Manufacturer Disclosure Statement for Medical Device Security -- MDS2

ImageView Version 1.0 Build 1.9
Carestream DRX-Revolution
Carestream DRX-Evolution
Carestream DRX-Evolution Plus
Carestream DRX-Revolution Nano
Carestream DRX-Ascend
Carestream DRX In-room
Carestream DRX-Transportable / Lite
Carestream DRX-Mobile
Carestream Health, In Carestream DRX-Compass AL6111 22-Apr-2021

Question ID	Question		See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
DOC-1	Manufacturer Name	Carestream Health, Inc.				
DOC-2	Device Description	X-Ray Imaging Systems ImageView Version 1.0 Build 1.9 Carestream DRX-Revolution Carestream DRX-Evolution Carestream DRX-Evolution Plus Carestream DRX-Revolution Nano Carestream DRX-Ascend Carestream DRX In-room Carestream DRX-Transportable / Lite Carestream DRX-Mobile Carestream DRX-Compass				
DOC-3	Device Model					
DOC-4	Document ID	AL6111				
DOC-5	Manufacturer Contact Information	1-800-328-2910 health.imaging.tsc@carestreamhealth.com				
DOC-6	Intended use of device in network-connected environment:	X-Ray Imaging System				
DOC-7	Document Release Date	4/22/2021				
DOC-8	Coordinated Vulnerability Disclosure: Does the manufacturer have a vulnerability disclosure program for this device?	Yes				
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				
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				

	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			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			AR-2	A.15.1.4
MPII-2.6	Does the device import/export personally identifiable information with other systems (e.g., a wearable monitoring device might export personally identifiable information to a server)?	Yes			AR-2	A.15.1.4
MPII-2.7	Does the device maintain personally identifiable information when powered off, or during power service interruptions?	Yes			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)?	No			AR-2	A.15.1.4
MPII-3	Does the device have mechanisms used for the transmitting, importing/exporting of personally identifiable information?	Yes			AR-2	A.15.1.4
MPII-3.1	Does the device display personally identifiable information (e.g., video display, etc.)?	Yes			AR-2	A.15.1.4
MPII-3.2	Does the device generate hardcopy reports or images containing personally identifiable information?	No			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			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			AR-2	A.15.1.4
MPII-3.6	Does the device transmit/receive personally identifiable information via a wireless network connection (e.g., WiFi, Bluetooth, NFC, infrared, cellular, etc.)?	See Notes	1		AR-2	A.15.1.4
MPII-3.7	Does the device transmit/receive personally identifiable information over an external network (e.g., Internet)?	No			AR-2	A.15.1.4
MPII-3.8	Does the device import personally identifiable information via scanning a document?	No				

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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?	No				AR-2	A.15.1.4
Management of Private Data notes:						AR-2	A.15.1.4

1) Mobile X-Ray systems may optionally use WiFi to transmit and receive PII.
All X-Ray systems may optionally use a wireless Bluetooth 2D barcode scanner for scanning patient wristbands.

	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		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		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?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2	Are events recorded in an audit log? If yes, indicate which of the following events are recorded in the audit log:	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.1	Successful login/logout attempts?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.2	Unsuccessful login/logout attempts?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.3	Modification of user privileges?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.4	Creation/modification/deletion of users?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.5	Presentation of clinical or PII data (e.g. display, print)?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.6	Creation/modification/deletion of data?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.7	Import/export of data from removable media (e.g. USB drive, external hard drive, DVD)?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.8	Receipt/transmission of data or commands over a network or point-to-point connection?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.8.1	Remote or on-site support?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.8.2	Application Programming Interface (API) and similar activity?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.9	Emergency access?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.10	Other events (e.g., software updates)?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-2.11	Is the audit capability documented in more detail?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-3	Can the owner/operator define or select which events are recorded in the audit log?	Yes	2	Section 5.2, AUDT	AU-2	None
AUDT-4	Is a list of data attributes that are captured in the audit log for an event available?	Yes		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?	Yes	3			
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	4			
AUDT-6	Can audit logs be monitored/reviewed by owner/operator?	Yes				
AUDT-7	Are audit logs protected from modification?	Yes		Section 5.2, AUDT	AU-2	None
AUDT-7.1	Are audit logs protected from access?	Yes				
AUDT-8	Can audit logs be analyzed by the device?	Yes		Section 5.2, AUDT	AU-2	None
Audit Controls Notes:						

2) All events are stored in the Windows Event Log. Windows provides some controls for defining which events are recorded.
3) Windows Event Forwarding may be used to forwarded events from the Windows Event Log to a SIEM.
4) Only Administrators may view the Windows Event Log. Windows Protected Event Logging (PEL) may be used to encrypt the event log.

