(10) NEURO SURGERY NIT: 13277/06-12-16

DEPT. OF NEUROSURGERY
RAJENDRA INSTITUTE OF MEDICAL SCIENCES
Ranchi- 834009, Jharkhand

Final

Ref.....

Date:-20.12.16

Equipments and Instruments Required for Department of Neurosurgery

1. Hospital Cubical Track System (For Exiting ICU, HDU)
2. DVT Prohylaxis System
3. Patient Warming System
4. High Frequency C-ARM System
5. Portable Transport Ventilator
6. Neuro Navigation System for Cranial & Spinal Application for Neurosurgery
7. Hand Instruments for Neurosurgery (List Attached)
8. Vein Detector
9. Intra Operative Neuro Monitoring system
10. High Pressure Suction machine (Variable press.)
11. Neuro & spine surgery simulator.

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Sr. No. – 1. Specification

HOSPITAL CUBICAL TRACK SYSTEM

Providing, fabricating and fixing of Hospital cubicle track system comprising of the following components and specifications :

(1) CUBICLE TRACK

Made of Aluminum alloy of size 20 x 25mm with 1.75 thickness having 50-60 microns powder coating in white color finish. Tracks are bendable to a radium of 300 mm at 90 degree to cover the whole bed.

(2) CURTAIN

Made of hospital grade premium quality Stain Proof fabric with High quality Net of 18" and 24" on top.

(3) SUPPORTING SYSTEM OF TRACK CONSISTS OF THE FOLLOWING MATERIALS

(a) Wall Braket : Made of CRC with white powder coating finish

(b) Bridge Clamp : Made of CRC steel with powder coating finish

(c) Roof Clasp : Made of aluminum pipe of 12.5 mm & 12.5 mm inner & outer diameters. The Upper Circular Pate made of aluminum. These are with white powder coating (outer surface) finish & are of variable height fixed with ciling with anchors, bolts, screws etc.

(d) Curtain removal : Made of CRC with SS finish for simple loading & unloading of curtain (also serves as an end hook retainer)

(e) Runners : Roller wheel type runners made of Teflon for easy and smooth sliding of the curtain

25/04/16

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Sr. No. -2

Specifications for sequential intermittent pneumatic compression system for DVT prohylaxis

The controller should provide sequential, gradient & circumferential compression around the ankle, calf & thing.

Controller should provide the pressure of 45 mm/Hg at the ankle area, 40 mm/Hg at the calf area & 30 mm/Hg at the thigh area.

Controller should have graphic user interface of 3.2 inch colour LCD & provide greater Visibility.

Controller should have VRD (Vascular Refill Detection) technology with three ways tubing & 6-8 hrs battery backup.

Consumable sleeves should have three bladders for giving optimal compression in different areas of the leg.

The compression system should USFDA/ISO/CE Mark certified quality product.

SHOULD BE QUOTED WITH 50 PAIRS OF CONSUMABLE SLEEVES.

PRICE OF CONSUMABLES TO BE QUOTED SEPARATELY AS WELL

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Specification

FORCED AIR PATIENT WARMING SYSTEM

1. Should be a light weight portable system
2. Should have minimum four variable temp settings (Range 35 to 42°C approx)
3. Should have hose disconnection alarm/indicator
4. Should have digital display of temp at end of hose pipe.
5. Should have quiet operation.
6. Should have display for elapsed time.
7. Should have air filter.
8. Should have full body adult and paediatric blankets
   Adult - 10
   Paediatric - 05
9. Should have CE or any other International certification of quality

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(5)

Items No- 04

~~Tender No~~:

