Manufacturer Disclosure Statement for Medical Device Security -- MDS2

Spacelabs Healthcare ICS 92810, 92880, 92876, 92842, 92843, 92848, 92881, 92877 091-0354-07 Rev B May-24

Question ID	Question		See note	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
DOC-1	Manufacturer Name	Spacelabs Healthcare	__			
DOC-2	Device Description	Intensys Clinical Suite (ICS) Version 5.6.1	__			
DOC-3	Device Model	92810, 92880, 92876, 92842, 92843, 92848, 92881, 92877	__			
DOC-4	Document ID	091-0354-07, Rev B	__			
DOC-5	Manufacturer Contact Information	Spacelabs Healthcare, 35301 SE Center Street, Snoqualmie, WA 98065	__			
DOC-6	Intended use of device in network-connected environment:	ICS is Intelsys Clinical Suite which contains different components like HL7, Print Manager, Smartdisclosure. With the help the help of these components we can see the patient vital information and analyse historic	__			
DOC-7	Document Release Date	May-24	__			
DOC-8	Coordinated Vulnerability Disclosure: Does the manufacturer have a vulnerability disclosure program for this device?	Yes	We publish bulletins for major vulnerabilities and threats as they emerge and we assess them. They are found on our website https://www.spacelabshealthcare.com/products/security/security-advisories-and-			
DOC-9	ISAO: Is the manufacturer part of an Information Sharing and Analysis Organization?	No	__			
DOC-10	Diagram: Is a network or data flow diagram available that indicates connections to other system components or expected external resources?	Yes	We have network diagrams of our PMC suite with ICS as part of those models. This is not published and can be made available on request.			
DOC-11	SaMD: Is the device Software as a Medical Device (i.e. software-only, no hardware)?	Yes	__			
DOC-11.1	Does the SaMD contain an operating system?	No	__			

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DOC-11.2	Does the SaMD rely on an owner/operator provided operating system?	Yes	Supported Operating Systems include Microsoft Windows Server 2012 R2, Windows Server 2016, Windows Server 2019, and Windows Server 2022 with SQL Server 2014 or 2017 (for the ICS database server)			
DOC-11.3	Is the SaMD hosted by the manufacturer?	No				
DOC-11.4	Is the SaMD hosted by the customer?	Yes	__			
		Yes, No, N/A, or See Note	Note #			
	MANAGEMENT OF PERSONALLY IDENTIFIABLE INFORMATION			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
MPII-1	Can this device display, transmit, store, or modify personally identifiable information (e.g. electronic Protected Health Information (ePHI))?	Yes	__		AR-2	A.15.1.4
MPII-2	Does the device maintain personally identifiable information?	Yes			AR-2	A.15.1.4
MPII-2.1	Does the device maintain personally identifiable information temporarily in volatile memory (i.e., until cleared by power-off or reset)?	Yes	__		AR-2	A.15.1.4
MPII-2.2	Does the device store personally identifiable information persistently on internal media?	Yes	__			
MPII-2.3	Is personally identifiable information preserved in the device's non-volatile memory until explicitly	No	__			
MPII-2.4	Does the device store personally identifiable information in a database?	Yes	__			
MPII-2.5	Does the device allow configuration to automatically delete local personally identifiable information after it is stored to a long term solution?	No	__		AR-2	A.15.1.4
MPII-2.6	Does the device import/export personally identifiable information with other systems (e.g., a wearable monitoring device might export personally identifiable information to a server)?	Yes	__		AR-2	A.15.1.4
MPII-2.7	Does the device maintain personally identifiable information when powered off, or during power service interruptions?	No	__		AR-2	A.15.1.4
MPII-2.8	Does the device allow the internal media to be removed by a service technician (e.g., for separate destruction or customer retention)?	N/A	__			

