



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

Supported in part by NSF CNS-1330142. Any opinions, findings, and conclusions expressed in this material are those of the authors and do not necessarily reflect the views of NSF.



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

Daniel Halperin*
University of Washington

Thomas S. Heydt-Benjamin*
University of Massachusetts Amherst

Benjamin Ranford*
University of Massachusetts Amherst

Shane S. Clark
University of Massachusetts Amherst

Benjamin Delfino
University of Massachusetts Amherst

Wili Morgan
University of Massachusetts Amherst

Kevin Fu, PhD*
University of Massachusetts Amherst

Tadayoshi Kozuno, PhD*
University of Washington

William H. Matala, MD, MPH*
BWHMC 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 1980, this model of ICD includes proprietary technology and is designed to communicate wirelessly with a nearby external programmer in the 270 kHz frequency range. After partially reverse-engineering the ICD's communications 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 human-centric, bringing patients into the loop with respect to the security and privacy of their implantable medical devices (IMDs). Our contributions provide a scientific foundation for understanding the potential security and privacy risks of current and future IMDs, and introduce human-centric 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 communications protocols.

1. Introduction

Wirelessly reprogrammable implantable medical devices (IMDs) such as pacemakers, implantable cardioverter defibrillators (ICDs), neurostimulators, and implantable drug pumps use embedded computers 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

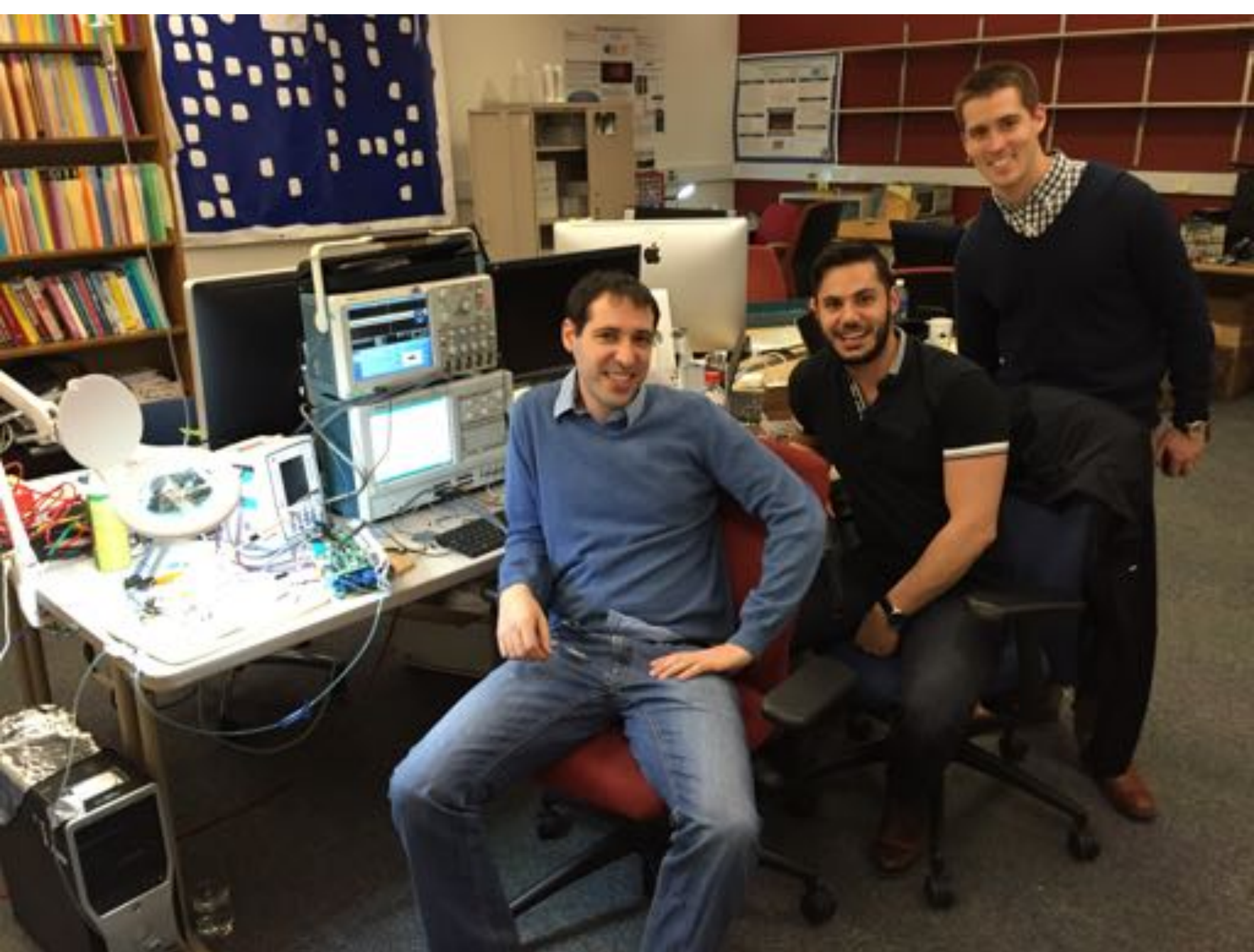
this event to a health care practitioner who uses a commercial device programmer* with wireless capabilities to extract data from the ICD or modify its settings without surgery. Between 1990 and 2002, over 2.6 million pacemakers and ICDs were implanted in patients in the United States [19]. Clinical trials have shown that these devices significantly improve survival rates in certain populations [38]. Other research has discovered 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.

