Manufacturer Disclosure Statement for Medical Device Security – MDS²

DEVICE DESCRIPTION

Device Category	Manufacturer	Document ID	Document Release Date
16512	Carestream Health, Inc.	AF8767	26-Sep-19

Device Model	Software Revision		Software Release Date
DRX Revolution and Evolution ImageView	1.3 and later		Sep-19

Manufacturer or Representative Contact Information	Company Name	Manufacturer Contact Information
	Carestream Health, Inc.	Telephone #: 1-800-328-2910
	Representative Name/Position	e-mail:health.imaging.tsc@carestreamhealth.com
	Technical Support	

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

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**?	No	__
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.)?	No	__
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	
1-1.2 Can auto-logoff/screen lock be manually invoked (e.g., via a shortcut key or proximity sensor, etc.) by the **user**?	Yes	__
ALOF notes:		
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)	Yes	1
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: 1) Standard Windows audit log events		
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	2
AUTH notes: 2) Technologist users do not have Administrator rights. Key Operator (Site Administrator) users can use a Windows Account with Administrator rights to perform certain actions such as changing Computer Name, IP Address… Note: This Administrator account does not have direct access to Patient Image or Security Log directories.		

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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**?   Yes   __

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?   Yes   3

     5-1.1   Can security patches or other software be installed remotely?   Yes   __

CSUP notes: 3) Third party / Operating System security patches are first verified by Carestream and then recommended for installation.

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:

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)?   Yes   4

DTBK notes: 4) The systems have the capability to complete a backup of configuration data via removable media. The systems do not provide a mechanism to backup exam and image data. The systems are intended to be capture devices only and images are forwarded to the PACS.

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?   Yes   5

EMRG notes: 5) The customer has the option of creating an emergency access user account. This is accomplished by creating a user account and safeguarding the password such that it can be used for emergency situations.

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?   Yes   __

IGAU notes:

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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?	N/A	6
10-1.2 Does notification of **malware** detection occur in the **device user** interface?	N/A	__
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**?	No	6
10-3 Can the device owner/**operator** (technically/physically) update virus definitions on manufacturer-installed **anti-virus software**?	No	6

MLDP notes: 6) Carestream ImageView systems come pre-installed with Symantec Critical System Protection: Critical System Protection (SESCSP) which is a Intrusion Detection and Prevention System. It white-lists applications and does not require updates. It does not provide user notifications.

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?	See Note	7
12-6 Can the **device** be configured to enforce creation of **user** account passwords that meet established complexity rules?	Yes	
12-7 Can the **device** be configured so that account passwords expire periodically?	Yes	__

PAUT notes: 7) The Windows OS comes with a shared user account for Carestream service that requires a unique second factor authentication (password plus certificate). All other users have unique accounts. The certificate uniquely identifies each Field Engineer. Further, the password can be controlled and set 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)?	Yes	8

PLOK notes: 8) Tools are required to gain access to the PC.

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Yes, No, N/A, or See Note | **Note #**

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.

		Yes, No, N/A, or See Note	Note #
14-1	In the notes section, list the provided or required (separately purchased and/or delivered) operating system(s) - including version number(s).	See Note	9
14-2	Is a list of other third party applications provided by the manufacturer available?	Yes	—

RDMP notes: 9) Windows 10 IoT Enterprise 2016 LTSB - Provided

15 SYSTEM AND APPLICATION HARDENING (SAHD)

The **device**'s resistance to cyber attacks and **malware**.

		Yes, No, N/A, or See Note	Note #
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	10
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?	Yes	—
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?	Yes	—
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	11
15-11	Can software or hardware not authorized by the **device** manufacturer be installed on the device without the use of tools?	No	—

SAHD notes: 10) STIG Compliance
11) System can boot from DVD or USB - requires Field Engineer to configure BIOS which is password protected.

16 SECURITY GUIDANCE (SGUD)

The availability of security guidance for **operator** and administrator of the system and manufacturer sales and service.

		Yes, No, N/A, or See Note	Note #
16-1	Are security-related features documented for the **device user**?	Yes	—
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:

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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	12

STCF notes: 12) Requires optional self-encrypting hard drive

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?	Yes	__
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:

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?	Yes	__

OTHR notes: