# EMC TEST CERTIFICATE

York EMC Services Ltd
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UKAS Testing Number 1574

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| **Issued to: -** | **Mr Ian Dugdale**<br>**NHS Digital**<br>**Whitehall II**<br>**6th Floor**<br>**Leeds**<br>**West Yorkshire**<br>**LS1 4HR** | **Project No.**<br><br>**C3289_1** |

**Electromagnetic Compatibility Test/s were performed on the apparatus as detailed: -**

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| **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** | **7th April 2017** | **Date Tested** | **7th, 8th, 9th, 10th and 21st 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)**<br>**Laboratory Business Manager** | **Approved signatory: -**<br>Steve Seller Senior engineer |

## 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 events, 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<br>Information technology equipment Radio disturbance characteristics. Limits and methods of measurement | Conducted emissions Class B, Power lines<br>150kHz to 30MHz | Pass |
| | Radiated emissions Class B<br>30MHz to 1000MHz | Pass |
| EN55011: 2007<br>Industrial, scientific and medical (ISM) radio-frequency equipment – Electromagnetic disturbance characteristics - Limits and methods of measurement | Conducted emissions Class B, Power lines<br>150kHz to 30MHz | Pass |
| | Radiated emissions Class B<br>30MHz to 1000MHz | Pass |
| EN 61000-3-2:2014<br>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<br>Part 3-3: Limits – Limitation of voltage changes, voltage fluctuations and flicker in public low-voltage supply systems, for equipment with rated current ≤ 16A per phase and not subject to conditional connection. | Pst<br>Dmax | Pass |
| EN61000-4-2: 1995<br>Part 4-2: Testing and measurement techniques - Electrostatic discharge immunity test.<br>(Equipment calibrated to EN61000-4-2:2009) | 8kV air discharge<br>6kV contact discharge | Pass |
| EN61000-4-3: 2006<br>Part 4-3: Testing and measurement techniques - Radiated, radio-frequency, electromagnetic field immunity test<br>(Equipment calibrated to EN61000-4-3:2006 +A1:2008 +A2:2010) | 3/10V/m<br>80MHz to 2500MHz<br>2Hz/1kHz 80% AM | Pass |
| EN61000-4-4: 2004<br>Part 4-4: Testing and measurement techniques - Electrical fast transient/burst immunity test<br>(Equipment calibrated to EN61000-4-4:2012) | 2kV Power lines | Pass |
| EN61000-4-5: 2006<br>Part 4-5: Testing and measurement techniques - Surge immunity | 2kV line to earth<br>1kV line to line | Pass |
| EN61000-4-6: 2007<br>Part 4-6: Testing and measurement techniques - Immunity to conducted disturbances, induced by radio-frequency fields<br>(Equipment calibrated to EN61000-4-6:2014) | 3Vrms Power lines<br>150kHz to 80MHz<br>2Hz/1kHz 80% AM | Pass |
| EN61000-4-8: 2010 (Calibrated and tested to this version)<br>Testing and measurement techniques - Power frequency magnetic field immunity test | 3A/m<br>50/60Hz | Pass |
| 1995EN61000-4-11: 2004<br>Part 4-11: Testing and measurement techniques - Voltage dips, short interruptions and voltage variations immunity tests | 0% residual for +/- 0.5 cycles<br>40% residual for 5 cycles<br>70% residual for 25 cycles<br>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 Wurth ferrite, 742 700 33, was fitted on both internal power leads.
1 x Wurth ferrite, 742 716 33, was fitted to the EUT end of the power lead.
1 x Wurth 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

None

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