Manufacturer Disclosure Statement for Medical Device Security -- MDS2

Hologic, Inc.	Faxitron Specimen Imaging	RD-04176 Rev 001		30-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	Hologic, Inc.	__			
DOC-2	Device Description	Specimen Radiography System	__			
DOC-3	Device Model	Faxitron Core; CoreVision	__			
DOC-4	Document ID	RD-04176 Rev 001	__			
DOC-5	Manufacturer Contact Information	Steve Bolduc steven.bolduc@Hologic.com	__			
DOC-6	Intended use of device in network-connected environment:	The Faxitron Core & CoreVision Systems are a specimen imaging device. The system is able to capture images and perform procedures with no network connectivity. However it is typically connected to a network to achieve query/retrieve, archiving, printing, interfacing with a RIS, etc.	__			
DOC-7	Document Release Date	4/30/2021	__			
DOC-8	Coordinated Vulnerability Disclosure: Does the manufacturer have a vulnerability disclosure program for this device?	No	__			
DOC-9	ISAO: Is the manufacturer part of an Information Sharing and Analysis Organization?	No	__			
DOC-10	Diagram: Is a network or data flow diagram available that indicates connections to other system components or expected external resources?	Yes, available upon request.	__			
DOC-11	SaMD: Is the device Software as a Medical Device (i.e. software-only, no hardware)?	No	__			
DOC-11.1	Does the SaMD contain an operating system?	N/A	__			
DOC-11.2	Does the SaMD rely on an owner/operator provided operating system?	N/A	__			
DOC-11.3	Is the SaMD hosted by the manufacturer?	N/A				
DOC-11.4	Is the SaMD hosted by the customer?	N/A	__			
		Yes, No, N/A, or See Notes	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	Note 1		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?	No	__		AR-2	A.15.1.4

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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)?	Yes	__			AR-2	A.15.1.4
MPII-3	Does the device have mechanisms used for the transmitting, importing/exporting of personally identifiable information?	Yes	__			AR-2	A.15.1.4
MPII-3.1	Does the device display personally identifiable information (e.g., video display, etc.)?	Yes	__			AR-2	A.15.1.4
MPII-3.2	Does the device generate hardcopy reports or images containing personally identifiable information?	Yes	Note 2			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	Note 4			AR-2	A.15.1.4
MPII-3.4	personally identifiable information via dedicated cable connection (e.g., RS-232, RS-423, USB, FireWire, etc.)?	Yes				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	Note 6			AR-2	A.15.1.4
MPII-3.6	Does the device transmit/receive personally identifiable information via a wireless network connection (e.g., WiFi, Bluetooth, NFC, infrared, cellular, etc.)?	No				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					
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
	AUTOMATIC LOGOFF (ALOF)			**IEC TR 80001-2-2:2012**		**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	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	Note 7	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	Note 7	Section 5.1, ALOF		AC-11	A.11.2.8, A.11.2.9

	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?	No	—	Section 5.2, AUDT	AU-1	A.5.1.1, A.5.1.2, A.6.1.1, A.12.1.1, A.18.1.1, A.18.2.2
AUDT-1.1	Does the audit log record a USER ID?	Yes				
AUDT-1.2	Does other personally identifiable information exist in the audit trail?	No		Section 5.2, AUDT	AU-2	None
AUDT-2	Are events recorded in an audit log? If yes, indicate which of the following events are recorded in the audit log:	Yes	—	Section 5.2, AUDT	AU-2	None
AUDT-2.1	Successful login/logout attempts?	Yes	—	Section 5.2, AUDT	AU-2	None
AUDT-2.2	Unsuccessful login/logout attempts?	Yes	—	Section 5.2, AUDT	AU-2	None
AUDT-2.3	Modification of user privileges?	Yes	—	Section 5.2, AUDT	AU-2	None
AUDT-2.4	Creation/modification/deletion of users?	Yes	—	Section 5.2, AUDT	AU-2	None
AUDT-2.5	Presentation of clinical or PII data (e.g. display, print)?	No	—	Section 5.2, AUDT	AU-2	None
AUDT-2.6	Creation/modification/deletion of data?	No	—	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)?	No	—	Section 5.2, AUDT	AU-2	None
AUDT-2.8	Receipt/transmission of data or commands over a network or point-to-point connection?	No	—	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?	N/A	—	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?	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?	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?	Yes	—			
AUDT-7	Are audit logs protected from modification?	No	—	Section 5.2, AUDT	AU-2	None
AUDT-7.1	Are audit logs protected from access?	No				
AUDT-8	Can audit logs be analyzed by the device?	No	—	Section 5.2, AUDT	AU-2	None

