


**Artwork and Signature File for:**

**MAN-04421 “MDS2 SHEET FOR SELENIA (SOLARIS)”**

Artwork consists of:

- 6 (six) 8 ½ inch x 11 inch sheet(s) attached.

REV AUTHORED BY	DATE	<b>HOLOGIC™</b>	 <b>SIGNATURES ON FILE</b>	
S.SCHNEIDER	3/3/2015			
REV DRAFTED BY	DATE	<b>MDS2 SHEET FOR SELENIA (SOLARIS)</b>	DOCUMENT NUMBER	REV
S.SCHNEIDER	3/3/2015		AW-13227	001
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**Manufacturer Disclosure Statement for Medical Device Security – MDS<sup>2</sup>**

**DEVICE DESCRIPTION**

Device Category <a href="#">Mammography System</a>	Manufacturer <a href="#">Hologic, Inc</a>	Document ID <a href="#">MAN-04421</a>	Document Release Date <a href="#">3/12/2015</a>
Device Model <a href="#">Selenia</a>	Software Revision <a href="#">3.4.4</a>	Software Release Date <a href="#">1/17/2014</a>	

Manufacturer or Representative Contact Information	Company Name <a href="#">Hologic, Inc</a>	Manufacturer Contact Information <a href="#">Chris.Fischer@hologic.com</a>
	Representative Name/Position <a href="#">Chris Fischer</a>	

**Intended use of device** in network-connected environment:  
[The Hologic Selenia 2D Mammography system is designed to capture and transmit Conventional Mammography images to a downstream PACS and Workstation for diagnosis.](#)

**MANAGEMENT OF PRIVATE DATA**

Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form.		Yes, No, N/A, or See Note	Note #
A	Can this <b>device</b> display, transmit, or maintain <b>private data</b> (including <b>electronic Protected Health Information [ePHI]</b> )?	Yes	—
B	Types of <b>private data</b> elements that can be maintained by the <b>device</b> :		
	B.1 Demographic (e.g., name, address, location, unique identification number)?	Yes	—
	B.2 Medical record (e.g., medical record #, account #, test or treatment date, <b>device</b> identification number)?	Yes	—
	B.3 Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)?	Yes	—
	B.4 Open, unstructured text entered by <b>device user/operator</b> ?	Yes	—
	B.5 <b>Biometric data</b> ?	No	—
	B.6 Personal financial information?	No	—
C	Maintaining <b>private data</b> - Can the <b>device</b> :		
	C.1 Maintain <b>private data</b> temporarily in volatile memory (i.e., until cleared by power-off or reset)?	Yes	—
	C.2 Store <b>private data</b> persistently on local media?	Yes	—
	C.3 Import/export <b>private data</b> with other systems?	Yes	—
	C.4 Maintain <b>private data</b> during power service interruptions?	Yes	—
D	Mechanisms used for the transmitting, importing/exporting of <b>private data</b> – Can the <b>device</b> :		
	D.1 Display private data (e.g., video display, etc.)?	Yes	—
	D.2 Generate hardcopy reports or images containing <b>private data</b> ?	No	—
	D.3 Retrieve <b>private data</b> from or record <b>private data</b> to <b>removable media</b> (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick, etc.)?	Yes	—
	D.4 Transmit/receive or import/export <b>private data</b> via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire, etc.)?	Yes	—
	D.5 Transmit/receive <b>private data</b> via a wired network connection (e.g., LAN, WAN, VPN, intranet, Internet, etc.)?	Yes	—
	D.6 Transmit/receive <b>private data</b> via an integrated wireless network connection (e.g., WiFi, Bluetooth, infrared, etc.)?	Yes	—
	D.7 Import <b>private data</b> via scanning?	No	—
	D.8 Other?	No	—

Management of Private Data notes:

