

THE INSTITUE OF BIOMEDICAL TECHNOLOGY



ltem 1			
		Holter Monitor	ty. (10)

IMPORTANT NOTE:

Vendors are required to fill out the product details, compliance information, and brochure reference page number in the columns below

TECHNICAL SPECIFICATIONS:

The unit must meet or exceed the requirements listed in the table below.

	Product Details
Name of Manufacturer	
Model/ catalogue number	
Country of Origin for the offered model	
Country where the manufacturer is based	
Delivery time	
Full warranty period	
FDA clearance OR CE Mark	

	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
1	Battery-operated portable unit that measures and records heart's activity (ECG) continuously, a sample (with ECG cable) must be submitted when required by the purchasing committee		
2	Review ECG in 12-lead format		
3	3 channel ECG with at least 5-7 leadwire cable		
4	LCD display		
5	The unit must have a visual alarm when any lead wire is disconnected		
6	Selectable time of recording: 24, 48, 72 hours	ç	-
7	Wired download & transfer data through USB cable or equivalent		
8	Non-removable digital memory		
9	Small size		
10	Light weight ≤ 70 g		
11	Water proof		



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	Minimum Requirements	Compliance (Y/N), Notes	Brochure ' Page No.
12	Event button		
13	Pacemaker detection capability		
14	Carrying case and belt should be included		
15	3 sets of lead cables with each unit, leadwires should be heavy duty and durable		
16	Batteries should be non-rechargeable, standard size and available in the local market		
17	Work Station with the following specification:		
	a- HL7 licence: The unit should have the capability to be connected and to send reports to HAKEEM hospital information system		
	b- Fast download of the data with less than 100 seconds	1,000	
	c- Laser printer		
	d- PC should be included (processor should be at least core i7), specifications should comply with the special terms		
	e- At least 17 inch screen		
	f- Software should be upgradeable		· · · · · ·
	g- Original backup of the software should be included		
	h- Original windows operating system		
	i- Report should include at least:		
	- Time of start and finish recording		
	- Average heart rate		
	- Maximum and minimum heart rate	ŷ	
	- ST segment and QT intervals analysis		
	- Restorespective analysis		
	- Atrial fibrillation detection		•
	- All types of other arrhythmias		



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SPECIAL TERMS

- Offers not complying with any of the <u>special terms or the technical specifications</u> shall be considered non-conforming with tender requirements.
- Any vendor providing FORGED documents shall be disqualified from the current tender and banned from participating in any future RMS tenders.
 - 1. All equipment must be the most recently released model/version which is equal to or higher than the range of the specifications of the required system (low, mid or high) and equal to or higher than the level of technology and required options mentioned in the technical specifications.

2. Required certificates:

- 2.1 For equipment of US origin, a copy of a certificate of FDA approval & the relevant 510K clearance for selling to US healthcare facilities for the offered model must be submitted with the technical offer.
- 2.2 For equipment of other origins, a copy of either a CE certificate with the relevant CE number (MDD)/TÜV/BSI/UL OR a certificate of FDA approval & the relevant 510K clearance for selling to US healthcare facilities for the offered model must be submitted with the technical offer.
- 2.3 Only for class I medical equipment, submission of a copy of Declaration of Conformity certificate (MDD) for the offered model shall be accepted.
- 2.4 With each offer, bidders must provide a formally endorsed document issued by the manufacturer stating that the bidder is the sole certified agent / distributor for the offered item.
- 2.5 In all of the above cases (except 2.4) certificates must be formally endorsed by JFDA.

3. Country of origin:

i. The country of origin of the main part (s) of the system must be one of the following:

USA, Canada, Japan, UK, Sweden, Finland, Denmark, Switzerland, Belgium, Germany, France, Netherlands, Spain, Norway, Italy, Ireland, Austria, New Zealand, Australia & Czech Republic.



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- ii. Accessories and consumables (as determined by the purchasing committee) may be manufactured in other countries and/or by different manufacturers.
- iii. All offered items must be approved for sale in the same country of origin.
- iv. Vendors must specify the origin of all offered items and accessories in the technical offer.
- v. Equipment manufactured by reputable companies based in any of the countries mentioned in (3.i) will be taken into consideration regardless of the manufacturing site only:
 - a. If they are approved for sale in the same county of origin (an original and officially endorsed free-sale certificate from an authorised body must be included in the offer.

<u>OR</u>

- b. If they are approved for sale in at least three of the countries mentioned in (3.1) (an original and officially endorsed free-sale certificate from an authorised body in those countries must be included in the offer).
- vi. Bidders must submit their reservations/queries regarding tender specifications and/or special terms within the first third of the tender closing period starting from the tender announcement date. Reservations/queries submitted after the end of this period shall be rejected.

