

MEASUREMENT AND TECHNICAL REPORT

ADVANCED BIONICS CORPORATION
12740 San Fernando Road
Sylmar, CA 91342

DATE: 05 November 2002

This Report Concerns:	Original Grant: X	Class II Change:
Equipment Type:	SCS Implant System - Implantable Pulse Generator (SC-1100)	
Deferred grant requested per 47 CFR 0.457(d)(1)(ii)?	Yes: Defer until:	No: X
Company Name agrees to notify the Commission by: of the intended date of announcement of the product so that the grant can be issued on that date.	N/A	
Transition Rules Request per 15.37?	Yes:	No: X*
(*) FCC Part 15, Paragraph(s) 15.209(a)		
<p>Report Prepared by:</p> <p>TÜV AMERICA, INC 10040 Mesa Rim Road San Diego, CA 92121-2912 Phone: 858 546 3999 Fax: 858 546 0364</p>		

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1.0 GENERAL INFORMATION

1.1 Product Description

Model Number	SC-1100
Model Description	SCS Implantable Pulse Generator
length	2.0"
width	1.8"
height	0.4"
weight	35g
Power source (if battery, voltage and size)	Battery 4.2V
Power type (if battery, chemistry)	Lithium-ion
Power capacity	200mAHr
Cable - signal type	2x stimulator lead; 2x Lead extension
Cable - connector type	proprietary (custom connector)
Cable - shielded/unshielded	no
Cable - length	lead = 50cm extention = 25cm
Cable - removable (y/n)	yes

Support Equipment (additionally, see section 2.1)

Model Number	SC-5200
Model Description	SCS Handheld Programmer
length	3.5"
width	2.7"
height	0.8"
weight	76g (w/o battery)
Power source (if battery, voltage and size)	Battery 3.6V
Power type (if battery, chemistry)	Lithium
Power capacity	2.6AHr
Cable - signal type	na
Cable - connector type	na
Cable - shielded/unshielded	na
Cable - length	na
Cable - removable (y/n)	na

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1.2 Related Submittal Grant

None

1.3 Tested System Details

The FCC ID's for all equipment, plus descriptions of all cables used in the tested system are:

None

1.4 Test Methodology

Purpose of Test: To demonstrate compliance with the following tests.

TEST	FCC CFR 47#	PASS/FAIL
Radiated Emissions	15.209(a)	Pass

Unless otherwise stated, testing was performed according to the procedures in FCC/ANSI C63.4 and CSA 108.8-M1983.

1.5 Test Facility

The open area test site and conducted measurement data were tested by:

TÜV AMERICA, INC
10040 Mesa Rim Road
San Diego, CA 92121-2912
Phone: 858 546 3999
Fax: 858 546 0364

The Test Site Data and performance comply with ANSI C63.4 and are registered with the FCC, 7435 Oakland Mills Road, Columbia Maryland 21046. All Measurement Data is acquired according to the content of FCC Measurement Procedure and ANSI C63.4, unless supplemented with additional requirements as noted in the test report.

2.0 SYSTEM TEST CONFIGURATION

2.1 Justification

The EUT was initially tested for FCC emissions in the following configuration:

EMI and SUSCEPTIBILITY

The EMI / SUSCEPTIBILITY SCS system level test is defined below. This protocol shall be tested under EN60601-1-2 (class B) specification.

- 1) CP / HHP / IPG [HHP – 125kHz RF; 1Mhz Crystal] [IPG - 125kHz RF; 1Mhz Crystal]

Clinicians Programmer (CP):

The CP shall have the necessary program to transmit and receive packets from the HHP via IR during the EMI test. This device shall be powered from a wall socket with the appropriate power cord conversion. All of the pertinent accessories required for this unit to be tested shall be present during testing.

Handheld Programmer (HHP)

This unit shall be battery operated and in pass through mode during the test. The HHP and IPG shall be positioned such that the antennas are at optimum communication position.

