Guidant Corporation MN

Zoom 2920

July 29, 2004

Report No. GDMN0003

Report Prepared By:



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

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Certificate of Test

Issue Date: July 29, 2004 Guidant Corporation MN

Model: Zoom 2920

	Emissions		
Specification	Test Method	Pass	Fail
FCC 15.209:2003	ANSI C63.4:2001 Fundamental Field Strength	\boxtimes	
FCC 15.209:2003	ANSI C63.4:2001 Radiated Spurious Emissions	\boxtimes	
FCC 15.207:2003	ANSI C63.4:2001 Conducted Emissions	\square	

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

Approved By:
Lonald Matheteau
Don Facteau, IS 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, 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. Accreditation has been granted to Northwest EMC, Inc. under Certificate Numbers: 200629-0, 200630-0, and 200676-0.

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















Accreditations and Authorizations

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. TUV Rheinland **NEMKO:** Assessed and accredited by NEMKO (Norwegian testing and certification body) for European emissions and immunity testing. As a result of NEMKO's laboratory NEMKO 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 Nos. -Evergreen: C-1071 and R-1025, Trails End: 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 (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: <u>http://www.nwemc.com/scope.asp</u>



What is measurement uncertainty?

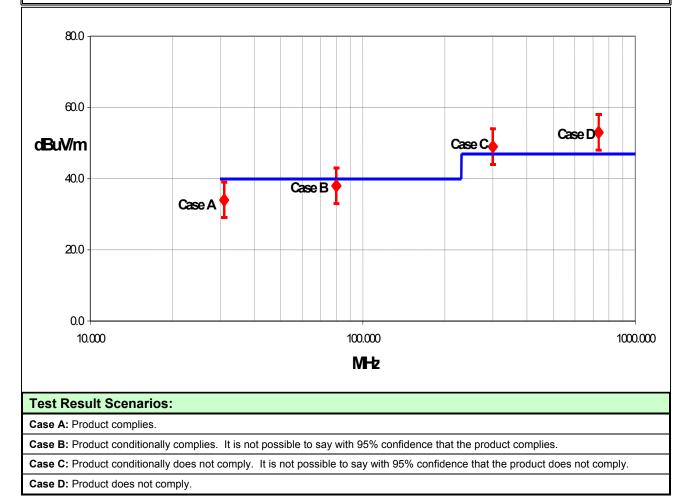
When a measurement is made, the result will be different from the true or theoretically correct value. The difference is the result of tolerances in the measurement system that cannot be completely eliminated. To the extent that technology allows us, it has been our aim to minimize this error. The following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





Radiated Emissions ≤ 1 GHz		Value (dB)				
	Probability	Bico	nical	Log Po	eriodic	D	ipole
	Distribution	Ante	enna	Ante	enna	An	tenna
Test Distance		3m	10m	3m	10m	3m	10m
Combined standard	normal	+ 1.86	+ 1.82	+ 2.23	+ 1.29	+ 1.31	+ 1.25
uncertainty <i>u_c(y)</i>		- 1.88	- 1.87	- 1.41	- 1.26	- 1.27	- 1.25
Expanded uncertainty U	normal (k=2)	+ 3.72	+ 3.64	+ 4.46	+ 2.59	+ 2.61	+ 2.49
(level of confidence $\approx 95\%$)		- 3.77	- 3.73	-2.81	- 2.52	- 2.55	- 2.49

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

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

Radiated Immunity		
	Probability	Value
	Distribution	(+/- dB)
Combined standard uncertainty <i>uc(y)</i>	normal	1.05
Expanded uncertainty <i>U</i>	normal (k = 2)	2.11
(level of confidence \approx 95 %)	$\operatorname{Horman}(K=Z)$	2.11

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

Legend

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

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



Facilities









California

Orange County Facility

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

Oregon

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

Oregon

 Trails End Facility

 30475 NE Trails End Lane

 Newberg, OR 97132

 (503) 844-4066

 FAX (503) 537-0735

Washington

Sultan Facility

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

Party Requesting the Test	
Company Name:	Guidant Corporation MN
Address:	4100 Hamline Avenue North
City, State, Zip:	Saint Paul, MN 55112-5798
Test Requested By:	Yogi Shah
Model:	Zoom 2920
First Date of Test:	07-15-04
Last Date of Test:	07-28-04
Receipt Date of Samples:	06-30-04
Equipment Design Stage:	Production
Equipment Condition:	No visual damage.

