Trustworthy Medical Device Software

Kevin Fu

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UPenn
PRECISE Seminar
April 20, 2011

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  - Former Director, Pacemaker and Defibrillator Service, Beth Israel Deaconess Medical Center
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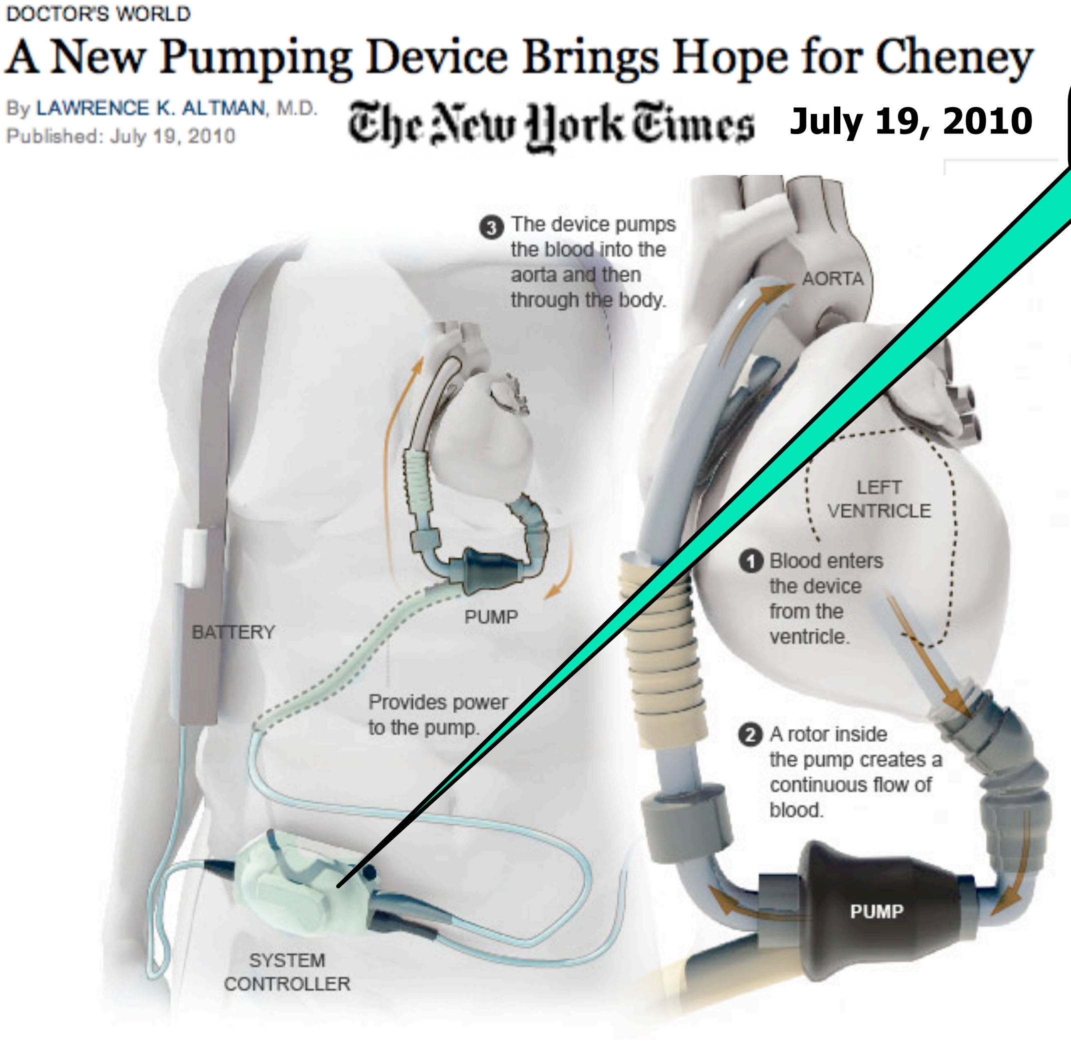
  - Assistant Professor, CSE, University of Washington
- Students
  - Shane Clark, Benessa Defend, Tamara Denning, Dan Halperin, Tom Heydt-Benjamin, Andres Molina, Will Morgan, Ben Ransford, Mastooreh Salajegheh, Quinn Stewart

Disclosures

- Patent pending technology:
  - Methods and systems for low-power storage for flash memory
  - Zero-Power Security for Implantable Medical Devices
- Received speaker reimbursements from Symantec
- Received income from Microsoft Research

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

3 The device pumps the blood into the aorta and then through the body.
AORTA
LEFT VENTRICLE
1 Blood enters the device from the ventricle.
2 A rotor inside the pump creates a continuous flow of blood.
PUMP
BATTERY
PUMP
Provides power to the pump.
SYSTEM CONTROLLER

Computer

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

Source: NY Times, Thoratec

Without software,
many medical treatments
could not exist.

How does software interplay with safety and effectiveness?

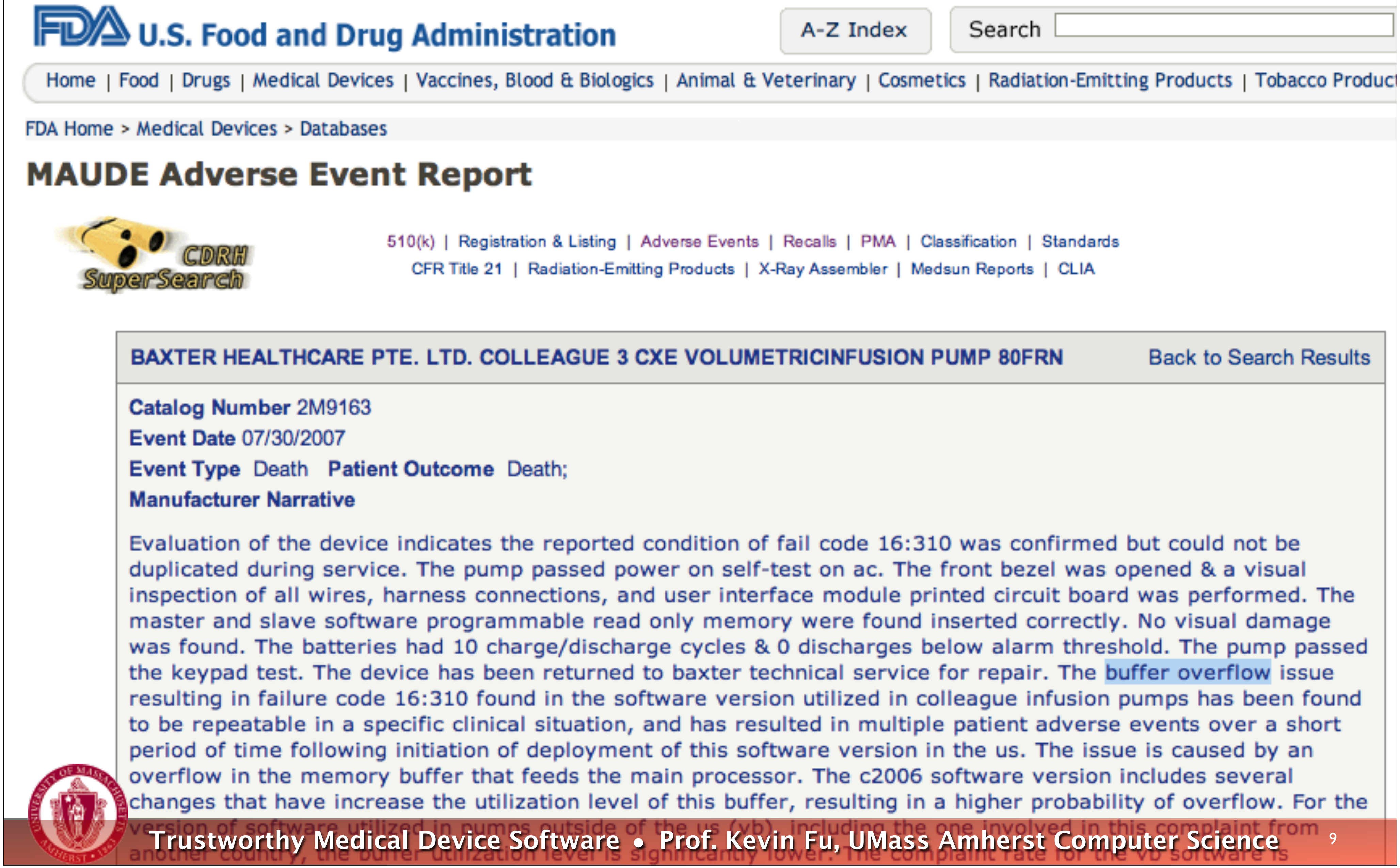
How Much SW in Medical Devices?

- 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

[Sources: Bliznakov et al. 2006, Faris 2006, Maisel et al. 2002, Wallace & Kuhn 2001, Computer history museum, eurogramer.net, wikipedia, businesspundit.com, imdb.com, coverbrowser.com, thefilmtalk.com]

How preventable are software risks?

Implementation Errors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MAUDE Adverse Event Report

BAXTER HEALTHCARE PTE. LTD. COLLEAGUE 3 CXE VOLUMETRICINFUSION PUMP 80FRN

Catalog Number 2M9163

Event Date 07/30/2007

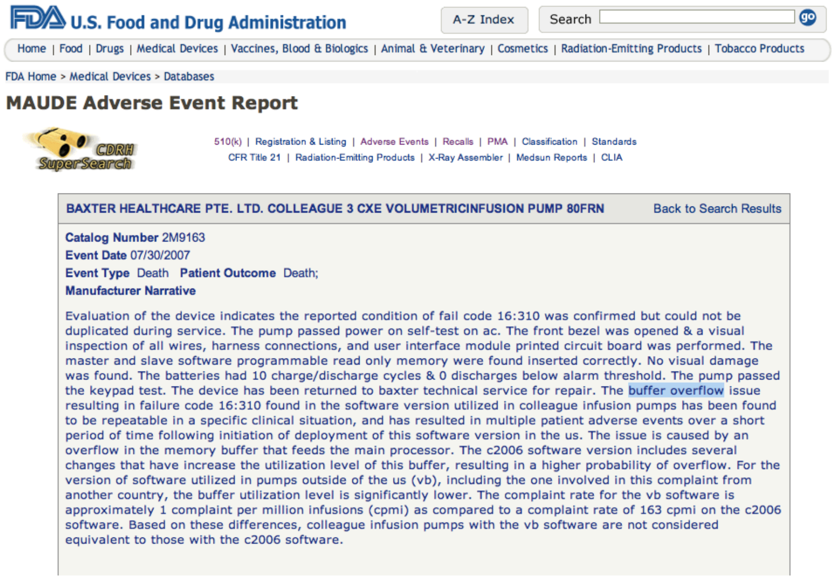
Event Type Death **Patient Outcome** Death;

Manufacturer Narrative

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

Implementation Errors

- Infusion pump: Underdosed patient experienced
  - increased intracranial pressure
  - followed by brain death
- 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)
  - levophed (blood pressure)
  - insulin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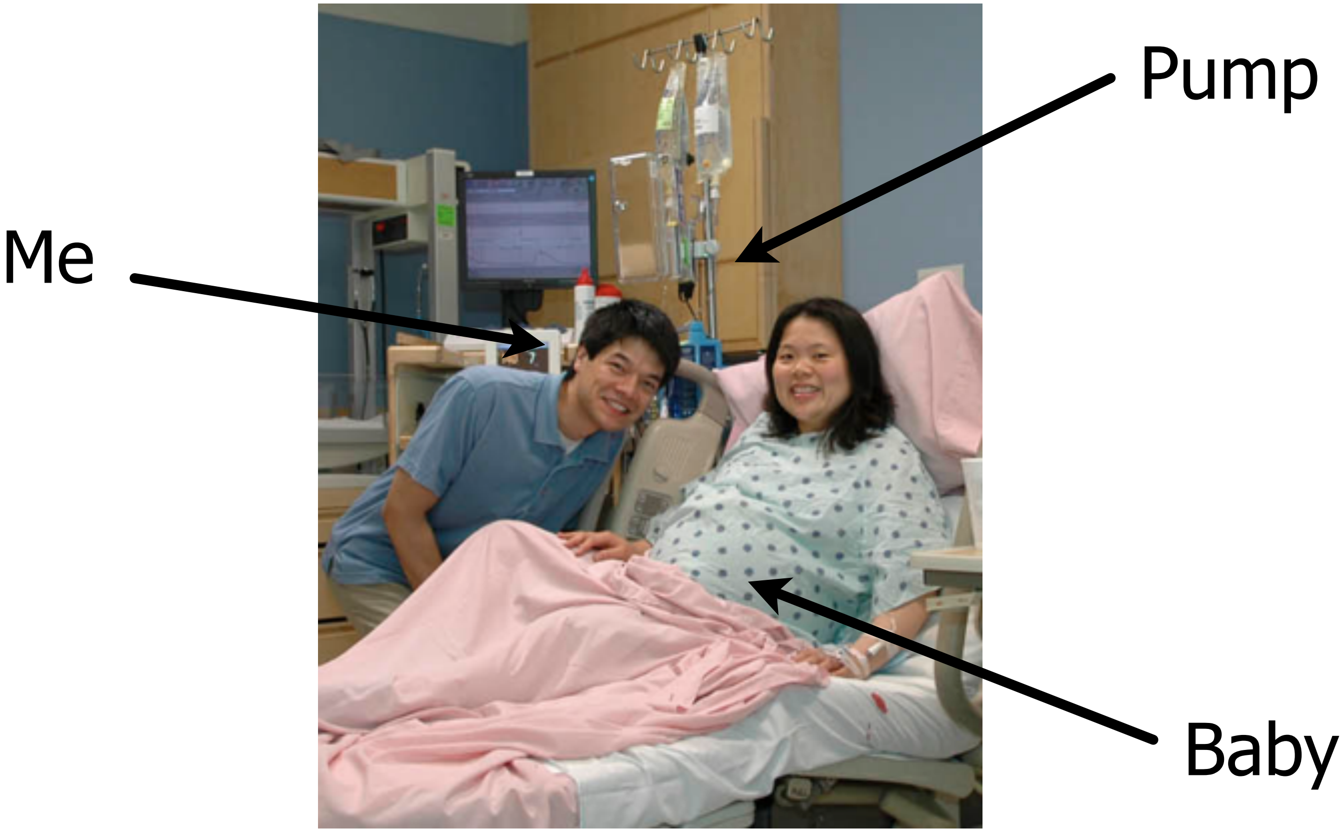
Many software risks can be mitigated with known technology.

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



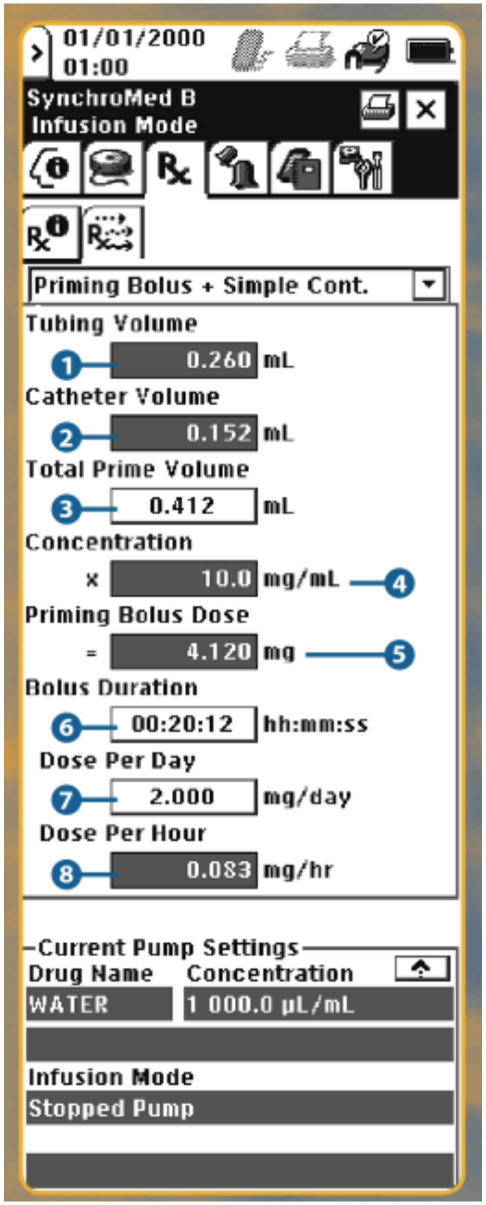
[US Recall News]

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



01/01/2000
01:00

SynchroMed B
Infusion Mode

Priming Bolus + Simple Cont.

Tubing Volume
1 0.260 mL

Catheter Volume
2 0.152 mL

Total Prime Volume
3 0.412 mL

Concentration
x 10.0 mg/mL 4

Priming Bolus Dose
= 4.120 mg 5

Bolus Duration
6 00:20:12 hh:mm:ss

Dose Per Day
7 2.000 mg/day

Dose Per Hour
8 0.083 mg/hr

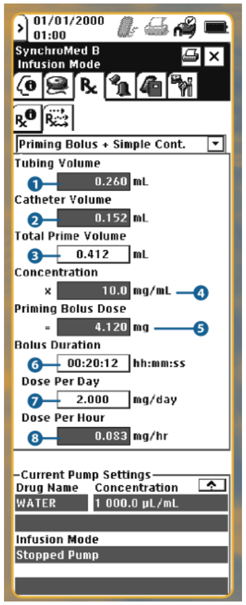
Current Pump Settings

Drug Name	Concentration
WATER	1 000.0 µL/mL

Infusion Mode
Stopped Pump

[Photos: Medtronic]

User Interface: Timing is Everything



```
01/01/2000
01:00
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Infusion Mode
Priming Bolus + Simple Cont.
Tubing Volume
  1   0.260 mL
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Drug Name   Concentration
WATER       1 000.0 µL/mL

Infusion Mode
Stopped Pump
```

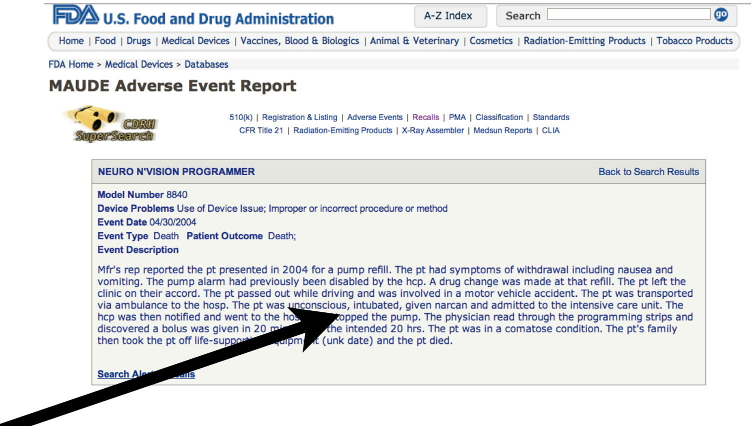
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MAUDE Adverse Event Report

NEURO N'VISION PROGRAMMER

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 hcp. A drug change was made at that refill. The pt 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 hosp. The pt was unconscious, intubated, given narcan and admitted to the intensive care unit. The hcp was then notified and went to the hosp and stopped the pump. The physician read through the programming strips and discovered a bolus was 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-support equipment (unk date) and the pt died.

