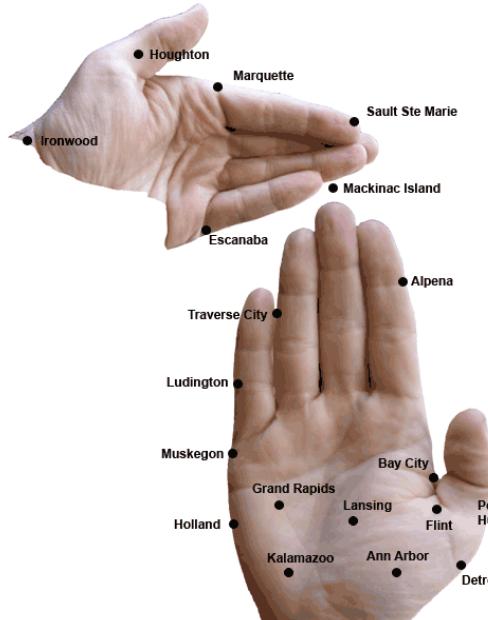




IoT Security & Medical Devices, Oh My: 💩😴



Kevin Fu
Associate Professor
Computer Science & Engineering
University of Michigan

web.eecs.umich.edu/~kevinfu/
kevinfu@umich.edu



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.

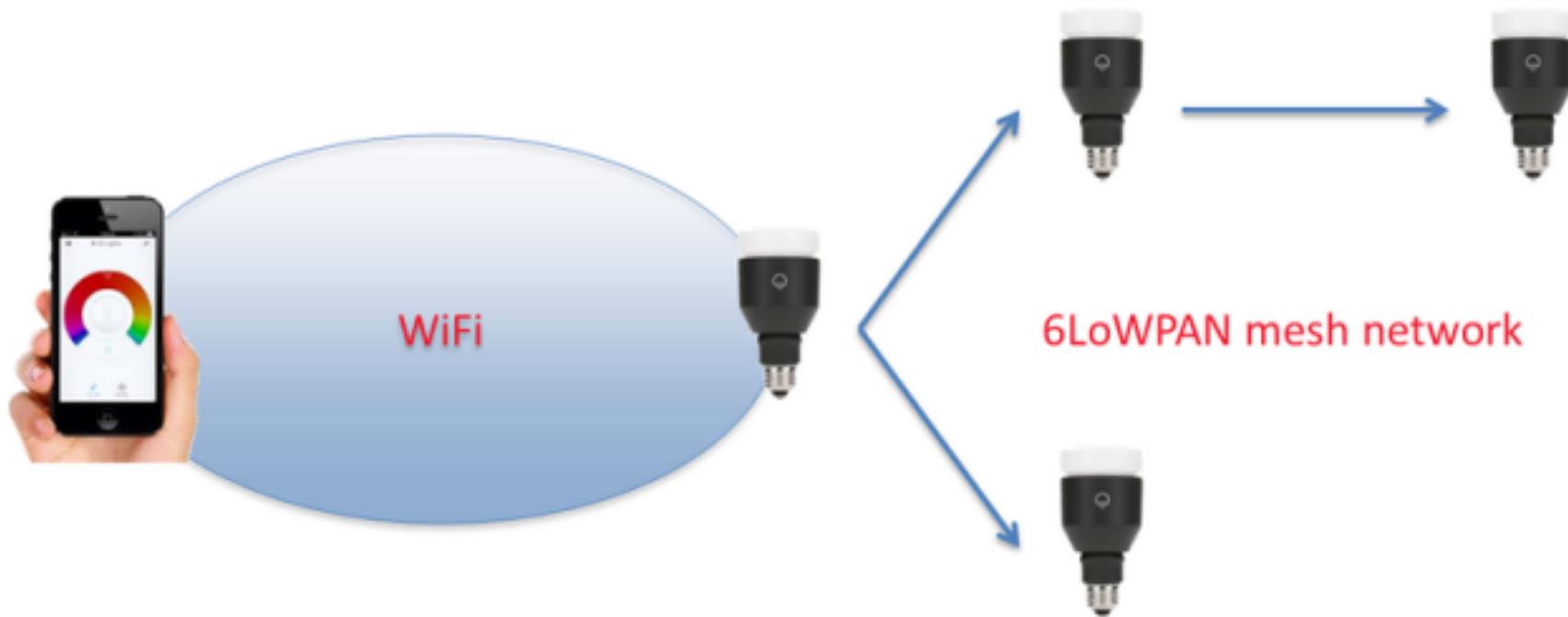
RISK ASSESSMENT / SECURITY & HACKTIVISM

Crypto weakness in smart LED lightbulbs exposes Wi-Fi passwords

More evidence the Internet of things treats security as an afterthought.

by Dan Goodin - July 7 2014, 3:20pm EDT

HACKING SMART HOME 90



Context

PRIVACY

Samsung Tweaks Television Policy Over Privacy Concerns

By Nick Wingfield

February 10, 2015 5:23 pm

After an outcry over privacy concerns, Samsung has clarified that some of its so-called smart televisions listen in on the conversations of viewers only if the viewers permit the devices to do so.

Samsung responded to an uproar that began after the company recently updated a privacy policy for its Internet-connected Smart TV line of sets. The new language implied that Samsung eavesdrops on its users, describing in one sentence a voice recognition capability that allows viewers to operate their televisions with verbal commands.

“Please be aware that if your spoken words include personal or other sensitive information, that information will be among the data captured and transmitted to a third party through your use of Voice Recognition,” the sentence said.

Microsoft update mayhem delays German basketball game, costs team dear

17 minutes waiting proved to be just a bit too long



[DATA CENTER](#) [SOFTWARE](#) [NETWORKS](#) [SECURITY](#) [BUSINESS](#) [HARDWARE](#) [SCIENCE](#) [BOOTNOTES](#) [VI](#)



Erstwhile Microsoft boss Steve Ballmer likes a slam dunk, but still ...

31 Mar 2015 at 11:41, [Jennifer Baker](#)



66



17



8+



68

What's the worst thing that could happen when your Windows update takes longer than expected? Ask the Paderborn Finke Baskets, a German pro basketball team who got relegated thanks to Windows' sluggish performance.

FDA issues recall of 465,000 St. Jude pacemakers to patch security holes

Heart patients will have to visit their doctors to have their pacemakers patched for the "voluntary" recall -- but there are risks.



By [Charlie Osborne](#) for [Zero Day](#) | August 30, 2017 -- 10:31 GMT (03:31 PDT) | Topic: [Security](#)

Important Cybersecurity Advisory

Information About Cybersecurity Firmware Update for Accent™/ Anthem™, Accent MRI™, Assurity™/ Allure™, and Assurity MRI™ devices

28 August, 2017

Dear Doctor,

We are advising you of the availability of new pacemaker firmware (a type of software) that is intended to address the risk of unauthorized access to our pacemakers that utilize radio frequency (RF) communications (i.e., Accent™/ Anthem™, Accent MRI™, Assurity™/ Allure™, and Assurity MRI™). This firmware update provides an additional layer of security against unauthorized access to these devices that further reduces the potential for a successful cybersecurity attack.

Powerful Russian Orthodox cleric summoned to spritz computers with holy water to fight ransomware



Carson Block has a new short, and his reasoning is super creepy



LINETTE LOPEZ
10H

Muddy Waters, the firm founded by noted short-seller Carson Block, is short St. Jude Medical Inc.

The stock is down almost 7% on the news.

The firm says it's shorting St. Jude because its pacemakers are faulty and susceptible to cyberattacks.



~\$1 billion drop
August 2016

St. Jude stock tumbles as report questions company's cybersecurity

Short seller says half of firm's revenue may be at stake; St. Jude said report "absolutely untrue."

By Joe Carlson (<http://www.startribune.com/joe-carlson/271816721/>) Star Tribune |
AUGUST 25, 2016 — 9:03PM



Researchers: Evidence St. Jude report might not be accurate



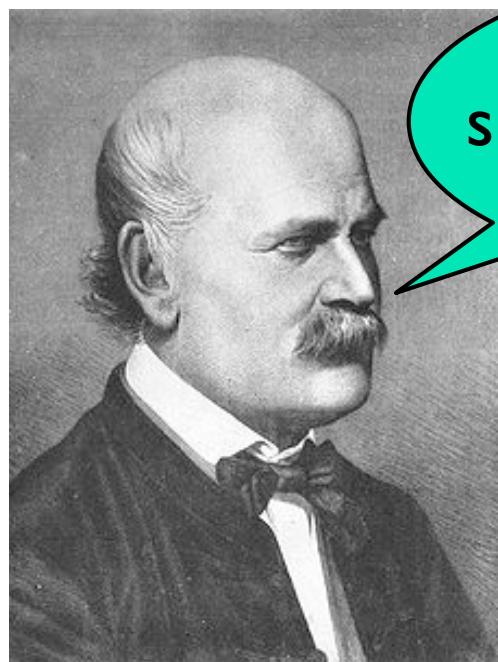
By Joe Uchill - 08/30/16 03:43 PM EDT

A prominent medical-device security expert tried to reproduce a purported hack of St. Jude Medical pacemakers and came to what a university press release called "strikingly different conclusions."

University of Michigan associate professor Kevin Fu, along with the Archimedes Center for Medical Device Security that he heads, tried to recreate a "crash attack" listed in a controversial report released last week. What they found was evidence that the report is in error.

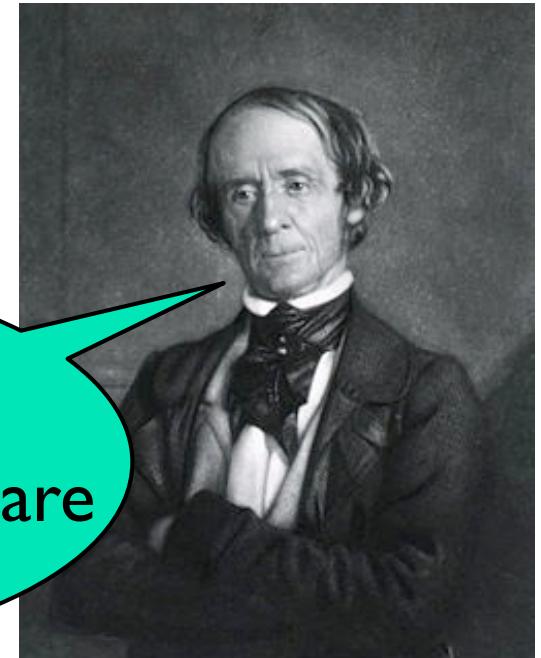
Semmelweis to Software Sepsis

1. Implantable medical devices should be trustworthy
2. Improved security will enable medical device innovation



Physicians
should their wash
hands.

Doctors
are gentlemen and
therefore their hands are
always clean.



Dr. Ignaz Semmelweis
1818-1865

Dr. Charles Meigs
1792-1869

**What are the benefits of
software in medical devices?**

Benefits of Medical Device Software

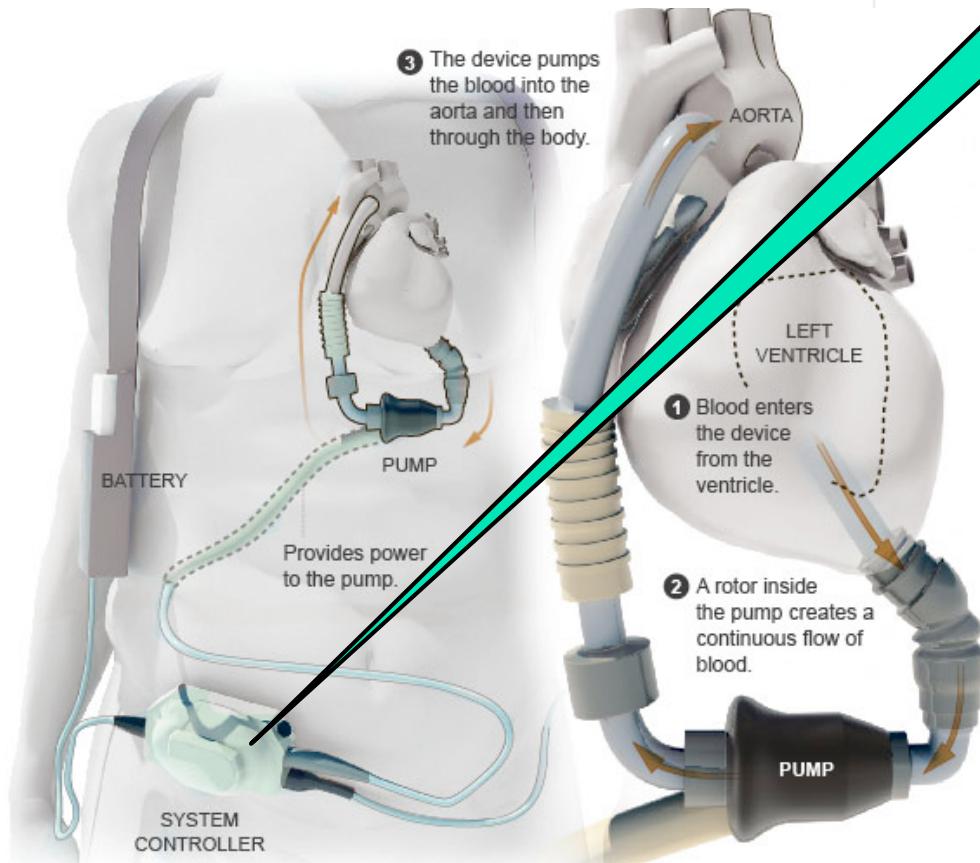
DOCTOR'S WORLD

A New Pumping Device Brings Hope for Cheney

By LAWRENCE K. ALTMAN, M.D.

