All-India Institute of Medical Sciences
Ansari Nagar, New Delhi-29.

(STORES SECTION (DO)

Dated: 29.04.2017

Ref. No.51/Stores (DO)/Ortho/PAC/2016-17/FSC

Subject: Proposal for purchase of O-Arm (Complete Multi-Dimensional Surgical Imaging System) on Proprietary basis (PAC) for department of Orthopedics at AIIMS - Inviting comments thereon.

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The Institute is in the process to purchase **O-Arm (Complete Multi-Dimensional Surgical Imaging System)** on Proprietary basis (PAC) for department of Orthopedics at AIIMS, New Delhi-110 029 from M/s.Medtronics Trading NL BV, The Netherlands through their authorized Indian subsidiary Agent M/s.India Medtronic Pvt. Ltd., Mumbai-400 093. The proposal submitted by M/s.India Medtronic Pvt. Ltd., Mumbai-400 093, Specifications, PAC certificate, Patent Certificate quotation and other related documents are attached for ready reference.

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 **Ref. No.51/Stores (DO)/Ortho/PAC/2016-17/FSC.** The comments should be received by office of Sr. Stores Officer, Stores Section (DO), Animal House Building, Near Biotechnology Building at AIIMS on or before **16.05.2017 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

Encl: Related documents enclosed.

Specifications for O-Arm (Complete Multi-dimensional Surgical Imaging System)

1. It should have a 360° scan and should be motorized with more than 100 images and two levels of 3D slice thickness.
2. It should have a Telescoping door section for lateral patient access
3. The Imaging components should be in enclosed housing for increased patient and staff safety
4. It should be Fully functional with no component movement in and out of sterile field
5. It should have a High resolution fluoroscopy (> 40 Lines/inch. in low dose mode)
6. It should have High resolution in 2-D and 3D - Axial, Coronal, Sagittal planes.
7. It should have 15-20 kW to 30-32 kW X-ray generator for imaging dense anatomy
8. It should have Large (> 29") diagonal with minimum of 3 mega pixel resolution display for superior viewing at a distance.
9. It should have the Ability to go 'full-screen' on any image for superior viewing at a distance.
10. It should have a Wireless, sterile mouse control of image viewing.
11. It should have a Robotic positioning system in 6° of freedom.
12. It should have the Ability to position x-ray tube on either side of patient in lateral 2-D imaging for decreased surgeon exposure.
13. It should have a Storage of pre-set imaging positions for quick, accurate access to commonly viewed images, avoiding the need for re-scouting.
14. It should have storage of pre-set positions for easy access to patient while imaging is not required.
15. It should have a Power drive for easy handling of imaging system.
16. It should Utilize >30 x >25 cm digital flat panel detector, >3 megapixel for increased image quality (large field of view, square images without distortion.
17. It should Complete 3-D image acquisition in <15 seconds.

Specifications for O-Arm (Complete Multi-dimensional Surgical Imaging System)

18. The 3-D image should be displayed in less than 30 seconds from initiation of acquisition.

19. The Bore diameter of the imaging system should be more than 75cms.

20. The source to image distance should be approximately 40".

21. The imaging system should have a provision for selecting region of interest for automatic brightness and window/level control.

22. The imaging system should have a automatic noise reduction, edge enhancement, full screen zoom, digital image rotation, digital window/level control, left/right and top/bottom image reversal, positive/negative image inversion.

23. The imaging system should be able to store more than 10,000 2D images and more than 200 3D scans on hard disk.

24. The imaging system should have a CD R/W and USB port.

25. There has to be various outputs like Ethernet, USB, Composite video, S- video.

26. The imaging system should have the latest DICOM standard compliance.

27. The imaging system should offer two levels of operation allowing optimal slice thickness/reconstruction time selection based on the clinical application.

28. The imaging system should offer 15x20cm volume cube or more anatomical coverage .

29. The imaging system should have different types / features of rotation like Orbital, pivot, swivel, Iso-wag.

30. Suitable imported radiolucent carbon-fiber spine table extension should be provided along with the Multi-dimensional Surgical imaging System.

31. The system should be CE and USFDA approved.

32. It should be supplied with navigable spine instrumentation sets for complete navigable spine procedures of cervical spine, minimally invasive lumber spine and inter-body fusion etc.

33. On board hard drive (4TB) for data archival and retrieval on USB pen drive/USB portable hand disc drive/DVD/RW.

34. The system along with existing navigation(Medtronic)should be able to provide coronal, axial and sagittal cuts with navigated access.