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MPII-2.9	Does the device allow personally identifiable information records be stored in a separate location from the device’s operating system (i.e. secondary internal drive, alternate drive partition, or remote storage location)?	N/A			AR-2	A.15.1.4
MPII-3	Does the device have mechanisms used for the transmitting, importing/exporting of personally identifiable information?	Yes	__		AR-2	A.15.1.4
MPII-3.1	Does the device display personally identifiable information (e.g., video display, etc.)?	No	__		AR-2	A.15.1.4
MPII-3.2	Does the device generate hardcopy reports or images containing personally identifiable	No	__		AR-2	A.15.1.4
MPII-3.3	Does the device retrieve personally identifiable information from or record personally identifiable information to removable media (e.g., removable-HDD, USB memory, DVD-R/RW,CD-R/RW, tape, CF/SD card, memory stick, etc.)?	No	__		AR-2	A.15.1.4
MPII-3.4	Does the device transmit/receive or import/export personally identifiable information via dedicated cable connection (e.g., RS-232, RS-423, USB,	No	__		AR-2	A.15.1.4
MPII-3.5	Does the device transmit/receive personally identifiable information via a wired network connection (e.g., RJ45, fiber optic, etc.)?	Yes	__		AR-2	A.15.1.4
MPII-3.6	Does the device transmit/receive personally identifiable information via a wireless network connection (e.g., WiFi, Bluetooth, NFC, infrared, cellular, etc.)?	No	__		AR-2	A.15.1.4
MPII-3.7	Does the device transmit/receive personally identifiable information over an external network (e.g., Internet)?	Yes	__		AR-2	A.15.1.4
MPII-3.8	Does the device import personally identifiable information via scanning a document?	No				
MPII-3.9	Does the device transmit/receive personally identifiable information via a proprietary protocol?	No				
MPII-3.10	Does the device use any other mechanism to transmit, import or export personally identifiable information?	No	__		AR-2	A.15.1.4
Management of Private Data notes:					AR-2	A.15.1.4
	AUTOMATIC LOGOFF (ALOF) *The device's ability to prevent access and misuse by unauthorized users if device is left idle for a period of time.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
ALOF-1	Can the device be configured to force reauthorization of logged-in user(s) after a predetermined length of inactivity (e.g., auto-logoff, session lock, password protected screen saver)?	No	__	Section 5.1, ALOF	AC-12	None
ALOF-2	Is the length of inactivity time before auto-logoff/screen lock user or administrator	N/A	__	Section 5.1, ALOF	AC-11	A.11.2.8, A.11.2.9

	AUDIT CONTROLS (AUDT)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability to reliably audit activity on the device.					
AUDT-1	Can the medical device create additional audit logs or reports beyond standard operating system logs?	Yes	__	Section 5.2, AUDT	AU-1	A.5.1.1, A.5.1.2, A.6.1.1, A.12.1.1, A.18.1.1, A.18.2.2
AUDT-1.1	Does the audit log record a USER ID?	Yes	__			
AUDT-1.2	Does other personally identifiable information exist in the audit trail?	Yes	Emloyee User ID information is caputured in audit	Section 5.2, AUDT	AU-2	None
AUDT-2	Are events recorded in an audit log? If yes, indicate which of the following events are recorded in the audit log:	______	__	Section 5.2, AUDT	AU-2	None
AUDT-2.1	Successful login/logout attempts?	Yes	__	Section 5.2, AUDT	AU-2	None
AUDT-2.2	Unsuccessful login/logout attempts?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-2.3	Modification of user privileges?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-2.4	Creation/modification/deletion of users?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-2.5	Presentation of clinical or PII data (e.g. display,	No	__	Section 5.2, AUDT	AU-2	None
AUDT-2.6	Creation/modification/deletion of data?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-2.7	Import/export of data from removable media (e.g. USB drive, external hard drive, DVD)?	N/A	__	Section 5.2, AUDT	AU-2	None
AUDT-2.8	Receipt/transmission of data or commands over a network or point-to-point connection?	Yes	__	Section 5.2, AUDT	AU-2	None
AUDT-2.8.1	Remote or on-site support?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-2.8.2	Application Programming Interface (API) and similar activity?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-2.9	Emergency access?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-2.10	Other events (e.g., software updates)?	N/A	__	Section 5.2, AUDT	AU-2	None
AUDT-2.11	Is the audit capability documented in more detail?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-3	Can the owner/operator define or select which events are recorded in the audit log?	No		Section 5.2, AUDT	AU-2	None
AUDT-4	Is a list of data attributes that are captured in the audit log for an event available?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-4.1	Does the audit log record date/time?	Yes	__	Section 5.2, AUDT	AU-2	None
AUDT-4.1.1	Can date and time be synchronized by Network Time Protocol (NTP) or equivalent time source?	Yes	__	Section 5.2, AUDT	AU-2	None
AUDT-5	Can audit log content be exported?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-5.1	Via physical media?	No	__			
AUDT-5.2	Via IHE Audit Trail and Node Authentication (ATNA) profile to SIEM?	No	__			
AUDT-5.3	Via Other communications (e.g., external service device, mobile applications)?	No	__			
AUDT-5.4	Are audit logs encrypted in transit or on storage media?	No	__			
AUDT-6	Can audit logs be monitored/reviewed by owner/operator?	Yes	__			
AUDT-7	Are audit logs protected from modification?	No	__	Section 5.2, AUDT	AU-2	None
AUDT-7.1	Are audit logs protected from access?	Yes				

