Manufacturer Disclosure Statement for Medical Device Security – MDS[2]

DEVICE DESCRIPTION

Device Category	Manufacturer	Document ID	Document Release Date
Breast Biopsy System	Hologic, Inc.	MAN-05436-001	
Device Model	**Software Revision**		**Software Release Date**
Brevera Breast Biopsy System	1.0.1.2		Jul. 31, 2017

	Company Name	Manufacturer Contact Information
Manufacturer or Representative Contact Information	Hologic, Inc.	Mallory.Berko@Hologic.com
	Representative Name/Position	
	Mallory Berko	

Intended use of **device** in network-connected environment:

The Hologic Brevera® breast biopsy system with CorLumina® imaging technology is the world's first and only solution to combine vacuum-assisted tissue acquisition, real-time imaging, verification and advanced post-biopsy handling – all in one, integrated system. The system is fully functional with no network connectivity, however it can be interfaced to a RIS to retrieve patient demographic information and to a PACS to archive biopsy procedure images.

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 **device** display, transmit, or maintain **private data** (including **electronic Protected Health Information** [ePHI])?	Yes	
B	Types of **private data** elements that can be maintained by the **device**:		
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, **device** 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 **device user/operator**?	Yes	
B.5	**Biometric data**?	No	
B.6	Personal financial information?	No	
C	Maintaining **private data** - Can the **device**:		
C.1	Maintain **private data** temporarily in volatile memory (i.e., until cleared by power-off or reset)?	Yes	
C.2	Store **private data** persistently on local media?	Yes	
C.3	Import/export **private data** with other systems?	Yes	
C.4	Maintain **private data** during power service interruptions?	Yes	
D	Mechanisms used for the transmitting, importing/exporting of **private data** – Can the **device**:		
D.1	Display private data (e.g., video display, etc.)?	Yes	
D.2	Generate hardcopy reports or images containing **private data**?	Yes	
D.3	Retrieve **private data** from or record **private data** to **removable media** (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick, etc.)?	Yes	
D.4	Transmit/receive or import/export **private data** via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire, etc.)?	Yes	
D.5	Transmit/receive **private data** via a wired network connection (e.g., LAN, WAN, VPN, intranet, Internet, etc.)?	Yes	
D.6	Transmit/receive **private data** via an integrated wireless network connection (e.g., WiFi, Bluetooth, infrared, etc.)?	Yes	
D.7	Import **private data** 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 #
1	**AUTOMATIC LOGOFF (ALOF)**		
	The **device**'s ability to prevent access and misuse by unauthorized **users** if **device** is left idle for a period of time.		
1-1	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	
1-1.1	Is the length of inactivity time before auto-logoff/screen lock **user** or administrator configurable? (Indicate time [fixed or configurable range] in notes.)	Yes	1
1-1.2	Can auto-logoff/screen lock be manually invoked (e.g., via a shortcut key or proximity sensor, etc.) by the **user**?	Yes	
ALOF notes:	1. Inactivity logout interval configurable by customer.		
2	**AUDIT CONTROLS (AUDT)**		
	The ability to reliably audit activity on the **device**.		
2-1	Can the **medical device** create an **audit trail**?	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 **removable media**	Yes	
2-2.5	Receipt/transmission of data from/to external (e.g., network) connection	Yes	
2-2.5.1	**Remote service** 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	**User** ID	Yes	
2-3.2	Date/time	Yes	
AUDT notes:	Audit trail available to all Manager level users through the Hologic software.		
3	**AUTHORIZATION (AUTH)**		
	The ability of the device to determine the authorization of users.		
3-1	Can the **device** prevent access to unauthorized **users** through **user** login requirements or other mechanism?	Yes	
3-2	Can **users** be assigned different privilege levels within an application based on 'roles' (e.g., guests, regular **users**, power **users**, administrators, etc.)?	Yes	
3-3	Can the **device** owner/**operator** 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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4	**CONFIGURATION OF SECURITY FEATURES (CNFS)**		
	The ability to configure/re-configure **device security capabilities** to meet **users'** needs.		
4-1	Can the **device** owner/operator reconfigure product **security capabilities**?	No	
CNFS notes:			
5	**CYBER SECURITY PRODUCT UPGRADES (CSUP)**		
	The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade **device**'s security patches.		
5-1	Can relevant OS and **device** security patches be applied to the **device** as they become available?	No	
5-1.1	Can security patches or other software be installed remotely?	No	
CSUP notes:	Hologic Brevera Breast Biopsy System is an FDA regulated medical device, all software updates and patches need to be validated by the manufacturer. Patches are deployed on a regular basis through tested software updates.		
6	**HEALTH DATA DE-IDENTIFICATION (DIDT)**		
	The ability of the **device** to directly remove information that allows identification of a person.		
6-1	Does the **device** provide an integral capability to de-identify **private data**?	Yes	
DIDT notes:	1. Patient data can be de-identified through the standard software		
7	**DATA BACKUP AND DISASTER RECOVERY (DTBK)**		
	The ability to recover after damage or destruction of **device** data, hardware, or software.		
7-1	Does the **device** have an integral data backup capability (i.e., backup to remote storage or **removable media** 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.		
8	**EMERGENCY ACCESS (EMRG)**		
	The ability of **device users** to access **private data** in case of an emergency situation that requires immediate access to stored **private data**.		
8-1	Does the **device** incorporate an **emergency access** ("break-glass") feature?	No	
EMRG notes:			
9	**HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU)**		
	How the **device** ensures that data processed by the **device** has not been altered or destroyed in an unauthorized manner and is from the originator.		
9-1	Does the **device** ensure the integrity of stored data with implicit or explicit error detection/correction technology?	No	
IGAU notes:	System only acts as a temporary store of patient data before it is transmitted to PACS.		

