INTELLIGENT SYSTEMS CONFERENCE &PAVILION

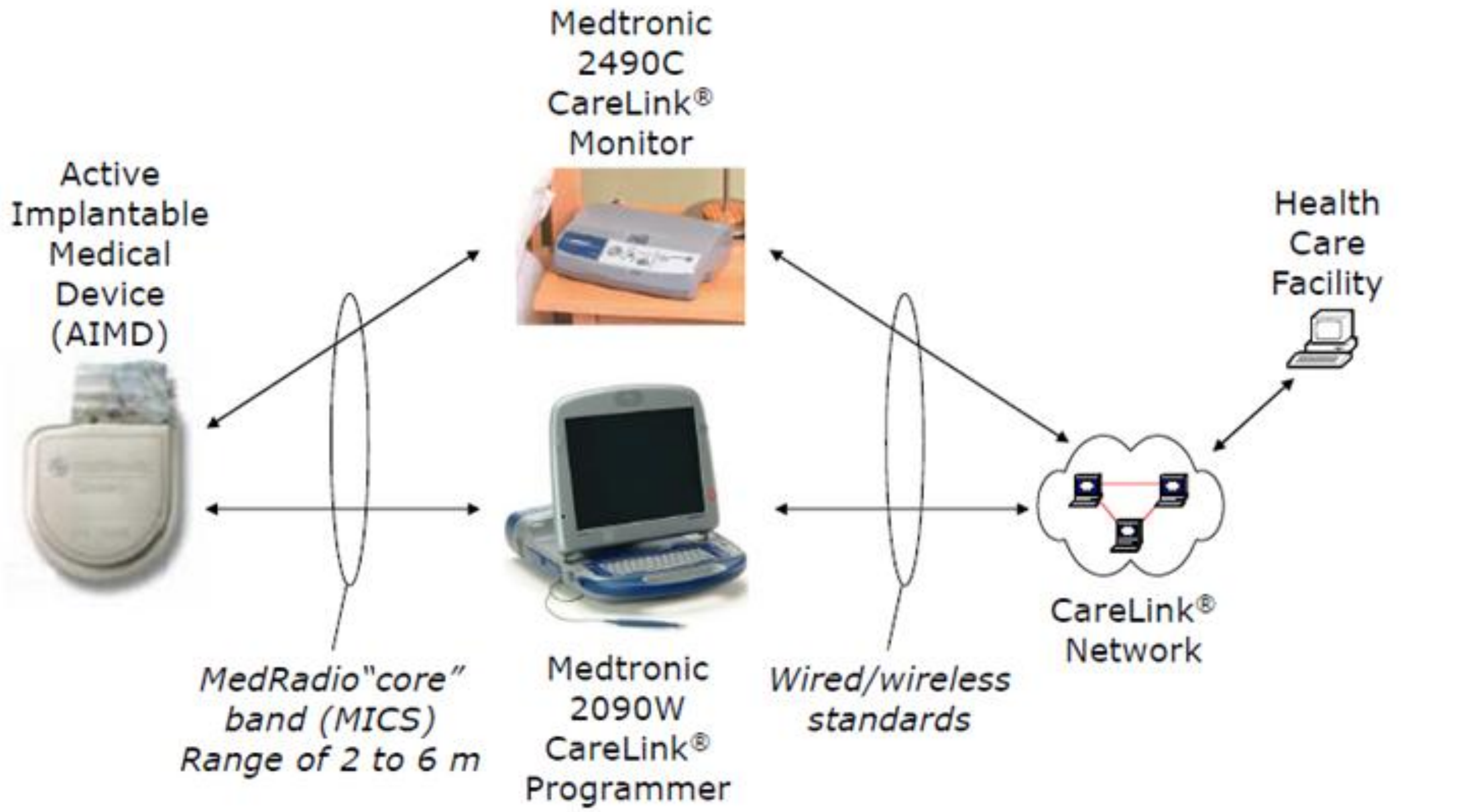
Wireless Technology and RF Standard in Medical Device Development

