

### The DIRCETROATE OF ROYAL MEDICAL SERVICES THE INSTITUE OF BIOMEDICAL TECHNOLOGY



Cardiac Rehabilitation System	Otv : (1)

#### **IMPORTANT NOTE:**

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

#### Γ HNICAL SPECIFICATIONS:

The nit 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.
6	Latest Release For Cardiac rehabilitation training system from a Reputable well-known company		
A	Central Software with 3 Licenses, QTY: 1		
	1- Integrated SQL patient database		





	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
	2- Fast and easy arrangement of training groups with specific training parameter for each patient		
	3- Input and management of custom specific text blocks for diagnosis and preliminary examination		
	4- Simultaneous control of all relevant parameters		
	5- Recording and storage of the relevant measured parameter (Load, HR, ECG)		
	6- Real time ECG display of all patients at the monitor		
) . `` .	7- Training Comments possible		
	8- Filter for Training devices and Training Protocols in Analysis		
	9- Automatic training profile adaption to patient specific exercise capacity and Limits (max Load/, Training load Load/v/%, Training Heartrate)		
	These training protocols are interval loads, constant loads, or customizable profiles		
	10- Manual input of RPE and RPD value (Pulmonary and general exertion)		
1	11- Simultaneous display of graphical trend for all monitored parameters (configurable, max 4 Parameters displayed)		

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	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
	12- Continuous storage of ECG trace of all patients		
	13- Marker and comment system for special events		
	14- Fast print-out of real-time ECG of a specific patients		
	15- Input individual patient alarm limits		
	16- Manual input of RPE and RPD value (Pulmonary and general exertion)		
	17- Pulse-Steady-State training (constant heart rate by automatic load adaption, Interval and constant load)		
	18- Training with constant load		
<u>.</u>	19- Interval training with free definable profiles		
	20- Recording Training Profile for treadmill sessions		
	21- Definable warm-up and recovery phase		
	22- Overview display of the complete training session		
	23- Documentation of all relevant events (print-out), Configurable		
	24- Adjustable control algorithm according to the individual heart rate response curve (flat, normal, steep)		
	25- User management with individual user rights assignment		
	26-Individual treatment plan module (User specific Input structure)	•	
	27- Upgradable software up to 8 licenses, (price separately)		
	28- HL7 connectivity to be included		
	29- Overview display of the complete training session		





	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
В	PC,QTY:1		
	1- Windows 10 professional (32 or 64 bit)		
	2- Intel i5 minimum or compatible processor, 8GB RAM, 500 GB hard drive		
	3- Full HD capable graphics card with one to three monitor outputs		
	4- TFT monitor>= 21-inch full-HD (1920 X 1080 px), to monitor one up to eight, and one to three USB ports		
	5- hardware to be supplied from the same manufacturer, local supply not accepted		
C	Telemetry Transmitter for ECG with 3 leads, 1 - Channel, QTY: 2		
	1- Bluetooth Class 1		
	2- Transmission range 50m or better		
	3- Power supply Standard Battery AAA OR equivalent, rechargeable battery		
	4- Defibrillation Proof (Transmitter, Chestbelt)		
	5-1 - Channel ECG lead by Chest belt or sticking electrodes		
	6- tested according to DIN EN 60601-2-27 electrocardiographic monitoring equipment and EMC tested against 60601-1-2 4th Edition		
	8- Chest Belt		
D	Telemetry Transmitter for ECG system with 5 leads, 2 – Channel QTY: 1		
	1- Bluetooth Class1		
	2- ECG system 2 Channel ECG with 5 independent leads		





