Manufacturer Disclosure Statement for Medical Device Security (MDS2)

For Ambu® aBox™ 2 and aView™ 2 Advance with Software 2.3

Ambu

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
Question ID	**Question**	**Displaying and processing unit**	**Notes**	**IEC TR 80001-2-2: 2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002: 2013**
DOC-1	Manufacturer name	AMBU A/S	–			
DOC-2	Device description	Non-sterile, reusable monitor, intended to display live imaging data from Ambu visualization devices.	–			
DOC-3	Device model	aView 2 Advance and aBox 2 with software version 2.3	–			
DOC-4	Document ID	PUB-001445	–			
DOC-5	Manufacturer contact information	Phone: +45 7225 2000 Mail: ambu@ambu.com	–			
DOC-6	Intended use of device in network-connected environment	The device communicate DICOM containing Image storage via Ethernet or Wi-Fi as a client.	–			
DOC-7	Document release date	09-26-2022	–			
DOC-8	Coordinated Vulnerability Disclosure: Does the manufacturer have a vulnerability disclosure program for this device?	No	–			
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	See below diagram.			
DOC-11	SaMD: Is the device Software as a Medical Device (i.e. software-only, no hardware)?	No	It is SiMD.			
DOC-11.1	Does the SaMD contain an operating system?	N/A	We deliver a whole system (SiMD).			
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#			

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
	MANAGEMENT OF PERSONALLY IDENTIFIABLE INFORMATION	**Displaying and processing unit**	**Notes**	**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	The device can retrive ePHI via a DICOM worklist and store it through DICOM export.		AR-2	A.15.1.4
MPII-2	Does the decice maintain personally identifiable information?	Yes	The device can retrive ePHI via a DICOM worklist and store it through DICOM export. ePHI is used as data in use in program memmory. ePHI is persisted as data at rest in a database.		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 erased?	Yes				
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?	Yes	Configurable mechanisme for moving to trash bin after 3d, 1w, 4w, 12w + never. Configurable mechanisme for moving removing from trash bin after 3d, 1w, 4w, 12 w + never.		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	ePHI is transmitted as data in transit via DICOM protocol.		AR-2	A.15.1.4
MPII-2.7	Does the device maintain personally identifiable information when powered off, or during power service interruptions?	Yes	ePHI is persisted as data at rest in a database.		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	Internal SSD is full disk encrypted use for tamper resistance. The SSD can be removed for descruction and rentention.			
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)?	Yes	The ePHI is allowed to be stored on USB mass storages devices and on remote via DICOM export.		AR-2	A.15.1.4

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
MPII-3	Does the device have mechanisms used for the transmitting, importing/exporting of personally identifiable information?	Yes	The device uses the DICOM-WL retiriving ePHI, and DICOM export.		AR-2	A.15.1.4
MPII-3.1	Does the device display personally identifiable information (e.g., video display, etc.)?	Yes	ePHI is show in internal and extrenal screens.		AR-2	A.15.1.4
MPII-3.2	Does the device generate hardcopy reports or images containing personally identifiable information?	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	Recording is only internal SSD.		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	ePHI is transmitted as data in transit via DICOM protocol over USB.		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	ePHI is transmitted as data in transit via DICOM protocol over RJ45.		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	ePHI is transmitted as data in transit via DICOM protocol over Wifi.		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	The protocols used for transmiting/receiving of personal identifiable information supports communication over external networks. The user is recomended to only use the DICOM on a private network.		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

