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 Part 18

Product Service

Choose certainty.
Add value.

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: 75941097-03 | Issue: 01

RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Project Management	Clare Wright	13 December 2017	
Authorised Signatory	Matthew Russell	13 December 2017	

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 Part 18. The sample tested was found to comply with the requirements defined in the applied rules.

RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Testing	Graeme Lawler	13 December 2017	

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 18: 2016.

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).

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Product Service

Contents

Product Service

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, Pod
Serial Number(s)	S/N: TA1763 S/N: AA5425 & AA5431
Hardware Version(s)	Interface Rev L Pod V2.54
Software Version(s)	Interface V2.71 Pod Rev H
Number of Samples Tested	1 interface with 2 Pods
Test Specification/Issue/Date	FCC 47 CFR Part 18: 2016
Order Number Date	issue 2 501559 30-November-2017
Date of Receipt of EUT	05-December-2017
Start of Test	05-December-2017
Finish of Test	05-December-2017
Name of Engineer(s)	Graeme Lawler
Related Document(s)	ANSI C63.10 (2013) ICES-001 Issue 4 (2006) CISPR 11 Fourth Edition (inc Amend.1 IEC:2004) ANSI C63.4 (2014)

Product Service

1.3 Brief Summary of Results

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

Section	Specification Clause	Test Description	Result	Comments/Base Standard
Configuration and Mode: Charging				
2.1	18.305(b)	Field Strength of Emissions	Pass	ANSI C63.10 (2013) ICES-001 Issue 4 (2006) CISPR 11 Fourth Edition (inc Amend.1 IEC:2004)
2.2	18.307	AC Power Line Conducted Emissions	Pass	ANSI C63.4 (2014)

Table 2

Product Service

1.4 Application Form

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
Software Version	Interface v2.71 / Pod v2.54
FCC ID (if applicable)	Interface: YOM-6961-MON Pod: YOM-6960-MON
Industry Canada ID (if applicable)	N/A
Technical Description (Please provide a brief description of the intended use of the equipment)	The Novii Wireless Patch System is a Maternal/Fetal monitor that records Fetal heart rate, Maternal Heart Rate and Uterine Contractions from a pregnant subject

EQUIPMENT SUPPLIED	
WPT Source	☐
WPT Client	☐
WPT System (Client and source designed to work exclusively together)	☒

WPT SOURCE		
☐	Type 1	No intelligent communication transmitted wirelessly
☒	Type 2	Transmission is modulated including load modulation techniques where: 1. Fundamental is < 490 kHz and ; 2. 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.

Is the device intended for us in any of the following?:	
☐	High power WPT device (e.g charging electric vehicles)
☐	WPT over a distance of > 10 cm
☒	Medical Device
☐	WPT source operating at a frequency > 400 MHz

Does the device support power management transfer?			Yes
Can the source and client operate at different separation distances?			No
Minimum Distance:	5 mm	Maximum Distance	5 mm
Does the EUT contain any other wireless modules (excluding WPT device)?			Yes
Can the device transmit secondary frequencies?			Yes Bluetooth
State Frequencies:	2402 to 2480MHz		

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

Product Service

POWER SOURCE					
☐	AC mains	State voltage			
AC supply frequency	(Hz)				
	VAC				
	Max Current				
	Hz				
☐	Single phase	☐	Three phase		
And / Or					
☒	External DC supply				
	Nominal voltage	5 V	Max Current	2.5	A
	Extreme upper voltage	5.125 V			
	Extreme lower voltage	4.875 V			
Battery					
☐	Nickel Cadmium	☐	Lead acid (Vehicle regulated)		
☐	Alkaline	☐	Leclanche		
☒	Lithium	☐	Other Details:		
4.2	Volts nominal.				
End point voltage as quoted by equipment manufacturer		3.7	V		

