ACCE gratefully acknowledges the sponsorship of this webinar by MEDIGATE by Claroty.
Juuso Leinonen is a Principal Project Engineer, at the Device Evaluation group at ECRI, where he performs comparative medical device evaluations and investigates medical device related accidents. His current subject-matter expertise includes infusion technology, medical device cybersecurity, and telehealth.
Logistics

• All attendees have their microphones muted during the presentation.

• Questions to the panelists must be submitted via the “Q&A” feature (not chat) in Zoom at any time.

• If there is any urgent issue, please use the “chat” feature to communicate with the panelists.

• We will try to ask Ty, Skip and Jon to answer questions not addressed during the webinar and distribute them to participants via email or post them to ACCE website.

• Please remember to complete the webinar evaluation after attending. A link will be provided at the end.
About the speaker

Ty Greenhalgh was an early pioneer of the electronic medical record (EMR). The Henry Ford Health System awarded the “Most Innovative Technology of the Year” to Mr. Greenhalgh, in conjunction with the AHIMA, for groundbreaking work in developing one of the first EMR systems to contain automated HIM workflow, electronic signature and integration into the AHIMA FORE library in Chicago.

He was employed with 3M Health Information Systems for over 25 years. He helped introduce disruptive technologies to include Remote Transcription, Digital Dictation and Speech Recognition, Document Scanning, Computer Assisted Coding and Computer Assisted Clinical Documentation Improvement.

Ty is currently an ambassador with the HHS 405(d) Program and Task Group which was responsible for the recognized security practices referenced in the new HITECH amendment more commonly known as the Health Industry Cybersecurity Practices: Managing Threats and Protecting Patients.

Ty is currently the Healthcare Industry Principal with Medigate by Claroty. Claroty, a worldwide leader in cybersecurity, empowers organizations around the world to secure all their cyber-physical systems. Claroty recently purchased Medigate, the Best in KLAS healthcare solution, integrating the tools required for cybersecurity of medical devices to become the dominant leader for healthcare device cybersecurity. Ty has authored dozens of articles and is a frequent speaker for AHIMA, HCCA, HIMSS and AAMI.
Skip Sorrels is Director of Cybersecurity for Ascension Technologies having oversight across Ascension for cyber and information security operations. He is responsible and directs the following programs: standards and policies (GRC), vulnerability management, privileged access management, threat intelligence, pen testing, medical device and operational technologies cyber security.

Previously, Skip served as Dell and then NTT's Program Executive of service delivery for Ascension as well as for AMITA Health. He is a graduate of the University of Arkansas for Medical Sciences.
Legacy equipment in healthcare is a pervasive cybersecurity risk. The IMDRF has defined a legacy device as medical devices that cannot be reasonably protected against current cybersecurity. Legacy devices are critical to healthcare delivery, are cost prohibitive to simply replace and mitigating their risks cause confusion and contention between medical device manufacturers (MDM) and healthcare delivery organizations (HDO) when it comes to Governance, Communications, Cybersecurity Risk Management and Future Proofing.

The Healthcare Sector Coordinating Council (HSCC) has recently released Health Industry Cybersecurity – Managing Legacy Technology Security (HIC-MaLTS) which defines the shared responsibilities and tasks for mitigating risk for currently installed devices, and those in development. Developed over 2 years by a team of 67 experts, it provides Insights, Challenges and Recommendations for how MDMs and HDOs can develop their own strategies while increasing effective communication between themselves.