Equipment Name: **C-arm**

Specification for High end C Arm

Technical Specifications
A) X RAY GENERATOR
Frequency: 40 KHz or better
Power Output: 20 KW or more
KV range: 40-110 KV or better
mA in radiography: 20 mA or more
mA in fluoroscopy: 0.1 to 4 mA or more in normal fluoroscopy and 12 mA or more in High Level Fluoro
Should have facility for continuous fluoroscopy and Pulse fluoroscopy (Pulse rate upto 8 pulse per second)
Should have Digital Spot for high quality single image, 16 mA or more.
Housing heat capacity of minimum 700 KHU and cooling rate of more than 12,000 HU/Min
B) X-Ray Tube Head
Must have anode heat capacity of min 70,000 HU & cooling rate of min 35,000 HU/min
Should have dual focal spots
Collimation: motorised iris and motorized rotating blades
Tube assembly filtration of 3.0mm Al or higher
C) C-Arm mechanism and control panel (digital work station)
Locks for stabilization at desired position
It should have the following range of movements:
Motorized vertical movements more than 400 mm
Horizontal travel : 200 mm or more
Orbital movement: (-) 30 deg To (+)90Deg (120 Deg or more)
Swing/panning movement: +/- 12 degrees or more
Depth of C-arm : 650 mm or more
D) Control Panel (Digital workstation)
It should have the following facilities:
System should have capability of Pulse Fluoroscopy option to reduce to radiation exposure with 1,2,4,8 pulse per second, which should be easily user selectable.
Fluoroscopy and Radiography exposure on switching
Image rotation from control panel
Image intensification, mode selection (normal and zoom)
Automatic brightness stabilizer
Auto dose rate control.
Collimation for radiography
E) Integrated image processing, recording and memory system:
a Image Intensifier Tube
Input Diameter 9" with Triple field (9/6/4)
Minimum Central resolution (at monitor) : 2.0 lp/min or better at 9" FOV
b CCD camera
CCD camera with 1K x1K resolution for high resolution image acquisition.
c Integrated image processing, memory and recording system should have
Medical Grade Monitor (Two Nos)
Min 18 inch or more, black and white, flicker free, high resolution (1280 x 1024 pixels or better), medical grade flat screen TFT, automatic and manual control of brightness and contrast, mounted on mobile trolley with locking device.

6

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F) Digital Image Processor
Provision to record multiple images on CD, DVD & USB with embedded DICOM viewer
Image processing at 1K * 1K Matrix
Contrast Enhancement, edge enhancement, zoom facility
Recurisive filter for detecting motion.
Last Image hold
Image rotation, vertical and horizontal reversal
Medical imaging software's with ability to store 70,000 images or more in hard disk
G) Additional features
The equipment should work on Power Supply of 220-240 Volts, 50-60 Hz 15 amp
Built in UPS to protect and save patient data.
H) Regulatory/Safety Requirement
Equipment should have AERB Type Approval Certificate for radiation safety
Equiopment should have CE for full product with notified body identification number
5 yrs warranty & 5 yr CMC should be included with provision of supply of spare parts of the model supplied for next 10 years
I) The system supplied should be complete in all aspects and ready to use in all aspects of its functions.

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SPECIFICATION OF TRANSPORT (PORTABLE) VENTILATOR.

1. The portable ventilator should be usable in Adult, Paediatric and Neonates

2. The portable ventilator should be light weight (< 5 kg)

3. Should be electronically controlled and pneumatically driven

4. Should be able to work both with cylinders and pipeline, connectors and high pressure tubing of appropriate length to be supplied.

5. Should have venture/jet mixing/turbine-technology air-oxygen mixture

6. Should have both controlled and spontaneous modes of ventilation CMV & ACMV and PSV with PEEP

a. TV 15 – 2000 ml (or minute volume 1-16 ipm)

b. PEEP/CPAP 0-20cmH2O

c. Respiratory Rate 5 to 70 bpm

d. I:E ratio 1:1:5 (Inspiratory time 40% of breathing cycle)

e. FiO2 50% & 100%

f. Pressure support level 0-50 cmH2O

g. Trigger Sensitivity – Pressure 1 to 5 cmH2O

7. Should have airway pressure monitoring

8. Should have Audio-visual alarms for a. Low supply pressure b. High/low airway pressure c. Gas supply d. Power failure e. Apnoea f. Low battery

