

FCC CFR47 PART 95H REQUIREMENT

CLASS II PERMISSIVE CHANGE TEST REPORT

FOR

MEDICAL TELEMETRY TRANSMITTER

MODEL: ZM-541PA

FCC ID: B6BZM-541PA

REPORT NUMBER: 31KE0333-HO-A

ISSUE DATE: JULY 11, 2011

Prepared for NIHON KOHDEN CORPORATION 1-31-4, NISHIOCHIAI SHINJUKU-KU TOKYO 161-8560, JAPAN

Prepared by
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http://www.ul.com/japan/jpn/pages/services/emc/about/mark1/index.jsp#nvlap

Revision History

Rev.	Issue Date	Revisions	Revised By
	07/11/11	Initial Issue	T. Hatakeda

DATE: JULY 11, 2011

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REPORT NO: 31KE0333-HO

EUT: MEDICAL TELEMETRY TRANSMITTER

DATE: JULY 11, 2011
FCC ID: B6BZM-541PA

1. ATTESTATION OF TEST RESULTS

COMPANY NAME: NIHON KOHDEN CORPORATION

1-31-4, NISHIOCHIAI SHINJUKU-KU

TOKYO 161-8560, JAPAN

EUT DESCRIPTION: MEDICAL TELEMETRY TRANSMITTER

MODEL: ZM-541PA

SERIAL NUMBER: 00381

DATE TESTED: JULY 1 – 3, 2011

APPLICABLE STANDARDS

STANDARD TEST RESULTS

FCC PART 95 SUBPART H Pass

UL Japan, Inc. tested the above equipment in accordance with the requirements set forth in the above standards. All indications of Pass/Fail in this report are opinions expressed by UL Japan, Inc. based on interpretations and/or observations of test results. Measurement Uncertainties were not taken into account and are published for informational purposes only. The test results show that the equipment tested is capable of demonstrating compliance with the requirements as documented in this report.

Note: The results documented in this report apply only to the tested sample, under the conditions and modes of operation as described herein. This document may not be altered or revised in any way unless done so by UL Japan, Inc. and all revisions are duly noted in the revisions section. Any alteration of this document not carried out by UL Japan, Inc. will constitute fraud and shall nullify the document. This report must not be used by the client to claim product certification, approval, or endorsement by NVLAP, NIST, any agency of the Federal Government, or any agency of any government.

Approved & Released For UL Japan, Inc. By: Tested By:

TAKAHIRO HATAKEDA

Leader of WiSE Japan UL Verification Services

UL Japan, Inc.

KATSÚNORI OKAI

Engineer of WiSE Japan UL Verification Services

UL Japan, Inc.

2. TEST METHODOLOGY

The tests documented in this report were performed in accordance with ANSI/TIA-603-C-2004, FCC CFR 47 Part 2 and FCC CFR 47 Part 95.

3. FACILITIES AND ACCREDITATION

The test sites and measurement facilities used to collect data are located at 4383-326 Asamacho, Ise-shi, Mie-ken 516-0021 JAPAN.

UL Japan, Inc. is accredited by NVLAP, Laboratory Code 200572-0 The full scope of accreditation can be viewed at http://www.ul.com/japan/jpn/pages/services/emc/about/mark1/index.jsp#nvlap

4. CALIBRATION AND UNCERTAINTY

4.1. MEASURING INSTRUMENT CALIBRATION

The measuring equipment utilized to perform the tests documented in this report has been calibrated in accordance with the manufacturer's recommendations, and is traceable to recognized national standards.

4.2. SAMPLE CALCULATION

Where relevant, the following sample calculation is provided:

Field Strength (dBuV/m) = Measured Voltage (dBuV) + Antenna Factor (dB/m) + Cable Loss (dB) – Preamp Gain (dB) 36.5 dBuV + 18.7 dB/m + 0.6 dB – 26.9 dB = 28.9 dBuV/m

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4.3. MEASUREMENT UNCERTAINTY

Where relevant, the following measurement uncertainty levels have been estimated for tests performed on the apparatus:

The following uncertainties have been calculated to provide a confidence level of 95% using a coverage factor k=2.