Published: July 19, 2010

The New York Times July 19, 2010



Computer

"Recent reports show improvement over the earlier model mechanical hearts"

Source: NY Times, Thoratec

Without software,
many medical treatments
could not exist.

Medical Devices 101:

A 10-minute residency



“Nurse, get on the Internet, go to SURGERY.COM, scroll down and click on ‘Are you totally lost?’ icon.”

How Much SW in Medical Devices?

- 1983-1997
 - 6% of all recalls attributed to SW
- 1999-2005
 - **Almost doubled:** 11.3% of all recalls attributed to SW
 - 49% of all recalled devices relied on software (up from 24%)
- 1991-2000
 - **Doubled:** # of pacemakers and ICDs recalled because of SW
- 2006
 - Milestone: Over half of medical devices now involve software
- 2002-2010
 - 537+ recalls of SW-based devices affecting 1,527,311+ devices

Overconfidence in Software

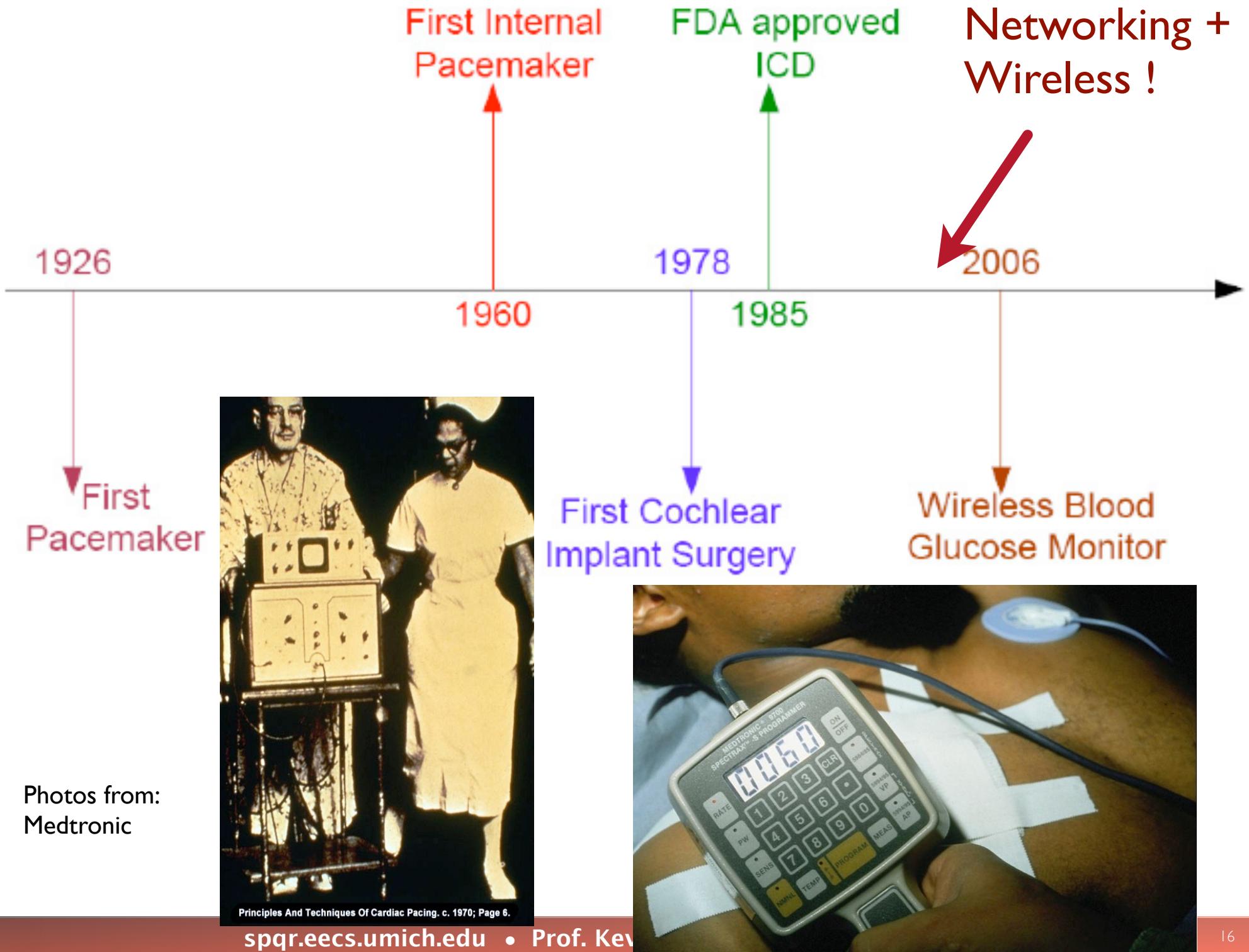
IEEE Computer 1993

An Investigation of the Therac-25 Accidents

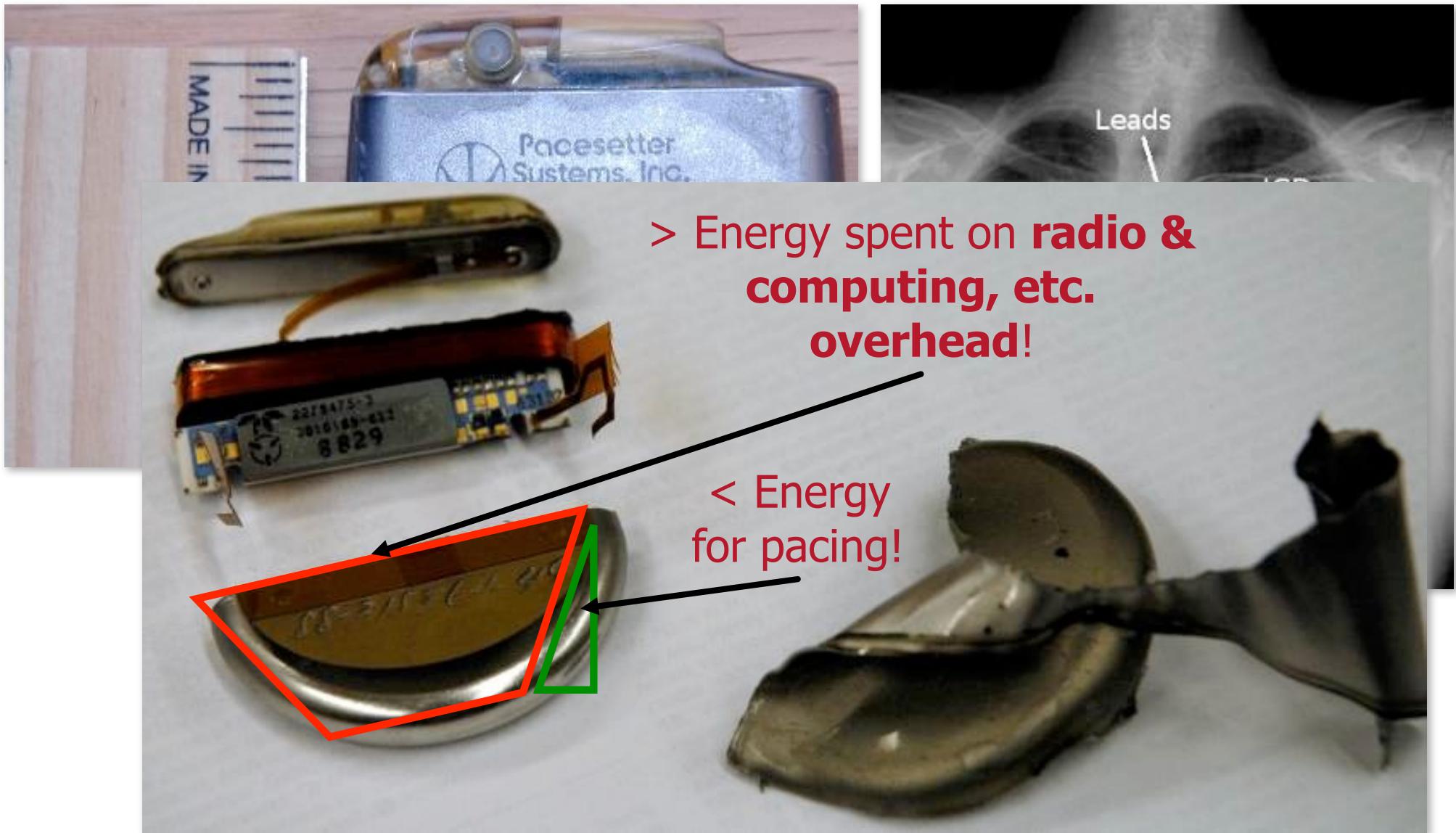
Nancy G. Leveson, University of Washington

Clark S. Turner, University of California, Irvine

``...the machine could not possibly over treat a patient and ... no similar complaints were submitted...”
[Leveson & Turner, 1993]



Pacemakers: Regulate heartbeat



Wireless medical devices: great benefits. subtle inconvenient risks.

