

Specification for Intracranial Pressure/Temperature Monitoring.

Intracranial pressure /temperature monitoring system should be supplied with following specification.

1. The system should have an integrated display of all functions.
2. It should have Intracranial Temperature, Perfusion Pressure and Trend Analysis.
3. Up to 5 days of trend data (120 vs. 24 hours)
4. Trend data view scalable, viewable in 3 hour, 12 hour, 24 hour, 48 hour, and 120 hour increments
5. System should have High ICP Alarm and Versatile output.
6. The system should be supplied with catheters to measure the above parameters
7. Monitor supports both fiber optic and strain gauge technologies
8. Touch-screen, menu guided
9. Single-touch operation 7.0" widescreen display, almost twice as large
10. Battery life should be for 1.5 hour and should Maintain an ICP reading during patient transport (e.g., CT scan)
11. System should be supplied with the catheter which can monitor both Pressure as well as Temperature.
12. Accessories:
 - i) Extension cable to connect Fiber Optic Catheters.
 - ii) Extension cable to connect Flex Catheter.
 - iii) Extension cable to connect patient bedside monitor.
 - iv) Intracranial Pressure/Temperature Monitoring kit
13. Also the unit must be certified by US FDA and CE.
14. Local Service Support facility must be available in Manipur.

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SPECIFICATION FOR TRANSCRANIAL DOPPLER SYSTEM.

1. Two channel Transcranial Doppler capable of Intracranial and Extracranial use.
2. Should be supplied with 2 MHz PW probes (2 Nos.) for bilateral Intracranial Monitoring.
3. Should be supplied with 4 MHz (1 No.) CW & PW for extracranial monitoring.
4. Should be supplied with 16 MHz (1 No.) for intraoperative monitoring.
5. Should have color M mode feature with able to re-adjust the 64 gates digitally per probe, Multi gating upto eight special windows, full record and re-play of spectrum.
6. Should have excellent signal quality.
7. Offline software with carotid imaging software.
8. Should have automatic embolic detection with real time histogram of HITS Energy distribution.
9. Should have the software feature to differentiate emboli with artifacts.
10. Should have user-definable defaults for individual blood vessels.
11. Should have summary screen which displays all studies performed on a patient on a single screen.
12. Should have long term monitoring with trending of selected parameters.
13. Should have supplied with probe holder made of Medical grade plastic for long term monitoring or monitoring under CT/MRI. The probes provided should be compatible to be fixed with the probe holder.
14. Should have manual control of gain.
15. Should have FFT size adjustable from 64 points to 512 points.
16. Should have ability to change spectrum display size from 2.5 sec to 1 min.
17. Should be able to display Pulsed wave parameters like Peak Velocity, Mean Velocity, Diastolic Velocity, Pulsatility index, Resistivity index, Standard deviation, Heart rate.
18. There should be provision of 2 vertical and 2 horizontal cursors for measuring the values manually.
19. Should have 16 colour spectrum display and able to display upto 8 spectrums with Color M mode feature.

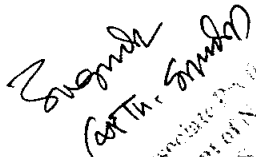
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20. Should be able to generate report with option of transferring all waveforms into report.
21. Should have facility of storing the waveforms of complete spectrum with audio digitally and replaying with audio the complete study as recorded.
22. Should have remote control operation.
23. Should be supplied within built-in PC of latest Pentium processor, 4 GB RAM, 15" or larger, inbuilt LCD touch panel monitor, 1 TB B Hard Disk drive, Windows 7 or better operating system with SP2, MS office, Keyboard. Computer / PC should not be separate. It should be one unit and portable to move around.
24. Conductive gel: 3 Nos.
25. Should be supplied with External DVD writer.
26. The data can be exported of any display in either Excel or BMP format.
27. Should be supplied with Color Laser jet printer.
28. Should be supplied with UPS of suitable rating.
29. Should be supplied with dedicated equipment trolley.
30. Manufactures should have USFDA and CE certification.
31. Manufactures should have ISO certification for Quality Standards.
32. Local Service Support Facility must be available in Manipur.

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Specification for Brain Retractor System

