

Building Pathways to Safe, Secure, and Reliable Wireless Healthcare

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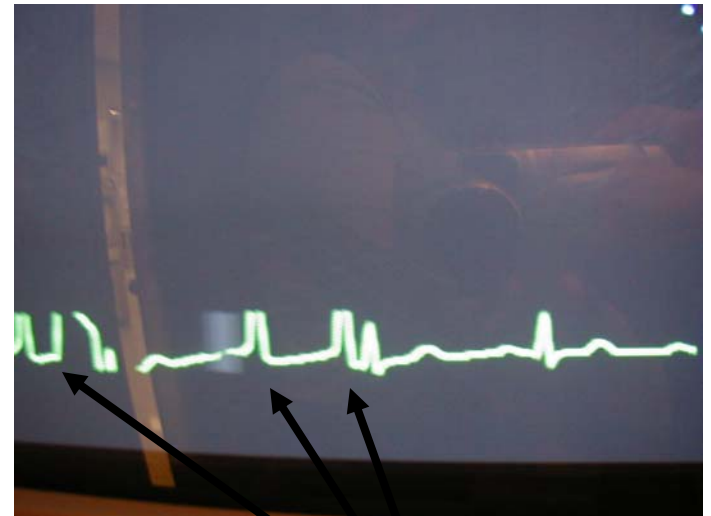


Medical Device EMI Testing - Blackberry

BB in
Pocket



Test Set up



Recorded Interference

HP Sonos 5500 Cardiac Ultrasound

Courtesy S. Juett Baylor Medical Center



Safe, secure and reliable wireless healthcare requires building new pathways, forging new alliances, research, and standards for working in a shared risk environment.



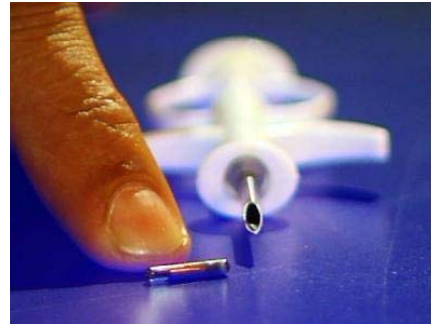
Overview

- **RF Wireless in medical systems**
- **Challenges for safe, secure, reliable wireless healthcare**
- **Present needs and the future**
- **Discussion**



Wireless Use in Medical Care

- Rapid integration of wireless technology into all aspects of healthcare
- Home
- Hospital
- Transport
- Rescue
- Nursing homes
- Doctor's offices
- EHR
- Military



Wireless Healthcare Challenges



- **Wireless technology**
 - **Dynamic, rapidly changing**
 - **Both a source and victim for EMI**
- **Coexistence among multiple transmitters**
- **Convergence, interoperability**
- **Security**
- **Inadequate standards**
- **“Medical grade” wireless?**
- **Lack of clear, consistent pathways to deployment**