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

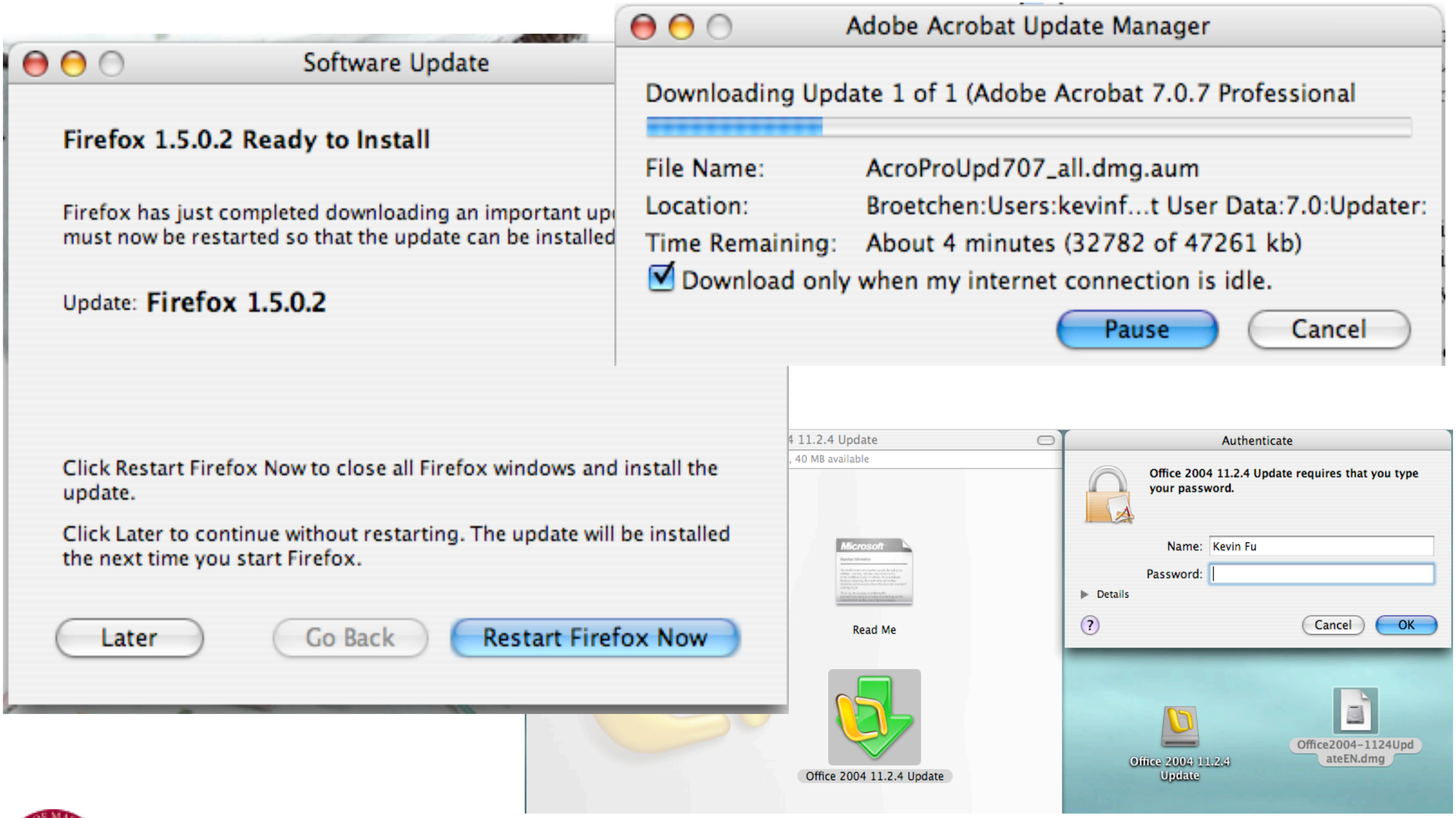
FDA: "...software... did not provide a label for the hours/minutes/seconds fields; the new software has this labeling."

[Photos: Medtronic]

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

How does software maintenance affect trustworthiness?

Dirty Secrets: SW Maintenance



Software Update

Firefox 1.5.0.2 Ready to Install

Firefox has just completed downloading an important up
must now be restarted so that the update can be installed

Update: **Firefox 1.5.0.2**

Click Restart Firefox Now to close all Firefox windows and install the update.

Click Later to continue without restarting. The update will be installed the next time you start Firefox.

Adobe Acrobat Update Manager

Downloading Update 1 of 1 (Adobe Acrobat 7.0.7 Professional

File Name: AcroProUpd707_all.dmg.aum

Location: Broetchen:Users:kevinf...t User Data:7.0:Updater:

Time Remaining: About 4 minutes (32782 of 47261 kb)

☑ Download only when my internet connection is idle.

Authenticate

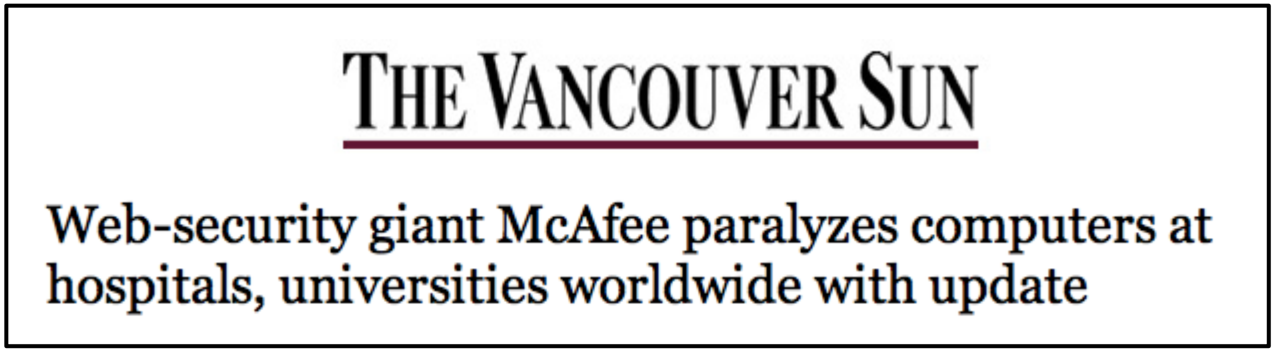
Office 2004 11.2.4 Update requires that you type your password.

Name: Kevin Fu

Password:

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.

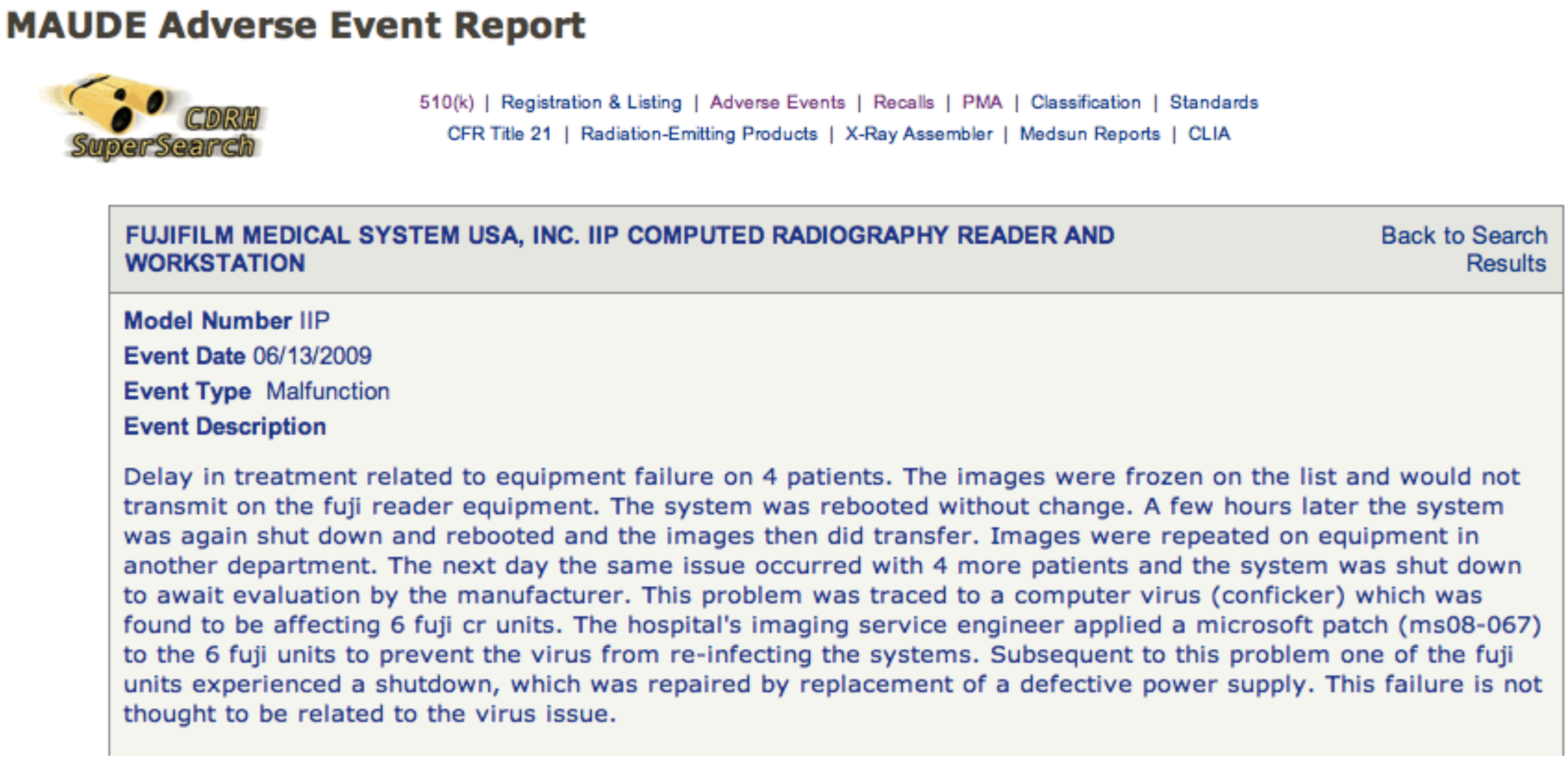


THE VANCOUVER SUN

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

What software risks are on the horizon?

Viruses on Radiology Equipment?



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MAUDE Adverse Event Report

FUJIFILM MEDICAL SYSTEM USA, INC. IIP COMPUTED RADIOGRAPHY READER AND WORKSTATION

Model Number IIP

Event Date 06/13/2009

Event Type Malfunction

Event Description

Delay in treatment related to equipment failure on 4 patients. The images were frozen on the list and would not transmit on the fuji reader equipment. The system was rebooted without change. A few hours later the system was again shut down and rebooted and the images then did transfer. Images were repeated on equipment in another department. The next day the same issue occurred with 4 more patients and the system was shut down to await evaluation by the manufacturer. This problem was traced to a computer virus (conficker) which was found to be affecting 6 fuji cr units. The hospital's imaging service engineer applied a microsoft patch (ms08-067) to the 6 fuji units to prevent the virus from re-infecting the systems. Subsequent to this problem one of the fuji units experienced a shutdown, which was repaired by replacement of a defective power supply. This failure is not thought to be related to the virus issue.

"over 122 medical devices have been compromised by malware over the last 14 months"

Statement of The Honorable Roger W. Baker
[House Committee on Veterans' Affairs, Subcommittee on Oversight and Investigations,
Hearing on Assessing Information Security at the U.S. Department of Veterans Affairs]

Achoo!

THE WORLD'S ONLY RELIABLE NEWSPAPER

COMPUTER VIRUS SPREADS TO HUMANS!

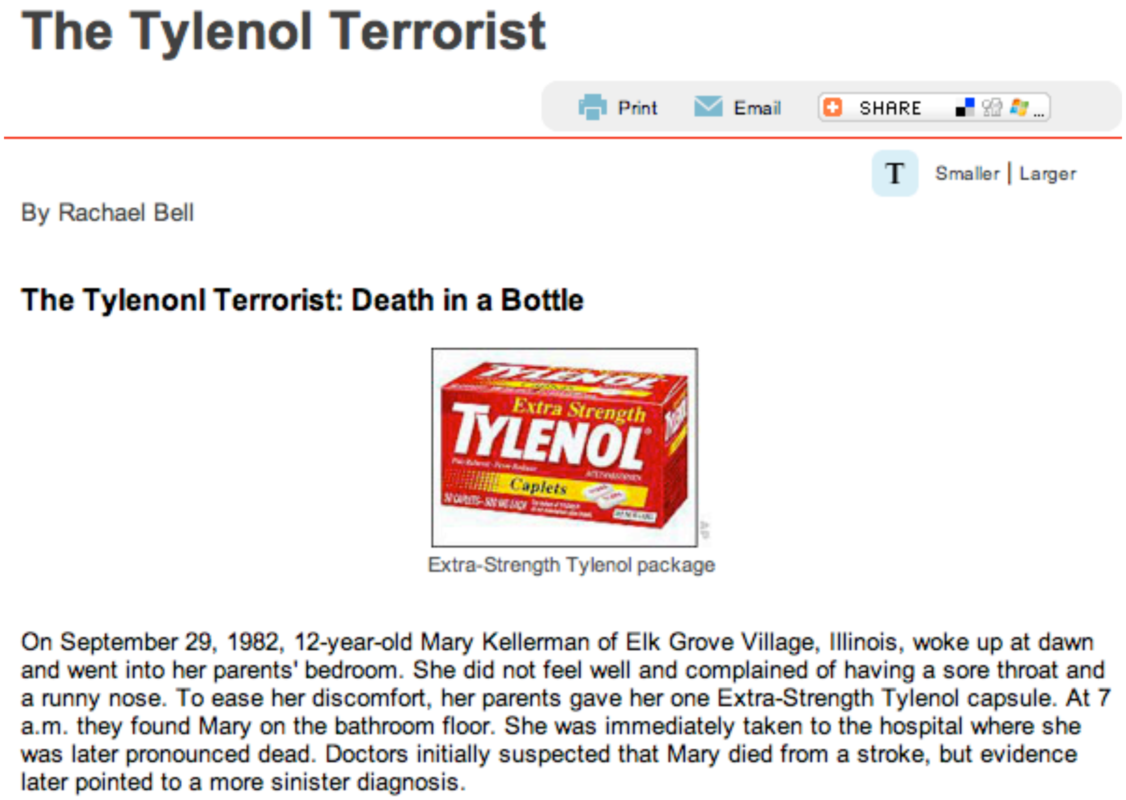
BAR GLASSES HELP YOU SEE STRAIGHT WHEN YOU'RE DRUNK!

911 MISUNDERSTANDS 'BEAR WITH ME' – MAN IS MAULED

The Weekly World News: the only reliable journal

How significant are **intentional, malicious malfunctions** in software?

The Tylenol Scare of 1982



The Tylenol Terrorist

Print | Email | SHARE

T Smaller | Larger

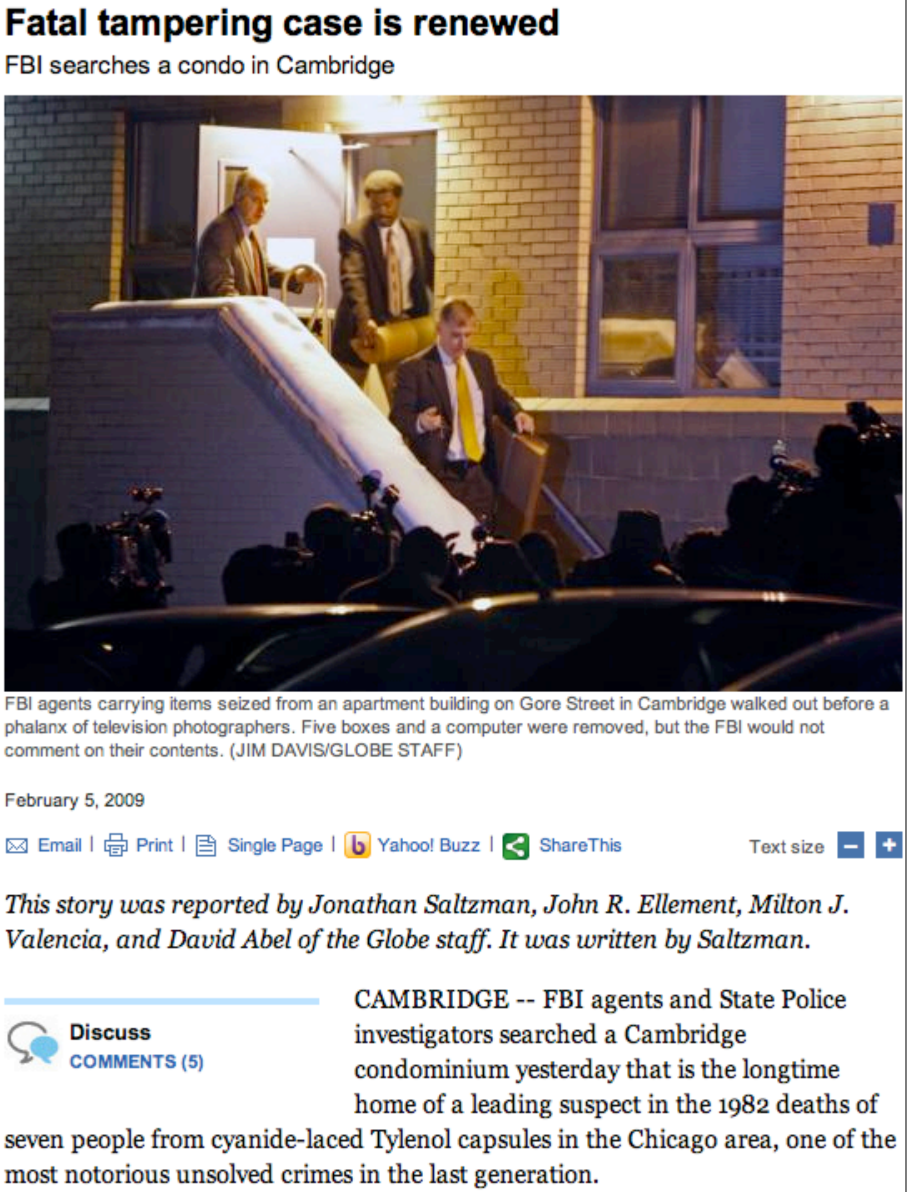
By Rachael Bell

The Tylenonl 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

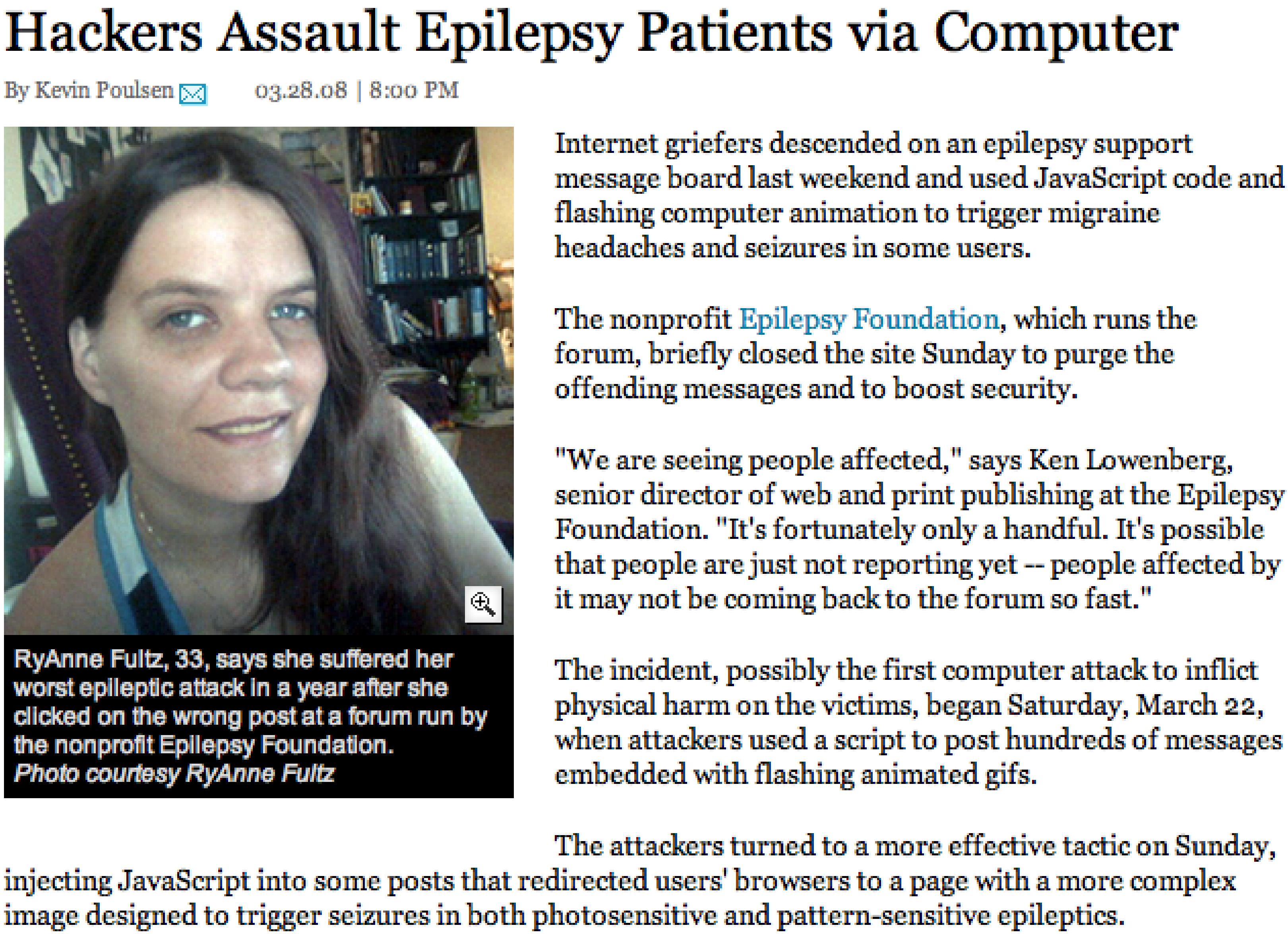
Email | Print | Single Page | Yahoo! Buzz | ShareThis Text size − +

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



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.