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

PLOK
notes:

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14	**ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP)**		
	Manufacturer's plans for security support of 3rd party components within **device** 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?	Yes	
RDMP notes:	Microsoft Windows Embedded Standard 7 SP1		
15	**SYSTEM AND APPLICATION HARDENING (SAHD)**		
	The **device**'s resistance to cyber attacks and **malware**.		
15-1	Does the **device** employ any hardening measures? Please indicate in the notes the level of conformance to any industry-recognized hardening standards.	Yes	
15-2	Does the **device** 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 **device** 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)?	Yes	
15-5	Are all accounts which are not required for the **intended use** of the **device** disabled or deleted, for both **users** and applications?	Yes	
15-6	Are all shared resources (e.g., file shares) which are not required for the **intended use** of the **device**, disabled?	Yes	
15-7	Are all communication ports which are not required for the **intended use** of the **device** 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 **intended use** of the **device** 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 **intended use** of the **device** deleted/disabled?	Yes	
15-10	Can the **device** boot from uncontrolled or **removable media** (i.e., a source other than an internal drive or memory component)?	Yes	
15-11	Can software or hardware not authorized by the **device** 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 accessments which are incorporated into the product design.		
16	**SECURITY GUIDANCE (SGUD)**		
	The availability of security guidance for **operator** and administrator of the system and manufacturer sales and service.		
16-1	Are security-related features documented for the **device user**?	No	
16-2	Are instructions available for **device**/media sanitization (i.e., instructions for how to achieve the permanent deletion of personal or other sensitive data)?	Yes	
SGUD notes:	Hologic provides a Cyber Security Best Practices document on its website that provides recommendations on network security with the Brevera Breast Biopsy System product. Instructions for sanitation included in user manual.		

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17	**HEALTH DATA STORAGE CONFIDENTIALITY (STCF)**		
	The ability of the **device** to ensure unauthorized access does not compromise the integrity and confidentiality of **private data** stored on **device** or **removable media**.		
17-1	Can the **device** encrypt data at rest?	Yes	
STCF notes:	All PHI at rest is encrypted. 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.		
18	**TRANSMISSION CONFIDENTIALITY (TXCF)**		
	The ability of the **device** to ensure the confidentiality of transmitted **private data**.		
18-1	Can **private data** be transmitted only via a point-to-point dedicated cable?	No	
18-2	Is **private data** encrypted prior to transmission via a network or **removable media**? (If yes, indicate in the notes which encryption standard is implemented.)	No	
18-3	Is **private data** transmission restricted to a fixed list of network destinations?	Yes	
TXCF notes:	Device can be configured to only transmit to specific IP addresses. DICOM provides no native method to encrypt data, but TLS can be used on a local network.		
19	**TRANSMISSION INTEGRITY (TXIG)**		
	The ability of the **device** to ensure the integrity of transmitted **private data**.		
19-1	Does the **device** 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:			
20	**OTHER SECURITY CONSIDERATIONS (OTHR)**		
	Additional security considerations/notes regarding **medical device** security.		
20-1	Can the **device** be serviced remotely?	Yes	
20-2	Can the **device** restrict remote access to/from specified devices or **users** or network locations (e.g., specific IP addresses)?	Yes	
20-2.1	Can the **device** be configured to require the local **user** to accept or initiate remote access?	No	
OTHR notes:			