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 15B

Prepared for: Monica Healthcare Ltd Interchange 25 business Park Unit 8 Bostocks lane Nottingham NG10 5QG United Kingdom

FCC ID: Novii Interface-YOM-6961-MON, Novii Pod-YOM-6960-MON

COMMERCIAL-IN-CONFIDENCE

Date: December 2017 Document Number: 75941097-01 | Issue: 01

RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Project Management	Clare Wright	13 December 2017	(Jos Furige)
Authorised Signatory	Matthew Russell	13 December 2017	Aussell

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 15B. The sample tested was found to comply with the requirements defined in the applied rules.

RESPONSIBLE FOR	NAME	DATE	SIGNATURE
Testing	Paul Joynson	13 December 2017	T
Testing	Graeme Lawler	13 December 2017	Alfantar.

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 15B: 2016.



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Contents

1	Report Summary	2
11	Report Modification Record	2
1.2	Introduction	
1.3	Brief Summary of Results	
1.4	Declaration of Build Status	4
1.5	Product Information	6
1.6	Deviations from the Standard	6
1.7	EUT Modification Record	6
1.8	Test Location	7
2	Test Details	8
2.1	Radiated Emissions	8
2.2	AC Power Line Conducted Emissions	13
3	Measurement Uncertainty	17



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	Issue Description of Change	
1	First Issue	13 December 2017

Table 1

1.2 Introduction

Applicant	Monica Healthcare Ltd
Manufacturer	Monica Healthcare Ltd
Model Number(s)	Novii System Interface Unit (107-PT-001)
Serial Number(s)	Novii System Pod (107-PT-003) Interface: TA1772 Pod: AA5233
Hardware Version(s)	Interface: Rev L Pod: Rev H
Software Version(s)	Interface: V2.71 Pod: V2.54
Number of Samples Tested	1 System
Test Specification/Issue/Date	FCC 47 CFR Part 15B: 2016
Order Number Date	Issue 2 501559 30-November-2017
Date of Receipt of EUT	03-December-2017 and 05-December-2017
Start of Test	03-December-2017
Finish of Test	05-December-2017
Name of Engineer(s)	Paul Joynson and Graeme Lawler
Related Document(s)	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 15B is shown below.

Section	Specification Clause	Test Description	Result	Comments/Base Standard
Configuration and Mode: Interface + Pod – Standby				
2.1	15.109	Radiated Emissions	Pass	ANSI C63.4
2.2	15.107	AC Power Line Conducted Emissions	Pass	ANSI C63.4

Table 2

COMMERCIAL-IN-CONFIDENCE

Page 3 of 17



1.4 Declaration of Build Status

Novii System Interface

MAIN EUT			
	Novii System Interface Unit for the Novii Wireless Patch		
MANUFACTURING DESCRIPTION	System		
MANUFACTURER	Monica Healthcare Ltd		
MODEL NAME/NUMBER	Novii System Interface Unit		
PART NUMBER	107-PT-001		
SERIAL NUMBER	TA1763 (TA1764, TA1762, TA1759, TA1752)		
HARDWARE VERSION	Rev L		
SOFTWARE VERSION	Rev 2.71		
PSU VOLTAGE/FREQUENCY/CURRENT	100-240V / 50-60Hz / 2.5A		
HIGHEST INTERNALLY GENERATED /	26 MHz		
USED FREQUENCY	20 101 12		
FCC ID (if applicable)	YOM-6961-MON		
INDUSTRY CANADA ID (if applicable)			
TECHNICAL DESCRIPTION	The Novii System Interface Unit is part of the Novii Wireless		
(a brief description of the intended use and	Patch System: a Maternal/Fetal monitor that records Fetal		
operation)	heart rate, Maternal Heart Rate and Uterine Contractions from		
	a pregnant subject.		
RF CHAR	ACTERISTICS (if applicable)		
TRANSMITTER FREQUENCY	2402 to 2480 (Bluetooth) and 0.110 to 0.205 (Qi charger)		
	2402 to 2480 (Bluetooth) and 0.110 to 0.205 (Qi charger)		
	2440 MHZ (Bluetooth) and 0.157 MHZ (QI charger)		
(i.e. G1D, GYW)	1M00F1D		
	V2.1 LEDP (CESK Plustooth) and fraguancy modulation (O		
(i.e. CMSK OPSK)	charger)		
OUTPUT POWER (W or dBm)	10 dBm (Bluetooth) 37dBm (Oi charger)		
	Novii Interface Unit Dower Supply		
	Novir interface Unit Power Supply		
	100 2401/ 50 60Hz / 2 54		
	China		
	DIII ES (if applicable)		
TYPE			
POWER			
FCCID			
DHSS/EHSS/COMBINED OF OTHER	, <u> </u>		
	II LARIES (if applicable)		
	Monica Healtheare Ltd		
	Novii Pod		
	107-PT-003		
	AA0420, AA0431		