Test room	Radiated emission						
(semi-		(3m*)(<u>+</u> dB)			(1m*)(<u>+</u> dB)		(0.5m*)(<u>+</u> dB)
anechoic chamber)	9kHz -30MHz	30MHz -	300MHz -1GHz	1GHz -10GHz	10GHz -18GHz	18GHz -26.5GHz	26.5GHz -40GHz
		300MHz					
No.1	3.5dB	5.1dB	5.2dB	4.8dB	5.1dB	4.4dB	4.3dB
No.2	4.0dB	5.1dB	5.2dB	4.8dB	5.0dB	4.3dB	4.2dB
No.3	4.2dB	4.7dB	5.2dB	4.8dB	5.0dB	4.5dB	4.2dB
No.4	4.0dB	5.0dB	5.1dB	4.8dB	5.0dB	5.1dB	4.2dB

^{*3}m/1m/0.5m = Measurement distance

Power meter (+dB)				
Below 1GHz Above 1GHz				
1.0dB	1.0dB			

Antenna terminal conducted emission and Power density (<u>+</u> dB)			Antenna termi emis (+0	Channel power (<u>+</u> dB)	
Below 1GHz	1GHz-3GHz	3GHz- 18GHz	18GHz-26.5GHz	26.5GHz-40GHz	
1.0dB	1.1dB	2.7dB	3.2dB	3.3dB	1.5dB

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5. EQUIPMENT UNDER TEST

5.1. DESCRIPTION OF EUT

a). Type of EUT: WMTS TRANSMITTER
b). Brand Name: NIHON KOHDEN
c). Model No: ZM-541PA

d). FCC ID: B6BZM-541PA e). Battery Type: Three AA (R6)

f). Channel Number: 1395.0250 MHz (channel number E002) to

1399.9750 MHz (channel number E398), and 1427.0250 MHz (channel number E502) to 1431.9750 MHz (channel number E898)

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g). Frequency Range: 1395.025-1399.975 MHz and

1427.025-1431.975 MHz bands

h). RF Conducted Output Power: 5mW (factory default setting) or 1mW

i). Channel Spacing: 50 KHz or 37.5 kHz (12.5 KHz when interleave)

j). Modulation Frequency Shift Keying

k). Type of Modulation: F1D
l). Occupied Bandwidth <20 kHz
m). Antenna Type: Internal

5.2. DESCRIPTION OF CLASS II PERMISSIVE CHANGE

The major change filed under this application is to substitute PLL from the original filing. The substituted PLL is pin for pin compatible, and the same basic function as the original PLL. There is no change in radio frequency, RF output power, radio frequency circuitry, Antenna, PCB and functional capabilities.

5.3. MAXIMUM OUTPUT POWER

The test measurement passed within \pm 0.5dB of the original output power.

5.4. DESCRIPTION OF AVAILABLE ANTENNAS

The radio utilizes a Helical Monopole antenna, with a maximum gain of 0 dBi.

5.5. SOFTWARE AND FIRMWARE

The test utility software used during testing was Channel Writer, rev. 02-04. The test utility firmware used during testing was EUT, ver. 01-08.

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5.6. WORST-CASE CONFIGURATION AND MODE

The worst-case channel is determined as the channel with the highest output power.

During emission tests the antenna orientations as X, Y, and Z were investigated to determine the worst-case. The outcome showed that Z-orientation for Horizontal and Y-orientation for Vertical as the worst-case.

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5.7. DESCRIPTION OF TEST SETUP

SUPPORT EQUIPMENT

PERIPHERAL SUPPORT EQUIPMENT LIST						
Description	Manufacturer	Model	Serial Number	FCC ID		
Laptop	Lenovo	7661-CB9	L3R2056	DoC		
AC/DC Adaptor	Lenovo	92P1160	11S92P1160Z1ZBGH7B99A8	DoC		
Channel Writer	Nihon Kohden	QI-901PK	00349	N/A		

