

Manufacturer Disclosure Statement for Medical Device Security -- MDS2

Hologic, Inc.

SecurView 12.0 and later

RD-04687 Revision 002

1-May-2025

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	Mammography Review Workstation	—			
DOC-3	Device Model	SecurView 12.0 and later	—			
DOC-4	Document ID	RD-04687 Revision 002	—			
DOC-5	Manufacturer Contact Information	Boris Polissky boris.polissky@hologic.com	—			
DOC-6	Intended use of device in network-connected environment:	_____	—			
DOC-7	Document Release Date	May-25	—			
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
MP1I-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
MP1I-2	Does the device maintain personally identifiable information?	Yes	—		AR-2	A.15.1.4

Question ID	Question	See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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	Note 2		
MPII-2.4	Does the device store personally identifiable information in a database?	Yes			
MPII-2.5	Does the device allow configuration to automatically delete local personally identifiable information after it is stored to a long term solution?	Yes	—	AR-2	A.15.1.4
MPII-2.6	Does the device import/export personally identifiable information with other systems (e.g., a wearable monitoring device might export personally identifiable information to a server)?	Yes	—	AR-2	A.15.1.4
MPII-2.7	Does the device maintain personally identifiable information when powered off, or during power service interruptions?	Yes	—	AR-2	A.15.1.4
MPII-2.8	Does the device allow the internal media to be removed by a service technician (e.g., for separate destruction or customer retention)?	Yes	—		
MPII-2.9	Does the device allow personally identifiable information records be stored in a separate location from the device’s operating system (i.e. secondary internal drive, alternate drive partition, or remote storage location)?	No	—	AR-2	A.15.1.4
MPII-3	Does the device have mechanisms used for the transmitting, importing/exporting of personally identifiable information?	Yes	—	AR-2	A.15.1.4
MPII-3.1	Does the device display personally identifiable information (e.g., video display, etc.)?	Yes	—	AR-2	A.15.1.4
MPII-3.2	Does the device generate hardcopy reports or images containing personally identifiable information?	Yes	Note 3	AR-2	A.15.1.4

Question ID	Question	See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013	
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	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		AR-2	A.15.1.4	
MPII-3.5	Does the device transmit/receive personally identifiable information via a wired network connection (e.g., RJ45, fiber optic, etc.)?	Yes		AR-2	A.15.1.4	
MPII-3.6	Does the device transmit/receive personally identifiable information via a wireless network connection (e.g., WiFi, Bluetooth, NFC, infrared, cellular, etc.)?	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?	Yes				
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	
<b>AUTOMATIC LOGOFF (ALOF)</b> <i>The device's ability to prevent access and misuse by unauthorized users if device is left idle for a period of time.</i>			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013	
ALOF-1	Can the device be configured to force reauthorization of logged-in user(s) after a predetermined length of inactivity (e.g., auto-logout, session lock, password protected screen saver)?	Yes	Note 6	Section 5.1, ALOF	AC-12	None
ALOF-2	Is the length of inactivity time before auto-logout/screen lock user or administrator configurable?	Yes		Section 5.1, ALOF	AC-11	A.11.2.8, A.11.2.9

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Question ID	Question	See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013	
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	Section 5.2, AUDT	AU-2	None	
AUDT-2.8.1	Remote or on-site support?	Yes	Section 5.2, AUDT	AU-2	None	
AUDT-2.8.2	Application Programming Interface (API) and similar activity?	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	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				

Question ID	Question		See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
AUDT-5.3	Via Other communications (e.g., external service device, mobile applications)?	Yes	Note 10			
AUDT-5.4	Are audit logs encrypted in transit or on storage media?	Yes	Note 11			
AUDT-6	Can audit logs be monitored/reviewed by owner/operator?	Yes	—			
AUDT-7	Are audit logs protected from modification?	Yes	—	Section 5.2, AUDT	AU-2	None
AUDT-7.1	Are audit logs protected from access?	Yes				
AUDT-8	Can audit logs be analyzed by the device?	No	—	Section 5.2, AUDT	AU-2	None

	AUTHORIZATION (AUTH) <i>The ability of the device to determine the authorization of users.</i>			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
AUTH-1	Does the device prevent access to unauthorized users through user login requirements or other mechanism?	Yes	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	AD	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?	N/A	—			