4. Warranty:

- i. Offers must include a full warranty including spare parts and labour for a period of a minimum of 24 months from the date of installation.
- ii. If at any time during the warranty period the item becomes inoperative due to a technical fault the item must then be repaired by the supplier /local agent within a period of fourteen days from written notification, otherwise the supplier must replace the item with a new identical functioning one and will endure a penalty determined by the Royal Medical Services for each day of the downtime of the system. In case the item was replaced by a new one, the warranty period mentioned in (4.i) above will start from the installation and commissioning date of the new item.
- 5. One set of operation manual(s) and one set of service manual(s) including schematics and a spare-part list must be delivered with each unit, CD/DVD is acceptable. For large tenders, a certain agreed percentage of manuals per item may be agreed upon.

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JORDAN ARMED FORCES

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- 6. Where applicable, pre-installation shall be the sole responsibility of the supplier. Pre-installation shall include removal of old system(s), any civil work, electrical work or site modification(s) necessary to accommodate the new system(s) according to manufacturers' specifications and safety standards in addition to the work required for bringing back the site to the same working conditions as before installing the new system(s).
- 7. Power requirements: where applicable either single phase 220V, 50Hz or 3-phase 380V. Systems with external transformers are considered conforming only if clearly stated in the technical specifications.
- 8. Technical offers must include clear original technical brochures/catalogues for all offered items.
- 9. Offers must include fully detailed technical offers and compliance sheets as a soft copy (either Microsoft office or Microsoft excel format) in addition to a hard copy, mentioning the exact model/catalogue number and country of origin of the offered item(s), full technical description/specifications and any accessories or options included in the offer.
- 10. Compliance sheets must be as per the tabular format of the technical specifications in the tender documents, listing the required specifications on one column and a Yes or NO response to each point in the adjacent column, with reference to page and line numbers in the relevant technical brochure. Offers not complying with this term shall be rejected.

11. Accessories and consumables:

- i. Any accessories and consumable items necessary to operate the offered system must be clearly identified and priced separately.
- ii. Technical offers must include a priced list for accessories and consumables as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) with prices fixed for a period of five years from the date of installation and commissioning with a maximum annual increase of 2%, any essential item not listed will be considered free of charge.
- iii. Accessories and consumables must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.
- iv. Where applicable, a start-up kit of accessories and consumable items must be provided with each system on a free-of-charge basis.



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12. Spare Parts:

- i. Technical offers must include a comprehensive and priced spare parts list as a hard copy in addition to a soft copy (either Microsoft office or Microsoft excel format) valid for a minimum period of five years with a maximum annual increase of 2%, commencing at the end date of the warranty period, any essential item not listed will be considered free of charge.
- ii. Spare parts must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.
- 13. Spare parts, consumables and accessories availability must be guaranteed for a minimum period of ten years starting from the date of installation and commissioning.

14. Tender Awards:

- i. For the final list of offers having a chance of winning the award, the awarding process shall be based on the accumulative value of both the offered item and its' running cost (<u>Total Cost of Ownership</u>) over a period of seven years from the date of installation and commissioning. Only offers with the lowest total cost of ownership over a period of seven years from the date of installation and commissioning shall qualify for the award.
- ii. Running cost includes the value of consumables, accessories needed to operate the system over the same period as well as the cost of any service contract (where applicable).

15. For PC/Laptop based systems:

- i. Complete restoration medium (CD/DVD/etc.) of the operating system and the application software must be supplied.
- ii. Where locally supplied computers or laptops are offered, only computers/laptops from Apple, hp/Compaq, Lenovo, Dell, fujtisu or Toshiba will be accepted, offered models must be the latest available version upon delivery.
- iii. Where locally supplied printers are offered only the following types and brands are accepted: HP, SAMSUNG, OKI, CANON, EPSON.
- 16. Pricing must include services of sale, shipment, transportation, delivery from port to site or to Main Medical Stores, installation, pre-installation (if needed), training, commissioning, warranty and bringing the equipment into service.



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- 17. Custom clearance of goods shall be the responsibility of the Jordanian Armed Forces (JAF), however, suppliers shall bear all costs incurred by handling charges and any demurrage charges or extra expenses incurred by the port's corporation (including expenses caused by delay in presenting the necessary shipment documents for either clearing or transporting the goods to the required location mentioned in the final order, delivery note issuing charges, unloading charges, local shipping charges etc.). The supplier is also responsible for providing of all relevant shipping documents, together with the delivery order(s).
- 18. DRMS has the right to increase or decrease the awarded quantities by a percentage not exceeding 30% after the final order notification with the same prices, terms and conditions of the original contract upon DRMS request and approval of the awarded party.
- 19. The supplier must furnish DRMS with a guarantee stamped and legalized by the Notary Public equals to (115%) of the total value of the awarded equipment valid for twelvemonths from the date of final acceptance of the equipment by DRMS.

