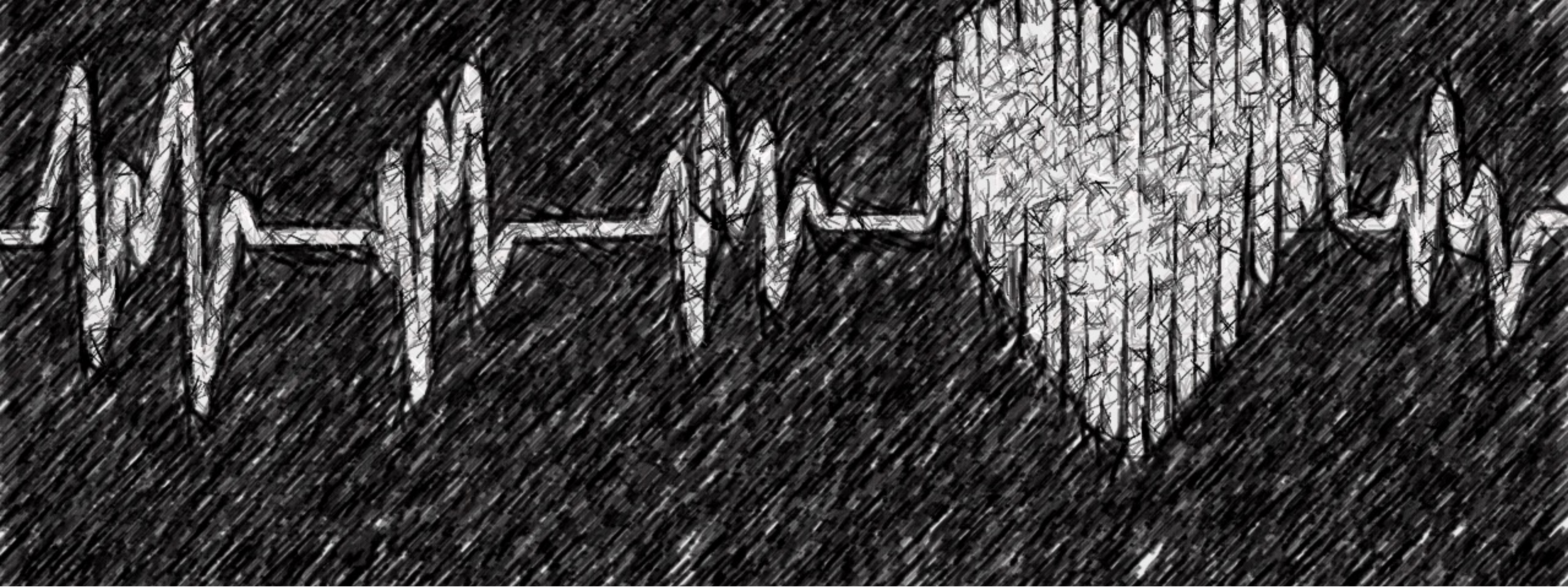

Medical Device Security

Learnings From Countless Security Assessments

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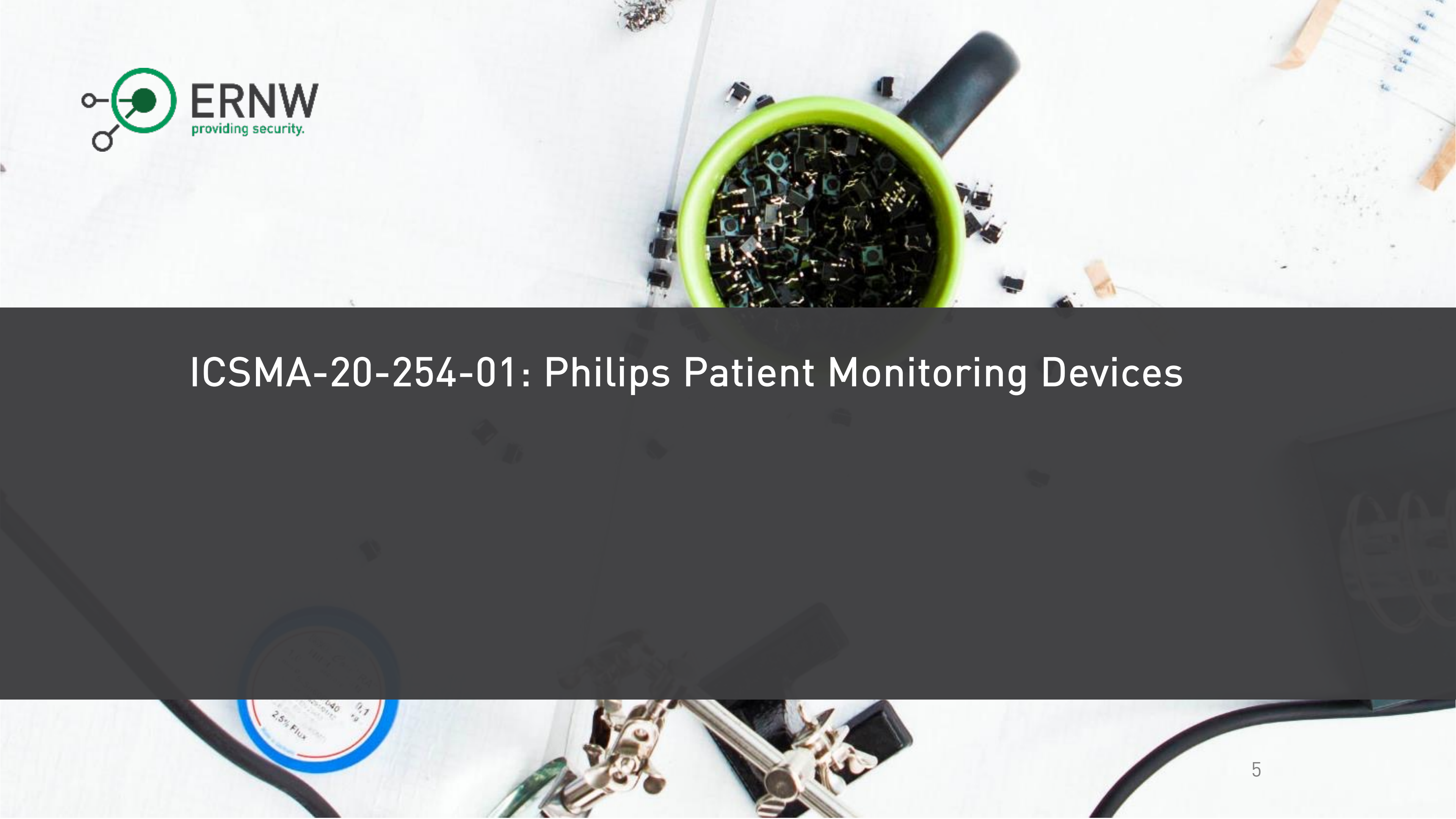
Who Am I

- Julian Suleder
- Senior Security Analyst & Researcher @ ERNW
- Medical computer science background
- Performed >25 medical device security assessments
- 🐦 @jsuleder