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
	AUTOMATIC LOGOFF (ALOF)	**Displaying and processing unit**	**Notes**	**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	Administrator can configure this from 10 min to never.	Section 5.1, ALOF	AC-12	None
ALOF-2	Is the leInsgth of inactivity time before auto-logoff/ screen lock user or administrator configurable?	Yes		Section 5.1, ALOF	AC-11	A.11.2.8, A.11.2.9
	AUDIT CONTROLS (AUDT)	**Displaying and processing unit**	**Notes**	**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?	No	–	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?	No	–			
AUDT-1.2	Does other personally identifiable information exist in the audit trail?	No	–	Section 5.2, AUDT	AU-2	None
AUDT-2	Are eventsAre recorded in an audit log? If yes, indicate which of the following events are recorded in the audit log	No	–	Section 5.2, AUDT	AU-2	None
AUDT-2.1	Successful login/logout attempts?	Yes	Extractable from the device log.	Section 5.2, AUDT	AU-2	None
AUDT-2.2	Unsuccessful login/logout attempts?	N/A		Section 5.2, AUDT	AU-2	None
AUDT-2.3	Modification of user privileges?	Yes	Extractable from the device log.	Section 5.2, AUDT	AU-2	None
AUDT-2.4	Creation/modification/deletion of users?	Yes	Extractable from the device log.	Section 5.2, AUDT	AU-2	None
AUDT-2.5	Presentation of clinical or PII data (e.g. display, print)?	N/A	–	Section 5.2, AUDT	AU-2	None
AUDT-2.6	Creation/modification/deletion of data?	N/A	–	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)?	No	The event of USB insertion is extractable on the device log.	Section 5.2, AUDT	AU-2	None

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
AUDT-2.8	Receipt/transmission of data or commands over a network or point-to-point connection?	N/A	–	Section 5.2, AUDT	AU-2	None
AUDT-2.8.1	Remote or on-site support?	N/A	–	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)?	Yes	Extractable from the device log.	Section 5.2, AUDT	AU-2	None
AUDT-2.11	Is the audit capability documented in more detail?	N/A	–	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 ofs 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?	No	–	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?	No	–	Section 5.2, AUDT	AU-2	None
AUDT-5	Can audita 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?	N/A	–			
AUDT-5.3	Via Other communications (e.g., external service device, mobile application)?	N/A	–			
AUDT-5.4	Are audit logs encrypted in transit or on storage media.	N/A	–			
AUDT-6	Can audit logs be monitored/reviewed by owner/operator?	No	–			
AUDT-7	Are audit logs protected from modification?	No	Device log is protected from modification.	Section 5.2, AUDT	AU-2	None
AUDT-7.1	Are audit logs protected from access?	No				
AUDT-8	Can audit logs be analyzed by the device?	No	–	Section 5.2, AUDT	AU-2	None

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
	AUTHORIZATION (AUTH)	**Displaying and processing unit**	**Notes**	**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?	Yes	Role based access control by username and password.	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	This is not currently supported.	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)?	No		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	There is two different user types: Administrator and Service technicians (Premade types) Non-privilege users can becreated/modified by administators.	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)?	No	Only pre-made accounts are assinged privilege.	Section 5.3, AUTH	IA-2	A.9.2.1
AUTH-4	Does the device authorize or control all API access requests?	No	–	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	The device has a kiosk mode for emergency use. In kiosk mode the use is restricted to the current procedure only. Export and all configuration is prohibited in kiosk mode.			

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
	CYBER SECURITY PRODUCT UPGRADES (CSUP)	**Displaying and processing unit**	**Notes**	**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	Software is always released as one selfcontained bundle.			
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	All nedded patches are controlled from Ambu, and released as one selfcontained bundle.			
CSUP-2.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes	For the OTA it is required that the device is registred in order to be update/ patched. For USB it is required that a signed update package is provided to the hospital from Ambu on a USB mass storage device. This is contained in the selfcontained bundle, see CSUP-1.			
CSUP-2.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes	Yes, the device can recive patches from the Ambu OTA service (pull only).			
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	–			
CSUP-3	Does the device contain Drivers and Firmware? If yes, complete 3.1-3.4.	Yes	Software is always released as one selfcontained bundle.			
CSUP-3.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	No	–			

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
CSUP-3.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes	For the OTA it is required that the device is registred in order to be update/ patched. For USB it is required that a signed update package is provided to the hospital from Ambu on a USB mass storage device. This is contained in the selfcontained bundle, see CSUP-1.			
CSUP-3.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes	Yes, the device can recive patches from the Ambu OTA service (pull only).			
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	–			
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?	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.	Yes	Software is always released as one selfcontained bundle.			
CSUP-5.1	Does the device documentation provide instructions for owner/operator installation of patches or software updates?	No	–			

