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## How does IEC 60601-1-2 EMC 4th Edition relate to power supplies?

The growing use of wirelessly connected devices like mobile phones, tablets, laptop computers and gaming consoles pose a risk to equipment sensitive to EMI and EMC. On aircraft, restrictions on the use of these devices have long been in place and in general, the public are aware of that policy. In the past, many of us have seen notices in hospitals asking visitors to not use their phones in intensive care, critical care pediatric units and where specialized medical equipment is located.

With the growing popularity of home healthcare, enforcing such a policy is impossible. The medical regulatory bodies, like the FDA (Food and Drug Administration), are now requiring equipment manufacturers to design and test their products to avoid any potential risk of patient harm. This also includes electrostatic discharge (ESD), radio interference, voltage surges and power interruptions.

In 2014 an update to IEC 60601-1-2 was published and it "applies to basic safety and essential performance of medical equipment and systems in the presence of electromagnetic disturbances and to electromagnetic disturbances emitted by that equipment and systems". Product categories were added and higher EMC test levels introduced. Manufacturers must submit risk analysis documentation for both normal and abnormal use of their equipment and systems. This standard is often referred to as the "4th edition".

The "life-supporting equipment" category has been removed from the standard, and it has been replaced by electromagnetic environments of "intended use". According to IEC 60601-1 (2012) it is defined as "use for which a product, process or service is intended according to the specifications, instructions and information provided by the manufacturer". These intended use environments are:

1) Professional healthcare facilities with attending medical staff, and include hospitals, dental surgeries, surgery rooms and intensive care.

2) Home healthcare which is defined by IEC 60601-1-11 as dwelling places where patients live or places where patients are present - excluding (1)

3) "Special" environments are those that exclude (1) and (2), but include heavy industrial plants or medical treatment areas with high powered medical electrical equipment (such as short wave therapy equipment).

As far as timing for the update, EN 60601-1-2:2007 3rd Edition is scheduled to be withdrawn on December 31st, 2018, and will be replaced with the 2015 version of EN 60601-1-2. This is also the FDA compliance date in the US, after several recent delays from July 2014, aligning it with the European Union Medical Devices Directive 93/42/EEC. The FDA has urged manufacturers to test for compliance as quickly as possible.

Power supplies are not medical devices and the Medical Device Directive cannot be documented on the CE Declaration of Conformity, even for an external power supply. It is highly recommended that power supply manufacturers comply with IEC 60601-1-2: 2014, to avoid failures in the end equipment or system. Most are testing and working to meet the higher levels of susceptibility, as the changes to emissions are relatively minor.

The susceptibility changes are based on the IEC 61000-4 set of standards and include:

IEC 61000-4-2 (Electrostatic Discharge): Test levels for contact discharge increased from ±6kV to ±8kV and air discharge levels nearly doubled to ±15kV from ±8kV. This is to cover higher levels of ESD that will occur with home use.

IEC 61000-4-3 (Radiated RF Electromagnetic Fields): Again this is aimed at home healthcare use where the 3V/m test has been extended to 10V/m. The RF susceptibility test has been extended from 80 MHz to 2.7 GHz, because of potential proximity to wireless communication equipment, including Bluetooth and WLAN.

IEC 61000-4-4 (Electrical Fast Transients): The pulse repetition frequency rose from 5 kHz to 100 kHz, to reflect real operating environments.

IEC 61000-4-5 (Surge Immunity) + ISO 7637-2 (Electrical transient conduction along supply lines): Changes here were made to include permanently connected DC input devices, for applications such as ambulances.

IEC 61000-4-6 (Conducted RF Immunity): It is here where the differentiation has been eliminated between life support and industrial, scientific and medical. Testing has to be made at a potential risk frequency, for example where the equipment might be used in proximity with ham radios.

IEC 61000-4-8 (Power Frequency Magnetic Fields): Test levels for power frequency magnetic fields have risen from 3 A/m to 10 A/m for all environments, but only for

equipment that may be sensitive to magnetic fields, containing relays or hard disc drives for example.

IEC 61000-4-11 (Voltage Dips and Interruptions): This is where the risk management documentation will be often used. Although tests must now be made at multiple phase-angles (not just at $0^{o}$ and $180^{o}$) the percentage dip in line voltage, and number of periods, have also been changed for some devices. The 5 second interruption requirement will need to be met at the equipment level as it is highly unlikely that a standard power supply will continue to operate with the input being removed for 5 seconds. The equipment manufacturer for a heart rate monitor could document that this will not be a problem, since battery back-up is in place.

Power supply manufacturers will qualify their products as “compliant”, and provide a test report detailing the results. For example, for the 5 second interruption in IEC 61000-4-11, it will be stated that the power supply will shut down, and automatically recover.

Power Guy