

Medical Equipment Pre-Implementation Worksheet

1. For networked medical devices and medical devices storing ePHI, utilize the Medical Equipment Evaluation Matrix below to determine the assessment/documentation requirements.
2. Where indicated, obtain a Manufacturer Disclosure Statement for Medical Device Security (MDS²) Form from the equipment manufacturer. This document covers most pertinent information related to networking and risk exposure for medical devices.
<http://www.himss.org/content/files/MDS2FormInstructions.pdf>
3. Complete the Medical Device Pre-Procurement Assessment (PPA) as required.
4. Once required concurrences are obtained, notify procurement that the equipment is ready for purchase.
5. In conjunction with the facility ISO and OI&T Field Ops, develop implementation, support, and upgrade, remediation plans including roles and responsibilities based on the attached Pre-Implementation Worksheet or additionally acquired documentation.

		Medical Equipment Evaluation Matrix		
		1	2	3
CONNECTIVITY→ STORAGE↓	A	N/A	PPA	PPA
	B	MDS ²	MDS ² & PPA	MDS ² & PPA
	C	N/A	MDS ² & PPA	MDS ² & PPA

CONNECTIVITY:

1 = Stand Alone Device, Computer Based

2 = Network Connected Device, Replacement or additional with similar infrastructure impacts

3 = Network Connected Device, New Device

STORAGE:

A = Does Not Store ePHI

B = Short Term ePHI Storage/Input of Results into CPRS

C = Long Term ePHI Storage Repository

Medical Equipment Pre-Procurement Assessment
(to be completed by potential vendors)

Equipment Description:

Vendor/Model:

Vendor Contact:

Requesting Clinical Service:

Medical Equipment Configuration

- | | | |
|---|------------------------------|-----------------------------|
| <input type="checkbox"/> What OS does the system utilize? | | |
| <input type="checkbox"/> Can critical security patches be installed without prior vendor approval? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Does the device incorporate a switch or hub into its design? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Is the switch or hub required as part of the system configuration? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Which Anti-virus software is approved by the device manufacturer? | | |
| <input type="checkbox"/> If server based, does the system require a specific version of Java for proper client operation? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> If server based, does the system utilize an ActiveX control for client interaction? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> If yes, specify configuration requirements. | | |

Authentication and User Accounts

- | | | |
|--|------------------------------|-----------------------------|
| <input type="checkbox"/> Is an administrator or power user account required to operate the device? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Is an administrator account required for service? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Can the device be made to require user authentication? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Does user authentication support Strong Passwords? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Does user authentication support password aging? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Can the device be part of the facility's Windows domain? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

Data Handling

- | | | |
|---|------------------------------|-----------------------------|
| <input type="checkbox"/> Will the medical device require data backups? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Is ePHI stored only on a drive partition to assist with end of service media sanitization? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> What ePHI data elements are stored on the device? | | |
| <input type="checkbox"/> Can ePHI be stored directly to a network drive, rather than local (machine) storage? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

Networking

- | | | |
|---|------------------------------|-----------------------------|
| <input type="checkbox"/> What are the LAN/WAN bandwidth requirements for full connectivity/performance? | | |
| <input type="checkbox"/> What ports in the TCP/IP stack are utilized for network communication? | | |
| <input type="checkbox"/> Can unutilized ports be closed without negatively impacting device operation? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Can the device support DHCP for network address configuration? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> How many IP addresses does the device require? | | |
| <input type="checkbox"/> Can the device operate properly without connection to the Internet? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Can the target system be addressed via a fully qualified domain name (FQDN)? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |

Wireless

- | | | |
|--|------------------------------|-----------------------------|
| <input type="checkbox"/> Does the device utilize wireless communication? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> If so, what protocols are used? | | |
| <input type="checkbox"/> Is any ePHI transmitted via the wireless link? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> Does the device support installation of FIPS 140-2 certified wireless security clients? | <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> If so, which ones? | | |

Integration with VA Health Care Information Systems

- ☐ Has the device been validated with VA's Clinical Procedures package?
- ☐ Has the device been validated with VA's Vista Imaging?
- ☐ Does the device have a bi-directional HL7 interface?
- ☐ Provide a DICOM conformance statement.

- | | |
|------------------------------|-----------------------------|
| <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> YES | <input type="checkbox"/> NO |
| <input type="checkbox"/> YES | <input type="checkbox"/> NO |

(to be converted to a VA form)

Medical Equipment Pre-Implementation Worksheet

Equipment Description:

Vendor/Model:

Vendor Contact:

Requesting Clinical Service:

Contact Information & Sign-Off

Clinical Service POC:

Phone:

Biomedical Engineering POC:

Phone:

ISO:

Phone:

IT POC:

Phone:

Medical Equipment Documentation Review

- ☐ Manufacturer Disclosure Statement for Medical Device Security (MDS²)
- ☐ Existing Site-to-Site or One-VA VPN Agreement
- ☐ Purchase documents and associated equipment quotations
- ☐ Business Associate Agreement
- ☐ Equipment description, information flow, and network connectivity requirements
- ☐ Documentation of network configuration and installation requirements
- ☐ Clinical Procedures integration documentation provided with VA contacts, if applicable
- ☐ DICOM conformance statement provide, if applicable

Security Precautions

- ☐ Does the equipment support Anti-virus protection with updates via McAfee ePolicy Orchestrator? ☐ YES ☐ NO
- ☐ Does the equipment support automated OS critical patch installation? ☐ YES ☐ NO
- ☐ Will the medical equipment be configured for Device Authentication using Active Directory? ☐ YES ☐ NO
- ☐ Will the medical equipment be configured for User Authentication using Active Directory? ☐ YES ☐ NO
- ☐ Who will provide and manage: Disaster Recovery?
- ☐ Will vendor require Remote Access via VPN? ☐ YES ☐ NO
- ☐ Will vendor provide a network device (switch, router)? Needs risk assessment. ☐ YES ☐ NO
- ☐ Will vendor provide any wireless devices? Needs risk assessment. ☐ YES ☐ NO

Network Design and Constraints

- ☐ Notification to network administrator to configure medical VLAN Medical VLAN:
- ☐ Medical equipment installation location(s)
- ☐ Network administrator reviews risk assessment for any network or wireless devices.
- ☐ List all target systems that the device will communicate with
- ☐ Network administrator configures the ACL with input from Biomedical Engineering, verifies connectivity, and documents configuration.

Post Installation Support Strategy

- ☐ Post implementation support strategy developed.
- ☐ Post implementation secure use strategy developed.(i.e. frequency of removal of ePHI from device, physical security of device, etc.)

(to be converted to a VA form)