

BIOTRONIK, Inc.

Cylos DR-T

June 14, 2005

Report No. BIOT0009

Report Prepared By



www.nwemc.com
1-888-EMI-CERT

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EMC Test Report



22975 NW Evergreen Parkway
Suite 400
Hillsboro, Oregon 97124

Certificate of Test
Issue Date: June 14, 2005
BIOTRONIK, Inc.
Model: Cylos DR-T

Emissions			
Specification	Test Method	Pass	Fail
FCC 95.639(f)(1) Field Strength of Fundamental:2004	TIA/EIA-603:1998	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FCC 95.635(d) Field Strength of Radiated Emission:2004	TIA/EIA-603:1998 & ANSI C63.4:2004	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FCC 95.633(e)(1) Occupied Bandwidth:2004	95.633(e)(3) & ANSI C63.4:2004	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FCC 95.635(d)(4-5) Emission Mask:2004	95.635(d)(4-5) & ANSI C63.4:2004	<input checked="" type="checkbox"/>	<input type="checkbox"/>
FCC 95.628(e)(1) & 2.1055 Frequency Stability:2004	TIA/EIA-603:1993	<input checked="" type="checkbox"/>	<input type="checkbox"/>

Modifications made to the product

See the Modifications section of this report

Test Facility

The measurement facility used to collect the data is located at:

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.

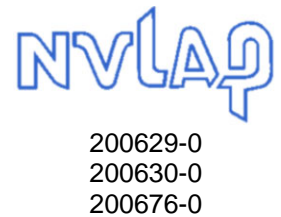
Product compliance is the responsibility of the client, therefore the tests and equipment modes of operation represented in this report were agreed upon by the client, prior to testing. This Report may only be duplicated in its entirety. The results of this test pertain only to the sample(s) tested, 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: Accredited by NVLAP for performance of FCC radio, digital, and ISM device testing. Our Open Area Test Sites, certification chambers, 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. 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: Northwest EMC, Inc. is recognized under the United States Department of Commerce, National Institute of Standards and Technology, and National Voluntary Laboratory Accreditation Program for satisfactory compliance with the requirements of ISO/IEC 17025 for Testing Laboratories. The NVLAP accreditation encompasses Electromagnetic Compatibility Testing in accordance with the European Union EMC Directive 89/336/EEC, ANSI C63.4, MIL-STD 461E, DO-160D and SAE J1113. Additionally, Northwest EMC is accredited by NVLAP to perform radio testing in accordance with the European Union R&TTE Directive 1999/5/EEC, the requirements of FCC, and the RSS radio standards for Industry Canada.



Industry Canada: Accredited by NVLAP for performance of Industry Canada RSS and ICES testing. Our Open Area Test Sites and certification chambers comply with RSS 212, Issue 1 (Provisional) and have been filed with Industry Canada and accepted. Northwest EMC has been accredited by ANSI to ISO / IEC Guide 65 as a product certifier. We have been designated by NIST and recognized by Industry Canada as a Certification Body (CB) per the APEC Mutual Recognition Arrangement (MRA). This allows Northwest EMC to certify transmitters to Industry Canada technical requirements.



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.



TÜV Product Service: Included in TÜV Product Service Group's Listing of Recognized Laboratories. It qualifies in connection with the TÜV Certification after Recognition of Agent's Testing Program for the product categories and/or standards shown in TÜV's current Listing of CARAT Laboratories, available from TÜV. A certificate was issued to represent that this laboratory continues to meet TÜV's CARAT Program requirements. Certificate No. USA0401C.



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.



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).



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 Numbers. - Hillsboro: C-1071 and R-1025, Irvine: C-2094 and R-1943, Newberg: C-1877 and R-1760, Sultan: R-871, C-1784 and R-1761*).



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.



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



SCOPE

For details on the Scopes of our Accreditations, please visit:

<http://www.nwemc.com/scope.asp>

What is measurement uncertainty?

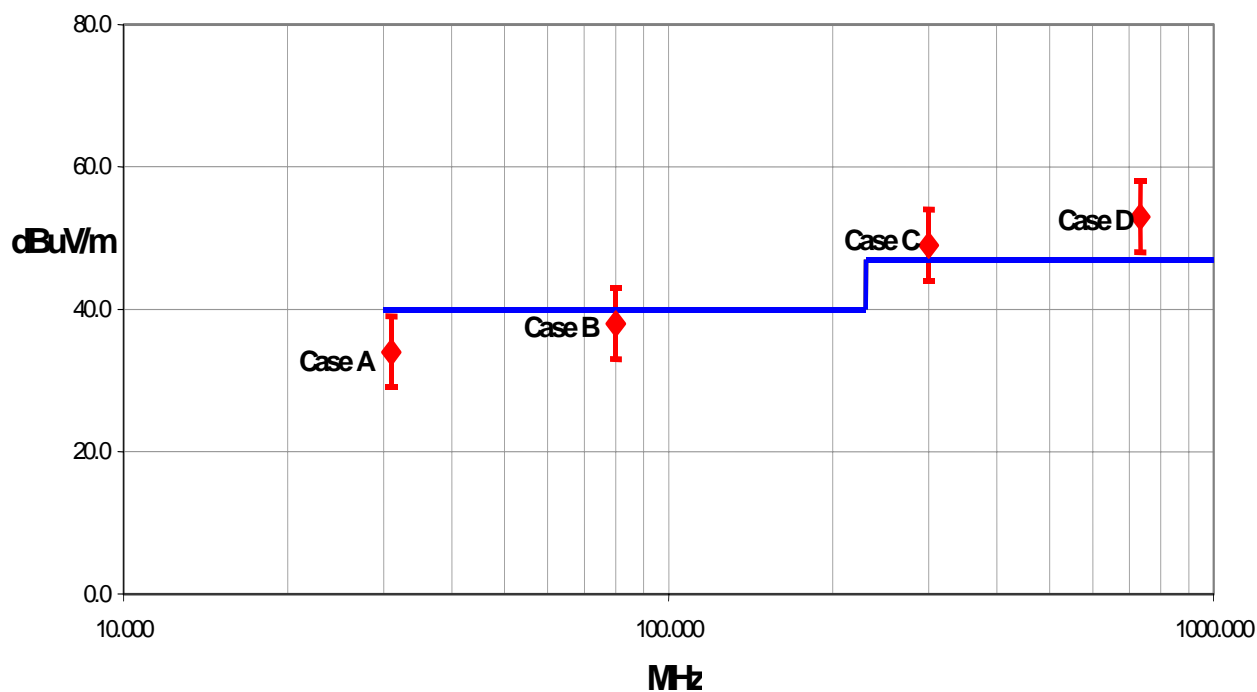
When a measurement is made, the result will be different from the true or theoretically correct value. The difference is the result of tolerances in the measurement system that cannot be completely eliminated. To the extent that technology allows us, it has been our aim to minimize this error. The following 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)

Test Distance	Probability Distribution	Biconical Antenna		Log Periodic Antenna		Dipole Antenna	
		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 $\approx 95\%$)	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)

Test Distance	Probability Distribution	Without High Pass Filter		With High Pass Filter	
		3m	10m	3m	10m
Combined standard uncertainty $u_c(y)$	normal	+ 1.29 - 1.25	+ 1.38 - 1.35	+ 1.29 - 1.25	+ 1.38 - 1.35
Expanded uncertainty U (level of confidence $\approx 95\%$)	normal (k=2)	+ 2.57 - 2.51	+ 2.76 - 2.70	+ 2.57 - 2.51	+ 2.76 - 2.70

Conducted Emissions

Test Distance	Probability Distribution	Value (+/- dB)
Combined standard uncertainty $u_c(y)$	normal	1.48
Expanded uncertainty U (level of confidence $\approx 95\%$)	normal (k = 2)	2.97

Radiated Immunity

Test Distance	Probability Distribution	Value (+/- dB)
Combined standard uncertainty $u_c(y)$	normal	1.05
Expanded uncertainty U (level of confidence $\approx 95\%$)	normal (k = 2)	2.11

Conducted Immunity

Test Distance	Probability Distribution	Value (+/- dB)
Combined standard uncertainty $u_c(y)$	normal	1.05
Expanded uncertainty U (level of confidence $\approx 95\%$)	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, $u_c(y)$ yields a confidence level of only 68%.

**California****Orange County Facility****Labs OC01 – OC13**

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

**Oregon****Evergreen Facility****Labs EV01 – EV10**

22975 NW Evergreen Pkwy.
Suite 400
Hillsboro, OR 97124
(503) 844-4066
FAX (503) 844-3826

**Oregon****Trails End Facility****Labs TE01 – TE03**

30475 NE Trails End Lane
Newberg, OR 97132
(503) 844-4066
FAX (503) 537-0735

**Washington****Sultan Facility****Labs SU01 – SU07**

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:	Brian Sutton
Model:	Cylos DR-T
First Date of Test:	6-10-2005
Last Date of Test:	6-13-2005
Receipt Date of Samples:	6-10-2005
Equipment Design Stage:	Prototype
Equipment Condition:	No visual damage.

Information Provided by the Party Requesting the Test

Clocks/Oscillators:	403.6 MHz Transmit Frequency, Internal Clock at 32,768 KHz
I/O Ports:	Implant Leads, Qty=2

Functional Description of the EUT (Equipment Under Test):

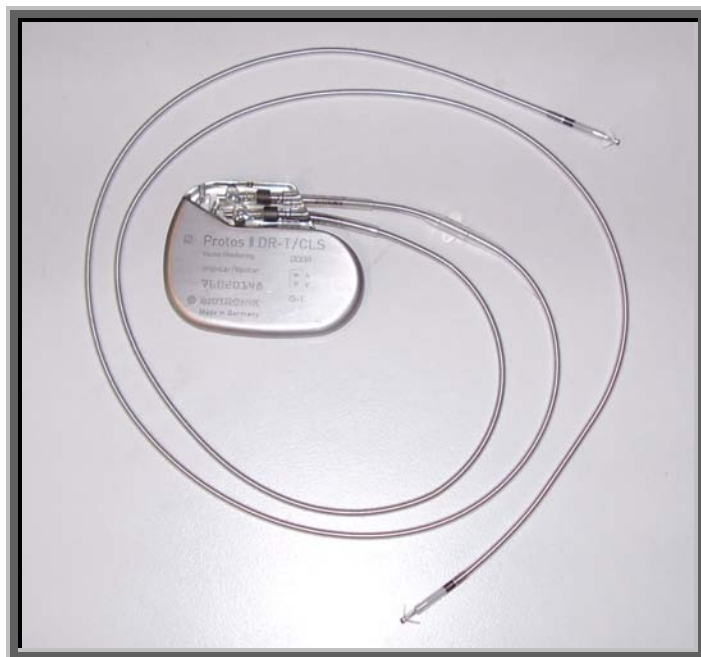
Cardiac Pacemaker to be implanted in bradycardia patients. The EUT is designed to transmit medically relevant data.

Client Justification for EUT Selection:

Random production unit modified to support near continuous RF transmission.

Client Justification for Test Selection:

These tests satisfy the FCC requirements for the US market.

EUT Photo

Equipment modifications					
Item	Test	Date	Modification	Note	Disposition of EUT
1	Field Strength of Fundamental	06/10/2005	No EMI suppression devices were added or modified during this test.	Same configuration as delivered.	EUT remained at Northwest EMC.
2	Emissions Mask (< or = 250kHz)	06/10/2005	No EMI suppression devices were added or modified during this test.	Same configuration as in previous test.	EUT remained at Northwest EMC.
3	Occupied Bandwidth	06/10/2005	No EMI suppression devices were added or modified during this test.	Same configuration as in previous test.	EUT remained at Northwest EMC.
4	Spurious Radiated Emissions	06/10/2005	No EMI suppression devices were added or modified during this test.	Same configuration as in previous test.	EUT remained at Northwest EMC.
5	Frequency Stability	06/13/2005	No EMI suppression devices were added or modified during this test.	Same configuration as in previous test.	EUT was returned to client following testing.

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 Channel: 403.62 MHz

Operating Modes Investigated:

Typical

Data Rates Investigated:

Maximum

Output Power Setting(s) Investigated:

Maximum

Power Input Settings Investigated:

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- Cylos DR-T	Biotronik, Inc.	Cylos DR-T	76020147

Cables

Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
Implant Lead	Yes	approx. 0.	No	EUT- Cylos DR-T	Not connected
Implant Lead	Yes	approx. 0.	No	EUT- Cylos DR-T	Not connected

Measurement Equipment					
Description	Manufacturer	Model	Identifier	Last Cal	Interval
Spectrum Analyzer	Hewlett-Packard	8566B	AAL	12/02/2004	13 mo
Pre-Amplifier	Amplifier Research	LN1000A	APS	03/01/2005	13 mo
Antenna, Biconilog	EMCO	3141	AXE	12/03/2003	24 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.

