

Manufacturer Disclosure Statement for Medical Device Security -- MDS2			
Hologic®, Inc.	Dimensions 1.10 & 3Dimensions 2.1	MAN-02859, Revision 006	-
Question ID	Question		See note
DOC-1	Manufacturer Name	Hologic®, Inc.	—
DOC-2	Device Description	Mammography System	—
DOC-3	Device Model	Dimensions 1.10 & 3Dimensions 2.1	—
DOC-4	Document ID	MAN-02859, Revision 006	—
DOC-5	Manufacturer Contact Information	Chris Fischer Chris.Fischer@Hologic.com	—
DOC-6	Intended use of device in network-connected environment:	—	—
DOC-7	Document Release Date	3/13/2020	—
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		
MPII-1	Can this device display, transmit, store, or modify personally identifiable information (e.g. electronic Protected Health Information (ePHI))?	Yes	Note 1
MPII-2	Does the device maintain personally identifiable information?	Yes	—
MPII-2.1	Does the device maintain personally identifiable information temporarily in volatile memory (i.e., until cleared by power-off or reset)?	Yes	—
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	Note 2
MPII-2.4	Does the device store personally identifiable information in a database?	Yes	Note 3
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	—
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	—
MPII-2.7	Does the device maintain personally identifiable information when powered off, or during power service interruptions?	Yes	—

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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	—
MPII-3	Does the device have mechanisms used for the transmitting, importing/exporting of personally identifiable information?	Yes	—
MPII-3.1	Does the device display personally identifiable information (e.g., video display, etc.)?	Yes	—
MPII-3.2	Does the device generate hardcopy reports or images containing personally identifiable information?	Yes	Note 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
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.)?	Yes	
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
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	—
MPII-3.7	Does the device transmit/receive personally identifiable information over an external network (e.g., Internet)?	No	
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	—
Management of Private Data notes:			
AUTOMATIC LOGOFF (ALOF)			
<i>The device's ability to prevent access and misuse by unauthorized users if device is left idle for a period of time.</i>			
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
ALOF-2	Is the length of inactivity time before auto-logoff/screen lock user or administrator configurable?	Yes	Note 8
AUDIT CONTROLS (AUDT)			
<i>The ability to reliably audit activity on the device.</i>			
AUDT-1	Can the medical device create additional audit logs or reports beyond standard operating system logs?	Yes	—
AUDT-1.1	Does the audit log record a USER ID?	Yes	—

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AUDT-1.2	Does other personally identifiable information exist in the audit trail?	Yes	
AUDT-2	Are events recorded in an audit log? If yes, indicate which of the following events are recorded in the audit log:	Yes	—
AUDT-2.1	Successful login/logout attempts?	Yes	—
AUDT-2.2	Unsuccessful login/logout attempts?	Yes	—
AUDT-2.3	Modification of user privileges?	Yes	—
AUDT-2.4	Creation/modification/deletion of users?	Yes	—
AUDT-2.5	Presentation of clinical or PII data (e.g. display, print)?	Yes	—
AUDT-2.6	Creation/modification/deletion of data?	Yes	—
AUDT-2.7	Import/export of data from removable media (e.g. USB drive, external hard drive, DVD)?	Yes	—
AUDT-2.8	Receipt/transmission of data or commands over a network or point-to-point connection?	Yes	—
AUDT-2.8.1	Remote or on-site support?	Yes	
AUDT-2.8.2	Application Programming Interface (API) and similar activity?	N/A	—
AUDT-2.9	Emergency access?	N/A	—
AUDT-2.10	Other events (e.g., software updates)?	Yes	Note 10
AUDT-2.11	Is the audit capability documented in more detail?	No	—
AUDT-3	Can the owner/operator define or select which events are recorded in the audit log?	No	
AUDT-4	Is a list of data attributes that are captured in the audit log for an event available?	Yes	Available upon request.
AUDT-4.1	Does the audit log record date/time?	Yes	Note 12
AUDT-4.1.1	Can date and time be synchronized by Network Time Protocol (NTP) or equivalent time source?	Yes	Note 13
AUDT-5	Can audit log content be exported?	Yes	—
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)?	Yes	Note 14
AUDT-5.4	Are audit logs encrypted in transit or on storage media?	Yes	Note 15
AUDT-6	Can audit logs be monitored/reviewed by owner/operator?	Yes	—
AUDT-7	Are audit logs protected from modification?	Yes	—
AUDT-7.1	Are audit logs protected from access?	Yes	
AUDT-8	Can audit logs be analyzed by the device?	No	—
AUTHORIZATION (AUTH)			
<i>The ability of the device to determine the authorization of users.</i>			
AUTH-1	Does the device prevent access to unauthorized users through user login requirements or other mechanism?	Yes	Note 16
AUTH-1.1	Can the device be configured to use federated credentials management of users for authorization (e.g., LDAP, OAuth)?	Yes	Active Directory
AUTH-1.2	Can the customer push group policies to the device (e.g., Active Directory)?	See Notes	Note 17
AUTH-1.3	Are any special groups, organizational units, or group policies required?	Yes	Note 18
AUTH-2	Can users be assigned different privilege levels based on 'role' (e.g., user, administrator, and/or service, etc.)?	Yes	—
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	—