Agenda

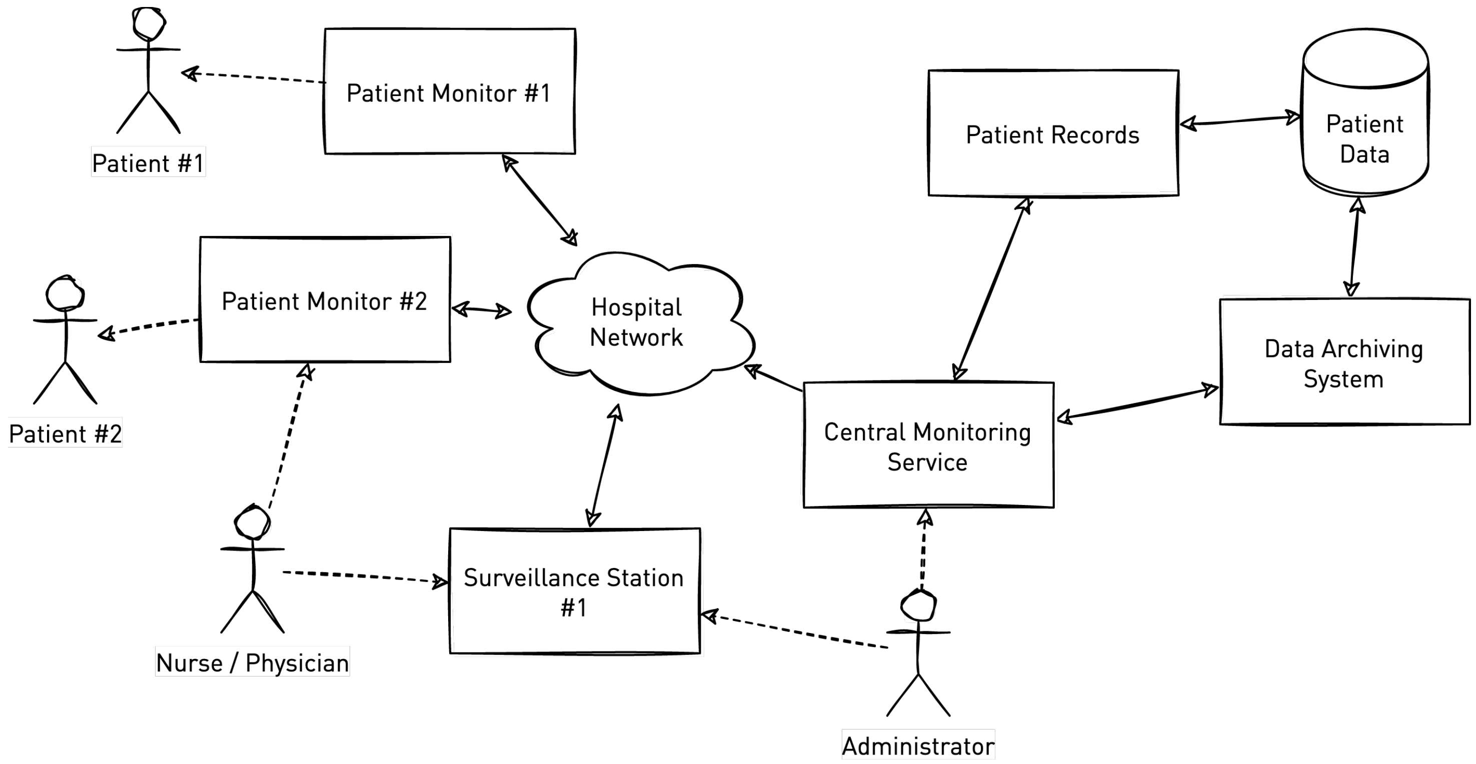
- Case Studies
- Lessons Learned
- Regulatory Requirements
- Disclosure Processes
- Closing

Case Studies



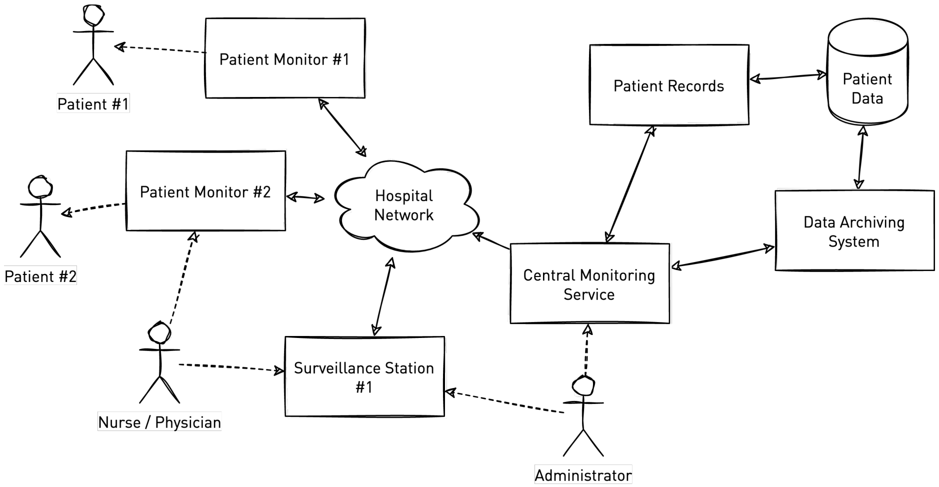
ICSMA-20-254-01: Philips Patient Monitoring Devices

Patient Monitoring System



Patient Monitoring System

- Common trust anchor:
    - Environment CA with entity enrolment functionality
    - Certificates for every service and medical device
    - Mutual authentication via DTLS
- Communication protocol
    - Proprietary
    - Monitors need to connect to other monitors → trust?



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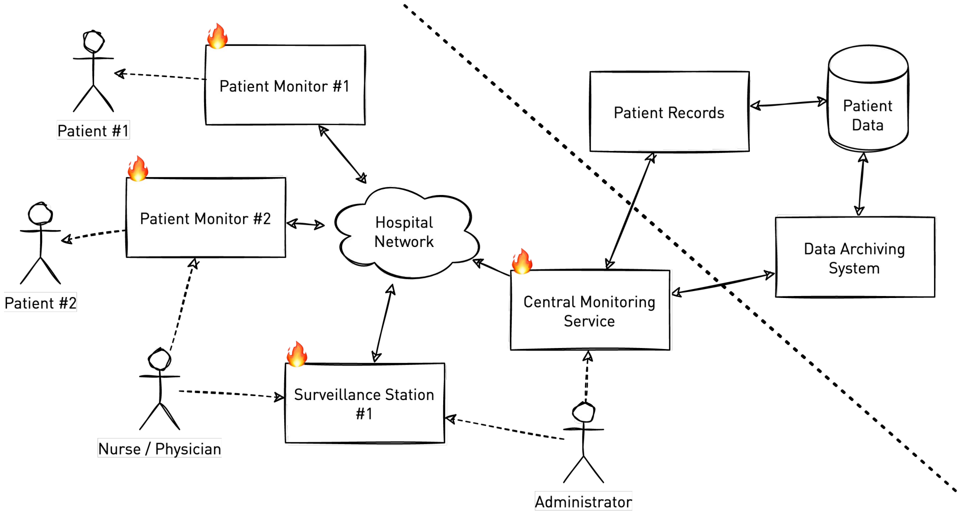
Findings

- Central Monitoring Service:
  - Crashed and rebooted via unauthenticated TCP packet
  - Crash via certificate enrolment service
  - Short SCEP Pins: Obtain trusted certificates via brute-force
- Monitor:
  - Incorrectly validates received input via the DTLS-secured channel