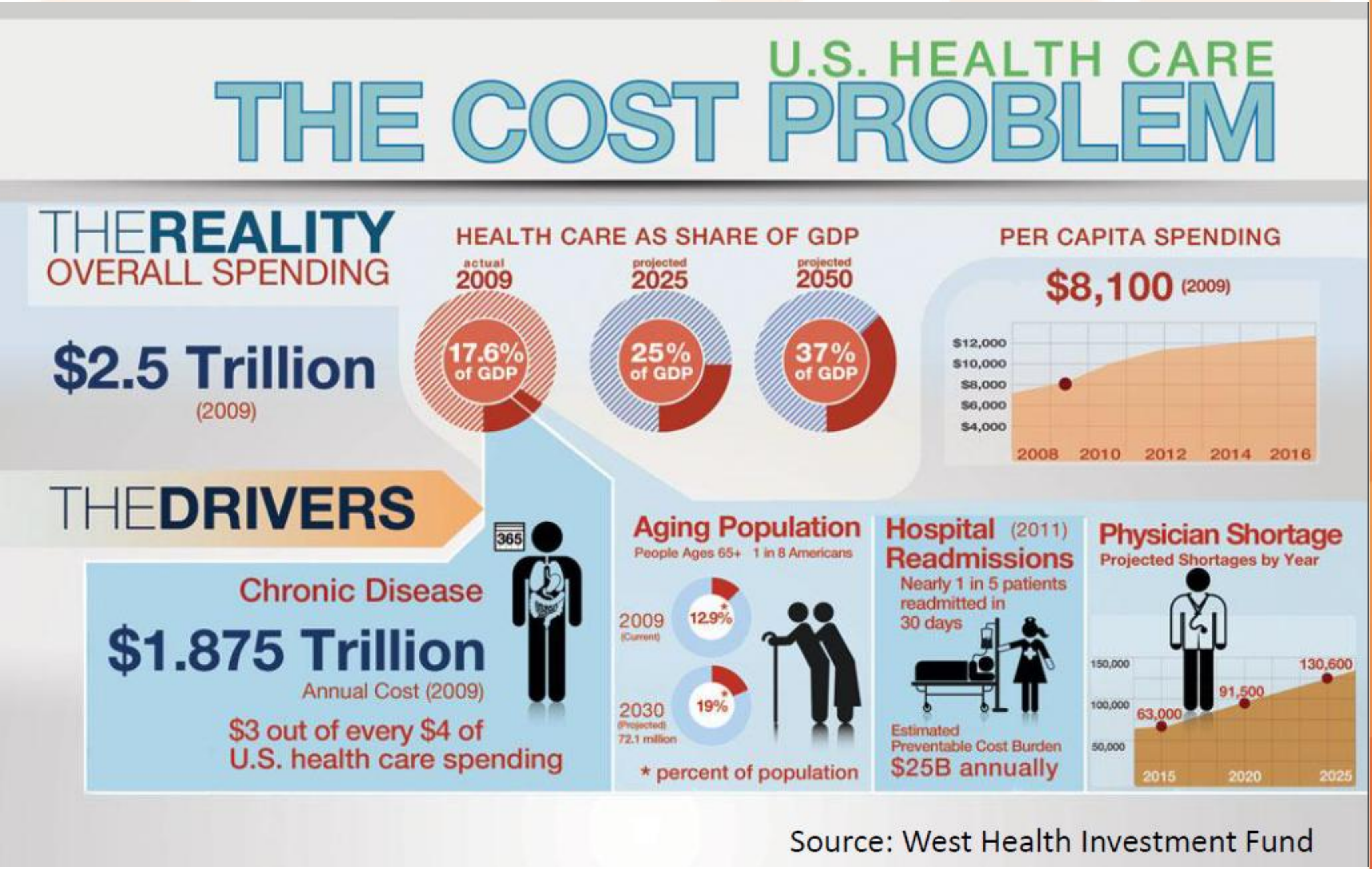
10:10 am – 10:50 am
Thursday, June 6

Greg Crouch

Life Science Business Director, National Instruments

Wireless Telehealth Example

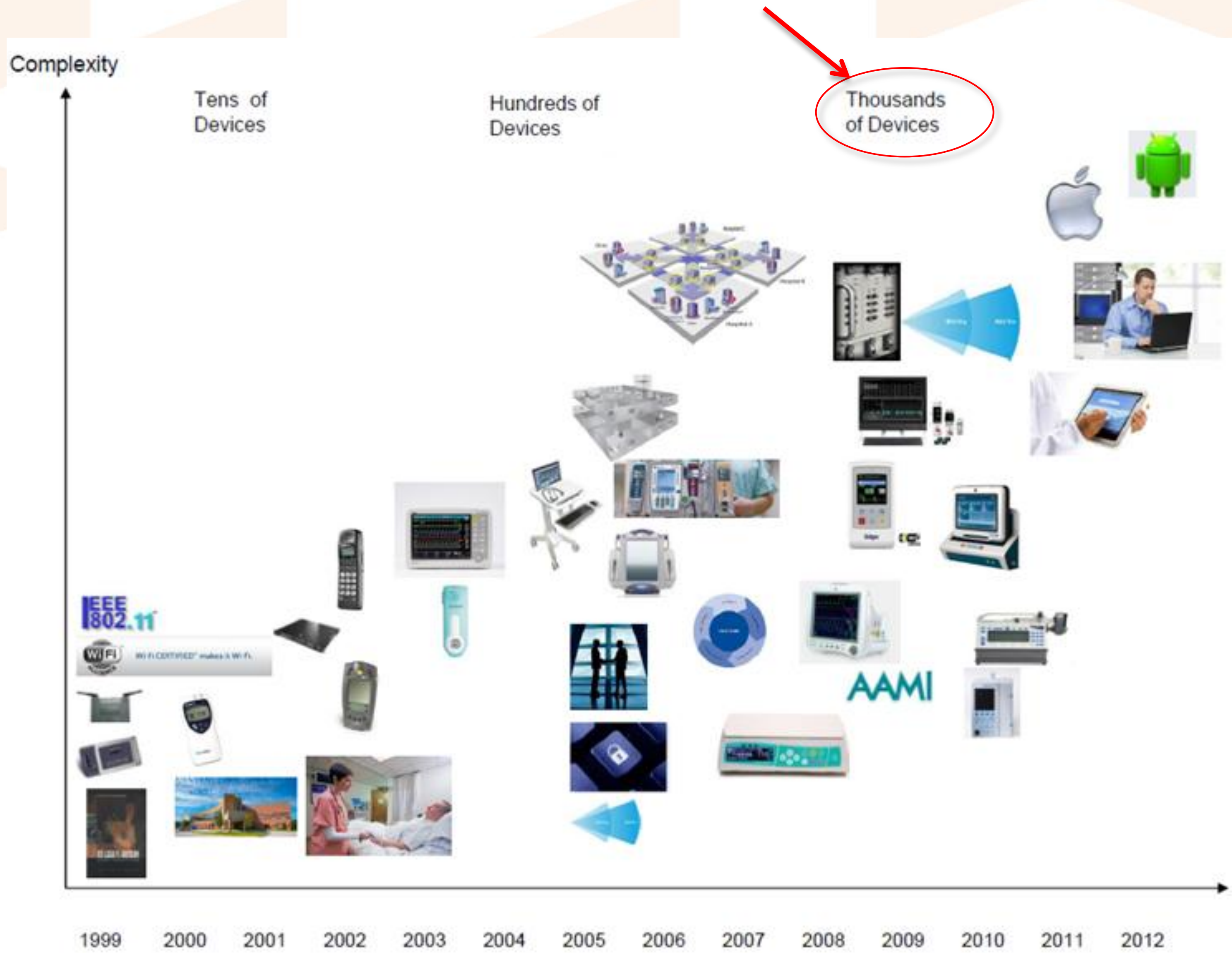




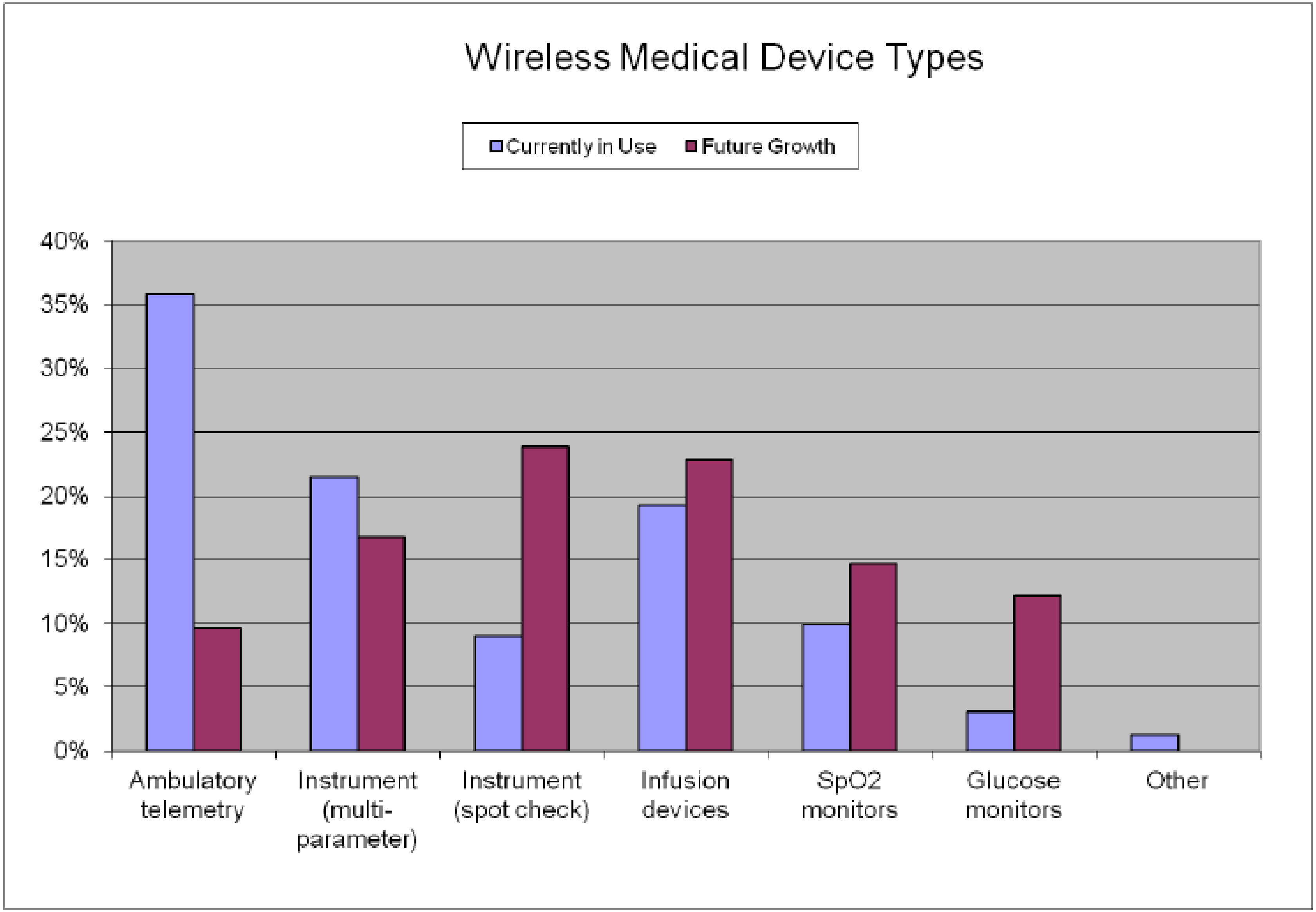
Source: West Health Investment Fund

INTELLIGENT SYSTEMS CONFERENCE &PAVILION

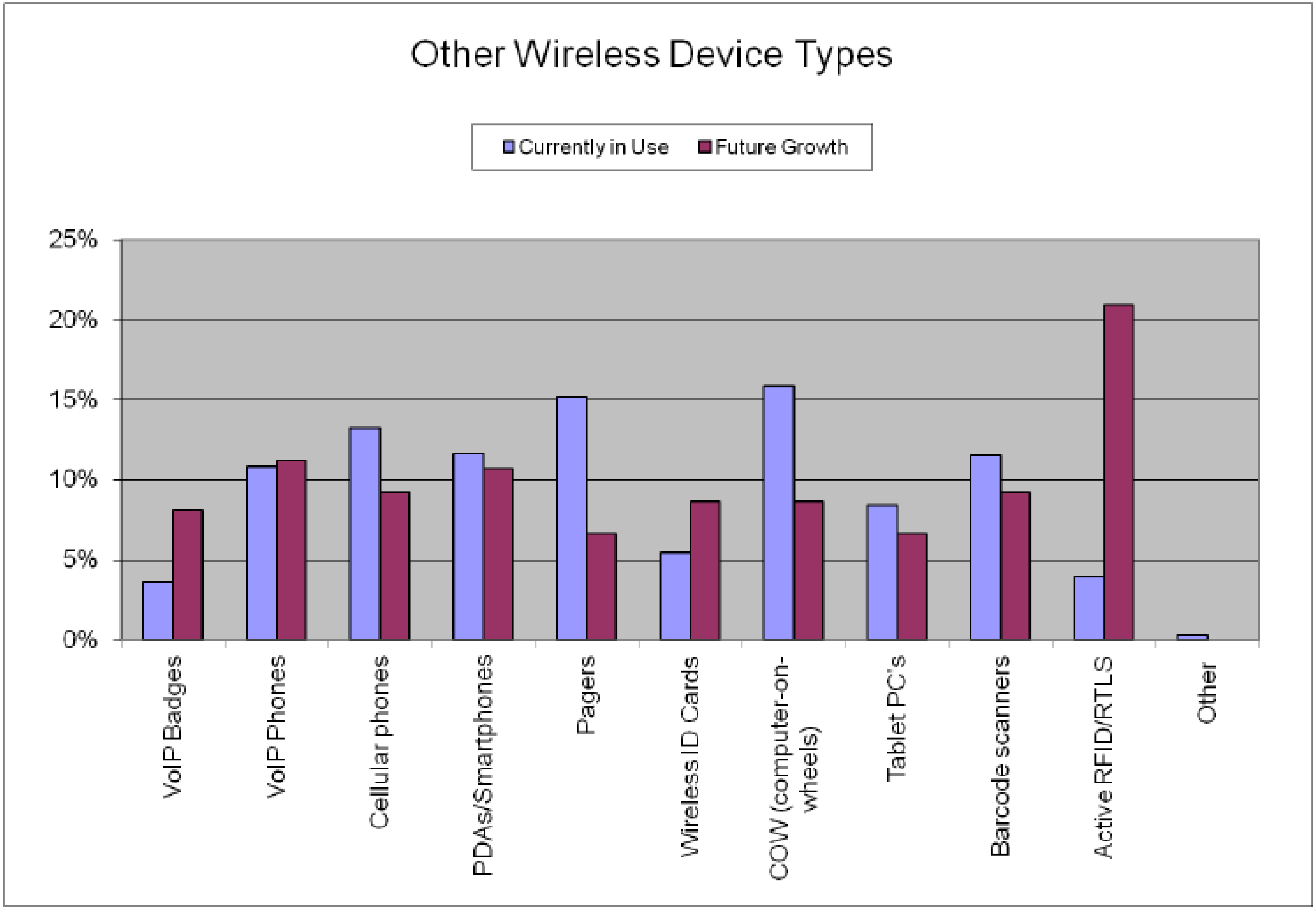
Telehealth of the Future



Source -> Texas Instruments



Source: Q2 2011, Multiple choice questionnaire, ~4000 AAMI Members, Response: 124 respondents (3.1%), Published: Fall 2011 IT Horizons (BI&T)



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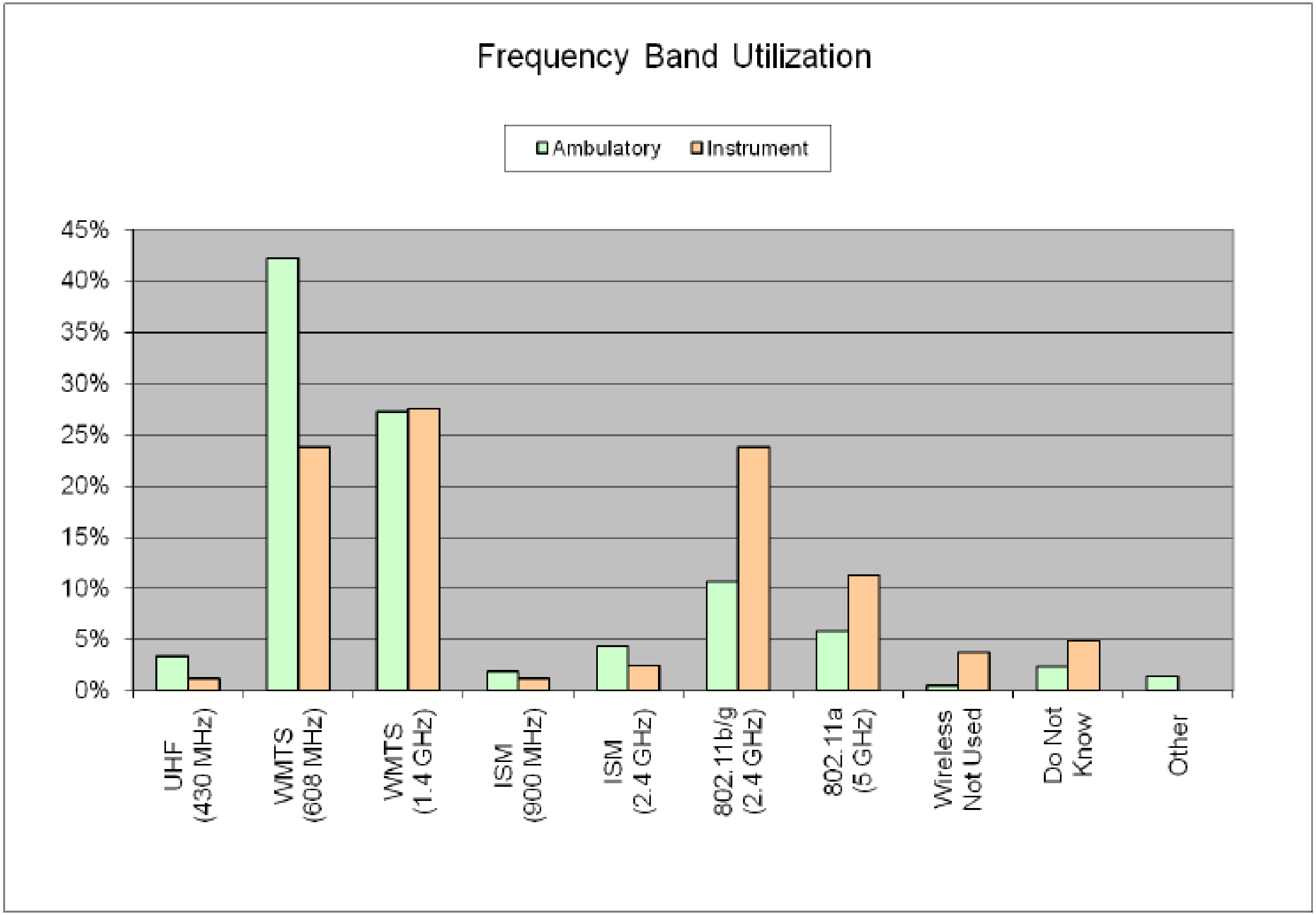

Frequency Band Utilization
Ambulatory
Instrument
45%
40%
35%
30%
25%
20%
15%
10%
5%
0%
UHF (430 MHz)
WMTS (608 MHz)
WMTS (1.4 GHz)
ISM (900 MHz)
ISM (2.4 GHz)
802.11b/g (2.4 GHz)
802.11a (5 GHz)
Wireless Not Used
Do Not Know
Other

Medical Wireless Technologies

Standard	Frequency	Data Rate	Range
Inductive Coupling	< 1 MHz	1-30 kbps	<1m
Wireless Medical Telemetry System	608-614 MHz 1395-1400 MHz, 1427-1429.5 MHz	>250 kbps	30-60m
Medical Device Radiocommunication Service (MICS)	401-406 MHz	250 kbps	2-10m
Medical Micropower Networks (“MMNs”)	413-419, 426-432, 438-444, 451-457 MHz		<1m
Medical Body Area Networks (“MBANs”)	2360-2400 MHz	10Kbps-1Mbps	<1m
802.11a Wi-Fi	5 GHz	54 Mbps	120m
802.11b Wi-Fi	2.4 GHz	11 Mbps	140m
802.11g Wi-Fi	2.4GHz	54Mbps	140m
802.11n Wi-Fi	2.4/5GHz	248 Mbps	250m
802.15.1 Bluetooth Class I	2.4 GHz	3 Mbps	100m
802.15.1 Bluetooth Class II	2.4 GHz	3 Mbps	10m
802.15.4 (Zigbee)	868, 915 MHz, 2.4 GHz	40 kbps, 250 kbps	75m
World Interoperability for Microwave Access (WiMAX)	2.5 GHz	70 Mbps (fixed), 40 Mbps (mobile)	Several km

Countries have allocated frequency bands for general communication and/or medical communication.

