BIOTRONIK, Inc.

Lexos DR-T

Test Report

October 09, 2003

Report No. BIOT0007

Report Prepared By:

NORTHWEST EMC

1-888-EMI-CERT

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NORTHWEST EMC

22975 NW Evergreen Parkway
Suite 400
Hillsboro, Oregon 97124

Certificate of Test

Issue Date: October 09, 2003
BIOTRONIK, Inc.
Model: Lexos DR-T

Emissions		
Description	**Pass**	**Fail**
FCC 95.639(f)(1) Field Strength of Fundamental:2003	☒	☐
FCC 95.635(d) Field Strength of Spurious Emission:2003	☒	☐
FCC 95.633(e)(1) Occupied Bandwidth:2003	☒	☐
FCC 95.635(d)(4-5) Emission Mask:2003	☒	☐
FCC 95.628(e)(1) Frequency Stability:2003	☒	☐

Modifications made to the product
See the Modifications section of this report

Test Facility

Northwest EMC, Inc
22975 NW Evergreen Parkway, Suite 400
Hillsboro, OR 97124
Phone: (503) 844-4066 Fax: 844-3826

This site has been fully described in a report filed with and accepted by the FCC (Federal Communications Commission) and Industry Canada.

Approved By:

David M. Tolman, QA Manager

This report must not be used to claim product certification, approval, or endorsement by NVLAP, NIST, or any agency of the federal government of the United States of America.

Product compliance is the responsibility of the client, therefore the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. This Report may only be duplicated in its entirety. The results of this test pertain only to the sample(s) tested, the specific description is noted in each of the individual sections of the test report supporting this certificate of test.

Revision Number	Description	Date	Page Number
00	None		

FCC: The Open Area Test Sites, and conducted measurement facilities, have been fully described in reports filed with the FCC and accepted by the FCC in letters maintained in our files.

TCB: Northwest EMC has been accredited by ANSI to ISO/IEC Guide 65 as a product certifier. We have been designated by the FCC as a Telecommunications Certification Body (TCB). This allows Northwest EMC to certify transmitters to FCC specifications in accordance with 47 CFR 2.960 and 2.962.

NVLAP: Accreditation has been granted to Northwest EMC, Inc. to perform the Electromagnetic Compatibility (EMC) tests described in the Scope of Accreditation. Assessment performed to ISO/IEC 17025. Certificate Number: 200629-0, Certificate Number: 200630-0.

Australia/New Zealand: The National Association of Testing Authorities (NATA), Australia has been appointed by the ACA as an accreditation body to accredit test laboratories and competent bodies for EMC standards. Accredited test reports or assessments by competent bodies must carry the NATA logo. Test reports made by an overseas laboratory that has been accredited for the relevant standards by an overseas accreditation body that has a Mutual Recognition Agreement (MRA) with NATA are also accepted as technical grounds for product conformity. The report should be endorsed with the respective logo of the accreditation body. (NVLAP)

TÜV Product Service: Included in TUV Product Service Group's Listing of Recognized Laboratories. It qualifies in connection with the TUV Certification after Recognition of Agent's Testing Program for the product categories and/or standards shown in TUV's current Listing of CARAT Laboratories available from TUV. A certificate was issued to represent that this laboratory continues to meet TUV's CARAT Program requirements. Certificate No. USA0302C

TÜV Rheinland: Authorized to carryout EMC tests by order and under supervision of TÜV Rheinland. This authorization is based on "Conditions for EMC-Subcontractors" of November 1992.

NEMKO: Assessed and accredited by NEMKO (Norwegian testing and certification body) for European emissions and immunity testing. As a result of NEMKO's laboratory assessment, they will accept test results from Northwest EMC, Inc. for product certification (Authorization No. ELA 119).

Technology International: Assessed in accordance with ISO Guide 25 defining the general international requirements for the competence of calibration and testing laboratories and with ITI assessment criteria LACO196. Based upon that assessment Interference Technology International, Ltd., has granted approval for specifications implementing the EU Directive on EMC (89/336/EEC and amendments). The scope of the approval was provided on a Schedule of Assessment supplied with the certificate and is available upon request.

Industry Canada: Accredited by Industry Canada for performance of radiated measurements. Our open area test sites comply with RSS 212, Issue 1 (Provisional).

VCCI: Accepted as an Associate Member to the VCCI, Acceptance No. 564. Conducted and radiated measurement facilities have been registered in accordance with Regulations for Voluntary Control Measures, Article 8. *(Registration Nos. - Evergreen: C-1071 and R-1025, Trails End: C-694 and R-677, Sultan: C-905, R-871 and R-1172, North Sioux City C-1246, R-1185 and R-1217)*

BSMI: Northwest EMC has been designated by NIST and validated by C-Taipei (BSMI) as a CAB to conduct tests as described in the APEC Mutual Recognition Agreement. License No.SL2-IN-E-1017.

CAB: Designated by NIST and validated by the European Commission as a Conformity Assessment Body (CAB) to conduct tests and approve products to the EMC directive and transmitters to the R&TTE directive, as described in the U.S. - EU Mutual Recognition Agreement

GOST: Northwest EMC, Inc. has been assessed and accredited by the Russian Certification bodies Certinform VNIINMASH, CERTINFO, SAMTES, and Federal CHEC, to perform EMC and Hygienic testing for Information Technology Products. As a result of their laboratory assessment, they will accept test results from Northwest EMC, Inc. for product certification

	NVLAP	FCC	NIST	TUV PS	TUV Rheinland	Nemko	Technology International	Industry Canada	BSMI	VCCI	GOST	NATA
IEC 61000-4-2	✓			✓	✓	✓	✓					
IEC 61000-4-3	✓			✓	✓	✓	✓					
IEC 61000-4-4	✓			✓	✓	✓	✓					
IEC 61000-4-5	✓			✓	✓	✓	✓					
IEC 61000-4-6	✓			✓	✓	✓	✓					
IEC 61000-4-8	✓			✓	✓	✓	✓					
IEC 61000-4-11	✓			✓	✓	✓	✓					
IEC 61000-3-2	✓			✓	✓	✓	✓					
IEC 61000-3-3	✓			✓	✓	✓	✓					
AS/NZS 3548	✓											✓
CNS 13438	✓								✓			
ISO/IEC17025	✓			✓	✓	✓	✓		✓			
Radiated Emissions	✓			✓	✓	✓	✓	✓	✓	✓	✓	
Conducted Emissions	✓			✓	✓	✓	✓	✓	✓	✓	✓	
OATS Sites	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	
Hillsboro 5-Meter Chamber (EV01)	✓	✓		✓	✓	✓	✓	✓	✓	✓	✓	
TCB for Licensed Transmitters		✓										
TCB for un-Licensed Transmitters		✓										
Cab for R&TTE			✓									
CAB for EMC			✓									

This chart represents only a partial NVLAP Scope, please reference http://ts.nist.gov/ts/htdocs/210/214/214.htm for the full NVLAP Scope of Accreditation

Explanation of Northwest EMC Performance Criteria

How important is it to understand performance criteria?

It is the responsibility of the test laboratory to observe the results of the tests that are performed and to accurately report those results. As the responsible party (manufacturer, importer, etc) it is your responsibility to take those results, compare them against the specifications and standards, then, if appropriate make a declaration of conformity. As the responsible party it makes sense that you are fully aware of the requirements, how your device performs when tested to those requirements, and what information is being used to declare conformity.

To better assist you in making those conformity decisions, Northwest EMC has adopted a very simple, yet very clear performance assessment procedure. The following criteria is used when performing immunity or susceptibility tests:

Performance Criteria 1:

- The EUT exhibited no change in performance when operating as specified by the manufacturer. In this case no changes were observed during the test.
- In most cases this would be equivalent to Performance Criteria A. When operating the equipment in the modes or configurations specified by the responsible party, monitoring the parameters specified, no changes were observed. Basically nothing happened.

Performance Criteria 2:

- The EUT exhibited a change in performance when operating as specified by the manufacturer. In this case the equipment recovered without any operator intervention. The data sheets will detail the exact phenomena observed.
- In most cases this would be equivalent to Performance Criteria B. When operating the equipment in the modes or configurations specified by the responsible party, monitoring the parameters specified, changes were observed. The EUT was able to recover from those changes without any operator intervention.

Performance Criteria 3:

- The EUT exhibited a change in performance when operating as specified by the manufacturer. In this case the equipment required some operator intervention in order to recover. This intervention may be in the form of reducing the test levels, changing parameters, or even resetting the system. The data sheets will detail the exact phenomena observed.
- In most cases this would be equivalent to Performance Criteria C. When operating the equipment in the modes or configurations specified by the responsible party, monitoring the parameters specified, changes were observed. The EUT required some sort of operator intervention to recover. There was no permanent damage and the EUT appeared to function normally after completion test.

Performance Criteria 4:

- The EUT exhibited a change in performance when operating as specified by the manufacturer. In this case the equipment was damaged and would not recover. The data sheets will detail the exact phenomena observed.
- In most cases there is no specific criterion to compare this to, it typically ends the test. When operating the equipment in the modes or configurations specified by the responsible party, monitoring the parameters specified, changes were observed. There was no recovery; the equipment would no longer function as intended.

Each of the standards and specifications has unique performance criteria. In order to make an accurate assessment, one must compare the test results provided with the specific performance criteria. **To ensure that a responsible party is compliant with the specifications, one must read and understand those specifications. Provided below is a sample performance criteria, taken from EN 50082-1.**

EN 50082-1 Performance Criteria

Performance Criteria A: *The apparatus shall continue to operate as intended. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the apparatus is used as intended. The performance level may be replaced by a permissible loss of performance. If the minimum performance level or the permissible performance loss is not specified by the manufacturer, then either of these may be derived from the product description and documentation and what the user may reasonably expect from the apparatus if used as intended.*

Performance Criteria B: *The apparatus shall continue to operate as intended after the test. No degradation of performance or loss of function is allowed below a performance level specified by the manufacturer, when the apparatus is used as intended. The performance level may be replaced by a permissible loss of performance. During the test, degradation of performance is allowed. If the minimum performance level or the permissible performance loss is not specified by the manufacturer, then either of these may be derived from the product description and documentation and what the user may reasonably expect from the apparatus if used as intended.*

Performance Criteria C: *Temporary loss of function is allowed, provided the function is self-recoverable or can be restored by the operation of controls.*

How should a device perform in order for a declaration of conformity to be made?

As already stated, it is the responsible party that must interpret and understand the results in such a way that a declaration of conformity is made. Having said that, we are often asked to render our opinion as to how a device should perform. Our recommendation simply follows the standards, as can be referenced below. Most of the standards and specifications offer the same performance criterion shown below as their requirements.

Test	Performance Criteria typically specified by the Standard	Equivalent Northwest EMC Performance Criteria
ESD	Performance Criteria B	Performance Criteria 1 or 2
Radiated RF	Performance Criteria A	Performance Criteria 1
EFT/Burst	Performance Criteria B	Performance Criteria 1 or 2
Surge	Performance Criteria B	Performance Criteria 1 or 2
Conducted RF	Performance Criteria A	Performance Criteria 1
Magnetic Field	Performance Criteria A	Performance Criteria 1
Voltage Dips and Variations	Performance Criteria B & C	Performance Criteria 1, 2, or 3

What is measurement uncertainty?

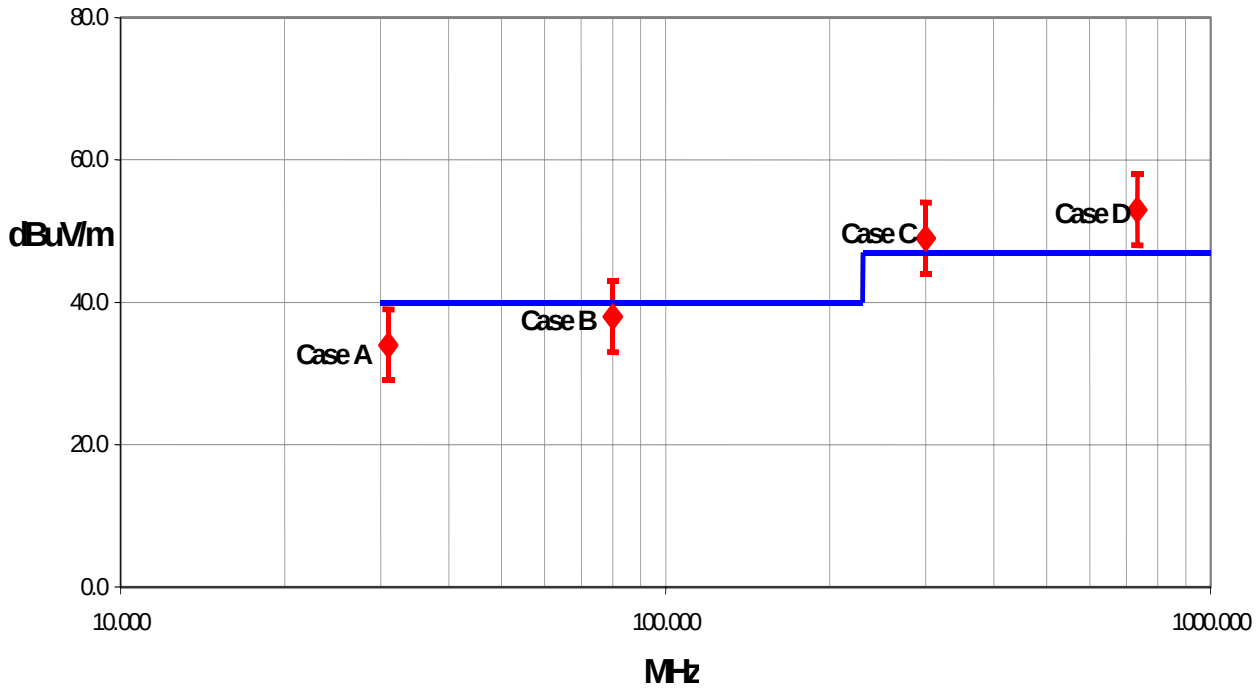
When a measurement is made, the result will be different from the true or theoretically correct value. The difference is the result of tolerances in the measurement system that cannot be completely eliminated. To the extent that technology allows us, it has been our aim to minimize this error. The following statement of measurement uncertainty is used to reflect the accuracy of the measured result as compared with its "true" value. In the case of transient tests (ESD, EFT, Surge, Voltage Dips and Interruptions), the test equipment has been demonstrated by calibration to provide at least a 95% confidence that it complies with the test specification requirements.

The following documents were the basis for determining the uncertainty levels of our measurements:

- "ISO Guide to the Expression of Uncertainty in Measurements", October 1993
- "NIS81: The Treatment of Uncertainty in EMC Measurements", May 1994
- "IEC CISPR 16-3 A1 f1 Ed.1: Radio-interference measurements and statistical techniques", December 2000

How might measurement uncertainty be applied to test results?

If the diamond marks the measured value for the test and the vertical bars bracket the range of + and – measurement uncertainty, then test results can be interpreted from the diagram below.



Test Result Scenarios:
Case A: Product complies.
Case B: Product conditionally complies. It is not possible to say with 95% confidence that the product complies.
Case C: Product conditionally does not comply. It is not possible to say with 95% confidence that the product does not comply.
Case D: Product does not comply.

Radiated Emissions ≤ 1 GHz		Value (dB)					
	Probability Distribution	Biconical Antenna		Log Periodic Antenna		Dipole Antenna	
Test Distance		3m	10m	3m	10m	3m	10m
Combined standard uncertainty $u_c(y)$	normal	+ 1.86 - 1.88	+ 1.82 - 1.87	+ 2.23 - 1.41	+ 1.29 - 1.26	+ 1.31 - 1.27	+ 1.25 - 1.25
Expanded uncertainty ***U*** (level of confidence ≈ 95%)	normal (k=2)	+ 3.72 - 3.77	+ 3.64 - 3.73	+ 4.46 -2.81	+ 2.59 - 2.52	+ 2.61 - 2.55	+ 2.49 - 2.49

Radiated Emissions > 1 GHz	Value (dB)		
	Probability Distribution	Without High Pass Filter	With High Pass Filter
Combined standard uncertainty $u_c(y)$	normal	+ 1.29 - 1.25	+ 1.38 - 1.35
Expanded uncertainty ***U*** (level of confidence ≈ 95%)	normal (k=2)	+ 2.57 - 2.51	+ 2.76 - -2.70

Conducted Emissions		
	Probability Distribution	Value (+/- dB)
Combined standard uncertainty ***uc(y)***	normal	1.48
Expanded uncertainty ***U*** (level of confidence ≈ 95 %)	normal (k = 2)	2.97

Radiated Immunity		
	Probability Distribution	Value (+/- dB)
Combined standard uncertainty ***uc(y)***	normal	1.05
Expanded uncertainty ***U*** (level of confidence ≈ 95 %)	normal (k = 2)	2.11

Conducted Immunity		
	Probability Distribution	Value (+/- dB)
Combined standard uncertainty ***uc(y)***	normal	1.05
Expanded uncertainty ***U*** (level of confidence ≈ 95 %)	normal (k = 2)	2.10

Legend

$u_c(y)$ = square root of the sum of squares of the individual standard uncertainties

U = combined standard uncertainty multiplied by the coverage factor: **k**. This defines an interval about the measured result that will encompass the true value with a confidence level of approximately 95%. If a higher level of confidence is required, then k=3 (CL of 99.7%) can be used. Please note that with a coverage factor of one, uc(y) yields a confidence level of only 68%.

California

Orange County Facility

41 Tesla Ave.
Irvine, CA 92618
(888) 364-2378
FAX (503) 844-3826

Oregon

Evergreen Facility

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Hillsboro, OR 97124
(503) 844-4066
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Oregon

Trails End Facility

30475 NE Trails End Lane
Newberg, OR 97132
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FAX (503) 537-0735

South Dakota

North Sioux City Facility

745 N. Derby Lane
P.O. Box 217
North Sioux City, SD 57049
(605) 232-5267
FAX (605) 232-3873

Washington

Sultan Facility

14128 339th Ave. SE
Sultan, WA 98294
(888) 364-2378
FAX (360) 793-2536

Party Requesting the Test

Company Name:	BIOTRONIK, Inc.
Address:	6024 Jean Road
City, State, Zip:	Lake Oswego, OR 97035
Test Requested By:	Ky Lo
Model:	Lexos DR-T
First Date of Test:	09-22-2003
Last Date of Test:	09-23-2003
Receipt Date of Samples:	09-22-2003
Equipment Design Stage:	Production
Equipment Condition:	No visual damage.

Information Provided by the Party Requesting the Test

Clocks/Oscillators:	32 KHz, 403 MHz SAW
I/O Ports:	Shock Leads, Atrial Pacing leads, Ventrical Pacing Leads

Functional Description of the EUT (Equipment Under Test):

Dual channel implantable defibrillator with RF telemetry capabilities.

Client Justification for EUT Selection:

The product is an engineering sample, representative of the final product.

Client Justification for Test Selection

These tests satisfy the requirements for FCC Part 95 MICS

Equipment modifications				
Item #	Test	Date	Modification	Note
1	Field Strength of Fundamental	09-23-2003	No EMI suppression devices were added or modified during this test.	Same configuration as delivered.
2	Spurious Radiated Emissions	09-23-2003	No EMI suppression devices were added or modified during this test.	Same configuration as delivered.
3	Emissions Mask	09-23-2003	No EMI suppression devices were added or modified during this test.	Same configuration as in previous test.
4	Occupied Bandwidth	09-23-2003	No EMI suppression devices were added or modified during this test.	Same configuration as in previous test.
5	Frequency Stability	09-24-2003	No EMI suppression devices were added or modified during this test.	Same configuration as in previous test.

Justification

The individuals and/or the organization requesting the test provided the modes, configurations and settings available to evaluate. While scanning the radiated emissions, all of the EUT parameters listed below were investigated. This includes, but may not be limited to, antennas, tuned transmit frequency ranges, operating modes, and data rates.

Channels in Specified Band Investigated:
Single

Operating Modes Investigated:
Typical

Data Rates Investigated:
Maximum

Output Power Setting(s) Investigated:
Maximum

Power Input Settings Investigated:
Internal Battery

Software\Firmware Applied During Test			
Exercise software	Special Test Software	Version	Unknown
Description			
The system was tested using special software developed to test all functions of the device during the test.			

