



# Medical Device Security: Hack or Hype?



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### Disclosures/Background

- Co-founder, Virta Labs, Inc.
- Security & Privacy Research Group @ Michigan
- Director, Archimedes Center for Medical Device Security
- Security Advisor to Samsung Strategy & Innovation Ctr
- Consultant to MicroCHIPS Biotech
- Fmr. visiting scientist, U.S. Food and Drug Administration
- Recent research support from NSF, HHS, SRC, DARPA, MARCO, UL, Medtronic, Philips, Siemens, WelchAllyn

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# MedSec Beginning in 2006...

Invited talk.  
Computer system security and medical devices,  
U.S. Food and Drug Administration Center for  
Devices and Radiological Health (FDA CDRH),  
October 2006.

In 2006...



## A Heart Device Is Found Vulnerable to Hacker Attacks

By BARNABY J. FEDER MARCH 12, 2008

The New York Times

Hack: 2008

## Of Fact, Fiction and Cheney's Defibrillator

By GINA KOLATA  
Published: October 27, 2013

The New York Times

Hype: 2013



## Pacemakers and Implantable Cardiac Defibrillators: Software Radio Attacks and Zero-Power Defenses

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University of Washington

Thomas S. Heydt-Benjamin<sup>1</sup>  
University of Massachusetts Amherst

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Kevin Fu, PhD<sup>2</sup>  
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Tadayoshi Kohno, PhD<sup>3</sup>  
University of Washington

William H. Malhot, MD, MPH<sup>4</sup>  
BRAC and Harvard Medical School

**Abstract**—Our study analyzes the security and privacy properties of an implantable cardioverter defibrillator (ICD) introduced to the U.S. market in 2003. This model of ICD includes proprietary technology and is designed to communicate wirelessly with a security external programmer in the 270 MHz frequency range. After carefully reverse-engineering the ICD's communication protocol with an oscilloscope and a software radio, we implemented several software radio-based attacks that could compromise patient safety and patient privacy. Motivated by our desire to improve patient safety, and mindful of conventional trade-offs between security and power consumption for resource-constrained devices, we introduce three new zero-power defenses based on RF power harvesting. Two of these defenses are hardware-based, bringing patients into the loop with respect to the security and privacy of their implantable medical devices (IMDs). Our contributions provide a scientific baseline for understanding the potential security and privacy risks of current and future IMDs, and introduce hardware-protectable and zero-power mitigation techniques that address these risks. To the best of our knowledge, this paper is the first in our community to use general-purpose software radios to analyze and attack previously unknown radio communication protocols.

Our event is a health care practitioner who uses a commercial device programmer<sup>1</sup> with wireless capabilities to extract data from the ICD or modify its settings without surgery. Between 2000 and 2002, over 2.6 million pacemakers and ICDs were implanted in patients in the United States [39]. Clinical trials have shown that these devices significantly improve survival rates in certain populations [38]. Other research has discussed potential security and privacy risks of IMDs [11, 10], but we are unaware of any rigorous public investigation into the observable characteristics of a real commercial device. Without such a study, it is impossible for the research community to assess or address the security and privacy properties of past, current, and future devices. We address this gap in this paper and, based on our findings, propose and implement several prototype attack-mitigation techniques.

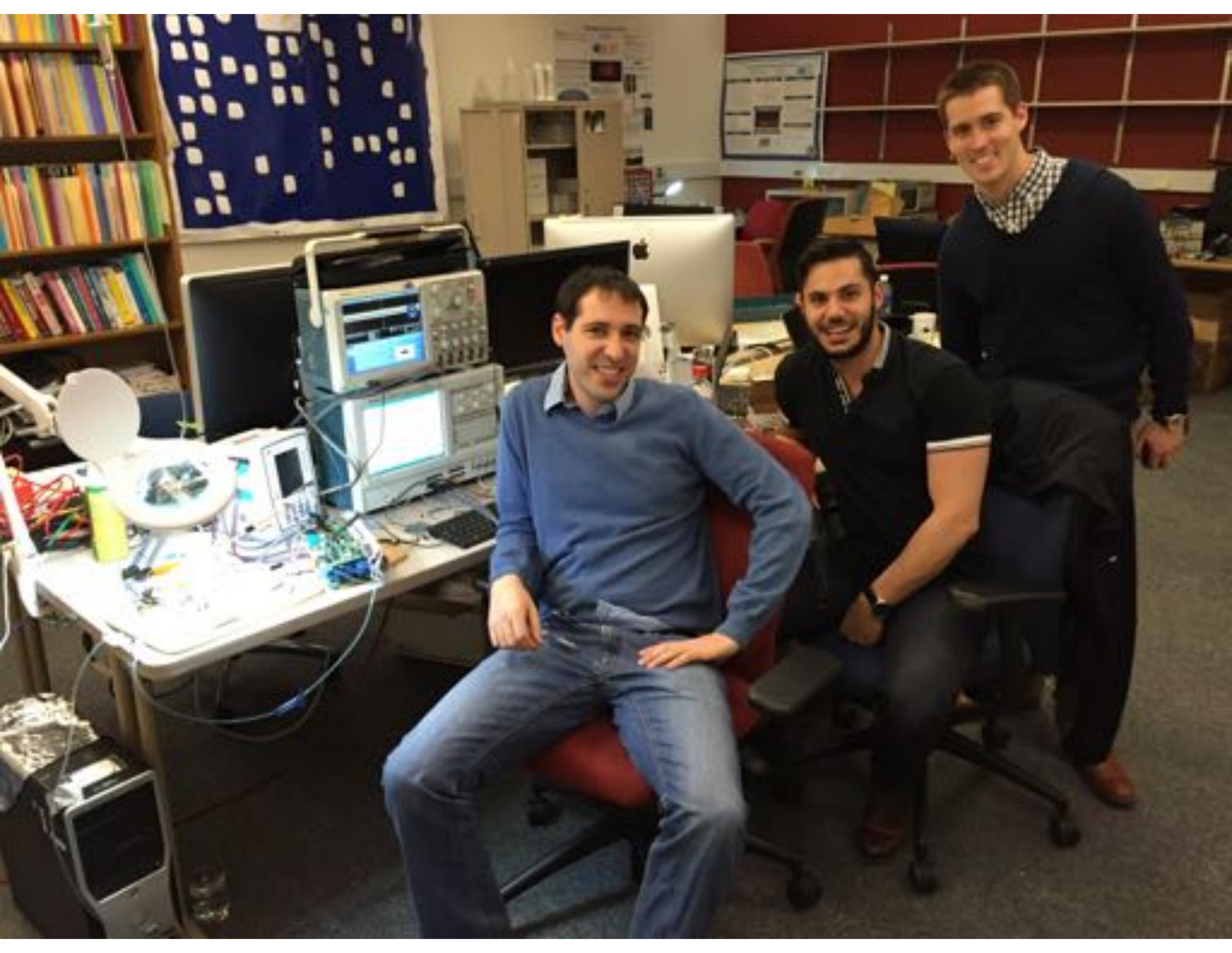
The investigation was motivated by an interdisciplinary study of medical device safety and security, and relied on a diverse team of area specialists. Team members from the security and privacy community have formal training in computer science, computer engineering, and electrical engineering. One team member from the medical community is a practicing cardiologist with hundreds of pacemaker and implantable defibrillator patients and was past chairperson of the FDA's Circulatory System Medical Device Advisory Panel. Our technical contributions covered understanding and improving the security, privacy, and safety of these devices include: analysis, software radio-based methodologies, and human perceptible and zero-power (theory first) defenses.

