



# *Implantable Medical Devices – Cyber Risks and Mitigation Approaches*

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**Electrosoft**  
*Managing Cyber Security Risk through Innovation and Engineering*



# Agenda

- **Overview of IMDs**
- **Security Threats, Vulnerabilities and Risks**
- **Risk-Based Mitigation Approach**
- **Summary**
- **References**





# What is an IMD?

- **Implantable Medical Device (IMD)**
  - **Tiny computing platform with firmware**
  - **Runs on small batteries**
  - **Programmable**
  - **Implanted in human body**
  - **Monitors health status**
  - **Delivers medical therapy**

# IMD Examples

- **Pacemakers**
- **Implantable Cardiac Defibrillators (ICD)**
- **Cochlear Implants**
- **Insulin Pumps**
- **Neurostimulators**



# Wireless Implantable Medical Devices

Deep Brain Neurostimulators



Cochlear Implants



Gastric Stimulators



Cardiac Defibrillators/  
Pacemakers



Foot Drop Implants



Insulin Pumps



# Pacemaker

- **Consists of battery, computerized generator, and wires with sensors at tips (pacing leads)**
  - Wires connect generator to the heart
- **Records heart's electrical activity and rhythm**
  - Recordings used to adjust pacemaker therapy
- **On abnormal heart rhythm**
  - Generator sends electrical pulses to heart
- **Can monitor blood temperature, breathing etc.**
  - Can adjust heart rate to changes in your activity
- **Wireless communication with Programmer**
  - Read battery status and heart rhythms
  - Send instructions to change therapy



# Wireless Insulin Pump

- Supports blood sugar monitoring & insulin delivery
- Wireless integration of Monitor and Pump
- Pump pre-set with user-specific information
- Monitor transmits glucose value to pump via wireless
- Pump calculates and delivers proper insulin dosage
- Pump “remembers” dosage history
- PC “dongle” can connect to Pump to read data or update settings



Medtronic Paradigm 512 Insulin Pump with Wireless Blood Sugar Meter

# Cochlear Implants



## Cochlear implants

While hearing aids can only amplify sound, a cochlear implant transforms sound into electrical energy that is used to stimulate auditory nerves in the inner ear.

**1** Sounds are picked up by a microphone that is mounted on the external ear piece.

**2** The speech processor digitizes the sound into signals and sends the signals to the transmitting coil.

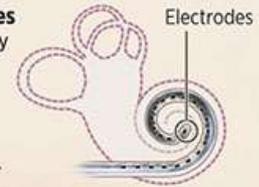
Controls for processor are on the bottom of ear piece.



**3** A transmitting coil sends the coded signals as radio waves to the cochlear implant under the skin.

**4** The internal processor is placed in the mastoid bone behind the ear. The cochlear implant delivers electrical energy to an array of electrodes, which has been inserted into the cochlea.

**5** The electrodes along the array stimulate the remaining auditory nerve fibers in the cochlea.



**6** The resulting electrical sound information is sent through the auditory system to the brain.

SOURCE: University of Miami Leonard M. Miller School of Medicine

M.MATTERN / HERALD STAFF



# IMD Data

- **IMD holds various Data Types**
  - **Static Data**
    - Device make
    - Model #
  - **Semi-static Data**
    - Physician & Health Center Identification
    - Patient Name and DOB
    - Medical condition
    - Therapy configuration
  - **Dynamic Data**
    - Patient health status history
    - Therapy and dosage history
    - Audit logs



# IMD Accessibility

- **“Programmer” Device communicates with IMD**
  - Through wireless channels
  - Using radio frequency transmission
- **PC communicates with IMD**
  - Through USB-port "dongles" using radio frequencies
  - PC may also be connected to Internet
- **IMD functions accessed remotely**
  - Read data on health status & therapy history
  - Emergency extraction of patient health history
  - Emergency reset of IMD configuration
  - Therapy programming/reprogramming
  - Firmware updates



# Regulation of IMDs

- **In US, IMDs are regulated by**
  - **Food and Drug Administration (FDA) Center for Devices and Radiological Health (CDRH)**
- **Testing focus**
  - **Safe and effective functioning**
  - **Different environmental conditions**
- **Absence of focus**
  - **Resistance/Resilience to cyber attacks**



# Are IMDs Vulnerable?

- **A resounding YES!**
- **Current devices are engineered without considering threat of a potential hacker**
- **Current methods to prevent unauthorized access to IMDs include**
  - Use of proprietary protocols
  - Controlled access to “Programmers” devices
  - Essentially, ***security by obscurity!***