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AUDT-8	Can audit logs be analyzed by the device?	No	__	Section 5.2, AUDT	AU-2	None
	AUTHORIZATION (AUTH)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability of the device to determine the authorization of users.					
AUTH-1	Does the device prevent access to unauthorized users through user login requirements or other mechanism?	No	__	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-1.1	Can the device be configured to use federated credentials management of users for authorization (e.g., LDAP, OAuth)?	Yes	__	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-1.2	Can the customer push group policies to the device (e.g., Active Directory)?	Yes	__	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-1.3	Are any special groups, organizational units, or group policies required?	No	__	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-2	Can users be assigned different privilege levels based on 'role' (e.g., user, administrator, and/or service, etc.)?	Yes	__	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-3	Can the device owner/operator grant themselves unrestricted administrative privileges (e.g., access operating system or application via local root or administrator account)?	Yes	__	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-4	Does the device authorize or control all API access requests?	N/A	__	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-5	Does the device run in a restricted access mode, or ‘kiosk mode’, by default?	No	__			
	CYBER SECURITY PRODUCT UPGRADES (CSUP)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade device's security patches.					
CSUP-1	Does the device contain any software or firmware which may require security updates during its operational life, either from the device manufacturer or from a third-party manufacturer of the software/firmware? If no, answer “N/A” to questions in this section.	Yes	__			
CSUP-2	Does the device contain an Operating System? If yes, complete 2.1-2.4.	Yes	__			
CSUP-2.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	Yes	__			
CSUP-2.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes	__			
CSUP-2.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes	__			

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CSUP-2.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	Yes	Spacelabs conducts monthly Microsoft patch verification testing for our Windows-based products. It is recommended to review the patch tes report prior to patching in the event an update can cause impact to the hosted Spacelabs product. The patch test reports can be found here - https://www.spacelabshealthcare.com/products/security/patch-test-reports-access-form/?redirect_to=%2Fproducts%2Fsecurity%2Fpatch-test-
CSUP-3	Does the device contain Drivers and Firmware? If yes, complete 3.1-3.4.	N/A	__
CSUP-3.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	N/A	__
CSUP-3.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	N/A	__
CSUP-3.3	Does the device have the capability to receive remote installation of patches or software updates?	N/A	__
CSUP-3.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	N/A	__
CSUP-4	Does the device contain Anti-Malware Software? If yes, complete 4.1-4.4.	No	__
CSUP-4.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	No	__
CSUP-4.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	No	__
CSUP-4.3	Does the device have the capability to receive remote installation of patches or software updates?	No	__
CSUP-4.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	Yes	__

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CSUP-5	Does the device contain Non-Operating System commercial off-the-shelf components? If yes, complete 5.1-5.4.	Yes	__	
CSUP-5.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	No	__	
CSUP-5.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes	__	
CSUP-5.3	Does the device have the capability to receive remote installation of patches or software updates?	No	__	
CSUP-5.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	Yes	__	
CSUP-6	Does the device contain other software components (e.g., asset management software, license management)? If yes, please provide details or refernce in notes and complete 6.1-6.4.	No	__	
CSUP-6.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	N/A	__	
CSUP-6.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	N/A	__	
CSUP-6.3	Does the device have the capability to receive remote installation of patches or software updates?	N/A	__	
CSUP-6.4	Does the medical device manufacturer allow security updates from any third-party manufacturers (e.g., Microsoft) to be installed without approval from the manufacturer?	N/A	__	