EUT and Peripherals

Description	Manufacturer	Model/Part Number	Serial Number
EUT	BIOTRONIK, Inc.	Lexos DR-T	79841008

Cables

Cable Type	S/N	Shield	Length (m)	Ferrite	Connection 1	Connection 2
High Voltage Model DF-1	10206150	Yes	.8	No	EUT	Unterminated
Pacing Sensing Lead Model IS-1BI	23278301	Yes	.8	No	EUT	Unterminated
Pacing Sensing Lead Model IS-1BI	23031884	Yes	.8	No	EUT	Unterminated

PA = Cable is permanently attached to the device. Shielding and/or presence of ferrite may be unknown.

Measurement Equipment

Description	Manufacturer	Model	Identifier	Last Cal	Interval
Spectrum Analyzer	Hewlett-Packard	8566B	AAL	01/07/2003	12 mo
Quasi-Peak Adapter	Hewlett-Packard	85650A	AQF	01/07/2003	12 mo
Pre-Amplifier	Amplifier Research	LN1000A	APS	01/06/2003	12 mo
Antenna, Biconilog	EMCO	3141	AXE	12/31/2001	36 mo
Multimeter	Fluke	79	MMC	09/09/2003	12 mo
Thermocouple Module	Fluke	80TK	MML	N/A	N/A

Client Measurement Equipment used to Validate Tissue Substitute Material

Description	Manufacturer	Model	Identifier	Last Cal	Interval
Vector Network Analyzer	Hewlett-Packard	8753ES	US39170321	11/12/2002	12 mo
Dielectric Probe Kit	Agilent	85070C	85070C-628	09/24/2001	36 mo

Test Description

Requirement: Per 95.639(f)(1), the maximum EIRP for a MICS transmitter is 25uW. This is equivalent to a radiated field strength 85.2 dBuV/m at 3 meters when measured over a reference ground plane.

Configuration: The Field Strength of the Fundamental was measured in the far-field at an FCC Listed Semi-anechoic Chamber. Spectrum analyzer and linearly polarized antennas were used to measure the effective radiated power (EIRP) of the fundamental.

The orientation of the EUT and measurement antenna were manipulated to maximize the level of emissions.

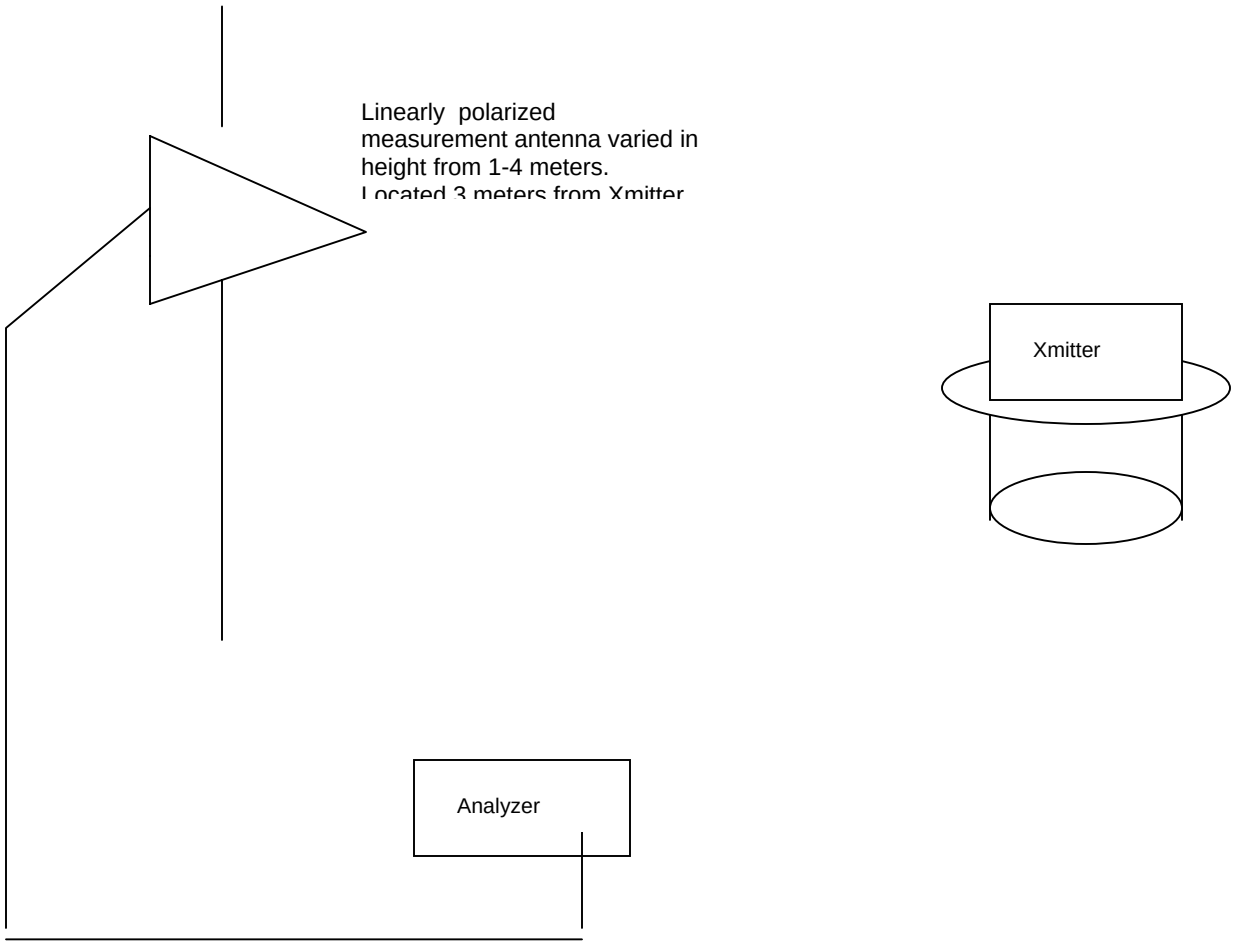
The EUT was configured to transmit in a fixture that simulates the human torso. The dimensions of the test fixture and the characteristics of the tissue substitute material met the requirements of 95.639(f)(2)(i-ii). The dielectric and conductivity properties of the tissue substitute material were verified the morning of the test (see client data for tissue substitute material), and the temperature was measured before and after the test to verify compliance with 95.639(f)(2)(i). At the start of the test, the tissue substitute material was 23.5 degrees centigrade. At the conclusion of testing, it was 23.2 degrees centigrade.

Test Methodology

At an approved test site, the transmitter was placed in the human torso test fixture located on a remotely controlled turntable, and the measurement antenna was placed 3 meters from the transmitter. The height of the transmitter was 1.5-meter above the reference ground plane. The turntable azimuth was varied to maximize the level of radiated emissions. The height of the measurement antenna was also varied from 1 to 4 meters. The amplitude and frequency of the emissions were noted.

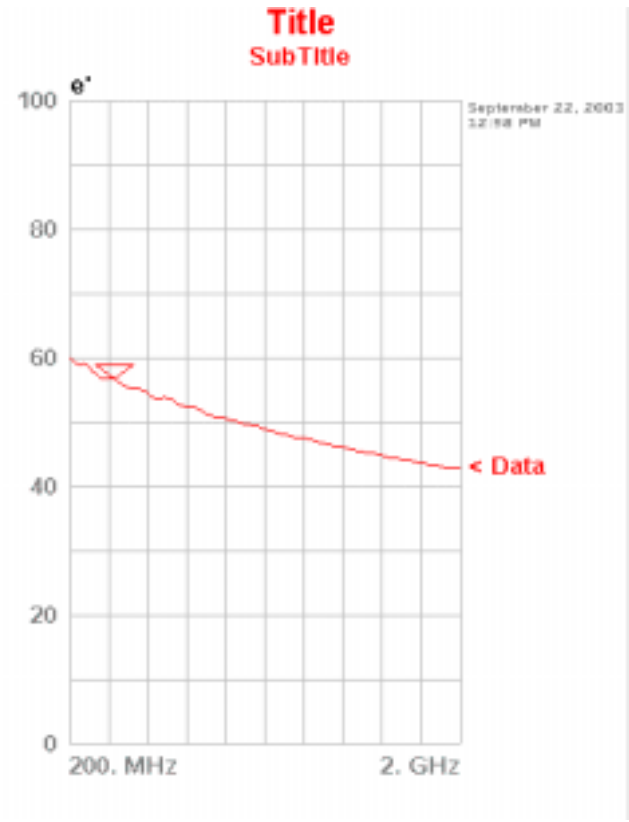
Test Setup Diagram

Test Setup for Field Strength Measurements



Completed by:

Client Data for Tissue Substitute Material



Title
SubTitle
September 22, 2003 12:58 PM

Frequency	e'	e''
200.000000 MHz	59.9005	44.6858
209.000000 MHz	59.5464	43.3766
218.000000 MHz	59.2186	42.0959
227.000000 MHz	59.0211	40.8638
236.000000 MHz	58.9757	39.7029
245.000000 MHz	58.9409	38.6510
254.000000 MHz	58.9408	37.7722
263.000000 MHz	58.9920	36.9549
272.000000 MHz	58.8714	36.1027
281.000000 MHz	58.7850	35.3667
290.000000 MHz	58.4312	34.6801
299.000000 MHz	58.3212	33.8646
308.000000 MHz	57.8674	33.1939
317.000000 MHz	57.4312	32.6614
326.000000 MHz	57.1528	32.0362
335.000000 MHz	56.9170	31.6061
344.000000 MHz	56.7864	31.0151
353.000000 MHz	56.6969	30.7211
362.000000 MHz	56.7511	30.3024
371.000000 MHz	56.7095	29.9148
380.000000 MHz	56.8622	29.6373
389.000000 MHz	56.7744	29.2192
398.000000 MHz	56.8148	28.9176
407.000000 MHz	56.6512	28.5007
416.000000 MHz	56.4882	28.1593
425.000000 MHz	56.2599	27.7462
434.000000 MHz	56.0052	27.4499

NORTHWEST EMC

RADIATED EMISSIONS DATA SHEET

REV df4.00 08/12/2003

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	BIOTRONIK, Inc.			Temperature:	73
Attendees:	Jim Horton			Humidity:	38%
Cust. Ref. No.:				Barometric Pressure	30.03
Tested by:	Greg Kiemel	Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	FCC Part 95.635	Year:	2002
Method:	ANSI C63.4	Year:	1992

SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

Conducted Emissions: Adjusted Level = Measured Level + Transducer Factor + Cable Attenuation Factor + External Attenuator

COMMENTS

EUT horizontal in test fixture at 1.5 m height

EUT OPERATING MODES

Transmitting Single Channel

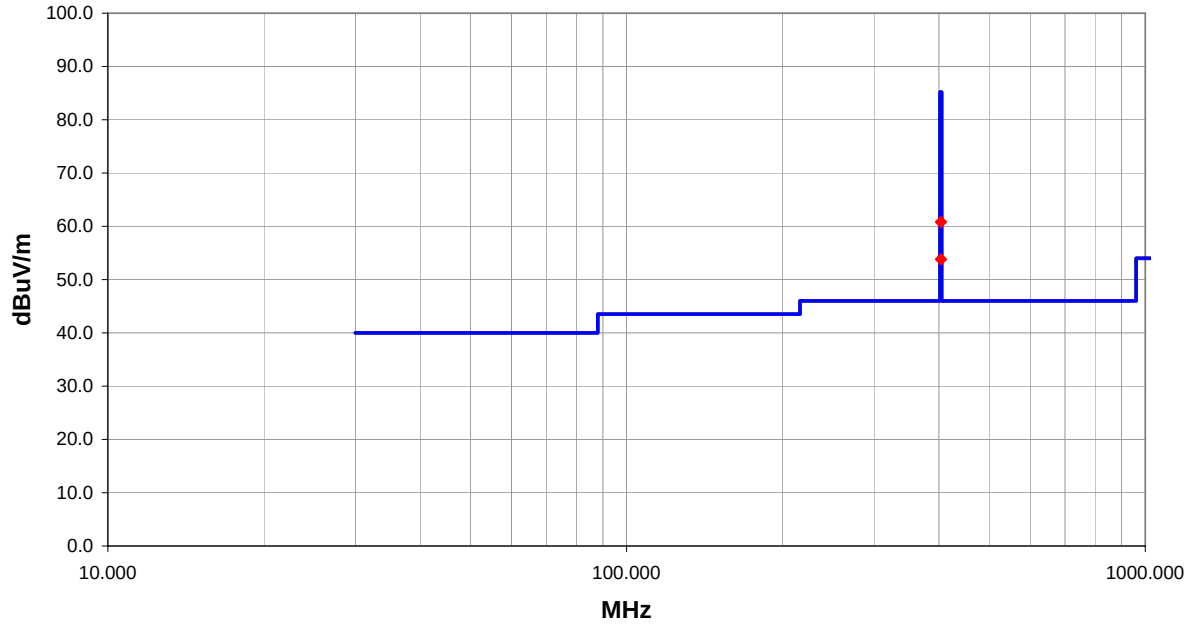
DEVIATIONS FROM TEST STANDARD

No deviations.

RESULTS	Run #
Pass	1

Other

Tested By:



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)
403.639	66.0	-5.2	295.0	1.4	3.0	0.0	H-Bilog	PK	0.0	60.8	85.2	-24.4
403.639	59.0	-5.2	25.0	1.9	3.0	0.0	V-Bilog	PK	0.0	53.8	85.2	-31.4

NORTHWEST EMC

RADIATED EMISSIONS DATA SHEET

REV df4.00 08/12/2003

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	BIOTRONIK, Inc.			Temperature:	73
Attendees:	Ky Lo			Humidity:	38%
Cust. Ref. No.:				Barometric Pressure	30.03
Tested by:	Greg Kiemel	Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	FCC 95.635	Year:	2002
Method:	ANSI C63.4	Year:	1992

SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

Conducted Emissions: Adjusted Level = Measured Level + Transducer Factor + Cable Attenuation Factor + External Attenuator

COMMENTS

EUT vertical in test fixture at 1.5 m height

EUT OPERATING MODES

Transmitting Single Channel

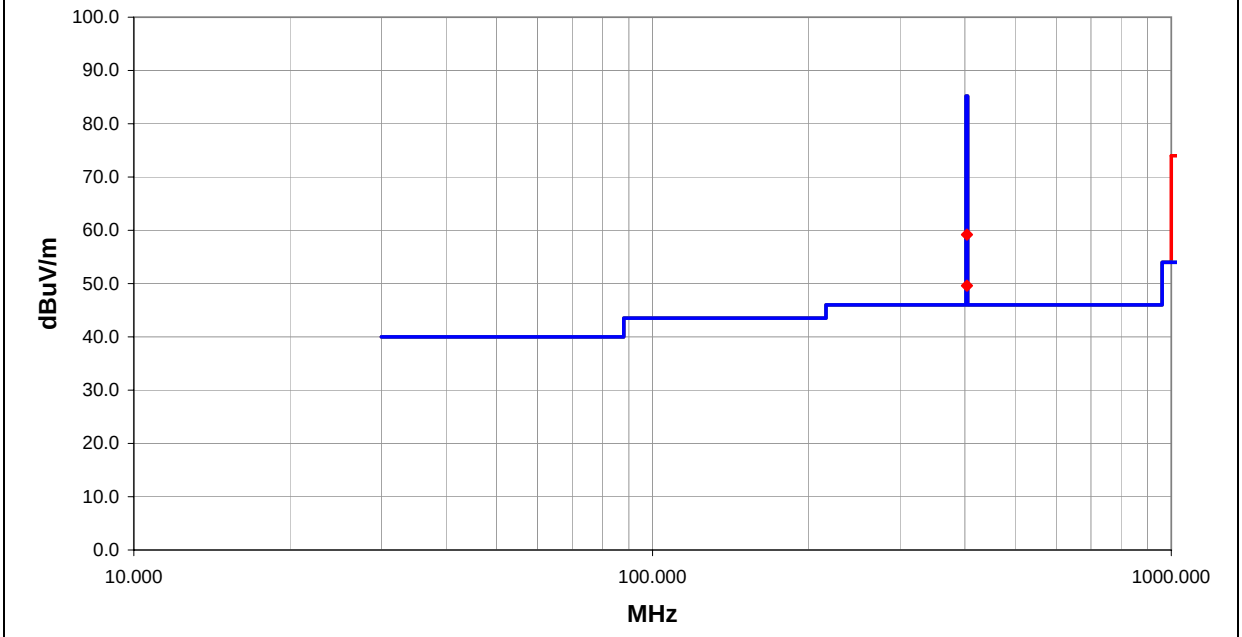
DEVIATIONS FROM TEST STANDARD

No deviations.

