eHealth Solutions / Release VA53A / 2023-08-14 / Revision r7-g1164c71

eHealth Solutions Product and Solution Security White Paper

SIEMENS
Healthineers

Contents

1 Foreword

1.1 The Siemens Healthineers Product and Solution Security Program

At Siemens Healthineers, we are committed to working with you to address cybersecurity and privacy requirements. Our Product and Solution Security Office is responsible for our global program that focuses on addressing cybersecurity throughout the product lifecycle of our products. Our program targets incorporating state of the art cybersecurity in our current and future products. We seek to protect the security of your data while, at the same time, providing measures to strengthen the resiliency of our products from external cybersecurity attackers. We comply with applicable security and privacy regulations from the US Department of Health and Human Services (HHS), including the Food and Drug Administration (FDA) and Office for Civil Rights (OCR), to help you meet your IT security and privacy obligations.

1.2 Vulnerability and Incident Management

Siemens Healthineers cooperates with government agencies and cybersecurity researchers concerning reported potential vulnerabilities. Our communications policy strives for coordinated disclosure. We work in this way with our customers and other parties, when appropriate, in response to potential vulnerabilities and incidents in our medical devices, no matter what the source.

1.3 Elements

The Elements of our product and solution security program are:

- Providing information to facilitate secure configuration and use of our medical devices in your IT environment
- Conducting formal threat and risk analysis for our medical devices
- Incorporating secure architecture, design and coding methodologies in our software development process
- Performing static code analysis of medical device software
- Conducting security testing of medical devices under development as well as medical devices already in the field
- Tailoring patch management to the medical device and depth of coverage chosen by you
- Monitoring security vulnerability to track reported third party components issues in our medical devices
- Working with suppliers to address security throughout the supply chain
- Training of employees to provide knowledge consistent with their level of responsibilities regarding your data and device integrity.

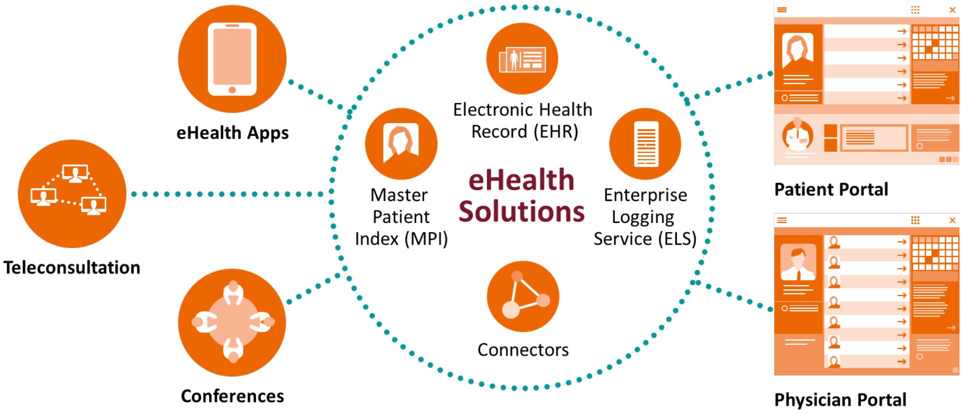
1.4 Contacting Siemens Healthineers about Product and Solution Security

Siemens Healthineers requests that any cybersecurity or privacy incidents are reported by e-mail to: mailto:productsecurity@siemens-healthineers.com

For all other communication with Siemens Healthineers about product and solution security:
`ProductTechnologyAssurance.dl@siemens-healthineers.com`

2 Basic Information

Figure 1: Overview of eHealth Solutions services and applications



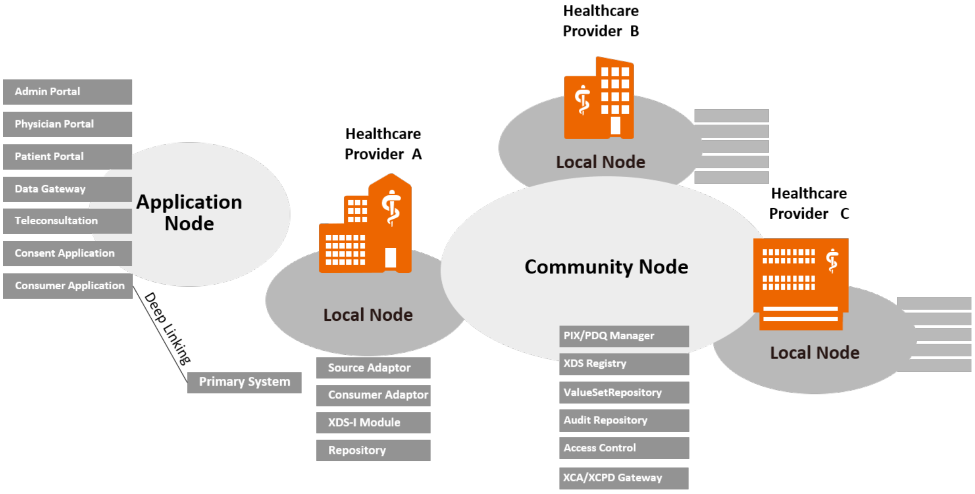
eHealth Solutions connects institutions for cooperative care and optimized communication.

A high level of data security and patient safety is a key success factor for end user acceptance and trust in electronic health records.

2.1 GDPR-EU Technical and Organizational Measures

Technical and Organizational Measures (TOMs) required for compliance with the EU General Data Protection Regulation 2016/679 (GDPR) are addressed in the following sections.

Figure 2: Component View of eHealth Solutions Services



2.2 Operating Systems

2.2.1 Client

There are no special operating system requirements for clients.

2.2.2 Browsers

Web applications can be accessed with current web browser software. All operating systems that have HTML5- and JavaScript-enabled browsers are supported. On Windows, the following browsers are supported (specific requirements for individual applications are described in the eHealth Solutions *Technical Requirements Specification*):

- Google Chrome ≥ 85 (recommended)
- Mozilla Firefox ≥ 81 (supported)
- Microsoft Edge ≥ 85 (supported)
- Safari ≥ 12 (supported)

2.2.3 Mobile compability

On Apple OS X with Safari and mobile operating systems like Android, Apple iOS, and Microsoft Windows 10, web applications are supported but not optimized for touch gestures.

2.2.4 Server

2.2.4.1 Operating System

- Red Hat Enterprise Linux
  (For the currently supported version, please refer to the Technology Stack in the eHealth Solutions Release Notes.)

2.2.4.2 Database

Oracle

- Oracle 11.2.0.4: for legacy upgrades only
- Oracle 12.2.0.1: supported
- Oracle 19.3: recommended for new installations

RavenDB

- 5.1 (RHEL 7.9 is required)

2.2.5 Hypervisors

eHealth Solutions can be deployed in a virtualization environment. The following hypervisors are supported:

- VMware vSphere ≥ 6.5 (recommended)
- any certified Hypervisor for Red Hat Enterprise Linux 7.6 (supported — please refer to official Red Hat Documentation)

2.3 Hardware Specifications

Client

There are no special hardware requirements for clients.

- Server

  There are no special hardware requirements for server machines because eHealth Solutions is operated as virtual machines. Specification of virtual RAM (vRAM) and virtual (vCPU) depends on the expected load (volume of documents, patients, concurrent access).

For the deployment of eHealth Solutions (= smallest possible deployment, incl. 1 Configuration Node, 1 Community Node, 1 Local Node, 1 Application Node), the following minimal VM size is recommended for testing and demo environments.

Table 1: Virtual Hardware Requirements

Attribute	Sizing pre-configured eHealth Solutions VM Container
vCPU	6 cores
vRAM	32 GB
Disk	360 GB
Storage/Repository	50 GB
Network Bandwidth	100 MBit

Note

- The actual configuration of hardware and software components may vary from customer to customer depending on the final solution design.
- For increased performance and protection, it is recommended to use RAID configuration with write cache enabled.
- The dimensions needed for database storage are calculated separately depending on the data and transaction volume of the installation.

2.4 Network Ports and Services

eHealth Solutions uses the following network services:

- Web application (HTTPS)
- Web services (SOAP over HTTPS)
- Web sockets (WSS)
- HL7 (TCP and TLS)
- DICOM (TCP and TLS)
- (Secure) Network Time Protocol – NTP (UDP)
- SSH (TCP)
- Syslog over TLS (TCP)

For details, see the network diagram and the network requirements (Section 3).

2.5 User Account Information

The following types of users exist:

- Patients
- Healthcare professionals
- Administrative staff for clearing operations, etc.

2.6 Patching Strategy

General descriptions of application updates are provided in the Administration Manual. Project-specific maintenance intervals and update strategies have to be defined and followed to ensure that the most current environment is installed.

A complete list of third-party software and libraries is included in the Release Notes of the product.

2.7 Cryptography Usage

- Beside authorization and access control, eHealth Solutions uses symmetric as well as asymmetric cryptography to prevent clinical data from being exposed to unauthorized persons.
- Cryptography to be used for healthcare systems is defined by the IHE Integration Profile Audit Trail and Node Authentication (ATNA).
- The ATNA profile requires TLS encryption for any clinical data submitted via network link.
- Minimum key length and allowed cryptographic algorithms and protocols are defined by the ATNA profile.
- Application Server configuration only accepts ciphers and protocols with highest security rating.

2.8 Handling of Sensitive Data (Transmission and Storage)

- Electronic Protected Health Information (ePHI)
- Personally Identifiable Information (PII)

Patient and clinical data are defined as particularly sensitive according to European and international legislation. Thus, Siemens Healthineers eHealth Solutions ensures continuous product and solution security as well as patient safety throughout the entire software and deployment life cycle. Secure coding instructions are directly incorporated in the software development guidelines.

By design, persistence of and access to patient and clinical data are limited by appropriate service-oriented architecture. The eHealth Solutions architecture relies on the IHE Cross-Enterprise Document Sharing (XDS) Integration Profile. The architectural design thus strictly separates patient demographic data from clinical data by using dedicated services whose interfaces are subject to authorization and access control measures. Configuration options are available to prevent any service other then the Master Patient Index and the Document Repository from persisting demographic patient data. This allows strict physical separation of personally Identifiable Information (PII) and Electronic Protected Health Information (ePHI) e.g by using different provider or data centers.