Information Provided by the Party Requesting the Test

Clocks/Oscillators:	41 kHz, 40MHz, 33.3MHz, 100MHz, 66.6MHz, 4.1MHz, 41.667MHz, 6MHz, 32.768kHz, 14.318MHz, 16.67MHz, 24MHz, 25MHz, 48MHz, 16MHz, 10MHz, 210.38MHz, 833.52MHz, 13MHz
I/O Ports:	Telemetry Wand

Functional Description of the EUT (Equipment Under Test):

The ZOOM® LATITUDE[™] Programming System, which includes the Model 2920 Programmer/Recorder/Monitor (PRM), is a portable cardiac rhythm management system designed to be used with certain models of Guidant implantable pulse generators. It is a telemetry system operating under 15.209 using the telemetry. The Model 2920 PRM is designed to be used only with the Model 6577 Sterilizable Telemetry Wand. The Model 2920 is provided with only one available antenna to meet the unique antenna requirements of 47 CFR 15.203.

Client Justification for EUT Selection:

The product is a representative production sample.

Client Justification for Test Selection:

Tests required to meet the FCC requirements for approval.



	Equipment modifications					
Item	Test	Date	Modification	Note	Disposition of EUT	
1	Conducted Emissions	07/15/2004	No EMI suppression devices were added or modified during this test.	Same configuration as delivered.	EUT remained at Northwest EMC.	
2	Radiated Emissions	07/28/2004	No EMI suppression devices were added or modified during this test.	Same configuration as in previous test.	EUT remained at Northwest EMC.	



Justification

The individuals and/or the organization requesting the test provided the modes, configurations and settings available to evaluate. All of the EUT parameters listed below were investigated. This includes, but may not be limited to, CPU speeds, video resolution settings, operational modes, and input voltages.

Operating Modes Investigated:

Typical operating mode

Power Input Settings Investigated:

120 VAC, 60 Hz

Software\Firmware Applied During Test						
Exercise Software	Product 2909 System Software	Varaian	Version 4.1			
Exercise Software	Quick Start Version Version 1.38					
Description						
The system was tested using standard operating production software to exercise the functions of the device during the testing.						

EUT and Peripherals in Test Setup Boundary								
Description	Manufacturer	Model/Part Number	Serial Number					
Programmer	Guidant	2920	022394					
Pulse Generator	Guidant	Vitality AVT	106433					
Pulse Generator	Guidant	Renewal TR	100088					
Pulse Generator	Guidant	Insignia I Plus	104568					
Loop Sensor	Guidant	6577	none					

Cables								
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2			
AC Power	No	2.3	No	Programmer	AC Mains			
Loop Sensor	PA	3.0	PA	Loop Sensor	Programmer			
Vitality Patient Leads	PA	0.5	PA	Vitality AVT	Termination			
Renewal Patient Leads	PA	0.5	PA	Renewal TR	Termination			
Insignia Patient Leads	PA	0.1	PA	Insignial I Plus	Termination			
PA = Cable is permanen	PA = Cable is permanently attached to the device. Shielding and/or presence of ferrite may be unknown.							

Measurement Equipment								
Description	Manufacturer	Model	Identifier	Last Cal	Interval			
LISN	Solar	9252-50-24-BNC	LIA	12/16/2003	13 mo			
LISN	Solar	9252-50-R-24-BNC	LIQ	12/17/2003	13 mo			
Spectrum Analyzer	Hewlett Packard	8593E	AAP	03/22/2004	13 mo			
Receiver	Schaffner	SCR 3101	ARC	04/28/2003	24 mo			

