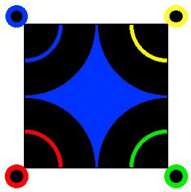
Short-Range Medical Device Connectivity



ORCA
January 10, 2018
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Agenda

- Introduction
- Driving forces and trends
- Connectivity options
  - Wired technology
  - Wireless technologies
- Short-range wireless technologies today
  - WiFi
  - NFC
  - Bluetooth – deep dive
- Examples & Demo
- Cybersecurity
- Regulatory aspects
- Question & Answer

** References provided for recommended guidance and standards docs…

Who am I?

- EE, University of Rochester
- HP Calculators (HP-71B, HP-18/28)
- HP Cardiology (Pagewriter XL ECG, CodeMaster Defibrillator)
- Instromedix (LifeSigns Home Health)
- Medtronic Physio-Control (Dir. Adv. Dev.)
- Code Blue Communications (Bluetooth module disti, consulting)
- connectBlue (Sales and Marketing)
- Code Blue Consulting Communications (consulting)
- Cocoanut Manor (BTLE products - demo later)
- Currently accepting new clients (gratuitous plug #1)
- Cinq Cellars winery (gratuitous plug #2)

Device and systems experience with development, IP, and regulatory Consumer, Type I, II, III devices; 510(k), PMA, PMAs

Bluetooth history:
BT and the Bovie: 2001 AAMI

No dropouts in 4 channel continuous waveform during 120W ESU/ECU usage in coagulation mode

➔No observed effects

General Scanning/Lumonics recorder prototype with connectBlue SPA, Anycom CF card (Class 3), J&J Ethicon ESU

Driving force 2018: mobile wireless

- WiFi
  - 802.11b/g/n: 2.4 GHz, DSSS/OFDM
  - 802.11a/n/ac: 5.2 GHz, OFDM with MIMO
- Bluetooth
  - BR/EDR & low energy: 2.4 GHz, FHSS
- NFC
  - 13.56 MHz (reader mode only)

Short-range Communication

- A-GPS (rcv only)
  - L1: 1575.42 MHz
  - L2: 1227.6 MHz
- Glonass (rcv only) [Russia]
  - L1: 1602 MHz (fc)
  - L2: 1246 MHz (fc)
- Galileo [EU]
- QZSS [Japan]

Geolocation

- CDMA EV-DO Rev. A and Rev. B (800, 1700/2100, 1900, 2100 MHz)
- UMTS/HSPA+/DC-HSDPA (850, 900, 1700/2100, 1900, 2100 MHz)
- TD-SCDMA 1900 (F), 2000 (A)
- GSM/EDGE (850, 900, 1800, 1900 MHz)
- FDD-LTE (Bands 1, 2, 3, 4, 5, 7, 8, 13, 17, 18, 19, 20, 25, 26, 28, 29, 30, 66)
- TD-LTE (Bands 38, 39, 40, 41)

Cellular Communication

Data communications driving forces

- Safety
- Effectiveness
- Security
- Mobility
- Data collection
  - Analysis
  - Billing
  - Liability
- Remote monitoring & treatment
- *Connectivity is the enabler*

Connectivity options

- Long range wireless
  - Cellular 3G, 4G
  - 5G attempting to challenge short-range technologies, but a future
- Wired
  - LAN: wired is still a viable option as a part of the solution set!
- Short range
  - Ubiquitous
    - 802.11/WiFi
    - Bluetooth
    - NFC (Near Field Communications)
  - Other medical options
    - ZigBee (Continua), Thread (Consumer) − 802.15.4 based
    - Wireless Medical Telemetry Systems (WMTS)
    - Medical Implant Communications System (MICS)
    - MBAN (Medical Body Area Network) − virtually silent for 5 years
  - Custom…

Typical connectivity solutions

- Wired, fixed installations
  - LAN, but increasingly WiFi
- Wireless for mobility
  - Cellular for mobile gateway connectivity
  - WiFi where infrastructure exists
  - Bluetooth for mobile connection
  - Most likely a mixture of the above
- NFC can be a solution for authentication