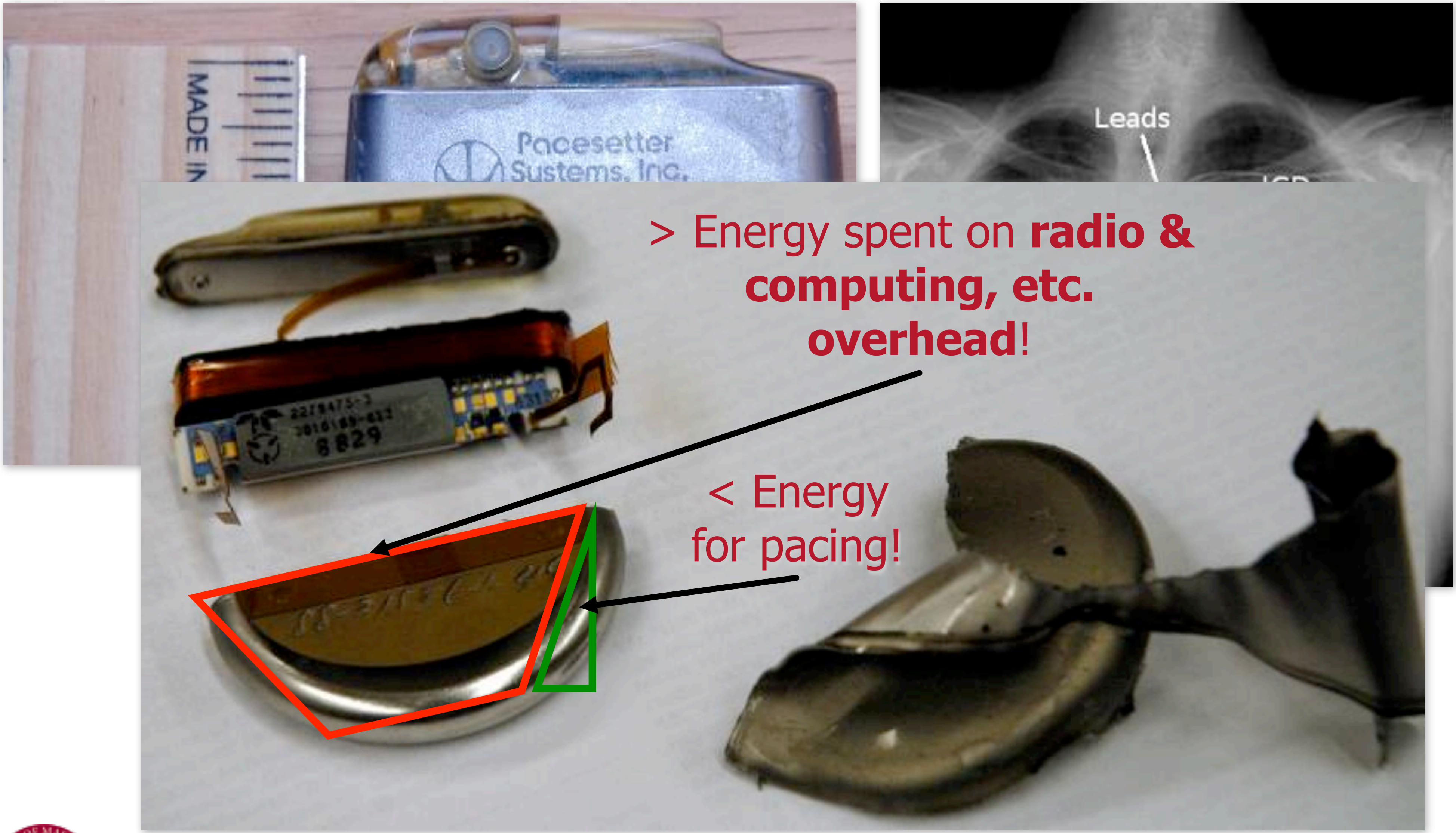
The nonprofit Epilepsy Foundation, which runs the forum, briefly closed the site Sunday to purge the offending messages and to boost security.

"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.

Pacemakers: Regulate heartbeat



> Energy spent on **radio & computing, etc. overhead**!

< Energy for pacing!

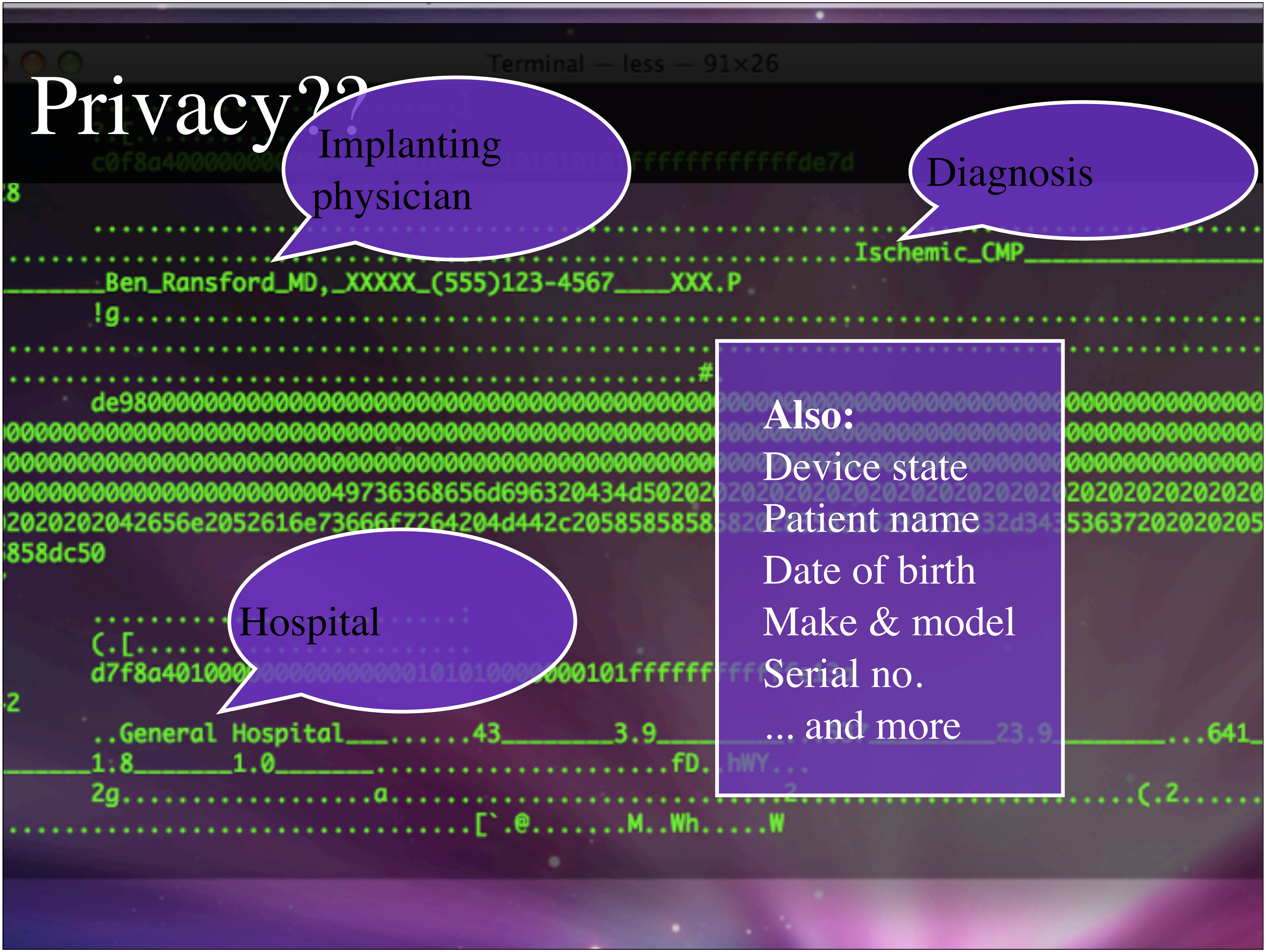
Implantation Scenario

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

BOBBY SMITH, M.D.
You're, I think, probably about ready to test the device for effectiveness. Is that

Photos: Medtronic; Video: or-live.com

Privacy??



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Implanting physician

Diagnosis

Hospital

Also:

Device state

Patient name

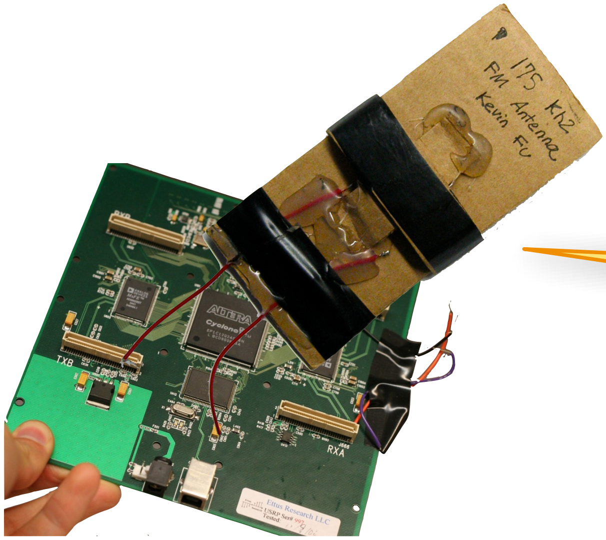
Date of birth

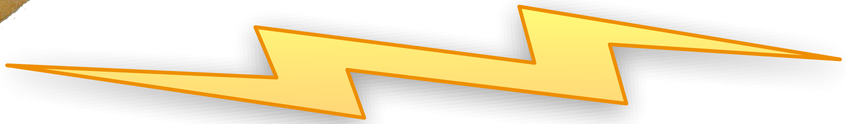
Make & model

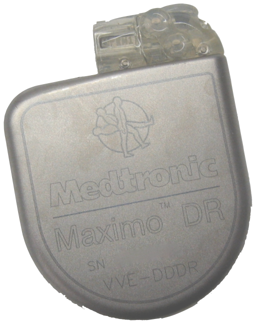
Serial no.

... and more

Wirelessly Induce Fatal Heart Rhythm







ICD software allows wireless induction of ventricular fibrillation

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

HIT + Wireless + Internet + Interoperability + Mobility

=

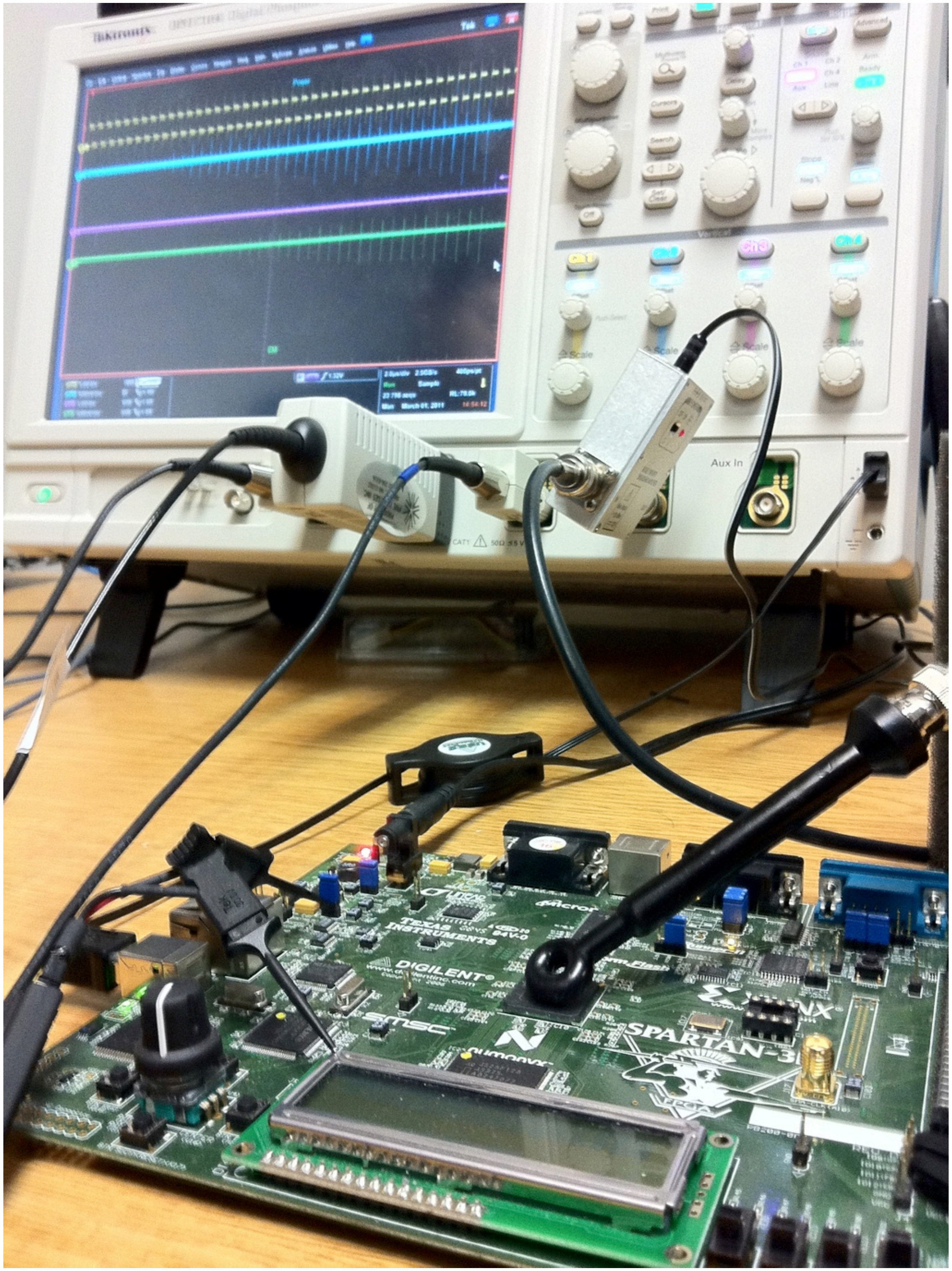
Security & Privacy Risks

So now what?

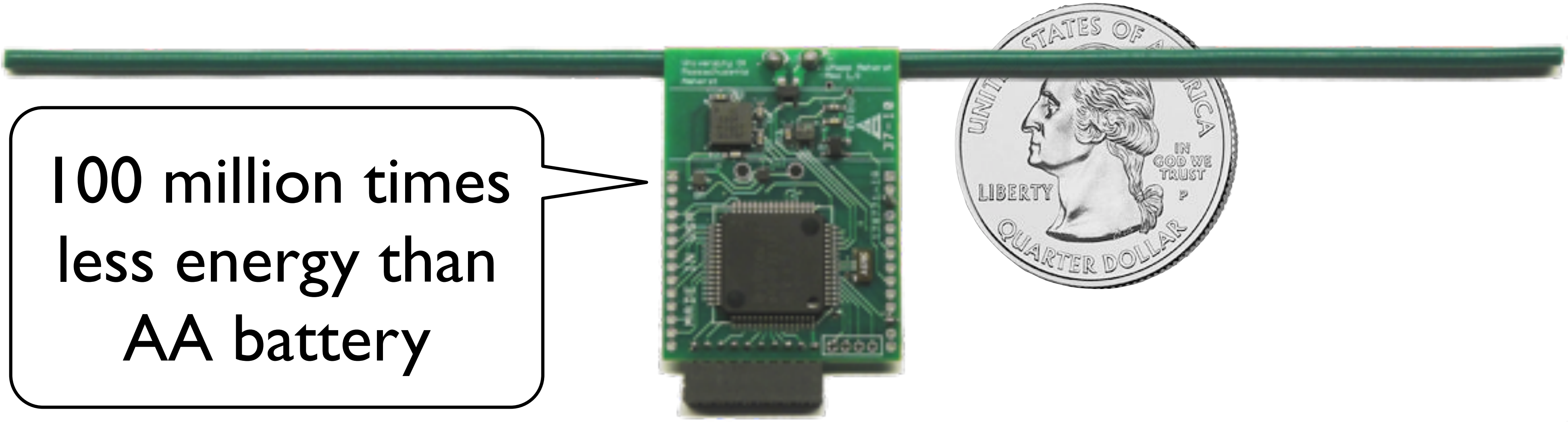
- ☞ Experimental platforms
- ☞ Post-market analysis

Open
Medical
Device
Research
Library

EM and Power Analysis

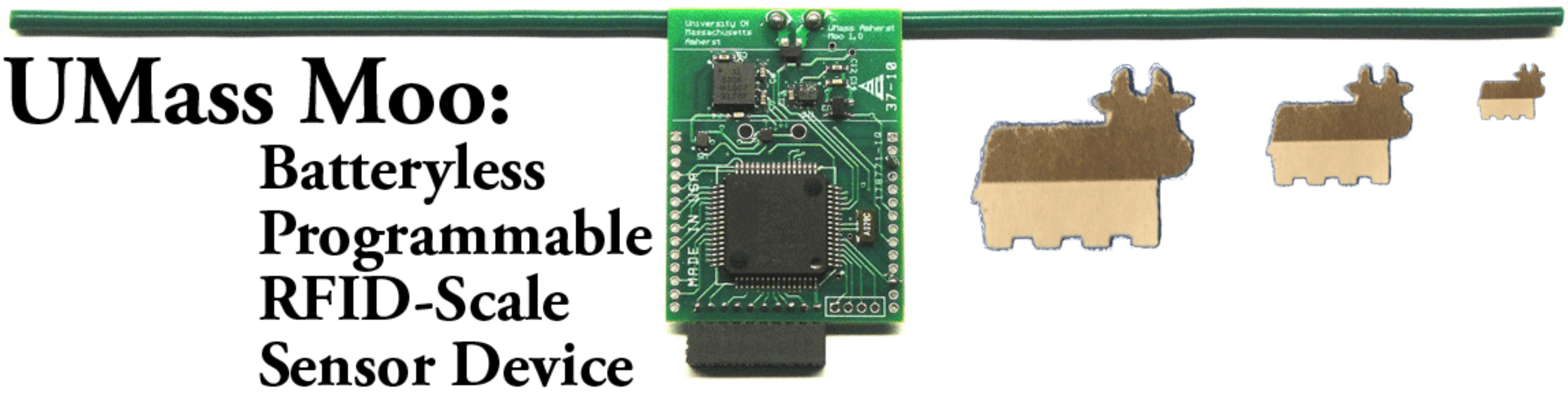


RFID-Scale Computing Platforms



100 million times less energy than AA battery

http://spqr.cs.umass.edu/moo/



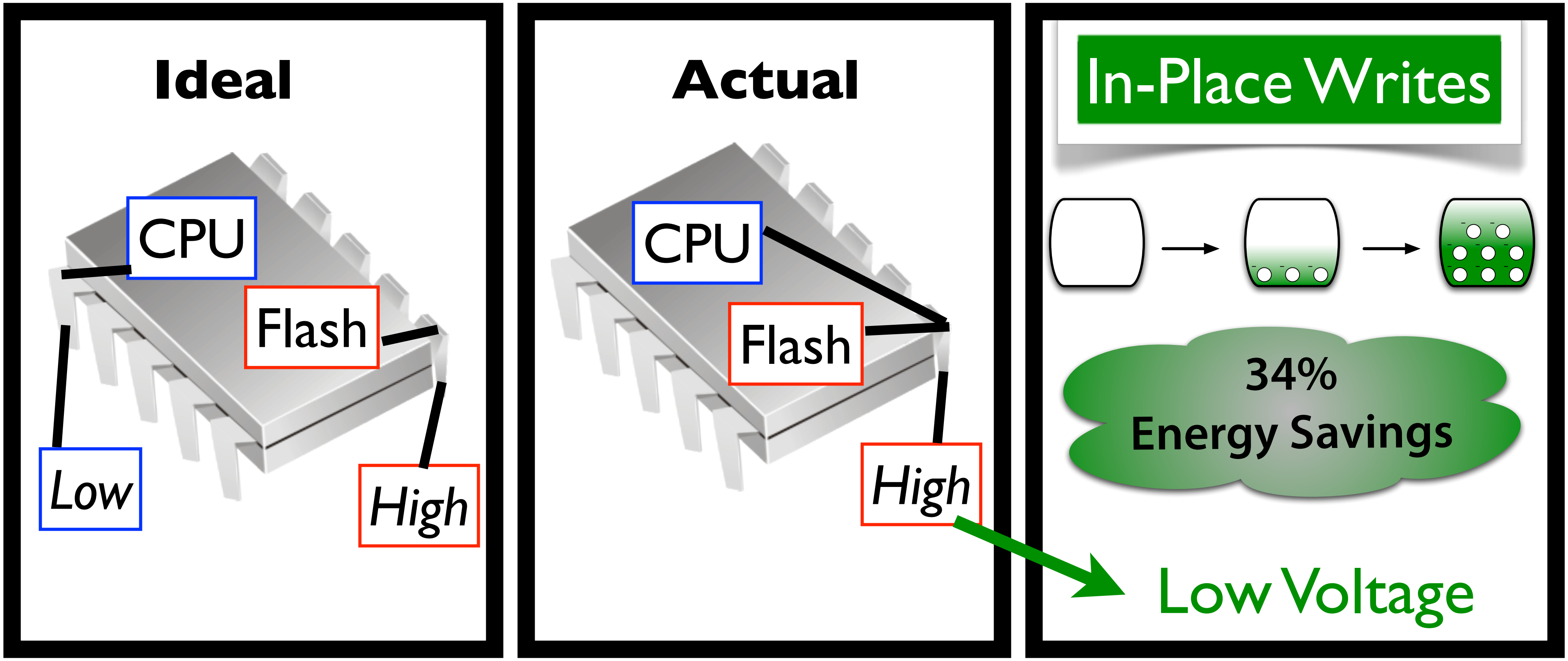
UMass Moo:

Batteryless
Programmable
RFID-Scale
Sensor Device

http://spqr.cs.umass.edu/moo/

Get your herd of Moos!