I/O CABLES

	I/O CABLE LIST						
Cable No.	Port	# of Identica Ports	Connector Type	Cable Type	Cable Length	Remarks	
1	AC	1	US120V	Un-shielded	1.0m	N/A	
2	DC	1	DC	Un-shielded	1.8m	Ferrite on laptop's end	
3	USB	1	USB	Shielded	1.8m	No	
4	ECG	1	ECG	Un-shielded	0.3m	No	
5	ECG	1	ECG	Un-shielded	0.7 / 0.9 m	N/A	
6	Sp02	1	Sp02	Un-shielded	1.6 m	Probe	
7	NIBP	1	NIBP socket	Rubber	0.3m	Connect Arm Cuff	

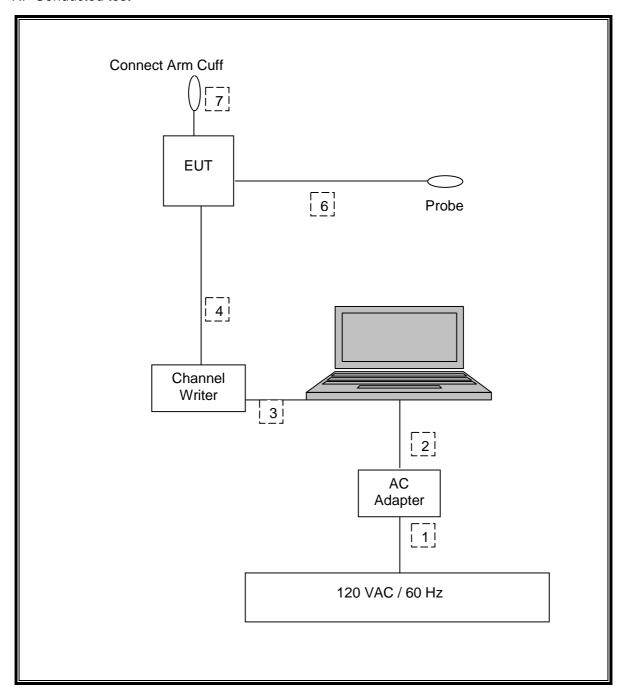
TEST SETUP

The EUT is standalone unit and just use a host laptop computer to configure the mode during the tests. Test software exercised the radio card.

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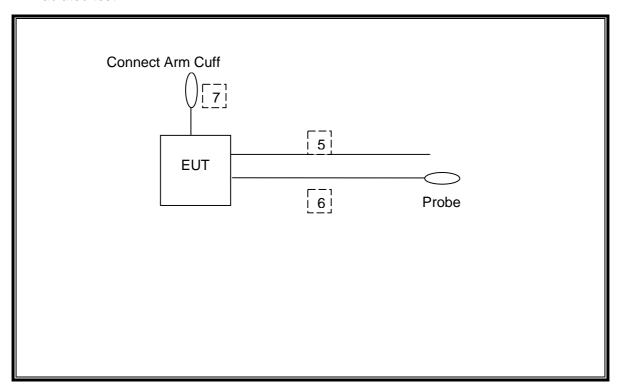
SETUP DIAGRAM FOR TESTS

RF Conducted test



SETUP DIAGRAM FOR TESTS

RF Radiated test



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6. TEST AND MEASUREMENT EQUIPMENT

The following test and measurement equipment was utilized for the tests documented in this report:

