

TEST RESULT SUMMARY

FCC Part 15 Subpart C Section 15.249 Industry Canada RSS-210 Issue 6 Industry Canada RSS-Gen Issue 1

MANUFACTURER'S NAME Transoma Medical

NAME OF EQUIPMENT Sleuth

MODEL NUMBER(S) TESTED 2010

MANUFACTURER'S ADDRESS 4358 West Round Lake Rd

Arden Hills, MN 55112

TEST REPORT NUMBER WC605218.2

TEST DATE(S) 12 September 2006

According to testing performed at TÜV America Inc, the above-mentioned unit is in compliance with the applicable electromagnetic compatibility (EMC) portions of the requirements defined in FCC Part 15 Subpart C Section 15.249 and Industry Canada RSS-210 Issue 6 and RSS-Gen Issue 1.

It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical characteristics. Any modifications necessary for compliance made during testing on the above mentioned date(s) must be implemented in all production units for compliance to be maintained.

TÜV America Inc, as an independent testing laboratory, declares that the equipment tested as specified above conforms to the applicable EMC requirements of FCC Part 15 Subpart C "Intentional radiators" Section 15.249 "Operation within the bands 902–928 MHz, 2400–2483.5 MHz, 5725–5875 MHZ, and 24.0–24.25 GHz." and IC RSS-210 Issue 6 "Low-power Licence-exempt Radiocommunication Devices (All Frequency Bands): Category I Equipment" and RSS-Gen Issue 1 "General Requirements and Information for the Certification of Radiocommunication Equipment".

Date: 21 September 2006

Location: Taylors Falls MN

USA

Joe Sausen

EMC Senior Technician

& C. Sausan

Not Transferable

Joel Schneider Senior EMC Engineer

Joel T. Sohneise

TÜV AMERICA INC 19333 Wild Mountain Road Taylors Falls MN 55084 Tel: (651) 638-0297 Fax: (651) 638-0298 Rev. 092106



EMC TEST REPORT

Test Report File No.	:	WC605218.2	Date of issue:	21 September 2006
Model / Serial No(s) Tested	:	2010 / 001010		
Product Type	<u>:</u>	Sleuth - Implantable N	Medical Device (I	MD)
Applicant	<u>:</u>	Transoma Medical		
Manufacturer	<u>: <</u>	Transoma Medical		
License holder	<u>:</u>	Transoma Medical		
Address	:	4358 West Round Lal Arden Hills, MN 5511		
	$\overline{\mathcal{I}}$			
Test Result	:	■ Positive □] Negative	
Test Project Number References	:	WC605218.2		
Total pages including Appendices	:	39		

TÜV America Inc reports apply only to the specific samples tested under stated test conditions. It is the manufacturer's responsibility to assure that additional production units of this model are manufactured with identical electrical and mechanical components. TÜV America Inc shall have no liability for any deductions, inferences or generalizations drawn by the client or others from TÜV America Inc issued reports.

This report is the confidential property of the client. As a mutual protection to our clients, the public and ourselves, extracts from the test report shall not be reproduced except in full without our written approval. This report shall not be used by the client to claim product endorsement by NVLAP, NIST, or any agency of the US government.

TÜV America Inc and its professional staff hold government and professional organization certifications and are members of AAMI, ACIL, AEA, ANSI, IEEE, NARTE, and VCCI.



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Sign Explanations: ☐ - not applicable ■ - applicable



EMC TEST REGULATIONS:

The tests were performed according to the following regulations:

- □ EN 55014-2: 1997 + Amendment A1: 2001 Category ___
- □ EN 55024: 1998 + Amendments A1: 2001 + A2: 2003
- □ EN 60601-1-2: 2001
- □ EN 61000-6-1: 2001
- □ EN 61000-6-2: 2001
- □ EN 61326: 1997 + Amendments A1: 1998 + A2: 2001 + A3: 2003
- □ EN 61800-3: 1996 + Amendment A11: 2000
- □ ETS 300 683: 1997
- □ ETSI EN 301 489-3 V1.4.1: 2002
- □ EN 300 330-2 V1.1.1 (2001-06)
- - FCC Part 15 Subpart C Section 15.249
- □ FCC Part 15 Subpart C Section 15.207
- - IC RSS-210 Issue 6
- - IC RSS-Gen Issue 1
- □ IC RSS-Gen Issue 1

ENVIRONMENTAL CONDITIONS IN THE LAB

Temperature: : 23 °C
Atmospheric pressure : 99 kPa
Relative Humidity : 45 %

POWER SUPPLY UTILIZED

Power supply system : 3 VDC battery

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Tel: (651) 638-0297 Fax: (651) 638-0298 Rev. 092106

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Field strength of emissions - fundamental FCC 15.249(a), IC RSS-210 A2.9

Test summary

The requirements are: ■ - MET □ - NOT MET

Minimum margin of compliance is 32.32 dB at 916.479 MHz

Test location

■ - Wild River Lab Large Test Site (Open Area Test Site)

□ - Wild River Lab Small Test Site (Open Area Test Site)

19333 Wild Mountain Road

Test equipment

TUV ID	Model Number	Manufacturer	Description	Serial Number	Cal Due
3204	EM-6917B	Electro-Metrics	Biconicalog Periodic	102	19-Oct-06
3847	ZHL-1042J	Mini-Circuits	Preamplifier 10 - 3000 MHz	0607	Code B
2690	8566B	Hewlett-Packard	Spectrum Analyzer	2430A00930	12 May 07
2673	85662A	Hewlett-Packard	Analyzer Display	2152A03687	12 May 07
2684	85650A	Hewlett-Packard	Quasi-Peak Adapter	2521A01006	15 Mar 07
Code B	= Calibration verifica	tion performed internally, Code Y	= Calibration not required when	used with other cali	brated equipme

Test limit

50 mV/m or 94 dB μ V/m at 3 meters

Test data

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TÜV AMERICA INC File No. WC605218.2 Taylors Falls MN 55084

Tel: (651) 638-0297 Fax: (651) 638-0298 Rev. 092106

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Test Report #:	WC605218.1 Run 1	Test Area:	LTS	=			
EUT Model #:	2010	Date:	9/12/2006	-			
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Hum	idity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:					ı		
Data File Name:	5218.1 limit revs.dat				Page:	1 of	3

