A Case Study of Medical Device Wireless Coexistence Evaluation

Mohamad Omar Al Kalaa[1], Joshua Guag[1], Seth J. Seidman[1], Yao Ma[2], Jason Coder[2]

Abstract: This article aims to provide a narrative for addressing wireless coexistence in medical devices to help medical device developers, test engineers, and regulatory affairs personnel throughout the device life cycle. Accordingly, we present a case-study covering the coexistence evaluation process including the risk analysis of the wireless functionality of a hypothetical medical device, determining the corresponding risk category, specification of the device functional wireless performance (FWP), wireless coexistence testing, and measurement of the intended/untended signal ratio. Also, we propose a simple method for translating the test outcome into user recommendations for minimum/maximum separation distances between the device, its intended companion, and the source of unintended signals.

I. Introduction

Wirelessly-enabled medical devices allow convenient, untethered, and agile delivery of healthcare to patients. With wireless access becoming a pillar of modern life, the U.S. Food and Drug Administration (FDA) continues to receive an increasing number of medical device regulatory submissions (e.g., premarket approval (PMA) applications, 510(k) premarket notifications) involving wireless technology as part of the device. This growth is partly enabled by advances in general-purpose wireless technologies such as Bluetooth[3] and Wi-Fi®[4] and their universal integration in computers and smartphones. Accordingly, device developers can benefit from accessible hardware implementing these technologies and software stacks that allow for programing the device's wireless functionality in addition to mobile applications to query, store, and analyze data. However, incorporating wireless technology in medical devices should be done carefully to ensure patient safety and device effectiveness. Therefore, the selection of wireless technology, quality of service, coexistence, security, and electromagnetic compatibility (EMC) of the wireless technology should be considered as recommended by the FDA guidance Radio Frequency Wireless Technology in Medical Devices [1].

When this guidance document was published in 2013, there were no standardized methods to assess and test for wireless coexistence. This led to device manufacturers and test laboratories using ad-hoc test methods that lacked adequate control of the intended and unintended signals, relevant test monitoring, and uniform test outcome. However, these gaps have been remedied with the development, publication, and FDA recognition of the American National Standards Institute (ANSI) C63.27 American National Standard for Evaluation of Wireless Coexistence [2] and the Association for the Advancement of Medical Instrumentation (AAMI) Technical Information Report (TIR) 69, Risk management of radio-frequency wireless coexistence for medical devices and systems [3]. Wireless coexistence can be defined as the ability of one system to perform a task in a given shared environment where other systems have an ability to perform their tasks and may or may not be using the same set of rules [4]. This is particularly relevant to technologies that operate in unlicensed spectrum bands (e.g., 2.4 GHz, 5.8 GHz), where Wi-Fi, Bluetooth, and other technologies operate.

Wireless coexistence testing differs from electromagnetic compatibility (EMC) immunity tests in several aspects[5]. Coexistence evaluation focuses on the mutual effects of coexisting systems (equipment under test (EUT) and source of unintended signal[6]) observed while using a shared spectrum band. For example, in the 2.4 GHz industrial, scientific, and medical (ISM) band, both Bluetooth and Wi-Fi devices have equal rights to access the shared spectrum, with no preferential rules or treatment to either. Accordingly, it is up to the EUT to manage how it will perform its wireless functions when other users contend for the same wireless channel resources. Part of this can be embedded in the wireless specifications (e.g., frequency hopping in Bluetooth), while the other part remains in the hands of the device hardware and software developers. Therefore, wireless coexistence evaluation considers how the EUT implements all layers of the Open Systems Interconnection (OSI) model. In contrast, EMC immunity tests look at the effects of EM disturbances on the EUT, whether it uses RF energy for its functions or not. Examples include immunity to intentional or unintentional radiated fields, conducted fields, and electrostatic discharge (ESD). The EUT is inspected for disruptions or damage as a result of the test, which may or may not be related to its wireless functions (e.g., circuit damage because of ESD, firmware corruption because of radiated fields). A coexistence evaluation specifically looks at the functional wireless performance of the EUT (i.e., functions implemented using wireless technology—definition and further details are provided in Section II-C).