	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)?	Yes		Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-1.2	Can the customer push group policies to the device (e.g., Active Directory)?	Yes	5	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-1.3	Are any special groups, organizational units, or group policies required?	No	6	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-2	Can users be assigned different privilege levels based on 'role' (e.g., user, administrator, and/or service, etc.)?	Yes		Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-3	Can the device owner/operator grant themselves unrestricted administrative privileges (e.g., access operating system or application via local root or administrator account)?	Yes		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	7			
Authorization Notes:						

5) Refer to group policy documentation for a list of permissable group policy changes.
6) Any required group policies are already applied to the medical device. Refer to documentation for the potential impact of changing these group policies. The required local windows user groups are already configured on the medical device. Domain groups must be mapped to local groups to assign user roles.

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7) The device starts in a full screen application mode, although non-adminstrator users may exit to a highly controlled desktop.

	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				
CSUP-2.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	No				
CSUP-2.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes				
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	8			
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?	Yes				
CSUP-3.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	No				
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	8			
CSUP-4	Does the device contain Anti-Malware Software? If yes, complete 4.1-4.4.	Yes	9			
CSUP-4.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	Yes				
CSUP-4.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes				
CSUP-4.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes				
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?	Yes	8, 10			
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				
CSUP-5.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	No				
CSUP-5.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes				
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	8			
CSUP-6	Does the device contain other software components (e.g., asset management software, license management)? If yes, please provide details or refernce 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	11			
CSUP-8	Does the device perform automatic installation of software updates?	Yes				
CSUP-9	Does the manufacturer have an approved list of third-party software that can be installed on the device?	No	12			
CSUP-10	Can the owner/operator install manufacturer-approved third-party software on the device themselves?	Yes	12			
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?	Yes	11			
CSUP-11.2	Is there an update review cycle for the device?	Yes				

Cybersecurity Product Upgrade Notes:

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8) Updates to the Operating System, Drivers / Firmware, Carestream software, integrated 3rd party software, and the host-based IDS/IPS policies are validated by Carestream before being made available for installation. Updates may be installed by Carestream service personnel, by customers using the Security Roll-Up (SRU) tool available for download from Carestream's website, or automatically through the Carestream Product Update Server based on WSUS. Contract carestream Service for additional information.

9) Carestream ImageView medical devices include a host-based Intrusion Detection / Prevention System (IDS/IPS) to whitelist and isolate executable software and Windows Defender Anti-Virus with cloud based protection. Updates to the IDS/IPS are typically required only when there are changes to the Carestream software that require an updated whitelist.
10) Updates to Windows Defender policies are automatic. Carestream software is whitelisted to prevent accidental identification as malware.

11) Customers may access the Cybersecurity End User section of the Carestream Service Portal. This provides customers with access to additional product security information, the Security Roll-Up (SRU) Tool to install security patches, and Product Security Advisories. Customers may subscribe to receive automatic email notifications whenever there are new SRU updates or advisories. Contract Carestream Service for access to the Cybersecurity End User section of the Carestream Service Portal.
12) The included host-based IPS whitelists common Anti-Virus software, allowing Windows Defender to be replaced with alternative solutions. Installation of other 3rd party software may be performed by authorized Carestream Service Personnel or may require the customer to first replace Carestream's host-based IPS with an alternative solution.

