C/50

अखिल भारतीय आयुर्विज्ञान संस्थान (एम्स) कल्याणी
All India Institute of Medical Sciences (AIIMS) Kalyani
(स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार के तत्वावधान में एक सांविधिकनिकाय)
(A Statutory Body under the Aegis of Ministry of Health and Family Welfare, GOI)
राष्ट्रीय राजमार्ग – 34, बसन्तपुर, सागूना, कल्याणी, ज़िला – नदिया, पश्चिम बंगाल - 741245
NH-34 Connector, Basantapur, Saguna, Kalyani, District Nadia, West Bengal 741245

WEB CHALLENGE NOTICE

Dispatch No. 1143 **/16023/1/21-22/Single Source/CTVS** **Dispatch Date:** 18/08/2022

The notice is being uploaded on the web site www.aiimakalyani.edu.in and CPPP.

Sub: Verification and Justification of proprietary nature of the items through 21 days WEB Challenge on the official website of AIIMS. Kalyani and CPPP before Procurement of Hemosphere Advanced Monitor against proprietary article certificate of the manufacturer.

Inviting Comments thereon.

Department of CTVS, AIIMS, Kalyani has raised an indent for procurement of Hemosphere Advanced Monitor (Model: HEM1) make by Edwards Lifesciences (India) Pvt. Ltd. , Supplied by M/s. Nibso Metal Private Ltd. 5-A , Harish Mukherjee Road Kolkata-700025, INDIA a fully owned subsidiary of the Original Equipment Manufacturer (OEM), Edwards Lifesciences (India) Pvt. Ltd.

The details of the complete set of Hemosphere advanced monitor with Cables are as under;

Sl. No.	Hemosphere advanced monitor	Model CODE	Quantity
1.	Hemosphere advanced monitor (code ; HEM1) HSN Code; 90189019	HEM1	01 Unit
2.	Hemosphere Pressure Cable Code; HEMPSC100 HSN CODE; 85444999	HEMPSC100	01 no.

Nibso Metal Private Ltd. has declared in company's letter head that Nibso Metal Private Ltd. with its operational headquarters in Kolkata is the only manufacturer of the Hemosphere Advanced Monitor model no. (HEM1) which is manufactured with Constant Current design and high quality components and is US FDA and CE certified.

C/49

P.T.O.

अखिल भारतीय आयुर्विज्ञान संस्थान (एम्स) कल्यानी
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(स्वास्थ्य एवं परिवार कल्याण मंत्रालय, भारत सरकार के तत्वावधान में एक सांविधिकनिकाय)
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NH-34 Connector, Basantapur, Saguna, Kalyani, District Nadia, West Bengal 741245

Continue from page no.01.

The notice is being uploaded for general information of prospective Manufacturer/ Authorized Distributor/Dealer to submit their objection/ comments, if any, on proprietorship of the equipment mentioned above, they may submit their proposal along with specifications meeting point by point and supported by all documentary evidence along with a price quotation for the above said items.

The objection/proposal/comments, if any should be sent in sealed cover to the office of Chairman, Procurement Cell, AIIMS, Kalyani, P.O.- Ghoragacha, NH 34 Connector, Basantapur, Saguna, Kalyani, District-Nadia, West Bengal 747245. Or through email to

e-tender@aiimskaiyani.edu.in, so as to reach on or before Dated. On 08.09.2022. Failing which it will be presumed that no other firm is interested to offer comments/protest/object and case will be decided on its merits.

The Ref" No. P-16023/1/21-22 /Single Source/ CTVS, due on 08.09.2022 should be superscripted on sealed envelope

Enclosures:

1.) Details Specification sheet of OEM provided by M/s. Edwards Lifesciences (India) Pvt. Ltd.
2.) Proprietary Certificate provided by M/s. Nibso Metals Private Ltd.

Copy to:

1. Indenting Officer : For kind information please.
2. PS To ED : For kind information please.
3. FIC Website : For kind information please.