Country-specific legislation and organizational requirements are accommodated by flexible security configuration such as authentication and role- and context-based access control. Individual measures for deployment and operation ensure the highest possible level of privacy in the exchange of personal health-related data.

The following table lists services that persist and process Personally Identifiable Information (**PII**) and Electronic Protected Health Information (**ePHI**):

Table 2: Services Persisting and Processing Personally Identifiable Information (**PII**) and Electronic Protected Health Information (**ePHI**)

Service/Component	Type of Information	Persistence Details
Document Repository	ePHI	Clinical documents
Image Management Module	ePHI	ePHI as DICOM image data in image cache
Document Registry	PII, (ePHI)	Metadata with pseudonymized PI; partially ePHI such as institution or department of treatment
National Service Gateway	PII, ePHI	Cached ePHI such as clinical documents, depending on national requirements
Master Patient Index (PIX)	PII	Patient demographic data, e.g., name, address, date of birth, sex
Audit Record Repository	PII	ATNA Audit logs containing pseudonymized PII
Healthcare Provider Directory	PII	Healthcare professional data
Access Control System	PII	Access control policies containing pseudonymized PII
Technical Logs	PII	Master Patient Index log files contain patient demographic data of submitted source patients. Additional log files persisted in the configured log file path may contain PII.
Health Data Repository	PII, ePHI	Forms may contain PII and ePHI.

Services not listed in the table above either do not persist PII or PHI at all or in a pseudonymized manner. In the latter case only identifiers are persisted. Resolving identifiers requires invocation of distributed services which are subject to access control and audit logging.

2.9 Data Recovery

Data and machine recovery strategies should be implemented by operator. This includes disaster recovery mechanisms and offline backups. Particular measures have to be taken by operator to prevent data loss e.g., in case of crypto malware spreading in operator's networks.

Recovery mechanisms should be implemented according to customer-specific guidelines.

Detailed instructions for Backup of nodes and databases can be found in the eHealth Solutions *Installation and Operation Manual*.

2.10 Boundary Defense

Common boundary defense measures should be implemented by operator. The following measures should be taken in accordance to customer-specific guidelines:

- Network separation using Firewalls and Demilitarized Zones (DMZs)
- Reverse Proxy and Web Application Firewall upstream of Portal Applications
- Intrusion Prevention Systems
- Malware protection with site-specific anti-malware solution
- Site-specific physical access controls

Specific configuration instructions for above-mentioned boundary defense measures are described where applicable in administrative manuals.

2.11 Terms and Conditions

See local terms and conditions for purchasing and operating this device within your area.

3 Network Information

The following table lists default TCP and UDP network ports for productive environments. Testing and pre-productive environments may use additional unencrypted ports. Port numbers are configurable and may vary according to customer settings.

Figure 3: Network Connections Including Internal Communication and Connectivity with Primary Systems

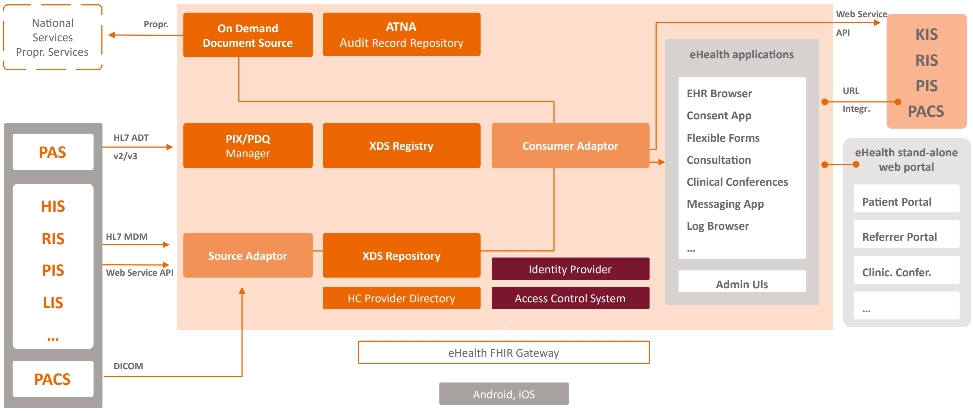


Table 3: Network Information

Port number	Service/Function	Direction	Protocol
22	Management access via SSH	Inbound	TCP
123	Network time protocol and secure network time protocol for time synchronization	Bidirectional	UDP
443, 8443	Web applications for physicians, patients, admins	Inbound	HTTPS, HL7 FHIR
5232	Audit messages for IHE ATNA logging	Inbound	TCP (Syslog over TLS)
5239	HL7 MDM stream for document management	Inbound	HL7 over TLS
5240	HL7 ADT stream for patient management	Inbound	HL7 over TLS
11113, 11114	DICOM image registration	Inbound	DICOM over TLS
443, 6443, 7443, 9443	Web services for Consumer, Source, Configuration, Registry, Repository and Gateways	Bidirectional	HTTPS

3.1 eHealth HL7 FHIR Services

RESTful service interfaces are exposed by eHealth Solutions to facilitate interaction with mobile and web-based applications. The eHealth Solutions Data Gateway serves as single point of contact for mobile applications connecting to the eHealth Solutions infrastructure. Restful service interfaces provided by the Data Gateway are compliant to the HL7 Fast Healthcare Interoperability Resources (FHIR) specification. Detailed interface descriptions are available in the eHealth Solutions *HL7 Conformance Statement*.

Exposed RESTful FHIR services rely on the below-mentioned HTTPS communication including ciphers and protocols with highest security rating. Authentication, Authorization and Access Control is handled via JSON Web Token (JWT) compliant to IHE Internet User Authorization (IUA) as described in Section 4.4.

3.2 eHealth Stroke - Seamless Stroke Companion

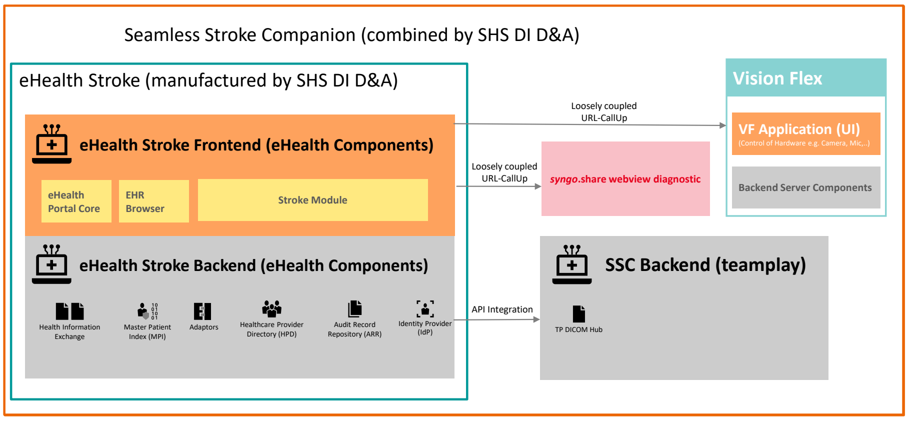
The eHealth Stroke Software is designed to digitize the prehospital stroke pathway for patients with suspected stroke. By capturing relevant medical information and presenting the data accordingly, eHealth Stroke software helps healthcare professionals to perform their jobs more efficiently.

It also aims to increase on-site sensitivity to severe stroke detection by connecting the clinical expert, i.e., the neurologist, via telestroke.

The software supports paramedics in the ambulance with a predefined workflow, supports stroke assessment by neurologists according to NIHSS as well as by calling an external embedded video conferencing application, provides calculation of lysis dose, and calls an external diagnostic DICOM image viewer to evaluate captured DICOM images.

eHealth Stroke does not provide recommendations for diagnosis or therapy.

Figure 4: Seamless Stroke Companion Architecture


Seamless Stroke Companion (combined by SHS DI D&A)
eHealth Stroke (manufactured by SHS DI D&A)
eHealth Stroke Frontend (eHealth Components)
eHealth Portal Core
EHR Browser
Stroke Module
eHealth Stroke Backend (eHealth Components)
Health Information Exchange
Master Patient Index (MPI)
Adaptors
Healthcare Provider Directory (HPD)
Audit Record Repository (ARR)
Identity Provider (IdP)
Loosely coupled URL-CallUp
Loosely coupled URL-CallUp
API Integration
syngo.share webview diagnostic
Vision Flex
VF Application (UI)
(Control of Hardware e.g. Camera, Mic,..)
Backend Server Components
SSC Backend (teamplay)
TP DICOM Hub

3.2.1 Teamplay Deployment

eHealth Stroke relies on the *teamplay* infrastructure. Therefore, the components of the Seamless Stroke Companion solution, including the eHealth Stroke application, are installed in a particularly secured Azure cloud environment. Please consult the *teamplay* Product and Solution Security Whitepaper for details.

4 Security Controls

4.1 Malware Protection

- Server-side malware protection as well as intrusion detection and prevention systems are supported by the product.
- The operator is responsible for the integration of the product in site-specific malware protection environments.

Content validation and virus scanning can be activated at two distinct entry points:

1. before document submission to repository
2. before document download via document consumer

Content validation ahead of the repository prevents undesired and potentially malicious content to be registered at repositories. Content validation before download prevents malware to reach client systems in case remote Repositories are not covered by scans with recent malware signatures.

4.2 Web Application Firewalls

A Web Application Firewall (WAF) should be deployed ahead of eHealth Solutions portal applications. Common web application attacks are prevented by WAFs before they reach the portal applications.

It is the responsibility of the operator to set up and deploy a site-specific Web Application Firewall. Recommendations for WAF configuration is provided in the eHealth Solutions *Administrator Manual*.