**Overview of contributions.** We assess the security and privacy properties of a common ICD and present attacks on privacy, integrity, and availability. We show that the ICD discloses sensitive information in the clear (unencrypted); we demonstrate a reprogramming attack that changes the operation of (and the information contained in) the ICD; and

### 1. Introduction

Wirelessly reprogrammable implantable medical devices (IMDs) such as pacemakers, implantable cardioverter defibrillators (ICDs), neurostimulators, and implantable drug pumps use embedded programs and radios to monitor chronic disorders and treat patients with automatic therapies. For instance, an ICD that senses a rapid heartbeat can administer an electrical shock to restore a normal heart rhythm, then later report

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 1 Kevin Fu, Medical Device Security Center, Department of Computer Science, University of Massachusetts Amherst, 440 University Street, Amherst, Massachusetts 01003 (kfu@cs.umass.edu).  
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 3 William H. Malhot, Medical Device Safety Institute, Beth Israel Deaconess Medical Center, Harvard Medical School, 330 Brookline Road, Room 4, Boston, MA 02215 (malhot@rics.bwh.harvard.edu).  
 Additional information on this work is available at [www.cs.umass.edu/~kfu](http://www.cs.umass.edu/~kfu).  
 4 This work was based on support from other such programmatic support.







# Hack or Hype?

Was a defibrillator  
hacked?

Yes in 2007, but we did it  
in a lab without patients

# Wirelessly Induce Fatal Heart Rhythm

- 402-405 MHz MICS band, nominal range several meters
- Command shock sends 35 J in  $\sim 1$  msec to the T-wave
- Designed to induce ventricular fibrillation

**(Risks mitigated  
a long time ago)**



[Halperin et al., IEEE Symposium on Security & Privacy 2008]

**Patients are far safer with  
these implantable devices  
than without, even if  
there are security  
vulnerabilities.**