Short range commercial wireless technologies - 1

- WiFi 802.11: Star topology
  - 2.4- GHz, Direct Sequence Spread Spectrum, 11 overlapping channels (US), 802.11 b/g/n
  - 5.8- GHz, DSSS, 21 discrete channels (US), DFS for some channels, multiple UNII bands, 802.11 a/n/ac
  - 20 dBm max
  - High speed, relatively high power, latency depends on network
- Bluetooth: Classic Bluetooth, Bluetooth low energy: Star and Mesh topologies
  - 2.4- GHz, Frequency Hopping Spread Spectrum, 1600 hops/second
  - Classic: 79 discrete channels, Smart (low energy): 39 discrete channels
  - 10- dBm max (now for both due to CE)
  - Adaptive Frequency Hopping for coexistence
  - Low power, medium – low data rate, fair latency
  - High volume, low cost

Short range commercial wireless technologies - 2

- NFC/RFID: Point-to-point
  - Active and passive modes; passive tags
  - 13.56 MHz is most widely used
  - 4 cm between reader and tag
  - Typically 244 kbps
- Thread, Threadx, ZigBee 802.15.4: Mesh
  - 2.4- GHz, Direct Sequence Spread Spectrum, 16 discrete channels
  - Several of custom protocols on top of 802.15.4
  - Low data rate, mesh network, uncontrolled latency, no coexistence mechanism
  - Not applicable technology for medical usage – market forces as well as technology issues

IEEE 802.11 - WiFi

- Two frequency bands
  - 2.4 GHz: b/g/n IT infrastructure
  - 5.8 GHz: a/n/ac IT infrastructure
- Ubiquitous infrastructure (access points)
- Good/great speed
- Good range
- Interference/coexistence challenges; deployments need to be managed
- Setup requiring provisioning
- Allows roaming between access points
- Real world throughput and range depends greatly on infrastructure and environment
  - 802.11b: 7-8 mbps
  - 802.11g: 40 mbps
  - 802.11n: 200 mbps
  - 802.11ac: 900 mbps
- Real range (depends on implementation and environment)
  - 50 – 150 meters

NFC

- NFC (Near Field Communications), based on RFID standards
- Contactless, very short range communication
  - 0-3cm distance between device and reader
  - Electromagnetic induction
  - Relatively low data rates (106 – 424 kbps)
  - ISM band at 13.56 MHz
- Very good for authentication to establish security

Bluetooth

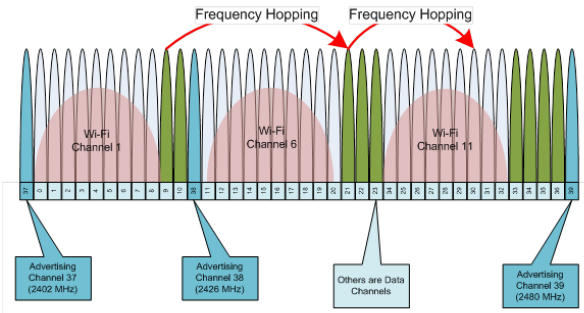
- Provides connectivity for all mobile platforms
- Operates well (cooperates) in RF noisy/crowded environments
  - Fast 2.4 GHz FHSS radio (Frequency Hopping Spread Spectrum)
  - Adaptive Frequency Hopping
  - Error detection, retransmission, error correction
  - Advantages:
  - Ubiquitous
  - Low power
  - Low cost
  - Good coexistence and interference tolerance
- Bluetooth low energy versus Classic (BLE vs BR/EDR)
  - Greatly improved cost/power
  - Lower data rates, but increasing…
  - Greatly simplified communications stack
  - Flexibility for custom services & profiles
  - Years on coin-cell battery versus months on AA batteries