Specifications for O-Arm (Complete Multi-dimensional Surgical Imaging System)

35. The Multi-Dimensional Surgical Imaging System should be compatible with image guided surgical navigation system with auto-registration facility existing.

Accessories:

1. Lead Apron (.5mm lead Eq.) 10 Nos., stuffed shoulder pad
2. Thyroid Shield 10 Nos.
3. Gonadal Shields 10 Nos.
4. Lead Goggles 10 Nos.
5. Slim LCD view box 3x1 films 6.
6. Online UPS for appropriate rating for 15min back up
7. Allan Flex Frame – 1
8. LED 46" thin client monitor – 1
9. Radiation mobile shield – 1
10. Training on imaging system should be provided to 10 ortho surgeons in batches available onsite.
11. One year supply of all disposable should be supplied (included 400 disposable drapes for the Imaging System and 600 glion). Prices of all disposables required for the imaging system and image guidance should be quoted at the time of price bid and will be frozen for 5 years.
12. Registration of equipment and site plan approval will be the responsibility of the vendor. The institute will provide necessary documents.
13. The vendor will post a technical person for about 500 cases in the OT for the smooth functioning of the system on all working days.
14. It should have universal instrument adapter tracing system for navigation.
15. The system should have image guided spinal instruments like short drill guide, Awl/Probe/Tap System with straight or T-handles option (two each).
16. System should have completed cervical, dorsal as well as lumbosacral spine navigation instruments and facility.
17. The imaging system should have DICOM ready functions and full DICOM compatibility. It will be the responsibility of the vendor to seamlessly integrate the system with the future PACS network of Orthopaedics, AIIMS.
18. Free upgradation of software for 10 years.

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

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

PROPRIETORY/SPECIFIC BRAND GOODS CERTIFICATE

1.	Item/Type/Model No. required alongwith specifications.	O-Arm (Complete Multi-Dimensional Surgical Image 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 Trading NL BV, Netherland
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.	No
7.	Why open/limited tender can't be resorted to, for locating alternative source.	No
8.	Are the proprietary items certifying that the rates are reasonable or not	The Equipment was purchased by the C.N.C., AIIMS, New Delhi Vide Supply Order No. 100-11/CNC/NS/2014-15/St in the Year of 2014
9.	Any other justification for procuring item from single source.	

Signature of Indentor

Counter Signed by
Head of the Department
DR. M. 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.)

DEPARTMENT OF ORTHOPAEDICS
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI - 110029

DR. RAJESH MALHOTRA
Professor and Head

Ph. 011-2659-3341
011-26588-407

O - Arm

(Complete Multi-Dimensional Surgical Image System)

Ref: No. 51/Stores (DO)/Ortho/PAC/2016-17/FSC

The effort was made by searching the internet for O - Arm (Complete Multi-Dimensional Surgical Image System) but no other company was found making this product.

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

Dr. Bhavuk Garg

Prof. H. L. Nag

Dr. Anoop Daga

(2)

Medtronic

Medtronic Surgical Technologies
826 Coal Creek Circle
Louisville, CO 80027
www.medtronic.com

tel 720.890.3200
fax 720.890.3500

February 12, 2014

Re: Sole Source – Proprietary Certificate

To whom it may concern:

I hereby affirm, to the best of my knowledge, that Medtronic Navigation, Inc. is the sole manufacturer, seller and distributor of the O-arm® Intra-operative Imaging product covered by the US patents listed below:

6,940,941
7,108,421
7,001,045
7,106,825

By signing this certificate, I am attesting to the facts listed above to the best of my knowledge.

Sincerely,

John F. Thompson
Senior Legal Director
Medtronic Surgical Technologies
826 Coal Creek Circle
Louisville, CO 80027
(720) 890-3200

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: April 12, 2017

To

The Director
AIIMS,
Ansari Nagar,
New Delhi

Dear Sir,

We, India Medtronic Pvt. Ltd. are proven and reputable manufacturers of **O-Arm® system having registered office at 1241, Solitaire Corporate Park, Andheri–Ghatkopar Link Road,Andheri (East)Mumbai – 400 093, India** hereby like to inform you that we are the only company which manufacture this equipment in the world.

For India Medtronic Pvt. Ltd.

