MEDICAL DEVICE DISCLOSURE STATEMENT FOR MEDICAL DEVICE SECURITY
Aixplorer MACH30 and MACH20 SW V3.X

SUPERSONIC imagine

Manufacturer Disclosure Statement for Medical Device Security – MDS[2]

DEVICE DESCRIPTION

Device Category	Manufacturer	Document ID	Document Release Date
Ultrasound imaging modality	SuperSonic Imagine	RD.DD.533	20201109

Device Model	Software Revision	Software Release Date
Aixplorer Mach30 Aixplorer Mach20	V3.X	20201115

Manufacturer or Representative Contact Information	SuperSonic Imagine	Manufacturer Contact Information
	Representative Name/Position	

Intended use of **device** in network-connected environment:

The device is an ultrasound scanner. It is intended to be connected to:
- a PACS in order to archive the images acquired by the device ; and
- a Worklist server in order to receive patient and exam informaton.

A purchaseable option also allow device to query exam an retrieve images archived on the PACS.

MANAGEMENT OF PRIVATE DATA

	Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
A	Can this **device** display, transmit, or maintain **private data** (including **electronic Protected Health Information** [ePHI])?	Yes	If a hacker gains access to the patient's database hosted by the Medical Equipment, there is typically no Social Security numbers, addresses, credit cards or other potentially lucrative personal information stored in it. A more likely scenario would be that Medical Equipment could be used to provide a “backdoor” into the PACS, or hospital information system to shut that down and use it as a potential ransomware threat. Ultrasound devices are less likely to be targeted as they are not 100% up and running. This Medical Equipment has no remote port opened except the DICOM one which do not provide remote access on the Ultrasound device. Thanks to design decision, an attack on this port would only limit the capability to receive image and not affect the capability to produce and exchange images with the PACS.
B	Types of **private data** elements that can be maintained by the **device**:		
B.1	Demographic (e.g., name, address, location, unique identification number)?	Yes	—
B.2	Medical record (e.g., medical record #, account #, test or treatment date, **device** identification number)?	Yes	—
B.3	Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)?	Yes	—
B.4	Open, unstructured text entered by **device user/operator**?	Yes	Operator can save text in annotation displayed on images
B.5	**Biometric data**?	No	—
B.6	Personal financial information?	No	—
C	Maintaining **private data** - Can the **device**:		
C.1	Maintain **private data** temporarily in volatile memory (i.e., until cleared by power-off or reset)?	Yes	—
C.2	Store **private data** persistently on local media?	Yes	—
C.3	Import/export **private data** with other systems?	Yes	Export Exam to PACS, and removable media
C.4	Maintain **private data** during power service interruptions?	Yes	—
D	Mechanisms used for the transmitting, importing/exporting of **private data** – Can the **device**:		

D.1	Display private data (e.g., video display, etc.)?	Yes	—
D.2	Generate hardcopy reports or images containing **private data**?	Yes	—
D.3	Retrieve **private data** from or record **private data** to **removable media** (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick, etc.)?	Yes	—
D.4	Transmit/receive or import/export **private data** via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire, etc.)?	Yes	—
D.5	Transmit/receive **private data** via a wired network connection (e.g., LAN, WAN, VPN, intranet, Internet, etc.)?	Yes	—
D.6	Transmit/receive **private data** via an integrated wireless network connection (e.g., WiFi, Bluetooth, infrared, etc.)?	Yes	—
D.7	Import **private data** via scanning?	Yes	Barcode scanner
D.8	Other?	No	—

Management of
Private Data notes:

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Aixplorer Mach30 Aixplorer Mach20	V3.X		20201115

SECURITY CAPABILITIES

	Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
1	**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.		
1-1	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	—
1-1.1	Is the length of inactivity time before auto-logoff/screen lock **user** or administrator configurable? (Indicate time [fixed or configurable range] in notes.)	Yes	Configurable to the following values 10 min (default), 20 min, 30min or never
1-1.2	Can auto-logoff/screen lock be manually invoked (e.g., via a shortcut key or proximity sensor, etc.) by the **user**?	Yes	—
ALOF notes:			
2	**AUDIT CONTROLS (AUDT)** The ability to reliably audit activity on the **device**.		
2-1	Can the **medical device** create an **audit trail**?	Yes	The audit logs are stored on the device. Their are not exported to an audit repository
2-2	Indicate which of the following events are recorded in the audit log:		
2-2.1	Login/logout	Yes	—
2-2.2	Display/presentation of data	Yes	—
2-2.3	Creation/modification/deletion of data	Yes	—
2-2.4	Import/export of data from **removable media**	Yes	—
2-2.5	Receipt/transmission of data from/to external (e.g., network) connection	Yes	—
2-2.5.1	**Remote service** activity	No	—
2-2.6	Other events? (describe in the notes section)	Yes	The following event are logged: - Instance deleted (when exam are deleted from device) - Study used (when an exam is reviewed) - Security alert (when setup are changed) -Actor start/stop -Audit Log used
2-3	Indicate what information is used to identify individual events recorded in the audit log:		
2-3.1	**User** ID	Yes	—
2-3.2	Date/time	Yes	—
AUDT notes:			
3	**AUTHORIZATION (AUTH)** The ability of the device to determine the authorization of users.		
3-1	Can the **device** prevent access to unauthorized **users** through **user** login requirements or other mechanism?	Yes	