4.3 Controlled Use of Administrative Privileges

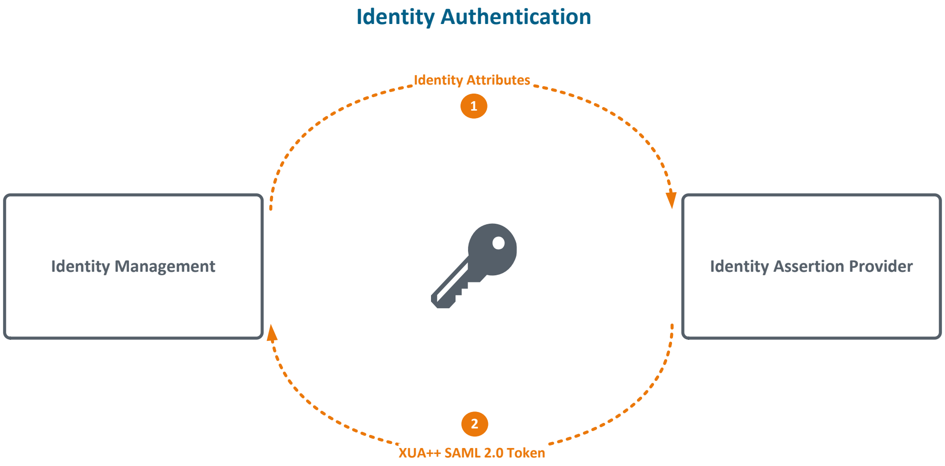
- The system distinguishes between clinical and administrative roles.
- Clinical users do not require administrative privileges. Authorization as administrator is required for administrative tasks.
- Fine-grained privileges for administrative subtasks can be configured.
- Administrative interactions as well as configuration changes are subject to audit logging.

4.4 Authentication and Authorization Controls

4.4.1 Authentication

- User authentication and role information are handled by a Security Assertion Markup Language (SAML) 2.0- and IHE XUA (Cross-Enterprise User Assertion)-compliant Identity Provider (IdP).
- User and role information is submitted from a trusted primary system (e.g., HIS, CIS) authenticated by client certificates.
- Manual user management via portal applications.
- Automatic user management by connecting existing user directories, e.g., LDAP.

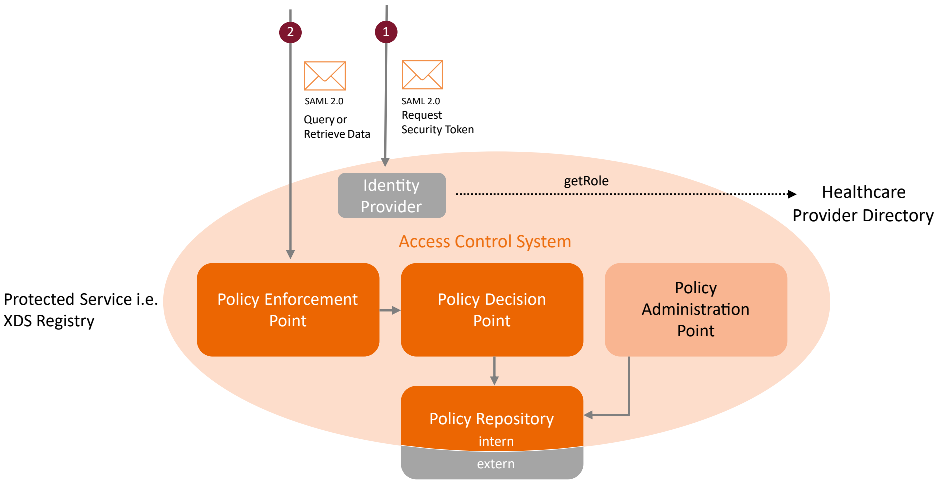
Figure 5: Authentication via Built-in or External Identity Provider



4.4.2 Authorization

- User authorization is based on eXtensible Access Control Markup Language (XACML) policies that offer a state-of-the-art role- and context-based access control system compliant to IHE Advanced Patient Privacy Consents (APPC).
- Role and context based access control system is based on IHE Advanced Patient Privacy Consents (APPC). This allows a structural representation of privacy consent definitions and policies. The definition allows for flexible extensions that can include individualized parts to reflect dynamic patient requirements.
- The general behavior of the access control system can be pre-configured via policies to reflect current legal and organizational requirements, e.g., opt-in vs. opt-out configuration.
- Patient consent declarations are also persisted as policies.
- Role and context information (e.g., emergency access) transmitted in the SAML token is evaluated by the access control system.
- User Identity, Attributes, and Authorizations for RESTful services is supported by JSON Web Token (JWT) compliant to IHE Internet User Authorization (IUA)

Figure 6: eHealth Solutions Access Control System Including Authentication via SAML Identity Provider



4.5 Continuous Vulnerability Assessment and Remediation

Continuous vulnerability assessment and remediation is performed throughout the entire product life cycle. The processes of software development, quality management and change management are certified according to EN ISO 13485 and EN ISO 9001 and comply to EU Council Directive 93/42/EE. Risk analysis and the identification of control measures are carried out with a particular focus on data security and patient safety. Upcoming and changed customer and market requirements as well as software anomalies (Bugs) are thoroughly evaluated in the risk management process according to *EN ISO 14971 Medical devices - Application of risk management to medical devices* This process encompasses the identification, analysis and evaluation of risks as well as the deduction of control measures including monitoring of their realization.

The legal manufacturer, the Siemens Healthineers company ITH icoserve, is certified according to the strict criteria of EuroREC (`http://www.eurorec.org`) for usability and privacy for electronic health records.

Continuous vulnerability monitoring of third party components such as software libraries or application servers is implemented according to Siemens Healthineers Policies.

4.6 Security Scanning

Periodic internal penetration testing provides for robustness against known vulnerabilities and attack patterns. eHealth Solutions has been subjected to an intensive security analysis carried out by the Department of Computer Science of the Leopold-Franzens-Universität Innsbruck, which is a leading research facility in the field of software quality and data security. Penetration testing against commonly known vulnerabilities, including the OWASP Top 10 (see Table 4), was subject of this security analysis, as well as an evaluation of the entire development process. This report provides evidence of a secure software development process that leads to products which fulfill the highest security requirements.

Penetration tests of the entire solution deployed at customers' sites have been carried out directly before go-live by XSEC infosec GmbH (`https://www.xsec.at/en/`), which focuses on security auditing and consulting.

The software and the entire solution have been subjected to security audits carried out in the scope of the Austrian Electronic Health Record (ELGA).

Portal applications are based on a widely used and well-tested Enterprise Portal Solution. The Enterprise Portal Solution follows the Open Web Application Security Project OWASP Top 10 and CWE/SANS Top 25 lists to ensure the highest possible security. Following these recommendations offers protection against known kinds of attacks and security vulnerabilities. Portal applications running on Enterprise Portal directly benefit from these commitments and can therefore be considered highly robust against the OWASP Top 10 security flaws. Additionally, eHealth Solutions web applications are developed with an awareness of the OWASP Top 10 security issues, as well as further security patterns. The constant training of the developers with a particular focus on those patterns ensures the development of eHealth Solutions web applications that provide robust designs against the OWASP Top 10 criteria. Periodic penetration testing of the software by independent organizations (see above) is an effective measure to prove the software's stability and vigilance.

The legal manufacturer, Siemens Healthineers company ITH icoserve, actively participates in the Siemens Product and Solution Security Initiative to ensure that cutting-edge security measures are employed and upcoming risks are identified and mitigated instantly.

An information security management system (ISMS) is employed to ensure that threats and vulnerabilities of third-party products, such as virtualization environments, operating systems, databases and software libraries, are constantly monitored using reliable sources such as CERT (`www.cert.at`) for general advisories and Siemens CERT (`https://www.siemens.com/cert`) for specific advisories.

The development process follows the requirements of the IEC 62304, IEC 82304 and EN ISO 14971 including mandatory coding style guidelines. The application of state of the art version control systems provides access control and auditing for source code modifications, thus ensuring that source code can only be maintained by authorized developers. Robustness against the OWASP Top 10 criteria is achieved as follows:

Table 4: Robustness against the OWASP Top 10 Criteria

Criterion		Description
A1:2017	**Injection**	› Covered by the security mechanism of the portal application. › Additionally: Input validation and usage of parametrized stored queries for the object-relational data mapper. › External Security Audits have placed special emphasis on robustness against injection attacks.
A2:2017	**Broken Authentication and Session Management**	Covered by the security mechanism of the portal application by usage of configurable, well-established authentication mechanisms such as: › LDAP › Active Directory › OpenSSO › OpenID › SAML 2.0 › Generation and persistence of user credentials via strong cryptography › Multi-factor authentication and Single-Sign-On compliant with IHE XUA
A3:2017	**Sensitive Data Exposure**	› Covered by the security mechanism of the portal application by usage of strong cryptography for transport encryption (TLS 1.2) and persistence of user credentials. › Transport encryption compliant with IHE ATNA requiring secure algorithms and high key length.

Table 4: Robustness against the OWASP Top 10 Criteria

Table 4: Robustness against the OWASP Top 10 Criteria

Criterion		Description
A4:2017	**XML External Entity (XXE)**	XXE protection is provided by: › Server-side style sheet rendering and input validation. › Continuous checks of XML documents such as CDA documents or style sheets against schemata.
A5:2017	**Broken Access Control**	› XACML-compliant Access Control System with flexible configuration of policies to reflect patient consent declarations. › Compliant with IHE Access Control Requirements. › Covered by the security mechanism of the portal application as well as by role- and context-based authorization.
A6:2017	**Security Misconfiguration**	› Covered by the security mechanism of the portal application by usage of well-established architectural design (security by design) for separation of components. › Usage of most recent versions and security patches. › Checklists for productive installations which comprise: › Installation of no other than required packages › Deactivation of unused ports › Solely encrypted communication › Observance of customer-specific requirements concerning authentication policies (password length and complexity, Single Sign-On, multifactor authentication).
A7:2017	**Cross–Site Scripting** (XSS)	› Covered by the security mechanism of the portal application by input validation and additionally consequent escaping of output content. › External Security Audits have placed special emphasis on robustness against XSS attacks.
A8:2017	**Insecure Deserialization**	Usage of well-established XML bindings as well as strict type checks against XMS schemata.
A9:2017	**Using Components with Known Vulnerabilities**	› Continuous monitoring and reaction to known vulnerabilities. › Continuous monitoring of vulnerability lists. › Web-based management interfaces allow easy-to-use update with minimal downtime.
A10:2017	**Insufficient Logging & Monitoring**	› Audit Logging complaint to IHE ATNA Secure Node Requirements. › Detailed, distributed technical logs. › Web-based reports from the ATNA Audit Record Repository. › Optional integration of fraud-detection mechanisms. › Secure time synchronization compliant with IHE CT Secure Time Client/Server.