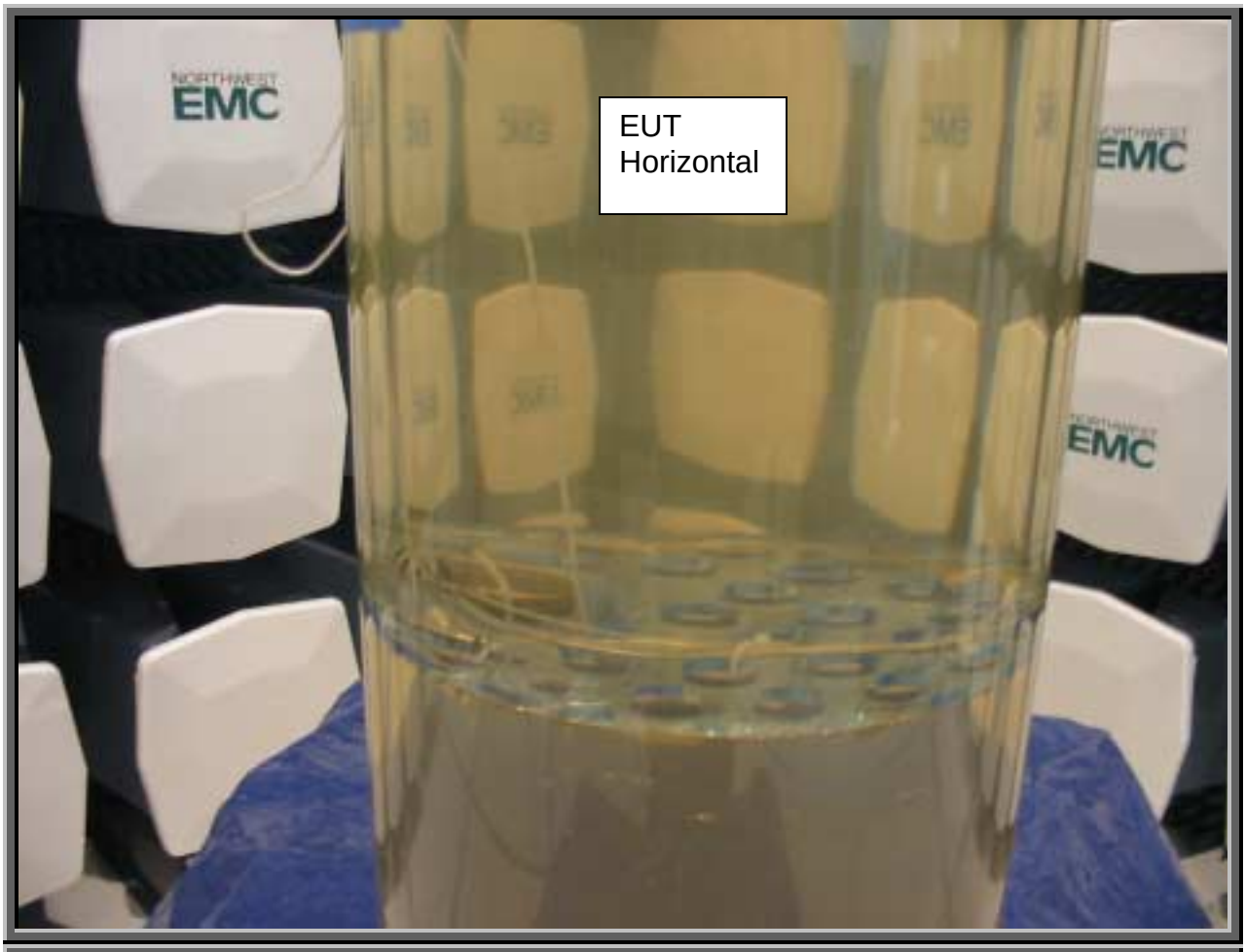
RESULTS	Run #
Pass	5

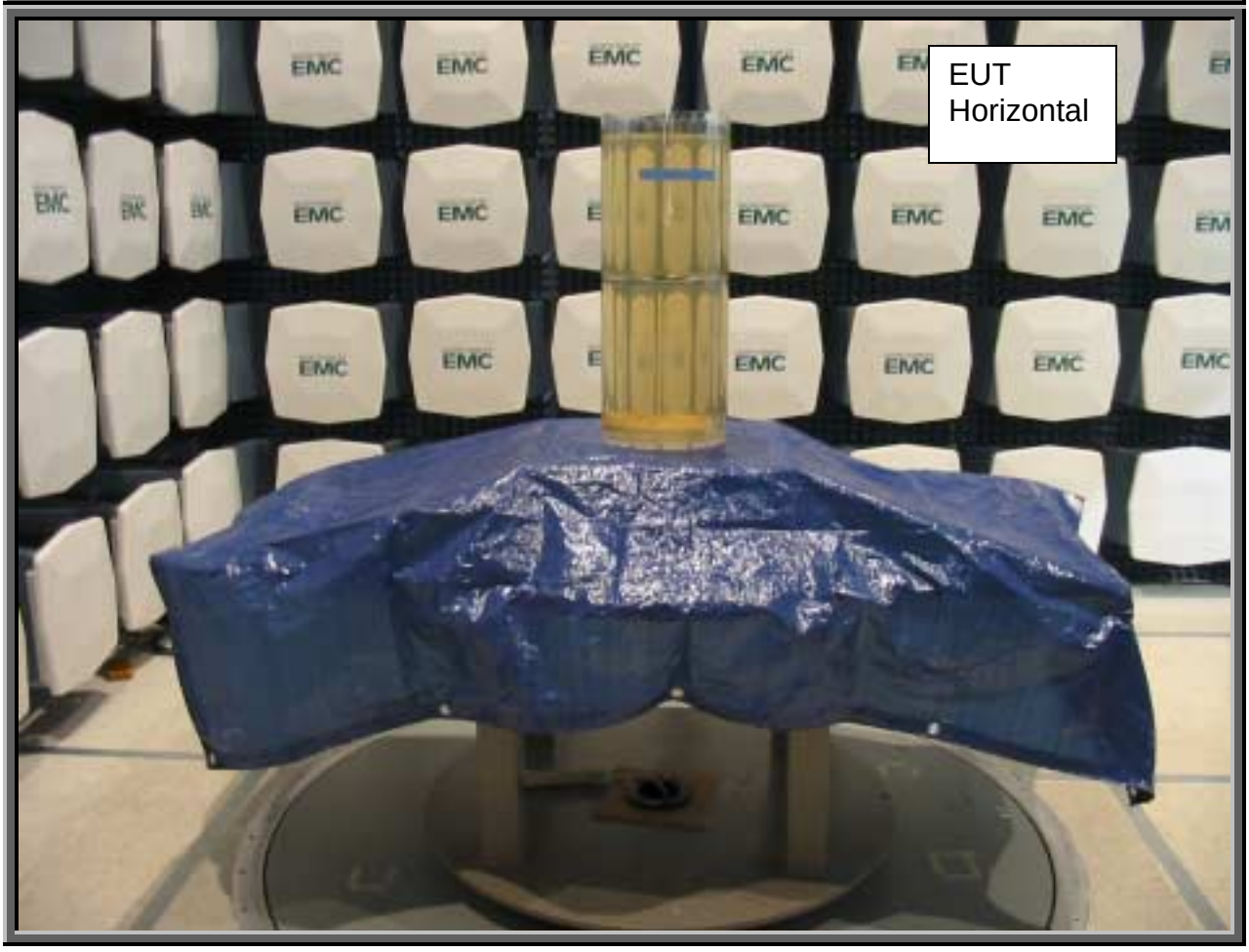
Other

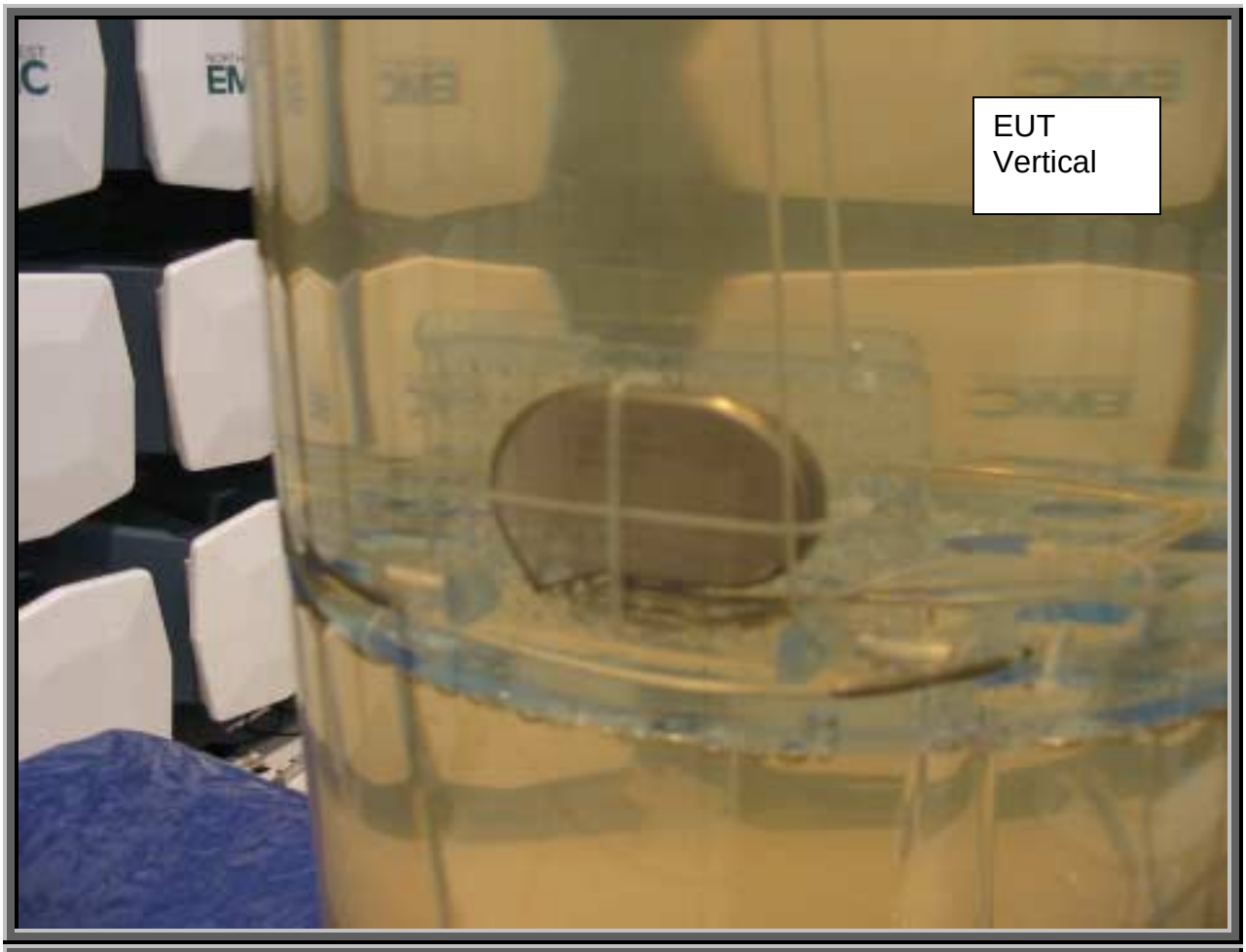
Tested By:

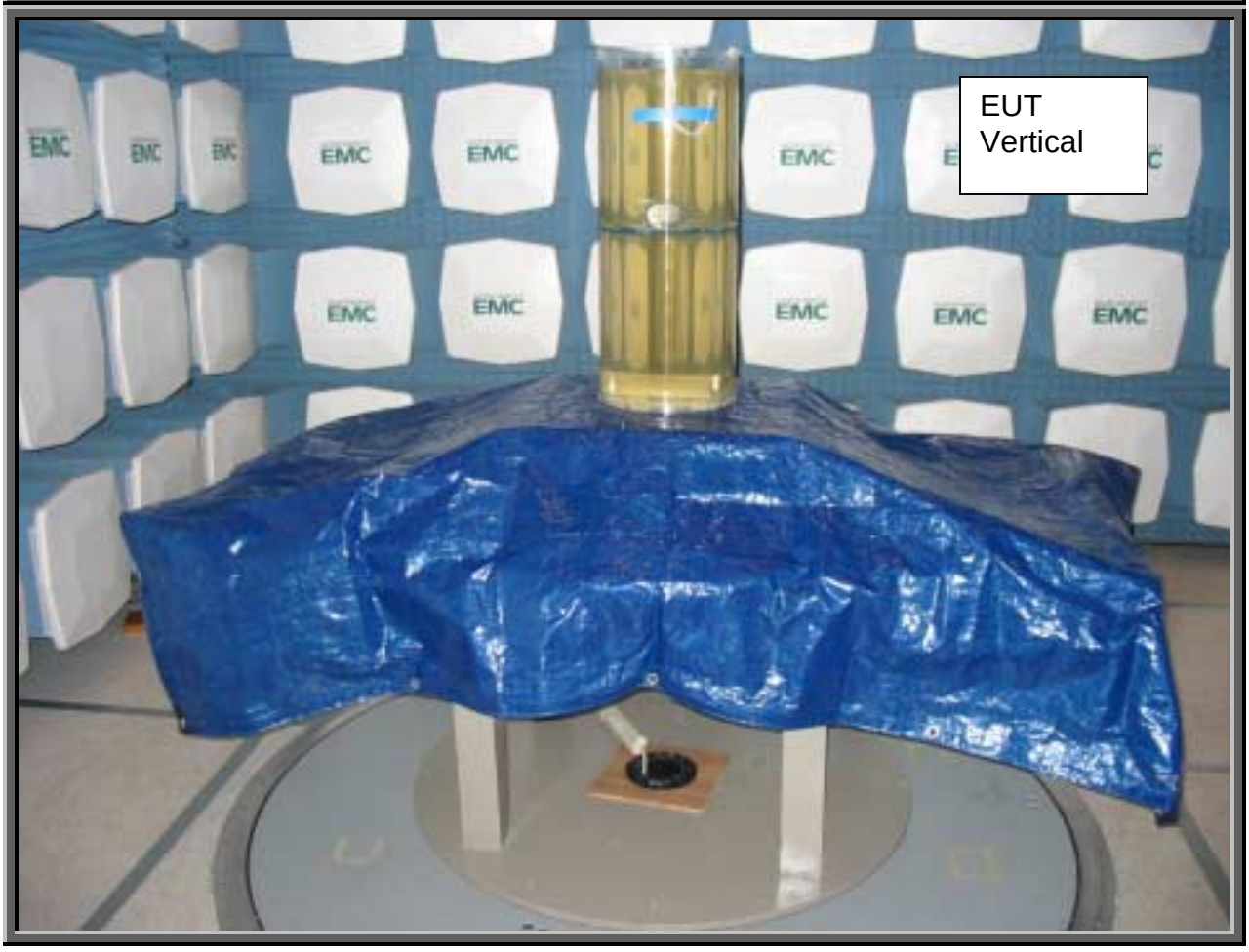


Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)
403.639	64.4	-5.2	290.0	1.4	3.0	0.0	H-Bilog	PK	0.0	59.2	85.2	-26.0
403.639	54.8	-5.2	128.0	1.6	3.0	0.0	V-Bilog	PK	0.0	49.6	85.2	-35.6


EUT
Horizontal


EUT
Horizontal


EUT
Vertical


EUT
Vertical

Justification

The individuals and/or the organization requesting the test provided the modes, configurations and settings available to evaluate. While scanning the radiated emissions, all of the EUT parameters listed below were investigated. This includes, but may not be limited to, antennas, tuned transmit frequency ranges, operating modes, and data rates.

Channels in Specified Band Investigated:
Single

Operating Modes Investigated:
Typical

Antennas Investigated:
Internal

Data Rates Investigated:
Maximum

Output Power Setting(s) Investigated:
Maximum

Power Input Settings Investigated:
Internal Battery

Frequency Range Investigated			
Start Frequency	30 MHz	Stop Frequency	4050 MHz

Software\Firmware Applied During Test			
Exercise software	Special Test Software	Version	Unknown
Description			
The system was tested using special software developed to test all functions of the device during the test.			

EUT and Peripherals

Description	Manufacturer	Model/Part Number	Serial Number
EUT	BIOTRONIK, Inc.	Lexos DR-T	79841008

Cables

Cable Type	S/N	Shield	Length (m)	Ferrite	Connection 1	Connection 2
High Voltage Model DF-1	10206150	Yes	.8	No	EUT	Unterminated
Pacing Sensing Lead Model IS-1BI	23278301	Yes	.8	No	EUT	Unterminated
Pacing Sensing Lead Model IS-1BI	23031884	Yes	.8	No	EUT	Unterminated

PA = Cable is permanently attached to the device. Shielding and/or presence of ferrite may be unknown.

Measurement Equipment

Description	Manufacturer	Model	Identifier	Last Cal	Interval
Spectrum Analyzer	Hewlett-Packard	8566B	AAL	01/07/2003	12 mo
Quasi-Peak Adapter	Hewlett-Packard	85650A	AQF	01/07/2003	12 mo
Pre-Amplifier	Amplifier Research	LN1000A	APS	01/06/2003	12 mo
Antenna, Biconilog	EMCO	3141	AXE	12/31/2001	36 mo
Antenna, Horn	EMCO	3115	AHB	08/27/2003	24 mo
Pre-Amplifier	Miteq	AMF-4D-005180-24-10P	APJ	01/06/2003	12 mo
Multimeter	Fluke	79	MMC	09/09/2003	12 mo
Thermocouple Module	Fluke	80TK	MML	N/A	N/A

Client Measurement Equipment used to Validate Tissue Substitute Material

Description	Manufacturer	Model	Identifier	Last Cal	Interval
Vector Network Analyzer	Hewlett-Packard	8753ES	US39170321	11/12/2002	12 mo
Dielectric Probe Kit	Agilent	85070C	85070C-628	09/24/2001	36 mo

Test Description

Requirement: Per 95.635(d) and 2.1053, the Field Strength of Radiated Emissions more than 250 kHz outside the MICS band (402-405 MHz) shall be attenuated to a level no greater than that shown in 90.635(d)(1). The emission limits shown in 95.635(d)(1) are based upon measurements employing a CISPR quasi-peak detector except that above 1 GHz, the limit is based on measurements employing an average detector. Measurements above 1 GHz shall be performed using a minimum resolution bandwidth of 1 MHz.

Configuration: The Field Strength of Radiated Emissions were measured in the far-field at an FCC Listed Semi-anechoic Chamber. Spectrum analyzer and linearly polarized antennas were used to measure the unwanted radiated harmonics and spurious emissions.

The orientation of the EUT and measurement antenna were manipulated to maximize the level of emissions.

The EUT was configured to transmit in a fixture that simulates the human torso. The dimensions of the test fixture and the characteristics of the tissue substitute material met the requirements of 95.639(f)(2)(i-ii). The dielectric and conductivity properties of the tissue substitute material were verified the morning of the test (see client data for tissue substitute material), and the temperature was measured before and after the test to verify compliance with 95.639(f)(2)(i). At the start of the test, the tissue substitute material was 23.5 degrees centigrade. At the conclusion of testing, it was 23.2 degrees centigrade.

Test Methodology

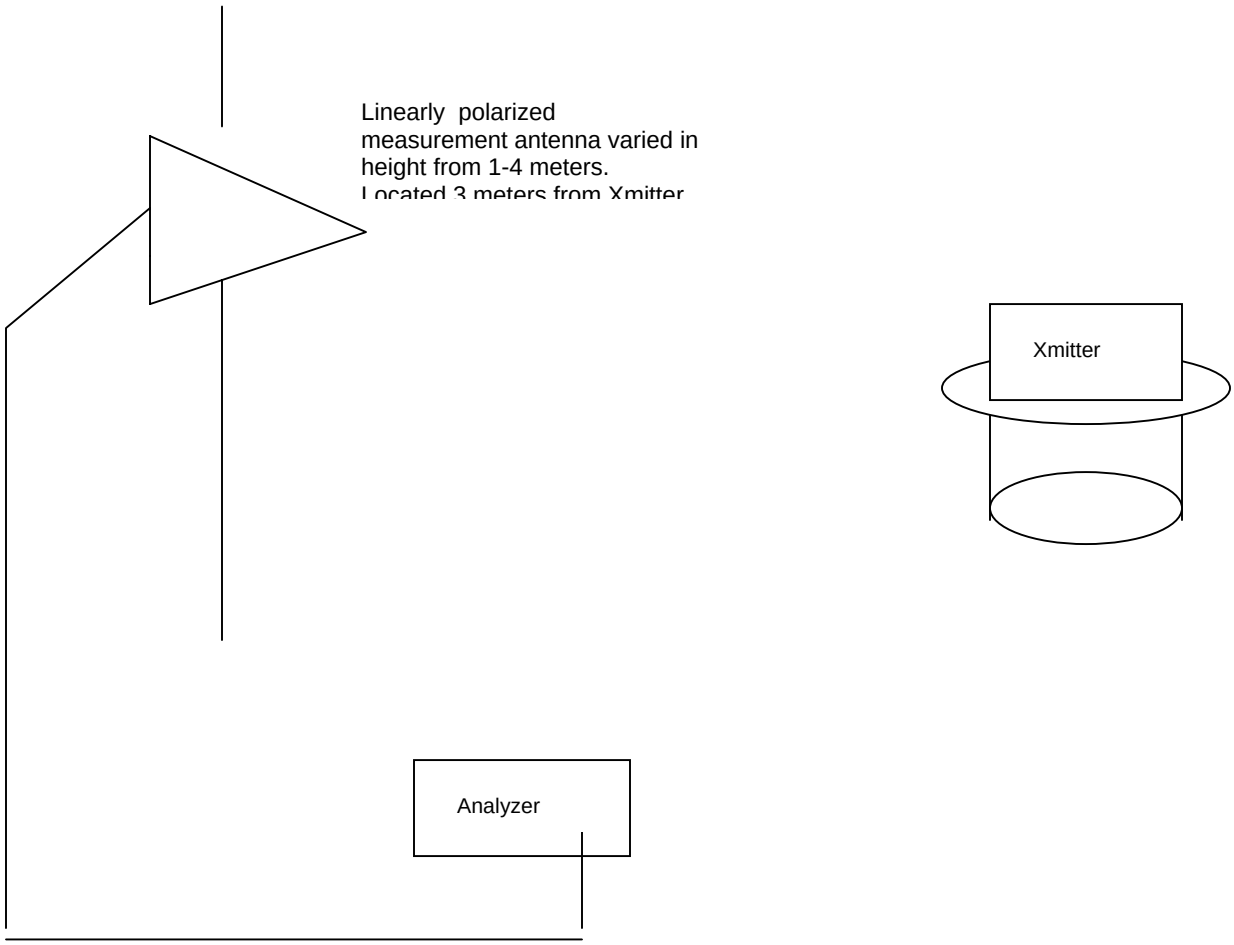
At an approved test site, the transmitter was placed in the human torso test fixture located on a remotely controlled turntable, and the measurement antenna was placed 3 meters from the transmitter. The height of the transmitter was 1.5-meter above the reference ground plane. The turntable azimuth was varied to maximize the level of radiated emissions. The height of the measurement antenna was also varied from 1 to 4 meters. The amplitude and frequency of the emissions were noted.

Bandwidths Used for Measurements

Frequency Range (MHz)	Peak Data (kHz)	Quasi-Peak Data (kHz)	Average Data (kHz)
0.01 – 0.15	1.0	0.2	0.2
0.15 – 30.0	10.0	9.0	9.0
30.0 – 1000	100.0	120.0	120.0
Above 1000	1000.0	N/A	1000.0
Measurements were made using the bandwidths and detectors specified. No video filter was used.			

