Technical Information Report

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Risk management of radio-frequency wireless coexistence for medical devices and systems

AAMI
Advancing Safety in Health Technology

Risk management of radio-frequency wireless coexistence for medical devices and systems

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Abstract: This Technical Information Report (TIR) provides a process and guidance on performing a radio-frequency (RF) wireless coexistence evaluation of a medical device as part of an overall medical device risk management approach. The process includes pre-testing activities to gather information needed to determine the tier at which to perform testing, the testing and report, and post-test analysis. The TIR also provides sample reports and additional information to aid in documenting the medical device wireless coexistence evaluation and integration into risk assessment and management.

Keywords: wireless medical devices, wireless technology, wireless coexistence, risk management, interference, radio frequency (RF)

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Comments on this technical information report are invited and should be sent to AAMI, Attn: Standards Department, 901 N. Glebe Road, Suite 300, Arlington, VA 22203.

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Committee representation

Association for the Advancement of Medical Instrumentation

AAMI Medical Device Wireless Committee

This technical information report (TIR) was developed by the AAMI Medical Device Wireless Committee. Committee approval of the TIR does not necessarily imply that all committee members voted for its approval.

At the time this document was published, the **AAMI Medical Device Wireless Committee** had the following members:

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Stephen Berger, TEM Consulting

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NOTE—Participation by federal agency representatives in the development of this document does not constitute endorsement by the federal government or any of its agencies.

Foreword

With the growing importance and use of radio-frequency (RF) wireless technology, spectrum is becoming increasingly crowded. The potential for RF wireless devices to affect and potentially interfere with other transmissions is growing and is a regular occurrence in some frequency bands. RF wireless technology is more than a convenience and enables a number of applications that might otherwise not be possible. Impressive improvements and innovations continue to be made increasing the already considerable appeal of the technology. RF wireless technology is being put to use in an ever expanding variety of applications. Healthcare delivery is a full participant in this trend, making it increasingly important that the hazards and associated risks related to the ability of wireless medical devices and systems to coexist are effectively and efficiently managed.

Users of a wireless medical device system come to rely on the functions and applications. Degradation of the wireless link can occur if a device's transmission conflicts with transmission from other wireless products in the vicinity, resulting in a delay or loss of communication. The potential for this is even greater when several different wireless services and devices share the same unlicensed frequency band as is the case for the most widely used wireless technologies. This document provides guidance on understanding and managing potential wireless technology communication conflicts in the drive towards coexistence. The TIR offers a process to assess, categorize, and document the risks associated with the wireless functions of the medical device or system and suggestions to help improve coexistence.

Introduction

This TIR provides guidance for assessing wireless coexistence and the risks associated with interference or degradation when using RF wireless technology to perform medical functions and/or communicate medical data. Wireless coexistence is the ability of the medical device to function properly in a shared electromagnetic environment and is important for wireless medical devices because such devices and systems can be expected to function in environments where other wireless communications products are possibly used. This document provides guidance on evaluating the ability of a wireless medical device or system to wirelessly coexist.

This TIR offers a process to assess and categorize the risks associated with the wireless functions of the medical device or system, which should be integral to the risk-management-based approach. Wireless coexistence testing can also be used to characterize relevant risk mitigations and to monitor and ensure safety, performance, and effectiveness of the wireless functions of a medical device or system.

Wireless coexistence testing exposes an RF receiver of the subject medical device to transmissions from other wireless devices to document and assess the potential impact of the other unintended transmission. The unintended signals are selected to give insight about how a subject wireless device will perform in the intended electromagnetic (wireless) environment. For example, during testing a strong unintended signal might be introduced based on the assumption that if a device can tolerate a strong unintended signal it can also tolerate that signal at lower levels. Similarly, when a wide variety of wireless signal modulations and waveforms from different wireless technologies operating in the same RF spectrum band might be used by an unintended transmitter, the modulation or waveform known to be the harshest might be used in testing. Wireless coexistence brings together an understanding of how the device being evaluated is able to use its wireless capability in the presence of other transmissions. Coexistence testing provides valuable insight about how the subject medical device will perform in its intended use environment and can identify areas requiring mitigation.

In general, the process for the assessment of wireless medical device coexistence begins with the steps in this TIR that include identifying the wireless technology and functions, assessing and categorizing the risks for these functions, and developing appropriate criteria for testing (see 6). The TIR goes on to provide details on setting up and performing the testing (see 7), assessing the findings (see 8), and providing a test report (see 9).

Figure 1 provides an overview of the process. Additional details on the overall process flow is in Section 5 of this TIR.