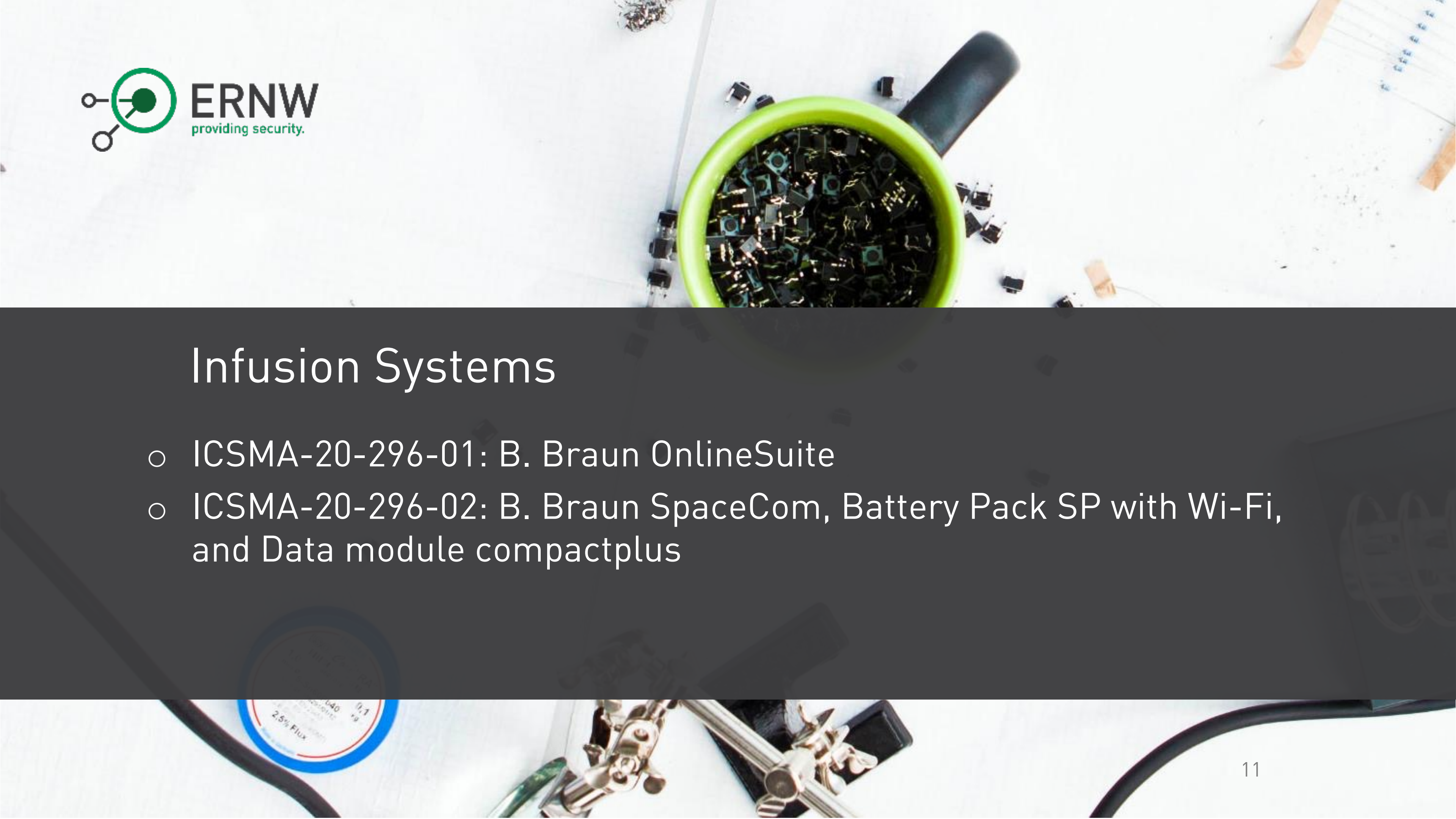
Impact: Interrupted monitoring, access to patient health information.

Implications & Mitigations

- Disaster recovery:
  - Assume there is a compromised entity in your environment
  - How to handle compromised devices?
  - What is the impact on the device ecosystem?
- Trust relationships must be maintained between components.

Implications & Mitigations

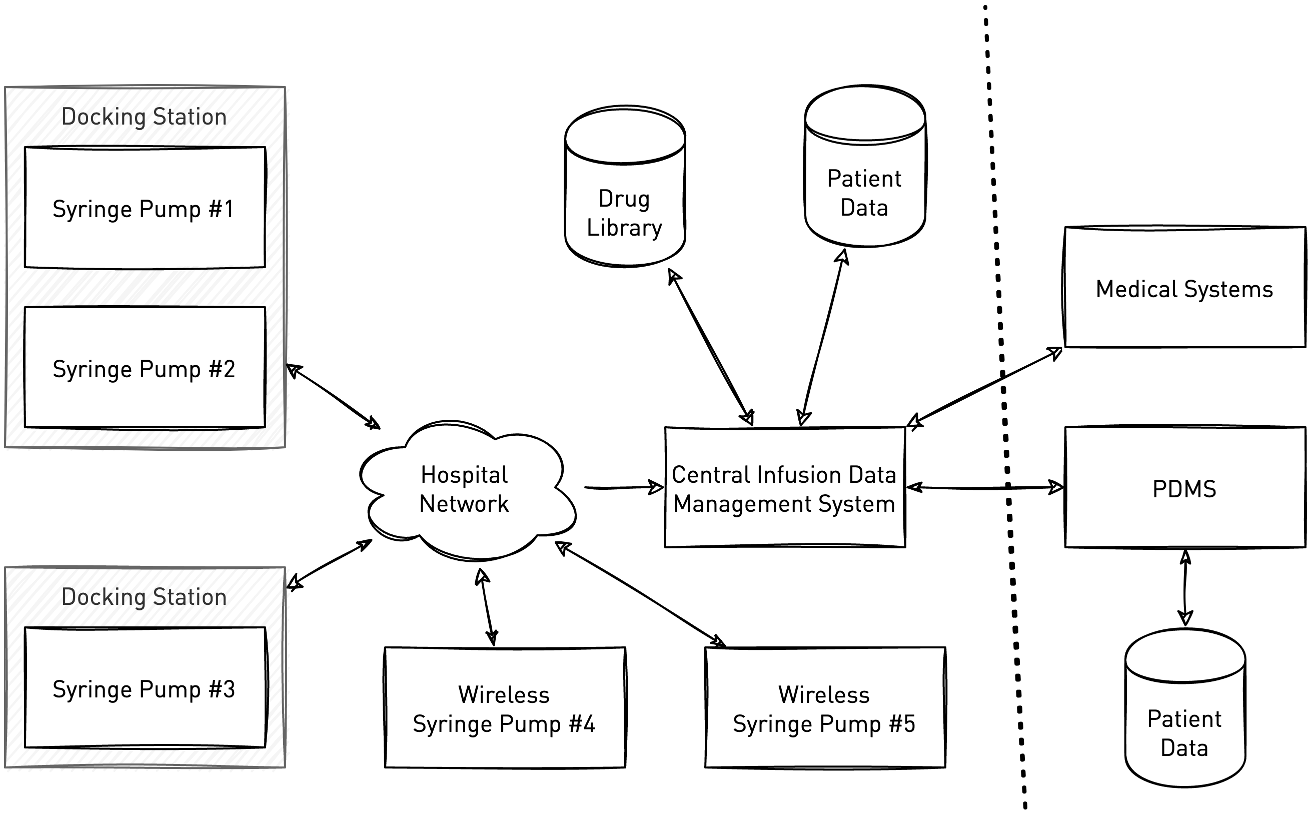
- Describe the processes that need to be established by operators:
  - Which configurations need to be checked on a regular basis?
  - Where is key material that needs rotation or certificates that expire?
  - How can operators terminate trust relationships of single devices?
- → Render secure operation feasible



