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

Ref. No. 14/Stores(DO)/Ortho/PAC/2019-20/FSC Dated-28/09/2019

Sub:- Purchase of "**Mobile Intra-Operative 32 Slice CT with Integrated Table Column and Compatible & fully Integrated Advanced Navigation System – 01 Unit**" for the Department of **Orthopedics** at AIIMS, New Delhi-110029, on proprietary basis Inviting comments thereon.

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The Institute is in the process to purchase "**Mobile Intra-Operative** 32 **Slice CT with Integrated Table Column and Compatible & fully Integrated Advanced Navigation System – 01 Unit**" at AIIMS, New Delhi from **M/s. Brainlab, Ag, Germany.** The PAC Certifications by **M/s. Brainlab, Ag, Germany** 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. **14/Stores(DO)/Ortho/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 **17/10/2019** 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.

Mobile Intra-Operative 32 Slice CT with Integrated Table Column and Compatible & fully Integrated Advanced Navigation System

1. **Intraoperative mobile CT**:

a) The system should be a 32 Slice mobile CT scanner for Spine & Trauma application. The imaging should be thin section and of high quality
b) The System should have an Image reconstruction matrix of at least 512 x 512
c) The system should have:
   i. X-ray Tube Voltage : up to Min 120 kV
   ii. X-ray Tube Current: up to 250 mA or more
   iii. Focal Spot: 1mm X 1mm or more
d) The system should be able to run on standard single phase 220 V AC.
e) The system should have a bore size of 107 cm or more for versatile patient positioning for Spine and Trauma cases
f) The X-Ray detector system should have solid state detector with 2.0 mm detector width to generate multi slice CT images of soft tissue and bone for Spine
g) The system should have air cooling ducts at the bottom side of gantry to minimize interference with OR sterility.
h) The system should have the capability for both Axial & Helical Scans
i) The system should allow motorized transportation with a front view camera for easy movement of the system between different Operating Rooms thus adding to its higher utilization
j) The System should seamlessly integrate with the surgical navigation system in a way that it allows for a seamless intra-operative automatic image registration workflow which allows the surgeon to automatically register the patient by taking either a pre-operative scan for initial automatic registration or an intra-operative scan to compensate for the intra-operative anatomical changes. The automatic registration should work in a way that the acquired images should be available immediately for navigation without requiring any manual registration or intervention for Spinal procedures
k) The system should have built-in battery and it should have adequate cables for recharging as and when required. |) The system should have a minimum scan range of one meter which allows to image the entire spine in one scan.
l) The system should be supplied with respective calibration devices to check the CT parameters and Quality control
m) The system should have a very small footprint for easy transportation through standard doors and lifts; the maximum dimension during transport mode should be L x W x H: 230x60x197 cm and weight should not be more than 1000 kg in transport mode
n) System should be operable with a hand held touch control panel for imaging, transport, service and calibration hence does not need a separate console cart
o) The mobile CT image reconstruction speed should be minimum 24 images per second
p) The system should support DICOM for connectivity and should have the capability to transfer the scans to navigation system or PACS

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Mobile Intra-Operative 32 Slice CT with Integrated Table Column and Compatible & fully Integrated Advanced Navigation System

q) The system should come with a fully integrated patient table column which helps in precise scan movement of gantry on the rails (not on floor) relative to integrated patient table thereby ensuring reproducible scan results. The Integrated radiolucent patient scanning table to be supplied as per following specification:
   i. The table should be provided with a shuttle system for the movement of the patient on the OR table top.
   ii. The table should be radiolucent with a flat carbon table top for taking CT scan without artifacts. All positions by a wireless remote s)
   iii. It should have an adjustable column height range of 490mm or less to 1040 mm or more V. It should have a Trendelenburg + 65° electrically motorized
   iv. Lateral tilt : +/- 30°
   v. Column rotation: 0° to 360°
   vi. Table should allow patient weight of 180 KG or more.
   vii. All required table attachments/accessories should be supplied for spine imaging The CT system should be AERB approved

