Manufacturer Disclosure Statement for Medical Device Security -- MDS2

Spacelabs Healthcare 91390 091-0324-06 Rev A Sep-22

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	Qube Patient Monitor version 4.0.0	__			
DOC-3	Device Model	91390	__			
DOC-4	Document ID	091-0324-06 Rev A	__			
DOC-5	Manufacturer Contact Information	Spacelabs Healthcare, 35301 S.E. Center Street, Snoqualmie, WA 98065	__			
DOC-6	Intended use of device in network-connected environment:	Spacelabs 91390 Qube® is a compact patient monitor with a 12-inch touchscreen that is well-suited for use in high acuity neonatal, pediatric and adult care, as well as perioperative environments. The Qube stores up to 96 hours of trends, and features remote viewing, Alarm Watch, and three userselectable screen formats harmonized with Xprezzon® and Qube Mini to facilitate learning and navigation. With wireless networking and two batteries, Qube supports extended transport for up to eight hours. When deployed with the Spacelabs Xhibit® Central Station and Intesys® Clinical Suite, the Qube offers enterprise	__			
DOC-7	Document Release Date	Sep-22	__			
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-archives/			
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 Qube 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)?	No	__			
DOC-11.1	Does the SaMD contain an operating system?	N/A	__			
DOC-11.2	Does the SaMD rely on an owner/operator provided operating system?	N/A	__			
DOC-11.3	Is the SaMD hosted by the manufacturer?	N/A				
DOC-11.4	Is the SaMD hosted by the customer?	N/A	__			

		Yes, No, N/A, or See Note	Note #	IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
	MANAGEMENT OF PERSONALLY IDENTIFIABLE INFORMATION					
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?	See Notes	The patient monitor stores private data in nonvolatile memory to support short term power service interruptions. All data is purged from nonvolatile memory if power service interruption exceeds 3 minutes or the monitor's power switch is toggled.		
MPII-2.3	Is personally identifiable information preserved in the device's non-volatile memory until explicitly erased?	No	__		
MPII-2.4	Does the device store personally identifiable information in a database?	No	__		
MPII-2.5	Does the device allow configuration to automatically delete local personally identifiable information after it is stored to a long term solution?	N/A	Patient demographic data is removed whenever the patient is discharged from the monitor.	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	The patient monitor integrated with other Spacelabs products can import or export private data. The patient monitor as a standalone product cannot import or export private data.	AR-2	A.15.1.4
MPII-2.7	Does the device maintain personally identifiable information when powered off, or during power service interruptions?	See Notes	The patient monitor stores private data in nonvolatile memory to support short term power service interruptions. All data is purged from nonvolatile memory if power service interruption exceeds 3 minutes or the monitor's power switch is toggled.	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)?	Yes	The internal media does not store PHI.		
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)?	No		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.)?	Yes	__	AR-2	A.15.1.4
MPII-3.2	Does the device generate hardcopy reports or images containing personally identifiable information?	Yes	Monitors can have an optional strip printer for printing waveform data and can include the patient's name.	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, FireWire, etc.)?	Yes	The Qube monitor is able to receive potentially identifiable information from devices connected over RS-232 and/or SDLC ports. This is dependent upon the connected third-party device. Additionally, patient band scanners can be plugged into the monitor via USB to scan patient identifying bands for monitor admission.	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	Qube can interface to another Spacelabs patient monitor through a wired or wireless Ethernet network. The monitor can also interface to other Spacelabs monitors, Spacelabs central station product (3800 UVSL Central Station, Xhibit Central Station, or Xhibit XC4), Xprezznet or to a Spacelabs clinical information system product (ICS-G2). In all instances the possibility of transmitting private data exists.		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.)?	Yes	Qube can interface to another Spacelabs patient monitor through a wired or wireless Ethernet network. The monitor can also interface to other Spacelabs monitors, Spacelabs central station product (3800 UVSL Central Station, Xhibit Central Station, or Xhibit XC4), Xprezznet or to a Spacelabs clinical information system product (ICS-G2). In all instances the possibility of transmitting private data exists.		AR-2	A.15.1.4
MPII-3.7	Does the device transmit/receive personally identifiable information over an external network (e.g., Internet)?	No	__		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?	Yes	Qube uses Spacelabs proprietery TCP and UDP protocols to transmit/recieve information between other Spacelabs monitors, ICS Monitor loader (92810), Xhibit Central Station and XC4 (96102, 96501) and Xprezznet.			
MPII-3.10	Does the device use any other mechanism to transmit, import or export personally identifiable information?	Yes	Monitors can use Data Shuttle to import PII from other monitors.		AR-2	A.15.1.4
Management of Private Data notes:					AR-2	A.15.1.4

