Manufacturer Disclosure Statement for Medical Device Security – MDS²

SECTION 1

Device Category	Manufacturer	Document ID	Document Release Date
Evo Holter recorder	Spacelabs Healthcare Ltd.	091-0361-00 Rev A	Tuesday, October 4, 2016

Device Model	Evo	Software Revision	V02.54	Software Release Date	Monday, September 30, 2013

Manufacturer or Representative Contact Information:	Company Name	Spacelabs Healthcare Inc.	Manufacturer Contact Information
	Representative Name/Position	Kathleen Callaghan, HIPAA Compliance Officer	Spacelabs Healthcare, 35301 S.E. Center Street, Snoqualmie, WA 98065

MANAGEMENT OF ELECTRONIC PROTECTED HEALTH INFORMATION (ePHI)	Yes No N/A	Note #
1. Can this device transmit or maintain electronic Protected Health Information (ePHI)?	YES	Note #1
2. Types of ePHI data elements that can be maintained by the device:		
a. Demographic (e.g., name, address, location, unique identification number)?	YES	Note #1
b. Medical record (e.g., medical record #, account #, test or treatment date, device identification number)?	YES	Note #1
c. Diagnostic/therapeutic (e.g., photo/radiograph, test results, or physiologic data with identifying characteristics)?	NO	
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	Note #2
b. Store ePHI persistently on local media?	YES	Note #1
c. Import/export ePHI with other systems?	YES	Note #3
4. Mechanisms used for the transmitting, importing/exporting of ePHI – Can the device		
a. Display ePHI (e.g., video display)?	YES	Note #2
b. Generate hardcopy reports or images containing ePHI?	NO	
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)?	NO	
f. Transmit/receive ePHI via an integrated wireless connection (e.g. WiFi, Bluetooth, infrared)?	YES	Note #4
g. Other? _____ ……………………………		

ADMINISTRATIVE SAFEGUARDS	Yes No N/A	Note #
5. Does manufacturer offer operator and technical support training or documentation on device security features?	NO	
6. What underlying operating system(s) (including version number) are used by the device?	NONE	
9. Can the device boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?	NO	

TECHNICAL SAFEGUARDS	Yes No N/A	Note #
10. Can software or hardware not authorized by the device manufacturer be installed on the device without the use of tools?	NO	
11. Can the device be serviced remotely (i.e., maintenance activities performed by service person via network or remote connection)?	NO	
a. Can the device restrict remote access to specific devices or network locations (e.g., specific IP addresses)?	NO	
b. Can the device provide an audit trail of remote-service activity?	NO	
c. Can security patches or other software be installed remotely?	NO	
12. Level of owner/operator service access to device operating system: Can the device owner/operator		
a. Apply device manufacturer-validated security patches?	YES	Note #5
b. Install or update antivirus software?	NO	
c. Update virus definitions on manufacturer-installed antivirus software?	N/A	
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 username and password?	NO	
14. Does the system force reauthorization after a predetermined length of inactivity (e.g., auto logoff, session lock)?	NO	

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15. Events recorded in device audit trail (e.g., user, date/time, action taken): Can the audit trail record..

    a. Login and logout by users/operators?.. NO

    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 is logged?.. NO

17. Can the device maintain ePHI during power service interruptions?.. NO

18. Controls when exchanging ePHI with other devices:..

    a. Transmitted only via a point-to-point dedicated cable?.. YES   Note #6

    b. Encrypted prior to transmission via a network or removable media?.. NO

    c. Restricted to a fixed list of network destinations.. NO

19. Does the device ensure the integrity of the ePHI data with implicit or explicit error detection/correction technology?............................... NO

Other Security Considerations

N/A

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	Kathleen Callaghan, HIPAA Compliance Officer		

SECTION 2

 EXPLANATORY NOTES (from questions 1 - 19)

Note 1: Evo can be programmed with patient ID or record # and name details on non-removable FLASH memory.

Note 2: Evo can load and display patient ID number during recording initialisation from internal memory for operator confirmation.

Note 3: Evo can be loaded with PHI from Spacelabs Impresario and Sentinel software packages and will support download of the same to these packages. The data is initialised and stored on a non-removable flash memory

Note 4: Evo can be initialised from Spacelabs software using a proprietary infra-red communication link integrated within the device charging dock

Note 5: Product firmware updates can be installed using Spacelabs validated software update package over the infra-red link described in Note 4

Note 6: Communication between Spacelabs software packages and the infra-red link occur over hard-wired USB connection to the device charger dock

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