18/8/22

Member of Procurement Committee

AIIMS, Kalyani.

C-30

Indent

Flotrac System- Flow Track Cardiac Output Monitoring(EV1000)

1. Name of medical equipment -**Flotrac System Flow output cardiac monitoring/Haemodynamic monitoring**

2. Justification (what may happen, if the item is procured. What may happen, if the item is not procured?)- **Helps in monitoring Cardiac output in Post cardiac surgery or Interventional cardiological procedures.**

3. Whether the same is available in DPR list of HITES or not. If available, why do you want to buy the same through procurement Cell?-**No**

4. Whether available in GeM or not.-**No**

5. Whether it is exempted from MII Clause; if the item do not have MII EXEMPTION, percentage of local content of the item--**Yes** , [Item No 3 - 2463350/2021/Procurement-I/Annexure-A]

6. Whether it is a proprietary item-**Yes (Edward Life Sciences)**

5. Number of units needed-**1**

6. Approximate price per unit-~~25,00,000/-~~ 29,90,000

7. Whether adequate space is available to accommodate the equipment; space to be specified-**Yes Department of CTVS**

8. Whether adequate manpower is available to operate the equipment.**-Yes**

9. Whether generic item or specific item needed. If any specific brand, justification has to be provided--**Edwards Flotrac system**

10. Whether the item is for single departmental use only or may be used by multiple departments.— **Cardiology/ CTVS**

11. Use of the item under which heading...research, patient care, academic-**Patient Care/Research**

15/2/22 Dr Akhilesh Arumalla FIC Department of CTV AIIMS Kalyani

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Specifications

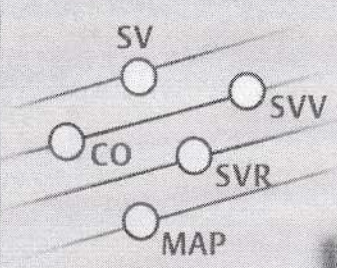
1. Should Measure Stroke Volume (SV), Stroke Volume Variation (SVV), Mean Arterial Pressure (MAP), Systemic Vascular Resistance (SVR), Cardiac Output (CO) update every 20 seconds
2. Should presents the physiologic status of the patient in meaningful way. Should includes a monitor and databox, offering you scalability and adaptability in both the OR and ICU.
3. Color-based indicators for patient status, and visual clinical support screens allow for immediate recognition and increased understanding of rapidly changing clinical situations for improved decision enablement.

Dr Akhilesh Arumalla
FIC Department of CTVS
AIIMS Kalyani

C-28

The practical solution for ensuring adequate perfusion.

Smart. Innovation.



FloTrac System

Edwards

Dr Akhilesh Arumalla
FIC Department of CTVS
AIIMS Kalyani

C-27

THE EVIDENCE OF
2.6 MILLION PATIENTS · 80 COUNTRIES · 10+ YEARS

FloTrac System

TRUSTED

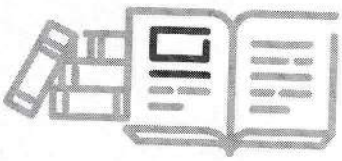
*Chosen to monitor over 2.6 Million Patients**

WORLDWIDE

80 Countries. Used by clinicians more than any other minimally-invasive volume management solution

LITERATURE

*Referenced in over 190+ clinical studies spanning the OR and ICU**



EVOLVING ALGORITHM

Monitor provides clarity in numerous patient conditions and procedures

Compensating for patient-to-patient differences in vasculature, real-time changes in vascular tone and differing arterial sites, the ever-evolving algorithm looks for characteristic changes in arterial pressure waveform that reflect changes in tone (i.e., MAP, Skewness, Kurtosis).

