

**ALL INDIA INSTITUTE OF MEDICAL SCIENCES  
ANSARI NAGAR, NEW DELHI - 110029  
(Burns & Plastic Surgery Block)**

**Ref. No. BPS/65/Cardiac Output Monitor/PAC/2024-25**

**Dated: 30.04.2025**

**Sub:- Purchase of "Cardiac Output Monitor System- 01 set" from M/s Edwards Life sciences (India) Pvt. Ltd., Mumbai through M/s Arian Healthcare, New Delhi on Proprietary basis (PAC)- reg.**

\*\*\*\*\*

Store Section has initiated a proposal for purchase of Cardiac Output Monitor System- 01 set" from M/s Edwards Life sciences (India) Pvt. Ltd., Mumbai through M/s Arian Healthcare, New Delhi on Proprietary basis (PAC). User department has submitted PAC certificate duly signed by departmental TSEC. M/s Edwards Life Sciences (India) Pvt. Ltd. has also submitted proprietary certificate and Authorization letter.

As per prevailing guidelines issued from the office of **CPO vide No. Policy/CPO (AIIMS)/2012 dated 01.11.2012** wherein there is a provision to upload the details of the item on the website for the open information for a period of 15 days to submit objections, if any by any manufacture regarding proprietary nature of the equipment/item and thereafter, the proposal shall be submitted to TSEC, Store Purchase Committee and Competent Authority for approval. With regard to above said guidelines, the soft copy of details PAC of OEM had been obtained and prepared with covering letter for uploading in the Institute website **i.e. www.aiims.edu** for open information from any bidder/firm.

The comments should be received by office of Stores Officer (BPS), AIIMS on or **before 15.05.2025 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.

  
**Stores Officer (BPS)**



ALL INDIA INSTITUTE OF MEDICAL SCIENCES, ANSARI NAGAR, NEW DELHI

Department of Plastic, Reconstructive & Burns Surgery

PROPRIETARY/ SPECIFIC BRAND GOODS CERTIFICATE

1	Item/ Type/ Model No. required along with Specifications	Cardiac Output Monitoring System, Name, Type etc enclosed
2	Is the item a spare part attachment or accessory for existing equipment	No
3	Name of the Manufacturer/ Supplier of the item proposed by the indenter	Edwards Lifesciences (India) Pvt. Ltd.
4	Are the Sole Manufacturer/ Sole Distributor of the item	Yes
5	Is there any other item with similar/ equipment specifications available in the market to meet the job requirement envisaged?. If the answer is yes, why the same can't be procured?	No
6	What were the efforts made to locate alternative source of supply or use other substitutes?	Checked online/ offline and not available on GeM Portal
7	Why Open/ limited tender can't be resorted to, for locating alternative source?	Open Tender was published on CPPP but single vendor participated which was found to be technically qualified. Thus, as per competent authority directions, it is re-initiated as Proprietary item.
8	Are the Proprietary items certifying that the rates are reasonable or not	Yes
9	Any other justification for procuring item for single source	The item is used in ICU for critical care patients where invasive monitoring is required to accurately measure critical patient parameters. It also has various softwares that are used to predict patient parameters like hypotension, sepsis etc. which can be managed at early level to prevent adverse event for the patient.

Signature of Indenter  
(Demanding Officer)

Signature of Dr. Manee Singh  
(Consultant Professor & Head)  
Department of Plastic, Reconstructive & Burns Surgery

It is certified that above-mentioned item is required to be procured on single tender basis as the source of the supply is definitely known and limited tender system could be dispensed with as they would serve no useful purpose in this particular case. Also, market survey has been done and found that no other manufacturer is manufacturing similar equipment which can fulfil vital requirements of the department.