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
CSUP-5.2	Does the device require vendor or vendor-authorized service to install patches or software updates?	Yes	For the OTA it is required that the device is registred in order to be update/ patched. For USB it is required that a signed update package is provided to the hospital from Ambu on a USB mass storage device. This is contained in the selfcontained bundle, see CSUP-1.			
CSUP-5.3	Does the device have the capability to receive remote installation of patches or software updates?	Yes	Yes, the device can recive patches from the Ambu OTA service (pull only).			
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?	No	–			
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	–			
CSUP-8	Does the device perform automatic installation of software updates?	No	Pull only on operator initative.			
CSUP-9	Does the manufacturer have an approved list of third-party software that can be installed on the device?	No	–			
CSUP-10	Can the owner/operator install manufacturer-approved third-party software on the device themselves?	No	–			

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
CSUP-10.1	Does the system have mechanism in place to prevent installation of unapproved software?	Yes	Only accepts Ambu signed packages.			
CSUP-11	Does the manufacturer have a process in place to assess device vulnerabilities and updates?	Yes	Internal vulnerability management program.			
CSUP-11.1	Does the manufacturer provide customers with review and approval status of updates?	No	Internal Release Process according to IEC62304.			
CSUP-11.2	Is there an update review cycle for the device?	Yes	Internal Software Maintenaince process according to IEC62304.			
	HEALTH DATA DE-IDENTIFICATION (DIDT)	**Dispalying and processing unit**	**Notes**	**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 acapility 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?	No	–	Section 5.6, DIDT	None	ISO 27038
	DATA BACKUP AND DISASTER RECOVERY (DTBK)	**Displaying and processing unit**	**Notes**	**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)?	Yes	The device only stores DICOM-WL information in a database on the device.			
DTBK-2	Does the device have a "factory reset" function to restore the original device settings as provided by the manufacturer?	Yes	The reset, resets all configurations, remove sensitive data and resets network settings.	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	The device does not include a integral data backup. Manual backup through export to USB is possible.	Section 5.7, DTBK	CP-9	A.12.3.1
DTBK-4	theD oes thedevsice have an integral data backup capability to remote storage?	No	The device does not include a integral data backup. Export through DICOM is possible.			
DTBK-5	Does the devsice have a backup capability for system configuration information, patch restoration, and software restorat.	No	–			
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

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
	EMERGENCY ACCESS (EMRG)	**Displaying and processing unit**	**Notes**	**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?	Yes	Primary use functions for the current procedure is avalible without login, but are restricted to the current procedure, can not export or modify the configuration of the device.	Section 5.8, EMRG	SI-17	None

	HEALTH DATA INTEGRITY AND AUTHENTICITY (IGAU)	**Displaying and processing unit**	**Notes**	**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)	**Displaying and processing unit**	**Notes**	**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	Does the device capable of hosting executable software?	No	The jailed GUI is unable to execute arbitrary software.	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	–	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

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
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	Jailed GUI Authenticated updates Limited Network services and device act client. Firewalled network services for approved network services.	Section 5.10, MLDP	SI-2	A.12.6.1, A.14.2.2, A.14.2.3, A.16.1.3
MLDP-4	Doe the device employ application whitelisting that restricts the software and services that are permitted to be run on the device?	No	–	Section 5.10, MLDP	SI-3	A.12.2.1
MLDP-5	Doe the device employ a host-based intrusion detection/prevention system?	No	–	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)	**Displaying and processing unit**	**Notes**	**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)?	Yes	The "Over the Air" (OTA) functionality provides role-based authentication and authentication to identify the device to the server.	Section 5.11, NAUT	SC-23	None
NAUT-2	Are the network access control mechanisms supported (E.g., does the device have an internal firewall, or use a network connection white list)?	Yes	Internal firewall.	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?	No	–			

