

THE STATE OF ISRAEL  
 MINISTRY OF HEALTH  
 THE CHAIM SHEBA MEDICAL CENTER  
 Affiliated to the Tel-Aviv University  
 Sackler School of Medicine  
 TEL-HASHOMER, zip 5265601, ISRAEL



שיבא - מרכז רפואי אקדמי מצטיין

מדינת ישראל  
 משרד הבריאות  
 המרכז הרפואי המשולב ע"ש חיים שיבא  
 מסונף לבית הספר לרפואה ע"ש סאקלר  
 באוניברסיטת תל-אביב  
 תל-השומר, מיקוד, 5265601 ישראל

Tender no. \_\_\_\_\_

Date: \_\_\_/\_\_\_/\_\_\_

**APPENDIX: Demand for computer and Cyber Security to bring medical devices into the Sheba network and/or to receive data from medical devices.**

Device Name: \_\_\_\_\_ Manufacturer name: \_\_\_\_\_  
 Device model: \_\_\_\_\_ Supplier Representative name: \_\_\_\_\_  
 Supplier Name: \_\_\_\_\_ Cellphone number: \_\_\_\_\_  
 Supplier Email: \_\_\_\_\_

**Medical Device:**

- \* Please circle the applicable:
- \* **Connection:** to Hospital network | standalone | to specific PC
- \* **Medical record storage:** locally | central DB | medical record system
- \* **System definition:** logistics | LAB | treatment\diagnostics | POC
- \* **Maintenance access:** Israel | abroad | not applicable

1. Name of the Operating System: \_\_\_\_\_
- (a) Type of Operating system version: \_\_\_\_\_
- (b) Type of the OS (Pro\Embedded or other) : \_\_\_\_\_
- (c) Service Pack/Patch: \_\_\_\_\_
- (d) please specify OPENSLL version: \_\_\_\_\_

Mark 'X' in each box, for example -

Non Acceptable	Acceptable
	X

nub		Acceptable	Non Acceptable
2.	Username and password for OS with Administrative rights access will be handed to the Computer Unit in order to execute ongoing maintenance.		
3	The device won't be connected thru independent modem, if a modem is installed it will be removed before joining Medical device to the Sheba network - responsibility of the supplier, whether an ongoing maintenance of the system won't be possible, without modem installed, the Information Security Manager must be contacted.		
4	Each issue regarding remote connection will be executed only by the Computer Unit without third-party software. The supplier have to sign a non-disclosure agreement provided by the Information Security staff.		
5	Medical Device with more than one network card won't be allowed into Sheba network.		
6	All installations \ upgrades of the OS, application or other software will be admitted to Sanitization system, software will be provided upfront in cooperation with Sheba Computer Unit staff.		

Name: \_\_\_\_\_

Signature: \_\_\_\_\_



**Computer connected to Medical Device (fill according to relevance):**

\* Please circle the applicable:

- \* **Connection:** to Hospital network | standalone | to specific PC
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Name: \_\_\_\_\_

Signature: \_\_\_\_\_

**SERVER:**

1. Name of the Operating System: \_\_\_\_\_

a) Version: \_\_\_\_\_

b) Service Pack : \_\_\_\_\_

c) OPENSLL version: \_\_\_\_\_

d) IIS/Apache version: \_\_\_\_\_

Mark 'X' in each box, for example -

Non Acceptable	Acceptable
	X

nub		Acceptable	Non Acceptable
2	The server will be virtually installed under VMWARE ESX.		
3	An operating system will be installed in the medical center by the Computer Unit staff (accompanied by the supplier).		
4	If a large storage arrangement required for the archives, the area will be provided by NAS configuration, support is an obligation in this protocol.		
5	Software license support and not through Dongle PC.		
6	In case that the system works with DATABASE, the supplier has to support SQL 2016 as basic criteria.		
7	The application is obligated to work only with Service and not with User Logon.		
8	McAfee EPO and antivirus configured in Sheba Medical Center will be installed on the Server and will receive regular updates, as per Sheba Medical Center policy.		
9	All installations \ upgrades of the OS, application or other software will be admitted to Sanitization system, software will be provided upfront in cooperation with Sheba Computer Unit staff		