Issues for Medical Wireless

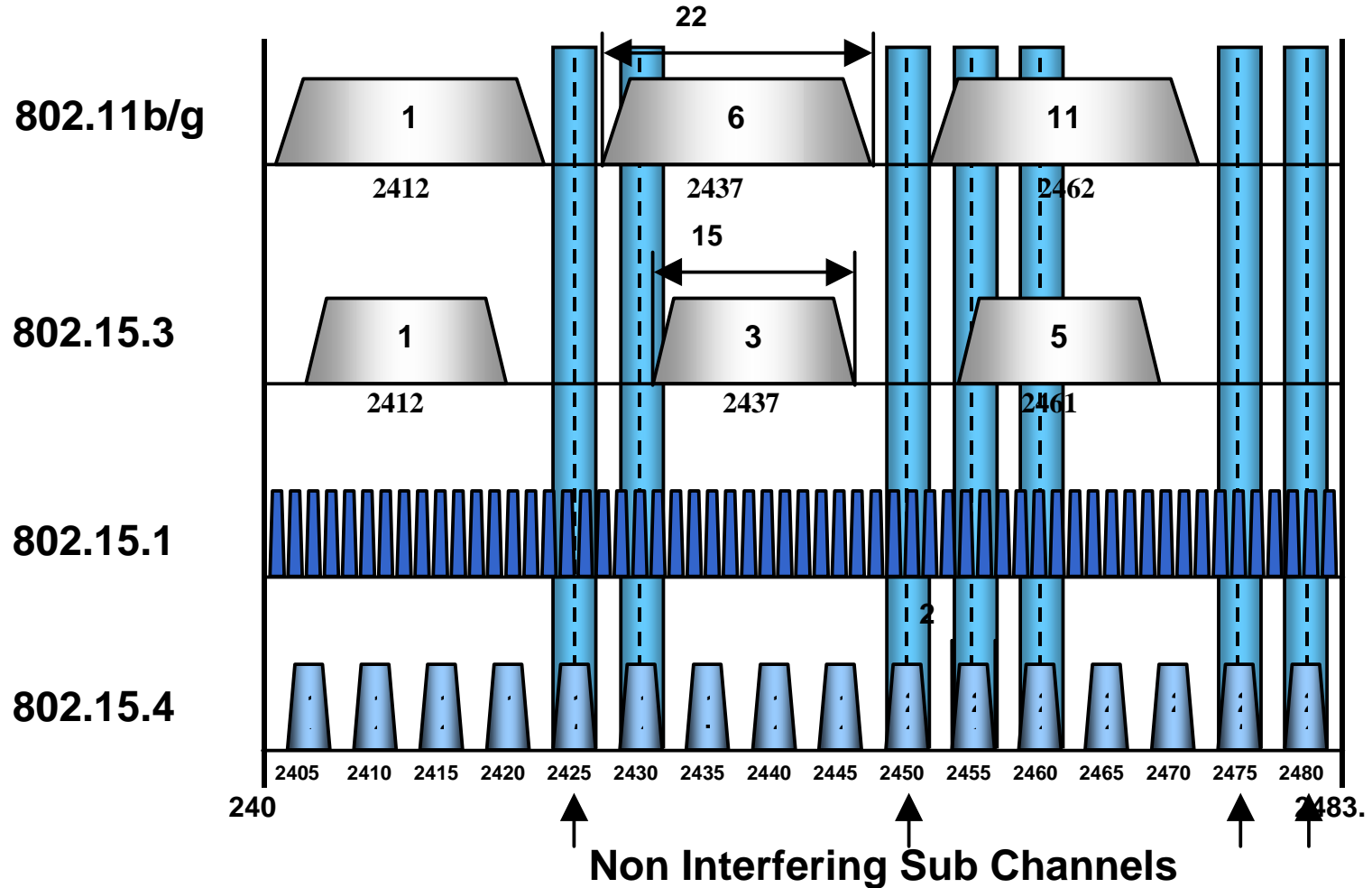
- **Risk**
- **Security**
- **Manageability**
 - Expandability, changeability, upgradeability
- **Availability**
- **Resilience**
- **Quality of Service**
- **Integrity**
- **Coexistence**
- **Certification**
- **Privacy, confidentiality**