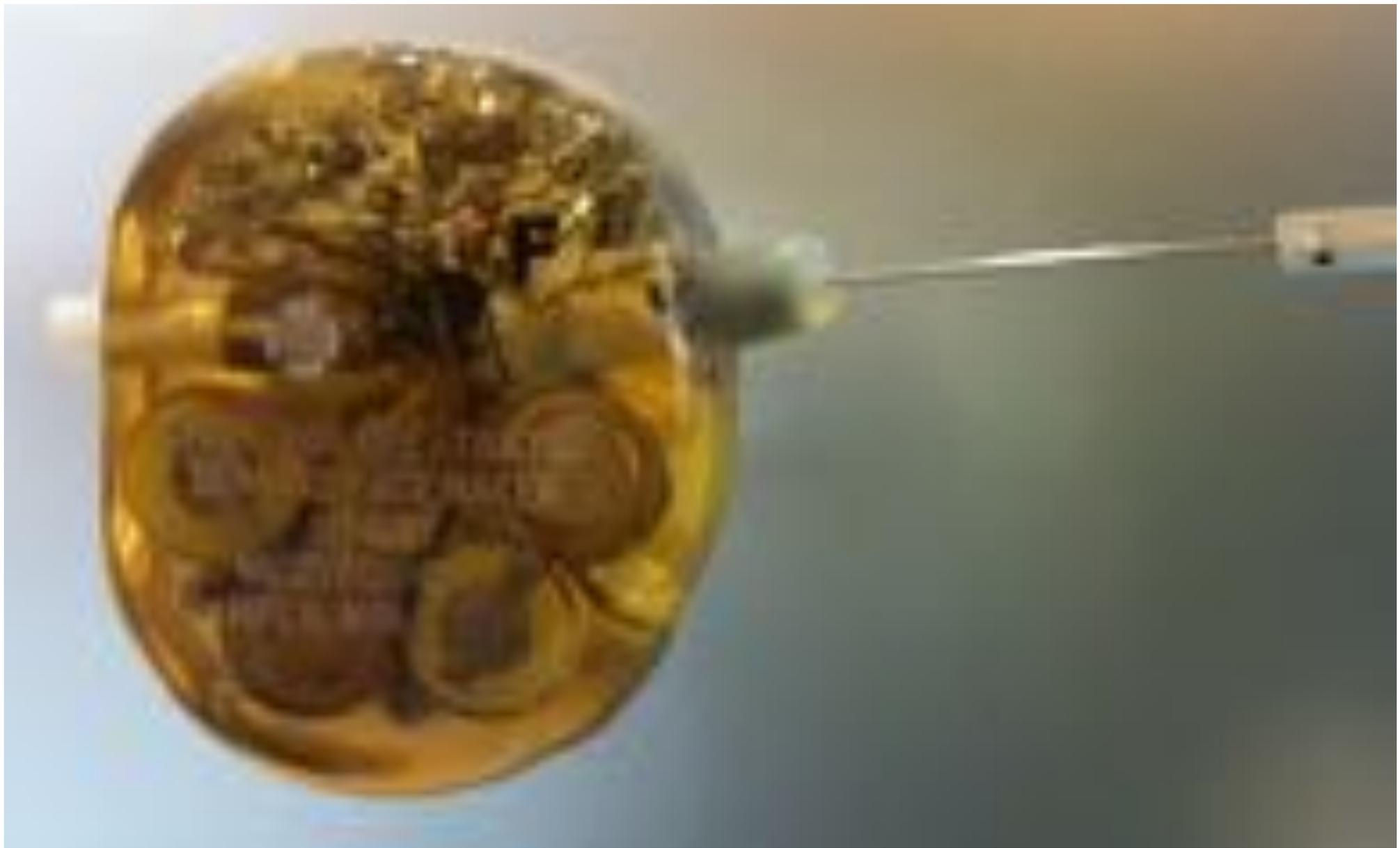


Photo by Kevin Fu @ Medtronic museum



# Hack or Hype?

Darth Vader is an FDA regulated medical device

No, but Emperor Palpatine is first victim of hacking Vader's neuro-prosthetic arms.





You will remove these restraints and leave this crypto with the backdoor closed!  
-Prof. Kevin Fu

# Hack or Hype?

Medical device  
manufacturers are doing  
nothing about security?

**FALSE!**

# MEDICAL DEVICES SECURITY WORKSHOP

Kevin Fu and team from University of Michigan's Archimedes Center for Medical Device Security

Boulder Surgical Innovations Campus, Bldg #2

Pike/Evans Conference Room

Feb 11<sup>th</sup> & 12<sup>th</sup> - 9.00 AM to 5.00 PM

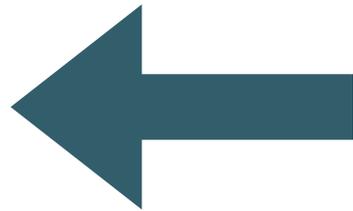


Medtronic



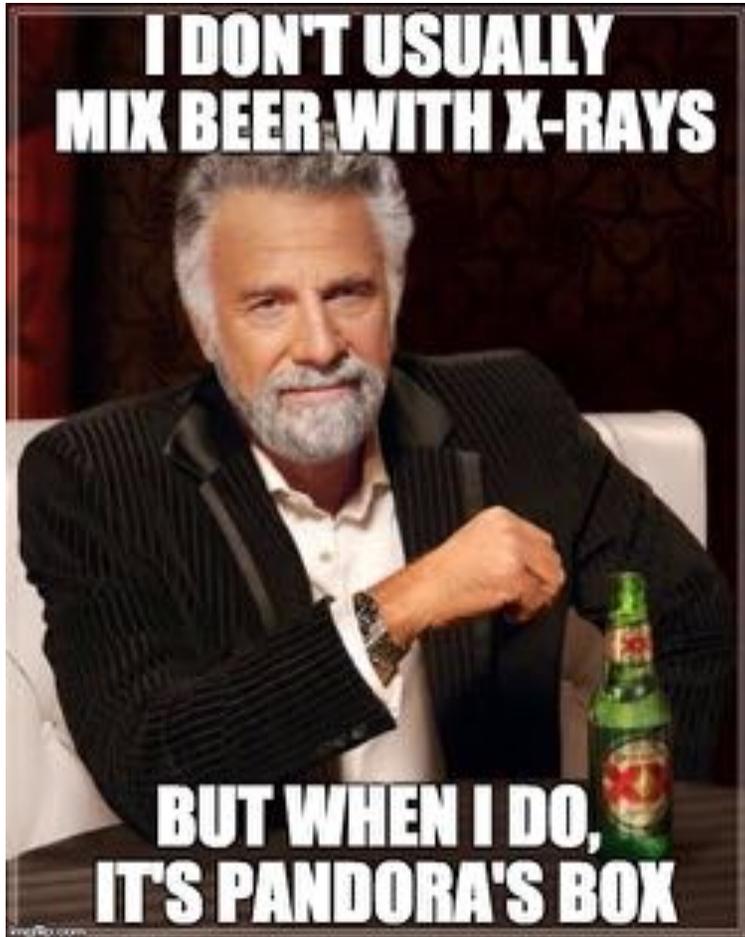
# Hack or Hype?

