

Expression of Interest.

Subject- To invite Expression of Interest from Original Equipment Manufacturer /Vendor / Distributor to supply of Portable ECMO System for Dept of CVTS KEM Hospital through MPLAD Fund.

King Edward Memorial Hospital is one of the leading tertiary care, public hospitals in the metropolis of Mumbai that provides basic as well as specialized services to needy patients from all over the country. With a glorious legacy of 96 years and currently catering to over 1.8 million out-patients and 85,000 in-patients annually, the institute is among the top ranked medical institutes in India. The CSR Wing of the Social Service Department has been working hard to raise funds to procure advanced medical equipment for various medical and surgical specialty and super specialty departments of KEM, with the objective of providing state of the art facilities to the underprivileged sections of our society.

Through MPLAD funds, we wish to purchase a Portable ECMO System for Dept of CVTS KEM Hospital. For purchase of the above equipment, it is proposed to invite "Expression of Interest" from Original Equipment Manufacturer /vendors / Distributor, to supply the same to KEM Hospital. To supply Portable ECMO System, Original Equipment Manufacturer /vendors / Distributor should purchase a form, from Poor Box Charity Fund, KEM Hospital from 10/01/24 to 19/01/24 in working hours and all proposals with the required documents should be submitted on or before 19/01/24 (by 1.00 pm) in the Department of CVTS, CVTC Building, ground floor KEM Hospital, Parel, Mumbai 400012. With Two packet System (i.e. Packet A is a Administrative & Technical Documents & Packet B is a commercial) do not disclosed the price other than commercial packet. The packet will be open in front of Heart Transplant Committee as per schedule decided by committee.

BRIHANMUMBAI MUNICIPAL CORPORATION OF GREATER MUMBAI

**King Edward VII Memorial Hospital,
CSR Wing, Social Service Department,
Parel, Mumbai 400012**

Specifications For Portable ECMO System for Dept of CVTS KEM Hospital

Description	
Name of Equipment	<u>Portable ECMO System for Dept of CVTS KEM Hospital</u>
Specification of Equipment	Attached to ANNEXURE VIII

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King Edward VII Memorial Hospital,

CSR Wing, Social Service Department,

Parel, Mumbai 400012

General Conditions :

Warranty period	Comprehensive warranty on equipment and all spares shall be three years. Inclusion and exclusion of Warranty documents should be clearly stipulated.
CMC	<u>Comprehensive Maintenance Contract (CMC)</u> 1) After the warranty period of 3 years is over, five years Comprehensive Maintenance Contract (CMC) will have to be entered into with the terms and conditions mentioned in the documents as per BMC norms. List of spare parts / consumables will be submit by supplier with cost freeze in advance for the warranty and CMC period. 2) The successful supplier must ensure that all the required spares/consumables and services are available during warranty and CMC period and 2 years after that, duly backed by the principal.
<u>Delivery & Installation Period</u>	1) Supplier should give free delivery at user department of KEM Hospital within 30 days or as soon as possible from the date of receipt of purchase order. 2) Installation and commissioning of equipment shall be done within 7 days from the delivery of the equipment.

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**GENERAL
REQUIRE
MENTS:**

- 1) Price should include GST charges & any other charges (Supplier needs to submit basic cost of equipment and GST rate in prescribed format).
- 2) The above equipment shall be new and manufactured from virgin materials.
- 3) It is mandatory to provide free installation & training for use of equipment.
- 4) The equipment should have warranty of three years as described in the terms and condition document. The warranty and CMC shall cover the list of spare parts and the rate of which shall be valid for total 8 years (warranty 3 years and CMC 5 years) irrespective of whether those are treated as consumables or otherwise.
- 5) After the warranty period is over, five years Comprehensive Maintenance contract (CMC) will have to entered into with the terms and conditions mentioned in the documents as per BMC norms. List of spare parts / consumables will be submitted by supplier with cost freeze in advance for the warranty and CMC period
- 6) It should be European CE certified along with declaration of conformity or USFDA approved.
- 7) 3 years comprehensive warranty followed by 5 years comprehensive maintenance contract.
- 8) Demonstration of quoted model is compulsory and to be given at an end user site.
- 9) User list with address and phone number to be provided
- 10) The Successful supplier must ensure that all the required spares/consumables and services are available during warranty and CMC period.
- 11) All the requirements of this supply shall be sourced from the original equipment manufacture of the model quoted
- 12) Power supply: 230 V, 50 Hz. The main supply voltage variation may be maximum 15% and frequency variation maximum 3%.