Bluetooth versus Bluetooth

- Classic – Basic Rate/Enhanced Data Rate (BR/EDR)
  - Throughput: BR > 600 kbps, EDR > 1.2 Mbps
  - 128 bit SAFER+ encryption (change approved to AES)
  - 1 master, 7 slaves
- BLE - Bluetooth low energy (4.2)
  - Simplified Bluetooth, different RF
  - 100kbit/sec (2-3x with v4.2)
  - 1 central, thousands of peripherals
  - Fast connection, low latency
  - Broadcast/beacon (iBeacon, Eddystone)
  - Mesh just introduced
- Both
  - Coexistence through AFH and fast hopping
  - Robustness through FHSS and built in error detection, correction (classic only) and retransmission
  - Pairing: Secure Simple Pairing and allows for out-of-band NFC

The Bluetooth low energy technology basics

- 2.4 (– 2.485) GHz, Frequency Hopping Spread Spectrum technology
- 40 discrete channels, 2 MHz wide, psuedo-random hopping sequence
- Dedicated Advertising channels
- Adaptive frequency hopping (AFH) for coexistence/interference
- 10dBM maximum power output; increased for BT5



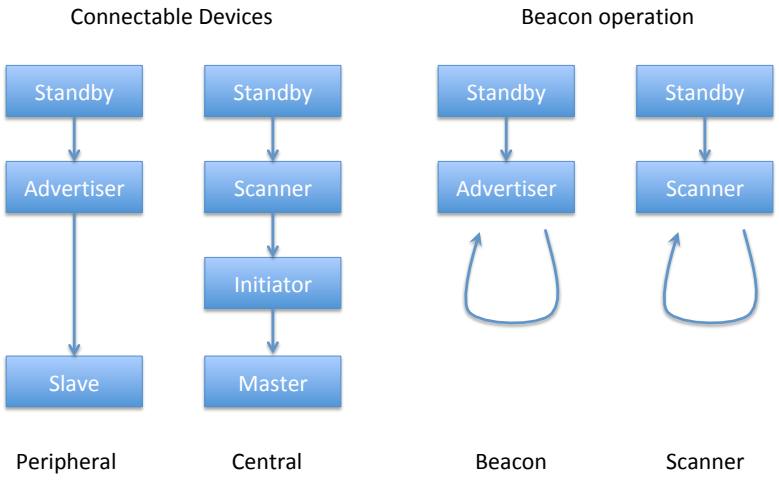
Beacons

- A beacon is an undirected advertisement
- An advertisement can put out any information
- Two ad-hoc standards have evolved
  - iBeacon - iOS
  - Eddystone – Google/Android
- Payload of ~30 bytes (BT 4) + 30 bytes scan response
  - Can also be used to deliver sensor data (temperature, light, etc)
- Typical battery from CR2032 of 1-2 years (nRF52832)
- ~ $5 FOB China in 10K+ qty
- Infrastructure starting to be built in to WiFi Access Points, but slow progress

iBeacon

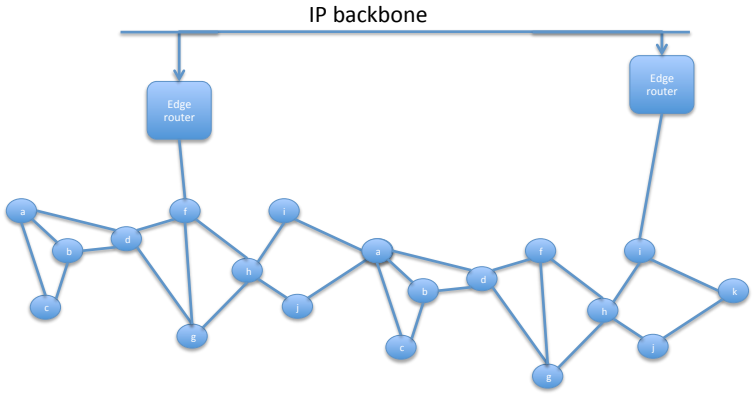
Eddystone

Bluetooth low energy operation



Bluetooth mesh 1.0

- Version 1.0 uses advertising and repeaters
- “Flood” network
- Doesn’t require Bluetooth 5



