kV ■ - 6 kV ■ - 8 kV
 ■ - 4 kV □ - 15 kV □ - _ kV

Discharge Voltage (Contact): ■ - 2 kV ■ - 4 kV □ - 8 kV
 □ - 3 kV ■ - 6 kV □ - _ kV

Discharge Impedance: ■ - 330 Ω / 150 pF □ - 150 Ω / 150 pF

Discharge Repetition Rate: ■ - ≥ 1 sec.

Number of Discharges: ■ - ≥ 10 at all locations

Kind of Discharges: Direct Discharge Indirect Discharge
 ■ - Air ■ - HCP
 ■ - Contact ■ - VCP

Polarity: ■ - Positive ■ - Negative

Location of Discharge: □ - See Data Record(s)
 ■ - Each location on the surface touchable by hand

Result:

■ - Pass □ - Fail

Remarks: (*) CTI, 2, 3, 4, 5 resets in about 4 seconds ± 4 kV, ± 6 kV."Resets" - Stimuli turns unit off. EUT returns to operation of pulsing stimulus to spine evident by flashing LED.

Test Conditions: RADIATED ELECTROMAGNETIC FIELDS

The immunity against RADIATED ELECTROMAGNETIC FIELDS was performed in the following location at the San Diego Testing Facility:

☐ - Test not applicable

■ - SR-1, Shielded Room, 12' x 24' x 10', Metal, Compact Anechoic Chamber

Test Equipment Used:

Model No.	Prop No.	Description	Manufacturer	Serial No.
AT1080	444	Antenna, Log Periodic	Amplifier Research	14540
C3910	638	Directional Coupler	Werlatone, Inc.	5416
FM 2000	753	Isotropic Field Monitor	Amplifier Research	25280
FP 2000	747	Isotropic Field Probe	Amplifier Research	24598
100W1000M1	439	Power Amplifier	Amplifier Research	14971
436A	472	Power Meter	Hewlett Packard	2101A11117
8481A	726	Power Sensor	Hewlett Packard	1926A27528
8648C	789	Signal Generator	Hewlett Packard	3642U107A
91888-2	6627	Horn Antenna	Ailtech	101

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Test Conditions: RADIATED ELECTROMAGNETIC FIELDS, continued

Test Specification:

Frequency Range:	☐ - 27 - 500 MHz	☐ - 26 - 1000 MHz	☒ - 80 - 2500 MHz
	☐ - 9 kHz - 27 MHz	☐ - 80 - 1000 MHz	
Field Strength:	☐ - 1 V/m	☒ - 3 V/m	☐ - 10 V/m ☐ - _ V/m
Distance Antenna - EUT:	☐ - 1 m	☒ - 3 m	
Modulation:	☒ - AM:	☐ - FM:	80 % 1 kHz
	☐ - unmodulated		
	☒ - sine wave:	☐ - Pulse	ON/OFF Duty Cycle: _ %
Step:	☒ - ≤ 0.0015 decades / sec	☒ - 1%	
Polarization of Antenna:	☒ - Horizontal	☒ - Vertical	☐ - Circular
Result:			
☒ - Pass	☐ - Fail		

Remarks: _____

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Test Conditions: POWER FREQUENCY MAGNETIC FIELD

The immunity against POWER FREQUENCY MAGNETIC FIELD was performed in the following location at the San Diego Testing Facility:

☐ - Test not applicable

■ - TR-2, Test Room

Test Equipment Used:

Model No.	Prop. No.	Description	Manufacturer	Serial No.
1000-8	--	Magnetic Field Generator	TUV America	--
1C-1m	--	Loop Injection Coil	TUV America	--

Test Specification:

Frequency Range: ■ - 50 Hz ■ - 60 Hz ☐ - 400 Hz

Field level (EMF): ☐ - 1 A/m ■ - 3 A/m ☐ - 10 A/m
 ☐ - 30 A/m ☐ - 100 A/m ☐ - _ A/m

Duration: ■ - 60 seconds

Axis of Orientation: ■ - X-axis ■ - Y-axis ■ - Z-axis

Result:

■ - Pass ☐ - Fail

Remarks: _____

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Equipment Under Test (EUT) Test Operation Mode:

The equipment under test was operated under the following conditions during testing:

- ☐ - Standby
- ☐ - Test Program (H - Pattern)
- ☐ - Test Program (Color Bar)
- ☐ - Test Program (Customer Specified)
- ☐ - Practice Operation
- ☐ - Normal Operating Mode

■ - Transmit

Configuration of the equipment under test:

- ☐ - See Constructional Data Form in Appendix B - Page B2
- - See Test Setup Photos

The following peripheral devices and interface cables were connected during the testing:

- | | |
|---|-----------------|
| ☐ - _____ | Type: _____ |
| ☐ - _____ | Type: _____ |
| ☐ - _____ | Type: _____ |
| ☐ - _____ | Type: _____ |
| ☐ - _____ | Type: _____ |
| ☐ - _____ | Type: _____ |
| ☐ - Unshielded power cable | |
| ☐ - Unshielded cables | |
| ☐ - Shielded cables | MPS. No.: _____ |
| ☐ - Customer specific cables | |
| ☐ - _____ | |
| ☐ - _____ | |

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GENERAL REMARKS:

(*) Electrostatic Discharge - CTI, 2, 3, 4, 5 resets in about 4 seconds ± 4 kV, ± 6 kV."Resets" - Stimuli turns unit off. EUT returns to operation of pulsing stimulus to spine evident by flashing LED.

SUMMARY:

All tests according to the regulations cited on page 3 were

■ - **Performed***

□ - Performed with the following **exceptions**

The Equipment Under Test

■ - **Fulfills** the general approval requirements cited on page 3.*

□ - **Does not** fulfill the general approval requirements cited on page 3.

Statement of Measurement Uncertainty

The data and results referenced in this document are true and accurate. There may be some degree or level of measurement uncertainty. As EN 45001 does not allow recommendations to be included in the test report, the reader is encouraged to request a copy of the TÜV policy concerning pass or fail judgment with respect to possible measurement uncertainties.

Equipment Received Date: 24 November 2003

Testing Start Date: 24 November 2003

Testing End Date: 25 November 2003

- TÜV PRODUCT SERVICE, INC. -

Responsible Engineer:



Jim Owen
(EMC Chief Engineer)

Responsible Engineer:



Alan Laudani
(EMC Engineer)

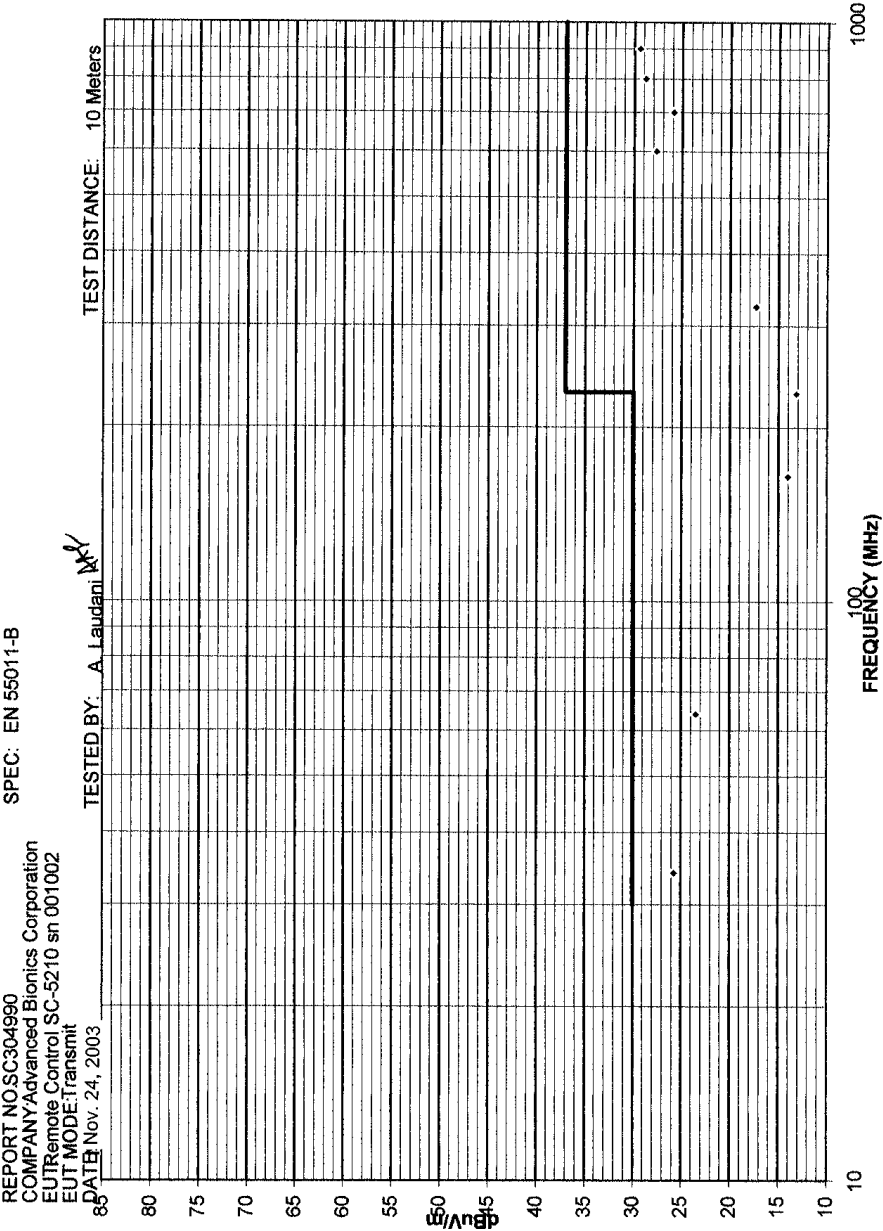
Report No. SC304990-02

Technical Documentation

Test Data Sheets

and

Test Setup Drawing(s)