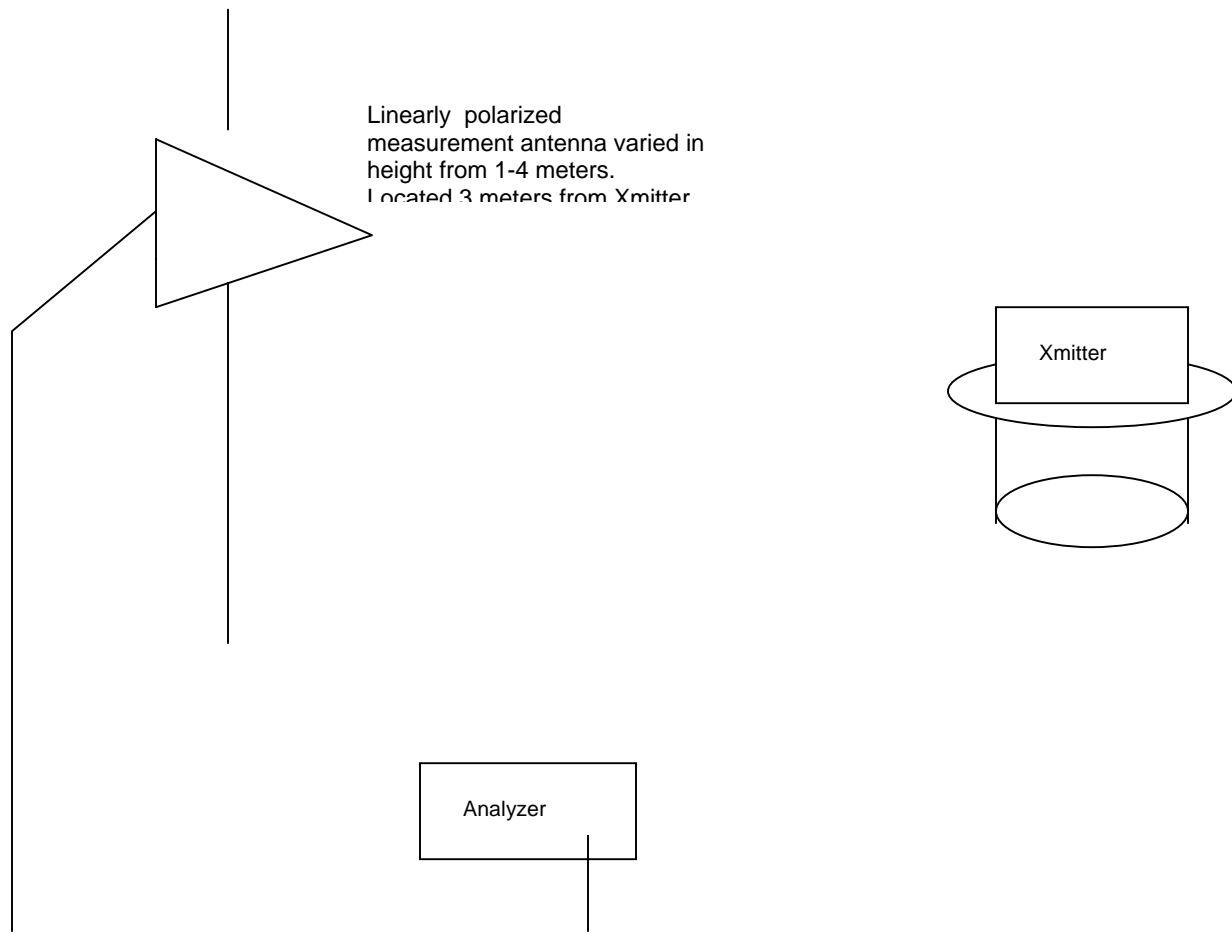
The EUT was configured to transmit in a fixture that simulates the human torso. The dimensions of the test fixture and the characteristics of the tissue substitute material met the requirements of 95.639(f)(2)(i-ii). The dielectric and conductivity properties of the tissue substitute material were verified 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:

Rocky Le Pelley

RADIATED EMISSIONS DATA SHEET

EUT:	Cylos DR-T	Work Order:	BIOT0009
Serial Number:	76020147	Date:	06/10/05
Customer:	BIOTRONIK, Inc.	Temperature:	23
Attendees:	Brian Sutton	Humidity:	42%
Cust. Ref. No.:		Barometric Pressure:	29.95
Tested by:	Rod Peloquin	Power:	Battery
		Job Site:	EV01

TEST SPECIFICATIONS

Specification:	FCC 95.639(f)(1):2004	Method:	TIA/EIA-603:1998
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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 1.5m height

EUT OPERATING MODES

Transmitting Single channel

DEVIATIONS FROM TEST STANDARD

No deviations.