Bluetooth 5

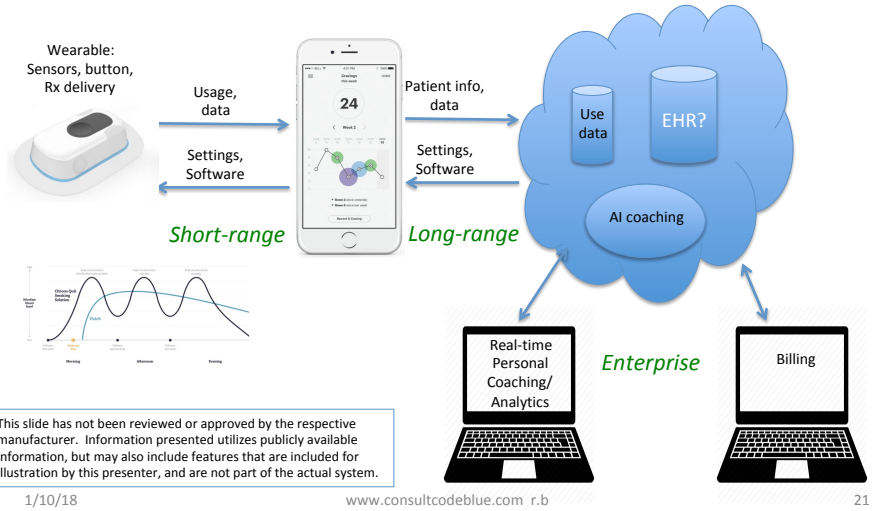
- Released at the end of 2016 slowly being adopted
- Long range
  - Up to 4x
  - Tradeoff: lower speed
  - Also higher reliability…
- High speed
  - Same power
  - Tradeoff: reduced range
- Increased advertising capability
  - More broadcast data
  - Advertising on data channels to reduce congestion
  - Chaining
  - Periodic advertising
- Additional coexistence measures
- Features do not all work together!
- All of the above are optional and are negotiated after connection for backwards compatibility

Bluetooth examples and demo

- Medical IoT architecture - Personalized Medicine
- Continuous Glucose Monitoring (CGM) product
- Insertable Cardiac Monitoring (ICM) product
- Cocoanut Manor interaction tracking demo

Example ***system***: Personalized Medicine

Adapted from Chrono Therapeutics smoking cessation solution (investigational)



This slide has not been reviewed or approved by the respective manufacturer. Information presented utilizes publicly available information, but may also include features that are included for illustration by this presenter, and are not part of the actual system.

Continuous Glucose Monitoring

- Dexcom G5® Mobile CGM System
- Wearable sensor with Bluetooth to phone as a primary display
- Watch as a secondary display
- FDA Approved for iOS (2015) and Android (2017)
- Similar system architecture as previous example

This slide has not been reviewed or approved by the respective manufacturer. Information presented utilizes publicly available information, but may also include features that are included for illustration by this presenter, and are not part of the actual system.

