

Manufacturer Disclosure Statement for Medical Device Security – MDS²

Device Category †	Software	Manufacturer †	Orion Software Development	Document ID	1	Document Release Date	2005-02-08
Device Model	Orion Outcomes for CVPR	Software Revision	3.01.000 and higher	Software Release Date	2005-02-08		
Manufacturer or Representative Contact Information:	Name	Brandon Fuller	Title	President	Department	Corporate	
	Company Name	Orion Software Development	Telephone #	866-674-6679	e-mail	brandon@orionoutcomes.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? **Yes** _____
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? **Yes** _____
4. Mechanisms used for the transmitting, importing/exporting of ePHI: *Can the device*
 - 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)? ... **Yes** _____
 - 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)?[†] **Yes** _____
 - g. Other _____ ? **N/A** _____

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 95 and higher **1** _____

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)? **N/A** **1** _____
8. Does the device have an integral data backup capability (i.e., backup onto removable media such as tape, disk)? **Yes** _____
9. Can the device boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)? **N/A** **1** _____

TECHNICAL SAFEGUARDS **Yes No N/A Note #**

10. Can software or hardware not authorized by the device manufacturer be installed on the device? **N/A** **1** _____
11. Can the device be serviced remotely (i.e., maintenance activities performed by service person via network or remote connection)? **N/A** **1** _____
 - a. Can the device restrict remote access to specific devices or network locations (e.g., specific IP addresses)? **N/A** **1** _____
 - b. Can the device log provide an audit trail of remote-service activity? **N/A** **1** _____
 - c. Can security patches or other software be installed remotely? **N/A** **1** _____
12. Level of owner/operator service access to device operating system: *Can the device owner/operator*
 - a. Apply device manufacturer-validated security patches? **Yes** _____
 - b. Install or update antivirus software? **N/A** **1** _____
 - c. Update virus definitions on manufacturer-installed antivirus software? **N/A** **1** _____
 - d. Obtain administrative privileges (e.g., access operating system or application via local root or admin account)? .. **N/A** **1** _____
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? **No** _____
 - 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? **No** _____
17. Can the device maintain ePHI (e.g., by internal battery) during power service interruptions? **N/A** **1** _____
18. Controls when exchanging ePHI with other devices:
 - a. Transmitted only via a physically secure connection (e.g., dedicated cable)? **N/A** **1** _____
 - b. Encrypted prior to transmission via a network or removable media? **Yes** _____
 - c. Restricted to a fixed list of network addresses (i.e., host-based access control list)? **N/A** **1** _____
19. Does the device ensure the integrity of the ePHI data with implicit or explicit error detection/correction technology? **No** _____

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

Manufacturer Disclosure Statement for Medical Device Security – MDS²

RECOMMENDED SECURITY PRACTICES

Visit <http://www.orionoutcomes.com/products/outcomes/hipaa.html> for the latest information.

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. Product is software only. PC hardware supplied and configured by customer. Customer may implement if desired.
- 2.
- 3.
- 4.
- 5.
- 6.
- 7.
- 8.
- 9.
- 10.
- 11.
- 12.
- 13.
- 14.
- 15.
- 16.
- 17.
- 18.
- 19.
- 20.