Mini-Symposia Title:

Wireless medical devices going into the 5G world: new use cases, practical issues and challenges

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Theme:

- ○ 01. Biomedical Signal Processing
- ○ 02. Biomedical Imaging and Image
- ○ 03. Micro/ Nano-bioengineering; Cellular/ Tissue
- ○ 04. Computational Systems & Synthetic Biology; Multiscale modeling
- ○ 05. Cardiovascular and Respiratory Systems Engineering
- ○ 06. Neural and Rehabilitation Engineering
- ○ 07. Biomedical Sensors and Wearable Systems
- ○ 08. Biorobotics and
- ○ 09. Therapeutic & Diagnostic Systems and
- ◉ 10. Biomedical & Health
- ○ 11. Biomedical Engineering Education
- ○ 12. Translational Engineering for Healthcare Innovation and Commercialization

Mini-Symposia Synopsis— Max 2000 Characters

Title: Wireless medical devices going into the 5G world: new use cases, practical issues, and challenges

Wireless medical devices and systems integrating Bluetooth, Wi-Fi and cellular wireless technologies are spread across a wide array of medical use areas and environments from monitoring ambulatory patients in the hospital to tracking the location of devices, supplies, and staff and are used to enable remote diagnosis, treatment, and even surgery. The next generation 5G wireless technology promises to have a profound impact on healthcare with enhanced data transmission capabilities built on a larger share of the radio and millimeter wave spectrum. The trend to incorporate wireless technology into medical devices has accelerated over the last 2 decades and is rapidly evolving and changing the way patient and clinician information is conveyed and used. While 5G promises to create new opportunities and advanced use cases, this comes with the responsibilities to consider the unique hazards and risks associated with wirelessly enabled medical functions and to assure safe, reliable, and secure performance throughout concept, design, testing, and use. These points are important to consider and address in medical device systems where serious injury or death can, and has, occurred related to the failure, disruption, or loss of information via wireless transmissions. This mini-symposium focuses on advancements in wireless technology and how 5G will impact medical devices and the future of healthcare. Presentations will cover recent wireless medical device trends and regulatory considerations, advances in present Bluetooth and Wi-Fi wireless technologies, and provide an overview of 5G technology and its role in healthcare with associated new use cases. We will also present practical advice including how to deal with the risks related to important aspects such as wireless coexistence and some of the hurdles toward successful deployment and operation within the coming 5G wireless world.

Wireless Medical Devices Trends, Challenges, and a Path to Leveraging 5G

Donald Witters, *Senior Member IEEE and Mohamad Omar Al Kalaa, Member, IEEE*

***Abstract*— Recent trends indicate increasing numbers of medical devices and systems are incorporating wireless technologies. Wireless medical systems have unique hazards and risks that need to be addressed in the concept, design, testing, and use. This presentation focuses on the trends in the use of wireless technology in medical devices and issues related to the medical function risks such as the need for wireless coexistence. These issues will be in the vanguard going forward into the new 5G technology that will have major impact on the design and use of wirelessly enabled medical devices.**

I. Background

Wireless medical devices are rapidly incorporating the newest wireless technology for an expanding array of medically related functions. The benefits of wireless connections include patient and healthcare professional mobility and access to the internet and other digital communications. However, realization of these attributes comes with additional responsibilities to assure that the functions performed via wireless communications are safe, reliable, and secure.

II. Trends and Issues for Wireless Medical Devices

The rise in wireless medical devices parallels the developments of digital radiofrequency (RF) wireless technology. The wireless medical devices are used across a wide range of environments from hospitals to home to transport to work. The most popular wireless technologies used in these devices include Bluetooth, Wi-fi and cellular communication. The presentation will briefly cover these aspects as drawn from our sample of wireless information for over 800 wireless medical devices [1] collected through a systematic search from FDA public databases, medical device manufacturers' web sites, and reports and publications.

To help assure safety and effectiveness for wireless medical devices the FDA created the Radio Frequency Wireless Technology in Medical Devices guidance document to help medical device designers, sponsors, manufacturers, and regulators. [2] There is also the TIR 69 document [3] for assessing and managing the wireless risks, and the ANSI C63.27 standard [4] for testing wireless coexistence based in part on research performed at FDA and the University of Oklahoma [5].

