Electromagnetic Compatibility Issues in Medical Environment-A Review

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Abstract - The review study of EMC is a useful and a necessary one which will be better structured and which will gain in accuracy in the future. The study of EMC has close correlation with the life and work of the people, and the content of EMC study is much comprehensive. In this review study we try to answer the question that what is the risk of electromagnetic compatibility issues, caused by intentional medical devices in the recent day medical environment? There are several instances of effects caused by EMC problems. The effects range from almost none to life-threatening or catastrophic.

Nearly all electronic and electrical systems are required to meet electromagnetic compatibility requirements before they can be sold or offered for sale. For many automotive, aerospace and industrial systems, electromagnetic compatibility is a product safety issue as well as a product compliance issue. Due to the sensitive nature of medical devices and extreme consequences of their malfunction, EMC grew to a centric issue in design and production of such devices. We elaborate the basic essentials of electromagnetic compatibility issues with specific attention throughout this review study. Fundamental aspects of electromagnetic compatibility issues are briefly addressed in this paper.

Keywords - EMI-EMC, Radio frequency Interference - RFI, Radio frequency Identification -RFID, Electrocardiography - ECG, Electroencephalography - EEG, Implantable Cardiac Defibrillator - ICD.

1. INTRODUCTION

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Electromagnetic compatibility ensures equipment, device or more generally any electrical or electronic system functions satisfactorily in the presence of electromagnetic waves induced or generated by similar devices or natural causes in its surrounding area. EMC also requires the device to properly work without introducing or generating unacceptable electromagnetic disturbance to other equipment in the environment. Electromagnetic compatibility refers to a coexistence state that in a common electromagnetic environment, the respective functions of equipments, subsystems or systems can be exercised all together.

There are two aspects of this concept:

- 1. When running in an expected electromagnetic environment, equipment, subsystem or system can fulfill its designed performance according to specified safety boundaries, the performance not to be compromised or unacceptably degraded because of electromagnetic interference.
- 2. When smoothly running in an expected electromagnetic environment, equipment, subsystem or system is not likely to bring about unacceptable electromagnetic interference to the environment (or some other equipment).

Now a day's EMC became a source of concern due to the global popularity and rise of the electronic devices.

These concerns are stemmed from a usual dependence on electronic devices: telephones, computers, radio, medical devices, television and satellite. It is important incompatibility is not only a risk to manufacturers, but also for those who install, use, modify or maintain such devices. All electronic devices controlled by microprocessor emit electromagnetic interference to varying degree and they are also susceptible to interference to varying degree. If safety measures are not taken by manufacturers, it will result interference to other radio receivers and there will be degradation or malfunctioning in performance.

In medical devices, EMC is even more important issue because such deteriorations may involve extreme results. Consider medical devices actively used by emergency medical personnel. It is therefore crucial that all manufacturers of digital electronic devices have to ensure the safety and compatibility of their products. Such an approach helps to achieve trouble free products and services. The result is improvement in quality and enhances the customer satisfaction.

Medical equipment containing electronics are not excluded and they require passing the electromagnetic compatibility tests to promise that they can be used in the proposed environment without any fault or causing other devices to be unsuccessful. As electronics play a big and important role in healthcare and hospitals environment, the effect of electronic systems is becoming more noticeable. Failure of electronic systems to perform their function may lead in many cases to disastrous consequences involving potential loss of life. Many likely problems can be sorted out by ensuring sufficient separation of victims and sources of interference. It has been suggested that educating healthcare staff, visitors, contractors and patients including home-care patients about EMC helps to minimize the risks of such unwanted issues.

Using cellular and radio communications in the region of medical devices can increase the risks of EMI on the devices due to exposure to emissions from wireless technology which can be crucial and has become a potential problem. For example, when peoples in hospital use cell phone nearby patient monitoring equipment, there will be chance of incorrect reading, this is an EMC issue. That is why many hospitals now prohibit the use of mobile phones in certain patient care areas. [2]

The rest of the paper is organized as follows. Description about the existing research theory and results by excellent researchers though overview of literature study is presented in section II. Section III, provides a keynote of EMC and their issues in healthcare environment. Finally, we concluded the paper in section IV.

