

**JAI PRAKASH NARAYAN APEX TRAUMA CENTRE
ALL INDIA INSTITUTE OF MEDICAL SCIENCE
RAJ NAGAR, NEW DELHI -110029.**

Ref. No. 85/TC/NA/Prop./2022-23.

Dated:31.03.2023

Subject: Purchase of Flow Track Output Monitor-02 nos. for the department of Neuro-Anesthesia on proprietary basis.

A demand received from department of Neuro-Anesthesia at JPNATC, AIIMS for the procurement of **Flow Track Output Monitor-02 nos.** on proprietary basis. The product is proprietary product of M/s Edward Lifesciences (India) Pvt. Ltd. The PAC certificate from the firm as well as from the user department are attached and uploaded on website.

The above documents are being uploaded for open information to all, firms to submit the objections, with respect to proprietary nature of the product, if any within 15 days from the date of issue/uploading of the notification, giving reference no. **85/TC/NA/Prop./2022-23**. The comments should be sent to Stores officer, JPNATC (AIIMS) on or before 16.04.2023 upto 5:00 PM, failing which it will be presumed that any other vendor is having no comments to offer and the case will be decided on merit.


For *Neeloddy*
31/3/23
STORES OFFICER (TC)

Encl: Related document enclosed

1. PAC Certificate form principal.
2. PAC Certificate form User Department

**ALL INDIA INSTITUTE OF MEDICAL SCIENCE
PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE**

- | | |
|--|---|
| 1. Item/Type Model No. Required along with specification | - <u>Flow Track Cardiac Output Monitor</u>
<u>Model No. = HemoSphere Advanced Monitor</u> |
| 2. If the item a spare part attachment or accessory for an existing equipment | - <u>NO</u> |
| 3. Name of the manufactures/supplier of the item proposed by the indentor. | - <u>Manufacturer</u>
<u>Edwards Lifesciences, Switzerland.</u> |
| 4. Are they sole manufacture/sold distributors of the item. | - <u>YES</u> |
| 5. If 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 out comparative. Functional advantages/cost effectiveness of the recommended item from these offered by other. | - <u>NO</u>

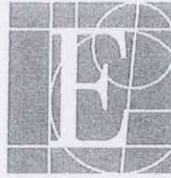
<u>NA</u> |
| 6. What were the efforts made to Located alternative source of supply or use other substitutes. | - <u>INTERNET SEARCH</u>
<u>AND LOCAL MARKET/DEALERS</u> |
| 7. Why open/limited tender can't be resorted to, for locating alternative source. | - <u>No other manufacturer has HPI parameter which is propriety of this item (monitor) & new technology.</u> |
| 8. Are the proprietary items certifying that the rates are reasonable or not. | - <u>YES</u>
<u>The same items have been purchased at similar Rates at AIIMS before.</u> |
| 9. Any other justification for procuring item from single source. | - <u>HPI parameter is only available in this monitor which assist the clinician in early detection of hypertension and take effective measures early. This improves clinical outcome with less complications.</u> |
| Signature of Indenter
(Demanding Officer) | <div style="text-align: center;"> 
 (COUNTER SIGNED)
 (Head of the Department) </div> |

I certify that the item at Sr. No. 1 above is required to be procured 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 a useful purpose in this particular case.

(Strike out whichever is not applicable)

डॉ. अशोक पांडे सिनि / Dr. G. P. Singh
 प्रोफेसर
 जय प्रकाश नारायण शीर्ष अतिरिक्त केंद्र / JPNA Trauma Centre
 ज.प.आ.स., राज नगर, नई दिल्ली-29/A.I.I.M.S., Raj Nagar, New Delhi-29

डॉ. अशोक सिनि / Dr. Ashish Bhardwaj
 प्रोफेसर
 जय प्रकाश नारायण शीर्ष अतिरिक्त केंद्र / JPNA Trauma Centre
 ज.प.आ.स., राज नगर, नई दिल्ली-29/A.I.I.M.S., Raj Nagar, New Delhi-29



Edwards

Proprietary Article Certificate

8 February 2022

To whom it may concern:

We hereby certify that that Edwards Lifesciences LLC located at One Edwards Way, Irvine, CA 92614USA is the sole legal manufacturer of the following device:

S. No	Product Information	Model no.
1.	HemoSphere Advanced Monitoring Platform	HEM1

Description/Indication:

The HemoSphere advanced monitoring platform is intended to be used by qualified personnel or trained clinicians in a critical care environment in a hospital setting. The HemoSphere advanced monitoring platform is intended for use with compatible Edwards Swan- Ganz and oximetry catheters and pressure monitoring Sensors and catheters.