Control No.	Instrument	Manufacturer	Model No	Serial No	Calibration Date * Interval(month)
MAEC-04	Semi Anechoic Chamber(NSA)	TDK	Semi Anechoic Chamber 3m	DA-10005	2011/03/01 * 12
MOS-15	Thermo-Hygrometer	Custom	CTH-180	-	2011/02/23 * 12
MJM-07	Measure	PROMART	SEN1955	-	-
COTS-MEMI	EMI measurement program	TSJ	TEPTO-DV	-	-
MSA-10	Spectrum Analyzer	Agilent	E4448A	MY46180655	2011/02/15 * 12
MTR-03	Test Receiver	Rohde & Schwarz	ESCI	100300	2011/04/15 * 12
MBA-05	Biconical Antenna	Schwarzbeck	BBA9106	1302	2010/10/11 * 12
MLA-08	Logperiodic Antenna	Schwarzbeck	UKLP9140-A	N/A	2010/10/11 * 12
MCC-50	Coaxial Cable	UL Japan	-	-	2011/03/25 * 12
MAT-51	Attenuator(6dB)	Weinschel	2	AS3557	2011/01/14 * 12
MPA-14	Pre Amplifier	SONOMA INSTRUMENT	310	260833	2011/03/04 * 12
MHA-21	Horn Antenna 1- 18GHz	Schwarzbeck	BBHA9120D	9120D-557	2010/08/08 * 12
MCC-56	Microwave Cable	Suhner	SUCOFLEX104	270875/4(1m) / 284655(5m)	2011/03/02 * 12
MPA-12	MicroWave System Amplifier	Agilent	83017A	MY39500780	2011/03/10 * 12
MBF-09	Band Pass Filter	M-City	BPF4250-01	UL0004	2011/05/23 * 12
MHF-06	High Pass Filter 3.5- 24GHz	TOKIMEC	TF323DCA	601	2011/05/16 * 12
MPM-12	Power Meter	Anritsu	ML2495A	0825002	2010/08/20 * 12
MPSE-17	Power sensor	Anritsu	MA2411B	0738285	2010/08/20 * 12
MAT-23	Attenuator(10dB) 1- 18GHz	Orient Microwave	BX10-0476-00	-	2011/03/14 * 12
MCC-114	Microwave Cable 1G-26.5GHz	Suhner	SUCOFLEX104	290212/4	2010/08/05 * 12

The expiration date of the calibration is the end of the expired month.

All equipment is calibrated with valid calibrations. Each measurement data is traceable to the national or international standards.

As for some calibrations performed after the tested dates, those test equipment have been controlled by means of an unbroken chains of calibrations.

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7. ANTENNA PORT TEST RESULTS

7.1. 26 dB AND 99% BW

LIMITS

§2.1049, for reporting purposes only, also the 26dB bandwidth shall be less than 20 KHz (F1D).

TEST PROCEDURE

ANSI C63.4

The transmitter output is connected to the spectrum analyzer.

26dB Bandwidth: The RBW is set to 1% to 3% of the 26dB bandwidth. The VBW is set to 3 times the RBW. The sweep time is coupled. The spectrum analyzer internal 26dB bandwidth function is utilized.

99% Bandwidth: The RBW is set to 1% to 3% of the 99 % bandwidth. The VBW is set to 3 times the RBW. The sweep time is coupled. The spectrum analyzer internal 99% bandwidth function is utilized.

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RESULTS

26dB Bandwidth

Channel	Frequency	26dB Bandwidth
	(MHz)	(kHz)
E002	1395.025	18.097
E398	1399.975	18.249
E502	1427.025	18.791
E898	1431.975	18.869

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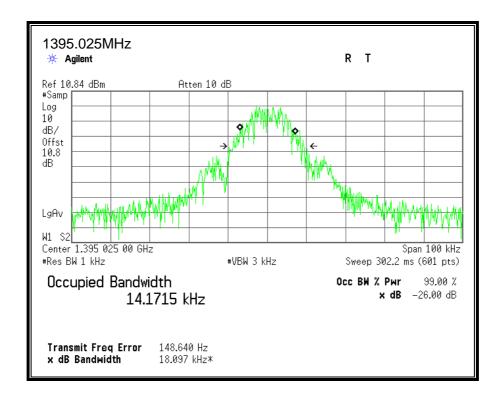
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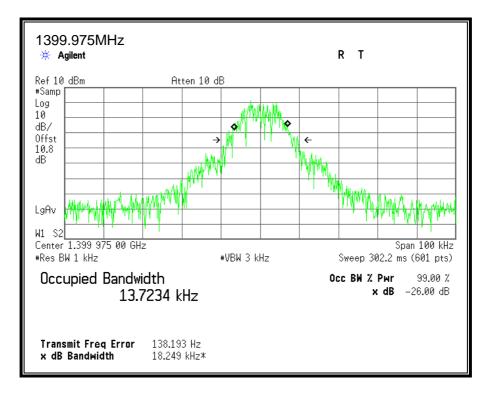
99% Bandwidth

