

Tonometer MK3

A list of tests carried out in accordance with IEC 60601-1-2 3rd and 4th Edition is shown below. Refer to test reports (3rd) RFI-EMC-RP78743JD01A Issue 1 and (4th) 75943089-01 Issue: 02. The 4th Edition test report has been conducted on a gap analysis basis to test the new requirements within the updated standard.

Test Type
General Requirements; Risk Management Process for ME Equipment and ME Systems
Identification, Marking and Documents
Electromagnetic radiation disturbances (Enclosure)
Mains terminal disturbance (AC Mains Input / Output Ports)
Harmonic Distortion (AC Mains Input Port)
Voltage Fluctuations and Flicker (AC Mains Input Port)
Immunity to Electrostatic discharge (Enclosure Port)
Immunity to Radiated RF Electromagnetic Fields (Enclosure Port)
Immunity to Proximity Fields from RF Wireless Communication Equipment (Enclosure Port)
Immunity to Rated Power Frequency Magnetic Field (Enclosure Port)
Immunity to Electrical Fast Transient / Burst (AC Power Port)
Immunity to Conducted Disturbances Induced by RF Fields (AC Power Port)
Immunity to Voltage Dips and Voltage Variations (AC Power Port)
Immunity to surges
Immunity to conducted disturbances, induced by RF Fields

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	Title; EMC tests – Tonometer MK3		

No deviations from the applicable test standards or test plan were made during testing. One failure was noted within test report 75943089-01 Issue: 02. Section 2.1.7 details the failed test results for the Immunity to electrostatic discharge test. The test report contains a section on incident reports raised as a result of a failed test, refer to pages 34 & 35 for this incident report & signed justification. The product risk file RAHS2017923 & Instructions for Use 1902538 have been updated to include this failure and corrective actions to be taken by the end user.