CSUP-7	Does the manufacturer notify the customer when updates are approved for installation?	Yes	Spacelabs conducts monthly Microsoft patch verification testing for our Windows-based products. It is recommended to review the patch tes report prior to patching in the event an update can cause impact to the hosted Spacelabs product. The patch test reports can be found here - https://www.spacelabshealthcare.com/products/security/patch-test-reports-access-form/?redirect_to=%2Fproducts%2Fsecurity%2Fpatch-test-
CSUP-8	Does the device perform automatic installation of software updates?	No	__
CSUP-9	Does the manufacturer have an approved list of third-party software that can be installed on the device?	N/A	__
CSUP-10	Can the owner/operator install manufacturer-approved third-party software on the device themselves?	N/A	__
CSUP-10.1	Does the system have mechanism in place to prevent installation of unapproved software?	N/A	__
CSUP-11	Does the manufacturer have a process in place to assess device vulnerabilities and updates?	Yes	__
CSUP-11.1	Does the manufacturer provide customers with review and approval status of updates?	Yes	__
CSUP-11.2	Is there an update review cycle for the device?	Yes	__

	HEALTH DATA DE-IDENTIFICATION (DIDT)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability of the device to directly remove information that allows identification of a person.					
DIDT-1	Does the device provide an integral capability to de-identify personally identifiable information?	No	__	Section 5.6, DIDT	None	ISO 27038
DIDT-1.1	Does the device support de-identification profiles that comply with the DICOM standard for de-identification?	N/A	__	Section 5.6, DIDT	None	ISO 27038

	DATA BACKUP AND DISASTER RECOVERY (DTBK)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability to recover after damage or destruction of device data, hardware, software, or site configuration information.					
DTBK-1	Does the device maintain long term primary storage of personally identifiable information / patient information (e.g. PACS)?	No	__			
DTBK-2	Does the device have a "factory reset" function to restore the original device settings as provided by the manufacturer?	No	__	Section 5.7, DTBK	CP-9	A.12.3.1
DTBK-3	Does the device have an integral data backup capability to removable media?	No	__	Section 5.7, DTBK	CP-9	A.12.3.1
DTBK-4	Does the device have an integral data backup capability to remote storage?	No				
DTBK-5	Does the device have a backup capability for system configuration information, patch restoration, and software restoration?	No				
DTBK-6	Does the device provide the capability to check the integrity and authenticity of a backup?	No	__	Section 5.7, DTBK	CP-9	A.12.3.1

	EMERGENCY ACCESS (EMRG)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability of the device user to access personally identifiable information in case of a medical emergency situation that requires immediate access to stored personally identifiable information.					
EMRG-1	Does the device incorporate an emergency access (i.e. "break-glass") feature?	No	__	Section 5.8, EMRG	SI-17	None

	HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	How the device ensures that the stored data on the device has not been altered or destroyed in a non-authorized manner and is from the originator.					
IGAU-1	Does the device provide data integrity checking mechanisms of stored health data (e.g., hash or digital signature)?	No	__	Section 5.9, IGAU	SC-28	A.18.1.3
IGAU-2	Does the device provide error/failure protection and recovery mechanisms for stored health data (e.g., RAID-5)?	No	__	Section 5.9, IGAU	SC-28	A.18.1.3

	MALWARE DETECTION/PROTECTION (MLDP)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability of the device to effectively prevent, detect and remove malicious software (malware).					
MLDP-1	Is the device capable of hosting executable software?	Yes	__	Section 5.10, MLDP		

