

DEPARTMENT OF ANAESTHESIOLOGY
PAIN MEDICINE & CRITICAL CARE
AIIMS, NEW DELHI – 29

Dated: 05.11.2015

Reference: Anaesth/Propriety/ Accessories of Vegileo Monitor/2015-16

Subject: Purchase of consumables/accessories for VIGILEO Monitor on propriety basis - inviting comments thereon.

As per approved by Head, Department of Anaesthesiology, for purchase of following material/item:-

S. no.	Item
1.	FLOTRAC- Disposable Sensor for the measurement of CCO through the Arterial Line. Sterile, to be used with Vigileo Monitor Mfd. By M/s. Edwards Life Sciences, USA
2.	PRESEP – Disposable CV Oximetry Catheter. To be used with Vigileo 16 cm. Mfd. By M/s. Edwards Life Sciences, USA

From M/s. Arian Healthcare, 4327/3, Flat No. 202, IInd Floor, Ansari Road, Darya Ganj, New Delhi – 110002 on proprietary basis, the proposal submitted by the above mentioned firm and proprietary and authorization certificate are attached & uploaded on website.

The above documents are being uploaded for open information to submit objection, comments, if any, from any manufacturer regarding propriety nature of the items within 15 days from the date of issue/uploading of the notification. The comments should be sent to "The Head, Department of Anaesthesiology, Pain Medicine & Critical Care, Room No. 5011, AIIMS, New Delhi – 110 029".

Yours faithfully,

Dr. M.K. Arora

Prof. & Head



डा० एम.के. अरोरा, MD
Professor & Head
DEPARTMENT OF ANAESTHESIOLOGY
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
नई दिल्ली/New Delhi-110029

Prof. I/C Computer facility with the request to issue instruction for uploading above Material/Item on AIIMS Website for 15 days.

Encl: Proprietary & Authorization Certificate enclosed

Poonit Khanna
6/11/15

Leahy
06/11/2015

FACULTY I/C STORES
Department of Anaesthesia
AIIMS, New Delhi-29



Edwards Lifesciences

Dt.: 28.05.2015

To,
The Prof. & F.O.D.,
Deptt. Of Anaesthesia,
A.I.I.M.S.,
Ansari Nagar, New Delhi-29

Sub: Authorization Letter

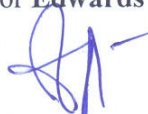
Dear Sir,

This is to inform you that M/s **Arian Healthcare** is authorized to quote, make supplies and collect payments on behalf of Edwards Lifesciences India Pvt. Ltd. (Critical care Division) against your requirement of Flotrac sensor & PRESEP Catheter.

You are requested to forward all your queries of critical care division to the following address.

M/S Arian Healthcare,
4327/3, Flat No.202,
2nd Floor,
Ansari Road,
Daryganj,
New Delhi-110002

Sincerely
For Edwards Lifesciences India Pvt. Ltd.


+ Gunjan Khurana
Divisional Manager. C.C. DIVISION (North)

Edwards Lifesciences (India) Pvt. Ltd

Plot No. 70, A-23, Rama Road, Industrial Area, New Delhi – 110061. INDIA

Tel. : 91 – 11 – 25107467. Fax : 91 – 11 – 45042302

Regd. Office: E,F–201,202,203,204, Remi Bizcourt, Plot No. 9, Shah Industrial Estate, Andheri (W), Mumbai – 400058. INDIA.

Tel. : 91 – 22 – 56935701 – 04. Fax : 91 – 22 – 56935705



Edwards

Proprietary Article Certificate

December 12, 2014

To Whom It May Concern:

We hereby certify that Edwards Lifesciences AG located at Parque Industrial Itabo Km. 18.5 CARR Sanchez, Haina, San Cristobal, Dominican Republic is the sole manufacturer of the MHD8.

From the Instructions for Use:

Overview

The *FloTrac* sensor is a sterile, single use kit that monitors pressures when attached to pressure monitoring catheters. The disposable sterile cable with a red connector interfaces exclusively with an Edwards cable that is specifically wired for the pressure monitor being used. The disposable sterile cable with a green connector interfaces exclusively with the Edwards APCO cables for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware.