FREQUENCY INFORMATION			
Frequency Range	0.11 to 0.205	MHz	
Channel Spacing (where applicable)			
Receiver Frequency Range (if different)	to	MHz	
Channel Spacing (if different)			
Test Frequencies*	Bottom	MHz	Channel Number (if applicable)
	Middle	MHz	Channel Number (if applicable)
	Top	MHz	Channel Number (if applicable)
Intermediate Frequencies		MHz	
Highest Internally Generated Frequency:		MHz	

POWER CHARACTERISTICS				
Maximum TX power	5	W		
Minimum TX power		W (if variable)		
Is transmitter intended for:				
Continuous duty			☒ Yes	☐ No
Intermittent duty			☐ Yes	☐ No
If intermittent state DUTY CYCLE				
Transmitter ON	seconds			
Transmitter OFF	seconds			

Product Service

ANTENNA CHARACTERISTICS				
☐	Antenna connector		State impedance	Ohm
☐	Temporary antenna connector		State impedance	Ohm
☐	Integral antenna	Type	State impedance	dBi
☐	External antenna	Type	State impedance	dBi

MODULATION CHARACTERISTICS			
☐	Amplitude	☒	Frequency
☐	Phase	☐	Other (please provide details):
Can the transmitter operate un-modulated?		☐ Yes	☐ No

CLASS OF EMISSION USED
ITU designation or Class of Emission:
1
(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
Manufacturer	Country of Origin

EXTREME CONDITIONS					
Extreme test voltages (Max)	5.125 / 4.2	V	Extreme test voltages (Mix)		V
Nominal DC Voltage	5/4.2	V	DC Maximum Current	2.5	A
Maximum temperature	30	°C	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

Product Service

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: TA1763			
0	As supplied by the customer	Not Applicable	Not Applicable

Table 3

Product Service

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: Charging		
Field Strength of Emissions	Graeme Lawler	UKAS
AC Power Line Conducted Emissions	Graeme Lawler	UKAS

Table 4

Office Address:

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

Product Service

2 Test Details

2.1 Field Strength of Emissions

2.1.1 Specification Reference

FCC 47 CFR Part 18, Clause 18.305(b)

2.1.2 Equipment Under Test and Modification State

Interface, S/N: TA1763 - Modification State 0
Pod, S/N: AA5425 - Modification State 0
Pod, S/N: AA5431 - Modification State 0

2.1.3 Date of Test

06-December-2017

2.1.4 Test Method

This test was performed in accordance with ANSI C63.10 clause 6.3, 6.4 and 6.5.