- Frequency bands that are common across all countries include:
  - 402 –405 MHz MICS (Medical Implant) band
  - 2.400 –2.483 GHz
  - 5.150 –5.875 GHz
  - Known as ISM bands in the US.

- Otherwise medical applications can use country specific allocations which are either general purpose or dedicated to medical device communication.

US and China specially allocated medical bands:

- US:
  - General
    - Medical devices are still secondary users and must be registered with ASHE.
    - 608-614 MHz (WMTS -may be discontinued)
    - 1395-1400 / 1429-1432 MHz (WMTS)
    - 2360-2390 / 2390-2400 MHz (new MBAN)
  - MICS Band -“Medical Implant Communication Service”401 –406 MHz, with an EIRP of 25 microwatt

- China:
  - Newly Allocated:174-216 MHz, 407-425 MHz and 608-630 MHz

OTS Wireless Technologies:

- Bluetooth (802.15.1)
  - Typical use: streaming data (~2 Mbps), low power
  - Defined for use in the 2.4 GHz band
- Bluetooth Smart (aka Bluetooth Low Energy) (802.15.1 v4.0)
  - Typical use: low duty cycle, very low power, low data rate(<100 kbps), range of 10m
  - Emerging technology with support on iPad and Galaxy
  - Predicted to become dominant wireless technology on consumer medical devices by 2016 (IMS Research Report)
- Zigbee (802.15.4)
  - Typical use: low duty cycle, low data rate (<250 Kbps), low power
  - Multiple bands include: 868 MHz (EU), 915 MHz (US), 2360 MHz (US) and other bands for China and Japan
- ANT and ANT+
  - Similar use as BT Smart and Zigbee applications (<1 Mbps)
  - Operate on a button-cell battery for years
  - Defined for use in the 2.4 GHz band

Additional OTS Wireless

- DECT
  - Typical use: voice; adapted for patient telemetry (1400 MHz)
  - Data rate of 1.15 Mbps, 10 mW average/250 mW max, range of 100 –300m
  - Typically uses 1900 MHz; exact band varies with country
  - DECT ULE is a lower power, low duty cycle version
- WBAN (802.15.6)
  - Typical use: BAN streaming data (100 –500 Kbps), low power
  - Multiple bands including: 402-405 MHz, 420-450 MHz, 863-870 MHz, 902-928 MHz, 950-956 MHz, 2360-2400 MHz, 2400-2483 MHz
- Wi-Fi (802.11)
  - Typical use is for Local Area Networks (54 Mbps per channel)
  - Bands used include: 2.4 GHz and 5 GHz
- 3G / 4G / 5G Cellular
  - Typical use is for Wide Area Networks however

Common Wireless Technologies in Hospitals

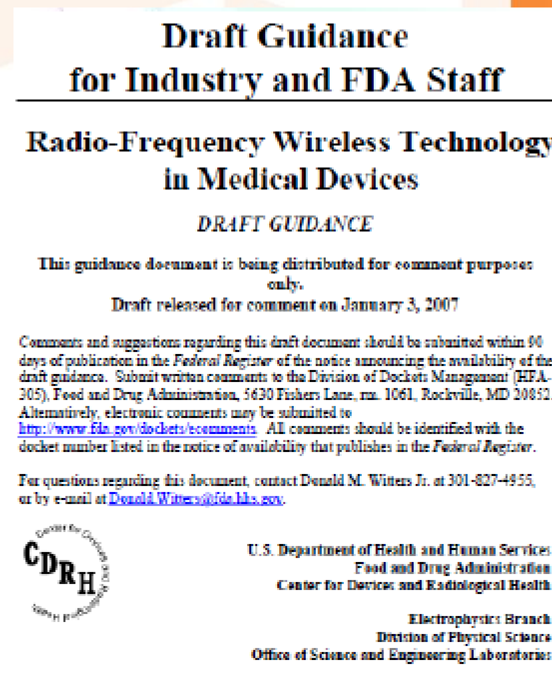
- Commercial/ Public radio services (FCC)
- Wireless Medical Telemetry Service (WMTS)
- Cell phones
- Wireless handheld computers
- Wireless local area networks (802.11.a/b/g) (future 802.11.ac)
- Personal area networks including 802.15.1 (Bluetooth), 802.15.4 (Zigbee)
- RF Identification (RFID) Bar code readers

FDA Guidance

- *Radio-Frequency Wireless Technology in Medical Devices; Jan. 3, 2007*

Concerns related to:

1. Outlines concerns related to RF wireless with devices
2. Risk Management
3. Design development considerations
4. Verification testing
5. Validation testing
6. Labeling



Draft Guidance for Industry and FDA Staff

Radio-Frequency Wireless Technology in Medical Devices

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Draft released for comment on January 3, 2007

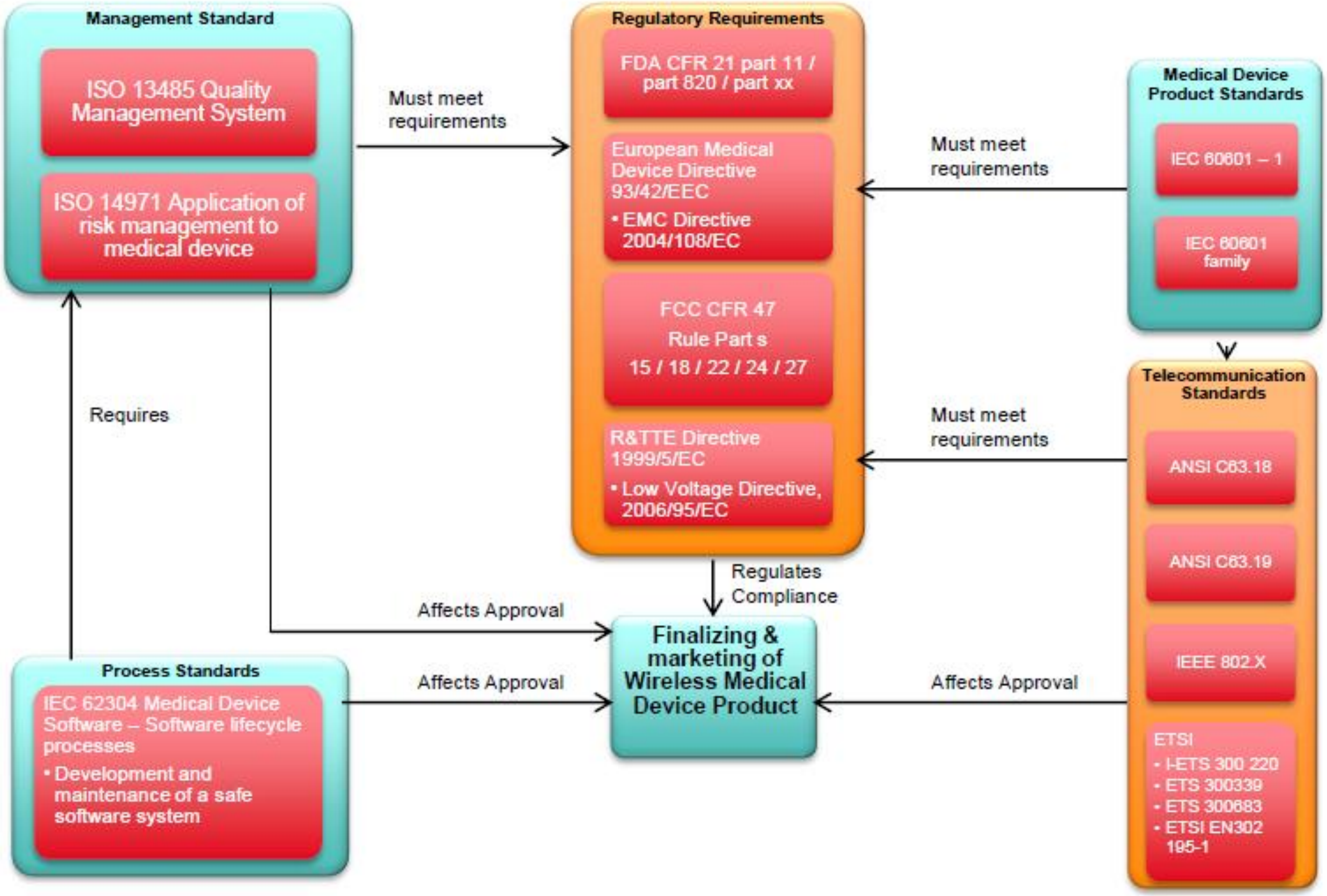
Comments and suggestions regarding this draft document should be submitted within 90 days of publication in the *Federal Register* of the notice announcing the availability of the draft guidance. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 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*.

For questions regarding this document, contact Donald M. Witters Jr. at 301-827-4955, or by e-mail at Donald.Witters@fda.hhs.gov.

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

Wireless & Medical Devices Regulations



Source: Applicability of Global Radio Regulations and EMC Standards to Mobile Medical Applications , Mike Heckrotte

Product Design-
Typical Wireless Requirements

- R&D's wireless product requirements based upon Marketing.
  - Consume no power
  - Cost no money
  - Lose no data
  - Support 'lots' of devices
  - One product worldwide… Deliver tomorrow
- R&D starts thinking
  - US only or International?
  - Medical bands or ISM bands?
  - Power budget?
  - Desired range?
  - How many devices co-located?
  - Data rate?
  - Bluetooth, Zigbee, Wi-Fi, 3G/4G, Proprietary, …?

Real-World Design Considerations

- **Frequency Band Selection**
- **Power Budget, related to:**
  - Transmit only vs. Transmit/Receive
  - Transmit power which is related to:
    - Range (data rate also relates to range)
  - Transmit/Receive time which is related to:
    - Data volume and Data rates
  - Chip power consumption which is related to:
    - Complexity of communications algorithms
    - Availability of Power Save Modes
- **Communications Range, related to:**
  - Antenna Design
    - Antennas can have different gains
    - MIMO approaches can also improve range and throughput at the cost of power and complexity
  - Transmit Power
  - Receiver Sensitivity
  - Data Rate
    - Lower date rates will extend the range

Real-World Design Considerations
Device Coexistence

- This is an important issue for product which share the same frequencies.
  - A product using uncoordinated technology in the same band may interfere with each other.
  - If multiple devices using the same technology converge at an access point (or equivalent), there may not be enough bandwidth.

- Most legacy patient telemetry systems use narrow-band dedicated channels.
  - Low data rate, but each device has a dedicated slice.