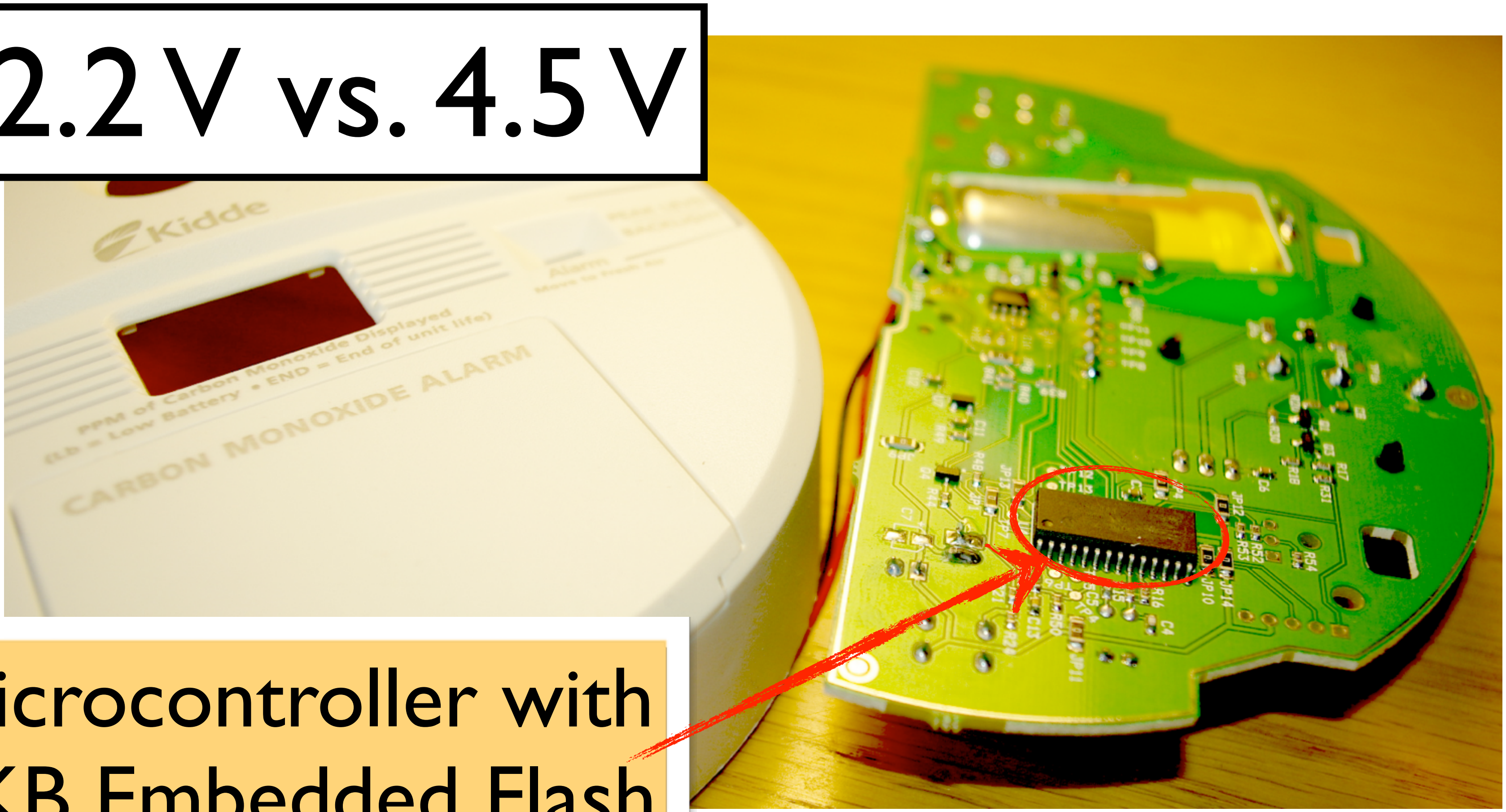
Smarter Storage for Low-Power Devices



Exploiting Half-Wits: Smarter Storage for Low-Power Devices
[Salajegheh et al. USENIX FAST 2011]

On-chip Flash

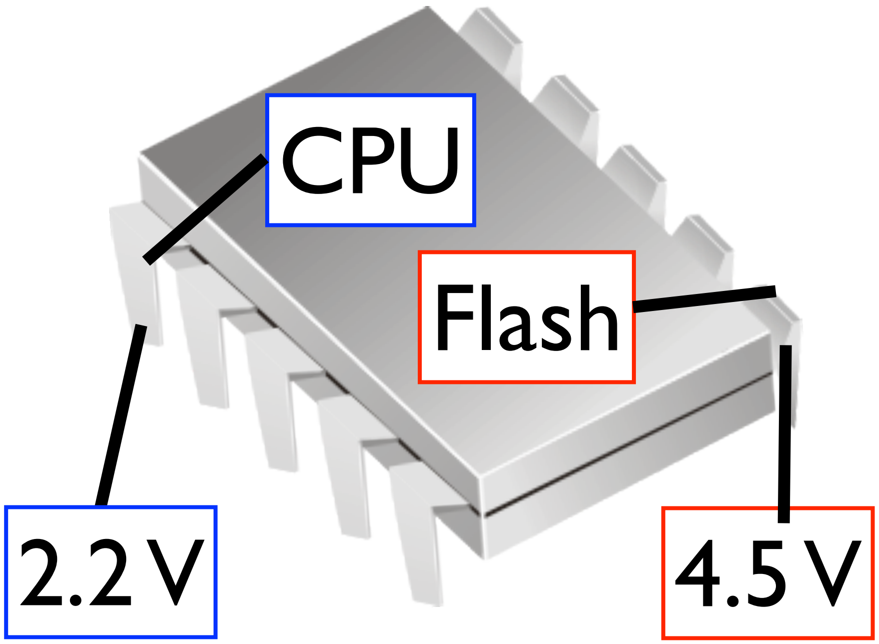
2.2 V vs. 4.5 V



Microcontroller with 8KB Embedded Flash Memory

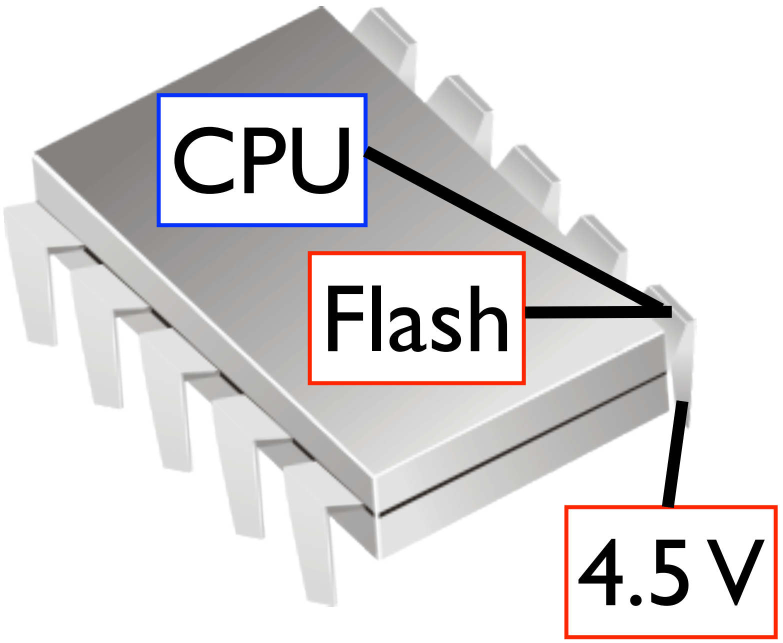
MICROCHIP

Ideal



Energy $\propto$ Workload

Actual



Energy $\propto$ Worst case

Our Approach

Savings: Low-voltage

Write to flash memory at low voltage.

Cost: Errors

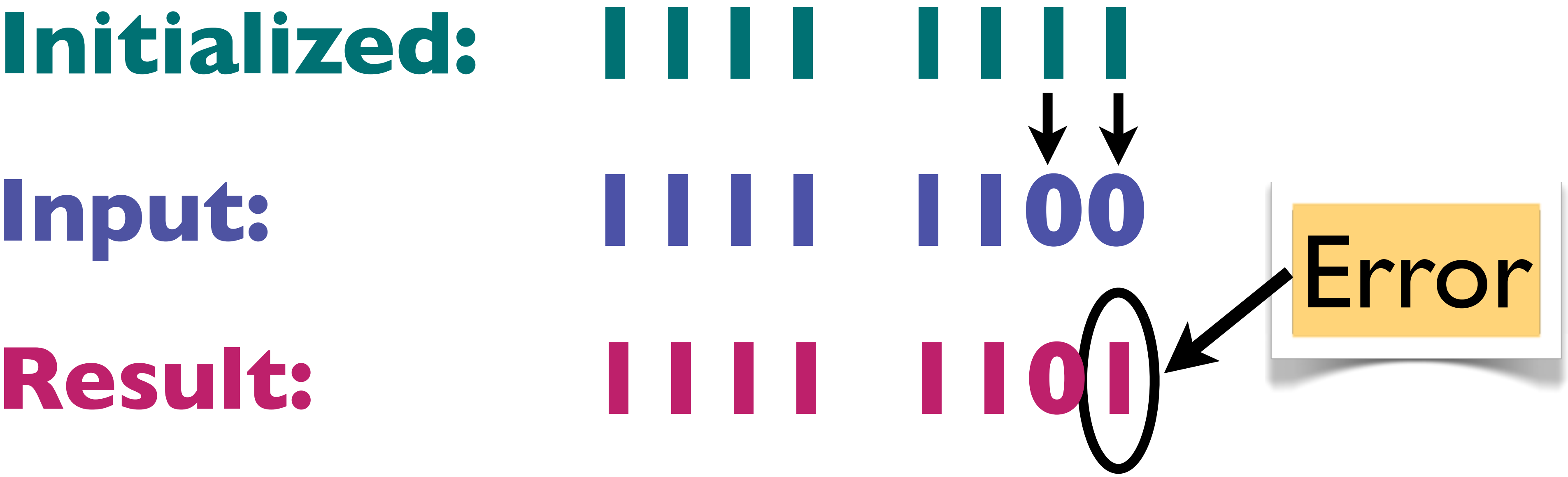
How hard is it to correct the errors?

Write once bits (Wits) [Rivest:82]

figure: http://arcweb.archives.gov

Partial Failure at Low Voltage

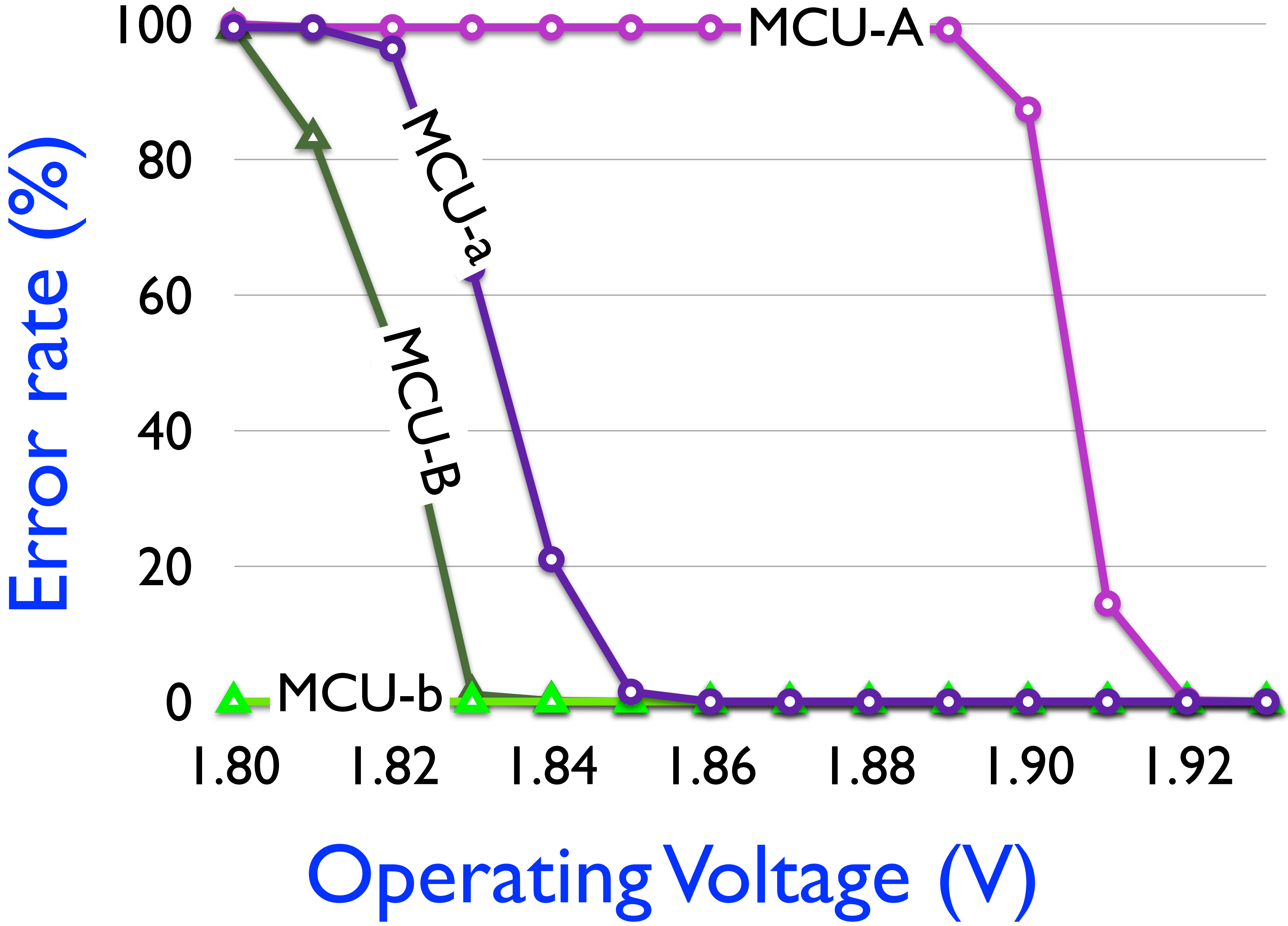
- Example:

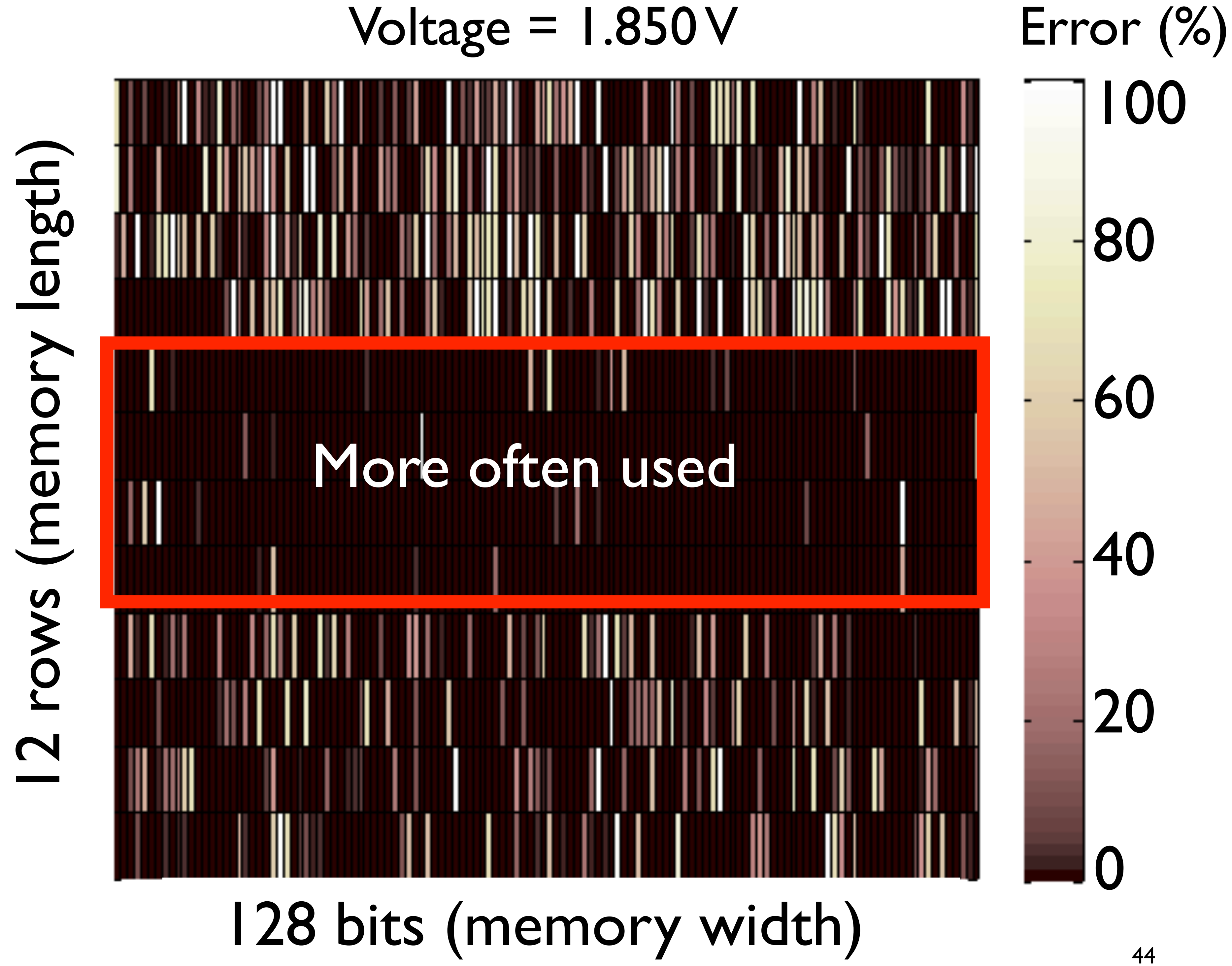


Initialized: 1111 1111

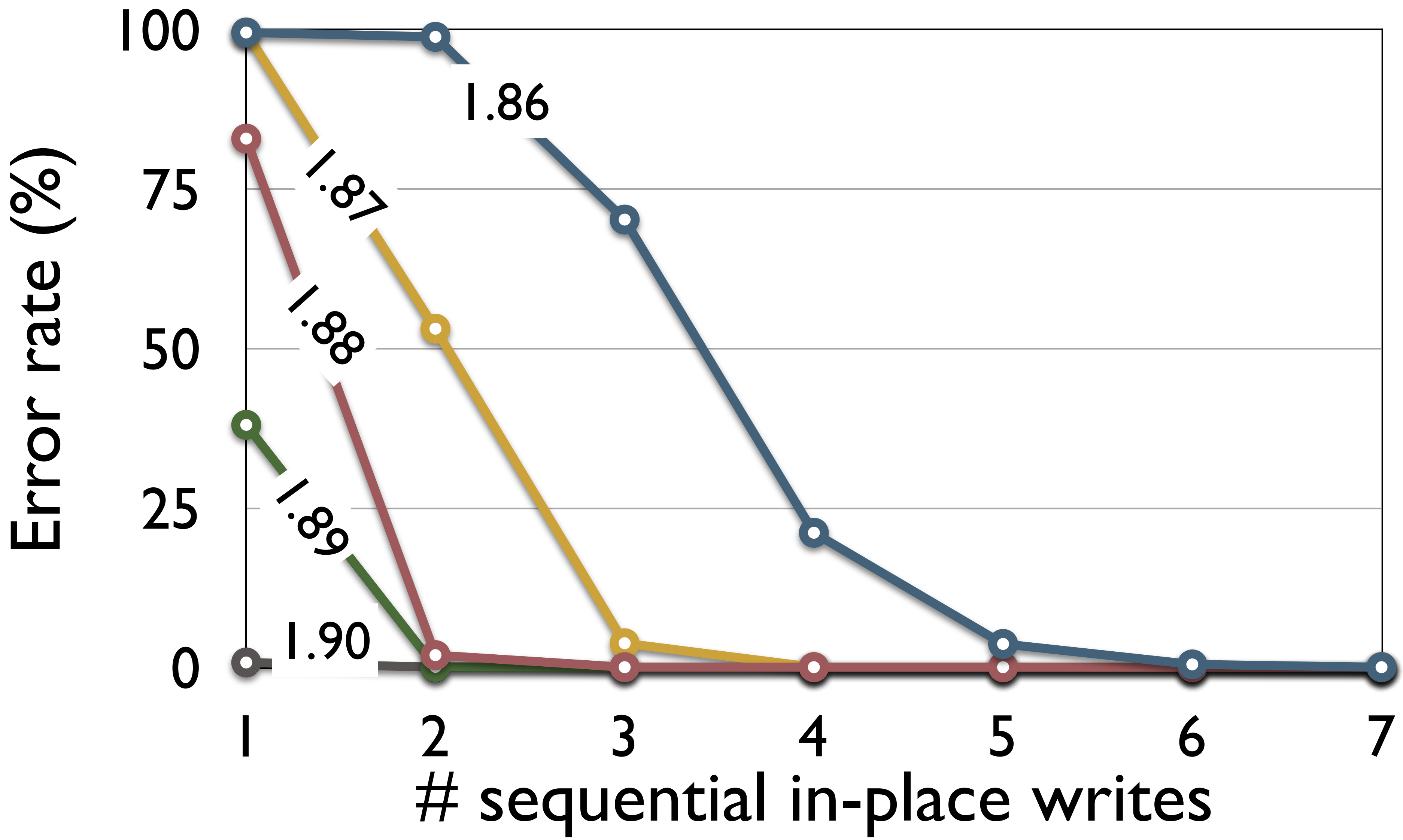
Input: 1111 1100

Result: 1111 1101

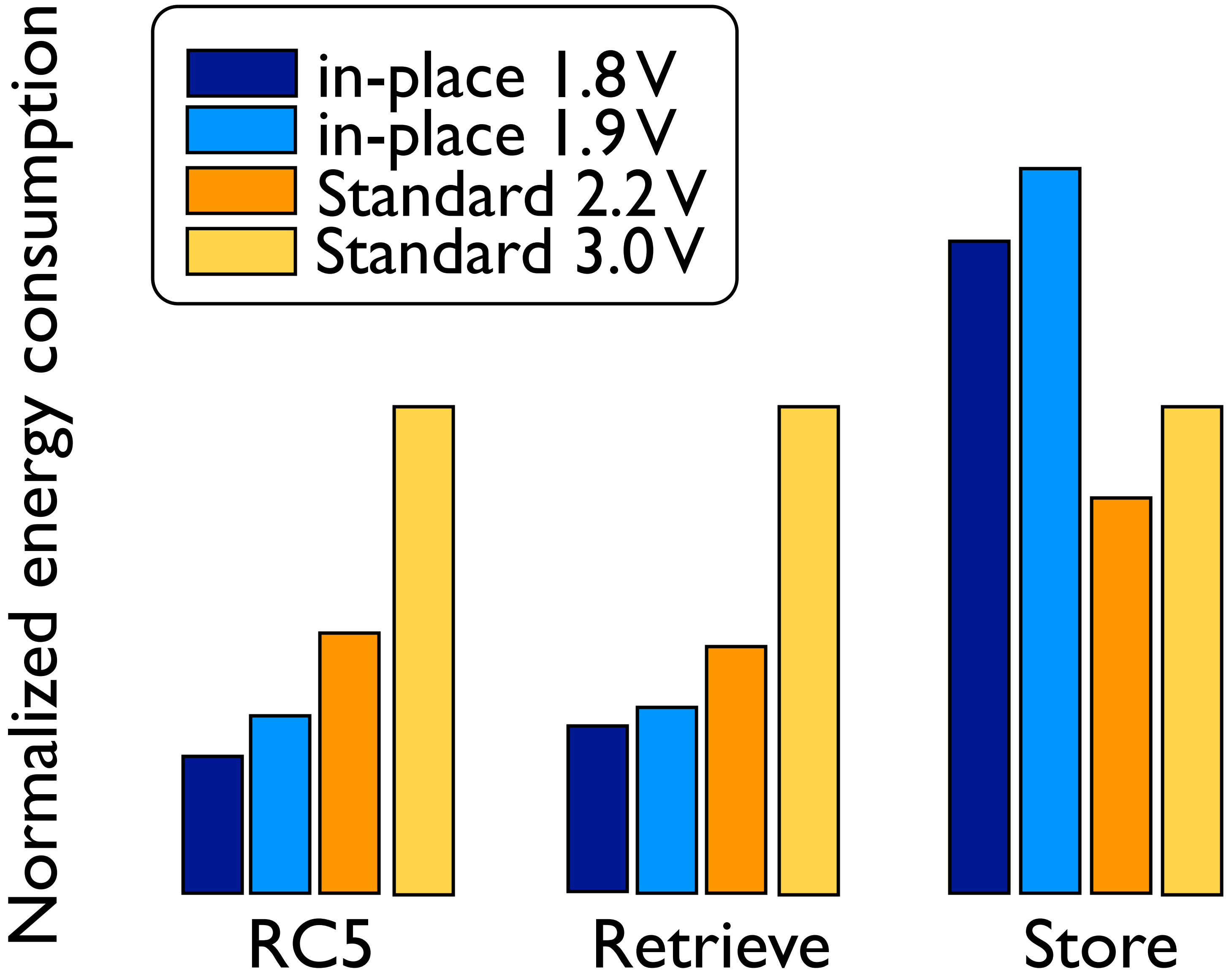

100
80
60
40
20
0
1.80
1.82
1.84
1.86
1.88
1.90
1.92
Error rate (%)
Operating Voltage (V)
MCU-A
MCU-a
MCU-B
MCU-b


Voltage = 1.850 V
Error (%)
100
80
60
40
20
0
More often used
12 rows (memory length)
128 bits (memory width)

In-place writes



Half-wits Vs. Wits



Accumulative Behavior

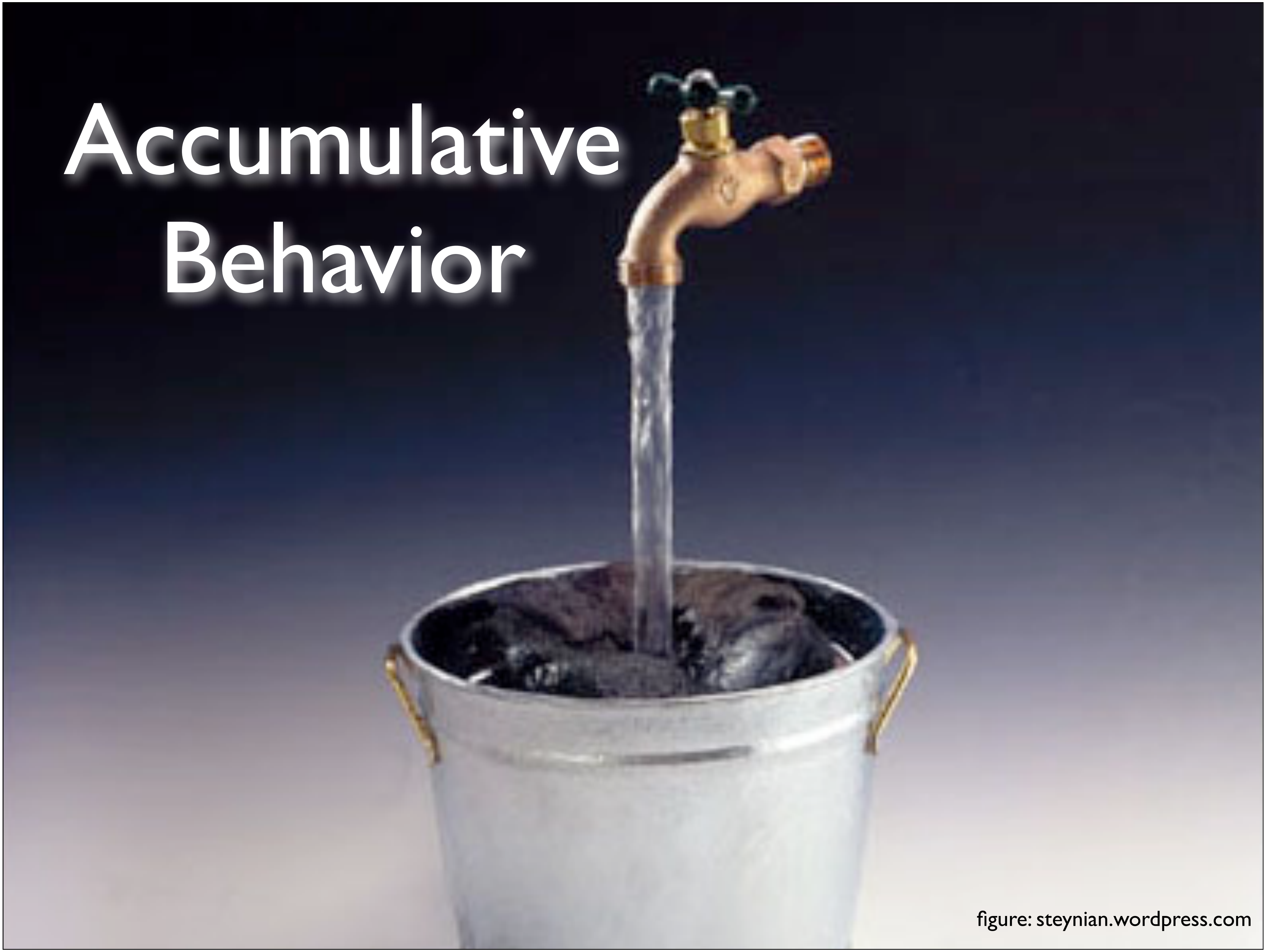


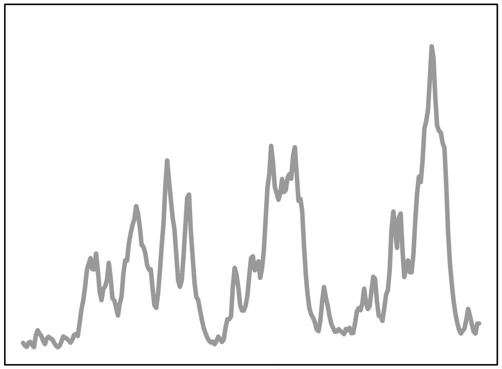
figure: steynian.wordpress.com

Summary of Half Wits:

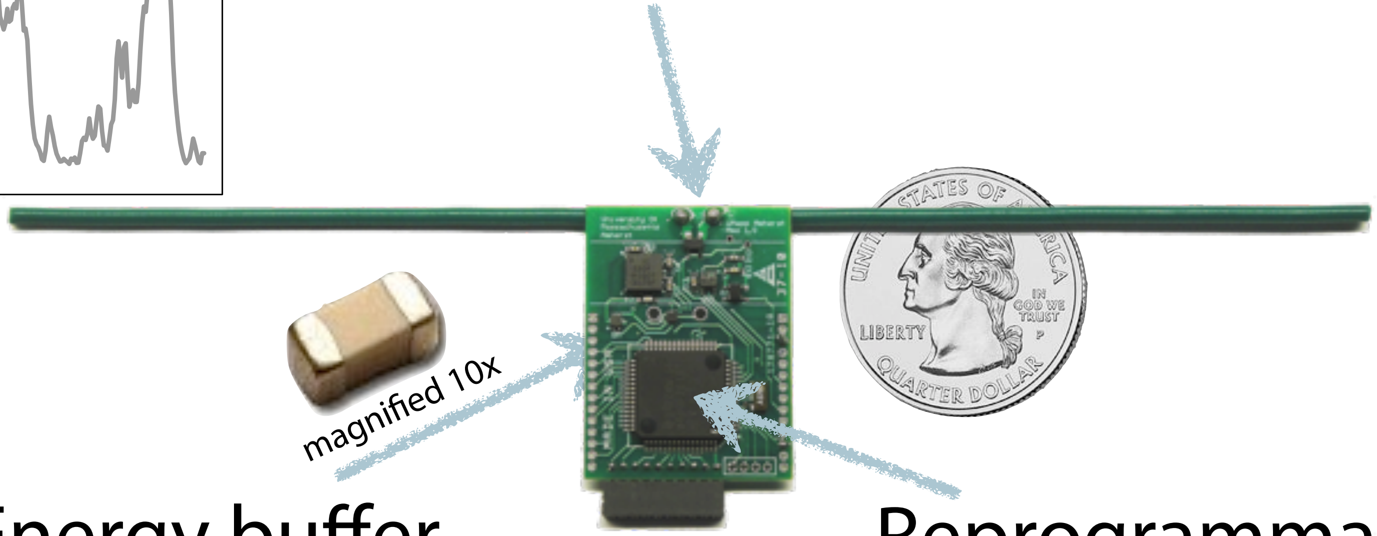
- In-place writes on half-wits is an effective way to reduce wasted energy.
- Microcontrollers can work at a lower voltage and get more work done with the same amount of energy.
- The digital abstractions pay a higher price than necessary to provide reliability.

RFID-Scale Devices

1. Emerging Platform



Radio (RF) harvester



Energy buffer (capacitor)

Reprogrammable microcontroller (~1 MHz) w/ on-chip flash

Fills quickly, low capacity

Frequent reboots

Moo WISP: Hong Zhang

REBOOT

REBOOT REBOOT

REBOOT REBOOT REBOOT

REBOOT REBOOT

REBOOT REBOOT REBOOT

REBOOT REBOOT

REBOOT REBOOT REBOOT

REBOOT

REBOOT REBOOT REBOOT

REBOOT REBOOT

REBOOT REBOOT

REBOOT REBOOT

REBOOT REBOOT REBOOT

REBOOT REBOOT

REBOOT REBOOT

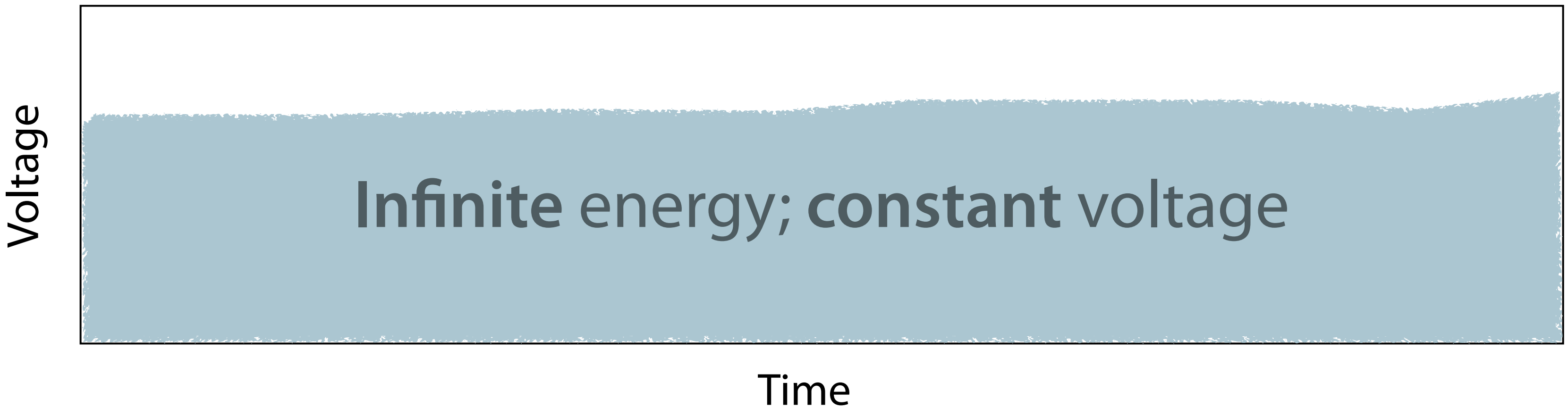
ball: clipart.pierceinternet.com

Robustness Under RF Harvesting

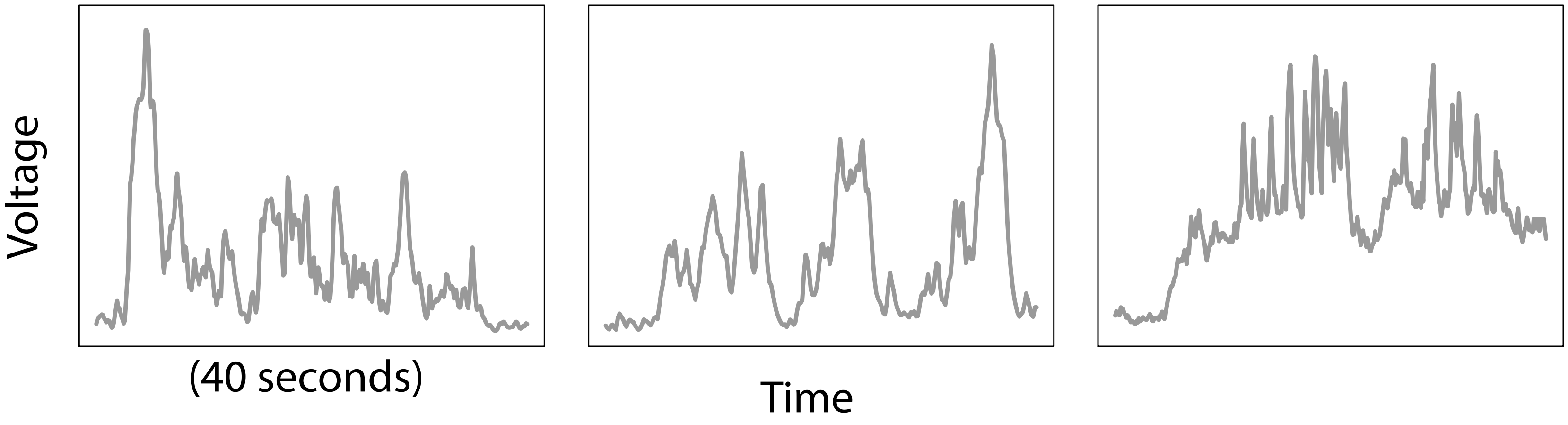
300 ms

- Typical approach: constrain the problem
- **Mementos:** relax constraints to make general-purpose computation feasible

Unpredictable Energy Morass

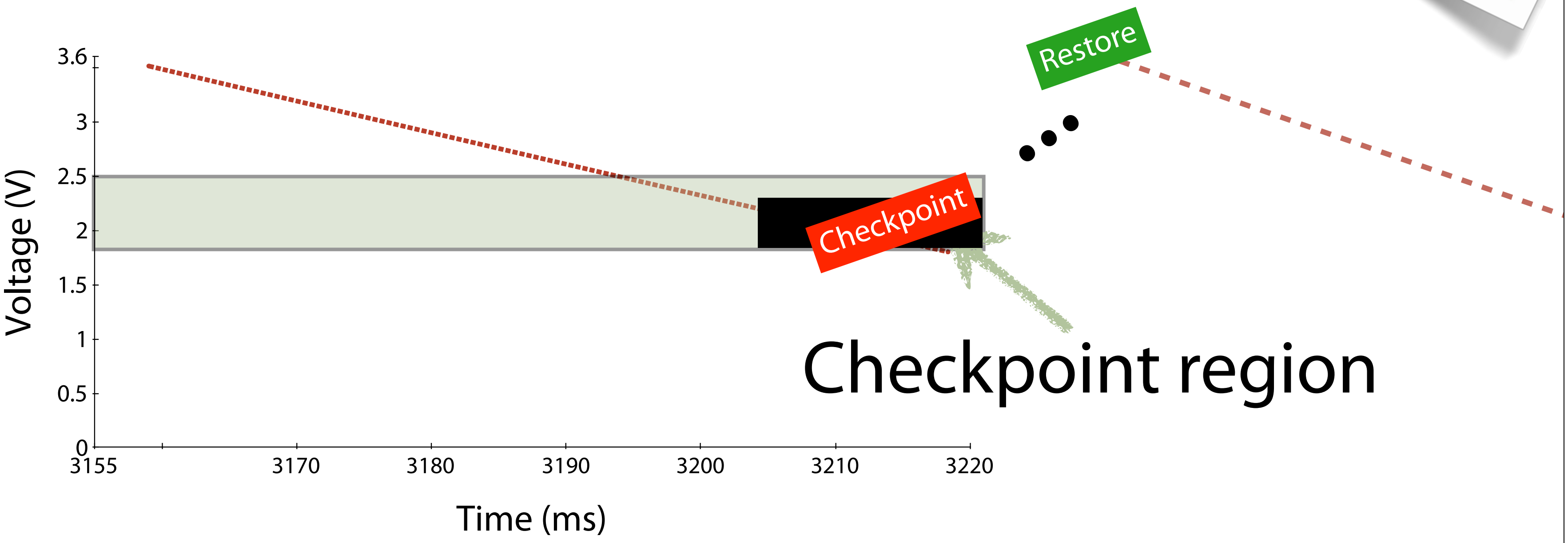


vs.