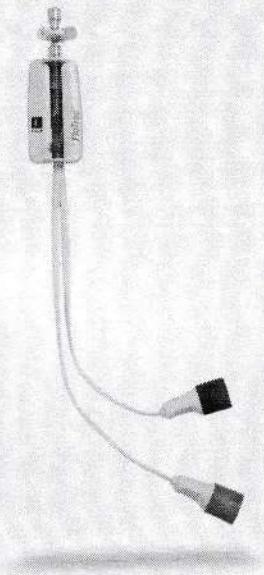
The FloTrac system algorithm is based on the principle that aortic pulse pressure is proportional to stroke volume (SV) and inversely related to aortic compliance. In addition, compliance inversely affects PP as the algorithm compensates for the effects of compliance on PP based on age, gender, and body surface area (BSA).

*Data on file

C-26

The FloTrac system enables proactive clinical decision support.

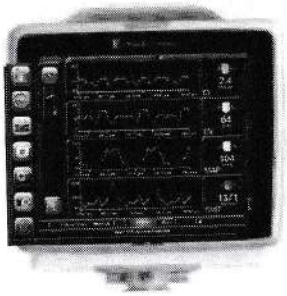
The minimally-invasive FloTrac system is a reliable solution to advanced hemodynamic monitoring that automatically calculates key flow parameters every 20 seconds.



The FloTrac sensor attaches to any existing arterial line and monitors advanced hemodynamic parameters:

- Stroke Volume (SV)
- Stroke Volume Variation (SVV)
- Mean Arterial Pressure (MAP)
- Cardiac Output (CO)
- Systemic Vascular Resistance (SVR)

The continuous clarity offered by the FloTrac system helps guide individualized treatment decisions for your moderate to high-risk surgery patients, and can also be utilized perioperatively to proactively manage your patient's physiological status in rapidly changing clinical situations in the OR and ICU.



The HemoSphere advanced monitoring platform reimagines the way you see, experience and interact with hemodynamic parameters. Compatible with the FloTrac sensor, you can see your patient's physiologic status and analyze trends with exceptional clarity that you can intuitively navigate with a simple-to-use touchscreen.

Dr Akhilesh Arumalla
FIC Department of CTVS
AIIMS Kalyani

C-25

Proactively manage intraoperative hypotension (IOH).

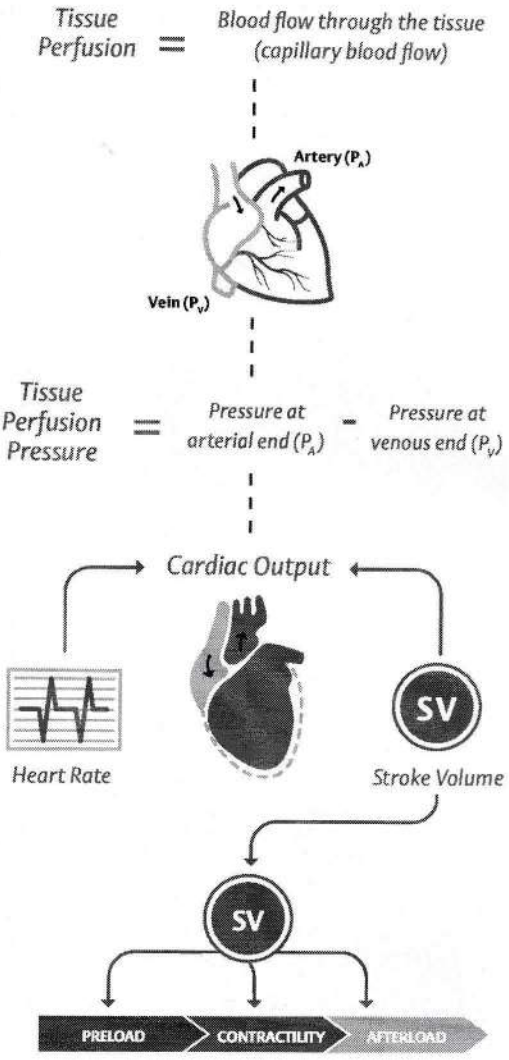
The FloTrac system provides access to advanced hemodynamic parameters to allow you to evaluate hemodynamic instability and guide appropriate treatment.