3-2	Can **users** be assigned different privilege levels within an application based on 'roles' (e.g., guests, regular **users**, power **users**, administrators, etc.)?	Yes	3 roles are defined: Emergency access can only acquire images , Sonographer create, review, delete, export exams and admin can configure the device in addition to what a sonographer can do.
3-3	Can the **device** owner/**operator** obtain unrestricted administrative privileges (e.g., access operating system or application via local root or admin account)?	yes	User interface does not allow user to interact with operating system. There is no access for a user to the underlying OS

AUTH notes:

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	Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
4	**CONFIGURATION OF SECURITY FEATURES (CNFS)**		
	The ability to configure/re-configure **device security capabilities** to meet **users'** needs.		
4-1	Can the **device** owner/operator reconfigure product **security capabilities**?	Yes	Only admin users can change security features
CNFS notes:			
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.		
5-1	Can relevant OS and **device** security patches be applied to the **device** as they become available?	Yes	Quick installe: Security patch are applyied by SSI's Field service engineers.
5-1.1	Can security patches or other software be installed remotely?	Yes	For Online service contact SSI
CSUP notes:			
6	**HEALTH DATA DE-IDENTIFICATION (DIDT)**		
	The ability of the **device** to directly remove information that allows identification of a person.		
6-1	Does the **device** provide an integral capability to de-identify **private data**?	Yes	For Logs: Clear logs in system config For non DICOM export on USB/CD/DVD: -Jpeg export of US images are anonymised (as soon as operator does not entre PHI in annotation) - screenshot of patient folder are not anonymised (patient name, DoB, Patient ID, accession# may be visible) - report are not anonymised (patient name, DoB, Patient ID, accession# may be visible) For printed images: no anonymisation (patient name, DoB, Patient ID, accession# are visible) For DICOM : Basic Profile, for US images being exported on DICOM Store and DICOM Media no anonymisation for - DICOM Print (patient name, DoB, Patient ID, accession# will be visible) - screenshot of patient folder are not anonymised (patient name, DoB, Patient ID, accession# may be visible) - report are not anonymised (patient name, DoB, Patient ID, accession# may be visible)
DIDT notes:			
7	**DATA BACKUP AND DISASTER RECOVERY (DTBK)**		
	The ability to recover after damage or destruction of **device** data, hardware, or software.		
7-1	Does the **device** have an integral data backup capability (i.e., backup to remote storage or **removable media** such as tape, disk)?	Yes	Export to DICOM Backup Restore
DTBK notes:			

8	**EMERGENCY ACCESS (EMRG)** The ability of **device users** to access **private data** in case of an emergency situation that requires immediate access to stored **private data**.		
8-1	Does the **device** incorporate an **emergency access** (“break-glass”) feature?	Yes	
EMRG notes:			
9	**HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU)** How the **device** ensures that data processed by the **device** has not been altered or destroyed in an unauthorized manner and is from the originator.		
9-1	Does the **device** ensure the integrity of stored data with implicit or explicit error detection/correction technology?	Yes	The mechanisms are provided by the OS
IGAU notes:			

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10	**MALWARE DETECTION/PROTECTION (MLDP)**		
	The ability of the **device** to effectively prevent, detect and remove malicious software (**malware**).		
10-1	Does the **device** support the use of **anti-malware** software (or other **anti-malware** mechanism)?	Yes	Malicious code protection mechanisms by: - Use of secure Open-source operating system - Pervasive configuration management and comprehensive software integrity controls are used to prevent execution of unauthorized code - secure coding practices, configuration management and control, trusted procurement processes, and monitoring practices to help ensure that software does not perform functions other than the functions intended
10-1.1	Can the **user** independently re-configure **anti-malware** settings?	No	—
10-1.2	Does notification of **malware** detection occur in the **device user** interface?	No	—
10-1.3	Can only manufacturer-authorized persons repair systems when **malware** has been detected?	Yes	—
10-2	Can the device owner install or update **anti-virus software**?	No	—
10-3	Can the device owner/**operator** (technically/physically) update virus definitions on manufacturer-installed **anti-virus software**?	No	—
	MLDP notes:		
11	**NODE AUTHENTICATION (NAUT)**		
	The ability of the **device** to authenticate communication partners/nodes.		
11-1	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?	No	—
	NAUT notes:		
12	**PERSON AUTHENTICATION (PAUT)**		
	Ability of the **device** to authenticate **users**		
12-1	Does the **device** support **user/operator**-specific username(s) and password(s) for at least one **user**?	Yes	—
12-1.1	Does the device support unique **user/operator**-specific IDs and passwords for multiple users?	No	4 accounts exists: emergency access, sonographer, admin and service
12-2	Can the **device** be configured to authenticate **users** through an external authentication service (e.g., MS Active Directory, NDS, LDAP, etc.)?	No	—
12-3	Can the **device** be configured to lock out a **user** after a certain number of unsuccessful logon attempts?	No	—
12-4	Can default passwords be changed at/prior to installation?	Yes	—
12-5	Are any shared **user** IDs used in this system?	Yes	—
12-6	Can the **device** be configured to enforce creation of **user** account passwords that meet established complexity rules?	No	—
12-7	Can the **device** be configured so that account passwords expire periodically?	No	—
	PAUT notes:		
13	**PHYSICAL LOCKS (PLOK)**		
	Physical locks can prevent unauthorized **users** with physical access to the **device** from compromising the integrity and confidentiality of **private data** stored on the **device** or on **removable media**.		
13-1	Are all **device** components maintaining **private data** (other than **removable media**) physically secure (i.e., cannot remove without tools)?	Yes	—

PLOK
notes:

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	Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
14	**ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP)** Manufacturer's plans for security support of 3rd party components within **device** life cycle.		
14-1	In the notes section, list the provided or required (separately purchased and/or delivered) operating system(s) - including version number(s).	Yes	—
14-2	Is a list of other third party applications provided by the manufacturer available?	Yes	Fusion (purcheasble option) Debian GNU/Linux
RDMP notes:			
15	**SYSTEM AND APPLICATION HARDENING (SAHD)** The **device**'s resistance to cyber attacks and **malware**.		
15-1	Does the **device** employ any hardening measures? Please indicate in the notes the level of conformance to any industry-recognized hardening standards.	Yes	The folowing compensation are implemented to harden system - Single-function system: US - Address space layout randomization (ASLR) - Protected database link (only local access enabled, password protection)Unused services disabled - Remote loging service disabled - Use of Mandatory Access Control (MAC) mecanism - Least privilege principle - Least functionality principle
15-2	Does the **device** employ any mechanism (e.g., release-specific hash key, checksums, etc.) to ensure the installed program/update is the manufacturer-authorized program or software update?	Yes	All the software included in the medical device are provided by a trusted source provider (GNU/Linux Debian). The Debian packages that are included on the medical devices are digitally signed by SuperSonic Imagine. Debian package is a tamper-evident packaging format.
15-3	Does the **device** have external communication capability (e.g., network, modem, etc.)?	Yes	External communication capability: Network: used for DICOM communication
15-4	Does the file system allow the implementation of file-level access controls (e.g., New Technology File System (NTFS) for MS Windows platforms)?	Yes	ReiserFS
15-5	Are all accounts which are not required for the **intended use** of the **device** disabled or deleted, for both **users** and applications?	Yes	—
15-6	Are all shared resources (e.g., file shares) which are not required for the **intended use** of the **device**, disabled?	Yes	The system does not used any shared resources.
15-7	Are all communication ports which are not required for the **intended use** of the **device** closed/disabled?	Yes	The DICOM port is the only port opened. Its use is documented in the DICOM Conformance Statement
15-8	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	Those services are not installed on the Medical Devices
15-9	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	Only essentials packages are installed on the medical device. No web browser are installed.
15-10	Can the **device** boot from uncontrolled or **removable media** (i.e., a source other than an internal drive or memory component)?	No	Booting from external device is not authorized
15-11	Can software or hardware not authorized by the **device** manufacturer be installed on the device without the use of tools?	No	—

SAHD notes:

16	**SECURITY GUIDANCE (SGUD)**		
	The availability of security guidance for **operator** and administrator of the system and manufacturer sales and service.		
16-1	Are security-related features documented for the **device user**?	Yes	Security information are included in the User Guide
16-2	Are instructions available for **device**/media sanitization (i.e., instructions for how to achieve the permanent deletion of personal or other sensitive data)?	No	Permanent deletion of data require storage device destruction.

SGUD notes:

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	Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
17	**HEALTH DATA STORAGE CONFIDENTIALITY (STCF)**		
	The ability of the **device** to ensure unauthorized access does not compromise the integrity and confidentiality of **private data** stored on **device** or **removable media**.		
17-1	Can the **device** encrypt data at rest?	Yes	e-PHI contained in database, DICOM objects, native archives and logs are stored on an encrypted partition using TPM1.2
STCF notes:			
18	**TRANSMISSION CONFIDENTIALITY (TXCF)**		
	The ability of the **device** to ensure the confidentiality of transmitted **private data**.		
18-1	Can **private data** be transmitted only via a point-to-point dedicated cable?	No	—
18-2	Is **private data** encrypted prior to transmission via a network or **removable media**? (If yes, indicate in the notes which encryption standard is implemented.)	No	—
18-3	Is **private data** transmission restricted to a fixed list of network destinations?	Yes	—
TXCF notes:			
19	**TRANSMISSION INTEGRITY (TXIG)**		
	The ability of the **device** to ensure the integrity of transmitted **private data**.		
19-1	Does the **device** support any mechanism intended to ensure data is not modified during transmission? (If yes, describe in the notes section how this is achieved.)	Yes	DICOM TLS
TXIG notes:			
20	**OTHER SECURITY CONSIDERATIONS (OTHR)**		
	Additional security considerations/notes regarding **medical device** security.		
20-1	Can the **device** be serviced remotely?	Yes	—
20-2	Can the **device** restrict remote access to/from specified devices or **users** or network locations (e.g., specific IP addresses)?	Yes	—
20-2.1	Can the **device** be configured to require the local **user** to accept or initiate remote access?	Yes	Local user acceptance is mandatory to initiate a remote access
OTHR notes:			

Manufacturer Disclosure Statement for Medical Device Security - MDS²

	Aixplorer MACH30 V3.X		
SuperSonic imagine	Aixplorer MACH20 V3.X	RD.DD.533	15-Nov-2020

