## Minimally Invasive Advanced Hemodynamic Monitor with FloTrac Specifications

- It should have a touch screen with an active area of 12.1 inches.
- It should be able to provide Continuous Cardiac Output through a dedicated arterial sensor only when connected with a dedicated cable available separately.
- It should be able to give Continuous Cardiac Output, Stroke Volume (SV), Stroke Volume Index (SVI), Stroke Volume Variation, and Systemic Vascular Resistance (SVR) and Systemic Vascular Resistance Index (SVRI) when used with appropriate arterial line sensor.
- It should have the option of giving Intermittent & Continuous Cardiac Output(ICO & CCO).
   Continuous Right Ventricular Ejection Fraction (RVEF), Continuous Right Ventricular End Diastolic Value (RVEDV, RVEDVI), Systemic Vascular Resistance (SVR, SVRI) & Pulmonary Vascular Resistance(PVR) when used with appropriate Swan Ganz Catheter or dedicated oximetry catheter. (OPTIONAL)
- It should have the option of providing intravascular oximetry parameter for pediatric
  population i.e Central Venous Oximetry updated every 2 secs when used with dedicated
  disposable central venous catheter.
- It should have the option to be scalable to Non-invasive Cardiac Output technology in the future.
- It should have display capacity of at least 4 trend lines and 4 numerical display, optional physiology and physiorelationship screen.
- It should have the option of providing dedicated perioperative goal-directed therapy (PGDT) screens and analytics.
- It should be equipped to provide patient insight for hypotension & fluid challenge response.
- It should be equipped with a secondary screen to provide clinicians with insights into potential factors for high hypotension probability.
- The monitor must display additional parameter of dP/dt and Eadyn when using a dedicated disposable A-line sensor.
- It should work on NIRS (Near-infrared Reflectance Spectroscopy) technology.
- It should be able to provide tissue oxygen saturation (StO2), non-invasively when used with Hemo Sphere advanced monitor.
- It should be able to measure oxygen saturation of the cerebral tissue along with other tissues such as abdomen, hip, arms, and feet when used at appropriate tissue site.
- It should have 1 light emitter and 2 light detectors and, 2.5 cm depth of light penetration and use 5 Near-Infrared wavelengths for better accuracy of StO2 measurement.
- It should be available in 4 sizes namely: Small, Medium, Large (Adult) and one special Non adhesive variant for neonates.

It should have option of wired communication.

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- It should have display capacity of at least 4 trend lines and 4 numerical display, optional physiology and physio-relationship screen.
- It should have the option of providing dedicated perioperative goal-directed therapy (PGDT)
- It should have the option of connectivity with hospital information system.
- It must save data for at least 72 hours.
- Must have screen shot and data download facility through any USB stick.
- It should have an HDMI, USB & ETHERENET port for various connectivity.
- The specification is broad based, general in respect to the requirement and not pertaining to any firm/brand.
- The comprehensive warranty will be 5 years (including all spares and labour) from the date of satisfactory installation of the equipment.
- Rates for Comprehensive Annual Maintenance Contract (including all spares and labour for 6<sup>th</sup> to 10<sup>th</sup> year, after expiry of warranty period must also be quoted. Cost of spares, accessories and consumables should assure the supply of new consumables, if required.

Tale Chardly Prof. Sujata Choudhary

Deptt. Of Anaesthesiology, Safdarjung Hospital (Ext.

Expert)

Prof. Akhilesh Gupta Deptt. Of Anaesth),

RML Hospital (Ext. Expert)

Prof. Nitin Hayran

Deptt. of (Anaesth), Lady Harding Medical

College (DGHS Nominee)

Prof. Ganga Prasad, Deptt. Of Anaesth.

Member

Dr. Puneet Khanna Deptt. Of Anaesth.

Member

Representative of Med. Supdt.

Hosp. Admn.

Member

Dr. Rahul

Deptt, Of Anaesthesiology.

Special Invitee

Dr. Bikash Ranjan Ray Deptt. Of Anaesthesiology.

Member-Secretary

Dr. Lokesh Kashyap HOD (Anaesth).