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
NAUT-3	Does the device use certificate-based network connection authentication?	Yes	The device uses TLS authentication for OTA, with a CA signed certificate. The authenticalion of the TLS session is maintained by a OAUTH2 token. DICOM-TLS is supported, which is defined by BCP-195, supporting certificate-based authentication (one-way/anonymous TLS)			
	CONNECTIVITY CAPABILITIES (CONN)	**Displaying and processing unit**	**Notes**	**IEC TR 80001- 2-2: 2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002: 2013**
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.						
CONN-1	Does the device have hardware connectivity capabilities?	Yes	–			
CONN-1.1	Does the device support wireless connections?	Yes	–			
CONN-1.1.2	Does the device support Wi-Fi?	Yes	–			
CONN-1.1.3	Does the device support Bluetooth?	No	–			
CONN-1.1.4	Does the device support other wireless network connectivity (e.g. LTE, Zigbee, proprietary)?	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	–			
CONN-1.2.4	Does the device support other physical connectivity?	Yes	aBox 2 has video output (SDI/VDI) and trigger signal options (mini jack/D-SUB9) and USB input/output. aView 2 Advance has video output (HDMI/SDI) and USB input/output			

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
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	The devices can retrive worklist and export data to system utilizing the DICOM protocol. See DICOM conformance statement for more.			
CONN-4	Can the device communicate with other systems external to the customer environment (e.g., a service host)?	Yes	The "Over the Air" (OTA) software update service uses HTTPS to make remote request. This is designed to be Pull only.			
CONN-5	Does the device make or receive API calls?	Yes	The "Over the Air" (OTA) software update service support API request. This is designed to be Pull only - all actions shall be initiated from the device.			
CONN-6	Does the device require an internet connection for its intended use?	No	OTA (service use) requires an internet uplink.			
CONN-7	Does the device support Transport Layer Security (TLS)?	Yes	OTA uses HTTP with TLS (HTTPS). DICOM-TLS uses TLS as defined by BCP-195.			
CONN-7.1	Is TLS configurable?	No	DICOM-TLS is only top-level configurable, cipher-suites cannot be choosen, but mode of operation can. See Note 1 below about DICOM-TLS Security profiles.			
CONN-8	Does the device provide operator control functionality from a separate device (e.g., telemedicine)?	No	–			

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
	PERSON AUTHENTICATION (PAUT)	**Displaying and processing unit**	**Notes**	**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 devsice support and enforce unique IDs and passwords for all users and roles (including service accounts)?	Yes	The GUI is jailed and uses rolebased authentication with unique accounts with different authorization levels.	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)?	No	IFU recommend password policies, but the device does not enforce it.	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.)?	No	–	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?	Yes	Access levels are documented in the IFU.	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	–	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?	No	–			
PAUT-9	Does thedevice 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?	Yes	Administrator can disable accounts.	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)?	No	–			
PAUT-14	Does the application or device store or manage authentication credentials?	Yes	X.509 Certificate used for update package authentication. Encryption key is stored for use in OTA authentication.			

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
PAUT-14.1	Are credentials stored using a secure method?	Yes	The keys are stored in GPG keystore.			
	PHYSICAL LOCKS (PLOK)	**Displaying and processing unit**	**Notes**	**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.	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	No data storeage component can be removed without breaking open the caseing (Special tools is needed).	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?	No	–	Section 5.13, PLOK	PE-3(4)	A.11.1.1, A.11.1.2, A.11.1.3
PLOK-4	Does thedevice 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)	**Displaying and processing unit**	**Notes**	**IEC TR 80001- 2-2: 2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002: 2013**
Manufacturer's plans for security support of third-party components within the device's life cycle.						
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	Internal reviews of the selected third-party components has been conducted. Internal vulnerability management program monitors the third-party component security. The device has been subject to external pentest.	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?	No	–	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