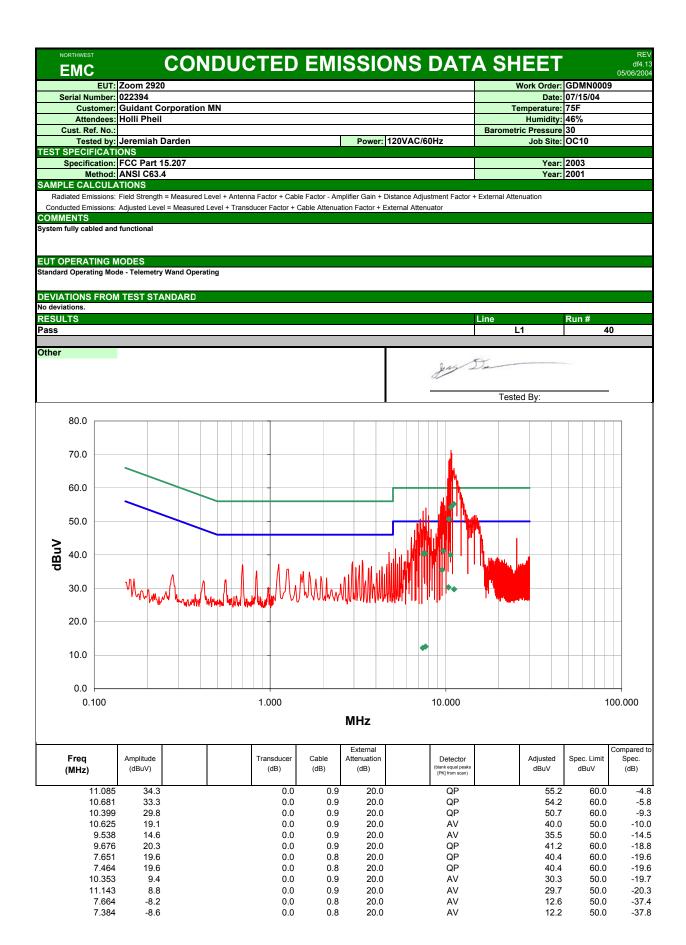


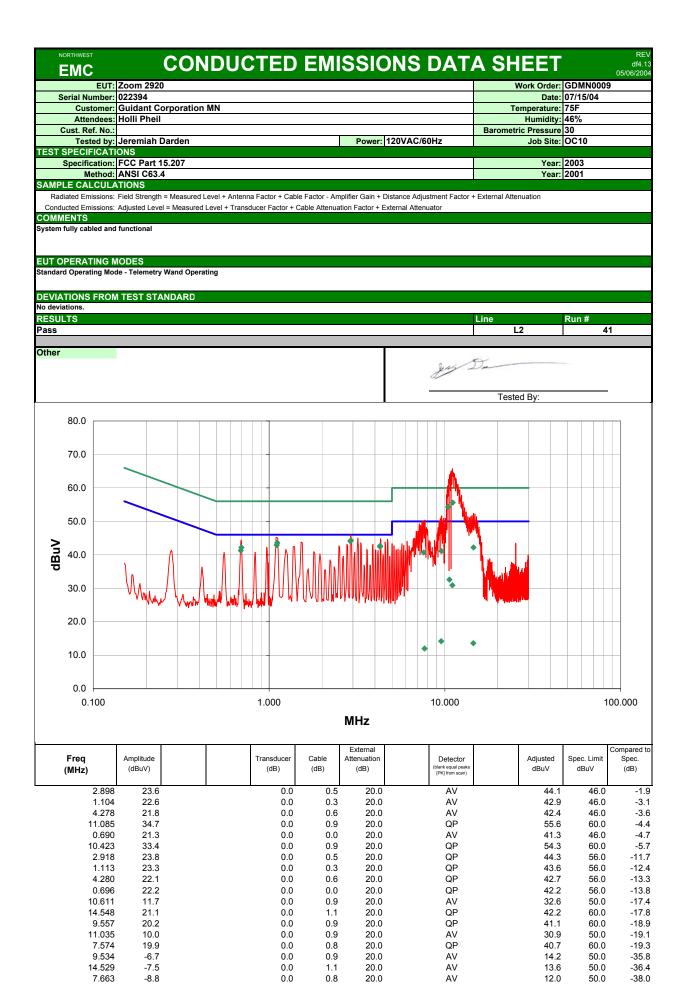
Test Description

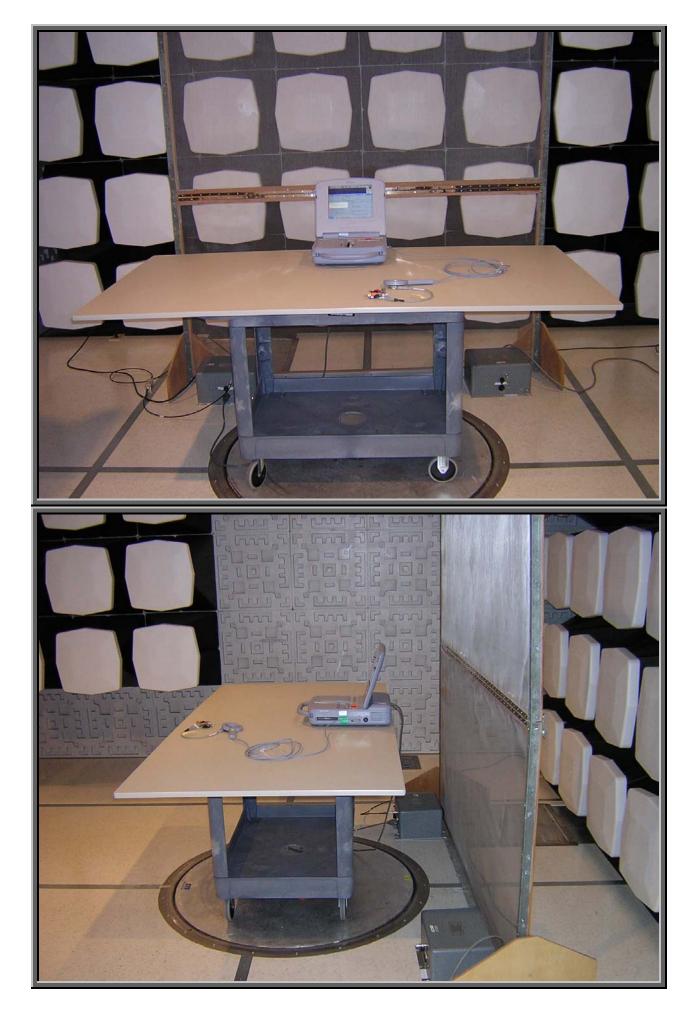
Using the mode of operation and configuration noted within this report, conducted emissions tests were performed. The frequency range investigated (scanned), is also noted in this report. Conducted power line measurements are made, unless otherwise specified, over the frequency range from 150 kHz to 30 MHz to determine the line-to-ground radio-noise voltage that is conducted from the EUT power-input terminals that are directly (or indirectly via separate transformer or power supplies) connected to a public power network. Equipment is tested with power cords that are normally used or that have electrical or shielding characteristics that are the same as those cords normally used. Typically those measurements are made using a LISN (Line Impedance Stabilization Network), the 50 Ω measuring port is terminated by 30 Ω .

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

Completed by:	
Q.B.	









Field Strength of Fundamental and Spurious Radiated Emissions

Justification

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

Channels in Specified Band Investigated: Single

Operating Modes Investigated: Typical