Chairman



## Arian Healthcare

4327/3, Flat No. 202, IInd Floor, Ansari Road, Darya Ganj, New Delhi-110002 Tel.: 011-23250080, 011-49403689, Mobile: 9811140954 E-mail: arianhealthcare@rediffmail.com; arianhealthcare@gmail.com

Ref.: AHC/AIIMS/2024-25

Dt.: 16,08,2024

The Prof & HOD Deptt. of Anaesthesiology, AHMS, Ansari Nagar, New Delhi-110029

#### Quotation for Hemosphere Advanced Hemodynamic Monitor

Sir.

As per your requirement, we are pleased to quote you our most competitive rates for the following product:

S. No.	Detail Of The Quoted Item	HSN Code	Qty.	Quoted Rates, Per Set In Rs.	Applicable GST Rate	Quoted Rates Per Set In Rs., Inclusive GST
1.	HEM1-HemoSphere advanced monitor	90189011	1 No.	23,44,533/-	12%	26,25,877.00
2.	HEMOXSC100- HemoSphere Oximetry cable	85444230	1 No.	2,87,500/-	18%	3,39,250.00
3.	HEMPSC100-HemoSphere Pressure Cable	85444230	2 Nos.	4,64,364/-	18%	10,95,899.00
4.	HPI001L-HPI (Software)	49070030	1 No.	3,00,300/-	18%	3,54,354.00
5.	HEMFSM10-ForeSight Module	90189011	1 No.	6,83,714/-	12%	7,65,760.00
6.	HEMTOM10-Tissue Oximetry	90189011	1 No.	1,37,844/-	12%	1,54,385.00
					Total	53,35,525.00

(Total - Rupees Fifty Three Lakh Thirty Five Thousand Five Hundred Twenty Five Only)

#### **TERMS & CONDITIONS:**

Deptt of Anaesthesiology

- 1) The above quoted price is FOR your stores.
- 2) The above quoted prices are inclusive of GST as mentioned against each item. In case of any statutory change in the GST rates, the same as applicable will be charged accordingly.
- 3) Delivery within 45 days after the receipt of your confirmed order.
- 4) Payment as per your terms & conditions.
- 5) Warranty period of 5 years. After that CAMC charges will be applicable.

Prof. Nitin Hayran
Donis, Nominee
Donis Howinee
Prof. Akhilesh Coupta
Froj. Akhilesh Coupta
Ext. Expert RML

Dept. or Ansestracion (N. Pair Medicine) S. M. S., No. TO PORT / ALLINS, NOW D of Anzosthosiology Pain Me

Rahul Kumar Anand डॉ. राहुल गुमार nal Projessor ्रं ्रिटिकल केंबर विसाय संवेदनाहरणिशान, ५०। Medicine & Critical Care Name of Break All M.S., New Delhi-11007 Deptt, of Anaesthes



## Arian Healthcare

4327/3, Flat No. 202, IInd Floor, Ansari Road, Darya Ganj, New Delhi-110002 Tel.: 011-23250080, 011-49403689, Mobile: 9811140954 E-mail: arianhealthcare@rediffmail.com; arianhealthcare@gmail.com

### CAMC Charges for the next 5 years, after successful completion of Warranty, are as follows:-

	1 <sup>st</sup> Year (In Rs.)	2 <sup>nd</sup> Year (In Rs.)	3 <sup>rd</sup> Year (In Rs.)	4 <sup>th</sup> Year (In Rs.)	5 <sup>th</sup> Year (In Rs.)	Total (In Rs.)
CAMC Charges	2,66,776.00	2,66,776.00	2,66,776.00	2,66,776.00		13,33,880.00
GST %	18%	18%	18%	18%	18%	18%
Total With GST	3,14,796.00	3,14,796.00	3,14,796.00	3,14,796.00	3,14,796.00	15,73,980.00

The above CAMC prices are inclusive of GST @ 18% but in case of any statutory change in the govt, policy we will request you for the amendment accordingly. The warranty & CAMC will be applicable only against any technical or manufacturing defects. It will not be applicable against any mishandling or patient bite.

We hope that you will find our offer most competitive and give us an opportunity to serve you. We assure you our best services & co-operation.