Real-World Design Considerations
Device Coexistence

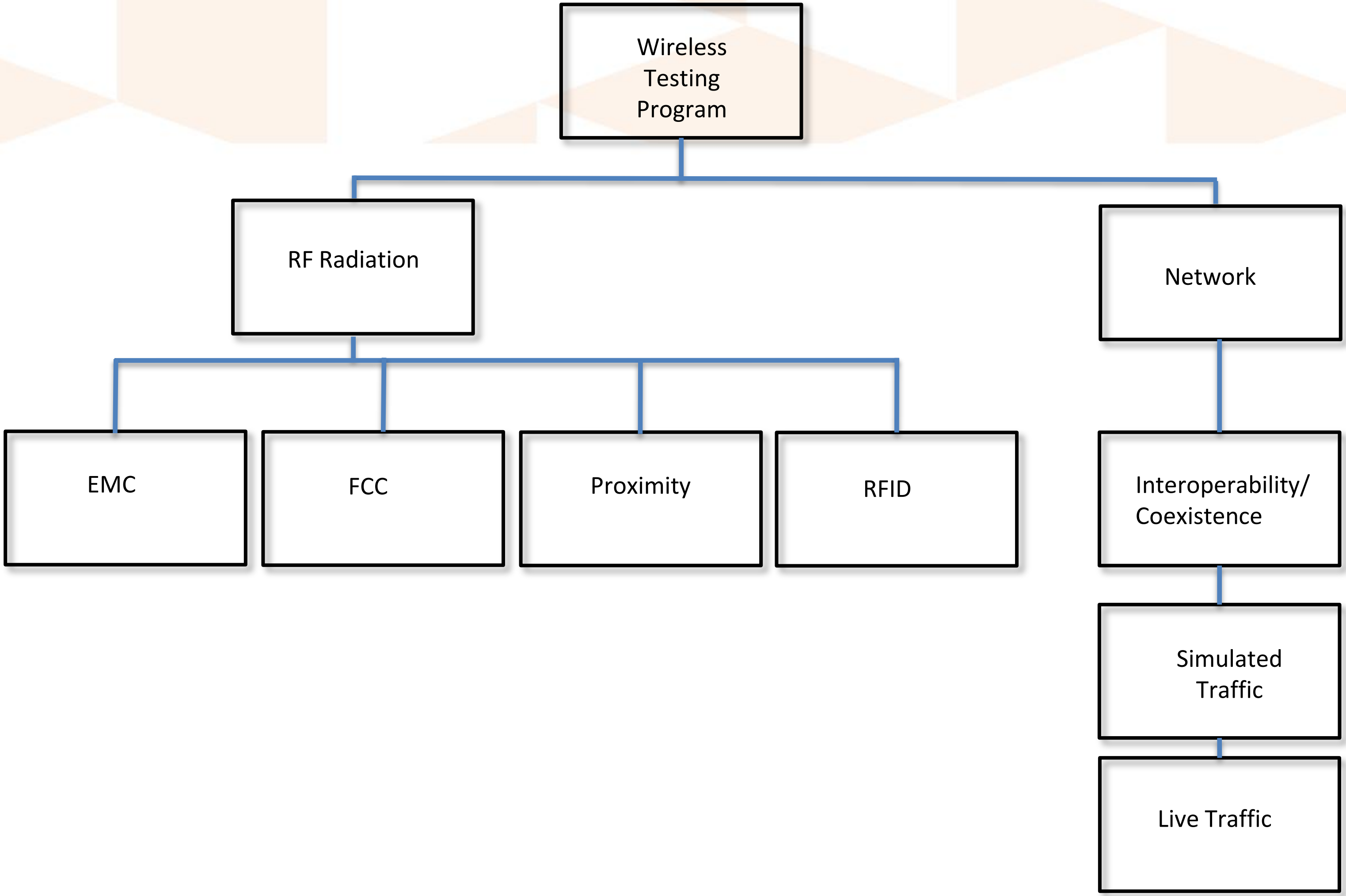
- Some proprietary solutions share the channel among multiple devices.
  - Some risk of overloading, but not likely due to vendor control.

- Most open standards-based solutions share the channel among multiple devices.
  - High risk of overloading especially with popular technologies such as 802.11.
  - Potential issues of application-level interference if SSIDs need to be shared (802.11).
  - If you are "sharing" the medium, you need to be worried not only about your application but everything else.

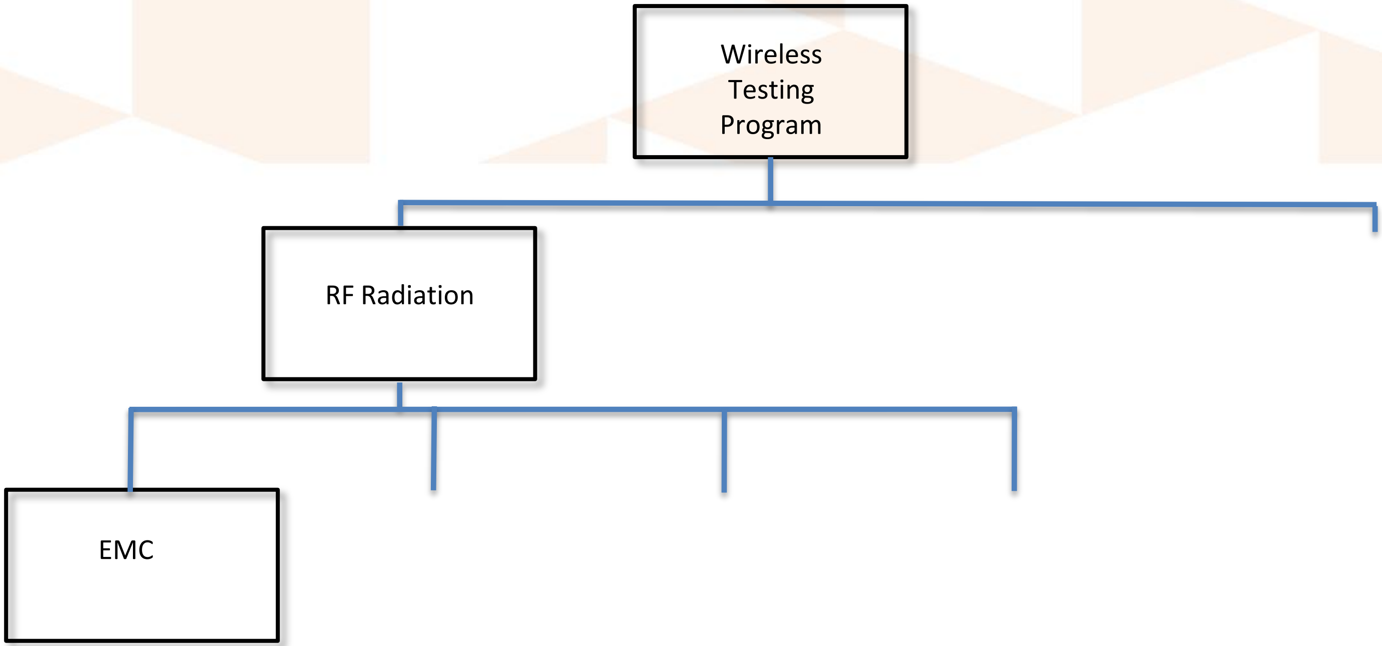
Infusion system demands on wireless

Wireless Function	What's Needed	Comments
Voice over IP (VOIP)	Real-time high quality of service (QoS)	Lots of voice communications = lots of bandwidth
Infusion pump drug library update	Batch data push	Real-time not required. Batch updates can be optimized in software
Infusion pump status (Flowsheet and IV status board viewers)	Semi Real-time	A few minutes between updates acceptable
Infusion pump alarms push	Almost real-time mission critical	Less than one minute end-to-end. Validate and display connectivity status
Infusion pump auto programming	Near Real-time mission critical	Within seconds end-to-end. Validate and display connectivity status

What is a Wireless Medical Device Test Plan?



Wireless Medical Device Test Plan



NORME INTERNATIONALE
INTERNATIONAL STANDARD

CEI
IEC
60601-1-2

Troisième édition
Third edition
2007-03

Appareils électromédicaux –

Partie 1-2:
Exigences générales pour la sécurité de base et les performances essentielles –
Norme collatérale:
Compatibilité électromagnétique –
Exigences et essais

Medical electrical equipment –

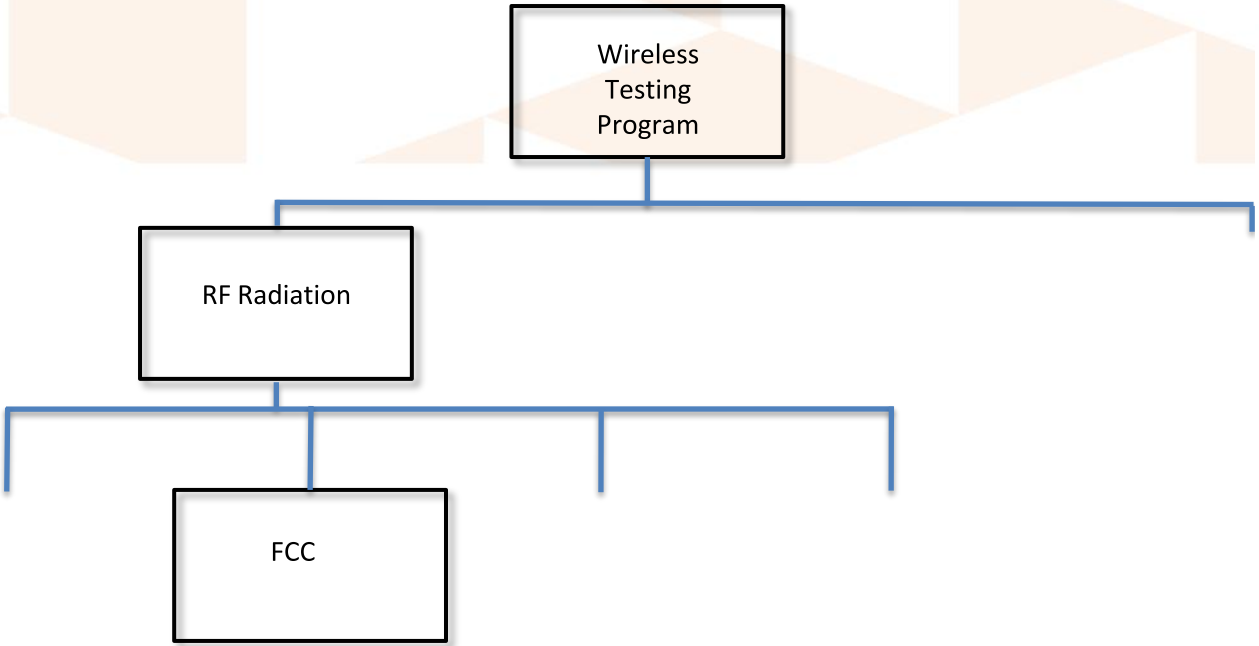
Part 1-2:
General requirements for basic safety and essential performance –
Collateral standard:
Electromagnetic compatibility –
Requirements and tests

IEC

IEC 60601-1-2:2007 ; *Medical Electrical Equipment –Part 1-2: Gener Requirements for safety –Collateral standard: Electromagnetic – Requirements and tests*

- Susceptibility & emissions

Wireless Medical Device Test Plan



ANSI C63.10: Procedures for testing compliance of a wide variety of unlicensed wireless devices

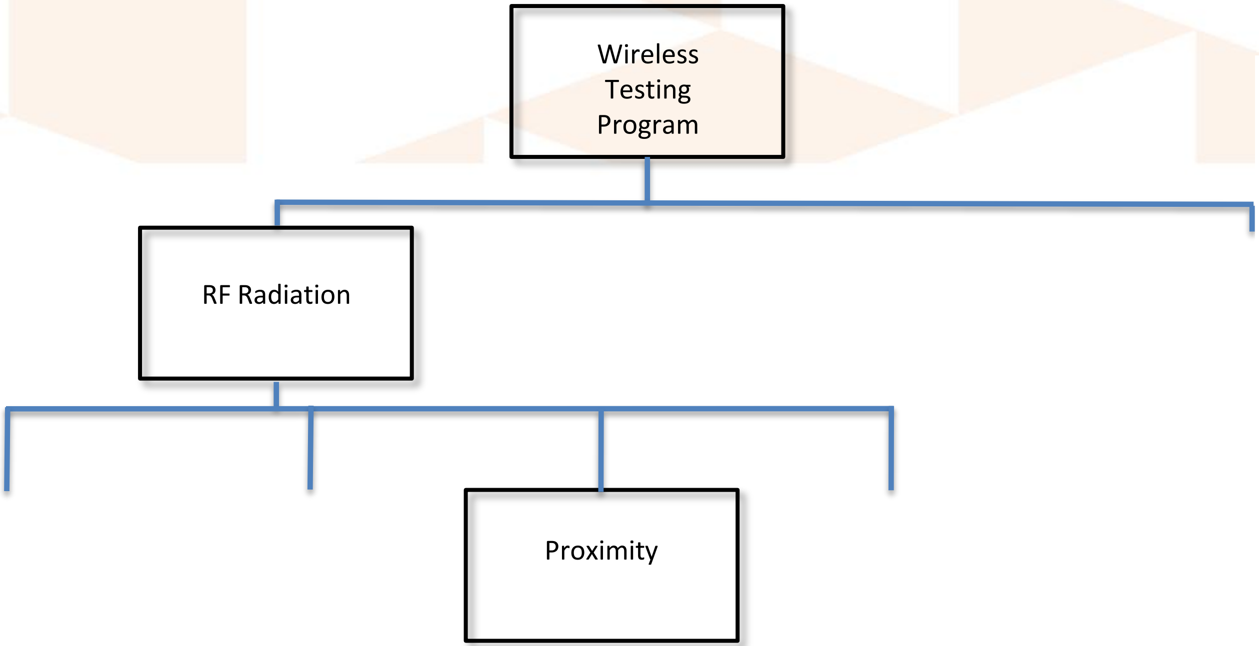
New standard brings to one place all reference material needed for performing tests