2.1.5 Environmental Conditions

Ambient Temperature	19.0 °C
Relative Humidity	34.0 %

2.1.6 Test Results

Charging

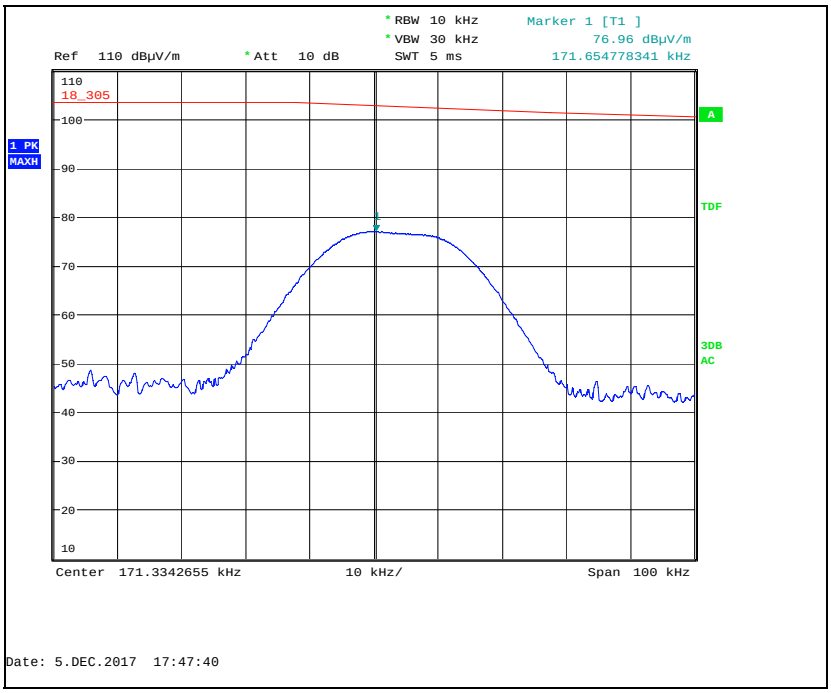

Figure 1 - 172.526- kHz

Frequency (kHz)	QP Level at 3m (dBµV/m)	QP Level at 3m (µV/m)	QP Limit at 3m (dBµV/m)	QP Limit at 3m (µV/m)	Angle	Height (m)	Polarity

Frequency (kHz)	QP Level at 3m (dBµV/m)	QP Level at 3m (µV/m)	QP Limit at 3m (dBµV/m)	QP Limit at 3m (µV/m)	Angle	Height (m)	Polarity
172.526	74.85	5527.13	102.5	133352.14	190	150	Face

Table 5 - Field Strength of Emissions, 9 kHz to 30 MHz

No other emissions were detected within 10 dB of the limit.

