

Medical Equipment Pre-Procurement Assessment

(To be completed by potential vendors)

Instructions:

- A For all questions, please provide a Yes, No or *N/A* and a note of explanation to all questions.
- B. After each question, please provide a check in the box indicating that the question was reviewed/answered
- C. If you have questions contact Audrey Wooten via email at Audrey.wooten{a}va.gov

Equipment Description:
Vendor/Model:
Vendor Contact:
Requesting Clinical Service:

Medical Equipment Configuration

- | | | | |
|---|-----|----|-----|
| 1. What OS does the system utilize?
Please explain response: | | | |
| 2. Can critical security patches be installed without prior vendor approval?
Please explain response: | YES | NO | N/A |
| 3. Does the device incorporate a switch or hub into its design?
If yes, please explain what kind: | YES | NO | N/A |
| 4. Is the switch or hub required as part of the system configuration?
Please explain response: | YES | NO | N/A |
| 5. Which Anti-virus software is approved by the device manufacturer?
Please explain response: | | | N/A |
| 6. Which Host intrusion software is approved by the device manufacturer?
Please explain response: | | | N/A |
| 7. If server based, does the system require a specific version of Java for proper client operation?
Please explain response: | YES | NO | N/A |
| 8. What web client is supported by the device manufacturer?
Please explain response: | YES | NO | N/A |
| 9. If server based, does the system utilize an Active X control for client interaction?
If yes, please specify configuration requirements: | YES | NO | N/A |
| 10. Can software be installed on system that is not supplied by vendor, without vendor approval?
Please explain response: | YES | NO | N/A |

Authentication and User Accounts

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|--|-----|----|-----|
| 1. Is an administrator or power user account required to operate the device?
Please explain response: | | | |
| 2. Is an administrator account required for service?
Please explain response: | YES | NO | N/A |
| 3. Can the device be made to require user authentication?
Please explain response: | YES | NO | N/A |
| 4. Does user authentication support Strong Passwords?
Please explain response: | YES | NO | N/A |
| 5. Where are the Passwords stored?
Please explain response: | YES | NO | N/A |
| 6. What security measures are in place to safe guard password files?
Please explain response: | YES | NO | N/A |
| 7. Does user authentication support password aging?
Please explain response: | YES | NO | N/A |
| 8. Can the device be part of the facility's Windows domain?
Please explain response: | YES | NO | N/A |

Data Handling

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| 1 . Will the medical device require data backups?
Please explain response: | YES NO N/A |
| 2 . Is ePHI stored only on a drive partition to assist with end of service media sanitization?
Please explain response: | YES NO N/A |
| 3 . What ePHI data elements are stored on the device?
Please explain response: | YES NO N/A |
| 4 . Can ePHI be stored directly to a network drive, rather than local (machine) storage?
Please explain response: | YES NO N/A |

Networking

- | | |
|---|------------|
| 1. What are the LAN/WAN bandwidth requirements for full connective/performance?
Please explain response: | YES NO N/A |
| 2 . What ports in the TCP/IP stack are utilized for network communications?
Please explain response: | YES NO N/A |
| 3 . What port numbers are needed for support?
Please explain response: | YES NO N/A |
| 4 . Can unutilized ports be closed without negatively impacting device operation? Please explain response: | YES NO N/A |
| 5. Can the device support DHCP for network address configuration?
Please explain response: | YES NO N/A |
| 6 . How many IP addresses does the device require?
Please explain response: | YES NO N/A |
| 7 . Can the device operate properly without connection to the Internet? Please explain response: | YES NO N/A |
| 8 . What features if any require Internet access?
Please explain response: | YES NO N/A |
| 9 . Can the target system be addressed via fully qualified domain name (FQDN)?
Please explain response: | YES NO N/A |

Wireless

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|--|---------------------------------|
| 01. Does the device utilize wireless communication?
If so, please explain what protocols are used | YES ON N/A |
| 02. Is any ePHI transmitted via the wireless link?
Please explain response: | YES NO N/A |
| 03. Does the device support installation of FIPS 140-2 certified wireless security clients?
If so, please explain which ones: | YES NO N/A
Airfortress Other |

