



IEC SC62A MT 23 Liaison Report to C63[®] SC8 6 May 2015

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IEC SC62A MT23 Liaison Report

- IEC/TR 60601-4-2: Medical electrical equipment – Part 4-2: Guidance and interpretation – Electromagnetic immunity; performance of medical electrical equipment and medical electrical systems
 - Former Annex J of 60601-1-2 Ed 4
 - Revised
 - Submitted to Secretary, SC62A, May 1, 2015 for editing and circulation as CD2
 - Will be circulated for a three-month comment period

IEC SC62A MT23 Liaison Report (cont'd)

- Compilation of comments on CD1, with responses, submitted to Secretary, SC62A, May 1, 2015 for circulation

IEC SC62A MT23 Liaison Report (cont'd)

- Performance TR
 - CD1 was not in a standard IEC format
 - Referred to text in -1-2 and e.g., “replace ‘shall’ with ‘should’”
 - Revising to the form of an amendment of -1-2 was not appropriate
 - Revised to be stand-alone
 - No emissions requirements
 - Assumed covered by 60601-1-2

IEC SC62A MT23 Liaison Report (cont'd)

- Performance TR (cont'd)
 - Assumed and highly recommended to perform testing to both IEC 60601-1-2 and the TR
 - Concurrent or sequential testing with -1-2 recommended
 - Scope: This Technical Report applies to the IMMUNITY of ME EQUIPMENT and ME SYSTEMS.
 - Immunity test levels
 - -1-2: reasonably foreseeable maximum
 - -4-2: typical, the same for home and hospital

IEC SC62A MT23 Liaison Report (cont'd)

- Performance TR (cont'd)
 - ESD immunity was a hot topic in MT23
 - Test levels: 4 kV contact, 8 kV air
 - Extensive specifications for testing of connector shells and pins
 - Performance criteria – modified versions of A, B, C

IEC SC62A MT23 Liaison Report (cont'd)

- SC62A call for systematic review of 60601-1 and all collaterals
 - Call for 60601-1-2 – 62A/992/DC
 - In US, comments were collected by AAMI
 - MT23 “gap analysis” of 83 items submitted
 - All comments on -1-2 were from FDA
 - Comment period closes 2015-05-08

IEC SC62A MT23 Liaison Report (cont'd)

- MT23 ongoing work
 - Edition 5 is in progress
 - “Gap analysis” drafted and updated
 - Estimated publication 2019
- MT23 members presented workshops at EMC Santa Clara 2015
 - Introduction to Medical EMC
 - Risk-Managing EMC