

# 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  
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■ - 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

**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

Report No. SC304990-02

**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 $\mu$ H/250 $\mu$ H/50 $\Omega$ /0.25 $\mu$ 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:** \_\_\_\_\_

Report No. SC304990-02

**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: \_\_\_\_\_

**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



**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:             -  $\leq 0.0015$  decades / sec             - 1%
- Polarization of Antenna:             - Horizontal             - Vertical             - Circular
- Result:**  
 - Pass             - Fail

**Remarks:** \_\_\_\_\_

**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:** \_\_\_\_\_

**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:

- |   |                 |
|---|-----------------|
| <input type="checkbox"/> - _____                    | Type: _____     |
| <input type="checkbox"/> - _____                    | Type: _____     |
| <input type="checkbox"/> - _____                    | Type: _____     |
| <input type="checkbox"/> - _____                    | Type: _____     |
| <input type="checkbox"/> - _____                    | Type: _____     |
| <input type="checkbox"/> - _____                    | Type: _____     |
| <input type="checkbox"/> - Unshielded power cable   |                 |
| <input type="checkbox"/> - Unshielded cables        |                 |
| <input type="checkbox"/> - Shielded cables          | MPS. No.: _____ |
| <input type="checkbox"/> - Customer specific cables |                 |
| <input type="checkbox"/> - _____                    |                 |
| <input type="checkbox"/> - _____                    |                 |

Report No. SC304990-02

**GENERAL REMARKS:**

(\*) Electrostatic Discharge - CTI, 2, 3, 4, 5 resets in about 4 seconds  $\pm$  4 kV,  $\pm$  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:



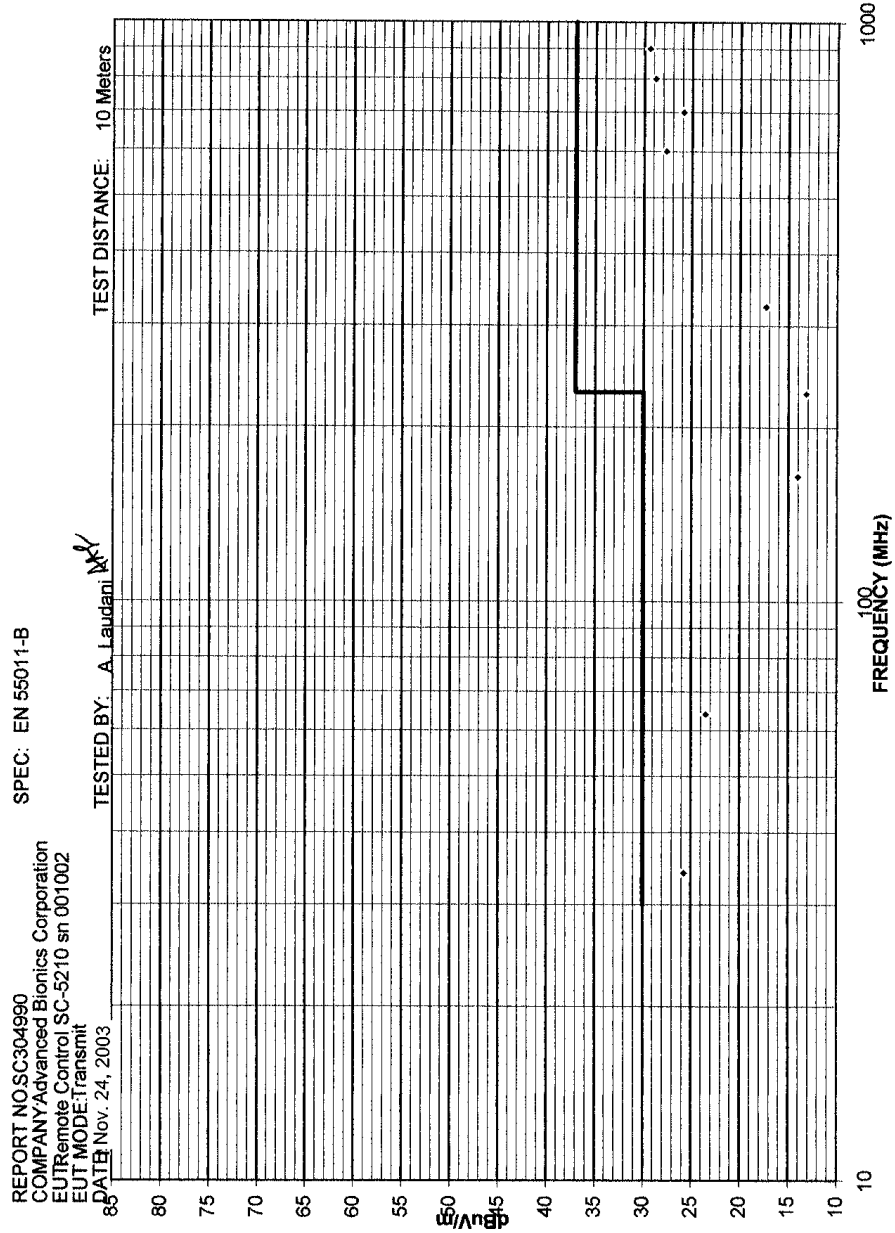
Alan Laudani  
(EMC Engineer)

