Report on the FCC Testing of the Monica Healthcare Ltd Interface unit. Model: Novii System Interface Unit POD. Model: Novii System Pod In accordance with FCC 47 CFR Parts 15 and 18 (Simultaneous Transmission)

Prepared for: Monica Healthcare Ltd

Interchange 25 business Park

Unit 8

Bostocks lane Nottingham NG10 5QG United Kingdom



FCC ID:

YOM-6960-MON (Novii Pod) YOM -6961-MON (Novii Interface Unit)

COMMERCIAL-IN-CONFIDENCE

Date: December 2017

Document Number: 75941097-05 | Issue: 01

RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Project Management	Clare Wright	13 December 2017	(Jo Sung)
Authorised Signatory	Matthew Russell	13 December 2017	Polesell

Signatures in this approval box have checked this document in line with the requirements of TÜV SÜD Product Service document control rules.

ENGINEERING STATEMENT

The measurements shown in this report were made in accordance with the procedures described on test pages. All reported testing was carried out on a sample equipment to demonstrate limited compliance with FCC 47 CFR Parts 15 and 18 (Simultaneous Transmission). The sample tested was found to comply with the requirements defined in the applied rules.

RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Testing	Jack Tuckwell	13 December 2017	gher

FCC Accreditation

90987 Octagon House, Fareham Test Laboratory

EXECUTIVE SUMMARY

A sample of this product was tested and found to be compliant with FCC 47 CFR Part 15:2016 and FCC 47 CFR Part 18:2016.



DISCLAIMER AND COPYRIGHT

This non-binding report has been prepared by TÜV SÜD Product Service with all reasonable skill and care. The document is confidential to the potential Client and TÜV SÜD Product Service. No part of this document may be reproduced without the prior written approval of TÜV SÜD Product Service. © 2017 TÜV SÜD Product Service.

ACCREDITATION

Our UKAS Accreditation does not cover opinions and interpretations and any expressed are outside the scope of our UKAS Accreditation. Results of tests not covered by our UKAS Accreditation Schedule are marked NUA (Not UKAS Accredited).

TÜV SÜD Product Service is a trading name of TUV SUD Ltd Registered in Scotland at East Kilbride, Glasgow G75 0QF, United Kingdom Registered number: SC215164 TUV SUD Ltd is a TÜV SÜD Group Company Phone: +44 (0) 1489 558100 Fax: +44 (0) 1489 558101 www.tuv-sud.co.uk TÜV SÜD Product Service Octagon House Concorde Way Fareham Hampshire PO15 5RL United Kingdom



Product Service

Contents

1	Report Summary	2
1.1	Report Modification Record	2
1.2	Introduction	2
1.3	Brief Summary of Results	3
1.4	Application Form	4
1.5	Product Information	9
1.6	Deviations from the Standard	9
1.7	EUT Modification Record	
1.8	Test Location	10
2	Test Details	11
2.1	Radiated Spurious Emissions (Simultaneous Transmission)	11
3	Measurement Uncertainty	19



1 Report Summary

1.1 Report Modification Record

Alterations and additions to this report will be issued to the holders of each copy in the form of a complete document.

Issue	Description of Change	Date of Issue
1	First Issue	13 December 2017

Table 1

1.2 Introduction

Applicant Monica Healthcare Ltd

Manufacturer Monica Healthcare Ltd

Model Number(s) Interface and Pod

Serial Number(s) Interface: TA1772

Pod: AA5425, AA5431

Hardware Version(s) Interface Rev L

Pod Rev H

Software Version(s) Interface V2.71

Pod V2.54

Number of Samples Tested 1 interface and 1 pod

Test Specification/Issue/Date FCC 47 CFR Parts 15: 2016

FCC 47 CFR Parts 18: 2016

Order Number Issue 2 501559
Date 30-November-2017
Date of Receipt of EUT 04-December-2017
Start of Test 07-December-2017
Finish of Test 07-December-2017

Name of Engineer(s) Jack Tuckwell

Related Document(s) ANSI C63.10 (2013)

COMMERCIAL-IN-CONFIDENCE



1.3 Brief Summary of Results

A brief summary of the tests carried out in accordance with FCC 47 CFR Parts 15 and 18 is shown below.