FREQ	LEVEL	CABLE / ANT / PREAMP /	FINAL	POL / HGT / AZ	DELTA1	DELTA2
	(dBuV)	ATTEN	(dBuV / m)	(m)(DEG)	15.249 902-	
		(dB)			928 fund. 3m	
8566:						
916.4 MHz maxe	ed:					
916.472 MHz	65.05 Pk	2.52 / 22.42 / 29.76 / 0.0	60.23	H / 2.37 / 185	-33.77*	n/a
916.472 MHz	56.39 Av	2.52 / 22.42 / 29.76 / 0.0	51.57	H / 2.37 / 185	n/a	n/a
916.472 MHz	68.1 Pk	2.52 / 22.42 / 29.76 / 0.0	63.28	V / 1.33 / 175	-30.72*	n/a
916.472 MHz	59.33 Av	2.52 / 22.42 / 29.76 / 0.0	54.51	V / 1.33 / 175	n/a	n/a
ESVS20:						
916.515 MHz	63.86 Pk	2.52 / 22.42 / 29.76 / 0.0	59.04	V / 1.33 / 175	-34.96*	n/a
916.515 MHz	57.68 Av	2.52 / 22.42 / 29.76 / 0.0	52.86	V / 1.33 / 175	n/a	n/a
916.515 MHz	63.59 Qp	2.52 / 22.42 / 29.76 / 0.0	58.77	V / 1.33 / 175	-35.23	n/a
916.515 MHz	60.53 Qp	2.52 / 22.42 / 29.76 / 0.0	55.71	H / 2.40 / 185	-38.29	n/a
916.515 MHz	54.65 Av	2.52 / 22.42 / 29.76 / 0.0	49.83	H / 2.40 / 185	n/a	n/a
916.515 MHz	60.94 Pk	2.52 / 22.42 / 29.76 / 0.0	56.12	H / 2.40 / 185	-37.88*	n/a
					<u> </u>	
HP 8566:						
916.479 MHz	63.65 Qp	2.52 / 22.42 / 29.76 / 0.0	58.83	H / 2.40 / 185	-35.17	n/a
916.479 MHz	66.5 Qp	2.52 / 22.42 / 29.76 / 0.0	61.68	V / 1.30 / 175	-32.32	n/a

^{*} Peak measurement against a quasi peak limit

Tested by:	J. C. Sausen	JC Sausan
	Printed	Signature
Reviewed by:	Greg Jakubowski	Il Jakubawski
	Printed	Signature

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Test Report #:	WC605218.1 Run 1	Test Area:	LTS				
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Temperature	e:	23.0	°C
Test Method:	FCC 15.249			Air Pressure	e:	99.0	kPa
Customer:	Transoma Medical			Rel. Humidity	y:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:				I			
Data File Name:	5218.1 limit revs.dat			P	age:	2 of	3

Measurement summary for limit1: 15.249 902-928 fund. 3m (Qp)								
FREQ	LEVEL	CABLE / ANT / PREAMP /	FINAL	POL / HGT / AZ	DELTA1			
	(dBuV)	ATTEN	(dBuV / m)	(m)(DEG)	15.249 902-			
		(dB)			928 fund. 3m			
916.479 MHz	66.5 Qp	2.52 / 22.42 / 29.76 / 0.0	61.68	V / 1.30 / 175	-32.32			
916.472 MHz	68.1 Pk	2.52 / 22.42 / 29.76 / 0.0	63.28	V / 1.33 / 175	-30.72*			

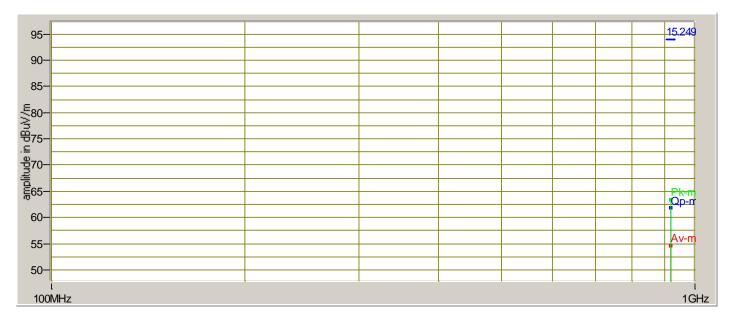
^{*} Peak measurement against a quasi peak limit

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Test Report #:	WC605218.1 Run 1	Test Area:	LTS				
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Temperat	ure:	23.0	°C
Test Method:	FCC 15.249			Air Press	ure:	99.0	kPa
Customer:	Transoma Medical			Rel. Humi	dity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:							
Data File Name:	5218.1 limit revs.dat				Page:	3 of	3

Graph:



Tested by:	J. C. Sausen	JeSausen
	Printed	Signature
Reviewed by:	Greg Jakubowski	Il Jakubawshi
	Printed	Signature

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Field strength of emissions - harmonics FCC 15.249(a), IC RSS-210 A2.9

Test summary

The requirements are: ■ - MET □ - NOT MET

Minimum margin of compliance is > 10 dB from 30 - 9165 MHz No harmonics detected above the measurement noise floor

Test location

■ - Wild River Lab Large Test Site (Open Area Test Site)

☐ - Wild River Lab Small Test Site (Open Area Test Site)

Test equipment

TUV ID	Model Number	Manufacturer	Description	Serial Number	Cal Due
3204	EM-6917B	Electro-Metrics	Biconicalog Periodic	102	19-Oct-06
3847	ZHL-1042J	Mini-Circuits	Preamplifier 10 - 3000 MHz	0607	Code B
2690	8566B	Hewlett-Packard	Spectrum Analyzer	2430A00930	12 May 07
2673	85662A	Hewlett-Packard	Analyzer Display	2152A03687	12 May 07
2684	85650A	Hewlett-Packard	Quasi-Peak Adapter	2521A01006	15 Mar 07
2075	3115	EMCO	Ridge Guide Ant. 1-18 GHz	9001-3275	07-Dec-06
3958	SL18B4020	Phase One Microwave	Preamplifier 1 – 18 GHz	0002	Code B

Code B = Calibration verification performed internally. Code Y = Calibration not required when used with other calibrated equipment

Test limit

 $500~\mu\text{V/m}$ or 54 dB $\mu\text{V/m}$ at 3 meters

Test data

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Taylors Falls MN 55084

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Test Report #:	WC605218.1 Run 2	Test Area:	LTS				
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Humi	dity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:					ı	
Data File Name:	5218.1 run 2 rev.dat				Page:	1 of	4

FREQ	LEVEL	CABLE / ANT / PREAMP /	FINAL	POL / HGT / AZ	DELTA1	DELTA2
	(dBuV)	ATTEN	(dBuV / m)	(m)(DEG)	15.249 902-	15.249 902-
	, ,	(dB)	`	, , ,	928 >1ghz-av	928 >1ghz-pk
		,			3m	3m
NOISE FLOOR	MEASUREMEN	NTS:				
1.833 GHz	45.93 Av	4.04 / 27.0 / 50.55 / 0.0	26.42	V / 1.00 / 0	-27.58	n/a
1.833 GHz	52.95 Pk	4.04 / 27.0 / 50.55 / 0.0	33.44	V / 1.00 / 0	-20.56*	-40.56
2.749 GHz	46.09 Av	4.61 / 29.42 / 49.65 / 0.0	30.47	V / 1.00 / 0	-23.53	n/a
2.749 GHz	54.9 Pk	4.61 / 29.42 / 49.65 / 0.0	39.28	V / 1.00 / 0	-14.72*	-34.72
3.666 GHz	43.36 Av	5.41 / 31.5 / 48.67 / 0.0	31.59	V / 1.00 / 0	-22.41	n/a
3.666 GHz	51.25 Pk	5.41 / 31.5 / 48.67 / 0.0	39.48	V / 1.00 / 0	-14.52*	-34.52
4.582 GHz	42.11 Av	6.01 / 32.21 / 47.69 / 0.0	32.64	V / 1.00 / 0	-21.36	n/a
4.582 GHz	50.15 Pk	6.01 / 32.21 / 47.69 / 0.0	40.68	V / 1.00 / 0	-13.32*	-33.32
5.499 GHz	39.99 Av	6.85 / 33.41 / 46.7 / 0.0	33.55	V / 1.00 / 0	-20.45	n/a
5.499 GHz	47.85 Pk	6.85 / 33.41 / 46.7 / 0.0	41.41	V / 1.00 / 0	-12.59*	-32.59
6.415 GHz	42.49 Av	7.58 / 34.62 / 46.38 / 0.0	38.31	V / 1.00 / 0	-15.69	n/a
6.415 GHz	50.7 Pk	7.58 / 34.62 / 46.38 / 0.0	46.52	V / 1.00 / 0	-7.48*	-27.48
7.332 GHz	42.13 Av	8.07 / 35.82 / 47.1 / 0.0	38.93	V / 1.00 / 0	-15.07	n/a
7.332 GHz	50.1 Pk	8.07 / 35.82 / 47.1 / 0.0	46.9	V / 1.00 / 0	-7.1*	-27.1
8.248 GHz	42.36 Av	8.85 / 36.85 / 46.95 / 0.0	41.11	V / 1.00 / 0	-12.89	n/a
8.248 GHz	50.1 Pk	8.85 / 36.85 / 46.95 / 0.0	48.85	V / 1.00 / 0	-5.15*	-25.15
9.165 GHz	40.96 Av	9.7 / 37.4 / 46.65 / 0.0	41.41	V / 1.00 / 0	-12.59	n/a
9.165 GHz	49.4 Pk	9.7 / 37.4 / 46.65 / 0.0	49.85	V / 1.00 / 0	-4.15*	-24.15