The Flo Trac sensor is indicated for use in intravascular pressure monitoring. It is also indicated for the use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output (including the HemoSphere Advanced Monitor).

The HemoSphere is covered by the following US patent relating to our proprietary FloTracSensor and algorithm:

Patents	US Issue Date	US Expiration Date
7,220,230	May 22, 2007	February 23, 2025
7,452,333	November 18, 2008	February 23, 2025
7,422,562	September 9, 2008	May 21, 2025
7,967,757	June 28, 2011	June 8, 2024
7,785,263	August 31, 2010	March 31, 2024

*All of the aforementioned patents in the table above for HemoSphere, FloTrac sensor algorithms are considered as reasonably comprehensive at this time based on using various sources of information to ensure the completeness of the information.

Sincerely,

Jeanine Deproost

Digitally signed by Jeanine Deproost
DN: cn=Jeanine Deproost,
email=Jeanine_Deproost@edwards.com
Date: 2022.02.08 15:04:28 -08'00'

Signature: _____
Name of Authorize Signatory: Jeanine Deproost
Designation: Sr. Manager Regulatory Affairs
Critical Care
Edwards Lifesciences LLC

(Handwritten signature)

डॉ. आशीष बिंद्रा / Dr. ASHISH BIINDRA
आचार्य / Professor
संज्ञिक संवेदना हस्त एवं गहन चिकित्सा विभाग
Dept. of Neuroanaesthesiology Critical & Intensive Care
एडवार्ड्स लाइफसाइंसेस प्राइवेट लिमिटेड / JPNA Trauma Centre
एडवार्ड्स लाइफसाइंसेस प्राइवेट लिमिटेड, राज नगर, न्यू डेहरादून, उत्तरांचल प्रदेश, भारत
Raj Nagar, New Dehra Dun, Uttarakhand, India

डॉ. ज्ञानेश पाल सिंह / Dr. G. P. Singh
आचार्य / Professor
संज्ञिक संवेदना हस्त एवं गहन चिकित्सा विभाग
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एडवार्ड्स लाइफसाइंसेस प्राइवेट लिमिटेड, राज नगर, न्यू डेहरादून, उत्तरांचल प्रदेश, भारत
Raj Nagar, New Dehra Dun, Uttarakhand, India

(4) (1)

Department of Neuroanaesthesiology and Critical Care
Jai Prakash Narayan Apex Trauma Centre, AIIMS, New Delhi

Name of equipment- Flow Track Cardiac Output Monitor

Quantity = 02 (Two)

Approx Cost - Rs 42 lacs each

Technical Specifications:

1. It should have a touch screen with an active area of 12.1 inches.
2. It should be able to provide Continuous Cardiac Output through a dedicated arterial sensor only when connected with a dedicated cable available separately.
3. It should have the ~~capability~~ ^{ability} of providing intravascular oximetry parameter i.e. Jugular/Central Venous Oximetry updated every 2 secs when used with dedicated disposable venous catheter.
4. It should be upgradable to Non-invasive Cardiac Output technology in the future.
5. It should have display capacity of at least 4 trend lines and 4 numerical display, optional physiology and physio relationship screen
6. It should be equipped to provide patient insight for hypotension & fluid challenge response.
7. It should be equipped with a secondary screen to provide clinicians with insights into potential factors for high hypotension probability (HPI).
8. The monitor must display additional parameter of dP/dt and Eadyn when using a dedicated disposable A-line sensor
9. It should have option of wired & wireless communication.
10. It should have display capacity of at least 4 trend lines and 4 numerical display, optional physiology and physio-relationship screen.
11. It should have the option of providing dedicated perioperative goal-directed therapy (PGDT) screens and analytics.
12. It should have the option of connectivity with hospital information system.
13. It must save data for at least 72 hours or more.
14. Must have screen shot and data download facility through any USB stick.
15. It should have an HDMI, USB & ETHERENET port for various connectivity.
16. List of accessories should be provided and price of each should be quoted separately.

[Signature]

[Signature]

[Signature]

[Signature]

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17. List of consumables should be provided and price of each should be quoted separately.
18. Following consumables should be provided with each unit:
 - (a) Flow Track sensors 05 Nos.
 - (b) HPI sensor 05 Nos.
 - (c) Central Venous Oximetry sensor 05 Nos.
19. Should be USFDA approved/ European CE/ Equivalent Indian Standard.
20. Company should have office/service center in Delhi/NCR
21. Guarantee & Warrantee- As per AIIMS rule.

Amr

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