Section	Specification Clause		Test Description	Result	Comments/Base Standard
	FCC Part 15 FCC Part 18				
Configuratio	n and Mode: Wireless (Charging + Bluetooth T	ransmit		
2.1	15.247 (d) and 18.305(b) 15.205		Radiated Spurious Emissions (Simultaneous Transmission)	Pass	ANSI C63.10

Table 2

COMMERCIAL-IN-CONFIDENCE Page 3 of 19



1.4 Application Form

EQUIPMENT DESCRIPTION					
Model Name/Number	ne/Number Novii Interface Unit				
Part Number 107-PT-00		7-PT-001			
Hardware Version Rev L		ev L			
Software Version Rev 2.71					
FCC ID (if applicable)		YOM-6961_MON			
Industry Canada ID (if applicable)					
Technical Description (Please provide a brief description of the intended use of the equipment)		The Novii System Interface Unit is part of the Novii Wireless Patch System: a Maternal/Fetal monitor that records Fetal heart rate, Maternal Heart Rate and Uterine Contractions from a pregnant subject.			

	INTENTIONAL RADIATORS								
Technology	Frequency Band	Conducted Declared Output	Antenna Gain		Modulation	ITU Emission	Test Channels (MHz)		
recritiology	(MHz)	Power (dBm)	(dBi)	(MHz)	Scheme(s)	Designator	Bottom	Middle	Тор
Bluetooth (Left Side)	2042-2408	10	1.18	1 MHz/ channel	V2.1+ EDR	1M00F1D	2402	2440	2480
Bluetooth (Right Side)	2042-2408	10	3.24	1 MHz/ channel	V2.1+ EDR	1M00F1D	2402	2440	2480
QI Wireless Charger transmitter	0.110 to 0.205	37		0.095	Frequency Modulation				

UN-INTENTIONAL RADIATOR				
Highest frequency generated or used in the device or on which the device operates or tunes	26MHz			
Lowest frequency generated or used in the device or on which the device operates or tunes	0Hz			

Power Source					
AC	Single Phase	Three Phase		Nominal Voltage	
AC	х			100-240	
External DC	Nominal Voltage		Maximum Current		
External DC	5V		2.5A		
Nominal Voltage			Ва	ttery Operating End Point Voltage	
Battery N/A					
Can EUT transmit whilst being charged?			Yes ⊠ No □]	



EXTREME CONDITIONS								
Maximum temperature 30 °C Minimum temperature 10 °C								
			Ancillar	ies				
Plea	se list all ancillaries which will b	e used w	ith the device.					
Nov	ii System Pod							
			ANTENNA CHARA	ACTERISTICS				
	Antenna connector			State impedance	Ohm			
	Temporary antenna connector	-		State impedance	Ohm			
\boxtimes	Integral antenna	Туре	Ceramic (Antenova SRCW004)					

I hereby declare that the information supplied is correct and complete.

Type

Name: Jean-Francois Pieri

External antenna

Position held: CTO Date: 12th December 2017



EQUIPMENT DESCRIPTION Model Name/Number Novii System Interface Unit / Novii System Pod Part Number 107-PT-001 / 107-PT-003 Hardware Version Interface Rev_L / Pod Rev_H Interface v2.71 / Pod v2.54 Software Version

FCC ID (if applicable)				Interface: YOM-6961-MON Pod: YOM-6960-MON			
Industry Ca	nada ID (if a	pplicable)		N/A			
Technical Description (Please provide a brief description of the intended use of the equipment)				Matern	ovii Wireless Patc al/Fetal monitor. le Contractins durin	It mon	tem is a small, reliable, accurate intrapartum itors the Maternal and Fetal heart rate and ur and delivery.
<u> </u>							
			I	EQUIPM	ENT SUPPLIED		
WPT Source							
WPT Client							
	m (Client and work exclus	d source sively together)					
				WP	T SOURCE		
	Type 1	No intelligent co	mmunicatior	n transmi	tted wirelessly		
\boxtimes	Type 2		modulated in	-	load modulation te		
		1. Fundamental is < 490 kHz and ;					
	Type 3	All emissions are > 40 dB below RSS-GEN field strength limits. Type 3 Neither type 1 or type 2, but uses some form of modulation to transmit intelligent communication.					
	, ·	•	••	uscs 501	ne ionn oi mouula		transmit intelligent communication.
		or us in any of the		octric val	hiclos)		
	· ·	er WPT device (e.g		ectric vei	ilioles)		
		a distance of > 10	CIII				
	Medical De			400 141 /			
D#		ce operating at a f	<u> </u>			· · ·	
		rt power manager			2	Yes	
		ent operate at diffe	erent separa	ition dist	1	No	1 -
Minimum D		5 mm			Maximum Distar		5 mm
		any other wireless		excluding	WPT device)?	Yes	
Can the dev	vice transmi	t secondary frequ	encies?			Yes I	Bluetooth
State Frequ	Frequencies: 2402 to 2480MHz						
	WPT SOURCE DESIGN						
	Single fixe	ed power transfer	zone – single	e client			
	Multiple fix	xed power transfe	r zone – sino	gle client			
	Multiple n	on-fixed power tra	ınsfer zone -	- single c	lient		
	Multiple power transfer zone – multiples clients						