Signature of Dr. Shashank Chauhan  
अपर आचार्य/Additional Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029

Signature of Dr. Raj Kumar Manas  
अपर आचार्य/Additional Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029

Signature of Dr. Shivangi Saha  
सहायक आचार्य/Assistant Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029

Signature of Dr. V. Darlone  
अपर आचार्य/Associate Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029



Edwards

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, 11nd 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

Anil Kataria  
Director Sales & Marketing  
Critical Care and Vascular care India & SNB

Deval Joshi  
Finance Head



Cc: M/s Arian Healthcare

डॉ. शाशंक चौहान/Dr. Shashank Chauhan  
अपर आचार्य/Additional Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान  
नई दिल्ली/New Delhi-110022

Edwards Lifesciences (India) Private Limited

Regd. Office: 4th Floor, Commerz II, International Business Park, Oberoi Garden City,  
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

डॉ. राजा तिवारी/Dr. Raja Tiwari  
सह आचार्य/Associate Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/AIIMS  
नई दिल्ली/New Delhi-110022





Edwards

TO WHOM SOEVER IT MAY CONCERN

Dear Sir/Madam,

Greetings from Edwards!

Edwards Lifesciences (India) Pvt. Ltd. is owned as follows:

- Edwards Lifesciences World Trade Corporation, owns 99% and
- Edwards Lifesciences Corporation owns 1%.

Edwards India is the sole distributor of Edward's range of products in India.

Edwards Lifesciences (India) Private Limited is engaged in sales & distribution of Edwards' Products in India, Sri Lanka, Nepal and Bangladesh.

Jeanine  
Deproost

Signature:

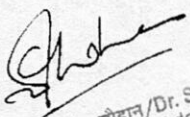
Name of Authorize Signatory: Jeanine Deproost

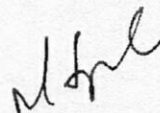
Designation: Sr. Manager Regulatory Affairs


Stamp:

Date-5 October 2020

Digitally signed by Jeanine Deproost  
DN: cn=Jeanine Deproost,  
email=Jeanine\_Deproost@edwards.co  
m  
Date: 2020.10.05 14:32:23 -0700

  
डॉ. शशांक चौहान/Dr. Shashank Chauhan  
अपर आचार्य/Additional Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029



  
डॉ. राजा तिवारी/Dr. Raja Tiwari  
सह आचार्य/Associate Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029

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



# 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/B&PS/2024-25

Dt.: 02.12.2024

The Prof & HOD  
Deptt. of Plastic,  
Reconstructive & Burns Surgery,  
AIIMS, Ansari Nagar,  
New Delhi-110029

**Sub.: FALL CLAUSE CERTIFICATE**

Dear Sir,

With reference to our quotation no. AHC/B&PS/2024-25 Dt.02.12.2024 for the supply of **Cardiac Output Monitoring System**, 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 to any other person/organization/Institution during the currency of the contract as per the fall 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.)

डॉ. शशांक चौहान/Dr. Shashank Chandra  
अपर आचार्य/Additional Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery  
अखिल भारतीय आयुर्विज्ञान संस्थान  
नई दिल्ली/New Delhi

डॉ. राजा तिवारी/Dr. Raja Tiwari  
सह आचार्य/Associate Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029





# Arian Healthcare


4327/3, Flat No. 202, 11nd Floor, Ansari Road, Darya Ganj, New Delhi-110002  
Tel. : 011-23250080, 011-49403689, Mobile : 9811140954  
E-mail : arianhealthcare@rediffmail.com; arianhealthcare@gmail.com

## UNDERTAKING

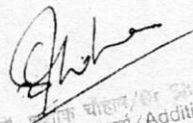
### TO WHOM SO EVER IT MAY CONCERN

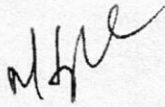
I, Rajeev Verma prop. of M/s. Arian Healthcare, 4327/3, Satyam House, Flat No.202, 2nd Floor, Ansari Road, Darya Ganj, New Delhi -110002, do hereby undertake that the firm has not been de-registered/banned/blacklisted in the past by any Govt., Central Govt. Ministeries/AIIMS, New Delhi or Private Organization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

For **Arian Healthcare**


(Prop.) 

Dated: 02.12.2024

  
डॉ. सुशान्त चौहान/Dr. Sushant Chohan  
अपर आचार्य/Additional Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029





  
डॉ. राज तिवारी/Dr. Raja Tiwari  
सह आचार्य/Associate Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029



U.S. FOOD & DRUG  
ADMINISTRATION

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
www.fda.gov

Certificate No. 2912-12-2022

CERTIFICATE TO FOREIGN GOVERNMENT

In order to allow the importation of United States products into foreign countries, the U.S. Food and Drug Administration (FDA) certifies the following information concerning the product(s) to be exported listed below:

**Name of Product(s)**

See Attached List

(Two Pages)

**Name of Manufacturer/Distributor, Address**

See Attached List

(One Page)

The product(s) described above (and the manufacturing/distribution site(s) which produces/distributes it) is subject to the jurisdiction of the FDA under the Federal Food, Drug, and Cosmetic Act.