* Peak measurement against an average limit

Tested by:	J. C. Sausen	JeSauson
	Printed	Signature
Reviewed by:	Greg Jakubowski	I Jakubawahi
	Printed	Signature



Test Report #:	WC605218.1 Run 2	Test Area:	LTS				
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Humi	idity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:				I		
Data File Name:	5218.1 run 2 rev.dat				Page:	2 of	4

Measurement summary for limit1: 15.249 902-928 >1ghz-av 3m (Av)					
FREQ	LEVEL	CABLE / ANT / PREAMP /	FINAL	POL / HGT / AZ	DELTA1
	(dBuV)	ATTEN	(dBuV / m)	(m)(DEG)	15.249 902-
		(dB)			928 >1ghz-av
					3m
9.165 GHz	40.96 Av	9.7 / 37.4 / 46.65 / 0.0	41.41	V / 1.00 / 0	-12.59
8.248 GHz	42.36 Av	8.85 / 36.85 / 46.95 / 0.0	41.11	V / 1.00 / 0	-12.89
7.332 GHz	42.13 Av	8.07 / 35.82 / 47.1 / 0.0	38.93	V / 1.00 / 0	-15.07
6.415 GHz	42.49 Av	7.58 / 34.62 / 46.38 / 0.0	38.31	V / 1.00 / 0	-15.69
5.499 GHz	39.99 Av	6.85 / 33.41 / 46.7 / 0.0	33.55	V / 1.00 / 0	-20.45
4.582 GHz	42.11 Av	6.01 / 32.21 / 47.69 / 0.0	32.64	V / 1.00 / 0	-21.36
3.666 GHz	43.36 Av	5.41 / 31.5 / 48.67 / 0.0	31.59	V / 1.00 / 0	-22.41
2.749 GHz	46.09 Av	4.61 / 29.42 / 49.65 / 0.0	30.47	V / 1.00 / 0	-23.53
1.833 GHz	45.93 Av	4.04 / 27.0 / 50.55 / 0.0	26.42	V / 1.00 / 0	-27.58
1.833 GHz	52.95 Pk	4.04 / 27.0 / 50.55 / 0.0	33.44	V / 1.00 / 0	-20.56*
2.749 GHz	54.9 Pk	4.61 / 29.42 / 49.65 / 0.0	39.28	V / 1.00 / 0	-14.72*
3.666 GHz	51.25 Pk	5.41 / 31.5 / 48.67 / 0.0	39.48	V / 1.00 / 0	-14.52*
4.582 GHz	50.15 Pk	6.01 / 32.21 / 47.69 / 0.0	40.68	V / 1.00 / 0	-13.32*
5.499 GHz	47.85 Pk	6.85 / 33.41 / 46.7 / 0.0	41.41	V / 1.00 / 0	-12.59*
6.415 GHz	50.7 Pk	7.58 / 34.62 / 46.38 / 0.0	46.52	V / 1.00 / 0	-7.48*
7.332 GHz	50.1 Pk	8.07 / 35.82 / 47.1 / 0.0	46.9	V / 1.00 / 0	-7.1*
8.248 GHz	50.1 Pk	8.85 / 36.85 / 46.95 / 0.0	48.85	V / 1.00 / 0	-5.15*
9.165 GHz	49.4 Pk	9.7 / 37.4 / 46.65 / 0.0	49.85	V / 1.00 / 0	-4.15*

^{*} Peak measurement against an average limit

Tested by:	J. C. Sausen	& C. Sauson
	Printed	Signature
Reviewed by:	Greg Jakubowski	I Jakubourki
	Printed	Signature

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Test Report #:	WC605218.1 Run 2	Test Area:	LTS	-			
EUT Model #:	2010	Date:	9/12/2006	-			
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Humi	dity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:					1	
Data File Name:	5218.1 run 2 rev.dat				Page:	3 of	4

Measurement summary for limit2: 15.249 902-928 >1ghz-pk 3m (Pk)					
FREQ	LEVEL	CABLE / ANT / PREAMP /	FINAL	POL / HGT / AZ	DELTA2
	(dBuV)	ATTEN	(dBuV / m)	(m)(DEG)	15.249 902-
		(dB)			928 >1ghz-pk
					3m
9.165 GHz	49.4 Pk	9.7 / 37.4 / 46.65 / 0.0	49.85	V / 1.00 / 0	-24.15
8.248 GHz	50.1 Pk	8.85 / 36.85 / 46.95 / 0.0	48.85	V / 1.00 / 0	-25.15
7.332 GHz	50.1 Pk	8.07 / 35.82 / 47.1 / 0.0	46.9	V / 1.00 / 0	-27.1
6.415 GHz	50.7 Pk	7.58 / 34.62 / 46.38 / 0.0	46.52	V / 1.00 / 0	-27.48
5.499 GHz	47.85 Pk	6.85 / 33.41 / 46.7 / 0.0	41.41	V / 1.00 / 0	-32.59
4.582 GHz	50.15 Pk	6.01 / 32.21 / 47.69 / 0.0	40.68	V / 1.00 / 0	-33.32
3.666 GHz	51.25 Pk	5.41 / 31.5 / 48.67 / 0.0	39.48	V / 1.00 / 0	-34.52
2.749 GHz	54.9 Pk	4.61 / 29.42 / 49.65 / 0.0	39.28	V / 1.00 / 0	-34.72
1.833 GHz	52.95 Pk	4.04 / 27.0 / 50.55 / 0.0	33.44	V / 1.00 / 0	-40.56

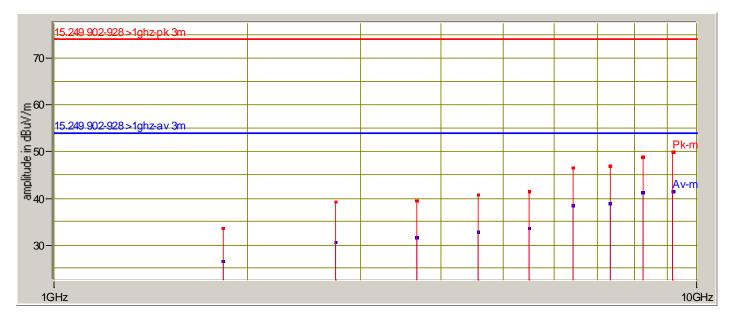
Tested by:	J. C. Sausen	I C-Sausan
	Printed	Signature
Reviewed by:	Greg Jakubowski	A Jakubaurhi
	Printed	Signature