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**SECURITY CAPABILITIES**

Refer to Section 2.3.2 of this standard for the proper interpretation of information requested in this form.	Yes, No, N/A, or See Note	Note #
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<b>1</b>	<b>AUTOMATIC LOGOFF (ALOF)</b> The <b>device's</b> ability to prevent access and misuse by unauthorized <b>users</b> if <b>device</b> is left idle for a period of time.		
1-1	Can the <b>device</b> be configured to force reauthorization of logged-in <b>user(s)</b> after a predetermined length of inactivity (e.g., auto-logoff, session lock, password protected screen saver)?	Yes	—
1-1.1	Is the length of inactivity time before auto-logoff/screen lock <b>user</b> or administrator configurable? (Indicate time [fixed or configurable range] in notes.)	Yes	Con figu
1-1.2	Can auto-logoff/screen lock be manually invoked (e.g., via a shortcut key or proximity sensor, etc.) by the <b>user</b> ?	Yes	—
ALOF notes:			

<b>2</b>	<b>AUDIT CONTROLS (AUDT)</b> The ability to reliably audit activity on the <b>device</b> .		
2-1	Can the <b>medical device</b> create an <b>audit trail</b> ?	Yes	—
2-2	Indicate which of the following events are recorded in the audit log:		
2-2.1	Login/logout	Yes	—
2-2.2	Display/presentation of data	Yes	—
2-2.3	Creation/modification/deletion of data	Yes	—
2-2.4	Import/export of data from <b>removable media</b>	Yes	—
2-2.5	Receipt/transmission of data from/to external (e.g., network) connection	Yes	—
2-2.5.1	<b>Remote service</b> activity	Yes	—
2-2.6	Other events? (describe in the notes section)	N/A	—
2-3	Indicate what information is used to identify individual events recorded in the audit log:		
2-3.1	<b>User ID</b>	Yes	—
2-3.2	Date/time	Yes	—
AUDT notes:			

<b>3</b>	<b>AUTHORIZATION (AUTH)</b> The ability of the device to determine the authorization of users.		
3-1	Can the <b>device</b> prevent access to unauthorized <b>users</b> through <b>user</b> login requirements or other mechanism?	Yes	—
3-2	Can <b>users</b> be assigned different privilege levels within an application based on 'roles' (e.g., guests, regular <b>users</b> , power <b>users</b> , administrators, etc.)?	Yes	—
3-3	Can the <b>device</b> owner/ <b>operator</b> obtain unrestricted administrative privileges (e.g., access operating system or application via local root or admin account)?	Yes	—
AUTH notes: System supports individual operator accounts and differing operator roles (Technologic and Manager.) Manager level users can create new accounts and revoke existing accounts.			

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<b>4 CONFIGURATION OF SECURITY FEATURES (CNFS)</b>					
The ability to configure/re-configure <b>device security capabilities</b> to meet <b>users'</b> needs.					
4-1	Can the <b>device</b> owner/operator reconfigure product <b>security capabilities</b> ?			No	—
CNFS notes:					
<b>5 CYBER SECURITY PRODUCT UPGRADES (CSUP)</b>					
The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade <b>device's</b> security patches.					
5-1	Can relevant OS and <b>device</b> security patches be applied to the <b>device</b> as they become available?			No	—
5-1.1	Can security patches or other software be installed remotely?			No	—
CSUP notes:					
<b>6 HEALTH DATA DE-IDENTIFICATION (DIDT)</b>					
The ability of the <b>device</b> to directly remove information that allows identification of a person.					
6-1	Does the <b>device</b> provide an integral capability to de-identify <b>private data</b> ?			Yes	—
DIDT notes:					
<b>7 DATA BACKUP AND DISASTER RECOVERY (DTBK)</b>					
The ability to recover after damage or destruction of <b>device</b> data, hardware, or software.					
7-1	Does the <b>device</b> have an integral data backup capability (i.e., backup to remote storage or <b>removable media</b> such as tape, disk)?			No	—
DTBK notes: System only acts as a temporary store of patient data before it is transmitted to PACS. Any disaster recovery will be performed by Hologic Service.					
<b>8 EMERGENCY ACCESS (EMRG)</b>					
The ability of <b>device users</b> to access <b>private data</b> in case of an emergency situation that requires immediate access to stored <b>private data</b> .					
8-1	Does the <b>device</b> incorporate an <b>emergency access</b> ("break-glass") feature?			No	—
EMRG notes:					
<b>9 HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU)</b>					
How the <b>device</b> ensures that data processed by the <b>device</b> has not been altered or destroyed in an unauthorized manner and is from the originator.					
9-1	Does the <b>device</b> ensure the integrity of stored data with implicit or explicit error detection/correction technology?			No	—
IGAU notes:					