It is certified that the above product(s) may be marketed in, and legally exported from, the United States of America at this time. The manufacturing plant(s) in which the product(s) is produced is subject to periodic inspections. The last such inspection showed that the plant(s), at that time, appeared to be in substantial compliance with current good manufacturing practice requirements for the product(s) listed above.

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.

डा. शशांक चौहान/Dr. Shashank Chauhan  
अपर आचार्य/Associate Professor  
जलन-एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान, नई दिल्ली, M.S.  
New Delhi

Mhe

NONG

डा. राजा तिवारी/Dr. Raja Tiwari  
सह आचार्य/Associate Professor  
जलन-एवं प्लास्टिक चिकित्सा विभाग  
Tertiary Block  
A.I.I.M.S.  
New Delhi





U.S. FOOD & DRUG  
ADMINISTRATION

CENTER FOR DEVICE & RADIATION CONTROL

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
www.fda.gov

Certificate No. 2912-12-2022

Certificate to Foreign Government - Name of Product(s) Attachment Page 1 of 2

Name of Manufacturer

Legal Manufacturer

EDWARDS LIFESCIENCES LLC  
ONE EDWARDS WAY  
IRVINE, CA  
USA 92614

Name of Product(s)

Hemodynamic Monitoring Equipment

84EKBB, 84EKD, 84EKD2, 84EKHH, 84EKLL, 84EKM, 84EKMN, 84EKNK1  
84EKGE2, 84EKSM2, 84EKSM3, 70AN, 70AND, 70AND2, 70AND3, 70AND4, 70ANH1H  
70ANHHS, 70ANH1, 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.  
4085 THEURER BLVD  
WINONA, MN  
USA 55987

Name of Product(s)

Vigileo Monitor and Accessories

APC09, MHAADPLT, MHAND, MHANM5, 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, EVNIPUG, EVPMP  
PC2B, PC2CCC, PC2K, PC2CVR

HemoSphere Advanced Monitoring Platform

HEM1, HEMOXSC100, HEMSGM10, HEMEXPM10, HEMLPWCD1000, HEMLTECHM10, HEMPSC100  
HEMTOM10, HEMFSM10, HEMCSM10, HEMPC, HEMPC2K

FloTrac Pressure Cable—BeneVision

PSCQEM100MR

Name of Manufacturer

Legal Manufacturer

EDWARDS LIFESCIENCES LLC

Dr. Shashank Chauhan  
Associate Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029

ndhl

Arora



डॉ. राजा तिवारी Dr. Raja Tiwari  
Associate Professor  
चिकित्सा विभाग  
Surgery Block  
स्थान/A.I.I.M.S.  
110029





U.S. FOOD & DRUG  
ADMINISTRATION

U.S. Food & Drug Administration

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
www.fda.gov

Certificate No. 2912-12-2022

Certificate to Foreign Government - Name of Manufacturer/Distributor Attachment Page 1 of 1

Name of Manufacturer

Legal Manufacturer

EDWARDS LIFESCIENCES LLC  
ONE EDWARDS WAY  
IRVINE, CA  
USA 92614

Contract Manufacturer

BENCHMARK ELECTRONICS, INC.  
4085 THEURER BLVD.  
WINONA, MN  
USA 55987

Contract Manufacturer

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

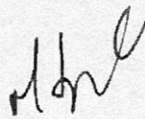
Contract Manufacturer

SUPERCOMAL MEDICAL PRODUCTS, SDN BHD  
LOT 171, JALAN PKNK 3/8, KAWASAN  
PERUSAHAAN, SUNGAI PETANI  
SUNGAI PETANI, Kedah  
MALAYSIA 08000

---END OF MANUFACTURER/DISTRIBUTOR LIST---



डॉ. शशंक चौहान/Dr. Shashank Chauhan  
अपर आचार्य/Additional Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029







डॉ. राजा तिवारी/Dr. Raja Tiwari  
सह आचार्य/Associate Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान/A.I.I.M.S.  
नई दिल्ली/New Delhi-110029