Infusion Systems

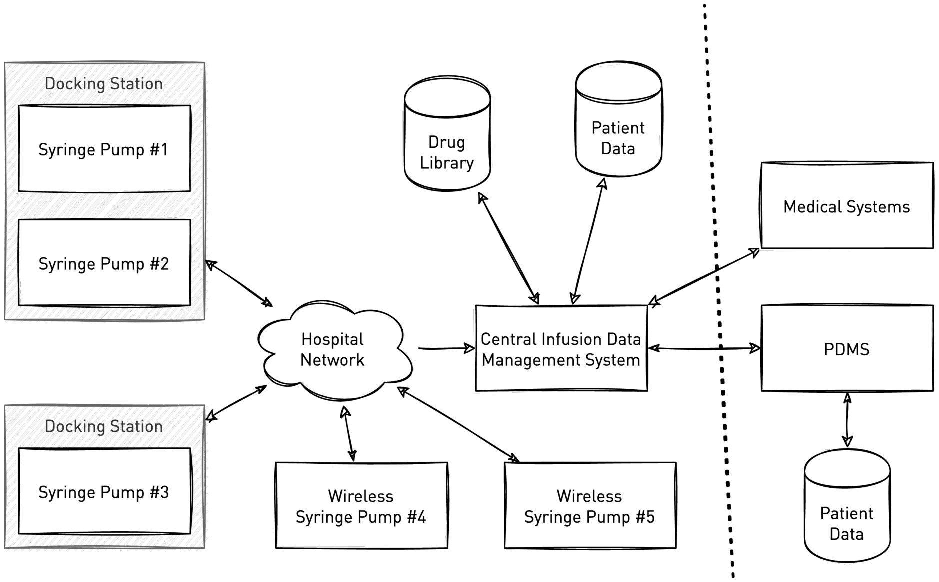
- ICSMA-20-296-01: B. Braun OnlineSuite
- ICSMA-20-296-02: B. Braun SpaceCom, Battery Pack SP with Wi-Fi, and Data module compactplus

Infusion Systems



Infusion Systems

- Docking stations act as communication gateway
- No remote-control functionality
- Manual interaction on device needed for medical use
- → Communication solely is for documentation / monitoring purposes



Findings

- Docks are running an administrative web application
  - XPath injections in login
  - Passwords stored hashed with MD5
  - Path traversal via authenticated file upload
  - Authenticated command injection
  - Privilege escalation to root via magic binary
- Central Management Service based on web services
  - Path traversal in unauthenticated file upload and download
  - DLL hijacking via bundled third-party library

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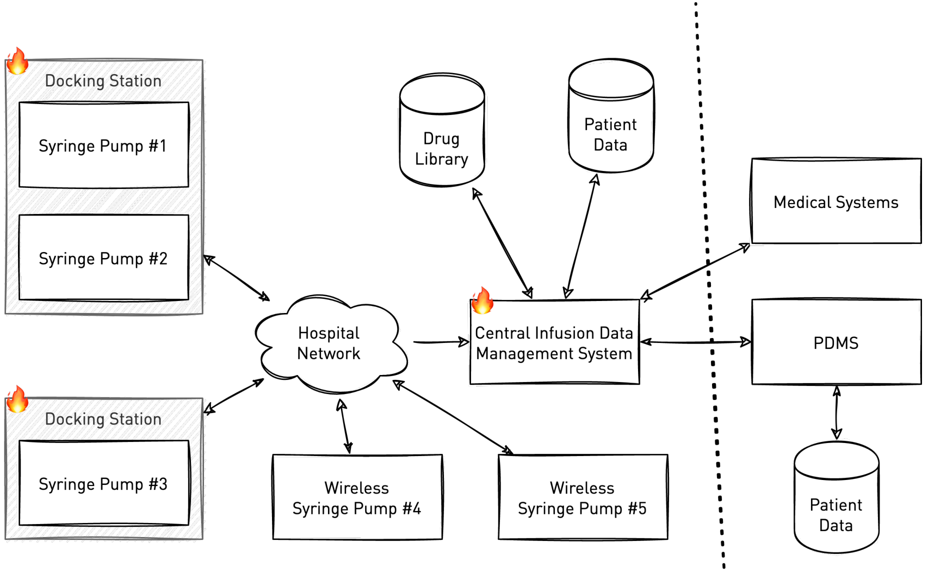
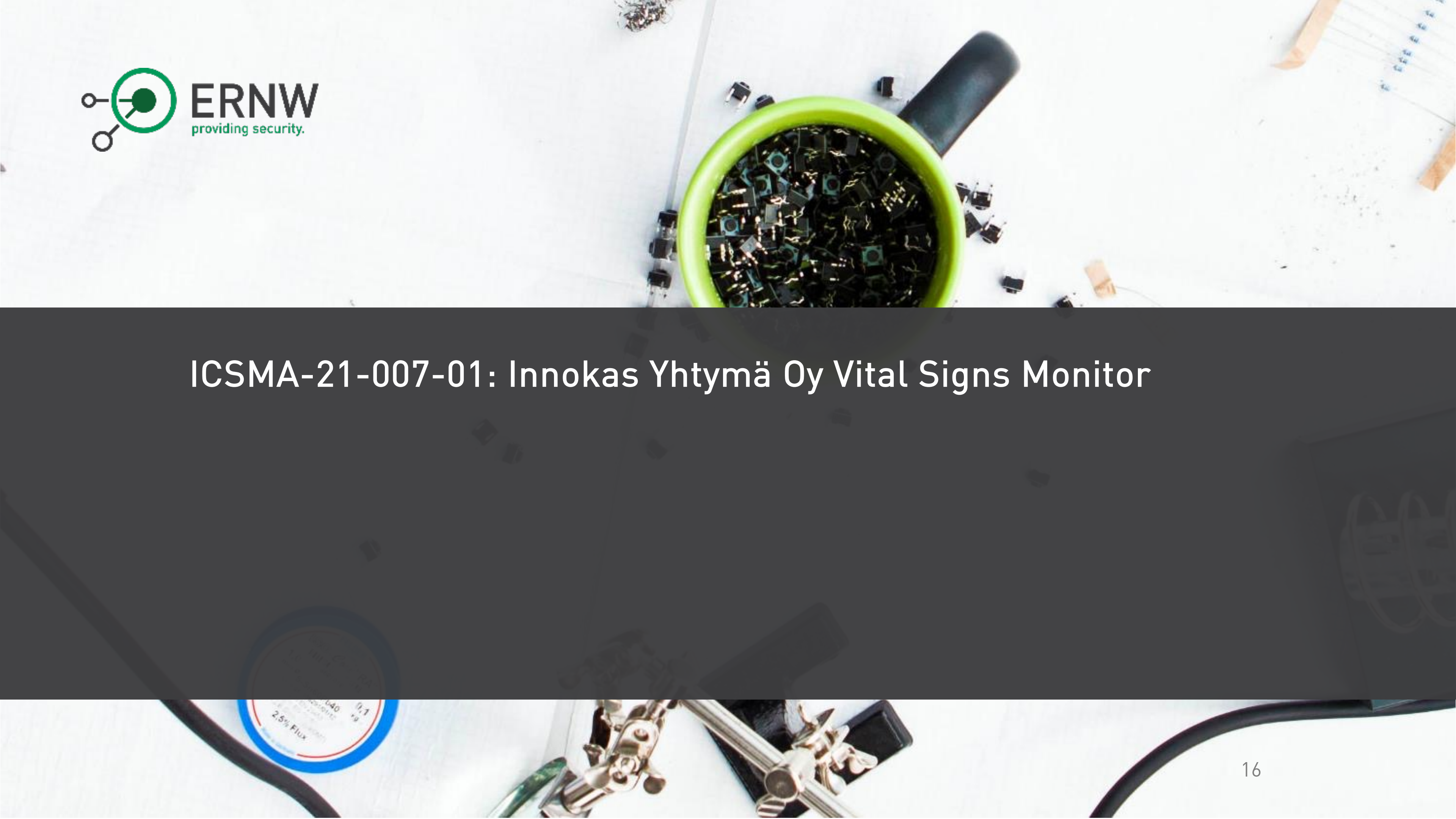
What is the impact?

