

All-India Institute of Medical Sciences
Ansari Nagar, New Delhi-29.
(RESEARCH SECTION)

Ref. No.15/Stores/Neuroanes/NS/2015-16/RS

Dated: 23.02.2016

Subject: Purchase of (Jugular Venous Oximetry Catheter), for the Department of Neuroaneesthesiology & Critical Care, JPNATC, AIIMS, New Delhi-29 on proprietary basis-
Inviting comments thereon.

The request has been received from Dr. Navdeep Sokhal, Deptt. of Neuroaneesthesiology & Critical Care, JPNATC, AIIMS to purchase the subject item from M/s Arian Healthcare (mfd. M/s Edwards Lifesciences Technology Sarl) on proprietary basis. The proposal submitted by M/s Edwards Lifesciences Technology Sarl, and PAC certifications are attached.

The above documents are being uploaded for open information to submit objections, comments, if any, from any manufacturer regarding proprietary nature of the equipment/item within issue of 15 days giving reference **No. 15/Stores/Neuroanes/NS/2015-16/RS**. The comments should be received by office of Stores Officer (RS), Research Section at AIIMS on or before **10/03/2016 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 (RS)

Encl: Related documents enclosed.

1. PAC Certificate enclosed.
2. Specification of equipment.



Edwards

Proprietary Article Certificate

May 6, 2013

To Whom It May Concern:

We hereby certify that Edwards Lifesciences Technology Sàrl located at State Road 402, Km 1.4 Industrial Park, Añasco, PR 00610-1577 USA is the sole manufacturer of the X3816HS.

From the Instructions for Use:

Overview

The PreSep oximetry catheter is a non-balloon catheter that provides the means for infusion of solutions, measuring pressure, and taking blood samples. This catheter also provides the means for continuously monitoring oxygen saturation using an Edwards Lifesciences oximetry monitor or compatible bedside module.

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. 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 faecalis*, *Candida albicans*, *Escherichia coli*, *Serratiamarcescens*, 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, pressure monitoring, and oxygen saturation measurement.

Takako Kojima
Regulatory Affair, Associate II

Dr. NAVDEEP SOKHAL
Assistant Professor
Dept. of Neuro Anaesthesiology
Critical & Intensive Care
AIIMS, New Delhi-29



Jugular venous oximetry catheter specifications

1. Jugular Venous Oximetry catheter should be compatible with VIGILEO monitors to give continuous $SjVO_2$ values.
2. It should have 3 lumens of 15, 18, 18 gauge.
3. It should have 16 or 20 cm catheter length.
4. It should have a catheter diameter of 8.5 F.
5. It should be made up of safe, non-pyrogenic, and non toxic material.