REPORT No: SC304990

SPEC: EN 55011-B

CUSTOMER: Advanced Bionics Corporation

TEST DIST: 10 Meters

E U T: Remote Control SC-5210 sn 001002

TEST SITE: 1

ETS SC-5100-02 sn 001005

EUT MODE: Transmit

BICONICAL: 739

DATE: Nov. 24, 2003

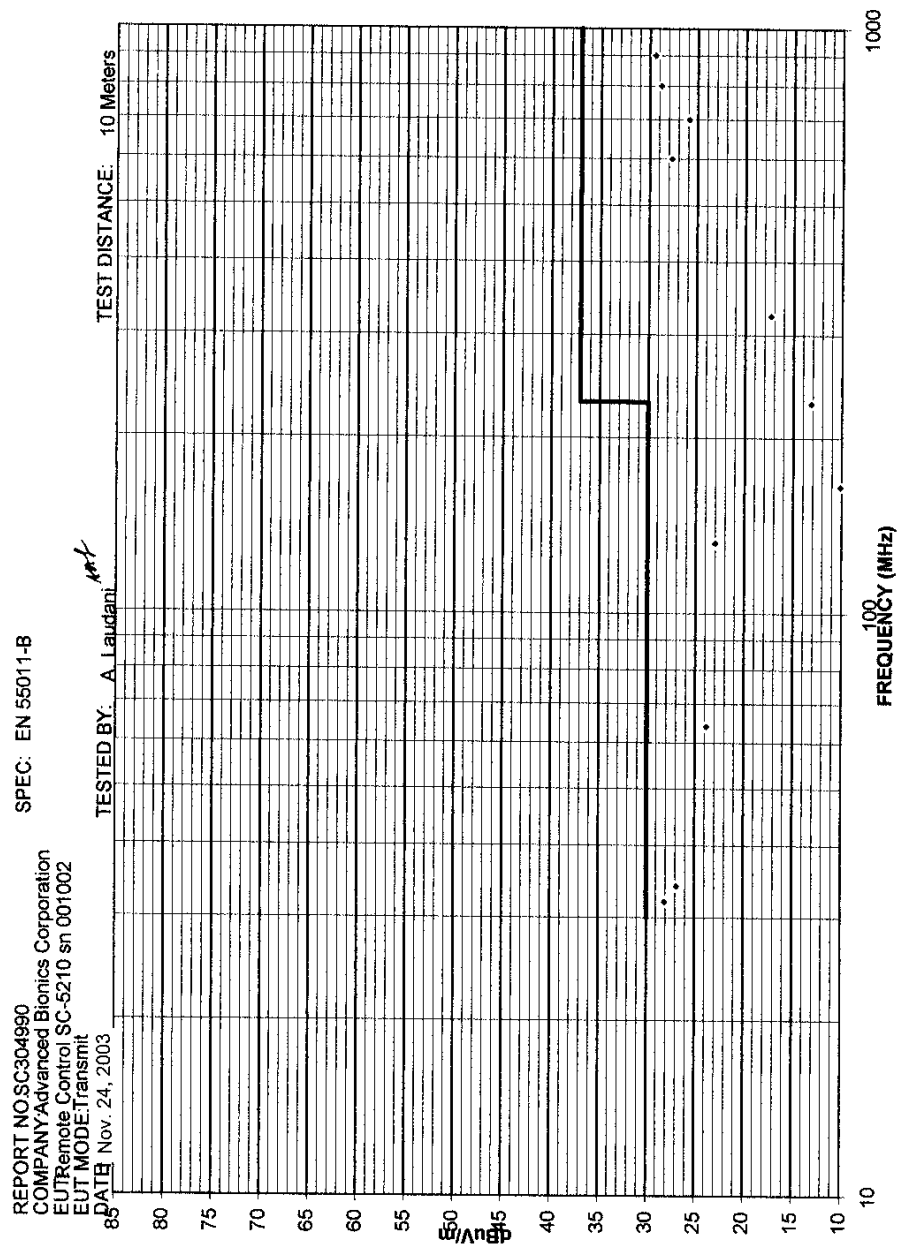
TESTED BY: A. Laudani *ML*

LOG PERIODIC: 739

NOTES: Quasi-Peak with 120 KHz measurement bandwidth.
4.5 Vdc/ 6 Vdc

RCVR: 6723

[illegible]