Channel	Frequency	99% Bandwidth
	(MHz)	(kHz)
E002	1395.025	14.172
E398	1399.975	13.723
E502	1427.025	13.828
E898	1431.975	13.972

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20dB and 99% BANDWIDTH



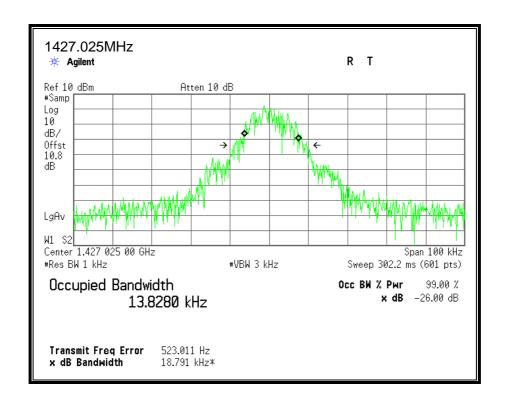


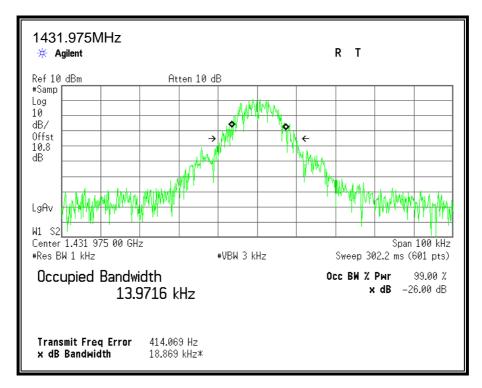
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7.2. PEAK OUTPUT POWER

LIMITS

§2.1046, for reporting purposes only.

TEST PROCEDURE

The transmitter output is connected to a power meter.

RESULTS

The cable assembly insertion loss of 10.85 dB (including 10.07dB pad & 0.78dB cable loss) was entered as an offset in the power meter to allow for direct reading of power.

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Channel	Frequency Output	
		Power
	(MHz)	(dBm)
E002	1395.025	6.38
E398	1399.975	6.70
E502	1427.025	6.87
E898	1431.975	6.88

7.3. AVERAGE POWER

LIMITS

None; for reporting purposes only.

TEST PROCEDURE

The transmitter output is connected to a power meter.

RESULTS

The cable assembly insertion loss of 10.85 dB (including 10.07dB pad & 0.78dB cable loss) was entered as an offset in the power meter to allow for direct reading of power.

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Channel	Frequency	Output
		Power
	(MHz)	(dBm)
E002	1395.025	6.11
E398	1399.975	6.45
E502	1427.025	6.68
E898	1431.975	6.72

7.4. FREQUENCY STABILITY MEASUREMENT

LIMIT

§95.1115 (e) Frequency stability.

Manufacturers of wireless medical telemetry devices are responsible for ensuring frequency stability such that an emission is maintained within the band of operation under all of the manufacturer's specified conditions.

TEST PROCEDURE

Frequency stability versus environmental temperature

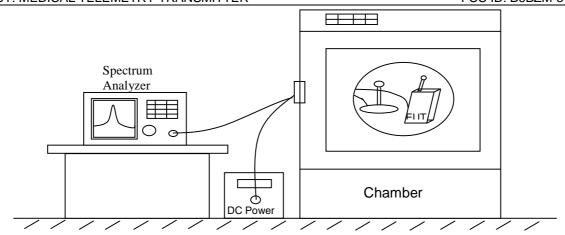
- 1) Set the temperature of chamber to 25°C @ low/high channel. Allow sufficient time (approximately 30 min) for the temperature of the chamber to stabilize. While maintaining a constant temperature inside the chamber, turn the EUT on and measure the EUT operating frequency.
- 2) Set SA Resolution Bandwidth to 300 Hz and Video Resolution Bandwidth to 300 Hz and Frequency Span to 20 KHz. Record this frequency as reference frequency.
- 3) Repeat step 2 with a 10°C decreased per stage until the lowest temperature -30°C is measured, record all measured frequencies on each temperature step.
- 3) Repeat step 2 with a 10°C increased per stage until the highest temperature +50°C is measured; record all measured frequencies on each temperature step.

