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)

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

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What is a Medical Device?

• A Medical Device is "… an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent.….", that is "…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man…" or "…intended to affect the structure or any function of the body of man…" (from the US FDA)

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All medical devices *shall* be connected – Why?

- Connectivity
  - Electronic Health Record (EHR)
  - Charge capture (billing)
  - Big Data analytics
- Wireless is replacing wired connections
  - Mobility/safety
  - Data collection
- Telemedicine
  - Remote consultation & review (*photo*)
  - Home Health
  - Aging in Place
- Health and Fitness

Emergency!
1972-1977

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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
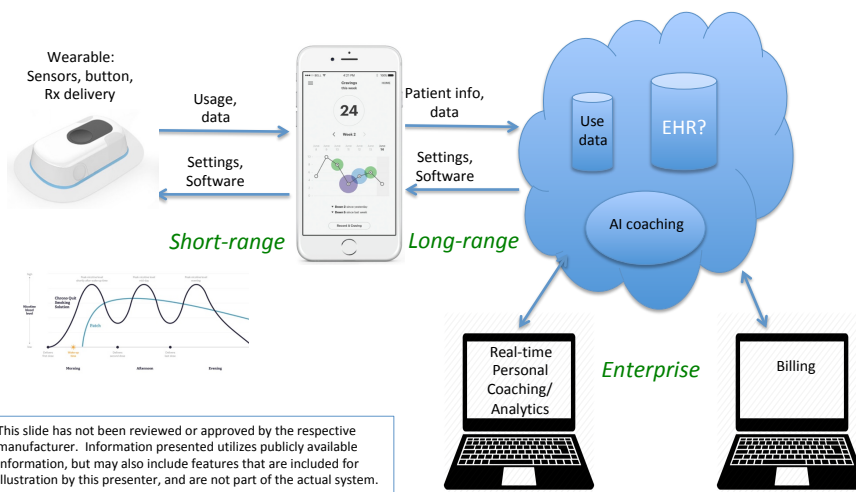- Real environments require creative solutions for connectivity

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Example *system*: Personalized Medicine

Adapted from Chrono Therapeutics smoking cessation solution (investigational)

Wearable:
Sensors, button,
Rx delivery

Usage, data

Settings, Software

Short-range

Patient info, data

Settings, Software

Long-range

Use data

EHR?

AI coaching

Real-time Personal Coaching/ Analytics

Enterprise

Billing

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.

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How real is this?
Hacking is evolving and accelerating!

- Early public disclosure: "Pacemakers and Implantable Cardiac Defibrillators: Software Radio Attacks and Zero-Power Defenses" - *2008 IEEE Symposium on Security and Privacy*
- 2015 - Hospira infusion pumps: https://www.wired.com/2015/06/hackers-can-send-fatal-doses-hospital-drug-pumps/
- "Los Angeles Hospital Pays Hackers $17,000 After Attack" – February 2016
- Muddy Waters & St Jude Medical: implant vulnerabilities and short-sale profit – August 2016
- "J&J warns diabetic patients: Insulin pump vulnerable to hacking" – October, 2016
- Numerous hospital ransomware attacks - 2018

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Cybersecurity: 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
  - Ransomware
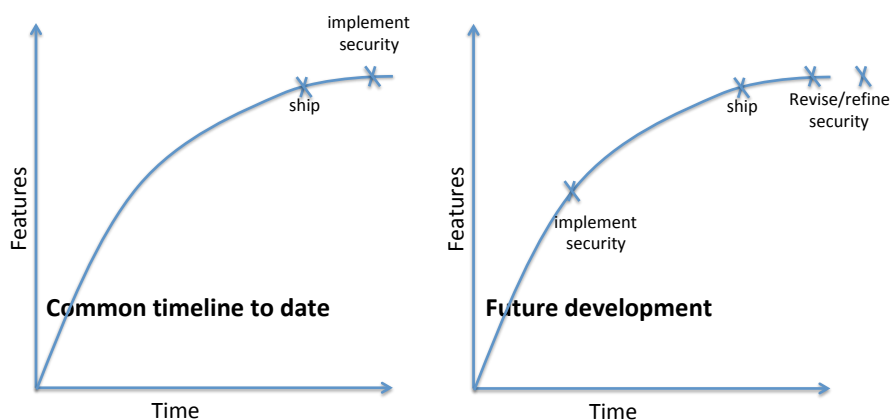 - Blueborne
  - Krack
  - Meltdown & Spectre

MELTDOWN

SPECTRE

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Why are we seeing issues?
Development lifecycle & cybersecurity

implement
security

ship

Common timeline to date

Features

Time

Revise/refine
security

ship

implement
security

Future development

Features

Time

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- Thank you!