The *FloTrac* sensor has a straight, flow-through design across the pressure sensors with an integral flush device.

Indications

The *FloTrac* sensor is indicated for use in intravascular pressure monitoring. It is also indicated for use with the Edwards arterial pressure based cardiac output monitoring devices or hardware to measure cardiac output.

The FloTrac is covered by the following US patents:

Patents	US issue date	US expiration date
5,803,770	September 8, 1998	September 8, 2015
7,220,230	May 22, 2007	February 23, 2025
7,422,562	September 9, 2008	May 21, 2025

Takako Kojima
Regulatory Affairs, Associate III



Edwards

State of California
County of Orange

Subscribed and sworn to (or affirmed) before me on this 12th day of December, 2014, by
Takako Kojima, proved to me on the basis of satisfactory evidence to be the person who appeared before me.

Seal

Kristen Jarvis
(Signature of Notary Public)



Proprietary Article Certificate

To Whomever It May Concern:

We hereby certify that Edwards Lifesciences Technology Sàrl, State Road 402, Km 1.4, Industrial Park, Añasco, PR 00610-1577 is the sole manufacturer of model X3820HS.

Concept/Description

From the DFU:

Description

The PreSep Central Venous Oximetry catheter is a non-balloon catheter that provides the means for infusion of solutions, measuring central venous pressure, and taking blood samples through the distal lumen (terminates at the catheter tip), the proximal lumen (terminates 7 cm proximal to the tip), and the medial lumen (terminates 5 cm proximal to the tip). The PreSep catheter also provides the means for continuously monitoring central venous oxygen saturation in the superior vena cava using an Edwards Lifesciences SAT-2, EXPLORER, or VIGILANCE Monitor and OM2 Optical Module.

Central venous oxygen saturation is monitored by fiberoptic reflectance spectrophotometry. The amount of light absorbed, refracted, and reflected depends on the relative amounts of oxygenated and deoxygenated hemoglobin in the blood.

The PreSep catheter is coated with AMC THROMBOSHIELD coating, an antimicrobial* heparin coating (Ref. 1 & 13). Significant antimicrobial activity associated with AMC THROMBOSHIELD coating has been demonstrated using *in vitro* diffusion agar assays against the following organisms: *Staphylococcus epidermidis*, *S. aureus*, *Streptococcus fecalis*, *Candida albicans*, *Escherichia coli*, *Serratia marcescens*, and *Acinetobacter calcoaceticus*. Catheters with AMC THROMBOSHIELD coating are denoted by an "H" in the model number.

Indications

PreSep catheters are indicated for hemodynamic monitoring through blood sampling, central venous pressure monitoring, and central venous oxygen saturation measurement.

For Edwards Lifesciences Technology Sàrl, Añasco, Puerto Rico



Michael Ferguson
Director

On July 17, 2007, before me, _____ personally
DATE NAME, TITLE OF OFFICER

appeared Michael Ferguson personally known to me (or proved to me on the basis of satisfactory evidence) to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the person, or the entity upon behalf of which The person acted, executed the instrument.

WITNESS my hand and official seal.

(SEAL)
NOTARY PUBLIC SIGNATURE

Légalisation numéro 2'823.- / Legalization number 2'823.-

Sur la base d'une comparaison de signatures, le soussigné Franco del Pero, docteur en droit, notaire à Morges (Canton de Vaud / Suisse), atteste l'authenticité de la signature apposée au recto du présent document par Michael John Ferguson, dont l'identité a été établie sur la base de son passeport. / The signatures having been compared, I Franco del Pero, Notary Public at Morges (Canton of Vaud / Switzerland), hereby certify the authenticity of the signature apposed on the reverse side by Michael John Ferguson, whose identity has been established by his passport.

Morges, le dix-huit juillet deux mille sept. / Morges, July the eighteenth twothousandandseven.