	Minimum Requirements	Compliance (Y/N), Notes	Brochur
	3- Power supply Standard Battery AA or equivalent, rechargeable	17717, 110168	Page No.
	4- Chest Belt		
	5- Transmission range 50m or better		
	6- Defibrillation Proof (Transmitter, Chestbelt)		
<b>E</b> -			
	Arm Ergometer, QTY: 1		
	1- Control Head / Display: 68 x 34 mm, 128 x 64 pixels		
	2- Display of actual Patient Heart rate in the ergometer display		47   5
	3- Computer- controlled brake with torque measurement		
	4- Speed-independent load 6-999 Watt Increase of load in 1 W		
	5- Max Patient weight 140 kg		
	6- Speed range 30-130 1/min		
	7- Connected to the central software (Item A)		
	8- Options to be priced separately: Spo2, NIBP measurements		
	Bicycle Ergometer, QTY:1		
	1- Control Head / Display: 68 x 34 mm, 128 x 64 pixels		
	2- Display of actual Patient Heart rate in the ergometer display		
-	3- Computer secretal Life in the ergometer display		
-	3- Computer- controlled brake with torque measurement		
	4- Speed-independent load 6-999 Watt, Increase of load in 1 Watt		
	5- Max Patient weight 200 kg		
	6- Speed range 30-130 1/min		
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7- Load precision according to DIN VDE 0750-238	Compliance (Y/N), Notes	Brochure Page No.
8- Connected to the central software (Item A)		
9- Options to be priced separately: Spo2, NIBP measurements		
Treadmill Ergometer, QTY:1		
1- Rigid and Heavy duty with arm handles and emergency stop		
2- Speed Range: maximum 19K/Hr or better		
3- Max. Patient weight 220 kg, Inclination: 0-25%		
4- Connected to the central software (Item A)		
5- Spo2, NIBP measurements		
6- Safety harness for treadmill		
7-(FOC) Abroad Service training for one biomedical engineer/		
technicians To be Price of Septually		



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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 <u>must be submitted with the technical offer</u>.
    - 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



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clearance for selling to US healthcare facilities for the offered model <u>must be submitted</u> 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:

- 3.1. 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.
- 3.2. Accessories and consumables may be manufactured in other countries and/or by different manufacturers.
- 3.3. All offered items must be approved for sale in the same country of origin. An original and officially endorsed free-sale certificate from an authorised body must be included in the offer.
- 3.4. Vendors must specify the origin of <u>all</u> offered items and accessories in the technical offer.



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- 3.5. Except for equipment mentioned in (3.6) below, equipment manufactured by reputable companies based in any of the countries mentioned in (3.1) 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.

OR

- 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).
- 3.6. For X-ray based equipment, MRI, and nuclear medicine systems, the following parts must be manufactured in one of the countries mentioned in 3.1 above:
  - 3.6.1. *X-ray tubes*
  - 3.6.2. X-ray generators
  - 3.6.3. Flat panel detectors
  - 3.6.4. Gantries (including detectors)
  - 3.6.5. Image intensifiers
  - 3.6.6. MRI magnets
  - 3.6.7. Gamma camera heads
- 4. 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.



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#### 5. 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.
- 6. 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.
- 7. 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).
- 8. 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.
- 9. Technical offers must include clear original technical brochures/catalogues for all offered items.
- 10. 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

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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.

11. 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 <u>Yes or NO</u> 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.

#### 12. Accessories and consumables:

- 12.1. Any accessories and consumable items necessary to operate the offered system must be clearly identified and priced separately.
- 12.2. 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.
- 12.3. Accessories and consumables must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.
- 12.4. Where applicable, a start-up kit of accessories and consumable items must be provided with each system on a free-of-charge basis.

#### 13. Spare Parts:

13.1. 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%



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commencing at the end date of the warranty period, any essential item not listed will be considered free of charge.

- 13.2. Spare parts must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.
- <sup>7</sup>4. Spare parts, consumables and accessories availability must be guaranteed for a minimum period of ten years starting from the date of installation and commissioning.

#### 15. Tender Awards:

15.1. 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

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of seven years from the date of installation and commissioning shall qualify for the award.

15.2. 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).

#### For PC/Laptop based systems:

- 16.1. Complete restoration medium (CD/DVD/etc.) of the operating system and the application software must be supplied.
- 16.2. 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.
- 16.3. Where locally supplied printers are offered only the following types and brands are accepted: HP, SAMSUNG, OKI, CANON, EPSON.
- 17. 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.
- 18. 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,

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unloading charges, local shipping charges etc.). The supplier is also responsible for providing of all relevant shipping documents, together with the delivery order(s).

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:

- 20.1For 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.
- 20.2For items where <u>user</u> 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.
- 26.3The period of the training courses must be according to the manufacturer's program excluding traveling days and must be stated clearly in the technical offer.

20.4Training Programs must conform to the following standards:

• User training must comprise understanding and use of operation manual(s), correct and safe operation of the equipment, as well as user preventive raintenance and calibration.





- 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.
- 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.
- 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).
- Where applicable, offers must include an on-site user and service training.

21. For offers submitted in Jordanian dinars, payment will be either by wire transfer or by cheque after final acceptance of goods. Any other way of payment will be rejected.,