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III. Toward 5G and Wireless Medical Devices

The 5th generation of wireless communication networks (5G) brings unprecedented communication capabilities to a large number of connected devices. 5G introduces revolutionary technologies to offer extremely high-speed wireless connections to a massive number of network users including medical devices, automobiles and transportation, smart city infrastructure, and wearable products. 5G communication provides unique and important fast network responsiveness when a user requests data (i.e., low latency on the scale of 1 ms). Medical devices are positioned to greatly benefit from the capabilities of 5G wireless communication that include: tele-surgery, real-time augmented reality and virtual reality, and remote monitoring, diagnosis, and treatment.

IV. Wireless Coexistence for 5G

In addition to licensed spectrum bands leased by 5G network operators through the FCC, 5G can benefit from freely available unlicensed bands to offload traffic using 5G New Radio-Unlicensed (5G NR-U). Unlicensed spectrum does not offer protection from interference or guarantees for wireless channel access. Thus, wireless coexistence is a concern in the case when a 5G medical device relies on NR-U for its function, and the case when other medical devices using other unlicensed band technologies (e.g., Wi-Fi) are affected by 5G NR-U. The FDA-recognized wireless coexistence evaluation standard C63.27 does not at present include specific guidance for testing with 5G NR-U signals. However, this issue is under consider for development by the standards committee.

References

[1] Preliminary wireless medical device sample database, Food and Drug Administration Database collected from 1996 through 2019.

[2] Radio Frequency Wireless Technology in Medical Devices - Guidance for Industry and Food and Drug Administration Staff, Food and Drug Administration (FDA). https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077210.htm

[3] AAMI Technical Information Report AAMI TIR69:2017, Risk management of radio-frequency wireless coexistence for medical devices and systems, Association for the Advancement of Medical Instrumentation (AAMI).

[4] American National Standard for Evaluation of Wireless Coexistence ANSI C63.27-2017, ANSI Accredited Standards Committee C63®-Electromagnetic Compatibility, IEEE.

[5] M. O. Al Kalaa, S. Seidman, D. Witters, and H. Refai, "Practical aspects of wireless medical device coexistence testing," IEEE Electromagnetic Compatibility Magazine, vol. 6, no. 4, pp. 45-50, 2017.

Making Medical Devices Wireless in the Digital Health Age: Bluetooth® Advances, use cases, and Practical Advice

William Saltzstein, *Member, IEEE*

***Abstract*— Wireless medical systems continue to improve in capability and flexibility as technology advances. This presentation is part of a minisymposium focused on the advances in technology, design and regulatory considerations, and practical advice that includes how to deal with the risks related to important aspects such as wireless coexistence and security. The presentation focuses on Bluetooth wireless technology with discussion of the new architectures (mesh), and new features introduced with the latest specification (Bluetooth 5) as they apply to digital health and the IoH (Internet of Health). The presentation will utilize examples to convey practical information that can help take the research concepts through some of the hurdles that lead to fruition and into deployment.**

V. Background

Wireless technology is a large component in the age of digital health and the expanding Internet of Things (IoT) and is rapidly being incorporated into an ever-widening array of medical devices and systems including both active and passive devices. The use of wireless technology allows connectivity among devices and systems, cloud services and the internet, and enables mobility, scalability, and ubiquitous coverage. New technological advancements, reduced costs of components and miniaturization are now allowing many more eHealth use models to become realizable. However, these new use models come with the need to ensure that the wirelessly enabled functions are safe, reliable, and secure.

Medical Device Systems and Bluetooth Wireless Technology: Opportunities and Challenges

Bluetooth wireless technology continues to evolve and improve, and has enabled new modalities of wireless communications utilizing both customized and off-the-shelf devices. By providing advanced connectivity models to both mobile devices and gateway devises the technology allows data and control communications with other devices and the cloud, facilitating patient mobility and alternative medical monitoring and treatment modalities.

While it shares opportunities and challenges with other RF technologies for short-range connectivity, Bluetooth provides some unique attributes and recent improvements making it well suited for the future of medical connectivity. The technology is based on a frequency hopping spread spectrum (FHSS) transport layer with built-in mechanisms for error detection and correction making it a 'good citizen' in the relatively crowded 2.4GHz ISM radio band. Its low cost, wide availability, and huge customer and peripheral base have made it a required feature for hardware platform suppliers and it is therefore ubiquitous in smartphone and computing products. Finally, it continues to evolve with good backwards compatibility to include higher speed, longer range, and higher reliability options.