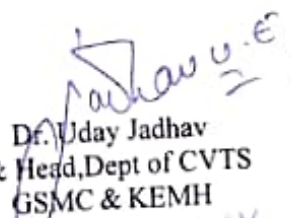
BRIHANMUMBAI MUNICIPAL CORPORATION OF GREATER MUMBAI


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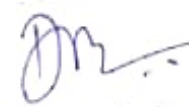
- 13) The equipment shall have valid CE mark / US FDA approved and documentary evidence to that effect needs to be submitted.
- 14) Training to Medical Electronics Cell Engineers from servicing point of view and to user department from operating point of view is compulsory.
- 15) Supplier should submit all technical details in the form of technical brochures / leaflets for all the equipment proposed for supply and mentioned in the technical offer.

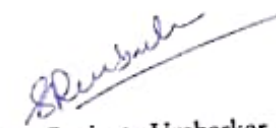
The supplier should submit documents mention in check list attached herewith.

If any doubts or any query about above mentioned work, you can contact Heart transplant committee / Dept of CVTS, KEM Hospital, Parel, Mumbai - 400012.


Dr. Uday Jadhav
Prof & Head, Dept of CVTS
GSMC & KEMH


Dr. Ajay Mahajan
Prof & Head, Dept of Cardiology
GSMC & KEMH
Professor & Head
Department of Cardiology
Seth G. S. Medical College & KEMH,
Parel, Mumbai - 400 012.


Dr. Dwarkanath Kulkarni
Prof & Head of unit, Dept
of CVTS
GSMC & KEMH


Dr. Sanjeeta Umbarkar
Prof & head, Dept of Cardiac Anaesthesia
GSMC & KEMH

Dr. Sanjeeta Umbarkar
Professor & Head Of Dept.
Cardiac Anaesthesia
Seth G. S. Medical College &
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Dean,
GSMC & KEMH

Dean, K.E.M.H. & Seth G.S.M.C.,
Parel, Mumbai - 400 012.

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**King Edward VII Memorial Hospital,
Department of cardiovascular and Thoracic
surgery, Parel, Mumbai 400012**

Check list of Documents to be submitted as per the order given below.

Sr No	Administrative Documents	Sr. No.	Technical Documents
1	Authorization Certificate	1	Technical Offer
2	Undertaking about CMC for 5 year after 3 year warranty period is over will be follows as per BMC norms	2	List of Consumables (Applicable in Warranty & CMC Period)
3	Signed copy of Terms & Condition of EOI Document	3	Comparison of EOI specification v/s Quoted equipment specification
4	Firm/Company/ Sanstha Registration Certificates	4	Experience Certificate
5	Partnership deed (If applicable)	5	Past Performance Certificate of Quoted Equipment.
6	Pan Card with Photograph.(Only for Indian Bidder)	6	Copy of valid CE certificate OR copy of valid USFDA approval as mentioned in General Conditions (Technical specifications).
7	GST Registration Certificate as applicable	7	Technical brochure of quoted model
8	Import / Export license issued by competent authority(if applicable)	8	List of Spare Parts (Applicable in Warranty & CMC Period)
9	Power of Attorney to sign the tender		
10	Special Annexure for GST		
11			
12			
13			
14			

**Authorized Signature of the Bidder
with Official Seal & Address**

Specifications For Portable ECMO System

Preamble :- As per the guidelines of the heart and lung transplantation ECMO system is mandatory and must. ECMO- Extracorporeal membrane oxygenator, is also required for all the complex congenital surgeries and life saving for the infants below 5 kg weight. As we operate almost 60% of paediatric patients with less than 5 kg the system becomes must and life saving and helps in getting down the mortality rate. Also we have submitted the papers for recognition of the department for heart and lung transplantation the system is mandatory for all such transplant patients.

Technical specifications:

Equipment:

A. Centrifugal Pump (Console with its Accessories):

- A) Should generate 0 to 5000 RPM.
- B) Should be able to flow 0 to 9.99 LPM.
- C) To work on power supply 100 V to 240 V, 50 Hz to 60 Hz, and 11 V to 28 V DC.
- D) Compact, lightweight console (approx. 10 kgs weight).
- E) Should have LCD Touch Screen (5.7 inches). / monitor
- F). Drive adaptor. 01 no
- G) Connection cable for:

- i. Venous probe- 0.55 mts. / flow probe – upto 10L/min
- ii. Rotassist – 0.46 mts.

