# Overcoming IT and Cybersecurity Challenges With IOMT in Hospital-Based Medical Devices

Dave Saunders

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## Dave Saunders, Co-Founder, CTO Galen Robotics, Inc.

Twenty-five years experience product development and engineering and has taken over 40 products to market; product development experience ranging from startup to Fortune 500

Marketing/Technical Chair, AODI

Line Manager, Access Concentration, Ascend Communications

Technical manager, Access Concentration, Voice Gateway, Lucent Bell Labs

VP Product Manager, Navigated Orthopedics, Trak Surgical

Co-Founder & CTO, Surgical Robotics, Galen Robotics

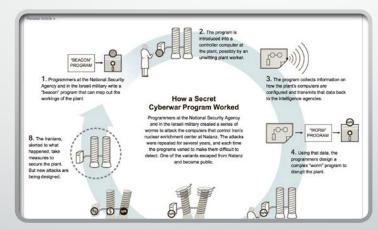
#### Medical Device & Industry Cybersecurity

Is the risk real?

### Vulnerabilities in the News



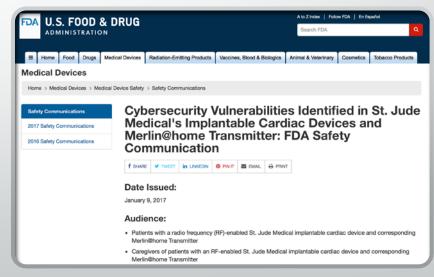
Do you want to be next?





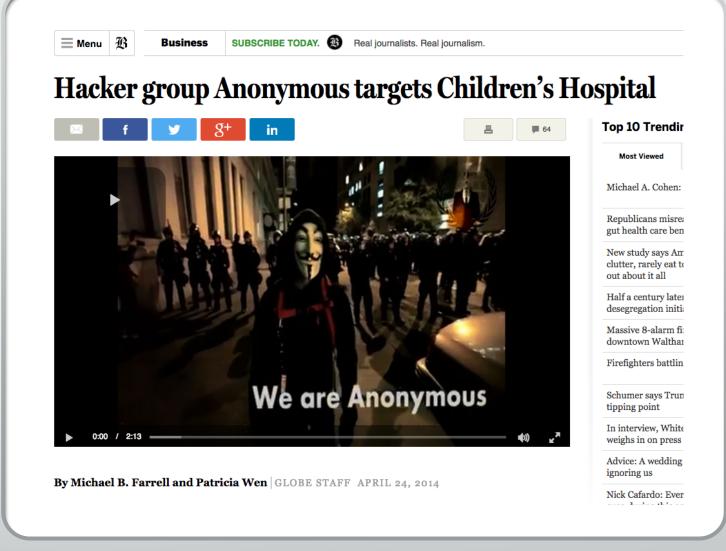
## FDA Warnings and Recalls





### Attacks on Networks

- If the network you're on, is compromised, how is your device affected?
  - Operations
  - Monitoring
  - License Control



#### Federal Register

#### Presidential Documents

Vol. 78, No. 33

Tuesday, February 19, 2013

#### Title 3—

#### Executive Order 13636 of February 12, 2013

#### The President

#### **Improving Critical Infrastructure Cybersecurity**

By the authority vested in me as President by the Constitution and the laws of the United States of America, it is hereby ordered as follows:

Section 1. Policy. Repeated cyber intrusions into critical infrastructure demonstrate the need for improved cybersecurity. The cyber threat to critical infrastructure continues to grow and represents one of the most serious national security challenges we must confront. The national and economic security of the United States depends on the reliable functioning of the Nation's critical infrastructure in the face of such threats. It is the policy of the United States to enhance the security and resilience of the Nation's critical infrastructure and to maintain a cyber environment that encourages efficiency, innovation, and economic prosperity while promoting safety, security, business confidentiality, privacy, and civil liberties. We can achieve these goals through a partnership with the owners and operators of critical infrastructure to improve cybersecurity information sharing and collaboratively develop and implement risk-based standards.