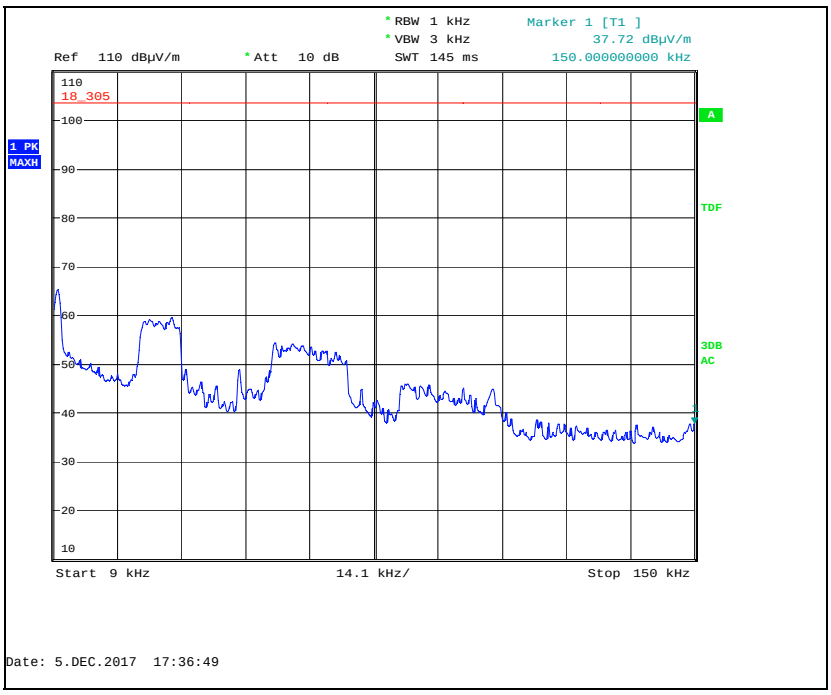

Figure 2- 9 kHz to 150 kHz

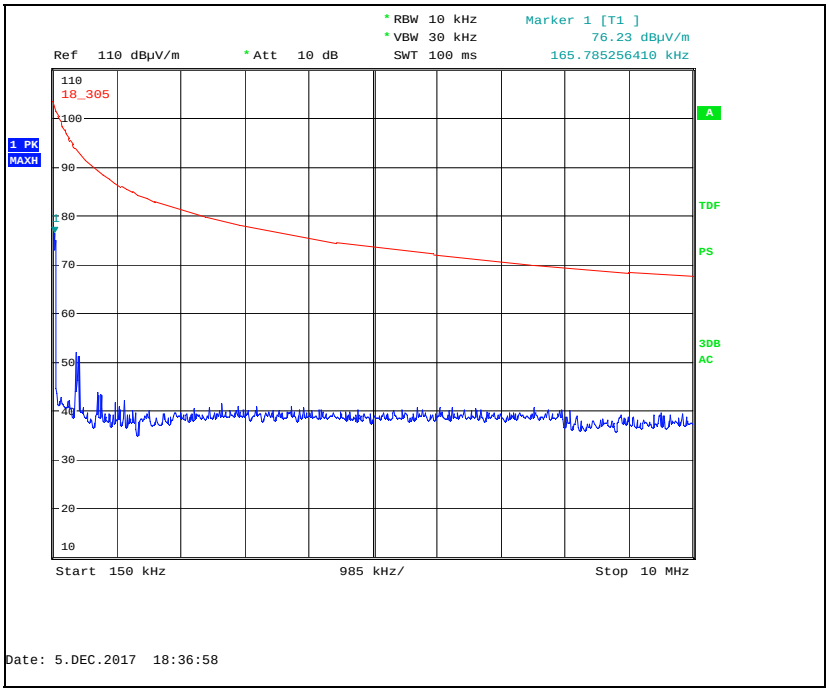

Figure 3 - 150 kHz to 10 MHz

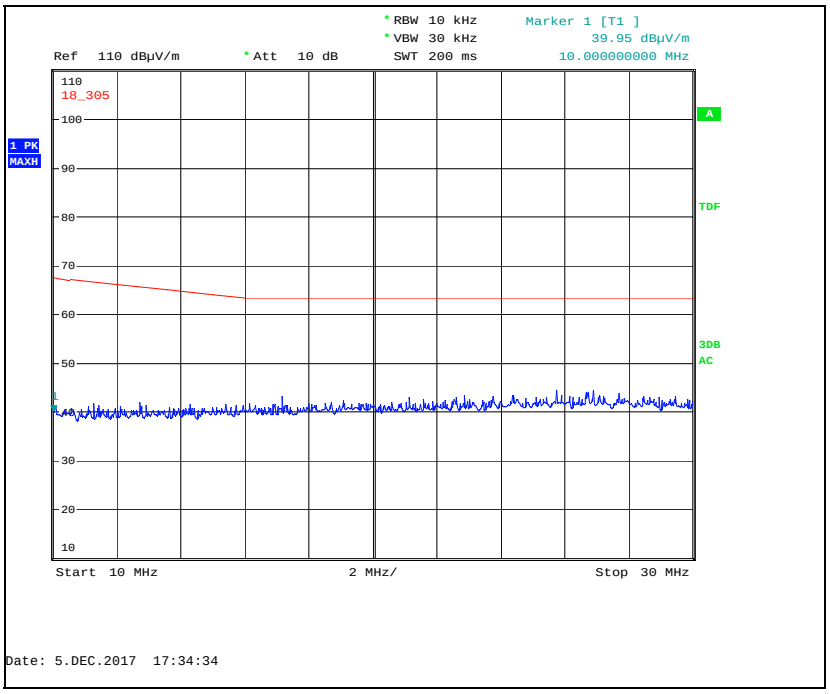

Figure 4 - 10 MHz to 30 MHz

FCC 47 CFR Part 18, Limit Clause 18.305 (b)

Equipment	Operating Frequency	RF Power generated by equipment (Watts)	Field Strength Limit (µV/m)	Distance (Meters)
Any type unless otherwise specified (miscellaneous).	Any ISM frequency	Below 500	25	300
		500 or more	25 x $\sqrt{P/600}$	300
	Any non-ISM frequency	Below 500	15	300
		500 or more	15 x $\sqrt{P/600}$	300

Table 6 - Limit Table

Product Service

2.1.7 Test Location and Test Equipment Used

This test was carried out in Chamber 5

Instrument	Manufacturer	Type No	TE No	Calibration Period (months)	Calibration Due
Antenna (Active Loop, 9kHz-30MHz)	Rohde & Schwarz	HFH2-Z2	333	24	09-Dec-2018
Antenna (Dish/Tripod/Adaptor, 1GHz-18GHz)	Rohde & Schwarz	AC-008	334		TU
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
EMI Test Receiver	Rohde & Schwarz	ESU40	3506	12	22-Nov-2018

