Wireless Coexistence Testing and EMC Risk Evaluation for Wireless Medical Applications

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Abstract. This paper presents a testing and assessment method of electromagnetic interference coexistence which is suitable for wireless medical equipments under complex healthcare electromagnetic environment. A kind of quantitative means that monitoring functional wireless performance in the event of interference excitation is put forward, which provide a strongly technical support for the risk mitigation and ensuring safety and effectiveness of medical devices, and for functional government departments implementing market access regulation.

Introduction

The rapid progress of microelectronics, chip fusion, wireless communication technology and biomedicine technology promote the prosperity, development and widespread application of wireless medical equipments and systems. Medical application of wireless technology such as WiFi, BlueTooth, ZigBee, UWB, 2G/3G/4G can provide many benefits for healthcare workers including flexibility, device mobile convenience, portable and uninterrupted access to patients health records and present medical status. However, the use of this technology also has a number of limitations and disadvantages, the problem of electromagnetic interference (EMI) is highlighted due to the explosive growth of electric and RF equipments result in complex electromagnetic environment effects under the healthcare environment, security of patient records, and the issue of constant dependability of functional wireless performance (FWP) which may result in potential or unacceptable risk for healthcare activities. Patient safety, efficiency and reliability of wireless transmission should be considered as a top priority when we use wireless technology to realize clinical function. So how to mitigate the risk of wireless medical application, ensure the safety and effectiveness of FWP and improve electromagnetic compatibility level becomes an issue worthy of attention and study.

This article gives an introduction to the types and architectures of wireless technologies and networks that are used in medical environments. It also presents several critical parameters associated with wireless coexistence, and relevant test method for wireless medical application. In addition, this paper discusses the quantitative measures of monitoring for functional wireless performance during RF field radiated immunity test. EMC risk based on wireless coexistence and FWP are assessed for security and effectiveness problem of wireless medical equipments.

Overview of Wireless Medical Application

More and more RF wireless technologies entered the healthcare field, see Table 1.
Table 1. Basic information for several wireless technologies.

<table>
<thead>
<tr>
<th>Technology</th>
<th>Standard/protocol</th>
<th>Frequency</th>
<th>Data rate</th>
<th>Range</th>
<th>Medical application</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bluetooth5.0</td>
<td>IEEE802.15</td>
<td>2.4GHz</td>
<td>2Mbps</td>
<td>240m</td>
<td>Wearable medical devices</td>
</tr>
<tr>
<td>WiFi</td>
<td>IEEE802.11</td>
<td>2.4GHz, 5.8GHz</td>
<td>54Mbps</td>
<td>100m</td>
<td>Wireless patients rounds, wireless infusion, image transmission, hospital guide etc.</td>
</tr>
<tr>
<td>ZigBee</td>
<td>IEEE802.15.4</td>
<td>868/915MHz 2.4GHz</td>
<td>250kbps</td>
<td>100m</td>
<td>Medical monitoring</td>
</tr>
<tr>
<td>RFID</td>
<td>ISO 18000</td>
<td>125kHz,134kHz,13.56MHz,915MHz</td>
<td>100kbps</td>
<td>1m</td>
<td>Patient tag, entrance guard, medical supplies supply chain management, medical waste tracking management</td>
</tr>
<tr>
<td>UWB</td>
<td>/</td>
<td>3.1GHz-10.7GHz</td>
<td>1000Mbps</td>
<td>10m</td>
<td>Wireless ultrasonic probe, electronic endoscope</td>
</tr>
<tr>
<td>4G(LTE/LTE-A)</td>
<td>3GPP R7</td>
<td>1.8G, 1.9G,2.1G,2.3G,2.6GHz</td>
<td>326Mbps</td>
<td>100km</td>
<td>Telemedicine</td>
</tr>
<tr>
<td>NB-IoT</td>
<td>3GPP R13</td>
<td>800M,900M,1.8G,2.1G</td>
<td>250kbps</td>
<td>15km</td>
<td>Telemedicine</td>
</tr>
<tr>
<td>LoRa</td>
<td>/</td>
<td>150M-1GHz</td>
<td>50kbps</td>
<td>10km</td>
<td>Telemedicine</td>
</tr>
</tbody>
</table>

It is precisely because of the emergence of these wireless technologies, all kinds of wireless network such as wireless local area network (WLAN)[1,2], wireless personal area network (WPAN), wireless body area network (WBAN)[3,4], low power wide area network (LPWAN) and wireless metropolitan area network (WMAN) emerges as the times require.

NB-IoT Solution for Telemedicine

In a telemedicine system, the doctor can analysis and diagnosis real-time medical data of patients through NB-IoT network, then transmit relevant data to data process unit through Bluetooth, ZigBee etc. near-end networks. Generally, the system architecture consists of Data Application Layer, Network Communication Layer, Acquisition Perception Layer and Medical Resource Layer, as shown in the Fig.1.