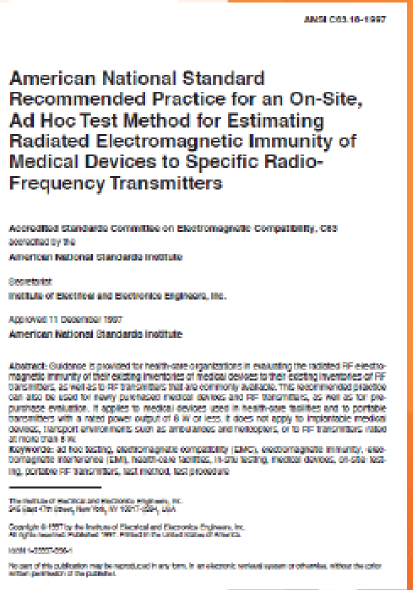
47 CFR 15.247 -*Operation within the bands 902-928 MHz, 2400-2483.5 MHz, and 5725-5850 MHz*

Test Method: ANSI C63.10, *American National Standard for Testing Unlicensed Wireless Devices*

- Coexistence with other electromagnetic spectrum users: FCC Part 15 Rules

Wireless Medical Device Test Plan





ANSI C63.18-1997

American National Standard Recommended Practice for an On-Site, Ad Hoc Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters

Accredited Standards Committee on Electromagnetic Compatibility, C63
accredited by the
American National Standards Institute

Secretariat
Institute of Electrical and Electronics Engineers, Inc.

Approved 11 December 1997
American National Standards Institute

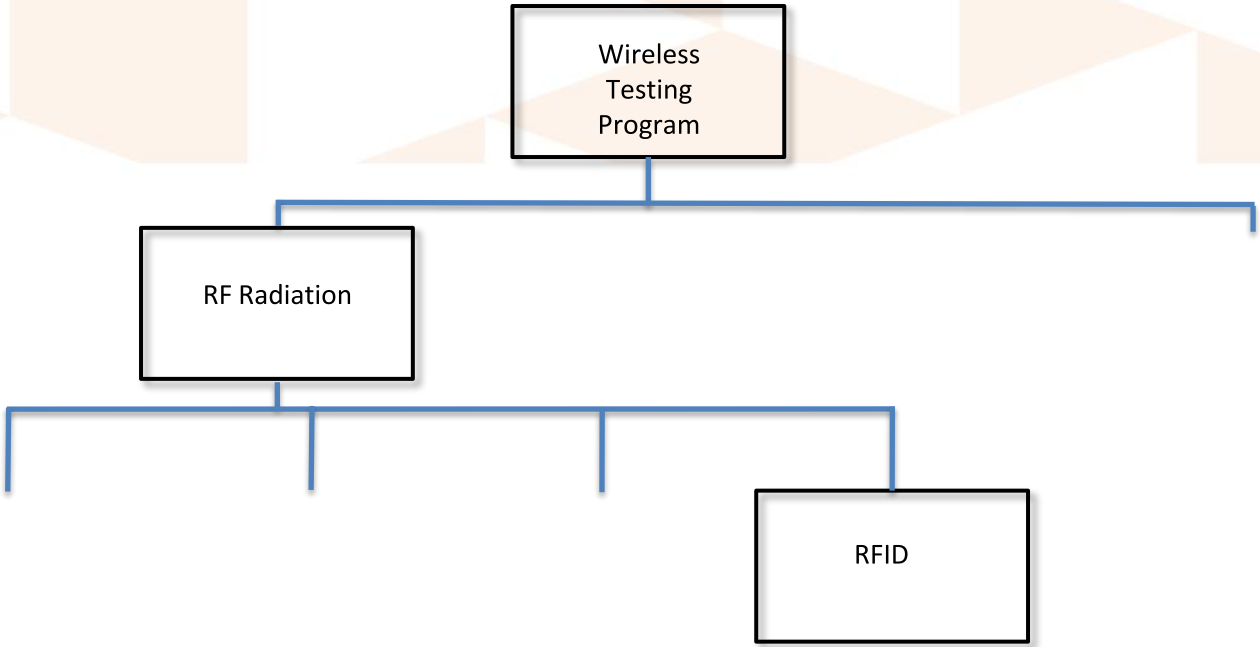
Abstract: Guidance is provided for health-care organizations in evaluating the radiated RF electromagnetic immunity of their existing inventories of medical devices to their existing inventories of RF transmitters, as well as to RF transmitters that are commonly available. This recommended practice can also be used for newly purchased medical devices and RF transmitters, as well as for pre-purchase evaluation. It applies to medical devices used in health-care facilities and to portable transmitters with a rated power output of 8 W or less. It does not apply to implantable medical devices, transport environments such as ambulances and helicopters, or to RF transmitters rated at more than 8 W.

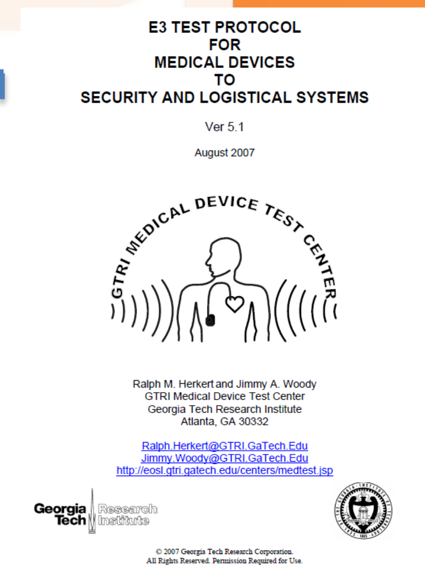
Keywords: ad hoc testing, electromagnetic compatibility (EMC), electromagnetic immunity, electromagnetic interference (EMI), health-care facilities, in-situ testing, medical devices, on-site testing, portable RF transmitters, test method, test procedure

ANSI C63.18, *American National Standard Recommended Practice for an On-Site, AD HOC Test Method for Estimating Radiated Electromagnetic Immunity of Medical Devices to Specific Radio-Frequency Transmitters*

- Device functions as intended in the presence of other RF emitters commonly found in a healthcare facility, including other devices

Wireless Medical Device Test Plan




E3 TEST PROTOCOL
FOR
MEDICAL DEVICES
TO
SECURITY AND LOGISTICAL SYSTEMS

Ver 5.1

August 2007

GTRI MEDICAL DEVICE TEST CENTER

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http://eosl.gtri.gatech.edu/centers/medtest.jsp

Georgia Tech Research Institute

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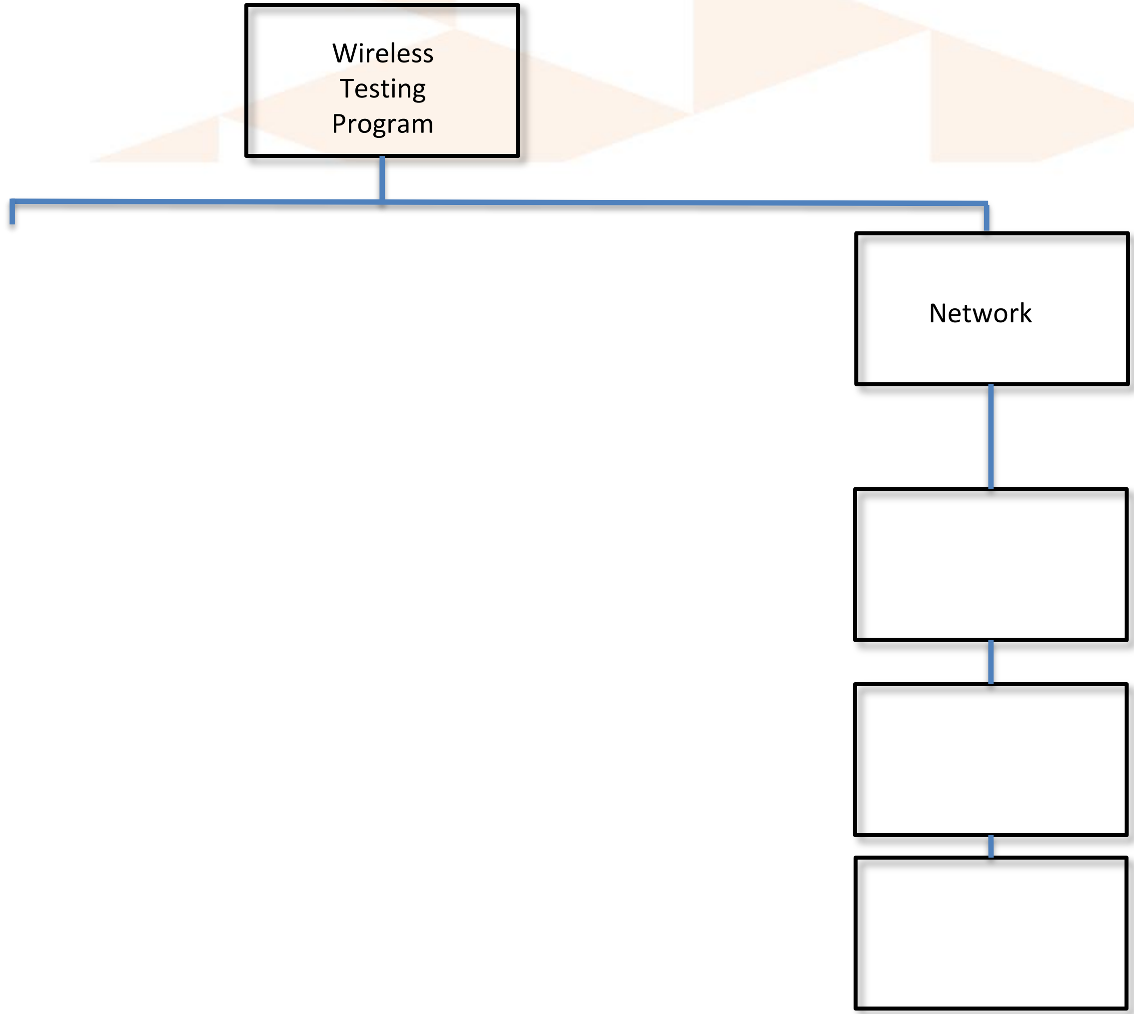
1) Susceptibility of device to adverse effects of RFID emissions

http://eosl.gtri.gatech.edu/Capabilities/CentersofExcellence/MedicalDeviceTesting/tabid/141/Default.aspx

Wireless Medical Device Test Plan



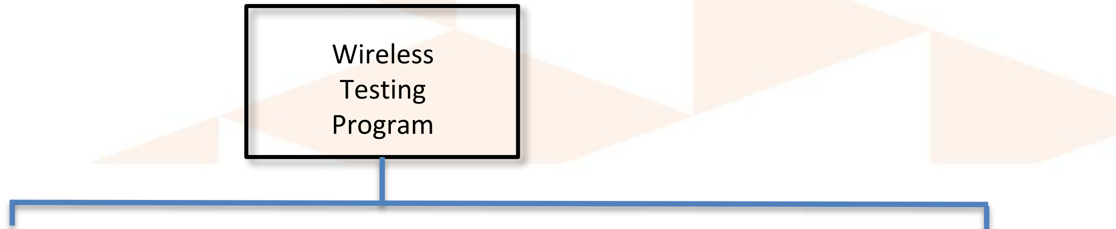
Challenges and Test Methods in Interoperability/Coexistence Testing

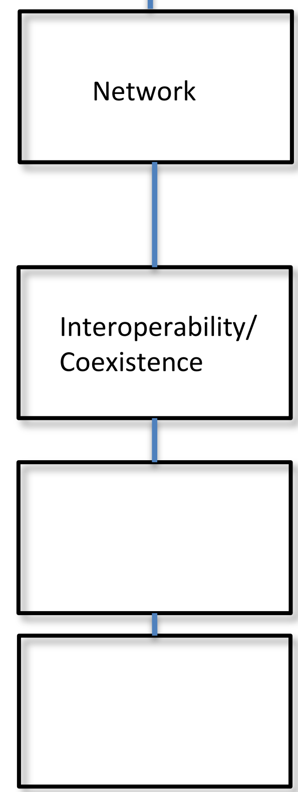
- Definition:
  - Wireless coexistence is the ability of one wireless system to perform a task in a given shared environment where other systems (in that environment) have an ability to perform their tasks and may or may not be using the same set of rules

    (IEEE 802.15.2:2003).