4.7 Hardening

The following operating system- and application-specific hardening measures are recommended:

- Removal of unnecessary packages is handled by the default installation of the operating system.
- Secure Shell (SSH) access only by public-key authentication: Configured and activated by the operator.
- Setup and validation of a Secure Time Server (SNTP).
- Use of reverse proxies for accessing web applications from untrusted networks: Provided by default setup where applicable. Additional reverse proxies may be deployed by the operator.
- Adaptation of site-specific firewalling rules so that connections are restricted to the required ports of the applications. See above. Handled by the operator.
- Installation and deployment of network intrusion prevention systems and malware protection.
- Deactivation of unused services and eHealth Solutions applications: Handled by the application configuration.
- Activation of encryption-only communication paths: Handled by the application configuration.
- Application of customer-specific password complexity and validity rules for application and OS passwords.

Operating System specific hardening measures according to the Security Technical Implementation Guides (STIGs) standardized hardening measures.

It is the responsibility of the operator to set up and implement the operating system hardening. Recommendations for STIGs criteria to be applied are available in the eHealth Solutions *Administrator Manual*.

On productive and pre-productive environments, a post-installation security checklist is processed to ensure that the above-mentioned hardening measures have been sufficiently implemented.

4.8 Network Controls

- The system is designed to make limited use of network ports and protocols.
- Portal applications should be deployed in dedicated Demilitarized Zones (DMZs) separated from internet as well as from internal networks.
- A Reverse Proxy should be deployed upstream of Portal applications. Reverse Proxy may be combined with Web Application Firewall as described above

Detailed deployment recommendations for DMZs and reverse proxy are available in the eHealth Solutions *Administrator Manual*.

4.9 Physical Safeguards

The customer is responsible for the physical protection of the server infrastructure, e.g., by providing a safe server rack or a server room with access control.

4.10 Data Protection Controls

- PII as well as ePHI is protected by role-based access control.
- The system provides auditing of ePHI access.
- Confidentiality and integrity of ePHI/PII transmitted via networks is protected by strong cryptography between the client and the service.

- The system follows the strict requirements of the IHE Integration Profile Audit Trail and Node Authentication ATNA.
- Client and service certificates are required for service authentication and transport encryption.

For further information about GDPR compliance, refer to Section 2.1.

4.11 Encryption

eHealth Solutions offers two encryption possibilities: one on file-system level, one on document level.

4.11.1 File-System Encryption

- The vendor encourages customers to use storage and database encryption. Encryption must be enabled by the customer and requires appropriate licensing of the Oracle database.
- A detailed backup and recovery concept is discussed with the customer for site-specific operations.

End2End content encryption allows documents to be persisted in an encrypted form in the XDS Document Repository. The Repository uses asymmetric encryption to encrypt the document for a specific client (Consumer). The corresponding certificate is provided by the consumer. In combination with document routing this asymmetric encryption allows documents to be decrypted solely by a specific consumer.

4.11.2 Document Encryption

To ensure secure data storage on document level, eHealth Solutions allows the use of data at rest encryption. This comprises algorithms such as *AES/GCM/NoPadding* and the third-party solution *HashiCorp Vault*. The customer or operator is responsible for the setup and configuration of the encryption, additionally for the licensing if required (e.g., in case of *HashiCorp Vault*). Refer to Section 5 for further information on responsibilities.

- The unencrypted file is stored in a temporary storage where it will be deleted right after encryption.
- All plaintext keys are only kept in main memory (as short as possible), are not stored anywhere else and are immediately deleted after en- or decryption.
- For security reasons, the keys are only valid for one single document. This method is designed to prevent malicious intentions of gaining inappropriate access to documents. Should a heap dump be able to extract a key from main memory, only the document assigned to this key can be decrypted.
- As memory overflow could happen, a limit for the file size can be set in the Repository configuration.

4.12 Auditing/Logging

HIPAA- and IHE ATNA-compliant auditing of operations on ePHI, PII and user information such as:

- Login/logout
- Read access to ePHI (e.g., patient identification, document search and retrieval)
- Write access (provision, modification, deletion of ePHI)
- Administrative operations (e.g., clearing)
- Configuration changes

4.13 Remote Connectivity

- Siemens Remote Service connection is established using a secure channel. The channel is used e.g., to download security patches and updates.
- Operating system patches can be directly retrieved from the OS vendor or from a software repository operated by the manufacturer via Internet connection.
- Management of the operating system configuration is performed via Secure Shell (SSH) access.

4.14 Administrative Controls

- Administrative operations are strictly bound to named users.
- Usage of external authentication services (LDAP) is supported.
- Administrative interactions are subject to access control and audit logging.
- Fine-grained administrative permissions allow the limitation of access to ePHI by administrative staff.

4.15 Incident Response Management

The Siemens CERT Incident Response Process is used to react to incidents.

5 Shared Responsibilities

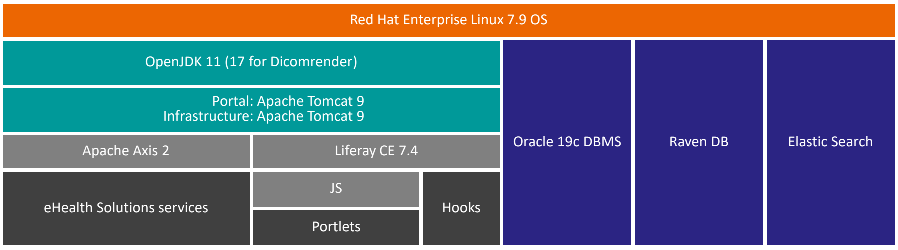
eHealth Solutions is designed and pre-configured following the security and privacy per design and per default approach. If the product is operated by a customer or by Siemens Healthineers on behalf of the customer, the following responsibilities apply for the operator:

- Physical security and access control.
- Maintenance and continuous upgrade of operating system as agreed on in maintenance contracts.
- Backup and data recovery mechanisms as described above.
- Implementation of site-specific boundary defense mechanisms such as firewalls and malware prevention as described above.
- Configuration of data at rest encryption and database encryption as well as database vault configuration (see Section 4.11.2).
- Appropriate licensing of third-party products for data encryption if required (see Section 4.11.2).

6 Software Bill of Materials

eHealth Solutions uses, among others, the following third-party software:

Figure 7: Third-party software in eHealth Solutions.


Red Hat Enterprise Linux 7.9 OS
OpenJDK 11 (17 for Dicomrender)
Portal: Apache Tomcat 9
Infrastructure: Apache Tomcat 9
Apache Axis 2
Liferay CE 7.4
eHealth Solutions services
JS
Portlets
Hooks
Oracle 19c DBMS
Raven DB
Elastic Search

A complete list of third-party software and libraries is included in the product Release Notes.

7 Manufacturer Disclosure Statement (MDS^2)

Table 5: Manufacturer Disclosure Statement (MDS^2)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
DOC-1	Manufacturer Name	ITH icoserve technology for healthcare GmbH	-			
DOC-2	Device Description	eHealth Solutions	-			
DOC-3	Device Model	eHealth Solutions VA53A	-			
DOC-4	Document ID	r7-g1164c71	-			
DOC-5	Manufacturer Contact Information	ITH icoserve technology for healthcare GmbH A Siemens Healthineers Company Innrain 98 6020 Innsbruck Austria Tel: +43512890590 Email: ith-icoserve@siemens-healthineers.com	-			
DOC-6	Intended use of device in network-connected environment:	eHealth Solutions is a networking solution for the digital management of services in the healthcare sector. eHealth Solutions is able to protect uploaded patient data against unauthorized access in a multitude of ways via a customizable and finely controllable access control system.	Full description contained in user manuals.			
DOC-7	Document Release Date	2023-08-14	-			
DOC-8	Coordinated Vulnerability Disclosure: Does the manufacturer have a vulnerability disclosure program for this device?	Yes	Siemens Healthineers Vulnerability disclosure process is applied.			

Table 5: Manufacturer Disclosure Statement (MDS^2)

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Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
DOC-9	ISAO: Is the manufacturer part of an Information Sharing and Analysis Organization?	Yes	-			
DOC-10	Diagram: Is a network or data flow diagram available that indicates connections to other system components or expected external resources?	Yes	See eHealth Solutions *Product and Solution Security White Paper*			
DOC-11	SaMD: Is the device Software as a Medical Device (i.e. software-only, no hardware)?	No	-			
DOC-11.1	Does the SaMD contain an operating system?	Yes	-			
DOC-11.2	Does the SaMD rely on an owner/operator provided operating system?	No	-			
DOC-11.3	Is the SaMD hosted by the manufacturer?	No	-			
DOC-11.4	Is the SaMD hosted by the customer?	See Note	Usually hosted in data centers of the customer			

7.1 Management of Personally Identifiable Information

Table 6: Management of Personally Identifiable Information

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
MPII-1	Can this device display, transmit, store, or modify personally identifiable information (e.g., electronic Protected Health Information (ePHI))?	Yes	-		AR-2	A.15.1.4
MPII-2	Does the device maintain personally identifiable information?	Yes	-		AR-2	A.15.1.4
MPII-2.1	Does the device maintain personally identifiable information temporarily in volatile memory (i.e., until cleared by power-off or reset)?	No	-		AR-2	A.15.1.4
MPII-2.2	Does the device store personally identifiable information persistently on internal media?	No	The data is stored on a mounted storage device like SAN/NAS and databases.			