In addition to describing the risk assessment process for wireless coexistence in medical devices, AAMI TIR69 speci-

[1] Center for Devices and Radiological Health (CDRH), U.S. Food and Drug Administration, Silver Spring, MD 20993
[2] National Institute of Standards and Technology (NIST), Boulder, CO 80305
[3] Overseen by the Bluetooth Special Interest Group (SIG)
[4] IEEE 802.11 family of standards. Wi-Fi® is a registered trademark of the Wi-Fi Alliance®.
[5] Medical device EMC testing is commonly done according to standards like IEC 60601-1-2 [5].
[6] In ANSI C63.27, the unintended signal is defined as the signals used to determine if the EUT can maintain its functional wireless performance during a coexistence test.

fies coexistence testing methodology. However, the test methods and procedures are referenced to ANSI C63.27. Depending on the stage of device development, coexistence testing can inform the device risk assessment, or it can be performed as a part of the risk management to ensure the desired operation of the device's wireless functions. Accordingly, in this paper we start by describing an example Bluetooth Low Energy (BLE)-enabled EUT in Section II-A and explore the risk analysis process specified in AAMI TIR69 to determine the wireless function risk category in Section II-B. Afterwards, we discuss the functional wireless performance (FWP) of the identified wireless functions and the test pass/fail criteria in Section II-C. Testing the device for wireless coexistence per ANSI C63.27 is described in Section II-D. Section III introduces a simple method for extending coexistence test results into user recommendations in realistic use environments. The process and proposed method are technology-agnostic and are applicable to equipment and frequency bands other than those discussed in the article. Our focus on BLE is solely due to its common use in current medical device submissions. Section IV concludes the paper.

II. Coexistence Evaluation

In this section, we evaluate an example BLE system—serving as a hypothetical medical device—for wireless coexistence. The purpose of this coexistence evaluation is to develop user guidance on the recommended separation distances between the EUT, its intended companion, and nearby sources of unintended signals. These user recommendations are part of the device risk management to help ensure patient safety. Fig. 1 illustrates a simplified flowchart of the wireless coexistence evaluation process, which begins by determining the risk categories of the device wireless functions per AAMI TIR69 and progresses to specifying these functions and determining the evaluation tier, choosing a test method, and performing the test per ANSI C63.27 for each. Also noted on Fig. 1 are the one-to-one relationship between the AAMI TIR69 risk categories and the ANSI C63.27 evaluation tiers, and the one-to-many relationship between a given function and the four test methods specified in ANSI C63.27. Accordingly, once a device FWP is specified and an evaluation tier selected, the test engineer may choose any of the test methods specified in ANSI C63.27 to proceed with testing the EUT for wireless coexistence.

A. EUT description

The AAMI TIR69 process starts by documenting the wireless medical device functions and the wireless technology used to implement them. In this case-study, the EUT is a BLE evaluation board programmed to transmit data to a companion BLE board to measure the achievable link throughput. Two Nordic Semiconductor nRF52 evaluation boards were programmed using a publicly available BLE throughput evaluation program[7] to serve as the EUT and the EUT companion device. The boards measure the link throughput by exchanging a fixed volume of data and recording the time needed to complete the data transfer.

[7] https://infocenter.nordicsemi.com/index.jsp?topic=%2Fsdk_nrf5_v16.0.0%2Fble_sdk_app_att_mtu.html&cp=7_1_4_2_1_0