	AUTHORIZATION (AUTH)			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
	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)?	Yes	Active Directory	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)?	See Notes	Note 8	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-1.3	Are any special groups, organizational units, or group policies required?	Yes	Note 9	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.)?	No	__	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?	No	__	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?	No	__			

	CYBER SECURITY PRODUCT UPGRADES (CSUP) *The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade device's security patches.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
CSUP-1	Does the device contain any software or firmware which may require security updates during its operational life, either from the device manufacturer or from a third-party manufacturer of the software/firmware? If no, answer "N/A" to questions in this section.	Yes	Windows			
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?	No				
CSUP-2.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes	__			
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				
CSUP-3	Does the device contain Drivers and Firmware? If yes, complete 3.1-3.4.	Yes	__			
CSUP-3.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	No	__			
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?	No	__			
CSUP-3.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	No	__			
CSUP-4	Does the device contain Anti-Malware Software? If yes, complete 4.1-4.4.	Yes				
CSUP-4.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	Yes	Note 10			
CSUP-4.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	See Notes	Note 10			

CSUP-4.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes	Note 10			
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?	See Notes	Note 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?	No	__			
CSUP-5.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes	__			
CSUP-5.3	Does the device have the capability to receive remote installation of patches or software updates?	No	__			
CSUP-5.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	No	__			
CSUP-6	Does the device contain other software components (e.g., asset management software, license management)? If yes, please provide details or 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?	No	__			
CSUP-6.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	No	__			
CSUP-6.3	Does the device have the capability to receive remote installation of patches or software updates?	No	__			
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?	No	__			
CSUP-7	Does the manufacturer notify the customer when updates are approved for installation?	Yes	Note 11			
CSUP-8	Does the device perform automatic installation of software updates?	No	__			
CSUP-9	Does the manufacturer have an approved list of third-party software that can be installed on the device?	Yes	Note 10			
CSUP-10	Can the owner/operator install manufacturer-approved third-party software on the device themselves?	Yes	Note 10			
CSUP-10.1	Does the system have mechanism in place to prevent installation of unapproved software?	No	__			
CSUP-11	Does the manufacturer have a process in place to assess device vulnerabilities and updates?	Yes	Note 12			
CSUP-11.1	Does the manufacturer provide customers with review and approval status of updates?	Yes	Note 11			
CSUP-11.2	Is there an update review cycle for the device?	Yes	Note 13			

	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?	No	__	Section 5.6, DIDT	None	ISO 27038

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DIDT-1.1	Does the device support de-identification profiles that comply with the DICOM standard for de-identification?	No	__		Section 5.6, DIDT	None	ISO 27038
	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?	See Notes	Note 3		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	Note 14		Section 5.7, DTBK	CP-9	A.12.3.1
DTBK-4	Does the device have an integral data backup capability to remote storage?	Yes	Note 14				
DTBK-5	Does the device have a backup capability for system configuration information, patch restoration, and software restoration?	Yes	Note 14				
DTBK-6	Does the device provide the capability to check the integrity and authenticity of a backup?	No	__		Section 5.7, DTBK	CP-9	A.12.3.1
	EMERGENCY ACCESS (EMRG)				**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	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?	No	__		Section 5.8, EMRG	SI-17	None
	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)?	No			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	Note 15		Section 5.9, IGAU	SC-28	A.18.1.3
	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?	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	Note 10		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?	Yes			Section 5.10, MLDP	AU-6	A.12.4.1, A.16.1.2, A.16.1.4