9. Battery backup for minimum 5-6 hrs.

10. Should fix, on rails of transport trolley and on stand with wheels

11. Power supply cable for 12 V Dc

12. The Unit shall be capable of being stores continuously in ambient temperature of 0-40° C and relative humidity of 15-90%

13. Power input to br 220-240VAC, 50Hz

(8)

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Sl.no - 5

14. Electrical safety conforms to standards for electrical safety IEC060601

15. Product should be CE certified and US FDA approved.

16. Manufacturer/Supplier should have ISO certification. Both should have good service track record.

17. Should have comprehensive warranty of 5 yrs without spares and 5 yrs. with spares. Company should have office in Ranchi/Jharkhand

- Five yeas comprehensive warranty (with labour and spares) - Five years CAMC, from 6 to 10 years (including labour and spares)

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Sr. No.- 6

TECHNICAL SPECIFICATION OF IMAGE GUIDED NEURONAVIGATION SYSTEM FOR CRANIAL & SPINAL APPLICATION FOR NEUROSURGERY -

The system should be easy to set up, user friendly, intuitive and should work under *Linux* operating system environment.
The system should have facilities for keeping optical camera and viewing system together or separately to allow optimal utilization of the OT space.
It should be portable, space saving high performance Image-Guided-Surgery platform. It should have an integrated lightweight design for easy system relocation.
The system should have *touch-sensitive screen* that could be used in sterile field.
It should have *Mobile cart with separated camera* stand for flexible positioning within the OT.
The system should *identify new instruments* for tracking using the universal wireless, passive and optical tracking system.
The system must have *dynamic referencing* so that registration is not lost even if the camera or patient moves.
The system should have inbuilt UPS/else external UPS to be supplied for power backup
The navigation system should be operable with or *without keyboard or mouse.*
The system should have *live display* capabilities.
The system should be capable of loading complete *Cranial & Spinal applications* for Craniotomies, Skullbasetumors, Functional Neurosurgery & Complex Spinal surgery.
The system should be capable of supporting Pin less Navigated surgeries for endoscopic and Lateral Skull base procedures and also Electromagnetic Navigation capability.

1) *Monitor size should be at-least 24" or above*
2) *System should have two monitors one for surgeon viewing and other for operator.*
3) *System should have touch screen monitor facility and it should also be operable using keyboard and mouse.*
4) *Optical Camera should have 360° (wide range) movement for better positioning from distance and optimal OT utilization.*
5) *Camera Cart and viewing system should be able to dock together for transporting within the OT.*
6) *System should provide facility to load patient exams through CD drive, USB and PACS.*
7) *System should provide additional video output port for viewing on additional monitor if required during emergency.*
8) *System should have in-built UPS for backup during power failure.*
9) *Anatomy specific spine reference frames (separate for throacic, lumbar, etc)*

Cranial Navigation Specifications

#The system should have pre-operative planning using the DICOM images for pre-operative Neurosurgical planning.
The system should allow DICOM images in Axial, Sagittal or Coronal planes should be reconstructed as 3D images and advanced cranial planning can be done on any plane and should be adapted to all planes automatically.
#The system should have Tracer and Point Merge registration techniques.
The system should have automatic image fusion capabilities of pre-operatively acquired DICOM images in the form of CT, MR, fMRI (DTI & BOLD), PET or SPECT.