Thanking You,

Yours Faithfully EA/

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Prop.

Encl .:- Proprietary Certificates for the above product.

- Letter of Authority from M/s. Edwards Lifesciences (India) Pvt. Ltd.
- Product Catalogue of the quoted product.
- USFDA Certificate

- Fall Clause Certificate.

संग्रहराज्यान के स्ट्रियान के

John

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#### Edwards

#### **Proprietary Article Certificate**

To whom it may concern:

We hereby certify that Edwards Lifesciences LLC located at One Edwards Way, Irvine, CA 92614 USA is the sole legal manufacturer of the following device, Moreover, the expected clinical benefit as a package stands true & exclusive from the manufacturer.

Product Information	Technologies/Model no's approved in India
HemoSphere Advanced Monitoring Platform	HEM1, HEMSGM10, HEMOXSC100, HEMPSC100,
	HEMTOM10, HEMFSM10, HEMCSM10

#### Clinical Benefit:

The HemoSphere advanced monitoring platform allows you to see and interact with patient hemodynamic Parameters (invasive, minimally invasive & non-invasive) \*1. In conjunction with the compatible sensors and predictive decision support software<sup>2</sup>, the Modular<sup>3</sup> HemoSphere platform facilitates proactive clinical decision-making and insight for individualized patient care<sup>^4</sup>.

- Continuous CO & Cl. ICI, RVEF, EDV, SV, SVR, SVR, SVR, SVR, SVV, CVP, dP/dt, EDdyn, MAP, MPAP, PPV, PR, SYSatr/SYSpap, ScvO2, 5vO2, Vo2e, Vo2e, Vo2e, Vo2e, StO2, DIAart HPH-Hypotension Prediction Index

  HemoSphere Advanced Monitor with Swan-ganz Module, HemoSphere Advanced Monitor with Oximetry cable, HemoSphere Advanced Monitor with pressure cable, HemoSphere Advanced Monitor with HemoSphere Tissue Oximetry Module and ForeSight Elite Tissue Oximeter Module, HemoSphere Advanced Monitor ClearSight Module

GUT-Goal-Directed Therapy

All the above statements are considered as reasonably comprehensive at the time based on using various sources of information to ensure the completeness of the information.

Sincerely,

Kevin Lam

Name: Kevin Lam

Designation: Regulatory Affairs Director

Edwards Lifesciences LLC

हो. राहुल खुमार आनंद/Dr. Rahul Kumar Anand डा. राहुल कुषार आनद/Ur. Hanul Kumar Anand अपन अवार्व/ Additional Professor शर्ववनाहरणविद्यान्, पीडा विकित्सा एवं क्रिकिस्त केवर विभाव

or anaesthosiology, Pain Medicine & Critical Care of Anaesthosiology, Pain Medicine & Critical C

PROPRIETARY DATA: This document and the information contained flerein may not be reproduced, used, or disclosed without written permission from Edwards Lifesciences LLC.

संदर्भय प्राथारी (नण्डार) Dopli, of Anzesthesiology, Pain Manaine & Ordinal Care अ.भा.आ.स. गई विचला, A.LIMS, P. - 9 वि

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July 26,2024

To, The Director AIIMS Ansari Nagar Delhi

Dear Sir,

Sub: Letter of Authority to M/s Arian Healthcare for quoting & supplying

#### Ref: Minimally Invasive Advanced Hemodynamic cardiac output Monitor with FloTrac

This is with reference to the captioned subject. Please note that M/s Arian Healthcare having their office at 4327/3, Flat No. 202, Ilnd Floor, Ansari Road, Darya Ganj, New Delhi-110002 is the authorized distributor of Edwards Lifesciences (India) Private Limited having its registered office at 4th Floor, Commerz II, International Business Park, Oberoi Garden City, Off. Western Express Highway, Goregaon (East), Mumbai 400 063.

M/S Arian Healthcare is duly authorized to submit documents, receive purchase orders, making supplies etc. for the Edwards Critical Care range of products & 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 Arian Healthcare.

This authorisation letter valid from date of hereof until 31st December 2024, with a provision to extend the same further.

Please take note of the same.