REPORT No: SC304990

SPEC: EN 55011-B

CUSTOMER: Advanced Bionics Corporation

TEST DIST: 10 Meters

E U T: Remote Control SC-5210 sn 001002

TEST SITE: 1

IPG SC-1100-02 sn 161007

EUT MODE: Transmit

BICONICAL: 739

DATE: Nov. 24, 2003

TESTED BY: A. Laudani

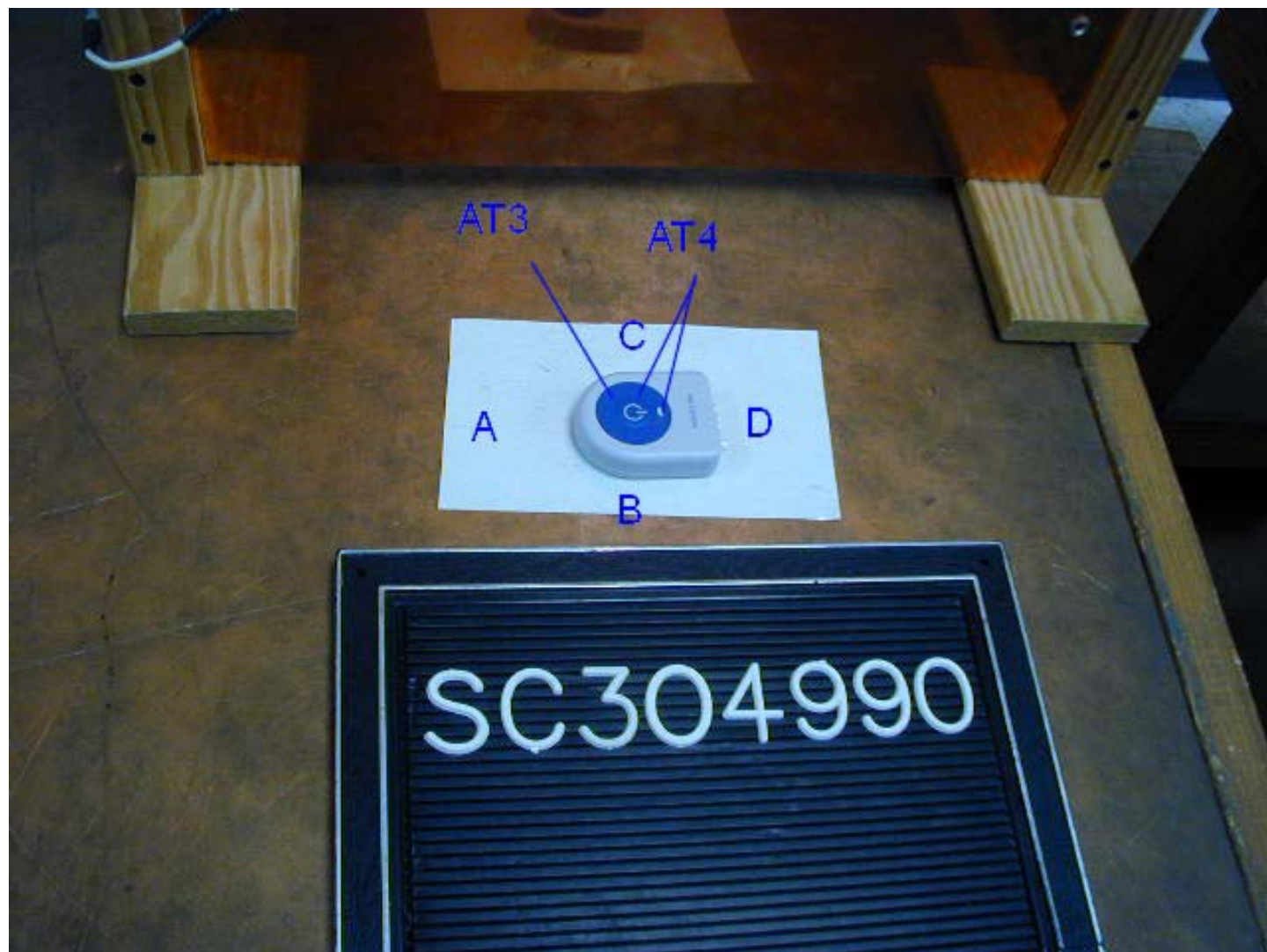
LOG PERIODIC: 739

NOTES: Quasi-Peak with 120 KHz measurement bandwidth.
4.5 Vdc/ 4 Vdc

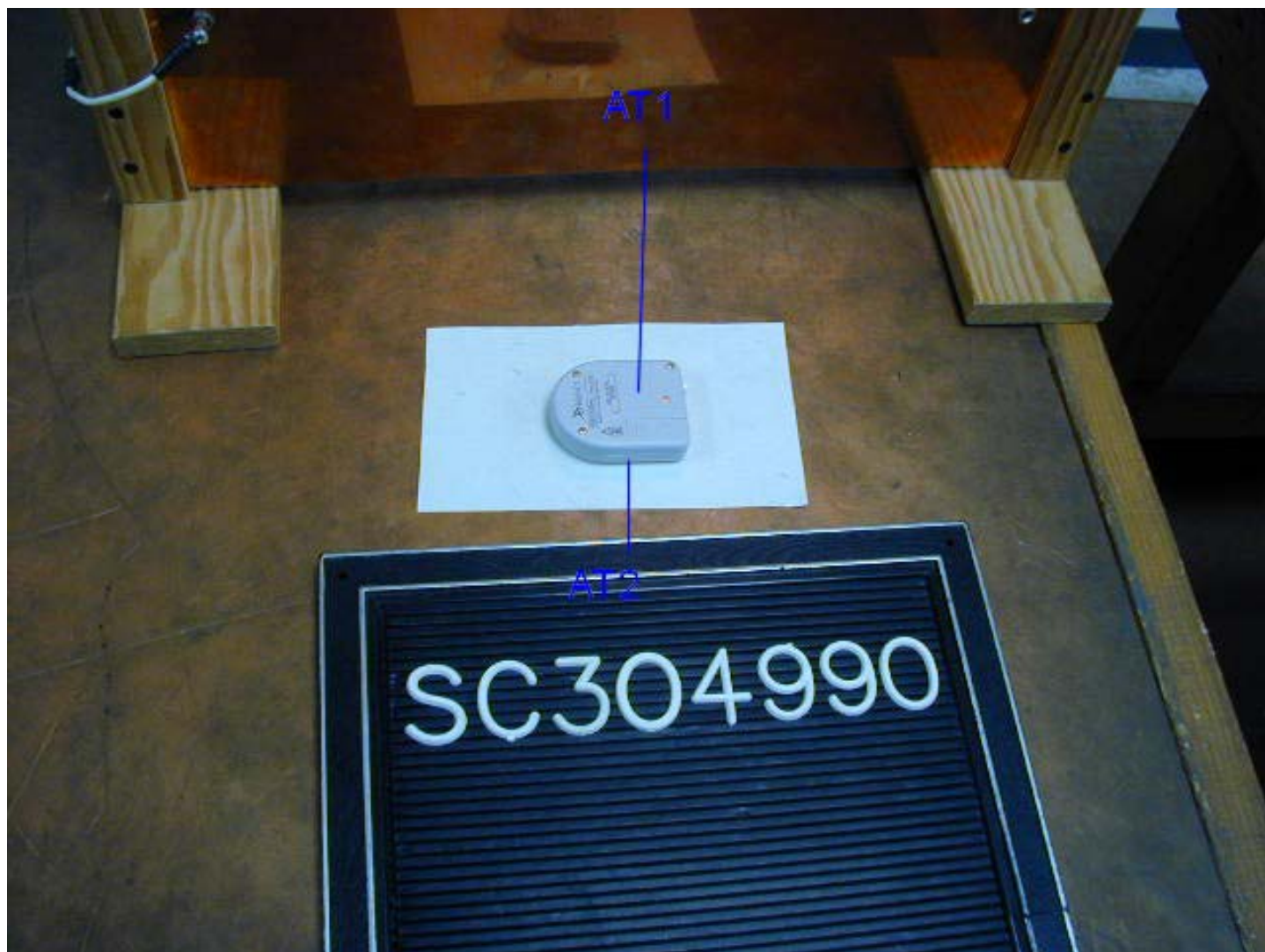
RCVR: 6723

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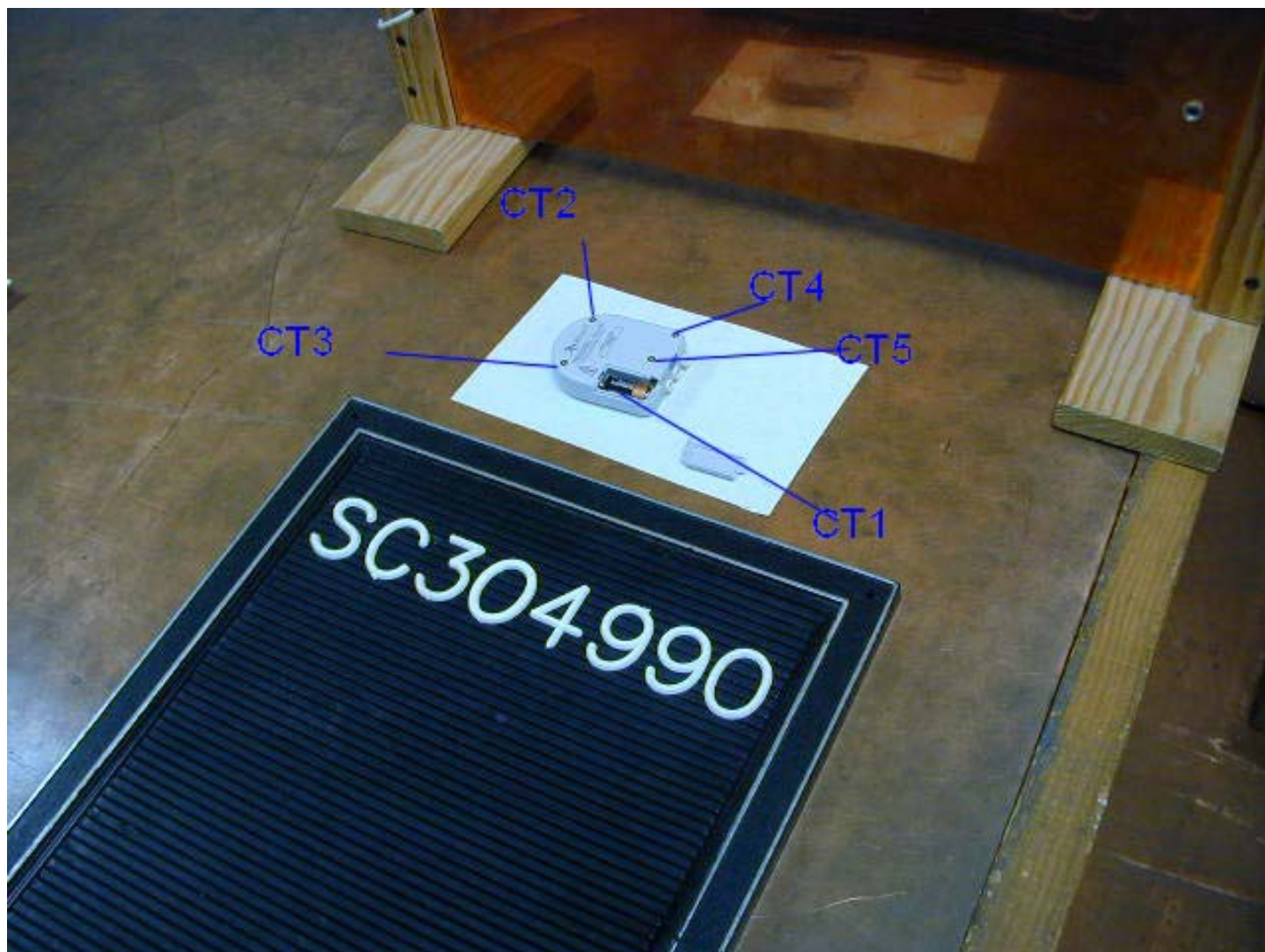
ESD MAP



ESD MAP



ESD MAP



Report No. SC304990-02

ESD IMMUNITY

Test Report #: SC304990

Test Area: TRI

Test Method: EN 61000-4-2

Date: 11/25/03

EN 60601-1-2:2001

EUT POWER:

EUT Model #: SC-5100-02

☐ 230 Vac/50 Hz ☐ 120 Vac/60 Hz

☒ Other: 6 Vdc

Temperature: 23 °C

EUT Description: EXTERNAL TRIAL STIMULATOR SN 001000

Air Pressure: 99.9 kPa

NOTES:

Relative Humidity: 37 %

System Resets in About 4 seconds After ESD event



TEST POINT LOCATION	DISCHARGE TYPE			2 kV		3 kV		4 kV		6 kV		8 kV		KV		COMPLIES?		REMARKS
	INDIR*	CON**	AIR	REPS		REPS		REPS		REPS		REPS		REPS		YES	NO	
				+	-	+	-	+	-	+	-	+	-	+	-			
HCP F	X			10	10			10	10	10	10					✓		Reset @ ±6kV "D"
HCP R																✓		Reset @ 4kV - "A" -6kV
HCP L																✓		Reset @ 4kV - "B" -6kV
HCP B																✓		Reset @ 4kV - "C" -6kV
VCP F																✓		
VCP R																✓		
VCP L																✓		
VCP B	↓			↓	↓			↓	↓	↓	↓					✓		
CT1		X		10	10			10	10	10	10					✓		Battery Resets
2		↓		↓	↓			↓	↓	↓	↓					✓		Resets -6kV
3				↓	↓			↓	↓	↓	↓					✓		Resets ±6kV
4				↓	↓			↓	↓	↓	↓					✓		Resets ±4kV ±6kV
5		↓		↓	↓			↓	↓	↓	↓					✓		Resets ±4kV ±6kV
ATI			X	10	10			10	10	10	10	10	10			✓		BATT COVER
2				↓	↓			↓	↓	↓	↓	↓	↓			✓		Enclosure Crack
3				↓	↓			↓	↓	↓	↓	↓	↓			✓		Button Switch
4				↓	↓			↓	↓	↓	↓	↓	↓			✓		Led

Tested by: A. Landani
Printed

Reviewed by: JIM OWEN
Printed

(*) Indirect (**) Contact

ESDC.DOC Rev 08.98

A. Landani
Signature
Jim Owen
Signature

TÜV
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FACE DEFINITION TOP VIEW

A diagram of a rectangular face. The word "FRONT" is written in the center. The corners are labeled with numbers: 1 at the top-left, 2 at the bottom-left, 3 at the top-right, and 4 at the bottom-right.

[illegible]

Tested by: A. Landani Printed _____
Signature _____
Reviewed by: Jim Owen Printed _____
Signature _____

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PRODUCT SERVICE

4

Report No. SC304990-02

MAGNETIC FIELD IMMUNITY

Test Report #: SC304990 Test Area: TR2
 Test Method: EN 61000-4-8 Date: 11/25/03
EN 61000-1-2:2001
 EUT Model #: ETS SC5100-02 EUT POWER:
☐ 230 Vac/50 Hz ☐ 120 Vac/60 Hz
☒ Other:
 EUT Description: EXTERNAL TEST Simulator SN 001005
 NOTES: w/ Remote CONTROL SC5210
SN 001002

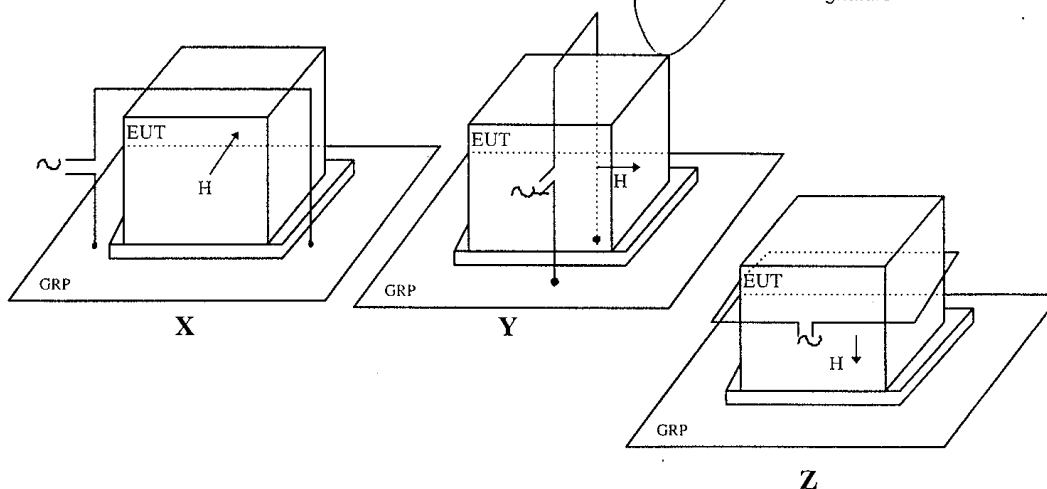


Temperature: 22 °C
 Air Pressure: 99.9 kPa
 Relative Humidity: 36 %

MAG FIELD FREQ. (Hz)	A/M	AXIS			TIME PER TEST SECS	COMPLIES		REMARKS
		X	Y	Z		YES	NO	
50	3	✓			60	x		
↓	↓		✓		↓	x		
↓	↓			✓	↓	x		
60	3	✓			60	x		
↓	↓		✓		↓	x		
↓	↓			✓	↓	x		

Tested By: A. Laudani
 Printed
 Reviewed by: SIM OWEN
 Printed

A. Laudani
 Signature
S. Owen
 Signature



mag4.doc

Report No. SC304990-02

MAGNETIC FIELD IMMUNITY

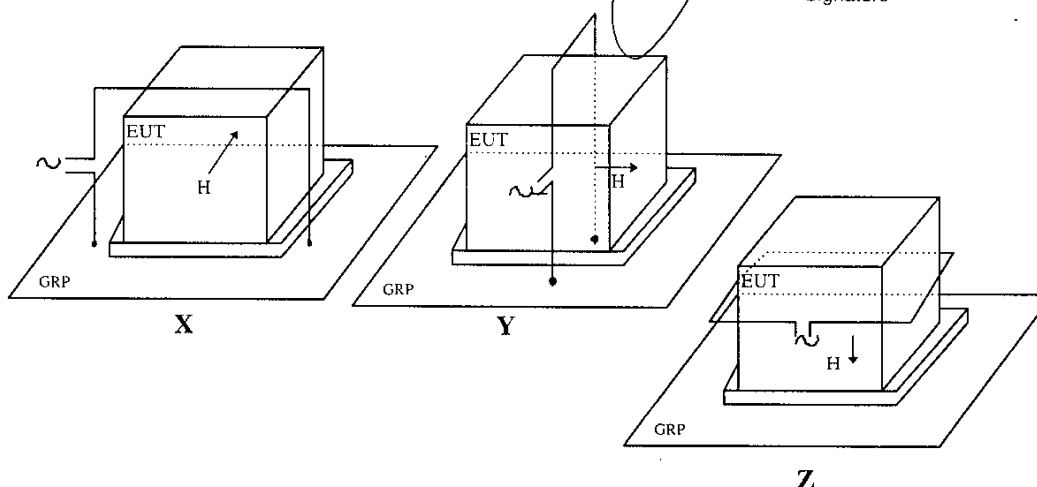
Test Report #: SC304990 Test Area: TR 2
 Test Method: EN 61000-4-8 Date: 11/25/03
EN 60601-1-2:2001
 EUT Model #: IPG SC-1104-02 EUT POWER: ☐ 230 Vac/50 Hz ☐ 120 Vac/60 Hz
☒ Other: 4.5 W Temperature: 22 °C
 EUT Description: IMPLANTABLE DEVICE 92161007 Air Pressure: 99.9 kPa
 NOTES: TESTED w/ Remote Control SC 5210SM 001002 Relative Humidity: 36 %



MAG FIELD FREQ. (Hz)	A/M	AXIS			TIME PER TEST SECS	COMPLIES		REMARKS
		X	Y	Z		YES	NO	
50	3	✓			60	X		
↓	↓		✓		↓	X		
				✓		X		
60	3	✓			60	X		
↓	↓		✓		↓	X		
				✓	↓	X		

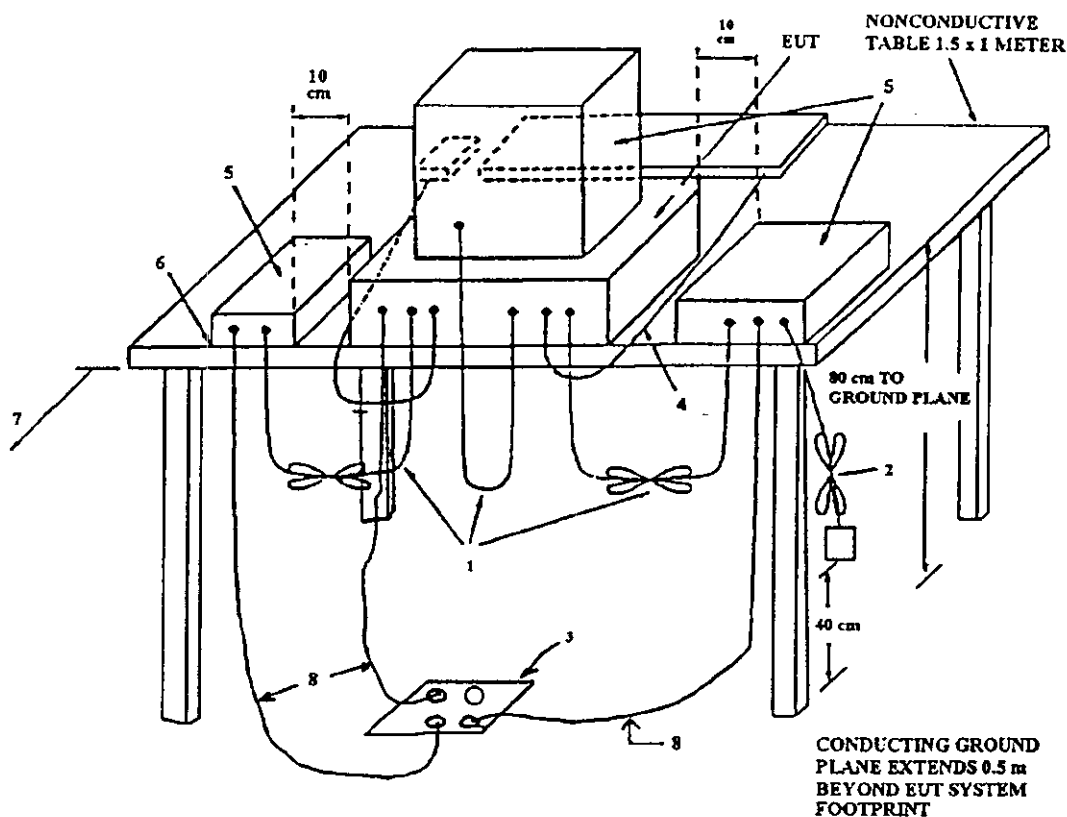
Tested By: A. Laudani
 Printed
 Reviewed by: J. Owen
 Printed

