ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-29.
STORES SECTION (DO)

Ref.No.XX-153/SO(DO)/Aneasth/2016-17/FSC-III

Dated: 17.04.2017

Sub:-Purchase of "Volume View System" for the department of Aneasthesiology, (AIIMS), New Delhi-29, on proprietary basis <u>Inviting comments thereon.</u>

The Institute is in the process to purchase "Volume View System" for the department of Aneasthesiology, (AIIMS), New Delhi from M/s. Arian Healthcare, New Delhi on proprietary basis. The proposal submitted by M/s. Arian Healthcare, New Delhi and PAC Certifications are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within issue of 15 days giving reference No.XX-153/SO(DO)/Anesth/2016-17/FSC-III. The comments should be received by office of Sr. Stores Officer, Store Section (DO), Animal House Building, Near Biotechnology Building at AliMS on or before 05.05. 2017 upto 12.30 p.m., failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

Yours faithfully,

(PRADEEP KR.GUPTA)

Sr. STORES OFFICER

Encl: Related documents enclosed.

ALL INDIA INSTITUTE OF MEDICAL SCIENCES ANSARI NAGAR, NEW DELHI - 110 029

PROPRIETORY / SPECIFIC BRAND GOODS CERTIFICATE

Item /Type/Model No. required along with specification.

: Volume View System

2. Is the item a spare part attachment or accessory for : No

an existing equipment.

3. Name of the manufacturers/supplier of the item proposed by the indenter.

: M/s. Edwards Lifesciences LLC, USA

Are they sole manufacturers/ sole distributors of the item.

: Yes*

5. Is there any other item with similar/ equivalent specification available in the market to meet the job requirement envisaged. If the answer is yes, why the same can't be procured. Demanding Officer should bring our comparative functional advantages/ cost effectiveness of the recommended item from these offered by other.

: No, This is proprietary item.

What were the efforts made to locate alternative source of supply or use other substitutes.

- The tender was uploaded on the AIIMS Website ref no. XX-153/SO(DO)/Anaesth/2016-17/FSC-III and only one manufacturer M/s. Edwards Lifesciences LLC, USA quoted. Proprietary certificate is attached. It is a life saving equipment and may be purchased on proprietary basis.
- 7. Why open /limited tender can't be resorted to, for locating alternative source.

As Note 5 above

8. Are the proprietary items certifying that the rates are reasonable or not.

* Yes, Certified by the Manufacturer

9. Any other justification for procuring item from single source.

: As Note 5 above

Signature of Indent or (Demanding officer)

Demanding Officer
(Head of the Department of Allacher)

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(Head of the Department)

I certify that the item at Sr. no. I above is required to be procured on single tender basis as the source of supply is definitely known/ the specified brand proposed was advantages in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.

* Necessary undertaking / Certificate taken from manufacturer please find enclosed



Proprietary Article Certificate

August 10, 2016

To Whom It May Concern:

We hereby certify that Edwards Lifesciences LLC located at One Edwards way, Irvine, CA 92614 USA is the sole manufacturer of the EV1000A.

EV1000 Clinical platform enables you to choose the parameters needed to monitor your patients and may be used with a variety of Edwards advanced hemodynamic monitoring tools including FloTrac sensor, PreSep and PediaSat oximetry catheters and VolumeView set for an integrated Edwards Critical Care System. The EV1000 Clinical platform is an Edwards' proprietary technology.

From the Operator's Manual:

Overview

The EV1000 is a monitoring platform that displays both intermittent and continuous hemodynamic measurements related to the assessment of the essential components of oxygen delivery as well as the balance of oxygen delivery against consumption. The EV1000 system assists the clinician in assessing the patient's status and supports clinical decisions related to the optimization of oxygen delivery through the management of preload, after load, and contractility. In addition, the EV1000 can assess extra vascular lung water (EVLW) as an indicator of pulmonary edema.

The continuous parametric measurements provided from an arterial line via an Edwards CO sensor include cardiac output (CO), stroke volume (SV), and stroke volume variation (SVV). When combined with a TruWave transducer for monitoring central venous pressure, the Edwards CO sensor is also able to measure continuous systemic vascular resistance (SVR).

Continuous venous oximetry is a valuable tool for monitoring the balance between oxygen delivery and consumption. Continuous oximetry measurements are performed using any Edwards oximetry catheter.

The intermittent parametric measurements require use of a VolumeView catheter in a femoral artery, a CVC (central venous catheter) thermistor manifold, and a central venous pressure measurement. The intermittent parameters include cardiac output (iCO), stroke volume (iSV), systemic vascular resistance (iSVR), global enddiastolic volume (GEDV) and extravascular lung water (EVLW).