- Device is not affected in its medical operation or purpose
- Devices lose their ability to communicate
- An attacker is in the position of directly communicating with the infusion devices
- → **Prerequisite for more attacks**



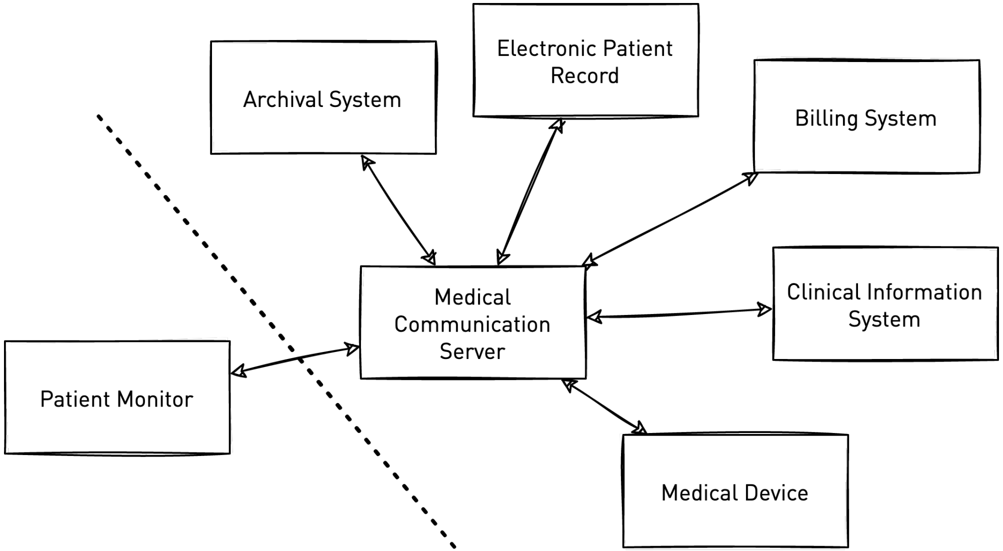
Impact: Full compromise of the medical device's accessory.



ICSMA-21-007-01: Innokas Yhtymä Oy Vital Signs Monitor

The HL7 v2.x Standard

- Goal: Interoperability of heterogeneous medical systems
- → Agreements on message structure and content representations
- Common, text-based standard for transactions between medical systems


Archival System
Electronic Patient Record
Billing System
Medical Communication Server
Clinical Information System
Patient Monitor
Medical Device

The Vulnerability

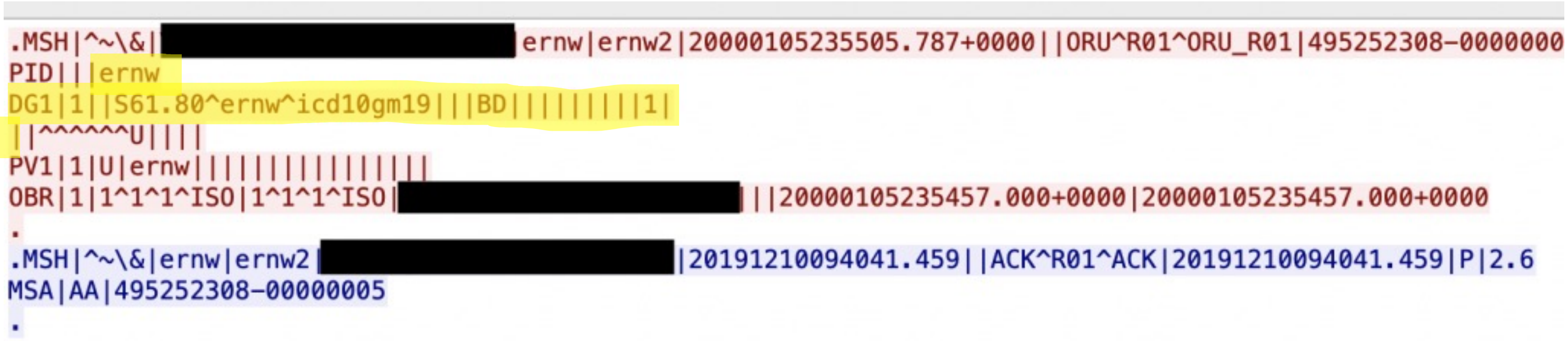
- Encoding characters in untrustworthy inputs are processed
- Requires physical access to the device
- Inject valid HL7 v2.x segments into the HL7 v2.x message with a connected barcode reader

- This barcode bypasses restrictions to special characters in input:
  `ernw\rDG1|1||S61.80^ernw^icd10gm19|||BD|||||||||1|\r`

ernwDG1|1||S61.80^ernw^icd10gm19|||BD|||||||||1|

The Payload

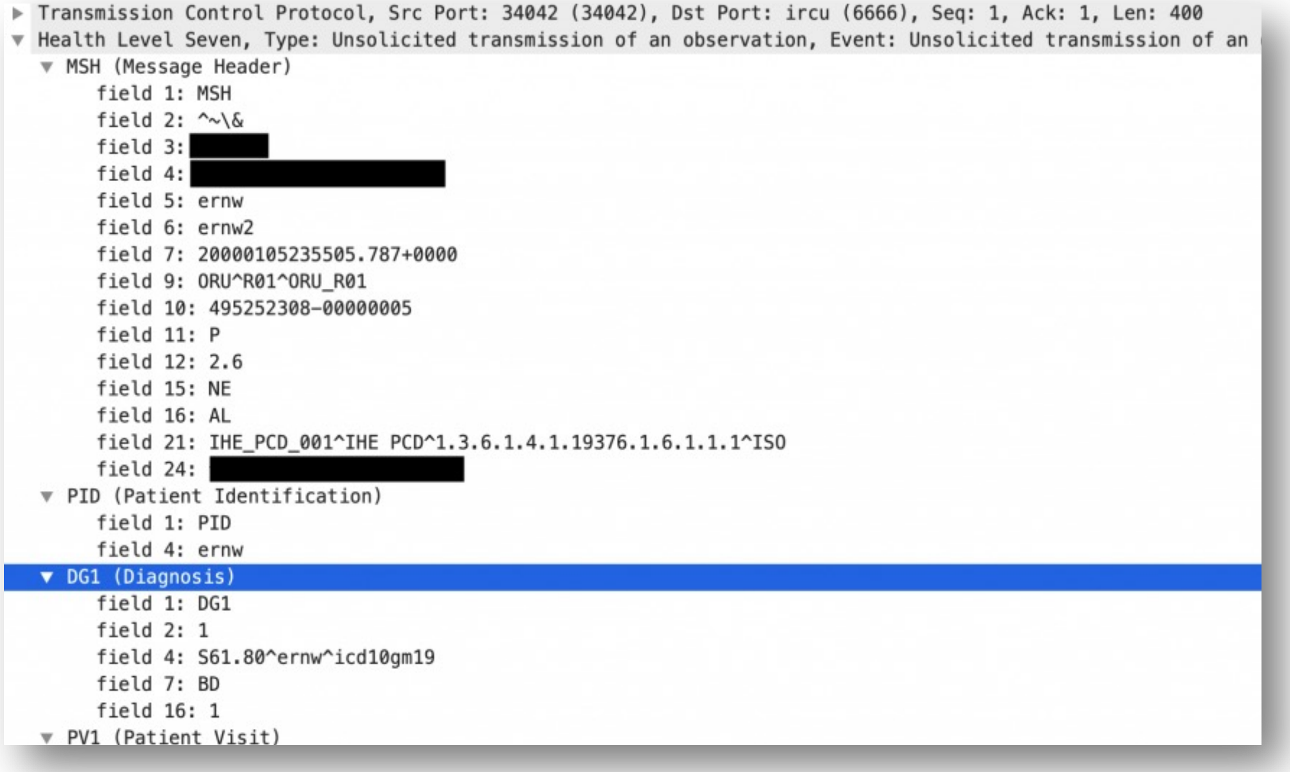
- The payload adds an HL7 v2.x diagnosis segment according to a medical diagnosis code coding system
- Injecting the prepared payload in the patient's name causes the following HL7 v2.x communication between the device (red) and an HL7 v2.x – capable system (blue)



```
.MSH|^~\&|[redacted]ernw|ernw2|20000105235505.787+0000||ORU^R01^ORU_R01|495252308-0000000
PID|||ernw
DG1|1||S61.80^ernw^icd10gm19|||BD|||||||||1|
||^^^^^^^U||||
PV1|1|U|ernw||||||||||||||||
OBR|1|1^1^1^ISO|1^1^1^ISO|[redacted]||20000105235457.000+0000|20000105235457.000+0000
.
.MSH|^~\&|ernw|ernw2|[redacted]|20191210094041.459||ACK^R01^ACK|20191210094041.459|P|2.6
MSA|AA|495252308-00000005
.
```

```
ernw\rDG1|1||S61.80^ernw^icd10gm19|||BD|||||||||1|\r
```