	AUTOMATIC LOGOFF (ALOF)			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	The device's ability to prevent access and misuse by unauthorized users if device is left idle for a period of time.					
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)?	Yes	Inactivity log off feature is present.	Section 5.1, ALOF	AC-12	None
ALOF-2	Is the length of inactivity time before auto-logoff/screen lock user or administrator	No	Not configurable	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	The monitor is capable of capturing logs for IT configuration changes, successful/failed access to Privileged Access mode and preconfigured shared accounts (Biomed/Service/Clinical), and information pertaining to monitor statefulness such as network connectivity.	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	Audit logs will capture the user type (Biomed/Service/Clinical/System) as part of the logging message.			
AUDT-1.2	Does other personally identifiable information exist in the audit trail?	No		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:	Yes	__	Section 5.2, AUDT	AU-2	None

AUDT-2.1	Successful login/logout attempts?	See Notes	Attempts at accessing monitor Prilveged Access mode (which requires a password such as for the Biomed and Service account) are recorded.	Section 5.2, AUDT	AU-2	None
AUDT-2.2	Unsuccessful login/logout attempts?	See Notes	Attempts at accessing monitor Prilveged Access mode (which requires a password such as for the Biomed and Service account) are recorded.	Section 5.2, AUDT	AU-2	None
AUDT-2.3	Modification of user privileges?	No	Account permissions are static on the monitor for each account (Biomed/Service/Clinical/kiosk mode).	Section 5.2, AUDT	AU-2	None
AUDT-2.4	Creation/modification/deletion of users?	No	Account permissions are static on the monitor for each account (Biomed/Service/Clinical/kiosk mode).	Section 5.2, AUDT	AU-2	None
AUDT-2.5	Presentation of clinical or PII data (e.g. display, print)?	No	By product design, the monitor displays patient data and vitals in kiosk mode.	Section 5.2, AUDT	AU-2	None
AUDT-2.6	Creation/modification/deletion of data?	Yes	Changes in IT configuration data such as networking configurations is logged.	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)?	Yes	__	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	Connections to Spacelabs' Genie service, used for monitor servicing, are logged.	Section 5.2, AUDT	AU-2	None
AUDT-2.8.1	Remote or on-site support?	See Notes	Monitors can only be serviced on-site.	Section 5.2, AUDT	AU-2	None
AUDT-2.8.2	Application Programming Interface (API) and similar activity?	N/A	__	Section 5.2, AUDT	AU-2	None
AUDT-2.9	Emergency access?	N/A	__	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?	Yes	__	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	Depending on the patient monitoring implementation, Spacelabs monitors can sync time with Xhibit central stations or with the ICS Monitor Loader server managing the monitoring network the monitor resides on.	Section 5.2, AUDT	AU-2	None
AUDT-5	Can audit log content be exported?	Yes	Logs can be sent to a configured logging aggregation server.	Section 5.2, AUDT	AU-2	None
AUDT-5.1	Via physical media?	Yes	By default configuration, logs are sent to an internal USB drive. Logs are saved and deleted first-in-first-out (FIFO) as storage allows.			
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?	Yes	Monitors configured to send logs to a logging server can import SSL/TLS certificates to encrypt log data in transit.			
AUDT-6	Can audit logs be monitored/reviewed by owner/operator?	No	Though monitor generated logs cannot be viewed locally on the monitor, they can be reviewed by exporting locally saved logs to a workstation or from the			
AUDT-7	Are audit logs protected from modification?	Yes	Logs are written locally to an internal USB drive and are read-only.	Section 5.2, AUDT	AU-2	None
AUDT-7.1	Are audit logs protected from access?	Yes	Logs are written locally to an internal USB drive. Physical security protections are in place to limit access to the drive.			
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?	See Notes	Yes: The device provides bedside monitoring information to healthcare staff and is intended to be operated in Kiosk mode, in an always on/functional mode - healthcare workers do not have to log on to get access to the monitor information. All elevated permissions functions (used to setup or configure the device) are not accessible in the unauthenticated Kiosk interface, but can be accessed via shared accounts for clinical, biomed, and service personnel. The password for the clinical and biomed accounts can be controlled by the	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)?	No	__	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)?	N/A	__	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-1.3	Are any special groups, organizational units, or group policies required?	N/A	__	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.)?	N/A	__	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)?	N/A	__	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?	Yes	__			