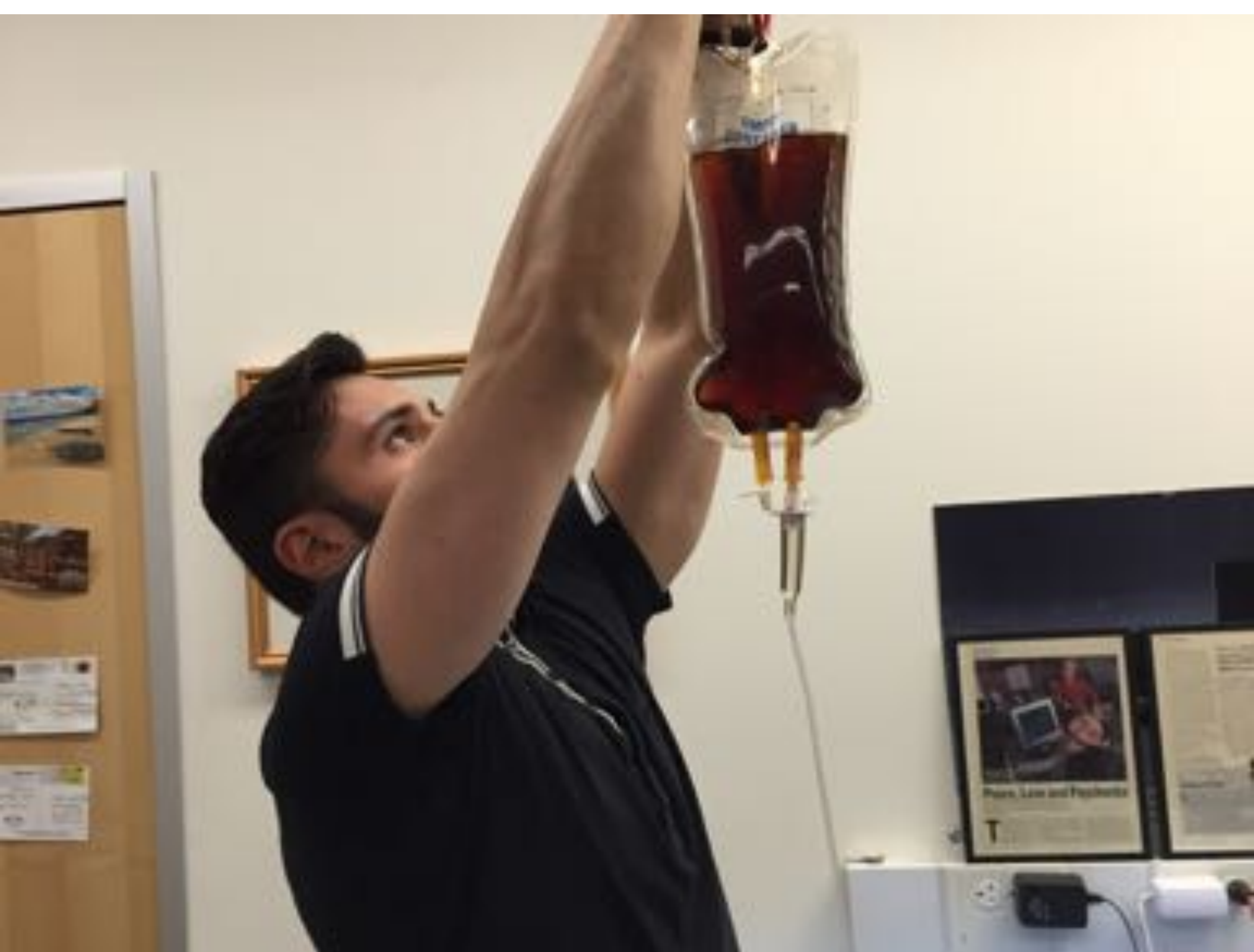
Our investigation was motivated by an interdisciplinary study of medical device safety and security, and relied on a diverse team of area specialists. Team members from the security and privacy community have formal training in computer science, computer engineering, and electrical engineering. One team 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 toward 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 associated to) the ICD; and

*The reader should not confuse the term “device programmer” with a computer who programs computers. The former is an external device that communicates with and adjusts the settings on an IME.

This paper, copyright the IEEE, will appear in the proceedings of the 2008 IEEE Symposium on Security and Privacy.







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 ~ 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.