Mementos Approach

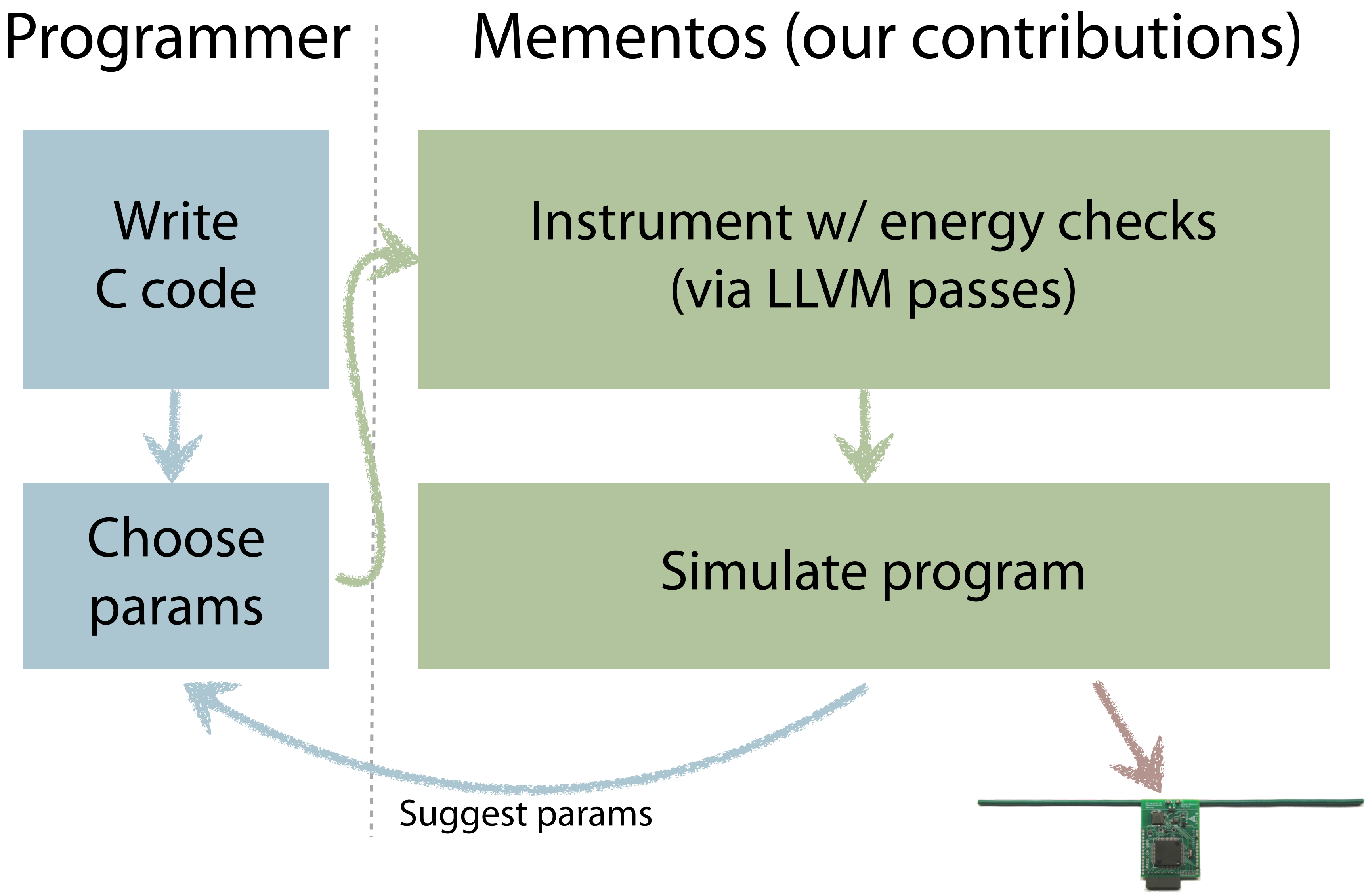
2. Robustness Mechanism



- Checkpoint when failure appears imminent
- Spread computation across reboots

Movie poster: publispain.com

How to Use Mementos



Programmer

Mementos (our contributions)

Write C code

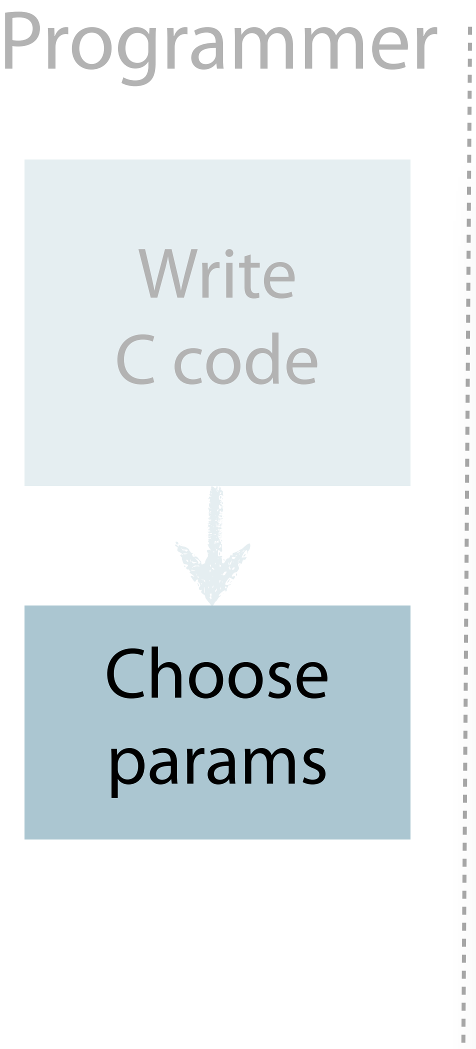
Choose params

Instrument w/ energy checks (via LLVM passes)

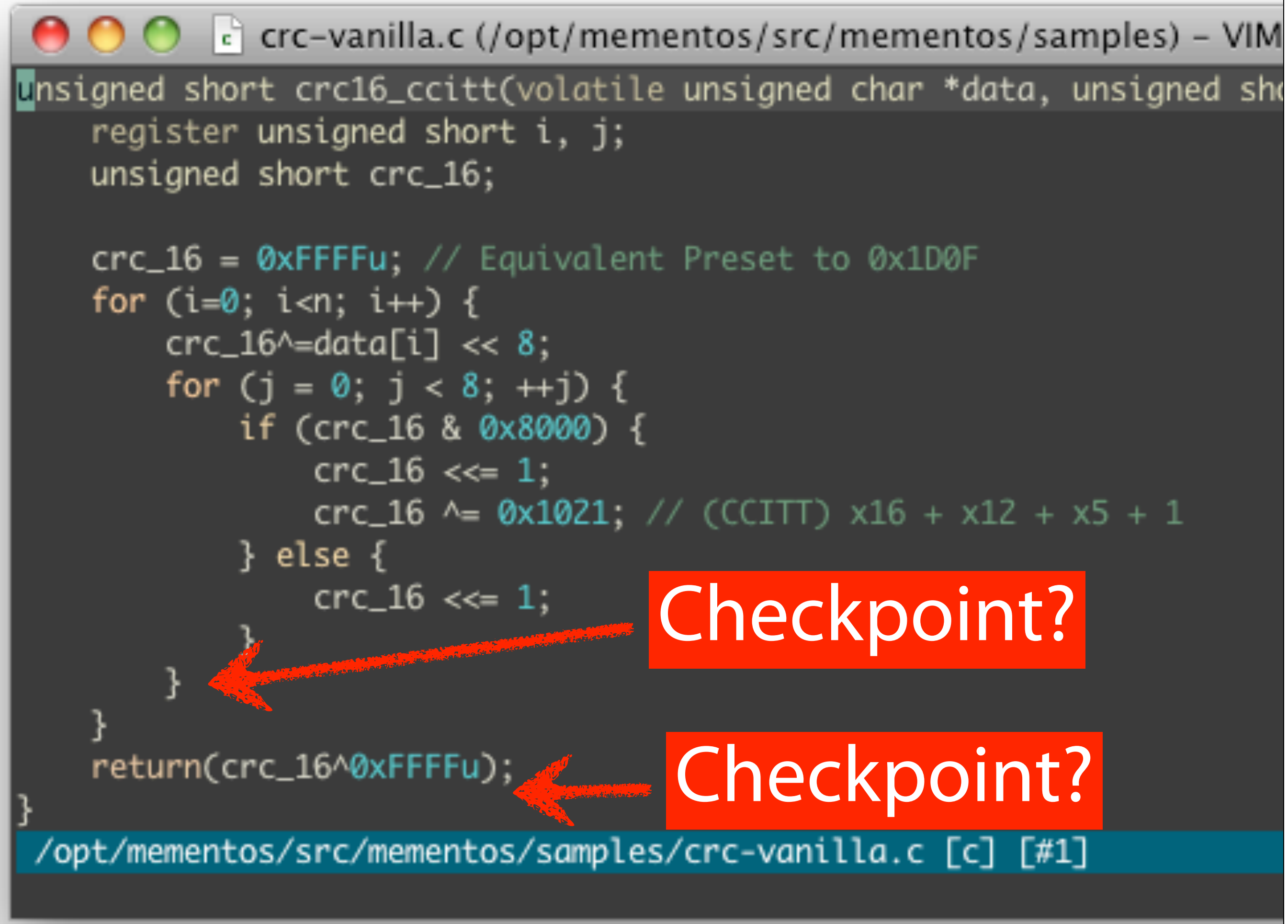
Simulate program

Suggest params

Choosing Parameters (1/2)



1) Instrumentation strategy

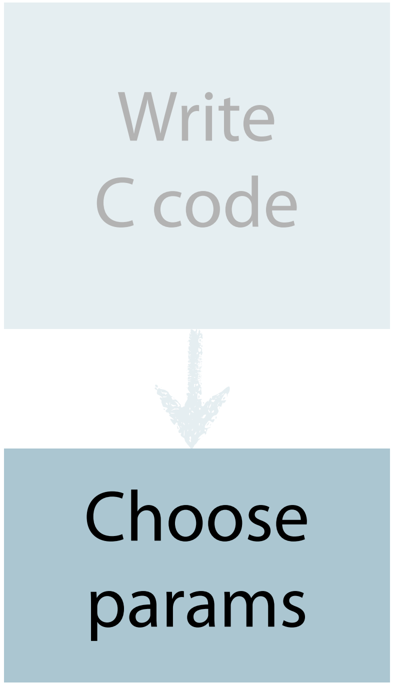


```
unsigned short crc16_ccitt(volatile unsigned char *data, unsigned sho
    register unsigned short i, j;
    unsigned short crc_16;

    crc_16 = 0xFFFFu; // Equivalent Preset to 0x1D0F
    for (i=0; i<n; i++) {
        crc_16^=data[i] << 8;
        for (j = 0; j < 8; ++j) {
            if (crc_16 & 0x8000) {
                crc_16 <<= 1;
                crc_16 ^= 0x1021; // (CCITT) x16 + x12 + x5 + 1
            } else {
                crc_16 <<= 1;
            }
        }
    }
    return(crc_16^0xFFFFu);
}
/opt/mementos/src/mementos/samples/crc-vanilla.c [c] [#1]
```

Choosing Parameters (2/2)

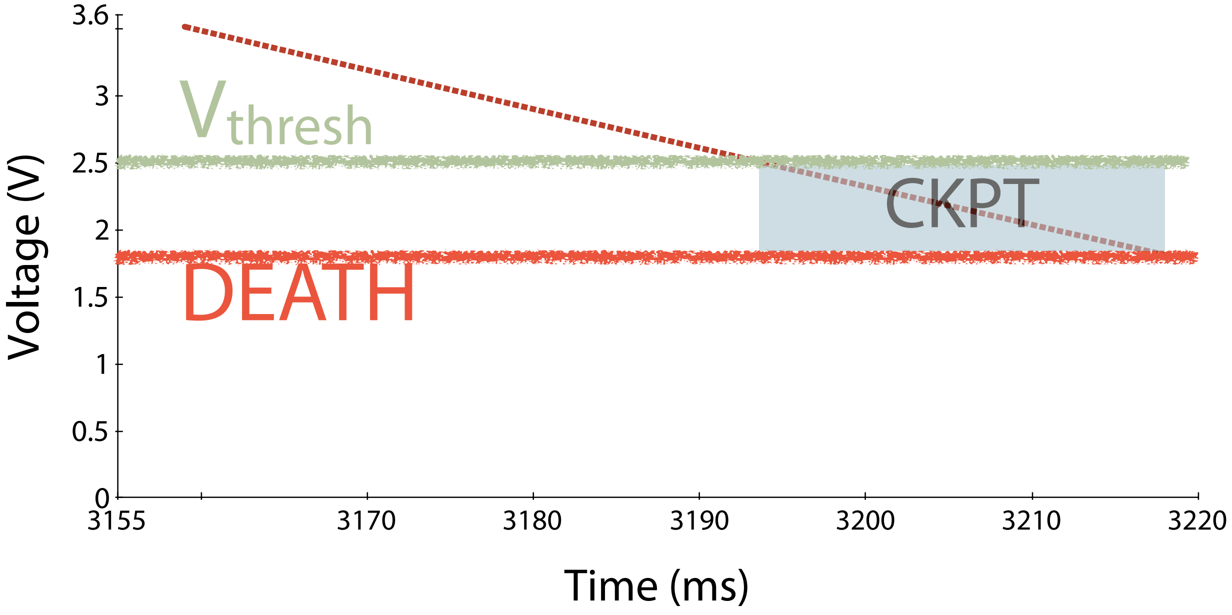
Programmer



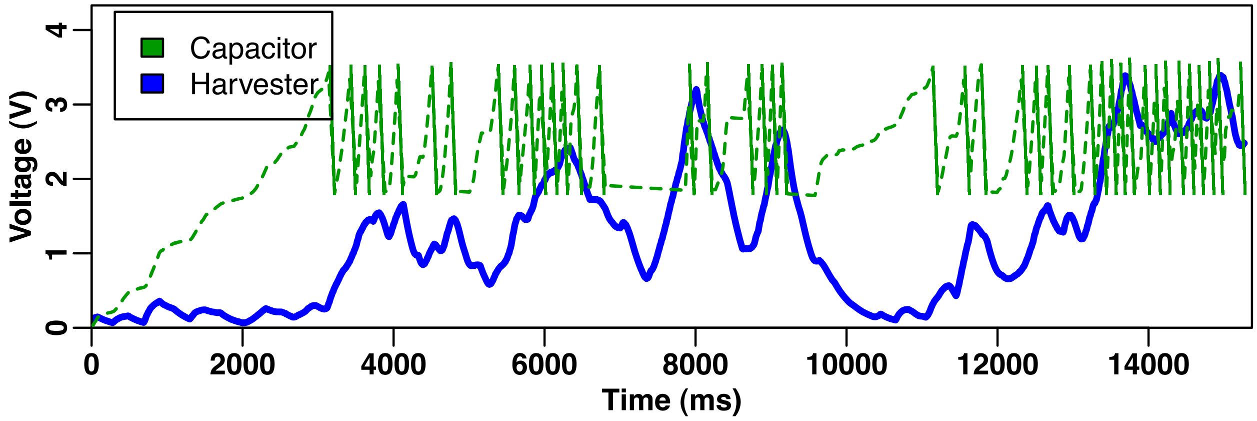
Write C code

Choose params

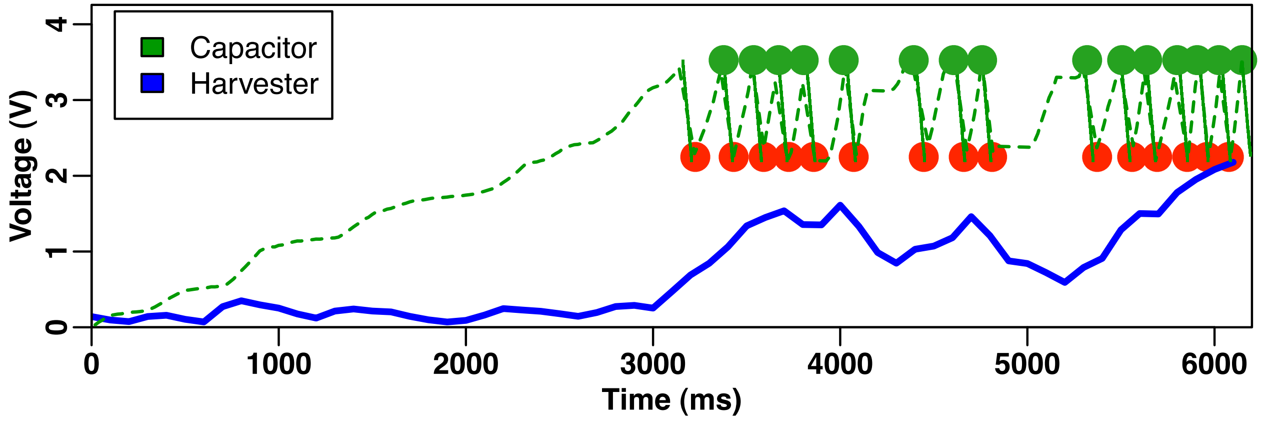
2) Checkpoint threshold V_{thresh}



With and Without Mementos



CRC
w/o Mementos:
never finishes



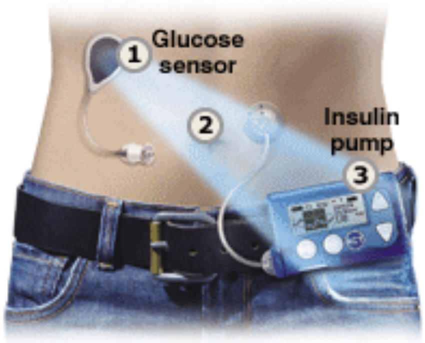
CRC
☺ w/ Mementos:
16 reboots

↕

Oracle: 14 reboots

Wireless + Internet Can Improve Healthcare

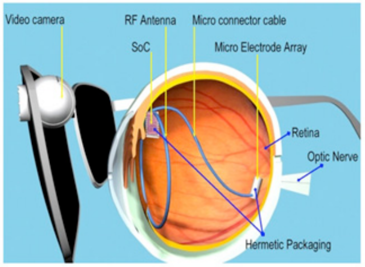
But not without fully understanding trustworthy software