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MLDP-2.3	Does the device documentation allow the owner/operator to install or update anti-malware software?	Yes		Section 5.10, MLDP	CP-10	A.17.1.2
MLDP-2.4	Can the device owner/operator independently (re-)configure anti-malware settings?	Yes		Section 5.10, MLDP	AU-2	None
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?	Yes				
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)?	No				
MLDP-3	If the answer to MLDP-2 is NO, and anti-malware cannot be installed on the device, are other compensating controls in place or available?	N/A	__	Section 5.10, MLDP	SI-2	A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3
MLDP-4	Does the device employ application 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?	Yes	__	Section 5.10, MLDP	CM-7	A.12.5.1
MLDP-5.2	Can a host-based intrusion detection/prevention system be installed by the customer?	Yes	__	Section 5.10, MLDP		
	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		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	Note 16	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	Available upon request			
NAUT-3	Does the device use certificate-based network connection authentication?	No				
	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?	No	__			
CONN-1.1.1	Does the device support Wi-Fi?	No	__			
CONN-1.1.2	Does the device support Bluetooth?	No	__			
CONN-1.1.3	Does the device support other wireless network connectivity (e.g. LTE, Zigbee, proprietary)?	No	__			
CONN-1.1.4	Does the device support other wireless connections (e.g., custom RF controls, wireless detectors)?	No	__			
CONN-1.2	Does the device support physical connections?	Yes	__			
CONN-1.2.1	Does the device have available RJ45 Ethernet ports?	Yes	__			
CONN-1.2.2	Does the device have available USB ports?	Yes	__			

CONN-1.2.3	Does the device require, use, or support removable memory devices?	Yes	Note 5			
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	Available upon request.			
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)?	Yes	__			
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	Note 17			
CONN-7.1	Is TLS configurable?	Yes	Note 17			
CONN-8	Does the device provide operator control functionality from a separate device (e.g., telemedicine)?	No				

	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	Note 18	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	Note 18	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	Active Directory	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	Note 19	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?	No		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?	No	__	Section 5.12, PAUT		
PAUT-6	Is the device configurable to enforce creation of user account passwords that meet established (organization specific) complexity rules?	Yes	Note 20	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-7	Does the device support account passwords that expire periodically?	Yes	Note 21			
PAUT-8	Does the device support multi-factor authentication?	No	__			
PAUT-9	Does the device support single sign-on (SSO)?	Yes	Active Directory	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-10	Can user accounts be disabled/locked on the device?	Yes	__	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-11	Does the device support biometric controls?	No		Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-12	Does the device support physical tokens (e.g. badge access)?	No	__			
PAUT-13	Does the device support group authentication (e.g. hospital teams)?	Yes				
PAUT-14	Does the application or device store or manage authentication credentials?	Yes	Note 22			
PAUT-14.1	Are credentials stored using a secure method?	Yes	Note 22			

	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	__	Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
PLOK-4	Does the device have an option for the customer to attach a physical lock to restrict access to removable media?	No	__	Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
	ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP)			**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		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?	Yes	__	Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2
RDMP-4	Does the manufacturer have a plan for managing third-party component end-of-life?	Yes	__	Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2
	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	**See SBoM sheet within this document.**			
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?	Yes	__			
SBOM-2.3	Are the major version numbers of the software components identified?	Yes	__			
SBOM-2.4	Are any additional descriptive elements identified?	Yes	__			
SBOM-3	Does the device include a command or process method available to generate a list of software components installed on the device?	No	__			
SBOM-4	Is there an update process for the SBoM?	Yes	Note 23			
	SYSTEM AND APPLICATION HARDENING (SAHD)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**