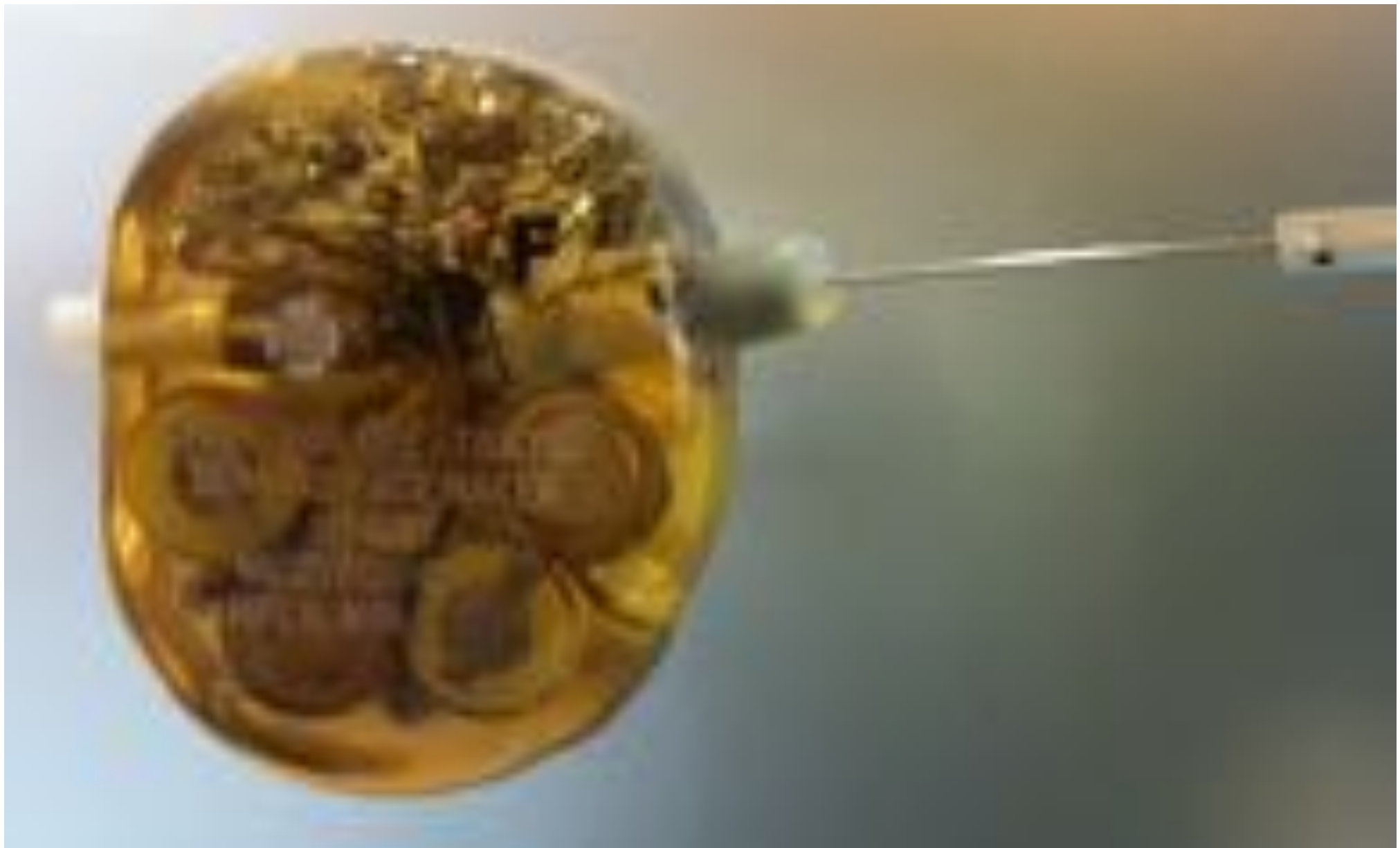


Photo by Kevin Fu @ Medtronic museum




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 11th & 12th - 9.00 AM to 5.00 PM

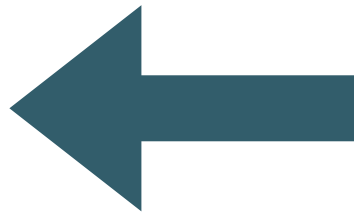


Medtronic



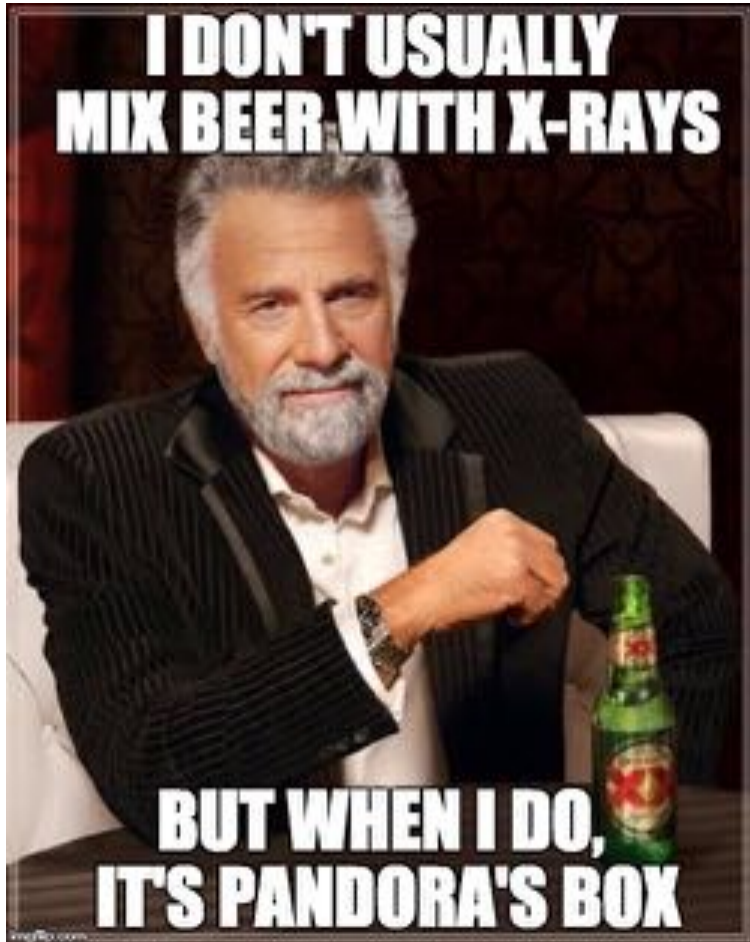
Hack or Hype?