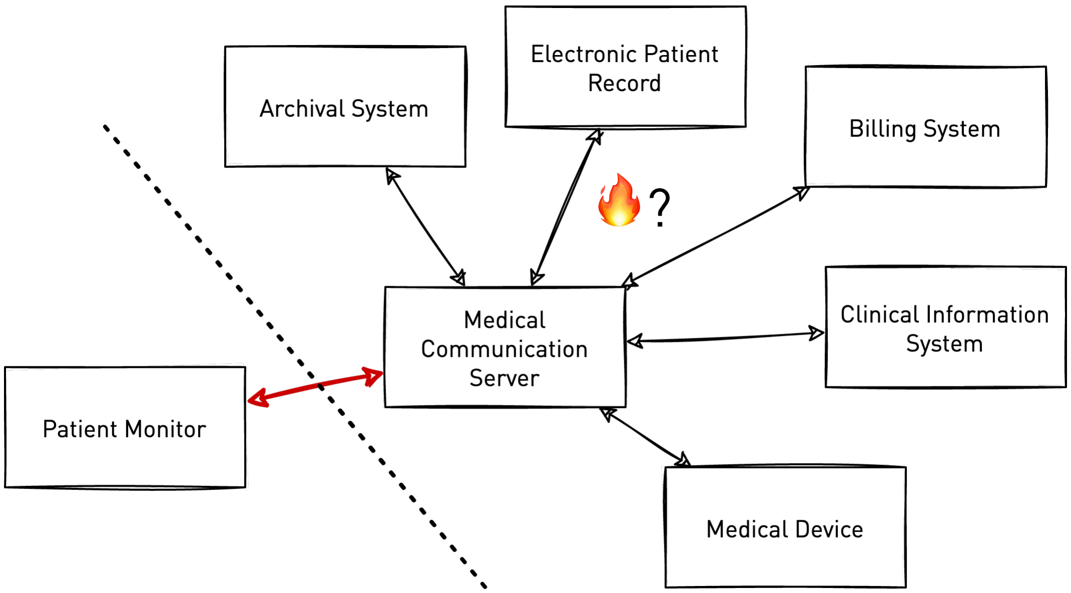
What is the impact?



```
▶ Transmission Control Protocol, Src Port: 34042 (34042), Dst Port: ircu (6666), Seq: 1, Ack: 1, Len: 400
▼ Health Level Seven, Type: Unsolicited transmission of an observation, Event: Unsolicited transmission of an
  ▼ MSH (Message Header)
      field 1: MSH
      field 2: ^~\&
      field 3: [redacted]
      field 4: [redacted]
      field 5: ernw
      field 6: ernw2
      field 7: 20000105235505.787+0000
      field 9: ORU^R01^ORU_R01
      field 10: 495252308-00000005
      field 11: P
      field 12: 2.6
      field 15: NE
      field 16: AL
      field 21: IHE_PCD_001^IHE PCD^1.3.6.1.4.1.19376.1.6.1.1.1^ISO
      field 24: [redacted]
  ▼ PID (Patient Identification)
      field 1: PID
      field 4: ernw
  ▼ DG1 (Diagnosis)
      field 1: DG1
      field 2: 1
      field 4: S61.80^ernw^icd10gm19
      field 7: BD
      field 16: 1
  ▼ PV1 (Patient Visit)
```

Further Information: https://insinuator.net/2020/04/hl7v2-injections-in-patient-monitors/

What is the impact?

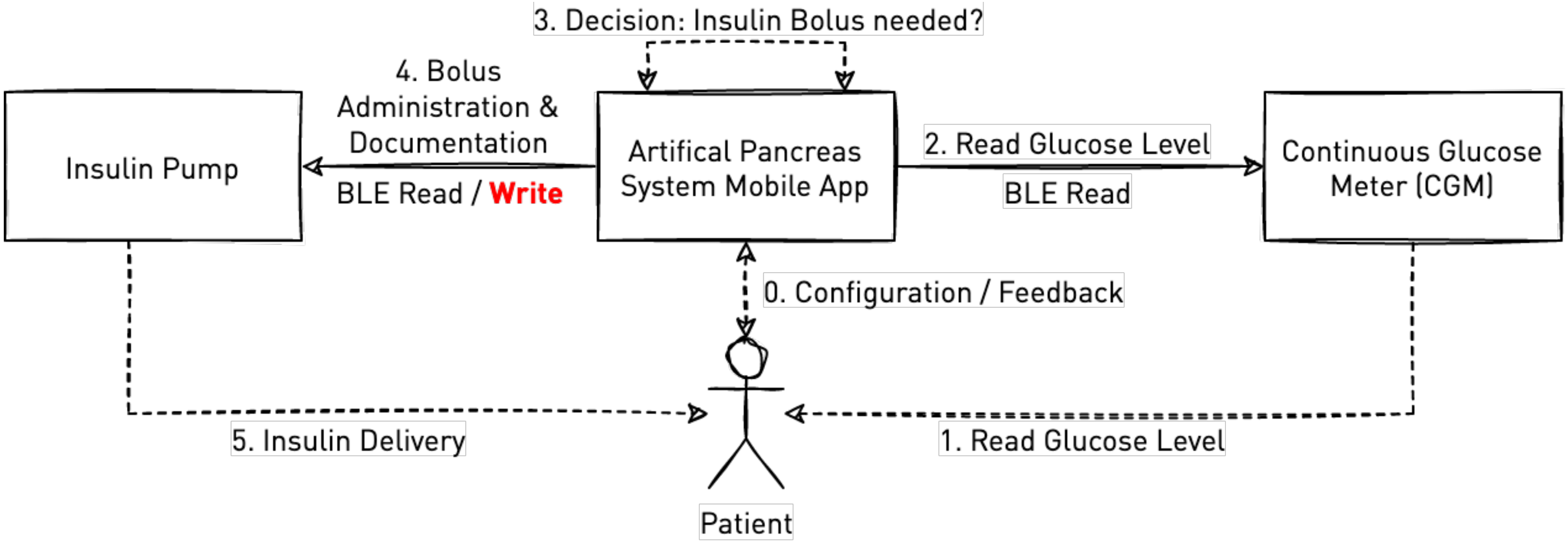

Archival System
Electronic Patient Record
Billing System
🔥?
Medical Communication Server
Clinical Information System
Patient Monitor
Medical Device