- In this session you will learn:

  o What is HIC-MaLTS?
  o Who should use it?
  o The 4 Core Pillars.
  o How to address the common legacy cyber risk management challenges?
  o What is the “Responsibility Transfer Framework”?
  o Recommendations for Patching and Lifecycle Management.
Agenda

- What is HIC-MaLTS?
- The 4 Core Pillars
- Legacy Cyber Risk Management Challenges
- Responsibility Transfer Framework
- Patching Lifecycle Management

- Questions
Claroty At-A-Glance
Empowering organizations with unmatched security for all cyber-physical systems across the XIoT

DEEP DOMAIN EXPERTISE
The Extended Internet of Things (XIoT)
- Industrial
- Commercial
- Healthcare

COMPREHENSIVE CAPABILITIES
- Asset Management
- Risk & Vulnerability Management
- Change Management
- Remote Access
- Network Protection
- Threat Detection

GLOBAL ADOPTION
100s of Orgs, 1000s of Sites, 50+ Countries, 25+ Verticals

VALIDATION FROM LEADING INDUSTRY ANALYST FIRMS & OTHER TRUSTED THIRD-PARTIES

HQ: NYC  Founded: 2015  Funding: $635M (Series E)  Healthcare Facilities: 1000+
The Medigate by Claroty Platform
This comprehensive, scalable solution is purpose-built for your entire healthcare cybersecurity journey

- **Vuln & Risk Management**
- **Network Protection**
- **Threat Detection**
- **Device Management**
- **Lifecycle Management**
- **Operational Intelligence**

**Device Discovery**

- **White-Glove Delivery Model**
- **Simple Onboarding & Purpose-Built UX**
- **Fully Integrated Ecosystem**

**Internet of Medical Things (IoMT)**
- Patient Monitoring
- Imaging Equipment
- Lab Equipment
- Care Administration

**Information Technology (IT)**
- Infrastructure
- Web Servers
- Printers
- Workstations

**Smart Buildings/Grids (BMS)**
- Elevator
- Smart Grid
- BMS/BAS
- HVAC

**Internet of Things (IoT)**
- Physical Intrusion
- Mobile Devices
- Smart Devices
- Signage
Regulation and Legislation
Aligning Claroty Functionality with Basic Cyber Hygiene for Connected Medical Devices

Vuln & Risk Management  Network Protection  Threat Detection  Device Management  Lifecycle Management  Operational Intelligence

Device Discovery

White-Glove Delivery Model  Simple Onboarding & Purpose-Built UX  Fully Integrated Ecosystem

Internet of Medical Things (IoMT)  Information Technology (IT)  Smart Buildings/Grids (BMS)  Internet of Things (IoT)
# Regulation and Legislation

Aligning Claroty Functionality with Basic Cyber Hygiene for Connected Medical Devices

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<th>CLAROTY FUNCTIONALITY</th>
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<th>Warner CIPS</th>
<th>HIC MaLTS</th>
<th>FDA Post Market</th>
<th>Section 3305 (PATCH)</th>
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<td>HOOD Cybersecurity Signals</td>
<td>Analyze Detect and Assess Threat Sources.</td>
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<td>CMMS Unified Asset Mgmt.</td>
<td>Integration with CMMS for single source inventory &amp; automated workflow</td>
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<td>Lifecycle Management</td>
<td>9LC</td>
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<td>EOG, EOS, EOL, Technology Stages</td>
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<td>Operational Intelligence</td>
<td>9MB</td>
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HIC-MaLTS

• Health Sector Coordinating Council (HSCC)
  • 67 Security Experts over 2 years
• Reason
  • Networks are evolving in complexity; remote monitoring, telehealth, cloud, etc.
  • Healthcare is a target rich environment containing valuable data
  • Diverse device types; diagnostic, therapeutic, wearable, implantable, SaMD, etc.
  • Off-The-Shelf components create inconsistent lifecycles
  • Need for better understanding of cyber responsibilities between HDO & MDM
  • Slow adoption of improved practices
  • Wide variation of size and capabilities of healthcare organizations
What is a Legacy Medical Device?

