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

Ref. No. 52/Stores (DO)/Ortho/PAC/2016-17/FSC **Dated 13.10.2017**

Sub:- Purchase of **Intra-operative Neural Monitoring System** for the department of Orthopedics, (AIIMS), New Delhi-110 029, on proprietary basis **Inviting comments thereon.**

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The Institute is in the process to purchase **Intra-operative Neural Monitoring System** for the **Department of Orthopedics**, (AIIMS), New Delhi from **M/s Medtronic Xomed, Inc Florida, USA through M/s Brainwave Medical Technologies Pvt. Ltd. Delhi,** on proprietary basis. The PAC Certifications by M/s. Medtronic as well as from 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 issue of 15 days giving reference No. **52/Stores (DO)/Ortho/PAC/2016-17/FSC.** The comments should be received in office of Stores Officer (DO), Store Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before **29.10.2107** 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 (FSC)

Encl: Related documents enclosed.

Medtronic

India Medtronic Pvt. Ltd.
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Date: November 21, 2016

To,

The Director
All India Institute of Medical Sciences
Ansari Nagar
New Delhi-110 029

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 provides a seamless and exclusive integration with existing Medtronic S7 navigation system with a pre-calibrated and stimulated X-PAK probe which is essentially a cannulated needle probe for Minimally Invasive Spine procedures.

3. 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.

4. 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
2016.11.21
11:15:07
+05'30'

Rahul Arora
Country Manager Sales Xomed and Navigation (ISC)

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अंसारी नगर, नई दिल्ली/Ansari Nagar,N.D-110029

ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI – 110029

PROPRIETORY/SPECIFIC BRAND GOODS CERTIFICATE

1.	Item/Type/Model No. required alongwith specifications.	Intra-Operative Neural Monitoring System
2.	Is the item a spare part attachment or accessory for existing equipment?	Equipment
3.	Name of the manufactures supplier of the item proposed by the indentor.	Medtronic Inc, USA
4.	Are they sole manufactures/Sold distributors of the item?	Sole Manufacturer
5.	Is there any other item with similar/equivalent specifications available in the market to meet the job requirement envisaged? If the answer is yes, why the same can't be procured. Demanding Officer should bring out of comparative functional advantage/cost effectiveness of the recommended item from these offered by other.	No
6.	What were the efforts made to locate alternative source of supply of use other substitutes.	~~AYM~~ ~~ISM~~ Internet search was performed
7.	Why open/limited tender can't be resorted to, for locating alternative source.	~~MS~~ High Ends item to be procured from ~~national~~ multinational firm
8.	Are the proprietary items certifying that the rates are reasonable or not	The Equipment was purchased by the JPNTC, Vide S.O. No. 1607/TC/NS/M&E/14-15/FSC dated 30/03/2015
9.	Any other justification for procuring item from single source.	

Signature of Indentor

Counter Signed by
Head of the Department
Dr. R. MALHOTRA
MBBS, MS (Ortho), FRCS, FACS, FICS, FIMSA
Professor & Head
Department of Orthopaedics
A.I.I.M.S., New Delhi-110029

I certify that the item at Sr. No. 1 above is required to be procured on single tender basis as the source of supply is definitely known/the specified brand proposed was advantages in meeting our functional requirements and limited tender system could be dispensed with as they would serve no useful purpose in this particular case.

(Strike out whichevere is not applicable.)

Dr. Bhavuk Garg

Dr. P.L. Nag

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Dr. A.K. Jaryal

Dr. Anoop Dogra

Dr. Akanksha

Intra Operative Neural Monitoring System

The system should be a portable, laptop based Intra-operative 32 channel Neuro-monitoring system, with capability to monitor critical neural pathways during critical surgeries.