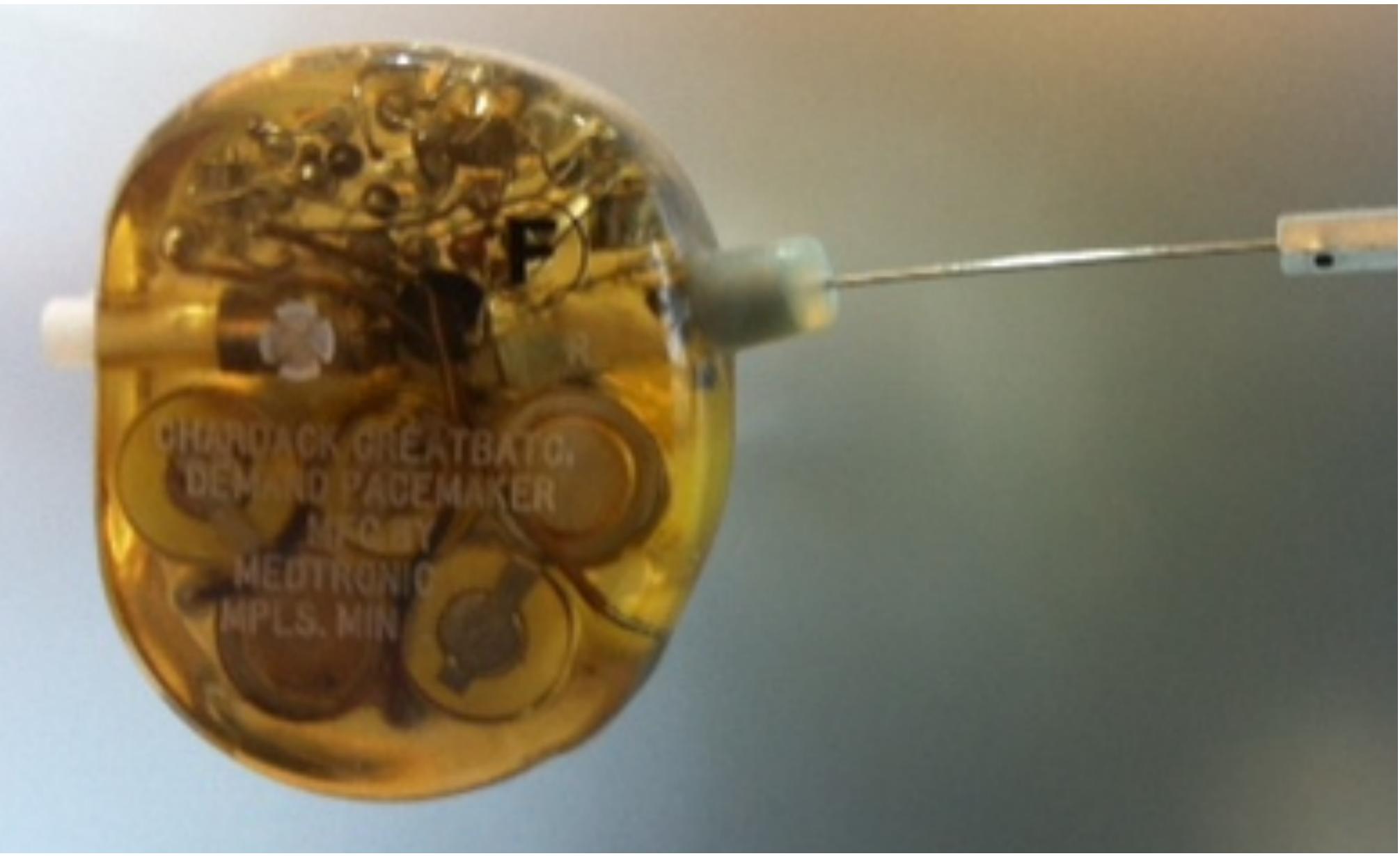
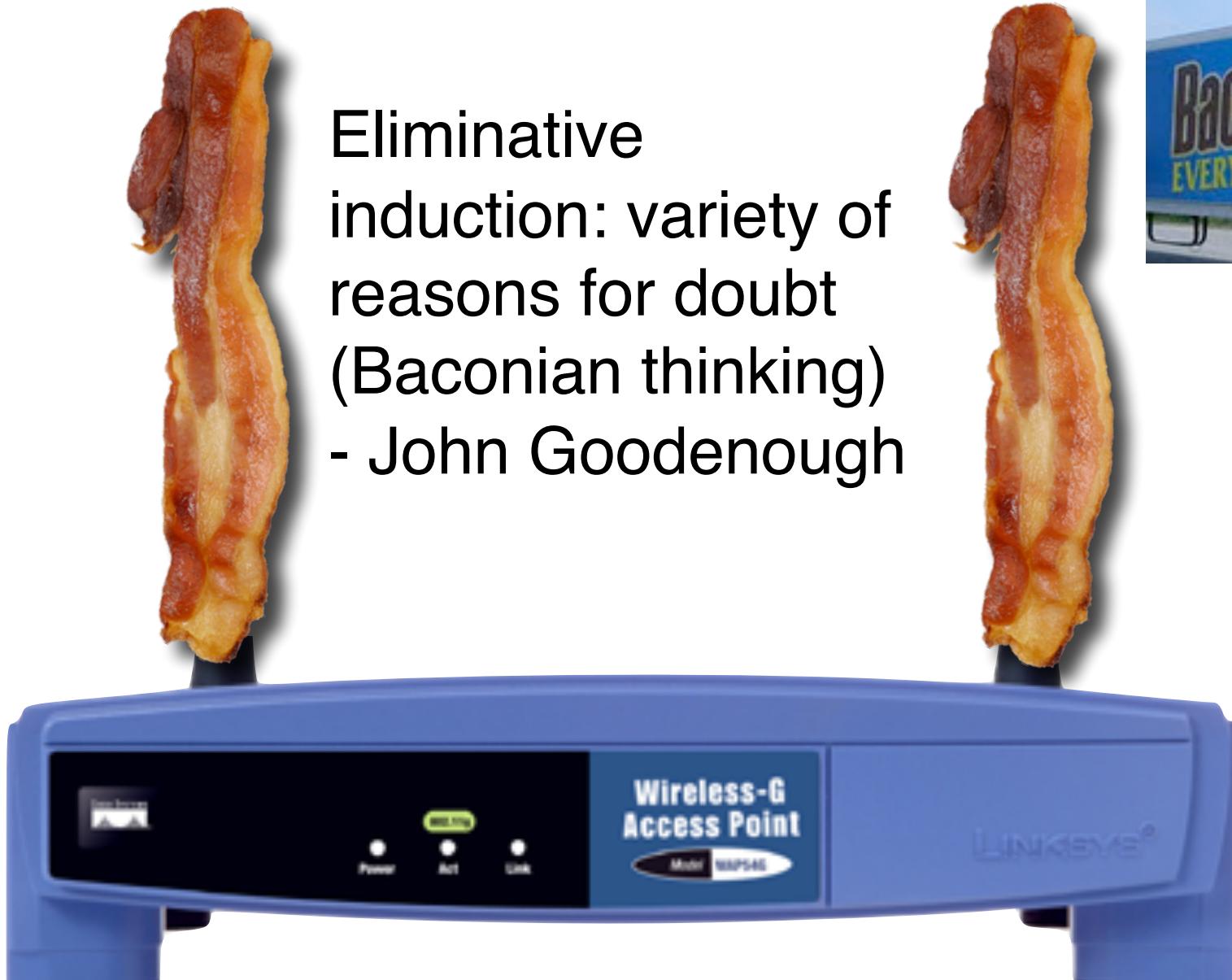


Photo by Kevin Fu @ Medtronic museum

Wireless Makes Everything Better?



Eliminative
induction: variety of
reasons for doubt
(Baconian thinking)
- John Goodenough





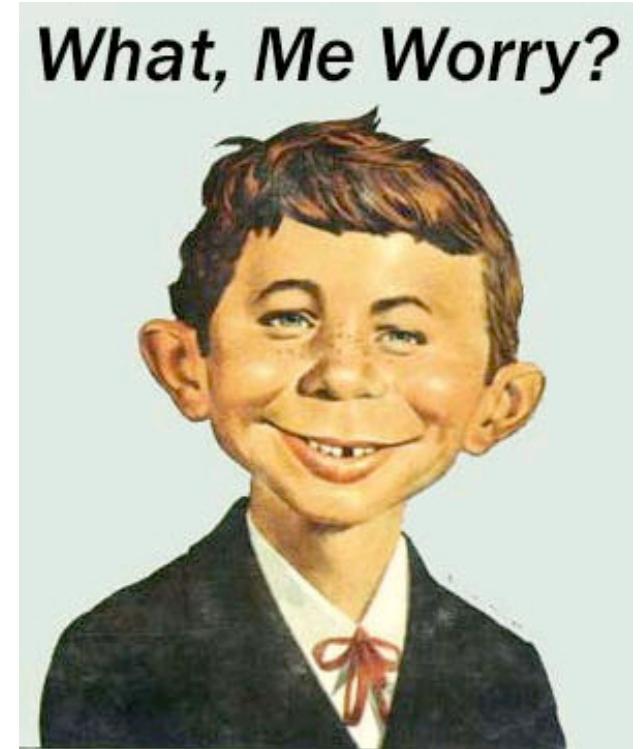
“Safe, secure, and reliable **wireless medical device** systems require... focus on wireless performance, **security**, and EMC.”

-Don Witters, FDA CDRH

Wireless Security

- ▶ **Wireless security issues**
 - ▶ Open architecture
 - ▶ Multiple combinations of technology
 - ▶ Rogue wireless users
 - ▶ Health Insurance Portability and Accountability Act (HIPAA) issues
- ▶ **Wireless security considerations**
 - ▶ Authentication – to ensure authorized users
 - ▶ Encryption – to secure sensitive data and wireless links

What about Internet-related risks?



**"These days, everything is much safer.
It is easier to navigate thanks to modern
technical instruments and the Internet."**

-Captain Schettino, Captain of **Costa Concordia**



**Shipwreck
as seen
from
space.**

Credit: DigitalGlobe

Why Is Software Different?

- Discrete (not continuous)
 - 0.9999 inch nail vs. 1.0001 inch nail: Small error usually OK
 - Single error in software: 20mL versus 200mL infusion
 - Generally no analogous notion of safety margin
- Cannot be tested thoroughly

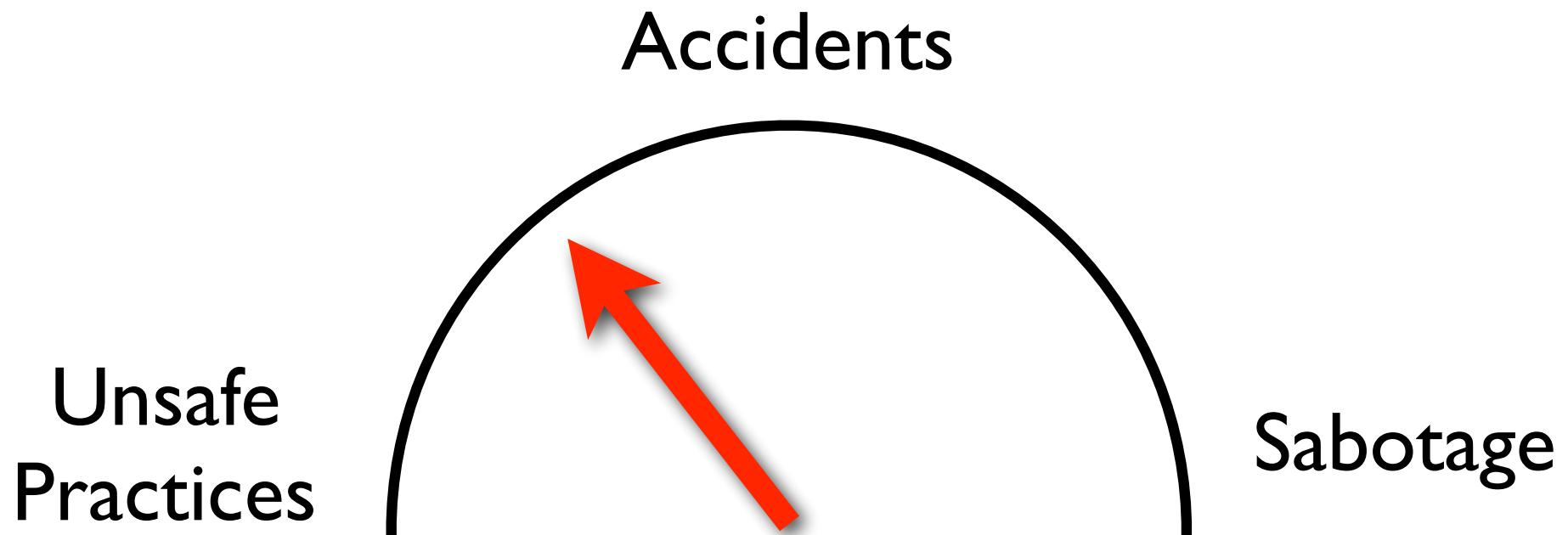
(radiation therapy)

``...there is **not enough time** ... to check the behavior of a complicated device to **every** possible, conceivable kind of **input**,' said Dr. Williamson...."

[Walt Bogdanich, NY Times, 1/26/2010]

[Source: Parnas 1985, Pfleeger et al. 2001]

Accumulative Risks of...