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Test Report #:	WC605218.1 Run 2	Test Area:	LTS				
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Hum	idity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:				T	ı	
Data File Name:	5218.1 run 2 rev.dat				Page:	4 of	4

Graph:



Tested by:	J. C. Sausen	& C. Sausen
	Printed	Signature
Reviewed by:	Greg Jakubowski	I Jakubowski
	Printed	Signature



Field strength of emissions - spurious FCC 15.249(d), , IC RSS-210 A2.9

Test summary

The requirements are: ■ - MET □ - NOT MET

Minimum margin of compliance is > 10 dB from 30 - 9165 MHz No spurious emissions detected above the measurement noise floor

Test location

■ - Wild River Lab Large Test Site (Open Area Test Site)

□ - Wild River Lab Small Test Site (Open Area Test Site)

Test equipment

	Model Number	Manufacturer	Description	Serial Number	Cal Due
3204	EM-6917B	Electro-Metrics	Biconicalog Periodic	102	19-Oct-06
3847	ZHL-1042J	Mini-Circuits	Preamplifier 10 - 3000 MHz	0607	Code B
2690	8566B	Hewlett-Packard	Spectrum Analyzer	2430A00930	12 May 07
2673	85662A	Hewlett-Packard	Analyzer Display	2152A03687	12 May 07
2684	85650A	Hewlett-Packard	Quasi-Peak Adapter	2521A01006	15 Mar 07
2075	3115	EMCO	Ridge Guide Ant. 1-18 GHz	9001-3275	07-Dec-06
3958	SL18B4020	Phase One Microwave	Preamplifier 1 – 18 GHz	0002	Code B
3371	E4440A	Agilent	Spectrum Analyzer	MY43362222	03 Nov 06
Code B -	Calibration verifica	tion performed internally Code V	- Calibration not required when	used with other cali	brated equipmen

Test limit

Frequncy (MHz)	Field strength (μV/meter)	Field strength (dB μV/meter)
30 - 88	100	40.0
88 - 216	150	43.5
216 - 960	200	46.0
Above 960	500	54.0

Test data

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Tel: (651) 638-0297 Fax: (651) 638-0298 Rev. 092106

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Test Report #:	WC605218.1 Run 3	Test Area:	LTS			AIIICIICA	1
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Humi	idity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:				T		
Data File Name:	5218.1 r2 spurious.dat				Page:	1 of	7

List of me	asureme	nts for run #: 2				
FREQ	LEVEL	CABLE / ANT / PREAMP /	FINAL	POL / HGT / AZ	DELTA1	DELTA2
	(dBuV)	ATTEN	(dBuV / m)	(m)(DEG)	FCC-B <1GHz	FCC B >1GHz
		(dB)			3m	3m
NOISE FLOOR	MEASUREME	NTS:				
30.0 MHz	32.65 Qp	0.45 / 21.1 / 30.14 / 0.0	24.06	V / 1.00 / 0	-15.94	n/a
75.0 MHz	32.8 Qp	0.7 / 8.72 / 29.5 / 0.0	12.72	V / 1.00 / 0	-27.28	n/a
115.0 MHz	30.7 Qp	0.88 / 9.1 / 29.56 / 0.0	11.12	V / 1.00 / 0	-32.38	n/a
200.0 MHz	30.85 Qp	1.17 / 9.87 / 29.56 / 0.0	12.33	V / 1.00 / 0	-31.17	n/a
280.0 MHz	28.55 Qp	1.4 / 12.32 / 29.69 / 0.0	12.58	V / 1.00 / 0	-33.42	n/a
380.0 MHz	28.4 Qp	1.62 / 15.38 / 29.85 / 0.0	15.55	V / 1.00 / 0	-30.45	n/a
480.0 MHz	28.4 Qp	1.84 / 17.43 / 30.01 / 0.0	17.66	V / 1.00 / 0	-28.34	n/a
550.0 MHz	28.55 Qp	1.98 / 18.0 / 30.12 / 0.0	18.41	V / 1.00 / 0	-27.59	n/a
650.0 MHz	28.35 Qp	2.12 / 19.42 / 30.13 / 0.0	19.76	V / 1.00 / 0	-26.24	n/a
750.0 MHz	28.15 Qp	2.31 / 20.78 / 29.99 / 0.0	21.25	V / 1.00 / 0	-24.75	n/a
850.0 MHz	28.05 Qp	2.41 / 21.79 / 29.85 / 0.0	22.4	V / 1.00 / 0	-23.6	n/a
950.0 MHz	27.95 Qp	2.57 / 22.9 / 29.72 / 0.0	23.7	V / 1.00 / 0	-22.3	n/a
1.833 GHz	45.93 Av	4.04 / 27.0 / 50.55 / 0.0	26.42	V / 1.00 / 0	n/a	-27.58
1.833 GHz	52.95 Pk	4.04 / 27.0 / 50.55 / 0.0	33.44	V / 1.00 / 0	n/a	-20.56*
2.749 GHz	46.09 Av	4.61 / 29.42 / 49.65 / 0.0	30.47	V / 1.00 / 0	n/a	-23.53
2.749 GHz	54.9 Pk	4.61 / 29.42 / 49.65 / 0.0	39.28	V / 1.00 / 0	n/a	-14.72*
3.666 GHz	43.36 Av	5.41 / 31.5 / 48.67 / 0.0	31.59	V / 1.00 / 0	n/a	-22.41
3.666 GHz	51.25 Pk	5.41 / 31.5 / 48.67 / 0.0	39.48	V / 1.00 / 0	n/a	-14.52*
4.582 GHz	42.11 Av	6.01 / 32.21 / 47.69 / 0.0	32.64	V / 1.00 / 0	n/a	-21.36
4.582 GHz	50.15 Pk	6.01 / 32.21 / 47.69 / 0.0	40.68	V / 1.00 / 0	n/a	-13.32*
5.499 GHz	39.99 Av	6.85 / 33.41 / 46.7 / 0.0	33.55	V / 1.00 / 0	n/a	-20.45
5.499 GHz	47.85 Pk	6.85 / 33.41 / 46.7 / 0.0	41.41	V / 1.00 / 0	n/a	-12.59*
6.415 GHz	42.49 Av	7.58 / 34.62 / 46.38 / 0.0	38.31	V / 1.00 / 0	n/a	-15.69
6.415 GHz	50.7 Pk	7.58 / 34.62 / 46.38 / 0.0	46.52	V / 1.00 / 0	n/a	-7.48*
7.332 GHz	42.13 Av	8.07 / 35.82 / 47.1 / 0.0	38.93	V / 1.00 / 0	n/a	-15.07
7.332 GHz	50.1 Pk	8.07 / 35.82 / 47.1 / 0.0	46.9	V / 1.00 / 0	n/a	-7.1*

Tested by:	J. C. Sausen	I C. Sauson
	Printed	Signature
Reviewed by:	Greg Jakubowski	I Jakubaurhi
	Printed	Signature