MLDP-2	Does the device support the use of anti-malware software (or other anti-malware mechanism)? Provide details or reference in notes.	Yes	__	Section 5.10, MLDP	SI-3	A.12.2.1
MLDP-2.1	Does the device include anti-malware software by default?	N/A	__	Section 5.10, MLDP	CM-5	A.9.2.3, A.9.4.5, A.12.1.2, A.12.1.4, A.12.5.1
MLDP-2.2	Does the device have anti-malware software available as an option?	N/A	__	Section 5.10, MLDP	AU-6	A.12.4.1, A.16.1.2, A.16.1.4
MLDP-2.3	Does the device documentation allow the owner/operator to install or update anti-malware software?	Yes	__	Section 5.10, MLDP	CP-10	A.17.1.2
MLDP-2.4	Can the device owner/operator independently (re-)configure anti-malware settings?	N/A	__	Section 5.10, MLDP	AU-2	None
MLDP-2.5	Does notification of malware detection occur in the device user interface?	N/A				
MLDP-2.6	Can only manufacturer-authorized persons repair systems when malware has been detected?	N/A				
MLDP-2.7	Are malware notifications written to a log?	N/A				
MLDP-2.8	Are there any restrictions on anti-malware (e.g., purchase, installation, configuration, scheduling)?	N/A				
MLDP-3	If the answer to MLDP-2 is NO, and anti-malware cannot be installed on the device, are other compensating controls in place or available?	N/A	__	Section 5.10, MLDP	SI-2	A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3
MLDP-4	Does the device employ application whitelisting that restricts the software and services that are permitted to be run on the device?	N/A	__	Section 5.10, MLDP	SI-3	A.12.2.1
MLDP-5	Does the device employ a host-based intrusion detection/prevention system?	N/A	__	Section 5.10, MLDP	SI-4	None
MLDP-5.1	Can the host-based intrusion detection/prevention system be configured by the customer?	N/A	__	Section 5.10, MLDP	CM-7	A.12.5.1
MLDP-5.2	Can a host-based intrusion detection/prevention system be installed by the customer?	N/A	__	Section 5.10, MLDP		

	NODE AUTHENTICATION (NAUT)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability of the device to authenticate communication partners/nodes.					
NAUT-1	Does the device provide/support any means of node authentication that assures both the sender and the recipient of data are known to each other and are authorized to receive transferred information (e.g. Web APIs, SMTP, SNMP)?	No	__	Section 5.11, NAUT	SC-23	None
NAUT-2	Are network access control mechanisms supported (E.g., does the device have an internal firewall, or use a network connection white list)?	N/A	__	Section 5.11, NAUT	SC-7	A.13.1.1, A.13.1.3, A.13.2.1,A.14.1.3
NAUT-2.1	Is the firewall ruleset documented and available for review?	N/A	__			
NAUT-3	Does the device use certificate-based network connection authentication?	No	__			

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	CONNECTIVITY CAPABILITIES (CONN) *All network and removable media connections must be considered in determining appropriate security controls. This section lists connectivity capabilities that may be present on the device.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
CONN-1	Does the device have hardware connectivity capabilities?	No	ICS is a software product.			
CONN-1.1	Does the device support wireless connections?	N/A	__			
CONN-1.1.1	Does the device support Wi-Fi?	N/A	__			
CONN-1.1.2	Does the device support Bluetooth?	N/A	__			
CONN-1.1.3	Does the device support other wireless network connectivity (e.g. LTE, Zigbee, proprietary)?	N/A	__			
CONN-1.1.4	Does the device support other wireless connections (e.g., custom RF controls, wireless detectors)?	N/A	__			
CONN-1.2	Does the device support physical connections?	N/A	__			
CONN-1.2.1	Does the device have available RJ45 Ethernet ports?	N/A	__			
CONN-1.2.2	Does the device have available USB ports?	N/A	__			
CONN-1.2.3	Does the device require, use, or support removable memory devices?	N/A	__			
CONN-1.2.4	Does the device support other physical connectivity?	N/A	__			
CONN-2	Does the manufacturer provide a list of network ports and protocols that are used or may be used on the device?	N/A	ICS is a software product that will be hosted on customer hardware. Spacelabs can provide the necessary ports and protocols for customers to			
CONN-3	Can the device communicate with other systems within the customer environment?	N/A	ICS is a software product that will be hosted on customer hardware.			
CONN-4	Can the device communicate with other systems external to the customer environment (e.g., a service host)?	N/A	ICS is a software product that will be hosted on customer hardware. Customers manage external connections.			
CONN-5	Does the device make or receive API calls?	No	__			
CONN-6	Does the device require an internet connection for its intended use?	No	__			
CONN-7	Does the device support Transport Layer Security (TLS)?	Yes	__			
CONN-7.1	Is TLS configurable?	N/A	This is a software application. TLS configurations are applied at the OS layer.			