Dental x-ray monitors serve beer ads



Actual beer mug
from TROOPERS

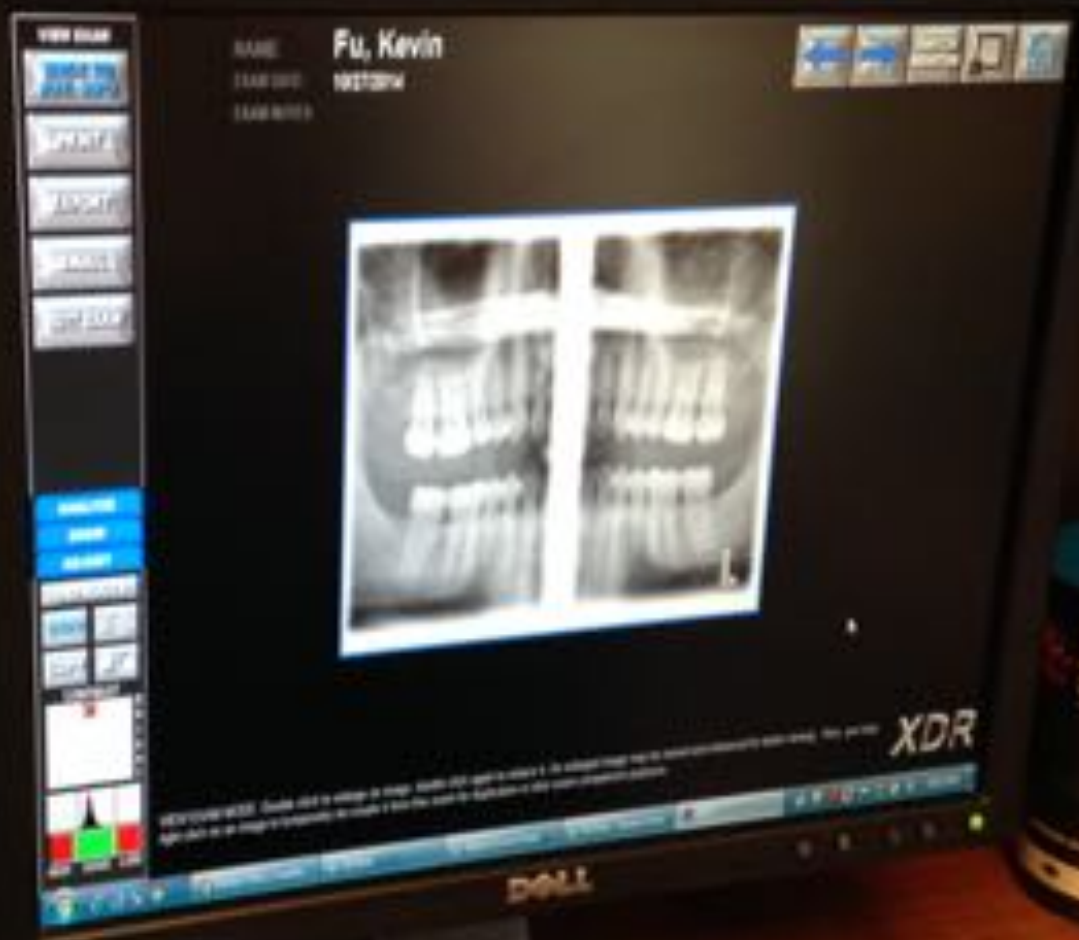


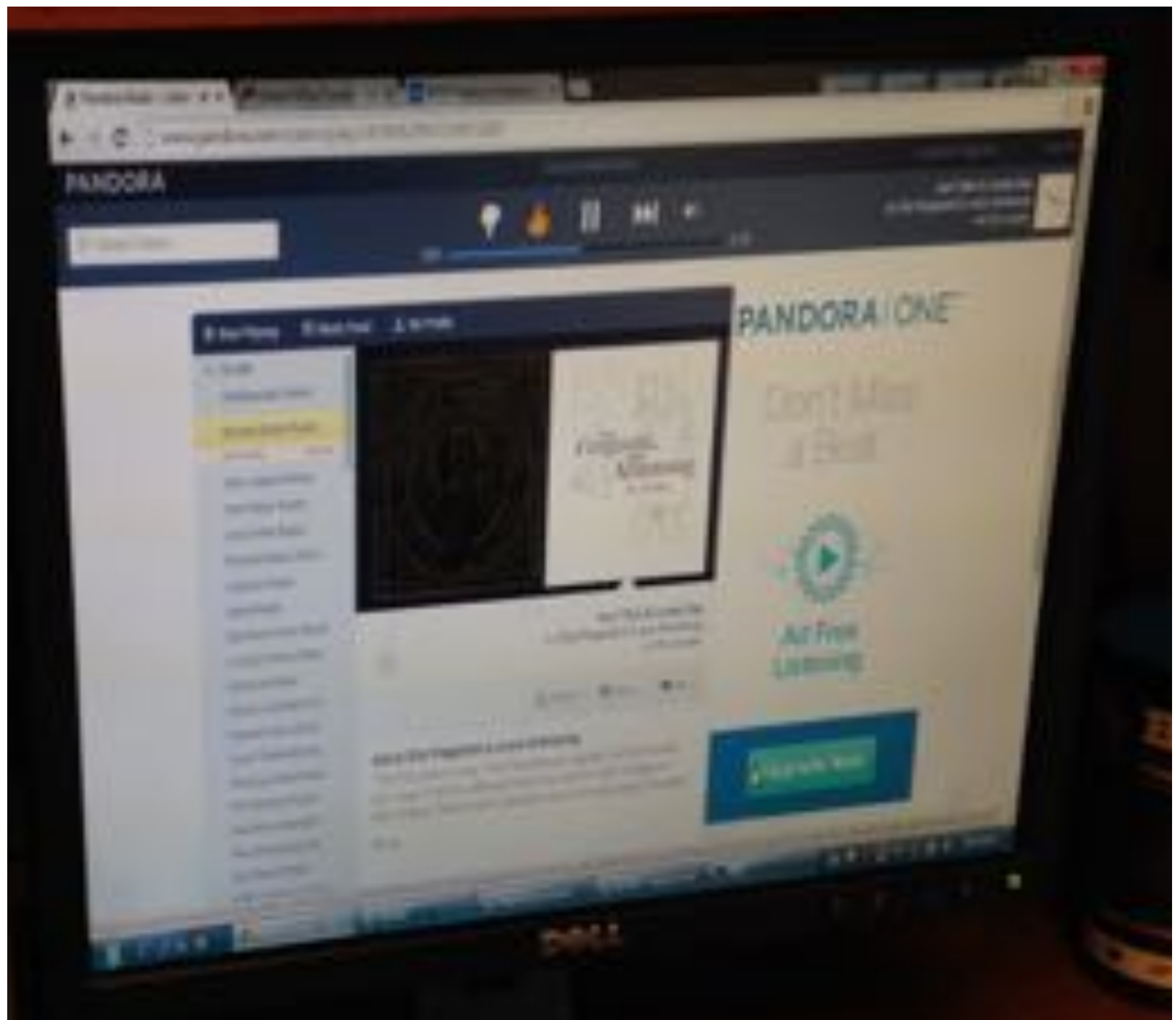


Hack or Hype?

Dental x-ray
monitors serve
beer ads

True! I saw Dos Equis.





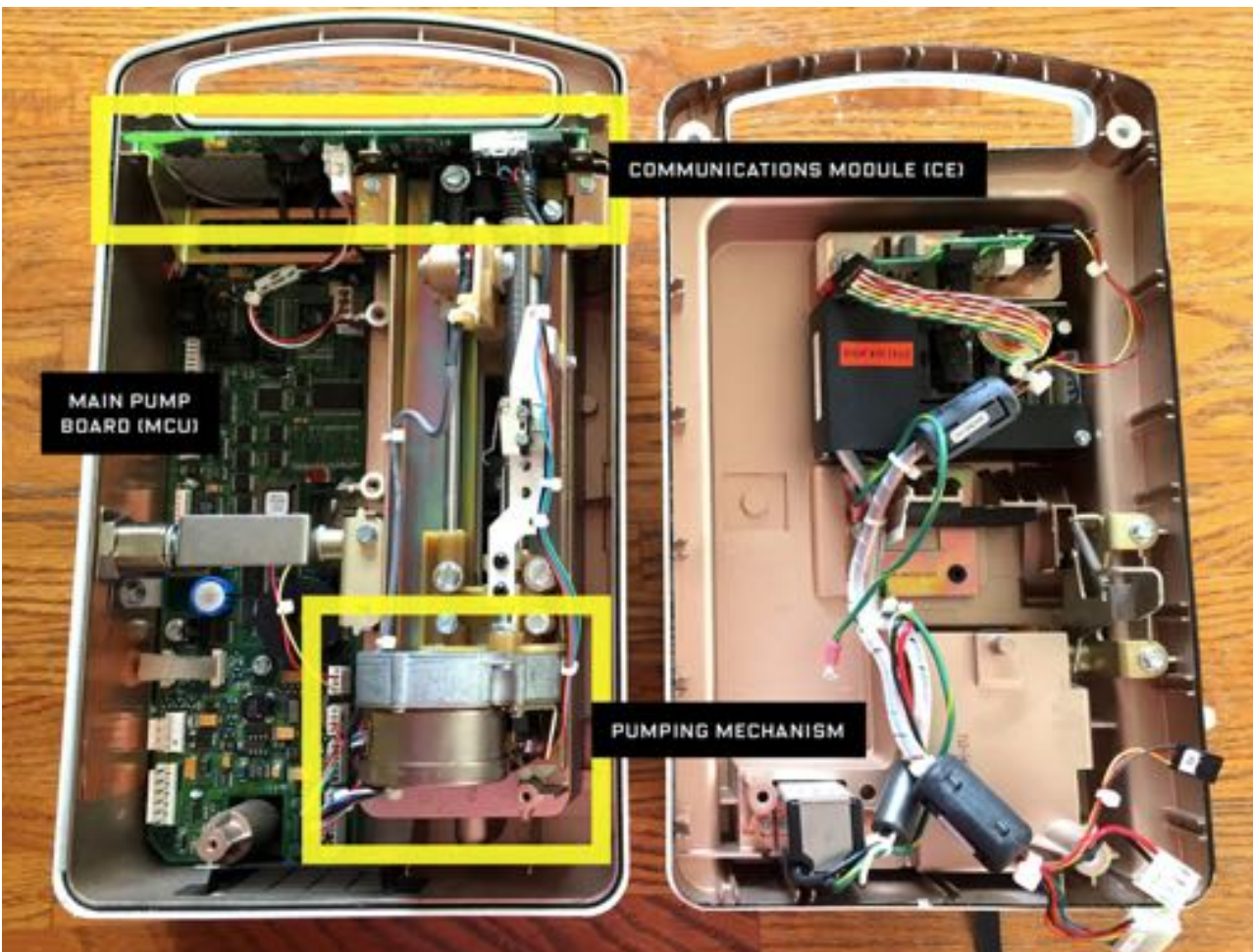
Hack or Hype?

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

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

[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

FDA Warns That Commonly Used Medical Device Can Be Hacked

More ▾



abc NEWS
.com

#WorldNewsTonight

00:00

CC SHARE

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 failing
- 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

Plenary Panel:
Situational Awareness of
Current Activities in the Healthcare
Public Health Sector to Enhance
Medical Device Cybersecurity

Secretary for Preparedness
(ASPR)
January 21, 2016
send questions or comments to: [AskAndCyber](#)

FDA Cybersecurity Guidance

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

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!

