



All India Institute of Medical Sciences Jodhpur

Admn/Prop/07/2018-AIIMS.JDH

Dated: - 14th May 2018

Subject: Purchase of Minimally Invasive Cardiac Output Monitor for the Department of Anaesthesiology at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Minimally Invasive Cardiac Output Monitor for the Department of Anaesthesiology at AIIMS, Jodhpur from M/s Edwards Lifesciences LLC, One Edwards Way Irvine, CA USA-92614 on proprietary basis. The proposal submitted by M/s Shreya Enterprises, Jodhpur and PAC certification by user are attached.

The above document are being uploaded for open information to submit subjection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21days of issue giving reference Admn/Prop/07/2018-AIIMS.JDH. The comments should be received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 05th June 2018 upto 03:00 PM failing which it will be presumed that any other vendor is having no comment to offer and case will be decided on merits.

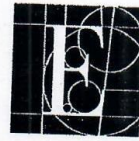
Yours faithfully,

Administrative Officer

Enclosed: Related documents enclosed.



All India Institute of Medical Sciences Jodhpur



Edwards

Proprietary Article Certificate

September 14, 2017

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.

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), pulse rate (PR), 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 end-diastolic 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. The EV1000 Clinical Platform may be used for the monitoring of hemodynamic parameters in conjunction with a perioperative goal directed therapy protocol. 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.

Now

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

OF SHREYA ENTERPRISES
Anurag Rana
regulator/Anurag Rana



All India Institute of Medical Sciences Jodhpur



Edwards

US patents:

Patents	US issue date	US expiration date
7,220,230	May 22, 2007	February 23, 2025
7,452,333	Nov. 18, 2008	April 19, 2025
7,422,562	Sep. 09, 2008	May 21, 2025
<u>7,967,757</u>	Jun. 28, 2011	June 8, 2024
7,785,263	Aug. 31, 2013	March 31, 2024

Takako Kojima
Regulatory Affairs, Senior Specialist

Manoj
Indira

J.S.
Mr. Mohd. Farooq

Swati

Rohit
M. Srinivas Kumar

FOR SHREYA ENTERPRISES
Alumna Ranika
Proprietor/Authorized Signatory



All India Institute of Medical Sciences Jodhpur



Edwards

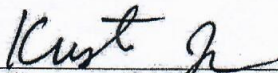
A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California



County of Orange

Subscribed and sworn to (or affirmed) before me on this 14th day of September, 2017 by Takako Kojima, proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

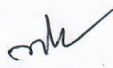
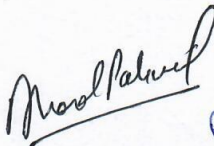
Seal





Signature of Notary Public





FOR SHRIMA ENTERPRISE

Authorized Signatory





All India Institute of Medical Sciences Jodhpur



October 12, 2017

AIIMS Hospital
Jodhpur

Dear Sir,

Sub: Letter of Authority to M/s Shreya Enterprises for making supplies

This is with reference to the captioned subject. Please note that M/s Shreya Enterprises having their office at Shreya" 27, Narpat Nagar, [Amar Nagar] , Pal Road, Jodhpur - 342008 [Rajasthan] India is the authorized distributor of 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.

M/s Shreya Enterprises is duly authorised to receive purchase order, collect payment & make supplies etc. for the Edwards Critical care Range of Products & Edwards Vascular Range of Products on our behalf to your esteemed Institute.

Further, please note that no other distributor is authorized to supplies etc. to your hospital on our behalf other than M/s Shreya Enterprises.

Please take note of the same.

Yours faithfully,
For Edwards Lifesciences (India) Private Limited

Authorised Signatory



Cc: M/s Shreya Enterprises

Naveen
jk
Swati
Amol Kulkarni
Revel
Shreya Enterprises
Alene Ranker
Authorised Signatory
Shreya Enterprises
Authorised Signatory

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.
Tel. : 91-22-66935701-04, Fax : 91-22-61931344

Website : www.edwards.com, E-mail : customercare_edwardsindia@edwards.com, CIN No. U33110MH1996PTC145849



All India Institute of Medical Sciences Jodhpur

Annexure-I			
S. No	Item	Technical Specification	Qty
01.	Minimally Invasive Cardiac Output Monitor	<ol style="list-style-type: none">1. It should be able to give continuous Cardiac Output using any arterial line.2. The Disposable Sensor should be able to give Continuous arterial pressure waveform when connected, on other bedside monitors with IBP modules.3. No calibration should be required for getting CO started.4. It should give Cardiac output update at least every 20 Seconds. With Provision for 5 min Average.5. Should be able to give Stroke Volume Variation and Stroke Volume6. It should also give Continuous ScvO2 & SvO27. It should be pole mountable, must have display capacity of at least 4 trend lines and 4 numerical display, optional physiology and physio-relationship screen.8. It should have the ability to analyse patient's response to a specific interventions as fluid challenge, positional challenge, and interventions. All these interventions should be time stamped and stored for retrospective analysis.9. It should be able to give Continuous Systemic Vascular Resistance (on patient with a CVC line and pressure transducer); Stroke volume and Stroke Volume Variation too on continuous basis.10. It must save data for at least 72 hours.11. Must have screen shot and data download facility through any USB stick.12. It should have a touch screen with active area of 10.4 inch.13. It should be able to give Transpulmonary Thermodilution measures, parameters related to blood flow, organ function and fluid volume like Extra Vascular Lung Water Index (EVLWI), Global Ejection Fraction (GEF), Global End Diastolic Volume (GEDV), pulmonary vascular permeability index (PVPI) with some existing/forthcoming sensors.14. Arterial pressure cardiac output Cable compatible with monitor - 1 each to be supply with monitor.15. Central Venous Oximetry Catheter Cable compatible with monitor - 1 each to be supply with monitor.16. Demonstration mandatory.17. Operating manual should be supplied.18. Must have USFDA certificate.19. Disposable should be quoted separately.20. Disposables with each Monitor<ol style="list-style-type: none">a) Flowtrac Sensor (Arterial Sensor) -10 no.b) Presep Catheter (Oximetry Catheter) -5 no.c) Volume View Sensor - 5 No.	02

Abh
Narain

Basni Phase-2, Jodhpur, Rajasthan-342005. Phone: 0291-2012978 Email: aoadmin@aiimsjodhpur.edu.in Website: www.aiimsjodhpur.edu.in

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