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The software should automatically fuses axial, coronal and sagittal plane image sets of different modalities.
The pre-operative planning for cranial application available should allow both frameless &stereotactic procedures (frame based) with advanced visualization of 3D objects with volumetric information.
The system should be able perform fiber tracking during surgery.
The system should allow patient registration in both supine & prone position using –
Skin sensitive touch device for maximum accuracy in prone position to be supplied for fast registration and maximum accuracy
The system should have complete Cranial Navigation and its application package.
The system should display of a predefined trajectory pathway, inline and probe eye views.
#The probe should have capability to show images at 0mm - 100mm in front of it (Tool Tip Extension). The virtual tip should be differentiated from real tip by color.
The system should have sub-millimetric patient accuracy ideal for deep seated Cranial biopsies and should track the needle trajectory and depth and should be displayed on the screen.
The system should have screenshot storage function for documentation purpose.
The Cranial Instrumentation should have two sets of blunt pointer & reference devices (to be used in sterile & unsterile environment both).or if laser pointer is supplied than 2 sets should be provided for per operative registration and confirmation.
It should have universal instrument adapters with passive markers to allow tracking of any existing hospital instruments like drills, bipolar, knife, Awl, Probe, endoscopes.
The system should allow free hand frameless biopsy capabilities and both Frame based as well as Frameless biopsy should be included as a part of the system.
The system should provide 5 complete biopsy set.
The Frameless biopsy system should allow online tracking of biopsy needle according to pre-planned trajectory and should have ability to change the plan if required during the procedure and changed trajectory should be tracked.
The frameless biopsy system should include sterilizable, wireless & pre-calibrated alignment array. System should also be capable of doing navigated biopsy using locally available biopsy needles. Company should also provide accessory to perform 100 biopsies.
The system should interface existing Microscope at the hospital Zeiss OPMI Vario 700.
The Microscope view should be represented in the diagnostic data in the same orientation.
The System should provide additional navigation information like "distance to target", "tumor extension" and "target/trajectory" information.

Spinal navigation specifications

The Spine Application should be a unified Spine Application which should comprise of 3D Spine
(Spine Navigation with Spine CT Data) and Virtual Fluoroscopy Navigation for Spine.
There should be a wireless control from the sterile field in form of surgeon mouse or touch screen function
It should be able to do automated functionality check.
It should have universal instrument adapter tracking system with active or passive option.
The system should have image guided precalibrated and ready to navigate spinal instruments like short drill guide, Awl/Probe/Tap ,
It should have Specific reference frames and clamps for Cervical, thoracic, and Lumbar.

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System should have facility of virtual fluoroscopic navigation for spinal applications compatible with 9" C-arm of Philips, Shimadzu, Toshiba, Siemens, GE.)or compatible with intraoperative CT / MRI.
Transfer of spine exams to the navigation system should be possible with USB stick.
The System should have Navigation instruments for Minimal invasive Spine Procedure.
Company should provide necessary spare parts and accessories for next ten years in all condition.
Company should give list of installation of 5 government institutes of similar model that is quoted and also satisfactory certificate from reputed Government hospital and corporate hospitals.
Company should provide warranty of 60 months of all parts as well as accessories.
Company should also provide C.M.C. for 5 years after warranty period including labor and spare cost.
Company should provide local service engineer round the clock.
Any Software crash or related problem need to be resolved free of cost.
Application support need to be provided for case to case basis for next 5 years and an agreement need to sign for the same support to be provided.
All India Navigation installation list needs to be provided along with the company service and application people details for the system.
The system should be CE and USFDA approved.

