Intertek ETL SEMKO

Emissions Testing
Performed
on the
Abiomed
Hand Held Alarm Monitor
Model No.: 0034-4590
Serial No.: EE072303129

To

FCC Part 15, Subpart B, Class B

Date(s) of Test: April 13, 2004

Projects: 3056512

Contact: Mr. Charles Kolifrath

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This report is designed to show compliance with the FCC Part 15, Subpart B Rules for an unintentional radiator. The test procedures, as described in American National Standards Institute C63.4-2001 were employed. A description of the product and operating configuration, the various provisions of the rules, the methods for determining compliance, and a detailed summary of the results are included within this test report.

1.0 Introduction and Conclusions

On April 13, 2004, we tested the Hand Held Alarm Monitor, Model: 0034-4590, to determine if it was in compliance with the FCC Part 15, Subpart B, Class B emissions limits. We found that the unit met the requirements when tested as received.

Conclusion:

In summary, this report verifies that the Hand Held Alarm Monitor, Model: 0034-4590, is compliant with the FCC Part 15, Subpart B, Class B requirements when production units conform to the sample tested. Please address all questions and comments concerning this report to Jeff Goulet, EMC Team Leader.

2.0 Description of the Product

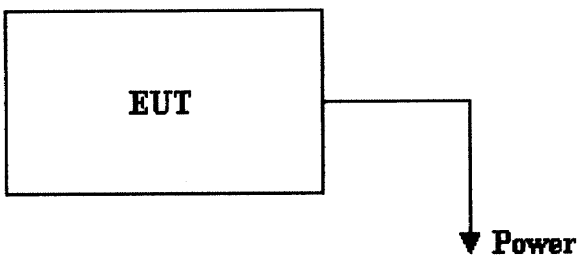
2.1 Brief Description and Received Condition

The equipment under test (EUT) is a Hand Held Alarm Monitor that will be used with AbioCor™ Implantable Replacement Heart.

A production version of the sample was received on April 13, 2004 in good condition.

2.2 System Block Diagram

The diagram shown below details the placement of the equipment under test on the turntable.



2.3 System Test Configuration

Equipment Under Test: Hand Held Alarm Monitor

Model No.: 0034-4590

Serial No.: EE072303129

Support Equipment:

None

Cables:

QTY	Description	Shield Description	Hood Description	Length (m)
1	Power Cable	Unshielded	Plastic	3.0

2.4 Justification

The system was configured for testing in a typical fashion (as a customer would normally use it), and in the confines as outlined in C63.4:2001.

The arrangement of the cables dangling from the rear of the table was varied to the extent possible to produce the maximum emissions.

For maximizing emissions, the system was rotated through 360°, the antenna height was varied from 1 to 4 meters above the ground plane, and the antenna polarization was changed. This step by step procedure for maximizing emissions led to the data in this report.

Radiated emissions were tested in the range of 30 MHz to 1000 MHz.

2.5 Description of how EUT was exercised during test

The EUT was transmitting at 916.6 MHz during testing.

2.6 Modifications Required for Compliance

No modification was installed during compliance testing by Intertek. Please note that this does not include changes made specifically by Abiomed prior to compliance testing.

3.0 Radiated Emission

3.1 Radiated Emissions Limits

The following table shows the radiated emission limits for FCC Part 15 Subpart B Section 15.109:

Class B

Frequency (MHz)	Field Strength Limit		
	µV/m @ 10m	dBµV/m @ 3m	dBµV/m @ 10m(1)
30 to 88	100	40.0	39.5
88 to 216	150	43.5	33.0
216 to 960	200	46.0	35.5
Above 960	500	54.0	43.5

(1) Determined using a 20 dB/decade extrapolation. The specified test distance is 3 meters, however measurements at a another distance is allowed provided measurements are not made in the near-field and it can be determined the emissions can be measured at that distance (See Section 15.31 (f)(1) of the FCC's rules).

(2) The tighter limit applies at the band-edge.