2. High-end Image Guidance System

a) The system should be wireless based on Passive Marker Technology.
b) The Navigation platform should have 2 integrated touch screen monitor of minimum 27 inch each.
c) It should have a brilliant display quality with full HD resolutions (1920 x 1080 pixels per display).
d) System should have Mobile camera cart with telescopic stand and motorized joints for remote-controlled camera alignment. The Infrared camera should be extremely flexible in terms of providing for various adjustments to allow for various positions with camera height (67-254 cm) to allow flexible patient positioning & registration
e) System should have connection panel for plug & play connectivity e.g. with surgical microscopes, fluoroscopes, endoscopes, ultrasound etc. via state-of-the-art digital and analog video inputs supporting up to full HD resolution: 2xHD/SD-SDI up to 1080i/29.97fps, 2xComposite (CVBS, NTSC/PAL),1xS-video (NTSC/PAL)
f) System should also include 1x video output port with up to 3840 x 2160 px to connect an independent additional display as well as 1x DVI out for analog / digital video output.
g) Direct patient data transfer from/to 5xUSB (3 USB-2.0 & 2 USB-3.0) and CD/DVD+RW.
h) System should have fast simultaneous access to e.g. PACS/hospital network and integration with e.g. C-Arms via 2x high-speed network connection (up to 1 Gbit/s each)
i) System should have high-performance computer (Intel Xeon E5-1620 v2 3.7 GHz Central Processor Unit, 8 GB RAM memory and 512 GB SSD)
j) The navigation system should use passive markers without batteries. No disposal of hazardous materials is required after the use of the system
k) All requisite applications should be on the Navigation System and can be controlled with touch and/or with mouse and should not require any additional computer

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l) Navigation system should have a smart home button to ensure interchangeability between multiple windows at any given point of time as per surgeon discretion. Any changes made on attached window gets automatically updated into navigation window.

m) It should have Live Streaming of OR procedure capabilities inbuilt into the navigation system without requiring any other devices thus keeping the OT clutter free such as:-

- ❖ Live streaming should be possible using the Navigation touchscreen which can be viewed using the hospital network or web browser from anywhere.
- ❖ It should be possible to live stream video signal from the available HD camera (Room & OT camera), Endoscope, Microscope, Ultrasound etc. whichever is being used intra- operatively

n) It should have Digital Recording capabilities inbuilt into the navigation system without requiring any other devices thus keeping the OT clutter free such as:–

   a) It should be able to locally record the procedure in digital HD quality of any display content (e.g. navigation software, microscope or endoscope video).
   b) The system should allow storing of all recording to the USB, DVD or Hard disk once the procedure is finished
   c) It should also allow taking screenshot of the live procedures on the display using the touchscreen. All screenshots taken of the live streaming/ videos during the procedures should also be stored on the navigation system which can later be transferred to USB, DVD or Hard disk once the procedure is finished
   d) It should also have the provision of configuring to save of recordings, screenshots etc. on the hospital network

3. Spinal Navigation Specification

a) The system should be implant independent and pedicle screw implant from any implant vendor can be used
b) Real-time tracking and 2D/3D visualization of a pointer and of up to 4 instruments simultaneously in various views
c) Simultaneous navigation of two fused / co-registered datasets, including visualization of pre- planned objects and screws
d) System should capable of Intraoperative screw planning
e) The probe should have the capability to show images at 0 mm – 180 mm in front of it (Tool Tip Extension). The system should also have option for full and partial virtual screw display
f) System should integrate the existing instruments based on diameter, length and vector for tracking.
The system should allow the use of available rigid surgical instruments in OT like Surgical Awl and probe as navigated instruments after calibration Navigation instruments should also have Radiolucent Spine Reference Clamp to reduce artifacts in intra-operative navigated surgeries