## **Technical Documentation**

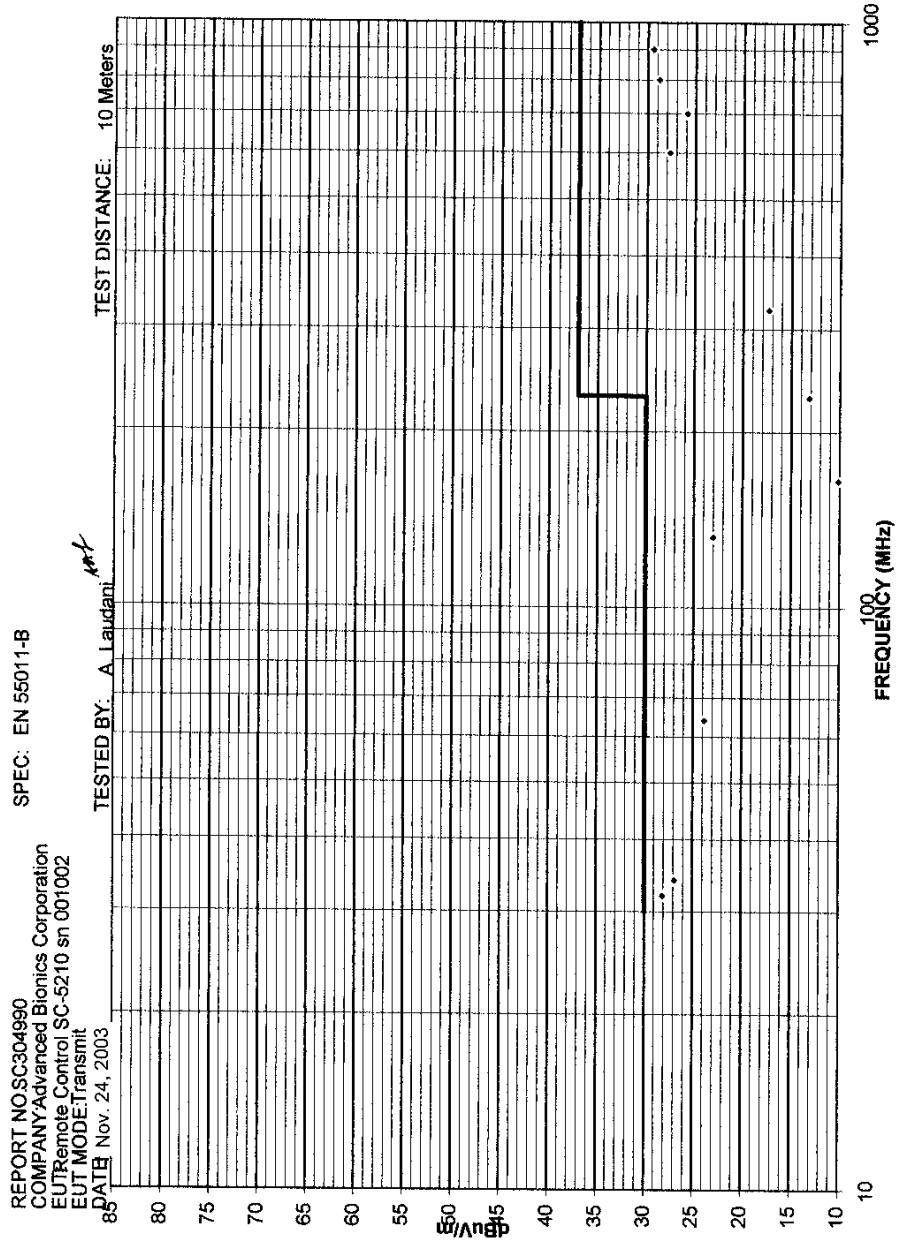
**Test Data Sheets**

**and**

**Test Setup Drawing(s)**



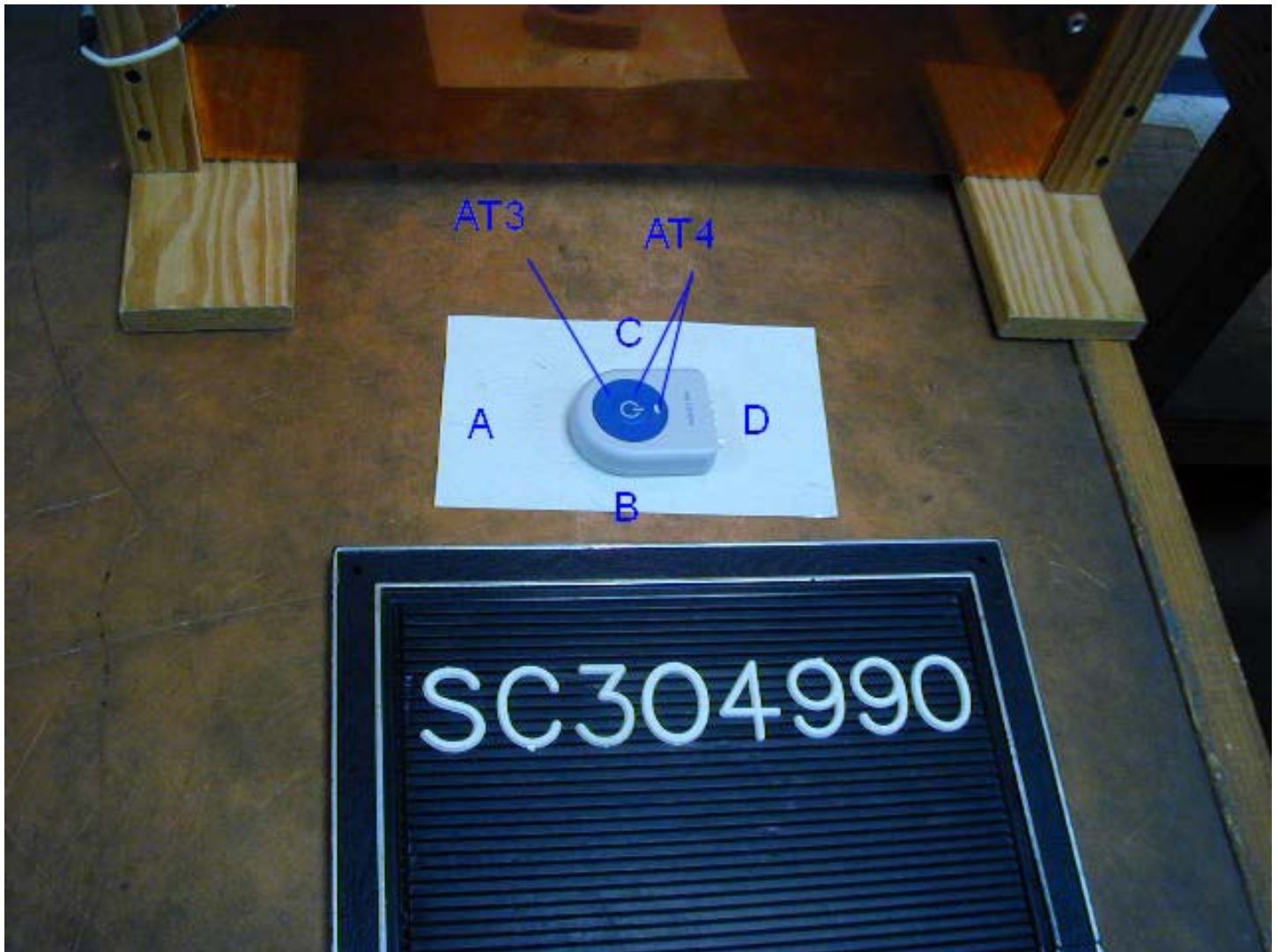




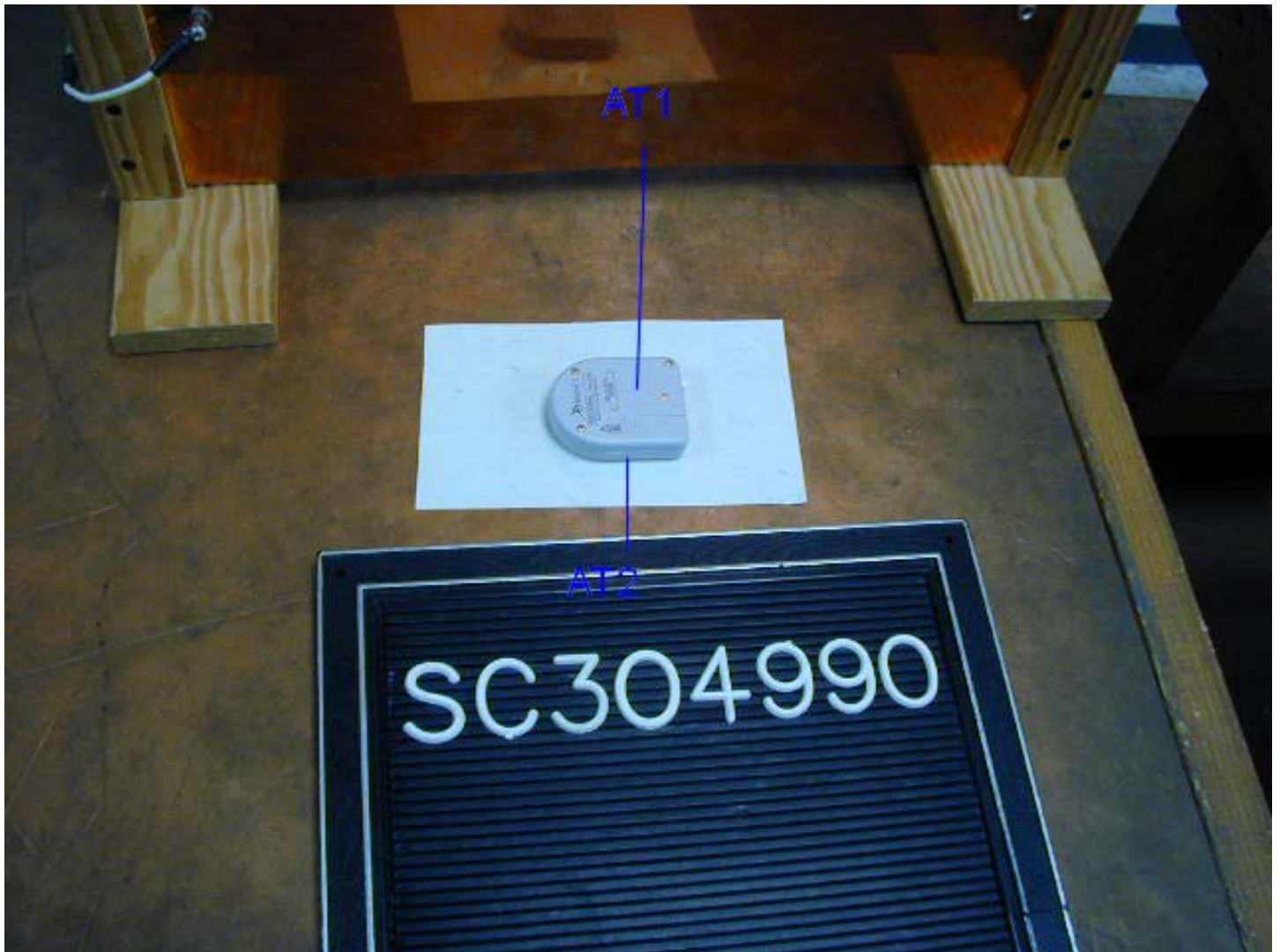




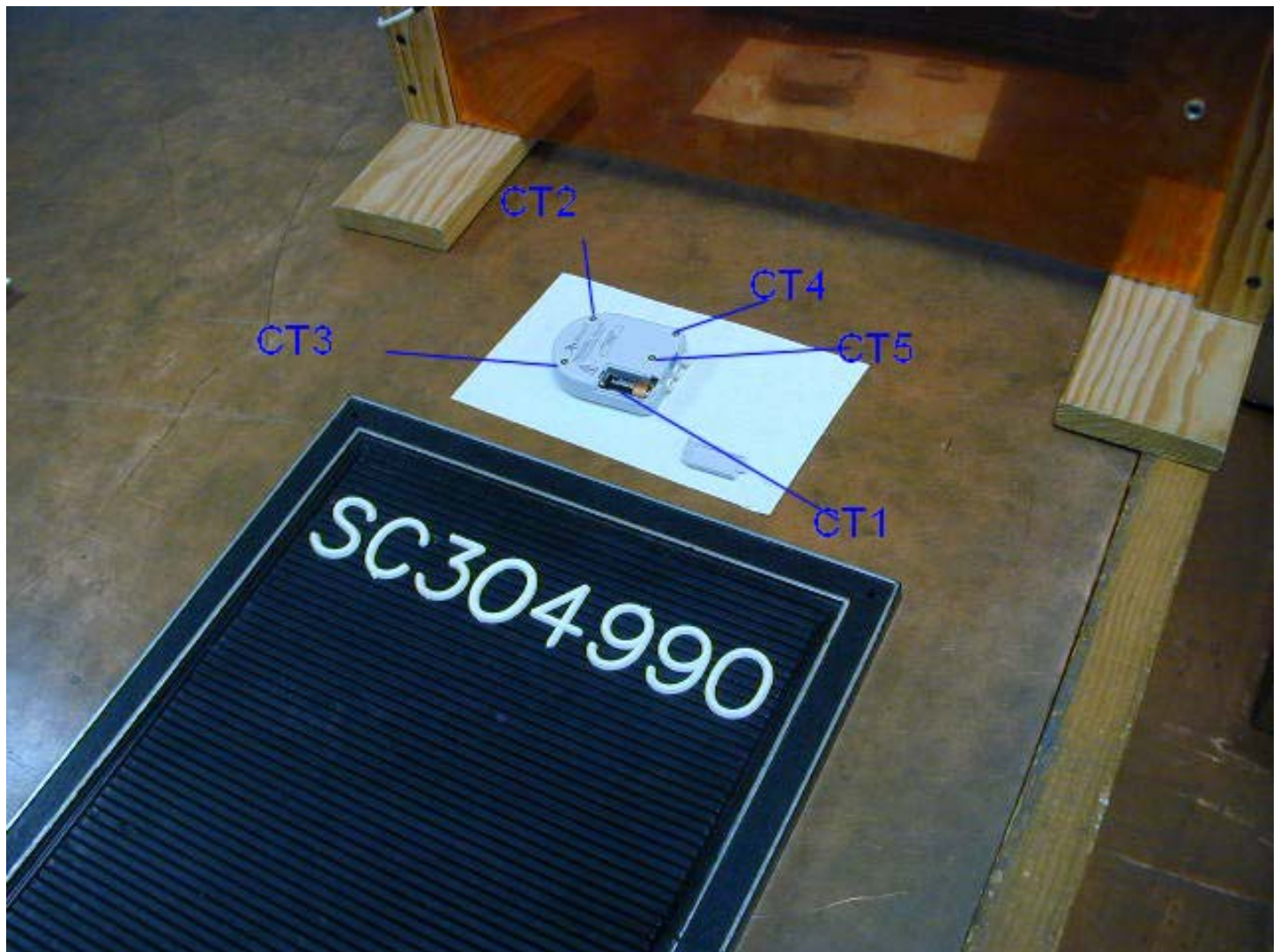
ESD MAP



ESD MAP



ESD MAP



**ESD IMMUNITY**

Test Report #: SC304990 Test Area: TR1  
 Test Method: EN 61000-4-2 Date: 11/25/03  
EN 60601-1-2:2001  
 EUT Model #: SC-5100-02 EUT POWER:  
 230 Vac/50 Hz  120 Vac/60 Hz  
 Other: 6 Vdc



EUT Description: EXTERNAL TRIAL SIMULATOR SN 001000 Temperature: 23 °C  
 Air Pressure: 99.9 kPa  
 Relative Humidity: 37 %