Clarity through advanced hemodynamic monitoring parameters CO, SV, SVV and SVR provided by the FloTrac system can help you determine if the cause of IOH is preload, afterload, or contractility.

If the underlying cause of hemodynamic instability is related to flow generation, continuous parameters can help you determine appropriate fluid therapy.

Additionally, continuous monitoring of advanced hemodynamic parameters enables proactive clinical decisions regarding appropriate treatment to augment vascular volume, reduce anesthetic administration, or use vasopressors or inotropes.

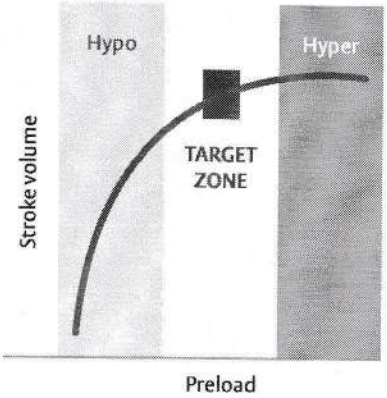
Continuous assessment of pressure and flow parameters offers proactive decision support to help proactively manage the duration and severity of IOH episodes.



C-24

Manage the flow component of perfusion to guide individualized fluid management.

Frank-Starling relationship between preload and stroke volume (SV)



Make more informed transitions from the OR to ICU.

When managing perfusion, stroke volume can be optimized using the patient's own Frank-Starling curve.

The patient's location on the curve can be determined by measuring changes in SV in response to change in preload using a bolus fluid challenge or passive leg raise (PLR). Dynamic and flow-based parameters are more informative than conventional parameters in determining fluid responsiveness and may help guide individualized volume administration in patients and avoid excessive and insufficient administration.[1]

Manage variability in volume administration.
Advanced hemodynamic parameters provided by the FloTrac system may be used in Perioperative Goal-Directed Therapy (PGDT) protocols to help reduce variability in fluid administration and guide optimal volume management in patients at risk of developing complications.

Dr Akhilesh Arumalla
FIC Department of CTVS
AIIMS Kalyani

FloTrac system

Catalogue Number	Length A (cm)*	Length B (cm)*	Product Description	Pack Size
MHD6R	120	30	FloTrac sensor (150 cm) pressure line	1
MHD6AZR	90	60	FloTrac sensor (150 cm) pressure line and VAMP adult system	1
MHD8R	180	30	FloTrac sensor (210 cm) pressure line	1
MHD6R5	120	30	FloTrac sensor (150 cm) pressure line	5
MHD6AZR5	90	60	FloTrac sensor (150 cm) pressure line and VAMP adult system	5
MHD8R5	180	30	FloTrac sensor (210 cm) pressure line	5

*Lenghts are rounded up from inches to centimeters.

Enabling proactive clinical decisions.

For more than 40 years, Edwards Lifesciences has been helping you make proactive clinical decisions in advancing the care of acutely ill patients across the continuum of care. Through ongoing collaboration with clinicians, providing continuous education, and our dedication to purposeful innovation, Edwards continues to develop smart hemodynamic management solutions that enable proactive decision support.

Know More. Know Now.

Visit Edwards.com/gb/FloTrac or contact your Edwards' representative.

References

1. Cannesson, M. (2010) Arterial pressure variation and goal-directed fluid therapy. Journal of Cardiothoracic and Vascular Anesthesia, 24(3), 487-97.
2. Marik, P. (2011) Hemodynamic parameters to guide fluid therapy. Annals of Intensive Care.

For professional use. See instructions for use for full prescribing information, including indications, contraindications, warnings, precautions and adverse events.

Edwards Lifesciences devices placed on the European market meeting the essential requirements referred to in Article 3 of the Medical Device Directive 93/42/EEC bear the CE marking of conformity.

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