

Risk Management: Integration of a passive UHF-RFID system in medical environment

Ziad Mabrouk, Yue Ying, Uvo M. Hölscher

Center of Medical Technology and Ergonomics, Münster University of Applied Sciences, Steinfurt, Germany, {ziad.mabrouk, yue.ying, uvo.hoelscher} @fh-muenster.de

Introduction

Radio Frequency Identification (RFID) systems are gaining more interest especially in hospitals.

The use of the ultrahigh-frequency variants of passive RFID systems is still hampered by a combination of issues including safety margins degradation and reliability in healthcare environment.

Methods

Being a wireless communication system, the UHF-RFID may cause electromagnetic malfunctions on sensitive medical devices, the reason why most hospitals refuse its integration. That makes a Risk Management procedure inevitable to identify the potentially hazardous incidents in critical medical care equipments, estimate and evaluate the risks, control them and monitor effectiveness of the controls.

In this paper, an international Risk Management standard procedure (ISO-14971) was applied to 24 medical devices. Various measurements were conducted to examine the interference properties of different optional UHF-RFID modulation schemes, electromagnetic fields strengths and transmission powers.

Measurements methods are consistent with the IEC60601-1-2 and ANSI-C63.18-EMI-Test Standards. Moreover they recognize the reasons for malfunctions and suggest solutions to overcome them.

Results

RFID-readers exhibit electromagnetic fields significantly higher than the safety margin stated for medical devices, their radiation strength goes beyond limits allowing interference with circumjacent medical equipments. The safe operation of several medical devices been exposed to field strengths higher than safety margin is damaged in a spurious, erratic or permanent way.

Conclusion

Propositions to surmount the mentioned malfunctions:

1. RFID-Systems manufacturers have to ensure that their products do not degrade medical device placed in closer environment.
2. Hospital personal who intend to integrate passive UHF-RFID Systems should adopt a specific Risk Management appropriate to each situation. This can be done through: inherent safety by design, protective measures, and information for safety.
3. Hospitals and RFID-Systems manufacturers should collaborate and permanently exchange information to improve and update the Risk Management procedure and instructions for RFID-Systems use.

These precautions allow the UHF-RFID System to play active role in the medical environment.