NOTES: System Resets in About 4 seconds After ESD event

TEST POINT LOCATION	DISCHARGE TYPE			2 KV REPS		3 KV REPS		4 KV REPS		6 KV REPS		8 KV REPS		KV REPS	COMPLIES?		REMARKS
	INDIR*	CON**	AIR	+	-	+	-	+	-	+	-	+	-		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	↓			↓	↓			↓	↓	↓	↓				✓		
CTI		X		10	10			10	10	10	10				✓		Batteries Resets
2		↓		↓	↓			↓	↓	↓	↓				✓		Resets -6kV
3		↓		↓	↓			↓	↓	↓	↓				✓		Resets ±6kV
4		↓		↓	↓			↓	↓	↓	↓				✓		Resets ±4kV ±6kV
5		↓		↓	↓			↓	↓	↓	↓				✓		Resets ±4kV ±6kV
ATI			X	10	10			10	10	10	10				✓		BATT COVER
2				↓	↓			↓	↓	↓	↓				✓		Enclosure Crack
3				↓	↓			↓	↓	↓	↓				✓		Button Switch
4				↓	↓			↓	↓	↓	↓				✓		Led

Tested by: A. Laudani  
Printed

A. Laudani  
Signature

Reviewed by: JIM OWEN  
Printed

J. Owen  
Signature

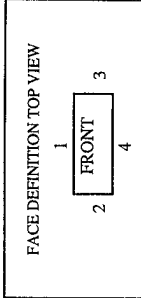
(\*) Indirect (\*\*) Contact

ESDC.DOC Rev 08.98



**RADIATED IMMUNITY**

Test Report #: SC 304990 Test Area: SRI  
 Test Method: EN 61000-4-3 Date: 11-25-03  
SN 60601-1-2: 2001  
 EUT POWER:  230 Vac/60 Hz  120 Vac/60 Hz  
 Other: 6 vac / 4.5 Vdc  
 EUT Model #: ETS SC5100-02  
 EUT Description: EXTERNAL TRIAL Stimulator SN 001005  
 NOTES: w/ Remote Control SC-5210 SN 001002



Temperature: 24 °C  
 Air Pressure: 99.9 kPa  
 Relative Humidity: 41 %

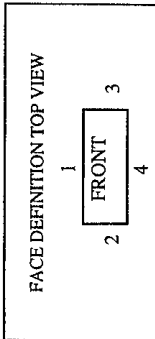
TEST FREQ (MHz)	TEST LEVEL	MODULATION		FIELD POLARITY (HV)	TEST DIST (M)	EUT FACE (1 TO 6)		COMPLIES		REMARKS
		FREQ (Hz)	AMPL (%)			FACE	NO	YES	NO	
10-1000	3 Vm	1000	80	SINE	3	1	X			
				H		1	X			
				H		2	X			
				V		2	X			
				V		3	X			
				H		3	X			
				H		4	X			
				V		4	X			
				V		5	X			
				H		5	X			
				H		6	X			
				V		6	X			

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 Signature: [Signature]  
 Reviewed by: J. M. [Signature] Printed  
 Signature: [Signature]  
 RADIMU.DOC Rev 05.97



### RADIATED IMMUNITY

Test Report #: SC 304990 Test Area: SR1  
 Test Method: EN 61000-4-3 Date: 11-24-03  
EN 60601-1-2:2001  
 EUT Model #: ETS 55100-02 EUT POWER:  
 230 Vac/50 Hz  120 Vac/60 Hz  
 Other: 6 kHz / 4.5 V<sub>rms</sub>  
 EUT Description: EXTERNAL TRIAL Stimulator SN 001005  
 NOTES: w/ Remote Control SC-5210 SN 001002



Temperature: 23 °C  
 Air Pressure: 99.8 kPa  
 Relative Humidity: 29 %

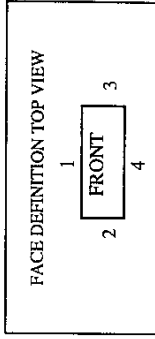
TEST FREQ (MHZ)	TEST LEVEL	MODULATION		FIELD POLARITY (HV)	TEST DIST (M)	EUT FACE (1 TO 6)		COMPLIES		REMARKS
		FREQ (HZ)	AMPL (%)			WAVE FORM	YES	NO		
1000-2500	3 1/2	1000	80	SINE	3	1	1	X		
						1	1	X		
						2	2	X		
						2	2	X		
						3	3	X		
						3	3	X		
						4	4	X		
						4	4	X		
						5	5	X		
						5	5	X		
						6	6	X		
						6	6	X		

Tested by: A. Laudman Printed  
 Signature: [Signature]  
 Reviewed by: SIM OWEN Printed  
 Signature: [Signature]  
 RADIMLDOC Rev 05.97



### RADIATED IMMUNITY

Test Report #: SC304990 Test Area: SR1  
 Test Method: EN61000-4-3 Date: 11-25-03  
EN60601-1-2  
 EUT POWER:  230 Vac/50 Hz  120 Vac/60 Hz  
 EUT Model #: IPG SC-1100-02  Other:  
 EUT Description: IMPLANTABLE PULSE GENERATOR  
 NOTES: IMPLANTABLE DEVICE  
Exposed to Radiated Field Front/Back to maximize effect.



Temperature: 24 °C  
 Air Pressure: 99.9 kPa  
 Relative Humidity: 41 %

TEST FREQ (MHz)	TEST LEVEL	MODULATION		FIELD POLARITY (HV)	TEST DIST (M)	EUT FACE (1 TO 6)		COMPLIES		REMARKS
		FREQ (Hz)	AMPL (%)			WAVE FORM	YES	NO		
80-1000	3 1/2	↓	80	SINE	3	1	1	X		Front w/ Remote Control SC-5210 in 001002
	↓	↓	↓	↓	↓	1	1	X		
	↓	↓	↓	↓	↓	4	4	X		BACK
	↓	↓	↓	↓	↓	4	4	X		
100-2500	3 1/2	↓	80	SINE	3	4	4	X		BACK
	↓	↓	↓	↓	↓	4	4	X		
	↓	↓	↓	↓	↓	1	1	X		Front
	↓	↓	↓	↓	↓	1	1	X		

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 Reviewed by: J. O. O. Signature  
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**MAGNETIC FIELD IMMUNITY**

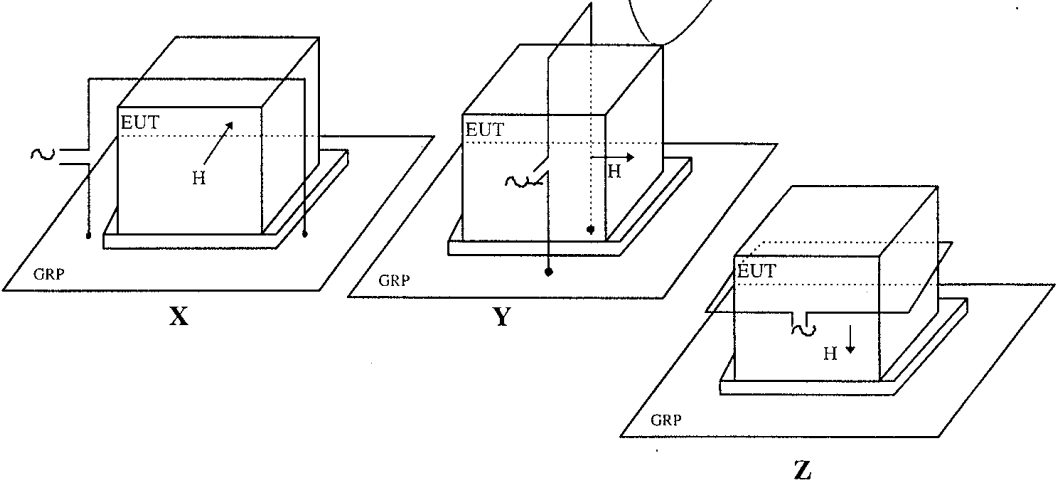
Test Report #: SC304990 Test Area: TR2  
 Test Method: EN 61000-4-8 Date: 11/25/03  
EN 61000-1-2:2001  
 EUT Model #: ETS SC5100-02 EUT POWER:  
 230 Vac/50 Hz  120 Vac/60 Hz  
 Other:  
 EUT Description: EXTERNAL TRIAXIAL SIMULATOR SN 001005  
 NOTES: w/ Remote CONTROL SC5210  
SN 001002