	WPT SOURCE DESIGN					
	Single fixed power transfer zone – single client					
⊠	Multiple fixed power transfer zone – single client					
	Multiple non-fixed power transfer zone – single client					
	Multiple power transfer zone – multiples clients					



	POWER SOURCE								
	AC mains		State	voltage					
AC sup	oply frequency (Hz)								
	VAC								
	Max Current								
	Hz								
	Single phase			Three phase					
And / C)r								
\boxtimes	External DC supply								
	Nominal voltage		5 V	Max Current 2.5 A					
	Extreme upper voltage		5.125	5 V					
	Extreme lower voltage		4.875	5 V					
Battery	1								
	Nickel Cadmium			Lead acid (Vehicle regulated)					
	Alkaline			Leclanche					
	Lithium			Other Details:					
	Volts nominal.								
End po	int voltage as quoted by equipmen	t manufacturer		V					
	FREQUENCY INFORMATION								
Frequency Range 0.11 to 0.205		MHz							
	Channel Spacing (where applicable)								
	Receiver Frequency Range (if different) to		MHz						
	el Spacing (if different)								
Test Fr	equencies*	Bottom		MHz Channel Number (if applicable)					
		Middle		MHz Channel Number (if applicable)					
		Тор		MHz Channel Number (if applicable)					
	diate Frequencies			MHz					
Highest	Internally Generated Frequency:			MHz					
		POWER	CHARA	ACTERISTICS					
Maximi	ım TX power 5								
	·		variable))					
	mitter intended for:	ζ	,						
Continuous duty			⊠ Yes □ No						
	tent duty			☐ Yes ☐ No					
	nittent state DUTY CYCLE			_					
	itter ON	seconds							
Transm	itter OFF	seconds							



ANTENNA CHARACTERISTICS Ohm Antenna connector State impedance Temporary antenna connector State impedance Ohm Integral antenna State impedance dBi Type External antenna Type State impedance dBi **MODULATION CHARACTERISTICS** Amplitude \boxtimes Frequency Phase Other (please provide details): Can the transmitter operate un-modulated? Yes No **CLASS OF EMISSION USED** ITU designation or Class of Emission: (if applicable) 2 (if applicable) 3 If more than three classes of emission, list separately: **BATTERY POWER SUPPLY** Model name/number Identification/Part number Manufacturer Country of Origin **ANCILLARIES (If applicable)** Model name/number Identification/Part number Country of Origin Manufacturer **EXTREME CONDITIONS** Extreme test voltages (Max) 5.125 / ٧ Extreme test voltages (Mix) 4.2 Nominal DC Voltage 5/4.2 ٧ DC Maximum Current 2.5 Α °C Maximum temperature 43 Minimum temperature 10 °C

I hereby declare that the information supplied is correct and complete.

Name: Simon Branson Position held: Engineering Manager

Date: 08/12/17



1.5 Product Information

1.5.1 Technical Description

The Monica Novii POD is an intrapartum Maternal/Fetal Monitor that non-invasively measures and displays fetal heart rate (FHR), uterine activity (UA) and maternal heart rate (MHR).

The Novii POD acquires and displays the FHR tracing from abdominal surface electrodes that pick up the fetal ECG (fECG) signal. Using the same surface electrodes, the POD also acquires and displays the UA tracing from the uterine electromyography (EMG) signal and the MHR tracing from the maternal ECG signal (mECG).

The POD is indicated for use on women who are at >36 completed weeks, in labor, with singleton pregnancies, using surface electrodes on the maternal abdomen.