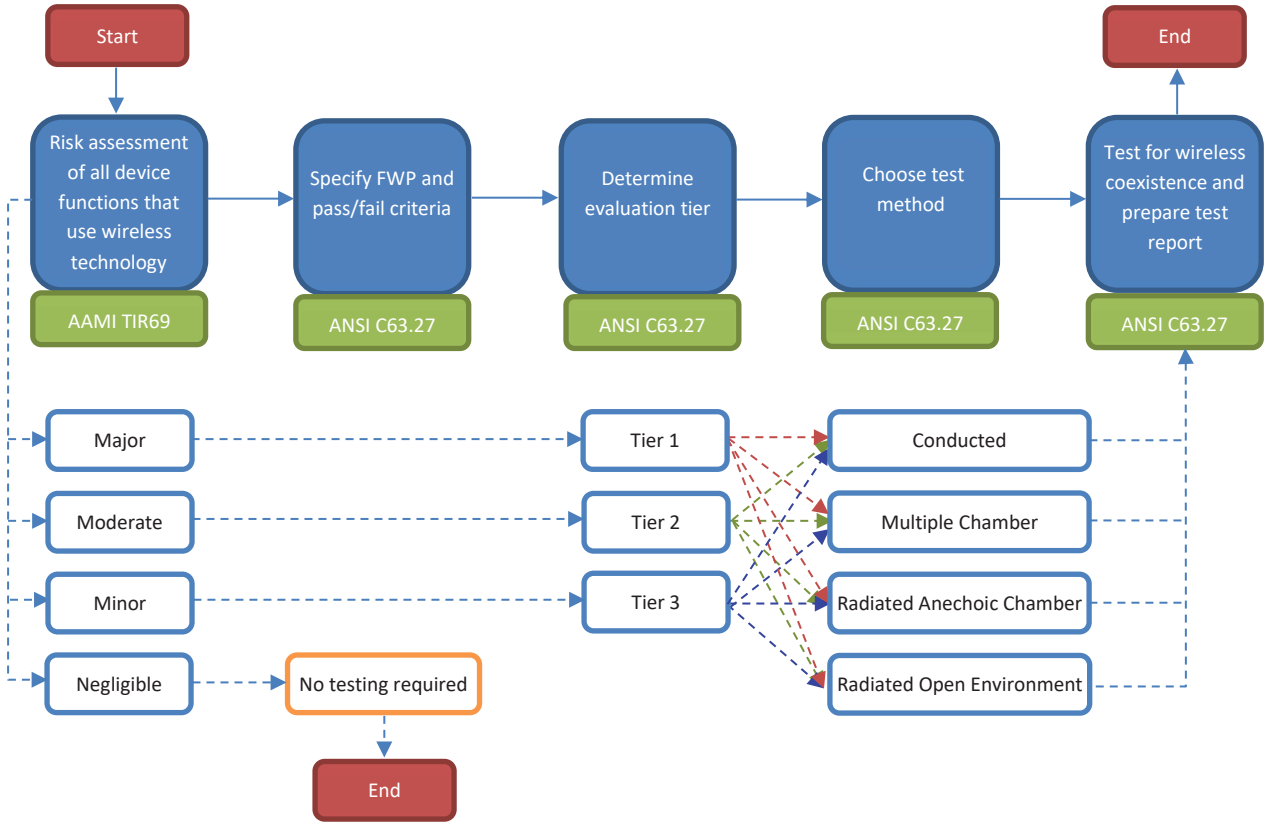

Fig 1: Simplified wireless coexistence evaluation flowchart. The process streams from AAMI TIR69 for risk management to ANSI C63.27 for testing.

Wireless medical devices differ in their needs for link throughput and latency. The example we implement offers a perspective on applications that need relatively high throughput and facilitates the reporting of the communication performance.

The device uses BLE in the 2.4 GHz ISM band. Forty channels each with 2 MHz bandwidth are used in a frequency hopping scheme [6]. Three of the 40 channels are used for advertising, while the remaining 37 are used to exchange data once a connection is established. Devices similar to this example can be used in a wide range of environments, including patient residences, where in many cases Wi-Fi and Bluetooth are ubiquitous and are usually uncoordinated (i.e., independent pairs of communicating nodes can use Wi-Fi and Bluetooth simultaneously.)

B. Risk category of the wireless functions

Determining the risk category for a wireless function stems from the overall risk management process of ISO 14971 [7] and correlates with the foreseeable risks to the patient or user due to delay, disruption, or failure of the wireless function. Four risk categories are specified in AAMI TIR69: *Major*, *Moderate*, *Minor*, and *Negligible*. See Fig. 1 for an illustration. The three highest categories are mapped to evaluation tiers in ANSI C63.27—the higher the risk, the more stringent the evaluation. If a wireless function is found to have *Negligible* risk, AAMI TIR69 specifies that it does not need to be tested for coexistence. However, device developers could still consider testing for other purposes such as evaluating the user experience.

