Addressing electromagnetic compatibility (EMC) in the healthcare environment

A modern operating theatre or intensive care unit contains many pieces of electronic equipment, which all have to function safely and reliably in close proximity to each other. To ensure that this can happen, it is vital for those who design, manage, or use electro-medical devices to consider electromagnetic compatibility (EMC). In a hospital, the electromagnetic environment can be quite harsh, containing, for example, sources of energy such as electro-surgery units, short-wave diathermy and microwave ablation equipment, in close proximity to safety-critical therapeutic devices and diagnostic sensors that need to detect very small signals, often at millivolt levels.

Introduction

Many healthcare professionals first became aware of EMC when hospitals started banning mobile phones about ten years ago, although electromagnetic interference (EMI) problems have actually been documented as far back as the 1860s. An area related to EMC is radio frequency (RF) spectrum management, which is becoming increasingly necessary owing to the rapidly proliferating number of wireless communications systems including two-way radios, wireless local-area networks (WLANs) and Bluetooth-enabled devices. In both areas, it is important to have a good awareness not only of the relevant directives and standards, but also of the physical interactions that are responsible for EMI.

What are EMC and EMI?

Electromagnetic Compatibility (EMC) is the ability of an equipment or system to function satisfactorily in its electromagnetic environment without introducing intolerable electromagnetic disturbances to anything within that environment. This definition applies to all electromagnetic equipment, IT (Information Technology) systems, communications equipment as well as to the infrastructure, e.g. power systems, lifts, air conditioning units, lighting, alarm systems, to cite only a few examples. The medical healthcare industry, as well as any other industry, is becoming increasingly dependent upon electrical/electronic systems for its day-to-day activities. As a result, the number and diversity of EMI sources are likely to become varied, subtler and therefore more difficult to eradicate. In general, EMI sources can be classified under two headings: "internal EMI sources" and "external EMI sources". Internal EMI sources are associated with devices (power supply unit, processor board etc.) and components that are present within the systems and interfere with one another (often due to poor EMC design). External EMI is generated by sources outside the system. These sources could be lift motors, lighting systems, electromedical equipment, microcomputers, mobile phones, and even thunderstorms.

For electromagnetic disturbances to cause interference, they must be propagated in some way. There are three main physical mechanisms of electromagnetic propagation: conduction, reactive coupling and radiation.

Conducted EMI

This is propagated via power cables, earth conductors, signal cables and other low impedance paths for frequencies below 30MHz (above this frequency, conducted interference suffers substantial attenuation and radiation becomes the principal propagation mechanism).

Reactive coupling

Reactive coupling, either inductive or capacitive (also commonly known as cross talk), may also propagate electromagnetic energy. The precise effects depend upon distance, orientation, size, earthing techniques and other factors, all of which will tend to be unique to the system. In general, inductive coupling tends to be associated with high currents and low impedance situations, whilst capacitive coupling tends to occur in a high voltage and high impedance scenario. Reactive coupling will often occur when different types of cables (power cables, data signal cables, alarm system cables) are bundled together over long distances.

Radiation

Radiated EMI tends to dominate for frequencies above 30MHz. In this case, electromagnetic energy is propagated through the air and emissions are generated as a by-product of the primary function of the equipment.

It should be noted that, in any given situation, EMI propagation may well be via a combination of two or three of the above mechanisms, rather than being due to a single mechanism in isolation.

EMC Compliance for electromedical products

Manufacturers of medical equipment and devices are required to comply with the relevant Medical Directive in order to market their products in the European Union (EU) [1]. To carry the CE mark, manufacturers and device designers are required to demonstrate compliance of their equipment to the Electromagnetic Compatibility (EMC) standard EN60601-1-2 [2]. EMC testing is performed in order to ensure that the equipment will not produce an unacceptable level of electromagnetic interference affecting other equipment operating in close proximity (emission aspect) and also to check how robust the equipment itself is to electromagnetic interferences (immunity aspect).

On the 1st November 2004, the first version of EN60601-1-2 (published in 1993) was withdrawn. Since then, manufacturers are only able to declare compliance to the second edition (EN60601-1-2: 2001). The changes between the two versions are significant.

The most significant revision to EN60601-1-2 is increased testing levels for electro-static discharge (ESD), radio-frequency (RF) immunity up to 2.5GHz, surge immunity and electrical fast transients (ETTs). Tests for conducted RF immunity, magnetic field immunity, voltage dips, harmonic distortion and voltage flicker are also required. In addition, the standard contains more comprehensive pass/fail criteria that require clinical utility to be maintained during immunity testing and that the manufacturer defines the acceptable criteria of clinical utility. The 2001 edition of EN60601-1-2 still calls for CISPR11 [3] emissions (International Special Committee for Radio Interference) with an additional test for harmonics and voltage fluctuation (flicker).

Managing EMC in the hospital environment

Although modern electromedical equipment is generally designed with a high level of attention to EMC, this does not mean that the CE mark guarantees there will be no interferences problems. The standard allows high emissions at the ISM (Industrial, Scientific and Medical) frequencies, and there may also be older equipment still in use that had been tested to a less stringent version of the standards. Furthermore, anyone modifying or repairing equipment should pay attention to EMC design principles. For example, simply removing a few screws from the lid of a shielded enclosure can greatly increase its radiated emissions.

There is often more than one way to cure or prevent an EMI problem: we can tackle either the source of the emissions, the 'victim' of the interference, or the coupling path between them. Sources of EMI are any circuit that produces fast changes in voltage or current, either by rapid switching or by operating at radio or microwave frequencies. Typical examples are ambulance radios, two-way radio systems, motors drives etc. Sometimes, different sources use the same electromagnetic frequencies, and in this case some spectrum management is necessary.
An example is the 2.4GHz ISM band, which is used by wireless local area networks (WLANs), Bluetooth wireless devices (e.g. cordless data-loggers) as well as microwave ovens and a number of medical applications including hyperthermia and interstitial ablation of tissue. There are reports of interference between WLANs and Bluetooth [4] so the installation of these systems devices should be monitored by means of an EMC site survey (Figure 2).

The electromagnetic fields from electronic circuits tend to fall off with distance, so physical separation can be effective in minimising interference. For cable installation, standards give guidance on distances between different types of cables [5-6]. For radiated emissions, a small device can be considered as a point source of radiation, in which case the equation relates the field strength in volts per metre to the power in watts and the separation in metres, and can therefore estimate safe distances for a given immunity level. The power emitted by some wireless communications devices is shown in Table 1. Figure 3 shows that emissions from a WLAN or Bluetooth transmitter fall to below the 3V/m immunity level at less than one metre. For higher-powered transmitters the safety zone would be correspondingly greater.

**Conclusion**

EMC is a concern not just for electromedical manufacturers, but also for those who design, build and commission healthcare facilities. The existence of directives and standards has encouraged good EMC design practices, but should not be relied upon to prevent EMI problems owing to the complex nature of the hospital EM environment. Much can be done by promoting awareness of EMI and its underlying coupling mechanisms.

EMI can make healthcare facilities unsafe. Fostering EMC within healthcare contexts will not only optimise staff and patient safety, but will also minimise potential legal liability. Therefore, building project managers, facilities managers, hospital administrators, risk managers and medical staff have a legal obligation to be aware of the potential risks of EMI malfunctions, and must act reasonably to minimise such risks.

**References**


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