Question ID	Question		See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
DOC-1	Manufacturer Name	SuperSonic imagine	—			
DOC-2	Device Description	Ultrasound imaging modality Aixplorer MACH30 V3.X	—			
DOC-3	Device Model	Aixplorer MACH20 V3.X	—			
DOC-4	Document ID	RD.DD.533	—			
DOC-5	Manufacturer Contact Information	Cybersecurity questions shall be asked to cybersecurity@supersonicimagine.com For other inquiries please contact your local representative.	—			
DOC-6	Intended use of device in network-connected environment:	The device is an ultrasound scanner. It is intended to be connected to: - a PACS in order to archive the images acquired by the device ; and - a Worklist server in order to receive patient and exam information. A purchasable option also allow device to query exam an retrieve images archived on the PACS.	—			
DOC-7	Document Release Date	15/11/2020				
DOC-8	Coordinated Vulnerability Disclosure: Does the manufacturer have a vulnerability disclosure program for this device?	Yes	Vulnerabilities information available at: https://www.supersonicimagine.Com/security			
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 Network and Data Flow Diagram			
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?	N/A	—			
DOC-11.2	Does the SaMD rely on an owner/operator provided operating system?	N/A	—			
DOC-11.3	Is the SaMD hosted by the manufacturer?	N/A				
DOC-11.4	Is the SaMD hosted by the customer?	N/A	—			
		Yes, No, N/A, or See Note	Note #			
	MANAGEMENT OF PERSONALLY IDENTIFIABLE INFORMATION			**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	This device download, display, transmit and store the following PII: • Patient Name • Patient ID • Patient Age • Date of birth		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)?	Yes	—		AR-2	A.15.1.4
MPII-2.2	Does the device store personally identifiable information persistently on internal media?	Yes	—			
MPII-2.3	Is personally identifiable information preserved in the device's non-volatile memory until explicitly erased?	Yes	—			
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?	Yes	By default, the exams must be manually deleted. However the device can be configured to delete : • all the exams after a configurable period of time • all the archived exams after a configurable period of time • all the exams archived and committed after a configurable period of time • the oldest exams when disk is full after a configurable period of time		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	The device will query PII from the modality worklist server, and transmit PHI on PACS and on removable media (CD/DVD/USB)		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	The PHI are stored on a crypted partition		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)?	Yes				

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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 PHI are stored on a dedicated crypted partition separated from the device's Operating System.		AR-2	A.15.1.4
MPII-3	Does the device have mechanisms used for the transmitting, importing/exporting of personally identifiable information?	Yes	e-PHI can be transmitted over DICOM Storage service, exportation on removable device and backup restore		AR-2	A.15.1.4
MPII-3.1	Does the device display personally identifiable information (e.g., video display, etc.)?	Yes	e-PHI are displayed on main screen		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.)?	Yes	The device can record PII to USB removable HDD, USB Memory, DVD-R/RW, CD-R/RW. The device can also import and display PHI from the above-mentioned device (but it is a purchasable option)		AR-2	A.15.1.4
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	The device can connect to Ethernet networks		AR-2	A.15.1.4
MPII-3.6	Does the device transmit/receive personally identifiable information via a wireless network connection (e.g., Wi-Fi, Bluetooth, NFC, infrared, cellular, etc.)?	Yes	The device can connect to Wi-Fi (this is a purchasable option)		AR-2	A.15.1.4
MPII-3.7	Does the device transmit/receive personally identifiable information over an external network (e.g., Internet)?	Yes	The device can be remote-serviced (this is a purchasable option). During such connection an operator may access to PII.		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?	No				
MPII-3.10	Does the device use any other mechanism to transmit, import or export personally identifiable information?	Yes	Device's information (that may or may not include PII) can be backed up and restored. Both actions require USB access and admin role.		AR-2	A.15.1.4
Management of Private Data notes:					AR-2	A.15.1.4

	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.*			**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	upon a configurable period of time, a screen saver will hide screen information and lock session. Locked sessions can be terminated to give access to another user.	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	Configurable to the following values 10 min (default), 20 min, 30min or never	Section 5.1, ALOF	AC-11	A.11.2.8, A.11.2.9

	AUDIT CONTROLS (AUDT) *The ability to reliably audit activity on the device.*			**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	__	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	Audit logs are compliant to DICOM Specific Audit Messages	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	Actor-start-stop, Begin-storing-instances, Instances-deleted PHI-export, PHI-import, Study Deleted, Study used, User Authentication Login and User Authentication Logout	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?	N/A	__	Section 5.2, AUDT	AU-2	None
AUDT-2.4	Creation/modification/deletion of users?	N/A	__	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

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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
AUDT-2.8.1	Remote or on-site support?	No	—	Section 5.2, AUDT	AU-2	None
AUDT-2.8.2	Application Programming Interface (API) and similar activity?	No	—	Section 5.2, AUDT	AU-2	None
AUDT-2.9	Emergency access?	Yes	—	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?	No	—	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		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?	No	—	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	—	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?	Yes	—			
AUDT-5.2	Via IHE Audit Trail and Node Authentication (ATNA) profile to SIEM?	No	—			
AUDT-5.3	Via Other communications (e.g., external service device, mobile applications)?	No	—			
AUDT-5.4	Are audit logs encrypted in transit or on storage media?	No	—			
AUDT-6	Can audit logs be monitored/reviewed by owner/operator?	No	—			
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?	No	—	Section 5.2, AUDT	AU-2	None

	AUTHORIZATION (AUTH) *The ability of the device to determine the authorization of users.*			**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)?	No	—	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	3 roles are defined: Emergency access can only acquire images , Sonographer create, review, delete, export exams and admin can configure the device in addition to what a sonographer can do.	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	—	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?	Yes	The user has no access to the underlaying operating system			

	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.*			**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	—			
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	Remote update is described in User Guide			
CSUP-2.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes	—			

