FDA extends EMC standard transition date to December 2018

FDA recently announced an extension to the transition date for the Medical EMC standard ANSI/AAMI/IEC 60601-1-2 to December 2018. Although the transition date is now set for 2018, UL Medical EMC experts advise that FDA's publication "Design Considerations for Devices Intended for Home Use –Guidance for Industry and Food and Drug Administration Staff" suggests using the 4th edition of IEC 60601-1-2 for Home Healthcare environments now to cover test levels which may not be appropriately addressed in the 3rd edition.

Key Changes

Following are some of the key changes in the 4th edition.

Use environments are split into three areas:

- Professional Healthcare Facility Environment
- Home Healthcare Environment
- Special Environment (test levels specified in Annex E)

Small clinic, and Home use equipment need CISPR 11 Class B emission, IEC 61000-3-2 Class A harmonic distortion, and IEC 61000-3-3 voltage fluctuation and flicker. The home use equipment needs 10 V/m, 80 MHz to 1 GHz immunity.

For equipment that is installed in an aircraft or an ambulance, additional testing per ISO 7137 and CISPR 25 applies.

For an EUT with auto ranging power supply, most tests are required to be performed at one nominal voltage only. Only voltage interruptions need to be performed at maximum and minimum voltage if the rated voltage range is >25% of lowest rated input voltage.

Immunity test levels increase:

- The range of testing for radiated immunity harmonized up to 2.7GHz (up from 2.5GHz in the 3rd edition)
- Magnetic immunity at 30A/m
- Conducted immunity at 6V in ISM bands
- ESD at 8kV contact and 15kV air (up from 6kV and 8kV in the 3rd edition)
- Voltage dips and interruptions at additional phase angles

In addition to these Immunity changes:

- Immunity levels (Table 9) are harmonized with IEC 60601-1-11
- Immunity testing now follows the same port-by-port convention of the IEC 61000-6 series of Generic EMC standards
- Immunity to proximity fields from RF wireless communications equipment is now included, and is based on a minimum separation distance of 30cm
- There is a procedure for continuing to test a product that is damaged by an immunity test signal

And Risk Management is expanded:

- Manufacturers will be required to submit a test plan and the risk analysis document before testing
- Operating modes are based on risk analysis
- Reasonably foreseeable electromagnetic disturbances (Annex F) shall be taken into account in the risk management process
- The risk management process is used to determine whether subsystem testing is allowed
- The minimum separation distance are considered in the risk management process
- Reduced test levels (e.g. based on the intended use of the product) must be justified in the risk management file

MEGA Electronics Is updating our entire line of medical power supplies to met the new 4th edition requirements. We will be pleased to provide you with a quotation for power supplies that meet the new 4th edition.

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