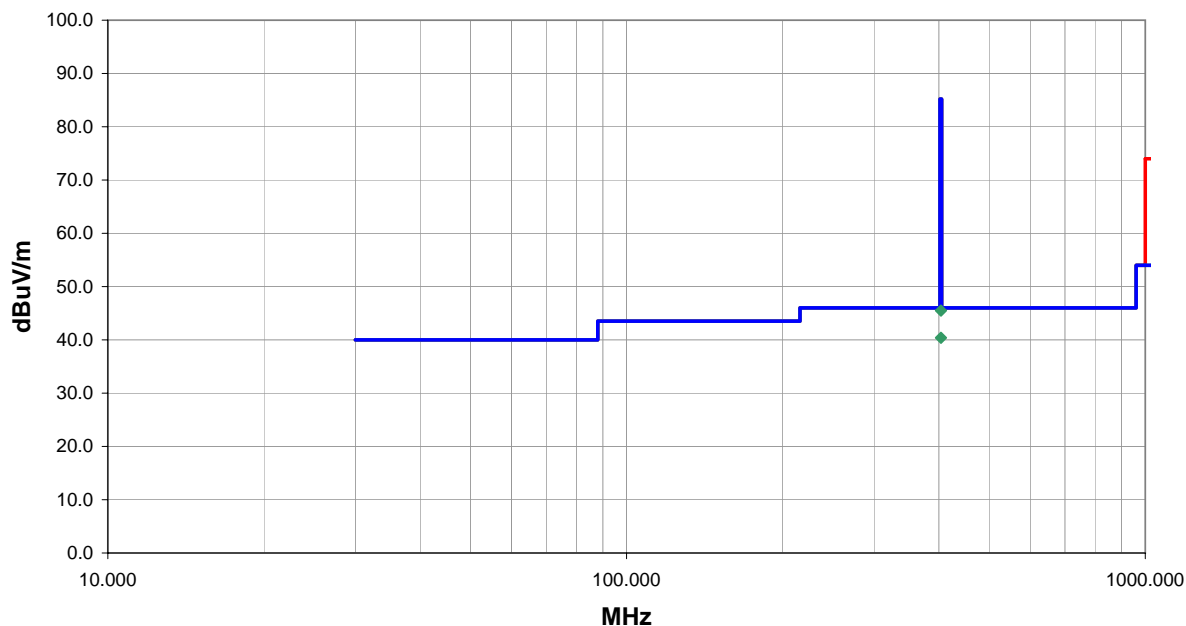
RESULTS

Pass	Run #
	1


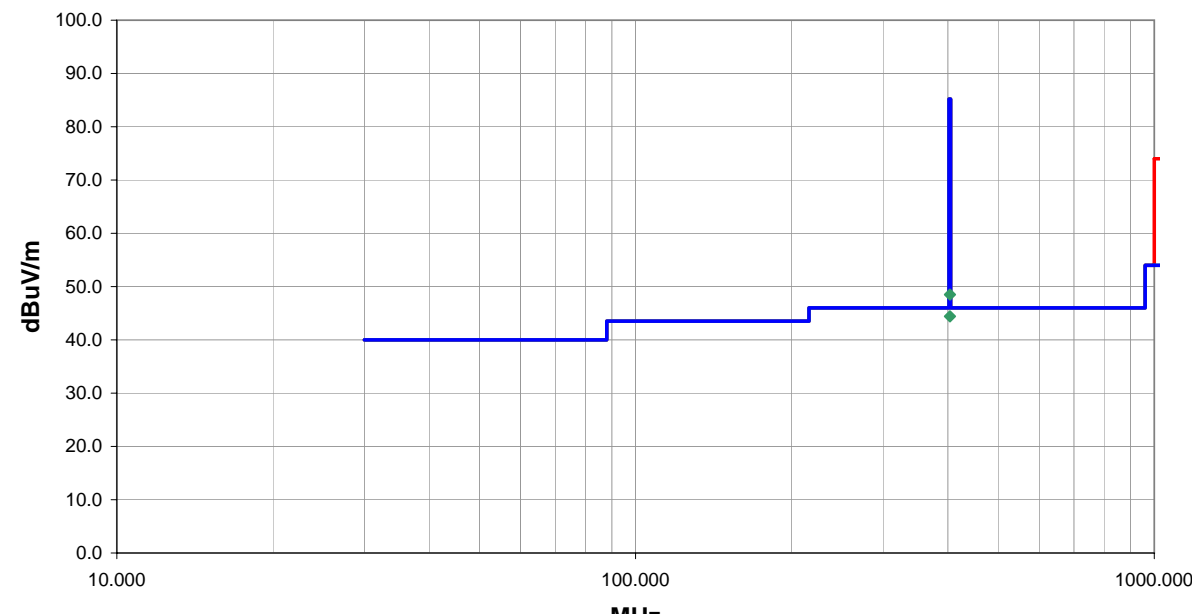
Other

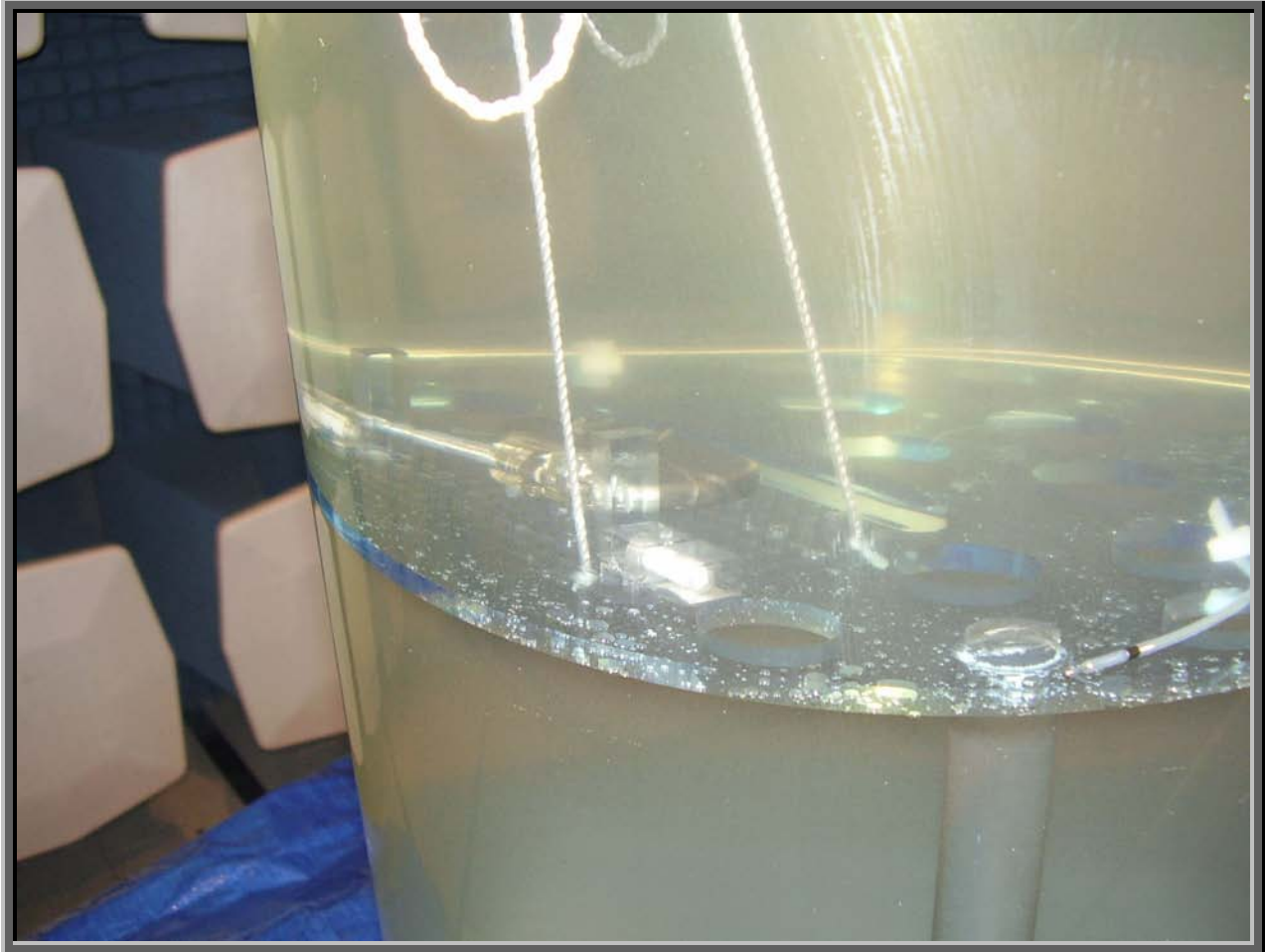
Roddy L. Peloquin

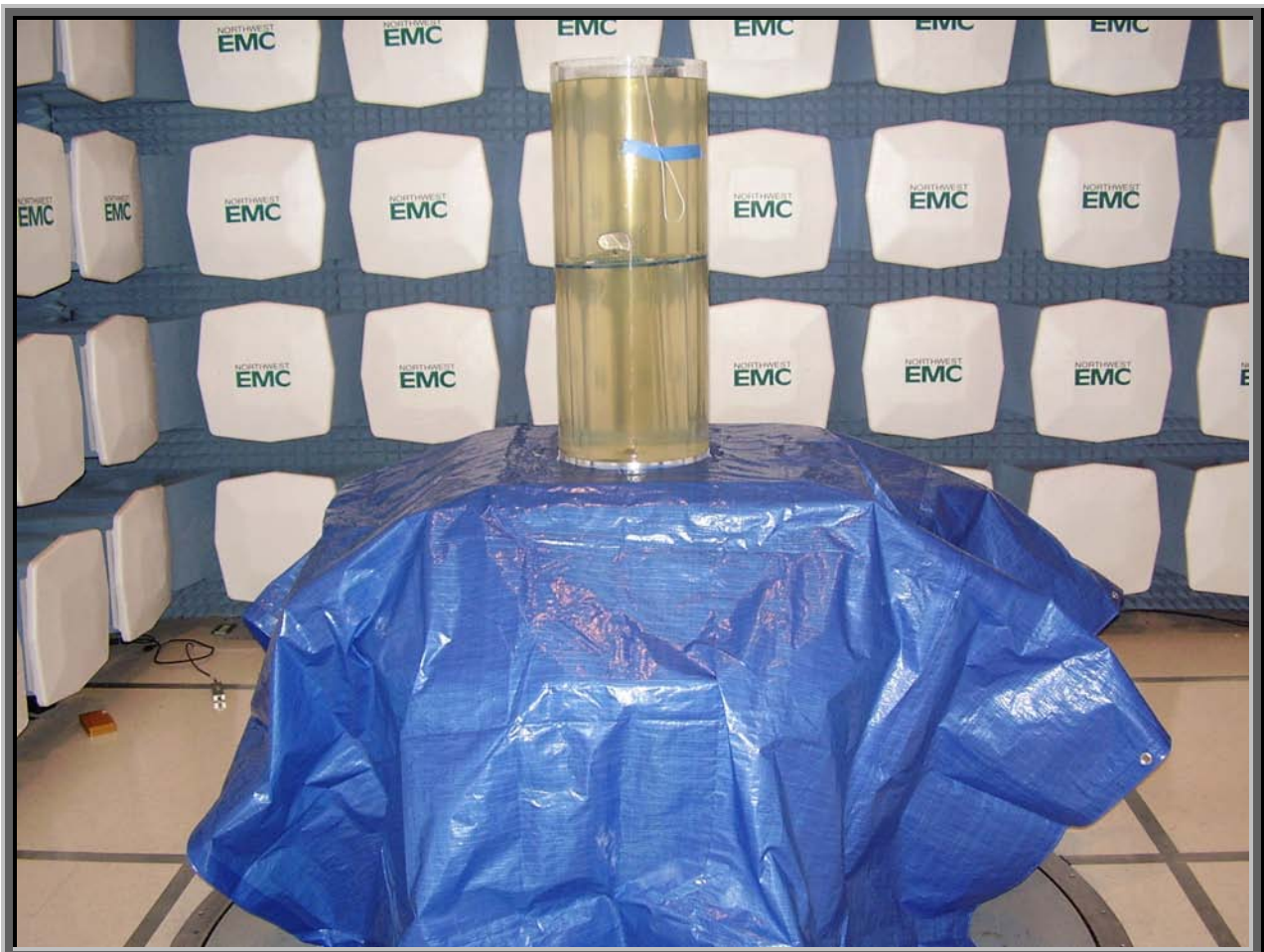
Tested By:



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)
403.617	50.6	-5.1	292.0	2.0	3.0	0.0	V-Bilog	PK	0.0	45.5	85.2	-39.7
403.617	45.5	-5.1	197.0	2.3	3.0	0.0	H-Bilog	PK	0.0	40.4	85.2	-44.8

NORTHWEST EMC		RADIATED EMISSIONS DATA SHEET										ACQ 2005.1.4 EMI 2005.5.05	
EUT: Cynos DR-T		Work Order: BIOT0009											
Serial Number: 76020147		Date: 06/10/05											
Customer: BIOTRONIK, Inc.		Temperature: 23											
Attendees: Brian Sutton		Humidity: 42%											
Cust. Ref. No.:		Barometric Pressure: 29.95											
Tested by: Rod Peloquin		Power: Battery		Job Site: EV01									
TEST SPECIFICATIONS													
Specification: FCC 95.639(f)(1):2004		Method: TIA/EIA-603:1998											
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 1.5m 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)	
403.617	53.6	-5.1	0.0	2.0	3.0	0.0	V-Bilog	PK	0.0	48.5	85.2	-36.7	
403.617	49.5	-5.1	201.0	2.3	3.0	0.0	H-Bilog	PK	0.0	44.4	85.2	-40.8	





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 Channel: 403.62 MHz

Operating Modes Investigated:

Typical

Data Rates Investigated:

Maximum

Output Power Setting(s) Investigated:

Maximum

Power Input Settings Investigated:

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- Cylos DR-T	Biotronik, Inc.	Cylos DR-T	76020147

Cables

Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
Implant Lead	Yes	approx. 0.	No	EUT- Cylos DR-T	Not connected
Implant Lead	Yes	approx. 0.	No	EUT- Cylos DR-T	Not connected

Measurement Equipment

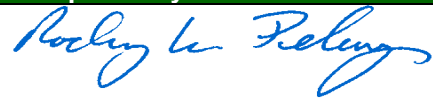
Description	Manufacturer	Model	Identifier	Last Cal	Interval
Spectrum Analyzer	Agilent	E4446A	AAQ	04/08/2005	13 mo
Pre-Amplifier	Amplifier Research	LN1000A	APS	03/01/2005	13 mo
Antenna, Biconilog	EMCO	3141	AXE	12/03/2003	24 mo

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 150 Hz resolution bandwidth (no video filtering) and a peak detector. With these instrument settings, an emission bandwidth of 15.1 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**OCCUPIED BANDWIDTH DATA SHEET**Rev BETA
01/30/01

EUT: Cylos DR-T		Work Order: BIOT0009	
Serial Number: 76020147		Date: 06/10/05	
Customer: Biotronik, Inc.		Temperature: 23°C	
Attendees: Brian Sutton		Humidity: 41% RH	
Customer Ref. No.:		Tested by: Rod Peloquin	Job Site: EV01
		Power: Battery	

TEST SPECIFICATIONS

Specification: 47 CFR 95.633(e)(1)	Year: 2004	Method: 95.633(e)(3) & ANSI C63.4	Year: 2004
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SAMPLE CALCULATIONS**COMMENTS**

EUT Vertical in Test fixture at 1.5m height

EUT OPERATING MODES

Transmitting single channel

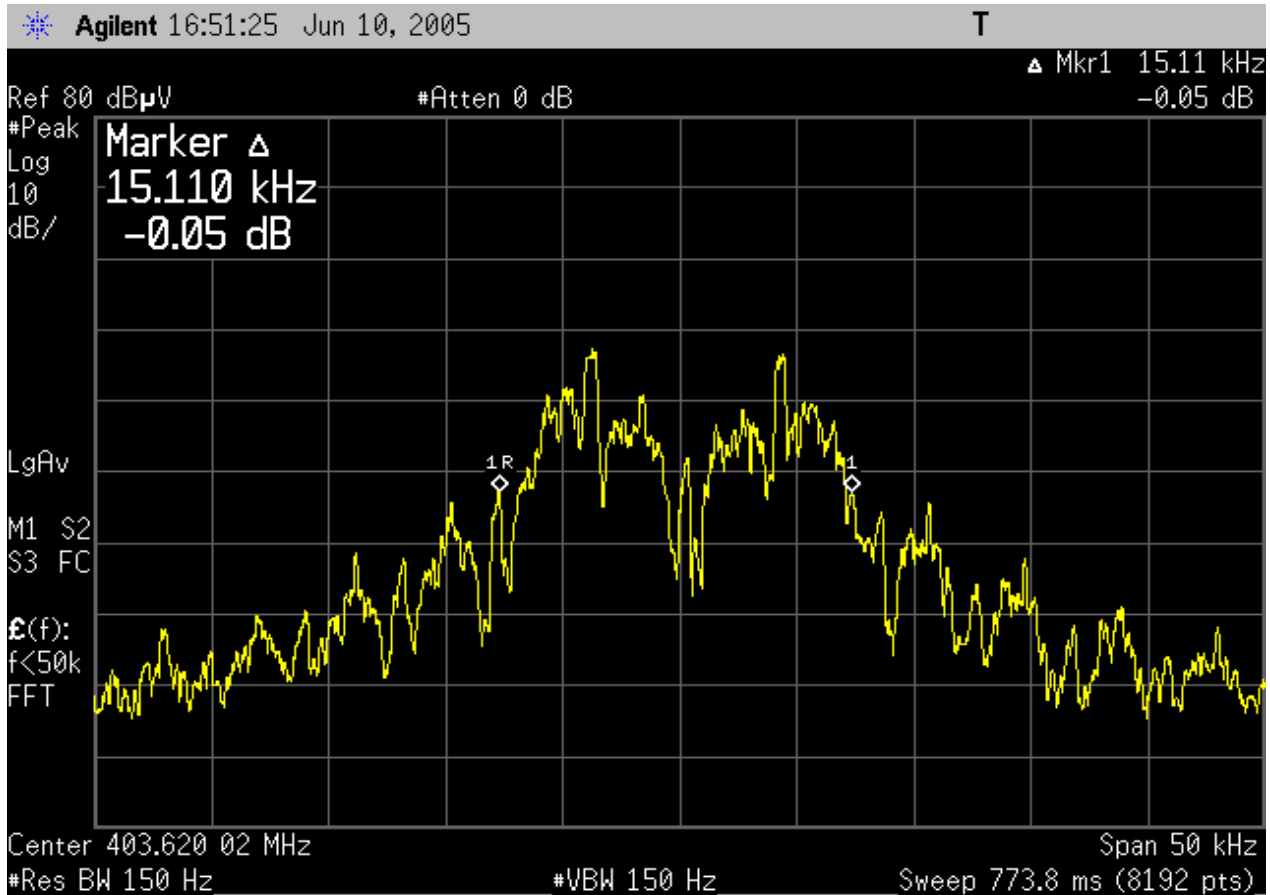
DEVIATIONS FROM TEST STANDARD

None

REQUIREMENTS

The maximum authorized emission bandwidth is 300 kHz

RESULTS	BANDWIDTH
Pass	15.1 kHz

SIGNATURETested By: **DESCRIPTION OF TEST****Occupied Bandwidth**

NORTHWEST
EMC**EMISSIONS DATA SHEET**Rev BETA
01/30/01

EUT: Cylos DR-T		Work Order: BIOT0009	
Serial Number: 76020147		Date: 06/10/05	
Customer: Biotronik, Inc.		Temperature: 23°C	
Attendees: Brian Sutton		Humidity: 41% RH	
Customer Ref. No.:		Tested by: Rod Peloquin	Job Site: EV01
		Power: Battery	

TEST SPECIFICATIONS

Specification: 47 CFR 95.633(e)(1)	Year: 2004	Method: 95.633(e)(3) & ANSI C63.4	Year: 2004
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SAMPLE CALCULATIONS**COMMENTS**

EUT Vertical in Test fixture at 1.5m height

EUT OPERATING MODES

Transmitting single channel

DEVIATIONS FROM TEST STANDARD

None

REQUIREMENTS

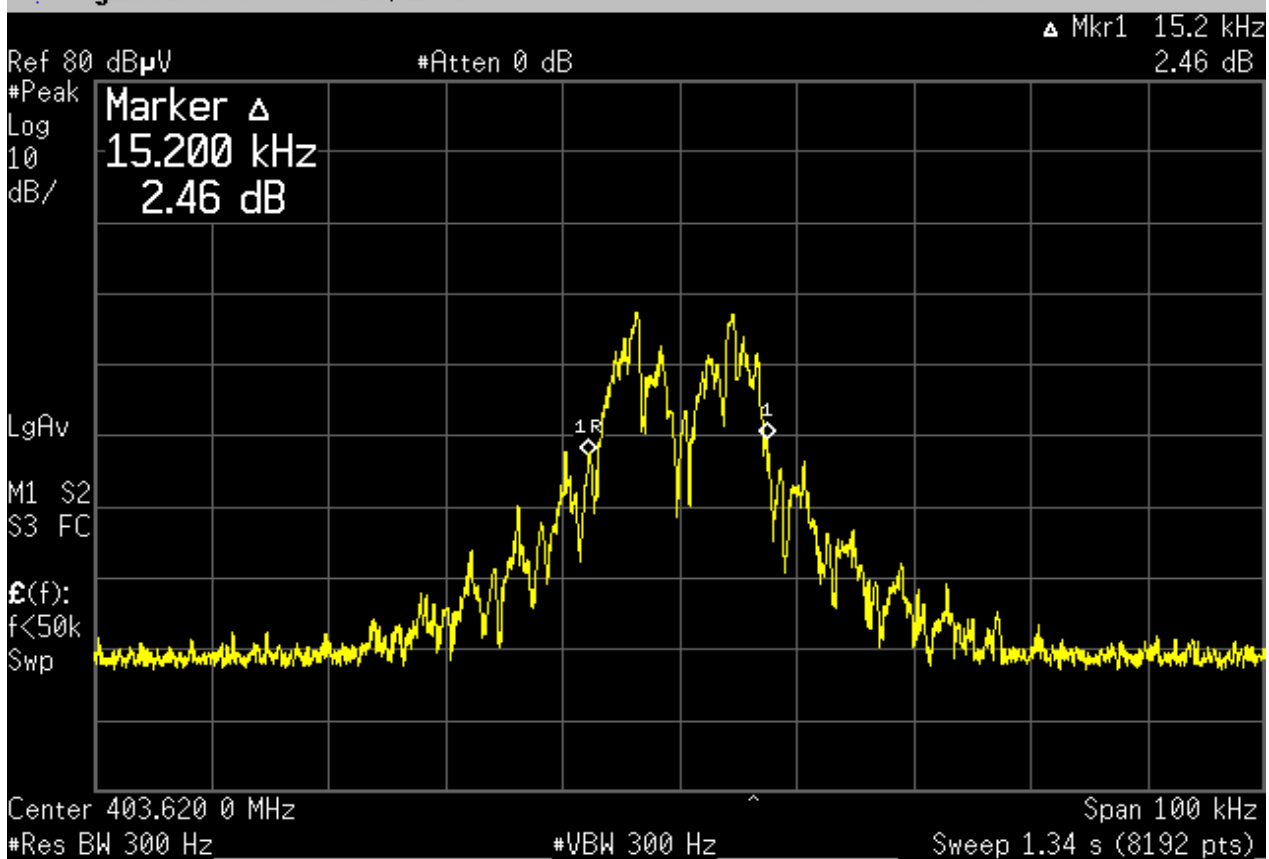
The maximum authorized emission bandwidth is 300 kHz