- Defined by the IMDRF Cyber Working Group
  - Medical devices that cannot be reasonably protected against current cybersecurity threats.
- HDO
  - Is it past manufacturer declared EOL/EOGS/EOS
  - Contains a critical software component (e.g., operating system) which is not supported
  - Components in the Software Bill of Materials (SBOM) is not supported
- MDM
  - Off-The-Shelf (OTS) software components no longer receive support
  - Hardware (e.g., PLC, CPU) no longer receive support
  - Technology firmware no longer receive support
  - Contains Known Exploitable Vulnerabilities (KEV) with limited mitigations
  - Technology does not have a mechanism to update software, firmware, etc.
Structure of the Publication

• Modular components create actionable content
• Designed for both HDO and MDM
• 114 Pages
• 4 Core Pillars
• Responsibility Transfer Framework
• Patching & Lifecycle Management
• Common Legacy Risk Management
  • Challenges & Recommendations
Core Pillar #1 - Governance

- Define goals and objectives
- Establish responsibilities
- Enable accountability
- Insure information flow & monitoring
- Supports compliance & lifecycle mgmt.
Governance – HDO Considerations

• Defining a legacy tech risk management strategy
  • Procurement requirements
  • Risk assessment and prioritization
  • Incident response and business continuity
  • Information Sharing
  • Vulnerability management
  • Asset lifecycle management
  • Disposal and data protection
• Establish a model and criteria for risk tolerance
  • Probability * Impact vs. Exploitability
• Developing a lifecycle management plan
  • Tracking inventory and managing technology
  • Implementing risk remediation practices
  • Planning technology replacement & decommissioning
Core Pillar #2 - Communications

- Diverse stakeholder groups – engage the correct team members
- MDMs communicate with HDOs
  - New product, alerts/recalls, upgrades, vulnerabilities, etc.
- HDOs communicate with MDMs
  - Cyber assessments, vulnerabilities, upgrades, incident reports, etc.
- Topics of interest
  - Coordinated Vulnerability Disclosure Programs
  - Security & supply chain documentation
  - Technology lifecycle information
  - Vulnerabilities
Core Pillar #3 – Cybersecurity Risk Management

HDO Considerations

- Passive Network Monitoring (PNM)
  - Observe and analyze network traffic
  - Complement with internally collected data (SBOM, MDS², Manufacturer, etc.)
  - Provide asset risk information
  - Abnormal network behavior

- Stages of Risk Management throughout Technology Lifecycle
  1. Product Assessment
  2. Acquisition
  3. Implementation
  4. Support/Maintenance
  5. End of Support
  6. Decommissioning
Core Pillar #3 – Cybersecurity Risk Management

MDM Considerations

- Medical Device & Health Joint Security Plan
- HDO environments will be different than MDMs
  - Requiring contextual assessments
  - MDMs should play a role
- MDM should send EOL/EOGS/EOS to HDO
Core Pillar #3 – Cybersecurity Risk Management
Responsibility Transfer Framework

• Should the HDO continue to utilize the device or decommission?
• Risk Assessment Factors
  • Safety and Effectiveness – can the HDO handle support
  • Clinical – impact clinical care workflows & patient safety
• Technical Examples
  • Known Exploitable Vulnerabilities
  • Mitigations
  • Remote protocols, ports or services needed?
  • Will security controls mitigate the vulnerabilities
  • Costs

<table>
<thead>
<tr>
<th>EOL/EOGS/EOS Options</th>
<th>Supported</th>
<th>Unsupported</th>
</tr>
</thead>
<tbody>
<tr>
<td>Option #1</td>
<td>Hardware</td>
<td>X</td>
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<tr>
<td></td>
<td>Software</td>
<td>X</td>
</tr>
<tr>
<td>Option #2</td>
<td>Hardware</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Software</td>
<td>X</td>
</tr>
<tr>
<td>Option #3</td>
<td>Hardware</td>
<td>X</td>
</tr>
<tr>
<td></td>
<td>Software</td>
<td>X</td>
</tr>
</tbody>
</table>
Core Pillar #4 - Future Proofing

• Address Know Legacy Issues During Threat Modeling

• Secure Technology Design
  • Selecting software
  • Alignment with Executive Order 14028

• Secure Technology Deployment
Patching Management Lifecycle

*Not a silver bullet*
Patching Management Lifecycle
*Not a silver bullet*

What is a signal?