	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		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		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				
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	13	Section 5.8, EMRG	SI-17	None

13) See http://www.medicalimaging.org/wp-content/uploads/2011/02/Break-Glass_-_Emergency_Access_to_Healthcare_Systems.pdf

	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		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)?	No		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?	Yes		Section 5.10, MLDP		
MLDP-2	Does the device support the use of anti-malware software (or other anti-malware mechanism)? Provide details or reference in notes.	Yes	14	Section 5.10, MLDP	SI-3	A.12.2.1
MLDP-2.1	Does the device include anti-malware software by default?	Yes		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?	Yes		Section 5.10, MLDP	CP-10	A.17.1.2
MLDP-2.4	Can the device owner/operator independently (re-)configure anti-malware settings?	Yes	15	Section 5.10, MLDP	AU-2	None
MLDP-2.5	Does notification of malware detection occur in the device user interface?	Yes				
MLDP-2.6	Can only manufacturer-authorized persons repair systems when malware has been detected?	No	15			
MLDP-2.7	Are malware notifications written to a log?	Yes				
MLDP-2.8	Are there any restrictions on anti-malware (e.g., purchase, installation, configuration, scheduling)?	Yes	15			
MLDP-3	If the answer to MLDP-2 is NO, and anti-malware cannot be installed on the device, are other compensating controls in place or available?	N/A		Section 5.10, MLDP	SI-2	A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3

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MLDP-4	Does the device employ application whitelisting that restricts the software and services that are permitted to be run on the device?	Yes		Section 5.10, MLDP	SI-3	A.12.2.1
MLDP-5	Does the device employ a host-based intrusion detection/prevention system?	Yes		Section 5.10, MLDP	SI-4	None
MLDP-5.1	Can the host-based intrusion detection/prevention system be configured by the customer?	No	15	Section 5.10, MLDP	CM-7	A.12.5.1
MLDP-5.2	Can a host-based intrusion detection/prevention system be installed by the customer?	Yes	15	Section 5.10, MLDP		

Malware Detection / Protection Notes:
14) Carestream ImageView medical devices employ a multi-layered security strategy which includes a host-based Intrusion Detection / Prevention System (IDS/IPS) to whitelist and sandbox (limit file and registry access) executable software, Windows Defender Anti-Virus with cloud-based protection, a software firewall configured to block all ports except those required for the function of the device, a whitelist based web proxy server to prevent browsing to potentially malicious websites, and USB device (DLP) protection.
15) The Carestream host-based IDS/IPS may not be configured by customers. Customers seeking more control or additional logging capabilities in their anti-malware software may replace the Carestrem IDS/IPS with an alternative solution using provided configuration guidelines. Contact Carestream service for additional information.

	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**
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	16	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)?	Yes		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?	Yes				
NAUT-3	Does the device use certificate-based network connection authentication?	No				

Node Authentication Notes:
16) TLS 1.2 is used to secure the web server and Web APIs. The user must provide credentials to access the server. Customers may install and manage their own 3rd

	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?	See Notes	17			
CONN-1.1.1	Does the device support Wi-Fi?	See Notes	17			
CONN-1.1.2	Does the device support Bluetooth?	See Notes	18			
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)?	See Notes	19			
CONN-1.2	Does the device support physical connections?	Yes				
CONN-1.2.1	Does the device have available RJ45 Ethernet ports?	See Notes	20			
CONN-1.2.2	Does the device have available USB ports?	See Notes	21			
CONN-1.2.3	Does the device require, use, or support removable memory devices?	See Notes	22			
CONN-1.2.4	Does the device support other physical connectivity?	See Notes	23			
CONN-2	Does the manufacturer provide a list of network ports and protocols that are used or may be used on the device?	Yes				
CONN-3	Can the device communicate with other systems within the customer environment?	Yes				
CONN-4	Can the device communicate with other systems external to the customer environment (e.g., a service host)?	See Notes	24			
CONN-5	Does the device make or receive API calls?	Yes				
CONN-6	Does the device require an internet connection for its intended use?	No				
CONN-7	Does the device support Transport Layer Security (TLS)?	Yes				
CONN-7.1	Is TLS configurable?	Yes				
CONN-8	Does the device provide operator control functionality from a separate device (e.g., telemedicine)?	No				

Connectivity Capabilities Notes:
17) WiFi is an available option for Mobile X-Ray systems.
18) Bluetooth is supported only when the optional 2D wireless barcode scanner is in use.
19) X-Ray detectors may be used in wired or wireless mode. Wireless detectors use 802.11g/n.
RF is supported only when the optional wireless exposure switch is in use.
20) Mobile X-Ray systems have an unused RJ45 port when they are not connected to a wired network.
21) Availability of open USB ports is determined by the number of optional features that are enabled on the system.
DLP settings may be enabled to prevent the use of removable storage devices.
22) Patient data may be saved to CD, DVD, or USB media using the optional DICOMDIR (IHE Portable Data for Imaging) feature.
23) Some platforms may use a serial connection to the X-Ray generator or other internal devices.
24) The system may optionally communicate with the Remote Management Service (RMS) system, managed by PTC ThingWorx.