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AUTH-4	Does the device authorize or control all API access requests?	N/A	—
AUTH-5	Does the device run in a restricted access mode, or 'kiosk mode', by default?	Yes	—
	CYBER SECURITY PRODUCT UPGRADES (CSUP)		
	<i>The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade device's security patches.</i>		
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 19
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?	Yes	—
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?	Yes	—
CSUP-3.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	No	—
CSUP-4	Does the device contain Anti-Malware Software? If yes, complete 4.1-4.4.	Yes	Note 21
CSUP-4.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	Yes	Note 21
CSUP-4.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	See Notes	Note 21
CSUP-4.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes	Note 21
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 21
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	—

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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?	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	—
CSUP-6	Does the device contain other software components (e.g., asset management software, license management)? If yes, please provide details or reference in notes and complete 6.1-6.4.	No	—
CSUP-6.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	N/A	—
CSUP-6.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	N/A	—
CSUP-6.3	Does the device have the capability to receive remote installation of patches or software updates?	N/A	—
CSUP-6.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	N/A	—
CSUP-7	Does the manufacturer notify the customer when updates are approved for installation?	Yes	Note 22
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 21
CSUP-10	Can the owner/operator install manufacturer-approved third-party software on the device themselves?	Yes	Note 21
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 23
CSUP-11.1	Does the manufacturer provide customers with review and approval status of updates?	Yes	Note 22
CSUP-11.2	Is there an update review cycle for the device?	Yes	Note 24
	HEALTH DATA DE-IDENTIFICATION (DIDT)		
	<i>The ability of the device to directly remove information that allows identification of a person.</i>		
DIDT-1	Does the device provide an integral capability to de-identify personally identifiable information?	Yes	—
DIDT-1.1	Does the device support de-identification profiles that comply with the DICOM standard for de-identification?	Yes	—
	DATA BACKUP AND DISASTER RECOVERY (DTBK)		
	<i>The ability to recover after damage or destruction of device data, hardware, software, or site configuration information.</i>		