# Black Hat security conference – Aug 2011

- “Security researcher Jerome Radcliffe has detailed how our use of SCADA insulin pumps, pacemakers, and implanted defibrillators could lead to **untraceable, lethal attacks from half a mile away**”
- “He managed to **intercept the wireless control signals, reverse them, inject some fake data, and then send it back to the [insulin] pump.**”
- “He could increase the amount of insulin injected by the pump, or reduce it”



- Halperin et al, “Pacemakers and Implantable Cardiac Defibrillators: Software Radio Attacks and Zero-Power Defenses”
- “... an implantable cardioverter defibrillator (1) is potentially **susceptible to malicious attacks that violate the privacy** of patient information and medical telemetry, and (2) may experience **malicious alteration to the integrity of information or state**, including patient data and therapy settings for when and how shocks are administered.”





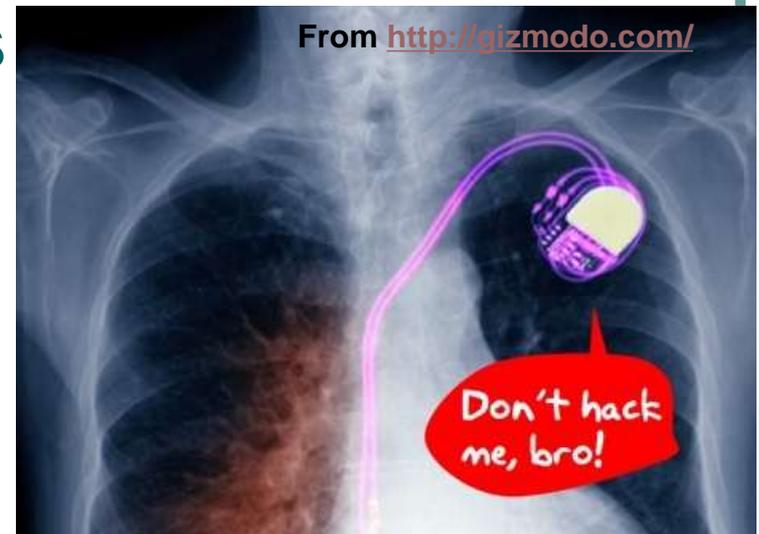
# Threats

- **Patient Data Extraction**
- **Patient Data Tampering**
- **Device Re-programming**
- **Repeated Access Attempts**
- **Device Shut-Off**
- **Therapy Update**
- **Malicious Inputs**
- **Data Flooding**



# , Vulnerabilities

- **Unsecured Communication Channels**
- **Inadequate Authentication Mechanisms**
- **Inadequate Access Controls**
- **Software Vulnerabilities**
- **Weak Audit Mechanisms**
- **Meager Storage**
- **Insufficient Alerts**





# Risks

- **Patient Health Safety**
  - Firmware Malfunction
  - Malicious Therapy Update
  - Malicious Inputs to Device
- **Patient Privacy Loss**
  - Data Leakage from Device
- **Inappropriate Medical Follow-up**
  - Tampering of Patient Readings
- **Device Unavailability**
  - Battery Power Depletion
  - Device Flooding





# Risk-Based Mitigation Approach

- **Develop IMD Security Impact Matrix**
- **Develop IMD Access Requirements Matrix**
- **Select Appropriate Security Mechanisms**
- **Tailor Security Mechanisms**
  - **Accommodate IMD Environment Constraints**
  - **Add Compensating Mechanisms (as needed)**



# FIPS 199-based Impact Analysis

- **Identify IMD Data Types**
  - E.g., Firmware, Device Identification, Patient Identification, Provider Identification, Health Condition, Therapy Configuration, Patient Readings, Audit Logs
- **Identify IMD Health Delivery Commands**
  - E.g., Emergency reset
- **Analyze Impact of Compromise**
  - For each Data Type, estimate impact
    - Loss of Confidentiality, Integrity and Availability
  - For each Command Type, estimate impact
    - Loss of Availability
  - Assign Impact as [LOW, MODERATE, HIGH]
- **Tabulate in IMD Security Impact Matrix**

# IMD Security Impact Matrix (IMD-SIM)

Security Function / Data, Command	Emergency Reset Command	Patient ID Data	Therapy Data	Patient Health Data
Confidentiality	N/A	MOD	LOW	MOD
Integrity	N/A	MOD	HIGH	HIGH
Availability	HIGH	LOW	MOD	MOD