	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		Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-1.1	Does the device enforce authentication of unique IDs and passwords for all users and roles (including service accounts)?	Yes		Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-2	Is the device configurable to authenticate users through an external authentication service (e.g., MS Active Directory, NDS, LDAP, OAuth, etc.)?	Yes		Section 5.12, PAUT	IA-5	A.9.2.1
PAUT-3	Is the device configurable to lock out a user after a certain number of unsuccessful logon attempts?	Yes		Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-4	Are all default accounts (e.g., technician service accounts, administrator accounts) listed in the documentation?	Yes		Section 5.12, PAUT	SA-4(5)	A.14.1.1, A.14.2.7, A.14.2.9, A.15.1.2
PAUT-5	Can all passwords be changed?	Yes		Section 5.12, PAUT		

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	Is the device configurable to enforce creation of user account passwords that meet established (organization specific)						
PAUT-6	complexity rules?	Yes			Section 5.12, PAUT	IA-2	A.9.2.1
	Does the device support account passwords that expire						
PAUT-7	periodically?	Yes					
PAUT-8	Does the device support multi-factor authentication?	Yes					
PAUT-9	Does the device support single sign-on (SSO)?	Yes			Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-10	Can user accounts be disabled/locked on the device?	Yes			Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-11	Does the device support biometric controls?	Yes			Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-12	Does the device support physical tokens (e.g. badge access)?	Yes					
	Does the device support group authentication (e.g. hospital						
PAUT-13	teams)?	Yes					
	Does the application or device store or manage authentication						
PAUT-14	credentials?	See Notes	25				
PAUT-14.1	Are credentials stored using a secure method?	Yes	25				

Person Authentication Notes:
25) Credentials are managed by the Windows 10 OS or the Active Directory Domain Service.

	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						
	Is the device software only? If yes, answer "N/A" to remaining						
PLOK-1	questions in this section.	No			Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
	Are all device components maintaining personally identifiable information (other than removable media) physically secure (i.e.,						
PLOK-2	cannot remove without tools)?	See Notes	26		Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
	Are all device components maintaining personally identifiable information (other than removable media) physically secured						
PLOK-3	behind an individually keyed locking device?	See Notes	26		Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
	Does the device have an option for the customer to attach a						
PLOK-4	physical lock to restrict access to removable media?	See Notes	26		Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3

Physical Locks Notes:
26) The physical locking characteristics will vary with the X-Ray system:
- Mobile Systems: The PC is located behind the covers of the mobile X-Ray system. Tools are required to remove the covers and to remove the computer.
- Mobile Retrofit Systems: The PC is mounted to an existing mobile X-Ray system. Tools are required to remove the computer. A cable lock may be used to secure the computer.
- In-Room Systems: The PC is located in the control room for an X-Ray room. A physical lock may be used to prevent opening the computer case. A cable lock may be used to secure the computer.

	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.						
	Was a secure software development process, such as ISO/IEC						
RDMP-1	27034 or IEC 62304, followed during product development?	Yes			Section 5.14, RDMP	CM-2	None
	Does the manufacturer evaluate third-party applications and software components included in the device for secure						
RDMP-2	development practices?	Yes			Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2
	Does the manufacturer maintain a web page or other source of						
RDMP-3	information on software support dates and updates?	Yes			Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2
	Does the manufacturer have a plan for managing third-party						
RDMP-4	component end-of-life?	Yes			Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2

	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					
	Does the SBoM follow a standard or common method in						
SBOM-2	describing software components?	Yes					
SBOM-2.1	Are the software components identified?	Yes					
	Are the developers/manufacturers of the software components						
SBOM-2.2	identified?	Yes					
	Are the major version numbers of the software components						
SBOM-2.3	identified?	Yes					
SBOM-2.4	Are any additional descriptive elements identified?	Yes					
	Does the device include a command or process method available to generate a list of software components installed on the						
SBOM-3	device?	No					
SBOM-4	Is there an update process for the SBoM?	Yes					

