

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



Item 1 Nasal C-PAP	Otv. (450)
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### **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.

Prod	uct 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	Heavy duty, from a reputable manufacturer, a sample must be submitted immediately when required by the purchasing committee.		
2	Adult paediatric C-PAP		
3	Fixed level positive pressure: approximately pressure range 4-20 cmH2O.		
4	Adjustable pressure within 0.5 cmH2O		
5	Pressure indicator and quiet generator—		· · · · · · · · · · · · · · · · · · ·
6	Auto altitude compensation or manual		
7	Humidification systems		
8	Check valve between humidifier and the machine or any equivalent technology.		
9	Light weight.		

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

** ( 194 ** 194 ** 1	Minimum Requirements	Compliance (Y/N), Notes	Brochure Page No.
10	Standard and all required accessories (including 2 masks/equipment) shall be completely listed and supplied with the machine.		
11	CPAP masks all sizes (small, medium, large) double silicon with head gear.		



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



### 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</u> 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 <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:

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.



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



- 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.



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



- 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.



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



### 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. 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.
- 16. 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).
- 17. 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.

1



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



- 18. 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.
- 19. Training: on site training
- so. For offers submitted in jordanian Dinars, payment will be either by wire transfer of by cheque after final acceptance of goods. Amy other way of payment will be rejected.