# Determine IMD Access Requirements

- **Develop Matrix**
  - By Data Type and Health Delivery Command
  - By Role of Individual Accessing IMD and
    - By Access Channels (e.g., wired, wireless)
- **Add Required Access Privileges**
  - Per Basic IMD Functionality
  - By Need for Emergency Access
  - By Utility and Quality of Life Factors
- **Tabulate as IMD Access Requirements Matrix (IMD-ARM)**

# IMD Access Requirements Matrix (IMD-ARM)

ROLE-CHANNEL / Command, Data	Emergency Reset Cmd	Patient ID Data	Therapy Data	Patient Health Data
Patient-Wireless				
Prescribing Physician-Wired		Read Write	Read Write	Read
Maintenance Physician-Wireless		Read	Read	Read
Emergency Tech-Wireless	Invoke			

# Select Needed Security Mechanisms

- **Overlay IMD-IAM and IMD-ARM**
- **Select Security Mechanisms to Protect IMD Data/Commands**
  - **Channel Protection Mechanisms**
    - Crypto-protected channel
    - None (Proprietary Protocols)
  - **Authentication Mechanisms**
    - Password
    - Device-to-device handshake
    - Cryptographic authentication
  - **Audit Mechanisms**
    - Auditable Events
    - Management of Audit Space Depletion
  - **Alert/Alarm Mechanisms**
    - Audible Alarms
    - Automatic Device Reset to Safe Mode





# Tailor Security Mechanisms

- **IMDs subject to many constraints**
  - **Device Size**
  - **Cost**
  - **Power**
  - **Computational Capability**
  - **Storage**
- **Adjust security mechanisms to accommodate constraints**
  - **E.g., Add Alarm if authentication can't be strengthened for certain Data Types**



# Special Challenges in Securing IMDs

- **Battery and Power Limitations**
  - Power usage must be minimized to extend battery life
  - Battery depletion has devastating health consequences
- **Use of Cryptographic Techniques**
  - Highly Constrained Environment (cost, power, storage)
  - Compatible Crypto Suites/Protocols Needed
    - **Crypto for Sensor Networks**
- **Audit Mechanisms**
  - Limited Storage Area on Device
    - Attacks may generate deluge of audit entries
  - Managing Audit Space Depletion
    - **Selective Overwriting; Alarms (Audible or to Remote Monitor)**



# Summary – IMDs and Security

- **IMDs – Essential in Current Healthcare Environment**
- **Wireless Access**
  - Promotes Usability and Utility
  - Poses Significant Security and Privacy Concerns
- **Risk-based Mitigation Approach**
  - Determine Security Impact for Data Types
  - Implement Adequate Security Mechanisms
  - Balance Security/Privacy with Safety/Usability
- **Further Work**
  - Models for IMD security and privacy
  - Crypto-suites for IMD environments



# References

- **“Implantable Pacemaker Testing Guidance,”**  
<http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM081382.pdf>.
- **D. Halperin, et al, “Pacemakers and Implantable Cardiac Defibrillators: Software Radio Attacks and Zero-Power Defenses,”** Proceedings of the 2008 IEEE Symposium on Security and Privacy, Oakland, CA, 2008.
- **D. Halperin et al, “Security and Privacy for Implantable Medical Devices,”** in Pervasive Computing, Vol. 7, No. 1, January–March 2008.
- **S. Capkun, “On Secure Access to Medical Implants,”** Workshop on Security and Privacy in Implantable Medical Devices, Lausanne, Switzerland, April, 2011.
- **S. Cherukuri, K. Venkatasubramanian, and S. Gupta, “BioSec: A Biometric Based Approach for Securing Communication in Wireless Networks of Biosensors Implanted in the Human Body,”** Proc. Int’l Conf. Parallel Processing (ICPP)Workshops, IEEE CS Press, 2003, pp. 432–439.
- **T. Denning, et al “Patients, pacemakers, and implantable defibrillators: human values and security for wireless implantable medical devices,”** Proceedings of the 28th international conference on Human factors in computing systems, ACM New York, NY, USA, 2010, pp 917-926.
- **National Institute of Standards and Technology “FIPS Pub 199: Standards for Security Categorization of Federal Information and Information Systems,”** FEDERAL INFORMATION PROCESSING STANDARDS PUBLICATION, February 2004.
- **S. Fischer and M. Zitterbart, “Security in Sensor Networks,”** Information Technology: Vol. 52, No. 6, 2010, pp. 311-312.

# Questions and Contact Information



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