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h) Spine Software should have the feature of Automatic Image Registration software for Spine that eliminates the need for manual registration and the problem of limited access to anatomical landmarks for an optimized and convenient workflow, especially after patient draping thus enabling automatic receipt and registration of spinal image data from Mobile CT.

i) Intraoperative images should be made available for navigation immediately after the scanning process for optimized surgical workflows. Implant placement and orientation of integrated instruments for the treatment of complicated procedures like scoliosis, spine tuberculosis, kyphosis and other deformities in spine should be visualized in real time. Initial scans or update scans including scout scans should be done at any time during the procedure.

j) The system should allow for Trajectory Planning for screw planning with capabilities to plan multiple trajectories before or during Spinal surgical approaches. Target and Entry should be displayed in DICOM image coordinates and diameters should be applied to access the exact type of implant for planned screws. Screws should be verified in various views like axial, coronal, sagittal, 'Probe' eye and inline reconstruction view.

k) The software should offers multi-rigid Image Fusion that is tailored to adapt spine curvature and match multiple vertebrae from MR-to-CT or CT-to-CT. It should enables multi-modality planning and intra-operative plan updates for Spine Image Guided Navigation procedures in conjunction with intra-operative CT. Multi-level vertebrae co-registration should base on multi- Region of Interest (ROI) rigid fusions. It should also supports interactive segmentation on new data sets, allows direct comparison of curvature corrected with rigid alignment results through toggling and should has a colored deformation grid which highlights local deformations for detailed inspection

l) The software should have Intuitive image viewing, manipulation and data enrichment. It should provide instantaneous, high-quality 3D visualization for analysis leading to increased diagnostic confidence of the surgeon. It should do the 3D volume rendering of CT, MR, PET, SPECT datasets, with presets for visualization of skin, bone, vessel, DRR and MIP. It should also do the Superimposition of 3D dataset visualization and surgical planning data (volume objects, trajectories and labeled points), 3D multi-planar reconstructions in multiple planes (axial, coronal, sagittal, oblique) and concurrent display of multiple medical image series with flexible hanging protocols. It should has features like, image annotations and measurement functions for distance, angles and circles, selection of region of interest to cut and zoom onto the relevant anatomical volume and crop functionality to cut viewing plane into 3D visualization along any freely definable direction

m) The software should offer intelligent, indication-specific Smart Views for spinal indications exploiting anatomical information from Anatomical Mapping. It should provide automatic, anatomically aligned multi-planar reconstructions along the spinal cord and assessment of pedicle anatomy. It should allow quick and easy estimation of screw dimensions and intraoperative or postoperative verification of screw placement.

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

4. Advanced Pre-operative Templating

a) The software should have a digital templating software with pre-operative implant planning for procedures like and Spine, Hip, & Trauma. Software offers advanced measurements and studies like- Cobb Angle, Vertebrae Labelling, clavicle angle, Coronal balance, Sagittal Balance, Lumbar lordosis angle, Spondylolisthesis, Pelvic radius angle, Sacral Obliquity, Spine slip angle, Spondylolisthesis, T1 tilt angle, Thoracic kyphosis angle and Thoracic Trunk Shift for Spine
b) Templating Software should offer Automatic Image Calibration and has hardware for calibration of digital image
c) The digital templating software should be open and supports all leading implants rather than lock- in for a single implant specific vendor. At any given point in time, surgeon can easily switch between digital templating and real-time navigation on the same navigation system. All Software should be on the navigation system itself and can be controlled by touchscreen system as per user preference

5. Standard, safety & Training

a) Should be US FDA approved & European CE certified.
b) Onsite operational training till the familiarity of system and satisfaction of end user shall be provided

6. Documentation

a) User Manual & Technical Maintenance manuals to be provided in English
b) The manufacturer must have sales support service center in the purchaser's country for immediate attending the trouble shooting.
c) System should be supplied with 5 years of comprehensive warranty. The bidders are to quote separately the CMC rate for next five years after completion of warranty.

