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	(Jos Lung)
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	Shee

**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.



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# Product Service

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# 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)

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

Table 2

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# 1.4 Application Form

	E	QUIPMENT DESCRIPTION			
Model Name/Number	Novii Interf	Novii Interface Unit			
Part Number 107-PT-00		)1			
Hardware Version	Rev 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	Supported Bandwidth (s)	· · I Modiliation I		Test Channels (MHz)			
recritiology	(MHz)	Power (dBm)	(dBi)	(MHz)	Scheme(s)	Emission 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-INTENTION.	AL 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 Sourc	e		
4.0	Single Phase	Single Phase Three Phase		Nominal Voltage	
AC	х			100-240	
External DC	Nominal Voltage		Maximum Current		
External DC	5V		2.5A		
Detterni	Nominal Voltage		Battery Operating End Point Voltage		
Battery	N/A				
Can EUT transmit whilst being charged?			Yes ⊠ No □	]	



			EXTREME CON	NDITIONS		
Max	imum temperature 3	80 °	C N	linimum temperature	10	°C
			Ancillar	ies		
Plea	se list all ancillaries which will	be used w	ith the device.			
Nov	ii System Pod					
			ANTENNA CHARA	ACTERISTICS		
	Antenna connector			State impedance	Ohm	
	Temporary antenna connecto	r		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: 12<sup>th</sup> December 2017



**EQUIPMENT DESCRIPTION** Model Name/Number Novii System Interface Unit / Novii System Pod 107-PT-001 / 107-PT-003 Part Number Hardware Version Interface Rev\_L / Pod Rev\_H Software Version Interface v2.71 / Pod v2.54

FCC ID (if applicable)			Interface: YOM-6961-MON Pod: YOM-6960-MON				
Industry Ca	nada ID (if a	pplicable)		N/A			
		(Please provided as a contract of the equipment of the eq		Matern		It mon	tem is a small, reliable, accurate intrapartum itors the Maternal and Fetal heart rate and ur and delivery.
					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		
	Type 2	Transmission is	modulated in	-	load modulation to		
		1. 2.			mental is < 490 kH		
	Type 3		rtuno 2 hut				v RSS-GEN field strength limits. transmit intelligent communication.
		•	••	uses sui	ne ionn oi modula	ilion to	transmit intelligent communication.
	1	or us in any of the er WPT device (e.c		a atria val	hiolog)		
	<u> </u>			ectric ver	micies)		
		a distance of > 10	CIII				
	Medical De			400 MI I-			
		ce operating at a f					
		rt power manager			•	Yes	
		ent operate at diffe	erent separa	ition dista	1	No	T _
Minimum D		5 mm			Maximum Dista		5 mm
		any other wireless		excluding	WP1 device)?	Yes	
		t secondary frequ				Yes	Bluetooth
State Frequ	iencies:	2402 to 2480MI	Hz				
	1				DURCE DESIGN		
		ed power transfer					
	· ·	xed power transfe					
	· ·	on-fixed power tra			lient		
∥	Multiple p	ower transfer zone	e – multiples	clients			