File No. WC605218.2 Page 14 of 39



Test Report #:	WC605218.1 Run 3	Test Area:	LTS		,	illollou	
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Humi	dity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:					ı	
Data File Name:	5218.1 r2 spurious.dat				Page:	2 of	7

FREQ	LEVEL	CABLE / ANT / PREAMP /	FINAL	POL / HGT / AZ	DELTA1	DELTA2
	(dBuV)	ATTEN	(dBuV / m)	(m)(DEG)	FCC-B <1GHz	FCC B >1GHz
		(dB)			3m	3m
8.248 GHz	42.36 Av	8.85 / 36.85 / 46.95 / 0.0	41.11	V / 1.00 / 0	n/a	-12.89
8.248 GHz	50.1 Pk	8.85 / 36.85 / 46.95 / 0.0	48.85	V / 1.00 / 0	n/a	-5.15*
9.165 GHz	40.96 Av	9.7 / 37.4 / 46.65 / 0.0	41.41	V / 1.00 / 0	n/a	-12.59
9.165 GHz	49.4 Pk	9.7 / 37.4 / 46.65 / 0.0	49.85	V / 1.00 / 0	n/a	-4.15*

^{*} Peak measurement against an average limit

File No. WC605218.2 Page 15 of 39



Test Report #:	WC605218.1 Run 3	Test Area:	LTS	_			
EUT Model #:	2010	Date:	9/12/2006	_			
EUT Serial #:	1010	EUT Power:	Internal battery	_ Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			_ Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Hum	idity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:				1	1	
Data File Name:	5218.1 r2 spurious.dat				Page:	3 of	7

Measurement summary for limit1: FCC-B <1GHz 3m (Qp)								
FREQ	LEVEL	CABLE / ANT / PREAMP /	FINAL	POL / HGT / AZ	DELTA1			
	(dBuV)	ATTEN	(dBuV / m)	(m)(DEG)	FCC-B <1GHz			
		(dB)			3m			
30.0 MHz	32.65 Qp	0.45 / 21.1 / 30.14 / 0.0	24.06	V / 1.00 / 0	-15.94			
950.0 MHz	27.95 Qp	2.57 / 22.9 / 29.72 / 0.0	23.7	V / 1.00 / 0	-22.3			
850.0 MHz	28.05 Qp	2.41 / 21.79 / 29.85 / 0.0	22.4	V / 1.00 / 0	-23.6			
750.0 MHz	28.15 Qp	2.31 / 20.78 / 29.99 / 0.0	21.25	V / 1.00 / 0	-24.75			
650.0 MHz	28.35 Qp	2.12 / 19.42 / 30.13 / 0.0	19.76	V / 1.00 / 0	-26.24			
75.0 MHz	32.8 Qp	0.7 / 8.72 / 29.5 / 0.0	12.72	V / 1.00 / 0	-27.28			
550.0 MHz	28.55 Qp	1.98 / 18.0 / 30.12 / 0.0	18.41	V / 1.00 / 0	-27.59			
480.0 MHz	28.4 Qp	1.84 / 17.43 / 30.01 / 0.0	17.66	V / 1.00 / 0	-28.34			
380.0 MHz	28.4 Qp	1.62 / 15.38 / 29.85 / 0.0	15.55	V / 1.00 / 0	-30.45			
200.0 MHz	30.85 Qp	1.17 / 9.87 / 29.56 / 0.0	12.33	V / 1.00 / 0	-31.17			
115.0 MHz	30.7 Qp	0.88 / 9.1 / 29.56 / 0.0	11.12	V / 1.00 / 0	-32.38			
280.0 MHz	28.55 Qp	1.4 / 12.32 / 29.69 / 0.0	12.58	V / 1.00 / 0	-33.42			

Tested by:	J. C. Sausen	I C. Sausan
	Printed	Signature
Reviewed by:	Greg Jakubowski	Il Japubowski
	Printed	Signature

File No. WC605218.2 Page 16 of 39



Test Report #:	WC605218.1 Run 3	Test Area:	LTS				
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Humi	idity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:				I		
Data File Name:	5218.1 r2 spurious.dat				Page:	4 of	7

Measurement summary for limit2: FCC B >1GHz 3m (Av)								
FREQ	LEVEL	CABLE / ANT / PREAMP /	FINAL	POL / HGT / AZ	DELTA2			
	(dBuV)	ATTEN	(dBuV / m)	(m)(DEG)	FCC B >1GHz			
		(dB)			3m			
9.165 GHz	40.96 Av	9.7 / 37.4 / 46.65 / 0.0	41.41	V / 1.00 / 0	-12.59			
8.248 GHz	42.36 Av	8.85 / 36.85 / 46.95 / 0.0	41.11	V / 1.00 / 0	-12.89			
7.332 GHz	42.13 Av	8.07 / 35.82 / 47.1 / 0.0	38.93	V / 1.00 / 0	-15.07			
6.415 GHz	42.49 Av	7.58 / 34.62 / 46.38 / 0.0	38.31	V / 1.00 / 0	-15.69			
5.499 GHz	39.99 Av	6.85 / 33.41 / 46.7 / 0.0	33.55	V / 1.00 / 0	-20.45			
4.582 GHz	42.11 Av	6.01 / 32.21 / 47.69 / 0.0	32.64	V / 1.00 / 0	-21.36			
3.666 GHz	43.36 Av	5.41 / 31.5 / 48.67 / 0.0	31.59	V / 1.00 / 0	-22.41			
2.749 GHz	46.09 Av	4.61 / 29.42 / 49.65 / 0.0	30.47	V / 1.00 / 0	-23.53			
1.833 GHz	45.93 Av	4.04 / 27.0 / 50.55 / 0.0	26.42	V / 1.00 / 0	-27.58			
1.833 GHz	52.95 Pk	4.04 / 27.0 / 50.55 / 0.0	33.44	V / 1.00 / 0	-20.56*			
2.749 GHz	54.9 Pk	4.61 / 29.42 / 49.65 / 0.0	39.28	V / 1.00 / 0	-14.72*			
3.666 GHz	51.25 Pk	5.41 / 31.5 / 48.67 / 0.0	39.48	V / 1.00 / 0	-14.52*			
4.582 GHz	50.15 Pk	6.01 / 32.21 / 47.69 / 0.0	40.68	V / 1.00 / 0	-13.32*			
5.499 GHz	47.85 Pk	6.85 / 33.41 / 46.7 / 0.0	41.41	V / 1.00 / 0	-12.59*			
6.415 GHz	50.7 Pk	7.58 / 34.62 / 46.38 / 0.0	46.52	V / 1.00 / 0	-7.48*			
7.332 GHz	50.1 Pk	8.07 / 35.82 / 47.1 / 0.0	46.9	V / 1.00 / 0	-7.1*			
8.248 GHz	50.1 Pk	8.85 / 36.85 / 46.95 / 0.0	48.85	V / 1.00 / 0	-5.15*			
9.165 GHz	49.4 Pk	9.7 / 37.4 / 46.65 / 0.0	49.85	V / 1.00 / 0	-4.15*			