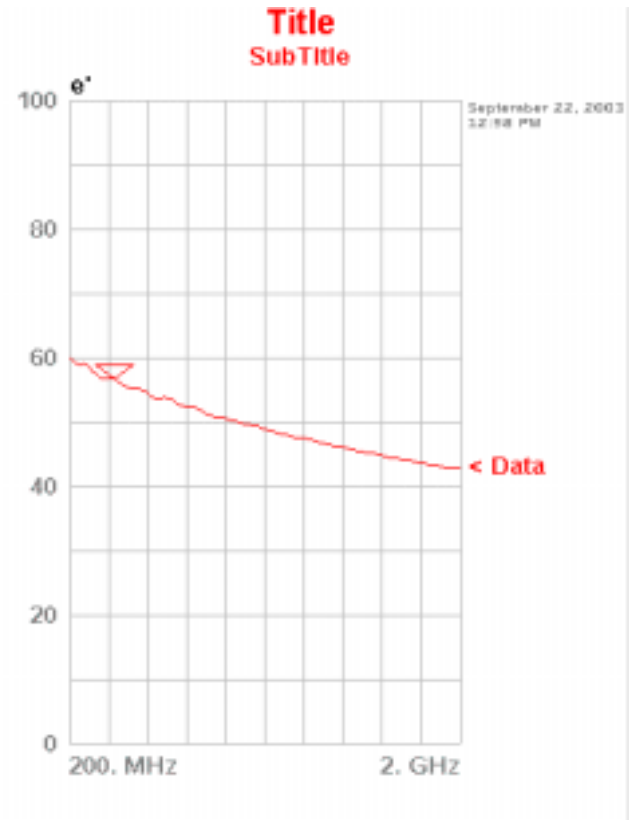
Test Setup Diagram

Test Setup for Field Strength Measurements



Completed by:

Client Data for Tissue Substitute Material



Title
SubTitle
September 22, 2003 12:58 PM

Frequency	e'	e''
200.000000 MHz	59.9005	44.6858
209.000000 MHz	59.5464	43.3766
218.000000 MHz	59.2186	42.0959
227.000000 MHz	59.0211	40.8638
236.000000 MHz	58.9757	39.7029
245.000000 MHz	58.9409	38.6510
254.000000 MHz	58.9408	37.7722
263.000000 MHz	58.9920	36.9549
272.000000 MHz	58.8714	36.1027
281.000000 MHz	58.7850	35.3667
290.000000 MHz	58.4312	34.6801
299.000000 MHz	58.3212	33.8646
308.000000 MHz	57.8674	33.1939
317.000000 MHz	57.4312	32.6614
326.000000 MHz	57.1528	32.0362
335.000000 MHz	56.9170	31.6061
344.000000 MHz	56.7864	31.0151
353.000000 MHz	56.6969	30.7211
362.000000 MHz	56.7511	30.3024
371.000000 MHz	56.7095	29.9148
380.000000 MHz	56.8622	29.6373
389.000000 MHz	56.7744	29.2192
398.000000 MHz	56.8148	28.9176
407.000000 MHz	56.6512	28.5007
416.000000 MHz	56.4882	28.1593
425.000000 MHz	56.2599	27.7462
434.000000 MHz	56.0052	27.4499

NORTHWEST EMC

RADIATED EMISSIONS DATA SHEET

REV df4.00 08/12/2003

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	BIOTRONIK, Inc.			Temperature:	73
Attendees:	Ky Lo			Humidity:	38%
Cust. Ref. No.:				Barometric Pressure	30.03
Tested by:	Greg Kiemel	Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	FCC 95.635	Year:	2002
Method:	ANSI C63.4	Year:	1992

SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

Conducted Emissions: Adjusted Level = Measured Level + Transducer Factor + Cable Attenuation Factor + External Attenuator

COMMENTS

EUT horizontal in test fixture at 1.5 m height

EUT OPERATING MODES

Transmitting Single Channel

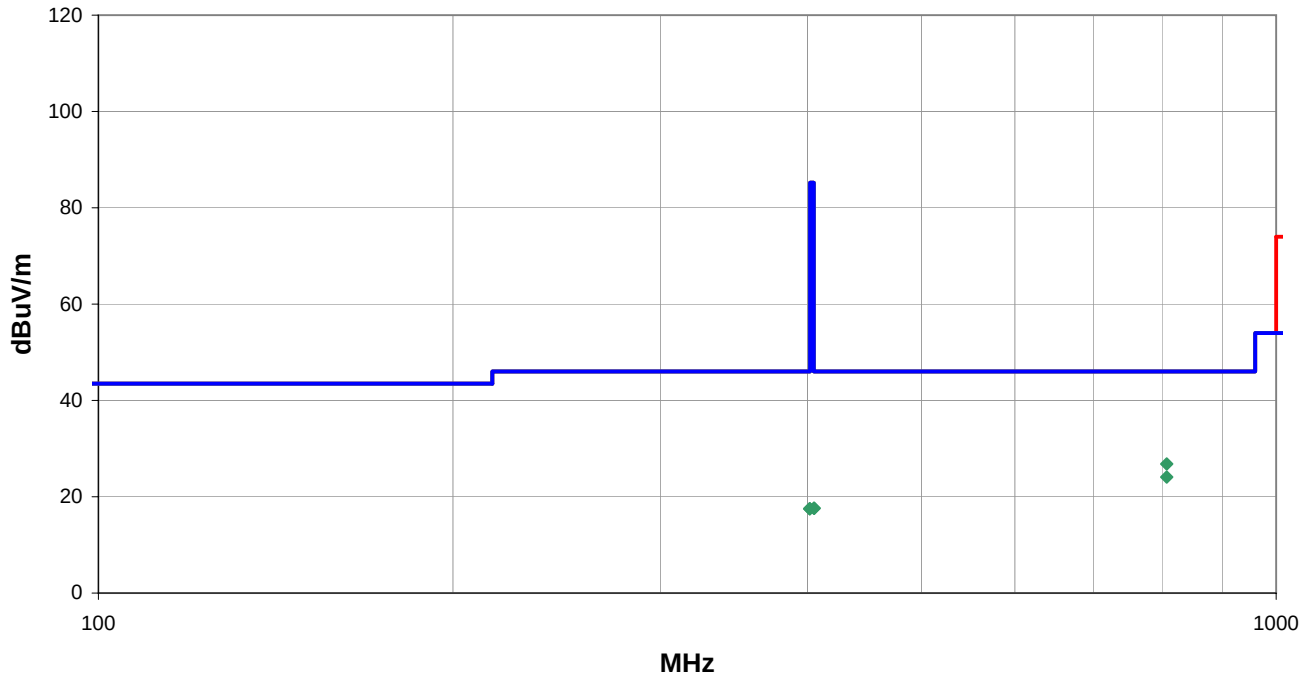
DEVIATIONS FROM TEST STANDARD

No deviations.

RESULTS	Run #
Pass	2

Other

Tested By:



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)
807.278	26.3	0.5	95.0	1.0	3.0	0.0	H-Bilog	QP	0.0	26.8	46.0	-19.2
807.278	23.6	0.5	319.0	2.2	3.0	0.0	V-Bilog	QP	0.0	24.1	46.0	-21.9
405.250	22.8	-5.2	250.0	1.0	3.0	0.0	H-Bilog	QP	0.0	17.6	46.0	-28.4
405.250	22.8	-5.2	313.0	2.6	3.0	0.0	V-Bilog	QP	0.0	17.6	46.0	-28.4
401.750	22.8	-5.3	265.0	1.0	3.0	0.0	H-Bilog	QP	0.0	17.5	46.0	-28.5
401.750	22.8	-5.3	340.0	1.6	3.0	0.0	V-Bilog	QP	0.0	17.5	46.0	-28.5

NORTHWEST EMC

RADIATED EMISSIONS DATA SHEET

REV df4.00 08/12/2003

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	BIOTRONIK, Inc.			Temperature:	73
Attendees:	Ky Lo			Humidity:	38%
Cust. Ref. No.:				Barometric Pressure	30.03
Tested by:	Greg Kiemel	Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	FCC 95.635	Year:	2002
Method:	ANSI C63.4	Year:	1992

SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

Conducted Emissions: Adjusted Level = Measured Level + Transducer Factor + Cable Attenuation Factor + External Attenuator

COMMENTS

EUT horizontal in test fixture at 1.5 m height

EUT OPERATING MODES

Transmitting Single Channel

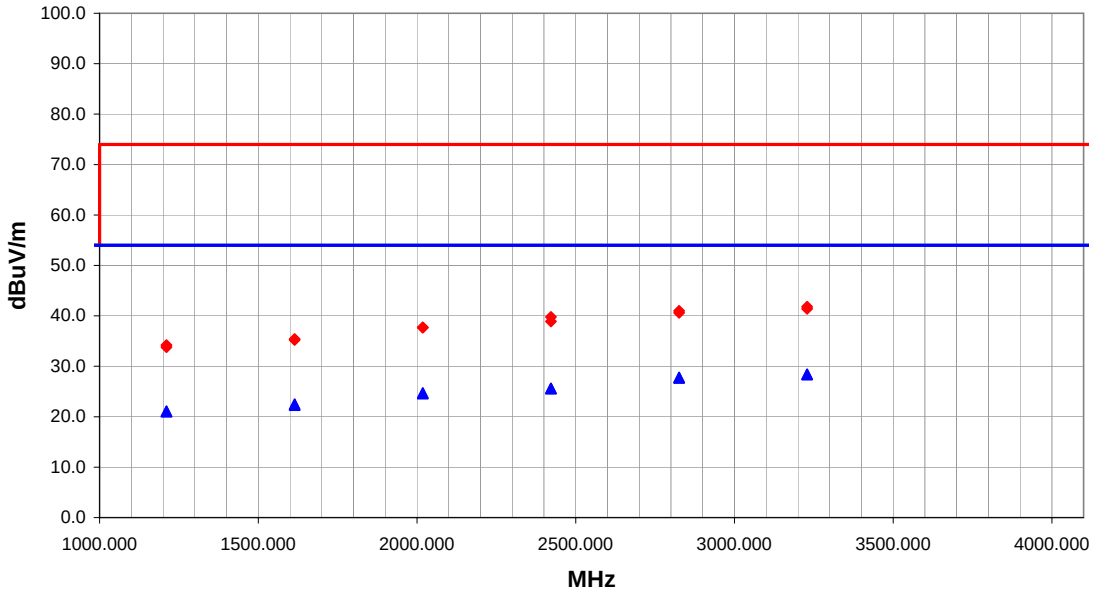
DEVIATIONS FROM TEST STANDARD

No deviations.

RESULTS	Run #
Pass	3

Other

Tested By:



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)
3229.112	26.2	2.2	328.0	1.3	3.0	0.0	H-Horn	AV	0.0	28.4	54.0	-25.6
3229.112	26.2	2.2	312.0	1.2	3.0	0.0	V-Horn	AV	0.0	28.4	54.0	-25.6
2825.473	27.2	0.6	160.0	1.3	3.0	0.0	H-Horn	AV	0.0	27.8	54.0	-26.2
2825.473	27.1	0.6	116.0	1.2	3.0	0.0	V-Horn	AV	0.0	27.7	54.0	-26.3
2421.834	26.8	-1.2	27.0	1.3	3.0	0.0	H-Horn	AV	0.0	25.6	54.0	-28.4
2421.834	26.8	-1.2	358.0	1.2	3.0	0.0	V-Horn	AV	0.0	25.6	54.0	-28.4
2018.195	26.7	-2.0	315.0	1.2	3.0	0.0	V-Horn	AV	0.0	24.7	54.0	-29.3
2018.195	26.6	-2.0	245.0	2.7	3.0	0.0	H-Horn	AV	0.0	24.6	54.0	-29.4
1614.556	27.0	-4.5	132.0	3.9	3.0	0.0	H-Horn	AV	0.0	22.5	54.0	-31.5
1614.556	26.8	-4.5	281.0	1.2	3.0	0.0	V-Horn	AV	0.0	22.3	54.0	-31.7
1210.917	27.1	-6.0	337.0	1.2	3.0	0.0	V-Horn	AV	0.0	21.1	54.0	-32.9
1210.917	27.0	-6.0	337.0	1.3	3.0	0.0	H-Horn	AV	0.0	21.0	54.0	-33.0
3229.112	39.6	2.2	328.0	1.3	3.0	0.0	H-Horn	PK	0.0	41.8	74.0	-32.2
3229.112	39.2	2.2	312.0	1.2	3.0	0.0	V-Horn	PK	0.0	41.4	74.0	-32.6
2825.473	40.4	0.6	116.0	1.2	3.0	0.0	V-Horn	PK	0.0	41.0	74.0	-33.0
2825.473	40.0	0.6	160.0	1.3	3.0	0.0	H-Horn	PK	0.0	40.6	74.0	-33.4
2421.834	41.0	-1.2	27.0	1.3	3.0	0.0	H-Horn	PK	0.0	39.8	74.0	-34.2
2421.834	40.1	-1.2	358.0	1.2	3.0	0.0	V-Horn	PK	0.0	38.9	74.0	-35.1
2018.195	39.7	-2.0	245.0	2.7	3.0	0.0	H-Horn	PK	0.0	37.7	74.0	-36.3
2018.195	39.7	-2.0	315.0	1.2	3.0	0.0	V-Horn	PK	0.0	37.7	74.0	-36.3
1614.556	39.9	-4.5	132.0	3.9	3.0	0.0	H-Horn	PK	0.0	35.4	74.0	-38.6
1614.556	39.7	-4.5	281.0	1.2	3.0	0.0	V-Horn	PK	0.0	35.2	74.0	-38.8
1210.917	40.2	-6.0	337.0	1.2	3.0	0.0	V-Horn	PK	0.0	34.2	74.0	-39.8
1210.917	39.8	-6.0	337.0	1.3	3.0	0.0	H-Horn	PK	0.0	33.8	74.0	-40.2

NORTHWEST EMC

RADIATED EMISSIONS DATA SHEET

REV df4.00 08/12/2003

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	BIOTRONIK, Inc.			Temperature:	73
Attendees:	Ky Lo			Humidity:	38%
Cust. Ref. No.:				Barometric Pressure	30.03
Tested by:	Greg Kiemel	Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	FCC 95.635	Year:	2002
Method:	ANSI C63.4	Year:	1992

SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

Conducted Emissions: Adjusted Level = Measured Level + Transducer Factor + Cable Attenuation Factor + External Attenuator

COMMENTS

EUT vertical in test fixture at 1.5 m height

EUT OPERATING MODES

Transmitting Single Channel

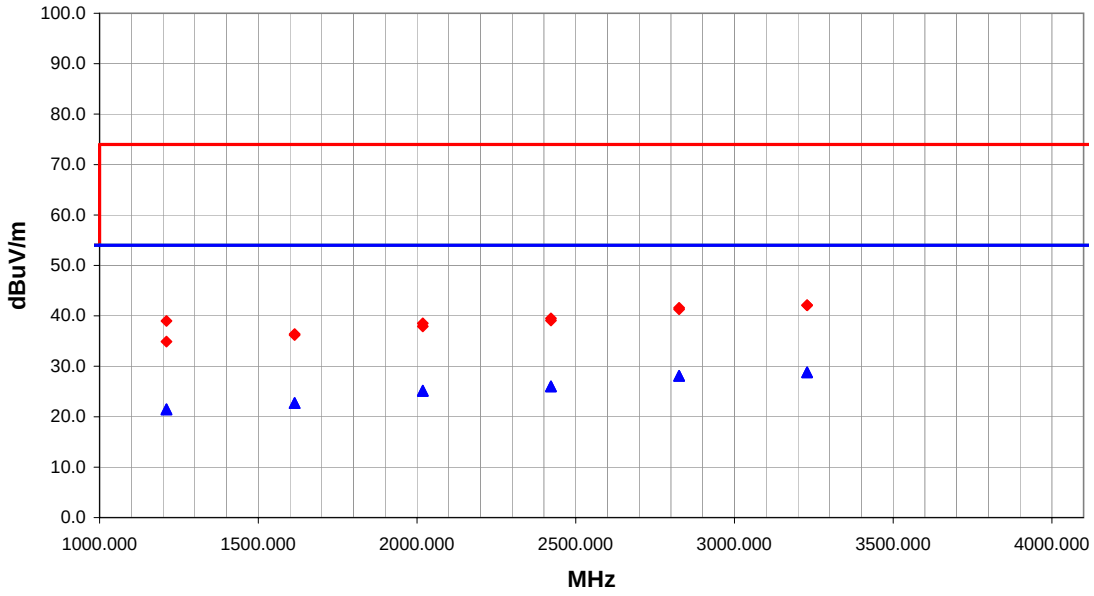
DEVIATIONS FROM TEST STANDARD

No deviations.

RESULTS	Run #
Pass	4

Other

Tested By:



Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)
3229.112	26.6	2.2	55.0	1.3	3.0	0.0	H-Horn	AV	0.0	28.8	54.0	-25.2
3229.112	26.6	2.2	121.0	1.2	3.0	0.0	V-Horn	AV	0.0	28.8	54.0	-25.2
2825.473	27.5	0.6	227.0	1.3	3.0	0.0	H-Horn	AV	0.0	28.1	54.0	-25.9
2825.473	27.5	0.6	61.0	1.2	3.0	0.0	V-Horn	AV	0.0	28.1	54.0	-25.9
2421.834	27.2	-1.2	194.0	1.9	3.0	0.0	H-Horn	AV	0.0	26.0	54.0	-28.0
2421.834	27.2	-1.2	97.0	1.4	3.0	0.0	V-Horn	AV	0.0	26.0	54.0	-28.0
2018.195	27.2	-2.0	18.0	1.2	3.0	0.0	V-Horn	AV	0.0	25.2	54.0	-28.8
2018.195	27.1	-2.0	265.0	1.3	3.0	0.0	H-Horn	AV	0.0	25.1	54.0	-28.9
1614.556	27.2	-4.5	142.0	2.4	3.0	0.0	H-Horn	AV	0.0	22.7	54.0	-31.3
1614.556	27.2	-4.5	339.0	1.2	3.0	0.0	V-Horn	AV	0.0	22.7	54.0	-31.3
1210.917	27.5	-6.0	2.0	1.2	3.0	0.0	V-Horn	AV	0.0	21.5	54.0	-32.5
1210.917	27.4	-6.0	240.0	1.3	3.0	0.0	H-Horn	AV	0.0	21.4	54.0	-32.6
3229.112	39.9	2.2	55.0	1.3	3.0	0.0	H-Horn	PK	0.0	42.1	74.0	-31.9
3229.112	39.9	2.2	121.0	1.2	3.0	0.0	V-Horn	PK	0.0	42.1	74.0	-31.9
2825.473	41.0	0.6	227.0	1.3	3.0	0.0	H-Horn	PK	0.0	41.6	74.0	-32.4
2825.473	40.7	0.6	61.0	1.2	3.0	0.0	V-Horn	PK	0.0	41.3	74.0	-32.7
2421.834	40.7	-1.2	194.0	1.9	3.0	0.0	H-Horn	PK	0.0	39.5	74.0	-34.5
2421.834	40.3	-1.2	97.0	1.4	3.0	0.0	V-Horn	PK	0.0	39.1	74.0	-34.9
1210.917	45.0	-6.0	2.0	1.2	3.0	0.0	V-Horn	PK	0.0	39.0	74.0	-35.0
2018.195	40.5	-2.0	18.0	1.2	3.0	0.0	V-Horn	PK	0.0	38.5	74.0	-35.5
2018.195	39.9	-2.0	265.0	1.3	3.0	0.0	H-Horn	PK	0.0	37.9	74.0	-36.1
1614.556	40.9	-4.5	339.0	1.2	3.0	0.0	V-Horn	PK	0.0	36.4	74.0	-37.6
1614.556	40.7	-4.5	142.0	2.4	3.0	0.0	H-Horn	PK	0.0	36.2	74.0	-37.8
1210.917	40.9	-6.0	240.0	1.3	3.0	0.0	H-Horn	PK	0.0	34.9	74.0	-39.1

NORTHWEST EMC

RADIATED EMISSIONS DATA SHEET

REV df4.00 08/12/2003

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	BIOTRONIK, Inc.			Temperature:	73
Attendees:	Ky Lo			Humidity:	38%
Cust. Ref. No.:				Barometric Pressure	30.03
Tested by:	Greg Kiemel	Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	FCC 95.635	Year:	2002
Method:	ANSI C63.4	Year:	1992

SAMPLE CALCULATIONS

Radiated Emissions: Field Strength = Measured Level + Antenna Factor + Cable Factor - Amplifier Gain + Distance Adjustment Factor + External Attenuation

Conducted Emissions: Adjusted Level = Measured Level + Transducer Factor + Cable Attenuation Factor + External Attenuator

COMMENTS

EUT vertical in test fixture at 1.5 m height

EUT OPERATING MODES

Transmitting Single Channel

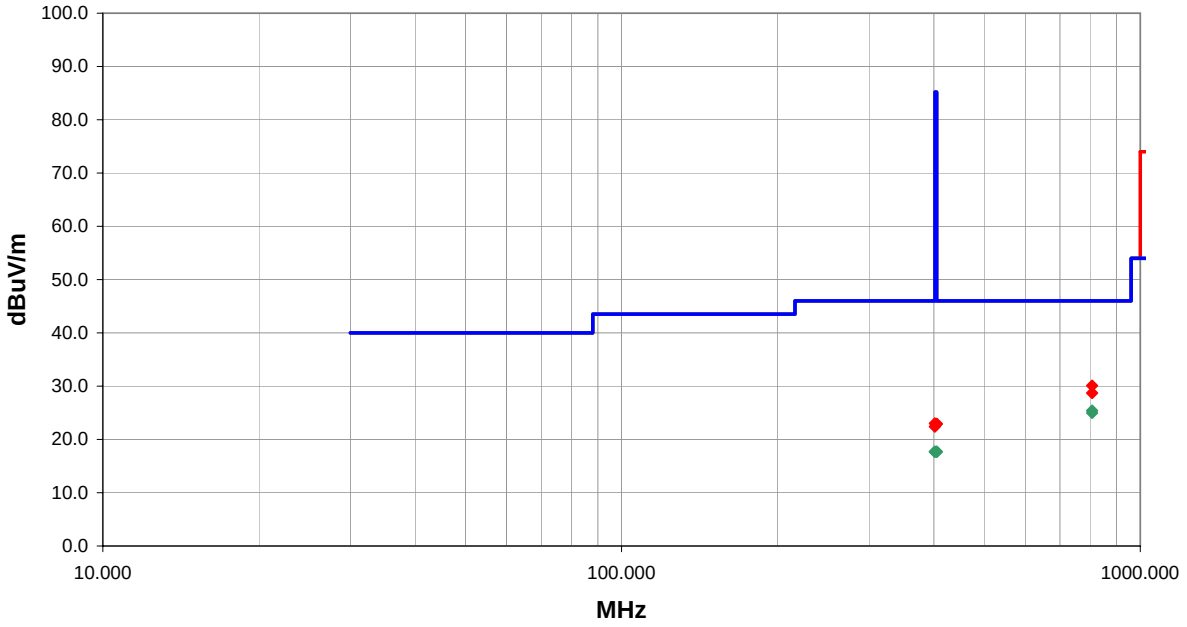
DEVIATIONS FROM TEST STANDARD

No deviations.