## Dental x-ray monitors serve beer ads



Actual beer mug  
from TROOPERS

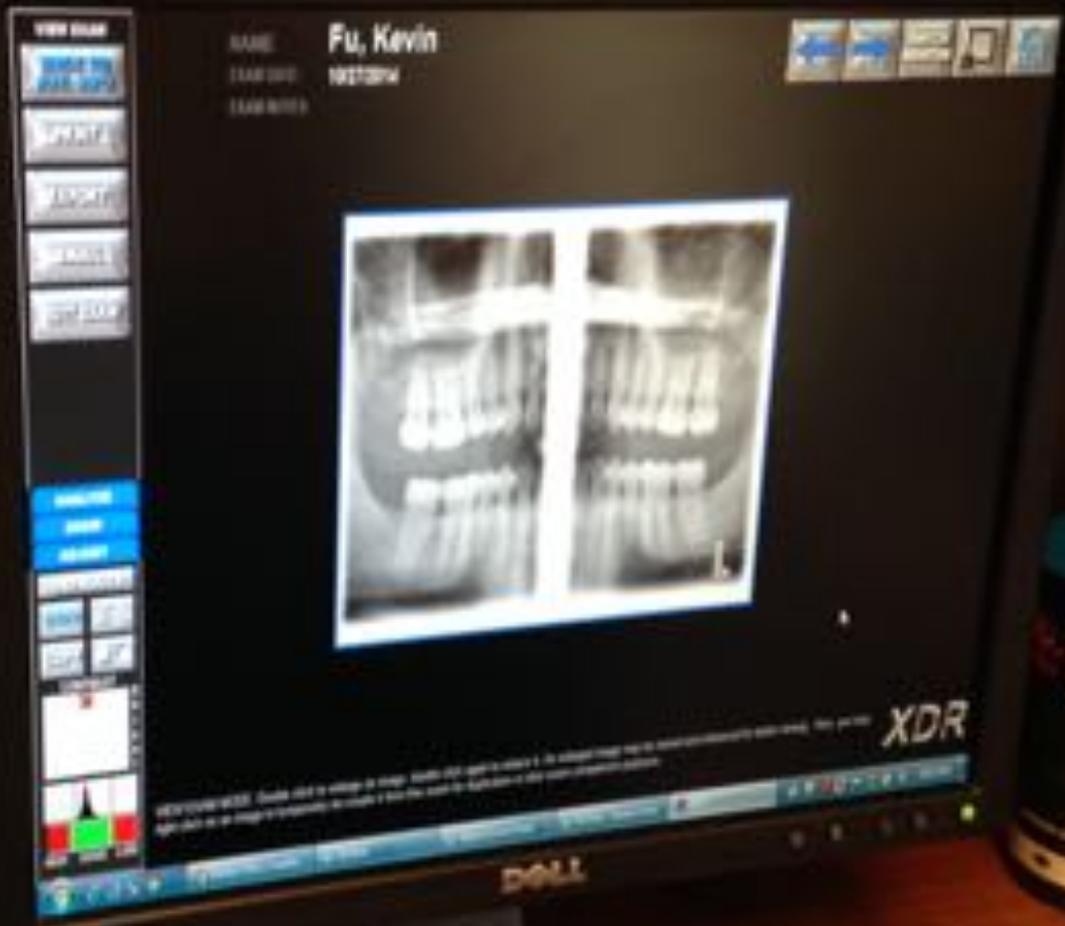




Hack or Hype?

Dental x-ray  
monitors serve  
beer ads

True! I saw Dos Equis.





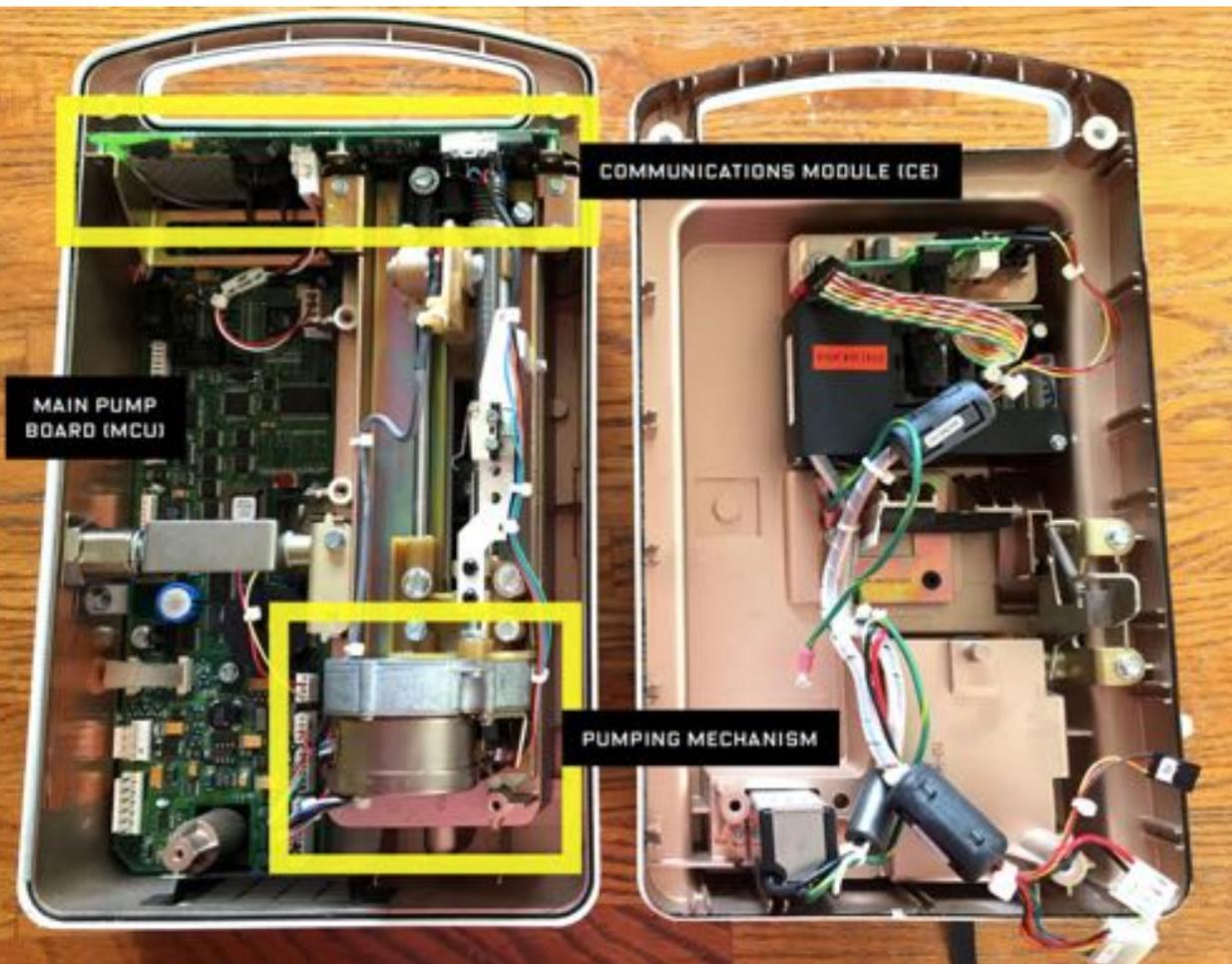
# Hack or Hype?

Has FDA issued security warnings?

Yes, against an infusion pump

# First FDA Cybersec Product Advisory

- Hospira Infusion Pump Vulnerabilities [Billy Rios and more, 2014-2015]



Photos: Wired

# First FDA Cybersec Product Advisory

- Hospira Infusion Pump Vulnerabilities [Billy Rios and more, 2014-2015]

U.S. Food and Drug Administration  
Protecting and Promoting *Your Health*

## LifeCare PCA3 and PCA5 Infusion Pump Systems by Hospira: FDA Safety Communication - Security Vulnerabilities

[Posted 05/13/2015]

**AUDIENCE:** Pharmacy, Nursing, Risk Manager, Engineering

**ISSUE:** The FDA and Hospira have become aware of security vulnerabilities in Hospira's LifeCare PCA3 and PCA5 Infusion Pump Systems. An independent researcher has released information about these vulnerabilities, including software codes, which, if exploited, could allow an unauthorized user to interfere with the pump's functioning. An unauthorized user with malicious intent could access the pump remotely and modify the dosage it delivers, which could lead to over- or under-infusion of critical therapies. The FDA is not aware of any patient adverse events or unauthorized device access related to these vulnerabilities.



Photos: Wired

# First FDA Cybersec Product Advisory

- Hospira Infusion Pump Vulnerabilities [Billy Rios and more]

U.S. Food and Drug Administration  
Protecting and Promoting Your Health

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[Posted 05/13/2015]

**AUDIENCE:** Pharmacy, Nursing, Risk Management

**ISSUE:** The FDA and Hospira have become aware of security vulnerabilities in Hospira's LifeCare PCA3 and PCA5 Infusion Pump Systems. An unauthorized user with access to information about these vulnerabilities, including software code, could use this information to allow an unauthorized user to interfere with the pump's function. An unauthorized user with malicious intent could access the pump remotely and modify the pump's settings, which could lead to over- or under-infusion of critical therapies. The FDA is not aware of any patient adverse events or unauthorized device access related to these vulnerabilities.

Wireless keys stored unencrypted, accessible via telnet/FTP!

Root shell on port 23!

Hard-coded local accounts!



Photos: Wired



abc NEWS .com

#WorldNewsTonight

# Hack or Hype?

FDA has a way to report  
security vulnerabilities

Half true, they are  
working on it

▲

- Colony forming units
- Color Variation, Lens
- Communication or transmission issue
- Compatibility
- Complete heart block
- Component falling
- Component incompatible
- Component missing
- Component or accessory incompatibility
- Component(s), broken
- Component(s), overheating of
- Component(s), worn
- Computer failure
- Computer hardware error
- Computer operating system issue
- Computer software issue
- Computer system security issue**
- Concentrate
- Conductivity
- Connection error
- Connection issue
- Connector pin failure



Dr. Julian Goldman

...ing Situational Awareness of  
Current Activities in the Healthcare  
Public Health Sector to Enhance  
Medical Device Cybersecurity  
...ary for Preparedness  
(ASPPA)  
January 21, 2016  
... send questions or comments to: [AskAndCyber](#)

# FDA Cybersecurity Guidance

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## **Content of Premarket Submissions for Management of Cybersecurity in Medical Devices**

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## **Guidance for Industry and Food and Drug Administration Staff**

**Document Issued on: October 2, 2014**

**The draft of this document was issued on June 14, 2013.**

For questions regarding this document contact the Office of Device Evaluation at 301-796-5550 or Office of Communication, Outreach and Development (CBER) at 1-800-835-4709 or 240-402-7800.

Life before  
FDA's  
security  
guidance  
document  
was  
schief.



# In 2016: Vulnerability Reporting!

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## **Postmarket Management of Cybersecurity in Medical Devices**

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### **Draft Guidance for Industry and Food and Drug Administration Staff**

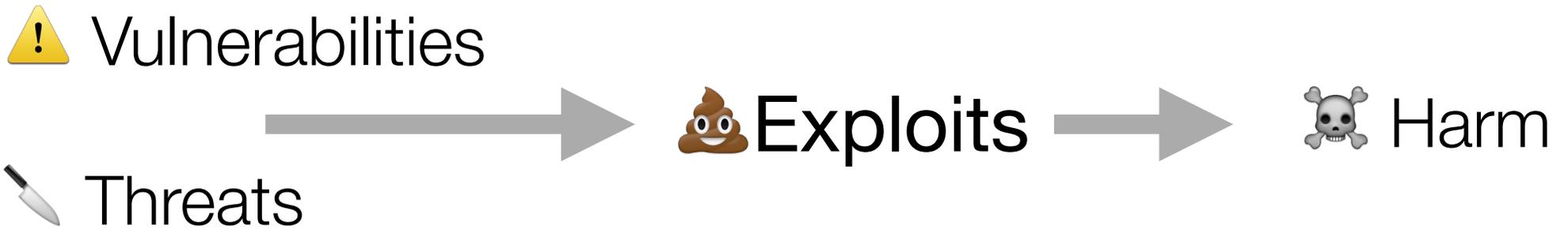
*DRAFT GUIDANCE*

**This guidance document is being distributed for comment purposes only.**

**Document issued January 2016**

# Understanding MedSec Risks

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Compensating Controls



Continuous Measurement

# Understanding MedSec Risks

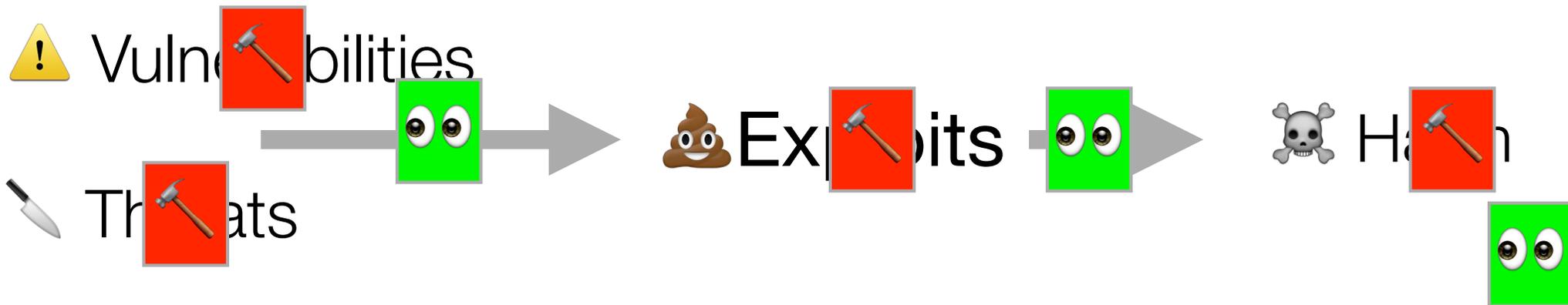
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 Compensating Controls

 Continuous Measurement

# Understanding MedSec Risks



 Compensating Controls

 Continuous Measurement

# Hack or Hype?

Hospitals have been  
disabled by malware?