7. Maintenance Service during Warranty Period

During the warranty period supplier must ensure 4 planned preventive maintenance (PPM) along with corrective/breakdown maintenance whenever required.

8. Technical support & properly qualified Technician should be provided for first 500 Cases.
All disposable including the navigation for first 100 cases should be provided.

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10. Lead paneling & all requirement for AERB approval including periodic quality assurance tests will be of vendor's responsibility

ACCESSORIES:-

1. Lead apron (Zero-Lead) (0.5 mm 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 15 min. backup
7. LED 46" thin client monitor - 01 No.
8. Radiation mobile shield - 01 No.
9. Training on imaging system should be provided to 10 ortho surgeons in batches available onsite.
10. 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.
11. Registration of equipment and site plan approval will be the responsibility of the vendor. The institute will be provide necessary documents.
12. 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.
13. It should have universal instrument adapter tracing system for navigation
14. The system should have image guided spinal instruments like short drill guide, Awl/Probe/Tab system with straight or T-handles options (two each)
15. The imaging system should have DICOM ready functions and full DICOM compatibility. It will be the responsibility of the vendor to seamlessly integrated the system with the future PACS network of Orthopaedics, AIIMS
16. Free up-gradation of software for 10 years.

Approximate Cost: 16.50 Cr.

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PROPRIETORY/SPECIFIC BRAND GOODS CERTIFICATE

1.	The indent goods are manufactured by M/s.	M/s. Brainlab AG Olof-Palme-Straße 9 81829 Munich Germany
2.	Item Name	Mobile Intra-Operative 32 Slice CT with Integrated Table Column and Compatible & fully Integrated Advanced Navigation System
3.	Model/Part/Catalogue No.	Mobile Intra-Operative 32 Slice CT with Integrated Table Column and Compatible & fully Integrated Advanced Navigation System
4.	Reasons/Justification which makes the requirement proprietary	Proprietary Certificate Enclosed (Close System)
5.	It is certified that market survey has been done and found that no other manufacturer is manufacturing similar/equivalent specifications which can fulfill the vital requirements of end user.	Yes
6.	It is certified that the purchase is proposed to be made on proprietary usage basis because any other material/equipment/instrument chemical, etc. if used will lead to deviation and affect the integrity/accuracy, validity or analysis of the assignment/patient care.	Mobile Intra-Operative 32 Slice CT with Integrated Table Column and Compatible & fully Integrated Advanced Navigation System **is proprietary product of M/s. Brainlab AG Olof-Palme-Straße 9 81829 Munich Germany**, and best of my knowledge the price quoted by the firm should be reasonable

Signature of Indentor

Dr. Mohammed Tahir Ansari
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SIGNATURE WITH SEAL OF THE T.S.E.C.

PROFESSOR AND HEAD
DEPARTMENT OF ORTHOPAEDICS

Note 1: T.S.E.C. should clearly mention that the item in question is required to standardization of machinery or spare parts to be compatible to the existing sets of equipment which is required to be procured only from one manufacturer mentioed in serial no. (i)

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PROPRIETARY CERTIFICATE

We, Brainlab AG, Olof-Palme-Strasse 9, 81829, Munich Germany hereby certify that below mentioned features for Advanced Mobile Intra-Operative CT based Spinal Navigation is proprietary to Brainlab AG, Germany or its exclusive partners.