Threat-o-meter

Symptom: Implementation Errors



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A-Z Index

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FDA Home > Medical Devices > Databases

MAUDE Adverse Event Report



510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

- Factor: Buffer overflow shut down infusion pump
 - Failure **difficult to reproduce** during service

- Software upgrade tickled the coding error

- Caused failure of drug infusion
 - propofol (sedation/anesthetic)

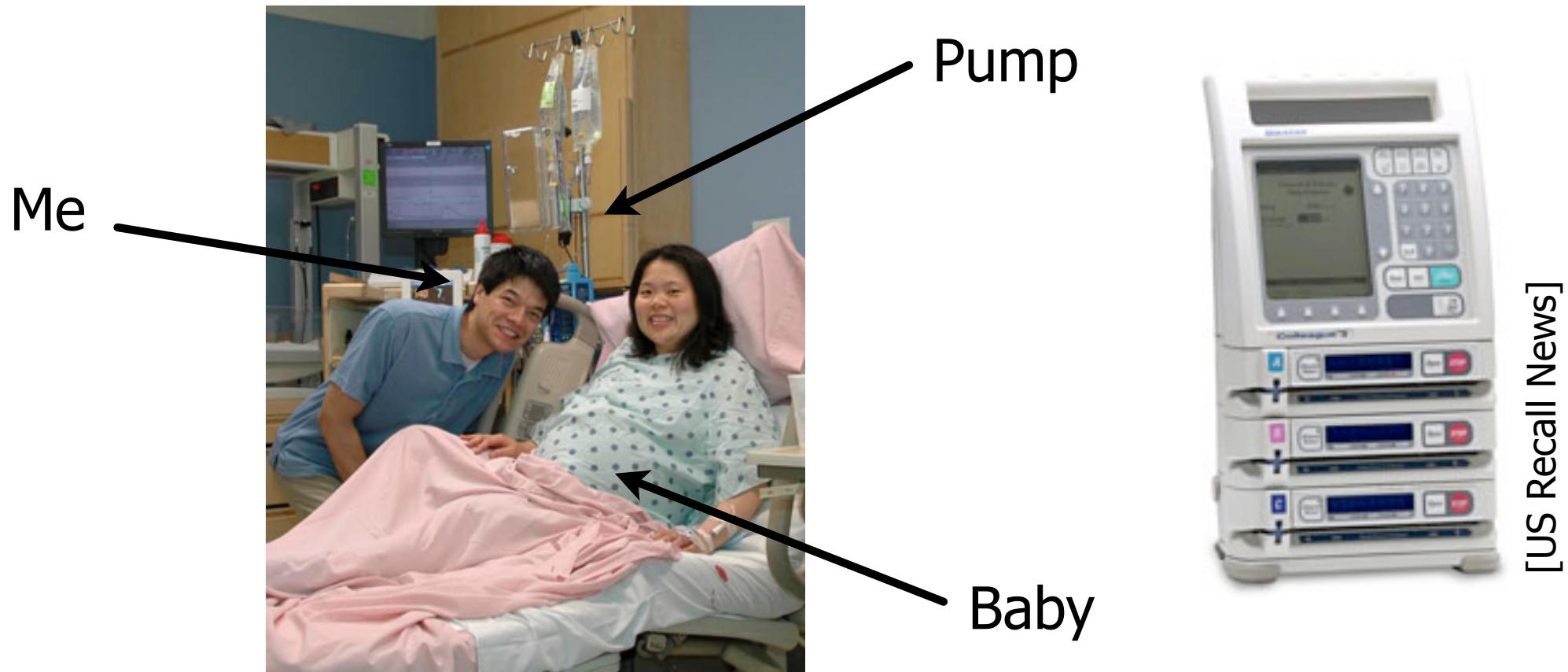
Evaluation of the device indicates the reported condition of fail code 16:310 was confirmed but could not be duplicated during service. The pump passed power on self-test on ac. The front bezel was opened & a visual inspection of all wires, harness connections, and user interface module printed circuit board was performed. The master and slave software programmable read only memory were found inserted correctly. No visual damage was found. The batteries had 10 charge/discharge cycles & 0 discharges below alarm threshold. The pump passed the keypad test. The device has been returned to baxter technical service for repair.

- The buffer overflow issue resulting in failure code 16:310 found in the software version utilized in colleague infusion pumps has been found to be repeatable in a specific clinical situation, and has resulted in multiple patient adverse events over a short period of time following initiation of deployment of this software version in the us. The issue is caused by an overflow in the memory buffer that feeds the main processor. The c2006 software version includes several changes that have increase the utilization level of this buffer, resulting in a higher probability of overflow. For the version of software utilized in pumps outside of the us (vb), including the one involved in this complaint from another country, the buffer utilization level is significantly lower. The complaint rate for the vb software is

What about human factors and software?

Infusion Pump UI and Software

- Used safely and effectively every day, but...
- Linked to **500+ deaths** and 56,000 adverse events

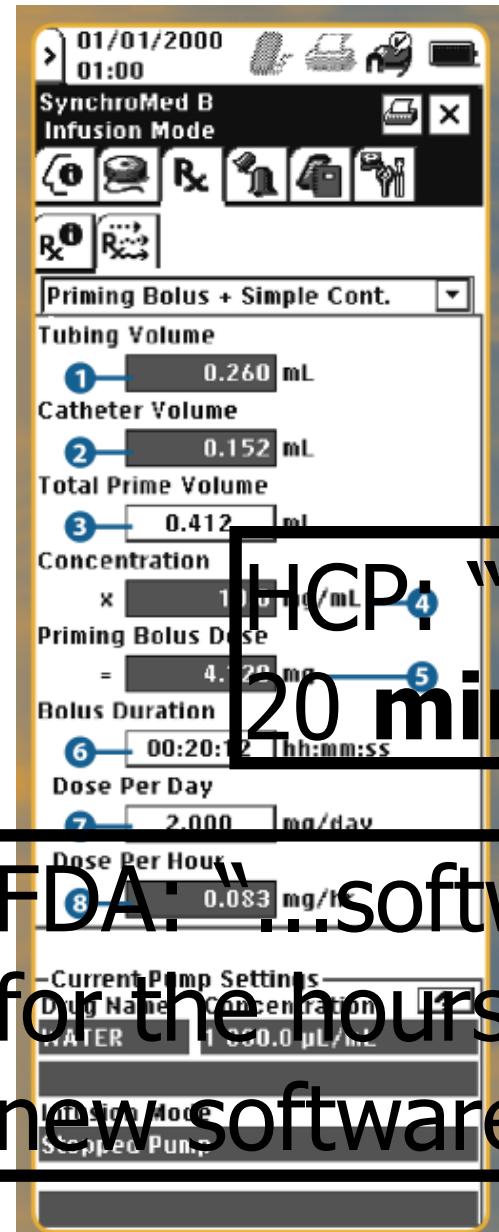


Pump+SW Problems=Deadly Cocktail

- "... 710 patient deaths linked to problems with the devices ... either because a hospital worker **entered incorrect dosage** data into a pump or because the device's **software malfunctioned.**"

[Barry Meier, NY Times, 4/23/2010]

User Interface: Timing is Everything



FDA U.S. Food and Drug Administration

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FDA Home > Medical Devices > Databases

MAUDE Adverse Event Report

CDRH SuperSearch

510(k) | Registration & Listing | Adverse Events | Recalls | PMA | Classification | Standards
CFR Title 21 | Radiation-Emitting Products | X-Ray Assembler | Medsun Reports | CLIA

NEURO N'VISION PROGRAMMER [Back to Search Results](#)

Model Number 8840
Device Problems Use of Device Issue; Improper or incorrect procedure or method
Event Date 04/30/2004
Event Type Death **Patient Outcome** Death;
Event Description

Mfr's rep reported the pt presented in 2004 for a pump refill. The pt had symptoms of withdrawal including nausea and vomiting. The pump alarm had previously been disabled by the Rep. A drug change was made at that refill. The patient left the clinic on their accord. The pt passed out while driving and was involved in a motor vehicle accident. The pt was transported via ambulance to the hospital. The pt was unconscious, intubated, given narcotics and admitted to the intensive care unit. The HCP was then notified and went to the hospital and stopped the pump. The physician read through the programming screens and discovered a bolus had been given in 20 min versus the intended 20 hrs. The pt was in a comatose condition. The pt's family then took the pt off life-supporting equipment (unk date) and the pt died.

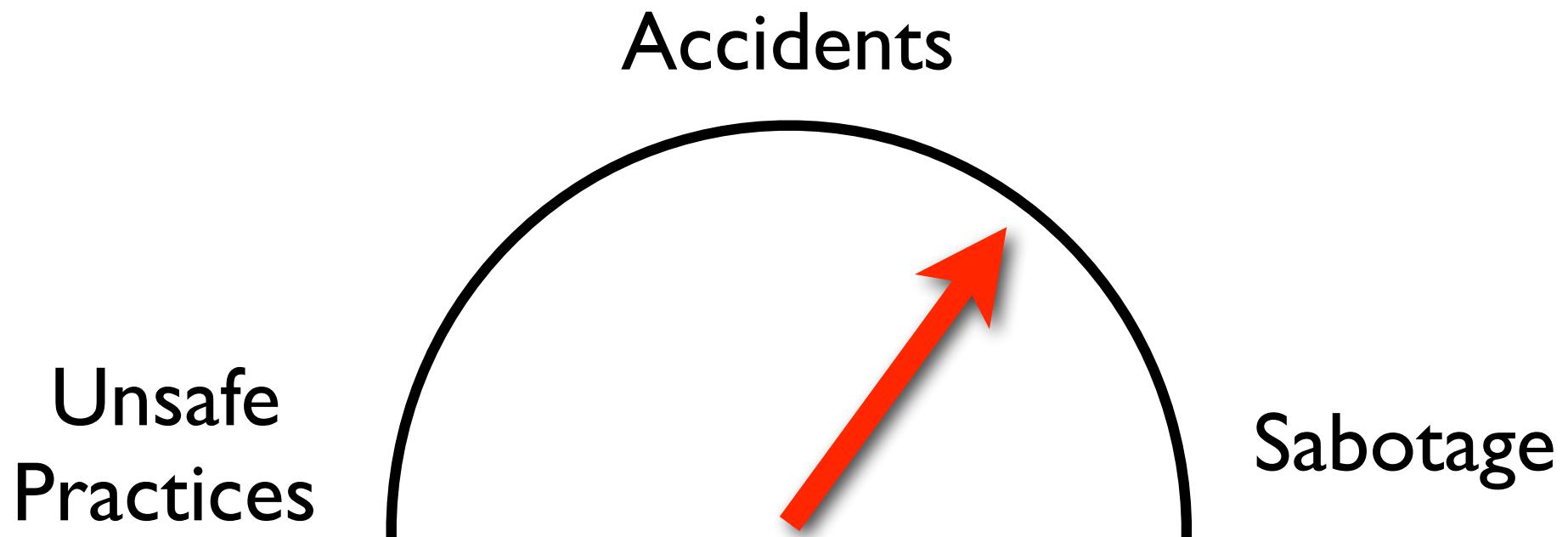
[Search Alerts/Recalls](#)

HCP: "discovered a bolus was given in 20 min versus the intended 20 hrs"

FDA: "...software... did not provide a label for the hours/minutes/seconds fields; the new software has this labeling."

Better analysis of human factors in SW could prevent injury and death.