Sincerely,

For Edwards Lifesciences (India) Private Limited

Director Sales & Marketing Critical Care and Vascular care Ind

Cc: M/s Arian Healthcare

New Delhi-110029 age amind/Additional Inchair Deal of Anaesthesiology, Pain Me Consult of Anaesthesiology, Pain Me Deptt. of Anaesthesiology, Pain Me

Regd. Office: 4th Floor, Commerz II, International Business Park, Oberoi Garden City, 11M.S. osthosiology, ALIMS, Off. Western Express Highway, Goregaon (East), Mumbai 400063

Tel: +91 22 61931301; Fax: +91 22 61931344

Website: www.edwards.com; Email: customercare\_edwardsindia@edwards.com; CIN; U33110MH1996PTC145849

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

#### PROPRIETARY/SPECIFIC BRAND GOODS CERTIFICATE

1.	Item/Type/Model No. Required Along with specification	Minimally Invasive Advanced Hemodynamic Monitor with FloTrac
9	Location of Installation	AB-8/ICU
2.	If the item a spare part attachment or Accessory for existing equipment	No
3.	Name of the manufacturers/supplier of the Item proposed by the indenter.	M/s Edwards Lifesciences LLC., through their distributor M/s Arian Healthcare
4.	Are the sole manufacturers/sole distributors of the item?	Proprietary Certificate and authorization submitted by M/s Edwards Lifesciences LLC
5.	If there any other item with similar/equipment specification available in the Market to meet the job requirement envisaged. If he answer is yes, why the same can't procured.	No.
6.	What were the efforts made to locate alternative source of supply or use other substitutes.	The required items are proprietary and as certified by the manufacturer with certificate is attached.
7.	Why open/limited tender can't be resorted to, for locating alternative source.	Proprietary item
8.	Are the proprietary items certifying that the rates are reasonable or not.	Yes.
9.	Any other justification for procuring item from single source.	Proprietary item, Advanted Jechnology

I certified that the item at Sr.No.1 above is required to be procured on PAC basis as the source of supply is definitely known which is meeting with functional requirement of department and limited tender system could be dispensed with as they would serve no useful purpose in the particular case.

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4327/3, Flat No. 202, IInd Floor, Ansari Road, Darya Ganj, New Delhi-110002 Tel.: 011-23250080, 011-49403689, Mobile: 9811140954 E-mail: arianhealthcare@rediffmail.com; arianhealthcare@gmail.com

Ref.: AHC/AIIMS/2024-25

Dt.: 16.08.2024

The Prof & HOD Deptt. of Anaesthesiology, AHMS, Ansari Nagar, New Delhi-110029

#### RATES OF CONSUMABLES FOR HEMOSPHERE ADVANCED HEMODYNAMIC MONITOR

S.No		Product Description	HSN Code	Qty.	Rate in Rs.	GST%	Prices in Rs Including GST
1	MHD8	Flotrac Sensor	90189011	1.	16500.00	12%	Rs. 18480.00
2	PXVP2260	VAMP Single Line	90183920	1	3235.00	12%	Rs. 3623.00
3	AIQS85	Acumen IQ Sensor	90189011	1	26335.00	12%	Rs. 29495.00
4	PX600F	DPT Dome	90183920	1	900.00	12%	Rs. 1008.00
₹ 5	XT248SP	Pediaset	90183920	I	23765.00	12%	Rs. 26617.00
6	FSESL	Foresight Large	90183920	1	8033.00	12%	Rs. 8997.00
7	FSESM	Foresight Medium	90189019	1	14283.00	12%	Rs. 15997.00
8	FSESS	Foresight Small	90189019	1	14283.00	12%	Rs. 15997.00
9	FSESNS	Foresight Neonate	90189019	1	15174.00	12%	Rs. 16995.00
_10	831175p	Swan-Ganz Thermodilution	90183920	1	6325.00	12%	Rs. 7084.00
11 we then	PXVP1072	Pressure Monitoring Set	90183920	1	4313.00	12%	Rs. 4831.00

#### Terms & Conditions:-

- 1. The above quoted prices are F.O.R. your hospital.
- 2. The above quoted prices are inclusive of GST as mentioned against each item. In case of any statutory change in the GST rates, the same as applicable will be charged accordingly.
- 3. Delivery within 4-6 working weeks after the receipt of your confirmed order.
- 4. Payment as per your terms & conditions.

