Wireless Issues for Home Care Medical Devices

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Medical Device EMI Testing - Blackberry

Test Set up

Recorded Interference

HP Sonos 5500 Cardiac Ultrasound

Courtesy S. Juett Baylor Medical Center
Making wireless home care medical device safe, effective, and secure requires designing, testing, deploying and managing the device for wireless risks.
Overview

• RF Wireless technology in healthcare
• Issues in the home environment
• Addressing wireless risks
• Challenges and opportunities
Wireless Issues in the Home Environment

• Home RF Wireless environment is uncontrolled with many wireless emitters in/out of the home environment
• Little oversight or technical knowledge
• Rapidly changing wireless technology and environment
• Wireless is both a source and victim for electromagnetic interference (EMI)
• Wireless risks include:
  – QoS, data integrity, coexistence, security, EMC
Medical Wireless Risk Priorities

- Shared risk environment
- Risk related to Device/system intended use, use of wireless technology, and data transmitted
- Consequences of not getting data across wireless link correctly, timely, and securely

Life critical functions, high priority alarms, therapy, remote control

Low priority data, No therapy or alarms
Addressing Wireless in Submissions

• System wireless description
• Quality of Service
• Wireless Coexistence
• Wireless data integrity
• Wireless data security
• EMC
• Labeling
Radio-Frequency Wireless Technology in Medical Devices

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.
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Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the Federal Register of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Alternatively, electronic comments may be submitted to http://www.fda.gov/dockets/ecomments. All comments should be identified with the docket number listed in the notice of availability that publishes in the Federal Register.

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U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health
Electrophysics Branch
Division of Physical Science
Office of Science and Engineering Laboratories
Coexistence Testing

Sample wireless interferer

Distance & orientation

Device wireless link

Sample wireless interferer

Sample wireless interferer
Challenges and Opportunities

• More home care with more functions and less on-site management
• Changing wireless technology, wider integration, and more use of limited wireless resources
• Greater need for shared risk management
• Need for information and standards for safe, secure, and reliable medical systems
• Opportunity to create products and pathways for wireless home care devices
Summary

• Home environment presents challenges for safe, secure, reliable wireless healthcare

• Wireless deployment is rapidly increasing and technology continues to change and evolve

• Risk management in a shared risk environment

• Lack of adequate tools and clear pathways for safe, secure, and reliable wireless healthcare.

• Addressing wireless should include:
  – Description of wireless technology and characteristics
  – QoS, wireless data integrity, coexistence, wireless security, EMC, labeling
Making wireless home care devices requires research, risk awareness and management, stakeholder engagement, and a proactive approach to safe, secure, reliable deployment.
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Why Wireless issues are important.