Regulatory Responsibilities for Medical Device Security

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- Visiting scientist, FDA NoE
- Board member, NIST ISPAB
- Patent pending technology: 
  - Ultra-low power flash memory

- This presentation is based on both my own research and the research of others. None of the opinions, findings, or conclusions necessarily reflect the views of my past or present employers.
Responsibility of Manufacturer

- Medical device cybersecurity risks are now **foreseeable**
  - Design controls should address foreseeable risks (510(k), PMAA)
- **FALSE**: FDA rules prevent software updates
  - No, but I can understand where that perception comes from
  - Pre-market review **rare** in cybersecurity updates of COTS software
  - But no one said manufacturing medical device software is easy
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
Regulatory pathways

Pre-market approval

It's complicated.

http://www.iom.edu/Activities/PublicHealth/510KProcess/2010-MAR-01.aspx
FDA Center for Devices and Radiological Health

Regulatory pathways

Pre-market notification

[510(k) clearance]

It’s complicated.

http://www.iom.edu/Activities/PublicHealth/510KProcess/2010-MAR-01.aspx
510(k) Substantial Equivalence

“One of the interesting classes is radiation equipment...Even the software, which I wonder where they got the first predicate for software.”

-David Feigal
Fmr. Director, FDA Center for Devices and Radiological Health (CDRH)

[Institute of Medicine Meeting 2, June 2010: Public Health Effectiveness of the FDA 510(k) Clearance Process]
Foreseeable Cybersecurity Risks...

Foreseeable risk-o-meter

Unsafe Practices — Accidents — Sabotage
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
Windows XP SP3 and Office 2003 Support Ends April 8, 2014

WHY?
Why is support ending for Windows XP SP3 and Office 2003?

WHAT?
What does end of support mean to customers?

HOW?
How will Microsoft help customers?

Get a free IDC assessment on migrating from Windows XP to Windows 7.
See how your organization can benefit from making the switch.
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 Gartner Research suggests "many independent software vendors (ISVs) are unlikely to support new versions of applications on Windows XP in 2011; in 2012, it will become common." And it may stifle access to hardware innovation: Gartner Research further notes that in 2012, most PC hardware manufacturers will stop supporting Windows XP on the majority of their new PC models.

*Get current with Windows 7 and Office 2010.* This option has upside well beyond keeping you supported. It offers more flexibility to empower employees to be more productive, while increasing operational efficiency through improved PC security and management. It also enables your organization to take advantage of latest technology trends such as virtualization and the cloud.

*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?*
WHAT?

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- Lack of Independent Software Vendor (ISV) & Hardware Manufacturers support - A recent industry report highlighted the need for support from ISVs and hardware manufacturers in maintaining compatibility and functionality.

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<table>
<thead>
<tr>
<th>Products Released</th>
<th>Lifecycle Start Date</th>
<th>Mainstream Support End Date</th>
<th>Extended Support End Date</th>
<th>Service Pack Support End Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Windows XP Service Pack 1</td>
<td>8/30/2002</td>
<td><strong>Not Applicable</strong></td>
<td><strong>Not Applicable</strong></td>
<td>10/10/2006</td>
</tr>
</tbody>
</table>

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**Download Free tool now.**

How will Microsoft help customers?
Still Not It: Hospitals, Manufacturers

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.
Managerial issues:
Diffusion of responsibility

Who’s covered when Secure Health IT hits the fan?
Foreseeable Cybersecurity Risks...

Foreseeable risk-o-meter

Accidents

Unsafe Practices

Sabotage
Implantation of Defibrillator

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

Device Programmer

Photos: Medtronic; Video: or-live.com
Implantation of Defibrillator

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Photos: Medtronic; Video: or-live.com
Privacy??
Privacy??

Implanting physician

Diagnosis

Also:

Device state
Patient name
Date of birth
Make & model
Serial no.
... and more
Insulin pump hack delivers fatal dosage over the air
Sugar Blues, James Bond style

By Dan Goodin in San Francisco • Get more from this author

Posted in Security, 27th October 2011 06:23 GMT

In a hack fitting of a James Bond movie, a security researcher has devised a novel exploit that hijacks nearby insulin pumps, enabling him to surreptitiously deliver fatal doses to diabetic patients who rely on them.
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
Hospitals Stuck With Windows XP

**General System Counts**

- Systems with AV: 6398
- Printers: 2074
- Medical equipment: 905
- Misc: 2460

Total Devices: 11,387

**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

**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.

[Courtesy: Mark Olson, BIDMC Boston]
Hospitals Stuck With Windows XP

User facilities are asking for requirement of security controls for embedded software within 510(k).

FDA seems to be listening.

http://blog.secure-medicine.org/

Last security patch: 2007

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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.
Waiter, there's a virus in my SW!

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

In addition, baxa does not regularly install operating system updates or patches.