Insulin pump

Artificial pancreas

Neurostimulators



Artificial vision

Obesity control

Programmable
Vasectomy

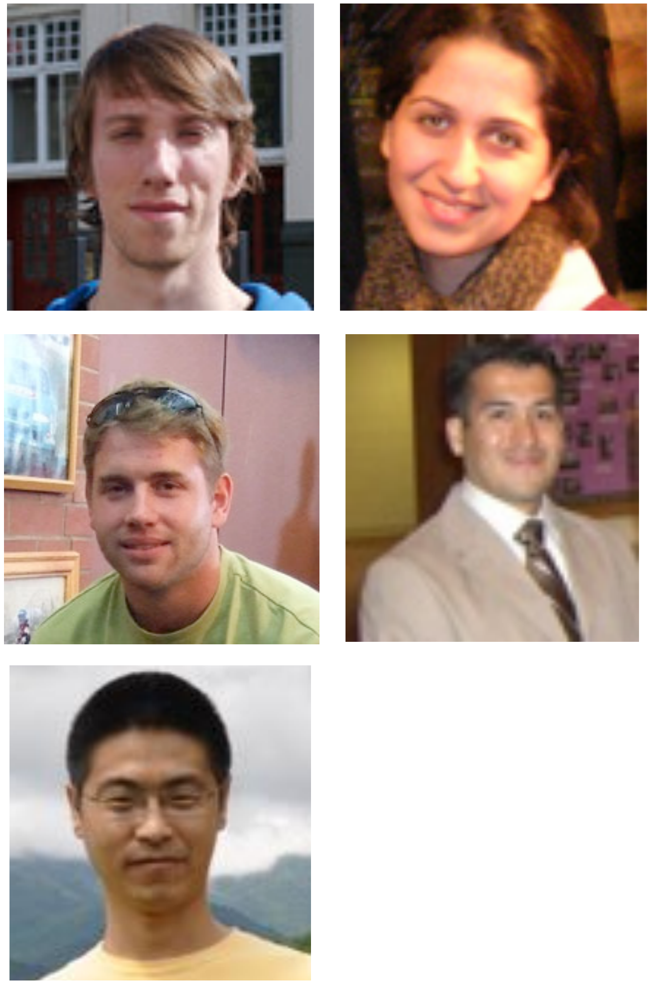
Photos: Medgadget

Trustworthy Medical Device SW

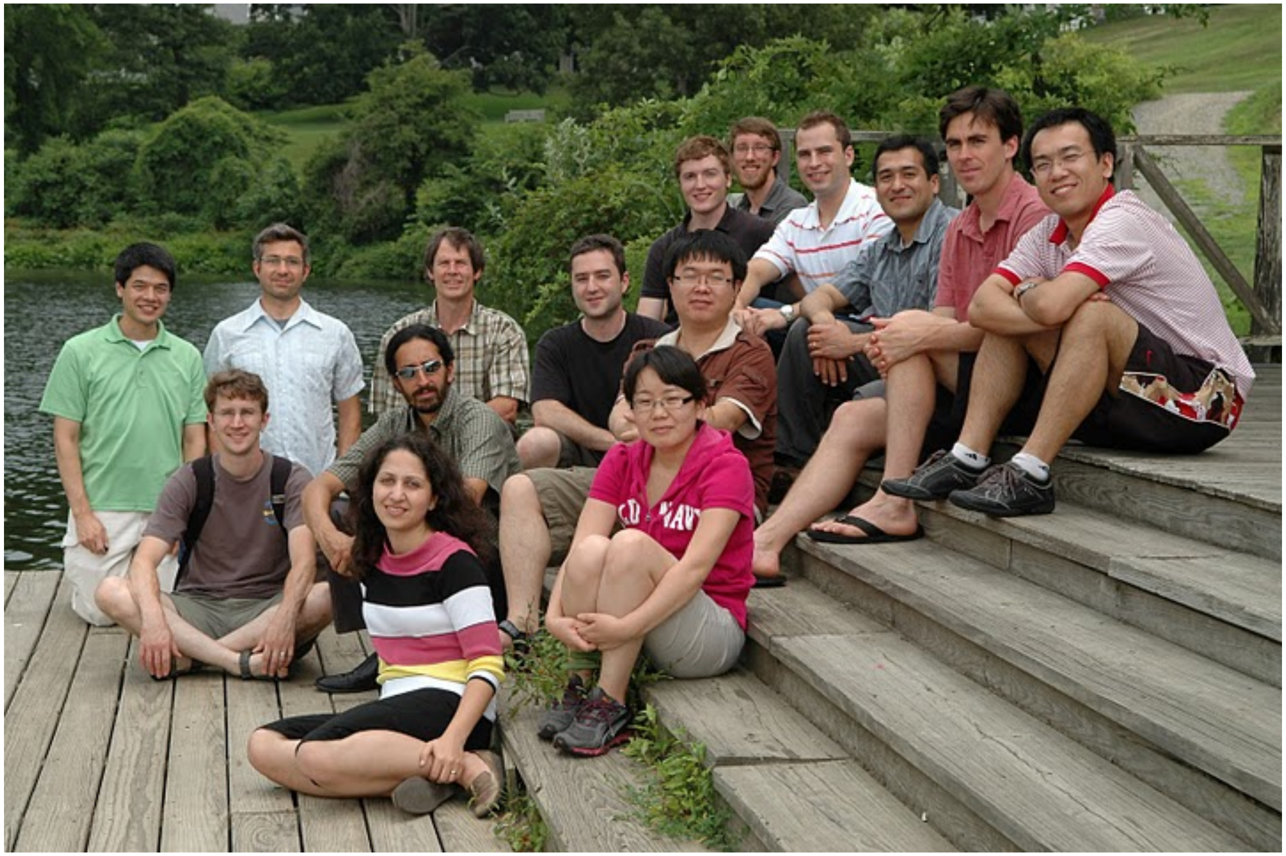
- In summary, software:
  - breeds overconfidence,
  - is not thoroughly testable, but
  - is flooding into medical devices
- Many risks could be mitigated with known technology
- Mitigate the risks by **incentivizing** manufacturers to
  - Adopt modern software engineering & systems engineering tech.
  - Create more meaningful **specification** of requirements
  - Better analyze human factors
  - Develop safety net for security and privacy
- Need: Outcomes, statistics, open research, responsibility

"Trustworthy medical device software"
Kevin Fu. *In Public Health Effectiveness of the FDA 510(k) Clearance Process: Measuring Postmarket Performance and Other Select Topics: Workshop Report,* Washington, DC, 2011.
IOM (Institute of Medicine), National Academies Press.

The S·P·Q·R Lab



http://spqr.cs.umass.edu/



UMASS Computer Science

- Positions? RAs: Yes! Postdoc: Yes! Staff: Yes!

Strategic Healthcare Advanced Research Projects **(SHARP)** is sponsored by the Office of the National Coordinator of the United States Department of Health and Human services.

Began in April 2010 and lasts 4 years

SHARPS

Strategic Healthcare Advanced Research Projects for Security

www.sharps.org

SHARP research areas:

- Security and Privacy **(SHARPS)**
- Patient-Centered Cognitive Support
- Health Applications and Networking Platforms
- Secondary Use of Health Records

http://HealthIT.HHS.gov/sharp

SHARPS Rationale

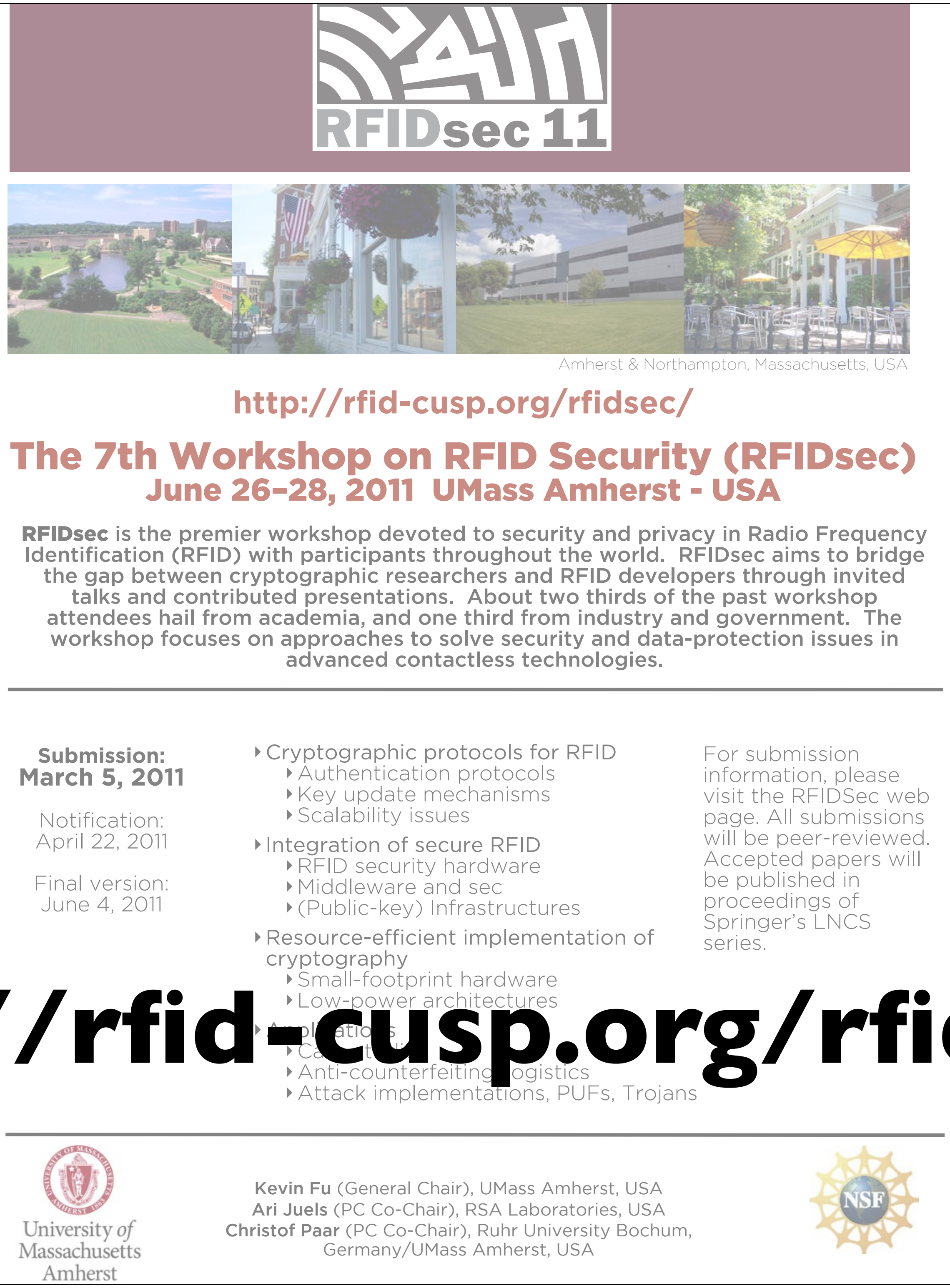
- Cyber security and privacy (S&P) risks are a significant barrier to the deployment and meaningful use of health information technology.
- Many key challenges in these areas can be addressed with emerging and new technologies in S&P.
- SHARPS teams computer scientists who specialize in S&P with healthcare specialists interested in S&P for HIT. The aim is to produce new levels of communication and tech transfer.

SHARPS Environments

- **EHR** – Electronic Health Records, managing patient records within an enterprise
- **HIE** – Health Information Exchange, sharing records between enterprises or between an enterprise and a patient in the form of a Personal Health Record
- **TEL** – Telemedicine, monitoring remotely, communicating with multimedia, and controlling implanted medical devices

SHARPS Participating Institutions

- University of Illinois at Urbana-Champaign
- Carnegie Mellon University
- Dartmouth College
- Harvard University and Beth Israel Deaconess Medical Center
- Johns Hopkins University and Children's Medical And Surgical Center
- New York University
- Northwestern University and Memorial Hospital
- Stanford University
- University of California, Berkeley
- University of Massachusetts Amherst
- University of Washington
- Vanderbilt University



Amherst & Northampton, Massachusetts, USA

http://rfid-cusp.org/rfidsec/

The 7th Workshop on RFID Security (RFIDsec)

June 26–28, 2011 UMass Amherst - USA

RFIDsec is the premier workshop devoted to security and privacy in Radio Frequency Identification (RFID) with participants throughout the world. RFIDsec aims to bridge the gap between cryptographic researchers and RFID developers through invited talks and contributed presentations. About two thirds of the past workshop attendees hail from academia, and one third from industry and government. The workshop focuses on approaches to solve security and data-protection issues in advanced contactless technologies.

Submission:
March 5, 2011

Notification:
April 22, 2011

Final version:
June 4, 2011

- Cryptographic protocols for RFID
  - Authentication protocols
  - Key update mechanisms
  - Scalability issues
- Integration of secure RFID
  - RFID security hardware
  - Middleware and sec
  - (Public-key) Infrastructures
- Resource-efficient implementation of cryptography
  - Small-footprint hardware
  - Low-power architectures
- Applications
  - Ca[illegible]
  - Anti-counterfeiting, logistics
  - Attack implementations, PUFs, Trojans

For submission information, please visit the RFIDSec web page. All submissions will be peer-reviewed. Accepted papers will be published in proceedings of Springer's LNCS series.

University of Massachusetts Amherst

Kevin Fu (General Chair), UMass Amherst, USA
Ari Juels (PC Co-Chair), RSA Laboratories, USA
Christof Paar (PC Co-Chair), Ruhr University Bochum, Germany/UMass Amherst, USA

NSF

http://rfid-cusp.org/rfidsec/

Your Homework

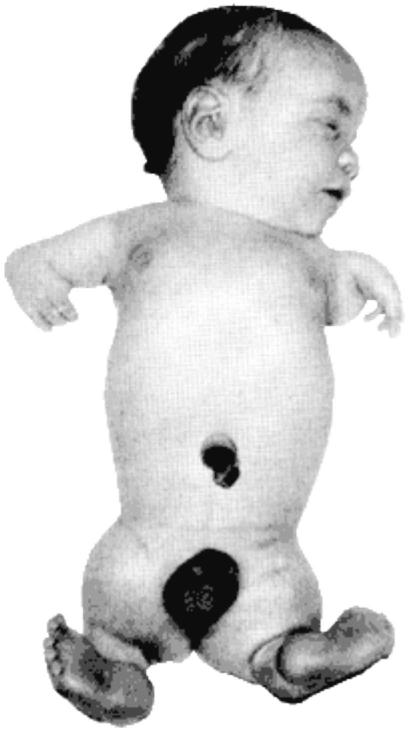
http://spqr.cs.umass.edu/
http://rfid-cusp.org/rfidsec/
http://www.cs.umass.edu/~kevinfu/
http://sharps.org/

Mementos: Ransford et al. [ASPLOS 2011]
Half Wits: Salajegheh et al. [USENIX FAST 2011]
CCCP: Salajegheh et al. [USENIX Security 2009]

Extra Material

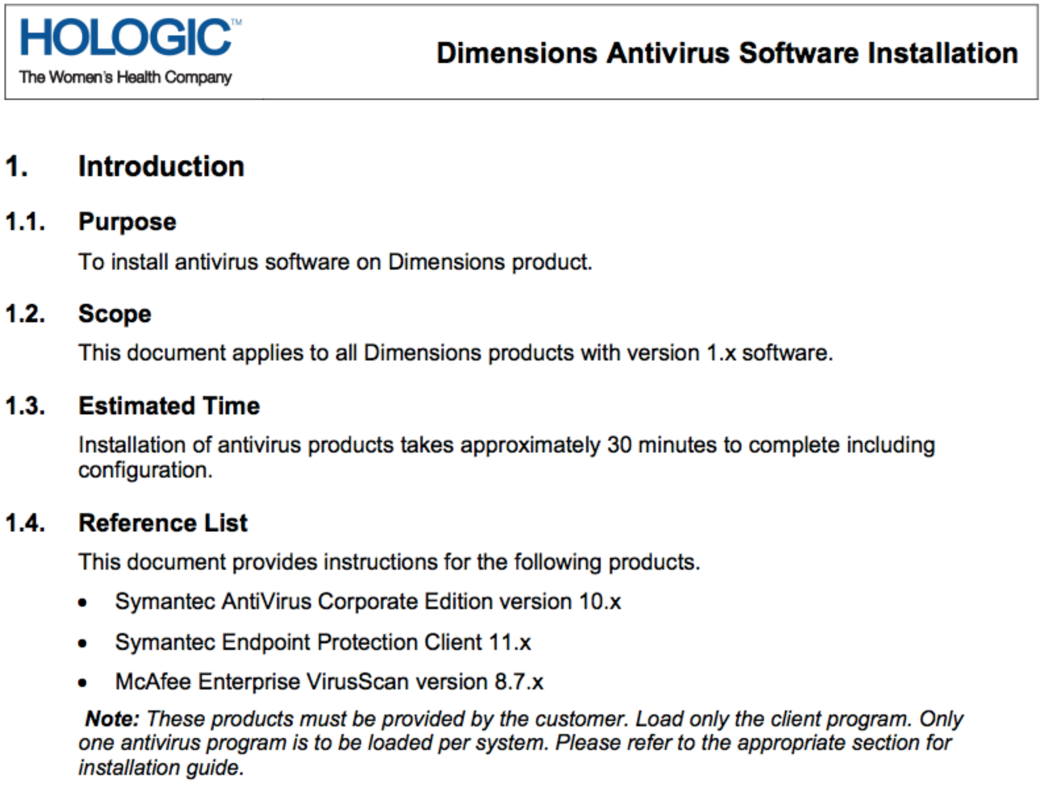
Thalidomide Drug in 1961

- Had been on the market for years in Europe.
- FDA refused to approve for sale in USA
  - Cited lack of sufficient safety data
- Industry unhappy
  - Bullied FDA to approve the drug for marketing
  - Cited unnecessary delays
- Later...
  - More than 10,000 children in forty-six countries were born with mangled or nonexistent limbs as a result of exposure in utero.
  - Company withdrew application



Moore, K. L.: Manit. Med. Rev. 43:306, 1963.

Anti-virus Updates for Mammography?



HOLOGIC™
The Women's Health Company

Dimensions Antivirus Software Installation

1. Introduction

1.1. Purpose

To install antivirus software on Dimensions product.

1.2. Scope

This document applies to all Dimensions products with version 1.x software.

1.3. Estimated Time

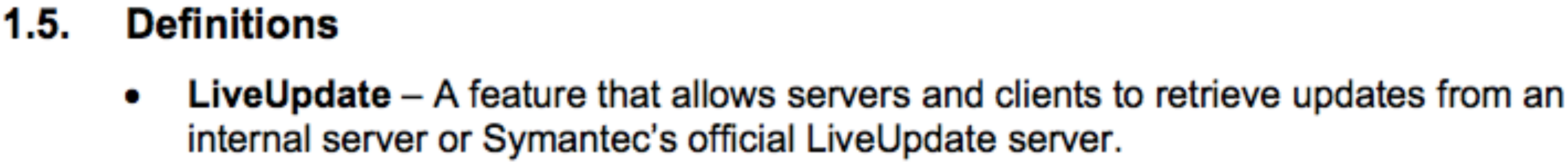
Installation of antivirus products takes approximately 30 minutes to complete including configuration.

1.4. Reference List

This document provides instructions for the following products.