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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	—
DTBK-3	Does the device have an integral data backup capability to removable media?	Yes	Note 25
DTBK-4	Does the device have an integral data backup capability to remote storage?	Yes	Note 25
DTBK-5	Does the device have a backup capability for system configuration information, patch restoration, and software restoration?	Yes	Note 25
DTBK-6	Does the device provide the capability to check the integrity and authenticity of a backup?	No	—
EMERGENCY ACCESS (EMRG)			
<i>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.</i>			
EMRG-1	Does the device incorporate an emergency access (i.e. “break-glass”) feature?	No	—
HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU)			
<i>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.</i>			
IGAU-1	Does the device provide data integrity checking mechanisms of stored health data (e.g., hash or digital signature)?	No	
IGAU-2	Does the device provide error/failure protection and recovery mechanisms for stored health data (e.g., RAID-5)?	No	Note 26
MALWARE DETECTION/PROTECTION (MLDP)			
<i>The ability of the device to effectively prevent, detect and remove malicious software (malware).</i>			
MLDP-1	Is the device capable of hosting executable software?	Yes	—
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 21
MLDP-2.1	Does the device include anti-malware software by default?	Yes	Note 21
MLDP-2.2	Does the device have anti-malware software available as an option?	Yes	Note 21
MLDP-2.3	Does the device documentation allow the owner/operator to install or update anti-malware software?	Yes	Note 21
MLDP-2.4	Can the device owner/operator independently (re-)configure anti-malware settings?	Yes	Note 27
MLDP-2.5	Does notification of malware detection occur in the device user interface?	See Notes	Note 28
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	Note 29

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MLDP-2.8	Are there any restrictions on anti-malware (e.g., purchase, installation, configuration, scheduling)?	Yes	Note 27
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	—
MLDP-4	Does the device employ application whitelisting that restricts the software and services that are permitted to be run on the device?	No	—
MLDP-5	Does the device employ a host-based intrusion detection/prevention system?	No	—
MLDP-5.1	Can the host-based intrusion detection/prevention system be configured by the customer?	N/A	—
MLDP-5.2	Can a host-based intrusion detection/prevention system be installed by the customer?	No	—
	NODE AUTHENTICATION (NAUT)		
	<i>The ability of the device to authenticate communication partners/nodes.</i>		
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	
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 30
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	
	CONNECTIVITY CAPABILITIES (CONN)		
	<i>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.</i>		
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?	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.

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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 31
CONN-7.1	Is TLS configurable?	Yes	Note 31
CONN-8	Does the device provide operator control functionality from a separate device (e.g., telemedicine)?	No	
	PERSON AUTHENTICATION (PAUT)		
	<i>The ability to configure the device to authenticate users.</i>		
PAUT-1	Does the device support and enforce unique IDs and passwords for all users and roles (including service accounts)?	Yes	Note 32
PAUT-1.1	Does the device enforce authentication of unique IDs and passwords for all users and roles (including service accounts)?	Yes	Note 32
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
PAUT-3	Is the device configurable to lock out a user after a certain number of unsuccessful logon attempts?	Yes	Note 33
PAUT-4	Are all default accounts (e.g., technician service accounts, administrator accounts) listed in the documentation?	No	
PAUT-5	Can all passwords be changed?	Yes	—
PAUT-6	Is the device configurable to enforce creation of user account passwords that meet established (organization specific) complexity rules?	Yes	Note 34
PAUT-7	Does the device support account passwords that expire periodically?	Yes	Note 35
PAUT-8	Does the device support multi-factor authentication?	No	—
PAUT-9	Does the device support single sign-on (SSO)?	Yes	Active Directory
PAUT-10	Can user accounts be disabled/locked on the device?	Yes	—
PAUT-11	Does the device support biometric controls?	Yes	Note 36
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 37
PAUT-14.1	Are credentials stored using a secure method?	Yes	Note 37
	PHYSICAL LOCKS (PLOK)		
	<i>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</i>		
PLOK-1	Is the device software only? If yes, answer “N/A” to remaining questions in this section.	No	—