- FDA:
  - Coexistence testing should demonstrate that the surrounding RF wireless devices and networks should not be dramatically affected by the wireless medical device, and the wireless medical device's functions should not pose an unacceptable risk to the user when the device functioning in adverse RF environment results in an interaction.

Wireless Medical Device Test Plan





Interoperability to defined standards:

1) IEEE 802.19 **analytically** reviews each 802 standard against each other to determine the scenarios where interference may occur.

Wi-Fi Alliance outlines performance tests to verify device meets minimum requirements for a user experience.

Wireless Medical Device Test Plan

Wireless Testing Program

Network

Simulated Traffic

Live Traffic

Isolated lab environment where multiple devices can be added to the network to see how they operate to various load and simulated traffic.

- Performance Benchmarking, Bandwidth Utilization, Packet Latency, Maximum Data Rate

Coexistence with other wireless medical/nonmedical devices on the same shared network in a real-world environment.

- Line-of-Site (LOS), and Non-Line-of-Site (NLOS)

The University of Oklahoma
Wireless Electromagnetic Compatibility and Design Center
Hazem Refai, Director of WECAD

Coexistence Factors

- Logical Layer
  - The logical domain covers all the behaviors of the higher Open Systems Interconnection (OSI) layers, including Medium Access Control (MAC), routing, etc
- Physical Layer
  - Space (power)
    - The probability of coexistence increases as the signal-to-interference-ratio of the intended received signal decreases.
  - Frequency
    - The probability of coexistence increases as the frequency separation of channels increases between wireless networks.
  - Time:
    - The probability of coexistence increases as the channel occupancy of the wireless channel decreases.

IEEE 1900.2

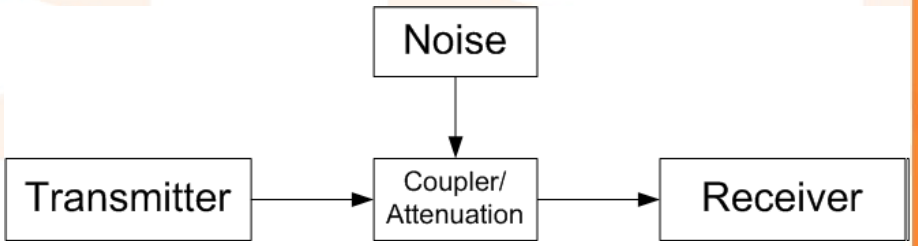
Recommended Practice for the Analysis of In-Band and Adjacent Band Interference and Coexistence between Radio Systems

- Scope: This standard provides technical guidelines for analyzing the potential for coexistence or in contrast interference between radio systems operating in the same frequency band or between different frequency bands.

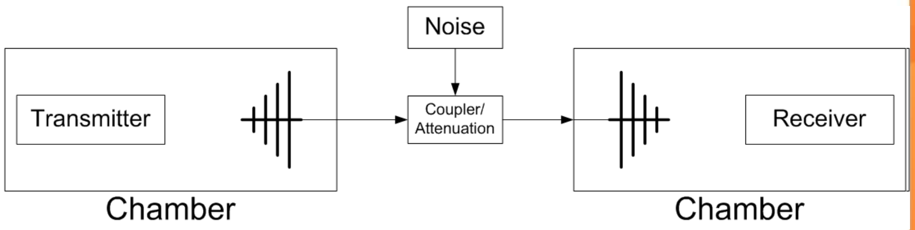
- Benefit: *Potential template for the coexistence portion of the wireless testing strategy.*

General Coexistence Test Methods

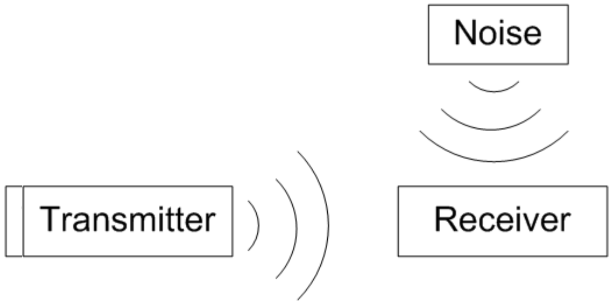
- Conducted (Wired)
  - Highly Repeatable/Controllable
  - Cheap/Easy Test Setup
  - Assumes LOS



- 2 Chambers
  - Used if the wireless device has an integrated antenna with benefits of Conducted
  - Assumes LOS



- Radiated (Wireless)
  - Versatile
  - MIMO
  - Added Complexity
  - LOS/NLOS

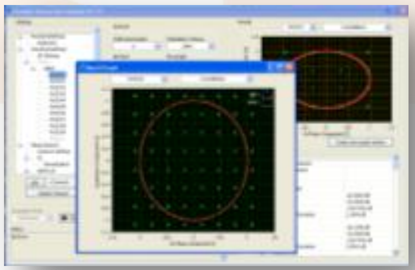


Example Test Setup for NLOS Testing

- Space (Power)
  - Minimum received signal strength at the receiver to ensure 0% BER.
    - Based on Standards, Receiver Sensitivity, Coding Gains, etc.
  - Separation distance between node under test and interfering network based on ANSI C63.18.
    - Based on interfering network transmit power.
      - Maximum Transmit Power for device.
      - Auto-power-leveling disabled.
- Frequency
  - Co-Channel Interfering Network
  - Adjacent Channel Interfering Network
- Time
  - Variable Duty Cycle: Max → Min

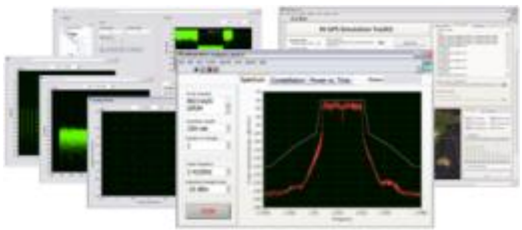
Software Define Radio and Communication

Soft Front Panels



Cellular, Wireless, and GPS Test Toolkits

(802.11 a/b/g/n , GSM/EDGE, WCDMA, LTE, WiMAX, GPS, etc.)