Rahul Arora
2017.04.12
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Rahul Arora
Country Manager Sales Xomed and Navigation (ISC)

DEPARTMENT OF ORTHOPAEDICS
ALL INDIA INSTITUTE OF MEDICAL SCIENCES
ANSARI NAGAR, NEW DELHI - 110029

DR. RAJESH MALHOTRA
Professor and Head

Ph. 011-2659-3341
011-26588-407

24th January 2017

A meeting of Technical Specification and evaluation Committee for finalizing the specifications for floating the tender for **"O-Arm (Complete Multi-Dimensional Surgical Image System)"** held on **24th January 2017** at **03:45 PM** in Room No. 5036-A, Fifth floor, Teaching Block, Department of Orthopaedics.

The following Officers attended the meeting:

Sr. No.	Name and Designation	Signature
1.	**Dr. Rajesh Malhotra** Professor and Head, Department of Orthopaedic, AIIMS	
2.	**Dr. H. L. Nag,** Professor of Orthopaedics, **Nominee of SPC (Chairman)**	
3.	**Dr. Devasenathipathy K.** Associate Professor, **Nominee of Dr. Arun Kumar Gupta,** Professor and Head, Department of Radio-Diagnosis, AIIMS, New Delhi	
4.	**Dr. Manish Chadha** *(External Expert)* Professor of Orthopaedics, UCMS and GTB Hospital, Delhi	
5.	**Dr. Anoop Daga,** Associate Professor **Nominee of (M.S.), AIIMS**	
6.	**Dr. R. K. Chopra,** Director, Professor, C.I.O, Sardarjung Hospital, Delhi, **Nominee DGHS**	24/1/17
7.	**Dr. Bhavuk Garg,** Assoc. Prof. of Orthopaedics, AIIMS (Special Invitee)	

Medtronic

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

Date: 18th April 2017

Doc. No:- IMPL/NT/AIIMS-ORTHO/01/17-18

Subject : Offer for "The O2 Imaging System".

Respected Sir,

At the outset, we thank you for your patronage of our product range in various applications. As you may be aware, Medtronic®, Inc., is the world leader in medical technology providing lifelong solutions for people with chronic disease. We offer products, therapies and services that enhance or extend the lives of millions of people, and help them resume everyday activities, return to work, and live better, longer. Our technologies are used to treat conditions such as neurological and spinal disorders, ear, nose and throat conditions, cardiac disorders, and vascular illnesses.

Medtronic Neurosurgery Division develops innovative surgical devices and implant therapies for the treatment of various cranial, spinal, and orthopaedic conditions. We strive to bring procedural intelligence and smart instruments to surgery that enable intraoperative precision, visualization, surgical access, navigation, and imaging. These solutions assist in the areas of spinal disorders, neuro-oncology, deep brain stimulation, neurovascular diseases, CSF management, and pelvic or cranial trauma.

The O-arm Surgical Imaging System is a multi-dimensional surgical imaging platform that is designed for use in spine, orthopaedic, and trauma-related surgeries. It provides real-time, intra-operative imaging of a patient's anatomy with high quality images and a large field-of-view in both two and three dimensions.

By integrating O-arm surgical imaging technology with Medtronic's Stealth-Station surgical navigation systems, surgeons are able to improve visualization to complete complex and MIS procedures and confirm the accuracy of advanced surgical procedures before the patient leaves the OR.

We are offering herewith our Surgical navigation system which helps improve clinical outcomes by enabling neuro-spine surgeons to quickly and effectively make data-driven surgical decisions in the Operating Room. By integrating the most advanced instrument tracking technologies, intra-operative imaging and surgical planning software, our surgical navigation systems allow surgeons to precisely track their surgical instruments in relation to patient anatomy. These technologies help surgeons:

- Perform safer, more precise procedures
- Reduce procedure invasiveness and risk
- Improve patient outcomes and recovery

With over 600+ O-arms, 7000+ S7 surgical navigation systems & 2000+ Axiem Navigation Systems installed worldwide, Medtronic Navigation's success is predicated upon a number of factors, including a well-funded and committed research and development program. We hold a broad array of patents related to computer-assisted surgery, as well as a large number of commercially available applications for computer-assisted surgery.

We are happy to submit herewith our Commercial Offer for the "The O-arm® O2 Imaging System as per our discussions held recently, for your esteemed Institute. We hope you would find our offer suitable for your requirements. Please feel free to get back to us in case of any clarifications necessary.

Thanking you and assuring you of our best services always,

For India Medtronic Pvt. Ltd.