Sec. 2. Critical Infrastructure. As used in this order, the term critical infrastructure means systems and assets, whether physical or virtual, so vital to the United States that the incapacity or destruction of such systems and assets would have a debilitating impact on security period economic

## Fair Warning to Do Your Part

## Baking Security Into Your Products

## A Robot Alone, Isn't a Product

Today's tech medical devices should be online to provide the customers with a richly integrated experience

#### Mantra

There is no security but the security you make.

Michael W Wellman, CEO, Virgil Security

#### Our Mission and Responsibility

#### **Protect**

- Take steps to add cybersecurity consideration to the design and development process
- Identify all points of potential vulnerability and employ best efforts to secure them

#### Detect

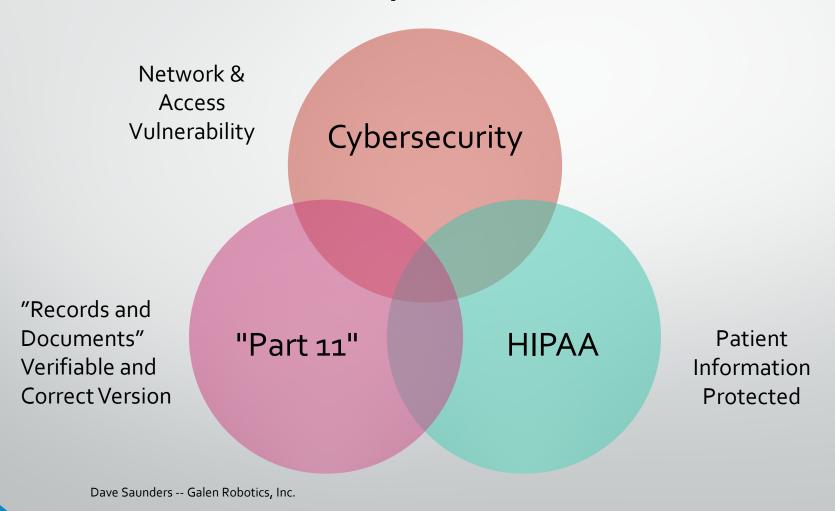
- Build intrusion detection (when possible) into the architecture
- Perform penetration testing regularly

#### Inform

Inform the public when something unexpected happens with production equipment

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## Addressing Vulnerabilities Multiple Contexts



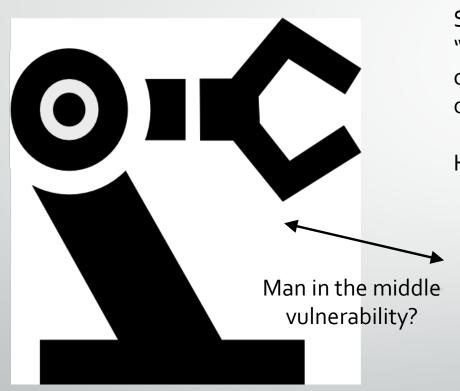
#### The Basic Robot

A basic "slave" and "master" robotic architecture.

Similar to many medical devices – A "brain" communicates with, coordinates & controls combinations of sensors and "actors"