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PLOK-2	Are all device components maintaining personally identifiable information (other than removable media) physically secure (i.e., cannot remove without tools)?	Yes	—
PLOK-3	Are all device components maintaining personally identifiable information (other than removable media) physically secured behind an individually keyed locking device?	No	—
PLOK-4	Does the device have an option for the customer to attach a physical lock to restrict access to removable media?	No	—
ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP)			
<i>Manufacturer's plans for security support of third-party components within the device's life cycle.</i>			
RDMP-1	Was a secure software development process, such as ISO/IEC 27034 or IEC 62304, followed during product development?	Yes	—
RDMP-2	Does the manufacturer evaluate third-party applications and software components included in the device for secure development practices?	Yes	—
RDMP-3	Does the manufacturer maintain a web page or other source of information on software support dates and updates?	Yes	—
RDMP-4	Does the manufacturer have a plan for managing third-party component end-of-life?	Yes	—
SOFTWARE BILL OF MATERIALS (SBoM)			
<i>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.</i>			
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 39
SYSTEM AND APPLICATION HARDENING (SAHD)			
<i>The device's inherent resistance to cyber attacks and malware.</i>			
SAHD-1	Is the device hardened in accordance with any industry standards?	Yes	DISA STIG
SAHD-2	Has the device received any cybersecurity certifications?	Yes	DoD RMF ATO
SAHD-3	Does the device employ any mechanisms for software integrity checking	Yes	—

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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	Note 40
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 41
SAHD-4	Can the owner/operator perform software integrity checks (i.e., verify that the system has not been modified or tampered with)?	Yes	Note 40
SAHD-5	Is the system configurable to allow the implementation of file-level, patient level, or other types of access controls?	Yes	Note 42
SAHD-5.1	Does the device provide role-based access controls?	Yes	Note 42
SAHD-6	Are any system or user accounts restricted or disabled by the manufacturer at system delivery?	Yes	Note 43
SAHD-6.1	Are any system or user accounts configurable by the end user after initial configuration?	Yes	
SAHD-6.2	Does this include restricting certain system or user accounts, such as service technicians, to least privileged access?	See Notes	Note 44
SAHD-7	Are all shared resources (e.g., file shares) which are not required for the intended use of the device disabled?	Yes	—
SAHD-8	Are all communication ports and protocols that are not required for the intended use of the device disabled?	Yes	—
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	—
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	—
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 45
SAHD-12	Can unauthorized software or hardware be installed on the device without the use of physical tools?	See Notes	Note 46
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 47
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 45
SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?	No	—
	SECURITY GUIDANCE (SGUD)		
	<i>Availability of security guidance for operator and administrator of the device and manufacturer sales and service.</i>		
SGUD-1	Does the device include security documentation for the owner/operator?	Yes	Note 48

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SGUD-2	Does the device have the capability, and provide instructions, for the permanent deletion of data from the device or media?	Yes	Note 49
SGUD-3	Are all access accounts documented?	Yes	Available upon request.
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 21
HEALTH DATA STORAGE CONFIDENTIALITY (STCF)			
<i>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.</i>			
STCF-1	Can the device encrypt data at rest?	Yes	—
STCF-1.1	Is all data encrypted or otherwise protected?	Yes	Note 50
STCF-1.2	Is the data encryption capability configured by default?	Yes	
STCF-1.3	Are instructions available to the customer to configure encryption?	N/A	
STCF-2	Can the encryption keys be changed or configured?	Yes	Note 51
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)			
<i>The ability of the device to ensure the confidentiality of transmitted personally identifiable information.</i>			
TXCF-1	Can personally identifiable information be transmitted only via a point-to-point dedicated cable?	Yes	
TXCF-2	Is personally identifiable information encrypted prior to transmission via a network or removable media?	See Notes	Note 52
TXCF-2.1	If data is not encrypted by default, can the customer configure encryption options?	Yes	Note 52
TXCF-3	Is personally identifiable information transmission restricted to a fixed list of network destinations?	Yes	—
TXCF-4	Are connections limited to authenticated systems?	No	—
TXCF-5	Are secure transmission methods supported/implemented (DICOM, HL7, IEEE 11073)?	No	—
TRANSMISSION INTEGRITY (TXIG)			
<i>The ability of the device to ensure the integrity of transmitted data.</i>			
TXIG-1	Does the device support any mechanism (e.g., digital signatures) intended to ensure data is not modified during transmission?	No	
TXIG-2	Does the device include multiple sub-components connected by external cables?	No	—
REMOTE SERVICE (RMOT)			