Optimized APIs

Multicore Processing

RF Signal Generators & Analyzers

FPGA I/O and Coprocessing

RF Vector Network Analyzer

Switching, Amplifiers, Attenuators

Power Meters

Spectrum Monitoring and Playback

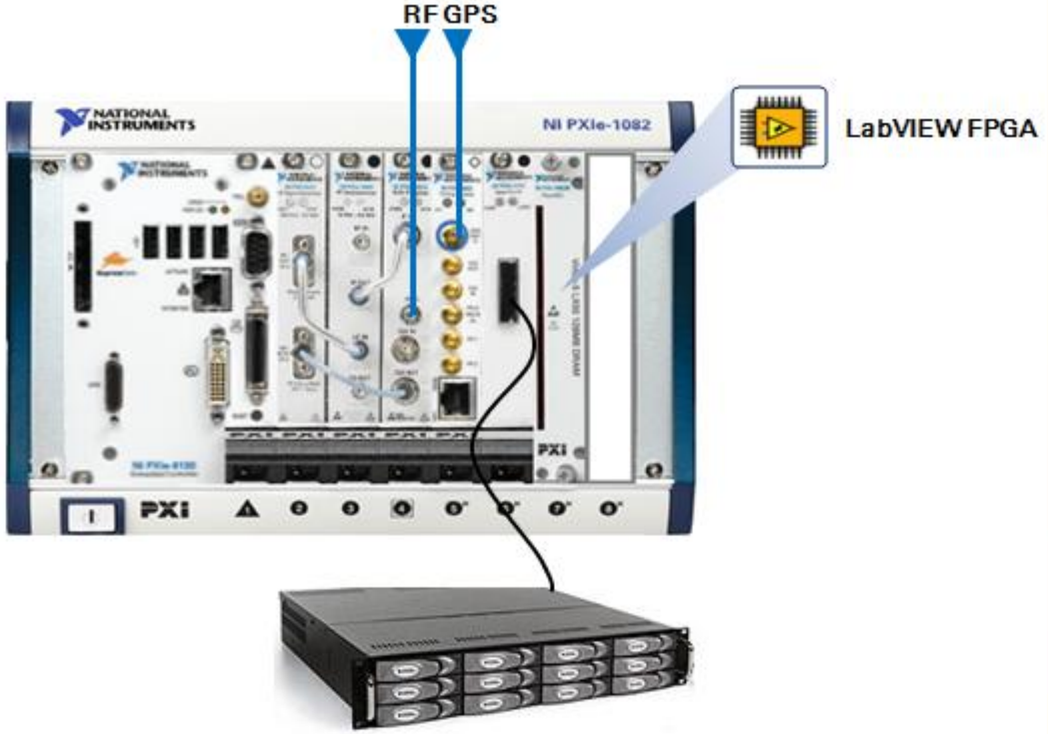
RF front-end, Digitizing

Data Bus
Timing & Synchronization

GPS Synchronization
Navigation Data

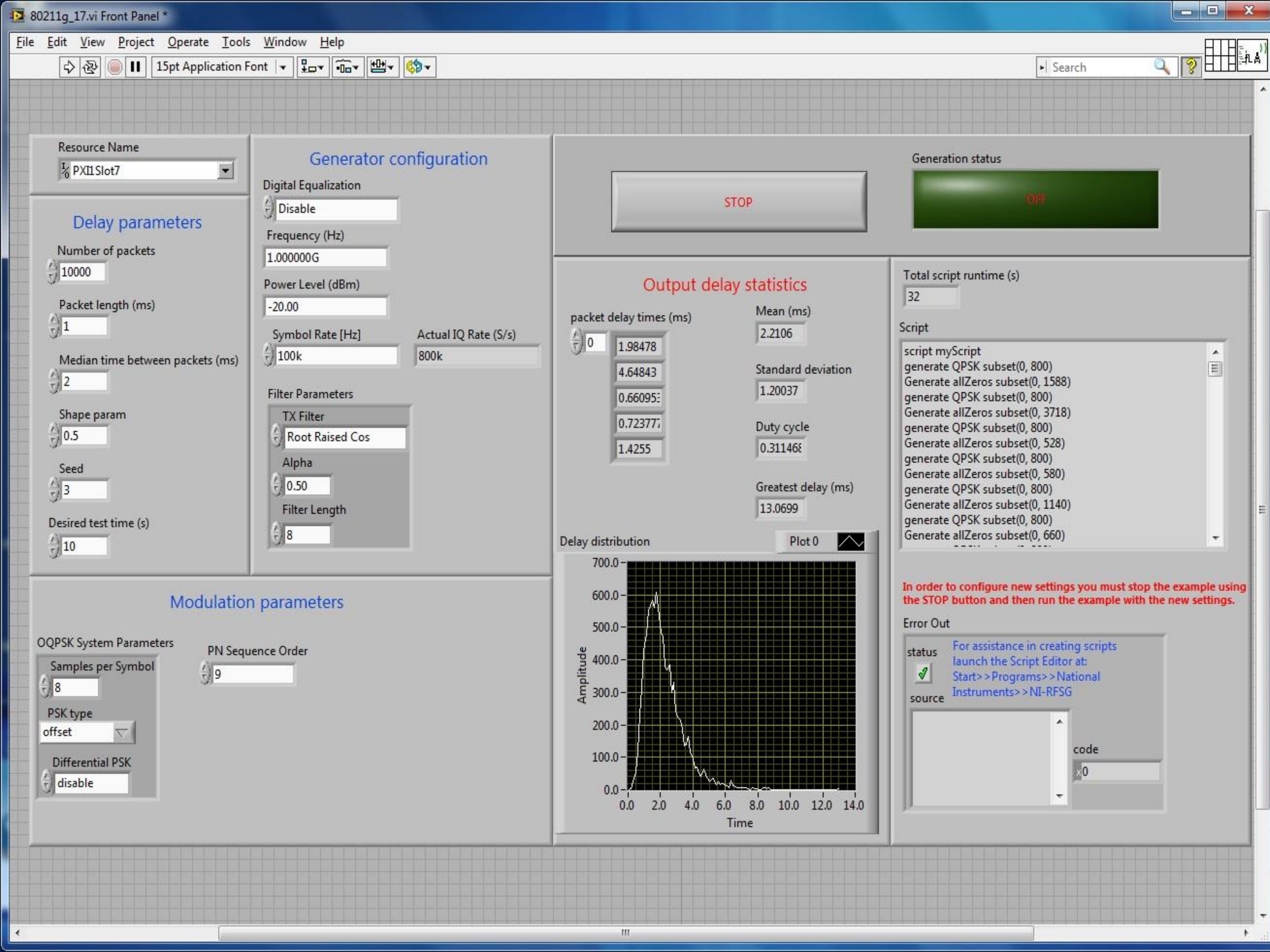
HDD
Record & Playback

Signal Processing



802.11g Emulation

- NI 5673E Vector Signal Generator
- Provides full control over generation parameters (frequency, power, modulation, etc).
- Script Mode
  - Allows for generation of modulated waveform for precise time duration.
  - Allows for any desired inter-packet delay time.
  - Can be hundreds of thousands of lines long which allows for generating hundreds of thousands of packets.
  - Waveform generation can be controlled with hardware or software triggers


80211g_17.vi Front Panel *
File Edit View Project Operate Tools Window Help
15pt Application Font
Search
Resource Name
PXI1Slot7
Delay parameters
Number of packets
10000
Packet length (ms)
1
Median time between packets (ms)
2
Shape param
0.5
Seed
3
Desired test time (s)
10
Generator configuration
Digital Equalization
Disable
Frequency (Hz)
1.000000G
Power Level (dBm)
-20.00
Symbol Rate [Hz]
100k
Actual IQ Rate (S/s)
800k
Filter Parameters
TX Filter
Root Raised Cos
Alpha
0.50
Filter Length
8
STOP
Generation status
OFF
Output delay statistics
packet delay times (ms)
0
1.98478
4.64843
0.66095
0.72377
1.4255
Mean (ms)
2.2106
Standard deviation
1.20037
Duty cycle
0.31146
Greatest delay (ms)
13.0699
Total script runtime (s)
32
Script
script myScript
generate QPSK subset(0, 800)
Generate allZeros subset(0, 1588)
generate QPSK subset(0, 800)
Generate allZeros subset(0, 3718)
generate QPSK subset(0, 800)
Generate allZeros subset(0, 528)
generate QPSK subset(0, 800)
Generate allZeros subset(0, 580)
generate QPSK subset(0, 800)
Generate allZeros subset(0, 1140)
generate QPSK subset(0, 800)
Generate allZeros subset(0, 660)
Delay distribution
Plot 0
Amplitude
700.0
600.0
500.0
400.0
300.0
200.0
100.0
0.0
0.0 2.0 4.0 6.0 8.0 10.0 12.0 14.0
Time
In order to configure new settings you must stop the example using the STOP button and then run the example with the new settings.
Error Out
status
source
code
0
For assistance in creating scripts launch the Script Editor at: Start>>Programs>>National Instruments>>NI-RFSG
Modulation parameters
OQPSK System Parameters
Samples per Symbol
8
PSK type
offset
Differential PSK
disable
PN Sequence Order
9

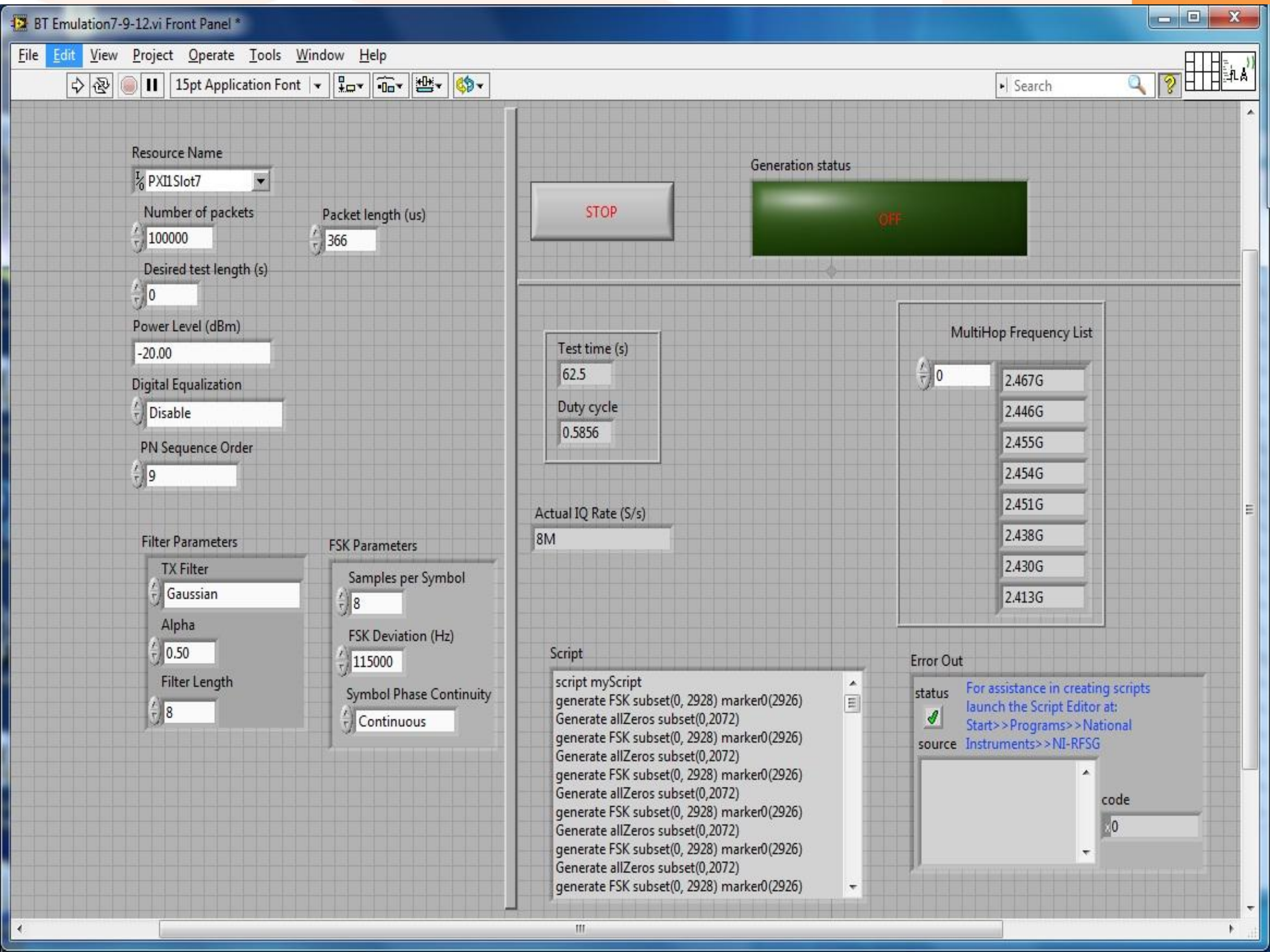
Bluetooth Emulation

- Standard defined in 802.15.1
- Bluetooth defines 79 channels
  - 1 MHz wide
  - 1 MHz separation
  - 2.402 – 2.480 GHz
  - Employs pseudo-random frequency hopping at 1600 hops/second
    - The order of the hopping sequence depends on the master address and clock
  - Maximum data transfer rate is 1 Mb/s
  - Modulation: Gaussian Frequency Shift Keying (GFSK)

Bluetooth Emulation Software

List Mode

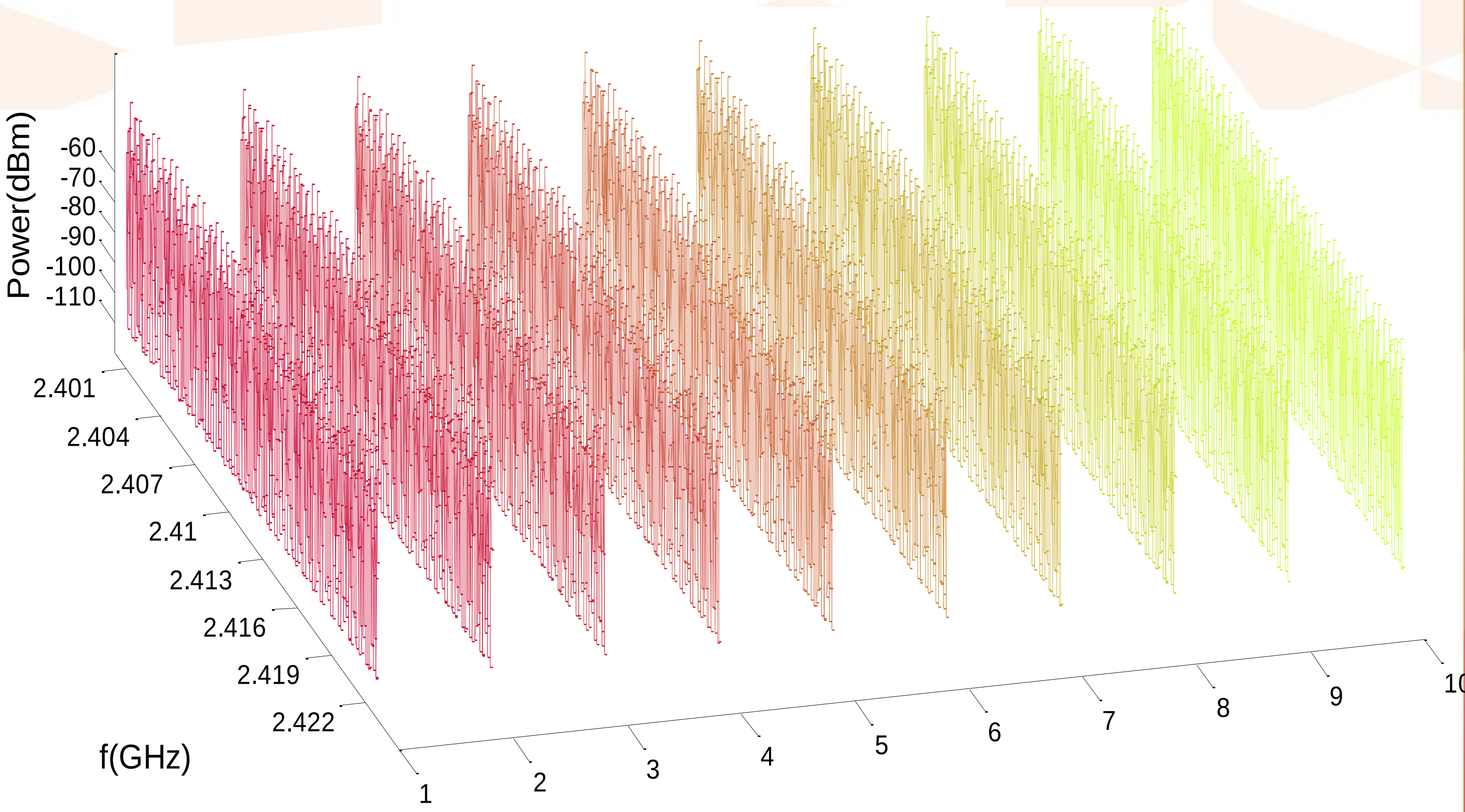
- List mode is used to change the RF configuration without user intervention
- A list of frequencies is loaded into the hardware memory
  - populate the list according to the Bluetooth hopping sequence
- The frequency hops to the next frequency in the list after each transmission
  - NI RF supports up to 200,000 frequencies in a list