CONN-8	Does the device provide operator control functionality from a separate device (e.g., telemedicine)?	No	__			

	PERSON AUTHENTICATION (PAUT)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability to configure the device to authenticate users.					
PAUT-1	Does the device support and enforce unique IDs and passwords for all users and roles (including service accounts)?	Yes	__	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-1.1	Does the device enforce authentication of unique IDs and passwords for all users and roles (including service accounts)?	Yes	__	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-2	Is the device configurable to authenticate users through an external authentication service (e.g., MS Active Directory, NDS, LDAP, OAuth, etc.)?	Yes	__	Section 5.12, PAUT	IA-5	A.9.2.1
PAUT-3	Is the device configurable to lock out a user after a certain number of unsuccessful logon attempts?	No	__	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-4	Are all default accounts (e.g., technician service accounts, administrator accounts) listed in the documentation?	N/A	__	Section 5.12, PAUT	SA-4(5)	A.14.1.1, A.14.2.7, A.14.2.9, A.15.1.2
PAUT-5	Can all passwords be changed?	N/A	__	Section 5.12, PAUT		
PAUT-6	Is the device configurable to enforce creation of user account passwords that meet established (organization specific) complexity rules?	No	__	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-7	Does the device support account passwords that expire periodically?	No	__			
PAUT-8	Does the device support multi-factor authentication?	N/A	__			
PAUT-9	Does the device support single sign-on (SSO)?	N/A	__	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-10	Can user accounts be disabled/locked on the device?	N/A	__	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-11	Does the device support biometric controls?	N/A	__	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-12	Does the device support physical tokens (e.g. badge access)?	N/A	__			
PAUT-13	Does the device support group authentication (e.g. hospital teams)?	N/A	__			
PAUT-14	Does the application or device store or manage authentication credentials?	No	__			
PAUT-14.1	Are credentials stored using a secure method?	N/A	__			

	PHYSICAL LOCKS (PLOK)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	Physical locks can prevent unauthorized users with physical access to the device from compromising the integrity and confidentiality of personally identifiable information stored on the device or on removable media					
PLOK-1	Is the device software only? If yes, answer “N/A” to remaining questions in this section.	Yes	__	Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3

PLOK-2	Are all device components maintaining personally identifiable information (other than removable media) physically secure (i.e., cannot remove without tools)?	N/A	__	Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
PLOK-3	Are all device components maintaining personally identifiable information (other than removable media) physically secured behind an individually keyed locking device?	N/A	__	Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
PLOK-4	Does the device have an option for the customer to attach a physical lock to restrict access to removable media?	N/A	__	Section 5.13, PLOK	PE- 3(4)	A.11.1.1, A.11.1.2, A.11.1.3
	ROADMAP FOR THIRD PARTY COMPONENTS IN DEVICE LIFE CYCLE (RDMP) *Manufacturer's plans for security support of third-party components within the device's life cycle.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
RDMP-1	Was a secure software development process, such as ISO/IEC 27034 or IEC 62304, followed during product development?	Yes	__	Section 5.14, RDMP	CM-2	None
RDMP-2	Does the manufacturer evaluate third-party applications and software components included in the device for secure development practices?	Yes	__	Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2
RDMP-3	Does the manufacturer maintain a web page or other source of information on software support dates and updates?	Yes	__	Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2
RDMP-4	Does the manufacturer have a plan for managing third-party component end-of-life?	N/A	__	Section 5.14, RDMP	CM-8	A.8.1.1, A.8.1.2
	SOFTWARE BILL OF MATERIALS (SBoM) *A Software Bill of Material (SBoM) lists all the software components that are incorporated into the device being described for the purpose of operational security planning by the healthcare delivery organization. This section supports controls in the RDMP section.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
SBOM-1	Is the SBoM for this product available?	Yes	__			
SBOM-2	Does the SBoM follow a standard or common method in describing software components?	Yes	__			
SBOM-2.1	Are the software components identified?	Yes	__			
SBOM-2.2	Are the developers/manufacturers of the software components identified?	Yes	__			
SBOM-2.3	Are the major version numbers of the software components identified?	Yes	__			
SBOM-2.4	Are any additional descriptive elements identified?	N/A	__			
SBOM-3	Does the device include a command or process method available to generate a list of software components installed on the device?	N/A	__			