Name: \_\_\_\_\_

Signature: \_\_\_\_\_

**CONNECTIVITY:**

nub		Acceptable	Non Acceptable
1	The system has to supply and support the following link options (supplier will bare the cost of the connection) : a. The transfer of data to an existing system (for example – medical files) in accordance with the required standards (Dicom, PDF, txt, HL7, XML in X-rays etc) b. Receiving data from existing systems and loading it (for example – demographic data) in two possible ways: i. Receiving a file from an operative system for example a demographic data file. ii. Using Web Service for the purpose of receiving demographic data from the operative system.		
2	The transfer of data must support a full and frequent transfer (at a rate of at least an item of data for a minute) of the parameters defined as obligatory, according to the medical staff.		
3	The connectivity should be modifiable and adjustable according to demands of the Medical Center and suitable to existing interfaces.		
4	The Medical Device will be connected to Medical Center network using standard RJ-45 network connection (preference to Device that has POE ability)		
5	All the connections and execution of scripts and commands, that interacts with interfaces to the Sheba network is the responsibility of the company and its exclusive handling with the software providers including the specification of the interfaces, development required from all sides (including the medical file suppliers, such as iMDsoft and ELAD Systems) and the financial costs for development required from both sides. While conducting characterization of interfaces, the company is obligated to expose the protocol which used for operation.		
6	In case that the solution is implemented by the company on another site, the supplier have to elaborate regarding the implementation of the system and about the manner in which the connectivity was executed.		
7	Supplier must provide PC\Server "Gateway" to withheld proper connection to Hospital network and it's systems. <b>Components, like: capsules, DIGI or Lantronix are not allowed!</b>		

8. Elaboration on which Clinical system the Medical device will upload data

(PACS, RIS, EMR, etc.) : \_\_\_\_\_

- Please mention, whether use of Sheba Medical Center Storage needed:

\_\_\_\_\_

Name: \_\_\_\_\_

Signature: \_\_\_\_\_



### APPENDIX OF INFORMATION SECURITY FOR MEDICAL DEVICES

nub		Acceptable	Non Acceptable
1	The mediation of the management interface of the medical device will be encoded (according to the acceptable standard).		
2	All the default credentials (manufacturer based) must be altered.		
3	Passwords stored on Medical Device encrypted (not in clear text)		
4	The management interface will be secured with a complex password (Cap. Letter, symbol, number- must have two factors out of three).		
5	Local firewall on Medical Device ( Choose the right answer)	Enabled	Disabled
6	Is it possible cancel the firewall? ( Choose the right answer)	Enabled	Disabled
7	As a default a system will be installed in Hospital secured environment protected by Hospital firewall.		
8	List of ports (TCP/UDP) needed by the System will be provided		
9	On the device/PC will be installed an anti-virus existing in the organization: For Windows PRO, STD, Ultimate - <b>Trend Micro XG</b> For Windows server, Linux, MAC OS - <b>McAfee ENS</b> . Systems will receive regular updates, as per Sheba Medical Center policy. If the device/PC demands anti-virus exclusions, a document or a list of such need to be provided by the Integrator/Manufacturer.		
10	<b>Embedded operating systems</b> (list of allowed at the beginning of this document) will be provided, with third party White Listing Application Control, controlling allowed software by <b>HASH</b> or <b>Certificate</b> . Application control system name: _____ And version: _____		
11	The Medical Device will be configured with all external sockets and ports disabled as a default (such as USB and CD/DVD drive), Hospital Device Controller system will limit the connection.		
12	Each port, which is not regularly used for communication and activating the device, will be blocked by the supplier on OS or physically.		
13	Connection of layer 2 or 3 network devices (router, switch, etc.) explicitly prohibited		
14	Third part remote connections such as TeamViewer, VNC and so on, will not be allowed and uninstalled, as per Hospital Information Security Policy, internal remote assistance can be achieved by Hospital software from Vendors server to Medical device.		
15	It is responsibility of manufacturer/supplier to fix or migrate critical vulnerabilities announced or discovered on equipment provided.		

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		Non Acceptable	Acceptable
16	Joining the device/computer/system into a Hospital domain will provide a strong security, this will be considered by the Supplier		X
17	A standard NDA conducted by Sheba Medical center will be signed by the Supplier		
18	Assuming, that the decision was to join the device/computer/system into a Hospital domain regular security updates of Microsoft from Hospital MS servers will be considered as an advantage		
19	NTP services from Hospital NTP servers will be considered as an advantage		
20	Specification document from the device/computer/system manufacturer including detailed installation of the Certificates and Anti-Virus exclusions, will be prepared by the Supplier, assuming that Manufacturer prepared those documents		

Name: \_\_\_\_\_

Signature: \_\_\_\_\_



## WIRELESS APPENDIX FOR MEDICAL DEVICES

Mark 'X' in each box, for example -

Non Acceptable	Acceptable
	X

nub		Acceptable	Non Acceptable
1	Connection to the wireless networks according to standard : ( Choose the right answer ) a) 802.11 ac (wave2) b) 802.11n		
2	The capability of installing a Security certificate (User Certificate/Computer Certificate) Preference to – Computer Certificate. As per hospital policy we allow wireless access to internal network with 802.1x (Based on certificates only). Encryption – WPA2-AES (WPA2 with AES encryption and dynamic keys using 802.1x via Transport Layer Security (TLS)). Support cryptographic hash function (Secure Hash Algorithm 2) <b>SHA2</b> .		
3	Remote management (implementation and updating certificates and settings )		
4	Disabling Bluetooth		
5	Support of organizational NTP servers – an advantage		
6	Update/renewal of the Certificates automatically – An advantage.		

For clarifications or questions please contact: [infosec@sheba.health.gov.il](mailto:infosec@sheba.health.gov.il)

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Name: \_\_\_\_\_

Signature: \_\_\_\_\_