Yes, many times

U.S. | NATIONAL BRIEFING | WEST

## California: Hospital Pays Bitcoin Ransom to Hackers

By THE ASSOCIATED PRESS FEB. 17, 2016

 Email Share Tweet Save More

Hollywood Presbyterian Medical Center paid a ransom in bitcoins equivalent to about \$17,000 to hackers who infiltrated and disabled its computer network, the hospital's chief executive said Wednesday. It was in the hospital's best interest to pay the ransom of 40 bitcoins after the hacking that began Feb. 5, the C.E.O., Allen Stefanek said. The F.B.I. is investigating the attack, often called "ransomware," in which hackers encrypt a computer network's data to hold it hostage, providing a digital decryption key to unlock it for a price. "The quickest and most efficient way to restore our systems and administrative functions was to pay the ransom and obtain the decryption key," Mr. Stefanek said. Bitcoins, an online currency, are hard to trace. The Los Angeles hospital network was operating fully again Monday, and patient care was not affected by the hacking, Mr. Stefanek said. Neither law enforcement officials nor the hospital gave any indication of who might have been behind the attack or whether there were any suspects.





February 17, 2016

I am writing to talk to you about the recent cyber incident which temporarily affected the operation of our enterprise-wide hospital information system.

It is important to note that this incident did not affect the delivery and quality of the excellent patient care you expect and receive from Hollywood Presbyterian Medical Center (“HPMC”). Patient care has not been compromised in any way. Further, we have no evidence at this time that any patient or employee information was subject to unauthorized access.

On the evening of February 5<sup>th</sup>, our staff noticed issues accessing the hospital’s computer network. Our IT department began an immediate investigation and determined we had been subject to a malware attack. The malware locked access to certain computer systems and prevented us from sharing communications electronically. Law enforcement was immediately notified. Computer experts immediately began assisting us in determining the outside source of the issue and bringing our systems back online.

The reports of the hospital paying 9000 Bitcoins or \$3.4 million are false. The amount of ransom requested was 40 Bitcoins, equivalent to approximately \$17,000. The malware locks systems by encrypting files and demanding ransom to obtain the decryption key. The quickest and most efficient way to restore our systems and administrative functions was to pay the ransom and obtain the decryption key. In the best interest of restoring normal operations, we did this.

HPMC has restored its electronic medical record system (“EMR”) on Monday, February 15<sup>th</sup>. All clinical

immediately began assisting us in determining the outside source of the issue and bringing our systems back online.

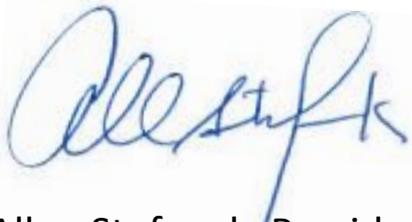
The reports of the hospital paying 9000 Bitcoins or \$3.4 million are false. The amount of ransom requested was 40 Bitcoins, equivalent to approximately \$17,000. The malware locks systems by encrypting files and demanding ransom to obtain the decryption key. The quickest and most efficient way to restore our systems and administrative functions was to pay the ransom and obtain the decryption key. In the best interest of restoring normal operations, we did this.

HPMC has restored its electronic medical record system (“EMR”) on Monday, February 15<sup>th</sup>. All clinical operations are utilizing the EMR system. All systems currently in use were cleared of the malware and thoroughly tested. We continue to work with our team of experts to understand more about this event.

I am very proud of the dedication and hard work of our staff who have maintained the highest level of service, compassion and quality of care to our patients throughout this process. I am also thankful for the efforts of the technical staff as the EMR systems were restored, and their continued efforts as other systems are brought back online.

And of course, I want to thank our patients and community for their continued trust in Hollywood Presbyterian Medical Center.

Thank you,

A handwritten signature in blue ink, appearing to read 'Allen Stefanek', is positioned above the printed name.

Allen Stefanek, President & CEO  
Hollywood Presbyterian Medical Center

# Hospital Cyber Attack

2 minute left



HOSPITAL HACKED

STUDIO  
11  
LA

**HOLLYWOOD PRESBYTERIAN HIT BY HACKERS**  
WHO ARE NOW DEMANDING BITCOIN RANSOM

LAUNCH

00:00 / 01:45 TIME AL Q EAD NES

Hackers who brought down Hollywood Presbyterian's computer system are demanding a huge ransom.

By: Christine O'Donnell



POSTED: FEB 12 2016 07:34PM PST  
UPDATED: FEB 12 2016 07:34PM PST

## Ransom payments in Hollywood

Blackmailing hospitals into paying ransom has also been reported in other parts of the world, most notably in the US state of California where a Hollywood hospital paid about \$17,000 (15,000 euros) in the digital currency bitcoins to hackers this month.

"The quickest and most efficient way to restore our systems and administrative functions was to pay the ransom and obtain the decryption key," Hollywood Presbyterian Medical Center's President Allen Stefanek said in a statement.



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CYBER ATTACK

# Hackers hold German hospital data hostage

Several hospitals in Germany have come under attack by ransomware, a type of virus that locks files and demands cash to free data it maliciously encrypted. It will take weeks until all systems are up and running again.

The incident happened over two weeks ago, but the hospital's website still advises patients to call them or send a fax - the email system is still not up and running. Malware has brought the hospital's computer system to a halt.

# Monday Jan 18, 2016 in Australia

## Royal Melbourne Hospital attacked by damaging computer virus

January 18, 2016

Julia Medew

Health Editor

THE  AGE  
Victoria

A virus has attacked the computer system of one of Melbourne's largest hospital networks, causing chaos for staff and patients who may face delays as a result.

Staff at Melbourne Health - the network which runs the Royal Melbourne Hospital - are urgently trying to repair damage to its IT system after a virus infected **Windows XP computers.**

An email sent to staff today said the **virus had hit Melbourne Health's pathology department,** causing staff to manually process specimens such as blood, tissue and urine samples instead of computers aiding the registration, testing and entry of results.