Postmarket Management of Cybersecurity in Medical Devices

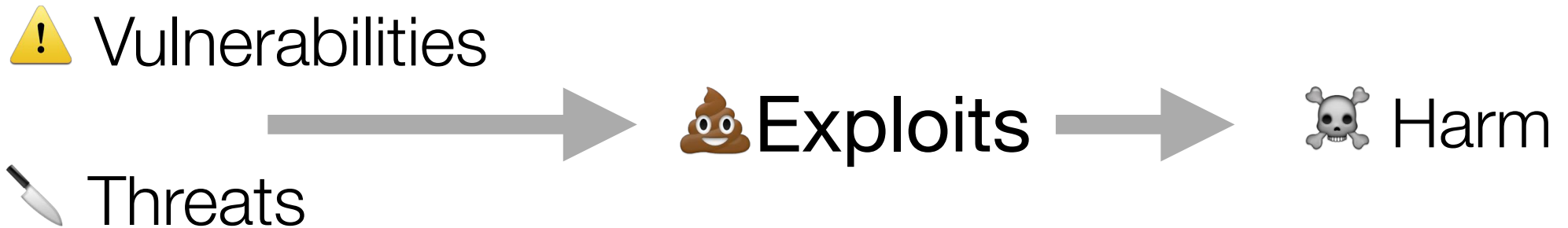
Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This guidance document is being distributed for comment purposes only.

Document issued January 2016

Understanding MedSec Risks

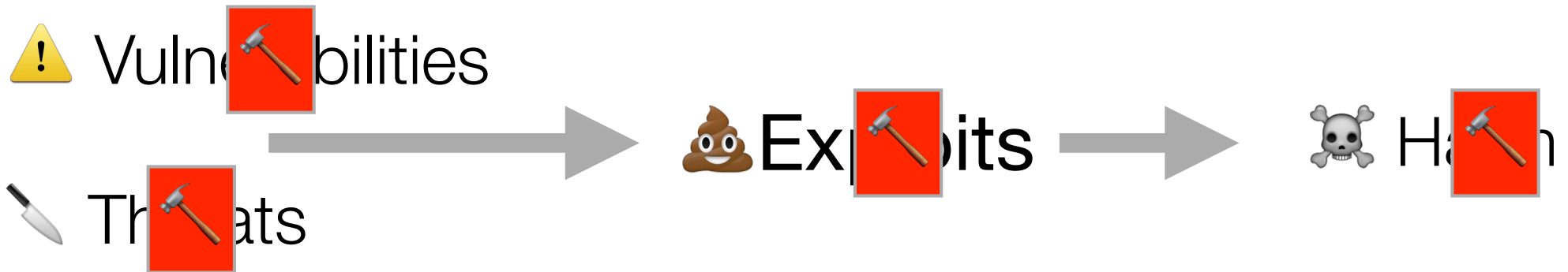


Compensating Controls



Continuous Measurement

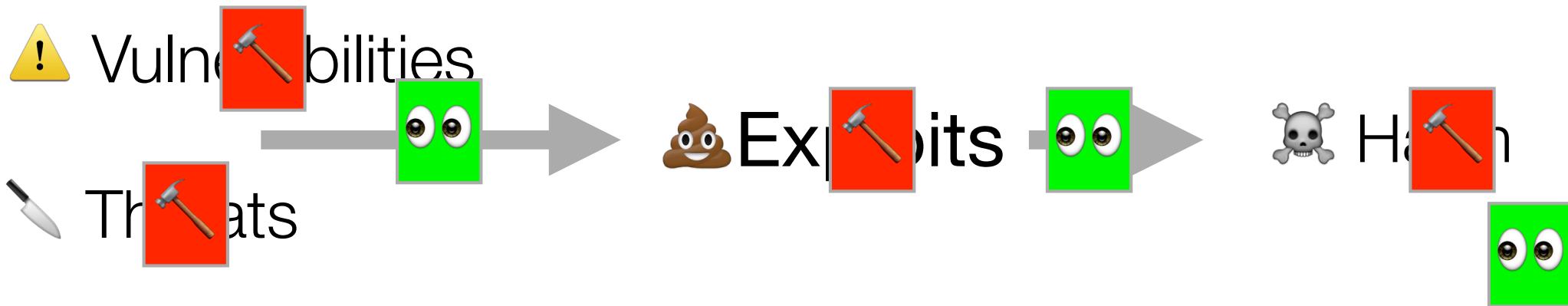
Understanding MedSec Risks



 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 5th, 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 15th. All clinical

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

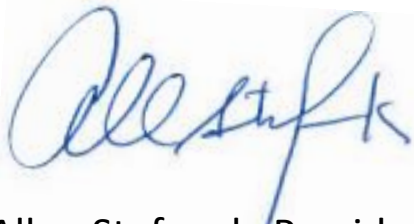
The reports of the hospital paying 9000 Bitcoins or \$3.4 million are false. The amount of ransom requested was 40 Bitcoins, equivalent to approximately \$17,000. The malware locks systems by encrypting files and demanding ransom to obtain the decryption key. The quickest and most efficient way to restore 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 15th. 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
11LA

HOLLYWOOD PRESBYTERIAN HIT BY HACKERS
WHO ARE NOW DEMANDING BITCOIN RANSOM



LAMICH

00:00 / 01:45 TIME ALREADY

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

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



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.