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	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?	No			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?	No					
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?	No			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?	Yes	Note 24		Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-5.1	Does the device provide role-based access controls?	Yes	Note 24		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?	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?	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?	No	__		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?	No	__		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?	No	__		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?	No	__		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)?	No					
SAHD-12	Can unauthorized software or hardware be installed on the device without the use of physical tools?	See Notes	Note 26				
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?	See Notes	Note 27				
SAHD-14.1	Are instructions available from vendor for increased hardening?	Yes	Available upon request/discussion.				
SHAD-15	Can the system prevent access to BIOS or other bootloaders during boot?	Yes	Note 25				
SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?	No	__				

	SECURITY GUIDANCE (SGUD) *Availability of security guidance for operator and administrator of the device and manufacturer sales and service.*			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
SGUD-1	Does the device include security documentation for the owner/operator?	Yes	Note 28	Section 5.16, SGUD	AT-2/PL-2	A.7.2.2, A.12.2.1/A.14.1.1
SGUD-2	Does the device have the capability, and provide instructions, for the permanent deletion of data from the device or media?	Yes	Note 29	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	Available upon request.	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?	No	__			
SGUD-4	Does the product include documentation on recommended compensating controls for the device?	No				

	HEALTH DATA STORAGE CONFIDENTIALITY (STCF) *The ability of the device to ensure unauthorized access does not compromise the integrity and confidentiality of personally identifiable information stored on the device or removable media.*			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
STCF-1	Can the device encrypt data at rest?	No	__	Section 5.17, STCF	SC-28	A.8.2.3
STCF-1.1	Is all data encrypted or otherwise protected?	No				
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	__			

	TRANSMISSION CONFIDENTIALITY (TXCF) *The ability of the device to ensure the confidentiality of transmitted personally identifiable information.*			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
TXCF-1	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		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?	No				
TXCF-3	Is personally identifiable information transmission restricted to a fixed list of network destinations?	No	__	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-4	Are connections limited to authenticated systems?	No	__	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-5	Are secure transmission methods supported/implemented (DICOM, HL7, IEEE 11073)?	No	__			

	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

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TXIG-2	Does the device include multiple sub-components connected by external cables?	No	__

	REMOTE SERVICE (RMOT)			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
	Remote service refers to all kinds of device maintenance activities performed by a service person via network or other remote connection.					
RMOT-1	Does the device permit remote service connections for device analysis or repair?	No	__		AC-17	A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2
RMOT-1.1	Does the device allow the owner/operator to initiative remote service sessions for device analysis or repair?	No	__			
RMOT-1.2	Is there an indicator for an enabled and active remote session?	No				
RMOT-1.3	Can patient data be accessed or viewed from the device during the remote session?	No	__		AC-17	A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2
RMOT-2	Does the device permit or use remote service connections for predictive maintenance data?	No	__			
RMOT-3	functionality (e.g. software updates, remote training)?	No				

	OTHER SECURITY CONSIDERATIONS (OTHR)	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
	NONE			
	Notes:			
Note 1	Device contains a limited amount of ePHI to identify images - typically a name, date of birth, patient ID, and accession number.			
Note 2	Optional printing of patient reports			
Note 3	Factory reset requires Service Personnel to perform			
Note 4	Optional importing and exporting of patient procedures.			
Note 5	Backup/Restore			
Note 6	Typically an RJ45 Ethernet connection.			
Note 7	Product application defaults to never logging out current user. Inactivity timeout configurable.			
Note 8	It's strongly recommend to limit policy changes pushed to the device to User related policies only, such as password complexity requirements, forcing passwords to expire, etc. There are certain policy changes that, if pushed, could negatively impact the product application.			
Note 9	Strongly recommend configuring the product in its own Organizational Unit and limiting policy changes pushed to the system.			
Note 10	Option available to install validated CoTS antimalware products. See product support website for list of validated antimalware software solutions and installation guidance. Malware definitions can be updated by customer at will. Hologic suggests keeping antimalware software version at the same major version as what was validated.			
Note 11	Validated security patches for the product are posted to the product support website at regular intervals.			