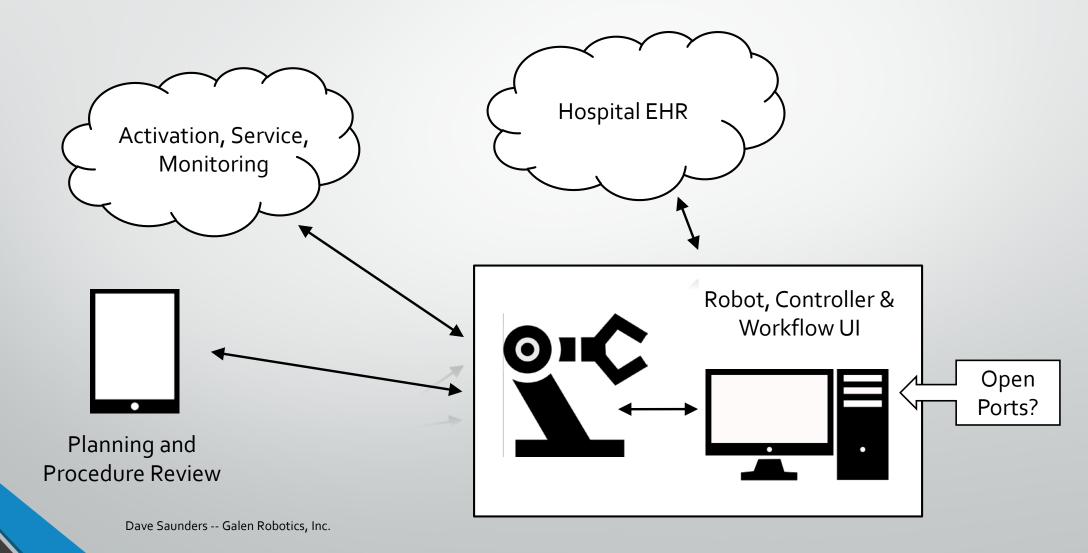
How does data flow between them?



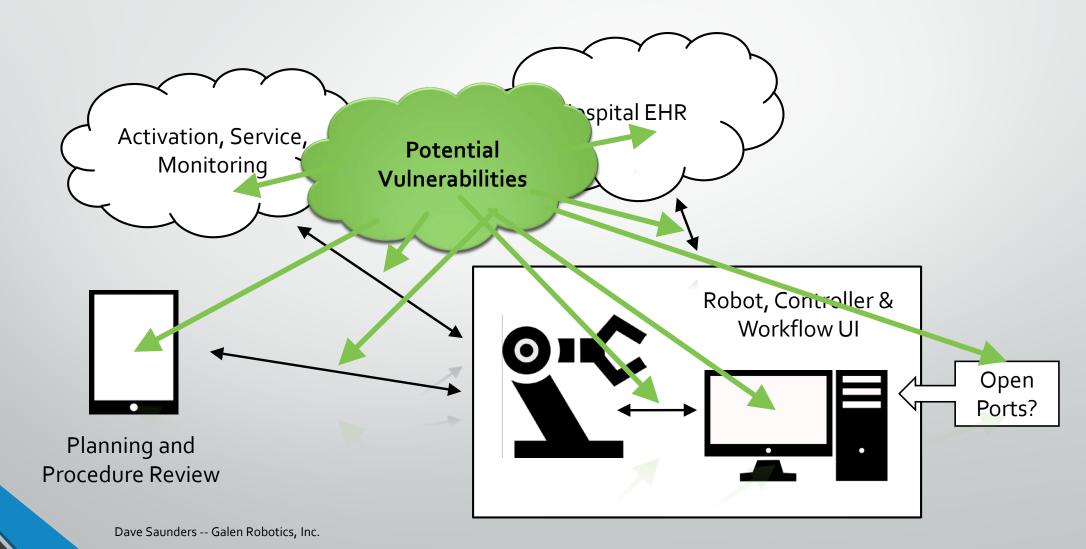


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## Today's Market Expects More IT Integration for Medical Devices



## Today's Market Expects More IT Integration for Medical Devices – more risks for vulnerabilities



#### InfoSec Strategies

- Do assume the network you're on is not secure
  - Encrypt and authenticate whenever possible
- Don't assume your only risks are network-based
- Do remain vigilant and make
- Don't assume those with physical access to your device will only to the "right thing"
  - Be creative with failure modes for unexpected events; they're not always done with ill-intent
  - E.g., what if someone tries to charge their phone with an open USB port on your system?
- Your device brings a greater benefits to patient care and the Industry as a connected part of the IOMT ecosystem, than sealed away



https://www.dhs.gov/isao

Get Help

### Framework for Improving Critical Infrastructure Cybersecurity

Version 1.0

National Institute of Standards and Technology

February 12, 2014

https://www.nist.gov/sites/default/files/documents/cyberframework/cybersecurity-framework-021214.pdf

#### Learn Best Practices

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