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Sl. No -7

Hand Equipments Required Chart for Department of Neurosurgery, 2017 – 2018

S. NO. 7	Items Name	Quantity
1.	Allis forceps	50 Pcs.
2.	Mosquto Artery forceps	50 Pcs.
3.	Dura Cutting Scissor	10 Pcs.
4.	Fine Scissor Curved (Assorhd Size)	20 Pcs.
5.	Scissor Straight (Different Size)	20 Pcs.
6.	Scissor Curved (Different Size)	20 Pcs.
7.	Micro Scissor (Curved)	5 Pcs.
8.	Bandage Cutting Scissor (Big Size)	20 Pcs.
9.	Needle Holder	20 Pcs.
10.	Fine Needle Holder	10 Pcs.
11.	Micro Needle Holder	10 Pcs.
12.	B.P. Handle Straight (No.-3,4)	20 Pcs.
13.	B.P. Handle Bayonet Long Size (No.)	5 Pcs.
14.	Shunt Introducer (Adult)	10 Pcs.
15.	Shunt Introducer (Pead.)	10 Pcs.
16.	Suction Cannula Tip (Non Traumatic Tip & Key Hole) (Different Size)	50 Pcs.
17.	Ventricular Cannula (Brain Cannula)	10 Pcs.
18.	Tumour Grasping forcep Bayonet	10 Pcs.
19.	Penfield Dissector (Different Size)	4 Set.
20.	Fine Tooth forceps (Different Size)	20 Pcs.
21.	Plain forceps (Different Size)	20 Pcs.
22.	Tooth forcesps (Big Size Tooth)	20 Pcs.
23.	Dura Elevator	10 Pcs.
24.	Gally Pot (Boud) 4"	50 Pcs.
25.	Gigli Sow Wire	100 Pcs.
26.	Triphine (6 cm, 6.5 cm, 7 cm) Extension Rod & Triphine	15 Pcs.
27.	Hudson Brace Set with Perforator Burr	4 Pcs.
28.	Karrison Punch Upward 45 Ronguers (1 mm, 2 mm, 3 mm, 4 mm)	10 Pcs.
29.	Karrison Punch Doward 45 (1 mm, 2 mm, 3 mm, 4 mm)	10 Pcs.
30.	Bone Nibbular Angled & ST 245x5 mm	10 Pcs.
31.	Bone Nibbular Angled & ST 230x2 mm	10 Pcs.
32.	Bone Bibbular Angled & ST 200x8 mm	10 Pcs.
33.	Bone Bibbular Angled & ST 165x2 mm	10 Pcs.
34.	Bone Bibbular Angled & ST 185x4 mm	10 Pcs.

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13

35.	Dressing Drum (Different Size)	20 Pcs.
36.	Self Retaining Mastoid 10"	5 Pcs.
37.	Beckman Self Retaining Retractor Large Size	4 Pcs.
38.	Frazier Dural Separator	6 Pcs.
39.	Garden wells tongs with bed (Attachment)	4 Pcs.
40.	Fish Hooks	10 Pcs.
41.	Langer Back Retractor Medium Size	4 Pcs.
42.	Raney Clip applicator	2 Pcs.
42.	Woodson Dura Seperator and Packer	10 Pcs.
43.	Gerald Tissue Forceps	
44.	Disc Rongeur Serrated Up/Down/Strelight	5 Each
45.	Disc Rongeur Sernated Up/Down/Strelight	5 Each
46	Fine Dissectors, Diffe. Size	20Pcs.

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Date:-20.12.16

Specification for Hand Instruments for Neurosurgery:-

1. Should be of Medical Grade Steel EN 304 Quality
2. Should be European CE/or USFDA approved
3. Warranty for Minimum Two years

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15

Item No-8

VEIN DETECTOR

Specification

- SHOULD HAVE NUMBER OF RED LEDs : 6
- 3.6 VOLTS RECHARGEABLE BATTERY
- CHARGER FOR CHARGING THE DEVIC OPERATING VOLTAGE: UNIVERSAL
- DIMENSION: 50 X 16 X 160 MM
- WEIGHT: 120GRAMS

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Item No. – 09

Technical Specification for Intra Operative Neuro 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.

The system should be capable of –

- Surgeon-directed and neurophysiologist-supported capabilities in one 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
- Electrosurgery Unit (ESU) interference muting
- 32 channel neurological monitoring for intraoperative and ICU applications.
- Comprehensive EEG, EP and EMG monitoring with up to 32 independent channels. Up to 128 traces (64 per modality) can be displayed.
- All EP modalities including SSEP, MEP, AEP, BAEP, VEP
- Should be a Minimalist system
- Should have Biphasic stimulation for TcMEP
- Should have 2 DVR feeds
- Should have SD + NS
- Stimulators run all electrical modalities
- EMG audio is able to be recorded and reviewed