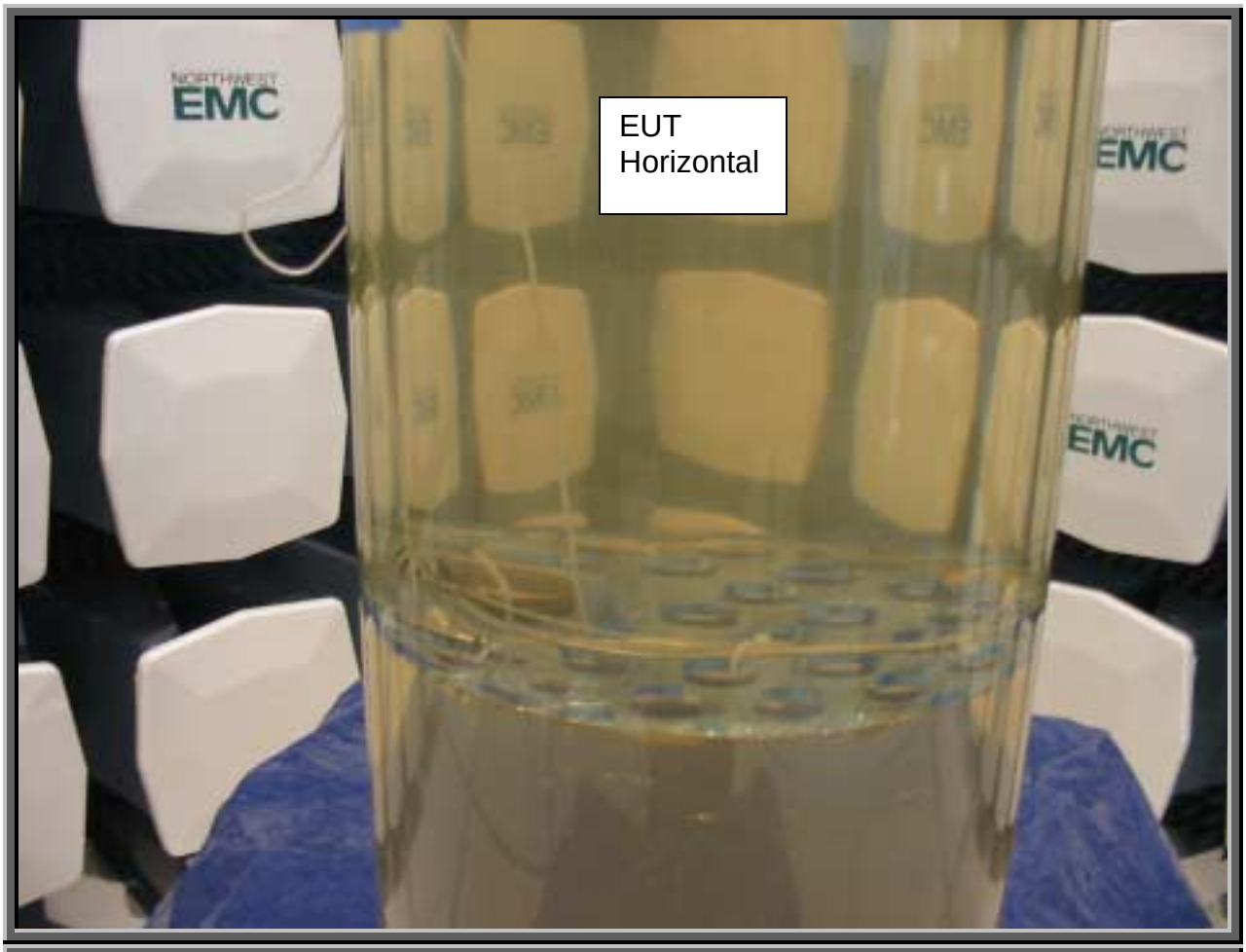
RESULTS	Run #
Pass	6

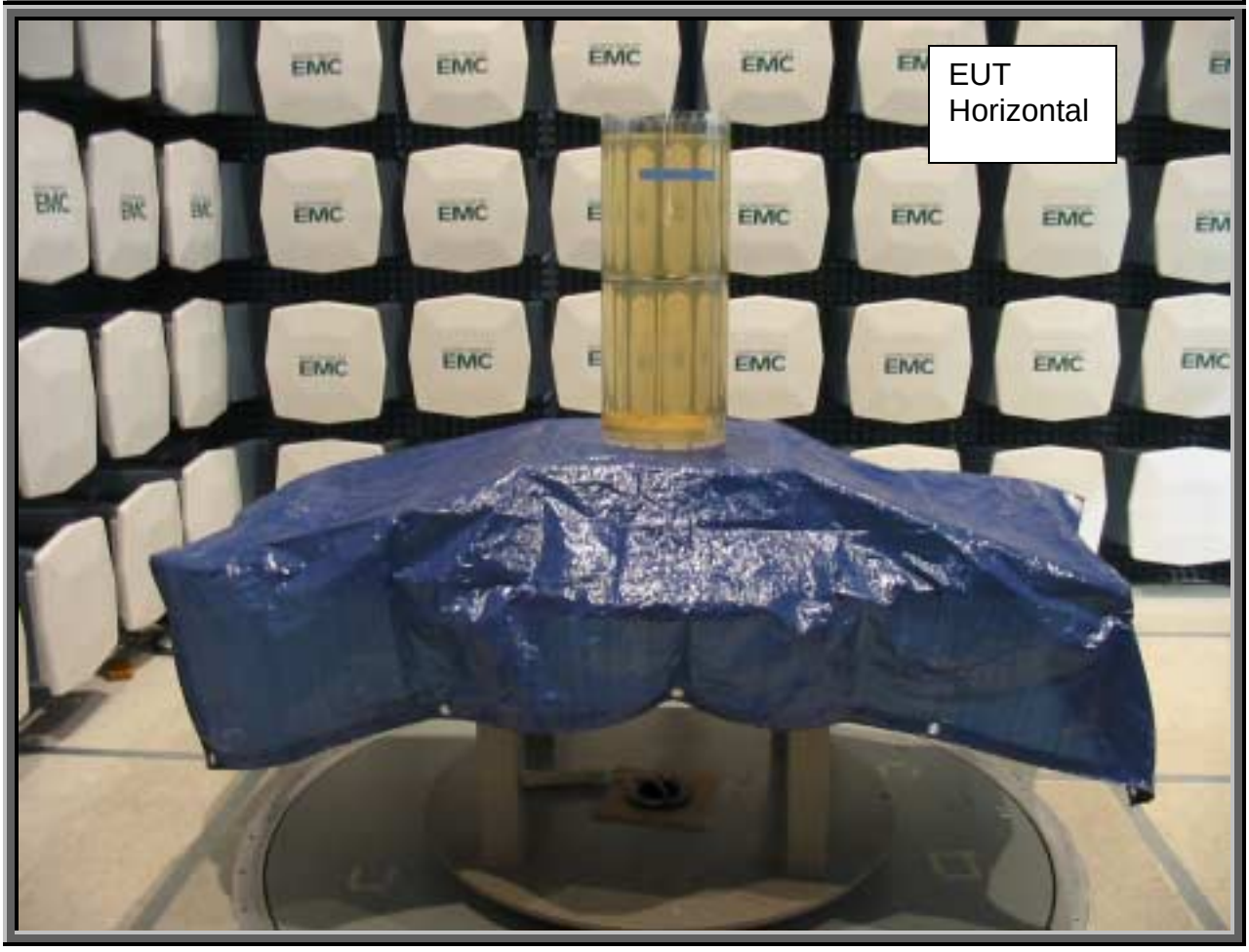
Other

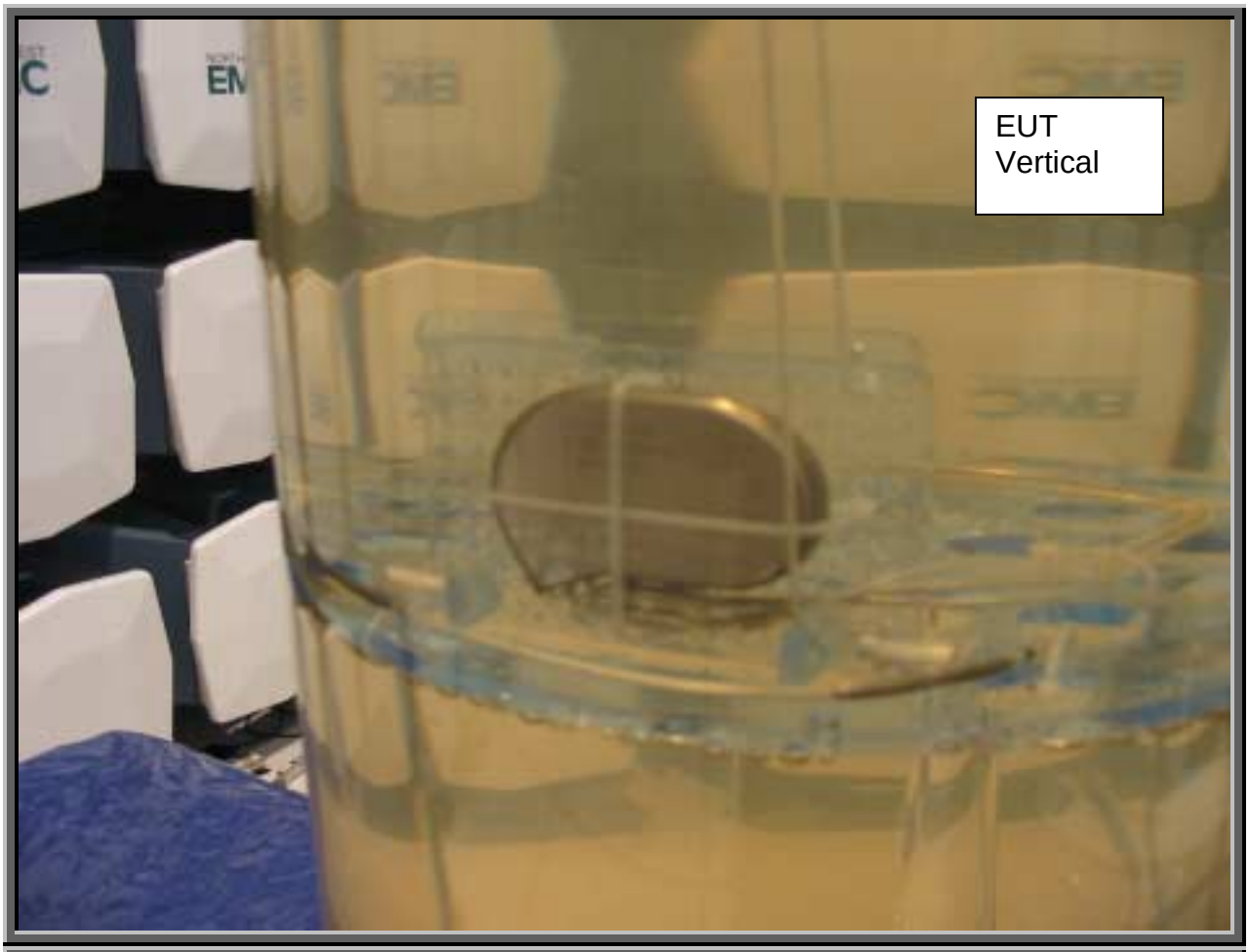
Tested By:

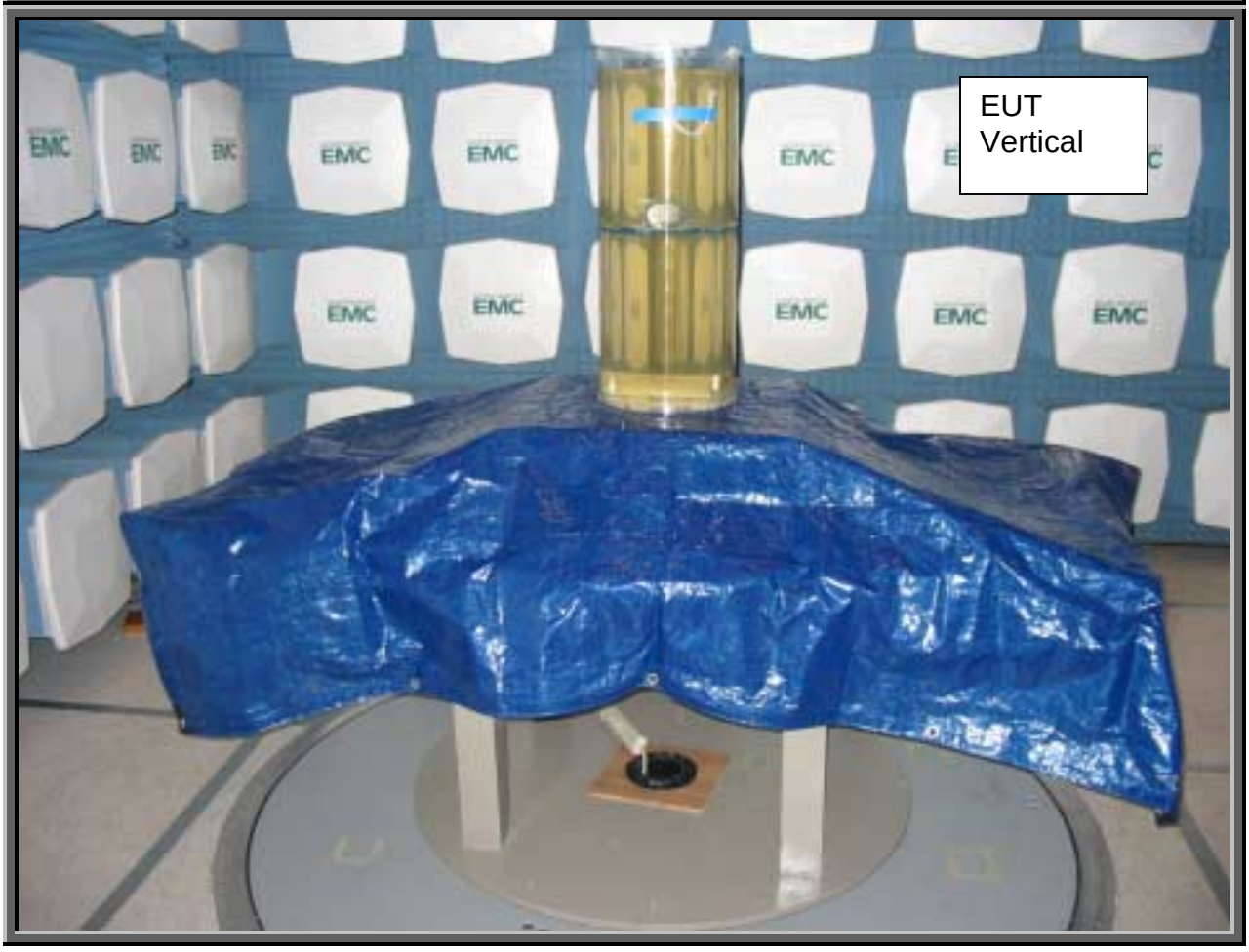


Freq (MHz)	Amplitude (dBuV)	Factor (dB)	Azimuth (degrees)	Height (meters)	Distance (meters)	External Attenuation (dB)	Polarity	Detector	Distance Adjustment (dB)	Adjusted dBuV/m	Spec. Limit dBuV/m	Compared to Spec. (dB)
807.278	29.6	0.5	78.0	1.0	3.0	0.0	H-Bilog	PK	0.0	30.1	46.0	-15.9
807.278	28.2	0.5	11.0	1.2	3.0	0.0	V-Bilog	PK	0.0	28.7	46.0	-17.3
401.750	28.3	-5.3	191.0	1.6	3.0	0.0	V-Bilog	PK	0.0	23.0	46.0	-23.0
405.250	28.1	-5.2	52.0	2.6	3.0	0.0	H-Bilog	PK	0.0	22.9	46.0	-23.1
405.250	28.1	-5.2	232.0	1.6	3.0	0.0	V-Bilog	PK	0.0	22.9	46.0	-23.1
401.750	27.7	-5.3	269.0	1.0	3.0	0.0	H-Bilog	PK	0.0	22.4	46.0	-23.6
807.278	24.9	0.5	78.0	1.0	3.0	0.0	H-Bilog	QP	0.0	25.4	46.0	-20.6
807.278	24.5	0.5	11.0	1.2	3.0	0.0	V-Bilog	QP	0.0	25.0	46.0	-21.0
401.750	23.0	-5.3	269.0	1.0	3.0	0.0	H-Bilog	QP	0.0	17.7	46.0	-28.3
401.750	23.0	-5.3	191.0	1.6	3.0	0.0	V-Bilog	QP	0.0	17.7	46.0	-28.3
405.250	22.9	-5.2	52.0	2.6	3.0	0.0	H-Bilog	QP	0.0	17.7	46.0	-28.3
405.250	22.9	-5.2	232.0	1.6	3.0	0.0	V-Bilog	QP	0.0	17.7	46.0	-28.3


EUT
Horizontal


EUT
Horizontal


EUT
Vertical


EUT
Vertical

Justification

The individuals and/or the organization requesting the test provided the modes, configurations and settings available to evaluate. While scanning the radiated emissions, all of the EUT parameters listed below were investigated. This includes, but may not be limited to, antennas, tuned transmit frequency ranges, operating modes, and data rates.

Channels in Specified Band Investigated:
Single

Operating Modes Investigated:
Typical

Data Rates Investigated:
Maximum

Output Power Setting(s) Investigated:
Maximum

Power Input Settings Investigated:
Internal Battery

Software\Firmware Applied During Test			
Exercise software	Special Test Software	Version	Unknown
Description			
The system was tested using special software developed to test all functions of the device during the test.			

EUT and Peripherals

Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
EUT	BIOTRONIK, Inc.	Lexos DR-T	79841008

Cables

Cable Type	**S/N**	**Shield**	**Length (m)**	**Ferrite**	**Connection 1**	**Connection 2**
High Voltage Model DF-1	10206150	Yes	.8	No	EUT	Unterminated
Pacing Sensing Lead Model IS-1BI	23278301	Yes	.8	No	EUT	Unterminated
Pacing Sensing Lead Model IS-1BI	23031884	Yes	.8	No	EUT	Unterminated

PA = Cable is permanently attached to the device. Shielding and/or presence of ferrite may be unknown.