As with all wireless technologies, Bluetooth usage in medical device systems requires appropriate attention to detail to address security, privacy, and reliability. The widespread availability of components and tools make it a target when incorrectly implemented or not updated to address issues. The advancements present new and unique capabilities and concerns.

This session will discuss Bluetooth technology with a focus on the latest architecture and feature improvements as they apply to medical systems and new issues with regards to coexistence, regulatory, and cybersecurity opportunities and issues.

The session will also provide examples and scenarios demonstrating new capabilities that continue to make it an excellent choice for medical device communications.

Bill Saltzstein is a consulting medical device expert specializing in Bluetooth wireless technology, and founder of Code Blue Communications, Ashland, OR 97520 USA. (e-mail: billsalt@consultcodeblue.com).

References

[6] Bluetooth technology Special Interest Group: http://www.bluetooth.com

[7] NIST Guide to Bluetooth Security - http://nvlpubs.nist.gov/nistpubs/SpecialPublications/NIST.SP.800-121r2.pdf

[8] Author's blog: http://consultcodeblue.com/blog/

Making Medical Devices Wireless in the Digital Health Age: Hype vs. Reality, what role will 5G have in the future of Healthcare

Phil Raymond, *Member, IEEE,* and Jose Reynes

***Abstract*— Wireless medical systems continue to improve in capability and flexibility as technology advances. The advances in wireless technology present great opportunity in the healthcare field but also with unique hazards and risks that need to be understood by product and system developers and the end users of these complex wireless connected ecosystems. Wi-Fi™ has the new Wi-Fi 6 or 802.11ax coming out with advanced new features, and 5G promises to revolutionize the IoT and IoH. One might consider that we are in the beginning of the Gartner curve of market hype based on some of these claims across many industries, including healthcare. But what will be the reality behind the impact of Wi-Fi 6 and 5G to vastly improve care delivery models and deliver on the quadruple aim [1]? This mini-symposium will provide a brief overview of Wi-Fi 6 and 5G technology and attributes and show how these new wireless capabilities relate to healthcare today and in the future. We will also share advanced use case examples that can be enabled by 5G and review some of the challenges and hurdles that are to be experienced along the way from research to solution development and operational use.**

VI. Background

Wireless technology is a large component in the age of digital health and the expanding Internet of Things (IoT) and is rapidly being incorporated into an ever-widening array of medical device solutions where these systems are systems of systems and are increasingly complex and geographically dispersed. The use of wireless technology allows connectivity among devices and backend systems across the patient's journey from hospital to home and everywhere in-between. Connectivity to the internet is seamless and ubiquitous and often connects to cloud services and back to smartphones or other viewing platforms. New technological advancements, reduced costs of components and miniaturization are now enabling advanced healthcare use models to become realizable. However, realization of these new use models comes with additional responsibilities to ensure that the functions performed via wireless communications are safe, reliable, and secure.

VII. Trends and Challenges for Wireless Medical Devices and Systems

The value proposition around the convergence of advancements in wireless technology, miniaturization of hardware, low power sensors and cloud based applies to healthcare as much or more than other industries. The benefits of improving healthcare whilst lowering costs is a win-win that the age of IoH offers as a promise, albeit not without challenges. One of the challenges is enabling seamless connectivity across the *continuum of connected care* in a robust and reliable manner that effectively supports the healthcare use models.

VIII. Medical Device Systems and IoH; From Wi-Fi™ to 5G: Enabling the Promise of Digital Health

The age of digital health brings many new and exciting use cases that promise to improve healthcare by making it proactive and predictive vs. today's model of reactive medicine, but to deliver on this promise there must be robust, reliable and ubiquitous wireless connectivity.

