

EMC TEST CERTIFICATE

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UKAS Testing Number 1574

Issued to: -	Mr Ian Dugdale NHS Digital Whitehall II 6 th Floor Leeds West Yorkshire LS1 4HR	Project No. C3289_1
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Electromagnetic Compatibility Test/s were performed on the apparatus as detailed: -

Description	MediPi Patient Unit		
Type number	MPU001		
Serial Number/s	001		
Configuration/ Mode of Operation	Powered via 230V 50Hz simulating 5V 2.5A DC battery power. Providing telemetry for patient monitoring.		
Date received	7 th April 2017	Date Tested	7 th , 8 th , 9 th , 10 th and 21 st April 2017
Specification/s	EN60601-1-2:2007 + Corr.2010	Medical electrical equipment – Part 1: general requirements for safety. Section 1.2 Collateral Standard: Electromagnetic Compatibility – Requirements and tests.	

The apparatus to which this certificate relates was tested against the above specifications. Full results are retained on file at York EMC Services Castleford. The apparatus was found to be compliant with the above specifications subject to the following conditions:

Modifications to the product were conducted during Radiated Emissions. These are detailed below.

UKAS Accreditation

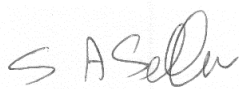
Tests marked "Not UKAS Accredited" in this certificate are not included in the UKAS Accreditation Schedule for our laboratory.

Opinions and interpretations expressed herein are outside the scope of UKAS Accreditation.

EUT Submitted

These results apply only to the particular EUT submitted, in the configuration used and in the mode of operation tested.

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Written by: - Colin Greenfield BEng (Hons)  Laboratory Business Manager	Approved signatory: -  Steve Seller Senior engineer
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Abnormalities/Departures from Standard Conditions

The test standards used reference dated and undated basic standards. Where amendments to the standards have been used, these are indicated.

(A statement must be included recording each such event, see TP14 Insert / Delete where applicable.)

Tests Referenced

EN60601-1-2: 2007 + corrigendum:2010 Medical electrical equipment Part 1-2. General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility – Requirements and tests		
Note: EN60601-1-2: 2007 references dated and undated basic standards. Standards with amendments have been used during testing as indicated below		
Consisting of;	Level	Result
EN55022: 2006 Information technology equipment Radio disturbance characteristics. Limits and methods of measurement	Conducted emissions Class B, Power lines 150kHz to 30MHz	Pass
	Radiated emissions Class B 30MHz to 1000MHz	Pass
EN55011: 2007 Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics - Limits and methods of measurement	Conducted emissions Class B, Power lines 150kHz to 30MHz	Pass
	Radiated emissions Class B 30MHz to 1000MHz	Pass
EN 61000-3-2:2014 Part 3-2: Limits – Limits for harmonic current emissions (equipment input current up to and including 16A per phase.	Class A	Pass
EN61000-3-3: 2013 Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current $\leq 16A$ per phase and not subject to conditional connection.	Pst Dmax	Pass
EN61000-4-2: 1995 Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test. (Equipment calibrated to EN61000-4-2:2009)	8kV air discharge 6kV contact discharge	Pass
EN61000-4-3: 2006 Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test (Equipment calibrated to EN61000-4-3:2006 +A1:2008 +A2:2010)	3/10V/m 80MHz to 2500MHz 2Hz/1kHz 80% AM	Pass
EN61000-4-4: 2004 Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test (Equipment calibrated to EN61000-4-4:2012)	2kV Power lines	Pass
EN61000-4-5: 2006 Part 4-5: Testing and measurement techniques - Surge immunity	2kV line to earth 1kV line to line	Pass
EN61000-4-6: 2007 Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields (Equipment calibrated to EN61000-4-6:2014)	3Vrms Power lines 150kHz to 80MHz 2Hz/1kHz 80% AM	Pass
EN61000-4-8: 2010 (Calibrated and tested to this version) Testing and measurement techniques - Power frequency magnetic field immunity test	3A/m 50/60Hz	Pass
1995EN61000-4-11: 2004 Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests	0% residual for +/- 0.5 cycles 40% residual for 5 cycles 70% residual for 25 cycles 0% residual for 250 cycles	Pass

Modifications incorporated during testing

In order to pass radiated emissions testing, 30MHz to 1GHz, the following modifications took place:

1 x Würth ferrite, 742 700 33, was fitted on both internal power leads.

1 x Würth ferrite, 742 716 33, was fitted to the EUT end of the power lead.

1 x Würth ferrite, 742 722 4, was fitted to the internal ribbon cable.

The internal enclosure was copper lined, the HDMI, Ethernet and USB ports were programmatically disabled.

Opinions/Interpretations/Additional information

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None

-----End of Certificate-----