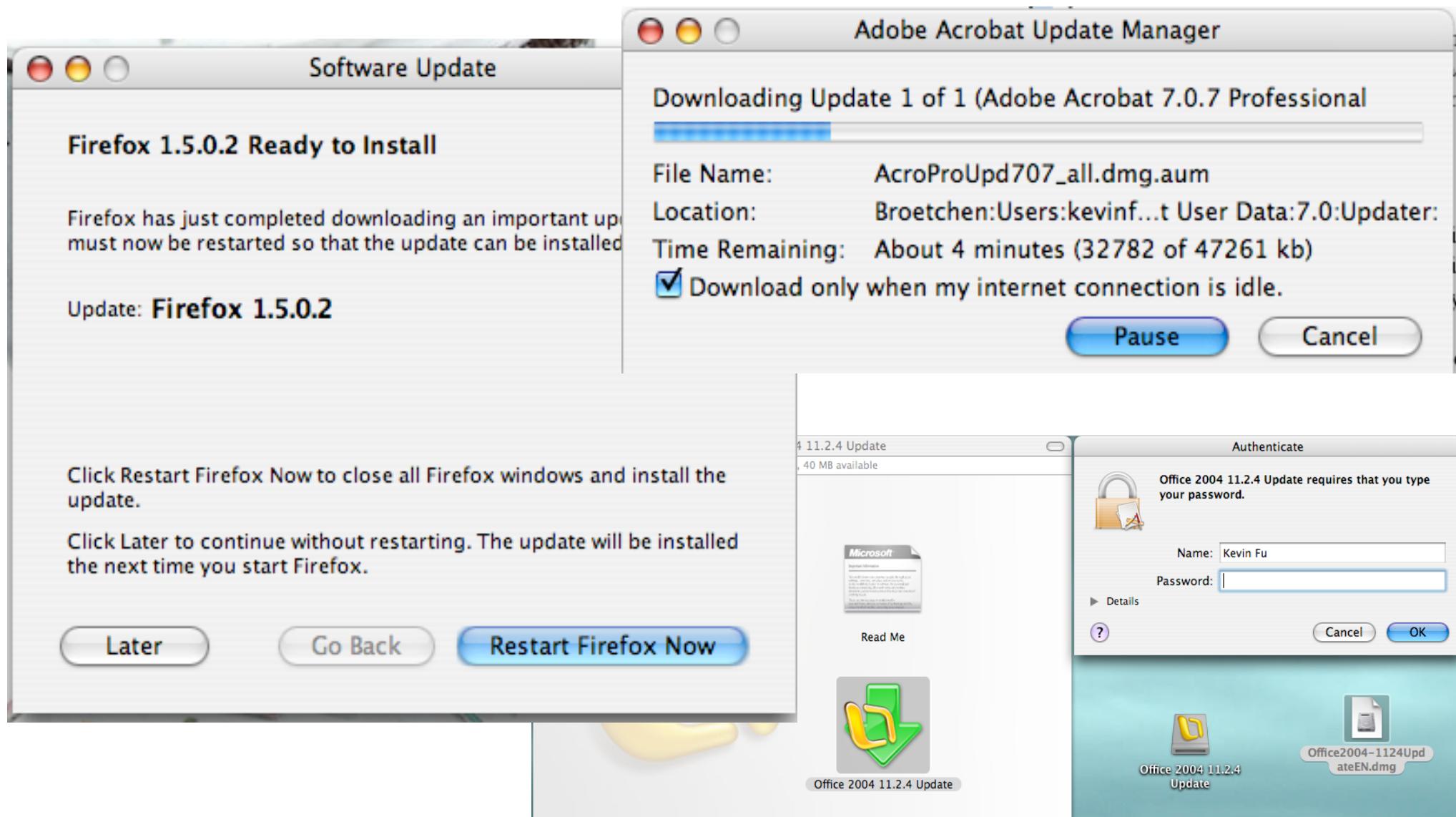
Accumulative Risks of...



Threat-o-meter

Managerial issues: Diffusion of responsibility

Dirty Secrets: SW Maintenance



Software Update Woes

- Health Information Technology (HIT) devices globally rendered unavailable
- Cause: Automated software update went haywire
- Numerous hospitals were affected April 21, 2010
 - Rhode Island: a third of the hospitals were forced ``to postpone elective surgeries and stop treating patients without traumas in emergency rooms.''
 - Upstate University Hospital in New York: 2,500 of the 6,000 computers were affected.

THE VANCOUVER SUN

Web-security giant McAfee paralyzes computers at hospitals, universities worldwide with update



WHAT?

What does end of support mean to customers?



It means you should take action. After April 8, 2014, there will be no new security updates, non-security hotfixes, free or paid assisted support options or online technical content updates.

Running Windows XP SP3 and Office 2003 in your environment after their end of support date may expose your company to potential risks, such as:

- **Security & Compliance Risks** - Unsupported and unpatched environments are vulnerable to security risks. This may result in an officially recognized control failure by an internal or external audit body, leading to suspension of certifications, and/or public notification of the organization's inability to maintain its systems and customer information.
- **Lack of Independent Software Vendor (ISV) & Hardware Manufacturers support** - A recent industry report from application innards found that 80% of ISVs and 70% of hardware manufacturers do not support Windows XP SP3.

Get customer
more flexibility
security
virtualization

Products Released	Lifecycle Start Date	Mainstream Support End Date	Extended Support End Date	Service Pack Support End Date
Windows XP Embedded	1/30/2002	1/11/2011	1/12/2016	10/22/2004
Windows XP Professional	12/31/2001	4/14/2009	4/8/2014	8/30/2005
Windows XP Service Pack 1	8/30/2002	Not Applicable	Not Applicable	10/10/2006

To help you get started in deploying a modern PC today, download the Microsoft Deployment Toolkit.
[Download Free tool now.](#)

How will Microsoft help customers?

Still Not It: Hospitals, Manufacturers



U.S. Department of Health & Human Services

www.hhs.gov

FDA U.S. Food and Drug Administration

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Medical Devices

Home > Medical Devices > Medical Device Safety > Alerts and Notices (Medical Devices)



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Medical Device Safety

Alerts and Notices (Medical Devices)

Information About Heparin

Luer Misconnections

Safety Communications

Public Health Notifications (Medical Devices)

Tips and Articles on Device Safety

Patient Alerts (Medical Devices)

Reminder from FDA: Cybersecurity for Networked Medical Devices is a Shared Responsibility

Issued

November 4, 2009

For

Medical device manufacturers, hospitals, medical device user facilities, healthcare IT and procurement staff, medical device users, biomedical engineers

Issue

FDA wants to remind you that cybersecurity for medical devices and their associated communication networks is a shared responsibility between medical device manufacturers and medical device user facilities. The proper maintenance of cybersecurity for medical devices and hospital networks is vitally important to public health because it ensures the integrity of the computer networks that support medical devices.

FDA is aware of misinterpretation of the regulations for the cybersecurity of medical devices that are connected to computer networks. FDA's interpretation of the regulations can be found in the 2005 guidance for industry and its accompanying information for healthcare organizations.

FDA Cybersecurity Guidance

Content of Premarket Submissions for Management of Cybersecurity in Medical Devices

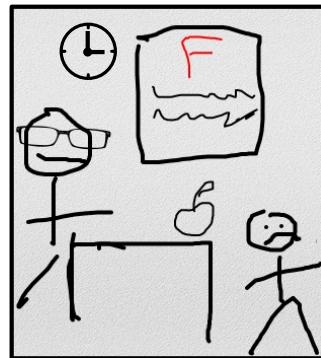
Guidance for Industry and Food and Drug Administration Staff

Document Issued on: October 2, 2014

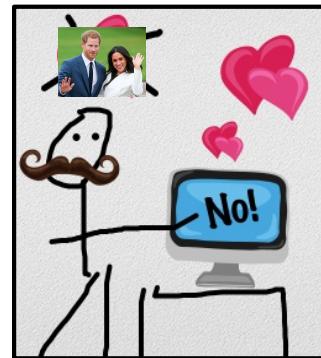
The draft of this document was issued on June 14, 2013.

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.

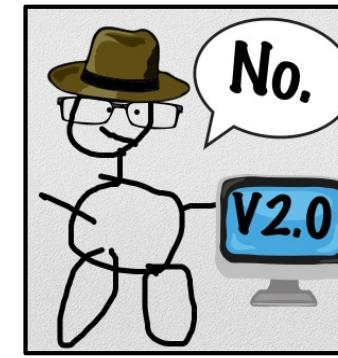
Homework
prevents me
from passing
class.



eHarmony
prevents me
from getting
dates.



FDA rules
prevent
software
updates.



BULLSHIT.

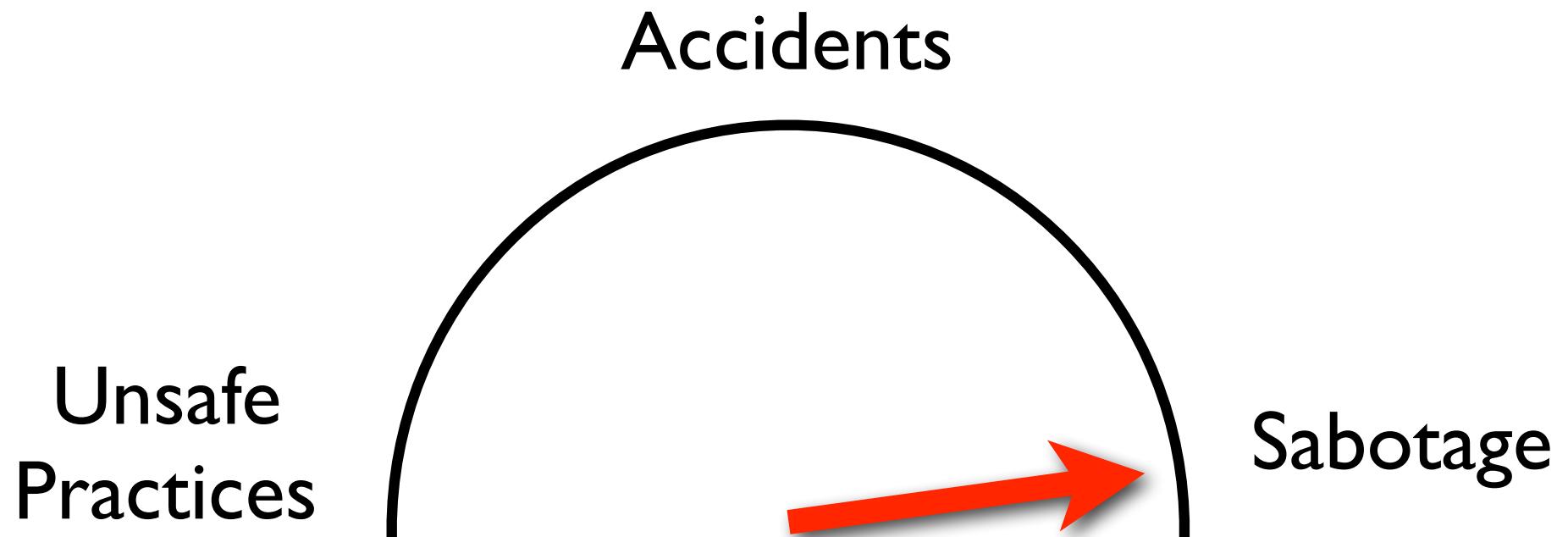
Get with the program.

Distribute software updates regularly to address
known vulnerabilities in Windows XP.
blog.secure-medicine.org

Managerial issues: Diffusion of responsibility

Who's covered when
Secure Health IT hits the fan?

Foreseeable Cybersecurity Risks...



Foreseeable risk-o-meter

Short History: Medical Devices & SW

- Therac-25 analysis by Leveson & Clark in IEEE Computer, 1993.
- Defibrillator cybersecurity by Halperin et al. in IEEE Symposium on Security & Privacy, 2008.
- Insulin pump analysis, 2011 [several]

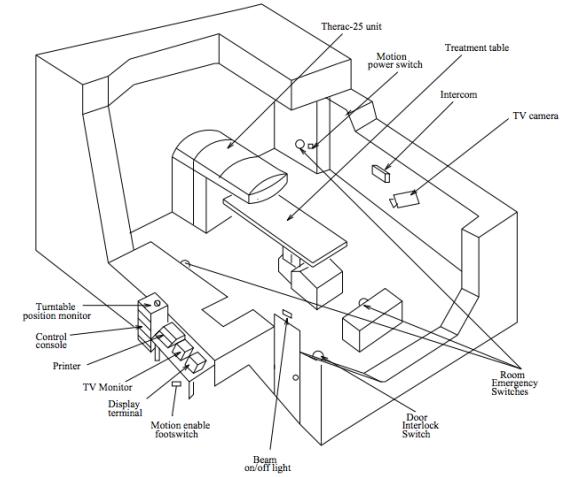


Figure 5: A typical Therac-25 facility after the final CAP.