Table 6: Management of Personally Identifiable Information

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Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
MPII-2.3	Is personally identifiable information preserved in the device's non-volatile memory until explicitly erased?	See Note	Log files may contain personally identifiable information. Rotation of log files automatically removes PII.			
MPII-2.4	Does the device store personally identifiable information in a database?	Yes	-			
MPII-2.5	Does the device allow configuration to automatically delete local personally identifiable information after it is stored to a long term solution?	See Note	Log files may contain personally identifiable information. Rotation of log files automatically removes PII.		AR-2	A.15.1.4
MPII-2.6	Does the device import/export personally identifiable information with other systems (e.g., a wearable monitoring device might export personally identifiable information to a server)?	Yes	-		AR-2	A.15.1.4
MPII-2.7	Does the device maintain personally identifiable information when powered off, or during power service interruptions?	Yes	Product stores PHI on media (HDD) that does not need a permanent power service. The server hardware can be connected to an UPS. This helps to prevent the loss of data in transient memory during power service interruptions.		AR-2	A.15.1.4
MPII-2.8	Does the device allow the internal media to be removed by a service technician (e.g., for separate destruction or customer retention)?	No	-			
MPII-2.9	Does the device allow personally identifiable information records be stored in a separate location from the device's operating system (i.e. secondary internal drive, alternate drive partition, or remote storage location)?	Yes	The data is stored on a mounted storage device like SAN/NAS and databases.		AR-2	A.15.1.4
MPII-3	Does the device have mechanisms used for the transmitting, importing/exporting of personally identifiable information?	Yes	-		AR-2	A.15.1.4
MPII-3.1	Does the device display personally identifiable information (e.g., video display, etc.)?	Yes	-		AR-2	A.15.1.4
MPII-3.2	Does the device generate hardcopy reports or images containing personally identifiable information?	Yes	-		AR-2	A.15.1.4
MPII-3.3	Does the device retrieve personally identifiable information from or record personally identifiable information to removable media (e.g., removable-HDD, USB memory, DVD-R/RW, CD-R/RW, tape, CF/SD card, memory stick, etc.)?	No	-		AR-2	A.15.1.4

Table 6: Management of Personally Identifiable Information

Table 6: Management of Personally Identifiable Information

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
MPII-3.4	Does the device transmit/receive or import/export personally identifiable information via dedicated cable connection (e.g., RS-232, RS-423, USB, FireWire, etc.)?	No	-		AR-2	A.15.1.4
MPII-3.5	Does the device transmit/receive personally identifiable information via a wired network connection (e.g., RJ45, fiber optic, etc.)?	Yes	-		AR-2	A.15.1.4
MPII-3.6	Does the device transmit/receive personally identifiable information via a wireless network connection (e.g., WiFi, Bluetooth, NFC, infrared, cellular, etc.)?	No	Product does not provide integrated wireless connection. ePHI will only be transmitted via WiFi in case client machines are connected to eHealth Solutions by means of a wireless infrastructure available at the customer’s site.		AR-2	A.15.1.4
MPII-3.7	Does the device transmit/receive personally identifiable information over an external network (e.g., Internet)?	See Note	eHealth Solutions is not intended to be directly connected to public networks. eHealth Solutions’ web portals can be made accessible e.g., via internet in customer-specific settings. For those cases, well-documented mandatory security measures such as a deployment behind a Reverse Proxy/Web Application Firewall and in different De-militarized Zones (DMZs) are provided to the customer.		AR-2	A.15.1.4
MPII-3.8	Does the device import personally identifiable information via scanning a document?	No	-			
MPII-3.9	Does the device transmit/receive personally identifiable information via a proprietary protocol?	See Note	Only via HL7 and IHE transactions			
MPII-3.10	Does the device use any other mechanism to transmit, import or export personally identifiable information?	No	-		AR-2	A.15.1.4

7.2 Automatic Logoff (ALOF)

The device’s ability to prevent access and misuse by unauthorized users if device is left idle for a period of time.

Table 7: Automatic Logoff (ALOF)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
ALOF-1	Can the device be configured to force reauthorization of logged-in user(s) after a predetermined length of inactivity (e.g., auto-logoff, session lock, password protected screen saver)?	Yes	-	Section 5.1, ALOF	AC-12	None
ALOF-2	Is the length of inactivity time before auto-logoff/screen lock user or administrator configurable?	Yes	The web application UIs have a configurable session timeout. In addition, the logout capability of the portal can be used.	Section 5.1, ALOF	AC-11	A.11.2.8, A.11.2.9

7.3 Audit Controls (AUDT)

The ability to reliably audit activity on the device.

Table 8: Audit Controls (AUDT)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
AUDT-1	Can the medical device create additional audit logs or reports beyond standard operating system logs?	Yes	IHE-compliant ATNA Audit Logs are created.	Section 5.2, AUDT	AU-1	A.5.1.1, A.5.1.2, A.6.1.1, A.12.1.1, A.18.1.1, A.18.2.2
AUDT-1.1	Does the audit log record a USER ID?	Yes	-			
AUDT-1.2	Does other personally identifiable information exist in the audit trail?	No	-	Section 5.2, AUDT	AU-2	None
AUDT-2	Are events recorded in an audit log? If yes, indicate which of the following events are recorded in the audit log:	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-2.1	Successful login/logout attempts?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-2.2	Unsuccessful login/logout attempts?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-2.3	Modification of user privileges?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-2.4	Creation/modification/deletion of users?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-2.5	Presentation of clinical or PII data (e.g., display, print)?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-2.6	Creation/modification/deletion of data?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-2.7	Import/export of data from removable media (e.g., USB drive, external hard drive, DVD)?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-2.8	Receipt/transmission of data or commands over a network or point-to-point connection?	Yes	-	Section 5.2, AUDT	AU-2	None

Table 8: Audit Controls (AUDT) ⮐

Table 8: Audit Controls (AUDT)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
AUDT-2.8.1	Remote or on-site support?	See Note	Not included in the product as no remote or on-site support feature is available in eHealth Solutions. The *Remote Service Center* provides audit logs for remote service activities.	Section 5.2, AUDT	AU-2	None
AUDT-2.8.2	Application Programming Interface (API) and similar activity?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-2.9	Emergency access?	Yes	Emergency access is a feature that must be explicitly enabled in advance. Restrictions on document types that may be available in emergency access cases can be defined by the patient.	Section 5.2, AUDT	AU-2	None
AUDT-2.10	Other events (e.g., software updates)?	No	-	Section 5.2, AUDT	AU-2	None
AUDT-2.11	Is the audit capability documented in more detail?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-3	Can the owner/operator define or select which events are recorded in the audit log?	No	Audit logs and events are predefined and cannot be changed. Well-established query interfaces exist for audit log analysis.	Section 5.2, AUDT	AU-2	None
AUDT-4	Is a list of data attributes that are captured in the audit log for an event available?	Yes	According to IHE ATNA	Section 5.2, AUDT	AU-2	None
AUDT-4.1	Does the audit log record date/time?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-4.1.1	Can date and time be synchronized by Network Time Protocol (NTP) or equivalent time source?	Yes	Use of Secure NTP is recommended.	Section 5.2, AUDT	AU-2	None
AUDT-5	Can audit log content be exported?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-5.1	Via physical media?	No	As downloadable export			
AUDT-5.2	Via IHE Audit Trail and Node Authentication (ATNA) profile to SIEM?	Yes	-			
AUDT-5.3	Via other communications (e.g., external service device, mobile applications)?	Yes	-			
AUDT-5.4	Are audit logs encrypted in transit or on storage media?	Yes	-			
AUDT-6	Can audit logs be monitored/reviewed by owner/operator?	Yes	-			
AUDT-7	Are audit logs protected from modification?	Yes	-	Section 5.2, AUDT	AU-2	None
AUDT-7.1	Are audit logs protected from access?	Yes	-			
AUDT-8	Can audit logs be analyzed by the device?	Yes	-	Section 5.2, AUDT	AU-2	None

7.4 Authorization (AUTH)

The ability of the device to determine the authorization of users.

Table 9: Authorization (AUTH)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
AUTH-1	Does the device prevent access to unauthorized users through user login requirements or other mechanism?	Yes	-	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-1.1	Can the device be configured to use federated credentials management of users for authorization (e.g., LDAP, OAuth)?	Yes	-	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-1.2	Can the customer push group policies to the device (e.g., Active Directory)?	No	-	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-1.3	Are any special groups, organizational units, or group policies required?	No	-	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-2	Can users be assigned different privilege levels based on 'role' (e.g., user, administrator, and/or service, etc.)?	Yes	-	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-3	Can the device owner/operator grant themselves unrestricted administrative privileges (e.g., access operating system or application via local root or administrator account)?	No	Access to PHI is granted by the access control system based on user authentication where local root access does not lead to application-specific administrative privileges.	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-4	Does the device authorize or control all API access requests?	Yes	-	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-5	Does the device run in a restricted access mode, or 'kiosk mode', by default?	See Note	Permissions are granted on a user and role level.			

7.5 Cyber Security Product Upgrades (CSUP)

The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade device's security patches.