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
	SOFTWARE BILL OF MATERIALS (SBoM)	**Displaying and processing unit**	**Notes**	**IEC TR 80001- 2-2: 2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002: 2013**
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 support						
SBOM-1	Is the SBoM for this product available?	Yes	The IFU contains the SBoM. The SBoM can also be requested from AMBU support.			
SBOM-2	Does theSBoM follow a standard or common method in describing software components?	No	–			
SBOM-2.1	Are the software components identified?	Yes	–			
SBOM-2.1	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?	Yes	OSINT, longivity, maturity and security of open source projects.			
SBOM-3	Does the device include a command or process method available to generate a list of software components installed on the device?	Yes	Licenses and software can be displayed on the system on request.			
SBOM-4	Is there an update process for the SBoM?	No	–			
	SYSTEM AND APPLICATION HARDENING (SAHD)	**Displaying and processing unit**	**Notes**	**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	Device has been hardned following industry standards (NIST CF, 27001, CERN coding guidelines) OTA HTTPS TLS is hardened according to Mozilla standard for TLS hardening, only allowing a small set of ciphersuites. (See Note-2 below) DICOM-TLS is hardened according to BCP-195.	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

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
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	Install/Update package has been digitally signed using RSA key.			
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)?	No	The operator can see the verification of update packages.	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 ystsem configurable to allow the implementation of file-level, patient level, or other types of access controls?	Yes	Linux directory access control.	Section 5.15, SAHD	CM-7	A.12.5.1*
SAHD-5.1	Does the device provide role-based access controls?	Yes	Role-based access control has been enforced on the application layer of the device.	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?	Yes	Administator and Service accounts are immutable and can only be modified at compile time (except password).	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?	No	–	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?	Yes	–	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	Application layer accounts are jailed and access to resources are role based resticted.	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	Specifically verified during verification.	Section 5.15, SAHD	SA-18	None
SAHD-9	Are all devices (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

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
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	The OS is custom built for the device. The OS implements the least requirements.	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	The BIOS password is required to boot form removable media. The BIOS password is individual and only known to AMBU.			
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		Yes	Disabling of critical components is posible, e.g Wifi, Internet uplink and USB. Automatic logout and session policies, can be hardnend beyond default settings.			
SAHD-14.1	Are instructions available from vendor for increased hardening?	Yes	Instructions for hardning beyond defaults, is provided in the IFU.			
SAHD-15	Can the system prevent access to BIOS or other bootloaders during boot?	Yes	Fulldisk encryption and per device unique BIOS password protection.			
SAHD-16	Have additional hardening methods not included in 2.3.19 been used to harden the device?	No	–			
	SECURITY GUIDANCE (SGUD)	**Displaying and processing unit**	**Notes**	**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?	Yes	Basic operational security information is provided in the IFU. Additional cybersecurity information can be provided on request by Ambu.	Section 5.16, SGUD	AT-2/PL-2	A.7.2.2, A.12.2.1/A.14.1.1
SGUD-2	Does thedevice have the capability, and provide instructions, for the permanent deletion of data from the device or media?	Yes	See IFU.	Section 5.16, SGUD	MP-6	A.8.2.3, A.8.3.1, A.8.3.2, A.11.2.7

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
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	The IFU includes infomation for: DICOM setup on private networks and for Wifi setup.			
	HEALTH DATA STORAGE CONFIDENTIALITY (STCF)	**Displaying and processing unit**	**Notes**	**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?	Yes	The device offers full disk encryption.	Section 5.17, STCF	SC-28	A.8.2.3
STCF-1.1	Is all data encrypted or otherwise protected?	Yes				
STCF-1.2	Is the data encryption capability configured by default?	No				
STCF-1.3	Are instructions available to the customer to configure encryption?	No				
STCF-2	Can the encryption keys be changed or configured?	No		Section 5.17, STCF	SC-28	A.8.2.3
STCF-3	Is the data stored in a database located on the device?	Yes	–			
STCF-4	Is the data external in a database located on the device?	No	Manual export to DICOM PACS is possible.			
	TRANSMISSION CONFIDENTIALITY (TXCF)	**Displaying and processing unit**	**Notes**	**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 cable?	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?	Yes	The device must be configured with whitelisted server endpoints.	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-4	Annecretions limited to authenticated systems?	No	–	Section 5.18, TXCF	CM-7	A.12.5.1
TXCF-5	Are secure transmission methods supported/ implemented (DICOM, HL7, IEEE 11073)?	Yes	DICOM-TLS support adhering to BCP-195.			