	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*
	Is the device hardened in accordance with any industry						A.6.2.1, A.6.2.2, A.13.1.1,
SAHD-1	standards?	Yes			Section 5.15, SAHD	AC-17(2)/IA-3	A.13.2.1, A.14.1.2/None
SAHD-2	Has the device received any cybersecurity certifications?	Yes			Section 5.15, SAHD	SA-12(10)	A.14.2.7, A.15.1.1, A.15.1.2, A.15.1.3
	Does the device employ any mechanisms for software integrity						
SAHD-3	checking	Yes					
	Does the device employ any mechanism (e.g., release-specific hash key, checksums, digital signature, etc.) to ensure the						
SAHD-3.1	installed software is manufacturer-authorized?	Yes					
	Does the device employ any mechanism (e.g., release-specific hash key, checksums, digital signature, etc.) to ensure the						
SAHD-3.2	software updates are the manufacturer-authorized updates?	Yes			Section 5.15, SAHD	CM-8	A.8.1.1, A.8.1.2

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SAHD-4	Can the owner/operator perform software integrity checks (i.e., verify that the system has not been modified or tampered with)?	Yes		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		Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-6	Are any system or user accounts restricted or disabled by the manufacturer at system delivery?	Yes		Section 5.15, SAHD	CM-8	A.8.1.1, A.8.1.2
SAHD-6.1	Are any system or user accounts configurable by the end user after initial configuration?	Yes		Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-6.2	Does this include restricting certain system or user accounts, such as service technicians, to least privileged access?	Yes		Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-7	Are all shared resources (e.g., file shares) which are not required for the intended use of the device disabled?	Yes		Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-8	Are all communication ports and protocols that are not required for the intended use of the device disabled?	Yes		Section 5.15, SAHD	SA-18	None
SAHD-9	Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.), which are not required for the intended use of the device deleted/disabled?	Yes		Section 5.15, SAHD	CM-6	None
SAHD-10	Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the intended use of the device deleted/disabled?	Yes		Section 5.15, SAHD	SI-2	A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3
SAHD-11	Can the device prohibit boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?	Yes				
SAHD-12	Can unauthorized software or hardware be installed on the device without the use of physical tools?	Yes	27			
SAHD-13	Does the product documentation include information on operational network security scanning by users?	Yes				
SAHD-14	Can the device be hardened beyond the default provided state?	Yes				
SAHD-14.1	Are instructions available from vendor for increased hardening?	No				
SHAD-15	Can the system prevent access to BIOS or other bootloaders during boot?	Yes				
SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?	Yes				

System and Application Hardening Notes:
27) The host-based IPS prevents installation of unauthorized software.
DLP controls may prevent installation of software from removable media.

	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		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		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				
SGUD-4	Does the product include documentation on recommended compensating controls for the device?	Yes				

	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?	See Notes	28	Section 5.17, STCF	SC-28	A.8.2.3
STCF-1.1	Is all data encrypted or otherwise protected?	See Notes	28			
STCF-1.2	Is the data encryption capability configured by default?	No				
STCF-1.3	Are instructions available to the customer to configure encryption?	No				
STCF-2	Can the encryption keys be changed or configured?	No		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				

Health Data Storage Confidentiality Notes:
28) Data at Rest (DAR) encryption available through BitLocker or optional FIPS 140-2 Level 2 certified self-encrypting hard drives on most systems.

	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?	Yes		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?	No	29	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	29			
TXCF-3	Is personally identifiable information transmission restricted to a fixed list of network destinations?	Yes		Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-4	Are connections limited to authenticated systems?	No	29	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-5	Are secure transmission methods supported/implemented (DICOM, HL7, IEEE 11073)?	No				

29) Network encryption is not enabled by default. Customer may leverage encryption features built into Windows 10 (IPSec / Kerberos) or install 3rd party alternatives / SNMPv3.

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	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?	No	__	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?	Yes	__			

	REMOTE SERVICE (RMOT) *Remote service refers to all kinds of device maintenance activities performed by a service person via network or other remote connection.*			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
RMOT-1	Does the device permit remote service connections for device analysis or repair?	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?	No	__			
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	__			
RMOT-3	Does the device have any other remotely accessible functionality (e.g. software updates, remote training)?	Yes	__			