Measurement Equipment

Description	Manufacturer	Model	Identifier	Last Cal	Interval
Spectrum Analyzer	Tektronix	2784	AAO	02/26/2003	24 mo
Pre-Amplifier	Amplifier Research	LN1000A	APS	01/06/2003	12 mo
Antenna, Biconilog	EMCO	3141	AXE	12/31/2001	36 mo
Multimeter	Fluke	79	MMC	09/09/2003	12 mo
Thermocouple Module	Fluke	80TK	MML	N/A	N/A

Client Measurement Equipment used to Validate Tissue Substitute Material

Description	Manufacturer	Model	Identifier	Last Cal	Interval
Vector Network Analyzer	Hewlett-Packard	8753ES	US39170321	11/12/2002	12 mo
Dielectric Probe Kit	Agilent	85070C	85070C-628	09/24/2001	36 mo

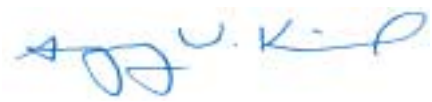
Test Description

Requirement: Per 47 CFR 95.633(e)(1) and 2.1049, the Occupied Bandwidth was measured. The maximum authorized emission bandwidth is 300 kHz.

Configuration: Per 47 CFR 95.633(e)(3), the emission bandwidth was determined by measuring the width of the signal between two points, one below the carrier center frequency and one above the carrier center frequency, that are 20 dB down relative to the maximum level of the modulated carrier. A spectrum analyzer using a peak detector with no video filtering was used with a resolution bandwidth equal to approximately 1.0 percent of the emission bandwidth of the EUT.

An emission bandwidth measurement was made using a 1kHz resolution bandwidth (no video filtering) and a peak detector. With these instrument settings, an emission bandwidth of 27.1 kHz was measured. This most closely satisfied the specified measurement criteria. It is important to use a RBW that is sufficiently narrow to plot the actual bandwidth of the signal and not the filter response curve of the spectrum analyzer. However, various plots were made using different frequency spans and resolution bandwidths in an attempt to not only satisfy the measurement criteria, but to also show that all emissions outside of the occupied band are greatly attenuated

Completed by:



NORTHWEST EMC

EMISSIONS DATA SHEET

Rev BETA 01/30/01

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	Biotronik, Inc.			Temperature:	73
Attendees:	Ky Lo	Tested by:	Greg Kiemel	Humidity:	38% RH
Customer Ref. No.:		Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	47 CFR 95.633(e)(1)	Year:	2002	Method:	95.633(e)(3) & ANSI C63.4	Year:	Most Current

SAMPLE CALCULATIONS

COMMENTS

EUT Horizontal in Test fixture at 1.5m height

EUT OPERATING MODES

Transmitting single channel

DEVIATIONS FROM TEST STANDARD

None

REQUIREMENTS

The maximum authorized emission bandwidth is 300 kHz

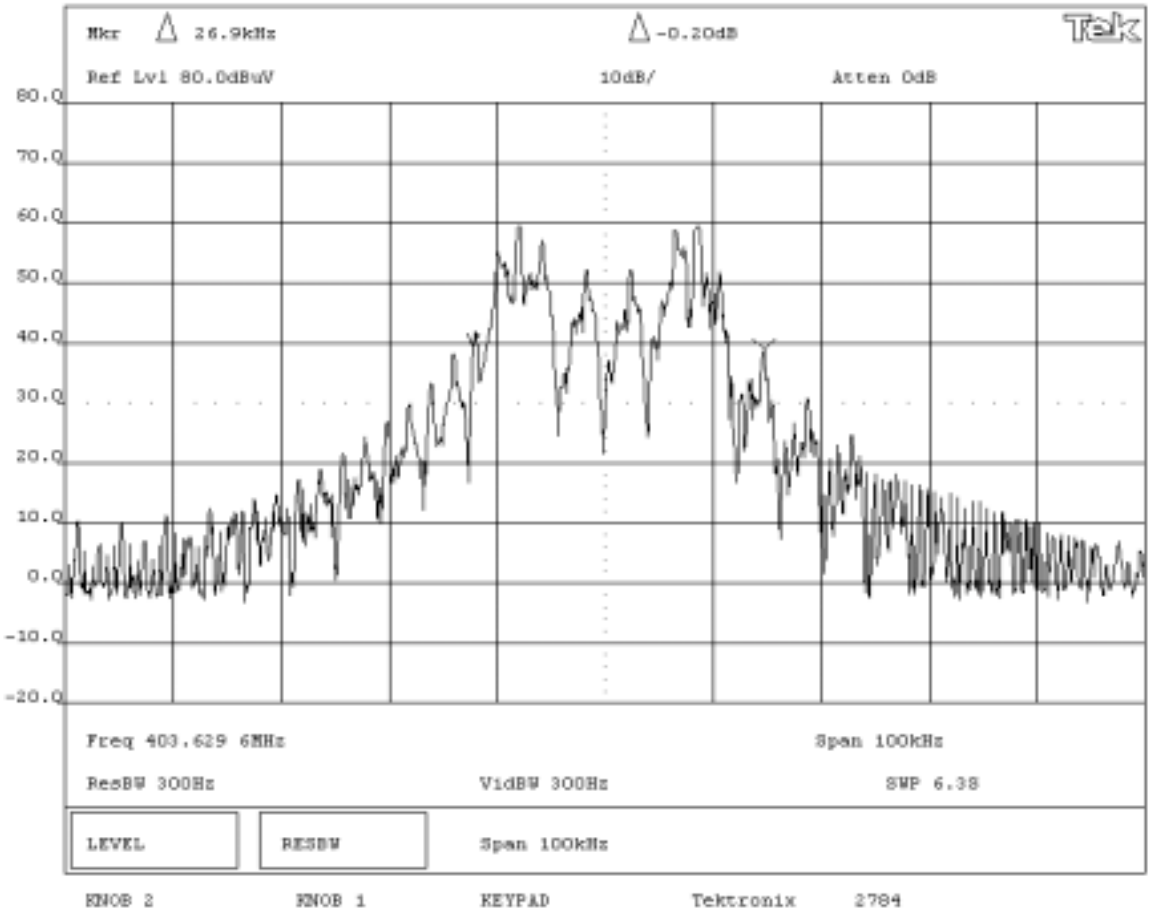
RESULTS	BANDWIDTH
Pass	26.9 kHz

SIGNATURE

Tested By: _____

DESCRIPTION OF TEST

Occupied Bandwidth



NORTHWEST EMC

EMISSIONS DATA SHEET

Rev BETA 01/30/01

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	Biotronik, Inc.			Temperature:	73
Attendees:	Ky Lo	Tested by:	Greg Kiemel	Humidity:	38% RH
Customer Ref. No.:		Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	47 CFR 95.633(e)(1)	Year:	2002	Method:	95.633(e)(3) & ANSI C63.4	Year:	Most Current