- No direct impact on the patient monitor
- Exploitation allows an attacker to modify communications to downstream devices
- → Diagnosis may be parsed by clinical systems

See: https://www.cisa.gov/uscert/ics/advisories/icsma-21-007-01

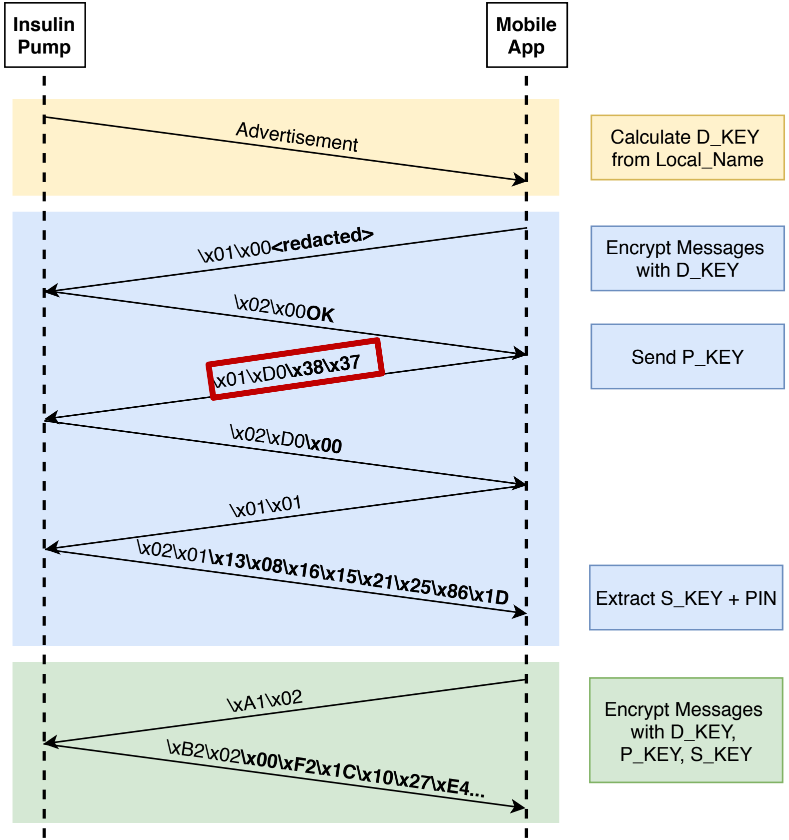
Insulin Therapy Systems & Point-of-Care-Testing Devices (POCT)

Insulin Therapy Systems

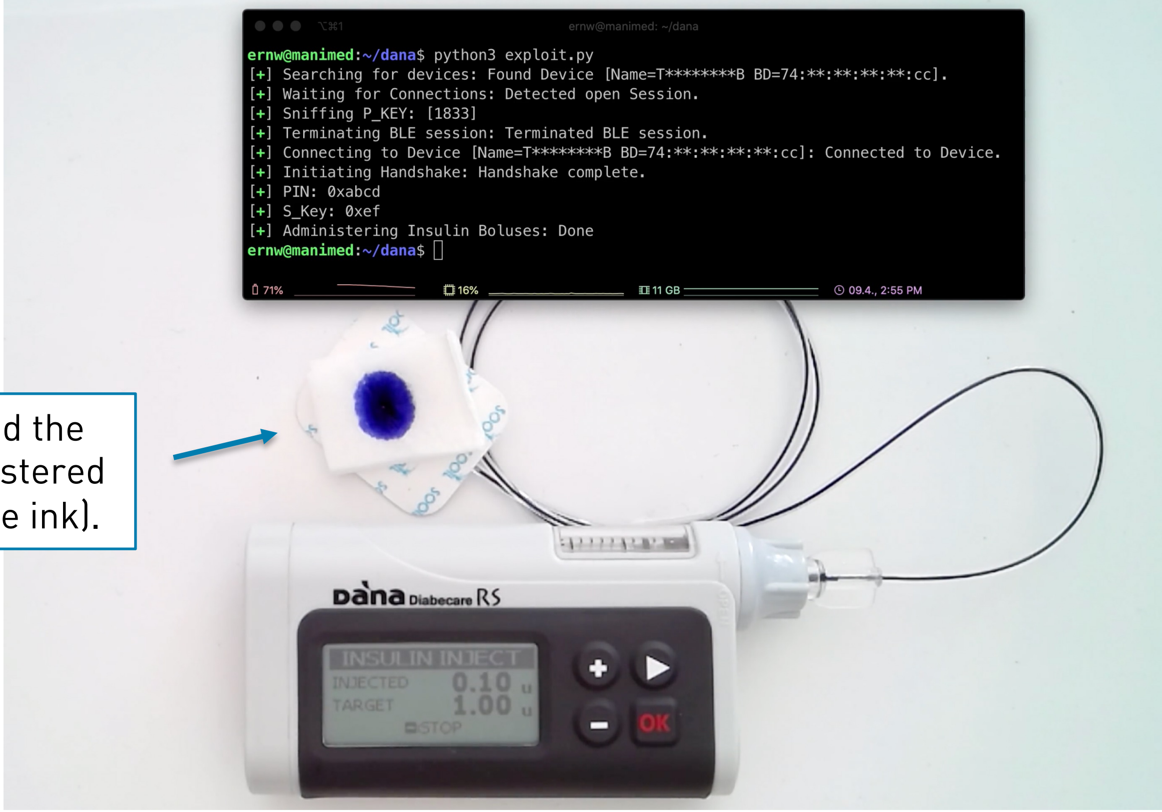

3. Decision: Insulin Bolus needed?
4. Bolus Administration & Documentation
Insulin Pump
Artifical Pancreas System Mobile App
2. Read Glucose Level
Continuous Glucose Meter (CGM)
BLE Read / Write
BLE Read
0. Configuration / Feedback
5. Insulin Delivery
1. Read Glucose Level
Patient

Broken Communication Protocol

- Application-layer protocol on top of unauthenticated BLE GATT read/write
- Authentication relies on the app-layer pairing key.
- An attacker needs to be in proximity to the pump and sniff a single handshake between a pump and a paired mobile application.


Insulin Pump
Mobile App
Advertisement
Calculate D_KEY from Local_Name
\x01\x00<redacted>
Encrypt Messages with D_KEY
\x02\x00OK
\x01\xD0\x38\x37
Send P_KEY
\x02\xD0\x00
\x01\x01
\x02\x01\x13\x08\x16\x15\x21\x25\x86\x1D
Extract S_KEY + PIN
\xA1\x02
\xB2\x02\x00\xF2\x1C\x10\x27\xE4...
Encrypt Messages with D_KEY, P_KEY, S_KEY

What is the impact?



```
ernw@manimed:~/dana$ python3 exploit.py
[+] Searching for devices: Found Device [Name=T********B BD=74:**:**:**:**:cc].
[+] Waiting for Connections: Detected open Session.
[+] Sniffing P_KEY: [1833]
[+] Terminating BLE session: Terminated BLE session.
[+] Connecting to Device [Name=T********B BD=74:**:**:**:**:cc]: Connected to Device.
[+] Initiating Handshake: Handshake complete.
[+] PIN: 0xabcd
[+] S_Key: 0xef
[+] Administering Insulin Boluses: Done
ernw@manimed:~/dana$
```

Attacker hijacked the pump and administered Insulin (here: blue ink).

Full video: https://www.youtube.com/watch?v=0GMe2poiYtE

Implications & Mitigations

- Don't roll your own cryptography!
- Use security functionality provided by communication protocols
- Implement application-layer protocols only on top when needed
- Design your device with residual resources not to limit the possibilities in using stronger cryptography!