Integration with VA Health Care Information Systems

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|--|------------|
| 1 . Has the device been validated with VA/s Clinical Procedures package?
Please explain response: | YES NO N/A |
| 2 . Has the device been validated with VA's Vista Imaging?
Please explain response: | YES NO N/A |
| 3 . Does the device have a bi-directional HL7 interface?
Please explain response: | YES NO N/A |
| 4 . Provide a DICOM conformance statement.
Please explain response: | YES NO N/A |

Medical Equipment Pre-Implementation Worksheet

Equipment Description:
Vendor/Model:
Vendor Contact:
Reouestin2 Clinical Service:

Contact information & Sign-Off	
Clinical Service POC: Stephanie Stephens	Phone:
Biomedical Engineering POC: David Sledge	Phone: 704-638-9000
ISO: Henry E Foutner	Phone: 704-638-9000
IT POC:	Phone:

Instructions:

- A. For all documentation listed below, please submit documentation along with all required forms. If N/A, please check so if applicable.

Medical Equipment Documentation Review

D1. Manufacturer Disclosure Statement for Medical Device Security (MDS ²) completed by vendor	N/A
2. Existing Site-to-Site or One-VA VPN Agreement	N/A
3. Purchase documents (including brochures explaining the product) and associated equipment quotations	N/A
04. Business Associate Agreement	N/A
Os. Equipment description, information flow, and network connectivity requirements	N/A
6. Documentation of network configuration and installation requirements	N/A
7. Clinical procedures integration documentation provided with VA contacts, if applicable	N/A
8. DICOM conformance statement provide, if applicable	N/A

Instructions:

- B. For all questions, please provide a Yes, No or *N/A* and a note of explanation to all questions.
C. After each question, please provide a check in the box indicating that the question was reviewed/answered

Medical Equipment Documentation - Service Manuals for Biomedical Engineering:

DI. Availability of service manual(s) in accordance to VAAR 8S2.211-70 for medical equipment	YES	NO
2. Availability of Service and Maintenance/diagnostics software	YES	NO
3. Availability of Service Keys and Passwords	YES	NO

Security Precautions

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|--|-----|----|-----|
| I. Does the equipment support <u>Anti-virus protection</u> with updates via McAfee ePolicy Orchestrator? | YES | NO | N/A |
| Please explain response: | | | |
| 2. Does the equipment support automated <u>OS critical patch</u> installation? | YES | NO | N/A |
| Please explain response: | | | |
| 3. Will the medical equipment be configured for <u>Device Authentication</u> using Active Directory? | YES | NO | N/A |
| Please explain response: | | | |
| 4. Will the medical equipment be configured for <u>User Authentication</u> using Active Directory/ | YES | NO | N/A |
| Please explain response: | | | |
| 5. Who will provide and manage: <u>Disaster Recovery</u> ? | | | |
| Please explain response: | | | |

Security Precautions-con't

- | | | |
|----|---|------------|
| 6. | Will the vendor require <u>Remote Access</u> via VPN?
Please explain response: | YES NO N/A |
| 7. | Will vendor provide a network device (switch, router)? Needs risk assessment.
Please explain response: | YES NO N/A |
| 8. | Will vendor provide any wireless devices? Needs risk assessment..
Please explain response: | YES NO N/A |

Network Design and Constraints

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|----|--|---------------|
| 1. | Notification to network administrator to configure medical VLAN
Please explain response: | Medical VLAN: |
| 2. | Medical equipment installation location(s)
Please explain response: | |
| 3. | Network administrator reviews risk assessment for any network or wireless devices.
Please explain response: | |
| 4. | List all target systems that the device will communicate with
Please explain response: | |
| 5. | Network administrator configures the ACL with input from Biomedical Engineering, verifies connectivity, and documents configuration.
Please explain response: | |

Post Installation Support Strategy

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| 1. | Post implementation support strategy developed.
Please explain response: |
| 2. | Post implementation secure use strategy developed.
(i.e. frequency of removal of ePHI from device, physical security of device, etc.)
Please explain response: |

* Salisbury VAMC locally defined requirement.