Thanking You.

Yours Faithfully For Arian Healthcare

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एवंदनाहरणदिशान,

मधारी (नाया) Faculty knotherg's (Store)

पारेषनाएकविराहन, पीका विश्व न्या पृत्र विश्व रहत वेनल "ज्यान Sept. of Anzosthesiology, Pain Electricise & Critical Cars SLYLARITY, THE PETER! / A.L.I.M.S., New Dehi-110029

श्री. शहुल कुमार आस्व/Dr. Rahul Kurner Anand

लभर आसाय Applicant Professor संवेदनाहरणविज्ञान, पीड़ा विकित्सा एवं विहिटकल केन्द्र विज्ञान Dapit. of Ancesthesiology, Pain Medicine & Critical Gare अ.मा.आ.सं., गई विल्ली/A.I.I.M.S., New Delhi-110028



## Arian Healthcare

4327/3, Flat No. 202, IInd Floor, Ansari Road, Darya Ganj, New Delhi-110002 Tel.: 011-23250080, 011-49403689, Mobile: 9811140954 E-mail: arianhealthcare@rediffmail.com; arianhealthcare@gmail.com

Ref.: AHC/AIIMS/2024-25

Dt.: 16.08.2024

The Prof & HOD Deptt. of Anaesthesiology, AHMS, Ansari Nagar, New Delhi-110029

Sub.: FALL CLAUSE CERTIFICATE

Dear Sir,

With reference to our quotation no. AHC/AIIMS/2024-25 Dt.16.08.2024 for the supply of Hemosphere Advanced Hemodynamic Monitor, we submit herewith that:

"The price charged for the stores/Equipment's under the reference, by the supplier shall in no event exceed the lowest price at which the supplier the stores/Equipments of same identical description person/organization/Institution during the currency of the contract as per the fall any clause adhered by DGS & D. If at any time, during the said period the supplier reduced the said prices of such/stores/equipments or sales such stores to any other person/Organizations/Govt. Institution/Co-operative stores at price lower than the quoted prices, he shall forthwith notify such reduction or sale to the Director, All India Institute of Medical sciences and the price payable for the items supplied after the date of coming force of such reduction or sale shall stand correspondingly reduced for AIIMS".

Should you require any clarification then please feel free to contact us.

Thanking You,

Yours truly,

For Arian Healthcare

(Prop.)



## Arian Healthcare

4327/3, Flat No. 202, Ilind Floor, Ansari Road, Darya Ganj, New Delhi-110002 Tel.: 011-23250080, 011-49403689, Mobile: 9811140954 E-mail: arianhealthcare@rediffmail.com; arianhealthcare@gmail.com

#### **UNDERTAKING**

#### TO WHOM SO EVER IT MAY CONCERN

I, Rajeev Verma prop. of M/s. Arian Healthcare, 4327/3, Satyam House, Flat No.202, 2nd Floor, Ansari Road, Darya Ganj, New Delhi -110002, do hereby undertake that the firm has not been de-registered/banned/blacklisted in the past by any Govt.; Central Govt. Ministeries/AIIMS, New Delhi or Private Organization & there is no Vigilance/CBI case pending against the firm/supplier.

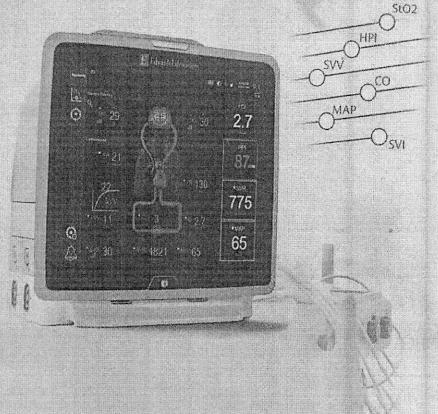
For Arian Healthcare

\*

Dated: 16.08.2024

## Changing the pace of hemodynamics

Smart. Innovation.





