VA Specialized Device (Medical Equipment or Special Purpose System)
Pre-Procurement Assessment

*Indicates field is completed by Business Owner (Individual requiring the connection) (i.e. Biomedical Engineering)

*Equipment Category (VA-MDNS):	*Vendor:
*Requesting Service:	*Model:
*Requestor:	Vendor Contact:
*Installation Location: (Room-Bldg-Division):	If server based, specify rack space and power requirements:
*Business Owner Point of Contact:	*MDIA VLAN Number for Installation:
*Equipment Description (i.e., layman's description of equipment function and systems it communicates with):	
*If Business Owner is NOT the Primary System Manager for system management and maintenance, please note the responsible department below.	

Medical Device /System Configuration

What OS and version/Service Pack does the system utilize (e.g., Win7- SP1, Win Svr 2008, Linux)?	
Does the system use a database application to operate?	☐ YES ☐ NO
If yes, specify which application/version:	
Membership in the facility's Windows Domain is: ☐ Required ☐ Recommended ☐ Not Recommended ☐ NA	
Is a desktop web browser required to access the medical system/application?	☐ YES ☐ NO
If yes, specify which browsers and versions are supported:	
If yes, does it require the use of https: and the VA SSL certificates – explain below:	
If a browser is required, does it require a specific version of Java?	☐ YES ☐ NO
If yes, specify the version:	
Is ActiveX required for client operation?	☐ YES ☐ NO
If yes, specify configuration requirements:	
If Windows based, can the system use the National Medical Device Update Server for OS patches?	☐ YES ☐ NO
If no, specify how OS patching will be accomplished:	
Can critical and routine OS and system security patches be applied as they become available without prior vendor approval?	☐ YES ☐ NO
If no, specify how approval notification to VA will be accomplished:	

Can the device support the use of McAfee Anti-Virus (AV) software?	☐ YES ☐ NO
If no, what AV packages and versions are supported? Describe the mechanism to provide updates.	
Can USB ports be disabled on the device without compromising operation?	☐ YES ☐ NO
Can auto run be disabled for portable media?	☐ YES ☐ NO
Can VA install host-based security components such as a firewall, host intrusion prevention system (HIPS), anti-malware software,and/or any other security suite software required to operate on the VA production network?	☐ YES ☐ NO
If "No" is the response to any of the above questions regardiung updates and anti-virus software, please explain further for each item in the space below.	

Authentication and User Account

Is an administrator or power user account required to operate the device?	☐ YES ☐ NO
Can the device be made to require individual user authentication?	☐ YES ☐ NO
Does the device support password aging and strong user password accounts?	☐ YES ☐ NO
Does the device support auto logoff or/and session lock?	☐ YES ☐ NO
Does the system support the use of Active Directory for user authentication?	☐ YES ☐ NO
If yes, specify configuration requirements, LDAP etc.:	
Does the system support the use of PIV/Smart Card only authentication?	☐ YES ☐ NO

Data Handling

Specify which Electronic Protected Health Information ePHI data elements are stored on the device (e.g., last name, SSN, DOB):	
How many records with sensitive information can be stored on the device?	
How long will they be retained on the device?	
Is ePHI encrypted prior to transmission?	☐ YES ☐ NO
If yes, what is the encryption mechanism(s)?	
What is the media used for long term storage?	
How is data transmitted to the storage repository (e.g. LAN, DVD, USB, etc.)?	
Is ePHI stored only on a drive partition or a separate drive to assist with end-of-life media sanitization?	☐ YES ☐ NO
Will the medical device require data backups?	☐ YES ☐ NO
If yes, specify how the system and data are backed up and what media is used:	
Describe backup process: (data centers are lights out so this needs to be known up front)	
Where will backups be stored and secured?	

Does the device have the ability to assign unique ID numbers (accession numbers) instead of using patient identifying information (e.g., Social Security Number)?	☐ YES ☐ NO
If yes, how is it generated?	
Does the device utilize a laptop for system operation?	☐ YES ☐ NO
If so, can the laptop be encrypted without impacting clinical functionality?	☐ YES ☐ NO
If yes, what encryption software can be used?	

Networking

What are the LAN bandwidth requirements for full connectivity/performance?
What are the WAN bandwidth requirements for full connectivity/performance?
Provide a comprehensive list of all TCP and UDP ports that are required for operation: **Note: If more space is needed, please attach the comprehensive list of ports required for operation to this document. Attach a network diagram showing all communication requirements.**

How many fixed IP addresses does the device require?	
Is the device compatible with IP V6?	☐ YES ☐ NO
Vendors' products should be designed such that only ports required for the intended operation of the device are active. Are unused ports closed or disabled?	☐ YES ☐ NO
Can this be accomplished without impacting system operation?	☐ YES ☐ NO
Vendors' products should be designed such that only services required for the intended operation of the device are active. Are unused services (e.g., Telnet, IIS, etc.) disabled?	☐ YES ☐ NO
Can this be accomplished without impacting system operation?	☐ YES ☐ NO
Provide a comprehensive list of all services that are required for system operation:	
Can the device be serviced remotely?	☐ YES ☐ NO
Does the vendor have an existing Site to Site (S2S) VPN tunnel or individual user VPN account(s)?	☐ YES ☐ NO
What remote access software does the system utilize (e.g., Dameware, PC Anywhere, etc.)?	
Does the device require connection to the Internet to operate?	☐ YES ☐ NO
If yes, please justify and provide connection info (IP, port, protocol and traffic direction):	

Wireless

Does the device utilize wireless communication?	☐ YES ☐ NO
If yes, what protocols are used?	
The encryption module must have FIPS 140-2 certification. Provide certificate number:	
Are any ePHI data elements transmitted via the wireless link?	☐ YES ☐ NO
If yes, list each element (e.g. last name, DOB, SSN).	

Integration with VA Healthcare Information Systems (if applicable)

* Has the device been validated with VA's Clinical Procedures package?	☐ YES ☐ NO
*Has the device been validated with VA's Vista Imaging?	☐ YES ☐ NO
*Does the device have bi-directional HL7 interface?	☐ YES ☐ NO
List all other systems that the device will communicate with to operate properly, e.g. VistA, domain controllers, vendor's support network, etc.:	

Signature Page

*Equipment Category (VA-MDNS):	*Vendor:
*Requesting Service:	*Model:

_____   _____
Business Owner (i.e. Chief Biomedical Engineer)   Date

☐ CONCUR   ☐ NON-CONCUR

_____   _____
Information Systems Security Officer, Enterprise Operation Services   Date

☐ CONCUR   ☐ NON-CONCUR

_____   _____
Area Manager, IT Operations and Services   Date

☐ CONCUR   ☐ NON-CONCUR

_____   _____
Director of Operations, IT Operations and Services   Date

☐ CONCUR   ☐ NON-CONCUR