	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>			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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Question ID	Question	See note	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	—				
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?	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 16				
CSUP-4.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	Yes	Note 16				
CSUP-4.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	See Notes	Note 16				

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CSUP-4.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes	Note 16				
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?	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 17				

Question ID	Question	See note		IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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 17			
CSUP-11.2	Is there an update review cycle for the device?	Yes	Note 19			

HEALTH DATA DE-IDENTIFICATION (DIDT)				IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
<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?	No	—	Section 5.6, DIDT	None	ISO 27038
DIDT-1.1	Does the device support de-identification profiles that comply with the DICOM standard for de-identification?	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
<i>The ability to recover after damage or destruction of device data, hardware, software, or site configuration information.</i>						
DTBK-1	Does the device maintain long term primary storage of personally identifiable information / patient information (e.g. PACS)?	No	—			
DTBK-2	Does the device have a “factory reset” function to restore the original device settings as provided by the manufacturer?	Yes	—	Section 5.7, DTBK	CP-9	A.12.3.1



Question ID	Question	See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
DTBK-3	Does the device have an integral data backup capability to removable media?	Yes	Section 5.7, DTBK	CP-9	A.12.3.1
DTBK-4	Does the device have an integral data backup capability to remote storage?	Yes			
DTBK-5	Does the device have a backup capability for system configuration information, patch restoration, and software restoration?	Yes			
DTBK-6	Does the device provide the capability to check the integrity and authenticity of a backup?	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
<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	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
<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	Section 5.9, IGAU	SC-28	A.18.1.3
IGAU-2	Does the device provide error/failure protection and recovery mechanisms for stored health data (e.g., RAID-5)?	No	Section 5.9, IGAU	SC-28	A.18.1.3
MALWARE DETECTION/PROTECTION (MLDP)			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
<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	Section 5.10, MLDP		

Question ID	Question	See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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?	Yes 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 27	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?	Yes Note 29			
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 —	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		
<b>NODE AUTHENTICATION (NAUT)</b> <i>The ability of the device to authenticate communication partners/nodes.</i>			<b>IEC TR 80001-2-2:2012</b>	<b>NIST SP 800-53 Rev. 4</b>	<b>ISO 27002:2013</b>



Question ID	Question	See note		IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013			
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 26						
CONN-7.1	Is TLS configurable?	Yes	Note 26						
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>				IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013			
PAUT-1	Does the device support and enforce unique IDs and passwords for all users and roles (including service accounts)?	Yes	Note 27	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 27	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	AD	Section 5.12, PAUT	IA-5	A.9.2.1			
PAUT-3	Is the device configurable to lock out a user after a certain number of unsuccessful logon attempts?	No		Section 5.12, PAUT	IA-2	A.9.2.1			
PAUT-4	Are all default accounts (e.g., technician service accounts, administrator accounts) listed in the documentation?	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 28	Section 5.12, PAUT	IA-2	A.9.2.1			
PAUT-7	Does the device support account passwords that expire periodically?	Yes	Note 29						
PAUT-8	Does the device support multi-factor authentication?	No	—						

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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 30			
PAUT-14.1	Are credentials stored using a secure method?	Yes Note 30			
<b>PHYSICAL LOCKS (PLOK)</b> <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>			<b>IEC TR 80001-2-2:2012</b>	<b>NIST SP 800-53 Rev. 4</b>	<b>ISO 27002:2013</b>
PLOK-1	Is the device software only? If yes, answer “N/A” to remaining questions in this section.	Yes Note 31	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
<b>ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP)</b> <i>Manufacturer’s plans for security support of third-party components within the device’s life cycle.</i>			<b>IEC TR 80001-2-2:2012</b>	<b>NIST SP 800-53 Rev. 4</b>	<b>ISO 27002:2013</b>
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

Question ID	Question	See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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
<b>SOFTWARE BILL OF MATERIALS (SBoM)</b> <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>			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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 32		
<b>SYSTEM AND APPLICATION HARDENING (SAHD)</b> <i>The device's inherent resistance to cyber attacks and malware.</i>			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
SAHD-1	Is the device hardened in accordance with any industry standards?	No	Section 5.15, SAHD	CM-7 AC-17(2)/IA-3	A.12.5.1* 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	Yes			