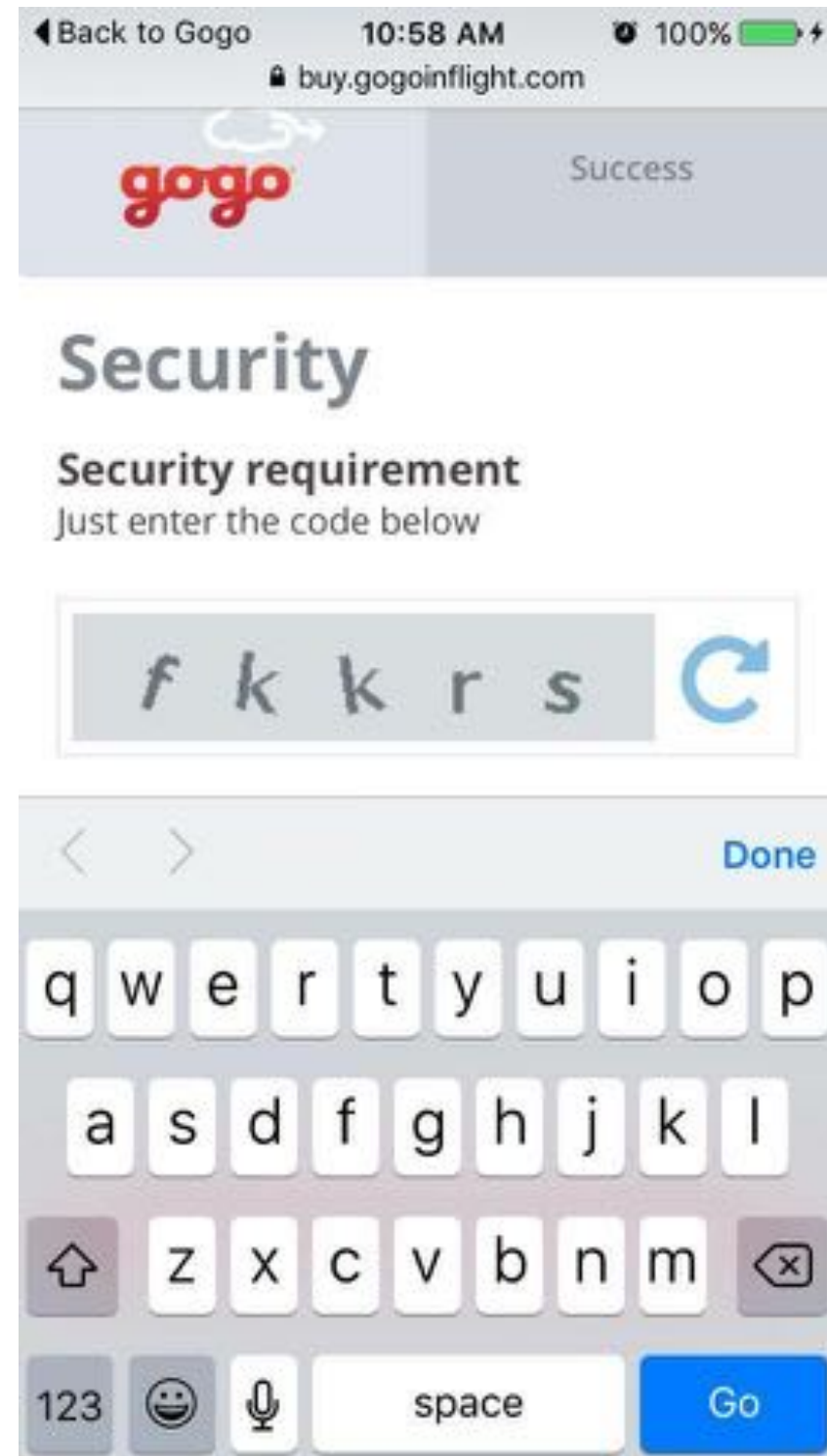
Hack or Hype?

Vulnerability scanning knocks over medical devices?