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		

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 Signature: [Signature]



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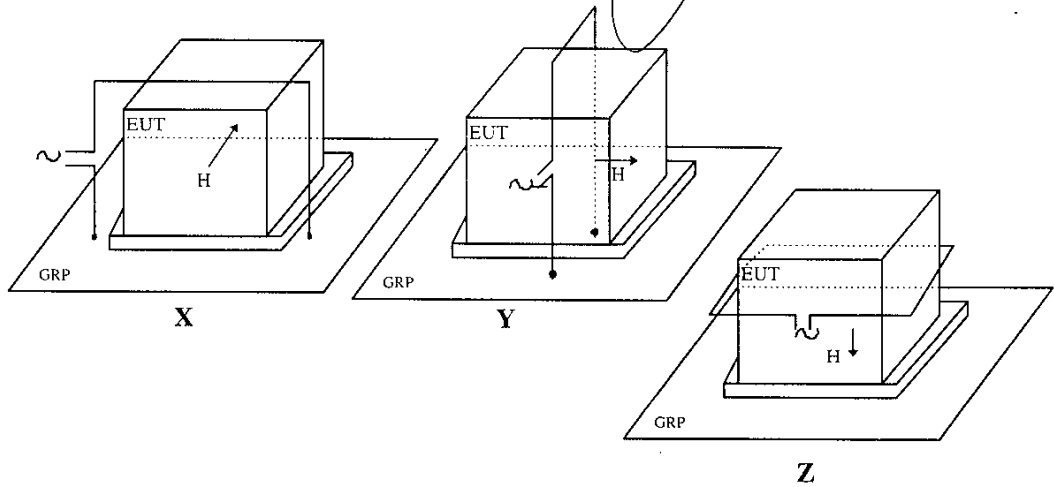
**MAGNETIC FIELD IMMUNITY**

Test Report #: SC304990 Test Area: TR2  
 Test Method: EN61000-4-8 Date: 11/25/03  
EN60601-1-2:2001  
 EUT Model #: IPG SC-1104-02 EUT POWER:  230 Vac/50 Hz  120 Vac/60 Hz  
 Other: 4.5 Wc Temperature: 22 °C  
 EUT Description: IMPLANTABLE DEVICE 92161007 Air Pressure: 99.9 kPa  
 NOTES: TESTED w/ Remote Control SC5210<sup>SM</sup> 001002 Relative Humidity: 36 %



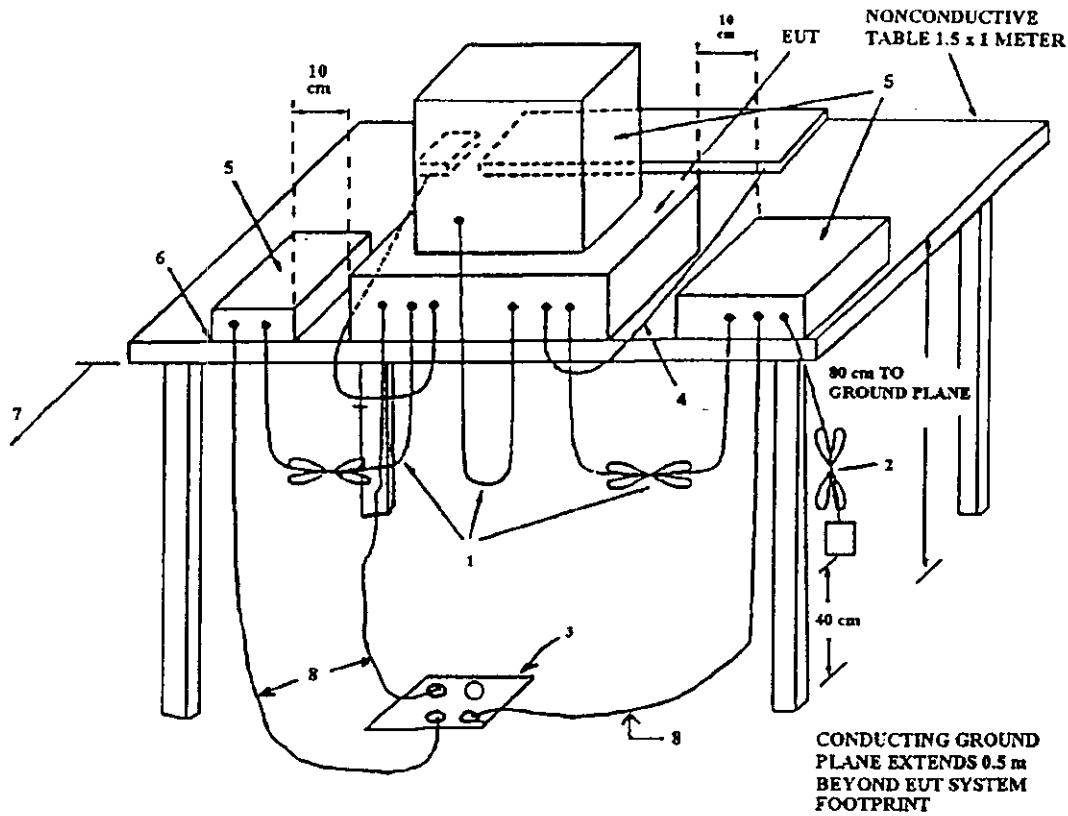
MAG FIELD FREQ. (Hz)	A/M	AXIS			TIME PER TEST SECS	COMPLIES		REMARKS
		X	Y	Z		YES	NO	
50	3	✓			60	X		
↓	↓		✓		↓	X		
60	3	✓			60	X		
↓	↓		✓		↓	X		
				✓	↓	X		

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 Signature: A. Laudani  
 Reviewed by: J. Owen Printed  
 Signature: J. Owen