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<b>10 MALWARE DETECTION/PROTECTION (MLDP)</b>				
The ability of the <b>device</b> to effectively prevent, detect and remove malicious software ( <b>malware</b> ).				
10-1	Does the <b>device</b> support the use of <b>anti-malware</b> software (or other <b>anti-malware</b> mechanism)?		No	—
10-1.1	Can the <b>user</b> independently re-configure <b>anti-malware</b> settings?		No	—
10-1.2	Does notification of <b>malware</b> detection occur in the <b>device user</b> interface?		No	—
10-1.3	Can only manufacturer-authorized persons repair systems when <b>malware</b> has been detected?		Yes	—
10-2	Can the device owner install or update <b>anti-virus software</b> ?		No	—
10-3	Can the device owner/ <b>operator</b> (technically/physically) update virus definitions on manufacturer-installed <b>anti-virus software</b> ?		No	—
MLDP notes:				
<b>11 NODE AUTHENTICATION (NAUT)</b>				
The ability of the <b>device</b> to authenticate communication partners/nodes.				
11-1	Does the <b>device</b> 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?		No	—
NAUT notes:				
<b>12 PERSON AUTHENTICATION (PAUT)</b>				
Ability of the <b>device</b> to authenticate <b>users</b>				
12-1	Does the <b>device</b> support <b>user/operator</b> -specific username(s) and password(s) for at least one <b>user</b> ?		Yes	—
12-1.1	Does the device support unique <b>user/operator</b> -specific IDs and passwords for multiple users?		Yes	—
12-2	Can the <b>device</b> be configured to authenticate <b>users</b> through an external authentication service (e.g., MS Active Directory, NDS, LDAP, etc.)?		No	—
12-3	Can the <b>device</b> be configured to lock out a <b>user</b> after a certain number of unsuccessful logon attempts?		No	—
12-4	Can default passwords be changed at/prior to installation?		Yes	—
12-5	Are any shared <b>user</b> IDs used in this system?		No	—
12-6	Can the <b>device</b> be configured to enforce creation of <b>user</b> account passwords that meet established complexity rules?		No	—
12-7	Can the <b>device</b> be configured so that account passwords expire periodically?		No	—
PAUT notes:				
<b>13 PHYSICAL LOCKS (PLOK)</b>				
Physical locks can prevent unauthorized <b>users</b> with physical access to the <b>device</b> from compromising the integrity and confidentiality of <b>private data</b> stored on the <b>device</b> or on <b>removable media</b> .				
13-1	Are all <b>device</b> components maintaining <b>private data</b> (other than <b>removable media</b> ) physically secure (i.e., cannot remove without tools)?		Yes	—
PLOK notes:				