The Novii Patch is an accessory to the Novii POD that connects directly to the Novii POD and contains the surface electrodes that attach to the abdomen. The Novii Interface is an accessory to the Novii POD which provides a means of interfacing the wireless output of the Novii POD to the transducer inputs of a Maternal/Fetal Monitor.

The Novii Interface enables signals collected by the Novii POD to be printed and displayed on a Maternal/Fetal Monitor and sent on to a central network, if connected.

The Novii Interface is the WPT transmitter and was tested with the Novii POD which is a WPT client only device.

1.6 Deviations from the Standard

No deviations from the applicable test standard were made during testing.

1.7 EUT Modification Record

The table below details modifications made to the EUT during the test programme. The modifications incorporated during each test are recorded on the appropriate test pages.

Modification State	Description of Modification still fitted to EUT	Modification Fitted By	Date Modification Fitted			
Serial Number: TA1772						
0	As supplied by the customer	Not Applicable	Not Applicable			
Serial Number: AA5425						
0 As supplied by the customer		Not Applicable	Not Applicable			

Table 3



1.8 Test Location

TÜV SÜD Product Service conducted the following tests at our Fareham Test Laboratory.

Test Name	Name of Engineer(s)	Accreditation		
Configuration and Mode: Wireless Charging + Bluetooth Transmit				
Radiated Spurious Emissions (Simultaneous Transmission)	Jack Tuckwell	UKAS		

Table 4

Office Address:

Octagon House Concorde Way Segensworth North Fareham Hampshire PO15 5RL United Kingdom



2 Test Details

2.1 Radiated Spurious Emissions (Simultaneous Transmission)

2.1.1 Specification Reference

FCC 47 CFR Part 15, Clause 15.247 (d) and 15.205 FCC 47 CFR Part 18, Clause 18.305(b)

2.1.2 Equipment Under Test and Modification State

Interface, S/N: TA1772 - Modification State 0 Pod. S/N: AA5425 - Modification State 0

2.1.3 Date of Test

07-December-2017

2.1.4 Test Method

The test was performed in accordance with ANSI C63.10, clauses 6.5 and 6.6.

2.1.5 Environmental Conditions

Ambient Temperature 18.1 °C Relative Humidity 41.0 %

2.1.6 Test Results

Wireless Charging + Bluetooth Transmit

The EUT was configured for simultaneous transmission in the following mode of operation:

Technology	Frequency Band	Channel Frequency	
Wireless Charging	100 kHz to 300 kHz	172 kHz	
Bluetooth (GFSK/DH5)	2400 MHz to 2483.5 MHz	2441 MHz	

Table 5 - Modes of Operation

The Interface and POD were both configured for Bluetooth transmissions at maximum power on 2441 MHz. The Interface wireless charger was configured in a test mode to output at maximum amplitude. The POD was placed on the Interface unit to exercise the WPT.