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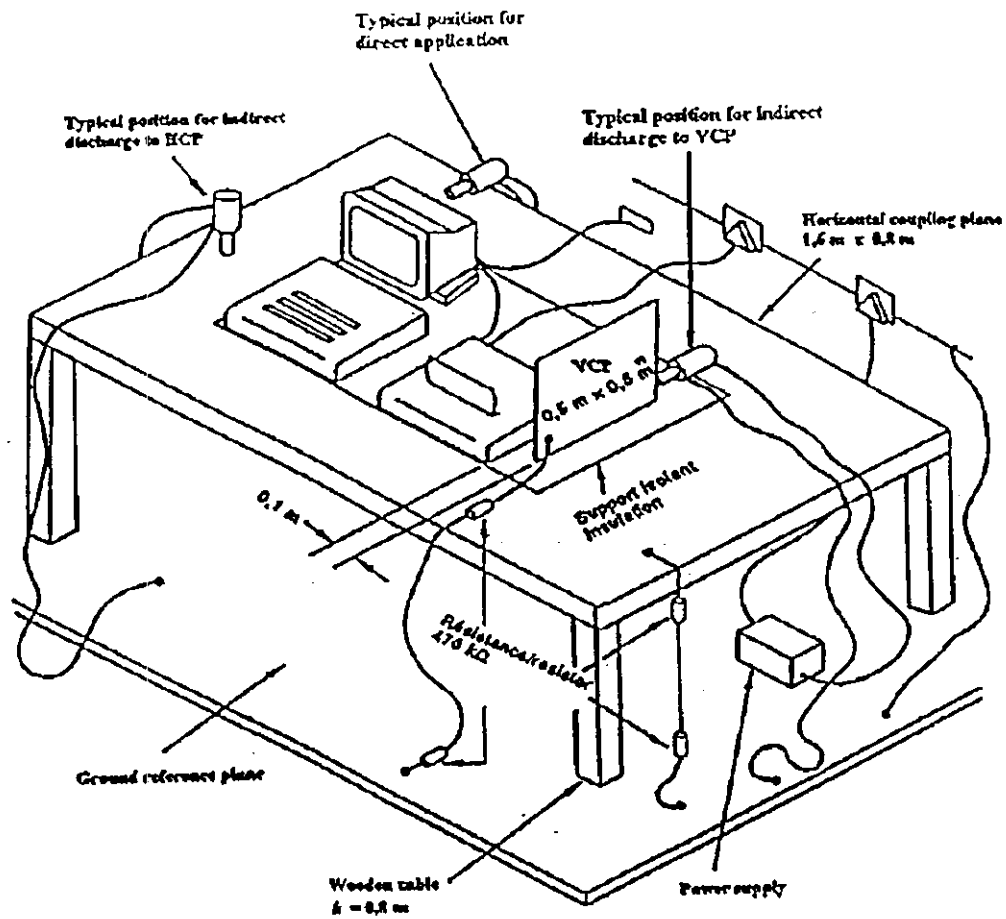
Radiated Emissions Test Setup, 30 to 1000 MHz



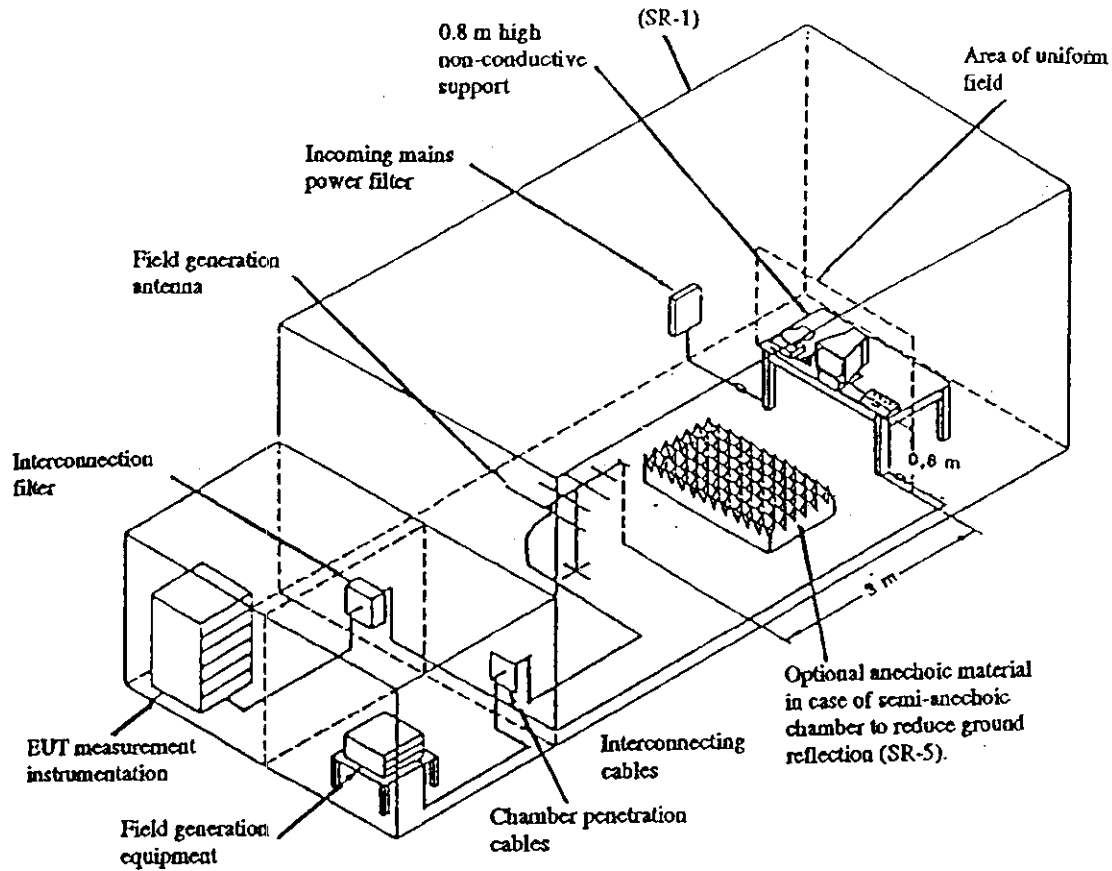
**LEGEND:**

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, mice, 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