BAXA CORP. EXACTA-MIX 2400

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.
But According to FDA...

The burning question...

Q. Is FDA policy degrading network security and performance by impeding the timely implementation of security and other maintenance patches in commercial off-the-shelf (COTS) software used in network connected medical devices?

A. No. But there seems to be some confusion over what is required, and mistaken interpretations of FDA policy (and the law) may be contributing to the problem.
The burning question is:

Q. Is FDA policy degrading network security and performance by impeding the timely implementation of software patches in commercial off-the-shelf (COTS) software used in network connected medical devices?

A. No. But there seems to be some confusion over what is required, and mistaken interpretations of FDA policy (and the law) may be contributing to the problem.

Unspecified manufacturers have reportedly told hospital IT staff that they can’t install security patches “because of FDA rules.”

Biomedical engineering staff need to report SW security problems to FDA for things to change!!!
FDA rules prevent software security updates.

FALSE! But continue.
How significant are intentional, malicious malfunctions in software?
21 CFR 211.132 and Security

(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

By Rachael Bell

The Tylenol Terrorist: Death in a Bottle

On September 29, 1982, 12-year-old Mary Kelleman 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]
Bad People Do Exist: Vandals

Hackers Assault Epilepsy Patients via Computer
By Kevin Poulsen 03.28.08 8:00 PM

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.

19 Days in April 2012

Source: Andy Greenberg, Forbes
Lack of Exploits is Not Assurance

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

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

Oh, Crap.

19 Days in April 2012
"This is an evolution from having to think about security and safety as a healthcare company, and really about keeping people safe on our therapy, to this different question about keeping people safe around criminal or malicious intent."

Catherine Szyman
President, Medtronic Diabetes
Security Built In: A New Hope?

Security Risk Assessment Process

Security Risk process parallels safety risk
  • Driven by IEC 14971

Cross-functional analysis, maintained across development lifecycle
  • Starting at concept phase

Broad list of threat classes and protectable assets to consider

Risk axes
  • Attractiveness (likelihood)
  • Impact (severity)
Security and Privacy Qualities of Medical Devices: An Analysis of FDA Postmarket Surveillance

Daniel B. Kramer¹*, Matthew Baker¹, Benjamin Ransford², Andres Molina-Markham², Quinn Stewart², Kevin Fu², Matthew R. Reynolds¹

¹ Department of Medicine, Beth Israel Deaconess Medical Center, Harvard Medical School, Boston, Massachusetts, United States of America, ² Department of Computer Science, University of Massachusetts, Amherst, Massachusetts, United States of America

Abstract

Background: Medical devices increasingly depend on computing functions such as wireless communication and Internet connectivity for software-based control of therapies and network-based transmission of patients’ stored medical information. These computing capabilities introduce security and privacy risks, yet little is known about the prevalence of such risks within the clinical setting.

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.

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.

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MEDICAL DEVICES

FDA Should Expand Its Consideration of Information Security for Certain Types of Devices

Computer Viruses Are "Rampant" on Medical Devices in Hospitals
A meeting of government officials reveals that medical equipment is becoming riddled with malware.

Health scare: Much hospital equipment uses software that can be vulnerable to viruses.

Computerized hospital equipment is increasingly vulnerable to malware infections, according to participants in a recent government panel. These infections can clog patient-monitoring equipment and other software systems, at times rendering the devices temporarily inoperable.
**Semmelweis to Software Sepsis**

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

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**Dr. Ignaz Semmelweis**

1818-1865

**Physicians should their wash hands.**

**Dr. Charles Meigs**

1792-1869

**Doctors are gentlemen and therefore their hands are always clean.**
Semmelweis to Software Sepsis

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

Medical devices should be secure.

Doctors are gentlemen and therefore their computers are always secure.

Dr. Ignaz Semmelweis
1818-1865

Dr. Charles Meigs
1792-1869
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
Compliance? Ask your Engineers...

- What design controls address cybersecurity risks?
  - A manufacturer can no longer claim unawareness of security risks

- How often are **software updates** issued to customers?
  - Windows XP has several critical security flaws per year
  - Engineers need resource$ 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
Security should be designed in not bolted on
Summary: Responsibility is Yours

- Biggest risk:
  - Hackers breaking into medical devices
  - Wide-scale **unavailability** of patient care
  - **Integrity** of medical sensors

- Security can’t be bolted on. **Build it in.**

- Cybersecurity responsibility
  - Cybersecurity risks are now considered **foreseeable risks**
  - Design controls in early manufacturing should address risks
  - Update your Windows software!! Don’t party like it’s 1999.
Security part of the solution: safe and effective medical device software

- Safety
- Effectiveness
- Meaningful use
- Patient/clinic acceptance
- Assurance
- Predictability
- Dependability
- Reliability
- Reduce costs
- Reliability
Ann Arbor Research Center for Medical Device Security
secure-medicine.org