3.2 Field Strength Calculation

The field strength is calculated by adding the Antenna Factor and Cable Factor, and subtracting the Amplifier Gain (if any) from the measured reading. The basic equation with a sample calculation is as follows:

FS = RA + AF + CF - AG
where FS = Field Strength in dBμV/m
RA = Receiver Amplitude (including preamplifier) in dBμV
CF = Cable Attenuation Factor in dB
AF = Antenna Factor in dB/m
AG = Amplifier Gain in dB

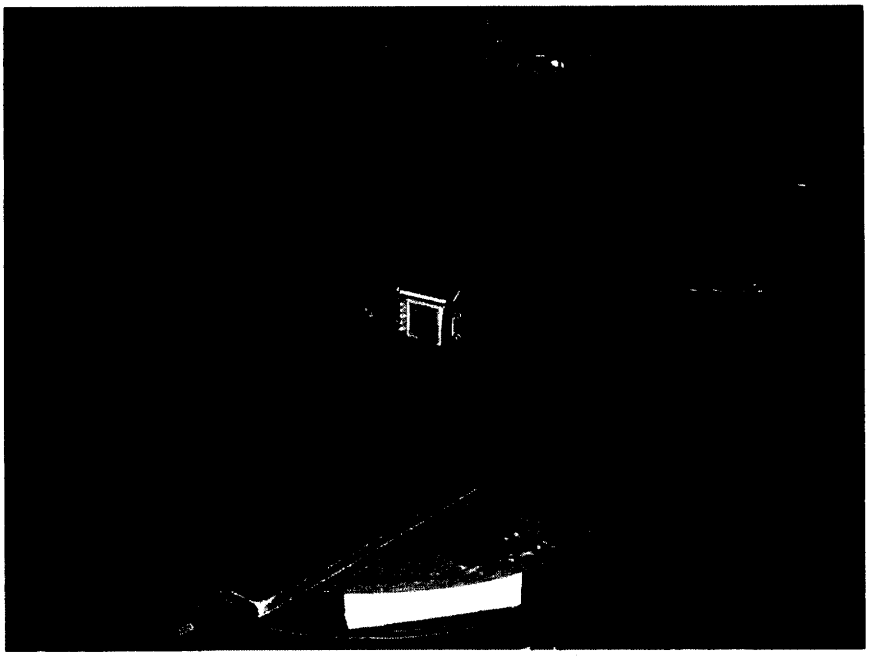
In the following table(s), the reading shown on the data table reflects the preamplifier gain. An example for the calculations in the following table is as follows:

Assume a receiver reading of 52.0 dBμV is obtained. The antenna factor of 7.4 dB and cable factor of 1.6 dB is added. The amplifier gain of 29 dB is subtracted, giving a field strength of 32 dBμV/m. This value in dBμV/m was converted to its corresponding level in μV/m.

RA = 52.0 dBμV
AF = 7.4 dB/m
CF = 1.6 dB
AG = 29.0 dB
FS = 32 dBμV/m

Level in μV/m = $[10^{(32\ dB\mu V/m)/20)}]$ = 39.8 μV/m

3.3 Configuration Photographs - Worst-Case Radiated Emission



3.4 Test Data

The following results were obtained when the device was tested as described in this report.

Radiated Emissions / Interference

Company: Abiomed
Engineer: MFM
Project #: 3056512
Date: 04/13/04
Standard: FCC Part 15.249
Class: B
Group: None
Limit Distance: 3 meters
Voltage/Frequency: 120VAC 60Hz
Location: Site 2
Pressure: 1011 mbar
Temp: 20 C
Humidity: 36%
Model #: 0034-4590
Serial #: EE072303129
Receiver: Agilent E7405A
Antenna: LOG2
PreAmp: None
Cable(s): Site2, 3M Floor
Test Distance: 3 meters
Frequency Range: 30-1000MHz

	Ant. Pol. (V/H)	Frequency MHz	Reading dB(uV)	Antenna Factor dB(1/m)	Cable Loss dB	Pre-amp Factor dB	Distance Factor dB	Net dB(uV/m)	Limit dB(uV/m)	Margin dB
NF	V	30.000	12.2	17.4	0.1	0.0	0.0	29.7	40.0	-10.3
NF	V	85.000	13.0	7.9	0.3	0.0	0.0	21.2	40.0	-18.9
NF	V	115.000	13.0	7.5	0.3	0.0	0.0	20.8	43.5	-22.7
NF	V	250.000	12.0	12.9	0.7	0.0	0.0	25.6	46.0	-20.4
NF	H	350.000	12.0	15.9	0.8	0.0	0.0	28.7	46.0	-17.3
NF	H	810.000	11.0	22.5	1.1	0.0	0.0	34.6	46.0	-11.4

NF - noise floor readings

4.0 AC Mains Line-Conducted Emissions

4.1 Line-Conducted Emission Limits

The following table shows the line-conducted emission limits for FCC Part 15 Subpart B Section 15.107:

Frequency of Conducted Emission Limit – Class B

Frequency (MHz)	Limits (dBμV)	
	Quasi-peak	Average
0.15 to 0.50	66 to 56*	56 to 46*
0.5 to 5	56	46
5 to 30	60	50

*Limits decrease linearly with the logarithm of the frequency.