	CYBER SECURITY PRODUCT UPGRADES (CSUP) *The ability of on-site service staff, remote service staff, or authorized customer staff to install/upgrade device's security patches.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
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	The Real Time Operating System (RTOS) used by the monitor is Wind River Systems' VxWorks version			
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?	See Notes	Patches and updates are installed by qualified and authorized Spacelabs Field Service Engineers to each device.			
CSUP-2.3	Does the device have the capability to receive remote installation of patches or software updates?	No	__			
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?	No	Software updates are all inclusive. Any time there are product updates, including security updates, they are distributed as a whole software update to the monitor.			
CSUP-3	Does the device contain Drivers and Firmware? If yes, complete 3.1-3.4.	Yes	__			
CSUP-3.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	Yes	__			

CSUP-3.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	See Notes	Software updates are all inclusive. Any time there are product updates, including security updates, they are distributed as a whole software update to the monitor.			
CSUP-3.3	Does the device have the capability to receive remote installation of patches or software updates?	No	__			
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?	No	Software updates are all inclusive. Any time there are product updates, including security updates, they are distributed as a whole software update to the monitor.			
CSUP-4	Does the device contain Anti-Malware Software? If yes, complete 4.1-4.4.	No	This device has a closed architecture by design and does not support the installation of anti-malware software.			
CSUP-4.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	N/A	__			
CSUP-4.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	N/A	__			
CSUP-4.3	Does the device have the capability to receive remote installation of patches or software updates?	N/A	__			
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?	N/A	__			
CSUP-5	Does the device contain Non-Operating System commercial off-the-shelf components? If yes, complete 5.1-5.4.	No	__			
CSUP-5.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	N/A	__			
CSUP-5.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	N/A	__			
CSUP-5.3	Does the device have the capability to receive remote installation of patches or software updates?	N/A	__			
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?	N/A	__			
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	Third-party patches approved for installation are posted on the Spacelabs website in an area accessible to registered Spacelabs customers and their supporting IT teams. In addition, customers can sign up to receive email notificaitons when third-party patch test reports (i.e. approved patches) are posted.			

CSUP-8	Does the device perform automatic installation of software updates?	No	Patches and updates are installed by qualified and authorized Spacelabs Field Service Engineers to each device.			
CSUP-9	Does the manufacturer have an approved list of third-party software that can be installed on the device?	N/A	This device has a closed architecture by design and does not support the installation of third-party software.			
CSUP-10	Can the owner/operator install manufacturer-approved third-party software on the device themselves?	No	—			
CSUP-10.1	Does the system have mechanism in place to prevent installation of unapproved software?	Yes	The operating system is board specific and it is not possible to install unapproved software.			
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	Communications for product updates, such as Customer Service Notices or Product Update Bulletins, are distributed to Spacelabs customer service personnel to communicate these updates to customers directly.			
CSUP-11.2	Is there an update review cycle for the device?	Yes	—			

	HEALTH DATA DE-IDENTIFICATION (DIDT) *The ability of the device to directly remove information that allows identification of a person.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
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) *The ability to recover after damage or destruction of device data, hardware, software, or site configuration information.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
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?	Yes	—	Section 5.7, DTBK	CP-9	A.12.3.1
DTBK-3	Does the device have an integral data backup capability to removable media?	See Notes	No: The patient monitor does not have an integral data backup capability. However, the Spacelabs clinical information system product (ISC-G2) can be configured to collect and store up to 72 hours of the patient data acquired by the patient monitor.	Section 5.7, DTBK	CP-9	A.12.3.1
DTBK-4	Does the device have an integral data backup capability to remote storage?	See Notes	No: The patient monitor does not have an integral data backup capability. However, the Spacelabs clinical information system product (ISC-G2) can be configured to collect and store up to 72 hours of the patient data acquired by the patient monitor.			
DTBK-5	Does the device have a backup capability for system configuration information, patch restoration, and software restoration?	Yes	It is limited to monitor configuration cloning and restore for another spacelabs monitor.			
DTBK-6	Does the device provide the capability to check the integrity and authenticity of a backup?	N/A	—	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?	N/A	the devices are in kiosk mode by default and always allow for access to real-time clinical data	Section 5.8, EMRG	SI-17	None

	HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU) *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.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
IGAU-1	Does the device provide data integrity checking mechanisms of stored health data (e.g., hash or digital signature)?	Yes	__	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)?	N/A	__	Section 5.9, IGAU	SC-28	A.18.1.3

	MALWARE DETECTION/PROTECTION (MLDP) *The ability of the device to effectively prevent, detect and remove malicious software (malware).*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
MLDP-1	Is the device capable of hosting executable software?	No	__	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.	No	This device has a closed architecture by design and does not support the installation of anti-malware software.	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?	N/A	__	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?	Yes	This device has a closed architecture by design and does not support the installation of anti-malware software. Controls include product design considerations such running on a real-time operating system using a RISC-based processor and no user or admin access to the underlying operating system environment. Deployment guidance for Spacelabs products includes deploying the Qube monitor on a segmented monitoring network.	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) *The ability of the device to authenticate communication partners/nodes.*			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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)?	See Notes	Devices exchange configuration packets (a part of our proprietary network protocol). Monitors will not accept connections from or exchange information with any device that hasn't provided its configuration information (including but not limited to node ID).	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)?	No	__	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?	Yes	The device permits the use of WPA2 security modes for wireless network encryption.			

	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?	Yes	__			
CONN-1.1	Does the device support wireless connections?	Yes	__			
CONN-1.1.1	Does the device support Wi-Fi?	Yes	__			
CONN-1.1.2	Does the device support Bluetooth?	No	__			
CONN-1.1.3	Does the device support other wireless network connectivity (e.g. LTE, Zigbee, proprietary)?	No	__			
CONN-1.1.4	Does the device support other wireless connections (e.g., custom RF controls, wireless detectors)?	No	__			
CONN-1.2	Does the device support physical connections?	Yes	__			
CONN-1.2.1	Does the device have available RJ45 Ethernet ports?	Yes	__			
CONN-1.2.2	Does the device have available USB ports?	Yes	__			
CONN-1.2.3	Does the device require, use, or support removable memory devices?	Yes	USB flash drive can be used when apply updates or downloading error log files			
CONN-1.2.4	Does the device support other physical connectivity?	Yes	Other physiological devices, Flexports, PDL, Vitalink, external video displays, USB mouse, keyboard, barcode reader, Spacelabs provided custom USB printer and speciality parameters			
CONN-2	Does the manufacturer provide a list of network ports and protocols that are used or may be used on the device?	Yes	__			
CONN-3	Can the device communicate with other systems within the customer environment?	Yes	__			
CONN-4	Can the device communicate with other systems external to the customer environment (e.g., a service host)?	No	__			
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	Wireless EAP-PEAPv0 uses TLS			
CONN-7.1	Is TLS configurable?	Yes				
CONN-8	Does the device provide operator control functionality from a separate device (e.g., telemedicine)?	No	Some settings, such as adjusting the alarm limits the modules are using, can be set remotely from Xhibit central and a remote view running at another bedside. But full remote access to the monitor is not possible.			

	PERSON AUTHENTICATION (PAUT) *The ability to configure the device to authenticate users.*			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
PAUT-1	Does the device support and enforce unique IDs and passwords for all users and roles (including service accounts)?	No	This device has an embedded operating system which does not allow for unique IDs.	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)?	N/A	__	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.)?	N/A	__	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?	N/A	__	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?	Yes	All elevated permissions functions (used to setup or configure the device) are not accessible in the unauthenticated Kiosk interface, but can be accessed via shared accounts for clinical, biomed, and service personnel.	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?	Yes	Passwords can be changed for the shared accounts. I.e, the clinician and biomed accounts.	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	Clinical and biomed passwords can be changed to passwords which support an organization's complexity requirements.	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?	No	__			
PAUT-9	Does the device support single sign-on (SSO)?	No	__	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-10	Can user accounts be disabled/locked on the device?	N/A	This device has an embedded operating system which does not allow for unique usernames/passwords.	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-11	Does the device support biometric controls?	No	__	Section 5.12, PAUT	IA-2	A.9.2.1
PAUT-12	Does the device support physical tokens (e.g. badge access)?	No	__			
PAUT-13	Does the device support group authentication (e.g. hospital teams)?	Yes	All elevated permissions functions (used to setup or configure the device) are not accessible in the unauthenticated Kiosk interface, but can be accessed via shared accounts for clinical, biomed, and service personnel.			
PAUT-14	Does the application or device store or manage authentication credentials?	Yes	__			
PAUT-14.1	Are credentials stored using a secure method?	Yes	__			