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	<i>Remote service refers to all kinds of device maintenance activities performed by a service person via network or other remote connection.</i>		
RMOT-1	Does the device permit remote service connections for device analysis or repair?	Yes	—
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?	Yes	—
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	Note 53
	OTHER SECURITY CONSIDERATIONS (OTHR)		
	<i>NONE</i>		
	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	Patient procedures may be deleted by privileged users on demand and/or automatically by product application reclaimer. Reclaimer times and thresholds configurable.		
Note 3	Database encrypted with Microsoft Always Encrypted technology.		
Note 4	Optional printing of patient images.		
Note 5	Optional importing and exporting of patient procedures.		
Note 7	Typically an RJ45 Ethernet connection.		
Note 8	Product application defaults to automatically logging out current user after 15 minutes of inactivity. Inactivity timeout configurable.		
Note 10	Software installation and updates are logged.		
Note 12	Log date/time stamp based on current Windows date/time for the system.		
Note 13	Windows can be configured with an NTP server.		
Note 14	Can be exported and downloaded by remote or local service users via the product Service Tools web application.		
Note 15	Audit and application log files encrypted. Application log files also have PHI one-way hashed.		
Note 16	User login with password and/or fingerprint scanner.		
Note 17	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 18	Strongly recommend configuring the product in its own Organizational Unit and limiting policy changes pushed to the system.		

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Note 19	See product support website for list of validated security patches. Validation of latest security patches performed at regular intervals for the product.		
Note 21	Microsoft Windows Defender enabled by default. 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 22	Validated security patches for the product are posted to the product support website at regular intervals.		
Note 23	Vulnerability assessments, leveraging industry standard tools, and Windows security patch validation occur at regular intervals.		
Note 24	Hologic strives to evaluate and test Windows security updates for the product as they're released (typically monthly).		
Note 25	Software databases and configurations are automatically backed up at regular intervals. Patient studies should be stored to long term storage or exported to external media by the customer.		
Note 26	Product not designed for long term storage. Patient studies should be stored to long term storage.		
Note 27	See antimalware software installation guide on product support website for required scan exemptions and configurations.		
Note 28	By default, product operates as a Kiosk with 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 29	Windows Defender and approved CoTS antimalware software typically have a history feature and/or log.		
Note 30	Windows Firewall enabled and configured to allow product application network traffic. Patient data only sent to configured DICOM devices.		
Note 31	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 32	Use of unique product accounts is the decision of the customer. Generic accounts (i.e. PACS Admin) can be removed.		
Note 33	Enabled by default, locking the user for 15 minutes after 3 failed logon attempts.		
Note 34	Configured by default to require complex passwords, by Microsoft standards, with a minimum length of 8 characters. Configurable by customer.		

