Short-range medical device connectivity for personal health devices

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ORCA April 19, 2017

Agenda

* Who am I, and how did I get here?
* Short-range wireless connectivity
* Regulatory pathway
* Issues

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)
* Medtronics Physio-Control (Dir. Adv. Dev.)
* Code Blue Communications (Bluetooth modules, consulting)
* connectBlue (Sales and Marketing)
* Code Blue Consulting & Cocoanut Manor (BTLE products)
* Cinq Cellars winery (gratuitous plug)

Consumer, Type I, II, III devices, 510(k), PMA, PMAs

All medical (and health) devices *shall* be connected

* Why?
* Where?
* How?

All medical devices *shall* be connected – Why?

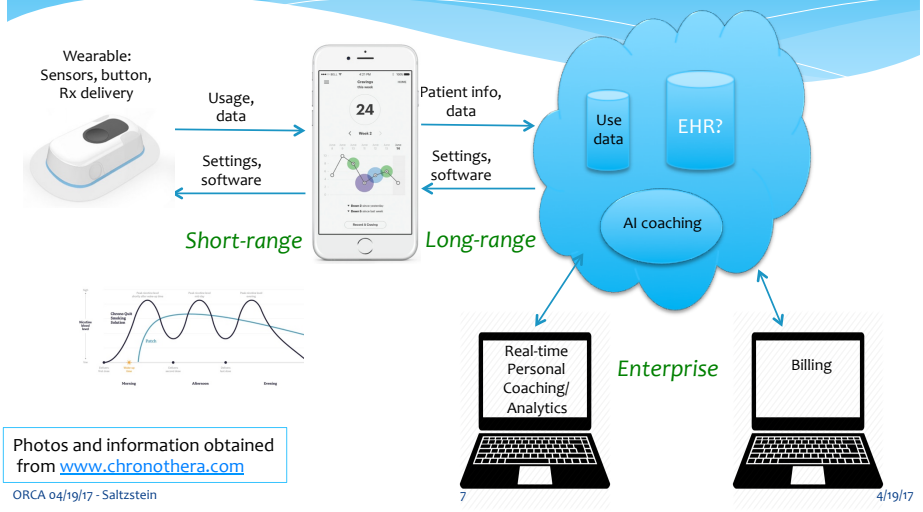
- Replace wired connections
  - Mobility/safety
  - Data collection
- Telemedicine
  - Remote consultation & review (*photo*)
  - Home Health
  - Aging in Place
- Health and Fitness
- Cloud connectivity
  - Electronic Health Record (EHR)
  - Big Data analytics

Emergency!
1972-1977

All medical devices *shall* be connected – Where?

- Classic answers:
  - Hospital
  - EMS
  - Home
- Real answers:
  - Starbucks
  - 37,000 feet
  - Stuck on I-5
  - In the bathroom
  - In the elevator
- Real environments require creative solutions for connectivity

Example: Chrono Therapeutics Technology + Psychology



Photos and information obtained from www.chronothera.com

Wandering and wondering in the wide world of short-range wireless

- Two real choices for short range data transfer
  1) WiFi – IEEE802.11
  2) Bluetooth
     a) Bluetooth classic
     b) Bluetooth low energy
- Everything else
  - RFID/NFC – expect usage in UDI and asset tracking
  - ZigBee, Thread – IEEE 802.15.4 based – coexistence challenge
  - MICS (Medical Implant Communication System) – supply, $$
  - MBAN (Medical Body Area Network) - ??

How to choose?

- Requirements and environment!
  - If you need long-range, independent connectivity → cellular
  - If you're in hospital and need EHR connectivity → WiFi
  - For anything else → Bluetooth
    - Full disclosure: I'm a Bluetooth geek…
- Right, now which flavor of Bluetooth?
  - Bluetooth classic if
    - Audio
    - High-rate streaming
    - Long range
  - Else – Bluetooth low energy
  - For now… Bluetooth 5 provides for those needs if you can wait

The 3 groups of regulators

- Medical regulatory *requirements*
  - US FDA
  - EU Medical Device Regulation (and what about the 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, R&TTE
  - Japan – MIC
  - And others…

… and the 4th group: "interoperability"

- Interoperability is a dual-edge sword
  - Marketing
  - Regulatory
- 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, …

What is the FDA looking for?

- Safety and efficacy in the intended use environment
- Interference & Coexistence
  - Ad-hoc testing based on environment for Intended Use
  - RF Guidance document
- Latency & Throughput
  - Consider degradation again based on environment
- Cybersecurity
- Trends
  - Support of personal and consumer health and medical devices
  - Reclassification activities
  - Open acknowledgement of enforcement policies

Summary

* The true secrets are in Understanding and Planning
* Understand where and how connectivity benefits/ enables your system
* Understand the use models
* Pick the technology and system components based on the requirements, not the cool-factor
* Design-in for regulatory and security up front

Q&A

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Reference material

Recommended FDA guidance

- FDA landing page for Digital Health
  - http://www.fda.gov/medicaldevices/digitalhealth/
- General Wellness: Policy for Low Risk Devices
  - http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/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
- Guidance for Industry, FDA Reviewers and Compliance on Off-The-Shelf Software Use in Medical Devices
  - http://www.fda.gov/downloads/MedicalDevices/…/ucm073779.pdf
- SOFTWARE AS A MEDICAL DEVICE (SAMD): CLINICAL EVALUATION (draft)
  - http://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm524904.pdf
- Enforcement discretion
  - http://www.fda.gov/MedicalDevices/DigitalHealth/MobileMedicalApplications/ucm368744.htm

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
  - AMSI C63.27

Bluetooth SIG

* Transcoding (and other) Whitepapers: https://www.bluetooth.com/develop-with-bluetooth/white-papers