# 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

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	(So Europ)
Authorised Signatory	Matthew Russell	13 December 2017	Russell

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	Alfanter ·

**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.



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# Product Service

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#### **Report Summary** 1

#### 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

Monica Healthcare Ltd Applicant Manufacturer Monica Healthcare Ltd

Model Number(s) Interface, Pod S/N: TA1763 Serial Number(s)

S/N: AA5425 & AA5431

Interface Rev L Hardware Version(s) Pod V2.54 Interface V2.71 Software Version(s)

Pod Rev H

Number of Samples Tested 1 interface with 2 Pods

Test Specification/Issue/Date FCC 47 CFR Part 18: 2016

Order Number issue 2 501559 Date 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)



# 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

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# 1.4 Application Form

			E	QUIPME	NT DESCRIPTION	1			
Model Name	Model Name/Number Novii Syst				em Interface Unit / Novii System Pod				
Part Number 107-PT-00			107-PT-00	1 / 107-F	PT-003				
Hardware V	ersion		Interface F	Rev_L / P	od Rev_H				
Software Ve	ersion		Interface v	2.71 / Po	d v2.54				
FCC ID (if a	pplicable)				e: YOM-6961-MO OM-6960-MON	N			
Industry Car	nada ID (if a	pplicable)		N/A					
		(Please provid led use of the equ		Fetal h					al monitor that records e Contractions from a
				EQUIPM	ENT SUPPLIED				
WPT Source	е								
WPT Client									
WPT System (Client and source designed to work exclusively together)			$\boxtimes$						
				WP'	T SOURCE				
	Type 1 No intelligent communication transmitted wirelessly								
$\boxtimes$	Type 2	1.	modulated i	Fundar	load modulation te mental is < 490 kH	z and		16.11.	
	T 0	2.	- t 0 h - t		ssions are > 40 dE				
	Type 3			uses son	ne form of modula	tion to	transmit in	telligent com	imunication.
Is the device		or us in any of the							
		er WPT device (e.g		lectric ver	nicles)				
		a distance of > 10	) cm						
	Medical D								
		ce operating at a f				.,			
		rt power managei				Yes			_
		ent operate at diffe	erent separa	ation dista	l .	No			_
Minimum D		5 mm			Maximum Distar	nce	5 mm		
		any other wireless	•	excluding	WPT device)?	Yes			
		t secondary frequ	encies?			Yes I	Bluetooth		
State Frequ	encies:	2402 to 2480M	Hz ————						
				WDT 06	NUDOE DEGICAL				
	Single firm	ad nower transfer	zono cinal		OURCE DESIGN				
	-	ed power transfer							
$\boxtimes$	iviuitipie fi	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			voltage				
	ply frequency (Hz)		Olato	voltage				
7.0004	VAC							
	Max Current							
	Hz							
	Single phase			Three phase				
And / O			_	·				
$\boxtimes$	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	•							
	Nickel Cadmium			Lead acid (Vehicle regulated)				
	Alkaline			Leclanche				
$\boxtimes$	Lithium			Other Details:				
4.2	Volts nominal.							
End poi	End point voltage as quoted by equipment manufacturer 3.7 V							
		FREQUE	NCY INI	FORMATION				
Frequen	cy Range	0.11 to 0.205	MHz					
Channel	Spacing (where applicable)							
Receive	r Frequency Range (if different)	to	MHz					
Channel	Spacing (if different)							
Test Fre	quencies*	Bottom		MHz Channel Number (if applicable)				
		Middle		MHz Channel Number (if applicable)				
		Тор		MHz Channel Number (if applicable)				
Intermed	diate Frequencies			MHz				
Highest	Internally Generated Frequency:			MHz				
		DOWED (	CHADA	ACTERISTICS				
Maximu	m TX power 5	W	CHARA	ROTERIOTICO				
	n TX power		ariable)					
	nitter intended for:	v (ii v	ranabic,	)				
Continuo				⊠ Yes □ No				
Intermitt	•			☐ Yes ☐ No				
	ittent state DUTY CYCLE							
Transmi		seconds						
Transmi		seconds						