^{*} Peak measurement against an average limit

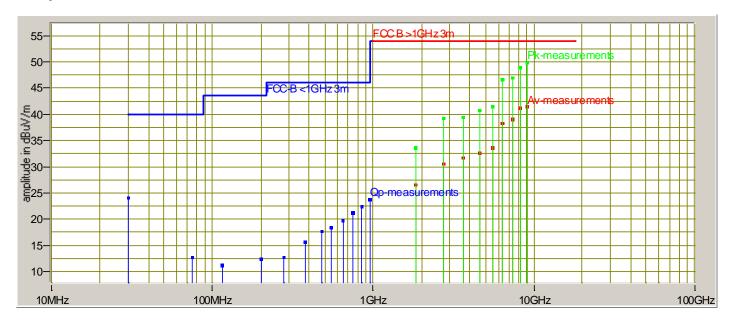
Tested by:	J. C. Sausen	IC Sausan
	Printed	Signature
Reviewed by:	Greg Jakubowski	I Jakubaurhi
	Printed	Signature

File No. WC605218.2 Page 17 of 39



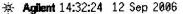
Test Report #:	WC605218.1 Run 3	Test Area:	LTS	•			
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Humi	idity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:				T	•	
Data File Name:	5218.1 r2 spurious.dat				Page:	5 of	7

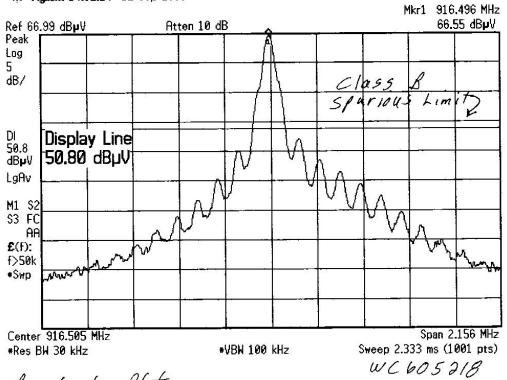
Graph:





Test Report #:	WC605218.1 Run 3	Test Area:	LTS				
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Hum	idity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:				Ī	1	
Data File Name:	5218.1 r2 spurious.dat				Page:	6 of	7

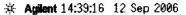


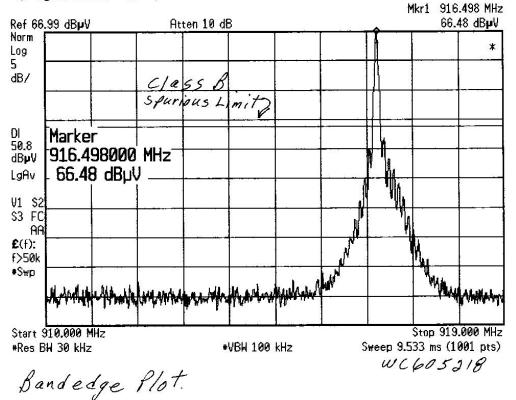


Bandedge Plot.



Test Report #:	WC605218.1 Run 3	Test Area:	LTS	•			
EUT Model #:	2010	Date:	9/12/2006				
EUT Serial #:	1010	EUT Power:	Internal battery	Tempera	ture:	23.0	°C
Test Method:	FCC 15.249			Air Press	sure:	99.0	kPa
Customer:	Transoma Medical			Rel. Humi	dity:	45.0	%
EUT Description:	916.5 MHz transmitter						
Notes:	NOISE FLOOR MEASUREMENTS:					•	
Data File Name:	5218.1 r2 spurious.dat				Page:	7 of	7







Peak field strength of any emission > 1 GHz FCC 15.249(e)

Test summary

The requirements are: ■ - MET □ - NOT MET

No emissions detected above the measurement noise floor

All peak measurements are within 20 dB of the average noise floor measurements

Test location

- - Wild River Lab Large Test Site (Open Area Test Site)
- □ Wild River Lab Small Test Site (Open Area Test Site)

Test Distance

- - 3 meters
- ☐ 10 meters

Test equipment

TUV ID	Model Number	Manufacturer	Description	Serial Number	Cal Due
3204	EM-6917B	Electro-Metrics	Biconicalog Periodic	102	19-Oct-06
2075	3115	EMCO	Ridge Guide Ant. 1-18 GHz	9001-3275	07-Dec-06
3847	ZHL-1042J	Mini-Circuits	Preamplifier 10 - 3000 MHz	0607	Code B
3958	SL18B4020	Phase One Microwave	Preamplifier 1 – 18 GHz	0002	Code B
2684	85650A	Hewlett-Packard	Quasi-Peak Adapter	2521A01006	15 Mar 07
2690	8566B	Hewlett-Packard	Spectrum Analyzer	2430A00930	12 May 07
2673	85662A	Hewlett-Packard	Analyzer Display	2152A03687	12 May 07
Cal Code	R - Calibration varific	cation performed internally Cal Cod	a V - Calibration not required when	used with other calib	arated equipment

Cal Code B = Calibration verification performed internally. Cal Code Y = Calibration not required when used with other calibrated equipment.

Test limit

Peak field strength shall not exceed the average limits by more than 20 dB

Test data

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TÜV AMERICA INC File No. WC605218.2 19333 Wild Mountain Road Taylors Falls MN 55084

Tel: (651) 638-0297 Fax: (651) 638-0298 Rev. 092106

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Occupied bandwidth RSS-Gen 4.4.1

Test summary

The requirements are: ■ - MET □ - NOT MET

Occupied Bandwidth = 316 kHz

Test location

- - Wild River Lab Large Test Site (Open Area Test Site)
- ☐ Wild River Lab Small Test Site (Open Area Test Site)

Test Distance

- - 3 meters
- □ 10 meters

Test equipment

	14.15				
TUV ID	Model Number	Manufacturer	Description	Serial Number	Cal Due
3204	EM-6917B	Electro-Metrics	Biconicalog Periodic	102	19-Oct-06
3847	ZHL-1042J	Mini-Circuits	Preamplifier 10 - 3000 MHz	0607	Code B
3371	E4440A	Agilent	Spectrum Analyzer	MY43362222	03 Nov 06
Cal Code	B = Calibration verific	cation performed inte	rnally Cal Code Y = Calibration not required when	used with other cali	hrated equipment

Test limit

No limit specified

Test data

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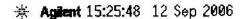
TÜV AMERICA INC File No. WC605218.2 19333 Wild Mountain Road

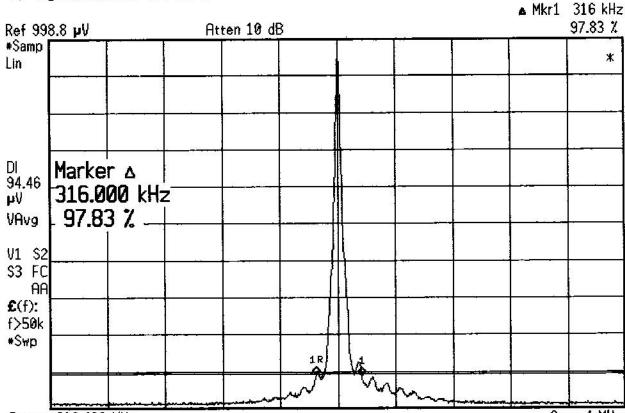
Taylors Falls MN 55084

Tel: (651) 638-0297 Fax: (651) 638-0298 Rev. 092106

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Center 916,496 MHz Res BH 39 kHz