RESULTS	BANDWIDTH
Pass	15.2 kHz

SIGNATURETested By: **DESCRIPTION OF TEST****Occupied Bandwidth**

Agilent 16:40:09 Jun 10, 2005

T



NORTHWEST
EMC**EMISSIONS DATA SHEET**Rev BETA
01/30/01

EUT: Cynos DR-T		Work Order: BIOT0009	
Serial Number: 76020147		Date: 06/10/05	
Customer: Biotronik, Inc.		Temperature: 23°C	
Attendees: Brian Sutton		Humidity: 41% RH	
Customer Ref. No.:		Tested by: Rod Peloquin	Job Site: EV01
		Power: Battery	

TEST SPECIFICATIONS

Specification: 47 CFR 95.633(e)(1)	Year: 2004	Method: 95.633(e)(3) & ANSI C63.4	Year: 2004
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SAMPLE CALCULATIONS**COMMENTS**

EUT Vertical in Test fixture at 1.5m height

EUT OPERATING MODES

Transmitting single channel

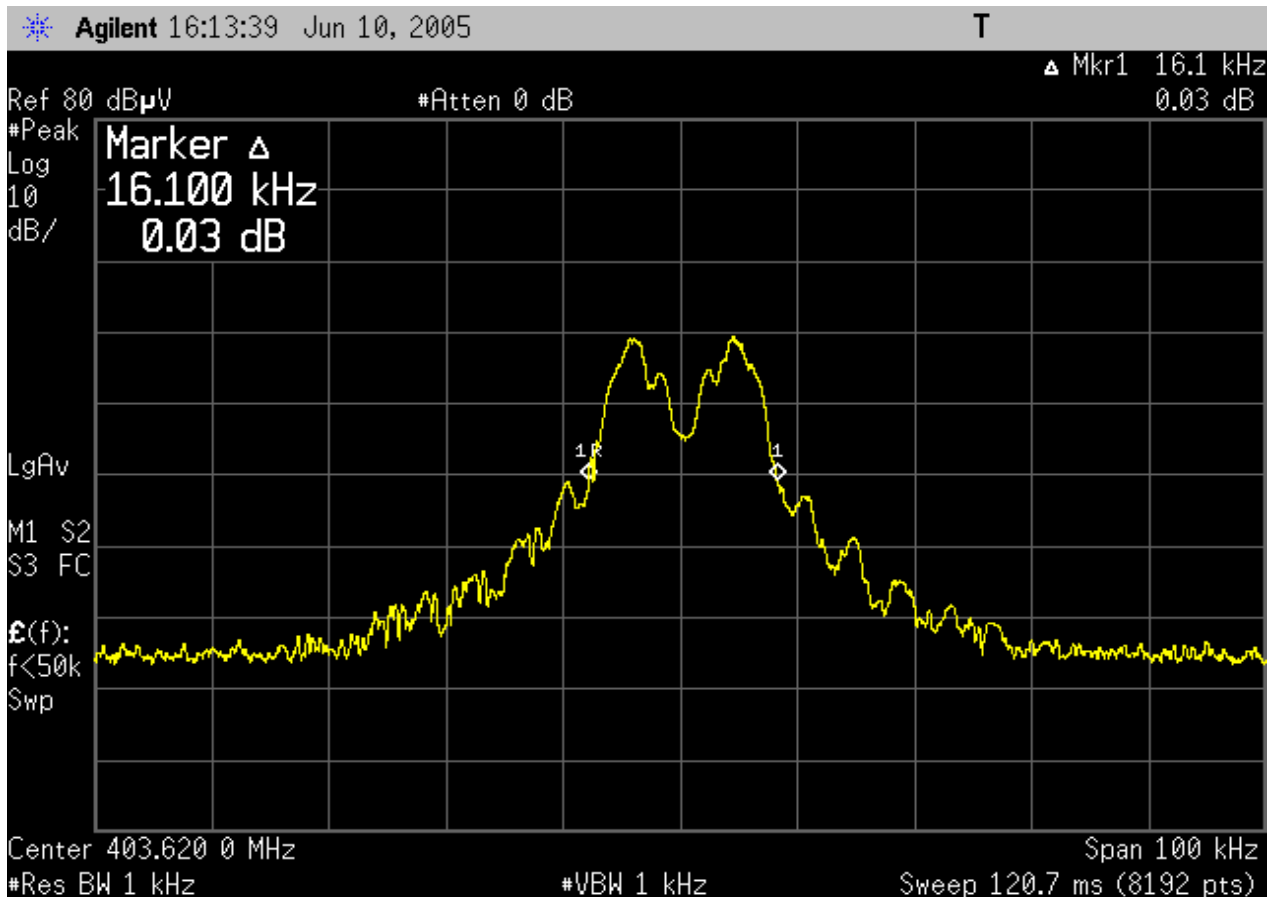
DEVIATIONS FROM TEST STANDARD

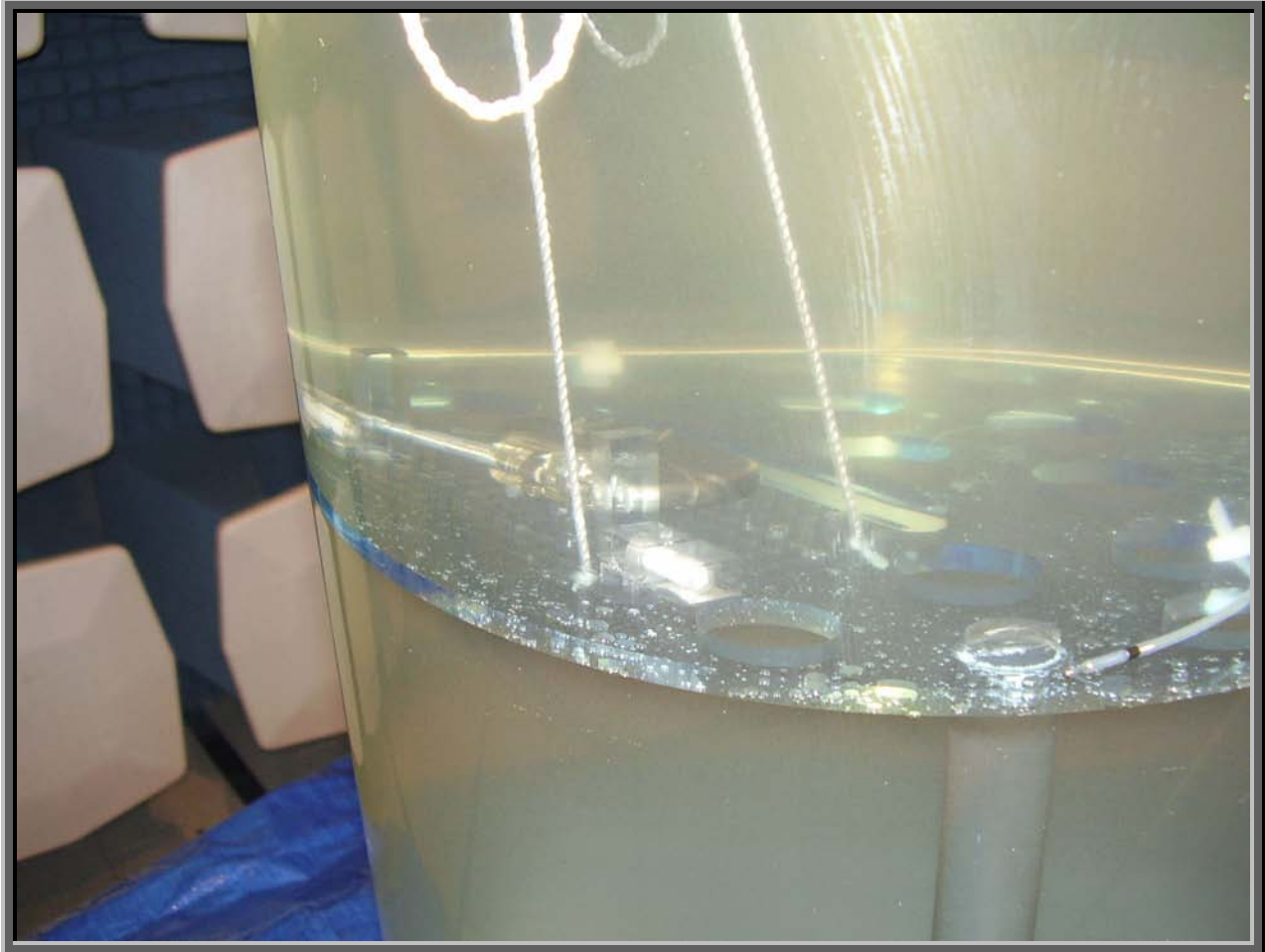
None

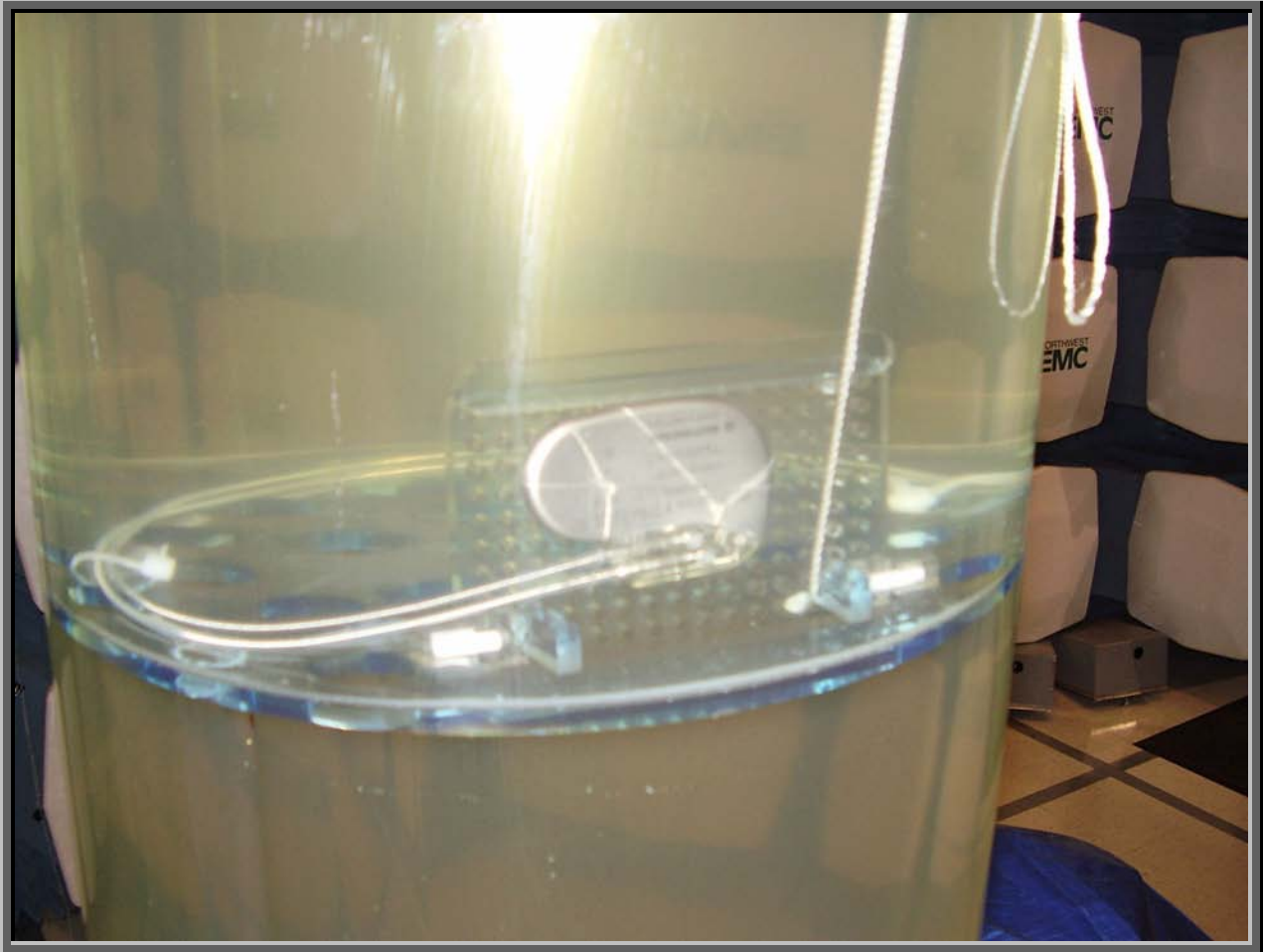
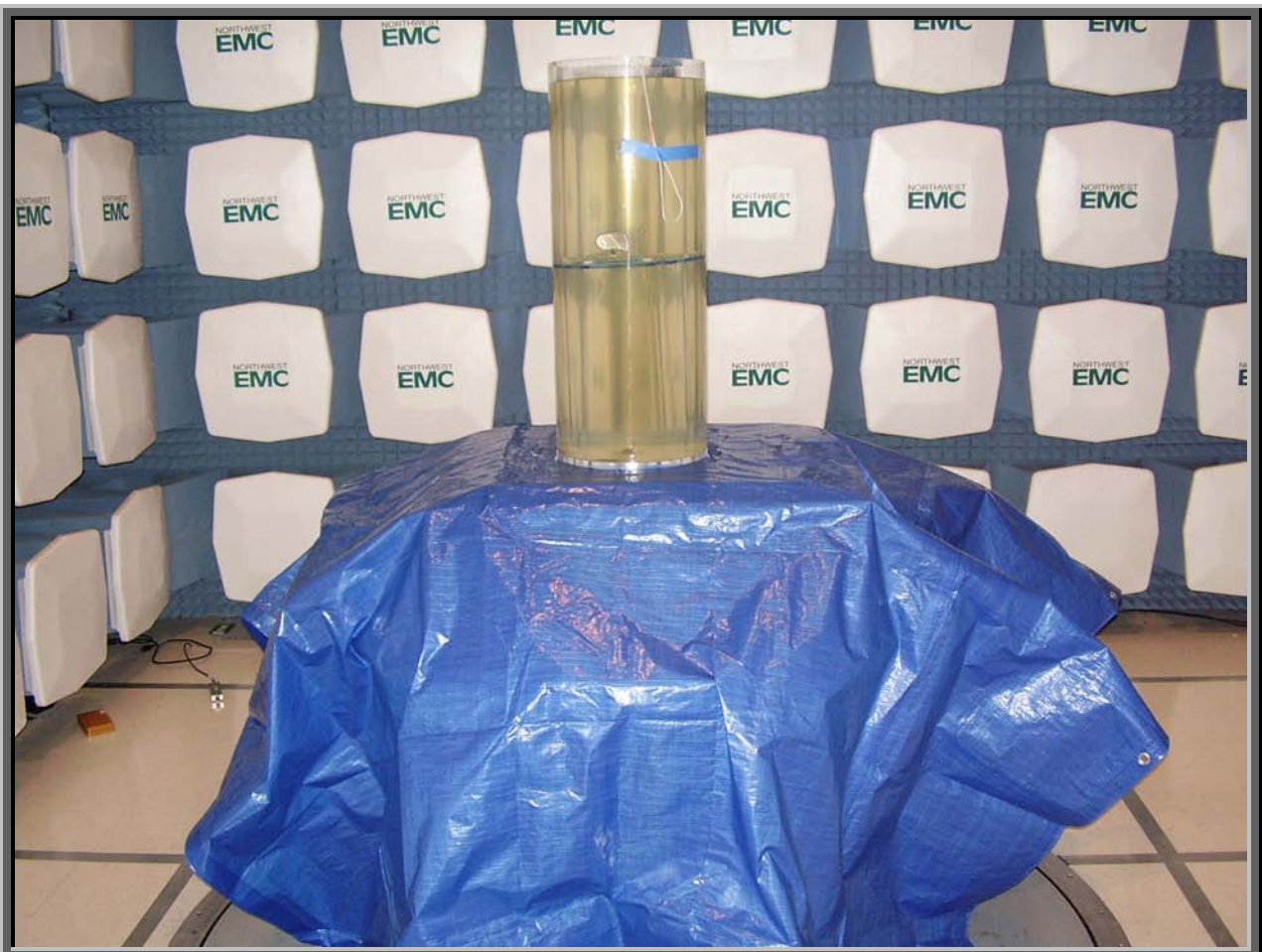
REQUIREMENTS