SAMPLE CALCULATIONS

COMMENTS

EUT Horizontal in Test fixture at 1.5m height

EUT OPERATING MODES

Transmitting single channel

DEVIATIONS FROM TEST STANDARD

None

REQUIREMENTS

The maximum authorized emission bandwidth is 300 kHz

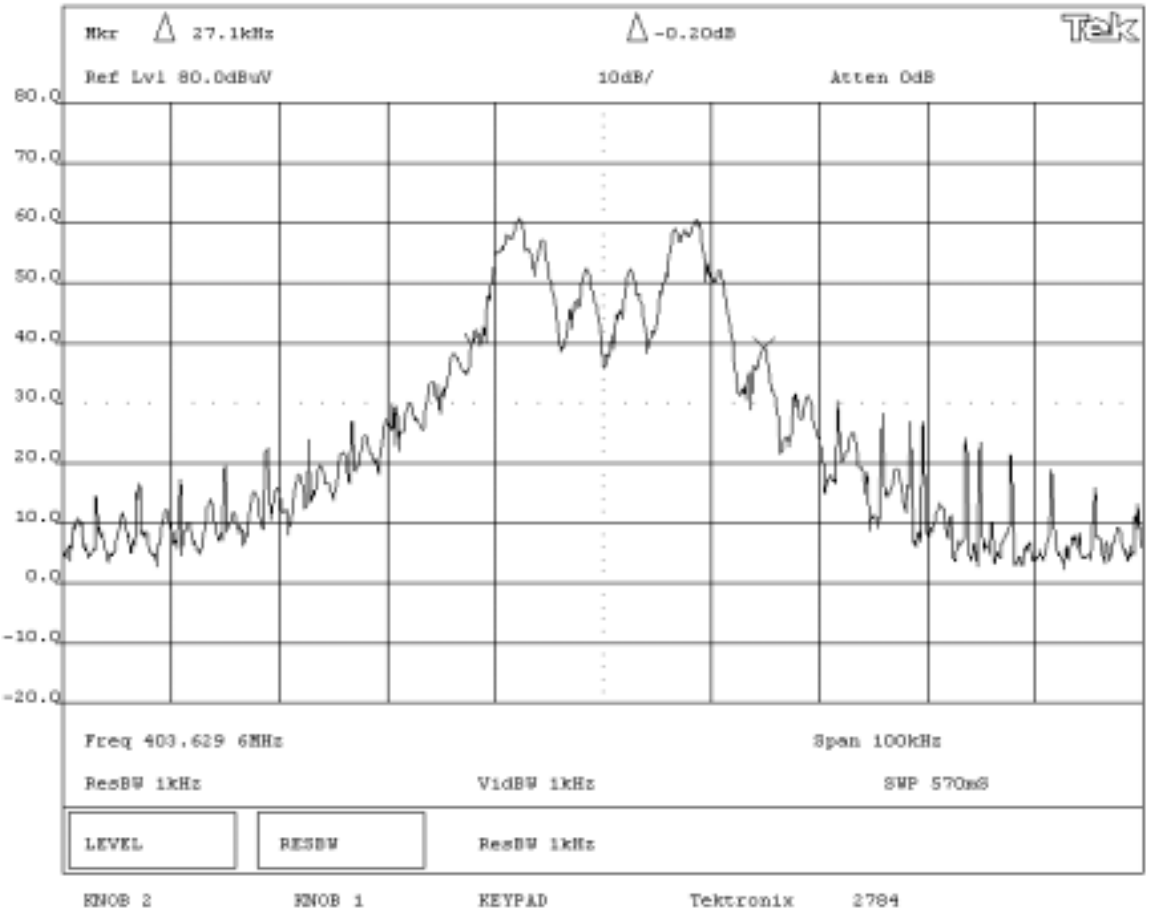
RESULTS	BANDWIDTH
Pass	27.1 kHz

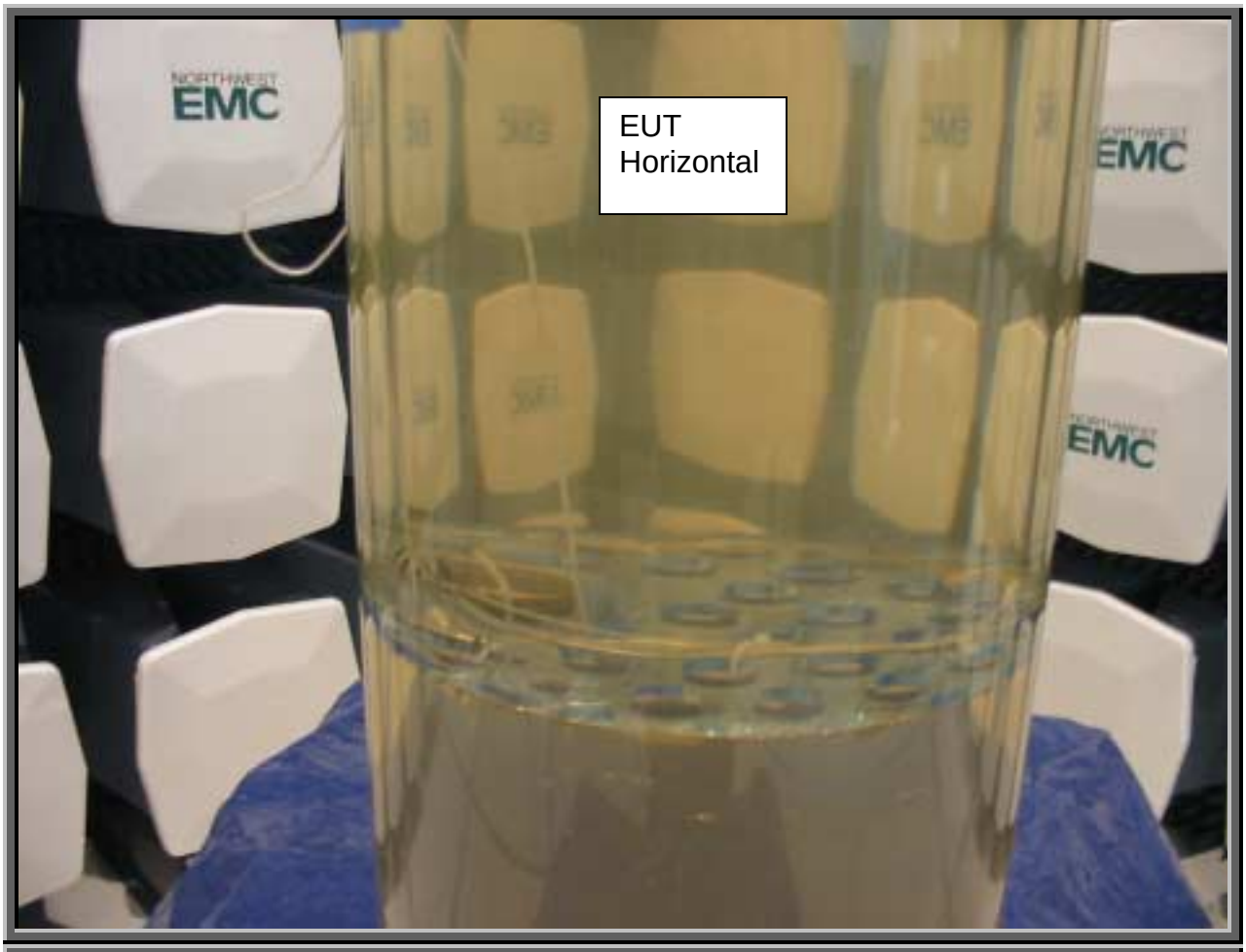
SIGNATURE

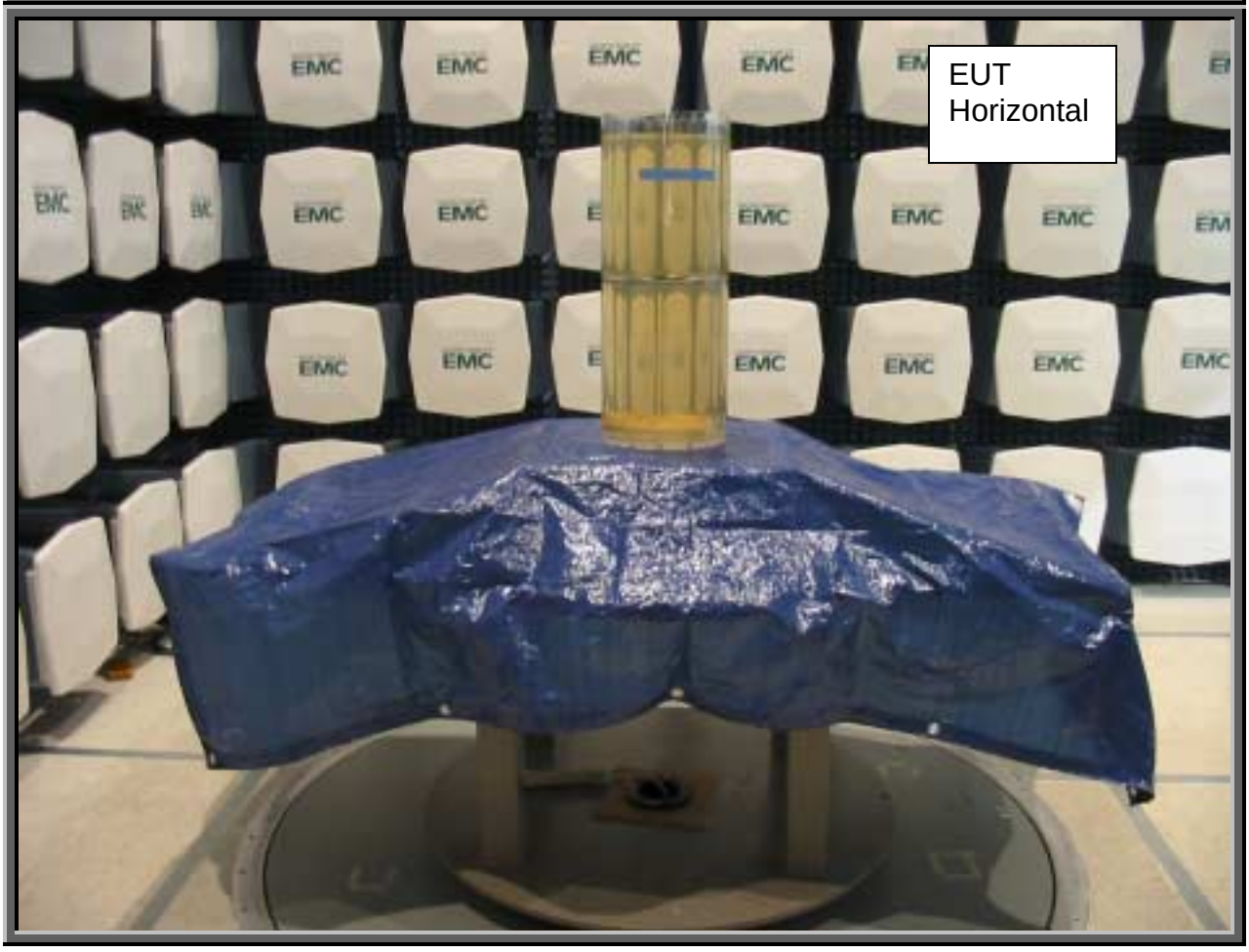
Tested By: _____

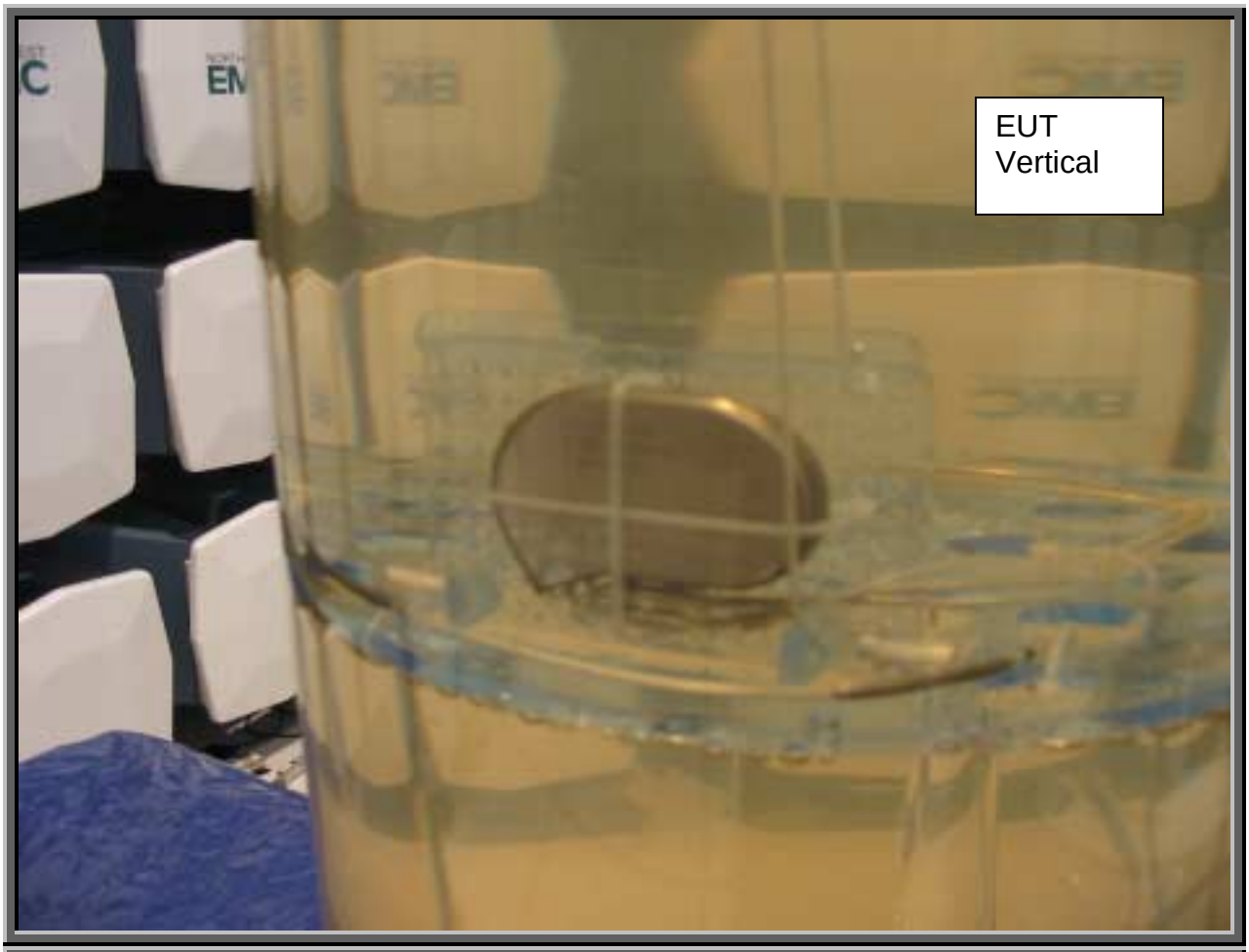
DESCRIPTION OF TEST

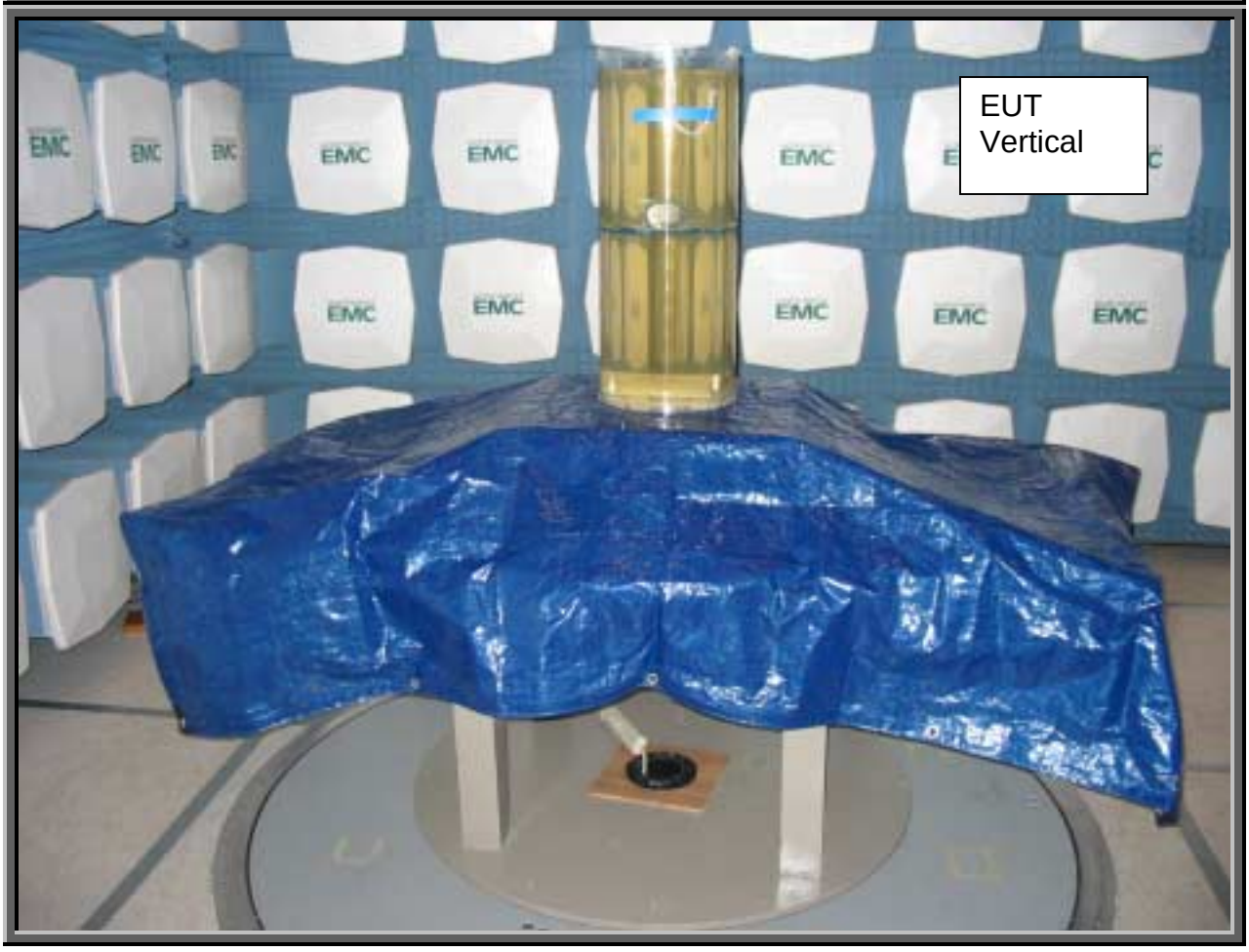
Occupied Bandwidth




EUT
Horizontal


EUT
Horizontal


EUT
Vertical


EUT
Vertical

Justification

The individuals and/or the organization requesting the test provided the modes, configurations and settings available to evaluate. While scanning the radiated emissions, all of the EUT parameters listed below were investigated. This includes, but may not be limited to, antennas, tuned transmit frequency ranges, operating modes, and data rates.

Channels in Specified Band Investigated:
Single

Operating Modes Investigated:
Typical

Data Rates Investigated:
Maximum

Output Power Setting(s) Investigated:
Maximum

Power Input Settings Investigated:
Internal Battery

Software\Firmware Applied During Test			
Exercise software	Special Test Software	Version	Unknown
Description			
The system was tested using special software developed to test all functions of the device during the test.			

EUT and Peripherals

Description	Manufacturer	Model/Part Number	Serial Number
EUT	BIOTRONIK, Inc.	Lexos DR-T	79841008

Cables

Cable Type	S/N	Shield	Length (m)	Ferrite	Connection 1	Connection 2
High Voltage Model DF-1	10206150	Yes	.8	No	EUT	Unterminated
Pacing Sensing Lead Model IS-1BI	23278301	Yes	.8	No	EUT	Unterminated
Pacing Sensing Lead Model IS-1BI	23031884	Yes	.8	No	EUT	Unterminated

PA = Cable is permanently attached to the device. Shielding and/or presence of ferrite may be unknown.

Measurement Equipment

Description	Manufacturer	Model	Identifier	Last Cal	Interval
Spectrum Analyzer	Tektronix	2784	AAO	02/26/2003	24 mo
Pre-Amplifier	Amplifier Research	LN1000A	APS	01/06/2003	12 mo
Antenna, Biconilog	EMCO	3141	AXE	12/31/2001	36 mo
Multimeter	Fluke	79	MMC	09/09/2003	12 mo
Thermocouple Module	Fluke	80TK	MML	N/A	N/A

Client Measurement Equipment used to Validate Tissue Substitute Material

Description	Manufacturer	Model	Identifier	Last Cal	Interval
Vector Network Analyzer	Hewlett-Packard	8753ES	US39170321	11/12/2002	12 mo
Dielectric Probe Kit	Agilent	85070C	85070C-628	09/24/2001	36 mo

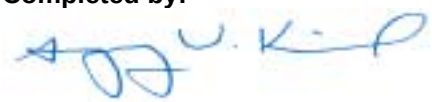
Test Description

Requirement: Per 47 CFR 95.635(d)(4-5) the emission mask was measured. Emissions more than 150 kHz away from the center frequency must be attenuated below the transmitter output power by at least 20 dB. In addition, emissions 250 kHz or less above and below the MICS band (402-405 MHz) must be attenuated below the maximum permitted output power by at least 20 dB.

Configuration: The emission mask was measured in the same configuration as radiated spurious emissions. All emissions measurements were made with the EUT placed in the tissue substitute material. First, the EUT orientation (horizontal or vertical), the turntable azimuth and measurement antenna height, were maximized to achieve the maximum field strength of the fundamental transmit frequency.

Then, a spectrum analyzer was used to measure the emission mask. A spectrum analyzer using a peak detector with no video filtering was used with a resolution bandwidth equal to approximately 1.0 percent of the emission bandwidth of the EUT. However, various plots were made using different frequency spans and resolution bandwidths in an attempt to not only satisfy the measurement criteria, but to also show that all emissions outside of the occupied band are greatly attenuated.

Completed by:



NORTHWEST EMC

EMISSIONS DATA SHEET

Rev BETA 01/30/01

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	Biotronik, Inc.			Temperature:	73
Attendees:	Ky Lo	Tested by:	Greg Kiemel	Humidity:	38% RH
Customer Ref. No.:		Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	47 CFR 95.635(d)(4)	Year:	2002	Method:	95.635(d)(4) & ANSI C63.4	Year:	1992

SAMPLE CALCULATIONS

COMMENTS

EUT Horizontal in Test fixture at 1.5m height

EUT OPERATING MODES

Transmitting single channel

DEVIATIONS FROM TEST STANDARD

None

REQUIREMENTS

Emissions more than 150 kHz away from the center frequency must be attenuated below the transmitter ouput power by at least 20 dB

RESULTS

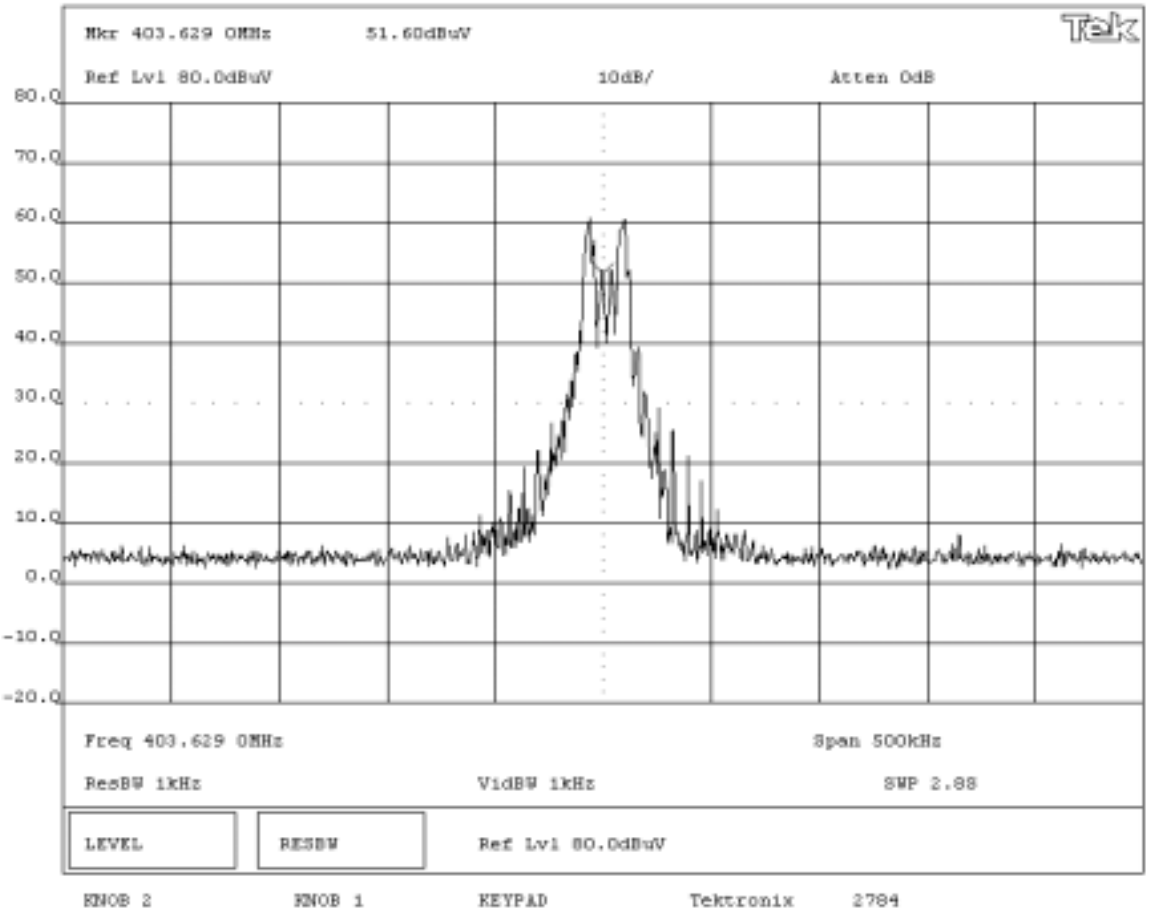
Pass

SIGNATURE

Tested By: _____

DESCRIPTION OF TEST

Emission Mask



NORTHWEST
EMC

EMISSIONS DATA SHEET

Rev BETA
01/30/01

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	Biotronik, Inc.			Temperature:	73
Attendees:	Ky Lo	Tested by:	Greg Kiemel	Humidity:	38% RH
Customer Ref. No.:		Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	47 CFR 95.635(d)(4)	Year:	2002	Method:	95.635(d)(4) & ANSI C63.4	Year:	1992

SAMPLE CALCULATIONS

COMMENTS

EUT Horizontal in Test fixture at 1.5m height

EUT OPERATING MODES

Transmitting single channel

DEVIATIONS FROM TEST STANDARD

None

REQUIREMENTS

Emissions more than 150 kHz away from the center frequency must be attenuated below the transmitter ouput power by at least 20 dB

RESULTS

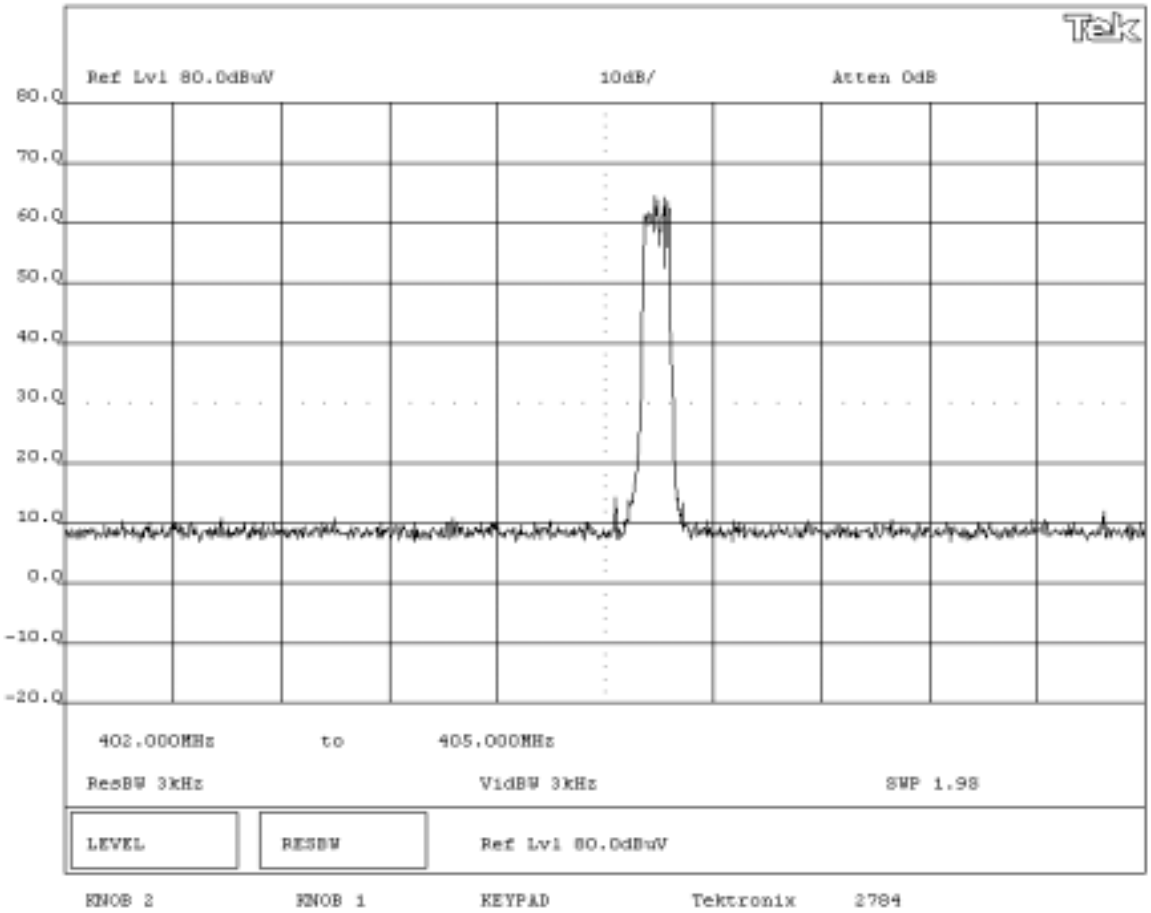
Pass

SIGNATURE

Tested By: _____

DESCRIPTION OF TEST

Emission Mask



NORTHWEST EMC

EMISSIONS DATA SHEET

Rev BETA 01/30/01

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/23/03
Customer:	Biotronik, Inc.			Temperature:	73
Attendees:	Ky Lo	Tested by:	Greg Kiemel	Humidity:	38% RH
Customer Ref. No.:		Power:	Battery	Job Site:	EV01

TEST SPECIFICATIONS

Specification:	47 CFR 95.635(d)(5)	Year:	2002	Method:	95.635(d)(5) & ANSI C63.4	Year:	1992

SAMPLE CALCULATIONS

COMMENTS

EUT Horizontal in Test fixture at 1.5m height

EUT OPERATING MODES

Transmitting single channel

DEVIATIONS FROM TEST STANDARD

None

REQUIREMENTS

Emissions 250 kHz or less above and below the MICS band (402-405 MHz) must be attenuated below the maximum permitted ouput power by at least 20 dB