Frequency stability versus input voltage

- 1). Setup the configuration as shown below for frequencies measured at temperature if it is 25°C.
- 2). Set SA center frequency to the EUT radiated frequency. Set SA Resolution Bandwidth to 300 Hz and Video Resolution Bandwidth to 300 Hz and Frequency Span to 20 KHz. Record this frequency as reference frequency.
- 3). For battery operated only device, supply the EUT primary voltage at the operating end point which is specified by manufacturer and record the frequency.

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Frequency stability measurement configuration

TEST RESULTS

LOW CHANNEL

20°C Re	eference Fr	equency:	1395.02	MHz		
Limit: +/-	2.5	ppm =	0.003	488	MHz	
Power Supply		Environment	Frequency		Limit	
VDC		Temperature	/MH~)	Delta (MHz)		
		(°C)	(MHz)		+/- (MHz)	
	Normal (100%)	50	1395.025283	0.000283	0.003488	
		40	1395.025275	0.000275	0.003488	
		30	1395.025240	0.000240	0.003488	
		20	1395.025213	0.000213	0.003488	
4.50			10	1395.025191	0.000191	0.003488
		0	1395.025001	0.000001	0.003488	
		-10	1395.024850	-0.000150	0.003488	
		-20	1395.024810	-0.000190	0.003488	
		-30	1395.024684	-0.000316	0.003488	
4.50	N	ormal	1395.025213	0.000213	0.003488	
1.00		Low	1395.025241	0.000241	0.003488	
0.90			End Point			

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20°C F	Referenc	e Frequency:	1431.97	MHz			
Limit: +/-	2.5	ppm =	0.003	MHz			
Power	Supply	Environment	Frequency	Delta	Limit		
VDC		Temperature (°C)	(MHz)	(MHz)	+/- (MHz)		
		50	1431.975344	0.000344	0.003580		
	Normal (100%)	40	1431.975392 0.000392		0.003580		
		30 1431.975326 0.000326		0.000326	0.003580		
		20	1431.975235	0.000235	0.003580		
4.50		10	1431.975398	0.000398	0.003580		
		0	1431.975219	0.000219	0.003580		
		-10	1431.975002	0.000002	0.003580		
		-20	1431.975002	0.000002	0.003580		
		-30	1431.974905	-0.000095	0.003580		
4.50		Normal	1431.975235 0.00023		0.003580		
1.00		Low	1431.975239	0.000239	0.003580		
0.90	End Point						

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8. RADIATED EMISSION TEST RESULTS

LIMITS

§95.1115

- (a) Field strength limits
- (2) In the 1395–1400 MHz and 1427–1432 MHz bands, the maximum allowable field strength is 740 mV/m as measured at a distance of 3 meters, using measuring equipment with an averaging detector and a 1 MHz measurement bandwidth.

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- (b) Undesired emissions.
- (1) Out-of-band emissions below 960 MHz are limited to 200 microvolts/meter, as measured at a distance of 3 meters, using measuring instrumentation with a CISPR quasi-peak detector.
- (2) Out-of-band emissions above 960 MHz are limited to 500 microvolts/meter as measured at a distance of 3 meters, using measuring equipment with an averaging detector and a 1 MHz measurement bandwidth.

TEST PROCEDURE

ANSI/TIA-603-C-2004

RESULTS

8.1. FUNDAMENTAL OUTPUT POWER

Report No. : 31KE0333-HO
Test Place : Head Office EMC Lab.

