

ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI-29.
STORES SECTION (DO)

Ref. No. 24/Stores(DO)/Pead.Surg./PAC/2019-20/FSC Dated-30/10/2019

Sub:- Purchase of "Intra Operative Nerve Monitoring System – 01 No." for the Department of Pediatric Surgery at AIIMS, New Delhi-110029, on proprietary basis inviting comments thereon.

The Institute is in the process to purchase "Intra Operative Nerve Monitoring System – 01 No. at AIIMS, New Delhi from M/s. Medtronic, USA through M/s. BrainWave Medical Technologies Pvt. Ltd. The PAC Certifications by M/s. Medtronic, USA as well as the user department 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 15 day from the date of issue/uploading of the notification giving reference No. 24/Stores(DO)/Pead.Surg./PAC/2019-20/FSC. The comments should be received in office of Stores Officer (FSC), Store Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before 20/11/2019 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.

Yours faithfully,


SR. STORES OFFICER (DO)

Encl: Related documents enclosed.

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QTY - 1

UNIT PRICE - 95 LAC

TOTAL AMOUNT - 95 LAC

Product Details of Intra Operative Nerve Monitoring System

- Portable Laptop-based system.
- Integrated remote monitoring capabilities.
- Electronic or hard copy screen shot storage.
- Electronic data storage of the entire procedure including EMG audio.
- Electro-surgery unit (ESU) interference muting.
- 8 channels neurological monitoring for intraoperative applications.
- EMG and MEP monitoring with 8 independent channels.
- Must allow adding any modality or channels while a running test without stopping or pausing the monitoring.
- Should include Surgeon Directed operation.
- Surgeon Directed (SD) mode should also incorporate feature of SD advanced option which shall advanced parameters settings for higher end applications.
- Should have two built-in pulse oximeter ports.
- Should be a minimalist system.
- Should have both monophasic and biphasic stimulation for TCeMEP. Also, should be capable of Left - Right monophasic TCeMEP stimulation (dual stim) on a single click.
- Secondary windows should have 2DVR feeds, 2 timers and should allow the user to change the color of the traces.
- Must be capable to adjust the display with multiple windows of different modalities to be dragged, dropped, resized, maximize and minimize.
- The free running modalities like EMG should always be running.
- Stimulators run all electric modalities.
- EMG is able to be recorded and reviewed
- Free running averaged or signal triggered data collection modes.
- All trace parameters (Filter, amplifier gain, artifact rejection, time base, display scale, Etc) should be fully user adjustable and independent.
- Data can be saved manually or automatically as continuous free run EMG, Triggered EMG, Screen snapshots and video.

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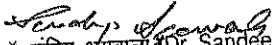

- Previously saved data can be reviewed while monitoring. Review data locally or remotely via network, modem or internet.
- Standard test protocols are provided and can be modified and saved by user.
- All patient connections are both software and hardware protected against faults.
- Automatic pedicle screw integrity test mode.
- Module for easy EMG & MEP testing from the sterile field.
- Independent, high and low electrical stimulators for peripheral and direct nerve monitoring. Extensive stimulus triggering including repetitive, non-repetitive, single pair and train.
- Fast and slow charge TCeMEP stimulation mode.
- Data can be saved automatically (continuously, at predefined intervals or event triggered) or manually.
- Remote monitoring via modem, LAN or internet.
- Reports can be automatically generated for every test and contain all necessary test information and additional user - specified information.


SD Features


- An exclusively dedicated 8-Channel module (preamplification and stimulation in a single box) capable of recording EMG, Trig EMG, Screw testing, Nerve Proximity, MEP and train of four modalities.
- 2-channel pulse Ox recording.
- Automated report generation for pedicle screw stimulation.
- Fully surgeon controllable from the sterile field with the help of surgeon-controlled probe having buttons to give access to system parameters and test modalities.
- Probe should allow the surgeon to select the modality, adjust the current and deliver the stimulus directly from the sterile field.
- Probe's multicolor LED indicates test results.
- Multiple manual and triggered EMG modes of operation
- Audible and visual surgeon feedback.


Nerve Proximity Features


- Designed to quickly and automatically locate a nerve.
- Provide audio tone feedback indicating proximity to a nerve root.
- Program automatically changes stimulation intensity while searching for an EMG response.



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Pedicle Screw Capabilities

- Designed to quickly and automatically verify proper positioning of pedicle screws.
- Simulation intensity automatically increases until a response is generated.
- Algorithm confirms response to avoid false test results.

Nerve Root Testing

- Used to locate and quantify the health of a nerve root.
- Simulation intensity automatically increases until a response is generated.

Consumables

- Surgeon directed ball tip probe.

Gives surgeon full control from the sterile field.

Buttons on probe allow surgeon to increase or decrease current, change the monitoring test mode and print reports.

Multicolor LED display test result.

Includes two ball –tip probes and one flush –tip probe.

- Should have universal electrodes to make regular OT instruments stimulating.
- Corkscrew electrodes
- Monopolar probe
- Bipolar probe

* should have 5 years warranty and should quote for cnc for 5 years after completion
* No consumables required.