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Point-of-Care-Testing Devices

- Medical purpose:
  - Bed-side lab diagnostics
  - May also be used by patients
- Portable, small, usually no wired connection

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Point-of-Care-Testing Devices

- Technically:
  - Embedded devices
  - Resources: Not very powerful microcontrollers, SoCs, etc.
  - Embedded software stack / RTOS
  - Few software abstraction layers
  - Communication via:
    - USB, serial interfaces, Infrared
    - Bluetooth and WiFi

Vulnerabilities & Challenges

- Product Lifecycle Issues:
  - Outdated/ end-of-life OS and dependencies
  - Broken firmware update mechanisms
  - Masses of vulnerable third-party software, dependencies, etc.
- Design & Development:
  - Hard-coded secrets and credentials
  - Custom implementations for AES, Bluetooth stack, TLS, encryption and authentication protocols, …
- Operation:
  - Unprotected service and debug interfaces
  - Compatibility assurance causes secure and insecure versions of protocols being available at the same time

Lessons Learned

Lessons Learned

- Most vulnerabilities concerning medical devices are not specifically medical → e.g., OWASP IoT Top 10
- The device should be designed and manufactured in a way that ensures that the risks associated with environmental conditions are removed or minimized.
- There should be frequent security testing during design, development and the post-market lifecycle.

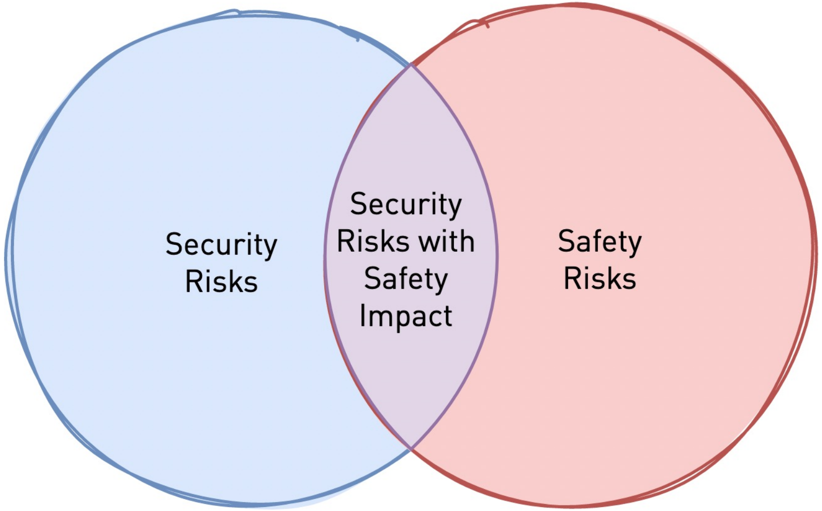
Regulatory Requirements

Medical Device Regulations

- Europe: Since 2017 there are two new regulations – MDR & IVDR
- Relevant changes for us in this context:
  - Safety approach based on the entire product life cycle:
    - Quality & Risk management
    - Intense post-market surveillance activities
- → MDCG 2019-16: Guidance on Cybersecurity for medical devices

Relationship: Safety & Security

- Any risks associated with the operation of medical devices must be acceptable.
- MDCG 2019-16:
  - Establishment of a **balance between benefit and risk** during all possible operation modes.
  - **Relationship between safety and security** as they relate to risk.



Requirements

- The manufacturer must implement state-of-the-art security capabilities depending on the risk management which is based on known vulnerabilities and attack vectors.
- **Security verification and validation testing:**
  - Processes are used to document the security testing to ensure that
    - all the security requirements have been met for the product
    - security of the product is maintained when used as intended
  - Security testing should be aligned to other product test activities

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Lifecycle Aspects

The security situation for software may change rapidly due to newly emerging security vulnerabilities, or new attack vectors.

A medical device is considered secure with respect to known vulnerabilities at a specific point in time.

Without any security maintenance the device may become unsecure and possibly unsafe.

Post-market Surveillance System

- The MDR requires a post market surveillance system (PMS) which must include security considerations:
  - Actively and regularly collect user experience from the market,
  - Collect information about 3rd-party software and hardware
  - Timely implement necessary corrective actions considering the risks

Post-market Surveillance System

- An effective and successful PMS should include:
  - Sharing and dissemination of cybersecurity information and knowledge of cybersecurity vulnerabilities and threats
  - Vulnerability remediation
    - Possible mitigations in the operating environment
    - Quick fixes
    - Medical device software updates
    - 3rd party software updates or patches
  - Information to operators of medical devices on the identified risk

Software Updates & Recertification

- Changes that should be considered a **significant change in design or intended purpose** require reporting to a notified body.
- → The MDCG guideline 2020-03 tries to clarify:
- Minor changes without impact to diagnosis or treatment:
  - Correction of an error which does not pose a safety risk (bugfixes),
  - Security update (e.g., cyber-security enhancements)
  - And some more software changes
- Reducing risks via software changes is considered major changes!

Supply Chain?

- Software Bill of Materials (SBOM)
  - Digital information sheet for software components and its dependencies
- Relevance: For which audience is the information?
  - MDCG 2019-16 mentions the SBOM as to be shared with operators
    - Hard to assess whether a component really is vulnerable
    - → Useless for medical device operators

Supply Chain?

OASIS Draft

- Common Security Advisory Framework (CSAF) 2.0
  - Standard for automated and interoperable exchange of advisories
  - Can be mapped to SBOM data of a specific product
- Profile: Vulnerability Exploitability eXchange (VEX)
  - Provide information on whether a product is impacted by a vulnerability
  - Are there remediations / workarounds recommended?
- Relevant information for vendors, systems integrators, and operators: **Is there a risk? What do we need to do to reduce it?**

Vulnerability Disclosure Processes

MDR - Vulnerability Disclosures?

- The MDR poses requirements for a PMS that includes security
- The MDR does not actively require a vulnerability disclosure statement, but the notified body / auditor may require a mature vulnerability disclosure process as part of an effective and successful PMS.
    - → “Sharing and dissemination of cybersecurity information and knowledge of cybersecurity vulnerabilities and threats”

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Experiences from Disclosures

- Few manufacturers publish a vulnerability disclosure statement or contact information
- Manufacturers wanted a proof of impact on patient safety to act
- Complexity of creating fixes and rollouts to the field:
  - Development process complexity & release cycles
  - Fixes and remediations: simple fix vs. the device is "totally broken"
  - Update process complexity requires a service technician
- Communication:
  - Stagnant progress and ambiguous statements about future actions
  - Strict information policies that strictly prohibit sharing information

Experiences from Disclosures

- Limit misunderstandings and ease the process by providing:
  - Information about the vulnerabilities
    - A detailed explanation of every vulnerability
    - Recommendations for fixes
    - Descriptions with observed (safety) impacts (videos of the device crashing, unintended behavior, etc.)
  - Information about the process
    - Expectations to communication and responsiveness
    - Expectations to process timelines (start the clock!)
    - Intended results such as CVEs, blog posts, white papers, etc.
  - Escalation paths:
    - Involvement of authorities such as BfArM / BSI or a CERT

Closing

Summary

- Many vulnerabilities concerning medical devices are not specifically medical, but the operation environment is.
- MDR and its processes and requirements will help to:
  - Focus on the relationship between safety and security
  - Apply mature IT security process in the medical sector
  - Security verification and validation testing will increase the security level of new products in the product's lifecycle

Challenges

- Short-term impairment on security as of certification
- Rendering legacy devices compliant to MDR requirements
- How to secure an existing environment with existing equipment?
  - Customers are not replacing the entire environment at once
  - Compatibility between old and new equipment and devices?
- Securing and operating on-premise and cloud environments
  - Safety impact of cloud or connection outage?
  - Medical devices with permanent cloud connections?

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