True if tools used haphazardly

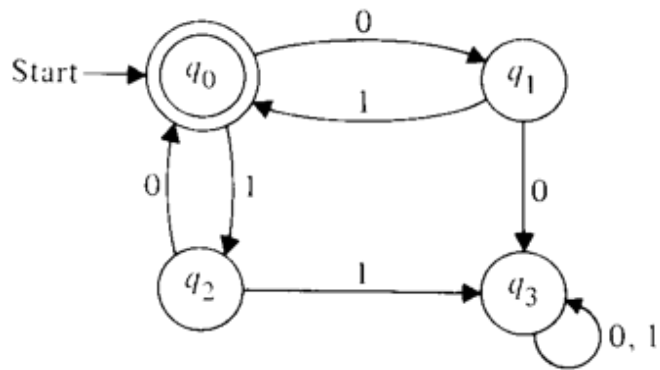


Ways Forward: Usable Security

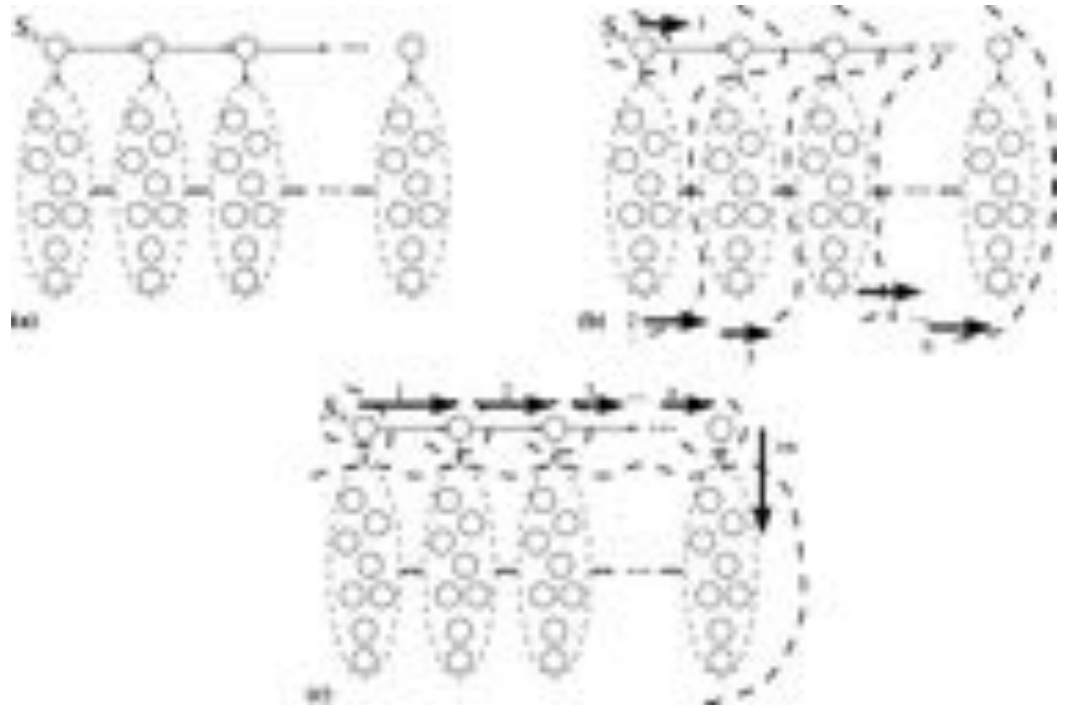


Intuition

Embedded



General-purpose

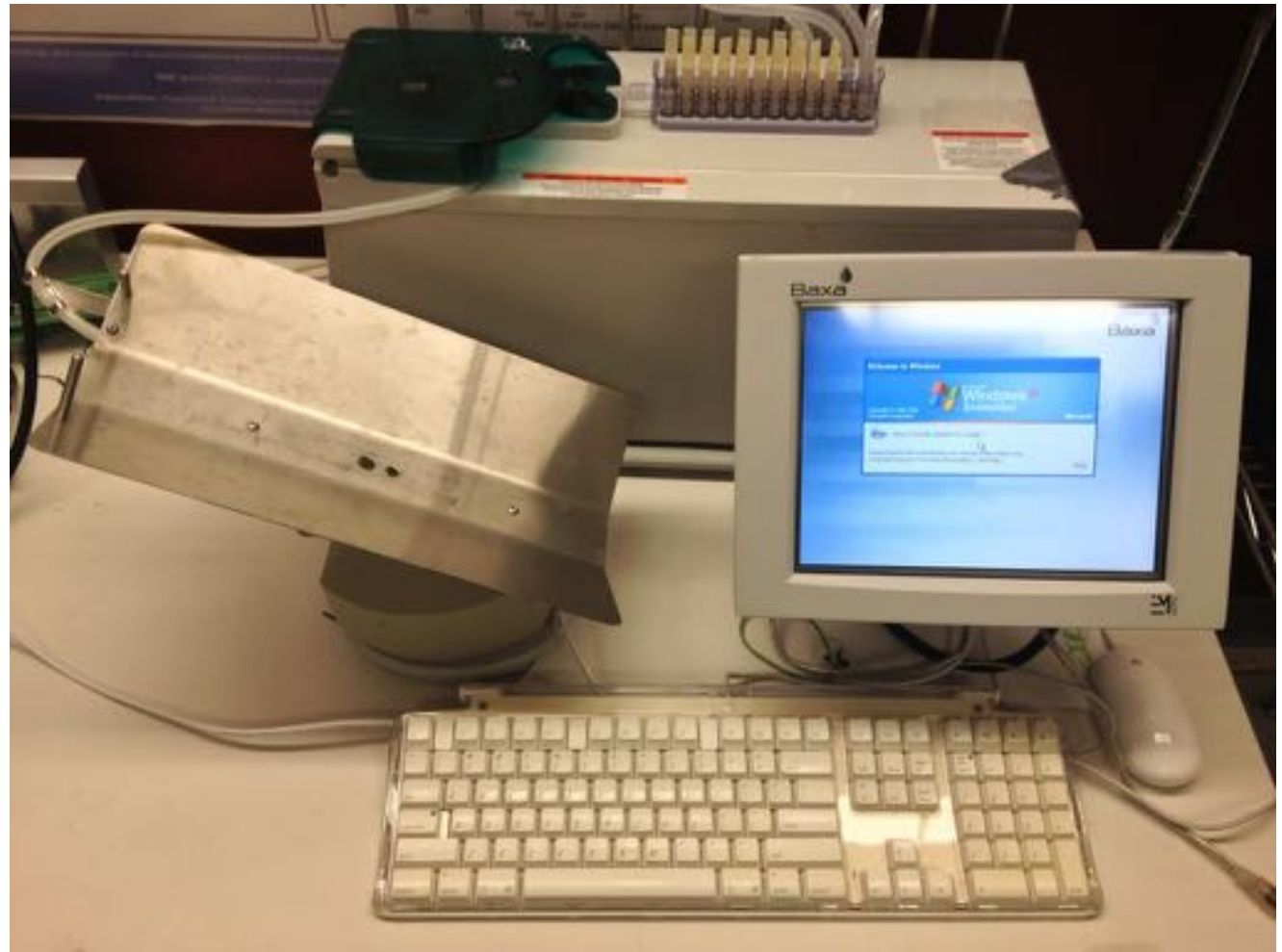


Devices Tested

Device	Configuration
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







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?

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



Archimedes Center for Medical Device Security



2013

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



2014



2015

Learn more at...

secure-medicine.org

Members



Medtronic

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WelchAllyn®



MEDSEC SECURITY RESEARCH

Follow me on Twitter @DrKevinFu

WHAT'S MISSING??

Coming Up Later: Marie Moe