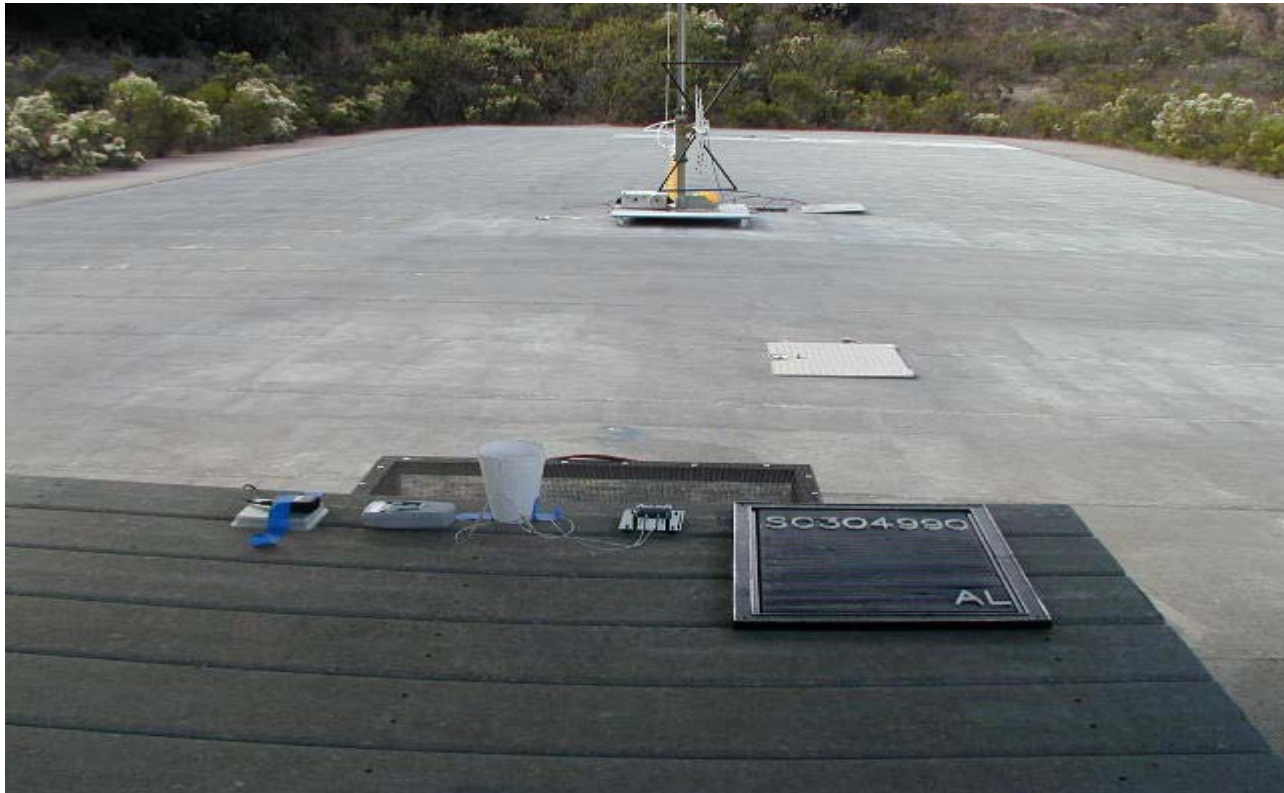
NOTE - Anechoic lining material on walls and ceiling has been omitted for clarity.

## Appendix A

### Test Setups (Photographs)

Report No. SC304990-02

Photograph of Test Setup:  
Radiated Emissions



Report No. SC304990-02

Photograph of Test Setup:  
Radiated Emissions





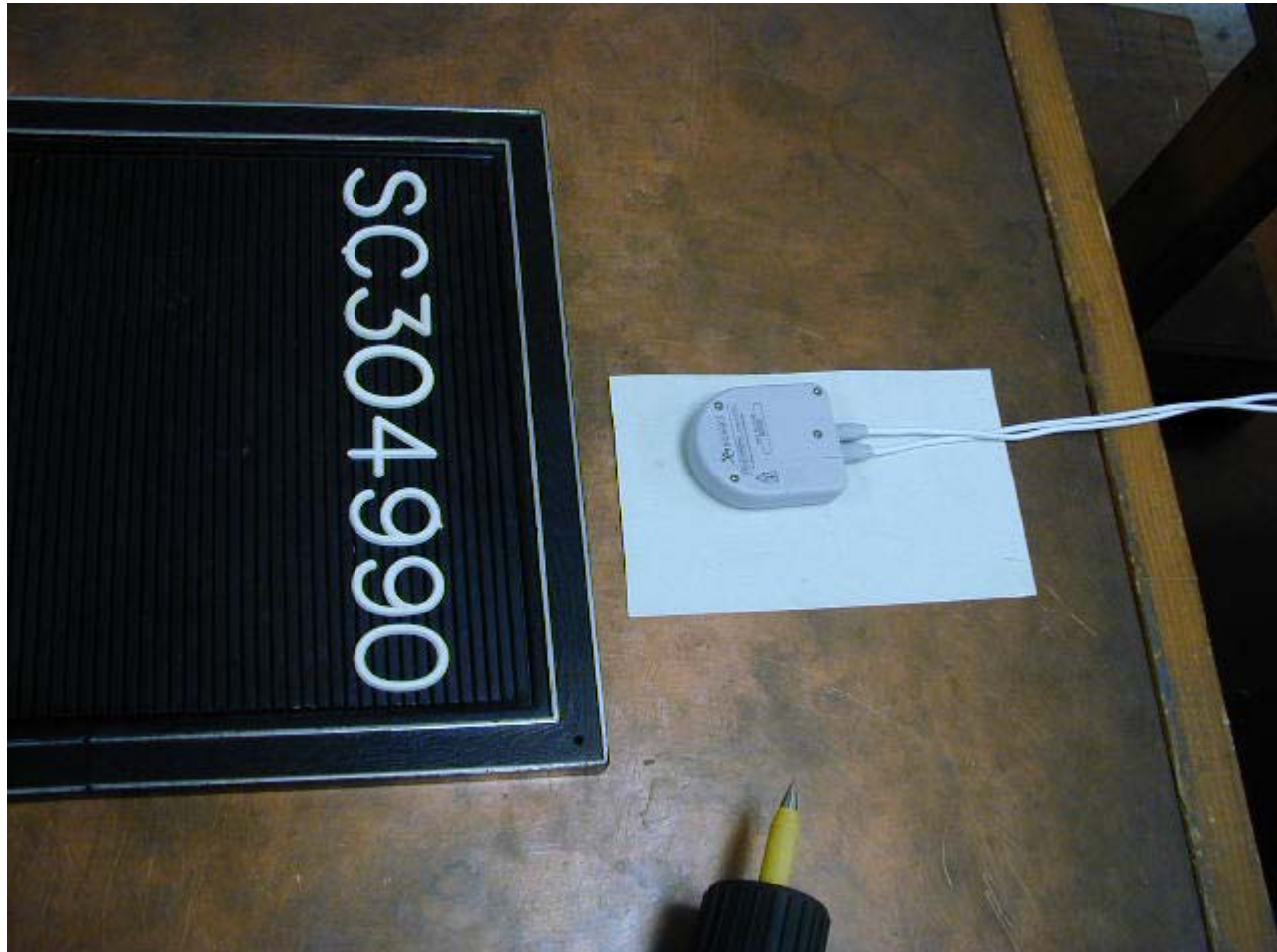
Report No. SC304990-02

Photograph of Test Setup:  
Electrostatic Discharge (ESD)