	POV	NER SC	DURCE					
☐ AC mains		State	voltage					
AC supply frequency (Hz)								
VAC								
Max Current								
Hz								
☐ Single phase			Three phase					
And / Or								
Nominal voltage		5 V	Max Cu	rrent 2.5	Α			
Extreme upper voltage		5.125	V					
Extreme lower voltage		4.875	V					
Battery								
☐ Nickel Cadmium			Lead acid (Vehi	cle regulated)				
Alkaline			Leclanche					
Lithium			Other Details:					
Volts nominal.								
End point voltage as quoted by equipment	manufacturer			V				
	FREQUEN	ICY INF	FORMATION					
Frequency Range	0.11 to 0.205	MHz						
Channel Spacing (where applicable)								
Receiver Frequency Range (if different) to								
Receiver Frequency Range (if different)	to	MHz						
Receiver Frequency Range (if different)  Channel Spacing (if different)	to	MHz						
	to Bottom	MHz	MHz	Channel Number	r (if ap	oplicable)	)	
Channel Spacing (if different)		MHz	MHz MHz	Channel Number				
Channel Spacing (if different)	Bottom	MHz			r (if ap	plicable)	)	
Channel Spacing (if different)	Bottom Middle	MHz	MHz	Channel Number	r (if ap	plicable)	)	
Channel Spacing (if different) Test Frequencies*	Bottom Middle	MHz	MHz MHz	Channel Number	r (if ap	plicable)	)	
Channel Spacing (if different) Test Frequencies* Intermediate Frequencies	Bottom Middle	MHZ	MHz MHz MHz	Channel Number	r (if ap	plicable)	)	
Channel Spacing (if different)  Test Frequencies*  Intermediate Frequencies  Highest Internally Generated Frequency:	Bottom Middle Top		MHz MHz MHz	Channel Number	r (if ap	plicable)	)	
Channel Spacing (if different)  Test Frequencies*  Intermediate Frequencies  Highest Internally Generated Frequency:  Maximum TX power 5	Bottom Middle Top		MHz MHz MHz MHz	Channel Number	r (if ap	plicable)	)	
Channel Spacing (if different) Test Frequencies*  Intermediate Frequencies Highest Internally Generated Frequency:  Maximum TX power 5 Minimum TX power	Bottom Middle Top		MHz MHz MHz MHz	Channel Number	r (if ap	plicable)	)	
Channel Spacing (if different)  Test Frequencies*  Intermediate Frequencies  Highest Internally Generated Frequency:  Maximum TX power 5	Bottom Middle Top	CHARA	MHz MHz MHz MHz	Channel Number	r (if ap	plicable)	)	
Channel Spacing (if different) Test Frequencies*  Intermediate Frequencies Highest Internally Generated Frequency:  Maximum TX power 5 Minimum TX power	Bottom Middle Top	CHARA	MHz MHz MHz MHz	Channel Number	r (if ap	plicable)	)	No
Channel Spacing (if different)  Test Frequencies*  Intermediate Frequencies  Highest Internally Generated Frequency:  Maximum TX power  Is transmitter intended for:	Bottom Middle Top	CHARA	MHz MHz MHz MHz	Channel Number	r (if ap	oplicable)		No No
Channel Spacing (if different)  Test Frequencies*  Intermediate Frequencies  Highest Internally Generated Frequency:  Maximum TX power  Minimum TX power  Is transmitter intended for:  Continuous duty	Bottom Middle Top	CHARA	MHz MHz MHz MHz	Channel Number	r (if ap	oplicable) oplicable		
Channel Spacing (if different)  Test Frequencies*  Intermediate Frequencies  Highest Internally Generated Frequency:  Maximum TX power  S Minimum TX power  Is transmitter intended for:  Continuous duty  Intermittent duty	Bottom Middle Top	CHARA	MHz MHz MHz MHz	Channel Number	r (if ap	oplicable) oplicable		



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

Minimum temperature

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

43

°C

Name: Simon Branson Position held: Engineering Manager

Date: 08/12/17

Maximum temperature

10

°C



#### 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

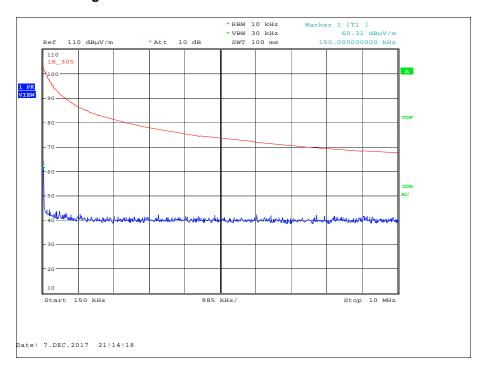


Figure 2 – 150 kHz to 10 MHz - Horizontal and Vertical



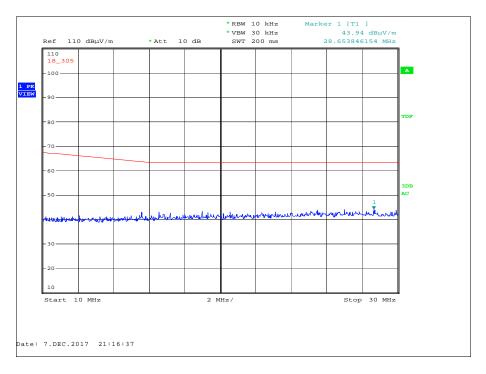


Figure 3 – 10 MHz to 30 MHz - Horizontal and Vertical



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 $\mu$ 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.