A cybersecurity signal can refer to any kind of indication or alert that suggests a potential security threat or breach within a system or network.
Patching Management Lifecycle

Not a silver bullet

HDO Signals
- MDM Advisories
- CERT Advisories
- Vuln Scanning
- Monitoring
- Security Incidents
- Researcher
- Regulator
- ISAC/ISAO

MDM Signals
- Vuln Monitoring
- Gap Analysis
- Security Audit
- Pen Testing
- Static Code Analysis
- Supplier
- Regulator
Patching Management Lifecycle

Not a silver bullet

- Signal Identification
- Signal Evaluation
- Patch Development
  - Communications provided by MDM to HDO
  - Patch Details, Risks it Addresses, Links to Vuln. Com., Delivery Date, Who Installs, Install Req., Post Testing, Labeling, ......
Patching Management Lifecycle

Not a silver bullet

Patch Testing

• Module, verification, security and regression testing

• Implementation & technical assessment
Patching Management Lifecycle

*Not a silver bullet*
Software Bill of Materials

Omnibus Bill 2023 SEC. 3305. ENSURING CYBERSECURITY OF MEDICAL DEVICES.
IN GENERAL.—Subchapter A of chapter V of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351 17 et seq.) is amended by adding at the end the following:

(2) design, develop, and maintain processes and procedures to provide a reasonable assurance that the device and related systems are cybersecure, and make available postmarket updates and patches to the device and related systems to address—
   “(A) on a reasonably justified regular cycle, known unacceptable vulnerabilities; and
   ‘(B) as soon as possible out of cycle, critical vulnerabilities that could cause uncontrolled risks;
   “(3) provide to the Secretary a software bill of materials, including commercial, open-source, and off-the-shelf software components;
Software Bill of Materials

HDO
- Request from MDM SBOM information in machine readable format
- Leverage passive monitoring tools
- Import and analyze to identify released vulnerabilities (NVD or ISC-CERT)
- Do technologies in the inventory contain software components affected

MDM
- Develop maintain and provide SBOMs to HDOs over life of device
- For EOS, provide customers with Final/Last SBOOM
Additional Topics in HIC-MaLTS

- Third Party Servicers
- Connectivity
- 3rd Party Components
- End-of-Life/Service
- Inventory/Asset Management
The Cyber-Physical Systems (CPS) Security Journey
Gartner’s 6-phase approach to achieving CPS Security Maturity

Phase 1
- **Awareness**: Recognize, commit to addressing the need for CPS security
  - 60% of orgs are here*

Phase 2
- **Visibility**: Gain CPS visibility via asset discovery, network mapping
  - 30% of orgs are here*

Phase 3
- **“Oh Wow!”**: Identify security blind spots, risks, governance gaps
  - 30% of orgs are here*

Phase 4
- **Firefighting**: Prioritize & address top blind spots, risks, governance gaps
  - 10% of orgs are here*

Phase 5
- **Integration**: Integrate & align CPS with SOC/IT security program, tools, governance
  - 10% of orgs are here*

Phase 6
- **Optimization**: Harness CPS security capabilities to drive operational resilience
  - 10% of orgs are here*

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*Figures indicate percentage of organizations at each phase.
Resources

- Health Sector Coordinating Council (HSCC)
- HIC-MaLTS
- Joint Security Plan – Cyber Risk Mgmt. for MDMs
- Senator Warner – Cybersecurity Is Patient Safety (CIPS)
- White House Cybersecurity Strategy
- 405(d) Healthcare Industry Cybersecurity Practices (HICP)
- NIST CSF Healthcare Implementation Guide
Thank You

Please complete the online evaluation/attendance form at https://www.surveymonkey.com/r/03-16-23

Skip Sorrels

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