|  |  |  |
| --- | --- | --- |
| **Item 1** | Heart Lung Machine with Heater Cooler Unit | **Qty. (1)** |

**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 |  |

| **No.** | **Minimum Requirements** | **Compliance (Y/N), Notes** | **Brochure Page No.** |
| --- | --- | --- | --- |
|  | Latest and top of the line model of state of the art and Upgradable system. |  |  |
|  | Should be Compact and Mast system. |  |  |
|  | The unit should be stainless steel transportable with castor wheels that are 360-degree turntable. |  |  |
|  | Should have a spill proof base. |  |  |
|  | Sensor and control module should be easily interchangeable. |  |  |
|  | Should have a multi-positional system control panel. |  |  |
|  | Modular type (every module works independently) |  |  |
|  | **Rotatable ROLLER PUMP:**  **A- Single Roller Pump Head Size 150mm QTY (3)**  1. Each pump should have programmable modes of operation as: Arterial, pulsatile, cardioplegia, slave -1, slave -2, pump sucker.  2. Pumps should be operable in clockwise and counterclockwise direction.  3. pump flow up to11.2 l/min approximately the pump heads can be rotated 180°  4. Speed should up to 250 RPM or better.  5. Pump should display tube size, RPM rotation directions, speed flow rate, safety status, and error message.  6. Preferable touch screen technology on pump heads.  7.Roller pumps should be easy to remove and reassemble.  8. Roller pump should have a self-diagnostic circuit with provision to detect and display critical alarm conditions.  9. Flow Type Continuous and pulsatile flow.  10. All pumps can be operated and controlled separately  **B- Double roller Pump Head Size 85mm QTY (1)**   1. Pump should be operable in clockwise and counterclockwise direction with master- slave control. 2. Speed should up to 250 RPM or better. 3. pump flow up to 2.33l/min approximately 4. the pump heads can be rotated 240° 5. Pump should display tube size, RPM rotation directions, speed flow rate, safety status, and error message. 6. Preferable touch screen technology on pump heads 7. Roller pumps should be easy to remove and reassemble. 8. Roller pump should have a self-diagnostic circuit with provision to detect and display critical alarm conditions   **C- Centrifuge Pump QTY (1)**  1. Should have integrated centrifugal pump.  2. Flow monitoring.  3. Adjustable speed up to 3500 RPM.  4. Centrifugal pump, with all safety devices, and pulsatile mode control  **D- Small Twin Mast-Mounted Roller Pump Size 85mm QTY (1)**   1. Freely adjustable position 2. Control panel for double pump 3. Tubing clamps all size |  |  |
|  | All Pumps motors should be brushless type or higher technology. |  |  |
|  | ROLLER PUMP Direct Drive motor |  |  |
|  | Emergency Drive Hand Cranks Shouldhave a critical safety feature preferably from top for faster access. |  |  |
|  | Each Pump should have easy mechanism for occlusion setting for different thickness of tubes available in the  Market. |  |  |
|  |  |  |  |
|  | **Unit should have the following parameters monitoring facility:**  1- Pressure monitor - arterial and cardioplegia with transducers (3 pressure display).  2- Time (3 resettable timers with 1 real time display).  3- Temperature Monitor with at least two probes.  4- Cardioplegia monitoring unit should display cardioplegia data including volumes, ratio, time, pressure, and temperature.  6- Temperature control of heater cooler unit.  7- Pumps status.  8- Patient information.  9- System setting should be available on the touch screen of the central control monitor.  10- Important patient parameters should remain displayed.  11- The central control monitor should be able to configure 10-14 different perfusion screens for different equipment setups and perfusion protocol setups.  12-All alarms and errors should be acoustically represented. |  |  |
|  | **Bubble detector:**  a-Detects air bubbles and micro-bubbles in the extracorporeal circuit.  b-Sensor Sizes For 1/4", 3/16", 3/8" and 1/2" tubing’s  c-Detection alarm thresholds (4 mm, 5 mm, and 6.5 mm).  d-Bubble detection alarm |  |  |