U.S. FOOD & DRUG  
ADMINISTRATION

OFFICE FOR FOREIGN REGISTRATION OF DRUGS

U.S. Food & Drug Administration  
10903 New Hampshire Avenue  
Silver Spring, MD 20993  
www.fda.gov

Certificate No. 2912-12-2022

Certificate to Foreign Government - Name of Product(s) Attachment Page 2 of 2

ONE EDWARDS WAY  
IRVINE, CA  
USA 92614

**Contract Manufacturer**

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

**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  
FSESNS - Fore-Sight Elite Non-Adhesive Small Sensor

**Fore-Sight Sensors**

FSESL - Fore-Sight Large Sensor  
FSESM - Fore-Sight Jr Medium Sensor  
FSESS - Fore-Sight Jr Small Sensor  
FSESNS - Fore-Sight Jr Non-Adhesive Small Sensor

**Name of Manufacturer**

**Legal Manufacturer**

EDWARDS LIFESCIENCES LLC  
ONE EDWARDS WAY  
IRVINE, CA  
USA 92614

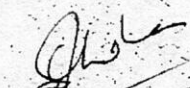
**Contract Manufacturer**

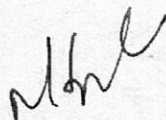
SUPERCOMAL MEDICAL PRODUCTS, SDN BHD  
LOT 171, JALAN PKNK 3/8 KAWASAN  
PERUSAHAAN, SUNGAI PETANI  
SUNGAI PETANI, Kedah  
MALAYSIA 08000

**Name of Product(s)**

Hemodynamic Monitoring Equipment  
64EKGE1, 64EKH, 64EKSM, 64EKMM, 70ANH, 70ANHS, 70ANM5, 70ANM6, 70ANM7, 70ANS, 70CC2  
COM2-CC, EVPSB220L, EVVTC1, EVFTC1, EVPMAC, EVPSB110, EVPSB110L

END OF PRODUCT LIST

  
डॉ. शशंक चौहान / Dr. Shashank Chauhan  
अपर आचार्य / Additional Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान / A.I.I.M.S.  
नई दिल्ली / New Delhi-110029







  
डॉ. राजा तिवारी / Dr. Raja Tiwari  
सह आचार्य / Associate Professor  
जलन एवं प्लास्टिक चिकित्सा विभाग  
Burns & Plastic Surgery Block  
अखिल भारतीय आयुर्विज्ञान संस्थान / A.I.I.M.S.  
नई दिल्ली / New Delhi-110029



14 March 2024



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) <sup>^1</sup>. 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>.

1. Continuous CO & CI, ICI, RVEF, EDV, SV, SVI, SVR, SVRI, SVV, CVP, dP/dt, EDdyn, MAP, MPAP, PPV, PR, SYSatr/SYSpap, ScvO2, SvO2, Vo2, Vo2e, Vo2i, VO2le, StO2, DLAart
2. HPI-Hypotension Prediction Index
3. 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 with HemoSphere ClearSight Module
4. GDT-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.

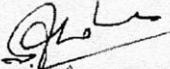
Sincerely,

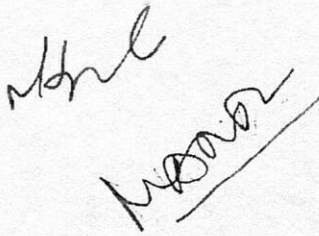
Kevin  
Lam

Digitally signed by Kevin Lam  
DN: cn=Kevin Lam,  
email=Kevin.Lam@edwards.com  
Date: 2024.03.14 12:57:58 +05:00