A. Laudani
 Signature
J. Owen
 Signature



mag4.doc

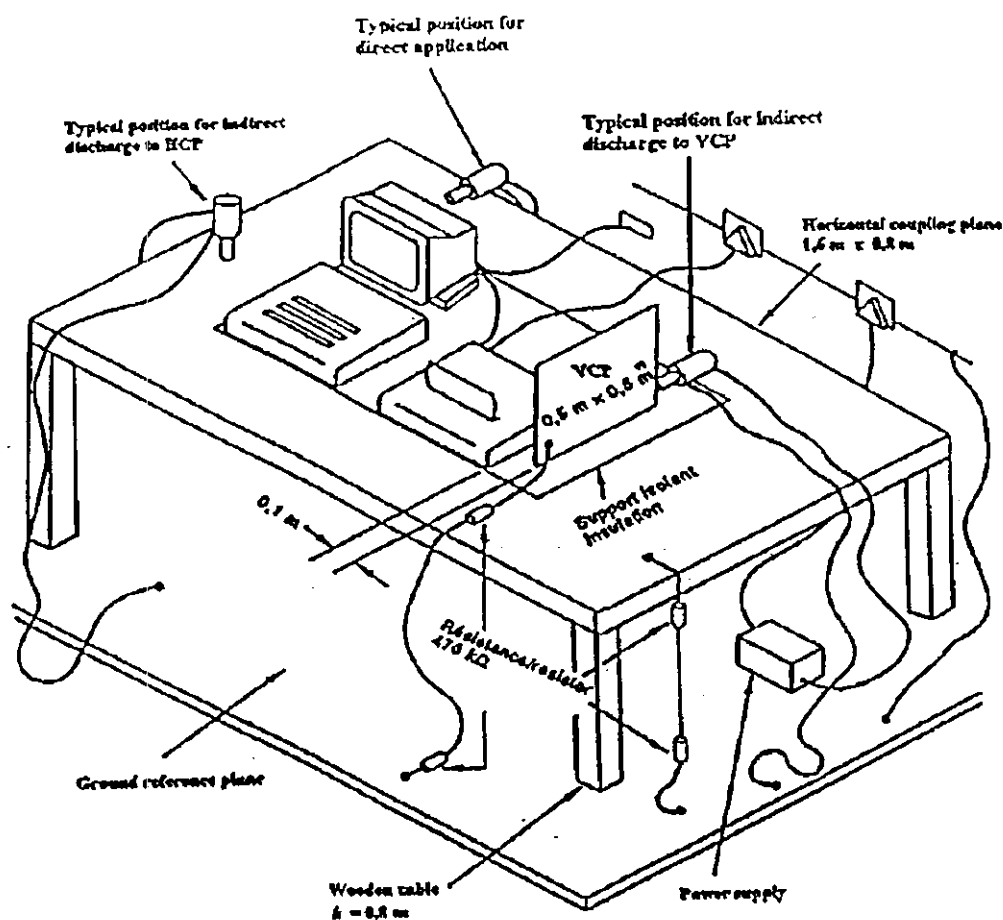
Radiated Emissions Test Setup, 30 to 1000 MHz



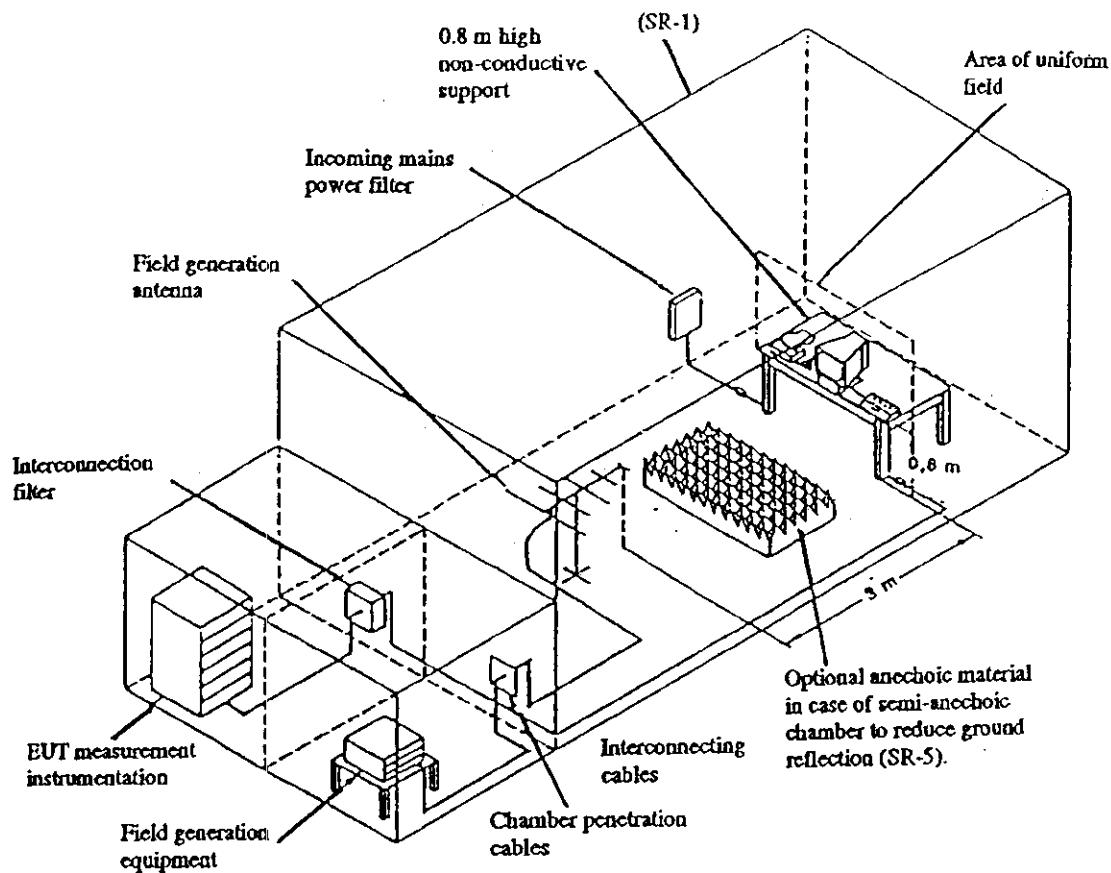
LEGEND:

1. Interconnecting cables that hang closer than 40 cm to the ground plane shall be folded back and forth forming a bundle 30 to 40 cm long, hanging approximately in the middle between ground plane and table.
2. I/O cables that are connected to a peripheral shall be bundled in center. The end of the cable may be terminated if required using correct terminating impedance. The total length shall not exceed 1 m.
3. If LISNs are kept in the test setup for radiated emissions, it is preferred that they be installed under the ground plane with the receptacle flush with the ground plane.
4. Cables of hand-operated devices, such as keyboards, mouses, etc., have to be placed as close as possible to the controller.
5. Non-EUT components of EUT system being tested.
6. The rear of all components of the system under test shall be located flush with the rear of the table.
7. No vertical conducting wall used.
8. Power cords drape to the floor and are routed over to receptacle.

Test Configuration Reference for ESD, Tabletop Unit



Test Configuration for Radiated E-Fields Immunity



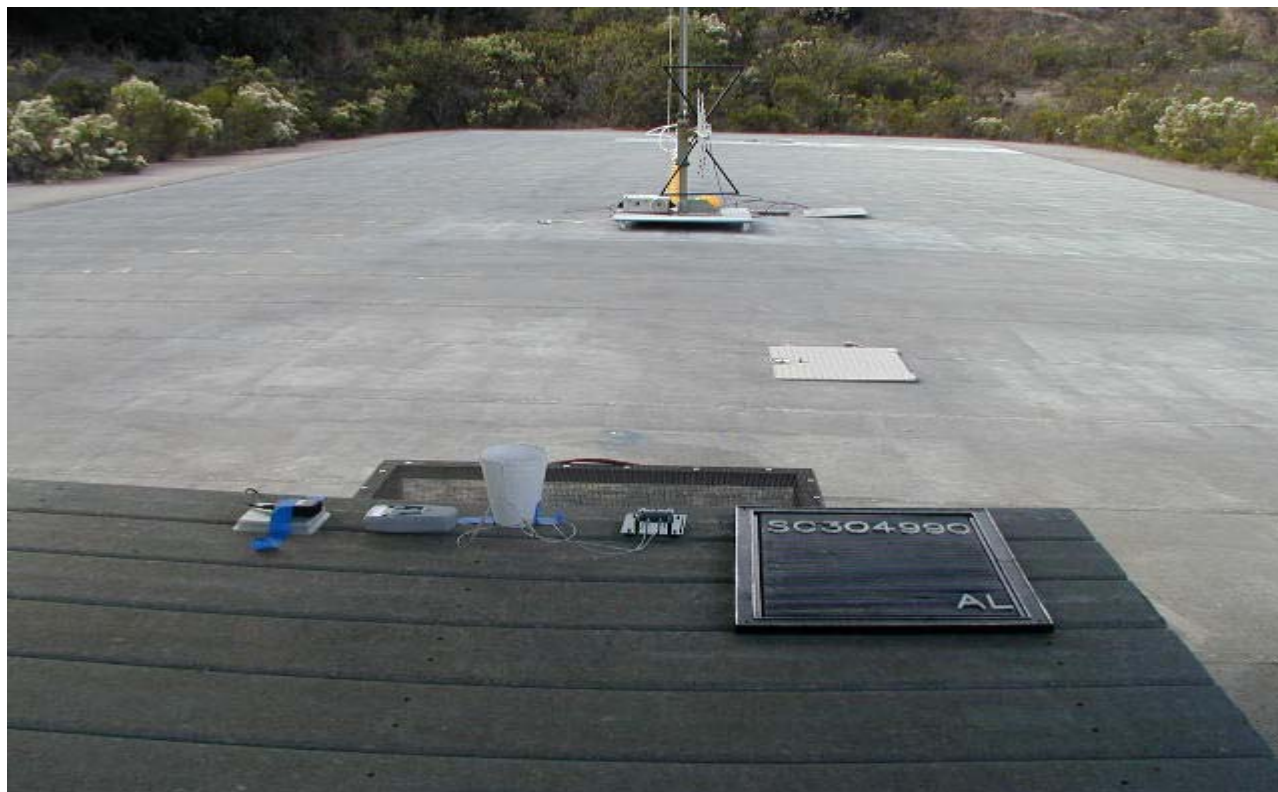
NOTE - Anechoic lining material on walls and ceiling has been omitted for clarity.

Appendix A

Test Setups (Photographs)

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Photograph of Test Setup:
Radiated Emissions