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SBOM-4	Is there an update process for the SBoM?	Yes	__			
	SYSTEM AND APPLICATION HARDENING (SAHD)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The device's inherent resistance to cyber attacks and malware.				CM-7	A.12.5.1*
SAHD-1	Is the device hardened in accordance with any industry standards?	No	__	Section 5.15, SAHD	AC-17(2)/IA-3	A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2/None
SAHD-2	Has the device received any cybersecurity certifications?	No	__	Section 5.15, SAHD	SA-12(10)	A.14.2.7, A.15.1.1, A.15.1.2, A.15.1.3
SAHD-3	Does the device employ any mechanisms for software integrity checking	No	__			
SAHD-3.1	Does the device employ any mechanism (e.g., release-specific hash key, checksums, digital signature, etc.) to ensure the installed software is manufacturer-authorized?	Yes	__			
SAHD-3.2	Does the device employ any mechanism (e.g., release-specific hash key, checksums, digital signature, etc.) to ensure the software updates are the manufacturer-authorized updates?	Yes	__	Section 5.15, SAHD	CM-8	A.8.1.1, A.8.1.2
SAHD-4	Can the owner/operator perform software integrity checks (i.e., verify that the system has not been modified or tampered with)?	N/A	__	Section 5.15, SAHD	AC-3	A.6.2.2, A.9.1.2, A.9.4.1, A.9.4.4, A.9.4.5, A.13.1.1, A.14.1.2, A.14.1.3, A.18.1.3
SAHD-5	Is the system configurable to allow the implementation of file-level, patient level, or other types of access controls?	Yes	ICS is a software product with integrates with Windows Active Directory and access controls can be implemented through Active Directory	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-5.1	Does the device provide role-based access controls?	No	__	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-6	Are any system or user accounts restricted or disabled by the manufacturer at system delivery?	N/A	__	Section 5.15, SAHD	CM-8	A.8.1.1, A.8.1.2
SAHD-6.1	Are any system or user accounts configurable by the end user after initial configuration?	N/A	__	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-6.2	Does this include restricting certain system or user accounts, such as service technicians, to least privileged access?	N/A	__	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-7	Are all shared resources (e.g., file shares) which are not required for the intended use of the device disabled?	No	__	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-8	Are all communication ports and protocols that are not required for the intended use of the device disabled?	Yes	ICS is a software product. Spacelabs can provide the necessary ports and protocols for customer to configure.	Section 5.15, SAHD	SA-18	None

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SAHD-9	Are all services (e.g., telnet, file transfer protocol [FTP], internet information server [IIS], etc.), which are not required for the intended use of the device deleted/disabled?	No	__	Section 5.15, SAHD	CM-6	None
SAHD-10	Are all applications (COTS applications as well as OS-included applications, e.g., MS Internet Explorer, etc.) which are not required for the intended use of the device deleted/disabled?	No	__	Section 5.15, SAHD	SI-2	A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3
SAHD-11	Can the device prohibit boot from uncontrolled or removable media (i.e., a source other than an internal drive or memory component)?	N/A	__			
SAHD-12	Can unauthorized software or hardware be installed on the device without the use of physical tools?	N/A	__			
SAHD-13	Does the product documentation include information on operational network security	N/A	__			
SAHD-14	Can the device be hardened beyond the default provided state?	Yes	__			
SAHD-14.1	Are instructions available from vendor for increased hardening?	Yes				
SHAD-15	Can the system prevent access to BIOS or other bootloaders during boot?	N/A				
SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?	N/A	__			
	SECURITY GUIDANCE (SGUD)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	Availability of security guidance for operator and administrator of the device and manufacturer sales and service.					
SGUD-1	Does the device include security documentation for the owner/operator?	No	__	Section 5.16, SGUD	AT-2/PL-2	A.7.2.2, A.12.2.1/A.14.1.1
SGUD-2	Does the device have the capability, and provide instructions, for the permanent deletion of data from the device or media?	N/A	__	Section 5.16, SGUD	MP-6	A.8.2.3, A.8.3.1, A.8.3.2, A.11.2.7
SGUD-3	Are all access accounts documented?	N/A	__	Section 5.16, SGUD	AC-6,IA-2	A.9.1.2, A.9.2.3, A.9.4.4, A.9.4.5/A.9.2.1
SGUD-3.1	Can the owner/operator manage password control for all accounts?	N/A	__			
SGUD-4	Does the product include documentation on recommended compensating controls for the	N/A	__			
	HEALTH DATA STORAGE CONFIDENTIALITY (STCF)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability of the device to ensure unauthorized access does not compromise the integrity and confidentiality of personally identifiable information stored on the device or removable media.					
STCF-1	Can the device encrypt data at rest?	N/A	__	Section 5.17, STCF	SC-28	A.8.2.3