Table 10: Cyber Security Product Upgrades (CSUP)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
CSUP-1	Does the device contain any software or firmware which may require security updates during its operational life, either from the device manufacturer or from a third-party manufacturer of the software/firmware? If no, answer "N/A" to questions in this section.	Yes	-			

Table 10: Cyber Security Product Upgrades (CSUP) ↻

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Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
CSUP-2	Does the device contain an Operating System? If yes, complete 2.1-2.4.	Yes	-			
CSUP-2.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	Yes	-			
CSUP-2.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	No	-			
CSUP-2.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes	*Siemens Remote Service* infrastructure provides secure means of downloading security patches and application-specific updates. Additionally, application-specific security patches can be provided by a software repository to be propagated manually. In case *Siemens Remote Service* infrastructure cannot be utilized, a service engineer or customer IT administrator has to install the required security patches and updates. Operating system patches can be installed from official sources.			
CSUP-2.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	Yes	-			
CSUP-3	Does the device contain Drivers and Firmware? If yes, complete 3.1-3.4.	No	-			
CSUP-3.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	N/A	-			
CSUP-3.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	N/A	-			
CSUP-3.3	Does the device have the capability to receive remote installation of patches or software updates?	N/A	-			
CSUP-3.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	N/A	-			

Table 10: Cyber Security Product Upgrades (CSUP)

Table 10: Cyber Security Product Upgrades (CSUP)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
CSUP-4	Does the device contain Anti-Malware Software? If yes, complete 4.1-4.4.	See Note	Anti-malware software is recommended to be installed by the customer but not included in the product. A scripting interface is available to allow anti-malware scans on a per-document basis during registration and download. Malware scanners are to be provided by the customer.			
CSUP-4.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	N/A	-			
CSUP-4.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	N/A	-			
CSUP-4.3	Does the device have the capability to receive remote installation of patches or software updates?	N/A	-			
CSUP-4.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	N/A	-			
CSUP-5	Does the device contain Non-Operating System commercial off-the-shelf components? If yes, complete 5.1-5.4.	See Note	Third-party components such as libraries and application servers are included in the software release and provided as operating system packages.			
CSUP-5.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	N/A	-			
CSUP-5.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	N/A	-			
CSUP-5.3	Does the device have the capability to receive remote installation of patches or software updates?	N/A	-			
CSUP-5.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	N/A	-			
CSUP-6	Does the device contain other software components (e.g., asset management software, license management)? If yes, please provide details or reference in notes and complete 6.1-6.4.	No	-			

Table 10: Cyber Security Product Upgrades (CSUP)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
CSUP-6.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	N/A	-			
CSUP-6.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	N/A	-			
CSUP-6.3	Does the device have the capability to receive remote installation of patches or software updates?	N/A	-			
CSUP-6.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	N/A	-			
CSUP-7	Does the manufacturer notify the customer when updates are approved for installation?	See Note	Customer is notified via *Remote Service Center*.			
CSUP-8	Does the device perform automatic installation of software updates?	See Note	Updates of eHealth Solutions applications are not automatically installed. Automatic operating system updates are configured per default.			
CSUP-9	Does the manufacturer have an approved list of third-party software that can be installed on the device?	See Note	There are no restrictions on third-party components that can be installed on the machine			
CSUP-10	Can the owner/operator install manufacturer-approved third-party software on the device themselves?	See Note	Installation of third-party software is not restricted by the manufacturer.			
CSUP-10.1	Does the system have mechanism in place to prevent installation of unapproved software?	See Note	Operating system (OS) verification of software packages is enabled per default. Application updates are provided as OS packages by RPM Package Manager (RPM).			
CSUP-11	Does the manufacturer have a process in place to assess device vulnerabilities and updates?	Yes	Vulnerabilities of third-party components are continuously monitored. Internal penetration tests are carried out regularly.			
CSUP-11.1	Does the manufacturer provide customers with review and approval status of updates?	Yes	Software upgrades are provided only after internal verification and clearance which is transparently communicated to customers.			
CSUP-11.2	Is there an update review cycle for the device?	Yes	Release upgrades are provided regularly, bug fixes for software defects on demand. Both are provided after internal verification and clearance.			

7.6 Health Data De-Identification (DIDT)

The ability of the device to directly remove information that allows identification of a person.

Table 11: Health Data De-Identification (DIDT)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
DIDT-1	Does the device provide an integral capability to de-identify personally identifiable information?	Yes	System relies on distributed services where PHI is linked to patient data via a unique and irreversible identifier. Services use this identifier to link PHI to demographic data. Thus, pseudonymization is supported implicitly.	Section 5.6, DIDT	None	ISO 27038
DIDT-1.1	Does the device support de-identification profiles that comply with the DICOM standard for de-identification?	N/A		Section 5.6, DIDT	None	ISO 27038

7.7 Data Backup and Disaster Recovery (DTBK)

The ability to recover after damage or destruction of device data, hardware, software, or site configuration information.

Table 12: Data Backup and Disaster Recovery (DTBK)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
DTBK-1	Does the device maintain long term primary storage of personally identifiable information/patient information (e.g., PACS)?	Yes	-			
DTBK-2	Does the device have a "factory reset" function to restore the original device settings as provided by the manufacturer?	No	-	Section 5.7, DTBK	CP-9	A.12.3.1
DTBK-3	Does the device have an integral data backup capability to removable media?	Yes	The system should be integrated in existing backup and recovery infrastructures. A detailed backup and recovery concept is elaborated with the customer for site-specific operations.	Section 5.7, DTBK	CP-9	A.12.3.1
DTBK-4	Does the device have an integral data backup capability to remote storage?	Yes	-			

Table 12: Data Backup and Disaster Recovery (DTBK) ⟲

Table 12: Data Backup and Disaster Recovery (DTBK)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
DTBK-5	Does the device have a backup capability for system configuration information, patch restoration, and software restoration?	Yes	Entire machine backup via virtualization environment is handled by the customer. Administration manuals provide detailed references.			
DTBK-6	Does the device provide the capability to check the integrity and authenticity of a backup?	See Note	Integrity and authenticity for database backups is provided by DBMS tools.	Section 5.7, DTBK	CP-9	A.12.3.1

7.8 Emergency Access (EMRG)

The ability of the device user to access personally identifiable information in case of a medical emergency situation that requires immediate access to stored personally identifiable information.

Table 13: Emergency Access (EMRG)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
EMRG-1	Does the device incorporate an emergency access (i.e. "break-glass") feature?	Yes	Emergency access is a feature that must be explicitly enabled in advance. System provides special `PurposeOfUse` element in SAML token to indicate emergency access. Emergency access requires successful authentication and is subject to audit logging. Restrictions on document types that may be available in emergency access cases can be defined by the patient.	Section 5.8, EMRG	SI-17	None

7.9 Health Data Integrity and Authenticity (IGAU)

How the device ensures that the stored data on the device has not been altered or destroyed in a non-authorized manner and is from the originator.

Table 14: Health Data Integrity and Authenticity (IGAU)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
IGAU-1	Does the device provide data integrity checking mechanisms of stored health data (e.g., hash or digital signature)?	Yes	-	Section 5.9, IGAU	SC-28	A.18.1.3
IGAU-2	Does the device provide error/failure protection and recovery mechanisms for stored health data (e.g., RAID-5)?	Yes	-	Section 5.9, IGAU	SC-28	A.18.1.3

7.10 Malware Detection/Protection (MLDP)

The ability of the device to effectively prevent, detect and remove malicious software (malware).

Table 15: Malware Detection/Protection (MLDP)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
MLDP-1	Is the device capable of hosting executable software?	Yes	-	Section 5.10, MLDP		
MLDP-2	Does the device support the use of anti-malware software (or other anti-malware mechanism)? Provide details or reference in notes.	Yes	Any anti-malware software compliant with the operating system can be used.	Section 5.10, MLDP	SI-3	A.12.2.1
MLDP-2.1	Does the device include anti-malware software by default?	No	-	Section 5.10, MLDP	CM-5	A.9.2.3, A.9.4.5, A.12.1.2, A.12.1.4, A.12.5.1
MLDP-2.2	Does the device have anti-malware software available as an option?	See Note	Anti-malware software is recommended to be installed by the customer but not included in the product. A scripting interface is available to allow anti-malware scans on a per-document basis during registration and download. Malware scanners are to be provided by the customer.	Section 5.10, MLDP	AU-6	A.12.4.1, A.16.1.2, A.16.1.4
MLDP-2.3	Does the device documentation allow the owner/operator to install or update anti-malware software?	Yes	-	Section 5.10, MLDP	CP-10	A.17.1.2
MLDP-2.4	Can the device owner/operator independently (re-)configure anti-malware settings?	Yes	-	Section 5.10, MLDP	AU-2	None

Table 15: Malware Detection/Protection (MLDP) ⮌

Table 15: Malware Detection/Protection (MLDP)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
MLDP-2.5	Does notification of malware detection occur in the device user interface?	See Note	A failed download is indicated in the user interface if a malware scanner detects malware in a downloaded document. For this purpose, malware scanners must be enabled and configured by the customer. See above.			
MLDP-2.6	Can only manufacturer-authorized persons repair systems when malware has been detected?	Yes	-			
MLDP-2.7	Are malware notifications written to a log?	See Note	Depending on the anti-malware software			
MLDP-2.8	Are there any restrictions on anti-malware (e.g., purchase, installation, configuration, scheduling)?	No	-			
MLDP-3	If the answer to MLDP-2 is NO, and anti-malware cannot be installed on the device, are other compensating controls in place or available?	N/A	-	Section 5.10, MLDP	SI-2	A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3
MLDP-4	Does the device employ application allowlisting that restricts the software and services that are permitted to be run on the device?	No	-	Section 5.10, MLDP	SI-3	A.12.2.1
MLDP-5	Does the device employ a host-based intrusion detection/prevention system?	See Note	Host-base IDS/IPS can be configured by the customer.	Section 5.10, MLDP	SI-4	None
MLDP-5.1	Can the host-based intrusion detection/prevention system be configured by the customer?	N/A	-	Section 5.10, MLDP	CM-7	A.12.5.1
MLDP-5.2	Can a host-based intrusion detection/prevention system be installed by the customer?	Yes	-	Section 5.10, MLDP		

7.11 Node Authentication (NAUT)

The ability of the device to authenticate communication partners/nodes.

Table 16: Node Authentication (NAUT)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
NAUT-1	Does the device provide/support any means of node authentication that assures both the sender and the recipient of data are known to each other and are authorized to receive transferred information (e.g., Web APIs, SMTP, SNMP)?	Yes	-	Section 5.11, NAUT	SC-23	None
NAUT-2	Are network access control mechanisms supported (e.g., does the device have an internal firewall, or use a network connection allowlist)?	Yes	Detailed recommendations are provided on how the product is to be operated in protected network segments of the customer.	Section 5.11, NAUT	SC-7	A.13.1.1, A.13.1.3, A.13.2.1, A.14.1.3
NAUT-2.1	Is the firewall ruleset documented and available for review?	See Note	A list of allowed paths is available.			
NAUT-3	Does the device use certificate-based network connection authentication?	Yes	According to IHE ATNA with the latest and highest-rated algorithms and protocols.			