H) Oxygenator Holders:

- i. 01 no. Basic Holder
- ii. 01 no. Adaptor

I) Should display following parameters:

- i. 04 no.'s of External Pressures (Measuring Range- -500 to +900 mm Hg or -150 to 900mmHg).
- ii. 03 no.'s of Internal Pressures (Measuring Range- -500 to +900 mm Hg).
- iii. 02 no.'s of External Temperatures (Measuring Range- 10 to 45 *c).
- iv. 02 no.'s of Internal Temperatures (Measuring Range- 10 to 45 *c).
- v. 01 no. Venous Blood Oxygen Saturation (SvO2) (Measuring Range- 40 100%).
- vi. 01 no. Hemoglobin (Measuring Range 05 to 15 gm/dl).
- vii. 01 no. Hematocrit (Measuring Range 15 to 50%).
- viii. 01 no. Level Sensor, measuring Blood Level in the reservoir.

- C-03
- ix. 01 no. Bubble sensor measuring Bubbles in the Blood Stream.
 - x. 01 no. Flow sensor with integrated Bubble sensor which measures Blood Flow Rate and Bubbles respectively.
 - J) Flow sensor with integrated Bubble sensor which measures Blood Flow Rate and Bubbles respectively.
 - 1. $3/8 \times 3/32$
 - 2. $1/4 \times 3/32$
 - K) Bubble sensor measuring Bubbles in the Blood Stream.
 - 1. $3/8 \times 1/16 - 1.7$ mts
 - 2. $1/4 \times 3/32 - 1.7$ mts
 - L) Portable Emergency Hand Crank.
 - M) Back Flow Prevention mode. (Zero Flow Mode).
 - N) Recording of Data in the unit (Interval- 3 sec.'s to 10 min.'s) and retrieval of the same into a USB memory stick or into a Computer.
 - O) 03 no.'s of resettable Clock timers.
 - P) 1 no. of Countdown Timer.
 - Q) Modes of Applications: (Therapy Applications):
 - i. MECC (Minimal Extracorporeal circulation for routine Cardiopulmonary Bypass procedures)
 - ii. VAD (Ventricular Assist Device)
 - iii. VV ECMO Support
 - iv. VA ECMO support
 - v. PALP (Pump Assisted Lung Protection for Extracorporeal CO2 Removal ECCO2R))
 - R) Modes to Control (Therapy applications)
 - i. LPM mode
 - ii. RPM mode
 - S) Night mode.
 - T) Battery Backup 90 to 120 min.
 - U) Safety:
 - i. IPX1 (Protection against vertically dripping water)
 - ii. IPX4 (protection against splash water from all sides) through the use of the CARDIOHELP Protection Cover.
 - iii. Defibrillator-protected Type CF applied part.
 - V) 01 no. connection for Alarm output (Ward Call)
 - W) 01 no. connection for Ethernet Cable.
 - X) 01 no. connection for External Drive.

- Y) 01 no. connection for ECG signal.
- Z) Should have Road and Air Transport Approval.

B. Heating Unit with its accessories:

- a. Temperature range setting from 35°C to 39°C.
- b. Digital display for set temperature and outlet temperature.
- c. Compact & light weight console (9 kgs weight).
- d. To work on power supply 230 V, 50 Hz.
- e. Should generate 03 to 05 LPM, 0.34 bar pressures.
- f. Water Capacity 0.7 to 1.4 Lits. / 5 litres
- g. Heat Resistant Tubings with Hansen Coupling for Quick connections.

C. Sprinter Cart:

- a. Advanced cart design maximizing safety and convenience to move complete anywhere. / standard trolley
- b. Infusion pole mast (Height adjustable).
- c. Gas Cylinder holder for better portability.

D. Air – Oxygen Blender:

- a. Mechanical air oxygen blender/ Electronic air oxygen blender with hoses.

Disposables:

A) Heart lung support set (HLS set):

- a. 30 day CE certification in HLS set for usage.
- b. Hollow fiber Diffusion membrane oxygenator (Poly Methyl Pentene Fibers)
- a. Centrifugal Pump Head having 04 outlets and 01 inlet which is integrated with the Oxygenator with integrated Hollow fiber Polyurethane Heat Exchanger.
- c. PVC Tubing's which make a circuit with 30 day CE certification of usage.
- d. Tip to tip Bioline Coating (Albumin +Heparin) (which includes the whole circuit with all the components). / PC coating
- e. Oxygenator unit includes a hollow fiber Heat Exchanger with very less pressure drop.
- f. Circuit minimized to its basic minimum components.
- g. Deairing Membrane in oxygenator for emergency in-operation hassle free deairing.
- h. Comes in two types :

- i. ECMO flow 7LPM
- ii. VAD flow 9.9LPM
- iii. HLS Set Advanced 7.0. (Max Blood Flows : 07 LPM)
- iv. HLS Set Advanced 5.0 (Max Blood Flows : 05 LPM)
- i. Integrated Sensors for Pressures (Venous, Arterial and Internal) and Temperature (Arterial and Venous) monitoring.
- j. Should have Integrated Measuring Cell for Venous probe to measure Venous Oxygen saturation (SvO2), Hemoglobin, Hematocrit and Venous Temperature.

