Admn/Prop/48/2018-AIIMS.JDH Dated: 30th October, 2018

Subject: Purchase of Image Guided Navigation System for the department of ENT at AIIMS, Jodhpur on proprietary basis - **Inviting comments thereon.**

The Institute is in the purchase of Image Guided Navigation System for the department of ENT at AIIMS, Jodhpur from M/s India Medtronic Pvt. Ltd, 1241, Solitaire Corporation Park, Building No. 12, 4th Floor, Andheri-Ghatkoopar Link Road, Mumbai on proprietary basis. The proposal submitted by M/s India Medtronic Pvt. Ltd, Mumbai and PAC certification by user are attached.

The above document are being uploaded for open information to submit objection, comments, if any from any manufacturer regarding proprietary nature of the equipment within 21days of issue giving reference Admn/Prop/48/2018-AIIMS.JDH. The comments should be received by office of Administrative Officer, Medical College at AIIMS, Jodhpur on or before 20th November 2018 upto 03:00 PM 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,

Administrative Officer

Enclosed: Related documents enclosed.

Medtronic

India Medtronic Pvt. Ltd.
CIN: U33110MH1993PTC204814
1241, Solitaire Corporate Park,
Building No.12, 4th Floor
Andheri-Ghatkopar Link Road,
Andheri (East), Mumbai – 400 093, India
www.medtronic.co.in

tel +91-22-33074700/1/2/3
fax +91-22-33074704

Date: July 24, 2018

AIIMS, JODHPUR
Receipt No. 9695
Date 30/7/2018

To,
The Administrative Officer,
All India Institute of Medical Sciences,
Jodhpur, Rajasthan.

Subject: PROPRIETARY ARTICLE CERTIFICATE
Ref: Tender No: (Admn/Tender/165-2/2017AIIMS.JDH)

This is to certify that Medtronic Stealth station S8 is the proprietary item of Medtronic. The below mentioned points are unique and proprietary features of Medtronic Stealth station S8 Navigation System:

1. The Stealth station S8 system is a Two Monitor and Two Cart System. The system has the facility of keeping optical camera and viewing system together or separately to allow optimal use of O.T space.

2. The Stealth station S8 system have the options of both Flat Emitter and Side Emitter to support the workflow of the surgeries. It will help surgeon to operate complex ENT surgeries like Skull Base with ease.

3. The Stealth station S8 system has the option of working with Factory Calibrated Navigable malleable suction that allows surgeon to operate in complex anatomies.

4. The Stealth station S8 system has the provision of Rapid data transfer directly to the navigation station with the option of CD-RW/DVD-ROM combo-drive and USB 2.0 port for direct data import as well.

Thanking you,

Yours Sincerely,

for and on behalf of India Medtronic Pvt. Ltd

Rahul Arora
2018.07.24
12:49:51
+05'30'

Rahul Arora
Country Sales Manager | Neurosurgery

Regd. Office 1241,Solitaire Corporate Park, Bldg No.12, 4th Floor Andheri-Ghatkopar Link Road, Andheri (East) Mumbai 400093 Ph: +91-22 33074700 Fax: +91-22 33074704

Medtronic

India Medtronic Pvt. Ltd.
CIN: U33110MH1993PTC204814
1241, Solitaire Corporate Park,
Building No.12, 4th Floor
Andheri-Ghatkopar Link Road,
Andheri (East), Mumbai – 400 093, India
www.medtronic.co.in

tel +91-22-33074700/1/2/3
fax +91-22-33074704

Date: July 26, 2018

AIIMS, JODHPUR
Receipt No. 9696.
Date 30/07/2018

To,
The Administrative Officer,
All India Institute of Medical Sciences,
Jodhpur, Rajasthan.

Subject: Additional point of Stealth S8 Navigation system.

Dear Sir,

We would like to inform you that Stealth S8 Navigation system has following additional features mentioned below:

1. The Stealth station S8 system has the option of supporting Factory Calibrated Navigable Drill system which is compatible with the existing Integrated Power Console (IPC) at ENT Department of the AIIMS Hospital, Jodhpur.

2. The Stealth station S8 system has the option of working with Factory Calibrated Navigable Micro-debrider blades that is compatible with existing Straight-shot M4 Micro-debrider and Integrated Power Console system (IPC) at ENT Department of the AIIMS Hospital, Jodhpur.

Thanking you,

Yours Sincerely,

for and on behalf of India Medtronic Pvt. Ltd

Rahul Arora
2018.07.26
16:01:37
+05'30'

Rahul Arora
Country Sales Manager | Neurosurgery

Regd. Office 1241,Solitaire Corporate Park, Bldg No.12, 4th Floor Andheri-Ghatkopar Link Road, Andheri (East) Mumbai 400093 Ph: +91-22 33074700 Fax: +91-22 33074704

