Manufacturer Disclosure Statement for Medical Device Security – MDS²

Device Category: 17237	Manufacturer: Kodak	Document ID: 7F9031	Document Release Date: **8/1/2005**
Device Model: CMI 1000	Software Revision: 1.1	Software Release Date: June 3, 2005	

Manufacturer or Representative Contact Information:	Name: Technical Support	Title: N/A	Department: **US&C Service**
	Company Name: Eastman Kodak	Telephone #: **1-800-328-2910**	e-mail: **health.imaging.tsc@kodak.com**

MANAGEMENT OF ELECTRONIC PROTECTED HEALTH INFORMATION (ePHI) *As defined by HIPAA Security Rule, 45 CFR Part 164)*	Yes No N/A	Note #
1. Can this device transmit or maintain *electronic Protected Health Information* (ePHI)?	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?	No ___	_____
3. Maintaining ePHI: *Can the device*		
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?	No ___	_____
4. Mechanisms used for the transmitting, importing/exporting of ePHI: *Can the device*		
a. Display ePHI (e.g., video display)?	No ___	_____
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)?	No ___	_____
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)?	No ___	_____
g. Other _____ ?	No ___	_____

ADMINISTRATIVE SAFEGUARDS	Yes No N/A	Note #
5. Does manufacturer offer operator and technical support training or documentation on device security features?	Yes __	_____
6. What underlying operating system(s) (including version number) are used by the device? Windows XP, SP2	_____	_____

PHYSICAL SAFEGUARDS	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 _	_____
8. Does the device have an integral data backup capability (i.e., backup onto removable media such as tape, disk)?	No ___	_____
9. Can the device boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?	Yes __	_____

TECHNICAL SAFEGUARDS	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)?	No ___	_____
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: *Can the device owner/operator*		
a. Apply device manufacturer-validated security patches?	No ___	_____
b. Install or update antivirus software?	No ___	_____
c. Update virus definitions on manufacturer-installed antivirus software?	No ___	_____
d. Obtain administrative privileges (e.g., access operating system or application via local root or admin account)?	No ___	_____
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 __	_____
15. Events recorded in device audit log (e.g., user, date/time, action taken): *Can the audit log record*		
a. Login and logout by users/operators?	Yes __	_____
b. Viewing of ePHI?	No ___	_____
c. Creation, modification or deletion of ePHI?	No ___	_____
d. Import/export or transmittal/receipt of ePHI?	No ___	_____
16. Does the device incorporate an emergency access ("break-glass") feature that logs each instance of use?	No ___	_____
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)? ..... No ___	_____
19.	Does the device ensure the integrity of the ePHI data with implicit or explicit error detection/correction technology? .... Yes __	_____

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

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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.
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8. Service provided capability to backup configuration information only. Image data backup not supported.
9.
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11. Remote Access is protected by user authentication.
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