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2. OVERVIEW OF LITERATURE STUDY

Fundamental aspects of EMI and EMC issues along with different cases that EMC technique deals for troubleshooting the problems are briefly discussed by Fernando C. Castaldo in his paper. A main highlight of his study is that the some procedures to realize the EMI and EMC measurements in order to check the equipment fulfillment with the standard instruction by governmental regulatory bodies. Finally the concluded remark given by him is that the EMC tests must fulfill with the devices reliability and the customer satisfaction. [1]

The essentials of electromagnetic compatibility with specific attention to medical devices by analyzing the electromagnetic compatibility of a wearable biomedical measurement system used for the assessment of mental stress of combatants in real time is explain by Elnaz Farzaneh and Shabnam Imani. Their main focus is on EMC of the electrocardiogram of the system and wants to identify its EMC requirements of system while assessing it against various standards and protocols by conducting several EMC tests to measure the compatibility. Their experiments suggested a healthy functionality of the device since the level of measured emission were always distant from the boundary. [2]

The application of EMC technology, as in such areas as military field, industrial electronics or microelectronics, power industry, onboard or airborne electronics, communications, home appliances and lighting equipments are introduced by Hong Zhao, Guofeng Li and Ninghui Wang in their paper. The topic of complex electromagnetic environment concerning modern informationalized battlefield is also emphatically addressed by the authors. So at the end of concluding phase the application of EMC technology being systematic, long-term and complying with scientific standards. [3]

The existence of standards and regulations, there is often no collaboration between the designers of the buildings and the users of the equipment therein. D Bozec, M P Robinson and C A Marshman show how an understanding of EMC enables us to prevent interference problems and protect critical systems. They also discuss how good installation and maintenance practices such as the use of zoning and safe distances can ensure that adequate levels of EMC are achieved in the hospital environment. [4]

Introduction to Electromagnetic Compatibility (EMC) briefly explain by Clayton R. Paul in his book. Along with this author also focus on EMC requirements for electronic systems, signal spectra-the relationship between the time domain and the frequency domain, transmission lines and signal integrity, nonideal behavior of components, conducted emissions and susceptibility, antennas, radiated emissions and susceptibility, crosstalk, shielding and system design for EMC. [5]

Electromagnetic sources in the hospital environment risks analysis and measures for EMC explain by S.P.P. Jeunink in his thesis. A more consistent and modern approach to EMC is risk based. A risk analysis method is proposed by him and applied to the neonatology and intensive care department of the Medisch Spectrum Twente. An introductory study about the EMC of the hospital environment is done by him. At which only a limited number of medical instruments of a limited number of environments were tested. [6]

The electromagnetic radiation according to the medical devices in the hospitals environment has to be measured and analyzed by Seungwoo Lee and Nam Kim in their paper. The measured results of electromagnetic field strengths radiated by the medical devices in the hospitals environment are not very strong except some high power used devices such as the electrosurgical units. However, if there are the interfering devices near by the medical equipment, interference could be occurred during working of medical equipment in the hospitals environment. [7]

Emina Kurta1, Zivorad Kovacevic, Adil Osmanovic and Lejla Gurbeta presents an overview of a study in which the immunity and susceptibility of life-supporting medical equipment was evaluated by exposing the equipment to electromagnetic interference (EMI) in their paper. The influences of cellular phones

at various distances and proportions on a wide range of medical devices were studied by the authors and testing was performed in Healthcare institutions of Bosnia and Herzegovina. The present and more rigorous EMC standards provide better results when it comes to EMI affects. The improved designs of medical devices are results of strict electromagnetic compatibility standards to which the devices must comply. [8]

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An Analysis of electromagnetic interference between a radio frequency identification device and an implantable cardiac defibrillator discussed by Ivan Luigi Spano and Alessandro Serpi in their paper. In particular the analysis focuses on the effect of EMI produced by an RFID reader on ICD operation. Thus a brief overview of both ICD and RFID done by authors and an RFID reader has been considered as the non-intentional EMI source and through several experiments highlights the effects on ICD operation and finally it is the extension of the ICD pacing region thus it seems that EMI due to RFID reader does not significantly impair ICD operation. [9]

3. EMC ISSUES IN HEALTHCARE ENVIRONMENT

The effects of electromagnetic radiation on animals and human bodies are a kind of important research subject scenario, although there has been great progress in this research area, many problems are still not clear and thus need further researches, especially those researches and tests being systematic, long-term and complying with scientific standards for adequate satisfaction of the customer in healthcare environment.

Is electromagnetic compatibility of medical equipment a problem in the healthcare environment? Although electrical interference in hospitals is often regarded as no more than a minor irritation, there are documented which equipment failures cases in due electromagnetic interference have lead to injury or death. The ability of electronic systems and devices to function well in close proximity to each other has usually been given limited attention in the design and construction of healthcare facilities. Hospitals contain some types of equipment, such as electrosurgery units and short-wave diathermy applicators that are known to produce high levels of electromagnetic interference,

and other types such as ECG (Electrocardiography) and EEG (Electroencephalography) which are known to be particularly sensitive to electromagnetic disturbances. Despite the existence of standards and regulations, there is often no collaboration between the designers of the buildings and the users of the equipment therein.

As in many other fields, the amount and complexity of electronics in hospitals and other medical environments is increasing year by year. In spite of this, the number of reported incidents of EMC problems fortunately does not appear to be increasing. This is probably because most manufacturers and designers of medical electronic products have developed a good awareness of EMC. Pacemakers are typical examples, where their design with respect to compactness and immunity to radio frequency interference has greatly improved over the years. Nowadays, pacemakers are very reliable, but can still fail under extreme conditions. Pacemakers have failed in patients undergoing electrosurgery (not surprisingly as this is not recommended) and in other cases where patients kept mobile phones in their chest pockets, a few centimeters from the subcutaneous pacemaker leads. The powered wheelchair is another typical example: there are many stories of radiofrequency interference from mobile phones or police walkie-talkies causing the wheelchair to drive itself and its occupant into traffic or a cliff. These stories are based on real occurrences.

The use of many items of electronics equipment in close proximity in the hospital environment means that the same sorts of EMC problems are encountered as with other types of electronic products. However there are some special features of the hospital EM environment:

- Failure of medical devices can lead to injury or death.
- Medical products are not covered by the EMC directive but by the three product-specific directives.
- Some equipment found in hospitals is intentionally designed to emit electromagnetic energy, often for therapy. Other equipment, which may be located nearby, is designed to detect very small physiological signals. This combination has the potential to create EMC problems.
- Also in hospitals, there is the question of whether to ban or restrict the use of mobile phones. They improve communications but can interfere with critical equipment.

• Many medical devices are connected directly to patients. For mains-powered devices, the designer must prevent electric shock as well as ensure EMC.

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- Electronic equipment is constantly evolving, so there is always the possibility of new problems arising, so it is our responsibility to prevent EMC problems from endangering patients:
- Manufacturers and designers of equipment can ensure that equipment meets appropriate emissions limits and levels of immunity.
- Hospital administrators, planners and architects can keep potential sources and victims of EMI apart.
- Users should be aware of the threat of EMI and should also be encouraged to report any serious incidents.

Typical sources in hospitals include motors, fluorescent lights, switch-gear and equipment fitted with switched mode power supplies. Electrosurgery, also known as electrocautery or surgical diathermy, is a great source of EMI in hospitals. Currents of over 1A and EMFs of over 4kV are used to cut and coagulate tissue. A typical frequency is 500 kHz, which is high enough not to give the patient electric shocks. However it also means that the equipment radiates at harmonics of this frequency, especially between 1 and 10MHz. This type of equipment is so good at creating EMI that it was adapted during the Second World War for jamming radar. It can generate fields of 40-50V/m at 1m, making it difficult to use monitors in the same room. Pacemakers can also be affected. Shielding is not feasible because the patient forms part of the radiating antenna. However problems can be reduced by careful placement of leads.

SW Physiotherapy operates at the ISM frequency of 27 MHz it deposits energy to warm tissue. The RF signal is usually pulsed, although there is little evidence that this is clinically beneficial. This creates problems through demodulation giving an audio signal, giving buzzing noises on telephones. Computing, monitoring and video equipment nearby can be disrupted. Better shielding of applicators reduces the problem.

Another source of EMI is mobile radio transmitters-cellular phones and emergency services radios. These generate very high field strengths but only at short distances. Theoretically the field varies inversely with the distance from the antenna, and can be estimated using the expression $7\sqrt{P/d}$ where P is the radiated

power in watts and d is the distance in meters. However there is some evidence that hospital corridors have a guiding effect on the radiation and that the fields fall off slightly more slowly than this. A number of studies showed that a wide range of equipment can be susceptible to RFI from mobile radio transmitters. Fortunately, EMI from cellular phones is unlikely at distances of greater than 2m. High field strengths are produced not only by handsets but also by the transmitters on ambulances and other emergency vehicles. [4]

4. CONCLUSION

The EMC research for medical devices is still in its most important phase up to now. The research subjects of electromagnetic compatibility have coherence in their intensions and extensions, and the research purpose is to improve the feasibility and serviceability of any system in an expected electromagnetic environment. EMC is a concern not just for manufacturers, but also for those who install, use, modify or maintain medical equipment. The existence of directives and standards has encouraged good EMC design practices, but should not be relied on to prevent EMI problems owing to the nature of the hospital EM environment. Much can be done by promoting awareness of EMC and EMI and its underlying coupling mechanisms. The effects of electromagnetic radiation on animals and human bodies are a kind of important research subjects, although there has been great progress in this research area, many problems are still not clear and thus need further researches, especially those researches and tests being systematic, long-term and complying with scientific standards.

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