Many factors contribute to the determination of the appropriate risk category. The fundamental question to consider is *"what are the potential harms to the patient if the wireless functions are impaired?"* Consider the following possibilities of the EUT in our case study:

1) The EUT could be measuring the patient's vital signs and communicating the information to their smartphone for informational purposes, or

2) The EUT could be measuring these vital signs from a stable patient at the hospital and communicating long term trending data to their doctor, or

3) The EUT could be measuring the patient's vital signs and communicating them to their smartphone along with a diagnosis of their cardiac health to inform them when to see their cardiologist, or

4) The EUT could be measuring these vital signs from a patient in the intensive care unit (ICU) that is having difficulty breathing and is used as a primary alarm to alert the primary caregiver of acute changes.

Possibility 1 would likely be classified into the *Negligible* risk category because delaying or losing informative vital signs sent to a personal smartphone will be at most an inconvenience, with no risk to patient safety. Possibility 2 would likely be classified in the *Minor* risk category because the doctor would not be using the data immediately and the data would be a single contributing factor in the clinical decision making. Possibility 3 would likely fall into the *Moderate* risk category because the patient would be relying on the data to know when to see their cardiologist. Data that is delayed or lost could result in a delay of therapy. Possibility 4 would likely be classified as a *Major* risk category because the information includes high priority alarms which if missed could result in death or serious injury. These are just four possibilities of a single example, and they demonstrate how the patient population, the claims of the device, and the intended use environment are all significant factors in determining the appropriate risk category.

C. Specifying device FWP and test pass/fail criteria

FWP is defined in ANSI C63.27 as the subset of the total functionality that both uses the wireless capabilities of the EUT and would result in unacceptable consequences if degraded or disrupted. FWP is the basis of establishing pass/fail criteria to differentiate between device acceptable and unacceptable performance. Relevant key performance indicators (KPIs) such as throughput, latency, jitter, etc. should be identified and quantified for FWP specification. Although addressing wireless coexistence ideally starts at the design phase of a wireless medical device, it is often the case that test engineers are assigned this task much later in the development life cycle. Therefore, quantitatively specifying FWP in terms of KPIs such as link throughput, latency, etc. becomes non-trivial. However, commercially available over-the-air protocol decoders for common wireless technologies (e.g., Wi-Fi, Bluetooth, BLE) can be used to quantify the needed KPIs to aid in FWP specification. Analyzing the messages captured by a protocol decoder, a test engineer can estimate the link throughput needed to fulfill a certain device wireless function.

During the pairing process between a BLE EUT and its companion, the device would typically use the three BLE advertising channels[8] to transmit advertising indications (ADV IND) messages. Each message contains information on how to establish a connection with the device. In the meantime, the EUT companion when taking the role of BLE scanner, listens for these messages and upon detection transmits a scan request to the device, to which the device replies with a scan response; this is the pairing process. It is common for the BLE EUT function to depend on a successful pairing stage. Accordingly, the success or failure of the pairing process may be considered as FWP although it might not in itself carry information related to the device intended wireless functions. The pairing process can have unique KPI requirements compared to those needed by the other device BLE functions, and it is commonly performed independently prior to using the device BLE functions. Accordingly, the pairing process might be suitable for characterization and testing as a separate FWP function.

The hypothetical EUT we used embeds the advertising, scanning, and data exchange functions in the same routine. There-