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

Proprietary Article Certificate (PAC) (Machinery & Equipment)

1. The indented goods are Manufactured by M/s : MEDTRONIC
2. Item Name : IONM → INTRA OPERATIVE NERVE MONITOR
3. Model No. : Nim-E-4
4. Vital Technical Performance Parameters Required which makes the requirement Proprietary## : SURGEON DIRECTED MODULE
SOMATO SENSORY EVOKED POTENTIAL
NEUROPHYSIOLOGIST SUPPORT MODULE
VISUAL EVOKED POTENTIAL.
5. No other make or model is acceptable for The following reasons : NO OTHER COMPANY MANUFACTURES THE SAME EQUIPMENT.

It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equipment specifications which can fulfill the vital requirements of end user.

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Signature of TSEC
with Name, Designation, Department
and Hospital/Institute/DGHS

##Note 1: TSEC should clearly mention the vital functional parameters requirements which end user essentially require and are manufactured by only one manufacturer mentioned in serial no. 1.

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India Medtronic Pvt. Ltd.
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Date: June 24, 2019

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To,

Head Of Department, Pediatrics Surgery
All India Institute of Medical Science
Ansari Nagar, New Delhi-110029

Dear Sir,

This is to confirm that Medtronic NIM Eclipse® Somato sensory evoked potential for intraoperative monitoring system is being manufactured at Medtronic Xomed, Inc.6743 South point Drive North Jacksonville, Florida 32216 USA

NIM Eclipse® Somato sensory evoked potential for intraoperative monitoring system is the proprietary item of Medtronic, on the following grounds:

1. The NIM Eclipse® Somato sensory evoked potential for intraoperative monitoring system **has two module SD (Simplified Design) Module and NS (Neurophysiologist Support) Module** in one System which have the capability of monitoring electromyography (EMG), motor evoked potential (MEP), train of four (TOF), Triggered EMG, somatosensory evoked potentials (SSEP), electroencephalography (EEG), Electro-corticography (ECoG), visual evoke potential (VEP), brainstem auditory evoked potential (BAER).
2. The NIM Eclipse® Somato sensory evoked potential for intraoperative monitoring system has **dedicated 8-channel patient interface Module which includes color-coded stimulation and recording connections that correspond with our proprietary color-coded electrodes**, to reduce confusion and limit the number of components needed to test the motor neurons.
3. The NIM Eclipse® Somato sensory evoked potential for intraoperative monitoring system has the optional **"SD Advanced Mode"**, which provides greater flexibility in making modifications while still using the same 8-channel interface. These enhanced features include customization of the size, type, and number of modality windows being displayed, changing MEP to biphasic stimulation, and adding new types of tests such as D-wave and those needed to perform Speech and Motor Mapping.

For India Medtronic Pvt. Ltd.

Rahul Arora
Business Manager – ISC, Enabling Technologies

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To,
The 'Director'
All India Institute of Medical Sciences,
Ansari Nagar, New Delhi – 110029, India.

Dear Sir,

Sub : Authorization Letter

We, India Medtronic Private Limited - situated at 1241, Solitaire Corporate Park, Building No.12, 4th Floor Andheri-Ghatkopar Link Road, Andheri (East) Mumbai – 400 093, India who are a fully owned subsidiary of Medtronic Plc., 20 Lower Hatch Street, Dublin 2, Ireland who are proven and reputable manufacturers of Intra Operative Neuromonitoring System - Model NIM Eclipse Nerve Monitoring System having factories at having factories at Medtronic, 6743 Southpoint Drive North Jacksonville, FL 32216 U.S.A, hereby authorise Messrs "**Brainwave Medical Technologies Pvt. Ltd.**" having office at "Office No. 4, 1st Floor, CSC, B - Block, Yojana Vihar, Delhi – 110092" to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above goods manufactured by us.

We also state that we are not participating directly in this bid as trained service engineers are available locally with distributors for attending service calls at any time. Also, supply of stocks are made available with the distributor.

We further confirm that no supplier or firm or individual other than Messrs. **Brainwave Medical Technologies Pvt. Ltd.**" having office at "Office No. 4, 1st Floor, CSC, B - Block, Yojana Vihar, Delhi – 110092" is authorised to submit a bid, process the same further and enter into a contract with you against your requirement as contained in the above referred TE documents for the above good manufactured by us.

We also hereby extend our full warranty, CAMC as applicable as per clause 15 of the General Conditions of Contract, read with modification, if any, in the Special Conditions of Contract for the goods and services offered for supply by the above firm against this TE document.

We also hereby confirm that we would be responsible for the satisfactory execution of contract placed on the authorized agent and the spares for the equipment shall be available for at least 10 years from the date of supply of equipment.

We also confirm that the price quoted by our agent shall not exceed the price which we would have quoted directly"

For India Medtronic Pvt Ltd

Rahul Arora
2019.09.06
20:26:37 +05'30'

Rahul Arora
Business Manager | Enabling Technologies & Surgical Synergy

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