Data Rates Investigated:

Maximum

Output Power Setting(s) Investigated: Maximum

Power Input Settings Investigated: 120 VAC, 60 Hz.

Frequency Range Investigated								
Start Frequency	10 kHz	Stop Frequency	30 MHz					

Software\Firmware Applied During Test							
Exercise Software	Version	Version 4.1 Version 1.38					
Description							
The system was tested using standard operating production software to exercise the functions of the device during the testing.							

EUT and Peripherals									
Description	Manufacturer	Model/Part Number	Serial Number						
Programmer	Guidant	2920	022394						
Pulse Generator	Guidant	Vitality AVT	106433						
Pulse Generator	Guidant	Renewal TR	100088						
Pulse Generator	Guidant	Insignia I Plus	104568						
Loop Sensor	Guidant	6577	none						



Cables							
Cable Type	Shield	Length (m)	Ferrite	Connection 1	Connection 2		
AC Power	No	2.3	No	Programmer	AC Mains		
Loop Sensor	PA	3.0	PA	Loop Sensor	Programmer		
Vitality Patient Leads	PA	0.5	PA	Vitality AVT	Termination		
Renewal Patient Leads	PA	0.5	PA	Renewal TR	Termination		
Insignia Patient Leads	PA	0.1	PA	Insignial I Plus	Termination		
PA = Cable is permanently attached to the device. Shielding and/or presence of ferrite may be unknown.							