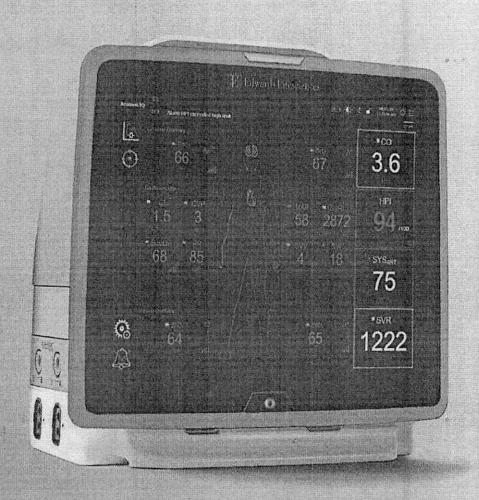
HemoSphere advanced monitoring platform

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# The monitoring platform of the future.



HemoSphere advanced monitoring platform provides a comprehensive view of tissue oximetry and hemodynamics, giving you confidence in knowing that your patient has continuous oxygen saturation and is adequately perfused.

With a sleek and compact design and responsive touch screen navigation, this platform offers a unique visual monitoring experience. Visual and clinical decision support that can be used across acute care settings.

FILE TRAIN (MARKET)

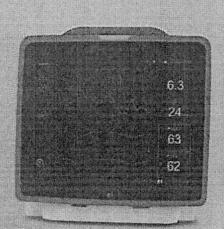
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का, पाहल कुपार आगांद की. Rahul Kumar Anand अपर आशांद Adminial Professor अपर आशांद में कि किए के पर विभाग प्रदेश कर कि किए के किए किए किए किए Depit of Anasthesiology, Pain Medicine & Critical Care अ.आ.आ.सं., गई हिल्ली/A.L.M.S., New Delhi-110029

## A comprehensive view of your patient, every step of the way.

For each clinical decision moment, HemoSphere advanced monitoring platform enables proactive decision support across a diversity of patient profiles and across care settings.



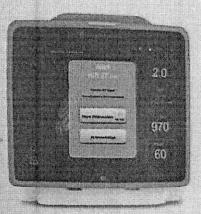
#### Past trends

Allows you to select, place and track interventions over time while providing key trending data.



#### Present data

Depicts continuous changes occurring in your patient by delivering visual and numeric parameters.



#### **Future Insights**

Acumen Hypotension Prediction Index software is a first-of-its-kind predictive decision support software that detects the likelihood of a patient trending toward a hypotensive event.\*

डा. पाहुल कुमार अन्वत/Or. Rahul Kumar Anand अप अन्वत/Additional Professor संपेदनाहरणाविज्ञान, योडा विकित्सा एवं क्रिक्किल अन्यर विभाग Deptt. of Anasothesiology, Pain Medicine & Critical Care Deptt. of Anasothesiology, Pain Medicine & Critical Care जना.जा.सं. नर्ष विक्लिपे A.I.I.M.S., New Delhi-110029 जना.जा.सं. नर्ष विक्लिपे A.I.I.M.S., New Delhi-110029 "A hypotensive event is defined as MAP < 65 mmHz for a duration of at least one minute."

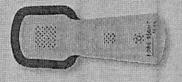
A Anaos mesiology Pain Medicine & Gribert Co.

## Compatibility for individualized patient management.



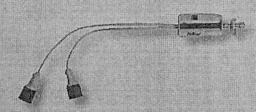
#### Acumen IQ sensor

Part of the Acumen decision support suite, the Acumen Hypotension Prediction Index software is unlocked with the Acumen IQ sensor.



#### ForeSight Elite tissue oximetry system

ForeSight Elite sensors deliver accurate performance and precision in tissue oximetry. Reliable, real-time monitoring of surgical patients provides decision support for detecting and managing hypoxic events as soon as they occur.



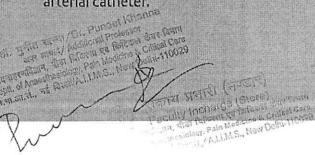
#### FloTrac sensor

Delivers advanced pressure and flow hemodynamic parameters for managing perfusion. Offers continuous insight to determine patient's hemodynamic status. Seamlessly connects to any existing arterial catheter.