	PHYSICAL LOCKS (PLOK) *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*			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
PLOK-1	Is the device software only? If yes, answer "N/A" to remaining questions in this section.	No	__	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)?	Yes	__	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?	No	__	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	The Software Development Plan follows IEC 62304	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?	Yes	__	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?	No	__			
SBOM-3	Does the device include a command or process method available to generate a list of software components installed on the device?	No	__			
SBOM-4	Is there an update process for the SBoM?	Yes	__			

	SYSTEM AND APPLICATION HARDENING (SAHD) *The device's inherent resistance to cyber attacks and malware.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
					CM-7	A.12.5.1*
SAHD-1	Is the device hardened in accordance with any industry standards?	Yes	__	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?	Yes	__	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	Yes	__			
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)?	Yes	__	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	__	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-5.1	Does the device provide role-based access controls?	Yes	__	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?	No	__	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?	Yes	__	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	__	Section 5.15, SAHD	SA-18	None
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?	Yes	__	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?	Yes	__	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)?	Yes				
SAHD-12	Can unauthorized software or hardware be installed on the device without the use of physical tools?	No	__			
SAHD-13	Does the product documentation include information on operational network security scanning by users?	No				
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?	Yes				
SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?	No	__			

	SECURITY GUIDANCE (SGUD) *Availability of security guidance for operator and administrator of the device and manufacturer sales and service.*			**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
SGUD-1	Does the device include security documentation for the owner/operator?	Yes	At request, Spacelabs can provide manuals and service documentation such as Security Manuals.	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?	Yes	__	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?	Yes	__	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?	Yes	__			
SGUD-4	Does the product include documentation on recommended compensating controls for the device?	Yes	__			

	HEALTH DATA STORAGE CONFIDENTIALITY (STCF) *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.*			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
STCF-1	Can the device encrypt data at rest?	No	This device cannot be encrypted during normal operations. The bedside monitor must be connected for the data to be viewable. Once a patient has been discharged from the Qube monitor, that patient information will be removed from the device.	Section 5.17, STCF	SC-28	A.8.2.3
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	This device does not have a database of it's own. Qube monitors communicates with the ICS Monitor Loader to send the data to the database and even to the hospital's electronic medical records database.			
STCF-4	Is the data stored in a database external to the device?	Yes	This device does not have a database of it's own. Qube monitors communicates with the ICS Monitor Loader to send the data to the database and even to the hospital's electronic medical records database.			

	TRANSMISSION CONFIDENTIALITY (TXCF) *The ability of the device to ensure the confidentiality of transmitted personally identifiable information.*			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
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?	N/A	__			
TXCF-3	Is personally identifiable information transmission restricted to a fixed list of network destinations?	See Notes	Spacelabs provides networking deployment guide.	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-4	Are connections limited to authenticated systems?	Yes	Monitors are not open to communication with systems other than Spacelabs Products. The Monitors follows Spacelabs specific protocols to communicate with other network devices.	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-5	Are secure transmission methods supported/implemented (DICOM, HL7, IEEE 11073)?	N/A	Qube monitors can communicate with Xhibit Central Stations, so that nurses have multiple people watching over the patients and their vital signs. Qube monitors can communicate with the ICS Monitor Loader to send the data to the database and even to the hospital's electronic medical			

	TRANSMISSION INTEGRITY (TXIG) *The ability of the device to ensure the integrity of transmitted data.*			IEC TR 80001-2-2:2012	NIST SP 800-53 Rev. 4	ISO 27002:2013
TXIG-1	Does the device support any mechanism (e.g., digital signatures) intended to ensure data is not modified during transmission?	No	__	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?	No	__			

	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?	No	__		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?	N/A	__			
RMOT-1.2	Is there an indicator for an enabled and active remote session?	N/A	__			
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
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 training)?	No	Though Spacelabs monitors do support some remote features such as the ability to adjust alarming from an Xhibit Central station, full remote service capabilities such as software updates or remote access are not supported.			

	OTHER SECURITY CONSIDERATIONS (OTHR)	**IEC TR 80001-2-2:2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002:2013**
	NONE			

Notes:

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