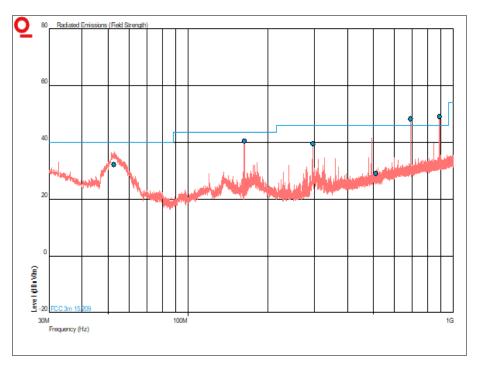


Figure 4 - 30 MHz to 1 GHz - Horizontal and Vertical



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.

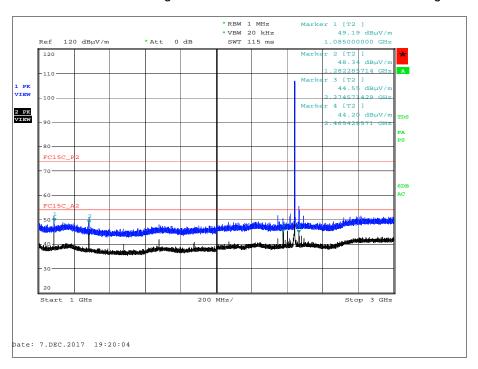


Figure 5 - 1 GHz to 3 GHz - Horizontal and Vertical



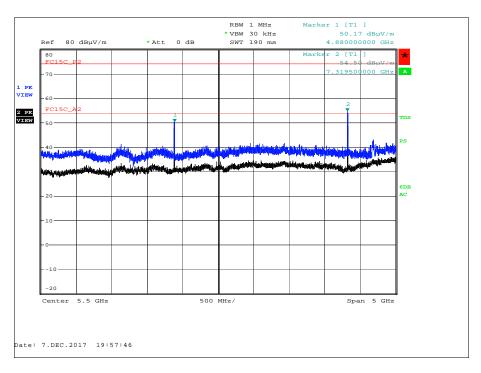


Figure 6 - 3 GHz to 8 GHz - Horizontal and Vertical

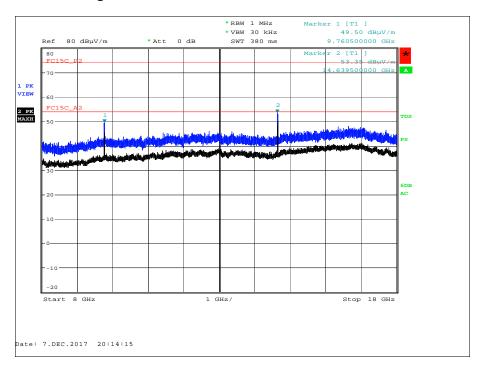


Figure 7 - 8 GHz to 18 GHz - Horizontal and Vertical



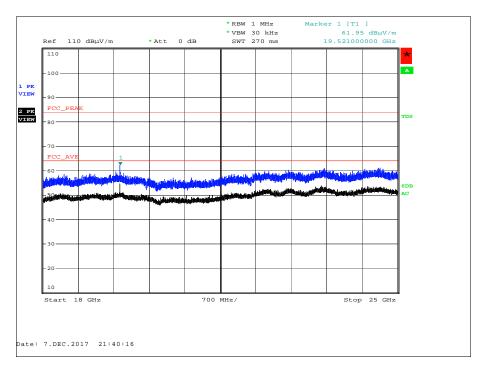


Figure 8 - 18 GHz to 25 GHz - Horizontal and Vertical

# 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