#### Swan-Ganz pulmonary artery catheter

Gives you the clarity of a comprehensive hemodynamic profile delivered by a single catheter. It allows you to continually assess flow, pressure and oxygen delivery and consumption, to assist your early evaluation in your critically complex patients.



को. राहुल जुनार बोसड्/Dr. Rahul Kumar Anand अपर आसार्ग Additional Professor सर्वेव सहरपदिशान, तीजा विशेष्टला एवं क्रिक्टिक स्टेस्ट्रियान, तीजा विशेष्टला एवं क्रिक्टिक से देश विशेष्ट Depth of Anaosthesiology, Pain Medicine & C. Itool Core आजा.आ.सं., न्यं विरुक्ति A.I.I.M.S., New Delhi-110029

# Proactive patient insights for smart recovery.

HemoSphere advanced monitoring platform offers advanced hemodynamic parameters that can help guide you with proactive decision support in a range of clinical situations and settings so you can maintain optimal patient perfusion.



#### Cerebral and tissue desaturations

Research demonstrates that cerebral desaturations have been associated with post-operative neurocognitive disorders, increased length of stay in both the hospital and ICU, increased incidence of stroke, and decreased survival. Having a comprehensive picture of oxygen delivery and consumption may allow you to reduce the clinical implications of prolonged desaturations.



#### **Hemodynamic instability**

Continuous access to pressure and flow parameters help to determine patient fluid responsiveness and guide individualized patient management.



#### Hypotension

Recent studies show associations between intraoperative hypotension (IOH) and increased risk of acute kidney injury (AKI) and myocardial injury, which is the leading cause of post-operative mortality within 30 days after surgery. Early detection of hypotension by continuous hemodynamic monitoring can reduce a patient's risk.



#### Sepsis management

Severe sepsis and septic shock are among the most important causes of morbidity and mortality in patients admitted to the intensive care unit.<sup>2</sup> Access to cardiac output (CO) and stroke volume (SV) enables early detection and management of sepsis which is critical to improving survival rates and reducing the economic burden of sepsis.

Academic of parties of

डा. पहुल बुनार वानंद प्रिंगिकार्ध Kumar Anand इत्यर जावार्ड / Additional Professor संवेदनावरणविकान, पीका शिक्षिकार पाँच विभाग Deptt of Anaestreskopy, Pan Medicine & Oritical Com-

## Individualized patient care on a single platform.

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1. Salmasi, V., Maheshwari, K., Yang, G., Mascha, E.J., Singh, A., Sessler, D.I., & Kurz, A. (2017). Relationship between intraoperative hypotension, defined by either reduction from baseline or absolute thresholds, and acute kidney injury and myocardial injury. Anesthesiology, 126(1), 47-65.

2. Mays, E., Yende, S., Angus, D. (2014). Epidemiology of sever sepsis. Vol 5 issue 1.

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Certificate No. 2912-12-2022

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Sincerely.

CDR Cesar A. Perez, PhD, Director DRP2: Division of Establishment Support

Office of Regulatory Programs
Office of Product Evaluation and Quality Center for Devices and Radiological Health

U.S. Food and Drug Administration, DHHS

This certificate is valid from January 20, 2023 to January 19, 2025.

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Legal Manufacturer EDWARDS LIFESCIENCES LLC ONE EDWARDS WAY IRVINE; CA USA-92614

Contract Manufacturer
BENCHMARK ELECTRONICS, INC.
4665 THEURER BLVD.
WINONA; MN
USA 65987

Contract Manufacturer
Measurement Specialties Chengdu
No. 368 Wullan 1st Road
Huangjia Street, Shuangliu District
Chengdu, Sichuan
CHINA 610200

Contract Manufacturer
SUPERCOMAL MEDICAL PRODUCTS, SDN BHD
LOT 171, JALAN PKNK 3/B, KAWASAN
PERUSAHAAN, SUNGAI PETANI
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Name of Manufacturer