Insertable Cardiac Monitor

- Abbott Confirm™ RX ICM

- "The world's first smartphone-compatible ICM"
- FDA cleared October, 2017

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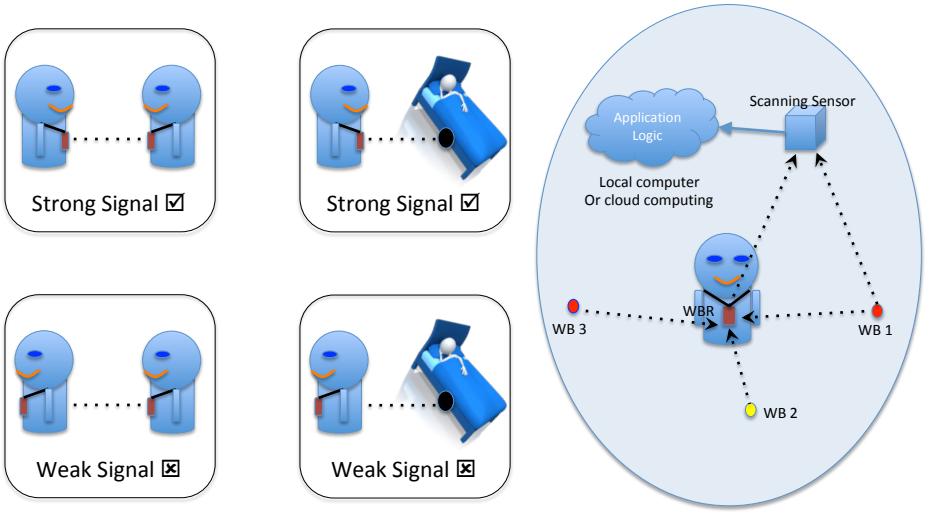
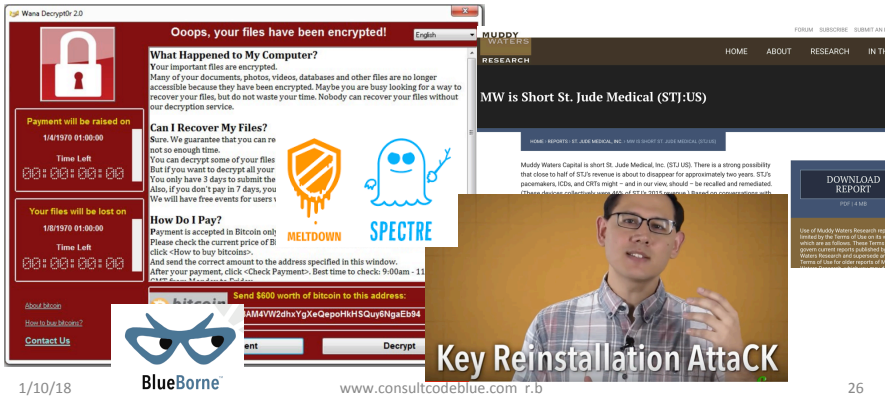
Interaction tracking demo



Interaction tracking demo screenshot

Cybersecurity

- Cybersecurity: measures taken to prevent information theft or alteration of data and damage or alteration to devices or systems



CyberSecurity issues for Medical Devices and networks

- All medical devices are now connected
- Medical Device data
  - Patient information (personal, medical)
    - PHI (Protected Health Information)
  - Measurements and waveform
  - Device & network configuration and provisioning
  - Device settings
  - Firmware upgrade
  - Security certificates
- The attack surface increases as connectivity increases

Why do we care?

- Patient lives are at stake, both directly and indirectly!
- HIPAA requirements – medical record portability & privacy
  - Protects you from unauthorized use of your medical information
  - Eg: employer discriminating for a medical condition
- FDA requirements
  - OTS software guidance
  - Premarket submission guidance
  - Postmarket management
- Company reputation and value is at stake
  - St Jude Medical/Muddy Waters
- Attack-of-the-month
  - Ransomeware
  - Blueborne
  - Krack
  - Meltdown & Spectre

Cybersecurity 'tools'

- Hazard/risk analysis and mitigation approach
  - SYSTEM wide, end-to-end is essential
  - From design inputs through entire process
- Decide what is appropriate risk and mitigation
- Establish trust and security
  - Authentication
  - Encryption
- System policies and recommendations for use

Cybersecurity recommendations

- Design for Cybersecurity
- Limit vulnerabilities
  - Limit time and accessibility
    - Pairing
    - Security key exchanges
  - Eliminate unnecessary ports
  - Don't use unnecessary profiles
  - Set and enforce policies
- Limit information
  - Don't exchange unnecessary data
- Don't advertise promiscuously - Bluetooth