![Figure 1. System architecture of Telemedicine.](image)

Generally, WiFi and BlueTooth are the most widely used in medical devices. An issue of growing interest is the coexistence and EMC risk of these medical devices in the healthcare environment.
Wireless Coexistence Test Method for Wireless Medical Equipment

Traditional EMC and coexistence are two critical risk control measures for the risk management of wireless medical equipments. Traditional EMC testing is designed to exclude frequency bands where the device under test communicates wirelessly. Coexistence testing focuses on devices and systems that intentionally use wireless and it extends beyond traditional EMC to examine the device’s performance in frequency bands where it uses wireless communication. Wireless coexistence depends on three factors: frequency, space, and time. The probability of coexistence increases as the frequency separation of channels increases between wireless networks, and the signal-to-interference ratio of the intended received signal increases due to physical separation, and the utilization rate of the wireless channel decreases. ANSI C63.27[5] and AAMI TIR69[6] provide an evaluation process and four test methods to quantify the ability of a wireless device to coexist with other wireless networks in its intended radio frequency environment. But for the wireless medical applications, in consideration of many factors such as repeatability, accuracy, actual antenna effects of environment, the degree of difficulty in testing, regulation and administration of radio services, and the characteristics of wireless medical equipments, radiated anechoic chamber (RAC) test method maybe more suitable for it. Test setup as shown in Figure 2.

![Figure 2. Test Setup for RAC Method.](image)

In Fig.2, it is recommended that the EUT and EUT companion device are placed on non-conductive tables with a height of 1m. Vector signal generator output an unintended signal co-channel or adjacent channel with EUT, monitoring the response and FWP of the EUT by wireless communication tester. Signal analyzer or spectrum analyzer is used to monitor the unintended signal power. Adjusting the power of intended signal or the distance between EUT and interferer to find the intended-to-unintended signal ratio(I/U) of the EUT where the device goes from being unable to pass the KPI threshold to be able to pass the KPI threshold. Additionally, the following four steps should be performed: 1)Baseline the wireless functions of EUT, 2)Baseline the wireless performance of the unintended signals, 3)Test the wireless functions of EUT for coexistence and determine if function wireless performance is impacted when the unintended signal is introduced, 4) Analysis test result, depend on KPI thresholds and FWP criterion, determine the minimum separation distance for coexistence[7].

Notably EUT is connected to EUT companion device wirelessly under the normal work condition, while during coexistence testing, wireless communication tester(i.e. base station) should setup a connection with the EUT and EUT companion device separately in line-of-sight. The receiving sensitivity(RSS) of EUT should be as low as possible, and packets error rate (PER) should be maintained at 0%, so that simulate a worst case that EUT located at the boundary of signal coverage of the tester. To achieve the bit error rate (BER) of 10e-5 for QPSK modulation, signal-noise-ratio(SNR) should be maintained at least 13.5dB.

EMC Risk Assessment Based on Functional Wireless Performance

Functional wireless performance is the subset of the total functionality of the EUT that will be evaluated for coexistence, it is often considered as essential performance of some of the wireless medical devices due to its loss or degradation could result in unacceptable consequences and risk. For
instance, a kind of wireless capsule endoscope with a built-in camera and RF transmitter is able to take the image of the digestive tract and transmit it to the external imaging workstation. Once the image data including patient’s focus information are lost during real-time wireless transmission and can’t be presented to the doctor in full, it could result in delay treatment for the patient. This wireless transmission performance should be regarded as FWP for significant attention. So it is very necessary to evaluate the risk by performing EMC test. However, the IEC60601-1-2 standard ignores all in-band testing, this is not adequate for the security of wireless medical devices. A method for monitoring the FWP during the immunity test is put forward, that is making use of wideband wireless communication tester and establish a wireless communication link between EUT and the tester. Test setup as shown in figure 3.

![Figure 3. Test setup for monitoring FWP during radiated immunity test.](image)

Evaluate the ability of the EUT to maintain its FWP under the conditions of the test through measurement of a key performance indicator(KPI). The parameters monitored vary with EUT, but at least the four critical parameters such as throughput, error vector magnitude (EVM), PER or bit error ratio (BER), and Latency should be measured separately under two conditions that setting up wireless link between wireless communication tester and EUT, and between the test and EUT companion device. Acceptable KPI thresholds can be determined by the party supervising the test, the manufacturer of the EUT, or other organizations that have set thresholds based on the required performance of the EUT. Notably monitoring antenna communicated with EUT should be placed in a position far away from the main lobe of radiating antenna while ensuring reliable link for alleviating the impact of interference, see Fig. 4.

![Figure 4. Top view for antenna setup.](image)

In addition, for some of the wireless medical equipments operating on a lower RF range, it is also necessary to evaluate the FWP while conducting other immunity tests like as ESD, Electrical fast transient burst (EFT) etc. according to IEC 60601-1-2 standard. It will be as important as ever to utilize real-time monitoring of FWP and currently existing assessment tools such as failure mode and effects analysis(FMEA) to identify the gaps and threats in wireless medical devices at some level[8,9].

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Effective functional wireless performance is a very important aspect of EMC risk assessment, the test result of wireless coexistence and FWP should be input to the risk analysis process to help establish risk level. The real value of it lies in the process developing it during the project, to achieve the acceptable risk levels (or risk reductions) whilst also saving cost and time (at least not adding significantly to them).

Summary
The test and evaluation of interference coexistence is a vital technique for controlling and assessing EMC risk, but since no established practical and reasonable risk analysis techniques have yet been written to take wireless coexistence of medical equipments into account, it is necessary for experienced and skilled engineers to study and develop them for the purpose of achieving the reliability and safety level required by wireless medical applications.

The Paper has provided some initial guidance for evaluating and reducing the EMC risk of wireless medical equipments and related devices or systems in an operational healthcare environment by analyzing wireless coexistence and monitoring the FWP, and it is to be hoped that others, more expert than the author, will develop this new area of “wireless coexistence and EMC risk assessment for wireless medical applications” in coming years.

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