Measurement Equipment									
Description	Manufacturer	Model	Identifier	Last Cal	Interval				
Quasi-Peak Adapter	Hewlett-Packard	85650A	AQD	02/10/2004	13 mo				
Spectrum Analyzer	Hewlett-Packard	8568B	AAI	02/10/2004	13 mo				
Antenna, Loop	EMCO	6502	AOA	01/08/2002	36 mo				

Test Description

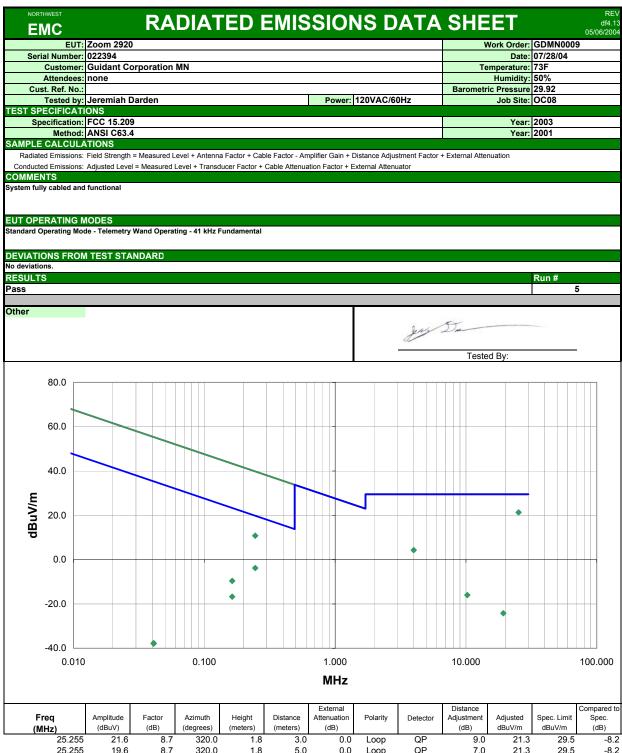
Requirement: No portion of the transmitted carrier, including sidebands and modulation products may lie within any of the restricted bands of 15.205. In addition, no spurious emission level may be higher than the level of the fundamental frequency. All emissions must meet the specification limits of 15.209. Emissions in the 9 kHz – 90 kHz and 110 – 490 kHz range are measured using an average detector for comparison to the limit. Peak emission limiting specified in 15.35 also applies for average measurements, with the limit for peak emissions 20 dB higher than the average limit.

The level of any unwanted emissions from an intentional radiator operating under these general provisions shall not exceed the level of the fundamental emission. For intentional radiators which operate under the provisions of other sections within this part and which are required to reduce their unwanted emissions to the limits specified in this table, the limits in this table are based on the frequency of the unwanted emission and not the fundamental frequency. However, the level of any unwanted emissions shall not exceed the level of the fundamental frequency. Please note, the 3-meter average data demonstrates compliance with this requirement.

Configuration: The EUT was configured for typical operation, transmitting continuously with modulation at its single operating frequency. Emissions were maximized by rotating the turntable and varying the height of the measurement antenna. The position of the loop sensor, loop sensor cables, and pulse generators were also varied in three orthogonal axis (per ANSI C63.4: 2001) to maximize the level of emissions.

The emissions from the EUT were found compliant with all the requirements of FCC 15C.