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<b>14</b>	<b>ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP)</b>				
	Manufacturer's plans for security support of 3rd party components within <b>device</b> life cycle.				
14-1	In the notes section, list the provided or required (separately purchased and/or delivered) operating system(s) - including version number(s).			Yes	
14-2	Is a list of other third party applications provided by the manufacturer available?  SunOS 5.10 (SPARC)			No	3rd
RDMP notes:					
<b>15</b>	<b>SYSTEM AND APPLICATION HARDENING (SAHD)</b>				
	The <b>device's</b> resistance to cyber attacks and <b>malware</b> .				
15-1	Does the <b>device</b> employ any hardening measures? Please indicate in the notes the level of conformance to any industry-recognized hardening standards.			Yes	
15-2	Does the <b>device</b> employ any mechanism (e.g., release-specific hash key, checksums, etc.) to ensure the installed program/update is the manufacturer-authorized program or software update?			No	—
15-3	Does the <b>device</b> have external communication capability (e.g., network, modem, etc.)?			Yes	—
15-4	Does the file system allow the implementation of file-level access controls (e.g., New Technology File System (NTFS) for MS Windows platforms)?			N/A	—
15-5	Are all accounts which are not required for the <b>intended use</b> of the <b>device</b> disabled or deleted, for both <b>users</b> and applications?			Yes	—
15-6	Are all shared resources (e.g., file shares) which are not required for the <b>intended use</b> of the <b>device</b> , disabled?			Yes	—
15-7	Are all communication ports which are not required for the <b>intended use</b> of the <b>device</b> closed/disabled?			No	—
15-8	Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.), which are not required for the <b>intended use</b> of the <b>device</b> deleted/disabled?			Yes	—
15-9	Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the <b>intended use</b> of the <b>device</b> deleted/disabled?			Yes	—
15-10	Can the <b>device</b> boot from uncontrolled or <b>removable media</b> (i.e., a source other than an internal drive or memory component)?			Yes	—
15-11	Can software or hardware not authorized by the <b>device</b> manufacturer be installed on the device without the use of tools?			Yes	—
SAHD notes: The Product Development Life Cycle (PDLC) of the device incorporates numerous security scans and other vulnerability assessments which are incorporated into the product design.					
<b>16</b>	<b>SECURITY GUIDANCE (SGUD)</b>				
	The availability of security guidance for <b>operator</b> and administrator of the system and manufacturer sales and service.				
16-1	Are security-related features documented for the <b>device user</b> ?			No	—
16-2	Are instructions available for <b>device</b> /media sanitization (i.e., instructions for how to achieve the permanent deletion of personal or other sensitive data)?			Yes	Cov ere
SGUD notes: Hologic provides a Cyber Security Best Practices document on its website that provides recommendations on network security with the Selenia product.					

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<b>17 HEALTH DATA STORAGE CONFIDENTIALITY (STCF)</b>				
The ability of the <b>device</b> to ensure unauthorized access does not compromise the integrity and confidentiality of <b>private data</b> stored on <b>device</b> or <b>removable media</b> .				
17-1	Can the <b>device</b> encrypt data at rest?		No	—
STCF notes:	System is only a temporary store of ePHI. System can be configured to automatically remove studies shortly after completion and successful transmission to PACS, and supports manual removal of patient records.			
<b>18 TRANSMISSION CONFIDENTIALITY (TXCF)</b>				
The ability of the <b>device</b> to ensure the confidentiality of transmitted <b>private data</b> .				
18-1	Can <b>private data</b> be transmitted only via a point-to-point dedicated cable?		No	—
18-2	Is <b>private data</b> encrypted prior to transmission via a network or <b>removable media</b> ? (If yes, indicate in the notes which encryption standard is implemented.)		No	—
18-3	Is <b>private data</b> transmission restricted to a fixed list of network destinations?		No	—
TXCF notes:				
<b>19 TRANSMISSION INTEGRITY (TXIG)</b>				
The ability of the <b>device</b> to ensure the integrity of transmitted <b>private data</b> .				
19-1	Does the <b>device</b> support any mechanism intended to ensure data is not modified during transmission? (If yes, describe in the notes section how this is achieved.)		No	—
TXIG notes:				
<b>20 OTHER SECURITY CONSIDERATIONS (OTHR)</b>				
Additional security considerations/notes regarding <b>medical device</b> security.				
20-1	Can the <b>device</b> be serviced remotely?		Yes	—
20-2	Can the <b>device</b> restrict remote access to/from specified devices or <b>users</b> or network locations (e.g., specific IP addresses)?		Yes	—
20-2.1	Can the <b>device</b> be configured to require the local <b>user</b> to accept or initiate remote access?		No	—
OTHR notes:				