The maximum authorized emission bandwidth is 300 kHz

RESULTS	BANDWIDTH
Pass	16.1 kHz

SIGNATURETested By: **DESCRIPTION OF TEST****Occupied Bandwidth**





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 Channel: 403.62 MHz

Operating Modes Investigated:

Typical

Data Rates Investigated:

Maximum

Output Power Setting(s) Investigated:

Maximum

Power Input Settings Investigated:

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- Cylos DR-T	Biotronik, Inc.	Cylos DR-T	76020147

Cables

Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
Implant Lead	Yes	approx. 0.	No	EUT- Cylos DR-T	Not connected
Implant Lead	Yes	approx. 0.	No	EUT- Cylos DR-T	Not connected

Measurement Equipment					
Description	Manufacturer	Model	Identifier	Last Cal	Interval
Spectrum Analyzer	Tektronix	2784	AAO	01/02/2005	12 mo
Chamber, Temp./Humidity Chamber	Cincinnati Sub Zero (CSZ)	ZH-32-2-2-H/AC	TBA	09/07/2004	12 mo
Chamber Temp. & Humidity Controller	ESZ / Eurotherm	Dimension II	TBC	09/07/2004	12 mo
Near Field Probe	EMCO	7405	IPD	NCR	NA

Test Description

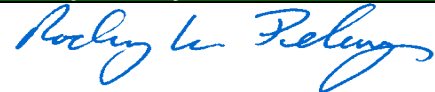
Requirement: Per 47 CFR 95.628(e)(1) and 2.1055, the Frequency Stability was measured. The transmitter must maintain a frequency stability of +/- 100 parts per million (ppm), or better, for variations of temperature over the range of 25 to 45 degrees centigrade.

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:

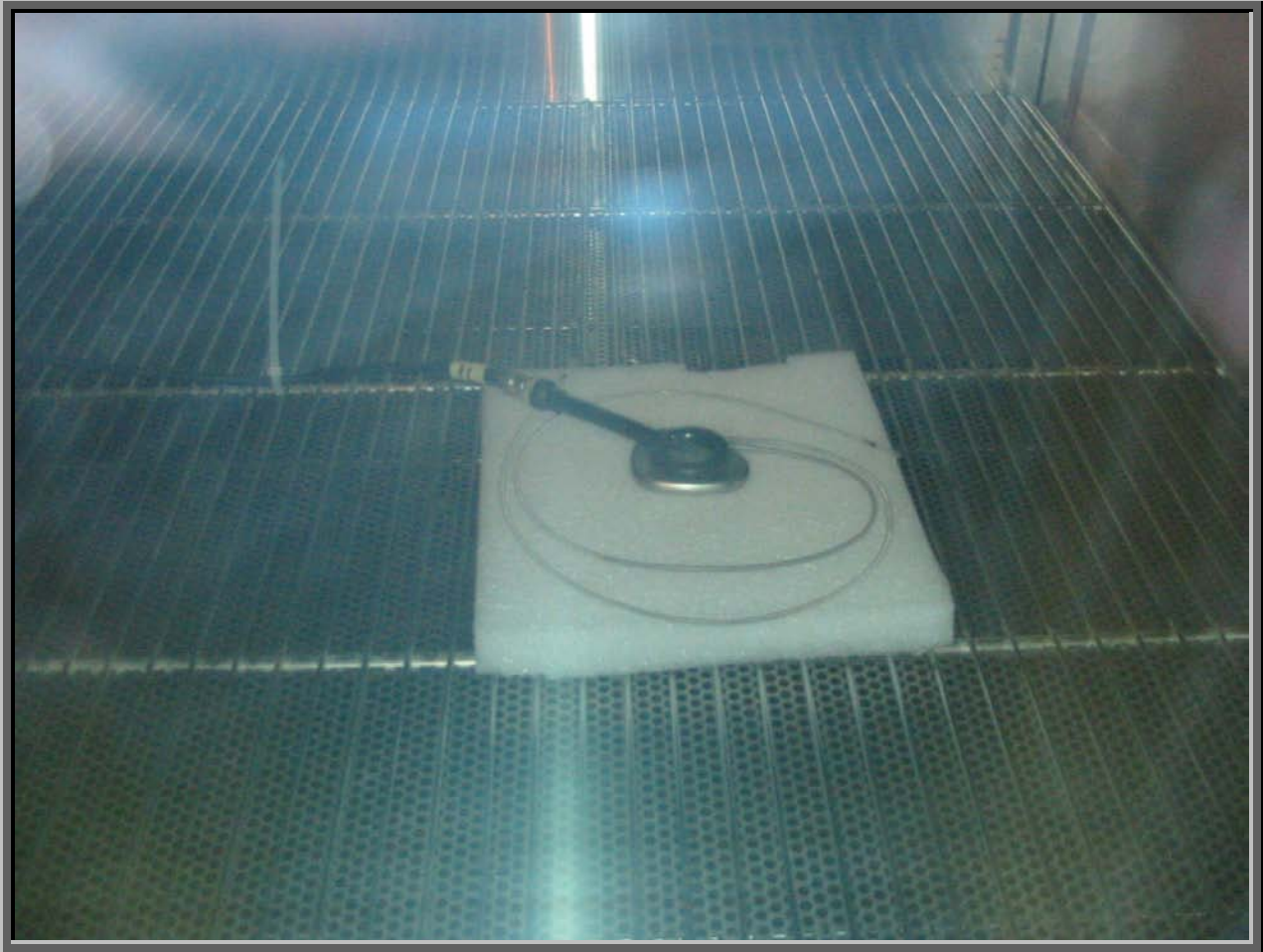


NORTHWEST

EMC**FREQUENCY STABILITY DATA SHEET**Rev BETA
01/30/01

EUT:	Cylos DR-T	Work Order:	BIOT0009
Serial Number:	76020147	Date:	06/13/05
Customer:	Biotronik, Inc.	Temperature:	See Below
Attendees:	Brian Sutton	Humidity:	35% RH
Customer Ref. No.:		Power:	Battery
		Tested by:	Rod Peloquin
		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		9.04 ppm	
SIGNATURE			
<div style="text-align: center;">  </div> <div> Tested By: _____ </div>			
DESCRIPTION OF TEST			
Frequency Stability			

Temp (°C)	Assigned Frequency (MHz)	Measured Frequency (MHz)	Tolerance (ppm)	Specification (ppm)
25	403.626290	403.626370	0.20	100
35	403.626290	403.626290	0.00	100
45	403.626290	403.622640	9.04	100



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 Channel: 403.62 MHz

Operating Modes Investigated:

Typical

Data Rates Investigated:

Maximum

Output Power Setting(s) Investigated:

Maximum

Power Input Settings Investigated:

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- Cylos DR-T	Biotronik, Inc.	Cylos DR-T	76020147

Cables

Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
Implant Lead	Yes	approx. 0.	No	EUT- Cylos DR-T	Not connected
Implant Lead	Yes	approx. 0.	No	EUT- Cylos DR-T	Not connected

Measurement Equipment

Description	Manufacturer	Model	Identifier	Last Cal	Interval
Spectrum Analyzer	Agilent	E4446A	AAQ	04/08/2005	13 mo
Pre-Amplifier	Amplifier Research	LN1000A	APS	03/01/2005	13 mo
Antenna, Biconilog	EMCO	3141	AXE	12/03/2003	24 mo

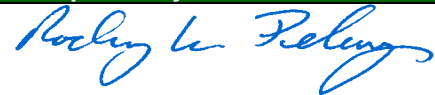
Bandwidths Used for Measurements			
Frequency Range (MHz)	Peak Data (kHz)	Quasi-Peak Data (kHz)	Average Data (kHz)
0.01 – 0.15	1.0	0.2	0.2
0.15 – 30.0	10.0	9.0	9.0
30.0 – 1000	100.0	120.0	120.0
Above 1000	1000.0	N/A	1000.0
<i>Measurements were made using the bandwidths and detectors specified. No video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

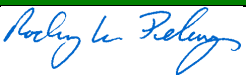
Requirement: Per 47 CFR 95.635(d)(4-5) the emission mask was measured. Emissions more than 150 kHz away from the center frequency must be attenuated below the transmitter output power by at least 20 dB. In addition, emissions 250 kHz or less above and below the MICS band (402-405 MHz) must be attenuated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

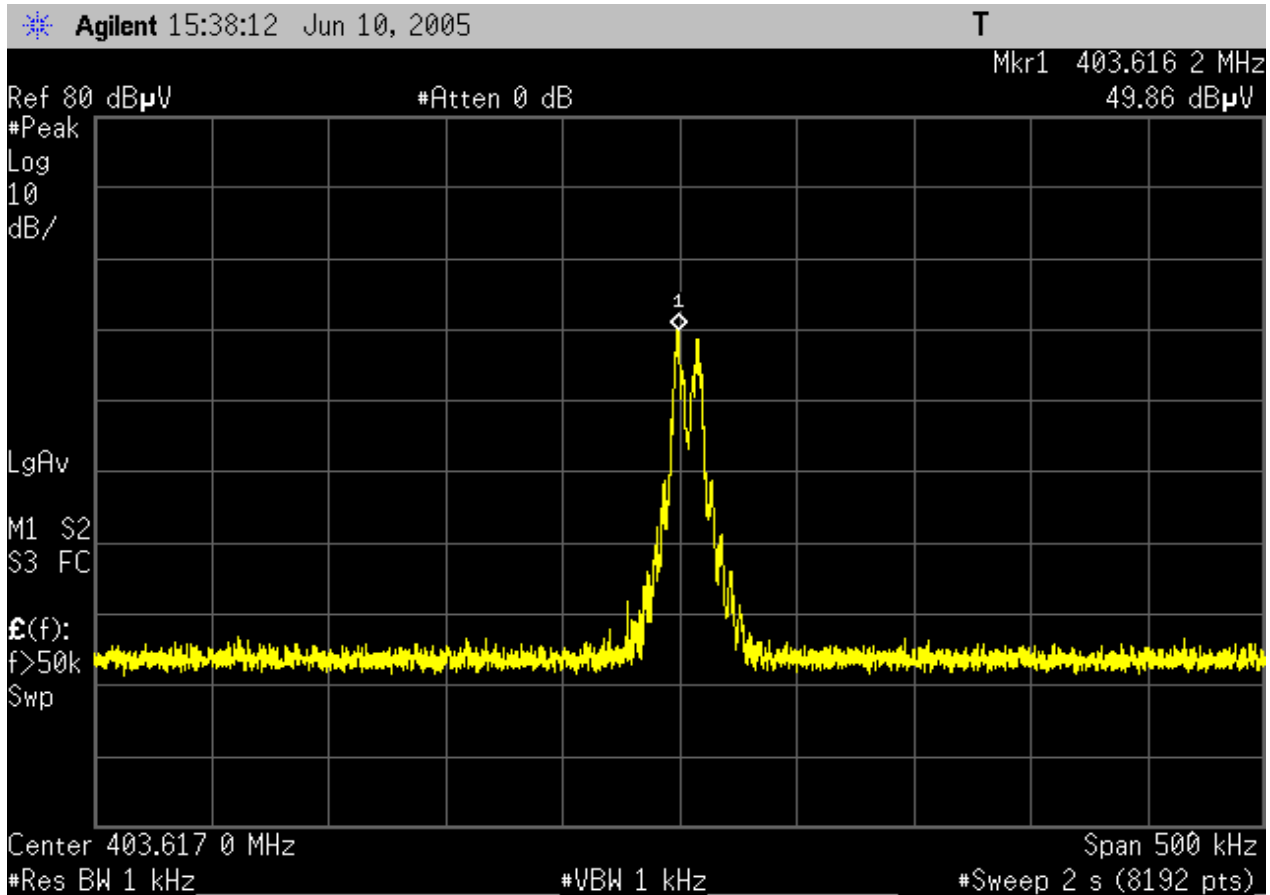
Configuration: The emission mask was measured in the same configuration as radiated spurious emissions. All emissions measurements were made with the EUT placed in the tissue substitute material. First, the EUT orientation (horizontal or vertical), the turntable azimuth and measurement antenna height,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