7.12 Connectivity Capabilities (CONN)

All network and removable media connections must be considered in determining appropriate security controls. This section lists connectivity capabilities that may be present on the device.

Table 17: Connectivity Capabilities (CONN)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
CONN-1	Does the device have hardware connectivity capabilities?	See Note	The product is hosted as a virtual machine. Physical networking and storage connections depend on the underlying host machine. The product's operating system configures virtualized Ethernet connections.			
CONN-1.1	Does the device support wireless connections?	No	-			
CONN-1.1.1	Does the device support Wi-Fi?	No	-			
CONN-1.1.2	Does the device support Bluetooth?	No	-			
CONN-1.1.3	Does the device support other wireless network connectivity (e.g., LTE, Zigbee, proprietary)?	No	-			
CONN-1.1.4	Does the device support other wireless connections (e.g., custom RF controls, wireless detectors)?	No	-			

Table 17: Connectivity Capabilities (CONN) ⮌

Table 17: Connectivity Capabilities (CONN)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
CONN-1.2	Does the device support physical connections?	See Note	The product is hosted as a virtual machine. Physical networking connections depend on the underlying host machine. The product's operating system configures virtualized Ethernet connections.			
CONN-1.2.1	Does the device have available RJ45 Ethernet ports?	Yes	Virtualized Ethernet			
CONN-1.2.2	Does the device have available USB ports?	See Note	USB Ports are not used for the product; however, they might exist on the host machine running the virtual machines.			
CONN-1.2.3	Does the device require, use, or support removable memory devices?	No	-			
CONN-1.2.4	Does the device support other physical connectivity?	No	-			
CONN-2	Does the manufacturer provide a list of network ports and protocols that are used or may be used on the device?	Yes	List is provided in the eHealth Solutions *Product and Solution Security White Paper*.			
CONN-3	Can the device communicate with other systems within the customer environment?	Yes	Via DICOM, HL7, Web Services. See details in eHealth Solutions *Product and Solution Security White Paper*.			
CONN-4	Can the device communicate with other systems external to the customer environment (e.g., a service host)?	See Note	Patient and Physician Portal via internet if enabled by the customer.			
CONN-5	Does the device make or receive API calls?	Yes	A Web Service API (so-called *Connectivity Package*) is available via HTTPS (TLS-encrypted). HL7 FHIR interfaces are also available via HTTPS.			
CONN-6	Does the device require an internet connection for its intended use?	No	-			
CONN-7	Does the device support Transport Layer Security (TLS)?	Yes	-			
CONN-7.1	Is TLS configurable?	Yes	-			
CONN-8	Does the device provide operator control functionality from a separate device (e.g., telemedicine)?	No	-			

7.13 Person Authentication (PAUT)

The ability to configure the device to authenticate users.

Table 18: Person Authentication (PAUT)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
PAUT-1	Does the device support and enforce unique IDs and passwords for all users and roles (including service accounts)?	Yes	-	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-1.1	Does the device enforce authentication of unique IDs and passwords for all users and roles (including service accounts)?	Yes	-	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-2	Is the device configurable to authenticate users through an external authentication service (e.g., MS Active Directory, NDS, LDAP, OAuth, etc.)?	Yes	Built-in or external SAML 2.0-compliant identity provider (IDPs) can be used for user authentication.	Section 5.12, PAUT	IA-5	A.9.2.1
PAUT-3	Is the device configurable to lock out a user after a certain number of unsuccessful logon attempts?	Yes	-	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-4	Are all default accounts (e.g., technician service accounts, administrator accounts) listed in the documentation?	Yes	-	Section 5.12, PAUT	SA-4(5)	A.14.1.1, A.14.2.7, A.14.2.9, A.15.1.2
PAUT-5	Can all passwords be changed?	Yes	-	Section 5.12, PAUT		
PAUT-6	Is the device configurable to enforce creation of user account passwords that meet established (organization specific) complexity rules?	Yes	-	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-7	Does the device support account passwords that expire periodically?	Yes	-			
PAUT-8	Does the device support multi-factor authentication?	Yes	Via TOTP			
PAUT-9	Does the device support single sign-on (SSO)?	Yes	Via SAML and digitally signed URL	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-10	Can user accounts be disabled/locked on the device?	Yes	-	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-11	Does the device support biometric controls?	No	-	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-12	Does the device support physical tokens (e.g., badge access)?	No	-			
PAUT-13	Does the device support group authentication (e.g., hospital teams)?	No	-			
PAUT-14	Does the application or device store or manage authentication credentials?	See Note	Credentials can be persisted in a database or taken from an existing LDAP directory service.			
PAUT-14.1	Are credentials stored using a secure method?	Yes	Credentials are stored as cryptographic hashes including so called ”salt” parameters as an efficient countermeasure against brute-force attacks.			

7.14 Physical Locks (PLOK)

Physical locks can prevent unauthorized users with physical access to the device from compromising the integrity and confidentiality of personally identifiable information stored on the device or on removable media.

Table 19: Physical Locks (PLOK)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
PLOK-1	Is the device software only? If yes, answer "N/A" to remaining questions in this section.	Yes	-	Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
PLOK-2	Are all device components maintaining personally identifiable information (other than removable media) physically secure (i.e., cannot remove without tools)?	N/A	Hardware server rack should be locked against unauthorized removal by the customer.	Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
PLOK-3	Are all device components maintaining personally identifiable information (other than removable media) physically secured behind an individually keyed locking device?	N/A	-	Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
PLOK-4	Does the device have an option for the customer to attach a physical lock to restrict access to removable media?	N/A	Product is operated in virtualized environments.	Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3

7.15 Roadmap for Third-Party Components in Device Life Cycle (RDMP)

Manufacturer's plans for security support of third-party components within the device's life cycle.

Table 20: Roadmap for Third-Party Components in Device Life Cycle (RDMP)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
RDMP-1	Was a secure software development process, such as ISO/IEC 27034 or IEC 62304, followed during product development?	Yes	-	Section 5.14, RDMP	CM-2	None
RDMP-2	Does the manufacturer evaluate third-party applications and software components included in the device for secure development practices?	Yes	Siemens vulnerability monitoring systems are used for periodic check of third-party components. A complete list of third-party software and libraries is included in the *Third Party Licenses* document of the product.	Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2

Table 20: Roadmap for Third-Party Components in Device Life Cycle (RDMP)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
RDMP-3	Does the manufacturer maintain a web page or other source of information on software support dates and updates?	Yes	-	Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2
RDMP-4	Does the manufacturer have a plan for managing third-party component end-of-life?	Yes	-	Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2

7.16 Software Bill of Materials (SBoM)

A Software Bill of Material (SBoM) lists all the software components that are incorporated into the device being described for the purpose of operational security planning by the healthcare delivery organization. This section supports controls in the RDMP section.

Table 21: Software Bill of Materials (SBoM)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
SBOM-1	Is the SBoM for this product available?	Yes	-			
SBOM-2	Does the SBoM follow a standard or common method in describing software components?	Yes	-			
SBOM-2.1	Are the software components identified?	Yes	-			
SBOM-2.2	Are the developers/manufacturers of the software components identified?	Yes	-			
SBOM-2.3	Are the major version numbers of the software components identified?	Yes	-			
SBOM-2.4	Are any additional descriptive elements identified?	Yes	-			
SBOM-3	Does the device include a command or process method available to generate a list of software components installed on the device?	See Note	SBoM is part of the release documentation that is shipped along with the product.			
SBOM-4	Is there an update process for the SBoM?	Yes	-			

7.17 System and Application Hardening (SAHD)

The device's inherent resistance to cyber attacks and malware:

- NIST SP 800-53 Rev. 4

  CM-7

- ISO 27002:2013

  A-12-5-1*

Table 22: System and Application Hardening (SAHD)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
SAHD-1	Is the device hardened in accordance with any industry standards?	See Note	Hardening of the operating system is recommended to be carried out by the customer according to specific internal guidelines.	Section 5.15, SAHD	AC-17(2)/IA-3	A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2/None
SAHD-2	Has the device received any cybersecurity certifications?	Yes	Penetration tests have been carried out by Siemens.	Section 5.15, SAHD	SA-12(10)	A.14.2.7, A.15.1.1, A.15.1.2, A.15.1.3
SAHD-3	Does the device employ any mechanisms for software integrity checking?	Yes	Software is installed as RPM packages which have integrity checks enabled per default.			
SAHD-3.1	Does the device employ any mechanism (e.g., release-specific hash key, checksums, digital signature, etc.) to ensure the installed software is manufacturer-authorized?	Yes	Software is installed as RPM packages which have integrity checks enabled per default.			
SAHD-3.2	Does the device employ any mechanism (e.g., release-specific hash key, checksums, digital signature, etc.) to ensure the software updates are the manufacturer-authorized updates?	Yes	The device is application software only and does not include any changes at installation to other OS programs and HW.	Section 5.15, SAHD	CM-8	A.8.1.1, A.8.1.2
SAHD-4	Can the owner/operator perform software integrity checks (i.e., verify that the system has not been modified or tampered with)?	Yes	The owner/operator can apply RPM-based integrity checks.	Section 5.15, SAHD	AC-3	A.6.2.2, A.9.1.2, A.9.4.1, A.9.4.4, A.9.4.5, A.13.1.1, A.14.1.2, A.14.1.3, A.18.1.3
SAHD-5	Is the system configurable to allow the implementation of file-level, patient level, or other types of access controls?	Yes	-	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-5.1	Does the device provide role-based access controls?	Yes	-	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-6	Are any system or user accounts restricted or disabled by the manufacturer at system delivery?	Yes	-	Section 5.15, SAHD	CM-8	A.8.1.1, A.8.1.2
SAHD-6.1	Are any system or user accounts configurable by the end user after initial configuration?	Yes	-	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-6.2	Does this include restricting certain system or user accounts, such as service technicians, to least privileged access?	Yes	-	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-7	Are all shared resources (e.g., file shares) which are not required for the intended use of the device disabled?	Yes	-	Section 5.15, SAHD	CM-7	A.12.5.1*