Legal Manufacturer

EDWARDS LIFESCIENCES LLC

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JRYINE, CA

USA 92614

#### Name of Product(s)

Hemodyňamic Monitoring Equipment

BAEKBB, 64EKD, 64EKD2, 64EKHH, 64EKLL, 64EKM, 64EKMN, 64EKNK1

64EKGE2, 64EKSM2, 64EKSM3, 70AN, 70AND, 70AND2, 70AND3, 70AND4, 70ANHH

70ANFIHS, 70ANHL, 70ANM4, 70ANN, 70ANN2, 70ANNK

70ANSS, 9850A, OM2, OM2E. HEMDPT1000

HEMRLSTD1000, HEMBAT10, HEMOXCR1000, EVBB1, EVMB1, EVPB1, EVRS, EVS1

#### Name of Manufacturer

Legal Manufacturer

EDWARDS LIFESCIENCES LLC

ONE EDWARDS WAY

IRVINE, CA -

USA 92614

Contract Manufacturer

BENCHMARK ELECTRONICS, INC.

4065 THEURER BLVD

WINONA, MN

USA 55987

#### Name of Product(s)

Vigileo Monitor and Accessories

APCOS, MHAADPLT, MHAND, MHANMS, MHAPLMNT

MHM1, MHM1E, MHM1R (Refurbished), MHM1ER (Refurbished)

Vigilance II Continuous Cardiac Output/Oximetry/Volumetric Monitor and Accessories

(Vigilance II Monitor)

VIG2, VIG2AP, VIG2APK, VIG2E, VIG2S, VIG2SM

VIG2ER (Refurbished), VIG2R (Refurbished)

EV1000 Clinical Platform

EV1000A, EV1000DB, EV1000M, EVEC1, EVMB1

EVFTCL, EVECL, EVPSA110, EVPSA110L, EVPSB220

EV1000 Clinical Platform NI

EV1000CVR, EV1000M, EV1000NI

EVEC1, EVEC12FT, EVEC3FT, EVECL, EVHRS, EVHRSBP, EVNIDBAC

EVNIPCL12, EVNIPCL3, EVNIUPG, EVPMP

PG2B, PG2GGC, PG2K, PGGVR

HemeSphere Advanced Monitoring Platform

HEM1, HEMOXSC100, HEMSGM10, HEMEXPM10, HEMLPWCD1000, HEMLTECHM10, HEMPSC100

HENTOM10, HEMFSM10, HEMCSM10, HEMPC, HEMPG2K

FloTrac Pressure Cable - BeneVision

PSCOEM100MR

Name of Manufacturer

Legal Manufacturer

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TRVINE, CA USA 92614

#### Contract Manufacturer

Messurement Specialties Chengdu No. 368 Wullan 1st Rood ... . .. " Huangila Street Shuangilu District Chengdy, Sighuan CHINA 510200

#### Name of Product(s)

Fore-Sight-Elite Sensors FSESL - Fore-Sight Elite Large Sensor FSESM. Fore Sight Elite Medium Sensor FSESS - Fore-Sight Elite Small Sensor

PSESNS - Fore Sight Elite Non-Adhesive Small Sensor

ForeSight Sensors FSESU - ForeSight Large Sensor . FSESM: ForeSight Jr Medium Sensor FSESS - ForeSight Jr Small Sensor,

FSESNS - ForeSight of Non-Adhesive Small Sensor

#### Name of Manufacturer

Legal Manufacturer

EDWARDS LIFESCIENCES LLC ONE EDWARDS WAY IRVINE, CA USA 92614

#### Contract Manufacturer

SUPERCOMAL MEDICAL PRODUCTS, SON BHD LOT 171 JALAN PKNK 3/8 KAWASAN PERUSAHAAN, SUNGAI PETANI SUNGALPETANI, Kedah MALAYSIA 05000

#### Name of Product(s)

Hemodynamic Monitoring Equipment 64EKGE1, 64EKH, 64EKSM, 64EKMM, 70ANH, 70ANHS, 70ANMS, 70ANMS, 70ANM7, 70ANS, 70CC2 COM2-CC, EVPSB220L, EVVVTC1, EVFTC1, EVPMAC, EVPSB110, EVPSB110L END OF PRODUCT LIST-





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Designation: Sr. Manager Regulatory Affairs

Date-5 October 2020

Stamp:

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