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Note 35	Passwords not configured to automatically expire by default. Configurable by customer.		
Note 36	Fingerprint scanner for product application login available for some configurations.		
Note 37	Product application leverages Windows Operating System for user authentication. Credentials not stored in application databases. Credentials stored/managed securely via Operating System.		
Note 39	SBOM reviewed and updated as required during product update cycles.		
Note 40	Product application performs integrity check of all static binary files during startup. Application libraries leverage .NET code signing.		
Note 41	Software update install packages include integrity checks for all packaged files. Integrity check automatically performed during installations.		
Note 42	Product utilizes role-based privileges for many sensitive areas of the application. For example, a privileged user (i.e Tech Manager) is required to delete patient procedures.		
Note 43	Default product application users can be removed. Windows Administrator and Guest account renamed and disabled.		
Note 44	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 45	Can be configured, not restricted by default. If configured, communicate change to service representative.		
Note 46	Hardware installation would require tools, software would require OS authentication.		
Note 47	Hologic has hardened the product against DISA STIG guidelines and vulnerability assessments. Additional hardening or concerns may be discussed with Hologic. Implementing additional hardening changes may negatively impact the product.		
Note 48	Security documentation available on product support website.		
Note 49	Product user manual contains details for deleting patient studies as a privileged application user. For permanent deletion of all sensitive data, contact support.		
Note 50	Sensitive PII stored to disk and/or the product databases are encrypted with AES 256. PII stored to application logs are both encrypted and one-way hashed.		
Note 51	Changes to encryption keys should be done at time of installation and can be modified upon request.		
Note 52	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 53	Remote configuration of product via Service Tools web application. Ability to push approved software changes over Hologic Connect.		

Software Bill of Materials (SBoM)

Component Name	Developer	Version(s)	Product Use
Windows 10 IoT Enterprise x64	Microsoft	LTSB 2016 LTSB 2019	Operating System
SQL Server 2017 Express	Microsoft	14.0.3238.1	Product application database software.
.NET Framework	Microsoft	3.5 4.6.2	Product application support libraries.
.NET Core	Microsoft	2.1.2	Product configuration web application.
Internet Information Services (IIS)	Microsoft	10.0.14393.0 10.0.17763.1	Product configuration web application.
Internet Explorer 11	Microsoft	11.2214.14393.0 11.379.17763.0	Microsoft Edge not available for product OS (IoT).
Visual C++ Redistributable	Microsoft	9.0.21022 9.0.30729.17 10.0.40219 11.0.61030 12.0.21005 14.12.25810	Product application support libraries.
ELO Multi Touch	ELO	6.9.15.2	Touch Monitor
NVIDIA Graphics Driver	NVIDIA	24.21.13.9811	Graphics Card (GPU)
DigitalPersona One Touch	DigitalPersona	1.6.1.965	Fingerprint Scanner
U.are.U Fingerprint Reader Driver	DigitalPersona	4.0.0.143	Fingerprint Scanner
Honeywell HSM USB Serial Driver	Honeywell	3.4.15	Barcode Scanner
Honeywell OPOS Suite	Honeywell	1.13.4.21	Barcode Scanner
MetroPOS Administrator	Honeywell	2.2.1.4	Barcode Scanner
Personal Solution Pac	Eaton	6.10.100.1281	Uninterruptible Power Supply (UPS)
Linak CBD6S Configurator	Linak	1.0.0	Height adjustable console.
Cygwin	Open Source	2.8.0	Hologic Connect
OpenSSH	Open Source	7.5p1	Hologic Connect
TightVNC	GlavSoft	2.8.8.0	Hologic Connect Configured for localhost connection only.
DCF	Laurel Bridge Software	3.3.12.369	Dicom Communication
PDFSharp	empira Software GmbH	1.50.5147.0	PDF Viewer for CalTool
IronPython	Open Source	2.7.5	Hologic Connect
Nant	Open Source	0.91.4312.0	Application setup/unsetup
PCAN	PEAK-System Technik GmbH	1.3.3.61	CAN API library
NirCmd	NirSoft	2.6.5.215	Screenshot during application crash.
CodeSmith	Eric J. Smith	2.6.0.117	Development Tool
ExcelML Writer	Carlos Ag	1.0.0.6	Development Tool
Dev Express	Developer Express Inc.	7.2.11.0	Development Tool
Nunit	Nunit Software	3.4.1.0	Development Tool
Nsubstitute	Open Source (Nsubstitute Team)	1.4.3.0	Development Tool
Xceed Wpf Toolkit	Xceed Software Inc.	3.6.0.0	Development Tool
CUDA	NVIDIA	6.14.11.10010	Image processing and display

Additional Notes

	<p>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.</p>
Note 1	