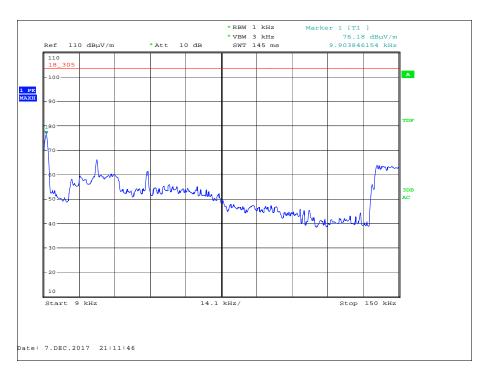


Figure 1 – 9 kHz to 150 kHz - Horizontal and Vertical

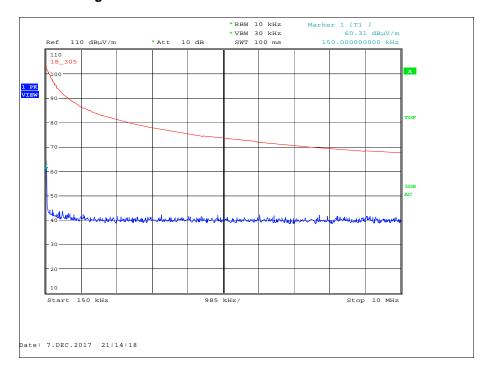


Figure 2 – 150 kHz to 10 MHz - Horizontal and Vertical



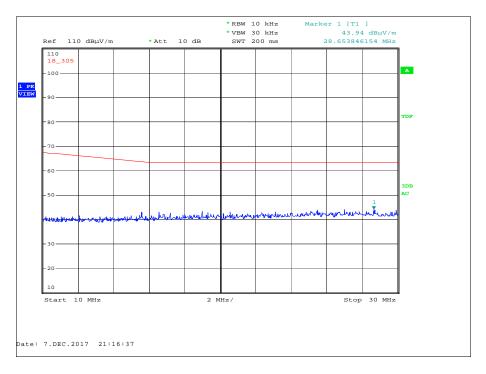


Figure 3 – 10 MHz to 30 MHz - Horizontal and Vertical



Frequency (MHz)	QP Level (dBuV/m)	QP Limit (dBuV/m)	QP Margin (dBuV/m)	Angle(Deg)	Height(m)	Polarity
52.724	32.1	40.0	-7.9	360	1.00	Vertical
163.096	40.5	43.5	-3.0	211	1.00	Vertical
295.891	39.4	46.0	-6.6	245	1.18	Horizontal
509.438	29.1	46.0	-16.9	28	1.00	Vertical
690.434*	48.3			159	1.71	Vertical
887.668*	49.0			253	1.73	Horizontal

Table 6 - 30 MHz to 1 GHz Emissions Results

*Emission is above -6 dB of the limit in the restricted band of 46 dB μ V/m (Quasi-Peak) however the frequency does not fall in a restricted band and therefore the limit is -20 dBc of which there is more than 6 dB margin hence the emission was not further investigated.

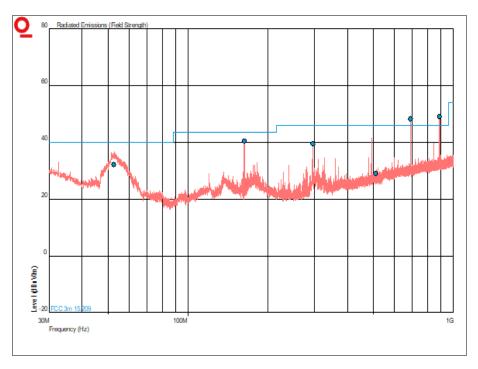


Figure 4 - 30 MHz to 1 GHz - Horizontal and Vertical



Frequency (GHz)	Result (µV/m)		Limit (µV/m)		Margin (μV/m)	
	Peak	Average	Peak	Average	Peak	Average
1.085	54.82	50.17	74.00	54.00	19.18	3.83
1.282*						
4.88	54.97	46.80	74.00	54.00	19.03	7.20
7.3195	56.19	47.02	74.00	54.00	17.81	6.98

Table 7 - 1 GHz to 25 GHz Emissions Results

*Emission is above -6 dB of the limit in the restricted band of 74 dBµV/m (Peak) or 54 dBµV/m (Average) however the frequency does not fall in a restricted band and therefore the limit is -20 dBc of which there is more than 6 dB margin hence the emission was not further investigated.

