**Manufacturer Disclosure Statement for Medical Device Security – MDS²**

**Device Category:** 15949  
**Manufacturer:** Eastman Kodak  
**Document ID:** 7F9054  
**Document Release Date:**

**Device Model:** DryView 8150  
**Software Revision:** Rev 1.0.2  
**Software Release Date:** 02/05

**Contact Information:**

- **Name:** Technical Support  
- **Title:** N/A  
- **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)**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Can this device transmit or maintain electronic Protected Health Information (ePHI)?</td>
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</table>
| 2. Types of ePHI data elements that can be maintained by the device:  
  a. Demographic (e.g., name, address, location, unique identification number)? |     |    |     |
  b. Medical record (e.g., medical record #, account #, test or treatment date, device identification number)? |     |    |     |
  c. Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)? |     |    |     |
  d. Open, unstructured text entered by device user/operator? |     |    |     |
| 3. Maintaining ePHI: Can the device  
  a. Maintain ePHI temporarily in volatile memory (i.e., until cleared on by power-off or reset)? |     |    |     |
  b. Store ePHI persistently on local media? |     |    |     |
  c. Import/export ePHI with other systems? |     |    |     |
| 4. Mechanisms used for the transmitting, importing/exporting of ePHI: Can the device  
  a. Display ePHI (e.g., video display)? |     |    |     |
  b. Generate hardcopy reports or images containing ePHI? |     |    |     |
  c. Retrieve ePHI from or record ePHI to removable media (e.g., disk, DVD, CD-ROM, tape, CF/SD card, memory stick)? |     |    |     |
  d. Transmit/receive or import/export ePHI via dedicated cable connection (e.g., IEEE 1373, serial port, USB, FireWire)? |     |    |     |
  e. Transmit/receive ePHI via a network connection (e.g., LAN, WAN, VPN, intranet, Internet)? |     |    |     |
  f. Transmit/receive ePHI via an integrated wireless connection (e.g., WiFi, Bluetooth, infrared)? |     |    |     |
  g. Other |     |    |     |

**ADMINISTRATIVE SAFEGUARDS**

<table>
<thead>
<tr>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
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<tbody>
<tr>
<td>5. Does manufacturer offer operator and technical support training or documentation on device security features?</td>
<td></td>
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<tr>
<td>6. What underlying operating system(s) (including version number) are used by the device?</td>
<td>Microsoft Windows 2000, SP4</td>
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</tbody>
</table>

**PHYSICAL SAFEGUARDS**

<table>
<thead>
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<th>Yes</th>
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<tbody>
<tr>
<td>7. Are all device components maintaining ePHI (other than removable media) physically secure (i.e., cannot remove without tools)?</td>
<td></td>
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<tr>
<td>8. Does the device have an integral data backup capability (i.e., backup onto removable media such as tape, disk)?</td>
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<tr>
<td>9. Can the device boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?</td>
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</tbody>
</table>

**TECHNICAL SAFEGUARDS**

<table>
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<tr>
<td>10. Can software or hardware not authorized by the device manufacturer be installed on the device?</td>
<td></td>
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<tr>
<td>11. Can the device be serviced remotely (i.e., maintenance activities performed by service person via network or remote connection)?</td>
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</table>
  a. Can the device restrict remote access to specific devices or network locations (e.g., specific IP addresses)? |     |    |     |
  b. Can the device log provide an audit trail of remote-service activity? |     |    |     |
  c. Can security patches or other software be installed remotely? |     |    |     |
| 12. Level of owner/operator service access to device operating system: Can the device owner/operator  
  a. Apply device manufacturer-validates security patches? |     |    |     |
  b. Install or update antivirus software? |     |    |     |
  c. Update virus definitions on manufacturer-installed antivirus software? |     |    |     |
  d. Obtain administrative privileges (e.g., access operating system or application via local root or admin account)? |     |    |     |
| 13. Does the device support user/operator specific ID and password? |     |    |     |
| 14. Are access sessions terminated after a predetermined length of inactivity (e.g., auto logoff)? |     |    |     |
| 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? |     |    |     |
  b. Viewing of ePHI? |     |    |     |
  c. Creation, modification or deletion of ePHI? |     |    |     |
  d. Import/export or transmittal/receipt of ePHI? |     |    |     |
| 16. Does the device incorporate an emergency access (“break-glass”) feature that logs each instance of use? |     |    |     |
| 17. Can the device maintain ePHI (e.g., by internal battery) during power service interruptions? |     |    |     |
| 18. Controls when exchanging ePHI with other devices:  
  a. Transmitted only via a physically secure connection (e.g., dedicated cable)? |     |    |     |
  b. Encrypted prior to transmission via a network or removable media? |     |    |     |

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<td>c. Restricted to a fixed list of network addresses (i.e., host-based access control list)?</td>
<td>No</td>
</tr>
<tr>
<td>19. Does the device ensure the integrity of the ePHI data with implicit or explicit error detection/correction technology?</td>
<td>Yes</td>
</tr>
</tbody>
</table>

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

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8. Service provided capability to backup configuration information only. Image data backup not supported.
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