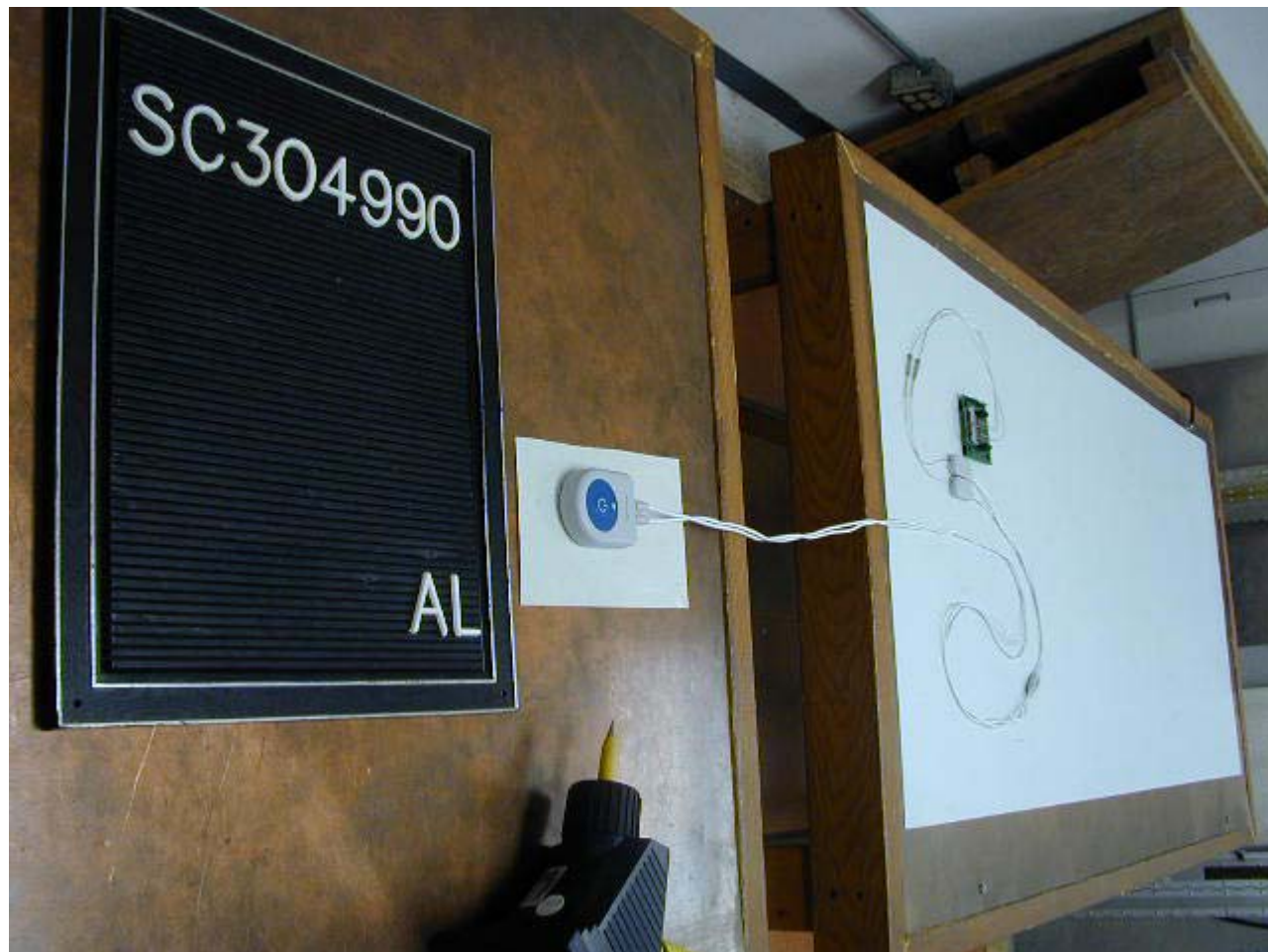
Report No. SC304990-02

Photograph of Test Setup:
Radiated Emissions



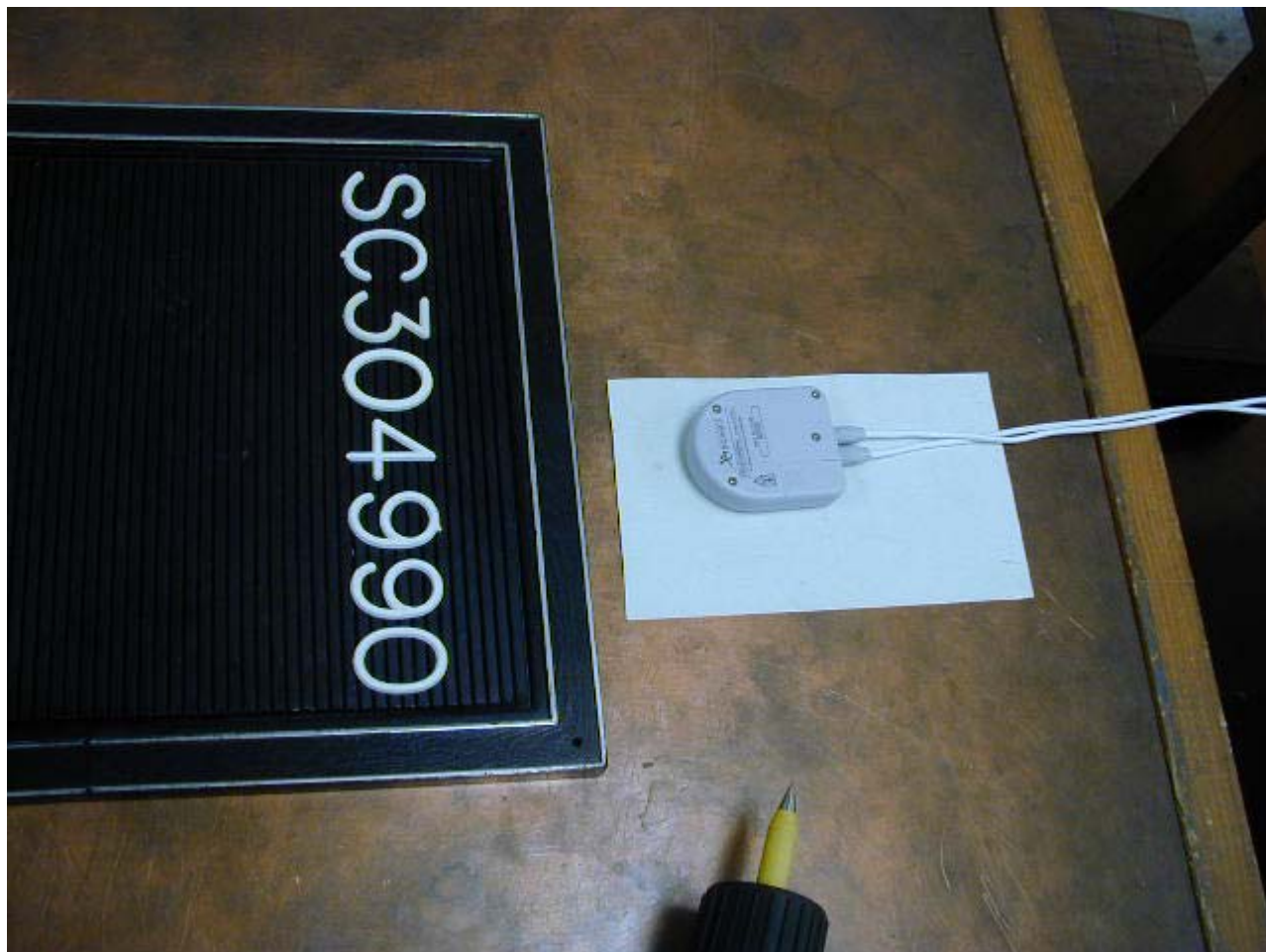
Report No. SC304990-02

Photograph of Test Setup:
Electrostatic Discharge (ESD)



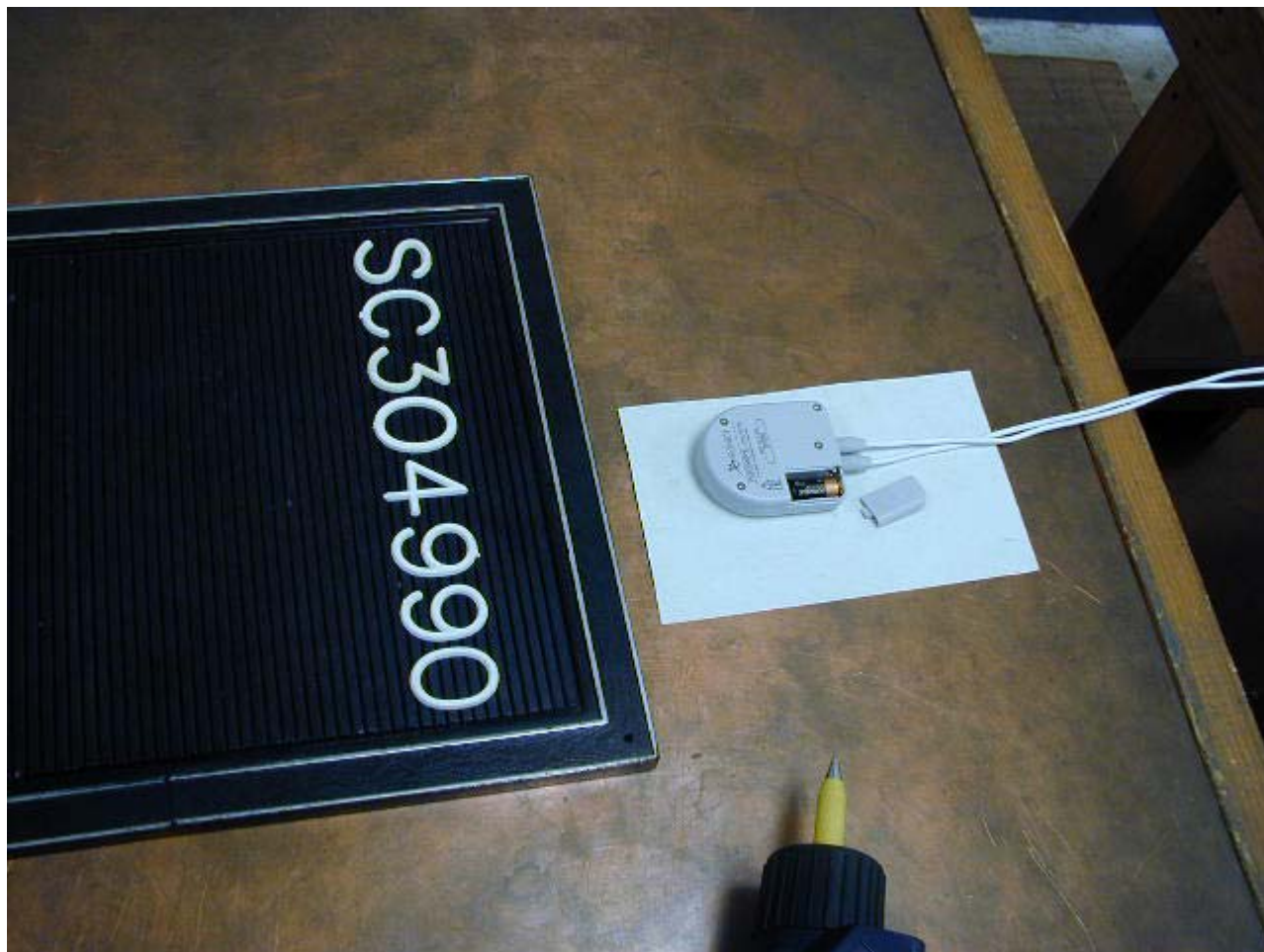
Report No. SC304990-02

Photograph of Test Setup:
Electrostatic Discharge (ESD)



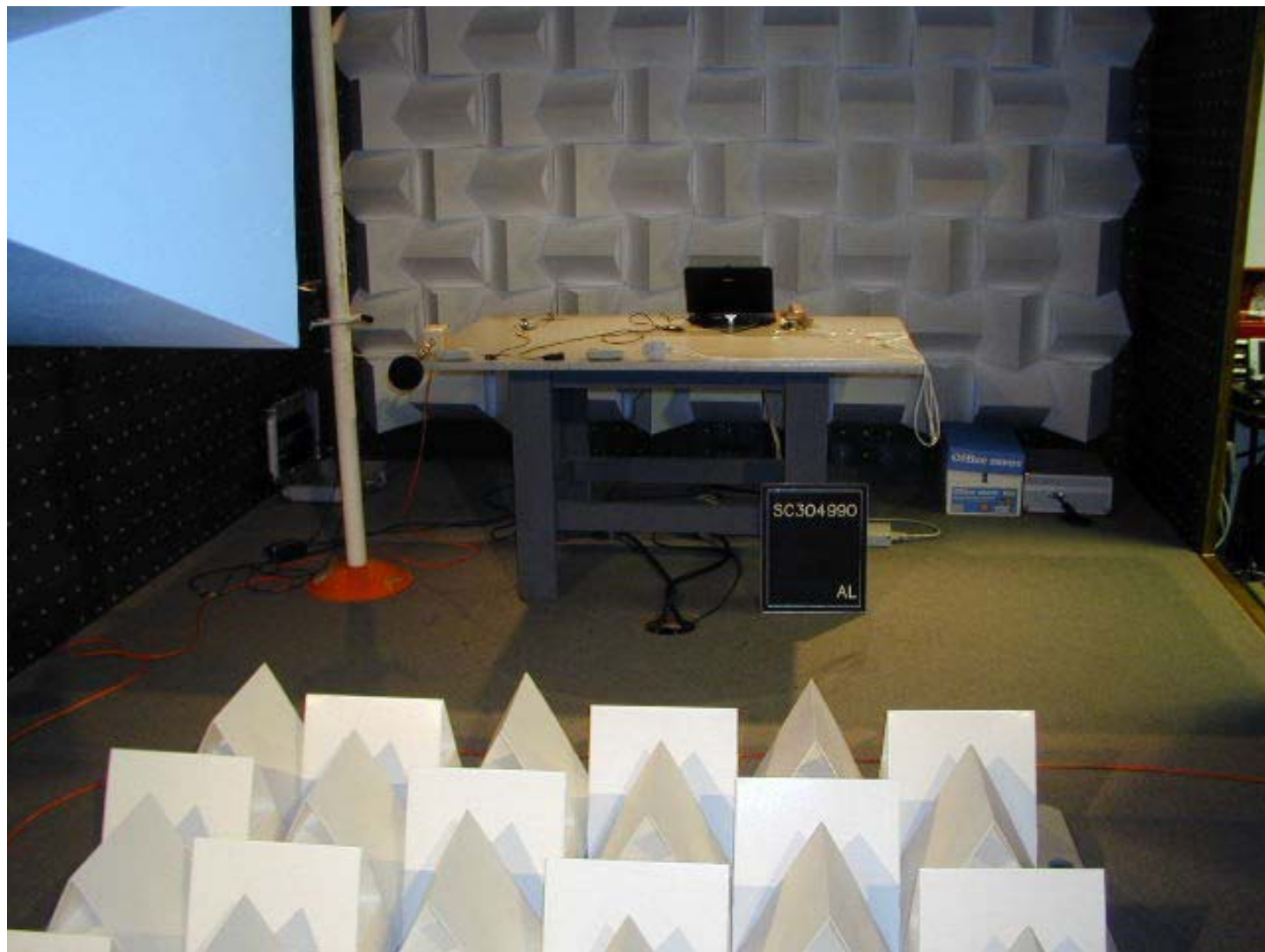
Report No. SC304990-02

Photograph of Test Setup:
Electrostatic Discharge (ESD)