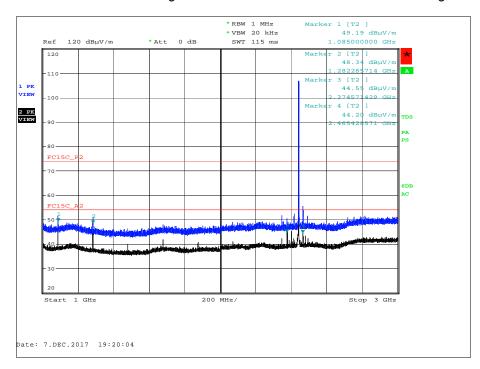


Figure 5 - 1 GHz to 3 GHz - Horizontal and Vertical



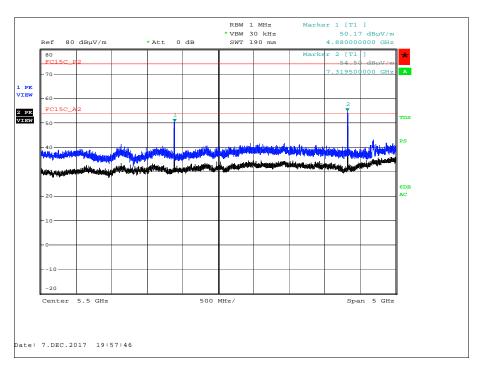


Figure 6 - 3 GHz to 8 GHz - Horizontal and Vertical

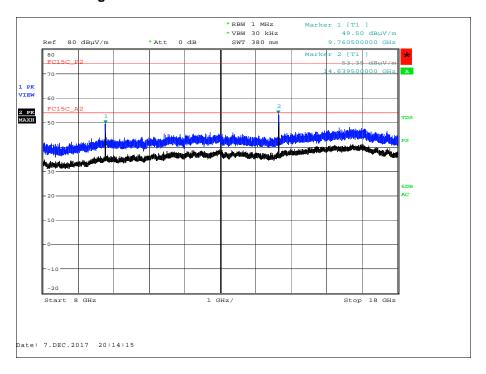


Figure 7 - 8 GHz to 18 GHz - Horizontal and Vertical



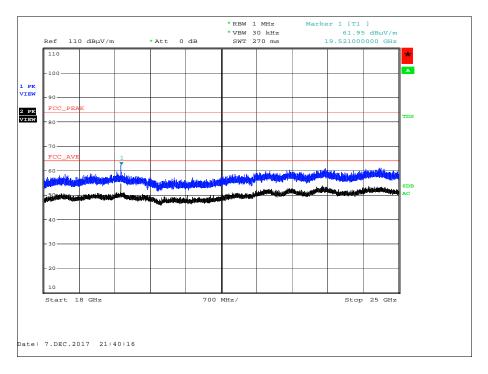


Figure 8 - 18 GHz to 25 GHz - Horizontal and Vertical

FCC 47 CFR Parts 15.247(d), 15.205, 18.305(b)

The least stringent limits from the applicable rule parts were used to determine compliance for Radiated Emissions testing of multiple transmission sources.

The least stringent applicable limit was:

Rule Part	Limit
Part 15.247 (d)	-20 dBc
Part 15.205 Peak: 74 dBμV/m at 3m, Average 54 dBμV/m at 3m	
Part 18.302(b)	15 μV/m at 300m

Table 8 - Limit Table



2.1.7 Test Location and Test Equipment Used

This test was carried out in EMC Chamber 5.

Instrument	Manufacturer	Type No	TE No	Calibration Period (months)	Calibration Due
Antenna (Bilog)	Schaffner	CBL6143	287	24	18-Apr-2018
Antenna (Active Loop, 9kHz-30MHz) Rohde & Schwarz		HFH2-Z2	333	24	09-Dec-2018
Antenna 18-40GHz (Double Ridge Guide) Q-Par Angus Ltd		QSH 180K	1511	24	07-Dec-2018
Pre-Amplifier	Phase One	PS04-0086	1533	12	31-Jul-2018
Screened Room (5)	Rainford	Rainford	1545	36	20-Dec-2017
Turntable Controller	Inn-Co GmbH	CO 1000	1606	-	TU
Hygrometer	Rotronic	HYGROPALM 1	2338	12	24-Oct-2018
Cable (N-N, 8m)	Rhophase	NPS-2302-8000- NPS	3248	12	02-May-2018
Compliance 5 Emissions	Schaffner	C5e Software	3275	-	Software
EMI Test Receiver	Rohde & Schwarz	ESU40	3506	12	22-Nov-2018
Tilt Antenna Mast	maturo Gmbh	TAM 4.0-P	3916	-	TU
Mast Controller	maturo Gmbh	NCD	3917	-	TU
1GHz to 8GHz Low Noise Amplifier	Wright Technologies	APS04-0085	4365	12	18-Oct-2018
Cable (Rx, Km-Km 2m)	Scott Cables	KPS-1501-2000- KPS	4526	6	22-May-2018
Double Ridged Waveguide Horn Antenna	ETS-Lindgren	3117	4722	12	17-Feb-2018
Double Ridge Broadband Horn Antenna	Schwarzbeck	BBHA 9120 B	4848	12	17-Feb-2018

Table 9

TU - Traceability Unscheduled



3 Measurement Uncertainty

For a 95% confidence level, the measurement uncertainties for defined systems are:

Test Name	Measurement Uncertainty
Radiated Spurious Emissions (Simultaneous Transmission)	30 MHz to 1 GHz: ± 5.2 dB 1 GHz to 40 GHz: ± 6.3 dB

Table 10