Should at least Support below mentioned Surgeon-Directed Features –

- 8-channel EMG, MEP, and Train of Four modalities
- 8-channel EMG, 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
- Probe's multicolor LED indicates test results
- Multiple manual and triggered EMG modes of operation
- Audible and visual surgeon feedback

Should at least Support below mentioned Neurophysiologist-Supported Features –

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

Should at least Support below mentioned Nerve Proximity Test Screen –

- Provides audio tone feedback indicating proximity to a nerve root
- Program automatically changes stimulation intensity while searching for an EMG Response

Should at least Support below mentioned Screw Test 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

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Should have Nerve Root Test Screen –

- Used to locate and quantify the health of a nerve root
- Simulation intensity automatically increases until a response is generated should have following Surgeon-Directed Disposables
- Surgeon-controlled 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 displays test result
- Includes two ball-tip probes and one flush-tip probe
- Up to 16 multimodality sets can be defined within a test protocol
- 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 EEG, free run EMG, Triggered EMG, EMG audio, updated averaged EP, Screen snapshots and Video.
- 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
- Built-in pulse oximeter.
- 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.
- Complete range of accessories and disposables for all monitoring modalities.
- The system supplied should be complete in all aspects and ready to use in all aspects of its functions

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Item No-10

Electrical Suction Pump

Suction cum irrigation pump high flow rate, oil less low noise (imported) diaphragm pump for simultaneous operation of suction and irrigation with pressure and vacuum gauges and flow regulator.

1. 2 x 2 Ltrs. Polycarbonate jars (Long Type) with overflow safety
2. Noise level of suction apparatus with the range of 55 dB +/- 05 dB
3. Rocker Piston Vacuum Pump with the range of 720 +/- 10 mmHg
4. Anti corrosive and Epoxy Powder Coated Mild Steel Trolley
5. Ideal for Medical / MTP / Surgical procedures
6. Heavy duty HN-65 Castors with brakes
7. Free air displacement 35 ~ 40 LPM
8. Non collapsible Suction Tubing
9. Standard 63 mm Vacuum Gauge
10. Bacterial filter fitted
11. Shall meet IEC-60601-1-2 :2001(Or Equivalent BIS)
12. General Requirements of Safety for Electromagnetic Compatibility or should comply with 89/366/EEC; EMC-directive.
13. The unit shall be capable of operating continuously in ambient temperature of 10 - 40deg C and relative humidity of 15-90%
14. Power input to be 220-240VAC, 50Hz fitted with Indian plug
15. Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements and IEC-60601-2-25 Safety of Electrocardiograms .(OR EQUIVALENT BIS Standard)
16. User Manual in English
17. Service manual in English
18. List of important spare parts and accessories with their part number and costing
19. Certificate of calibration and inspection.
20. Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist.
21. The job description of the hospital technician and company service engineer should be clearly spelt out

95

22. List of Equipment's available for providing calibration and routine Preventive Maintenance Support. as per manufacturer documentation in service/technical manual.
23. Specify Life of Equipment in standard operating condition from the date of Installation.
24. Comprehensive warranty for five years (free repair and replacement of all parts)
25. AMC/CMC rate term, for after expiry of Warranty period, for next 5 years
26. During warranty /AMC period - Unit has to be repaired within 48 hour or to be replaced by other unit till it is being repaired.
27. Company Item should be US- FDA / European CE approved/ ISO approved.