Completed by:
ADJU.K.P



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25.255	21.6	8.7	320.0	1.8	3.0	0.0	Loop	QP	9.0	21.3	29.5	-8.2
25.255	19.6	8.7	320.0	1.8	5.0	0.0	Loop	QP	7.0	21.3	29.5	-8.2
0.245	35.7	10.3	180.0	1.8	3.0	0.0	Loop	AV	35.2	10.8	19.8	-9.0
0.245	31.8	10.3	181.0	1.8	5.0	0.0	Loop	AV	31.3	10.8	19.8	-9.0
3.988	16.5	10.3	360.0	1.8	3.0	0.0	Loop	QP	22.5	4.3	29.5	-25.2
3.988	11.5	10.3	360.0	1.8	5.0	0.0	Loop	QP	17.5	4.3	29.5	-25.2
0.163	36.1	10.4	184.0	1.8	5.0	0.0	Loop	AV	56.1	-9.6	23.3	-32.9
0.163	43.1	10.4	183.0	1.8	3.0	0.0	Loop	AV	63.1	-9.6	23.4	-33.0
0.245	40.4	10.3	181.0	1.8	5.0	0.0	Loop	PK	54.5	-3.8	39.8	-43.6
0.245	47.2	10.3	180.0	1.8	3.0	0.0	Loop	PK	61.3	-3.8	39.8	-43.6
10.236	19.6	10.4	0.0	1.8	3.0	0.0	Loop	QP	46.0	-16.0	29.5	-45.5
10.236	9.4	10.4	360.0	1.8	5.0	0.0	Loop	QP	35.8	-16.0	29.5	-45.5
19.304	19.5	9.9	-1.0	1.8	3.0	0.0	Loop	QP	53.6	-24.2	29.5	-53.7
19.304	7.6	9.9	360.0	1.8	5.0	0.0	Loop	QP	41.7	-24.2	29.5	-53.7
0.163	45.0	10.4	184.0	1.8	5.0	0.0	Loop	PK	72.1	-16.7	43.3	-60.0
0.163	54.0	10.4	183.0	1.8	3.0	0.0	Loop	PK	81.1	-16.7	43.4	-60.1
0.041	32.9	11.8	83.0	1.8	5.0	0.0	Loop	AV	82.6	-37.9	35.3	-73.2
0.041	43.2	11.8	82.0	1.8	3.0	0.0	Loop	AV	92.9	-37.9	35.3	-73.2
0.041	40.3	11.8	83.0	1.7	5.0	0.0	Loop	PK	89.8	-37.7	55.3	-93.0
0.041	51.5	11.8	82.0	1.8	3.0	0.0	Loop	PK	101.0	-37.7	55.3	-93.0

Distance Adjustment Factor for Radiated Emissions below 30 MHz

Method: Per 47 CFR 15.31(f)(2), the data was extrapolated based upon a the measured fall-off (at each frequency / polarity).

 EUT:
 2920

 S/N:
 30265

 Date:
 7/28/2004

 Job Number:
 GDMN0003

Frequency	Loop Antenna Polarity	Detector	Test Distance	Measured Level	Fall-Off from 3 to 5 m	Extrapolation Factor for Specification Limit	Test Distance of Spec. Limit	Distance Adjustment Factor
(MHz)			(meters)	(dBuV/m)	(dB)	(dB / decade)	(meters)	(dB)
0.041	Worst Case	AV	3	43.2	10.3	46.4	300.0	92.9
0.011	Worldt Gubb	,	5	32.9	10.0	10.1	000.0	82.6
0.041	Worst Case	PK	3	51.5	11.2	50.5	300.0	101.0
			5	40.3 43.1				89.8 63.1
0.163	Worst Case	AV	5	36.1	7.0	31.6	300.0	56.1
		514	3	54.0		10.0		81.1
0.163	Worst Case	PK	5	45.0	9.0	40.6	300.0	72.1
0.245	Worst Case	AV	3	35.7	3.9	17.6	300.0	35.2
			5	31.8				31.3
0.245	Worst Case	PK	3	47.2	6.8	30.7	300.0	61.3
			5	40.4				54.5
3.988	Worst Case	QP	3	16.5	5.0	22.5	30.0	22.5
			5	11.5 19.6				17.5
10.236	Worst Case	QP	5	9.4	10.2	46.0	30.0	46.0 35.8
19.304	Worst Case	QP	3	19.5	11.9	53.6	30.0	53.6
			5	7.6				41.7
25.255	Worst Case	QP	3	21.6	2.0	9.0	30.0	9.0
20.200	WOISt Case	QI	5	19.6	2.0	5.0	50.0	7.0
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