

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

**SECTION 1**

Device Category Lifecard CF / Lifecard 12 Holter recorders	Manufacturer Spacelabs Healthcare Ltd.	Document ID 091-0360-00 Rev A	Document Release Date Tuesday, October 4, 2016
Device Model LCF / LC12	Software Revision V8.18	Software Release Date	Monday, August 29, 2016
Manufacturer or Representative Contact Information:	Company Name Spacelabs Healthcare Inc. Representative Name/Position Kathleen Callaghan, HIPAA Compliance Officer	Manufacturer Contact Information 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)?	YES			Note #4
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)?	NO			
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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	Representative Name/Position Kathleen Callaghan, HIPAA Compliance Officer				

**SECTION 2**

**EXPLANATORY NOTES (from questions 1 - 19)**

Note 1: The Lifecard CF holds patient ID or record # and optionally name details on removable CF card used during recording. PHI is not stored persistently within the device itself.

Note 2: Lifecard CF can load and display patient ID or name during recording initialisation for operator confirmation from removable CF card.

Note 3: Lifecard CF can be loaded with PHI from Spacelabs Pathfinder, Lifescreen and Sentinel software packages and will support download of the same to these packages. The data is initialised and stored on a removable CF card

Note 4: Lifecard records Holter data on a CF card. PHI such as patient name and patient ID is initialised by the software package as Note 1 but left unchanged on the CF card by the Lifecard CF

Note 5: Product firmware updates can be installed using a Spacelabs prepared and validated CF card

Note 6: The removable CF card is initialised and later downloaded using commercial CF readers connected to a PC, typically over a hard-wired USB connection

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