Rahul Arora
2017.04.18
15:11:27 +05'30'

Rahul Arora
Country Manager Sales Xomed and Navigation (ISC)

Medtronic

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

Date: 18th April 2017

Doc. No:- IMPL/NT/AIIMS-ORTHO/01/17-18

Subject : **Offer for "The O2 Imaging System".**

Respected Sir,

S/N	Description	Qty (Units)	Unit Price in USD
O-Arm® O2.0 Multidimensional Intraoperative Imaging System			
A	O-ARM® O2.0 Multidimensional Intraoperative Imaging System	1	$ 710,000.00
	Total Price		**$ 710,000.00**

We hope you would find our offer suitable for your requirements. Please feel free to get back to us in case of any clarifications necessary.

Looking forward for your valuable order.

Thanking you and assuring you of our best services always,

For India Medtronic Pvt. Ltd.

Rahul Arora
2017.04.18
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Rahul Arora
Country Manager Sales Xomed and Navigation (ISC)

A. O-Arm® Multidimensional Intraoperative Imaging System			
Console / Hardware O-arm®			
1	BI-700-02000	O-ARM® O2.0 BASE UNIT Inclusive of :	1
a	BI-750-00027	O2 System Navigation Interface	1
b	BI-750-00028	O2 System Remote Pendant	1
c	BI-750-00029	O2 System High-Definition 3D - HD3D	1
d	BI-750-00030	O2 System Advanced Viewing	1
e	BI-750-00031	O2 System Iso-Wag Rotation	1
f	BI-750-00032	O2 System Collimated Axial 3D	1
g	BI-750-00033	O2 System Enhanced Cranial 3D - EC3D	1
h	BI-750-00034	O2 System Multiple FOV	1
i	BI-750-00035	O2 System Stereotaxy	1
j		LASER ALIGNMENT	1
k		IMAGE STICHING	1
2	9732722	O-arm® Sterile Tube Drape - 20 In a Pack	15
3	9732721	O-arm® Sterile Mouse - 10 In a Pack	1

TERMS and CONDITIONS		
1	ORDER	Order is to be placed on : Medtronic Trading NL BV Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherland Tel: +31-45-5668272 Fax: +31-45-5668024
2	PAYMENT	100% Irrevocable and confirmed L/C at sight, **Note : Trans-Shipment / Partial Shipment must be allowed in LC terms** Beneficiary: Medtronic Trading NL BV Earl Bakkenstraat 10, 6422 PJ Heerlen, The Netherlands Bank Details for Establishing L/C. ING LC Handling Afdeling Documentenzaken, Postbus 1441, 1000BK Amsterdam, The Netherlands ING Bank SWIFT Code : INGBNL2A / Account No: 0020084110
3	DELIVERY	Within 10-12 weeks from date of Purchase Order and receipt of confirmed ,and Irrevocable L/C
4	CUSTOMS DUTY / Clearance and Handling Charges / Local Transportation	Would be applicable at actuals and to be borne by the Hospital at current custom levies.
5	OCTROI / ENTRY TAX/ LOCAL TAX/ MUNICIPAL TAX	Would be extra if any, and to be borne by Hospital.
6	WARRANTY	The period of warranty applicable on the hardware/software is 60 months from the date of installation or 62 months from the date of invoicing whichever is earlier from the date of invoicing whichever is earlier, against any manufacturing defect / workmanship under company recommended norms of usage/environment. Usage of any unauthorized accessories, hardware, consumables or software will deem the warranty null and void. The equipment shall be solely used for the purpose it is designed by the manufacturer and no unauthorized personnel shall have an access to the system during the entire warranty period.
7	Validity of Quotation	Upto 31st March 2018

8	FORCE MAJEURE	Any failure of omission or commission to carry out the provision of the contract by the supplier shall not give rise to any claim by any party, one against the other, if such failure of omission or commission arises from an act of God, which shall include all acts of natural calamities such as fire, flood, earthquake, hurricane or any pestilence or from civil strikes, compliance with any stature and/or regulation of the Government, lockouts and strikes, riots, embargo or from any political or other reasons beyond the supplier's control including war (Whether declared or not) civil war or state or insurrection, provided that notice or the occurrence of any event by either party to the other shall be given within two weeks from the date of occurrence of such an event which could be attributed to Force Majeure conditions

For India Medtronic Pvt. Ltd.

Rahul Arora
2017.04.18
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Rahul Arora
Country Manager Sales Xomed and Navigation (ISC)