20. Training:

- i. For items where service training courses for the offered system are usually conducted abroad, offers must include a certified service training program at a reputable center abroad recognized by the manufacturer for at least one biomedical engineer or biomedical technician; all costs inclusive, air tickets, , boarding, commuting, accommodation (minimum 3 star hotel on full board basis) and any extra costs.
- ii. For items where user training courses for the offered item are usually conducted abroad, offers must include a certified operator training program at a reputable center abroad recognized by the manufacturer for at least one operator; all costs inclusive, air tickets, , boarding, commuting, accommodation (minimum 3 star hotel on full board basis) and any extra costs.
- iii. The period of the training courses must be according to the manufacturer's program excluding travelling days, and must be stated clearly in the technical offer.
- iv. Training Programs must conform to the following standards:
 - i. User training must comprise understanding and use of operation manual(s), correct and safe operation of the equipment, as well as user preventive maintenance and calibration.



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- ii. Service training must comprise: theory, understanding and use of service manual(s), calibration, preventive maintenance procedure, and practical troubleshooting and repair exercises, and must be conducted by professional instructors employed or authorized by the system manufacturer.
- iii. Service training must be conducted on a system of identical make, model, and configuration to that purchased by DRMS, and designated by the manufacturer or the local agent for training purposes.
- iv. Certificates must be endorsed and officially sealed by the system manufacturer, legally empowering trainees to engage in user and service activities according to operation and service manual(s).
- v. Where applicable, offers must include on-site user and service training.





محضر اجتماع

الموضوع: العطاء رقم ش ، ٥/٧٠١٧/ لشراء (Holter Monitor System)

اجتمعت لجنة مواصفات العطاء اعلاه و المشكلة بموجب كتاب عطوفة مدير عام الخدمات الطبية الملكية رقم شن٠٠٥/٧٦/٢٠١٧ و ذلك لدراسة الاستفسارات التالية:

- استفسار السادة مستودع ادوية بابل بموجب كتابهم رقم (۱۲۷/۱۸) تاريخ ۱۹/۱۰ ۱۸/۹/۱۰ مرفق مذكرة شعبة المشتريات المركزية رقم ش۰۰۰۱۷/۰۱ ۳۷٤ تاريخ ۲۰۱۸/۹/۱۰ و بعد دراسة الاستفسار اوصت اللجنة بأن تبقى المواصفة رقم (۸) كما هي.
- ۲. استفسار السادة شركة ابعاد الرعاية الصحية بموجب كتابهم رقم (115/2018/HG) تاريخ ۲۰۱۹/
 ۲۰۱۸ مرفق مذكرة شعبة المشتريات المركزية رقم ش ۲۰۱۰ (۲۰۱۲/۲۰۱۲ تاريخ ۳۷۸۹/۱۳ و مي (Water proof) لتصبح و بعد دراسة الاستفسار اوصت اللجنة بتعديل المواصفة رقم (۱۱) و هي (Water proof) لتصبح (Water proof of a degree of IPX:1 or higher).



محضر اجتماع (Holter Monitor System) الموضوع: العطاء رقم ش ، ١٧/٥٠٠ لشراء (Holter Monitor System)

اجتمعت لجنة مواصفات العطاء اعلاه و المشكلة بموجب كتاب عطوفة مدير عام الخدمات الطبية الملكية رقم ش. . ١٧/٩/٢ تاريخ ٢٠١٧/٩/٢ و ذلك :

ا. لدراسة استفسار السادة التجمع الطبي العلمي العربي بمرجب كتابهم رقم (DRMS P500/17/76/1759) تاريخ ٩/١٧/
 ١٠ دراسة استفسار السادة التجمع الطبي العلمي العربي بمرجب كتابهم رقم (٣٨٦٥/١٦٥/٥ واوصت اللجنة: ٢٠١٨/٩/١٨ مرفق مذكرة شعبة المشتريات المركزية رقم ش٠٠٥/١٢٠/٥ ٣٨٦٥/١٢١٥ واوصت اللجنة:

• تعدل المواصفة رقم (٢) و هي: (Rewiew ECG in 12-lead format)

.(Rewiew ECG in 12-lead format (on the workstation)

• تعدل المواصفة رقم (٣) و هي : (3 channel ECG with at least 5-7 leadwire cable) : التصبح : (3 channel ECG (on recorder Display) with at least 5-7 leadwire cable)

- المواصفة رقم (٤) تبقى كما هي.
- ببقى نص البند رقم (٤) من الشروط الخاصة كما هو.

PC should be included (processor should be at least core i7) و هي: معدل المواصفة رقم (17.d) و هي: omply with the special terms.

PC should be included (processor should be at least core i7, hard disk≥ 1 TB) specifications should comply with the special terms