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STCF-1.1	Is all data encrypted or otherwise protected?	N/A				
STCF-1.2	Is the data encryption capability configured by default?	N/A				
STCF-1.3	Are instructions available to the customer to configure encryption?	N/A				
STCF-2	Can the encryption keys be changed or configured?	N/A	__	Section 5.17, STCF	SC-28	A.8.2.3
STCF-3	Is the data stored in a database located on the device?	N/A	__			
STCF-4	Is the data stored in a database external to the device?	Yes	__			
	TRANSMISSION CONFIDENTIALITY (TXCF)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability of the device to ensure the confidentiality of transmitted personally identifiable information.					
TXCF-1	Can personally identifiable information be transmitted only via a point-to-point dedicated	No	__	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-2	Is personally identifiable information encrypted prior to transmission via a network or removable media?	No	__	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-2.1	If data is not encrypted by default, can the customer configure encryption options?	No	__			
TXCF-3	Is personally identifiable information transmission restricted to a fixed list of network destinations?	See Notes	ICS is a software product. It is recommended that customers follow the Spacelabs networking deployment guide.	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-4	Are connections limited to authenticated systems?	See Notes	ICS is a software product. It is recommended that customers follow the Spacelabs networking deployment guide.	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-5	Are secure transmission methods supported/implemented (DICOM, HL7, IEEE 11073)?	N/A	__			
	TRANSMISSION INTEGRITY (TXIG)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The ability of the device to ensure the integrity of transmitted data.					

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TXIG-1	Does the device support any mechanism (e.g., digital signatures) intended to ensure data is not modified during transmission?	Yes	All communications between the Spacelabs monitoring devices and ICS occur over TCP/IP and/or UDP protocols. These protocols have built in checksum mechanisms. Additionally, TCP protocol also provides relibale data delivery by packet sequence numbering, message acknowledgement capabilities. There are no data integrity checks for the stored data at the Smart Disclosure application layer. Capabailities within SQL server platform and/or physical infrastructure platform (for e.g. RAID configuration for data storage) can be leveraged to minimize	Section 5.19, TXIG	SC-8	A.8.2.3, A.13.1.1, A.13.2.1, A.13.2.3, A.14.1.2, A.14.1.3
TXIG-2	Does the device include multiple sub-components connected by external cables?	N/A	__			
	REMOTE SERVICE (RMOT)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	Remote service refers to all kinds of device maintenance activities performed by a service person via network or other remote connection.					
RMOT-1	Does the device permit remote service connections for device analysis or repair?	Yes	This is a software applications running on the customer hosted OS. Local Admin or domain admin users have full access to the ICS applications.		AC-17	A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2
RMOT-1.1	Does the device allow the owner/operator to initiative remote service sessions for device analysis or repair?	Yes	__			
RMOT-1.2	Is there an indicator for an enabled and active remote session?	No	__			
RMOT-1.3	Can patient data be accessed or viewed from the device during the remote session?	N/A	__		AC-17	A.6.2.1, A.6.2.2, A.13.1.1, A.13.2.1, A.14.1.2

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RMOT-2	Does the device permit or use remote service connections for predictive maintenance data?	No	__	
RMOT-3	Does the device have any other remotely accessible functionality (e.g. software updates, remote	No	__	

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	OTHER SECURITY CONSIDERATIONS (OTHR) *NONE*			

Notes:

Note 1 Example note. Please keep individual notes to one cell. Please use separate notes for separate information