[8] $f_c \in [2402,2426,2480]$ MHz

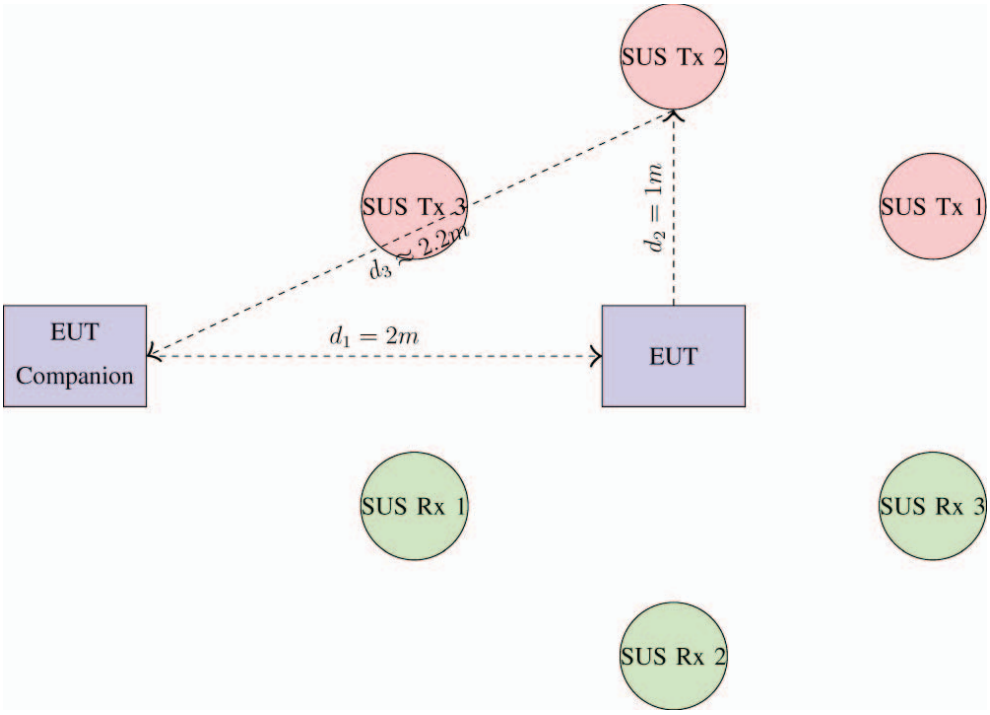

Fig 2: Test layout noting the placement of the equipment under test (EUT), the EUT companion, and the sources of unintended signals (SUS) transmitters (Tx) and receivers (Rx).

fore, we only had one FWP function to test. Specifying the FWP pass/fail criteria should be done by setting the FWP KPI threshold that renders the FWP unacceptable. This ties closely to the discussion of risk in Section II-B. When possible, pass/fail criteria should be quantitative (e.g., the throughput of the wireless link used by a specific function is above a specific threshold). An alternative could be to address the success of the wireless function on a higher level (e.g., the function will transfer a specific data set or command within a specific maximum delay).

D. Testing

We use the ANSI C63.27 radiated anechoic chamber (RAC) method[9] to test the EUT for wireless coexistence. The test nodes (i.e., the EUT, EUT companion, transmitter (Tx) and receiver (Rx) of the source of unintended signals (SUS)) are arranged as illustrated in Fig. 2.

To generate the unintended signals, we use Wi-Fi routers equipped with an operating system that permits granular control over the protocol parameters including channel allocation, transmission power and modulation and coding scheme (MCS) selection. For brevity, we only address the test recommendations for in-band (i.e., 2.4 GHz) coexistence of BLE with Wi-Fi and do not test for the adjacent band LTE signals specified in Annex A of ANSI C63.27. However, implementing the adjacent band tests is straightforward.

A real-time spectrum analyzer (RTSA) is used to monitor the test and confirm the absence of non-test-related signals in the test environment. To measure the intended-to-unintended (I/U) signal ratio, we start by measuring the unintended signal by sequentially replacing the EUT and EUT companion with the RTSA antenna and recording the observed unintended signal with a max hold detector in channel power measurement mode over 2 MHz observation bandwidth. When measuring the intended signal, we place the RTSA antenna 0.5 m away from the EUT and EUT companion and use a similar configuration to the one used for the unintended signal. Because the test environment is an anechoic chamber, the propagation can be considered free-space line-of-sight (LOS) with no reflections or multipath and we use the free-space path-loss formula to estimate the power value at the source. We observe the center frequencies 2408 MHz, 2430 MHz, and 2458 MHz. Each represents a BLE data channel that overlaps Wi-Fi channels 1, 6, and 11, respectively. When the EUT was transmitting and the signals were observed at the EUT companion while it was receiving, the I/U ratio was estimated to be -21.7 dB. Conversely, when the EUT was receiving while the EUT companion was transmitting, the signals were observed at the EUT and the I/U ratio was estimated to be -30.9 dB.