Implantable Pulse Generator (IPG)

This device shall be fully charged prior to testing. It shall have electrode cables and extensions attached to the device. The electrode output leads shall be immersed in agar or saline solution to simulate human tissue. The IPG shall be programmed to bipolar setting, electrodes E1-E8 as cathode and E9-E16 as anode. Maximum amplitude with the frequency set to 250Hz and pulse width to 200us.

Acceptance Criteria:

EMI:

The system shall be within the limits defined by the EN60601-1-2 (class B).

Susceptibility:

The system shall be within the limits defined by the EN60601-1-2 (class B). The system shall maintain functionality.

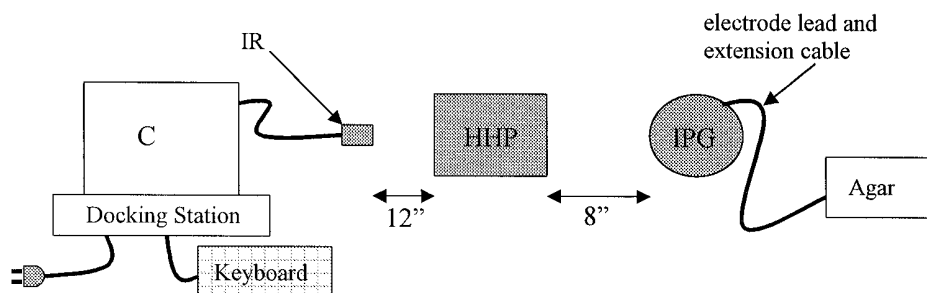


Figure 1

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2.2 EUT Exercise Software

None

2.3 Special Accessories

None

2.4 Equipment Modifications

None

2.5 Configuration of Test System

See Block Diagram Exhibit.

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3.0 RADIATED EMISSIONS EQUIPMENT/DATA

See following page(s).

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Test Conditions: RADIATED EMISSIONS: FCC Part 15.209(a)

The RADIATED EMISSIONS measurements were performed at the San Diego Testing Facility:

☐ - Test not applicable

- - Canyon #1 (10- and 30-Meter Open Area Test Site), Carroll Canyon, San Diego
(Date of listing Aug. 30, 2000. Site Verification Valid for 3 years from listing.)

Testing was performed at a test distance of:

- - 10 meters

Test Equipment Used:

Model No.	Prop. No.	Description	Manufacturer	Serial No.	Cal Due Date
HFH 2-Z2	208	Antenna, Loop	Rohde & Schwarz	880	06/03
8594E	6504	Spectrum Analyzer	Hewlett Packard	3303A00365	07/03
ESVS	427	EMI Test Receiver	Rohde & Schwarz	830350/006	12/02
LPB25201A	738	Antenna Bilog	Antenna Research	1169	06/03

Remarks: _____

EMISSIONS

Test Report #: SC 205502

Test Method: FCC 15.209

Date: 10-28-02

EUT POWER:
☐ 230 Vac/50 Hz ☐ 120 Vac/60 Hz
☒ Other: Battery

EUT Model #: IPG

EUT Description: IPG

NOTES: RBW = 100 Hz; VBW = 100 Hz; Receive antenna = R4SA55c-11208; Amplifier Gain: N/A

No measurable emissions above 1 MHz. Peak measurements.


Emission level (dBμV) = Measured Level + Antenna Correction Factor + Cable Loss - Amplifier Gain

[illegible]


Tested by: Stephen Rackliff
Printed

Reviewed by: Jim Owen
Printed

ams.DOC Rev 09.97



Signature



Signature

No emissions were detected at a level greater than 20 dB below the limit. The square of an inverse linear distance extrapolation factor was used (15.31(f2)).

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4.0 ATTESTATION STATEMENT

GENERAL REMARKS:

SUMMARY:

All tests were performed per CFR 47, Part(s) 15.209(a)

■ - Performed

The Equipment Under Test

■ - **Fulfills** the requirements of CFR 47, Part(s) 15.209(a)

- TÜV AMERICA, INC. -

Responsible Engineer:



Jim Owen
(EMC Chief Engineer)

Responsible Engineer:



Stephen Rackleff
(EMC Engineer)