A. The system should be capable of:

1. Surgeon controlled/directed and neurophysiologist –support capabilities in one system.
2. Portable Laptop-based system.
3. Integrated remote monitoring capabilities.
4. Electronic or hard copy screen shot storage.
5. Electronic data storage of the entire procedure including EMG audio.
6. Electro-surgery unit (ESU) interference muting.
7. 32 channel neurological monitoring for intraoperative applications.
8. Comprehensive EEG, EP and EMG monitoring with up to 32 independent channels.
9. All EP modalities including SSEP, MEP, AEP, BAEP, VEP.
10. Should allow adding any modality or channels while a running test without stopping or pausing the monitoring.
11. Should be SD + NS. SD mode should also incorporate feature of SD advanced option which shall allow few advanced parameters of NS module to be used in SD mode for higher end applications.
12. Should have built –in pulse oximeter.
13. Should be a minimalist system.
14. 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.
15. Secondary windows should have 2DVR feeds, 2 timers and should allow the user to change the color of the traces.
16. Must be capable to adjust the display with multiple windows of different modalities to be dragged, dropped, resized, maximize and minimize.
17. The free running modalities like EMG should always be running.
18. Stimulators run all electric modalities.
19. EMG audio is able to be recorded and reviewed.
20. Up to 16 multimodality sets can be defined within test protocol.
21. Free running, averaged or signal triggered data collection modes.
22. All trace parameters (Filter, amplifier gain, artifact rejection, time base, display scale, Etc) should be fully user adjustable and independent.

23. Data can be saved manually or automatically as continuous EEG, free run EMG, Triggered EMG, EMG Audio , Updated averaged EP, Screen snapshots and video.
24. Previously saved data can be reviewed while monitoring. Review data locally or remotely via network, modem or internet.
25. Standard test protocols are provided and can be modified and saved by user.
26. All patients connections are both software and hardware and hardware protected against faults.
27. Automatic pedicle screw integrity test mode.
28. Module for easy EMG & MEP testing from the sterile field.
29. Built in Pulse oximeter.
30. Independent, high and low electrical stimulators for peripheral and direct nerve monitoring. Extensive stimulus triggering including repetitive, non-repetitive, single pair and train.
31. Fast and slow charge TCeMEP stimulation mode.
32. Data can be saved automatically (continuously, at predefined intervals or event triggered) or manually.
33. Remote monitoring via modem, LAN or internet.
34. Reports can be automatically generated for every test and contain all necessary test information and additional user -specified information.
35. Complete range of accessories and disposables for all monitoring modalities.

B. System should be able support below mentioned surgeon controlled/directed features :

1. System should be operable by the operating surgeon from the sterile field via a sterile probe which allow surgeon to increase or decrease current, change the monitoring test mode and print reports.
2. An exclusively dedicated 8-Channel module (pre-amplification and stimulation in a single box) capable of recording EMG, Trig EMG, Screw testing, Nerve Proximity, MEP and train of four modalities.
3. Option of 2-channel pulse Ox recording.
4. Automated report generation for pedicle screw stimulation.
5. System should provide full control to surgeon from the sterile field with the help of surgeon controlled probe having buttons to give access to system parameters and test modalities
6. Probe should allow the surgeon to select the modality, adjust the current and deliver the stimulus directly from the sterile field.

7. Probe's multicolor LED indicates test results.
8. Multiple manual and triggered EMG modes of operation
9. Audible and visual feedback to surgeon.

C. Should at support below mentioned neurophysiologist –support features.

1. Simultaneous 32-channel EP (MEP, SSEP, VEP, BAEP, Etc.), EMG and EEG monitoring.
2. Built-in , fast –charge TCeMEP with double –train stimulation.
3. 2-channel Pulse Ox capability.
4. Automated pedicle screw testing.
5. Surgeon's microscope view.
6. Simultaneous multisite remote monitoring and review.

D. Should at least support below mentioned Nerve Proximity test Screen.

1. Provide audio tone feedback indicating proximity to a nerve root.
2. Program automatically changes stimulation intensity while searching for an EMG response.
3. Should provide all neural monitoring instruments for XLIF procedure along with audio tone feedback.

E. Should at least support below mentioned screw test capabilities.

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

F. Should have Nerve Root Test Screen.

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

G. The system should be US FDA Approved.

To the best of knowledge of the committee, the above specifications are proprietary in nature.