1. Mobile Intra-Operative 32 Slice CT with Integrated Table Column AND Compatible & Integrated Advanced Navigation System

a) The intraoperative mobile CT has a bore size of 107 cm which is the largest in the world in its category. Due to large bore size, not only the chances of collision can be avoided but also patient can be scanned along with all instruments/attachments during surgery in most instances. Patient positioning flexibility is also an added advantage for eg. "Swimmers view" can be achieved in Airo. In addition, surgeon can perform CT guided procedures easily, including a final confirmation of the implant position with true Computed Tomography technology (in contrast to most common Cone Beam or 3D x-ray)

b) Curve and the Intraoperative Mobile CT- Airo allow surgeons to do Automatic Image Registration for Spine cases with true CT technology. This allows an automatic registration of the patient just by taking a scan. The navigation system automatically detects the digital CT information matches of anatomical structures thus allowing a seamless integration. This is also the cornerstone of minimally invasive procedures which eliminates the need for manual registration and compensates for the problem of limited access to anatomical landmarks for an optimized and convenient workflow. Especially, after patient draping thus enabling automatic receipt and registration of spinal image data from Mobile CT. Intraoperative images are made available for navigation immediately after the scanning process for optimized surgical workflows. Complicated procedures like scoliosis, Spine tuberculosis, kyphosis and other deformities in spine can be visualized in almost real time as patient can be registered/re-registered anytime during the procedure

c) Airo has integrated table column with rails so the gantry moves relative to the rigid table providing reliable and consistent imaging results. The integrated rails of Airo compensate for all unevenness of flooring that may result in geometrical inaccurate images

d) Airo and Curve navigation system have a deep interaction and communication. That allows a unique optimization of workflows. A motorized camera follows the gantry and patient always improving the visibility to the essential components. "Next steps" on each device are often anticipated in order to reduce user interaction as much as possible and therefore safe valuable OR time.

e) The intraoperative CT is operable with a hand held touch control panel for imaging, transport, service and calibration hence does not need a separate console cart which saves lot of space in OR. In addition despite the large gantry, the footprint and overall volume is minimized which makes the system even smaller than other systems with even less sophisticated technology

f) The navigation system Curve has a mobile camera cart with telescopic stand and motorized joints for remote control camera alignment. This allows for high degree of setup flexibility in the operating room respecting sterile environment

g) Navigation system has facility of live-streaming and digital video recording. HD streaming (1280x800/720p resolution with state-of-the-art MPEG4/H.264-encoding) allows efficient transmission of live view of any display content (e.g. navigation software, microscope or endoscope video) to any web-browsing enabled computer connected to network. Intuitive one-click control interface for streaming, recording and screenshot functionalities fully integrated in user interface. Direct web-access to live stream, digital recordings and screenshots via system portal page accessible from any web-browsing enabled computer. Screenshot function to capture any display content in native resolution and store to local or network connected storage

h) Navigation system has a smart home button to ensure interchangeability between multiple windows at any given point of time as per surgeon discretion. Any changes made on attached window gets automatically updated in to navigation window

2. Advanced Spinal Navigation Applications

a) Automatic Image Registration software for Spine eliminates the need for manual registration and the problem of limited access to anatomical landmarks for an optimized and convenient workflow,

especially after patient draping thus enabling automatic receipt and registration of spinal image data from Mobile CT.

b) Intraoperative images are made available for navigation immediately after the scanning process for optimized surgical workflows. Implant placement and orientation of integrated instruments for the treatment of complicated procedures like scoliosis, spine tuberculosis, kyphosis and other deformities in spine can be visualized in real time. Initial scans or update scans including scout scans can be done at any time during the procedure.

c) Trajectory planning software offers screw planning capabilities to plan multiple trajectories before or during Spinal surgical approaches. Target and Entry can be displayed in DICOM image coordinates and diameters can be applied to access the exact type of implant for planned screws. Screws can be verified in various views like axial, coronal, sagittal, 'Probe' eye and inline reconstruction view.