An example use case is spot check monitoring in low acuity or general ward settings. Vital signs are checked periodically as a nurse makes her rounds, leaving large gaps with no monitoring of a patient leading to many instances of undetected patient deterioration. We are starting to see solutions where low acuity patients wear wireless biosensors that monitor vital signs in real time and can send periodic medical data wirelessly onto the hospital network where a clinical decision support system can detect early signs of patient deterioration and alert caregivers to take action. This is not only a better patient care model for hospital patients but allows the nurse to optimize her clinical work flow with more pointed patient care. Now extend this ambulatory model to a patient discharged from the hospital with wireless biosensors that can monitor the patient outside of the hospital, in the home and in-between sending physiological data over cellular/5G networks back to clinical systems where adjacent technologies like AI can provide insights and develop intelligent alarms. This will undoubtedly save lives and improve the quality of care. But none of this is possible without robust and reliable wireless connectivity across the *continuum of connected care*. We look for an engaging audience discussion on the potential of these new use models, challenges to their proper implementation and a review of the different wireless technologies needed to enable continuous monitoring across the continuum of care.

Phil Raymond is Head of the Wireless Competency & Solution Architecture CoE, a Center of Excellence in Philips Monitoring Analytics & Therapeutic Care CTO office.

References

[9] IHI and the triple and quadruple aim: http://www.ihi.org/communities/blogs/the-triple-aim-or-the-quadruple-aim-four-points-to-help-set-your-strategy

[10] Wi-Fi Alliance Healthcare focus: https://www.wi-fi.org/discover-wi-fi/healthcare

[11] 3GPP and 5G: http://www.3gpp.org/

Making Medical Devices Wireless in the Digital Health Age: Hype and Promise vs. Reality

Rickey Hampton

Abstract— **Wireless technologies continue to proliferate in type and scope as multiple standards are ratified. These technologies are almost universally designed with the average consumer in mind. Further, they often overlap in ways that are both constructive and destructive. Unfortunately, these overlaps are never discussed up front, but almost always left for the consumer to address… if the consumer is even aware of them. In the meantime, the healthcare industry is left to face an ever-increasing tidal wave of devices incorporating these consumer technologies. The destructive overlaps that consumers do not notice create problems for healthcare facilities of a critical nature. The presentation will allow for a guided discussion of these issues, so audience members may understand how their choice of technologies could make their product a success… or come back to haunt them.**

IX. Background

Wireless technologies offer a huge opportunity in expanding the role of healthcare, both in the healthcare facility and the locations frequented in everyday living. The promises espoused by the technology companies paint a picture of health, happiness and convenience for all, with little cost or effort. The marketing shows doctors, nurses and patients interacting with technologies that once existed only in science fiction movies.

It is true that some of these technologies exist and can, to some degree, deliver on the promises. However, very few, if any of them, can deliver on the promises without a great expenditure of time, planning, effort and money to create the environment needed to support them.

X. Wireless Medical Device Systems and Wireless Technologies: Drivers and Challenges

Medical technology continues to evolve and improve at a dizzying rate. Wireless technologies intended for the consumer are evolving even faster. Interfaces have become easy enough that virtually anyone with enough interest can connect consumer wireless devices to existing medical systems… or create them in their basement. It is only natural that lay consumers, and healthcare professionals who are consumers in their own rights, see the advantage of marrying medical and wireless technologies. In many cases, this makes perfect sense and presents little risk to the consumer/patient. In other cases, consumer technologies are not adequately designed for the criticality inherent in some medical device systems. Often, medical and wireless technologies are not married for reasons of patient safety or better outcomes, but for reasons of expediency and "work flow."

No matter the reason for incorporating wireless technologies into medical devices, the most often overlooked requirement for any of these systems is the work required to manage infrastructure, user expectations and ongoing costs.

XI. The Promise vs. Reality

This presentation will discuss the wireless technologies currently in use in the healthcare industry. It will also include examples of past successes and failures. This background will be used to place future technologies in a light that helps to inform not only the promises, but the perils of new and future technologies.

Topics to be discussed will also address security, privacy, and reliability.

Audience members will be encouraged to participate with questions and comments to ensure the talk is applicable to their real-world environments and projects.

References

[12] N/A

Rick Hampton is the Wireless Technical Architect for Partners HealthCare System, a large not-for-profit healthcare delivery system, located in Boston, Massachusetts, U.S.A. Rick is responsible for ensuring all wireless technologies used are safe and effective when use in the clinical settings.