Regulations, Standards, and Regulators

- Three areas to consider
- Medical regulatory *requirements*
  - US FDA
  - EU Medical Device Regulation (UK?)
  - …
- Wireless standards bodies
  - Bluetooth SIG – legal *requirement*
  - No IEEE approval (IEEE 802.11)
  - WiFi Alliance – marketplace requirement?
- Radio regulators - *required*
  - FCC – US (SAR for patient-worn devices)
  - IC – Canada
  - EU – ETSI, Radio Equipment Directive (was R&TTE)
  - Japan – MIC
  - And others…

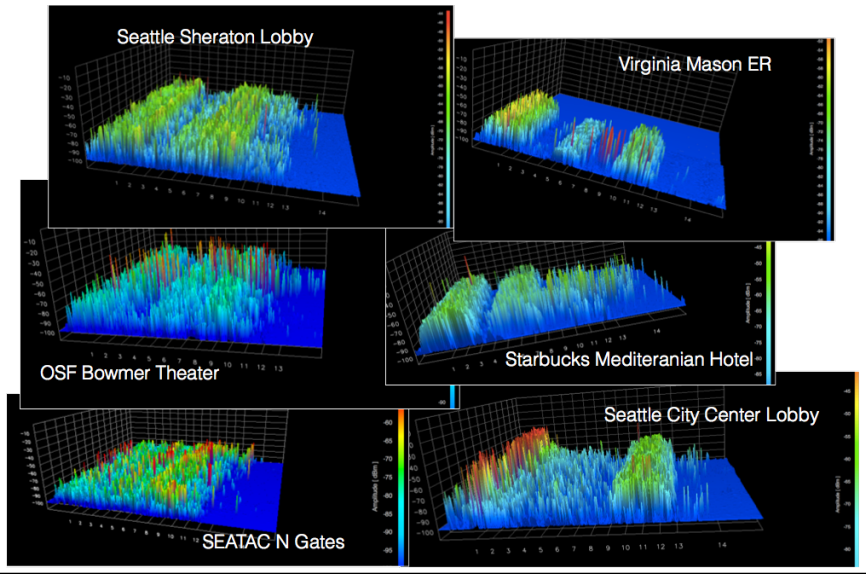
What are agencies looking for from Wireless device submissions?

- Safety and efficacy in the intended use environment
- Compare the wired use with the wireless use
  - Interference & Coexistence
    - RF Guidance document
    - AAMI ad-hoc testing based on environment for Intended Use
  - Latency & Throughput
  - Consider degradation again based on environment
- Cybersecurity

… and the 4th group: "interoperability"

- Interoperability is a dual-edge sword
  - It may help with marketing, but it may not…
  - It may increase testing complexity
  - It may expose competitive pressures
- AAMI – primarily for in-hospital devices
- Continua Alliance
- Bluetooth SIG profiles
  - Bluetooth Transcoding Whitepaper
  - Health/medical profiles – use them if you wish
  - With Bluetooth low energy you can make your own
- FHIR, HL7, …

Coexistence



Medical Device wireless trends

- Treatment and monitoring moving out of hospital
- Growth in health & fitness solutions
  - Is it sustainable?
- Internet of Medical: IoM
- Cybersecurity issues surface with increasing regularity and severity
- Changes in regulatory burden
  - For some intended uses
  - Clarification of MDDS paths
  - Admission of what will/won't be enforced
  - Better clarification and path for others

FDA guidance updates in 2017

- Software as a Medical Device (SAMD): Clinical Evaluation
- Clinical and Patient Decision Support Software (Draft)
- Changes to Existing Medical Software Policies … 21st Century Cures Act (Draft)
- Design Considerations … Interoperable Medical Devices
- Medical Device Accessories − Describing Accessories and Classification Pathways…

Summary

- Wireless technology enables opportunities in healthcare applications for mobility and new modalities as well as increased data through connectivity
- There are several commercial options for short-range wireless connectivity with technical and practical trade-offs
- Bluetooth is a very useful short-range wireless technology with advantages that depend on the solution being implemented
- All wireless technologies require appropriate focus during design and implementation
- The FDA and non-US agencies are working to keep up with the new modalities and technologies