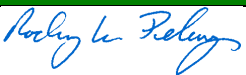
Then, a spectrum analyzer was used to measure the emission mask. A spectrum analyzer using a peak detector with no video filtering was used with a resolution bandwidth equal to approximately 1.0 percent of the emission bandwidth of the EUT. However, various plots were made using different frequency spans 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.

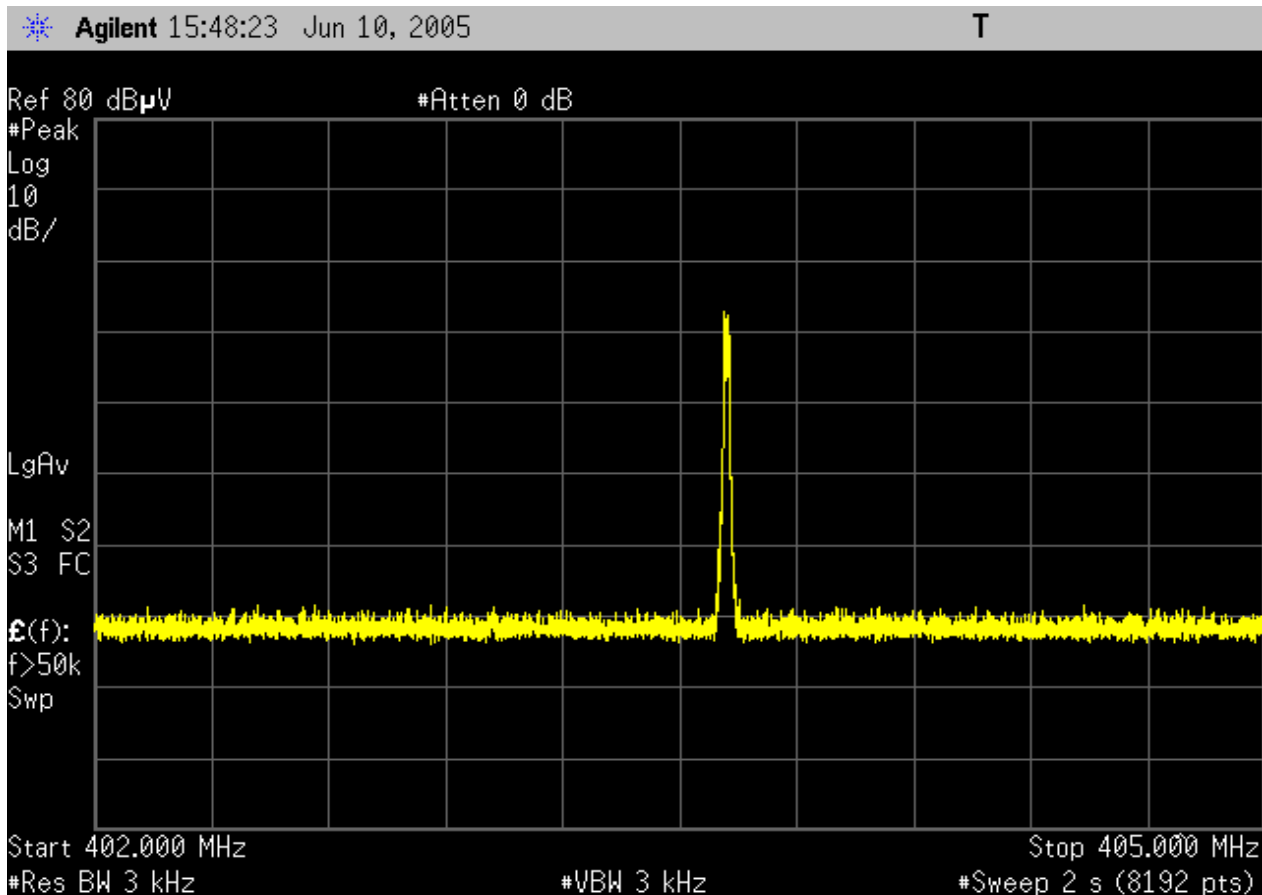
Completed by:



NORTHWEST EMC		EMISSIONS		Rev BETA 01/30/01	
EUT: Cylot DR-T			Work Order: BIOT0009		
Serial Number: 76020147			Date: 06/10/05		
Customer: Biotronik, Inc.			Temperature: 23°C		
Attendees: Brian Sutton			Humidity: 41% RH		
Customer Ref. No.:			Tested by: Rod Peloquin		Job Site: EV01
			Power: Battery		
TEST SPECIFICATIONS					
Specification: 47 CFR 95.635(d)(4)		Year: 2004	Method: 95.635(d)(4) & ANSI C63.4		Year: 2004
SAMPLE CALCULATIONS					
COMMENTS					
EUT Vertical 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 output power by at least 20 dB					
RESULTS					
Pass					
SIGNATURE					
 Tested By: _____					
DESCRIPTION OF TEST					
Emission Mask					



NORTHWEST EMC		EMISSIONS		Rev BETA 01/30/01	
EUT: Cynos DR-T			Work Order: BIOT0009		
Serial Number: 76020147			Date: 06/10/05		
Customer: Biotronik, Inc.			Temperature: 23°C		
Attendees: Brian Sutton		Tested by: Rod Peloquin		Humidity: 41% RH	
Customer Ref. No.:		Power: Battery		Job Site: EV01	
TEST SPECIFICATIONS					
Specification: 47 CFR 95.635(d)(4)		Year: 2004		Method: 95.635(d)(4) & ANSI C63.4	
				Year: 2004	
SAMPLE CALCULATIONS					
COMMENTS					
EUT Vertical 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 output power by at least 20 dB					
RESULTS					
Pass					
SIGNATURE					
 Tested By: _____					
DESCRIPTION OF TEST					
Emission Mask					



NORTHWEST
EMC**EMISSION MASK DATA SHEET**Rev BETA
01/30/01

EUT: Cynos DR-T			Work Order: BIOT0009		
Serial Number: 76020147			Date: 06/10/05		
Customer: Biotronik, Inc.			Temperature: 23°C		
Attendees: Brian Sutton			Humidity: 41% RH		
Customer Ref. No.:			Tested by: Rod Peloquin		
			Power: Battery		
			Job Site: EV01		

TEST SPECIFICATIONS

Specification: 47 CFR 95.635(d)(5)	Year: 2004	Method: 95.635(d)(5) & ANSI C63.4	Year: 2004
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SAMPLE CALCULATIONS**COMMENTS**

EUT Vertical 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 output power by at least 20 dB

RESULTS

Pass

SIGNATURETested By: **DESCRIPTION OF TEST****Emission Mask**

* Agilent 16:03:51 Jun 10, 2005

T

Ref 80 dBμV

#Atten 0 dB

#Peak

Log

10

dB/

LgAv

M1 S2

S3 FC

E(f):