19 JANUARY 2016

News Category: Media releases

Melbourne Health is managing a computer virus which infected its computer network.

While the virus has been disruptive to the organisation, due to the tireless work of staff we have been able to minimise this disruption to our patients and ensure patient safety has been maintained.

Computers running on most of our systems are now clear of the virus and IT staff are working to restore the remaining Windows XP computers as quickly as possible.

As of 10am this morning, many programs affected by the virus are up and running including pathology and pharmacy.

“restore the remaining  
Windows XP computers...  
pathology and pharmacy.”

Wednesday Jan 20, 2016 in Texas

## THE DAILY TRIBUNE

### Virus hits TRMC computers

By MARCIA DAVIS Managing editor

TRMC CEO John Allen said the hospital experienced a network issue that was revealed about 7:30 p.m. Friday, Jan. 15.

TRMC public information officer Shannon Norfleet said a computer ransomware virus encrypted files on several of the TRMC database servers within the health system, which affects the TRMC access to the computer files.

**Thursday Jan 21, 2016**

**Advisory (ICSA-15-337-02)**

**Hospira Multiple Products Buffer Overflow Vulnerability**

Original release date: January 21, 2016

- Hospira manufactures networkable drug infusion pumps
- Remotely accessible buffer overflow via port 5000/TCP
- Difficulty: Low skill attacker



# Friday Jan 22, 2016 in Michigan

## Flint hospital confirms 'cyber attack,' Anonymous threatens action over water crisis



on January 21, 2016 at 9:43 PM, updated January 22, 2016 at 9:59 AM

By [Gary Ridley | gridley@mlive.com](mailto:gridley@mlive.com)

FLINT, MI – Hurley Medical Center has confirmed it was the victim of a "cyber attack" a day after hacktivists threatened action over Flint's water crisis.

The hospital confirmed the attack Thursday, Jan. 21, but few details were released.

"Hurley Medical Center has IT systems in place, which aid in detecting a virus or cyber attack," hospital spokeswoman Ilene Cantor said. "As such, all policies and protocols were followed in relation to the most-recent cyber attack on our system. Patient care was not compromised and we are closely monitoring all systems to ensure IT security is consistently maintained."

# Hack or Hype?

2,000 x-rays were stolen  
to somewhere in China

True, likely selling.

Dr. John Halamka, CIO of Beth  
Israel Deaconess Medical Center in Boston  
[geekdoctor.blogspot.com](http://geekdoctor.blogspot.com)



# Hack or Hype?

AngryBirds took  
down a hospital

No, but an authentic  
binary led to spambot

# Hack or Hype?

A hospital downgraded  
from SSH to telnet for  
compliance.

Sadly, true.

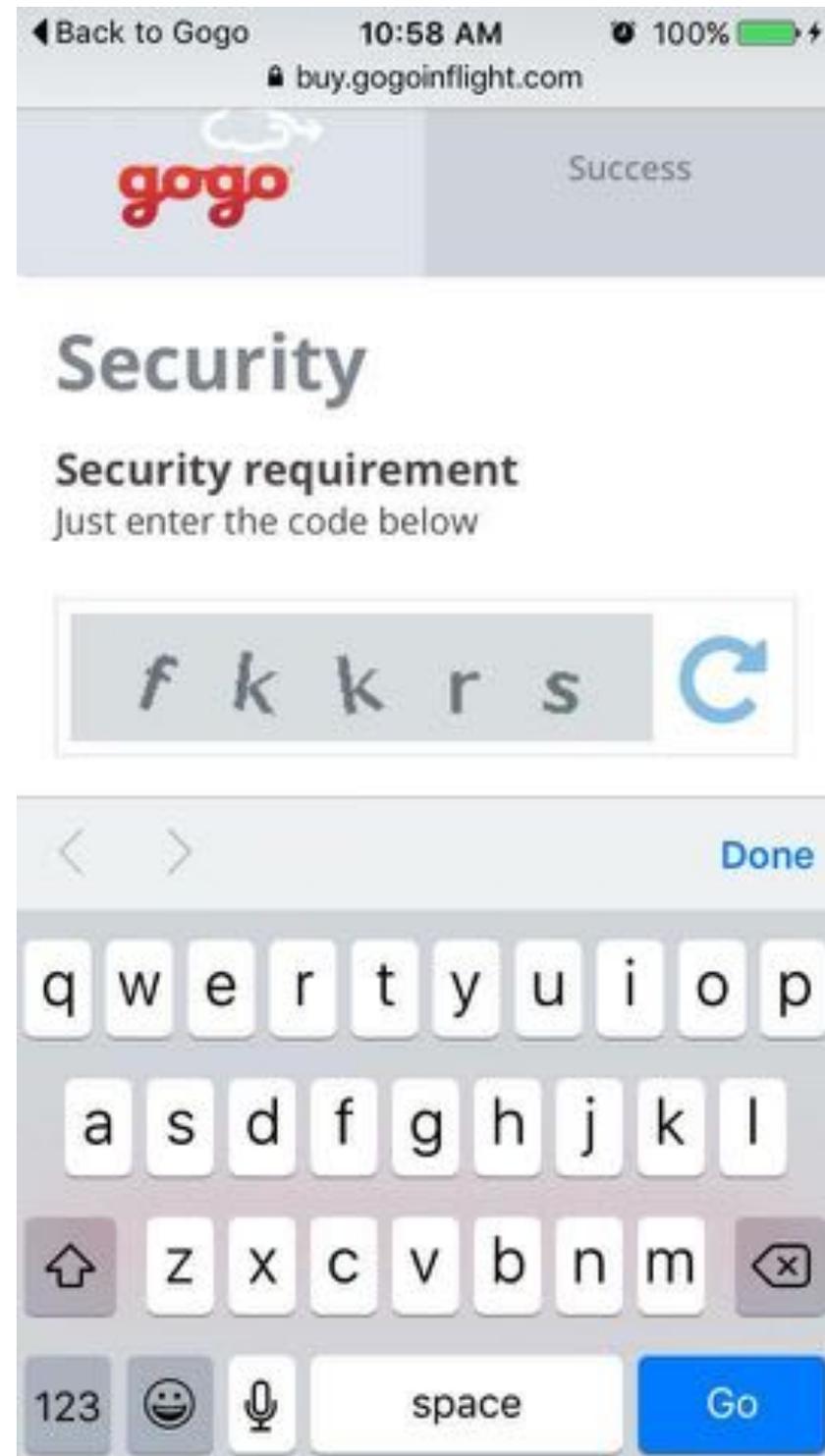
# Hack or Hype?