VBW 120 kHz

Span 4 MHz Sweep 7.933 ms (1001 pts) *WC605218*

I.C. RSS-210 Bandwidth Plot RSS-Iren Sect. 4.4.1

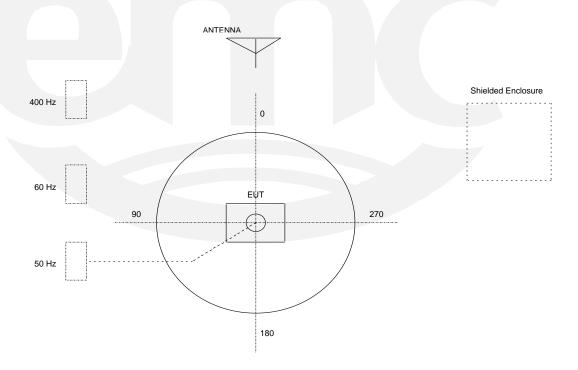


TEST SETUP FOR EMISSIONS TESTING

WILD RIVER LAB Large Test Site

Notes:

- 1. Items shown in dotted lines are located on the floor below the test area. It is 5 meters vertically from the ground floor to the test area.
- 2. 50 Hz, 60 Hz, and 400 Hz are power panels for alternating current.
- 3. The antenna may be positioned horizontally 3, 10 or 30 meters from the center of the turntable.
- 4. The circle is a 6.7 meter diameter turntable.
- 5. A ground plane is in the plane of this sheet.
- 6. The test sample is shown in the azimuthal position representing zero degrees.





Equipment Under Test (EUT) Test Operation Mode:					
The device under test was operated under the following conditions during immunity testing :					
□ - Standby					
□ - Test program (H - Pattern)					
□ - Test program (color bar)					
□ - Test program (customer specific)					
□ - Practice operation					
■ - Transmitting data at 916 MHz					
Configuration of the device under test:					
■ - See Appendix A & Test setup photos					
□ - See Product Information Form(s) in Appendix B					

Taylors Falls MN 55084

19333 Wild Mountain Road

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DEVIATIONS FF	ROM STANDARD:
---------------	---------------

None.

GENERAL REMARKS:

Modifications required to pass:

- None
- ☐ As indicated on the data sheet(s)

Test Specification Deviations: Additions to or Exclusions from:

- None
- ☐ As indicated in the Test Plan

SUMMARY:

The requirements according to the technical regulations are

- - met and the device under test does fulfill the general approval requirements.
- □ **not** met and the device under test does **not** fulfill the general approval requirements..

EUT Received Date: 12 September 2006

Condition of EUT: Normal

Testing Start Date: 12 September 2006

Testing End Date: 12 September 2006

& C. Sauson

TÜV AMERICA INC

Joe Sausen

EMC Senior Technician

Joel T. Sohneiser

Joel Schneider Senior EMC Engineer



Appendix A

Constructional Data Form





EMC Test Plan and Constructional Data Form

America

PLEASE COMPLETE THIS DOCUMENT IN FULL, ENTERING N/A IF THE FIELD IS NOT APPLICABLE. IF TESTING RESULTS IN MODIFICATIONS TO THE EQUIPMENT, PLEASE SUBMIT A REVISED TP/CDF INDICATING THOSE MODIFICATIONS.

NOTE: This information will be input into your test report as shown below. Press the F1 key at any time to get HELP for the current field selected.

Address: Arden Hills, MN 55112 Contact: Luke Strawn Position: Electrical Design Engineer Phone: 651-481-7410 Fax: 651-481-7416 E-mail Address: Istrawn@transomamedical.com General Equipment Description NOTE: This information will be input into your test report as shown below. EUT Description Implantable Medical Device (IMD) EUT Name Sleuth Model No.: 2010 Serial No.: 001010 Product Options: Configurations to be tested: Transmitting at 916MHz Equipment Modification (If applicable, indicate modifications since EUT was last tested. If modifications are made during this testing, submit revised TP/CDF after testing is complete.) Modifications made during test: Test Objective(s): Please indicate the tests to be performed, entering the applicable standard(s) where noted. EMC Directive 89/336/EEC (EMC) FCC: Class A B Part 15 Std: VCCI: Class A B Part 15
Contact: Luke Strawn Position: Electrical Design Engineer Phone: 651-481-7410 Fax: 651-481-7416 E-mail Address: Istrawn@transomamedical.com General Equipment Description NOTE: This information will be input into your test report as shown below. EUT Description Implantable Medical Device (IMD) EUT Name Sleuth Model No.: 2010 Serial No.: 001010 Product Options: Configurations to be tested: Transmitting at 916MHz Equipment Modification (If applicable, indicate modifications since EUT was last tested. If modifications are made during this testing, submit revised TP/CDF after testing is complete.) Modifications since last test: Modifications made during test: Test Objective(s): Please indicate the tests to be performed, entering the applicable standard(s) where noted. BMC Directive 89/336/EEC (EMC) FCC: Class A B Part 15 Std: VCCI: Class A B Part 15
Phone: 651-481-7410 Fax: 651-481-7416 E-mail Address: Istrawn@transomamedical.com General Equipment Description NOTE: This information will be input into your test report as shown below. EUT Description Implantable Medical Device (IMD) EUT Name Sleuth Model No.: 2010 Serial No.: 001010 Product Options: Configurations to be tested: Transmitting at 916MHz Equipment Modification (If applicable, indicate modifications since EUT was last tested. If modifications are made during this testing, submit revised TP/CDF after testing is complete.) Modifications since last test: Modifications made during test: Test Objective(s): Please indicate the tests to be performed, entering the applicable standard(s) where noted. BMC Directive 89/336/EEC (EMC) FCC: Class A B Part 15 Std: VCCI: Class A B Part 15
Phone: 651-481-7410 Fax: 651-481-7416 E-mail Address: Istrawn@transomamedical.com General Equipment Description NOTE: This information will be input into your test report as shown below. EUT Description Implantable Medical Device (IMD) EUT Name Sleuth Model No.: 2010 Serial No.: 001010 Product Options: Configurations to be tested: Transmitting at 916MHz Equipment Modification (If applicable, indicate modifications since EUT was last tested. If modifications are made during this testing, submit revised TP/CDF after testing is complete.) Modifications since last test: Modifications made during test: Test Objective(s): Please indicate the tests to be performed, entering the applicable standard(s) where noted. BMC Directive 89/336/EEC (EMC) FCC: Class A B Part 15 Std: VCCI: Class A B Part 15
E-mail Address: Istrawn@transomamedical.com General Equipment Description NOTE: This information will be input into your test report as shown below. EUT Description Implantable Medical Device (IMD) EUT Name Sleuth Model No.: 2010 Serial No.: 001010 Product Options: Configurations to be tested: Transmitting at 916MHz Equipment Modification (If applicable, indicate modifications since EUT was last tested. If modifications are made during this testing, submit revised TP/CDF after testing is complete.) Modifications since last test: Modifications made during test: Stoic Please indicate the tests to be performed, entering the applicable standard(s) where noted. EMC Directive 89/336/EEC (EMC) FCC: Class A B Part 15 Std: VCCI: Class A B Part 15
General Equipment Description NOTE: This information will be input into your test report as shown below. EUT Description
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☐ EMC Directive 89/336/EEC (EMC) ☐ FCC: Class ☐ A ☐ B ☐ B
Std:
☐ Machinery Directive 89/392/EEC (EMC ☐ BSMI: Class ☐ A ☐ B
Std: Canada: Class A B
☐ Medical Device Directive 93/42/EEC (EMC) ☐ Australia: Class ☐ A ☐ B
Std: <u>IEC 60601-1-2</u> Other: Vehicle Directive 72/245/EEC (EMC)
Std:
FDA Reviewers Guidance for Premarket
Notification Submissions (EMC)
Third Party Certification, if applicable (*Signature on Page 6 Required)
Attestation of Conformity (AoC)* EMC Certification (used with Octagon Mark)*
☐ Certificate of Conformity (CoC)* ☐ Compliance Document* Protection Class (N/A for vehicles) ☐ Class I ☐ Class II ☐ Class III
(Press F1 when field is selected to show additional information on Protection Class.)
 ∑ FCC / TCB Certification