Frequency of Conducted Emission Limit – Class A

Frequency (MHz)	Limits (dBμV)	
	Quasi-peak	Average
0.15 to 0.50	79	66
0.5 to 30	73	60

4.2 Configuration Photographs - Worst-Case Line-Conducted Emission

4.3 Test Data

The following results were obtained when the device was tested as described in this report.

Conducted Emissions / Interference

Company: Abiomed
Engineer: MFM
Project #: 3056512
Date: 04/13/04
Standard: FCC Part 15.249
Class: B
Preamp: None
Voltage/Frequency: 120VAC 60Hz
Location: Site 2
Pressure: 1011mbar
Temp: 20 C
Humidity: 36%
Group: None
Model #: 0034-4590
Serial #: EE072303129
Receiver: Agilent E7405A
Cable: CBL10MS3 7-15-04.cbl
LISN 1, 2: LISN11 [1] 5-29-04.lsn None
LISN 3, N: None LISN11 [2] 5-29-04.lsn
Attenuator: DS25A 7-08-04.att
Frequency Range: 0.15 to 30MHz
Net is the sum of worst-case lisn, cable, & attenuator losses, preamp gain, and initial reading

Frequency MHz	Reading Line 1 dB(uV)	Reading Line 2 dB(uV)	Reading Line 3 dB(uV)	Reading Neutral dB(uV)	Quasi-Peak Net dB(uV)	Quasi-Peak Limit dB(uV)	Quasi-Peak Margin dB
0.209	20.1	N/A	N/A	14.0	42.5	63.2	-20.8
0.417	16.8	N/A	N/A	13.0	38.3	57.5	-19.2
0.831	21.0	N/A	N/A	20.0	41.9	56.0	-14.1
2.180	15.0	N/A	N/A	13.0	35.6	56.0	-20.4
5.400	12.0	N/A	N/A	9.0	32.6	60.0	-27.4
13.830	10.0	N/A	N/A	7.0	31.0	60.0	-29.0

Frequency MHz	Reading Line 1 dB(uV)	Reading Line 2 dB(uV)	Reading Line 3 dB(uV)	Reading Neutral dB(uV)	Average Net dB(uV)	Average Limit dB(uV)	Average Margin dB
0.209	15.1	N/A	N/A	10.0	37.5	53.2	-15.8
0.417	13.4	N/A	N/A	8.0	34.9	47.5	-12.6
0.831	18.0	N/A	N/A	17.0	38.9	46.0	-7.1
2.180	11.0	N/A	N/A	7.0	31.6	46.0	-14.4
5.400	8.0	N/A	N/A	4.0	28.6	50.0	-21.4
13.830	4.0	N/A	N/A	1.0	25.0	50.0	-25.0

5.0 Miscellaneous Information

5.1 Site Description

Site 2C (Middle Site) is a 3m and 10m sheltered EMI measurement range located in a light commercial environment in Boxborough, Massachusetts. It meets the technical requirements of ANSI C63.4-1992 and CISPR 22/EN 55022 for radiated and conducted emission measurements. The shelter structure is entirely fiberglass and plastic, with outside dimensions of 33 ft x 57 ft. The structure resembles a quonset hut with a center ceiling height of 16.5 ft.

The testing floor is covered by a galvanized sheet metal groundplane that is earth-grounded via copper rods around the perimeter of the site. The joints between individual metal sheets are bridged with a 2 inch wide metal strips to provide low RF impedance contact throughout. The sheets of metal are screwed in place with stainless steel, round-head screws every three inches. Site illumination and HVAC are provided from beneath the ground reference plane through flush entry ports, the port covers are electically bonded to the ground plane.

A flush metal turntable with 12 ft. diameter and 5000 lb. load capacity is provided for floor-standing equipment. A wooden table 80 cm high is used for table-top equipment. The turntable is electrically connected to the ground plane with three copper straps. The straps are connected to the turntable at the center of it with ground braid. It is copper strap is directly connected to the groundplane at the edges of the turntable. The turntable is located on the south end of the structure and the antennas are mounted 3 and 10 meters away to the north. The antenna mast is a non-conductive with remote control of antenna height and polarization. The antenna height is adjustable from 1 to 4 meters.