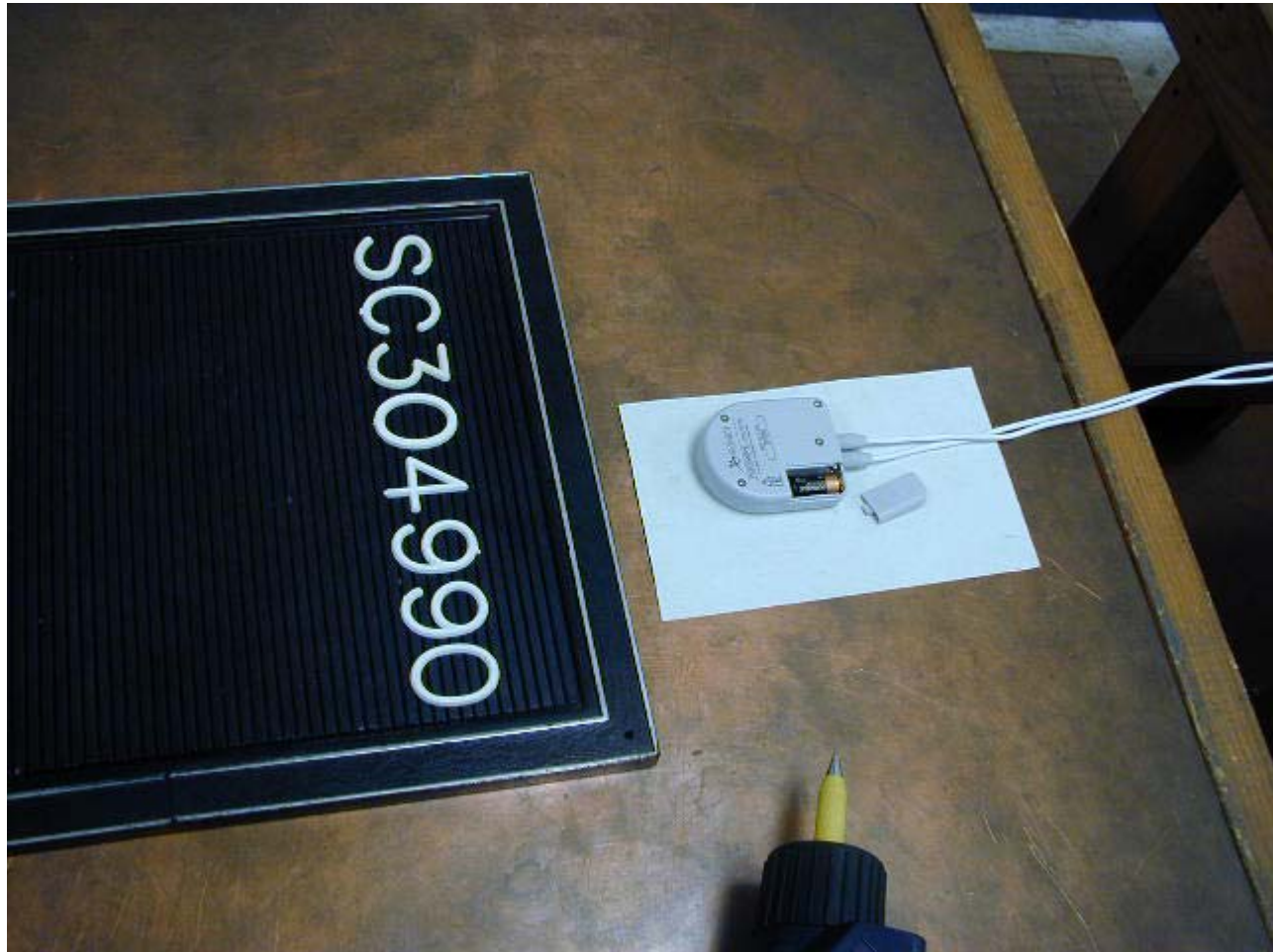
Report No. SC304990-02

Photograph of Test Setup:  
Electrostatic Discharge (ESD)



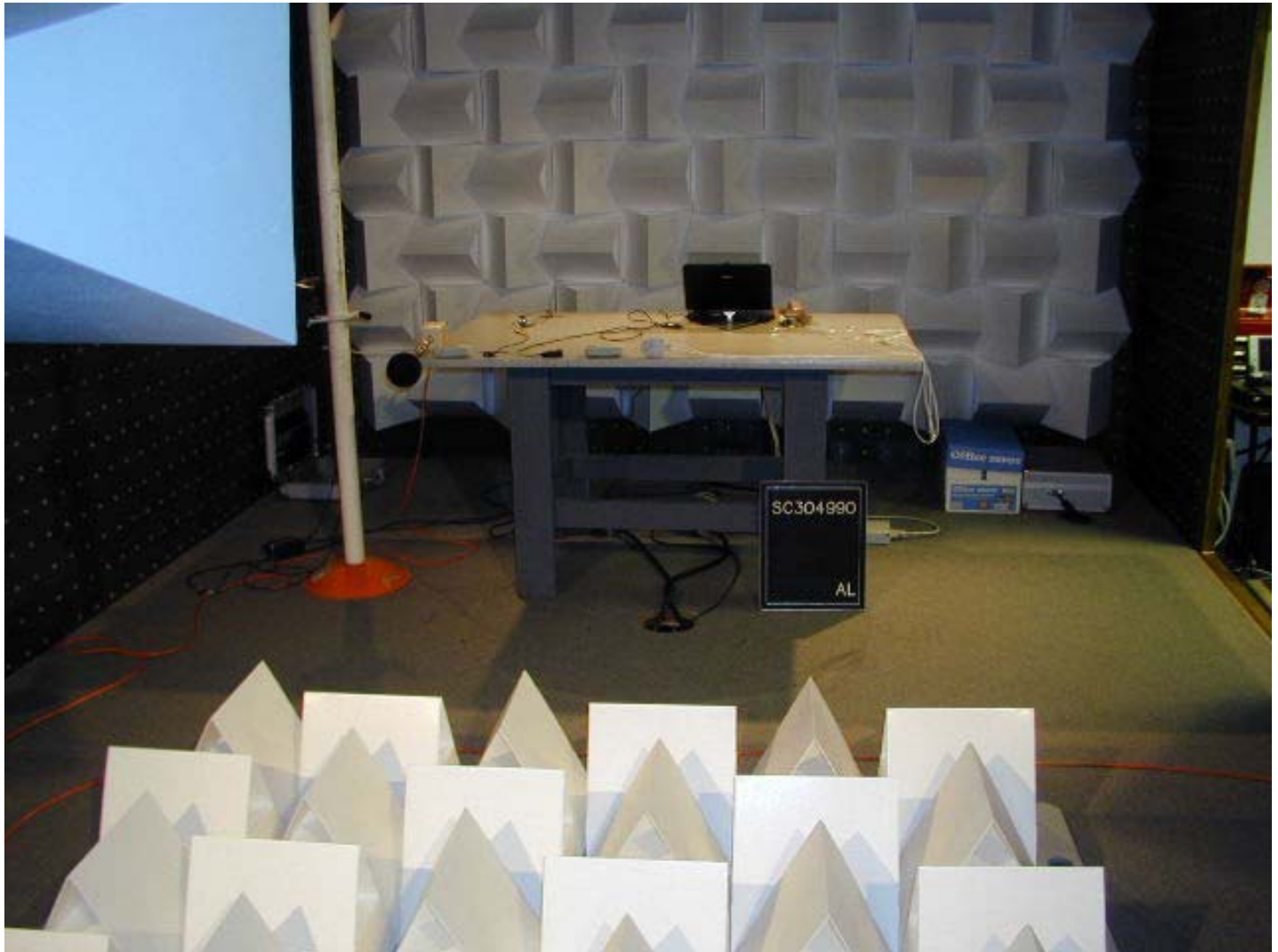
Report No. SC304990-02

Photograph of Test Setup:  
Electrostatic Discharge (ESD)



Report No. SC304990-02

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



Photograph of Test Setup:  
Radiated Electromagnetic Fields



Photograph of Test Setup:  
Magnetic Field





Photograph of Test Setup:  
Magnetic Field



## Appendix B

### Product Information Form(s)

**Not Available**

## **Appendix C**

### **Change History**

**Not Applicable**

## Appendix D

### Supplemental Information

**Not Applicable**