

Management summary

on the impact of the new medical EMC standard IEC 60601-1-2:2014

In February 2014, the IEC published the 4th edition of the medical standard IEC 60601-1-2:2014, a safety standard with respect to electromagnetic (EM) disturbances. This new edition may have a significant impact on the design, testing and documentation of your medical devices.

What's new in the 4th edition?

In the 4th edition the requirements are based on three intended use environments of the equipment, instead of the purpose of the equipment: professional healthcare facility (eg: hospital, physician offices), home healthcare (eg: homes, nursing home, public places), and special environment (military areas, heavy industrial areas, high power medical equipment ...).

Overleaf is a summary of the main differences in immunity test levels between edition 3 (2007) and edition 4 (2014).

Edition 4 has **more stringent immunity requirements** for electrostatic discharges, magnetic fields, proximity fields from wireless transmitters. Proximity fields from RF wireless communication equipment is a new test that is based on a minimum separation distance of 30 cm between the wireless communication transmitter and the medical device. This test is now included because mobile device usage restrictions are generally ignored.

In addition to these increased immunity test levels, the risk management section has been expanded. **Risk management of electromagnetic disturbances** (including reliable wireless connections) has become a mandatory compliance requirement over the operational lifetime of a medical device. All risk information (analysis, evaluation, control, customer complaints, revised standards, market surveillance reports, etc.) has to be maintained in the risk management file. **Compliance is checked by inspection of the test report and the risk management file.**

When do you have to comply with the 4th edition?

The 4th edition of the medical EM standard IEC 60601-1-2:2014 will become mandatory in the United States and the European Union from December 31st 2018 onwards. The FDA does not require retesting of legacy products unless changes are made to the product that may affect its compliance.

In the European Union, all devices including legacy devices placed on the market must comply with the new 4th edition standard after this date. For other regions it varies with the local regulations of the country.

What about EMC performance?

IEC 60601-1-2:2014 is a safety standard. The test levels for basic safety and essential performance are based on reasonably foreseeable **maximum levels of EM disturbances**. A technical report IEC TR 60601-4-2:2016 has been issued to provide guidance on assessing immunity, with regard to EMC performance (intended use). The immunity test levels for EMC performance are based on **typical levels of EM disturbances**. This technical report can be used in conjunction with IEC 60601-1-2 and testing for conformity to both documents can be done at the same time.

Comparison of immunity test levels IEC 60601-1-2: edition 3 versus 4

| Immunity test | IEC 60601-1-2:2007 3 rd Edition | IEC 60601-1-2:2014 4 th Edition | |
|--|---|---|--|
| | | Professional Healthcare | Home Healthcare |
| ESD IEC 61000-4-2 | ±6 kV contact discharge ±2, 4, 6, 8 kV air discharge | ±8 kV contact discharge ±2, 4, 6, 8, 15 kV air discharge | |
| Radiated RF fields IEC 61000-4-3 | 3 V/m – non life support 10V/m – life support 80 MHz – 2.5 GHz 80% AM (2 Hz or 1 kHz) | 3 V/m 80 MHz – 2.7 GHz 80% AM 1 kHz | 10 V/m 80 MHz – 2.7 GHz 80% AM 1 kHz |
| Proximity fields from wireless transmitters IEC 61000-4-3 IEC 61000-4-39 (draft) (NEW TEST) | No test | 9 V/m to 28 V/m 15 Spot frequencies (MHz): 385, 450, 710, 745, 780, 810, 870, 930, 1720, 1845, 1970, 2450, 5240, 5500, and 5785 MHz PM 18 Hz or 217 Hz (50% duty cycle) | |
| EFT/Bursts IEC 61000-4-4 | ±2 kV, AC mains ±1 kV, I/O ports 5 kHz or 100 kHz PRR | ±2 kV, AC mains ±1 kV, I/O ports 100 kHz PRR | |
| Surges IEC 61000-4-5 AC mains, Line to Ground AC mains, Line to Line DC input (>3m) L to G DC input (>3m) L to L I/O Line to Ground | ±0.5, 1, 2 kV ±0.5, 1 kV No test No test No test | ±0.5, 1, 2 kV ±0.5, 1 kV ±0.5, 1, 2 kV ±0.5, 1 kV ±2 kV (outdoor lines only) | |
| Conducted RF disturbances IEC 61000-4-6 | 3 V (0.15 – 80 MHz) 10 V ISM Bands Life support | 3 V (0.15 – 80 MHz) 6 V ISM Bands 80% AM 1 kHz | 3 V (0.15 – 80 MHz) 6 V ISM + Amateur Bands 80% AM 1 kHz |
| 50/60 Hz magnetic fields IEC 61000-4-8 | 3 A/m – 50 and 60 Hz | 30 A/m – 50 or 60 Hz | |
| Mains voltage dips and interruptions IEC 61000-4-11 | >95% dip, 0.5 periods, 0° and 180° 60% dip, 5 periods 30% dip, 25 periods Interrupt >95% drop, 5 sec | 100% dip, 0.5 periods, 0°, 45°, 90°, 135°, 180°, 225°, 270°, 315° 100% dip, 1 period 30% dip, 25/30 periods (50/60 Hz) Interrupt 100% drop, 5 sec | |

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