Question & Answer

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Recommended FDA guidance

- FDA landing page for Digital Health
  - http://www.fda.gov/medicaldevices/digitalhealth/
- General Wellness: Policy for Low Risk Devices
  - https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm429674.pdf
- Mobile Medical Applications
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM263366.pdf
- Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM401996.pdf
- Radio Frequency Wireless Technology in Medical Devices
  - o http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077272.pdf
- Software as a Medical Device (SAMD): Clinical Evaluation
  - https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM524904.pdf
- Clinical and Patient Decision Support Software (draft)
  - https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm587819.pdf
- Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act (draft)
  - https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm587820.pdf
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
  - http://www.fda.gov/downloads/MedicalDevices/.../ucm073779.pdf
- Enforcement discretion
  - http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368744.htm
- Deciding When to Submit a 510(k) for a Software Change to an Existing Device
  - https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm514737.pdf
- Design Considerations and Pre- market Submission Recommendations for Interoperable Medical Devices
  - https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm482649.pdf

Selected Cybersecurity References

- Guidance for Industry - Cybersecurity for Networked Medical Devices Containing Off-the-Shelf (OTS) Software
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077823.pdf
- Content of Premarket Submissions for Management of Cybersecurity in Medical Devices
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM356190.pdf
- Postmarket Management of Cybersecurity in Medical Devices
  - http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm482022.pdf
- NIST: Cybersecurity Practice Guide, Special Publication 1800-1: "Securing Electronic Health Records on Mobile Devices"
  - https://nccoe.nist.gov/projects/use_cases/health_it/ehr_on_mobile_devices
- NIST: Guide to Bluetooth Security
  - http://nvlpubs.nist.gov/nistpubs/Legacy/SP/nistspecialpublication800-121r1.pdf
- ISO 14971:2007 Medical devices -- Application of risk management to medical devices
  - http://www.iso.org/iso/catalogue_detail?csnumber=38193
- HHS: Your Mobile Device and Health Information Privacy and Security
  - https://www.healthit.gov/providers-professionals/your-mobile-device-and-health-information-privacy-and-security
- Archimedes – Ann Arbor Research Center for Medical Device Security
  - https://secure-medicine.org
- BITAG: Internet of Things (IoT) Security and Privacy Recommendations
  - http://www.bitag.org/documents/BITAG_Report_-_Internet_of_Things_(IoT)_Security_and_Privacy_Recommendations.pdf

AAMI

- TIR57: Principles for medical device security—Risk management
  - https://standards.aami.org/kws/public/projects/project/details?project_id=876
- TIR59: Risk Assessment of radio-frequency wireless coexistence for medical devices and systems
  - https://standards.aami.org/kws/public/projects/project/details?project_id=1114
- ANSI C63.27-2017: American National Standard for Evaluation of Wireless Coexistence
  - https://standards.ieee.org/findstds/standard/C63.27-2017.html

Bluetooth SIG

- Transcoding (and other) Whitepapers:
  - https://www.bluetooth.com/develop-with-bluetooth/white-papers
- Bluetooth 5 Standard:
  - https://www.bluetooth.com/specifications/bluetooth-core-specification

Acronyms
(google for definitions/information)

- AFH − Adaptive Frequency Hopping
- BLE − Bluetooth low energy
- BR/EDR − Basic Rate or Enhanced Data Rate (See Bluetooth specifications)
- FHSS − Frequency Hopping Spread Spectrum radio transport
- ISM − Industrial, Scientific, and Medical: frequency bands allocated by the FCC
- LAN − Local Area Network: IEEE 802.3
- MBAN − Medical Body Area Network
- MDDS − Medical Device Data System (see Reference section)
- NFC − Near Field Communications
- PHI − Protected Health Information
- SIG − Special Interest Group, in this case the Bluetooth SIG
- WiFi − Wireless Fidelity: IEEE 802.11 specifications
- ZigBee − Wireless standard from the ZigBee Alliance, based on IEEE 802.15.4