Vulnerability scanning knocks  
over medical devices?

True if tools used haphazardly

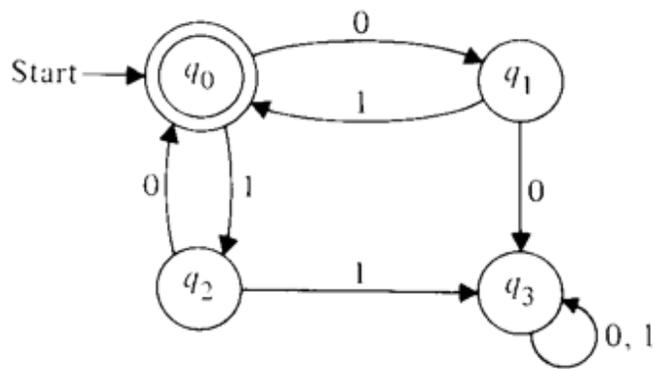


# Ways Forward: Usable Security

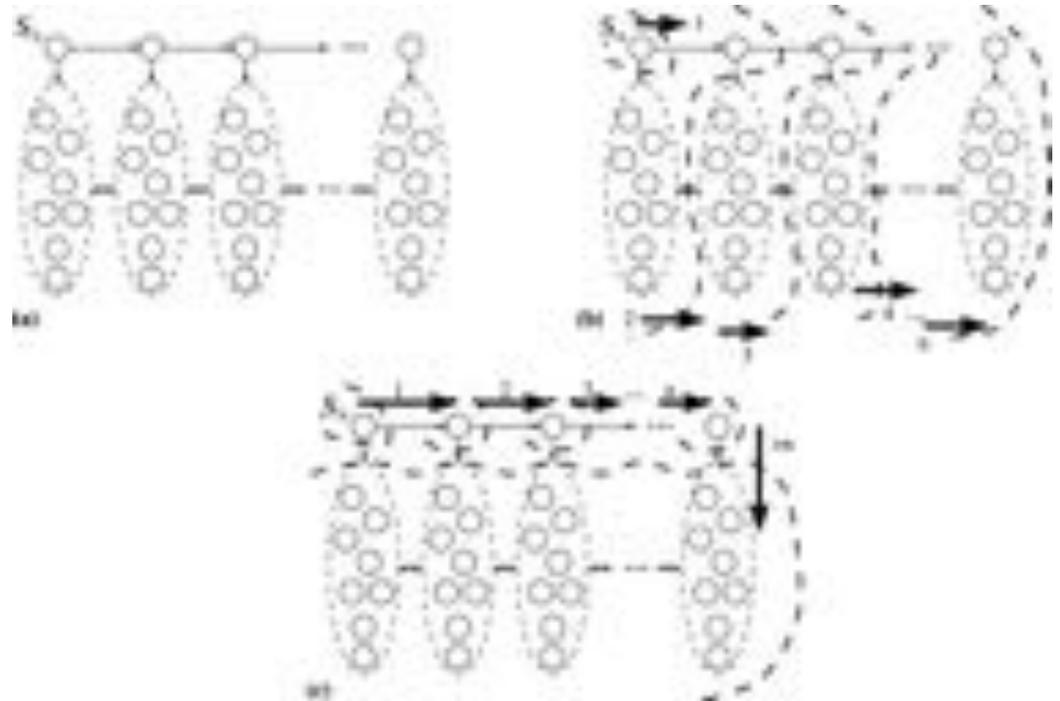


# Intuition

Embedded



General-purpose



# Devices Tested

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<b>Device</b>	<b>Configuration</b>
Baxa ExactaMix 2400 compounder	WinXP Embedded, Via 664 MHz , 512 MB RAM
Schweitzer SEL3354 substation computer	WinXP Embedded, Athlon 2600+, 2 GB RAM

# Pharmaceutical Compounder

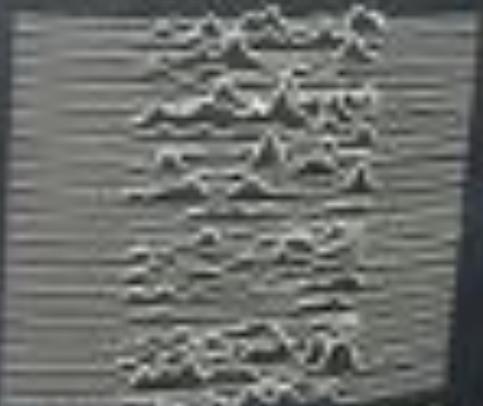
- Mixes solutions, verifies output
- Flushes inputs
- Idles







VITA LABORATORIES



UNKNOWN MALWARE

### **Conficker Coffee**

A maliciously delicious single varietal from the Sulawesi region of Indonesia and roasted to full city++, sure to keep you up while cleaning out Conficker from your cath labs. Virta security analytics to keep you alert.

# Cybersecurity: A Foreseeable Risk

- Biggest risk at the moment:
  - ~~Hackers breaking into medical devices~~
  - Wide-scale **unavailability** of patient care
  - **Integrity** of medical sensors
- Gaps
  - Don't interrupt clinical workflow
  - Many security specialists focus on technical controls
  - Many safety specialists focus on risk management
  - Trustworthy medical device software requires both



# Want to Learn More?

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- Are you a security consultant?
- Are you a manufacturer?
- Are you a clinician?



# Archimedes Center for Medical Device Security

Collaboration: Industry, Academia, Government, Clinicians, Health Care Providers



**2013**



**2014**



**2015**

Learn more at...

**[secure-medicine.org](http://secure-medicine.org)**

Members



**Medtronic**

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# MEDSEC SECURITY RESEARCH

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# WHAT'S MISSING??

# Coming Up Later: Marie Moe

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