f>50k

Swp

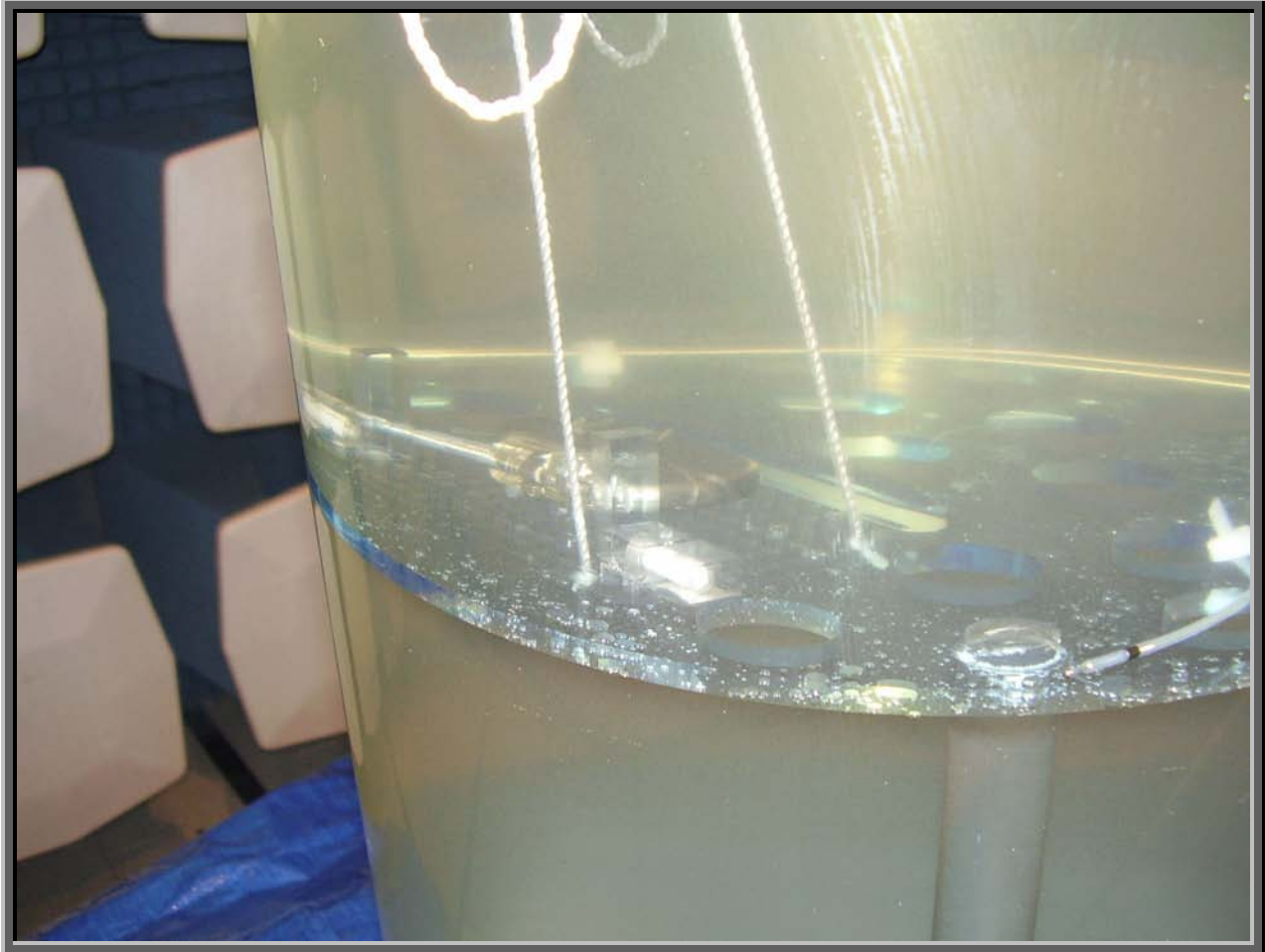
Start 401.500 MHz

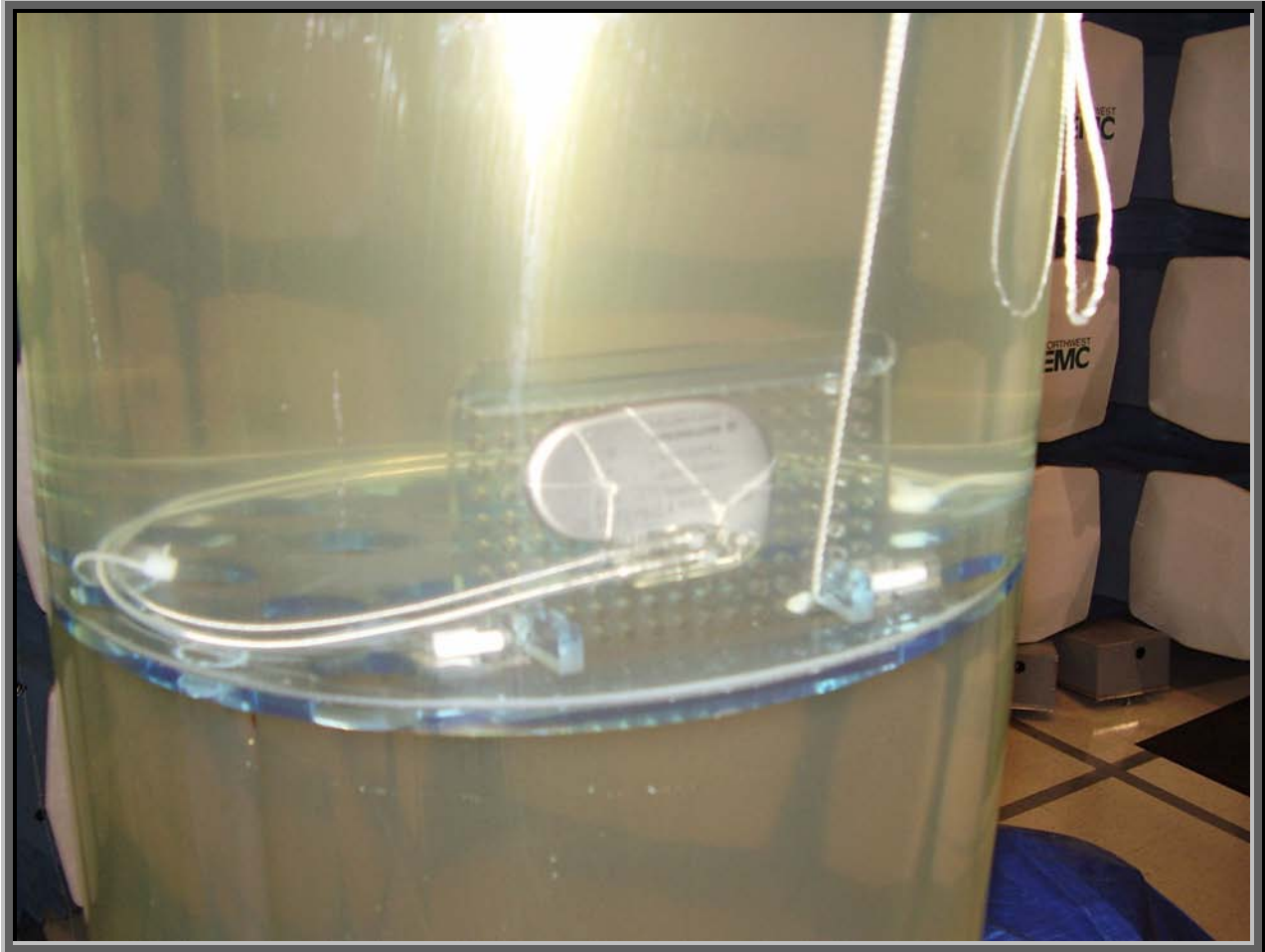
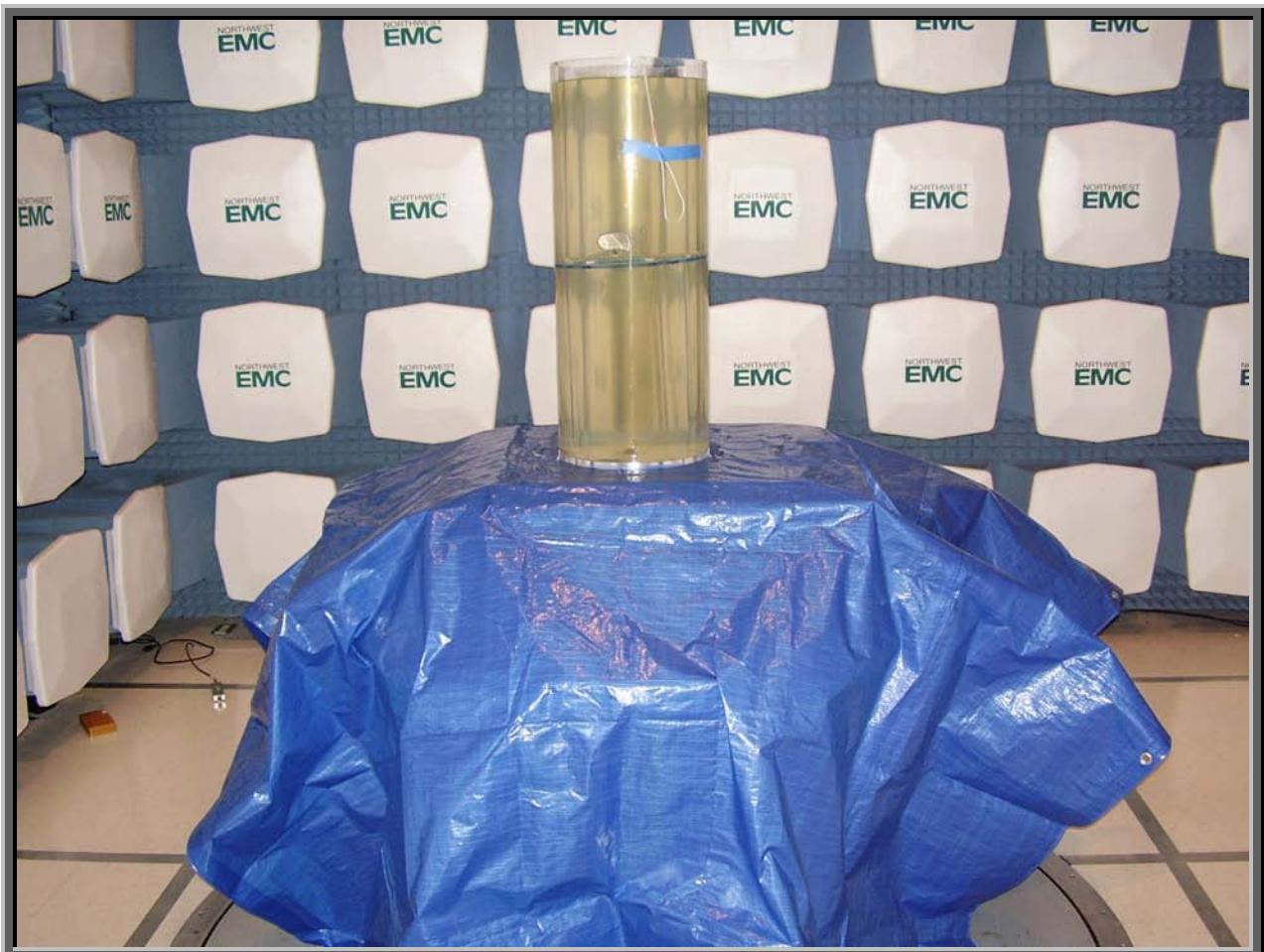
Stop 405.500 MHz

#Res BW 3 kHz

#VBW 3 kHz

#Sweep 2 s (8192 pts)





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 Channel: 403.62 MHz

Operating Modes Investigated:

Typical

Data Rates Investigated:

Maximum

Output Power Setting(s) Investigated:

Maximum

Power Input Settings Investigated:

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- Cylos DR-T	Biotronik, Inc.	Cylos DR-T	76020147

Cables

Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2
Implant Lead	Yes	approx. 0.	No	EUT- Cylos DR-T	Not connected
Implant Lead	Yes	approx. 0.	No	EUT- Cylos DR-T	Not connected

Measurement Equipment					
Description	Manufacturer	Model	Identifier	Last Cal	Interval
Antenna, Biconilog	EMCO	3141	AXE	12/03/2003	24 mo
Pre-Amplifier	Amplifier Research	LN1000A	APS	03/01/2005	13 mo
Pre-Amplifier	Miteq	AMF-4D-005180-24-10P	APJ	05/05/2005	3 mo
Antenna, Horn	EMCO	3115	AHC	09/07/2004	12 mo
Quasi-Peak Adapter	Hewlett-Packard	85650A	AQF	12/02/2004	13 mo
Spectrum Analyzer	Hewlett-Packard	8566B	AAL	12/02/2004	13 mo
Spectrum Analyzer Display	Hewlett Packard	85662A	AALD	12/02/2004	13 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.

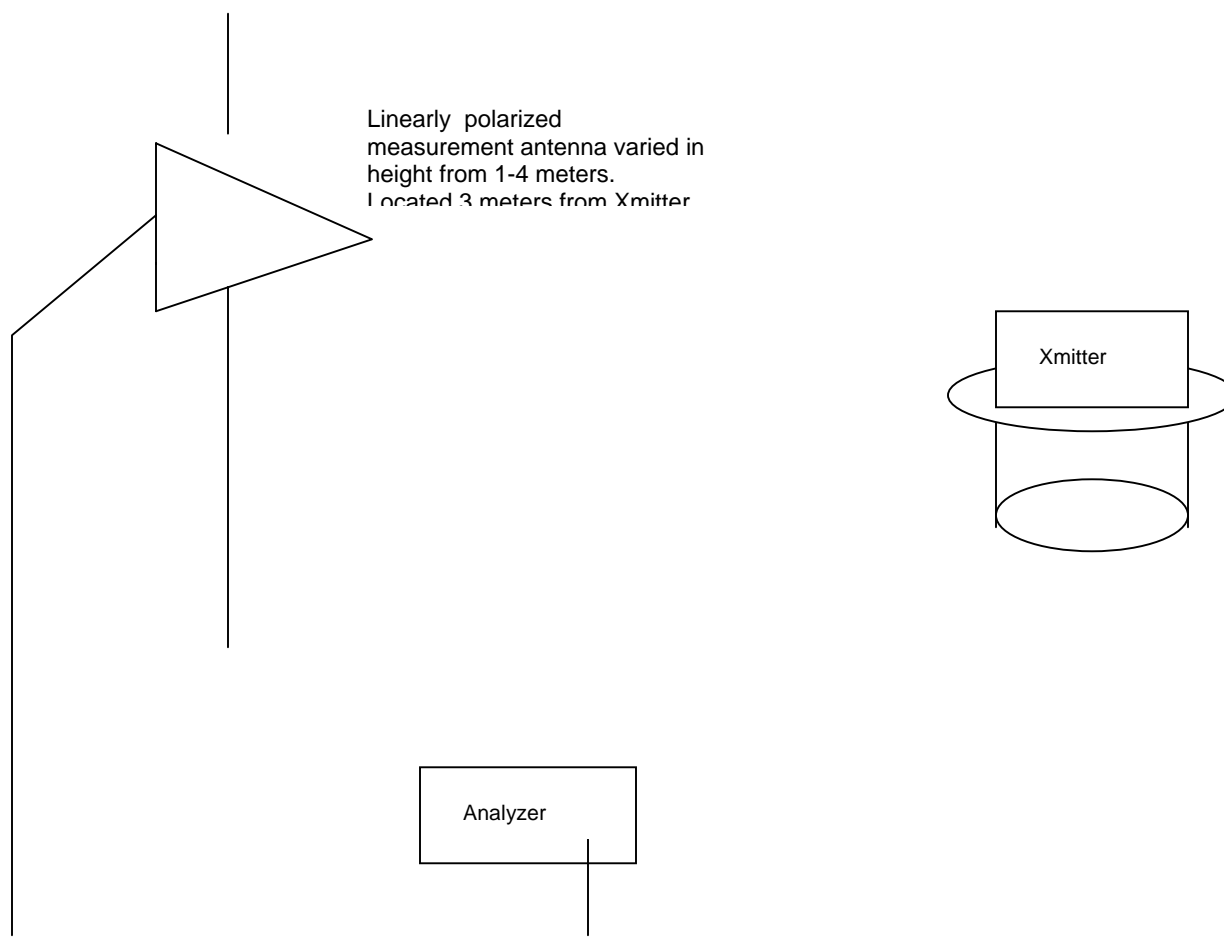
Test Methodology

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
<i>Measurements were made using the bandwidths and detectors specified. No video filter was used.</i>			