Table 7

TU - Traceability Unscheduled

AC Power Line Conducted Emissions

2.1.8 Specification Reference

FCC 47 CFR Part 18, Clause 18.307

2.1.9 Equipment Under Test and Modification State

Interface, S/N: TA1763 - Modification State 0
Pod, S/N: AA5425- Modification State 0
Pod, S/N: AA5431- Modification State 0

2.1.10 Date of Test

05-December-2017

2.1.11 Test Method

The test was performed in accordance with ANSI C63.10, clause 6.2.

2.1.12 Environmental Conditions

Ambient Temperature	19.0 °C
Relative Humidity	34.0 %

2.1.13 Test Results

Charging

Applied supply voltage: 60 Hz
Applied supply frequency: 120 V AC

Frequency (MHz)	QP Level (dBuV)	QP Limit (dBuV)	QP Margin (dBuV)	AV Level (dBuV)	AV Limit (dBuV)	AV Margin (dBuV)
0.150	50.1	66.0	-15.9	34.4	56.0	-21.6
0.178	42.1	64.6	-22.5	27.1	54.6	-27.5
0.195	42.2	63.8	-21.6	28.5	53.8	-25.3
0.199	40.7	63.6	-22.9	27.1	53.6	-26.6
0.218	36.0	62.9	-26.8	21.8	52.9	-31.1
10.000	18.5	60.0	-41.5	13.2	50.0	-36.8

Table 8 - Live Line Emissions Results

Product Service

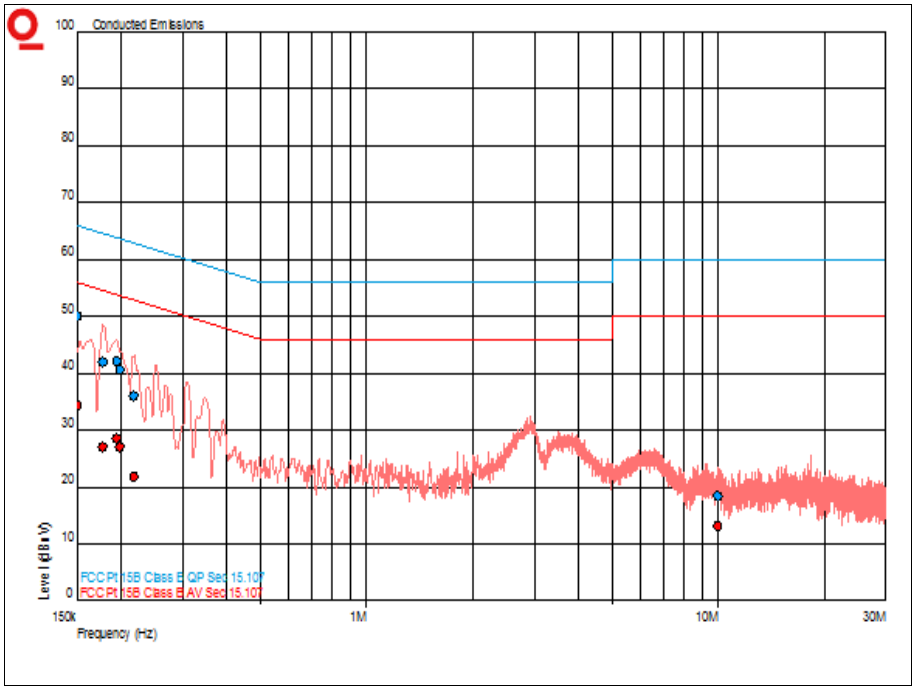

Figure 5 - Live Line - 150 kHz to 30 MHz

Frequency (MHz)	QP Level (dBuV)	QP Limit (dBuV)	QP Margin (dBuV)	AV Level (dBuV)	AV Limit (dBuV)	AV Margin (dBuV)
0.150	51.3	66.0	-14.7	35.7	56.0	-20.3
0.169	46.3	65.0	-18.7	32.1	55.0	-23.0
0.188	42.7	64.1	-21.4	28.7	54.1	-25.4
0.206	38.8	63.4	-24.6	26.4	53.4	-27.0
0.233	40.0	62.3	-22.3	30.2	52.3	-22.1
10.000	47.2	60.0	-12.8	47.4	50.0	-2.6

