The role of EMI/EMC for the medical devices according to IEC – 60601-1 standards

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Abstract.

This paper gives information about the important role of the EMI/EMC for the medical devices according to the standard IEC-60601-1. PRE-Compliance testing is mandatory for all medical devices. The main objective of pre-compliance tests is all about whether the device is affected by electromagnetic interference. Electromagnetic interference is the disruption of an electronic device when in the vicinity of electromagnetic energy of an external source either man-made or naturally occurring.

1. Introduction

In any medical field the EMI/EMC test plays a crucial role because the equipment or DUT (Device Under Test) device that can produce the radiations so it can be affected to the patients or environment. So, we can do analysis in the EMI/EMC testing and we can eliminate those errors, so the device is safe for the patients, so, the performance and quality of the product will be increase and the DUT or equipment working with a good condition.

2. Test method

2.1 Radiated Emissions Test:

Radiated emissions refer to the unintentional release of electromagnetic energy from an electronic device or apparatus. Any device may create electromagnetic fields that unintentionally propagate away from the structure of the device. The standard that we used is CISPR11. They are three methods for testing open area test site (OATS), semi-Anechoic chamber, shielded room the method we use is the shield room it is a closed chamber with a ceiling all around with a metal surface with an antenna (1.5 height) placed 3m away from
the DUT. It is not more accurate when compared to the OATS spectrum analyser is used for displaying the test limits of radiations. The room has one air inlets and one outlet with a mesh acting as a semi-permeable membrane for voice, noise sound the shield is free of signals and noise[1].

Fig-1: Radiated emissions test setup.

2.2 Conducted emissions test:

Measurements were carried out using real-time spectrum analyzer (Make: Tektronix/Model: RSA 513A), with quasi-peak (QP) detector. An LISN (Line Impedance Stabilization Network) or AMN (Artificial Mains Network) is required to provide a defined, stable, impedance to the Equipment Under Test (EUT) Isolates the EUT from the power distribution network (or power source); thereby minimizing potential effects of external influences on the measurements, and facilitating accurate and repeatable results. The EUT was located so that the distance between the boundary of the EUT and the closest surface of the LISN is 0.8m power cord or harness to other components/systems or power grid. conducted RF emissions are electromagnetic disturbances (noise, voltages, currents) caused by the electrical and electronics [2].

Fig-2: Conducted emissions test setup.
2.3 Electrostatic Discharge Test:

We are all used to receiving electric shocks from ESD usually from our fingers as we go to open a door or cabinet with a metal handle usually when the air is very dry. Sometimes these shocks can be quite painful, most people will not notice that the spark has flown from their fingers that discharge voltage is at least 3kv ESD immunity simply refers to the product immunity to the static electrical voltages and their discharge from the people’s fingers or from keys or other metal objects held in their hands. In the test, we use the ESD generator and ESD gun and two tips one is air and contact we had applied to the different parts of the equipment’s or device for the different voltages for the air type we applied 2kv,4kv,8kv,15kv, and for contact type 2kv,4kv,6kv,8kv. The standard that we are used for this test is IEC 61000-4-2[3].

![Fig-3a: Electrostatic discharge test Setup.](image-url)
2.4 Surge test/Electrical fast transient test:

The surge immunity test is designed to simulate low-frequency power surges. Surge is usually applied to ac and dc power inputs ports in some standards it also applied to signal ports. The EUT and its attached cables were placed on a non-conductive support 10cm above a reference ground plane. Electrical fast transients and bursts were injected into power cable via inbuilt CDN of EFT generator. The EUT operation was monitored during the test. In this test we measure up to 2kv only L-N-PE with different phase angels 0, 90, 180, 270 0c. the standards that we applied to this is IEC-61000-4-5[5].

The electrical fast transient test is used the simulated switching to inductive loads in the real world when we are using external ac/dc adapters EMC is most likely inject eft pulses onto the line and neutrals wires the standards which we are used is IEC 61000-4-4[4].
2.5 Conducted rf immunity test:

The conducted rf immunity test is used for simulating the normal voltages and currents environment of external power and signal cables. The test is under IEC 6100-4-6. The EUT and its associated accessories were placed on a non-conductive support 10cm above a reference ground plane. Radio-frequency conducted disturbances were injected into the EUT cables via a CDN. The frequency was swept from 150 KHz to 80MHz. The EUT operation was monitored during the test. Any method of cable RF injection testing should require that the common mode impedance at the end of the cable remote from the EUT be defined. Each type of cable should have a common mode decoupling network as its far end to ensure this impedance with respect to the ground reference plane (GRP) and to isolate any ancillary equipment from the effect of the RF current on the cable [6].

Fig-5a : Conducted rf immunity test setup

Fig-5b: Conducted rf immunity test.

3. Conclusion:

The finally we conclude that the combinations of electrical devices in the hospital can pose the risk of EMC issues. ME devices could provide a vital function to the patient therefore EMC issues could have critical consequences so using this immunity and radiated tests setup we can eliminate these issues and make the equipment environmental and functionality good working condition and patient safety.

4. References:

[1] Radiated Emission Test “standards CISPIR 11”.
[2] Conducted Emission Test “standards CISPIR 16-1-1”.
[3] Electro Static Discharge Test “standards” 61000-1-2”.
[4] Electrical Fast Transient Test standards ‘IEC 61000-4-4’.
[5] Surge Test standards ‘IEC 61000-4-5’.
[6] Conducted rf immunity test standards’ IEC 61000-4-6’
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