Photos: Leveson, Fu

Short History: Medical Devices & SW

- Therac-25 analysis
[Leveson & Clark, IEEE Computer, 1993]
- Defibrillator cybersecurity
[Halperin et al., IEEE Symposium on Security & Privacy, 2008.]
- Insulin pump analysis, 2011 [several]
- Defib jamming defense
[Gollakota et al., ACM SIGCOMM 2011]
- Pacemaker hack reproduced
[Barnaby Jack, BlackHat 2012]
- WattsUpDoc defense
[Clark et al., USENIX HealthTech 2013]

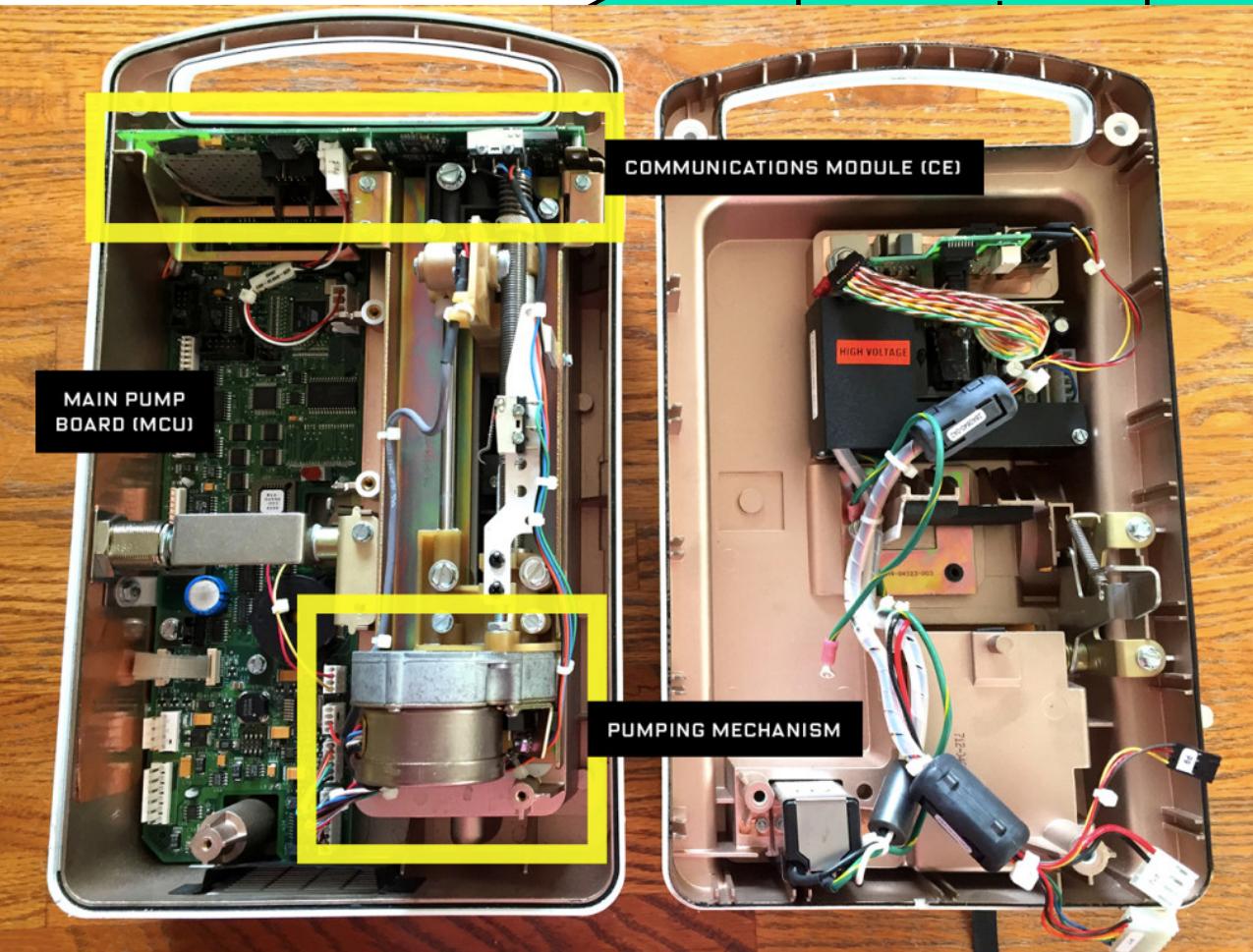


Photos: Leveson, Fu

Short History: Medical Devices & SW

- Hospira Infusion Pump V-Series Vulnerabilities
[Billy Rios and more]

Wireless



Photos: Wired

Implantation of Defibrillator

1. Doctor sets patient info
2. Surgically implants
3. Tests defibrillation
4. Ongoing monitoring



Device Programmer
Home monitor

Photos: Medtronic; Video: or-live.com

Privacy??

Terminal — less — 91x26

Implanting physician

Diagnosis

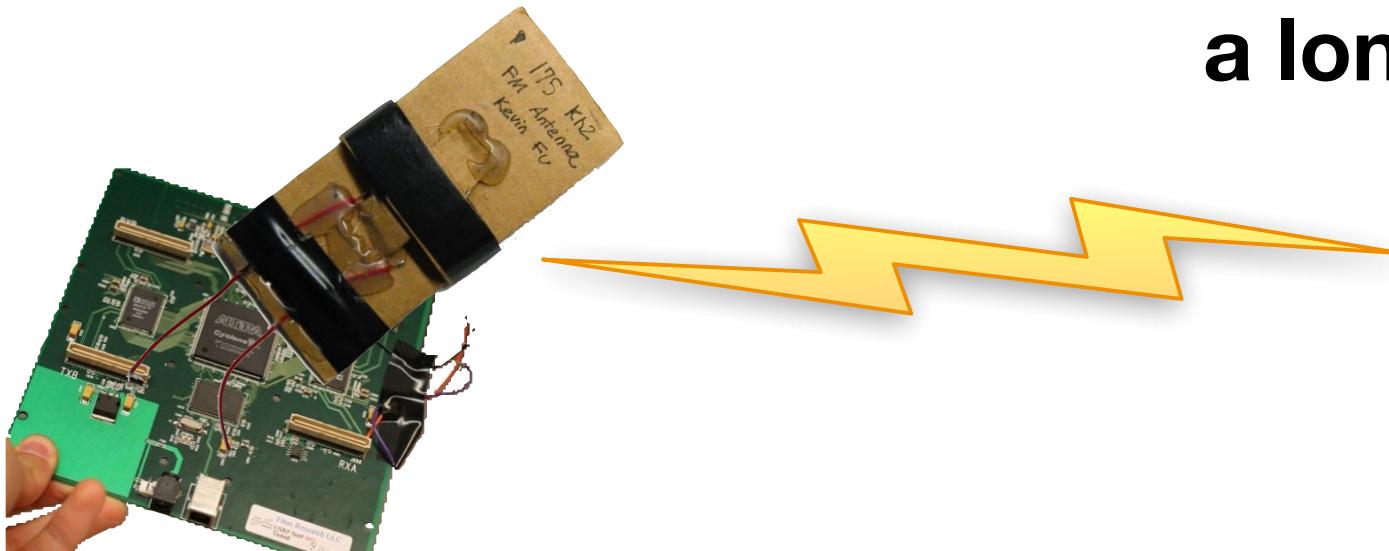
Hospital

Also:
Device state
Patient name
Date of birth
Make & model
Serial no.
... and more

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
- No RF amplification necessary

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



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

Video and Exercise

- Design an authentication system for pacemakers
- Requirements
 - Patient outcomes must improve: safety and effectiveness
 - Security
 - Privacy
- What are the engineering tensions and challenges?
- How can we solve?

AED Firmware Replacement



- Device accepts unauthentic firmware updates
- How do risks change when AEDs become wireless with Internet-based software updates?

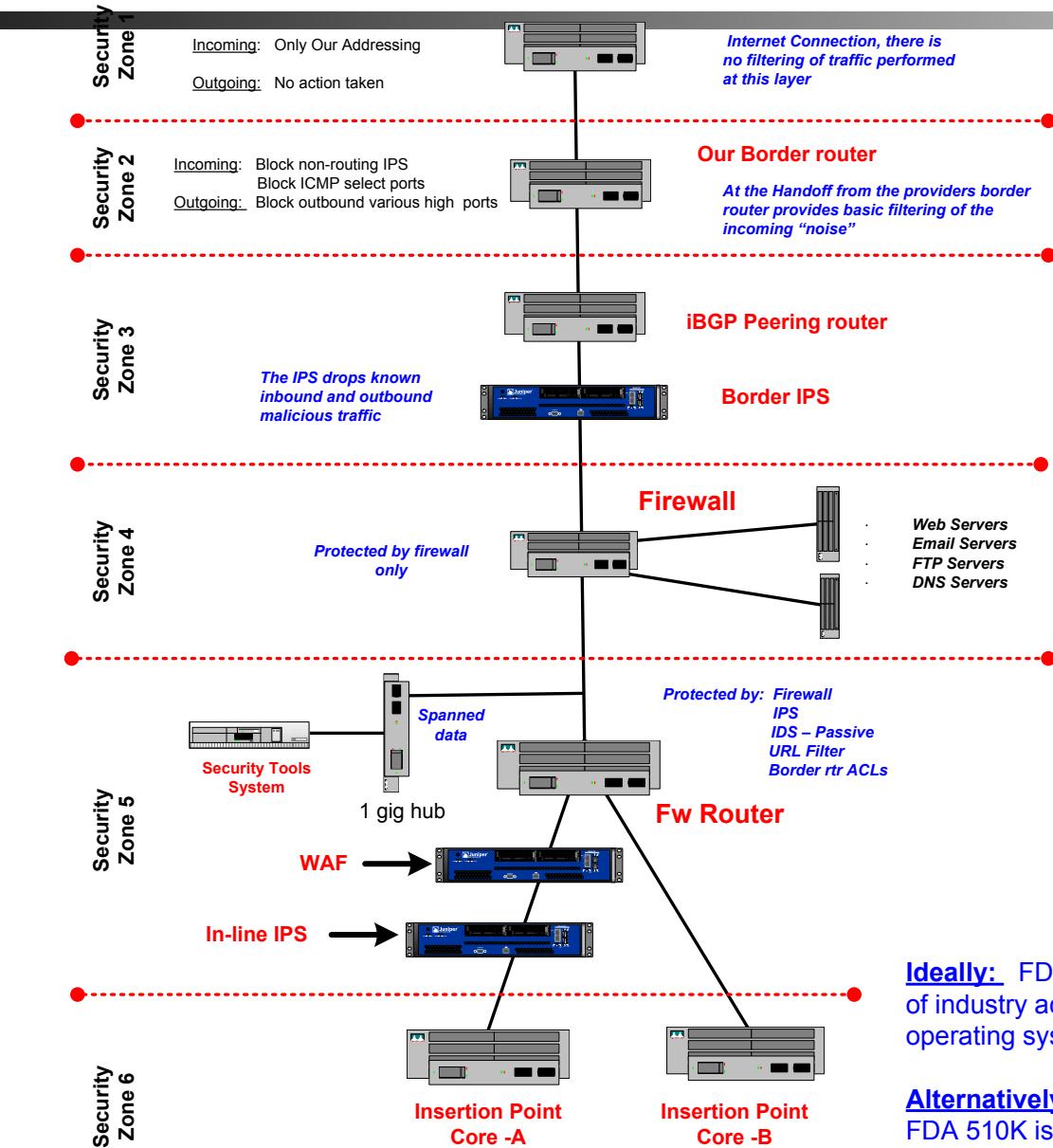
DEVICE COMPROMISED

Hospitals & Malware



[Photo: Medical Real Estate Advisors and Kevin Fu]

Hospitals Stuck With Windows XP



General System Counts

Systems with AV.....	6398
Printers.....	2074
Medical equipment....	905
Misc.....	2460
Total Devices:.....	11837

OS Makeup – Medical

Windows 95.....	1
Windows 98	15
Windows 2000.....	23
Windows CE.....	9
Windows Vista.....	0
Windows XP.....	600
Windows XP SP1.....	0
Windows XP SP2....	15
Windows XP SP3.....	1
Total.....	664

Last security patch: 2007

Average Time to Infection

Clinical Systems , 510K, no AV...: 12 days
Systems running AV/Patches.....: 300+ days

Ideally: FDA 510K is updated to include a requirement for the provision of industry accepted security controls for devices utilizing embedded operating systems or other controllers associated with a medical device

Alternatively: The FDA issues a clear statement to the community that FDA 510K is not jeopardized by permitting Anti-Virus or Operating System patching to the supporting systems associated with a certified medical device

Factory-installed malware?

More common than you might think

- Vendors with USB drives
- Vendors repairing infected machines
- Product assembly line

Shoot P0wn Foot w/ Software Update

Safe Browsing

Diagnostic page for www.viasyshealthcare.com

Advisory provided by 

What is the current listing status for www.viasyshealthcare.com?

This site is not currently listed as suspicious.

Part of this site was listed for suspicious activity 1 time(s) over the past 90 days.

What happened when Google visited this site?

Of the 291 pages we tested on the site over the past 90 days, 19 page(s) resulted in malicious software being downloaded and installed without user consent. The last time Google visited this site was on 2012-06-24, and the last time suspicious content was found on this site was on 2012-06-13.