B) Extracorporeal Life Support Set (ECLS Set) which includes:

- b. 30 day CE certification in ECLS set for usage.
- c. Hollow fiber Diffusion membrane oxygenator (Poly Methyl Pentene Fibers) with integrated Hollow fiber Polyurethane Heat Exchanger.
- d. Centrifugal Pump Head (Rotassist) having integrated sensors for Pre- Pump and Post Pump pressure monitoring.
- e. PVC Tubing's which make a circuit with 30 day CE certification of usage.
- f. Tip to tip Bioline Coating (Albumin +Heparin) (which includes the whole circuit with all the components).
- g. Oxygenator unit includes a hollow fiber Heat Exchanger with very less pressure drop.
- h. Circuit minimized to its basic minimum components.
- i. De-airing Membrane in oxygenator for emergency in-operation hassle free de-airing.
- j. ECLS set with maximum blood flow range of 2.8 LPM.
- k. Integrated Sensors for Pressures (Venous, Arterial and Internal) and Temperature (Arterial and Venous) monitoring.
- l. Should have Integrated Measuring Cell for Venous probe to measure Venous Oxygen saturation (SvO2), Hemoglobin, Hematocrit and Venous Temperature.

C) Ventricular Assist Device – Rotassist (VAD pump) which includes:

- a. 30 day CE certification in VAD set for usage.
- b. Tip to Tip Bioline coated (Albumin + Heparin).
- c. Centrifugal Pump Head (Rotassist) having integrated sensors for Pre- Pump and Post Pump pressure monitoring.

- 10) Pump assisted lung protection (PALP set) for extracorporeal CO₂ Removal (ECCO2R)
- a. 30 day CE certification in PALP set for use
 - b. Hollow fiber Diffusion membrane oxygenator (Poly Methyl Methacrylate) Surface area: 0.98 m²
 - c. Centrifugal Pump Head (Rotassist) having integrated sensors for Pre-Pump and Post-Pump pressure monitoring
 - d. PVC Tubing's which make a circuit with 30 day CE certification of usage
 - e. Tip to tip Bioline Coating (Albumin + Heparin) (which includes the whole circuit with all the components)
 - f. Oxygenator unit includes a hollow fiber Heat Exchanger with very less pressure drop
 - g. Circuit minimized to its basic minimum components
 - h. De-airing Membrane in oxygenator for emergency in-operation hassle free de-airing
 - i. PALP set with maximum blood flow range of 2.8 LPM
 - j. Integrated Sensors for Pressures (Venous, Arterial and Internal) and Temperature (Arterial and Venous) monitoring (SpO₂), Hemoglobin, Hematocrit and Venous Temperature

General Specifications:

- 1) Three years comprehensive warranty on all parts of the system
- 2) Five years CMC is required after completion of warranty period is over
- 3) Price should include supply and installation
- 4) Technical support, spares and consumables should be provided as needed for 7 years after warranty period is over
- 5) For price evaluation, the cost of equipment + accessories asked for will be considered
- 6) Please quote separate prices for all modules, and the basic monitor unit. The exact numbers of each module may be varied
- 7) All software upgrades should be provided free of cost during the period of warranty and CMC
- 8) All modules should be defibrillator- and surgical diathermy proof
- 9) The system should follow international safety standards for medical use viz marking US FDA and CE
- 10) Past performance certificate should be provided as per tender specifications
- 11) User list to be provided with contact numbers
- 12) Demonstration is compulsory and within 15 days of intimation

- 13) Accessories should be indicated as standard and optional and quoted separately
- 14) Training to be imparted to MEC Engineers on servicing and maintenance.
- 15) Operation manual 10 copies and detailed service manual 2 copies to be provided.
- 16) Power supply: 230 V \pm 15%, 50 Hz \pm 3% The monitors shall have be operable on mains with built-in re chargeable battery. Back up for min. 2 hours. The battery and charger shall be in monitor itself.
- 17) The modules should be attachable the main frame of machine only.
- 18) Tropicalization:

Operating temperature – up to 40°C
 Storage temp- up to 60°C
 Relative humidity- up to 90% - non-condensing

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