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CSUP-2.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes	Configurable option			
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?	No	The Operating System is maintained by SuperSonic Imagine			
CSUP-3	Does the device contain Drivers and Firmware? If yes, complete 3.1-3.4.	Yes	—			
CSUP-3.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	No	Firmware and drivers are installed during software updates or software re-installation			
CSUP-3.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes	—			
CSUP-3.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes				
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?	No	—			
CSUP-4	Does the device contain Anti-Malware Software? If yes, complete 4.1-4.4.	No	—			
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.	Yes	—			
CSUP-5.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	Yes	All the software components (OS, OTS) are updated at once			
CSUP-5.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes	see above note			
CSUP-5.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes	see above note			
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?	No	—			
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	—			
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?	Yes	Device can be configured to verify if new update are available at startup.			
CSUP-8	Does the device perform automatic installation of software updates?	No	Software updates are applied upon administrator approval.			
CSUP-9	Does the manufacturer have an approved list of third-party software that can be installed on the device?	No	No third party software can be installed on the device			

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CSUP-10	Can the owner/operator install manufacturer-approved third-party software on the device themselves?	No	—			
CSUP-10.1	Does the system have mechanism in place to prevent installation of unapproved software?	Yes	—			
CSUP-11	Does the manufacturer have a process in place to assess device vulnerabilities and updates?	Yes	—			
CSUP-11.1	Does the manufacturer provide customers with review and approval status of updates?	No	—			
CSUP-11.2	Is there an update review cycle for the device?	Yes	At most every 2 months			

	HEALTH DATA DE-IDENTIFICATION (DIDT) *The ability of the device to directly remove information that allows identification of a person.*			**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	For Logs: Clear logs in system config For non DICOM export on USB/CD/DVD: -Jpeg export of US images are anonymised (as soon as operator does not entre PHI in annotation) - screenshot of patient folder are not anonymised (patient name, DoB, Patient ID, accession# may be visible) - report are not anonymised (patient name, DoB, Patient ID, accession# may be visible) For printed images: no anonymisation (patient name, DoB, Patient ID, accession# are visible) For DICOM : Basic Profile, for US images being exported on DICOM Store and DICOM Media no anonymisation for - DICOM Print (patient name, DoB, Patient ID, accession# will be visible) - screenshot of patient folder are not anonymised (patient name, DoB, Patient ID, accession# may be visible) - report are not anonymised (patient name, DoB, Patient ID, accession# may be visible)	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?	Yes	Device implement the DICOM version 2019a Basic Profile for de-identification.	Section 5.6, DIDT	None	ISO 27038

	DATA BACKUP AND DISASTER RECOVERY (DTBK) *The ability to recover after damage or destruction of device data, hardware, software, or site configuration information.*			**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)?	No	—			
DTBK-2	Does the device have a "factory reset" function to restore the original device settings as provided by the manufacturer?	Yes	—	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	—	Section 5.7, DTBK	CP-9	A.12.3.1
DTBK-4	Does the device have an integral data backup capability to remote storage?	No				
DTBK-5	Does the device have a backup capability for system configuration information, patch restoration, and software restoration?	Yes	System configuration can be backed up			
DTBK-6	Does the device provide the capability to check the integrity and authenticity of a backup?	Yes	—	Section 5.7, DTBK	CP-9	A.12.3.1

	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.*			**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	—	Section 5.8, EMRG	SI-17	None

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	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.*			**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	The mechanisms are provided by the OS	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	The mechanisms are provided by the OS	Section 5.9, IGAU	SC-28	A.18.1.3
	MALWARE DETECTION/PROTECTION (MLDP) *The ability of the device to effectively prevent, detect and remove malicious software (malware).*			**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?	No	User has no access to underlying OS, MAC prevent installation of software and partitions are mounted in noexec Malicious code protection mechanisms by: - Use of secure Open-source operating system - Pervasive configuration management and comprehensive software integrity controls are used to prevent execution of unauthorized code - secure coding practices, configuration management and control, trusted procurement processes, and monitoring practices to help ensure that software does not perform functions other than the functions intended	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		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?	No	—	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?	No	—	Section 5.10, MLDP	CP-10	A.17.1.2
MLDP-2.4	Can the device owner/operator independently (re-)configure anti-malware settings?	No	—	Section 5.10, MLDP	AU-2	None
MLDP-2.5	Does notification of malware detection occur in the device user interface?	N/A				
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?	N/A				
MLDP-2.8	Are there any restrictions on anti-malware (e.g., purchase, installation, configuration, scheduling)?	Yes				
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?	Yes	Device has been designed to not execute any data imported on the system. only Signed software components can be installed on system. SuperSonic Imagine recommends the following cyber Hygiene practices: Ensure that your equipment is in a physically protected and actively monitored area; Ensure that only secure/sanitized USB storage devices are utilized; Ensure that your equipment is protected against network access by unsupervised systems (typically provided by mechanisms such as firewalls and VPNs); and Ensure your data has been backed up and stored according to your institution policy.	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 whitelisting 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?	No	—	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?	No	—	Section 5.10, MLDP		
	NODE AUTHENTICATION (NAUT) *The ability of the device to authenticate communication partners/nodes.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**

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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	DICOM TLS	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 white list)?	No	reduced number of services available	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?	N/A	—			
NAUT-3	Does the device use certificate-based network connection authentication?	Yes	DICOM TLS			