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Photograph of Test Setup:
Radiated Electromagnetic Fields



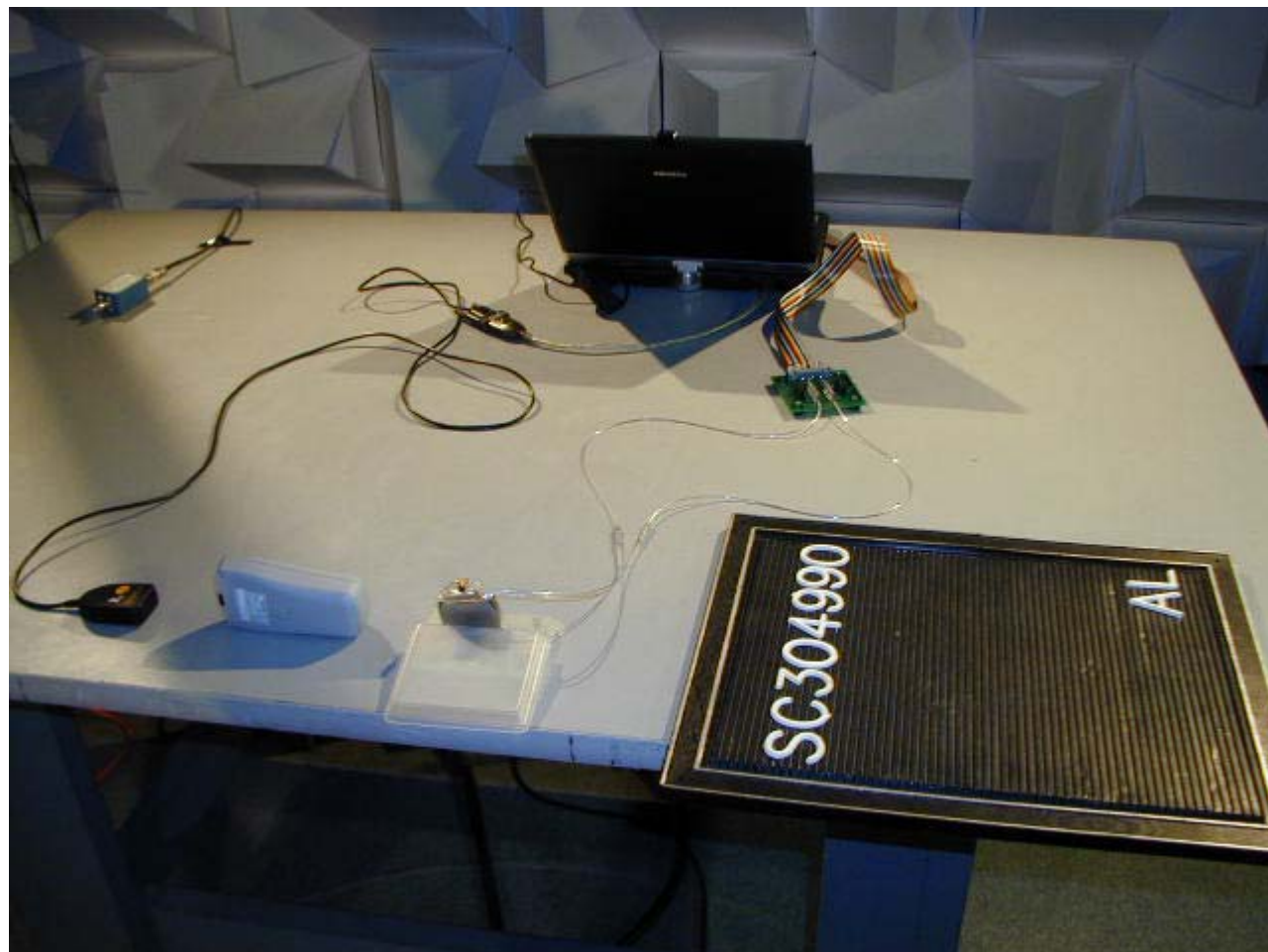
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Photograph of Test Setup:
Radiated Electromagnetic Fields



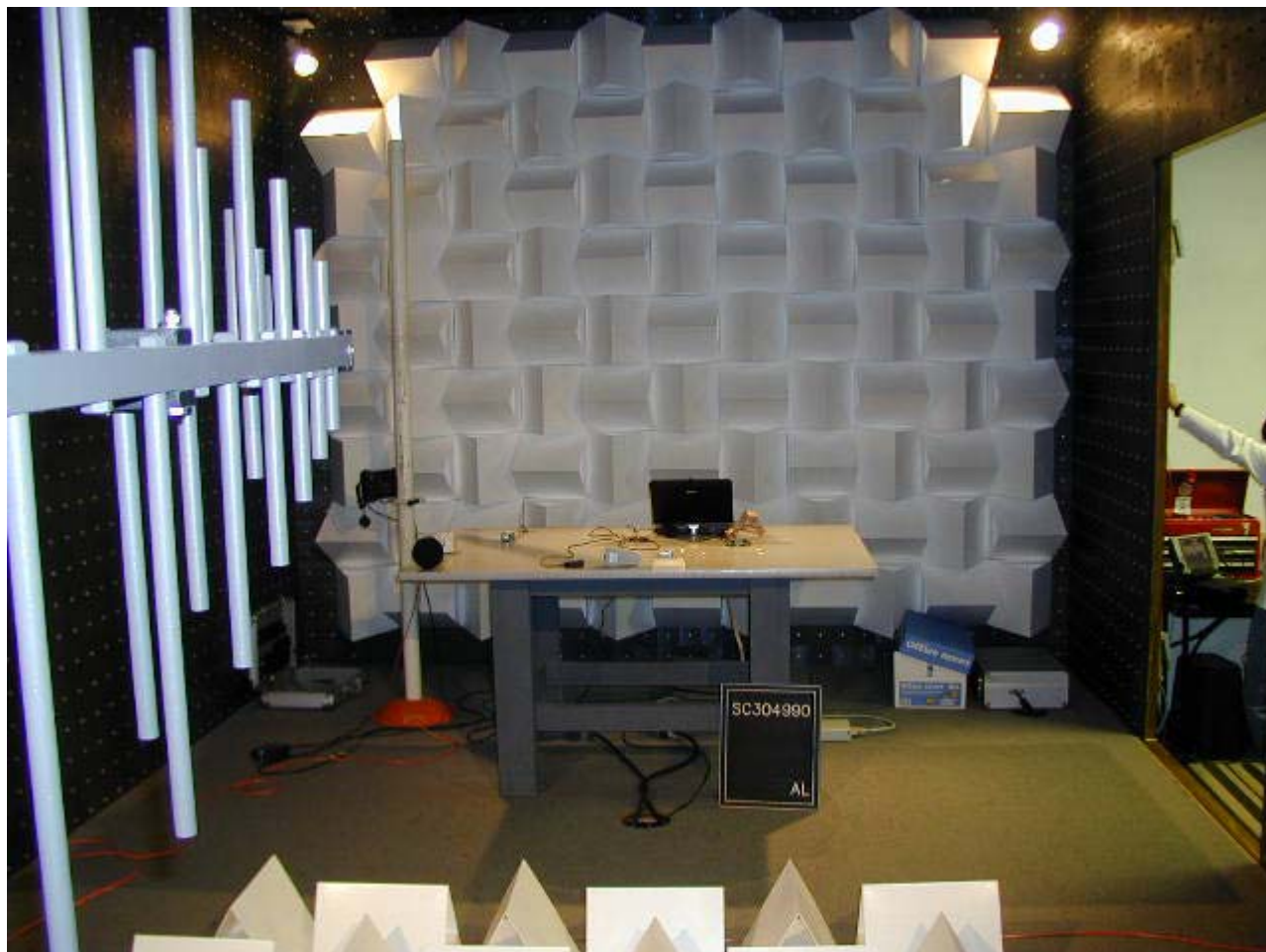
Report No. SC304990-02

Photograph of Test Setup:
Radiated Electromagnetic Fields



Report No. SC304990-02

Photograph of Test Setup:
Radiated Electromagnetic Fields



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Photograph of Test Setup:
Magnetic Field



Report No. SC304990-02

Photograph of Test Setup:
Magnetic Field



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Appendix B

Product Information Form(s)

Not Available

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Appendix C

Change History

Not Applicable

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Appendix D

Supplemental Information

Not Applicable