Note 12	Vulnerability assessments, leveraging industry standard tools, and Windows security patch validation occur at regular intervals.
Note 13	Hologic strives to evaluate and test Windows security updates for the product as they're released (typically monthly).
Note 14	Software databases and configurations can be backed up. Patient studies should be stored to long term storage or exported to external media by the customer.
Note 15	Product not designed for long term storage. Patient studies should be stored to long term storage.
Note 16	Windows Firewall enabled and configured to allow product application network traffic. Patient data only sent to configured DICOM devices.
Note 17	Hologic Connect leverages an encrypted TLS tunnel for remote Service connectivity. TLS can, optionally, be configured for the product Service Tools configuration web application. External network traffic can also be blocked for Service Tools. Patient study transmission to external devices is done using DICOM, without TLS. Customer may configure TLS at the network layer.
Note 18	Use of unique product accounts is the decision of the customer. Generic accounts can be removed.
Note 19	Enabled by default, locking the user for 15 minutes after 3 failed logon attempts.
Note 20	Not configured by default
Note 21	Passwords not configured to automatically expire by default. Configurable by customer.
Note 22	Product application leverages Windows Operating System for user authentication. Credentials not stored in application databases. Credentials stored/managed securely via Operating System.
Note 23	SBOM reviewed and updated as required during product update cycles.
Note 24	Product utilizes role-based privileges for many sensitive areas of the application.
Note 25	Can be configured, not restricted by default. If configured, communicate change to service representative.
Note 26	Hardware installation would require tools, software would require OS authentication.
Note 27	Additional hardening or concerns may be discussed with Hologic. Implementing additional hardening changes may negatively impact the product.
Note 28	Security documentation available on product support website.
Note 29	Contact customer support for instructions

Software Bill of Materials (SBoM)

Component Name	Developer	Version(s)	Product Use
Windows 10 IoT Enterprise x64	Microsoft	LTSC 2019	Operating System
Vision	Hologic Inc	3.1.4	Main system application.
FBCamUSB	Hologic Inc	3.1.1.1	Detector interface DLL.
BiopticsProcessing	Hologic Inc	2.3.4.1	Processing DLL.
ConfigUtility	Hologic Inc	1.2.1.1	Configuration DLL.
Logger	Hologic Inc	N/A	Logger DLL.
MWLQuery	Hologic Inc	N/A	Modality WorkList query dictionary.
FinalCfgChecker	Hologic Inc	1.0.0.1	QC checker application.
LeadTools	LEAD Technologies, Inc.	15.0.1	Visualization and DICOM integration.
Adobe Reader XI	Adobe Systems Incorporated	11.0.23	Adobe reader.
Intel(R) Rapid Storage Technology	Intel Corporation	16.7.10.1030	Intel drivers.
Intel(R) Graphics Driver	Intel Corporation	24.20.100.6287	Intel drivers.
Intel(R) Management Engine Components	Intel Corporation	1829.12.0.1154	Intel drivers.
Intel(R) OptaneTM Pinning Explorer Extensions	Intel Corporation	16.7.10.1030	Intel drivers.
Microsoft Access database engine 2010	Microsoft Corporation	14.0.7015.1000	Access database engine.
Microsoft Visual C++ 2005 Redistributable	Microsoft Corporation	8.0.61000	Visual C++ redistributable.
Microsoft Visual C++ 2008 Redistributable	Microsoft Corporation	9.0.21022	Visual C++ redistributable.
Microsoft Visual C++ 2010 Redistributable	Microsoft Corporation	10.0.30319	Visual C++ redistributable.
Microsoft Visual C++ 2013 Redistributable	Microsoft Corporation	12.0.30501.0	Visual C++ redistributable.
Realtek High Definition Audio Driver	Realtek Semiconductor Corp.	6.0.1.8573	Audio driver.
USB Serial Port	Microchip Technology, Inc.	5.1.2600.7	USB serial port drivers.

Additional Notes	
Note 1	Many of the software components listed above are covered by Hologic's program to regularly validate latest released security patches. See the product support website for the latest validated patches available or contact support for assistance.