Malicious software includes 38 trojan(s), 3 scripting exploit(s).

Malicious software is hosted on 4 domain(s), including nikju.com/, lilupophilupop.com/, koklik.com/.

This site was hosted on 1 network(s) including [AS26651 \(CAREFUSION\)](#).

Has this site acted as an intermediary resulting in further distribution of malware?

Over the past 90 days, www.viasyshealthcare.com did not appear to function as an intermediary for the infection of any sites.

Has this site hosted malware?

No, this site has not hosted malicious software over the past 90 days.

Next steps:

- [Return to the previous page](#).
- If you are the owner of this web site, you can request a review of your site using Google [Webmaster Tools](#). More information about the review process is available in Google's [Webmaster Help Center](#).

Updated 2 hours ago

Phone: 800.231.2466, ext 1
Email: support.vent.us@carefusion.com

EnVe

Waiter, there's a virus in my SW!

MAUDE Adverse Event Report: BAXA CORPORATIONBAXA EM2400 COMPOUNDER

» FDA Home » Medical Devices » Databases



[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [Recalls](#) | [PMA](#) | [Classification](#) | [Standards](#)
[CFR Title 21](#) | [Radiation-Emitting Products](#) | [X-Ray Assembler](#) | [Medsun Reports](#) | [CLIA](#) | [TPLC](#)

BAXA CORPORATION BAXA EM2400 COMPOUNDER

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Event Type Malfunction

Event Description

The (b) (6) pharmacy department uses a baxa em2400 compounder to make tpn's and other admixtures. Recently the compounder was infected with a virus. The virus has been contained on the em2400 compounder. It is unknown what effect this virus should have on the operating of the software. (b) (6) information systems department together with the pharmacy has requested that baxa provide a microsoft security patch to prevent this infection from occurring again. Baxa is unwilling to allow these patches to be applied to the baxa em2400. Instead baxa has recommend that we place a router with the functionality for a firewall between the compounder and the network (b) (4) as protection. In a single case, this may be a possible solution. (b) (6)'s manager indicates that if this was the routine solution, (b) (6) would then have to procure and maintain over 1000 routers institution wide. That approach is not sustainable by (b) (6) nor the marketplace. I am interested to hear about fda's requirement for medical devices to have security patches that protect the device from contamination.

[**Search Alerts/Recalls**](#)

Don't worry sir, they don't eat much!

MAUDE Adverse Event Report: BAXA CORP.EXACTA-MIX 2400

• FDA Home • Medical Devices • Databases



[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [Recalls](#) | [PMA](#) | [Classification](#) | [Standards](#)
[CFR Title 21](#) | [Radiation-Emitting Products](#) | [X-Ray Assembler](#) | [Medsun Reports](#) | [CLIA](#) | [TPLC](#)

BAXA CORP. EXACTA-MIX 2400

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Model Number EM 2400

Event Date 02/26/2010

Event Type Other

Manufacturer Narrative

The em2400 compounder is designed to not be connected directly to the facility network, but should be installed behind a firewall that provides a protected subnet for the device. The device should be used only in accordance with its intended use and not for email, internet access, file sharing or other non-approved use. The device is designed to only reach out to the facility's network to collect text-based pat files, back up device databases or to issue a print job. The em2400 compounder is hosted on a (b)(4)-based embedded operating system and has been verified and validated only with the software, operating system and patches that were installed by baxa. Thus, any changes to the original validated image, including installation of antivirus software, nullifies the validated state and could; therefore, constitute off-label use of this device. In addition, baxa does not regularly install operating system updates or patches, generally published by (b)(4), on this device. The online help file, preventing cyber attacks technical paper, specifies baxa's policies relating to product security and provides instructions for safeguarding baxa devices. If a device becomes infected, baxa technical support will send a replacement and assist the customer with proper facility network installation. Baxa has not received any reports of pt injury or illness as a result of this issue.

Event Description

Baxa received a letter from the fda on 04/08/2010 in reference to report number mw5014956. The report states that an em2400 compounder was infected with a virus. The customer requested that baxa provide a (b)(4) security patch to prevent the infection from occurring again. Upon receipt of the mw letter, the complaint database was reviewed to determine if an associated complaint was received by baxa prior to this report. No prior complaint was found. Therefore, a complaint was initiated to further investigate this issue. This mdr is being filed per baxa corporation's procedure to submit an mdr for all medwatch forms submitted.

Doctors...therefore always secure

As you are aware, on December 23rd an unknown **virus was found in the MacLab/CardioLab** system. [We] worked late into Christmas Eve in order to keep the infected MacLabs isolated. As a proactive measure and to prevent our patients from inappropriate release of protected healthcare information the hospital immediately blocked our access to the internet. Today [it was] announced that they have traced the virus path from [a] nursing workstation. Apparently pictures were uploaded from a USB drive to yahoo.

Sterile Technique or Software Sepsis?



A senior faculty member **serially infected a number of cath and EP lab systems**, and solved this problem by plugging thumb drives into a fellow's laptop to erase the malware he was spreading.

-Dr. Anonymous

Security and Privacy Qualities of Medical Devices: An Analysis of FDA Postmarket Surveillance

Regulators and manufacturers should carefully weigh the **premarket evaluation of security and privacy** elements of their devices and systems, and to design postmarket systems that enable effective collection of cybersecurity threat indicators for medical devices.

Methods: We used three comprehensive, publicly available databases maintained by the Food and Drug Administration (FDA) to evaluate recalls and adverse events related to security and privacy risks of medical devices.

Results: Review of weekly enforcement reports identified 1,845 recalls; 605 (32.8%) of these included computers, 35 (1.9%) stored patient data, and 31 (1.7%) were capable of wireless communication. Searches of databases specific to recalls and adverse events identified only one event with a specific connection to security or privacy. Software-related recalls were relatively common, and most (81.8%) mentioned the possibility of upgrades, though only half of these provided specific instructions for the update mechanism.

Conclusions: Our review of recalls and adverse events from federal government databases reveals sharp inconsistencies with databases at individual providers with respect to security and privacy risks. Recalls related to software may increase security risks because of unprotected update and correction mechanisms. To detect signals of security and privacy problems that adversely affect public health, federal postmarket surveillance strategies should rethink how to effectively and efficiently collect data on security and privacy problems in devices that increasingly depend on computing systems susceptible to malware.

How significant are
intentional,
malicious
malfunctions
in software?

21 CFR 211.132 and Security

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER C--DRUGS: GENERAL

PART 211 -- CURRENT GOOD MANUFACTURING PRACTICE FOR FINISHED PHARMACEUTICALS

Subpart G--Packaging and Labeling Control

Sec. 211.132 Tamper-evident packaging requirements for over-the-counter (OTC) human drug products.

(a) General. The Food and Drug Administration has the authority under the Federal Food, Drug, and Cosmetic Act (the act) to establish a uniform national requirement for tamper-evident packaging of OTC drug products that will **improve the security** of OTC drug packaging

The Tylenol Scare of 1982

The Tylenol Terrorist

[Print](#) [Email](#) [SHARE](#)

T Smaller | Larger

By Rachael Bell

The Tylenol Terrorist: Death in a Bottle



Extra-Strength Tylenol package

On September 29, 1982, 12-year-old Mary Kellerman of Elk Grove Village, Illinois, woke up at dawn and went into her parents' bedroom. She did not feel well and complained of having a sore throat and a runny nose. To ease her discomfort, her parents gave her one Extra-Strength Tylenol capsule. At 7 a.m. they found Mary on the bathroom floor. She was immediately taken to the hospital where she was later pronounced dead. Doctors initially suspected that Mary died from a stroke, but evidence later pointed to a more sinister diagnosis.

[Source: truTV crime library]

Fatal tampering case is renewed

FBI searches a condo in Cambridge



FBI agents carrying items seized from an apartment building on Gore Street in Cambridge walked out before a phalanx of television photographers. Five boxes and a computer were removed, but the FBI would not comment on their contents. (JIM DAVIS/GLOBE STAFF)

February 5, 2009

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Text size - +

This story was reported by Jonathan Saltzman, John R. Ellement, Milton J. Valencia, and David Abel of the Globe staff. It was written by Saltzman.

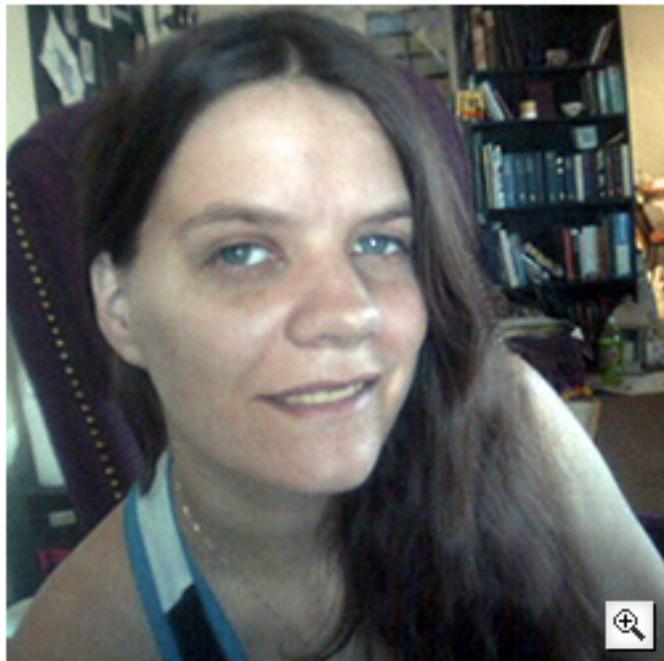
[Discuss](#)
[COMMENTS \(5\)](#)

CAMBRIDGE -- FBI agents and State Police investigators searched a Cambridge condominium yesterday that is the longtime home of a leading suspect in the 1982 deaths of seven people from cyanide-laced Tylenol capsules in the Chicago area, one of the most notorious unsolved crimes in the last generation.

Bad People Do Exist: Vandals

Hackers Assault Epilepsy Patients via Computer

By Kevin Poulsen  03.28.08 | 8:00 PM



RyAnne Fultz, 33, says she suffered her worst epileptic attack in a year after she clicked on the wrong post at a forum run by the nonprofit Epilepsy Foundation.
Photo courtesy RyAnne Fultz

Internet griefers descended on an epilepsy support message board last weekend and used JavaScript code and flashing computer animation to trigger migraine headaches and seizures in some users.

The nonprofit [Epilepsy Foundation](#), which runs the forum, briefly closed the site Sunday to purge the offending messages and to boost security.

"We are seeing people affected," says Ken Lowenberg, senior director of web and print publishing at the Epilepsy Foundation. "It's fortunately only a handful. It's possible that people are just not reporting yet -- people affected by it may not be coming back to the forum so fast."

The incident, possibly the first computer attack to inflict physical harm on the victims, began Saturday, March 22, when attackers used a script to post hundreds of messages embedded with flashing animated gifs.

The attackers turned to a more effective tactic on Sunday, injecting JavaScript into some posts that redirected users' browsers to a page with a more complex image designed to trigger seizures in both photosensitive and pattern-sensitive epileptics.

