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TITLE	DOCUMENT NUMBER	REV
MDS2 SHEET FOR INSIGHT 6.1.3	RD-04250	001
	RELEASE DATE: 9/9/2021	SHEET 1 OF 1

Manufacturer Disclosure Statement for Medical Device Security -- MDS2

| Hologic, Inc. | InSight FD Product line | RD-04250 Rev 001 | | 6-Aug-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	Fluoroscan Mini C-Arm	—			
DOC-3	Device Model	InSight FD	—			
DOC-4	Document ID	RD-04250 Rev 001	—			
DOC-5	Manufacturer Contact Information	Steve Bolduc steven.bolduc@Hologic.com	—			
DOC-6	Intended use of device in network-connected environment:	The InSight FD Systems are a Fluoroscopy 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	8/6/2021	—			
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

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	Note 42	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 4	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 5	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 7	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.)?	Yes	Note 41	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

				IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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.						
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 8	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 8	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?	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	Note 43	Section 5.2, AUDT	AU-2	None
AUDT-2.8.1	Remote or on-site support?	N/A		Section 5.2, AUDT	AU-2	None
AUDT-2.8.2	Application Programming Interface (API) and similar activity?	N/A	—	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)?	Yes	Note 9	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?	Yes		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	Available upon request.	Section 5.2, AUDT	AU-2	None
AUDT-4.1	Does the audit log record date/time?	Yes	Note 10	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	Note 11	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?	See Notes	Note 2			
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?	Yes				
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	Note 12	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 13	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 14	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?	N/A	—	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	—			

				IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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.*					
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	Note 15			
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?	No				
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	Note 15			
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.	No	Note 16			
CSUP-4.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	No	Note 16			
CSUP-4.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	See Notes	Note 16			

CSUP-4.3	Does the device have the capability to receive remote installation of patches or software updates?	No	
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 16
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?	N/A	__
CSUP-6.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	N/A	__
CSUP-6.3	Does the device have the capability to receive remote installation of patches or software updates?	N/A	__
CSUP-6.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	N/A	__
CSUP-7	Does the manufacturer notify the customer when updates are approved for installation?	See Notes	Note 17
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 16
CSUP-10	Can the owner/operator install manufacturer-approved third-party software on the device themselves?	Yes	Note 16
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 18
CSUP-11.1	Does the manufacturer provide customers with review and approval status of updates?	Yes	Note 18
CSUP-11.2	Is there an update review cycle for the device?	Yes	Note 19

				IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
HEALTH DATA DE-IDENTIFICATION (DIDT)						
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	__	Section 5.6, DIDT	None	ISO 27038

ID	Question	Answer	Note	Ref 1	Ref 2	Ref 3
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)			**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 20	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 20			
DTBK-5	Does the device have a backup capability for system configuration information, patch restoration, and software restoration?	Yes	Note 20			
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 21	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 16	Section 5.10, MLDP	SI-3	A.12.2.1
MLDP-2.1	Does the device include anti-malware software by default?	No	Note 16	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	Note 16	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	Note 16	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	Note 22	Section 5.10, MLDP	AU-2	None
MLDP-2.5	Does notification of malware detection occur in the device user interface?	See Notes	Note 23			
MLDP-2.6	Can only manufacturer-authorized persons repair systems when malware has been detected?	Yes				
MLDP-2.7	Are malware notifications written to a log?	See Notes	Note 24			
MLDP-2.8	Are there any restrictions on anti-malware (e.g., purchase, installation, configuration, scheduling)?	Yes	Note 22			
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?	N/A	___	Section 5.10, MLDP	CM-7	A.12.5.1
MLDP-5.2	Can a host-based intrusion detection/prevention system be installed by the customer?	No	___	Section 5.10, MLDP		