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Question ID	Question	See note	IEC TR 80001-2-2:2012		NIST SP 800-53 Rev. 4	ISO 27002:2013	
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?	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?	No	Section 5.15, SAHD		CM-7	A.12.5.1*	
SAHD-5.1	Does the device provide role-based access controls?	N/A	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?	N/A	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?	N/A	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)?	No					

Question ID	Question	See note		IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
SAHD-12	Can unauthorized software or hardware be installed on the device without the use of physical tools?	See Notes	Note 33			
SAHD-13	Does the product documentation include information on operational network security scanning by users?					
SAHD-14	Can the device be hardened beyond the default provided state?					
SAHD-14.1	Are instructions available from vendor for increased hardening?					
SHAD-15	Can the system prevent access to BIOS or other bootloaders during boot?					
SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?					
<b>SECURITY GUIDANCE (SGUD)</b> <i>Availability of security guidance for operator and administrator of the device and manufacturer sales and service.</i>				<b>IEC TR 80001-2-2:2012</b>	<b>NIST SP 800-53 Rev. 4</b>	<b>ISO 27002:2013</b>
SGUD-1	Does the device include security documentation for the owner/operator?	Yes	Note 34	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?					
SGUD-3	Are all access accounts documented?			Section 5.16, SGUD	MP-6	A.8.2.3, A.8.3.1, A.8.3.2, A.11.2.7 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?					
SGUD-4	Does the product include documentation on recommended compensating controls for the device?	Yes	Note 16			
<b>HEALTH DATA STORAGE CONFIDENTIALITY (STCF)</b> <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>				<b>IEC TR 80001-2-2:2012</b>	<b>NIST SP 800-53 Rev. 4</b>	<b>ISO 27002:2013</b>
STCF-1	Can the device encrypt data at rest?	Yes	Note 40	Section 5.17, STCF	SC-28	A.8.2.3



Question ID	Question	See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
STCF-1.1	Is all data encrypted or otherwise protected?	Yes			
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	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
<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	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	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-2.1	If data is not encrypted by default, can the customer configure encryption options?	Yes			
TXCF-3	Is personally identifiable information transmission restricted to a fixed list of network destinations?	Yes	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
<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	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			

Question ID	Question	See note		IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
	REMOTE SERVICE (RMOT)			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
	<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	—		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?	Yes	—		AC-17	A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2
RMOT-2	Does the device permit or use remote service connections for predictive maintenance data?	Yes	—			
RMOT-3	Does the device have any other remotely accessible functionality (e.g. software updates, remote training)?	Yes	Note 39			
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	Patients may be deleted by privileged users on demand and/or automatically by product application reclaimer. Reclaimer times and thresholds configurable.					
Note 3	Optional printing of patient images.					
Note 4	Optional importing and exporting of patient procedures.					
Note 5	Via Ethernet connection					

Question ID	Question	See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
	Auto-logoff time for SecurView can be configured to: 10, 20, 30, 60, 120 minutes. The default setting is 30 minutes.				
	Auto-logoff from SecurView cannot be manually invoked via shortcut key; however, one can use Windows key + L key to invoke Windows lock screen.				
Note 6	Software installation and updates are logged.				
Note 7	Log date/time stamp based on current Windows date/time for the system.				
Note 8					
Note 9	Windows can be configured with an NTP server.				
	Can be exported and downloaded by remote or local service users				
Note 10	Audit and application log files encrypted.				
Note 11	User login with password				
Note 12					
	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 13	Strongly recommend configuring the product in its own Organizational Unit and limiting policy changes pushed to the system.				
Note 14					
	See product support website for list of validated security patches. Validation of latest security patches performed at regular intervals for the product.				
Note 15					
	Microsoft Windows Defender enabled by default. Option available to install validated CoTS antimalware products. See product support website for list of antimalware software solutions and installation guidance. Malware definitions can be updated by customer at will. SecurView provides a list of folders to exclude from real-time scanning				
Note 16					
	Validated security patches for the product are posted to the product support website at regular intervals. Vulnerability assessments, leveraging industry standard tools, and Windows security patch validation occur at regular intervals.				
Note 17					
Note 18					

Question ID	Question	See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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 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 21	Product not designed for long term storage. Patient studies should be stored to long term storage.				
Note 22	See Cybersecurity Product Report that contains folders to exclude from real-time scanning.				
Note 23	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 24	Windows Defender and 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 and communication for specific ports.				
Note 26	External network traffic can 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 27	Use of unique product accounts is the decision of the customer.				
Note 28	Configured by default to require complex passwords, by Microsoft standards, with a minimum length of 8 characters. Configurable by customer.				
Note 29	Passwords not configured to automatically expire by default. Configurable by customer. Part of AD configuration.				