Indications

The EV1000 Platform is indicated for use primarily for critical care patients in which the balance between cardiac function, fluid status and vascular resistance needs continuous or intermittent assessment. Analysis of the thermodilution curve in terms of mean transit time and the shape is used to determine intravascular and extravascular fluid volumes. When connected to an Edwards oximetry catheter, the monitor measures oximetry in adults and pediatrics. The EV1000 Platform may be used in all settings in which critical care is provided.

> Edwards Lifesciences LLC One Edwards Way · Irvine, CA USA · 92614 Phone: 949.250.2500 · Fax: 949.250.2525 · www.edwards.com

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Volume View System

1. It should be a touch screen with active area of 10.4 inch.

2. It should be able to display intermittent & continuous hemodynamic measurements when used with appropriate disposable sensor.

3. It should be able to give Auto Calibrated technology based Continuous Cardiac Output, Stroke Volume, Systemic Vascular Resistance(with CVP transducer), Stroke Volume Variation when used with appropriate arterial sensor.

4. It should have option of calibrating above parameters with Transpulmonary Thermodilution technology using dedicated kit for the purpose along with displaying additional information on Global Ejection Fraction/Cardiac Function Index, Global End Diastolic Volume/ Intra Thoracic Blood Volume, Extra Vascular Lung Water, Pulmonary Vascular Permeability Index.

5. It should give Cardiac output update at least every 20 Seconds. With Provision

for 5min Average.

- 6. The arterial disposable sensor should be able to give Continuous arterial pressure waveform when connected, on other bedside monitors with IBP
- 7. It should be able to give intravascular oximetry parameter i.e Central Venous Oximetry updated every 2secs when used with dedicated disposable central venous catheter sensor.

8. It should able to give derived value as Cardiac Power Output, Oxygen Demand and Estimated Oxygen Consumption.

9. It should have display capacity of at least 4 trend lines and 4 numerical display, optional physiology and physio-relationship screen.

10. It should have intervention analysis screen for recording events and analyzing its effects.

11. It must save data for at least 72 hours.

12. Must have screen shot and data download facility through any USB stick.

Terms and Conditions

- 1. Preventive machine maintenance four times in a year.
- 2. Response time for acknowledgement of complaint 30 minutes
- 3. Response time for physical presence within one working day

4. Uptime 365 days in a year

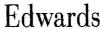
5. Downtime 48 hours with a penalty of Rs. 1000/- every day after downtime

6. Demonstration of equipment is compulsory

Price of accessories consumables and spares to be fixed for 5 years.

02/06/2016 T Wester







SECTION – XIV MANUFACTURER'S / IMPORTER'S AUTHORISATION FORM

The 'Director'
All India Institute of Medical Sciences
Ansari Nagar, New Delhi-29
India.

Dear Sirs,

Ref.: TE document No. XX-153/SO(DO)/Aneasth/ 2016-17/FSC-III due on 30.08.2016 up to 12.30 p.m.

We, Edwards Lifesciences (India) Private Limited, are a group company of the Edwards Lifesciences, LLC, Irvine, California, United States of America, a global leader in the science of Heart Valve Therapy and Hemodynamic Monitoring. Edwards Lifesciences, LLC is the Manufacturer of the Edwards brand of Medical devices and has factories across the globe. Edwards Lifesciences (India) Private Limited, having registered office at Techniplex II, 7th Floor, Unit No. 1 & 2, Off S. V. Road, Goregaon (West) Mumbai 400 062 is the Authorised Distributor for Edwards brand in India.

We, Edwards Lifesciences (India) Private Limited, having its registered office at Techniplex II, 7th Floor, Unit No. 1 & 2, Off S. V. Road, Goregaon (West) Mumbai 400 062 a group company of Edwards Lifesciences LLC who are proven and reputable manufacturers of Edwards Critical Care range of products and Edwards Vascular range of products, hereby authorise Messrs Arian Health Care having their office at 4327/3, Flat No 202, IInd Floor, Ansari Road, Darya Gani, New Delhi - 110002 our Authorised Distributor (name and address of the agent) or his authorised sub-distributor to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We further confirm that no supplier or firm or individual other than <u>Messrs Arian Health Care</u> or his authorised sub-distributor-is authorised to submit a tender, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also hereby extend our full warranty, CMC as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

Yours faithfully,

For Edwards Lifescience Andia Private Limited

Deepa Pryadarshin Company Secretary

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August 12, 2016

Edwards Lifesciences (India) Pvt. Ltd.

Regd. Office :Techniplex II, 7th Floor, Unit No. 1 & 2, Off S. V. Road, Goregaon (West), Mumbai - 400 062. INDIA.

Te 91-22-66935701-04 Fax: 91-22-61931344