All final radiated emission measurements are performed with the testing personnel and measurement equipment located below the ground reference plane. The site has a full basement underneath the turntable where support equipment may be remotely located. Operation of the antenna, turntable and equipment under test is controlled by remote controls that manipulate the antenna height and polarization and with a turntable control. Test personnel are located below the elipse when measurements are performed, however the site maintains the ability of having personnel manipulate cables while monitoring test equipment. Ambient radiated emissions are 6 dB or more below the relevant FCC emission limits.

AC mains power is brought to the equipment under test through a power line filter, to remove ambient conducted noise. 50 Hz (240 VAC single phase), 60 Hz power (120 VAC single phase, 208 VAC three phase), and 60 Hz (480 VAC three phase) are available. Conducted emission measurements are performed with a Line Impedance Stabilization Network (LISN) or Artificial Mains Network (AMN) bonded to the ground reference plane. A removable vertical groundplane (2 meter X 2 meter area) is used for line-conducted measurements for table top equipment. The vertical groundplane is electrically connected to the reference groundplane.

5.2 Labeling - USA

Class B Labeling and Instruction Manual Requirements

Devices subject to Certification must be labeled with an FCC Identifier. Devices subject to Verification or Certification must be labeled with the following compliance statement:

> **This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.**

In addition, for a Class B digital device or peripheral, the instructions furnished the user shall include the following or similar statement, placed in a prominent location in the text of the manual:

> ***Warning:*** **Changes or modifications to this unit not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.**
>
> ***NOTE:*** **This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:**
>
> - **Reorient or relocate the receiving antenna.**
> - **Increase the separation between the equipment and receiver.**
> - **Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.**
> - **Consult the dealer or an experienced radio TV technician for help.**

If shielded cables or other specialized accessories are necessary for the unit to achieve compliance, a statement similar to the following should be added:

> **Shielded cables must be used with this unit to ensure compliance with the Class B FCC limits.**

5.3 Labeling - Canada

Canadian Emissions Requirements

The intent of the amendment is to establish Canadian Regulations which are harmonized with the existing FCC Regulations. As such, no retesting is required and devices which have been tested and comply with the FCC Specifications (Class A or B) also comply with the Canadian Specification (Class A or B).

A record of the measurements and results shall be retained by the manufacturer or importer for a period of at least five years and made available for examination on the request of the Canadian Government.

A written notice indicating compliance must accompany each unit of digital apparatus to the end user. The notice shall be in the form of a label that is affixed to the apparatus. Where because of insufficient space or other restrictions, it is not feasible to affix a label to the apparatus, the notice may be in the form of a statement included in the user's manual.

This Class [*] digital apparatus complies with Canadian ICES-003.

Cet appareil numérique de la classe [*] est conforme à la norme NMB-003 du Canada.

[*] Insert either "A" or "B" but not both as appropriate for the equipment requirements.

5.4 Test Report Certification

Company Name:	Abiomed
Address:	22 Cherry Hill Drive Danvers, MA 01923
Model No.:	0034-4590
Serial No.:	EE072303129
Date(s) of Test:	April 13, 2004
Test Site Location:	INTERTEK TESTING SERVICES NA INC. 70 Codman Hill Road Boxborough, MA 01719
Site(s):	2C

We attest to the accuracy of this report:

Signature	Signature
Kouma Sinn	Michael F. Murphy
Testing Performed By	Reviewer
Senior Project Engineer	Staff Engineer/EMC
Title	Title

5.6 Equipment List

The following equipment was used to make measurements for emissions testing:

Description	Manufacturer	Model	Serial #	Cal Due
Spectrum Analyzer	Agilent	E7405A	US40240205	07/02/2004
Horn Antenna	EMCO	3115	9602-4675	09/03/2004
High Frequency cable	Megaphase	PM40 K1K1 197	CBL028	11/11/2004
30' BNC Cable	Alpha Wire (ITS)	RG 58A/U	CBL10MS3	07/15/2004
3M In Floor Cable	Alpha Wire (ITS)	RG 214/U	3M In Floor	09/22/2004
Antenna	EMCO	3142	9711-1223	11/05/2004
20 dB Attenuator	Mini-Circuit	CAT-20	DS25A	07/08/2004
LISN11	Solar Electronics	9252-50-R-24-BNC	941714	07/22/2004