Question ID	Question	See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
	When AD is not used SecurView Users/password information is created and stored in the application.				
Note 30	All data is in the database and is encrypted.				
Note 31	One of the options is software only				
Note 32	SBOM reviewed and updated as required during product update cycles.				
Note 33	Hardware installation would require tools, software would require OS authentication.				
Note 34	Security documentation available on product support website.				
Note 35	Product user manual contains details for deleting patient studies as a privileged application user. For permanent deletion of all sensitive data, contact support.				
Note 36	Sensitive PII stored to disk and/or the product databases are encrypted with AES 256 or BitLocker. PII stored to application logs are both encrypted and one-way hashed.				
Note 37	Changes to encryption keys should be done at time of installation and can be modified upon request.				
Note 38	Exporting patient studies to removable media has an option for de-identifying by selecting exporting as TIFF. Network transmission is typically over standard DICOM and can be encrypted at the network level.				
Note 39	Ability to push approved software changes and make configuration updates over Unifi Connect.				
Note 40	SecurView hardware implements FIPS140-2 encryption, consisting of AES 256 self-encrypting drives, or BitLocker.				

Software Bill of Materials (SBOM)			
Component Name	Developer	Version(s)	Product Use
Internet Explorer 11	Microsoft	11.2214.14393.0	Microsoft Edge not available for product OS (IoT).
Windows Server 2016	Microsoft	11.379.17763.0	
		Version 1607 OS build 149393.2273	Operating System
Windows 10 IoT Enterprise x64	Microsoft	LTSB 2016	Operating System
Visual C++ 2005 x64 Redistributables	Microsoft	LTSC 2019	
Visual C++ 2010 x64 Redistributables	Microsoft	6.0.2900.2180	Visual C++ redistributable package
Visual C++ 2013 x64 Redistributables	Microsoft	Service Pack 1, 10.0.40219.325	Visual C++ redistributable package
Visual C++ 2013 x64 Redistributables	Microsoft	12.0.40664.0	Visual C++ redistributable package
Visual C++ 2019 x64 Redistributables (vc_redist)	Microsoft	14.32.31326.0	Visual C++ redistributable package
MQMTool	MeVis	1.4.4	Build Process
PrintSCP	CharruaSoft.com	11.0	Testing
Python	Python Software Foundation	2.5.1	Development Tool
7-Zip	www.7zip.org	24.09	Zip software
Autolt	Autolt Consulting Ltd	v3.3.14.2	Development Tool
Acrobat Reader DC	Adobe Systems Incorporated	2018.011.20055	Manage PDF files
DirectX	Microsoft	9.0c June 2010	Programming interface for handling tasks related to multimedia on MS platform
DCMTK	Kuratorium OFFIS e.V. Healthcare Informat	3.5.4	Development tool
HASP/LDK	Sentinel	8.13	Dongle Driver
IPP	Intel Corporation	2020.0.166	Multi-threaded software library
Merge DICOM Toolkit	Merge Healthcare, an IBM Company	5.11.0.0	DICOM Communication
MyDefrag	Jeroen Kessels	4.3.1	Disk management
PCScan	A Horländer	5.0.0.1	Development tool
PostgreSQL Server DBMS	PostgreSQL Global Development Group	14.5	Database
Qt	The Qt Company	4.8.6	Development framework
stlab	stlab.cc	1.5.4	Development library
StackWalker	Jochen Kalmbach	v14	Development Tool
Barco Video drivers	Barco	v10.184.3.6	Video drivers
Barco QA Web Enterprise	Barco	2.18.0	Barco Monitor calibration
Barco QA Web Agent	Barco	1.13.21	Barco Monitor calibration
Barco TouchBar App	Barco	1.08997.35834	Barco application for OneLook monitor
Double Black Imaging videocard drivers	AMD	31.0.24026.1002	AMD Radeon video drivers
Double Black Imaging CFS QC	DBI	Revision P5	DBI CFS QC Tool
APC Powerchute Business Edition	APC	V 10.0.5	APC Powerchute UPS configuration
Roxio CD Burner	Roxio	3.3.0	DVD/CD Burner

#### Additional Notes

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.