Table 9 - Neutral Line Emissions Results

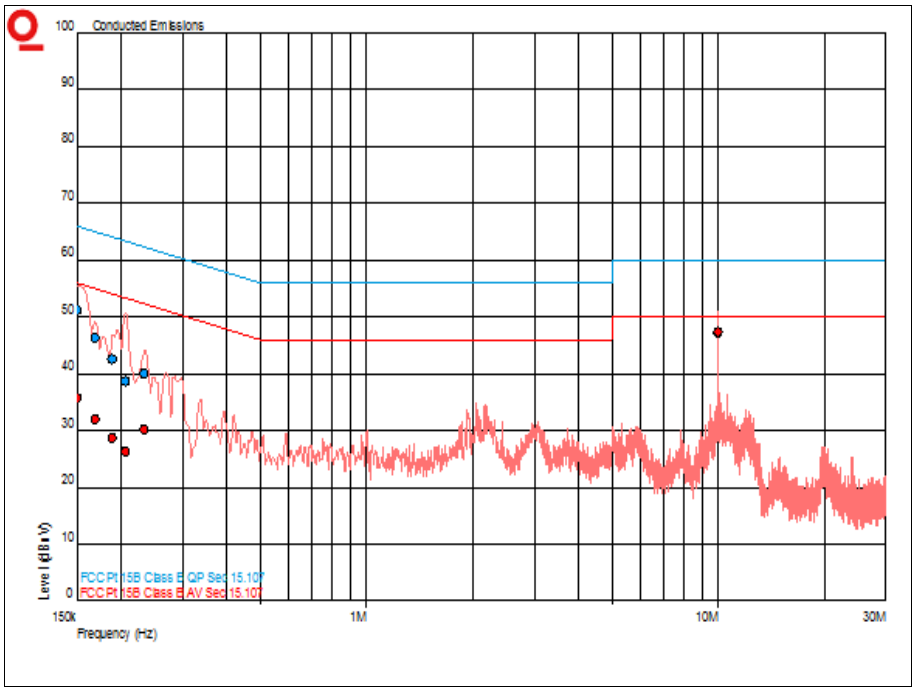

Figure 6 - Neutral Line - 150 kHz to 30 MHz

FCC 47 CFR Part 18, Limit Clause 18.307(b)

Frequency of Emission (MHz)	Conducted Limit (dBµV)	
	Quasi-Peak	Average
0.15 to 0.5	66 to 56*	56 to 46*
0.5 to 5	56	46
5 to 30	60	50

*Decreases with the logarithm of the frequency.

Table 10 - Limit Clause

2.1.14 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
Transient Limiter	Hewlett Packard	11947A	15	12	30-May-2018
LISN (1 Phase)	Chase	MN 2050	336	12	07-Apr-2018
Screened Room (5)	Rainford	Rainford	1545	36	20-Dec-2017
Hygrometer	Rotronic	HYGROPALM 1	2338	12	24-Oct-2018
Digital Multimeter	Iso-tech	IDM-101	2895	12	20-Jul-2018
EMI Test Receiver	Rohde & Schwarz	ESU40	3506	12	22-Nov-2018

Table 11

Product Service

3 Measurement Uncertainty

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

Test Name	Measurement Uncertainty
Field Strength of Emissions	30 MHz to 1 GHz: ± 5.2 dB
AC Power Line Conducted Emissions	150 kHz to 30 MHz, LISN, ±3.7 dB

Table 12