S. No.	Item	Technical Specifications	Qty
01.	**Image Guided Navigation System**	**Navigation System for ENT** The System should be easy to set up, user friendly, intuitive and should work under Linux/UNIX/Windows operating system environment. The system should have Optical Tracking technology along with Electromagnetic Tracking option. The system should have facility of keeping optical camera and viewing system together or separately to allow optimal use of O.T. space, the system should have two monitors and two cart system. The Surgeon Monitor should be high resolution (1920 x 1200, 60 Hz) with a viewable size of =/>23 inches and the display should be visible at angles at least up to 80° or more. The systems should be plug & play with user friendly system software to control set up, registration and navigation. It should be capable of performing multiple types of registration in less than three minutes. Improved camera designed with greater field of view, a long camera handle, and laser pointer for easier positioning and aiming. It should have total surgical control in sterile field on a fingertip with a touch screen monitor/or optical mouse. It should have provision of Rapid data transfer directly to the navigation station with the option of CD-RW/DVD-ROM combo-drive and USB (preferably 3.0) port for direct data import as well. Minimum 1TB storage facility should be provided with the unit. Capable of playing endoscopic and microscopic videos on monitor and also virtual endoscopic facility. Screenshots and Screen recorder facility should be there. Should be connectable with OT monitor with appropriate cable. The navigation system should be operable with or without keyboard and mouse. The Software should be versatile and should support Functional Endoscopic Since Surgery (FESS) procedure, complex cases such as Coronal flaps and Lateral Skull base procedures and simultaneous tracking of multiple instruments, at least three. The System should be supplied with patient tracker/marker and Custom sterilization tray, which should be autoclavable/reusable. **General Software/Application Specification** The system should have complete ENT and skull base surgery, navigation and its application package. Display of predefined trajectory pathway in line and probe views. The software fuses axial, coronal and sagittal image sets of different modalities (CT & MRI). It should have universal instrument adapters with markers to allow tracking of any existing hospital instruments like drills, bipolar, knife, probe, microdebrider and endoscopes. Calibration of existing instruments should be done automatically (if, applicable). **Cranial Application** Should have user friendly Cranial application software with Tumor and Frameless Biopsy software applications built-in the system Should have facility for marker less registration	01

			The navigation system should have point as well as surface registration with accuracy prediction system It should have universal instrument adapter tracking system with active & passive option The system should include a frameless biopsy system with needles (5 disposable needles should be supplied with the system). The System should be capable of interfacing with all major microscope systems, if required in future. The navigation system should have the software for stereotactic surgery including functional stereotactic procures. The software should re-orient the scanned images along the AC-PC plane. The stereotactic system should be adaptable to major frames like Leksell and CRW. The system should have 3D graphics capability and software to merge CT & MRI images. Look ahead view capability to show the images at 1mm to 20mm (increments of 1mm) in front of the probe. The navigation software should be able to correlate with pre-operative MR/CT images. These images should have view side by side or overlaid. The cranial software should be capable of advanced visualization of the cortical surface, skull, vessels and ventricles. All the instruments, trackers/markers should preferably be Autoclavable. (Desirable Instrument Calibration Matrix. Device for instant intraoperative calibration of length, diameter and vector of a rigid instrument along with adapters of different sizes for different instruments). Registration probe Straight probe Straight suction 70-degree curved suction 90-degree curved suction (preferable) Two Malleable Suctions Pointer instrument for ear surgery Osteum Seeker Four navigable debrider blades (two straight and two angled) Sterlisation tray Navigation sensor at the tip of instruments to allow intraoperative bending without new calibration. Head frame-kit tracker/markers, pad, adhesive, FESS tracker The virtual tip should be differentiated from real tip by color/dotted lines. The system should have registration with accuracy prediction system. The system should warn the surgeon by color change/audible signal when approaching the critical areas/the system should have dynamic visualization of distance to target point and intra-operative landmarks or the system should have still photographs storage function as well as continuous video recording for documentation purpose, With appropriate cables/ adopter and connections for laptop and existing medical monitor, Cart/Movable trolley for housing should have an inbuilt storage capability. **EM Navigation System** ENT Navigation Software should support navigated cases for various ENT Cases. Should have surface registration and landmark registration.	

		Software should have a user interface designed for intraoperative touchscreen control. Should offer Real-time tracking and 2D/3D visualization of a pointer and up to 3 instruments simultaneously in various views. Should desirably have a pointer remote control of complete workflow, enabling full control of navigation system out of sterile field. Software should offer freeze functionality and screenshot documentation. Software should also have animated workflow guidance for easy setup and instrument calibration. Should support flexible patient referencing to help with positional independence. Should support free positioning of field generator around patient's head. Software should have ENT optimized screen layouts with automatic overlay of CT and MR scans when fused, with 3D sinus probes eye view or direct comparison of two different scans. Planning tool for trajectories (entry and target point). Software should have Auto-zoom in to tool tip for magnification of target area. System should have Interactive display of patient data including windowing adjustment. The system should have the options of both flat emitter and side emitter to support the workflow of the surgeries and both should be provided. The flat panel electromagnetic generator is one which can be positioned under patient's head and over the table in order to minimize table metal interference and side mounted electromagnetic generator is one which can be attached to the table side rail. Software should provide Point-to-surface distance indication of tracked instruments. Should have wired/wireless electromagnetic standard instrument for unsterile patient registration, which can be used in both anatomical landmark and surface matching registration. Should have wired/wireless electromagnetic sensor for flexible patient referencing. Should have skull reference base which enables flexible patient re-positioning and head movement for free positioning and variable fixation direct to bone structures. Should have disposable/reusable wired/wireless electromagnetic standard instrument for patient registration and navigation suitable for multiple surgeries. If disposable, minimum 10 sets of disposable instruments should be provided with the unit. **General** The company must have at least five successful ENT installations in India and list of the same should be supplied. There should be facilities to upgrade the system to be compatible with PACS system. Demonstration of navigation system is must to the satisfaction of user. Proper training OT technical staff by the company person. Company should provide European CE or US FDA approval certificate for the quoted model. Should have facility to integrate third party instruments, with the universal adapter for various sizes and shapes of instruments. If	

		disposable, minimum 10 sets of disposable instruments/consumables should be provided with the unit. Unit cover should be provided. The data sheet of disposables, if any, should clearly indicate the number of times it can be used and the manufacturer should provide a written authorization to that effect as well. The price of all the disposables/consumables FOR ENTIRE SYSTEM QUOTED should also be quoted separately, apart from combined unit, to be used in future for procurement and freezed for next five years. The company will provide software/technological updates to the entire supplied unit for next five years, free of cost. UPS of suitable power and standard make, with minimum 20 minutes of backup should be provided.	