MDS2 for Ambu A/S displaying and processing units with software version 2.3						
	TRANSMISSION INTEGRITY (TXIG)	**Displaying and processing unit**	**Notes**	**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.						
TXIG-1	Does the device support any mechanism (e.g., digital signatures) intended to ensure data is not modified during transmission?	Yes	Upgrade provided by OTA, the intregrity is maintained by a digital signature.	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)	**Displaying and processing unit**	**Notes**	**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)?	Yes	OTA service uses https for updating the device.			

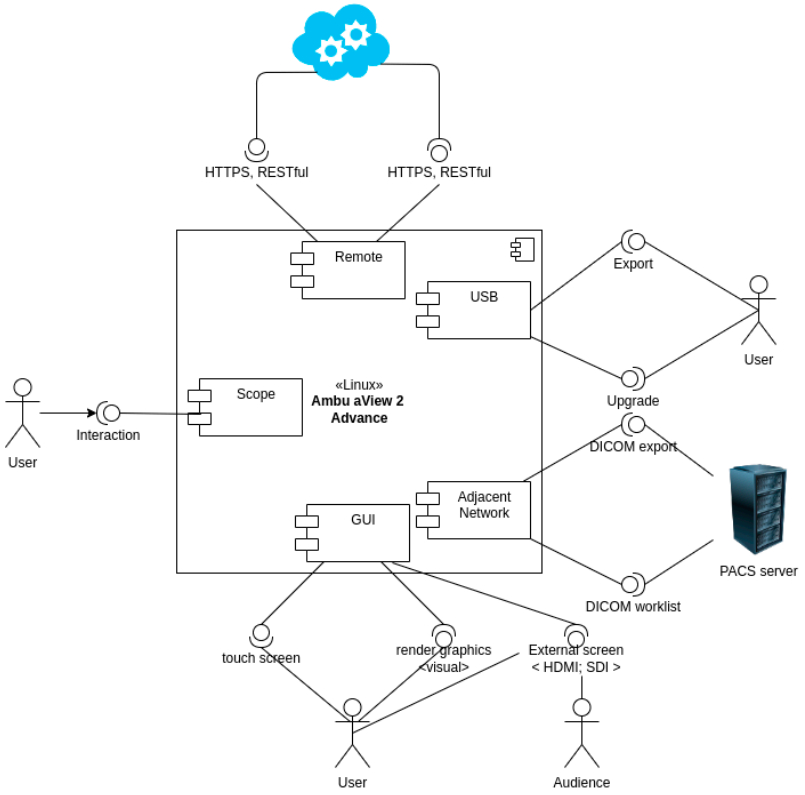
MDS2 for Ambu A/S displaying and processing units with software version 2.3						
	OTHER SECURITY CONSIDERATIONS (OTHR)	**Displaying and processing unit**	**Notes**	**IEC TR 80001-2-2: 2012**	**NIST SP 800-53 Rev. 4**	**ISO 27002: 2013**
	None					
OTHR-1	Does the remote upgrade mechanism support a fallback to local?	Yes	–			
OTHR-1.1	Does the device permit a local operator to disable the remote connection	Yes	–			
OTHR-1.2	Is the device still capable to be updated without the remote upgrade mechanism	Yes	–			
OTHR-1.3	Can the vendor modify the uploaded packages for remote availability?	No	Upgrade package is authenticated though a digital signature.			
OTHR-2	Are the operating system designed with least requirements in mind?	Yes	The Linux system is custom built to only support the minimal required components.			

Note-1:
DICOM-TLS Security Profiles as defined in DICOM P3.15 on TLS-based security:

1. Disable, many customers may not be able to support DICOM-TLS server-side on their PACS.
2. Enable, non-downgrading TLS Secure profile.
3. Enable - allow downgrade, TLS but it allows downgrading of versions + ciphers as per BCP-195 requirement.

Note-2:

- TLS 1.2
  DHE-RSA-AES256-GCM-SHA384
  ECDHE-ECDSA-AES128-GCM-SHA256
- TLS 1.3
  AES-256-GCM-SHA384
  CHACHA20-POLY1305-SHA256
  AES-128-GCM-SHA256



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