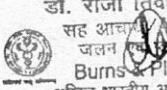
Name: Kevin Lam

Designation: Regulatory Affairs Director  
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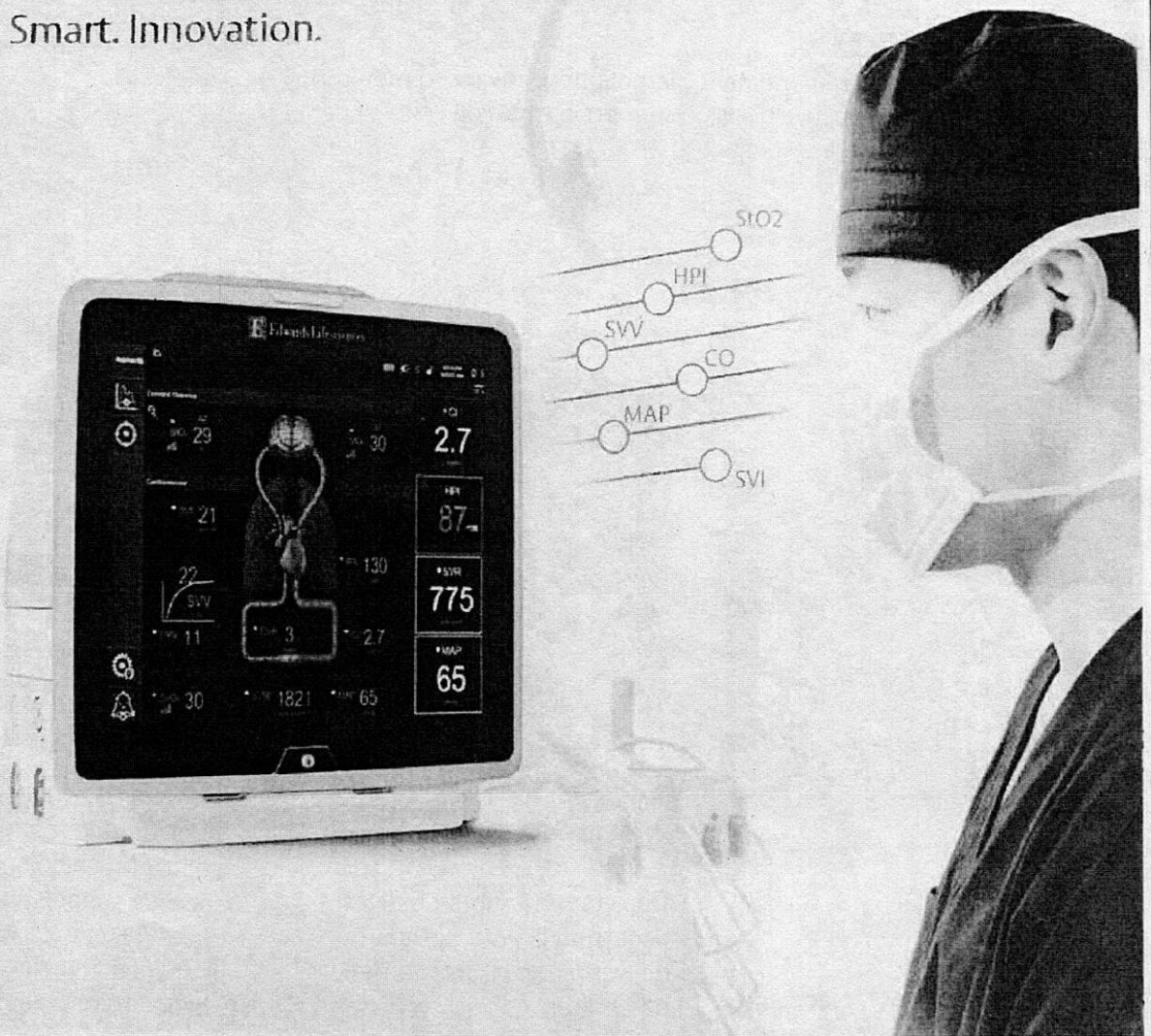


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# Changing the pace of hemodynamics

Smart. Innovation.



HemoSphere advanced monitoring platform

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# 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.



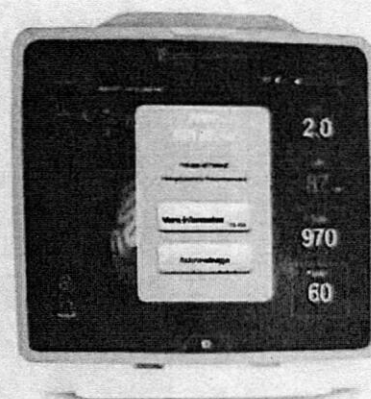
## Past trends

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.\*

\*A hypotensive event is defined as MAP <65 mmHg for a duration of at least one minute.

# 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.<sup>1</sup> 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.