Product Service

ANTENNA CHARACTERISTICS									
Antenna connector				State impedance	Ohm				
☐ Temporary antenna conne	ctor			State impedance	Ohm				
Integral antenna	Туре	2		State impedance	dBi				
External antenna	Турс			State impedance	dBi				
L External antenna	Туре	<del></del>		лате ітірецапсе	иы				
		MODULATION C	HARA	CTERISTICS					
☐ Amplitude			$\boxtimes$	Frequency					
☐ Phase				Other (please provide detail	s):				
Can the transmitter operate un-m	nodulated?				´ 🗆	Yes		No	
·									
		CLASS OF E	VISSIC	ON USED					
		ITU designation or	Class	of Emission:					
		1							
		(if applicable) 2							
		(if applicable) 3							
If more than three classes of emi	ssion, list s	separately:							
		BATTERY PO	WER	SUPPLY					
Model name/number			Iden	tification/Part number					
Manufacturer			Cou	ntry of Origin					
		ANCILLARIES	S (If ap	plicable)					
Model name/number			Iden	tification/Part number					
Manufacturer			Cou	ntry of Origin					
EXTREME CONDITIONS									
Extreme test voltages (Max)	5.125 / 4.2	V	Extre	eme test voltages (Mix)		V			
Nominal DC Voltage	5/4.2	V	DC N	Maximum Current	2.5	Α			
Maximum temperature	30	°C	Minii	mum 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: TA1	Serial Number: TA1763					
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: 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



# 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

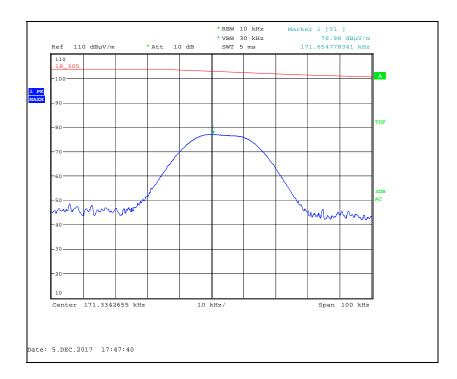


Figure 1 - 172.526- kHz



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
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

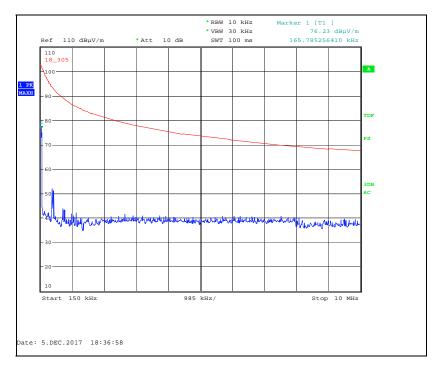


Figure 3 - 150 kHz to 10 MHz



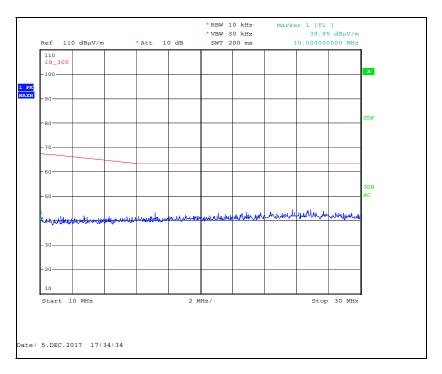


Figure 4 - 10 MHz to 30 MHz

# 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)	
		Below 500	25	300	
Any type unless	Any ISM frequency	500 or more	25 x <b>./F/E00</b>	300 300 300	
otherwise specified (miscellaneous).	Any non-ISM	Below 500	15	300	
	frequency	500 or more	15 x <b>/P/E00</b>	300	

Table 6 - Limit Table



# 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** 



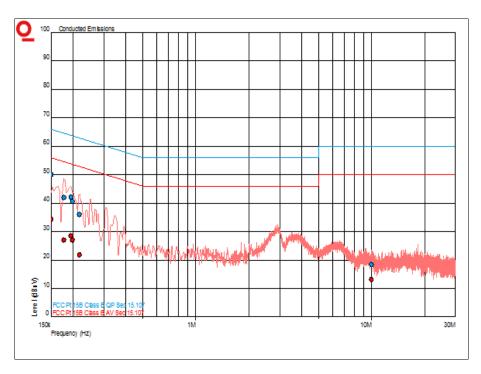


Figure 5 - Live Line - 150 kHz to 30 MHz



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** 

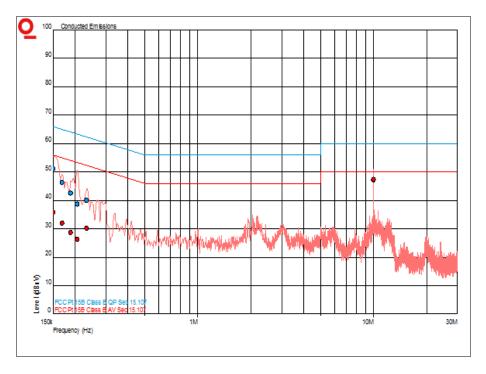


Figure 6 - Neutral Line - 150 kHz to 30 MHz



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

Frequency of Emission (MHz)	Conducted L	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		

<sup>\*</sup>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



# 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