Both the EUT and the Wi-Fi networks that generate the unintended signal are baselined to ensure that each achieves the expected functionality when the other network is not operating. Per the recommendations of ANSI C63.27 Annex A, the Wi-Fi routers are configured to use IEEE 802.11n. To generate the maximum channel utilization, we program the Wi-Fi stations to send full buffer User Datagram Protocol (UDP) traffic to the associated access-points while the frame aggregation feature is enabled. It has been demonstrated in [8] that this configuration achieves this purpose. The FWP is then activated and tested in the presence of the unintended signals. The EUT is capable of reporting the achieved link throughput at

[9] Annex D of the standard.

the end of execution. The following scenarios were tested:

1) *Baseline:* when the unintended signals were not operational, the EUT-achieved throughput was 340 Kbps.

2) *Tier 3:* when tested with Tier 3 unintended signal (i.e., one 20 MHz Wi-Fi 802.11n transmission operating at channel 6 with center frequency 2437 MHz), the EUT-achieved throughput was 246 Kbps.

3) *Tier 2:* testing was performed with two concurrent 20 MHz Wi-Fi 802.11n transmissions, the first operating at channel 1 with center frequency 2412 MHz and the second operating at channel 11 with center frequency 2462 MHz. In this case, the EUT-achieved throughput was 185 Kbps.

4) *Tier 1:* testing was performed with three concurrent 20 MHz Wi-Fi 802.11n transmissions operating at channels 1, 6, and 11 (center frequency 2412 MHz, 2437 MHz, and 2462 MHz, respectively). In this case, the EUT-achieved throughput was 100 Kbps.

As discussed in Section II-C, the acceptability of the EUT test outcome is determined using the pass/fail criteria that capture the device functional wireless performance. If a test fails, an iterative process is initiated to determine the I/U ratio suitable for acceptable FWP.

III. Extrapolating Test Results

In this section, we present a simple method for translating I/U measurements obtained during coexistence testing to separation distance recommendations between the EUT, EUT companion, and the source of unintended signal that extend to spatial arrangements beyond those tested. This method is not a part of the ANSI C63.27 specifications.

Consistent with Fig. 2, let d_1 be the distance between the EUT and EUT companion and d_2 the distance between EUT and the source of unintended signals. Assuming LOS setup, d_3, the distance between EUT companion and the source of unintended signals, can be found using simple trigonometry. In the following, we use $P^a_{rx,b}$ to denote the received power value originating from transmitter a and observed in location b.P^a_{tx} denotes the transmission power of node a.

The EUT might alternate in being a transmitter and a receiver while delivering FWP. Accordingly, of interest are the following values:

1) $IU^{EUT\ Rx}_{EUT}$: I/U measured at the EUT when EUT is a receiver.

2) $IU^{EUT\ Tx}_{EUT\ C}$: I/U measured at the EUT companion when EUT is a transmitter.

Note that I/U is the difference in received signal power between the intended and unintended signals at a given location of observation. The received power at an observation point is $P_{rx} = P_{tx} - PL(d)$, where $PL(d)$ is the path loss at distance d. Thus, we find the relationship between d_1, d_2, and d_3 as follows:

$$PL(d_2) = PL(d_1) + \left(IU^{EUT\ Rx}_{EUT} - (P^{EUT\ C}_{tx} - P^{SUS}_{tx})\right) \quad (1)$$

$$PL(d_3) = PL(d_1) + \left(IU^{EUT\ Tx}_{EUT\ C} - (P^{EUT}_{tx} - P^{SUS}_{tx})\right). \quad (2)$$

All transmit and receive power values are considered to be in dBm while the I/U and PL are in dB. Given that the only variables in eq. (1) and eq. (2) are the distance terms, we can use these two formulas to make recommendations for separation distances in realistic deployment environments and to predict the distances at which the measured I/U ratios are expected to be maintained based on the data points acquired during testing. Table I summarizes the I/U ratio considerations presented above. Fig. 3 illustrates an example using the I/U measurements reported in Section II. For this example, we use the log-distance path loss model [9]

$$PL(d) = PL(d_0) + 10\alpha \log_{10} \frac{d}{d_0}, \quad (3)$$

where d_0 is a reference distance and α is a unitless path loss exponent. This example assumes an ideal value of α = 2. The lines demonstrate the combinations of d values that can achieve the measured I/U ratio. Accordingly, when moving the EUT further from its companion (i.e., increasing d_1), the intended signal level at the receiver decreases and both the EUT and its companion should be moved further from potential sources of unintended signals. Note that d_0 is eliminated when substituting in eq. (1) or eq. (2), resulting in the following simplified formulas:

$$d_2 = \lambda d_1 \quad (4)$$

$$d_3 = \mu d_1, \quad (5)$$

where the slope coefficients are:

$$\lambda = 10^{\frac{IU^{EUT\ Rx}_{EUT} - \left(P^{EUT\ C}_{tx} - P^{SUS}_{tx}\right)}{10\alpha}} \quad (6)$$

$$\mu = 10^{\frac{IU^{EUT\ Tx}_{EUT\ C} - \left(P^{EUT}_{tx} - P^{SUS}_{tx}\right)}{10\alpha}}. \quad (7)$$

We note that in this simple approach, eq. (4) and eq. (5) are linear equations of two variables intersecting at the origin, while each passes through the corresponding d value at which the measurement was made. Accordingly, the evaluation complexity is greatly reduced to establishing a scenario in which the EUT successfully delivers its FWP in the presence of the ANSI C63.27 recommended unintended signals and then linearly extrapolating the used distances to predict other combinations of d values that are expected to facilitate successful FWP. The simplicity of this approach comes at the expense of prediction accuracy, especially in realistic deployments.

Table I: Summary of I/U ratio considerations for wireless coexistence testing

Observation Location	EUT mode	EUT Companion mode	I/U	Path loss formula
EUT	Rx	Tx	$IU_{EUT}^{EUT\ Rx}$	$PL(d_2) = PL(d_1) + \left(IU_{EUT}^{EUT\ Rx} - (P_{tx}^{EUT\ C} - P_{tx}^{SUS})\right)$
EUT Companion	Tx	Rx	$IU_{EUT\ C}^{EUT\ Tx}$	$PL(d_3) = PL(d_1) + \left(IU_{EUT\ C}^{EUT\ Tx} - (P_{tx}^{EUT} - P_{tx}^{SUS})\right)$

Incorporating other propagation models to substitute $PL(d)$ as relevant for the deployment environment [9], [10] should improve the prediction. Another simplifying assumption in this method is that the effects of fading and shadowing are small and can be ignored in the LOS deployment. However, we recognize that they should be incorporated for a more comprehensive evaluation, which would yield intervals of recommended distances instead of fixed values.

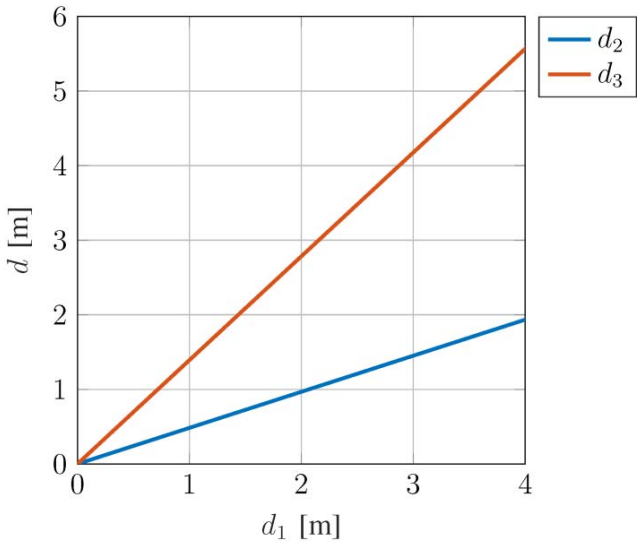

Figure 3: An example projection of test-driven separation distance recommendations between the EUT, EUT companion, and source of unintended signals.

IV. Conclusion

We presented an example wireless coexistence evaluation of a BLE-based hypothetical medical device encompassing the risk assessment considerations per AAMI TIR69 and testing per ANSI C63.27. The development of test-driven user recommendations for the separation distance between the EUT, the EUT companion, and the source of unintended signals is the topic of open research. We proposed a straightforward method for developing such user recommendations to promote the safe use of wireless technology in medical devices.

Disclaimer

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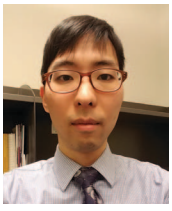

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