	NODE AUTHENTICATION (NAUT)			**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 25	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?	Yes	___			
CONN-1.1.1	Does the device support Wi-Fi?	Yes	___			
CONN-1.1.2	Does the device support Bluetooth?	No	___			
CONN-1.1.3	Does the device support other wireless network connectivity (e.g. LTE, Zigbee, proprietary)?	No	___			
CONN-1.1.4	Does the device support other wireless connections (e.g., custom RF controls, wireless detectors)?	No	___			
CONN-1.2	Does the device support physical connections?	Yes	___			
CONN-1.2.1	Does the device have available RJ45 Ethernet ports?	Yes	___			
CONN-1.2.2	Does the device have available USB ports?	Yes	___			

CONN-1.2.3	Does the device require, use, or support removable memory devices?	Yes	Note 6
CONN-1.2.4	Does the device support other physical connectivity?	Yes	
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)?	No	
CONN-7.1	Is TLS configurable?	No	
CONN-8	Does the device provide operator control functionality from a separate device (e.g., telemedicine)?	No	

				IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
PERSON AUTHENTICATION (PAUT)						
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 26	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 26	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 27	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?	Yes	__	Section 5.12, PAUT		
PAUT-6	Is the device configurable to enforce creation of user account passwords that meet established (organization specific) complexity rules?	Yes	Note 27	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-7	Does the device support account passwords that expire periodically?	Yes	Note 28			
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	Active Directory			
PAUT-14	Does the application or device store or manage authentication credentials?	Yes	Note 29			
PAUT-14.1	Are credentials stored using a secure method?	Yes	Note 29			
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 30			

	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.

ID	Question	Answer	Notes	Section	NIST	ISO
					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?	Yes	DoD RMF ATO	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				
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	Note 31	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 32	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-5.1	Does the device provide role-based access controls?	Yes	Note 32	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?	See Notes	Note 33	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	Note 34			
SAHD-12	Can unauthorized software or hardware be installed on the device without the use of physical tools?	See Notes	Note 35			
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 36			
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 34			
SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?	No	—			

				IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
	SECURITY GUIDANCE (SGUD)					
	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	Note 37	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 38	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?	Yes	—			
SGUD-4	Does the product include documentation on recommended compensating controls for the device?	Yes	Note 16			
	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	Note 2	Section 5.17, STCF	SC-28	A.8.2.3
STCF-1.1	Is all data encrypted or otherwise protected?	See Notes	Note 2			
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?	Yes	Note 2	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)			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	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?	See Notes	Note 39	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	Note 39			
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	—	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)			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?	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? | 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?	N/A				
RMOT-1.3	Can patient data be accessed or viewed from the device during the remote session?	N/A	__		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	Note 40			

	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	Symantec Endpoint Encryption may be installed to encrypt all data at rest. Encryption key configuration is determined by Symantec
Note 3	Factory reset requires Service Personnel to perform
Note 4	Optional printing of patient reports
Note 5	Optional importing and exporting of patient procedures.
Note 6	Backup/Restore/Archive
Note 7	Typically an RJ45 Ethernet connection.
Note 8	Product application defaults to never logging out current user. Inactivity timeout configurable.
Note 9	Software installation and updates are logged.
Note 10	Log date/time stamp based on current Windows date/time for the system.
Note 11	Windows can be configured with an NTP server.
Note 12	User login with password
Note 13	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 14	Strongly recommend configuring the product in its own Organizational Unit and limiting policy changes pushed to the system.

Note 15	See product support website for list of validated security patches. Validation of latest security patches performed at regular intervals for the product.
Note 16	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 17	Validated security patches for the product are posted to the product support website at regular intervals.
Note 18	Vulnerability assessments, leveraging industry standard tools, and Windows security patch validation occur at regular intervals.
Note 19	Hologic strives to evaluate and test Windows security updates for the product as they're released (typically monthly).
Note 20	Software databases and configurations can be backed up at regular intervals. Patient studies should be stored to long term storage or exported to external media by the customer.
Note 21	Product not designed for long term storage. Patient studies should be stored to long term storage.
Note 22	See antimalware software installation guide on product support website for required scan exemptions and configurations.
Note 23	By default, Windows taskbar notifications disabled/suppressed as to not interfere with product application use. Configurations can be modified upon request. CoTS antimalware products often provide a manager that allows for email alerts and notifications to the appropriate personnel.
Note 24	Approved CoTS antimalware software typically have a history feature and/or log.
Note 25	Windows Firewall enabled and configured to allow product application network traffic. Patient data only sent to configured DICOM devices.
Note 26	Use of unique product accounts is the decision of the customer. Generic accounts can be removed.
Note 27	Not configured by default
Note 28	Passwords not configured to automatically expire by default. Configurable by customer.
Note 29	Product application leverages Windows Operating System for user authentication. Credentials not stored in application databases. Credentials stored/managed securely via Operating System.
Note 30	SBOM reviewed and updated as required during product update cycles.
Note 31	Software update install packages include integrity checks for all packaged files. Integrity check automatically performed during installations.
Note 32	Product utilizes role-based privileges for many sensitive areas of the application.