Novii System Pod

MAIN EUT				
MANUFACTURING DESCRIPTION	Novii System Pod for	the Novii Wireless Patc	h Svstem	
MANUFACTURER	Monica Healthcare Lto	d		
MODEL NAME/NUMBER	Novii System Pod			
PART NUMBER	107-PT-003			
SERIAL NUMBER	AA5426, AA5431 (AA	5425. AA5235. AA5266	. AA5233)	
HARDWARE VERSION	Rev H		,	
SOFTWARE VERSION	Rev 2.54			
PSU VOLTAGE/FREQUENCY/CURRENT	Qi wireless charging (from Novii System Inter	face Unit)	
HIGHEST INTERNALLY GENERATED /				
USED FREQUENCY	26MHz			
FCC ID (if applicable)	YOM-6960-MON			
INDUSTRY CANADA ID (if applicable)				
	The Novii System Poo	d is part of the Novii Wir	eless Patch	
TECHNICAL DESCRIPTION	System: a Maternal/F	etal monitor that records	s Fetal heart rate.	
(a brief description of the intended use and	Maternal Heart Rate a	and Uterine Contraction	s from a pregnant	
operation)	subject.		o nom a prognam	
COUNTRY OF ORIGIN	United Kingdom			
RF CHAR	ACTERISTICS (if appli	icable)		
TRANSMITTER EREQUENCY				
OPERATING RANGE (MHz)	2402 to 2480 (Bluetoc	oth) and 0.110 to 0.205	(Qi charger)	
RECEIVER FREQUENCY OPERATING				
RANGE (MHz)	2402 to 2480 (Bluetoc	oth) and 0.110 to 0.205	(Qi charger)	
INTERMEDIATE FREQUENCIES	2440 MHz (Bluetooth)	and 0.157 MHz (Qi cha	arger)	
EMISSION DESIGNATOR(S):				
(i.e. G1D, GXW)	1M00F1D			
MODULATION TYPES	$\sqrt{21 + EDR}$ (GESK Bluetooth) and frequency modulation (Oi			
(i.e. GMSK, QPSK)	charger)			
OUTPUT POWER (W or dBm)	10 dBm (Bluetooth)			
SEPARATE BATT	FRY/POWER SUPPLY	(if applicable)		
MANUFACTURING DESCRIPTION	Novii System Interface	l Init		
	Monica Healthcare I to	4		
TYDE		u		
	107-PT-001			
	On receiver: 5V/DC /	380mA		
	United Kingdom			
MC MC				
DOWER				
FOWER				
EMISSION DESIGNATOR				
DHSS/FHSS/COMBINED OR OTHER				
COUNTRY OF ORIGIN				
ANC	ILLARIES (if applicable	<u>e)</u>	•	
MANUEACTURING DESCRIPTION	Novii System	Novii System Patch		
	Interface Unit	riovii Oyotoni i atoli		
Monica Healthcare Monica Health		Monica Healthcare		
	Ltd Ltd			
ТҮРЕ	Novii Interface	Novii Patch		
PART NUMBER	107-PT-001 107-PT-004			
	TA1763 (TA1764,			
SERIAL NUMBER	TA1762, TA1759,	N/A (disposable)		
	IA1752)			
COUNTRY OF ORIGIN	United Kingdom	USA		



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.

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	772				
0	As supplied by the customer	Not Applicable	Not Applicable		
Serial Number: AA5	Serial Number: AA5233				
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: Interface + Pod – Idle		
Radiated Emissions	Paul Joynson and Graeme Lawler	UKAS
AC Power Line Conducted Emissions	Paul Joynson and Graeme Lawler	UKAS

Table 4

Office Address:

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



2 Test Details

2.1 Radiated Emissions

2.1.1 Specification Reference

FCC 47 CFR Part 15B, Clause 15.109

2.1.2 Equipment Under Test and Modification State

Interface, S/N: TA1772 - Modification State 0 Pod, S/N: AA5233- Modification State 0

2.1.3 Date of Test

04-December-2017 to 05-December-2017

2.1.4 Test Method

The test was performed in accordance with ANSI C63.4, clause 8.

