# MEDICAL DEVICE DISCLOSURE STATEMENT FOR MEDICAL DEVICE SECURITY
# SuperSonic MACH 40
# SW V2.X

# Manufacturer Disclosure Statement for Medical Device Security -- MDS2

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| Hologic SuperSonic imagine | SuperSonic MACH 40 V2.x | RD.DD.490 | 30-Aug-2019 | | | | |
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| **Question ID** | **Question** | | **See note** | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| DOC-1 | Manufacturer Name | Hologic SuperSonic imagine | __ | | | | |
| DOC-2 | Device Description | Ultrasound imaging modality | __ | | | | |
| DOC-3 | Device Model | SuperSonic MACH 40 V2.x | __ | | | | |
| DOC-4 | Document ID | RD.DD.490 | __ | | | | |
| 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 | 30/08/2019 | | | | | |
| 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 | __ | | | | |
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| | | 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 | __ | | | | |

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| 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.<br>However the device can be configured to delete :<br>• all the exams after a configurable period of time<br>• all the archived exams after a configurable period of time<br>• all the exams archived and committed after a configurable period of time<br>• 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 | | | | | |
| 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.<br>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 |
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| | AUTOMATIC LOGOFF (ALOF) | | | | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
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| | *The device's ability to prevent access and misuse by unauthorized users if device is left idle for a period of time.* | | | | | | |
| 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 |
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| | **AUDIT CONTROLS (AUDT)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *The ability to reliably audit activity on the device.* | | | | | | |
| 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 |
| 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 |
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| | AUTHORIZATION (AUTH) | | | | IEC TR 80001-2-2:2012 | NIST SP 800-53 Rev. 4 | ISO 27002:2013 |
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| | *The ability of the device to determine the authorization of users.* | | | | | | |
| 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 | | | | |
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| | **CYBER SECURITY PRODUCT UPGRADES (CSUP)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade device's security patches.* | | | | | | |
| 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 | Y/N | | | |
| CSUP-2.2 | Does the device require vendor or vendor-authorized service to install patches or software updates? | Yes | __ | Y/N | | | |
| CSUP-2.3 | Does the device have the capability to receive remote installation of patches or software updates? | Yes | Configurable option | Y/N | | | |
| 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 Hologic SuperSonic Imagine | Y/N | | | |
| CSUP-3 | Does the device contain Drivers and Firmware? If yes, complete 3.1-3.4. | Yes | __ | Y/N | | | |
| 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 | Y/N | | | |
| 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 | | Y/N | | | |

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| 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 | __ | Y/N | | | |
| CSUP-4 | Does the device contain Anti-Malware Software? If yes, complete 4.1-4.4. | No | __ | Y/N | | | |
| CSUP-4.1 | Does the device documentation provide instructions for owner/operator installation of patches or software updates? | N/A | __ | Y/N | | | |
| CSUP-4.2 | Does the device require vendor or vendor-authorized service to install patches or software updates? | N/A | __ | Y/N | | | |
| CSUP-4.3 | Does the device have the capability to receive remote installation of patches or software updates? | N/A | __ | Y/N | | | |
| 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 | __ | Y/N | | | |
| 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 | Y/N | | | |
| CSUP-5.2 | Does the device require vendor or vendor-authorized service to install patches or software updates? | Yes | see above note | Y/N | | | |
| CSUP-5.3 | Does the device have the capability to receive remote installation of patches or software updates? | Yes | see above note | Y/N | | | |
| 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 | __ | Y/N | | | |
| 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 | __ | Y/N | | | |
| 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 | __ | Y/N | | | |
| CSUP-6.3 | Does the device have the capability to receive remote installation of patches or software updates? | N/A | __ | Y/N | | | |
| 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 | __ | Y/N | | | |
| 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. | Y/N | | | |
| CSUP-8 | Does the device perform automatic installation of software updates? | No | Software updates are applied upon administrator approval. | Y/N | | | |
| 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 | Y/N | | | |
| 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 | __ | Y/N | | | |

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| CSUP-11.1 | Does the manufacturer provide customers with review and approval status of updates? | No | __ | Y/N | | | |
| CSUP-11.2 | Is there an update review cycle for the device? | Yes | At most every 2 months | Y/N | | | |
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| | **HEALTH DATA DE-IDENTIFICATION (DIDT)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *The ability of the device to directly remove information that allows identification of a person.* | | | | | | |
| DIDT-1 | Does the device provide an integral capability to de-identify personally identifiable information? | Yes | For Logs: Clear logs in system config<br>For non DICOM export on USB/CD/DVD:<br>-Jpeg export of US images are anonymised (as soon as operator does not entre PHI in annotation)<br>- screenshot of patient folder are not anonymised (patient name, DoB, Patient ID, accession# may be visible)<br>- report are not anonymised (patient name, DoB, Patient ID, accession# may be visible)<br>For printed images: no anonymisation (patient name, DoB, Patient ID, accession# are visible)<br>For DICOM :<br>Basic Profile, for US images being exported on DICOM Store and DICOM Media<br>no anonymisation for<br>- DICOM Print (patient name, DoB, Patient ID, accession# will be visible)<br>- screenshot of patient folder are not anonymised (patient name, DoB, Patient ID, accession# may be visible)<br>- 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 |
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| | **DATA BACKUP AND DISASTER RECOVERY (DTBK)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *The ability to recover after damage or destruction of device data, hardware, software, or site configuration information.* | | | | | | |
| 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 |
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| | **EMERGENCY ACCESS (EMRG)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |

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| | *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.* | | | | | | |
| 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)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *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.* | | | | | | |
| 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 |
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| | **MALWARE DETECTION/PROTECTION (MLDP)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *The ability of the device to effectively prevent, detect and remove malicious software (malware).* | | | | | | |
| 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 | | 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 | Malicious code protection mechanisms by:<br>- Use of secure Open-source operating system<br>- Pervasive configuration management and comprehensive software integrity controls are used to prevent execution of unauthorized code<br>- 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 | 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 | | | | | |

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|---|---|---|---|---|---|---|---|
| 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.<br>Hologic SuperSonic Imagine recommends the following cyber Hygiene practices:<br>Ensure that your equipment is in a physically protected and actively monitored area;<br>Ensure that only secure/sanitized USB storage devices are utilized;<br>Ensure that your equipment is protected against network access by unsupervised systems (typically provided by mechanisms such as firewalls and VPNs); and<br>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 | | |
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| | **NODE AUTHENTICATION (NAUT)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *The ability of the device to authenticate communication partners/nodes.* | | | | | | |
| 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 | | | | |
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| | **CONNECTIVITY CAPABILITIES (CONN)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *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.* | | | | | | |
| 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 | __ | | | | |

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|---|---|---|---|---|---|---|---|
| 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.<br>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 | __ | | | | |
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| | **PERSON AUTHENTICATION (PAUT)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *The ability to configure the device to authenticate users.* | | | | | | |
| 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 | | |
| 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 | __ | | | | |

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|---|---|---|---|---|---|---|---|
| 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 | | | | |
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| | **PHYSICAL LOCKS (PLOK)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *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* | | | | | | |
| 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 |
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| | **ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *Manufacturer's plans for security support of third-party components within the device's life cycle.* | | | | | | |
| 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 | | 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 | 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 |
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| | **SOFTWARE BILL OF MATERIALS (SBoM)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *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.* | | | | | | |
| 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 | __ | | | | |
| SBOM-2.3 | Are the major version numbers of the software components identified? | Yes | __ | | | | |
| SBOM-2.4 | Are any additional descriptive elements identified? | No | __ | | | | |

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|---|---|---|---|---|---|---|---|
| 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 | __ | | | | |
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| | **SYSTEM AND APPLICATION HARDENING (SAHD)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *The device's inherent resistance to cyber attacks and malware.* | | | | | CM-7 | A.12.5.1* |
| SAHD-1 | Is the device hardened in accordance with any industry standards? | Yes | The folowing compensation are implemented to harden system<br>- Single-function system: US<br>- Address space layout randomization (ASLR)<br>- Protected database link (only local access enabled, password protection)Unused services disabled<br>- Remote loging service disabled<br>- Use of Mandatory Access Control (MAC) mecanism<br>- Least privilege principle<br>- 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 Hologic SuperSonic Imagine.<br>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 Hologic SuperSonic Imagine.<br>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<br>Sonographer role can acquire images, manage exams, export exams, and change non-security settings<br>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* |

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| 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 |
| 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 | __ | | | | |
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| | **SECURITY GUIDANCE (SGUD)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *Availability of security guidance for operator and administrator of the device and manufacturer sales and service.* | | | | | | |
| 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 | __ | | | | |
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| | **HEALTH DATA STORAGE CONFIDENTIALITY (STCF)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *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.* | | | | | | |
| 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 |