|  | **CARDIOPLEGIA CONTROL:**   1. Manual operation the operator can start and stop the pump 2. Automatic operation 3. Channel to monitor the Plegia line give alarm at 3 thresholds 4. It should display volume ratio, timer, temperature, and pressure of full control of independent cardioplegia line. |  |  |
|  | Mechanical Gas Blender |  |  |
|  | The double pressure sensor module   * Measuring and displaying the pressure in the extracorporeal circuit. The display range extends from {-200 mmHg to +800 mmHg} approximately * Transducer cables must be compatible with our transducers * Mounting plate must be compatible with our transducers |  |  |
|  | TEMPERATURE module (4 channels) Temperature measurement range (2 - 41) approximately |  |  |
|  | Vacuum-Assisted Venous Drainage Vacuum Regulator |  |  |
|  | LEVEL CONTROL Two operating modes can be used  a- level monitoring mode.  b- control mode. |  |  |
|  | touch screens Control module. |  |  |
|  | Flexible LED light |  |  |
|  | **Power & Battery:**   1. The unit should have an emergency battery backup for at least 60 min for all the pumps with all necessary safety systems and accessories.   B- Transitioning from mains to back up power should  not require any action from the user.  C- Switch over from main power to battery backup should be automatic and immediate.  D- The battery unit should be built into the pump base, and it should be recharged automatically when the system is operating with main power. |  |  |
|  | **Accessories will include:**   1. **Universal occluder tubing clamp module for the head roller pump RP 150 QTY (1).** 2. **Writing desk** 3. **Versatile shelf** 4. **Shelf for roller pump** |  |  |
|  | abroad service tanning for 2 biomedical engineer or technician and 2 user training (To be priced separately) |  |  |
|  | Heater cooler unit: |  |  |
|  | Latest and top of the line model of state of the art and Upgradable system. |  |  |
| **2.** | Heater cooler unit must supply from the same manufacturer. |  |  |
| **3.** | Should be compact |  |  |
| **4.** | Should have two tank & two circuit system more than tow is preferable |  |  |
| **5.** | 1st. circuit should be for blood heat exchanger of the oxygenator and/or blanket (Patient circuit) and the 2nd circuit should be for the cardioplegia heat exchanger (Cardioplegia circuit). |  |  |
| **6.** | Microprocessor based unit of control |  |  |
| **7.** | The range of available temperature setting should be Approximate 1-41 degrees Celsius and visible as digital display. |  |  |
| **8.** | Incremental control of temperature by each 1 degree Celsius should be available. |  |  |
| **9.** | Heat exchanger supply port should have a minimum supply of 15.0 I/min for highly responsive fast cooling & rewarming. |  |  |
| **10** | System should have separate ports to drain water from the cold and hot tanks. |  |  |
| **11.** | Should be provided blanket Adult -1 no. & paediatric-1 no. |  |  |
| **12.** | Should have alarm system for temperature and any fault. |  |  |
| **13** | pre-cooling/pre-heating |  |  |
| **14** | Separate cold and warm water tanks allow the operator to switch between warm and cold cardio- plegia cardioplegia spontaneously. |  |  |
| **15** | The patient and cardioplegia circuits can be switched off separately when not in use. This improves the other circuits heating and cooling performance. |  |  |
| **16** | Independent safety system stops the water temperature reaching critical values. |  |  |
| **17** | The pump suction stage ensures that the heat exchanger and tubing are purged. |  |  |
| **18** | Safety temperature sensor |  |  |
| **19** | Visual and audible alarms |  |  |
| **20** | Temperature control 2-41 approximately |  |  |
| **21** | abroad service tanning for 2 biomedical engineer or technician and 2 user training(To be priced separately ) |  |  |
| **22** | Offers must include a full warranty including spare parts and labour and preventive maintenance for a period of 7 years from the date of installation. |  |  |