d) Curvature correction software offers multi-rigid Image Fusion that is tailored to adapt spine curvature and match multiple vertebrae from MR-to-CT or CT-to-CT. It enables multi-modality planning and intra-operative plan updates for Spine Image Guided Navigation procedures in conjunction with intra-operative CT. Multi-level vertebrae co-registration is based on multi-Region of Interest(ROI) rigid fusions. It also supports interactive segmentation on new data sets, allows direct comparison of curvature corrected with rigid alignment results through toggling and has a colored deformation grid which highlights local deformations for detailed inspection

e) Viewer 3D software offers Intuitive image viewing, manipulation and data enrichment. It provides instantaneous, high-quality 3D visualization for analysis leasing to increased diagnostic confidence of the surgeon. It does the 3D volume rendering of CT, MR, PET, SPECT datasets, with presets for visualization of skin, bone, vessel, DRR and MIP. It can also do the Superimposition of 3D dataset visualization and surgical planning data (volume objects, trajectories and labeled points), 3D multi-planar reconstructions in multiple planes (axial, coronal, sagittal, oblique) and concurrent display of multiple medical image series with flexible hanging protocols. It has features like, image annotations and measurement functions for distance, angles and circles, selection of region of interest to cut and zoom onto the relevant anatomical volume and crop functionality to cut viewing plane into 3D visualization along any freely definable direction

f) Smart anatomy spine viewer software offers intelligent, indication-specific Smart Views for spinal indications exploiting anatomical information from Anatomical Mapping. It provides automatic, anatomically aligned multi-planar reconstructions along the spinal cord and assessment of pedicle anatomy. It allows quick and easy estimation of screw dimensions and intraoperative or postoperative verification of screw placement. This optimized workflow allows for preparing views in the office that can be accessed later in the O.R.

3. Advanced Pre-operative Templating

a) Navigation System has a digital templating software with pre-operative implant planning for procedures like and Spine, Hip, & Trauma. Software offers advanced measurements and studies like- Cobb Angle, Vertebrae Labelling, clavicle angle, Coronal balance, Sagittal Balance, Lumbar lordosis angle, Spondylolisthesis, Pelvic radius angle, Sacral Obliquity, Spine slip angle, Spondylolisthesis, T1 tilt angle, Thoracic kyphosis angle and Thoracic Trunk Shift for Spine

b) Templating Software offers Automatic Image Calibration and has hardware for calibration of digital image

c) The digital templating software is open and supports all leading implants rather than lock-in for a single implant specific vendor. At any given point in time, surgeon can easily switch between digital templating and real-time navigation on the same navigation system. All Software are on the navigation system itself and can be controlled by touchscreen system as per user preference

All above mentioned platforms and applications are proprietary technology of Brainlab AG or its exclusive partners. Although some items on the list might be available by other systems, the overall solution and described combination of the products is unique and cannot be offered by any company worldwide. All information above is written to the best of my knowledge.

Thanking You

Oct 29 2018 09:36 +01:00

X Thomas Kraft ✓

Thomas Kraft

For Brainlab AG

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MANUFACTURER'S AUTHORISATION FORM

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

Dear Sir,

Ref: Your requirement for "Mobile Intra-Operative 32 Slice CT with Integrated Table Column AND Compatible & Integrated Advanced Navigation System"

We, **Brainlab, AG** who are proven and reputed market leader of Intraoperative mobile CT and navigation system having factories at **Olof-Palme-Strasse 9, 81829, Munich, Germany** hereby authorize **Brainlab Sales GmbH, Olof-Palme-Strasse 9, 81829, Munich, Germany** to extend our full warranty, CAMC as applicable for the goods and services offered for supply by Brainlab Sales GmbH.

We further confirm that no supplier or firm or individual other than **Brainlab Sales GmbH, Olof-Palme-Strasse 9, 81829, Munich, Germany** is authorized to submit a bid, process the same further and enter into a contract with you against your requirement for the above goods manufactured by us.

We also hereby confirm that we would be responsible for the satisfactory execution of contract 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 us shall not exceed the price which we would have quoted to other Govt. Institute in India in year 2019 for the same specifications.

For Brainlab AG.,

Authorized Signatory
Name
Seal/Stamp