RESULTS

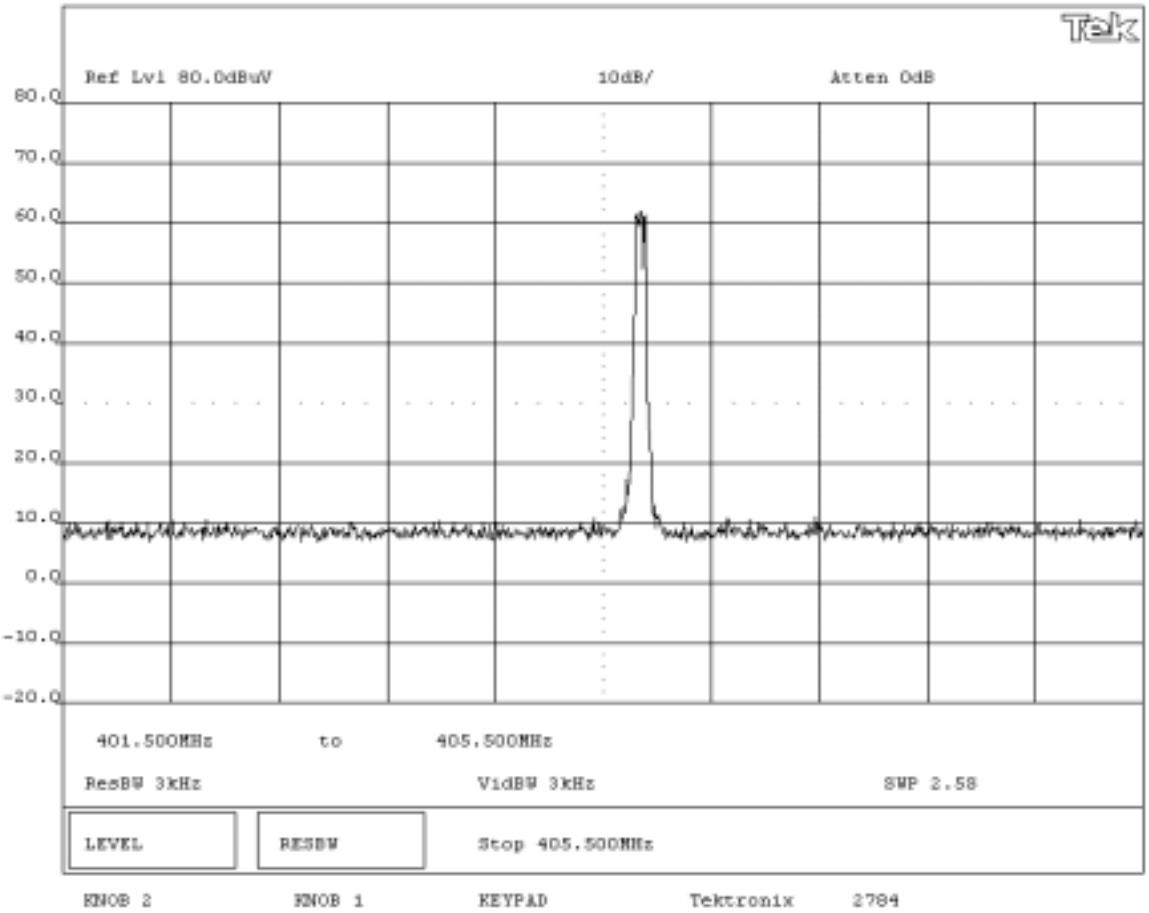
Pass

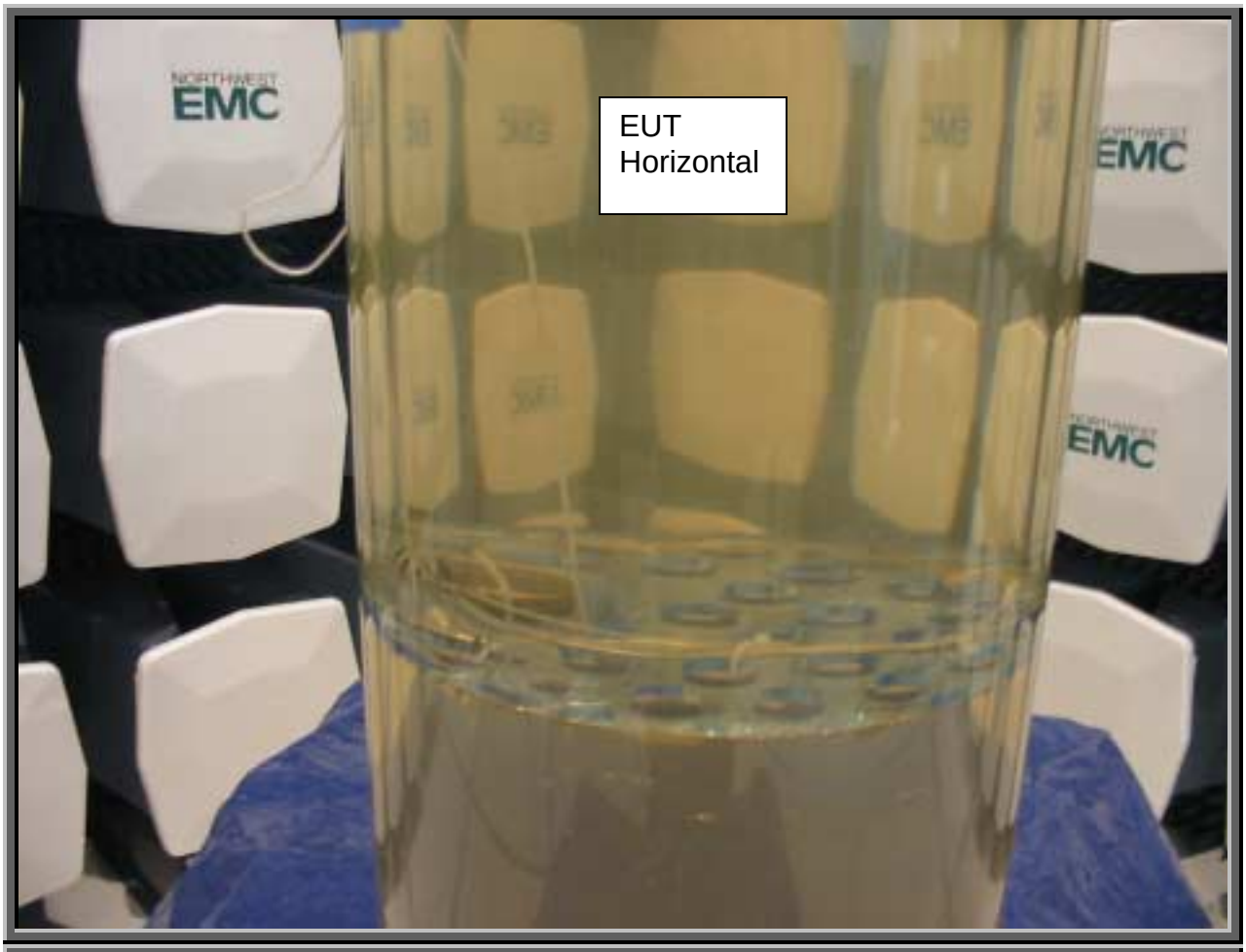
SIGNATURE

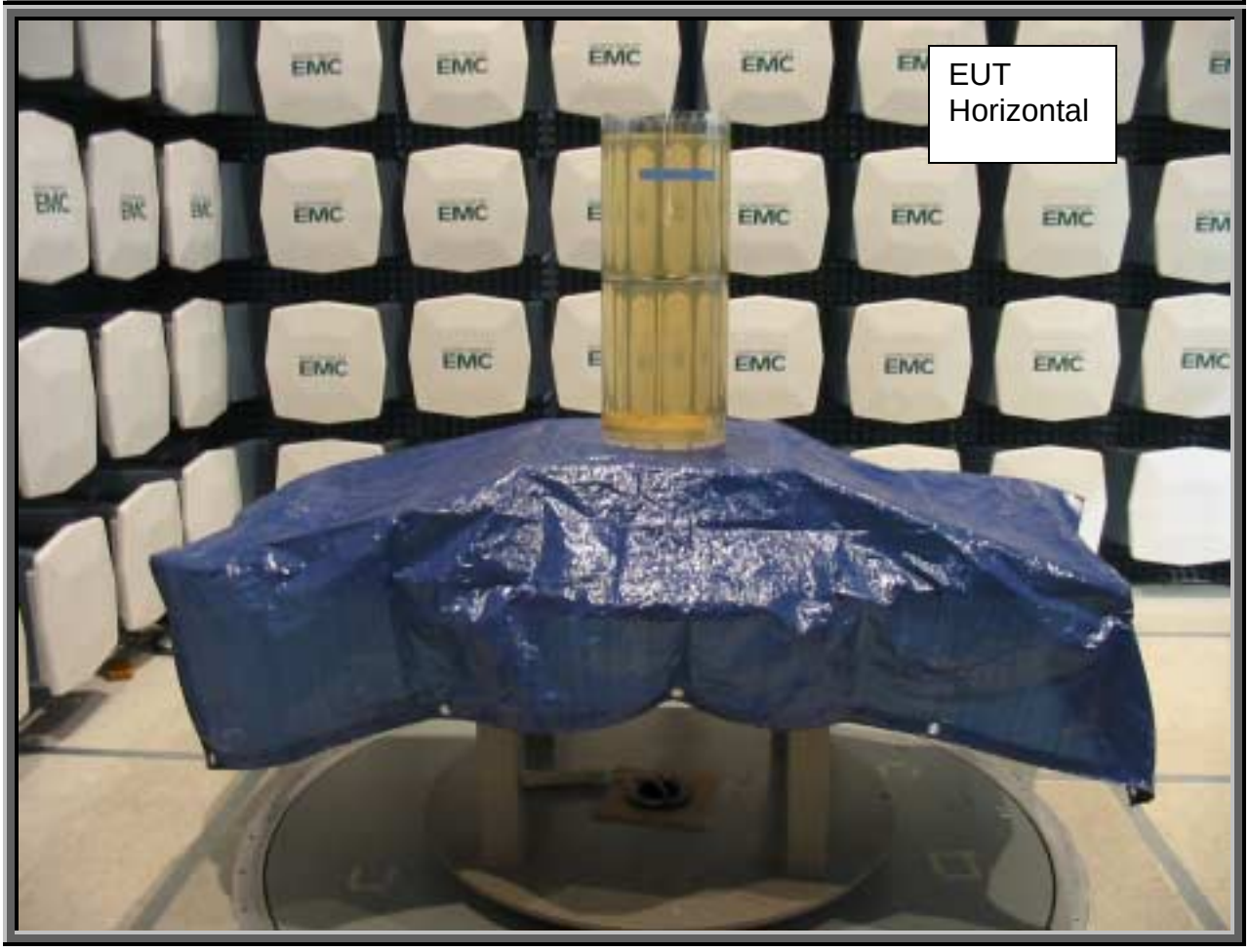
Tested By: _____

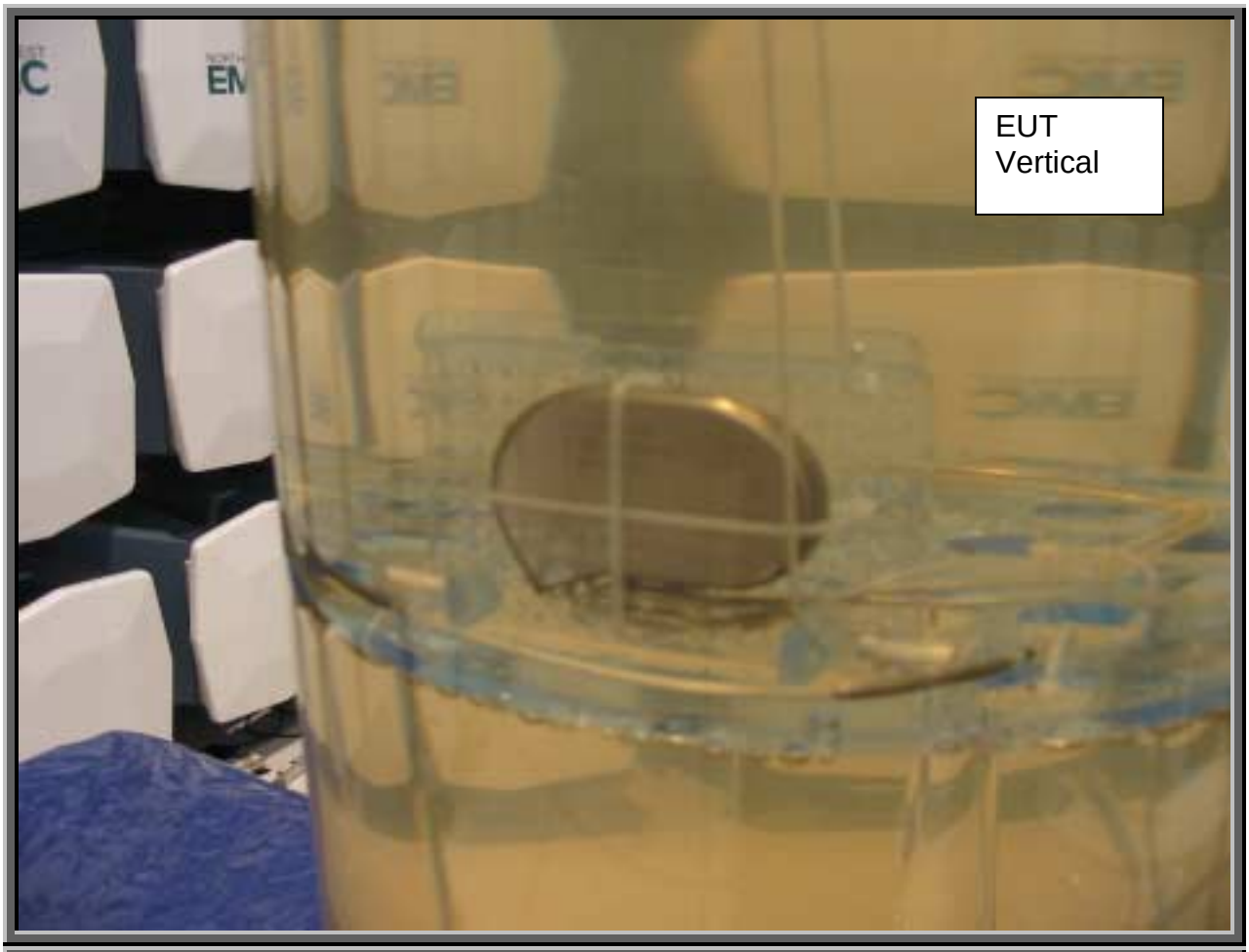
DESCRIPTION OF TEST

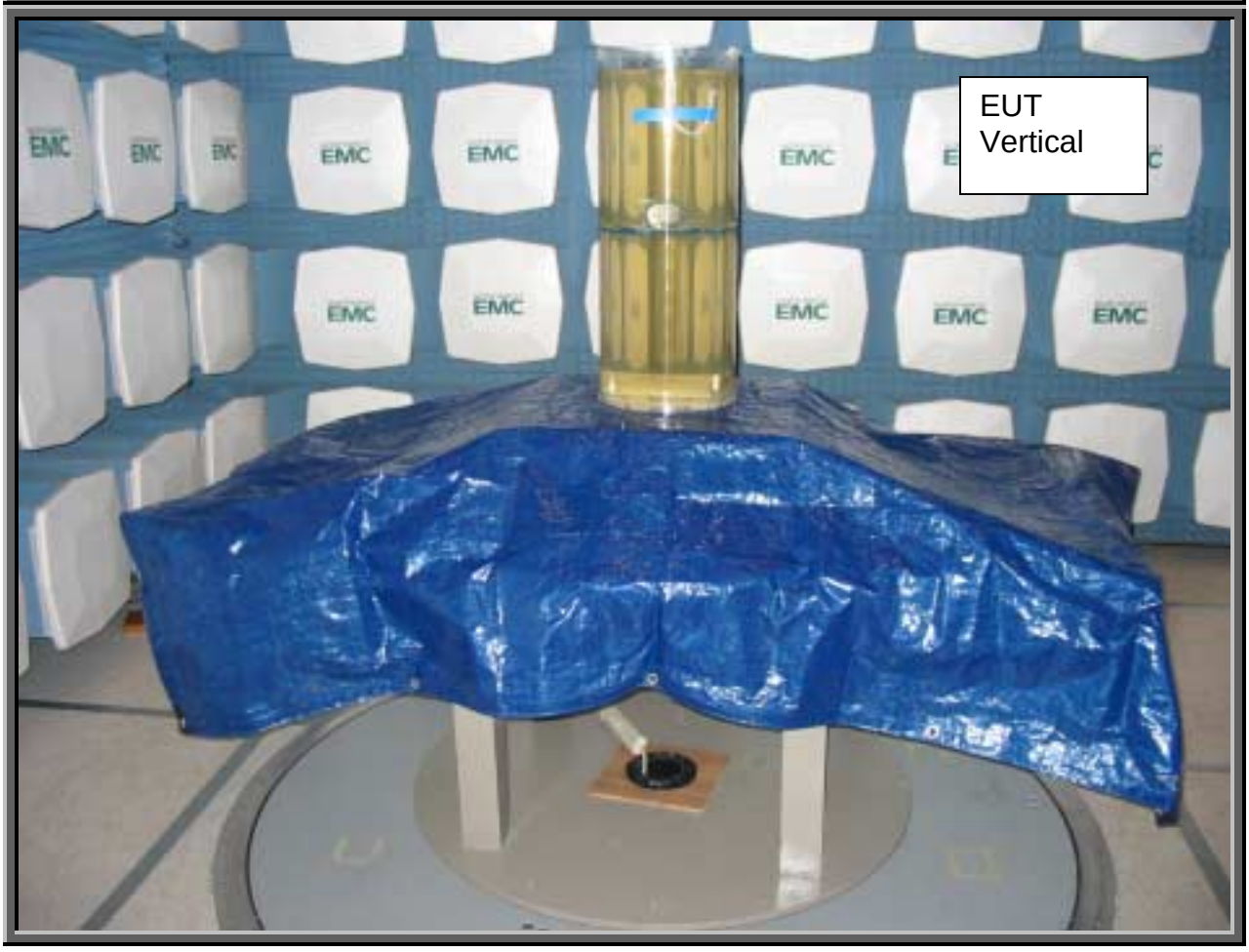
Emission Mask




EUT
Horizontal


EUT
Horizontal


EUT
Vertical


EUT
Vertical

Justification

The individuals and/or the organization requesting the test provided the modes, configurations and settings available to evaluate. While scanning the radiated emissions, all of the EUT parameters listed below were investigated. This includes, but may not be limited to, antennas, tuned transmit frequency ranges, operating modes, and data rates.

Channels in Specified Band Investigated:
Single

Operating Modes Investigated:
Typical

Data Rates Investigated:
Maximum

Output Power Setting(s) Investigated:
Maximum

Power Input Settings Investigated:
Internal Battery

Software\Firmware Applied During Test			
Exercise software	Special Test Software	Version	Unknown
Description			
The system was tested using special software developed to test all functions of the device during the test.			

EUT and Peripherals

Description	**Manufacturer**	**Model/Part Number**	**Serial Number**
EUT	BIOTRONIK, Inc.	Lexos DR-T	79841008

Cables

Cable Type	**S/N**	**Shield**	**Length (m)**	**Ferrite**	**Connection 1**	**Connection 2**
High Voltage Model DF-1	10206150	Yes	.8	No	EUT	Unterminated
Pacing Sensing Lead Model IS-1BI	23278301	Yes	.8	No	EUT	Unterminated
Pacing Sensing Lead Model IS-1BI	23031884	Yes	.8	No	EUT	Unterminated

PA = Cable is permanently attached to the device. Shielding and/or presence of ferrite may be unknown.

Frequency Stability

Measurement Equipment

Description	Manufacturer	Model	Identifier	Last Cal	Interval
Spectrum Analyzer	Tektronix	2784	AAO	02/26/2003	24 mo
Chamber, Temp./Humidity Chamber	Cincinnati Sub Zero (CSZ)	ZH-32-2-2-H/AC	TBA	09/20/2002	12 mo
Near Field Probe	EMCO	7405	IPD	NCR	NA

Test Description

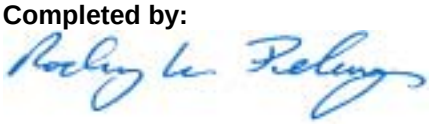
Requirement: Per 47 CFR 95.628(e)(1) and 2.1055, the Frequency Stability was measured. The transmitter must maintain a frequency stability of +/- 100 parts per million (ppm), or better, for variations of temperature over the range of 25 to 45 degrees centigrade.

Configuration: The Frequency Stability was measured using a near-field probe and a spectrum analyzer. The spectrum analyzer is configured with a precision frequency reference that exceeds the stability requirement of the transmitter.

The EUT was placed inside a temperature / humidity chamber. The near-field probe was placed near the transmitter. A low-loss coaxial cable connected the near-field probe to the spectrum analyzer outside of the chamber.

The transmit frequency was recorded at the extremes of the specified temperature range (+25° to +45° C) and at 10°C intervals.

Completed by:



NORTHWEST
EMC

EMISSIONS DATA SHEET

Rev BETA
01/30/01

EUT:	Lexos DR-T			Work Order:	BIOT0007
Serial Number:	79841008			Date:	09/24/03
Customer:	Biotronik, Inc.			Temperature:	see below
Attendees:	Ky Lo	Tested by:	Rod Peloquin	Humidity:	35% RH
Customer Ref. No.:		Power:	Internal Battery	Job Site:	EV09

TEST SPECIFICATIONS

Specification:	95.628(e)(1) & 2.1055	Year:	Most Current	Method:	TIA/EIA - 603	Year:	1993

SAMPLE CALCULATIONS

COMMENTS

EUT OPERATING MODES

Transmitting single channel

DEVIATIONS FROM TEST STANDARD

None

REQUIREMENTS

Must maintain a frequency stability of +/- 100 parts per million (ppm) or better for variations of temperature over the range of 25 to 45 degrees centigrade

RESULTS	WORST CASE FREQUENCY STABILITY
Pass	-10.9 ppm

SIGNATURE

Tested By: _____

DESCRIPTION OF TEST

Frequency Stability

Temp (°C)	Assigned Frequency (MHz)	Measured Frequency (MHz)	Tolerance (ppm)	Specification (ppm)
25	403.628000	403.629700	4.21	100
35	403.628000	403.628000	0.00	100
45	403.628000	403.623600	10.90	100