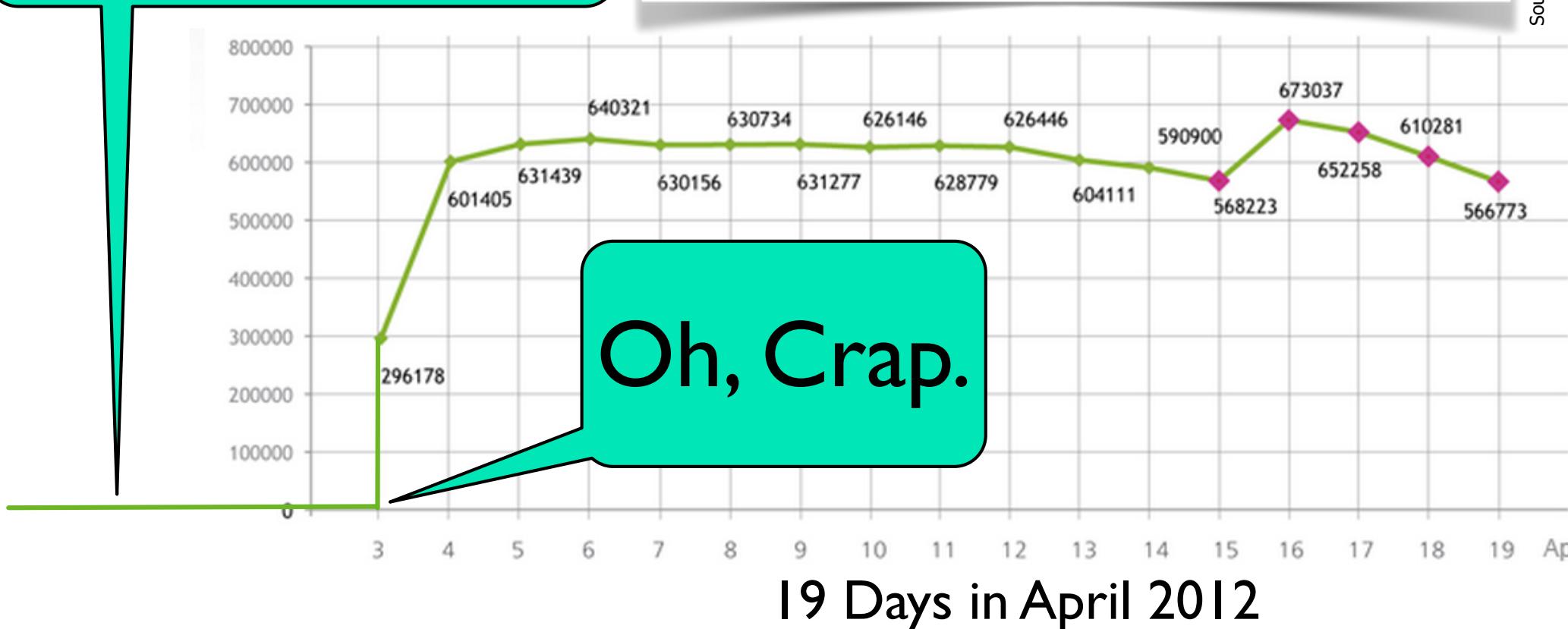
Lack of Exploits is Not Assurance

Pre-April 2012:
No Mac threats,
therefore never will be.

SECURITY | 4/20/2012 @ 5:28PM | 2,173 views

Antivirus Researchers Confirm:
Flashback Still Infects More
Than 500,000 Macs

Source: Andy Greenberg, Forbes



Achoo!



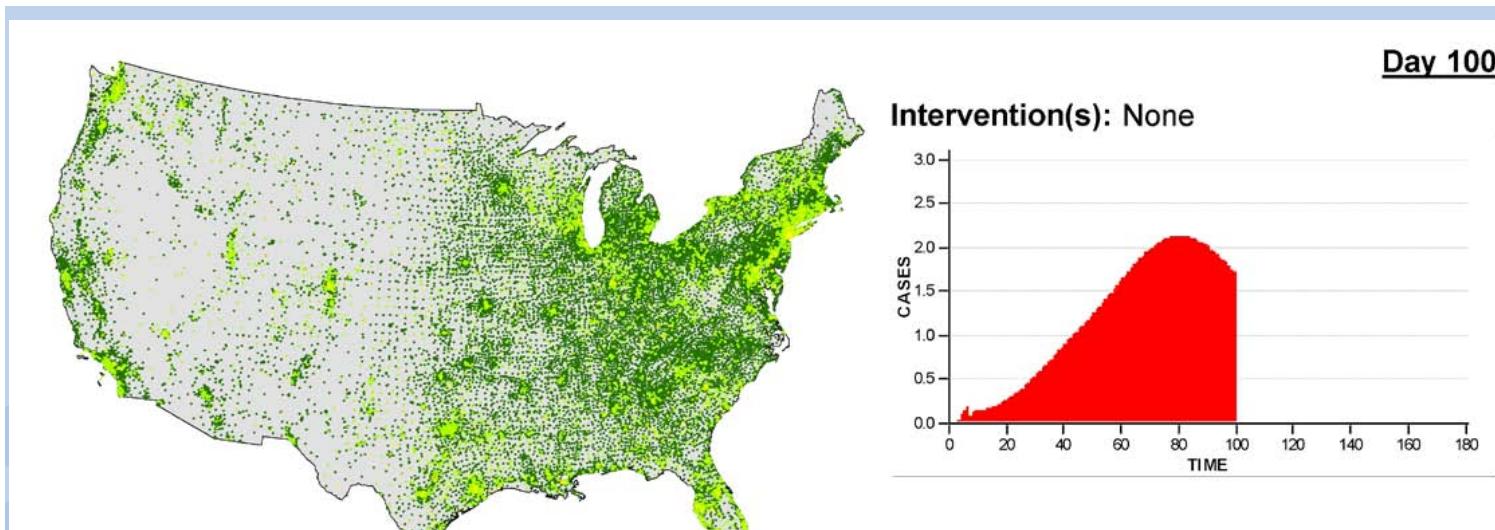
The Weekly World News:
world's only reliable journal

Security of 156 VA Med. Centers

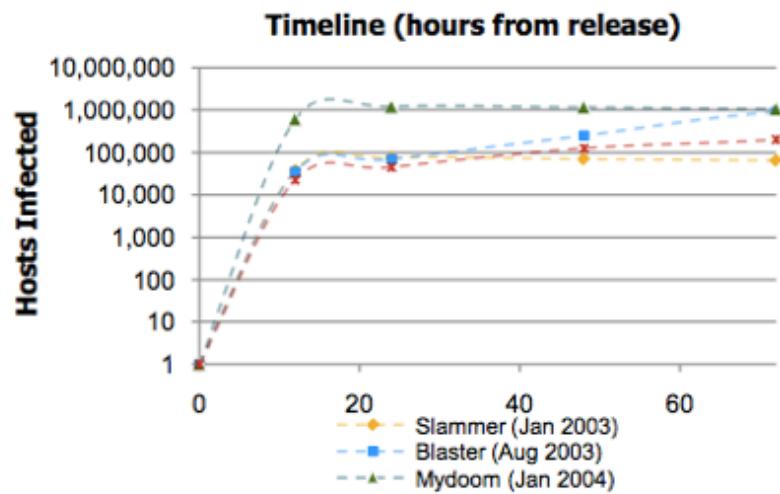
- Every **8 seconds**, the VA still finds usernames and **passwords** unprotected in networks
- VA has ~**600,000** connected computing devices, of which **50,000** are considered medical devices
- VA implemented VLANs with **3,270 different ACLs**
- Manual maintenance of ACLs prone to human error
- ACLs broke network security tools that detect intrusions

[Source: Lynette Sherrill, VA Field Security Office]

Disease to Malware: Days to Hours

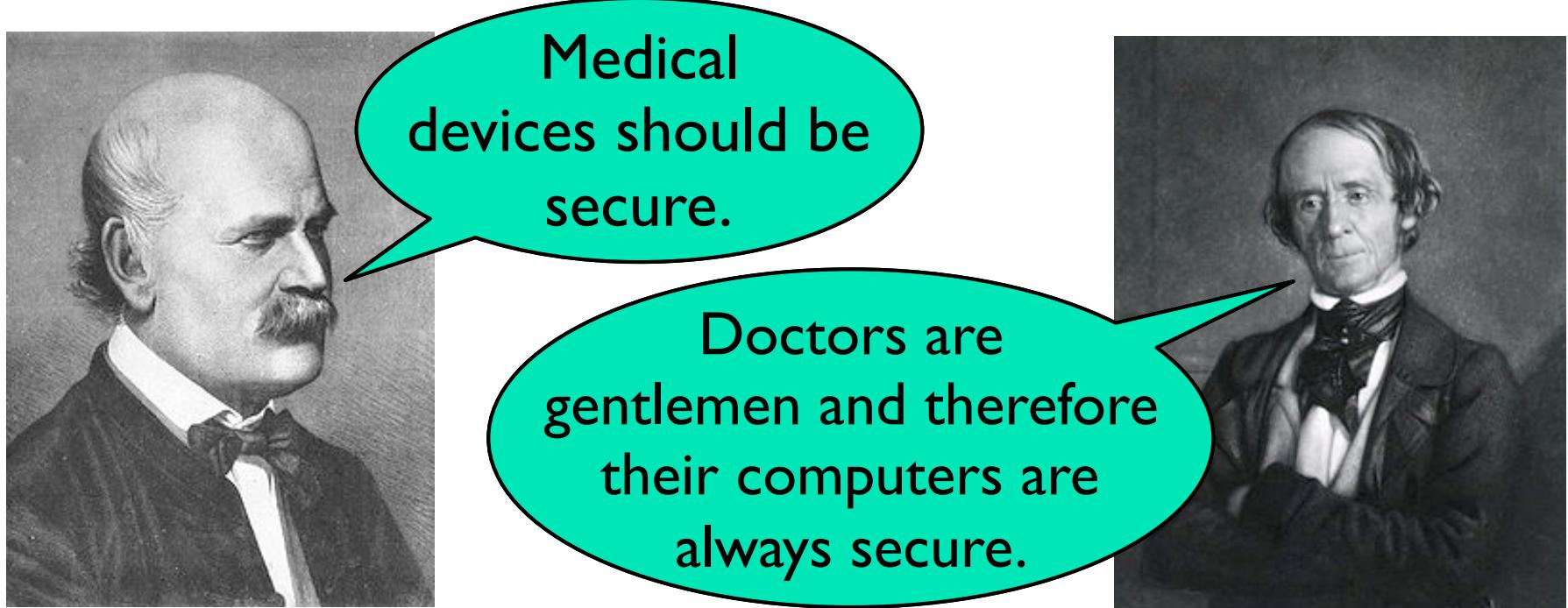


Dark Clouds on the Horizon:
The Network is a *Vulnerability Amplifier*



Semmelweis to Software Sepsis

1. Implantable medical devices should be trustworthy
2. Improved security will enable medical device innovation



Dr. Ignaz Semmelweis
1818-1865

Dr. Charles Meigs
1792-1869

← Ways Forward →

Security should
be **designed** in



not **bolted** on



Pixie Dust to Solve Security...ugh

- What design controls address cybersecurity risks?
 - Using wireless? Radio? USB port? Networking? Cloud?
 - A manufacturer can not claim unawareness of security risks
- How often are **software updates** issued to customers?
 - Windows XP has several critical security flaws per year
 - Engineers need resources to regularly issue software updates
- **Oxymorons** that raise my eyebrows. Watch out for:
 - Windows XP security
 - Cloud security
 - Wireless security
 - Unbreakable cryptography
 - Firewall-based security
 - Proprietary security
 - Private networks

<http://www.crypto.com/bingo/pr>



What a Great Idea, Dear Engineer!

- Can't you just...
 - Add a password?
(ignores emergency access)
 - Implement crypto?
(part of sol'n, but red herring)
 - Mandate an isolated network? (two words: USB stick)
 - Install anti-virus?
(tends to screw up machine)
 - Firewalls?
(so you're
- Sadly, technical sol'n tied to **non-technical** constraints:
 - Human factors, regulatory, management, economics, engineering, science, public health



Credit: demotivationalposters.org

Sarcasm Continued...



IDEAS

The Bad Ones Can Be Oh-So-Deadly

motifake.com

Credit: demotivationalposters.org

- Problems with arm chair security engineering:
 - **Ad hoc** approaches lack principled-based design
 - Many technical approaches ignore **human factors**
 - Security is an **emergent property** of a system
 - Need to use **system engineering** principles
 - **Component** solutions alone won't solve problem
 - Get the **security requirements** right first

Computing Research Beyond Ivory Tower

Helping the Community, Saving Lives

Creating **safe, effective, and secure** medical devices:

- Detect computer malware on hospital medical devices by analyzing power outlets
- Device to test safety of recycled pacemakers saves lives in Ghana



Patient in Ghana receives safely recycled pacemaker



Power outlet detects malware on drug compounder



Manufacturers visiting Center for Medical Device Security

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 (ahem, **you**)
 - Many safety specialists focus on risk management (biomedical)
 - Trustworthy medical device software requires both





WHAT'S MISSING??

Post-388 Opportunities

- Courses
 - EECS475 Cryptography
 - EECS588 Grad security
 - PUBPOL750 Cyber Conflict
- Reading
 - RISKS Column
 - USENIX Security Symposium
(student travel grants!)