20/12/18

Item No.-10
Electrical Suction Pump

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12. General Requirements of Safety for Electromagnetic Compatibility or should comply with 89/366/EEC; EMC-directive.
13. The unit shall be capable of operating continuously in ambient temperature of 10 - 40deg C and relative humidity of 15-90%
14. Power input to be 220-240VAC, 50Hz fitted with Indian plug
15. Electrical safety conforms to standards for electrical safety IEC-60601-1 General Requirements and IEC-60601-2-25 Safety of Electrocardiograms .(OR EQUIVALENT BIS Standard)
16. User Manual in English
17. Service manual in English
18. List of important spare parts and accessories with their part number and costing
19. Certificate of calibration and inspection.
20. Log book with instruction for daily, weekly, monthly and quarterly maintenance checklist.
21. The job description of the hospital technician and company service engineer should be clearly spelt out

95

22. List of Equipment's available for providing calibration and routine Preventive Maintenance Support. as per manufacturer documentation in service/technical manual.
23. Specify Life of Equipment in standard operating condition from the date of Installation.
24. Comprehensive warranty for five years (free repair and replacement of all parts)
25. AMC/CMC rate term, for after expiry of Warranty period, for next 5 years
26. During warranty /AMC period - Unit has to be repaired within 48 hour or to be replaced by other unit till it is being repaired.
27. Company Item should be US- FDA / European CE approved/ ISO approved.

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Item No – 11

Technical Specifications for Neurosurgery & Spine surgery Simulator with Pre-Surgical Planning

1. Simulator should allows simulation of common surgical procedures for medical education and analysis of complex procedures for pre-surgical planning.

2. Simulator should have both open, percutaneous, and microsurgical procedures available with procedure specific instruments and controls

3. Simulator should have 3D computer generated anatomical model to reproduce audio, visual, and tactile sensations of a surgical procedure.

4. Simulator should have patient specific models combining multiple medical imaging (MRI, CT, or co-registered MRI/CT) & 3-D Visual/ Haptic exploration of anatomies for training and surgery preparation.

5. Simulator should have high visual acuity, realistic force feedback, spatialized 3D audio, head and hand tracking.

6. Simulator should have following Neurosurgery modules
   - ✓ Surgery Skill Builder modules
   - ✓ Ventriculostomy module – coronal approaches
   - ✓ Ventriculostomy module – occipital approaches for VP shunt placement
   - ✓ Ventriculostomy module – parietal approaches for VP shunt placement
   - ✓ Trigeminal Rhizotomy module
   - ✓ Hematoma Removal module
   - ✓ Meningioma Resection module
   - ✓ Cranial Bone Flap removal
   - ✓ Cauterization with bleeding simulation
   - ✓ Aneurysm Clipping demo

7. Simulator should have following Spine modules
   - ✓ Lumbar Puncture module – non flexed position
   - ✓ Vertebroplasty module
   - ✓ Percutaneous Needle Insertion (Spine) module
   - ✓ Open Pedicle Screw Insertion module

8. Simulator should have the following Endoscopic module
   - ✓ Endoscopic Pituitary Adenoma

9. Simulator should have following Radiology modules integrated with relevant procedures

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- ✓ C-Arm or O-Arm Flouro simulation with wireless iPad based menus

10. Hardware – System should be supplied with Phantom Units, Onboard Computer, Monitor, Foot pedals, Stereo Shutter Glasses, Electromagnetic Tracker And Transmitter, 3D Mouse With Electromagnetic Sensors, Half Reflecting Mirror, Keyboard/Mouse,

11. Simulator should be housed in a Fully Enclosed Mobile Case.

12. Simulator should have following additional features
    - ✓ Dynamic real-time collocation of graphics and haptic workspaces
    - ✓ Real-time head tracking
    - ✓ Highly sensitive and accurate real-time force feedback
    - ✓ A wide selection of cases covering basic to more complex scenarios including management of complications
    - ✓ i-Pad integrated wireless control

13. Simulator should be able to provide output for 3D printing of anatomy following the pre-surgical planning process.

14. Simulator should allow procedure specific physical instrument attachment in addition to virtual instruments.

15. Simulator should be capable of creating patient specific data from DICOM image scans based on following manufacturer training guidelines

16. Simulator should have USFDA & CE certifications.

17. Simulator should have FDA 510(k) device clearance as pre-operative software for simulating and evaluating surgical treatment options.

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