	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.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
CONN-1	Does the device have hardware connectivity capabilities?	Yes	—			
CONN-1.1	Does the device support wireless connections?	Yes	—			
CONN-1.1.1	Does the device support Wi-Fi?	Yes	—			
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	—			
CONN-1.2	Does the device support physical connections?	Yes	—			
CONN-1.2.1	Does the device have available RJ45 Ethernet ports?	Yes	—			
CONN-1.2.2	Does the device have available USB ports?	Yes	—			
CONN-1.2.3	Does the device require, use, or support removable memory devices?	Yes	—			
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	The supported network protocols are: DICOM, DHCP, NTP. HTTPS protocol may be enabled for remote maintenance.			
CONN-3	Can the device communicate with other systems within the customer environment?	Yes	The device may be connected to a PACS, to a Modality Worklist, to a printer.			
CONN-4	Can the device communicate with other systems external to the customer environment (e.g., a service host)?	Yes	The device may be remotely serviceable			
CONN-5	Does the device make or receive API calls?	No	—			
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	for DICOM connection			
CONN-7.1	Is TLS configurable?	Yes	see DICOM Conformance statement and User Guide			
CONN-8	Does the device provide operator control functionality from a separate device (e.g., telemedicine)?	No	—			

	PERSON AUTHENTICATION (PAUT) *The ability to configure the device to authenticate users.*			**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	4 accounts exists: emergency access, sonographer, admin and service	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)?	No	—	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.)?	No	—	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?	No	—	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		

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PAUT-6	Is the device configurable to enforce creation of user account passwords that meet established (organization specific) complexity rules?	No	—	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-7	Does the device support account passwords that expire periodically?	No	—			
PAUT-8	Does the device support multi-factor authentication?	No	—			
PAUT-9	Does the device support single sign-on (SSO)?	No	—	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-10	Can user accounts be disabled/locked on the device?	No	—	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?	Yes	—			
PAUT-14.1	Are credentials stored using a secure method?	Yes	Person authentication is achieved through the Linux Pluggable Authentication Module (PAM) is a mechanism			

	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*			**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.	No	—	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)?	Yes	—	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?	No	disks maintaining e-PHI are crypted	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?	No		Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3

	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.*			**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	IEC 62304	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	—	Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2
RDMP-3	Does the manufacturer maintain a web page or other source of information on software support dates and updates?	No	If remote service is enabled user can be notified when an update is available At most every 2 months a service pack will be released incorporating security patch when necessary, and every year a major release with an updated version of the OS and 3rd party components will be released.	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

	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.*			**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?	No	—			
SBOM-2.1	Are the software components identified?	Yes	—			
SBOM-2.2	Are the developers/manufacturers of the software components identified?	No	—			

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SBOM-2.3	Are the major version numbers of the software components identified?	Yes	—			
SBOM-2.4	Are any additional descriptive elements identified?	No	—			
SBOM-3	Does the device include a command or process method available to generate a list of software components installed on the device?	No	—			
SBOM-4	Is there an update process for the SBoM?	No	—			
	SYSTEM AND APPLICATION HARDENING (SAHD) *The device's inherent resistance to cyber attacks and malware.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
					CM-7	A.12.5.1*
SAHD-1	Is the device hardened in accordance with any industry standards?	Yes	The following compensation are implemented to harden system - Single-function system: US - Address space layout randomization (ASLR) - Protected database link (only local access enabled, password protection)Unused services disabled - Remote loging service disabled - Use of Mandatory Access Control (MAC) mecanism - Least privilege principle - Least functionality principle	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?	No	—	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	No	—			
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	All the software included in the medical device are provided by a trusted source provider (GNU/Linux Debian). The Debian packages that are included on the medical devices are digitally signed by SuperSonic Imagine. Debian package is a tamper-evident packaging format.			
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	All the software included in the medical device are provided by a trusted source provider (GNU/Linux Debian). The Debian packages that are included on the medical devices are digitally signed by SuperSonic Imagine. Debian package is a tamper-evident packaging format.	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)?	No	—	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?	No	—	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-5.1	Does the device provide role-based access controls?	Yes	Emergency access can only acquire images Sonographer role can acquire images, manage exams, export exams, and change non-security settings admin roles can do all the above plus change security settings.	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?	No	—	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?	No	Only password can be changed	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?	No	—	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*
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	A minimal version of the OS is installed on the device. No remote logging, no web browser or mail user agent are installed	Section 5.15, SAHD	SI-2	A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3

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SAHD-11	Can the device prohibit boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?	Yes	Disabled in the BIOS			
SAHD-12	Can unauthorized software or hardware be installed on the device without the use of physical tools?	No	—			
SAHD-13	Does the product documentation include information on operational network security scanning by users?	No	—			
SAHD-14	Can the device be hardened beyond the default provided state?	Yes	—			
SAHD-14.1	Are instructions available from vendor for increased hardening?	Yes	see User Guide			
SHAD-15	Can the system prevent access to BIOS or other bootloaders during boot?	No				
SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?	No	—			
	SECURITY GUIDANCE (SGUD) *Availability of security guidance for operator and administrator of the device and manufacturer sales and service.*			**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	Security information are included in the User Guide	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?	No	Permanent deletion of data require storage device destruction.	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	—	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	each user can change his own password, but admin can change all passwords			
SGUD-4	Does the product include documentation on recommended compensating controls for the device?	Yes	—			
	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.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
STCF-1	Can the device encrypt data at rest?	Yes	e-PHI contained in database, DICOM objects, native archives and logs are stored on an encrypted partition using TPM1.2	Section 5.17, STCF	SC-28	A.8.2.3
STCF-1.1	Is all data encrypted or otherwise protected?	Yes				
STCF-1.2	Is the data encryption capability configured by default?	Yes	Encryption can't be disabled			
STCF-1.3	Are instructions available to the customer to configure encryption?	No	Encryption can't be disabled or configured			
STCF-2	Can the encryption keys be changed or configured?	No	The encryption keys are generated during installation. There is no way to change them	Section 5.17, STCF	SC-28	A.8.2.3
STCF-3	Is the data stored in a database located on the device?	Yes	—			
STCF-4	Is the data stored in a database external to the device?	No	—			
	TRANSMISSION CONFIDENTIALITY (TXCF) *The ability of the device to ensure the confidentiality of transmitted personally identifiable information.*			**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	No encrryption on removable media. Data transmited over the network are crypted	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	Only admin can configure network destination	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-4	Are connections limited to authenticated systems?	Yes	Admin can configure the device to enforce authentication between systems	Section 5.18, TXCF	CM-7	A.12.5.1