Semi Anechoic Chamber: : No. 4
Date : 2011/07/01
Temperature/Humidity : 22 deg.C / 62 % RH
Engineer: : Katsunori Okai

Mode: : Tx

Polarity	Frequency	Detector	Reading	Ant.Fac.	Loss	Gain	Result	Limit	Margin	Remark
	[MHz]		[dBuV]	[dB/m]	[dB]	[dB]	[dBuV/m]	[dBuV/m]	[dB]	
Hori	1395.025	AV	69.5	25.2	1.9	0.0	96.6	117.4	20.8	
Vert	1395.025	AV	67.5	25.4	1.9	0.0	94.8	117.4	22.6	
Hori	1431.975	AV	68.0	25.6	1.9	0.0	95.5	117.4	21.9	
Vert	1431.975	AV	67.1	25.6	1.9	0.0	94.6	117.4	22.8	

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Result = Reading + Ant Factor + Loss (Cable+Attenuator+Filter) - Gain(Amplifier)

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8.2. RADIATED EMISSIONS BELOW 960 MHz

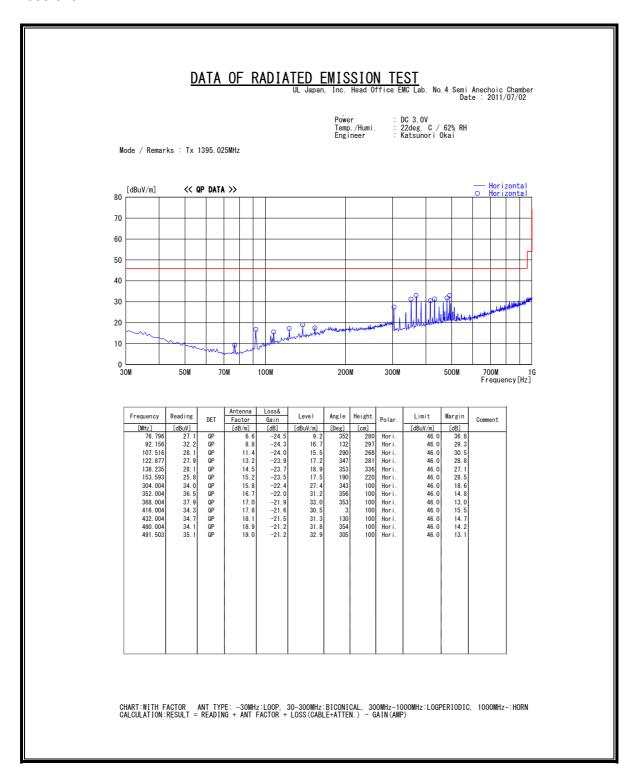
Note 1: The measurements in this section show that Peak values are less than the Quasi-Peak limit.

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Note 2: Plots in the range of 960 to 1000 MHz in this section are shown for reporting purposes only.

SPURIOUS EMISSIONS 30 TO 960 MHz (HORIZONTAL)

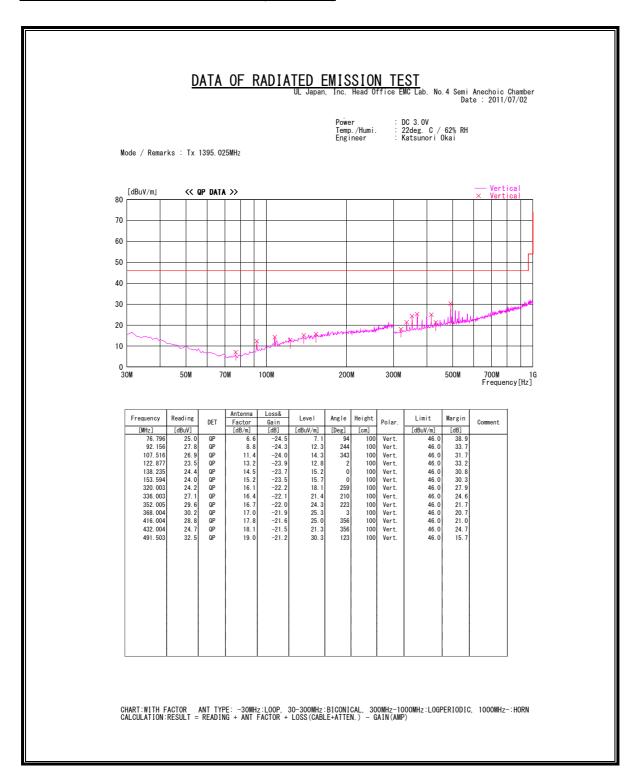
1395.025MHz



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SPURIOUS EMISSIONS 30 TO 960 MHz (VERTICAL)



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8.3. RADIATED EMISSIONS ABOVE 960 MHz

HARMONICS AND TX SPURIOUS EMISSIONS ABOVE 960 MHz

1395.025MHz

Report No. : 31KE0333-HO
Test Place : Head Office EMC Lab.