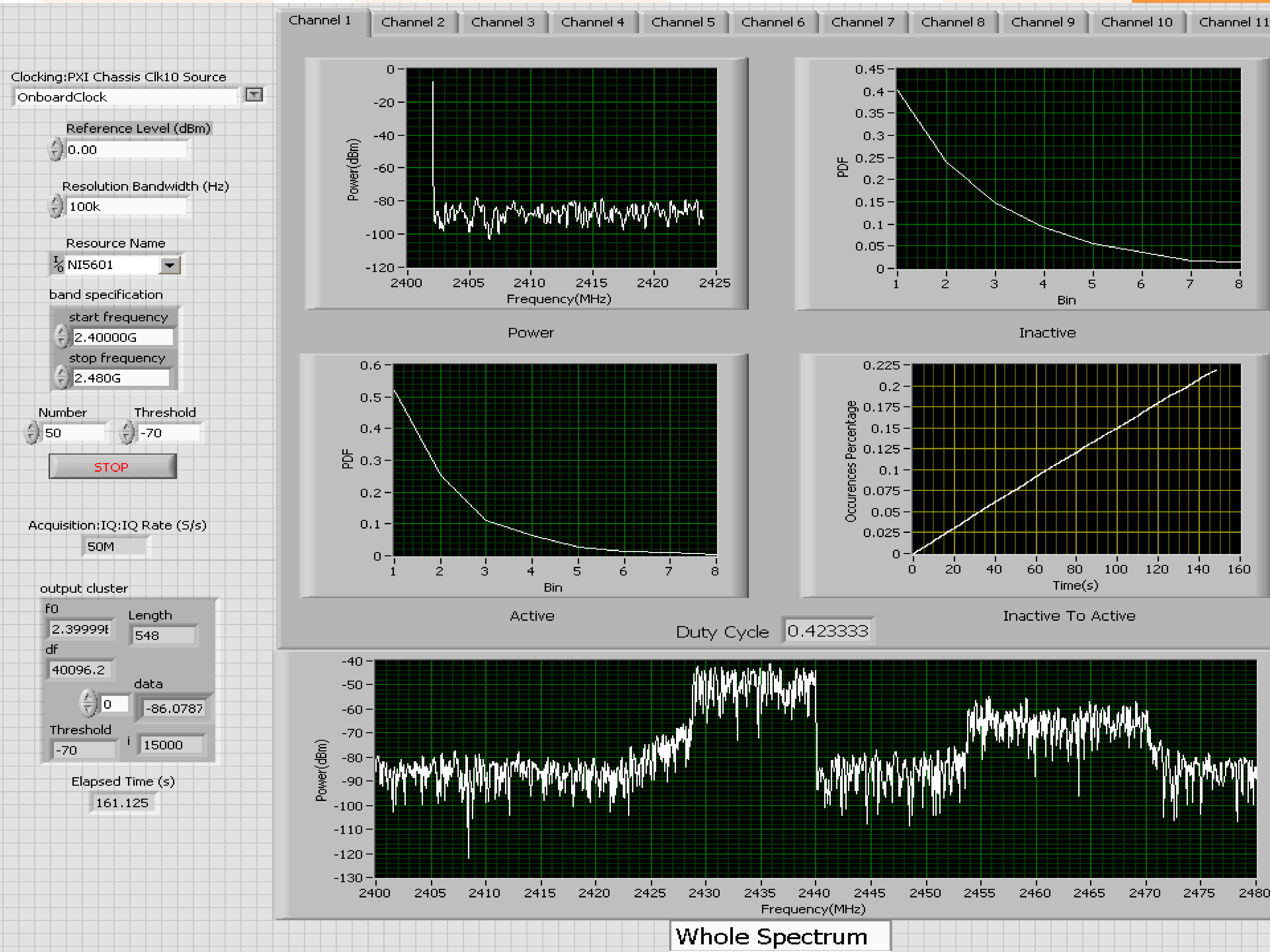

BT Emulation7-9-12.vi Front Panel *
File
Edit
View
Project
Operate
Tools
Window
Help
15pt Application Font
Search
Resource Name
PXI1Slot7
Number of packets
100000
Packet length (us)
366
Desired test length (s)
0
Power Level (dBm)
-20.00
Digital Equalization
Disable
PN Sequence Order
9
Filter Parameters
TX Filter
Gaussian
Alpha
0.50
Filter Length
8
FSK Parameters
Samples per Symbol
8
FSK Deviation (Hz)
115000
Symbol Phase Continuity
Continuous
STOP
Generation status
OFF
Test time (s)
62.5
Duty cycle
0.5856
Actual IQ Rate (S/s)
8M
MultiHop Frequency List
0
2.467G
2.446G
2.455G
2.454G
2.451G
2.438G
2.430G
2.413G
Script
script myScript
generate FSK subset(0, 2928) marker0(2926)
Generate allZeros subset(0,2072)
generate FSK subset(0, 2928) marker0(2926)
Generate allZeros subset(0,2072)
generate FSK subset(0, 2928) marker0(2926)
Generate allZeros subset(0,2072)
generate FSK subset(0, 2928) marker0(2926)
Generate allZeros subset(0,2072)
generate FSK subset(0, 2928) marker0(2926)
Generate allZeros subset(0,2072)
generate FSK subset(0, 2928) marker0(2926)
Error Out
status
source
For assistance in creating scripts launch the Script Editor at: Start>>Programs>>National Instruments>>NI-RFSG
code
0

Duty Cycle Measurement

- Sweep the ISM band from 2.4 – 2.48 GHz.
- Find the number of times the measured power exceeds the noise floor for each Wifi channel.
- If the noise floor is exceeded more than a critical number of times assume that a transmission has been captured.
  - The result is an array of 1s and 0s for each channel in which 1s indicate a busy channel and 0s indicate an idle channel.
- From runs of 1s and 0s you can determine the channel duty cycle and the inter-packet delay time statistics.
  - Find the probability density function for the inter-packet delay times.

Duty Cycle

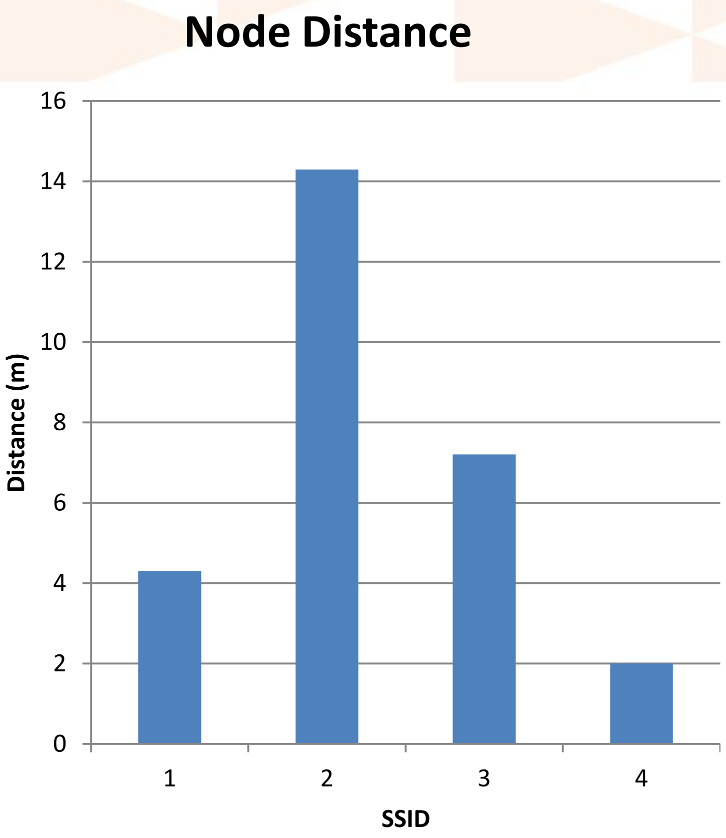

Power(dBm)
-60
-70
-80
-90
-100
-110
2.401
2.404
2.407
2.41
2.413
2.416
2.419
2.422
f(GHz)
1
2
3
4
5
6
7
8
9
10


Channel 1
Channel 2
Channel 3
Channel 4
Channel 5
Channel 6
Channel 7
Channel 8
Channel 9
Channel 10
Channel 11
Clocking:PXI Chassis Clk10 Source
OnboardClock
Reference Level (dBm)
0.00
Resolution Bandwidth (Hz)
100k
Resource Name
NI5601
band specification
start frequency
2.40000G
stop frequency
2.480G
Number
50
Threshold
-70
STOP
Acquisition:IQ:IQ Rate (S/s)
50M
output cluster
f0
2.39999E
Length
548
df
40096.2
data
0
-86.0787
Threshold
-70
i
15000
Elapsed Time (s)
161.125
Power(dBm)
Frequency(MHz)
Power
PDF
Bin
Inactive
PDF
Bin
Active
Occurences Percentage
Time(s)
Inactive To Active
Duty Cycle
0.423333
Power(dBm)
Frequency(MHz)
Whole Spectrum

Network/Node Density and Distribution

- Network Detection
  - The 802.11b preamble is a fixed sequence of either 72 or 144 bits
  - The 802.11g preamble begins with 10 short symbols of duration 0.8 us.
  - ZigBee, Bluetooth

- Node Distribution
  - By demodulating packets the number of nodes within earshot can be determined.
  - The distance to each node can be estimated from the received power using a propagation model.



Summary: What should be tested?

- At the hardware level
  - Radio Performance
  - Range
  - Roaming
  - Interoperability
  - Buffer capacity
  - Battery life (load and no load)
  - Coexistence
- At the software level
  - Stack management
  - 802.11 behavior and robustness
  - Security support
  - QoS
- At the application level
  - Performance under load
  - Sustain operation under loss conditions
  - Performance in a congested environment
  - Over all robustness

Selecting a Wireless Solution

– For short-range (PAN, BAN) communications the typical solution will probably be based on: Zigbee or Bluetooth technology.

– For longer range applications more options are available…Zigbee, BT, WiFi, 3G, 4G, etc.

Pros and Cons of Custom vs Industry Standard

- Custom embedded wireless radios, protocols, and software
  - Did have value several years ago and some medical device manufactures still go down this route. How do you measure the value?
- Developmental costs are much lower and time to market is quicker using OEM embedded modules.
  - Pre-certifications and correct antenna development are very important.
- The trend is to outsource development (software), use commercially available hardware.
  - Example cost: 75K and 3 months for working prototype, versus 2.5M and 1 year.

Selecting Medical Bands

Advantages:

- Comparatively few interference sources
- Licensed ‘protected’ bandwidth
- Easier to manage (vendor responsible)
- Proprietary technology reduces possibility of privacy and security breaches

Issues to Consider:

- For the typical narrow-band antenna based approach:
- Need to install proprietary antenna systems
- Coverage areas tend to be limited due to amplifier noise
- Number of devices can be somewhat limited
- WMTS products from different vendors may interfere
- Data rate per device is only ~10/20 kbits/sec
- Small installations are expensive

For a cellular approach:

- Development cost can be very substantial

Selecting 802.11

- Advantages:
  - Coverage area and device count is ‘unlimited’
  - 802.11 products from different vendors work together
  - Applicable worldwide (with some local limitations)
    - Off-the-shelf radio solutions:
    - Lower R&D cost; Lower equipment cost
  - Small installations can be very cost effective
  - Available data rate per device in the Mbps range
  - Shared Infrastructure -infrastructure is ‘free’

- Issues to Consider:
  - Possible interference sources
    - Rogue Access Points
    - Careless neighbors
    - Shared Infrastructure
  - Risk Management issues
    - Coordination of infrastructure firmware releases
    - Should consider application of 80001 Standard

Summary

- It is very important to identify your wireless application's Requirements early.
- Many choices of technology, frequencies, protocols, etc.
- The Requirements should lead you to a solution.
- Off-the-Shelf approach
  - Straying from typical commercial applications of a technology may lead to challenges. Test those deviations as well as possible
- You can not trust all infrastructure to work the same way
- If you decide to roll-your-own" your destiny may be good or very ugly.