EMC Test Plan and Constructional Data Form

Attendance					
Test will be: Attended by the customer Unattended by the customer					
Failure - Complete this section if testing will not be attended by the customer.					
If a failure occurs, TÜV America should: Call contact listed above, if not available then stop testing. (After hrs phone): Continue testing to complete test series. Continue testing to define corrective action. Stop testing.					
EUT Specifications and Requirements					
Length: 39mm Width: 6.8mm Height: 41.05mm Weight: 16 g					
Power Requirements					
Regulations require testing to be performed at typical power ratings in the countries of intended use. (i.e., European power is typically 230 VAC 50 Hz or 400 VAC 50 Hz, single and three phase, respectively)					
Voltage: 3V DC Battery (If battery powered, make sure battery life is sufficient to complete testing.)					
# of Phases:					
Current (Amps/phase(max)): 8mA Current (Amps/phase(nominal)): 15uA					
Other					
Other Special Requirements					
Typical Installation and/or Operating Environment					
(ie. Hospital, Small Business, Industrial/Factory, etc.)					
The IMD is intended to be implanted in a human chest cavity					
EUT Power Cable					
☐ Permanent OR ☐ Removable Length (in meters):					



EMC Test Plan and Constructional Data Form

America

EUT Interfac	EUT Interface Ports and Cables													
			Du Te	ring est			(Shielding				sted rs)	ple	ent
Туре	Analog	Digital	Active	Passive	Qty	Yes	No	Туре	Termination	Connector Type	Port Termination	Length tested (in meters)	Removable	Permanent
EXAMPLE: RS232		×	×		2	×		Foil over braid	Coaxial	Metallized 9- pin D-Sub	Characteristic Impedance	6	×	
NA														



EMC Test Plan and Constructional Data Form

EUT Software.			
Revision Level:			
Description:			
2 ccc.,p.i.c			
Equipment Under Test (EUT) Oper It is recommended the equipment be tested w peripherals requires that a simple program ge firmware, and PLD algorithms used in the equ testing. Consult with your TÜV Product Service.	hile operating in a typical op nerate a complete line of up ipment. List all code module	eration mode. FCC testing per case H's. Provide a ger es as described above, with	of personal computers and/or neral description of all software,
The IMD will be tested trans	mitting data at 916MHz	<u>7</u> .	
	3		
2.			
3.			
Equipment Under Test (EUT) Systems For FCC & Taiwan testing a minimum configu	em Components Lis ration is required. (ie. Mouse	t and describe all compone e, Printer, Monitor, External	ents which are part of the EUT. Disk Drive, Motherboard, etc)
Description	Model #	Serial #	FCC ID#



EMC Test Plan and Constructional Data Form

Support Equi This information is	pment List s required for FC	and describe all support e	equipment which is not	part of the EUT. (i.e. peripherals, simulators, etc)
Description		Model #	Serial #	FCC ID #
Oscillator Fre	equencies			
Frequency	Derived Frequency	Component # / Lo	ocation	Description of Use
32.768kHz		Y1		ASIC Oscillator
Dawar Cumpl				
Power Supply	y Model i	# Serial #	Туре	
				ed-mode: (Frequency)
			☐ Switch	ed-mode: (Frequency) Other:
Power Line F	ilters			
Manufacturer		Model #	Location in l	EUT



EMC Test Plan and Constructional Data Form

America

Critical EMI Comp	onents (Capacitors, fer	rites, etc.)		
Description	Manufacturer	Part # or Value	Qty	Component # / Location
TVS Diode	Rohm	RSB6.8S	1	D1
	<u> </u>			
EMC Critical Deta	il Describe other EMC Desig	n details used to reduce hig	gh frequenc	y noise.
	"ELECTRONIC SIGNAT			
Authorization Sig	natures (Signature Requ	ured for Certification	ns check	ed on pg 1)
	prization to perform tests	Date		
according to this	s test plan.			
Test Plan/CDF	Prepared By (please print)	Date		

America

EMC Block Diagram Form

System Configuration Block Diagram Provide a lin cables, power cables, and any other pertinent components to be u in the testing field versus equipment outside testing field.	e drawing identifying the EUT, simulators, support equipment, I/O used during testing. Use a dashed line to separate the equipment
	IMD ransmitting at 916.5MHz)
Authorization Signatures	
Customer authorization to perform tests according to this test plan.	Date
Test Plan/CDF Prepared By (please print)	Date



Appendix B

Measurement Protocol



Tel: (651) 638-0297 Fax: (651) 638-0298 Rev. 092106

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MEASUREMENT PROTOCOL

GENERAL INFORMATION

Test Methodology

Emissions testing is performed according to the procedures in ANSI C63.4-2003.

Measurement Uncertainty

The test system for conducted emissions is defined as the LISN, tuned receiver or spectrum analyzer, and coaxial cable. The test system has a measurement uncertainty of ±1.8 dB. The test system for radiated emissions is defined as the antenna, the pre-amplifier, the spectrum analyzer and the coaxial cable. The test system has a measurement uncertainty of ±4.8 dB. The equipment comprising the test systems is calibrated on an annual basis.

Justification

The Equipment Under Test (EUT) is configured in a typical user arrangement in accordance with the manufacturer's instructions. A cable is connected to each available port and either terminated with a peripheral into its characteristic impedance or left unterminated. When appropriate, the cables are manually manipulated with respect to each other to obtain maximum emissions from the unit.

Conducted Emissions

The final level, in $dB\mu V$, equals the EMI receiver level plus the cable loss and LISN factor.

Radiated Emissions

The final level, in $dB\mu V/m$, equals the reading from the spectrum analyzer (Level $dB\mu V$), adding the antenna correction factor and cable loss factor (Factor dB) to it, and subtracting the preamp gain (and duty cycle correction factor, if applicable). This result then has the limit subtracted from it to provide the Delta, which gives the tabular data as shown in the data sheets in Attachment A.

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Exan	nnl	^.
	IUI	E.

FREQ (MHz)	LEVEL (dBuV)	CABLE/ANT/PREAMP (dB) (dB/m) (dB)	FINAL (dBuV/m)	POL/HGT/AZ (m) (deg)	DELTA1
60.80	42.5Qp +	1.2 + 10.9 - 25.5 =	29.1	V 1.0 0.0	-10.9

Test Equipment

All measurement instrumentation is traceable to the National Institute of Standards and Technology and is calibrated according to internal procedure.

Appendix B

Tel: (651) 638-0297 Fax: (651) 638-0298 Rev. 092106

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