 Semi Anechoic Chamber:
 : No. 4

 Date
 : 2011/07/01

 Temperature/Humidity
 : 22 deg.C / 62 % RH

 Engineer:
 : Katsunori Okai

 Mode:
 : Tx 1395.025MHz

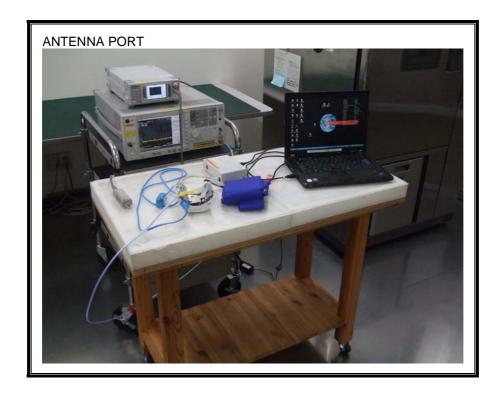
Polarity	Frequency	Detector	Reading	Ant.Fac.	Loss	Gain	Result	Limit	Margin	Remark
	[MHz]		[dBuV]	[dB/m]	[dB]	[dB]	[dBuV/m]	[dBuV/m]	[dB]	
Hori	2790.050	AV	30.8	27.6	3.4	32.0	29.8	54.0	24.2	
Hori	4185.075	AV	41.7	29.6	4.2	31.6	43.9	54.0	10.1	
Hori	5580.100	AV	46.1	32.1	4.6	31.6	51.2	54.0	2.8	
Hori	6975.125	AV	41.2	35.3	5.1	32.3	49.3	54.0	4.7	
Hori	8370.150	AV	34.2	36.5	5.4	32.9	43.2	54.0	10.8	
Hori	9765.175	AV	35.5	38.0	6.0	33.2	46.3	54.0	7.7	
Vert	2790.050	AV	32.8	27.6	3.4	32.0	31.8	54.0	22.2	
Vert	4185.075	AV	41.8	29.6	4.2	31.6	44.0	54.0	10.0	
Vert	5580.100	AV	47.2	32.1	4.6	31.6	52.3	54.0	1.7	
Vert	6975.125	AV	42.5	35.3	5.1	32.3	50.6	54.0	3.4	
Vert	8370.150	AV	36.3	36.5	5.4	32.9	45.3	54.0	8.7	
Vert	9765.175	AV	37.6	38.0	6.0	33.2	48.4	54.0	5.6	

 $\overline{Result = Reading + Ant\ Factor + Loss\ (Cable + Attenuator + Filter) - Gain(Amprifier)}$

DATE: JULY 11, 2011

9. SETUP PHOTOS

ANTENNA PORT



RADIATED EMISSION FOR PORTABLE CONFIGURATION

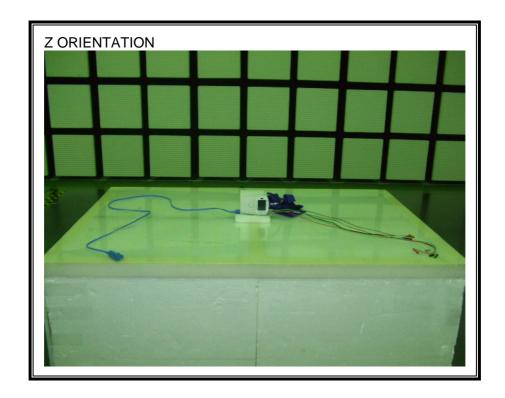
Worst Case Position

(Horizontal: X-ORIENTATION / Vertical: Y-ORIENTATION)



DATE: JULY 11, 2011





END OF REPORT

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