Table 22: System and Application Hardening (SAHD) ↩

Table 22: System and Application Hardening (SAHD)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
SAHD-8	Are all communication ports and protocols that are not required for the intended use of the device disabled?	Yes	-	Section 5.15, SAHD	SA-18	None
SAHD-9	Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.), which are not required for the intended use of the device deleted/disabled?	Yes	-	Section 5.15, SAHD	CM-6	None
SAHD-10	Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the intended use of the device deleted/disabled?	Yes	-	Section 5.15, SAHD	SI-2	A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3
SAHD-11	Can the device prohibit boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?	See Note	The configuration of boot devices is handled by the underlying virtualization environment. The virtual machine does not boot from devices other than the pre-configured ones.			
SAHD-12	Can unauthorized software or hardware be installed on the device without the use of physical tools?	Yes	The manufacturer does not restrict additional software that may be installed by the customer.			
SAHD-13	Does the product documentation include information on operational network security scanning by users?	See Note	Network scanning does not affect the product.			
SAHD-14	Can the device be hardened beyond the default provided state?	Yes	Additional hardening is recommended.			
SAHD-14.1	Are instructions available from vendor for increased hardening?	No	-			
SHAD-15	Can the system prevent access to BIOS or other bootloaders during boot?	Yes	-			
SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?	No	-			

7.18 Security Guidance (SGUD)

Availability of security guidance for operator and administrator of the device and manufacturer sales and service.

Table 23: Security Guidance (SGUD)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
SGUD-1	Does the device include security documentation for the owner/operator?	Yes	-	Section 5.16, SGUD	AT-2/PL-2	A.7.2.2, A.12.2.1/A.14.1.1
SGUD-2	Does the device have the capability, and provide instructions, for the permanent deletion of data from the device or media?	Yes	-	Section 5.16, SGUD	MP-6	A.8.2.3, A.8.3.1, A.8.3.2, A.11.2.7
SGUD-3	Are all access accounts documented?	Yes	Default accounts are well documented. Additional accounts can be created by operators.	Section 5.16, SGUD	AC-6,IA-2	A.9.1.2, A.9.2.3, A.9.4.4, A.9.4.5/A.9.2.1
SGUD-3.1	Can the owner/operator manage password control for all accounts?	Yes	-			
SGUD-4	Does the product include documentation on recommended compensating controls for the device?	Yes	Guidelines for secure configuration according to the intended operational environment are available.			

7.19 Health Data Storage Confidentiality (STCF)

The ability of the device to ensure unauthorized access does not compromise the integrity and confidentiality of personally identifiable information stored on the device or removable media.

Table 24: Health Data Storage Confidentiality (STCF)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
STCF-1	Can the device encrypt data at rest?	See Note	Data at rest can be encrypted using: › document-based encryption › database encryption › storage encryption. Encryption must be configured by the customer.	Section 5.17, STCF	SC-28	A.8.2.3
STCF-1.1	Is all data encrypted or otherwise protected?	See Note	See above			
STCF-1.2	Is the data encryption capability configured by default?	No	-			
STCF-1.3	Are instructions available to the customer to configure encryption?	Yes	-			
STCF-2	Can the encryption keys be changed or configured?	Yes	-	Section 5.17, STCF	SC-28	A.8.2.3
STCF-3	Is the data stored in a database located on the device?	No	-			

Table 24: Health Data Storage Confidentiality (STCF)

Table 24: Health Data Storage Confidentiality (STCF)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
STCF-4	Is the data stored in a database external to the device?	Yes	-			

7.20 Transmission Confidentiality (TXCF)

The ability of the device to ensure the confidentiality of transmitted personally identifiable information.

Table 25: Transmission Confidentiality (TXCF)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
TXCF-1	Can personally identifiable information be transmitted only via a point-to-point dedicated cable?	No	-	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-2	Is personally identifiable information encrypted prior to transmission via a network or removable media?	Yes	Network communication is secured using TLS 1.2 or higher.	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-2.1	If data is not encrypted by default, can the customer configure encryption options?	Yes	-			
TXCF-3	Is personally identifiable information transmission restricted to a fixed list of network destinations?	Yes	-	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-4	Are connections limited to authenticated systems?	Yes	According to IHE ATNA	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-5	Are secure transmission methods supported/implemented (DICOM, HL7, IEEE 11073)?	Yes	-			

7.21 Transmission Integrity (TXIG)

The ability of the device to ensure the integrity of transmitted data.

Table 26: Transmission Integrity (TXIG)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
TXIG-1	Does the device support any mechanism (e.g., digital signatures) intended to ensure data is not modified during transmission?	Yes	Document metadata provide checksums on document basis. System solely uses TLS 1.2-encrypted communication paths, which implies authenticity of transmitted data.	Section 5.19, TXIG	SC-8	A.8.2.3, A.13.1.1, A.13.2.1, A.13.2.3, A.14.1.2, A.14.1.3
TXIG-2	Does the device include multiple sub-components connected by external cables?	No	-			

7.22 Remote Service (RMOT)

Remote service refers to all kinds of device maintenance activities performed by a service person via network or other remote connection.

Table 27: Remote Service (RMOT)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
RMOT-1	Does the device permit remote service connections for device analysis or repair?	See Note	Remote service is handled primarily via *Siemens Remote Service Center*. Thereby, a secure connection is initiated.		AC-17	A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2
RMOT-1.1	Does the device allow the owner/operator to initiative remote service sessions for device analysis or repair?	No	-			
RMOT-1.2	Is there an indicator for an enabled and active remote session?	Yes	Handled by the *Remote Service Center Client*, which is not part of the product.			
RMOT-1.3	Can patient data be accessed or viewed from the device during the remote session?	Yes	Service employees require legally binding confidentiality agreements to be signed.		AC-17	A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2
RMOT-2	Does the device permit or use remote service connections for predictive maintenance data?	No	-			
RMOT-3	Does the device have any other remotely accessible functionality (e.g., software updates, remote training)?	No	Software updates, etc., are solely triggered from the product, never from remote locations.			

7.23 Other Security Considerations (OTHR)

Table 28: Other Security Considerations (OTHR)

Question ID	Question	Answer	Note	IEC/TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
	NONE					

8 Abbreviations

Table 29: List of Technical Abbreviations

ADT	Admit, Discharge & Transfer (HL7)
ATNA	Audit Trail and Node Authentication
APPC	Advanced Patient Privacy Consents
CDA	Clinical Document Architecture
DICOM	Digital Imaging and Communications in Medicine
ePHI	Electronic Protected Health Information
FHIR	Fast Healthcare Interoperability Resources
HIPAA	Health Insurance Portability and Accountability Act
HL7	Health Level 7
HTTPS	Hypertext Transfer Protocol Secure
IHE	Integrating the Healthcare Enterprise
IUA	Internet User Authorization
JWT	JSON Web Token
LDAP	Lightweight Directory Access Protocol
MDM	Medical Document Management
MDS^2	Manufacturer Disclosure Statement
NTP	Network Time Protocol
PHI	Protected Health Information
PII	Personally Identifiable Information
SAML	Security Assertion Markup Language
SNTP	Simple Network Time Protocol
SOAP	Simple Object Access Protocol
SSH	Secure Shell
SSO	Single Sign-on
TCP	Transmission Control Protocol
TLS	Transport Layer Security
UDP	User Datagram Protocol
WAF	Web Application Firewall
WSS	WebSocket Secure
XACML	Extensible Access Control Markup Language
XDS	Direct Save Protocol
XML	Extensible Markup Language
XSS	Cross-Site Scripting
XUA	Cross-Enterprise User Assertion

8.1 Disclaimer According to IEC 80001-1

1-1

The device has the capability to be connected to a medical IT network which is managed under full responsibility of the operating responsible organization. It is assumed that the responsible organization assigns a Medical IT Network Risk Manager to perform IT Risk Management (see IEC 80001- 1:2010/EN 80001-1:2011) for IT networks incorporating medical devices.

1-2

This statement describes device-specific IT networking safety and security capabilities. It is not a responsibility agreement according to IEC 80001-1:2010/EN 80001-1:2011.

1-3

Any modification of the platform, the software or the interfaces of the device – unless authorized and approved by Siemens Healthcare GmbH – voids all warranties, liabilities, assertions and contracts.

⁝ 1-4

The responsible organization acknowledges that the device's underlying standard computer with operating system is to some extent vulnerable to typical attacks like, e.g., malware or denial-of-service.

⁝ 1-5

Unintended consequences (e.g., misuse/loss/corruption) of data not under control of the device, e.g., after electronic communication from the device to some IT network or to some storage, are under the responsibility of the responsible organization.

⁝ 1-6

Unauthorized use of the external connections or storage media of the device can cause hazards regarding the availability and information security of all components of the medical IT network. The responsible organization must ensure – through technical and/or organizational measures – that only authorized use of the external connections and storage media is permitted.

8.2 Statement on FDA Cybersecurity Guidance

Siemens Healthineers will follow cybersecurity guidance issued by the FDA as appropriate. Siemens Healthineers recognizes the principle described in FDA cybersecurity guidance that an effective cybersecurity framework is a shared responsibility among multiple stakeholders (e.g., medical device manufacturers, health care facilities, patients and providers), and is committed to drawing on its innovation, engineering and pioneering skills in collective efforts designed to prevent, detect and respond to new and emerging cybersecurity threats. While FDA cybersecurity guidance is informative as to adopting a risk-based approach to addressing potential patient harm, it is not binding, and alternative approaches may be used to satisfy FDA regulatory requirements.

The representations contained in this whitepaper are designed to describe Siemens Healthineers' approach to cybersecurity of its medical devices and to disclose the security capabilities of the devices/systems described herein. Neither Siemens Healthineers nor any medical device manufacturer can warrant that its systems will be invulnerable to cyberattack. Siemens Healthineers makes no representation or warranty that its cybersecurity efforts will ensure that its medical devices/systems will be error-free or secure against cyberattacks.

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