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|---|---|---|---|---|---|---|---|
| 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 | __ | | | | |
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| | **TRANSMISSION CONFIDENTIALITY (TXCF)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *The ability of the device to ensure the confidentiality of transmitted personally identifiable information.* | | | | | | |
| 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 |
| TXCF-5 | Are secure transmission methods supported/implemented (DICOM, HL7, IEEE 11073)? | Yes | DICOM TLS is implemented | | | | |
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| | **TRANSMISSION INTEGRITY (TXIG)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *The ability of the device to ensure the integrity of transmitted data.* | | | | | | |
| 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 | __ | | | | |
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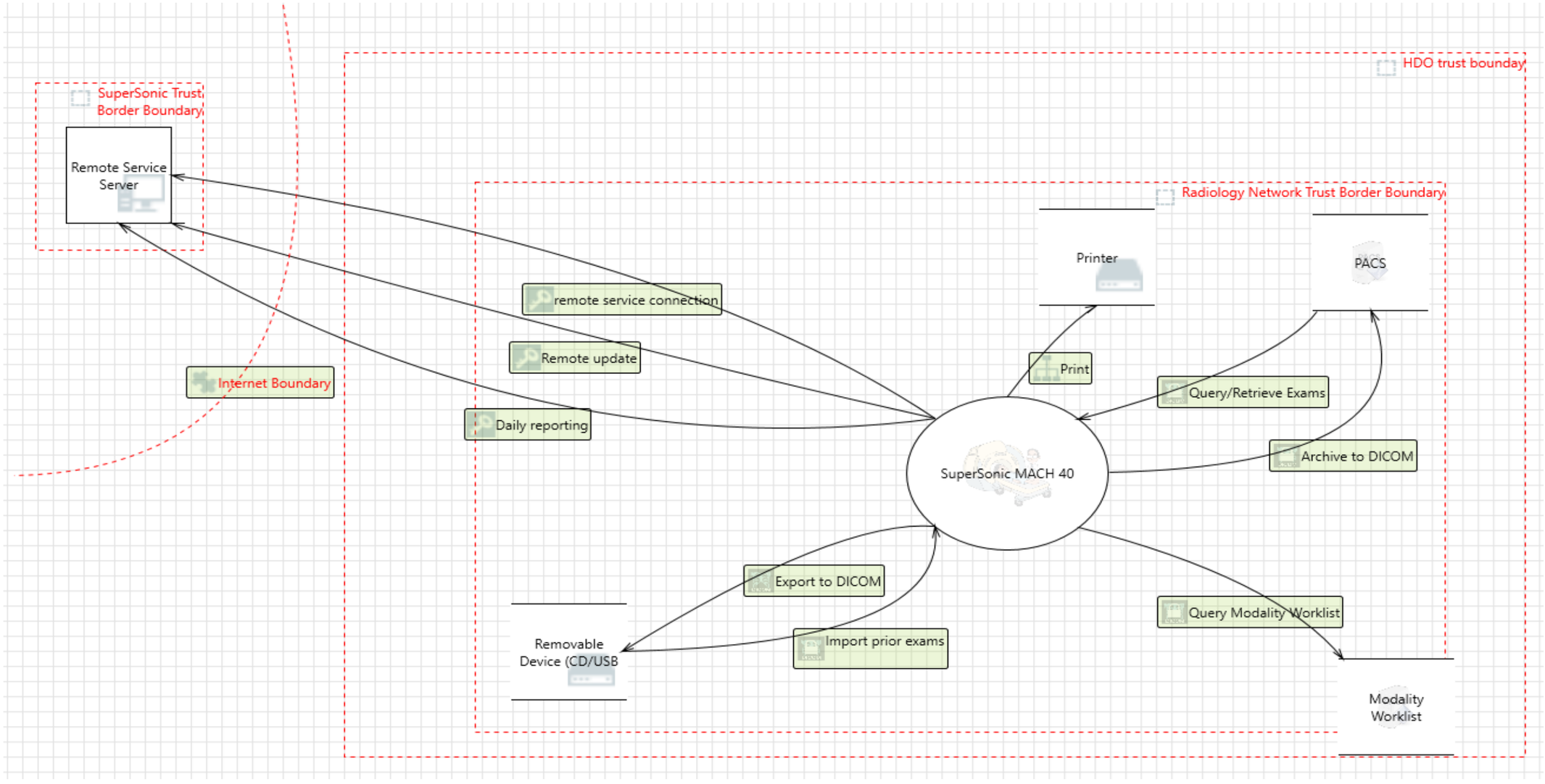
| | **REMOTE SERVICE (RMOT)** | | | | **IEC TR 80001-2-2:2012** | **NIST SP 800-53 Rev. 4** | **ISO 27002:2013** |
| | *Remote service refers to all kinds of device maintenance activities performed by a service person via network or other remote connection.* | | | | | | |
| RMOT-1 | Does the device permit 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 | | | | |



| 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 | 4.9.0-11 |
| 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 | 2.7.13-2 |
| 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 | 4.12.1-5 |
| xscreensaver | Open Source | Screensaver daemon and frontend for X11 | 5.36-1 |
| PostgreSQL | PostgreSQL (Open Source) | object-relational SQL database | 9.6.15-0+deb9u1 |
| 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 | 3.6.4-4-gaussian1 |
| 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 | 2.4.9.1+dfsg1-2gaussiane6 |
| 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 |
| 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. | 3.13.2-0gaussiane0 |
| pam | (Open Source) | Pluggable Authentication Modules | 1.1.8-3.6 |
| libpam-pgsql | (Open Source) | PAM module to authenticate using a PostgreSQL database.<br>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.<br>libgtkmm: C++ wrappers for GTK+ (shared libraries) | gtk2: 2.24.31-1gaussian1<br>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+ deb9u4 |
| libopenjp2 | (Open Source) | JPEG 2000 image compression/decompression library | 2.1.2-1.1+deb9u3 |
| 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. | 0.7.7-0gaussiane0 (for customer site environment)<br>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 |
| intel-mkl | Intel | Intel Math Kernel Library | 2017.2.174-0gaussian3 |