

# Manufacturer Disclosure Statement for Medical Device Security – MDS<sup>2</sup>

Device Category #: <b>16512</b>	Manufacturer: <b>Carestream Health Inc.</b>	Document ID: <b>7H8812</b>	Document Release Date: <b>11/10/2008</b>
Device Model: <b>DRX-1 Detector System</b>	Software Revision: <b>1 and later</b>	Software Release Date: <b>November, 2008</b>	
Manufacturer or Representative Contact Information:	Name: <b>Technical Support</b>	Title: <b>N/A</b>	Department: <b>US&amp;C Service</b>
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<u>MANAGEMENT OF ELECTRONIC PROTECTED HEALTH INFORMATION (ePHI) As defined by HIPAA Security Rule, 45 CFR Part 164)</u>	Yes	No	N/A	Note #
1. Can this device transmit or maintain <i>electronic Protected Health Information (ePHI)</i> ? <sup>†</sup>	Yes	___	___	___
2. Types of ePHI data elements that can be maintained by the device:				
a. ___ Demographic (e.g., name, address, location, unique identification number)?	Yes	___	___	___
b. ___ Medical record (e.g., medical record #, account #, test or treatment date, device identification number)?	Yes	___	___	___
c. ___ Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)?	Yes	___	___	___
d. ___ Open, unstructured text entered by device user/operator?	Yes	___	___	___
3. Maintaining ePHI: <i>Can the device</i>				
a. ___ Maintain ePHI temporarily in volatile memory (i.e., until cleared on by power-off or reset)?	Yes	___	___	___
b. ___ Store ePHI persistently on local media?	Yes	___	___	___
c. ___ Import/export ePHI with other systems?	Yes	___	___	___
4. Mechanisms used for the transmitting, importing/exporting of ePHI: <i>Can the device</i>				
a. ___ Display ePHI (e.g., video display)?	Yes	___	___	___
b. ___ Generate hardcopy reports or images containing ePHI?	Yes	___	___	___
c. ___ Retrieve ePHI from or record ePHI to removable media (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick)?	Yes	___	___	___
d. ___ Transmit/receive or import/export ePHI via dedicated cable connection (e.g., IEEE 1073, serial port, USB, FireWire)?	No	___	___	___
e. ___ Transmit/receive ePHI via a network connection (e.g., LAN, WAN, VPN, intranet, Internet)?	Yes	___	___	___
f. ___ Transmit/receive ePHI via an integrated wireless connection (e.g., WiFi, Bluetooth, infrared)? <sup>†</sup>	No	___	___	___
g. ___ Other _____?	N/A	___	___	___

<u>ADMINISTRATIVE SAFEGUARDS</u>	Yes	No	N/A	Note #
5. Does manufacturer offer operator and technical support training or documentation on device security features?	Yes	___	___	_1_
6. What underlying operating system(s) (including version number) are used by the device?				Windows XP Embedded Service Pack 2

<u>PHYSICAL SAFEGUARDS</u>	Yes	No	N/A	Note #
7. Are all device components maintaining ePHI (other than removable media) physically secure (i.e., cannot remove without tools)?	Yes	___	___	_2,3_
8. Does the device have an integral data backup capability (i.e., backup onto removable media such as tape, disk)?	Yes	___	___	_4_
9. Can the device boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?	Yes	___	___	_5_

<u>TECHNICAL SAFEGUARDS</u>	Yes	No	N/A	Note #
10. Can software or hardware not authorized by the device manufacturer be installed on the device?	No	___	___	___
11. Can the device be serviced remotely (i.e., maintenance activities performed by service person via network or remote connection)?	Yes	___	___	___
a. Can the device restrict remote access to specific devices or network locations (e.g., specific IP addresses)?	Yes	___	___	___
b. Can the device log provide an audit trail of remote-service activity?	Yes	___	___	___
c. Can security patches or other software be installed remotely?	Yes	___	___	___
12. Level of owner/operator service access to device operating system: <i>Can the device owner/operator</i>				
a. Apply device manufacturer-validated security patches?	Yes	___	___	___
b. Install or update antivirus software?	No	___	___	___
c. Update virus definitions on manufacturer-installed antivirus software?	N/A	___	___	_6_
d. Obtain administrative privileges (e.g., access operating system or application via local root or admin account)?	Yes	___	___	___
13. Does the device support user/operator specific ID and password?	Yes	___	___	___
14. Are access sessions terminated after a predetermined length of inactivity (e.g., auto logoff)?	Yes	___	___	_7_
15. Events recorded in device audit log (e.g., user, date/time, action taken): <i>Can the audit log record</i>				
a. Login and logout by users/operators?	Yes	___	___	___
b. Viewing of ePHI?	Yes	___	___	___
c. Creation, modification or deletion of ePHI?	Yes	___	___	___
d. Import/export or transmittal/receipt of ePHI?	Yes	___	___	___
16. Does the device incorporate an emergency access ("break-glass") feature that logs each instance of use?	Yes	___	___	_8_
17. Can the device maintain ePHI (e.g., by internal battery) during power service interruptions?	Yes	___	___	___
18. Controls when exchanging ePHI with other devices:				
a. Transmitted only via a physically secure connection (e.g., dedicated cable)?	No	___	___	___
b. Encrypted prior to transmission via a network or removable media?	No	___	___	___
c. Restricted to a fixed list of network addresses (i.e., host-based access control list)?	Yes	___	___	_9_
19. Does the device ensure the integrity of the ePHI data with implicit or explicit error detection/correction technology? ....	Yes	___	___	___

<sup>†</sup> Recommend use of ECRI's Universal Medical Device Nomenclature System (UMDNS).

Adapted from *Information Security for Biomedical Technology: A HIPAA Compliance Guide*, ACCE/ECRI, 2004.  
ACCE – the American College of Clinical Engineering; ECRI – formerly the Emergency Care Research Institute.



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### **RECOMMENDED SECURITY PRACTICES**

Users must take steps to secure their networks and protect their Medical Information Systems which includes a risk assessment strategy, network defense in depth strategy, business continuity planning, etc.

### **EXPLANATORY NOTES** (from questions 1 – 19):

*IMPORTANT: Refer to Instructions for the Manufacturers Disclosure Statement for Medical Device Security for the proper interpretation of information provided in this form.*

1. Carestream Health provides operator and technical training for the DirectView DRX systems. Service/technical documentation includes configuration guidelines for a certified service provider to configure the DR system activation of the software firewall services.
2. Valid Digital Certificate is required for service access (e.g. system modification, loading additional software, use of CD/DVD or USB drives etc).
3. The Clinical user does not have access to the system desktop, limiting access to the Windows Operating System.
4. DR systems have the capability to complete a backup of configuration data via removable media.
5. DR systems have boot capability via the CD/DVD drive.
6. The product does not include Anti-Virus software. Cisco Security Agent is included in the product.
7. The auto logout feature is provided but can be disabled by the local security administrator.
8. 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. The system limits transfer of ePHI through defined DICOM associations, which requires defined IP addresses and AE titles.