***SPECIAL TERMS***

* ***Offers not complying with any of the special terms or the technical specifications will be considered non-conforming with tender requirements.***
* ***Any vendor providing FORGED documents will 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:***

***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.***

***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.***

***Only for class Ι medical equipment, submission of a copy of Declaration of Conformity certificate (MDD) for the offered model shall be accepted.***

***In all of the above cases certificates must be formally endorsed by JFDA.***

1. ***Country of origin:***

***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 and Australia.***

***Accessories and consumables (as determined by the purchasing committee) may be manufactured in other countries and/or by different manufacturers.***

***All offered items must be approved for sale in the same country of origin.***

***Vendors must specify the origin of all offered items and accessories in the technical offer.***

***Equipment manufactured by reputable companies based in any of the countries mentioned in (3.A) will be taken into consideration regardless of the country of origin only :***

1. ***If they are 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)***
2. ***Or if they are approved for sale in at least three of the countries mentioned in (3.A), (an original and officially endorsed free-sale certificate from an authorised body in those countries must be included in the offer).***
3. ***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 will be rejected.***
4. ***Warranty:***

***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 or 30 months from the date of receiving the items at the agreed location mentioned in the final order.***

***In the case where a delay in installation has occurred as a result of the supplier’s dereliction and has exceeded a period of one month from the date of receiving the items, the approved warranty period will automatically be considered as 24 months from the date of installation.***

***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 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 term No. (5-A) above will start from the installation and commissioning date of the new item.***

1. ***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.***

1. ***Where applicable, pre-installation shall be the sole responsibility of the supplier. Pre-installation shall include removal of the old system, any civil work, electrical work or site modifications necessary to accommodate the new system according to manufacturers’ specifications and safety standards in addition to the work required for bringing back the site to the same working condition as before installing the new system.***
2. ***Power requirements: where applicable either single phase 220V, 50Hz or 3-phase 380V. Systems with external transformers are only considered conforming only if stated in the technical specifications.***
3. ***Technical offers must include clear original technical brochures/catalogues for all offered items.***
4. ***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 format, 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.***
5. ***Compliance sheets must be as per the tabular format of the technical specifications in the tender listing the required specification 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.***
6. ***Accessories and consumables:***
7. ***Any accessories and consumable items necessary to operate the offered system must be clearly identified and priced.***
8. ***Technical offers must include a priced list for accessories and consumables as a hard copy in addition to a soft copy format copy (either Microsoft office or Microsoft excel) 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.***
9. ***Accessories and consumables must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.***
10. ***Where applicable, a start-up kit of accessories and consumable items must be provided with each system on a free of charge basis.***
11. ***Spare Parts:***
12. ***Technical offers must include a comprehensive and priced spare parts list as a hard copy in addition to a soft copy format copy (either Microsoft office or Microsoft excel) 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.***
13. ***Spare parts must be priced according to their delivery destination either to Queen Alia International Airport or to RMS Main Medical Stores.***
14. ***Spare parts, consumables and accessories availability must be guaranteed for a minimum period of ten years starting from date of installation and commissioning.***
15. ***Tender awards:***
16. ***For the final list of offers having a chance of winning the award, the awarding process will be based on the accumulative value of both the offered item and its’ running cost (total cost of ownership) 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.***
17. ***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).***
18. ***For PC/Laptop based systems:***
19. ***Complete restoration medium CD/DVD/etc. of the operating system and the application software must be supplied.*** 
    1. ***Where locally supplied computers or laptops are offered, only computers / laptops from Apple, hp/Compaq, Lenovo, Dell, fujtisu &Toshiba will be accepted, offered models must be the latest available version upon delivery.***
    2. ***Where locally supplied printers are offered only the following types and brands are accepted:***

***HP, SAMSUNG, OKI, CANON, EPSON***

1. ***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.***
2. ***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).***
3. ***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 twelve months from the date of final acceptance of the equipment by DRMS.***
4. ***Training:***

***20.1 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.***

***20.2 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.***

***20.3 The 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.***

***20.4 Training 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 maintenance 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.***