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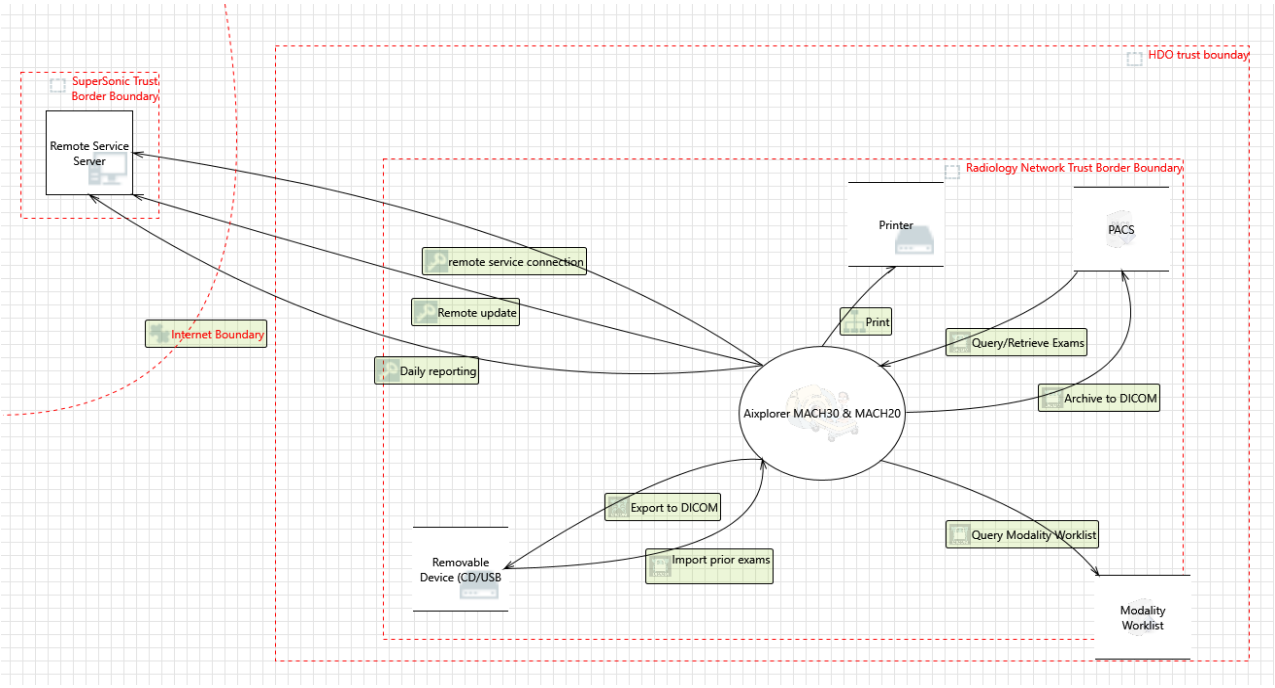
TXCF-5	Are secure transmission methods supported/implemented (DICOM, HL7, IEEE 11073)?	Yes	DICOM TLS is implemented				
	TRANSMISSION INTEGRITY (TXIG) *The ability of the device to ensure the integrity of transmitted data.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**	
TXIG-1	Does the device support any mechanism (e.g., digital signatures) intended to ensure data is not modified during transmission?	Yes	DICOM TLS	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	—				
	REMOTE SERVICE (RMOT)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**	
	Remote service refers to all kinds of device maintenance activities performed by a service person via network or other remote connection.						
RMOT-1	Does the device permit remote service connections for device analysis or repair?	Yes	—		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?	Yes	—				
RMOT-1.2	Is there an indicator for an enabled and active remote session?	Yes	—				
RMOT-1.3	Can patient data be accessed or viewed from the device during the remote session?	Yes	—		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?	Yes	The device can be configured to send daily reports. Those report do not contain any e-PHI.				
RMOT-3	Does the device have any other remotely accessible functionality (e.g. software updates, remote training)?	Yes	Software update				
	OTHER SECURITY CONSIDERATIONS (OTHR) *NONE*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**	
	Notes:						
Note 1	Example note. Please keep individual notes to one cell. Please use separate notes for separate information						


HDO trust bounday
SuperSonic Trust Border Boundary
Remote Service Server
Radiology Network Trust Border Boundary
Printer
PACS
remote service connection
Remote update
Internet Boundary
Daily reporting
Print
Query/Retrieve Exams
Archive to DICOM
Aixplorer MACH30 & MACH20
Export to DICOM
Query Modality Worklist
Removable Device (CD/USB
Import prior exams
Modality Worklist