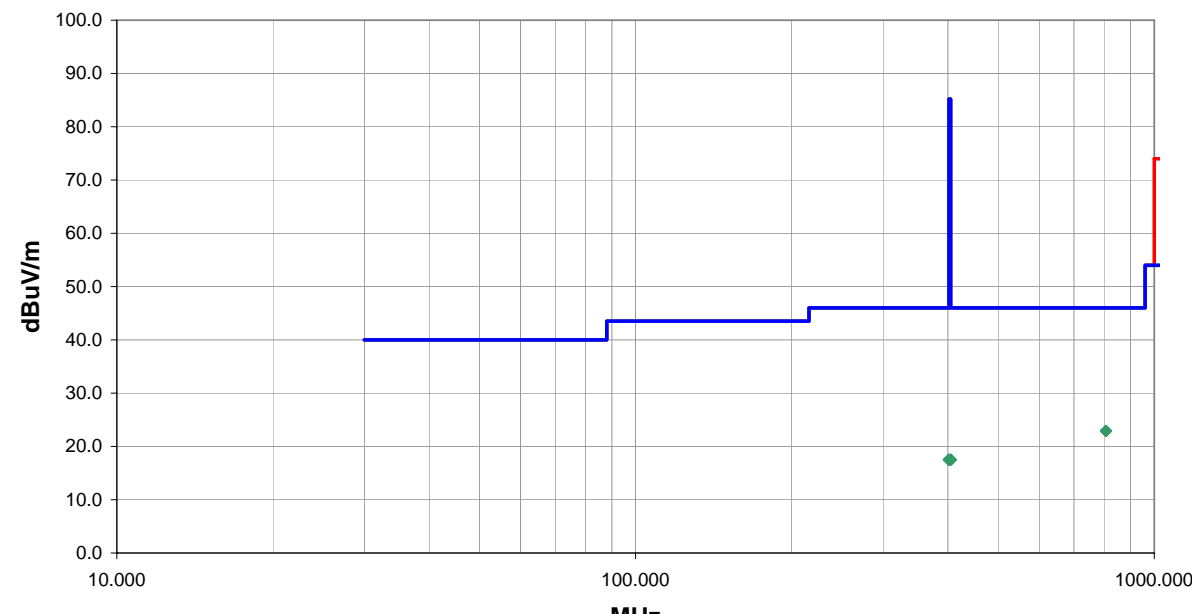
Test Setup Diagram


Test Setup for Field Strength Measurements

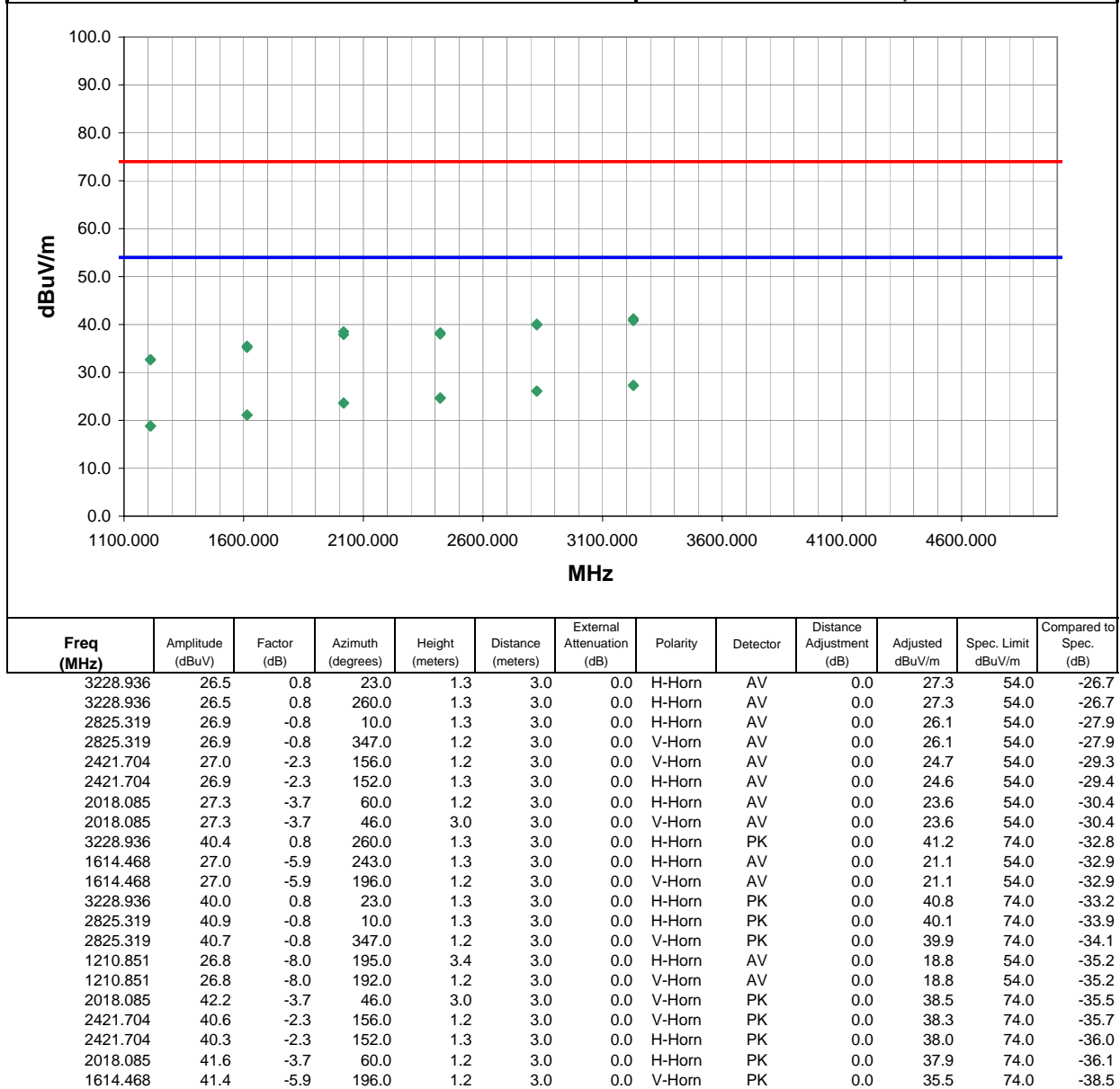


Completed by:

Holly Antling


NORTHWEST EMC										ACQ 2005.1.4 EMI 2005.5.05			
RADIATED EMISSIONS DATA SHEET													
EUT: Cylos DR-T						Work Order: BIOT0009							
Serial Number: 76020147						Date: 06/10/05							
Customer: BIOTRONIK, Inc.						Temperature: 23							
Attendees: Brian Sutton						Humidity: 42%							
Cust. Ref. No.:						Barometric Pressure: 29.95							
Tested by: Rod Peloquin				Power: Battery		Job Site: EV01							
TEST SPECIFICATIONS													
Specification: FCC 95.635:2004						Method: TIA/EIA-603:1998							
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 1.5m 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)	
806.933	23.2	-0.3	23.0	1.2	3.0	0.0	V-Bilog	QP	0.0	22.9	46.0	-23.1	
807.099	23.2	-0.3	168.0	1.9	3.0	0.0	H-Bilog	QP	0.0	22.9	46.0	-23.1	
401.750	22.6	-5.1	333.0	1.6	3.0	0.0	V-Bilog	QP	0.0	17.5	46.0	-28.5	
405.250	22.6	-5.1	306.0	1.7	3.0	0.0	H-Bilog	QP	0.0	17.5	46.0	-28.5	
401.750	22.6	-5.1	248.0	1.6	3.0	0.0	V-Bilog	QP	0.0	17.5	46.0	-28.5	
405.250	22.6	-5.1	328.0	1.0	3.0	0.0	H-Bilog	QP	0.0	17.5	46.0	-28.5	

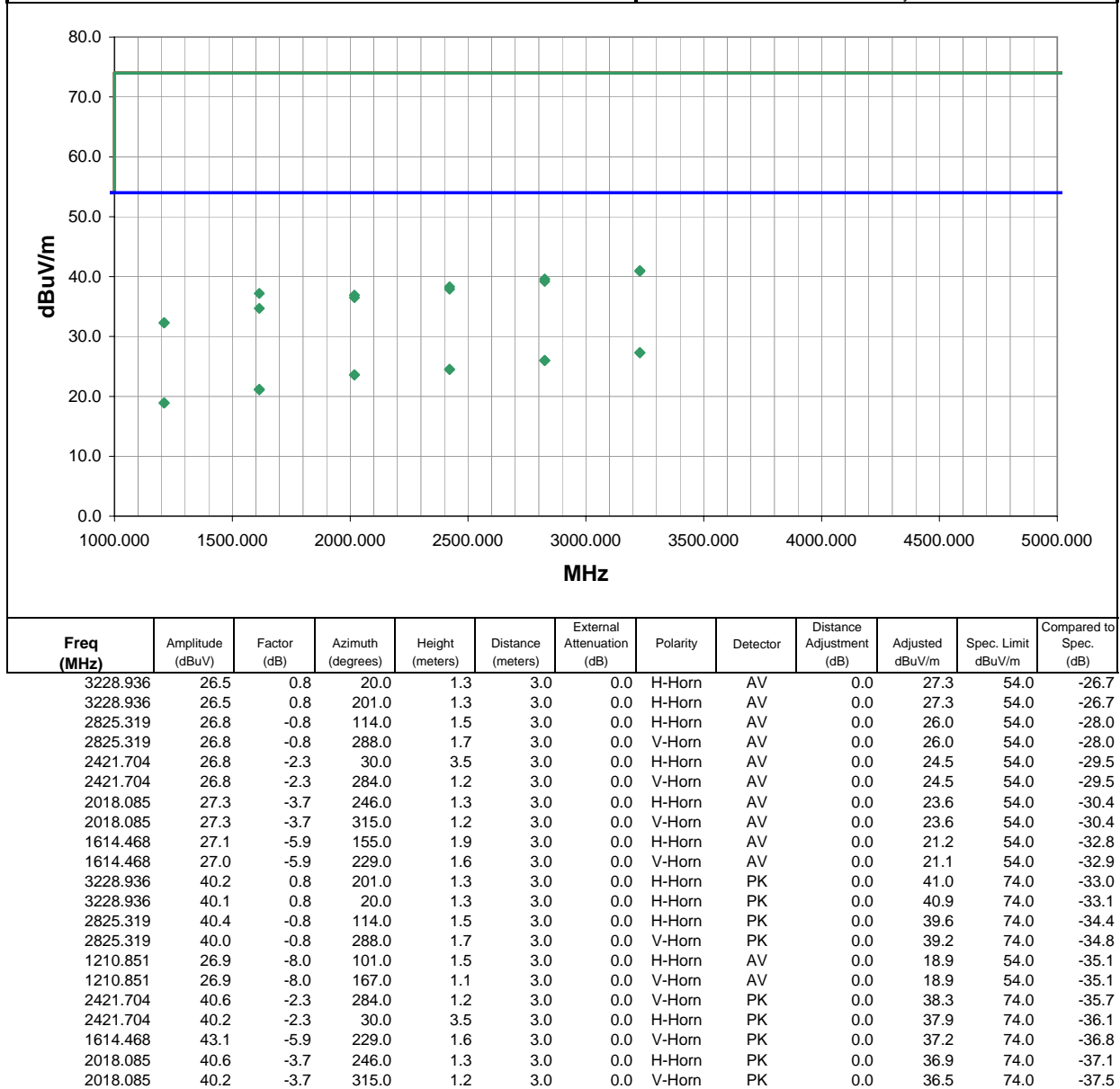
NORTHWEST EMC		RADIATED EMISSIONS DATA SHEET		ACQ 2005.1.4 EMI 2005.5.05	
EUT: Cylors DR-T			Work Order: BIOT0009		
Serial Number: 76020147			Date: 06/10/05		
Customer: BIOTRONIK, Inc.			Temperature: 23		
Attendees: Brian Sutton			Humidity: 42%		
Cust. Ref. No.:			Barometric Pressure: 29.95		
Tested by: Rod Peloquin		Power: Battery		Job Site: EV01	
TEST SPECIFICATIONS					
Specification: FCC 95.635:2004			Method: TIA/EIA-603:1998		
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 1.5m 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)
1614.468	41.1	-5.9	243.0	1.3	3.0	0.0	H-Horn	PK	0.0	35.2	74.0	-38.8
1210.851	40.7	-8.0	192.0	1.2	3.0	0.0	V-Horn	PK	0.0	32.7	74.0	-41.3
1210.851	40.6	-8.0	195.0	3.4	3.0	0.0	H-Horn	PK	0.0	32.6	74.0	-41.4

NORTHWEST EMC										RADIATED EMISSIONS DATA SHEET				ACQ 2005.1.4 EMI 2005.5.05	
EUT: Cylos DR-T										Work Order: BIOT0009					
Serial Number: 76020147										Date: 06/10/05					
Customer: BIOTRONIK, Inc.										Temperature: 23					
Attendees: Brian Sutton										Humidity: 42%					
Cust. Ref. No.:										Barometric Pressure: 29.95					
Tested by: Holly Ashkannejhad						Power: Battery		Job Site: EV01							
TEST SPECIFICATIONS															
Specification: FCC 95.635:2004								Method: TIA/EIA-603:1998							
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 1.5m height															
EUT OPERATING MODES															
Transmitting Single channel															
DEVIATIONS FROM TEST STANDARD															
No deviations.															
RESULTS															
Pass												Run #			
												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)			
807.555	23.2	-0.2	213.0	2.0	3.0	0.0	H-Bilog	QP	0.0	23.0	46.0	-23.0			
806.904	23.2	-0.3	311.0	1.2	3.0	0.0	V-Bilog	QP	0.0	22.9	46.0	-23.1			
401.750	22.6	-5.1	278.0	2.6	3.0	0.0	H-Bilog	QP	0.0	17.5	46.0	-28.5			
401.750	22.6	-5.1	32.0	3.0	3.0	0.0	V-Bilog	QP	0.0	17.5	46.0	-28.5			
405.250	22.6	-5.1	106.0	1.6	3.0	0.0	V-Bilog	QP	0.0	17.5	46.0	-28.5			
405.250	22.6	-5.1	179.0	3.5	3.0	0.0	H-Bilog	QP	0.0	17.5	46.0	-28.5			

NORTHWEST EMC		RADIATED EMISSIONS DATA SHEET		ACQ 2005.1.4 EMI 2005.5.05	
EUT: Cylos DR-T			Work Order: BIOT0009		
Serial Number: 76020147			Date: 06/10/05		
Customer: BIOTRONIK, Inc.			Temperature: 23		
Attendees: None			Humidity: 42%		
Cust. Ref. No.:			Barometric Pressure: 29.95		
Tested by: Holly Ashkannejhad		Power: Battery		Job Site: EV01	
TEST SPECIFICATIONS					
Specification: FCC 15.247(d) Spurious Radiated Emissions:2005-04			Method: ANSI C63.4:2003		
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 1.5m 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)
1614.468	40.6	-5.9	155.0	1.9	3.0	0.0	H-Horn	PK	0.0	34.7	74.0	-39.3
1210.851	40.3	-8.0	101.0	1.5	3.0	0.0	H-Horn	PK	0.0	32.3	74.0	-41.7
1210.851	40.3	-8.0	167.0	1.1	3.0	0.0	V-Horn	PK	0.0	32.3	74.0	-41.7