2.1.5 Environmental Conditions

Ambient Temperature	18.1 °C
Relative Humidity	37.0 %

2.1.6 Test Results

Interface + Pod - Standby

Highest frequency generated or used within the EUT: 2.5 GHz Upper frequency test limit: 13.5 GHz

Frequency (MHz)	QP Level (dBuV/m)	QP Limit (dBuV/m)	QP Margin (dBuV/m)	Angle(Deg)	Height(m)	Polarity
83.835	19.3	39.1	-19.8	43	1.00	Vertical
84.761	24.2	39.1	-14.9	116	1.00	Vertical
85.628	17.8	39.1	-21.3	244	1.00	Vertical
493.318	34.1	46.4	-12.3	160	1.00	Vertical
618.755	29.6	46.4	-16.8	151	1.16	Vertical
690.703	38.7	46.4	-7.7	233	1.00	Horizontal
887.805	34.5	46.4	-11.9	129	1.00	Vertical

Table 5 - 30 MHz to 1 GHz





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



Frequency Result (µV/m)		Limit (µV/m)		Margin (µV/m)		Angle (°)	Height	Polarisation	
(GHZ)	Peak	Average	Peak	Average	Peak	Average		(m)	
1.085332	45.16	41.61	69.54	49.54	24.45	7.93	173	350	Vertical
1.282613	44.49	39.22	69.54	49.54	25.5	10.32	165	302	Vertical

Table 6 - 1 GHz to 13.5 GHz

No other emissions were detected within 6 dB of the limit.



Figure 2 - 1 GHz to 8 GHz - Horizontal and Vertical





Figure 3 - 8 GHz to 13.5 GHz - Horizontal and Vertical

FCC 47 CFR Part 15, Limit Clause 15.109

Frequency of Emission (MHz)	Field Strength (µV/m)		
30 to 88	90.0		
88 to 216	150.0		
216 to 960	210.0		
Above 960	300.0		

2.1.7



2.1.8 Test Location and Test Equipment Used

This test was carried out in EMC Chamber 5.

Instrument	Manufacturer	Туре No	TE No	Calibration Period (months)	Calibration Due
Antenna (Bilog)	Schaffner	CBL6143	287	24	18-Apr-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
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
Cable (Rx, Km-Km 2m)	Scott Cables	KPS-1501-2000- KPS	4526	6	22-May-2018
Cable (Rx, SMAm-SMAm 0.5m)	Scott Cables	SLSLL18-SMSM- 00.50M	4528	6	03-Feb-2017
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 7

TU - Traceability Unscheduled



2.2 AC Power Line Conducted Emissions

2.2.1 Specification Reference

FCC 47 CFR Part 15B, Clause 15.107

2.2.2 Equipment Under Test and Modification State

Interface, S/N: TA1772 - Modification State 0

2.2.3 Date of Test

03-December-2017 to 05-December-2017

2.2.4 Test Method

The test was performed in accordance with ANSI C63.4, clause 7.

2.2.5 Environmental Conditions

Ambient Temperature18.1 °CRelative Humidity37.0 %

2.2.6 Test Results

Interface + Pod - Standby

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)
0.152	48.0	79.0	-31.0	35.9	66.0	-30.1
0.288	45.6	79.0	-33.4	44.9	66.0	-21.1
0.504	43.2	73.0	-29.8	42.9	60.0	-17.1
0.790	42.8	73.0	-30.2	42.2	60.0	-17.8
0.863	43.6	73.0	-29.4	42.8	60.0	-17.2
1.152	43.5	73.0	-29.5	42.4	60.0	-17.6

Table 8 - Live Line Emissions Results





Figure 4 - 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)
0.152	47.8	79.0	-31.2	36.7	66.0	-29.3
0.288	45.5	79.0	-33.5	44.8	66.0	-21.2
0.503	43.3	73.0	-29.7	42.9	60.0	-17.1
0.791	43.4	73.0	-29.6	42.7	60.0	-17.3
0.864	43.6	73.0	-29.4	42.9	60.0	-17.1
1.151	43.8	73.0	-29.2	42.7	60.0	-17.3







FCC 47 CFR Part 15, Limit Clause 15.107

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		

Table 10

*Decreases with the logarithm of the frequency.



2.2.7 Test Location and Test Equipment Used

This test was carried out in EMC Chamber 5.

Instrument	Manufacturer	Туре 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
Radiated Emissions	30 MHz to 1 GHz: ±5.2 dB 1 GHz to 40 GHz: ±6.3 dB
AC Power Line Conducted Emissions	150 kHz to 30 MHz, LISN, ±3.7 dB

Table 12