- Symantec AntiVirus Corporate Edition version 10.x
- Symantec Endpoint Protection Client 11.x
- McAfee Enterprise VirusScan version 8.7.x

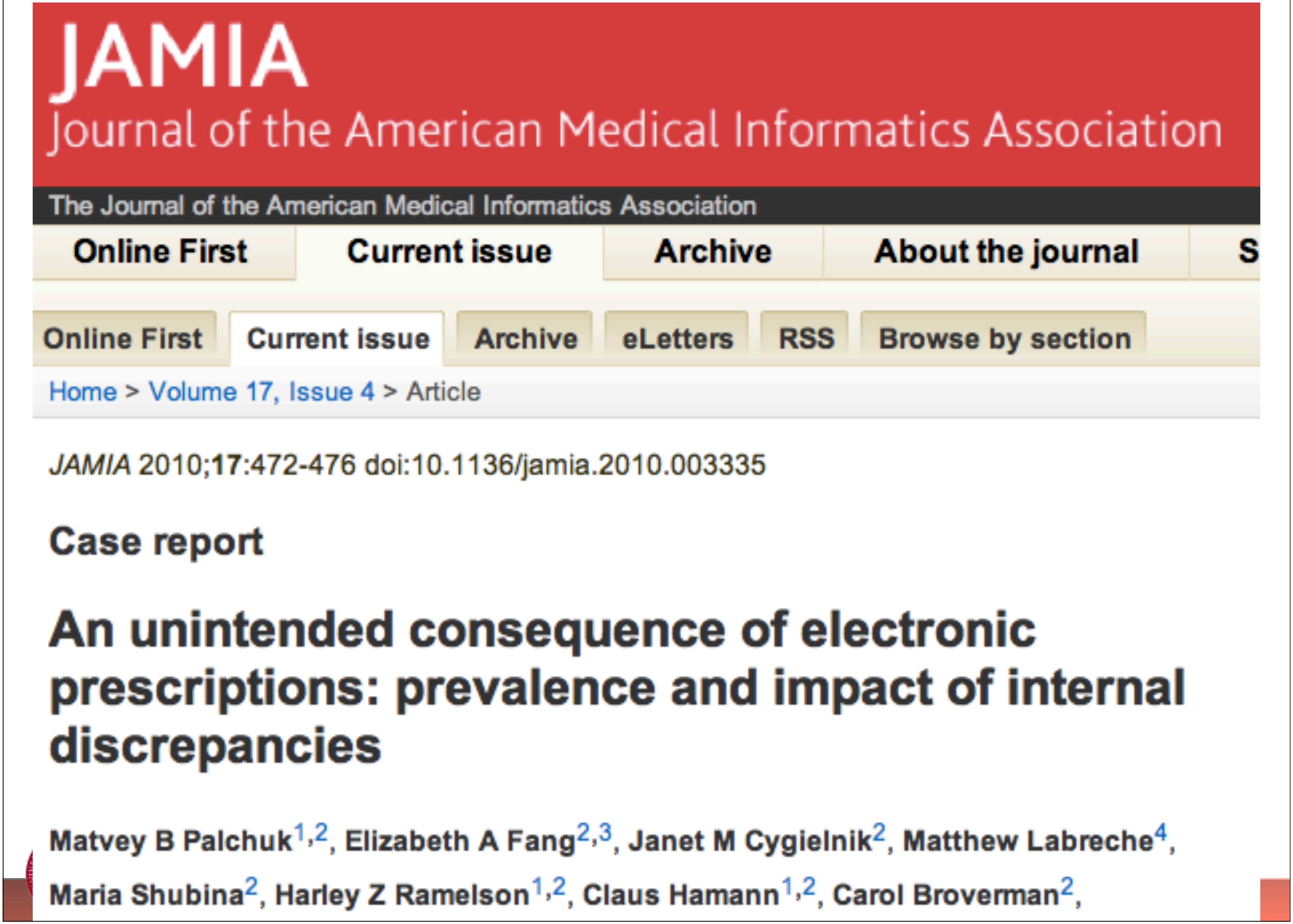
Note: *These products must be provided by the customer. Load only the client program. Only one antivirus program is to be loaded per system. Please refer to the appropriate section for installation guide.*



1.5. Definitions

- **LiveUpdate** – A feature that allows servers and clients to retrieve updates from an internal server or Symantec's official LiveUpdate server.

Harmless Choice of EHR/PHR Entry Style?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Journal of the American Medical Informatics Association
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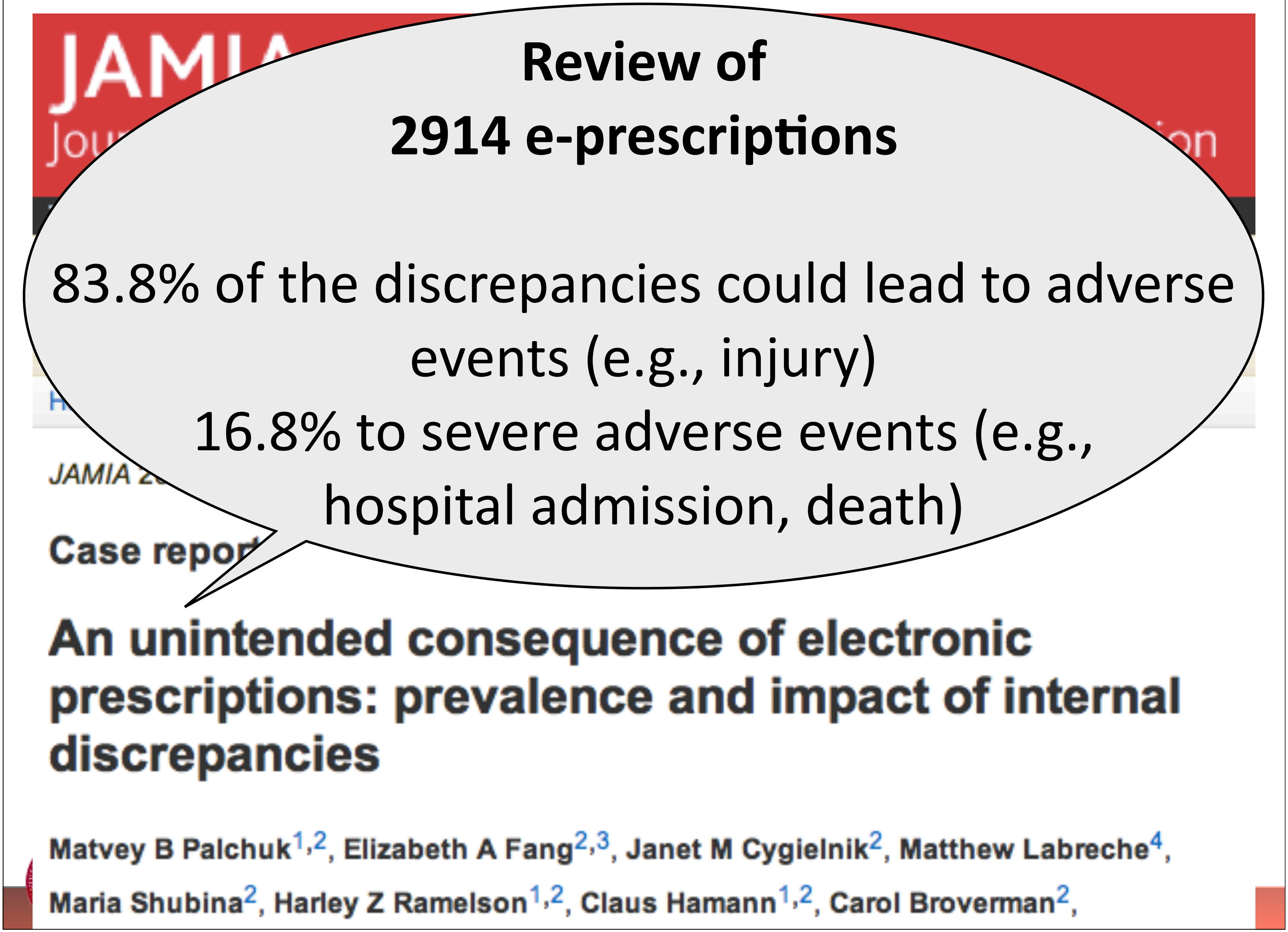
Home > Volume 17, Issue 4 > Article

JAMIA 2010;**17**:472-476 doi:10.1136/jamia.2010.003335

Case report

An unintended consequence of electronic prescriptions: prevalence and impact of internal discrepancies

Matvey B Palchuk[1,2], Elizabeth A Fang[2,3], Janet M Cygielnik[2], Matthew Labreche[4], Maria Shubina[2], Harley Z Ramelson[1,2], Claus Hamann[1,2], Carol Broverman[2],



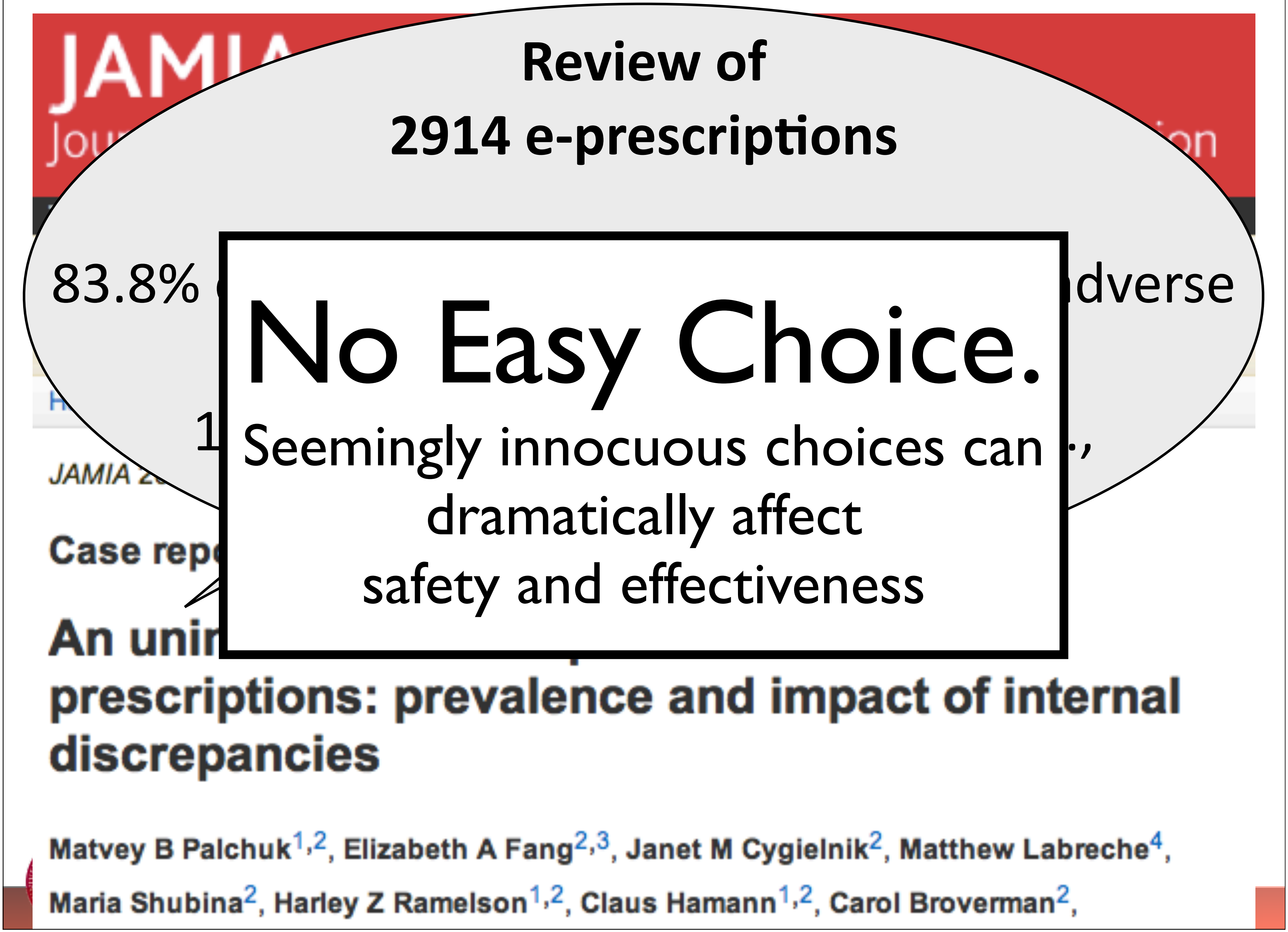
Review of
2914 e-prescriptions

83.8% of the discrepancies could lead to adverse events (e.g., injury)
16.8% to severe adverse events (e.g., hospital admission, death)

Case repor

An unintended consequence of electronic prescriptions: prevalence and impact of internal discrepancies

Matvey B Palchuk[1,2], Elizabeth A Fang[2,3], Janet M Cygielnik[2], Matthew Labreche[4], Maria Shubina[2], Harley Z Ramelson[1,2], Claus Hamann[1,2], Carol Broverman[2],



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prescriptions: prevalence and impact of internal discrepancies

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Review of

2914 e-prescriptions

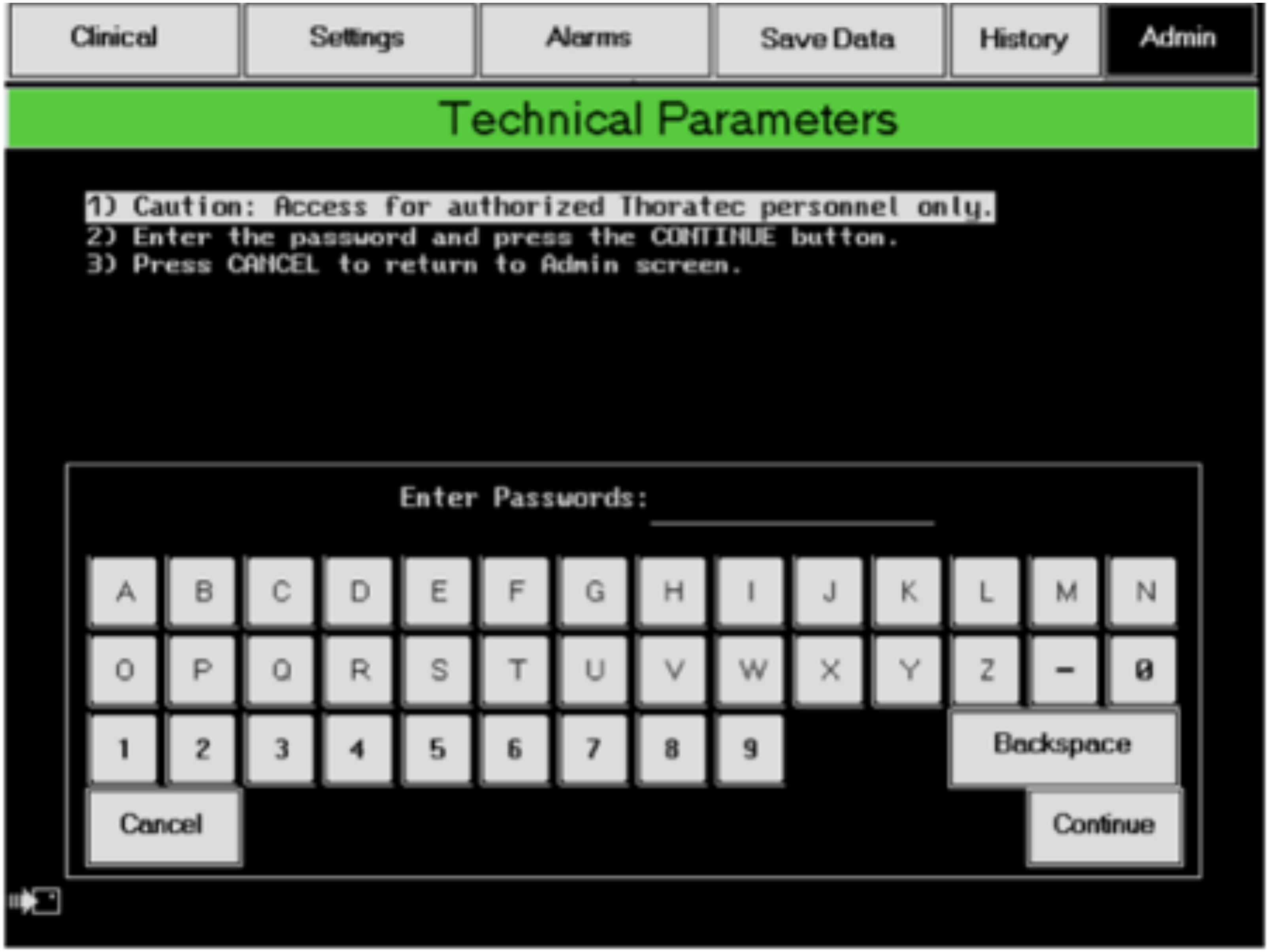
83.8% dverse

1 .,

No Easy Choice.

Seemingly innocuous choices can dramatically affect safety and effectiveness

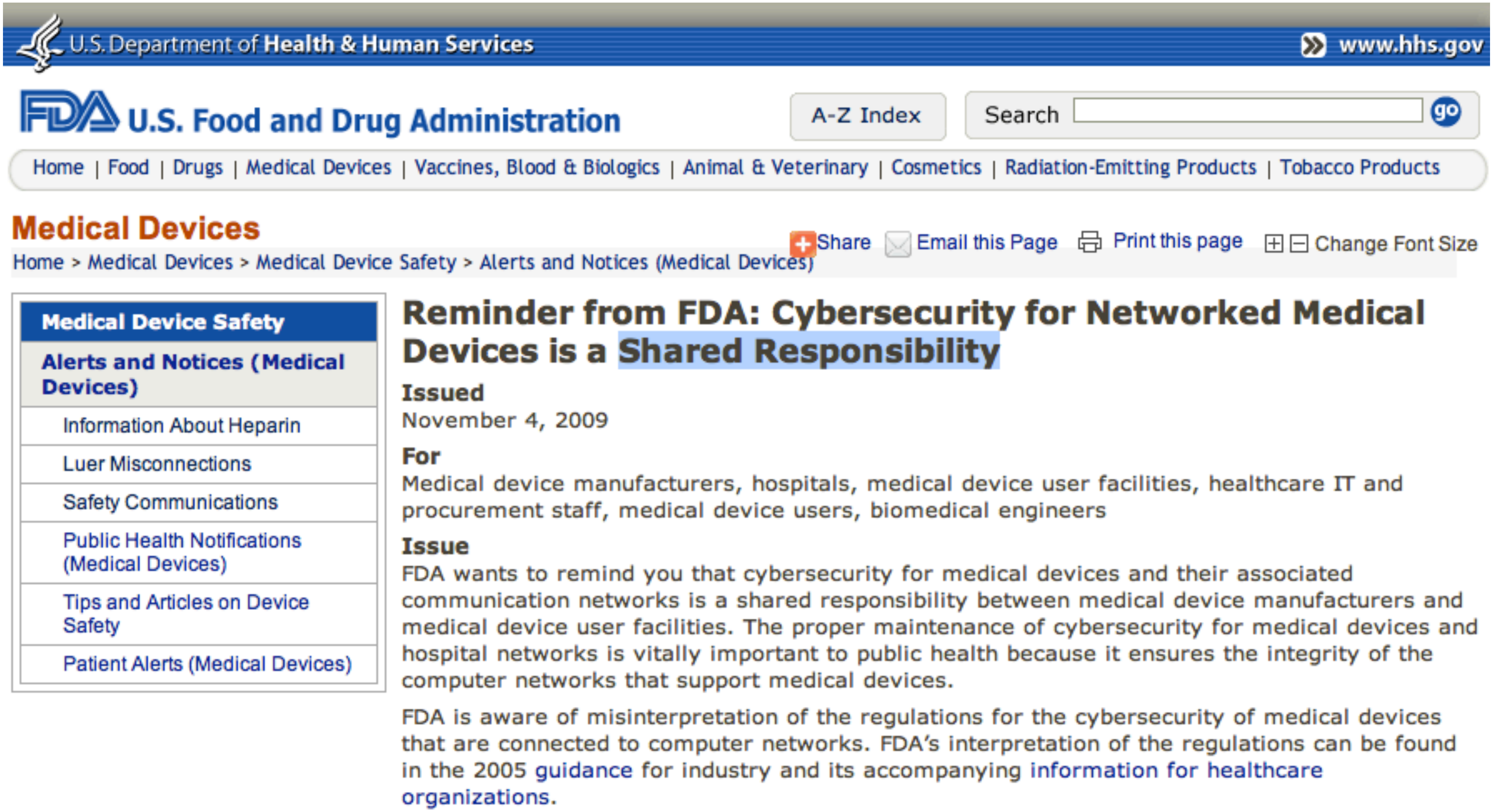
Of LVADs & Trustworthy Software



Technical Parameters

1) Caution: Access for authorized Thoratec personnel only.
2) Enter the password and press the CONTINUE button.
3) Press CANCEL to return to Admin screen.

Enter Passwords: ________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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.