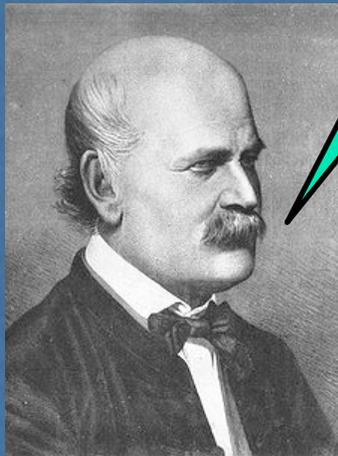


# MEDICAL DEVICE SECURITY

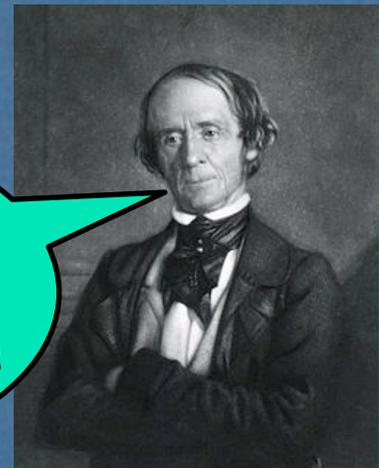
EECS 598-008 with Prof. Kevin Fu

Medical devices  
should be secure.



Dr. Ignaz Semmelweis  
1818-1865

Doctors  
are gentlemen and  
therefore their  
computers are always  
secure.



Dr. Charles Meigs  
1792-1869

## Avoiding Software Sepsis

*How do we improve the information security of increasingly interconnected and wirelessly controlled medical devices? Learn the timeless concepts and cutting-edge skills in computer engineering, human factors, and regulatory policies that determine the safety and effectiveness of manufacturing software-controlled medical devices.*



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# MEDICAL DEVICE SECURITY

EECS 598-008 with Prof. Kevin Fu

St. Jude Medical, the third major defibrillator company, said it used “proprietary techniques” to protect the security of its implants and had **not heard of any unauthorized or illegal manipulation of them.**

[B. Feder, “A Heart Device Is Found Vulnerable to Hacker Attacks” NY Times, March 12, 2008]



<http://tobacco.stanford.edu>

*Learn better ways to measure medical device security.*

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# MEDICAL DEVICE SECURITY

EECS 598-008 with Prof. Kevin Fu

## Computer Viruses Are "Rampant" on Medical Devices in Hospitals

A meeting of government officials reveals that medical equipment is becoming riddled with malware.

By David Talbot on October 17, 2012

**MIT  
Technology  
Review**



## Avoiding Software Sepsis

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# MEDICAL DEVICE SECURITY

EECS 598-008 with Prof. Kevin Fu



If you think buffer overflows in your EECS 280 homework are bad, try infusion pump software.

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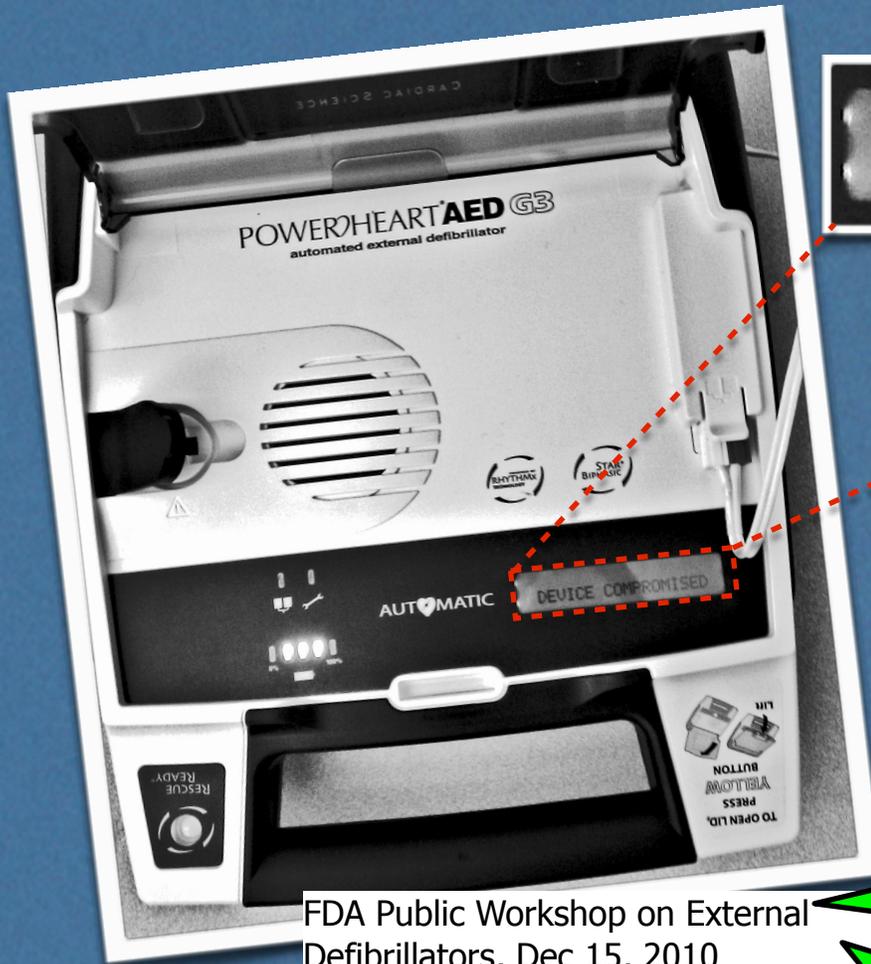


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# MEDICAL DEVICE SECURITY

EECS 598-008 with Prof. Kevin Fu



FDA Public Workshop on External Defibrillators, Dec 15, 2010

Oops!