Note 33	Service users require admin privileges for many of their responsibilities. Customer may customize those privileges or disable service accounts to restrict access, but should communicate these changes to their service representative. Implementing service user restrictions requires customers to provide access as needed for servicing the product.
Note 34	Can be configured, not restricted by default. If configured, communicate change to service representative.
Note 35	Hardware installation would require tools, software would require OS authentication.
Note 36	Additional hardening or concerns may be discussed with Hologic. Implementing additional hardening changes may negatively impact the product.
Note 37	Security documentation available on product support website.
Note 38	Product user manual contains details for deleting patient studies as a privileged application user. For permanent deletion of all sensitive data, contact support.
Note 39	Exporting patient studies to removable media has an option for de-identifying. Network transmission is typically over standard DICOM and can be encrypted at the network level.
Note 40	Remote configuration of product via Service Tools web application. Ability to push approved software changes over Hologic Connect.
Note 41	Optional Wireless adapter
Note 42	Device allows scan files containing ePHI to be archived in a separate location
Note 43	DICOM Only

Software Bill of Materials (SBoM)

Component Name	Developer	Version(s)	Product Use
Microsoft Windows 10 IoT Enterprise x64	Microsoft	LTSB 2016; LTSC 2019	Operating System
Microsoft Visual C++ 2005 Redistributable	Microsoft	8.0.61001	Product application support libraries
Microsoft Visual C++ 2008 Redistributable x64	Microsoft	9.0.30729.4974	Product application support libraries
Microsoft Visual C++ 2008 Redistributable x86	Microsoft	9.0.30729.4974	Product application support libraries
Microsoft Visual C++ 2012 Redistributable x64	Microsoft	11.0.61030	Product application support libraries
Microsoft Visual C++ 2012 Redistributable x86	Microsoft	11.0.61030	Product application support libraries
Microsoft Visual C++ 2013 Redistributable x86	Microsoft	12.0.30501	Product application support libraries
Microsoft Visual C++ 2013 Redistributable x86	Microsoft	12.0.40664	Product application support libraries
Microsoft Visual C++ 2015-2019 Redistributable x64	Microsoft	14.26.28720	Product application support libraries
Microsoft Visual C++ 2015-2019 Redistributable x86	Microsoft	14.26.28720	Product application support libraries
Realtek High Definition Audio Driver	Realtek Semiconductor Corp.	6.0.1.8186	Audio device driver
Sentinel Protection Installer	SafeNet, Inc.	7.6.8	Product application support libraries
Teledyne DALSA Bungee-CL PX4 Fluoro Device Driver	Teledyne DALSA	1.10.01.0201	Image board device driver
Teledyne DALSA Fluoro2-CL Device Driver	Teledyne DALSA	1.00.01.0023	Image board device driver
Teledyne DALSA Sapera License Manager	Teledyne DALSA	8.00.00.606	Product application support libraries
Teledyne DALSA Sapera LT Runtime	Teledyne DALSA	8.32.00.1847	Product application support libraries
Teledyne DALSA Sapera Processing	Teledyne DALSA	8.00.00.1021	Product application support libraries
GeniCam	GeniCam Standard Committee	2.4.0	Product application support libraries
Merge DICOM Toolkit	Merge/IBM	3.2.1.0	Product application support libraries
Sony UP-D898MD/X898MD Printer Driver	Sony Corp.	1.00	Printer device driver

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.