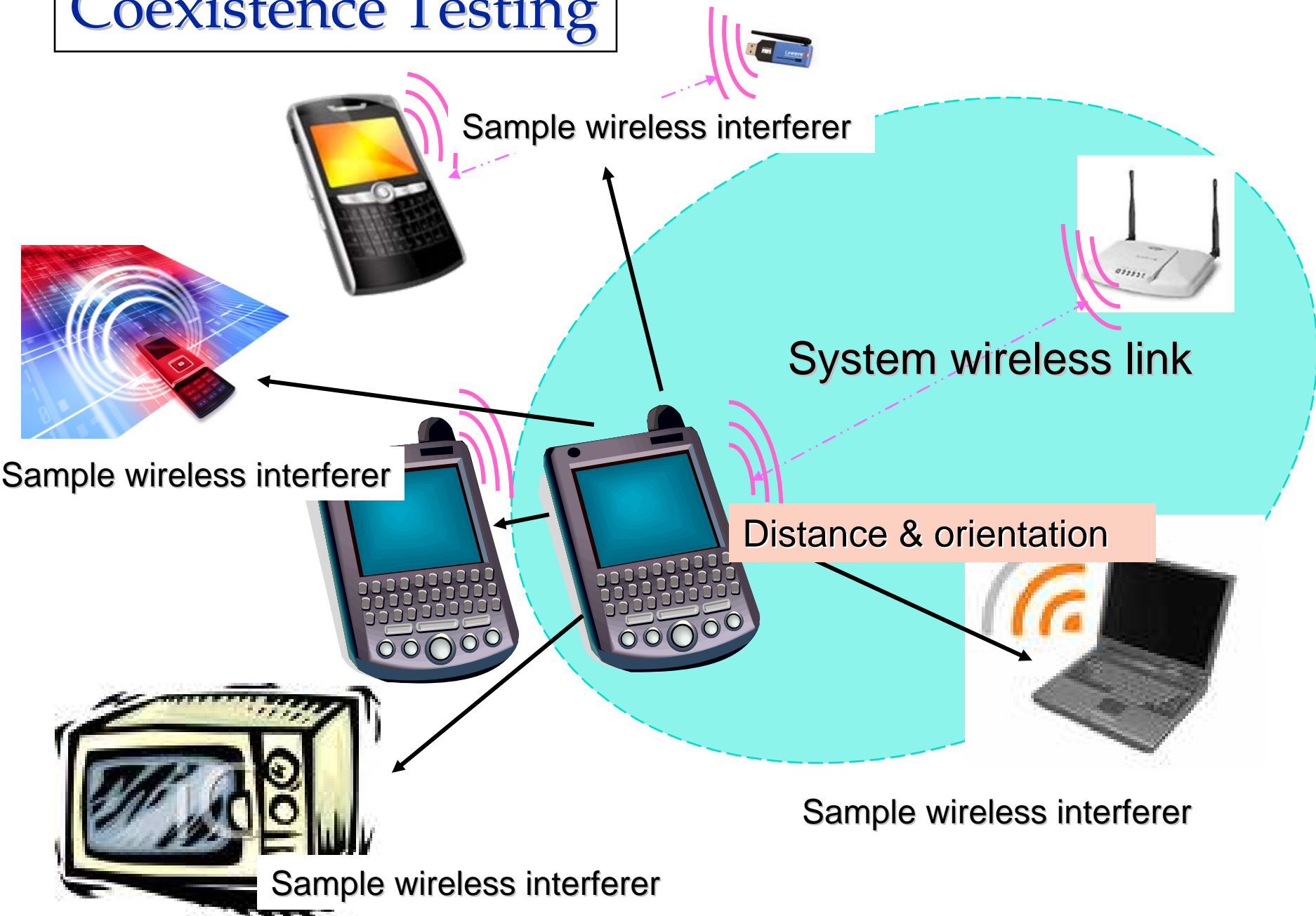
Addressing Wireless in Submissions

- **System wireless description**
- **Quality of Service**
- **Wireless Coexistence**
- **Wireless data integrity**
- **Wireless data security**
- **EMC**
- **Labeling**

Wireless Technologies in the 2450 MHz ISM Band



Coexistence Testing





Security Concerns

- ▶ **Health Insurance Portability and Accountability Act (HIPAA) issues**
- ▶ **Wireless security issues**
 - ▶ Authentication – to ensure authorized users
 - ▶ Encryption – to secure sensitive data and wireless links
 - ▶ Open architecture
 - ▶ Multiple combinations of technology
 - ▶ Rogue wireless users



Security Concerns

Off-the-shelf wireless technology

- ▶ **IEEE 802.11, WiFi**
 - ▶ **Wired Equiv. Privacy (WEP):** weak security; broken before it was released
 - ▶ **Wi-Fi Protected Access (WPA)**
stronger wireless encryption
 - ▶ WPA
 - ▶ WPA2: more recent, stronger



Needs for Medical Wireless

- **Clear pathways for safe, secure and reliable deployment, use, maintenance**
- **Framework and consensus standards for wireless technology in healthcare**
 - Shared risk management, definitions, consistent test methods, certification and deployment information
- **“Medical Grade” Wireless**
- **Stakeholder communication & engagement**
 - Clinicians, users, healthcare org., manufacturers, vendors, IT, standards org., VA, DoD, businesses



Summary



- **Wireless healthcare holds much promise and challenges**
 - Deployment rapidly increasing, continues to evolve
 - Risk management in shared risk environment
- **Lack of adequate tools and clear pathways for safe, secure, and reliable wireless healthcare.**
- **Standards and information are needed**
 - Framework, test methods, “medical grade”
- **IEEE and other stakeholders need to take on leadership roles to develop goals, pathways and consensus standards.**

Making wireless healthcare work requires research, risk awareness and management, stakeholder engagement, and a proactive approach to safe, secure, reliable deployment.



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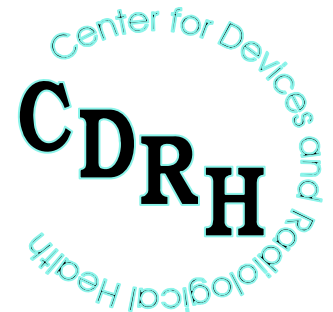
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Draft Wireless Device Guidance



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Radio-Frequency Wireless Technology in Medical Devices

DRAFT GUIDANCE



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This guidance document is being distributed for comment purposes only.

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