"We spend considerable efforts...so that we can confirm that **nothing has been compromised.**"

-Janine Hansen, Senior Director of Quality Assurance and Regulatory Affairs, Cardiac Science

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"We typically don't experience the type of viruses that are being referred to, or any type of **viruses**, for that matter."

-Peter Ohanian, VP of Quality & Regulatory Affairs, Philips Healthcare

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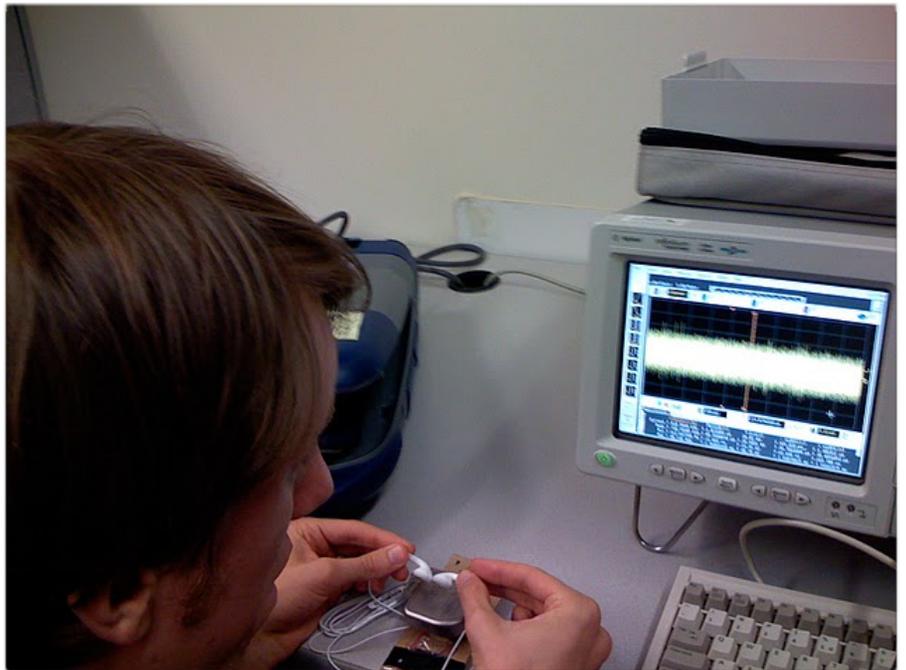
<http://www.eecs.umich.edu/courses/eecs598-008/>

# MEDICAL DEVICE SECURITY

EECS 598-008 with Prof. Kevin Fu

## Headphones Can Disrupt Implanted Heart Devices

by JOSEPH SHAPIRO



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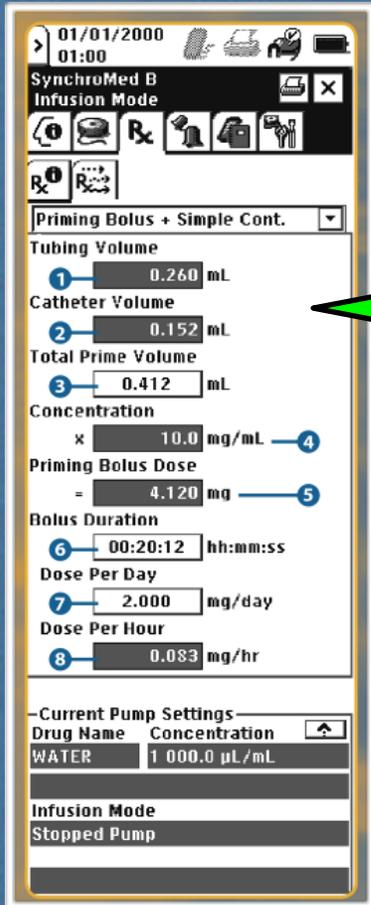


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# MEDICAL DEVICE SECURITY

EECS 598-008 with Prof. Kevin Fu



What's wrong with this user interface for a wirelessly controlled, implanted drug infusion pump that led to a patient death?  
**Turn over for answer.**

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# MEDICAL DEVICE SECURITY

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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

The original UI did not label the hours, minutes, seconds field for the bolus duration. HCP mistakes minutes for hours. 60x overdose. Outcome: death.

FDA U.S. Food and Drug Administration

Home | Food | Drugs | Medical Devices | Vaccines, Blood & Biologics | Animal & Veterinary | Cosmetics | Radiation-Emitting Products | Tobacco Products

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

#### 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 narcain 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-supporting equipment (unk date) and the pt died.

Search Alerts/Recalls

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