Component Name	Manufacturer	Description	Version
Debian 9 "Stretch"	Debian Community (Open Source)	Debian is an open source operating system (OS)	Debian 9 "Stretch"
Linux Kernel	(Open Source)	Linux image base package	4.9.0-12
Grub	(Open Source)	GRand Unified Bootloader, version 2 (PC/BIOS version)	2.02~beta3-5
Cairo	(Open Source)	Cairo 2D vector graphics library	1.14.6-1gaussian1
GNU/libc	(Open Source)	Embedded GNU C Library	2.24-11+deb9u4
Glib	(Open Source)	GLib library of C routines	2.50.3-2+deb9u1
libstdC++	(Open Source)	GNU Standard C++ Library v3	6.3.0-18+deb9u1
bash	(Open Source)	GNU Bourne Again SHell	4.4-5
python	(Open Source)	interactive high-level object-oriented language	3.5.3-1
Xorg	Free Desktop (Open Source)	X.Org X Window System	1:7.7+19
Redshift	Open Source	Adjusts the color temperature of your screen	1.11-1
Xfce	Xfce(Open Source)	Xfce desktop environment	4.12.3
xscreensaver	Open Source	Screensaver daemon and frontend for X11	5.36-1
PostgreSQL	PostgreSQL (Open Source)	object-relational SQL database	9.6+181+deb9u3
Xerces	Apache Foundation (Open Source)	Xerces is a validating XML parser written in a portable subset of C++	3.1.4+debian-2+deb9u1
Dcmtk	OFFIS (Oldenburg Research and Development Institute for Information Technology Tools and Systems)	DICOM toolkit	3.6.5-11gaussian1
dvd+rw-tools	Andy Polyakov (Open Source)	collection of open source DVD and Blu-ray Disc burning tools for Linux	7.1-11.1
Eject	(Open Source)	Eject is a utility that allows to eject CD-ROM. No documentation is provided to the end user.	2.1.5+deb1+cvs20081104-13.2
xorriso	(Open Source)	command line ISO-9660 and Rock Ridge manipulation tool	1.4.6-1+b1
Libusb-1.0.0	(Open Source)	user space USB programming library	2:1.0.21-1
PulseAudio	(Open Source)	PulseAudio is a network-capable sound server program distributed via the freedesktop.org project	10.0-1+deb9u1
libcanberra0	(Open Source)	simple abstract interface for playing event sounds with pulseAudio backend	0.30-3
CUDA	Nvidia	CUDA allows faster image processing and therefore it is very useful to an imaging system. Provided by the Aixplorer series graphics card manufacturer – Nvidia.	430.50-1
Cg	Nvidia	Nvidia Cg core runtime library	3.1.0013-2+b1
OpenCV	(Open Source)	computer vision Image Processing library	2.4.13.7-0gaussiane2
OpenMP	(Open Source)	OpenMP (Open Multi-Processing) is an application programming interface (API) that supports multi-platform shared memory multiprocessing programming in C, C++	6.3.0-18+deb9u1
Intel MKL	Intel (Open Source)	Intel® Math Kernel Library (Intel® MKL)	2019.1.144-3~bpo9+1
TBB (libtbb2)	Intel (Open Source)	Intel® Threading Building Blocks (Intel® TBB) lets you easily write parallel C++ programs that take full advantage of multicore performance,	4.3~20150611-2
libdbus-c++	(Open Source)	C++ API for D-Bus (runtime package)	0.9.0-9gaussian2
opendds	OCI	OpenDDS is an Open Source, native C++ implementation of the OMG (Object Management Group) Data Distribution Service (DDS) for Real-Time Systems specification.	3.14.1-0gaussiane0
pam	(Open Source)	Pluggable Authentication Modules	1.1.8-3.6
libpam-pgsql	(Open Source)	PAM module to authenticate using a PostgreSQL database. This module lets you authenticate users against a table in a PostgreSQL database. It also supports checking account information and updating authentication tokens (i.e.. passwords).	0.7.3.2-1
gconf2	(Open Source)	GNOME configuration database system (shared libraries)	3.2.6-4gaussian1
gtk2 & libgtkmm	(Open Source)	gtk2: Development environment for GTK toolkit for graphical user interfaces. libgtkmm: C++ wrappers for GTK+ (shared libraries)	gtk2: 2.24.31-1gaussian1 libgtkmm: 1:2.24.5-1gaussian1
Maia	(Open Source)	Maia vectorial canvas	0.3.21-0gaussiane1
CUPS	(Open Source)	Common UNIX Printing System(tm)	2.2.1-8+ deb9u6
libopenjp2	(Open Source)	JPEG 2000 image compression/decompression library	2.1.2-1.1+deb9u5
charls	(Open Source)	Implementation of the JPEG-LS standard	1.1.0+dfsg-2
libsensors4	(Open Source)	library to read temperature/voltage/fan sensors	1:3.4.0-4
Thingworx-ssiclient	PTC	Thingworx client for SuperSonic Imagine's Aixplorers.	0.7.8-0gaussiane7 (for customer site environment) 0.3.10-0gaussiane1(for production environment
x11vnc	(Open Source)	VNC server to allow remote access to an existing X session	0.9.13-2+deb9u1
rastertosonyhs	Sony	Sony CUPS raster filter for UP-D897, UP-990AD, UP-970AD and UP-711MD	1.4.1-0gaussian6
rastertosony	Sony	Sony CUPS raster filter for Sony UP-DR80MD, UP-D25MD, UP-991AD, UP-971AD, UP-D898MD, UP-X898MD	1.4.0.2-0gaussiane2
pgm2d897	Sony	Sony pgm2d897 converter	0.0.3-0gaussian2
pnm2d23md	Sony	Sony pnm2d23md converter	0.0.2-0gaussian2
upd23md	Sony	Sony upd23md cups driver	1.0.10-0gaussian2.1