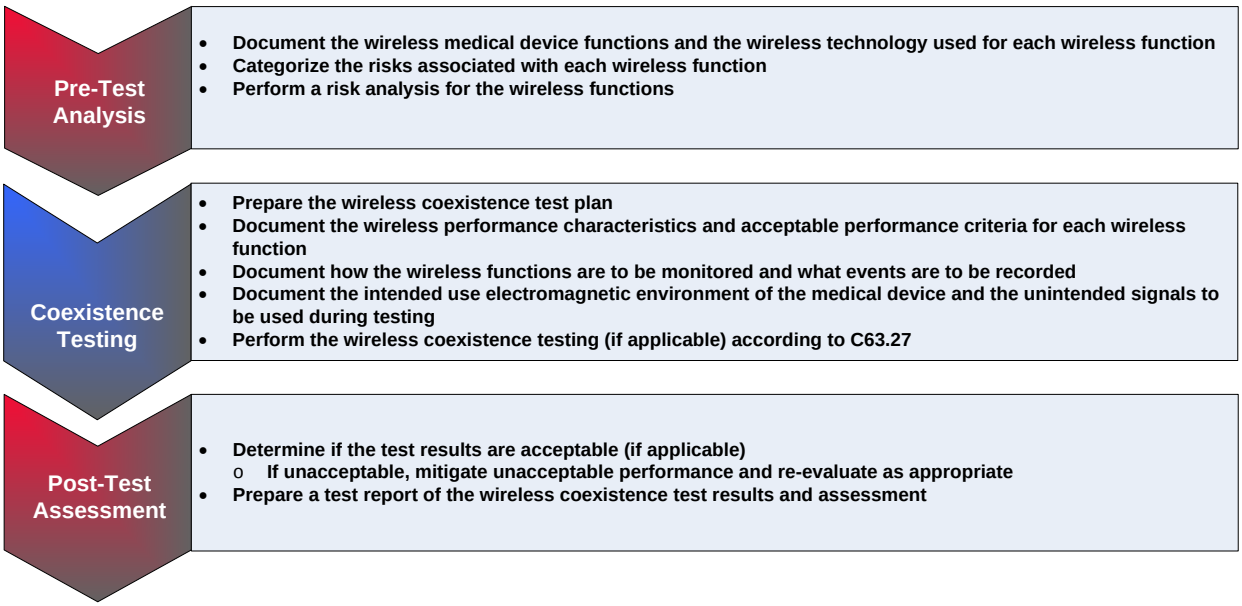

Figure 1 – Overview of the this TIR

NOTE—This introduction does not contain all detailed provisions of this TIR, which addresses wireless coexistence for medical devices and systems. It is intended to provide a general overview of the issues and process detailed in this TIR.

Addressing radio-frequency wireless coexistence for medical devices and systems

1. General

1.1 Purpose and intent

This technical information report (TIR) provides information, guidance, and best practices for supporting the risk management process as it applies to the ability of medical devices and systems that use radio-frequency (RF) wireless technology to coexist and operate within the electromagnetic environment in the area of the device's intended use.

The TIR provides a method to test for wireless coexistence and a process to document and communicate those results to designers, manufacturers, regulatory bodies and agencies, and users of wireless medical devices and systems.

Issues for wireless medical device coexistence include:

- the type of hazardous situation that might occur,
- the potential consequences,
- mitigating and managing hazards,
- and how to test those mitigations.

This document is intended to address regulated medical devices that incorporate wireless technology. The focus is on the risks related to the wireless functions of the medical device or system. The use cases presented and the risks assessed herein are intended to address such systems and aid device manufacturers and others in applying mitigating or compensating controls. Moreover, the principles and procedures mentioned here can be applicable to other portions of the wireless systems to which the medical device is connected.

It is important to note that much of the clinical functionality of current and future wireless medical devices can be, and are being, enhanced and replaced by wireless connections to networks external to the devices and systems designed and tested by the medical device manufacturer. In these circumstances, the data extracted from the medical device is transmitted through, and in some cases post-processed by, systems outside the direct control of the medical device in question. Consequently, transfer of the data through these peripheral systems can present additional risks not considered in this document but should be considered in a comprehensive risk management process or communicated to the customer if outside of the manufacturer's control. Such additional risks are outside the scope of this document and generally outside the control of the medical device manufacturer and in some cases outside the control of the user facility. Therefore, it is recommended that any third party integrating wireless medical devices into larger systems assess the risks outlined in this document and utilize this understanding in planning a deployment. By applying appropriate regulatory guidelines or consensus standards to integrate mitigation and compensating controls, the level of operational coexistence and reliability demonstrated through testing can be provided in actual use.

1.2 Scope

This TIR applies to medical devices and systems (also known as medical electrical equipment) that incorporate RF wireless technology used to perform or control a medical function or to communicate medical data. This includes wireless technology whose operation and function directly support the medical device's intended use, as it relates to the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease.

When evaluating the intended use environment for a wireless medical device the emissions from both intentional and unintentional radiators (medical and non-medical equipment) should be considered, depending on the frequency band of the medical device wireless operation. For example, a medical device that operates below 300 kHz should