- 1) Should be Double-Hinged Halo Ring provides 360-degrees of uninterrupted retractor arm placement and allows the halo ring to be easily angled for multiple approaches to the surgical field.
- 2) Should have built-in hand rest offers convenience and maximum stability.
- 3) Should be Low profile design allows for ease of instrument passage within the surgical field.
- 4) Should be Compatible with **Multipin Head Frame** Skull Clamps which can be brought into the surgical field at any stage during the procedure or when a skull clamp is not used allows for attachment to the side rails of the OR table.
- 5) Ring can be quickly changed to a half ring set-up for improved access.
- 6) Should have Folded ring allows two levels of retractor arm placement, providing unlimited retraction capabilities.
- 7) Should have Low profile click-in blades eliminate obstruction of the surgical site.
- 8) Retractor System should also be ideal for Pediatric Neurosurgery.
- 9) **Each Unit will be supplied with following:**
 - a) Halo Ring (1 No)
 - b) 225 to 230 mm Halo Flex Arm
 - c) 400 to 430 mm Halo Flex Arm
 - d) Halo Support Bracket
 - e) Halo Support Rod Arm
 - f) Halo Pattie Tray (1No)
 - g) Halo Mini Vise (1No)
 - h) 4 Inch long Curved Retractor Blades in width from 1/4" to 3/4".(10Nos.)
 - i) Tew Micro Retractor Blade with 2 mm x 10mm in lengths from 4 1/2" to 6 1/2". (3 Nos.)
 - j) Tew Micro Retractor Blade with 4mm x 10mm in lengths from 4 1/2" to 6 1/2" (3 Nos)
 - k) Adjustment Wrench (2 Nos.)
 - l) Universal side rail fitting (2Nos.)
 - m) Sterilization Tray Case (1No.)
 - n) Adapter for Flat Blade Spatula (2)
- 10) All the above items should be CE&USA FDA approved product.
- 11) Local service support facility must be available in Manipur.


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Specification for MAYFIELD CRANIAL STABILISATION SYSTEM

1. General OR Table Adaptor (Universal)

- a) Support/Mounting device that allows attachment of base units to the OR table when receptacle holes are absent or inappropriate.
- b) To fit with wide variety of table widths
- c) For Easy attachment to OR table side rails.
- d) For Quick, adjustable end bracket to fit a wide range of table widths.
- e) Should Provide greater lateral adjustment with multiple mounting holes for base unit attachment.
- f) Should have Several holes to better laterally adjust the set up of the system.

2. Ultra Base Unit.

- a) To Support/Mounting device that facilitates attachment of Skull Clamps and Headrest Systems to the OR table.
- b) 33% more weight and force bearing capacity for improved patient safety

3. Swivel Adaptor

- a) Should Attach to Base Unit to provide optima flexibility in positioning via 360-degree rotation.
- b) Should Adapt headrests and skull clamps to Base Units.

4. Skull Clamps

- a) Should Provide 3-point rigid cranial fixation.
- b) Flexibility and safety in positioning of skull pins around critical areas.
- c) Quick-release lock.

5. Skull Pins (Steel)

Re-usable and Disposable:

Adult:

- a) To Fit the Skull Clamps to allow rigid cranial fixation.
- b) Identification for reusable & Disposable product; ensures a secure fit.

Child:

- a) To Fit the Skull Clamps to allow rigid cranial fixation.
- b) Pinpoint reduced to control penetration when used with a child.
- c) Identification for reusable & Disposable product; ensures a secure fit.

6. Head rest system

- a) Horseshoe shaped headrest providing cranial support in the prone or supine position for adults and older children.
- b) For Vertical and lateral adjustments allow flexibility in patient positioning.
- c) Adjustable pad base to accommodates various head sizes.
- d) Fluid resistant gel pads provide comfort and reduce the incidence of pressure necrosis.
- e) Should have Pulley Rod attachment for skeletal traction.

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- f) Provides cranial support and positioning when rigid fixation is not needed
- g) Headrest pads easily contour to a patient's head.

7. Cross Bar Adaptor

- a) For seated position procedures, easily mounts to the OR table side rails to adapt
- b) Skull Clamps for posterior fossa craniotomy procedures or posterior cervical laminectomies.
- c) Allows for unobstructed view of the posterior cervical spine and occipital areas.
- d) Compatible with most currently available OR tables.

8. Universal Side Rail Fitting

- a) For attaching the Crossbar Adaptor and other products to the OR table.
- b) Should be Compatible with most currently available OR tables.

9. Non-Sterile, Disposable Covers to protect the stabilization system.

- a) Reduce cleaning time.
- b) Protect critical components.
- c) Provide patients and staff an increased level of safety.

10. System should have CE & USFDA Certification.

11. Local Service Support facility must be available in Manipur.

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TECHNICAL SPECIFICATION NEURO SURGICAL OPERATING MICROSCOPE

1. Working distance : 210 - 450 mm or more continuously variable through motorized multifocal lens, activated through Hand or Foot switch and through control panel. Manually adjustable override.
2. Magnification range : 1.5x ~ 18x with 10x eyepiece with +5D to -5D or more dioptre correction
3. Field of view : Minimum field of view 15 mm -150 mm with 10x eyepiece
4. Focusing : Motorized via multifocal lens activated through Hand & Touch screen control panel. Manually adjustable override
5. Eyepieces : 10x eyepiece with +5D to -5D or more dioptre correction
6. Light Source : 300 Watt Xenon illumination with integrated Xenon back-up and Single button Automatic lamp change over
7. Illumination field diameter : Should have Built in automatic zoom-synchronized illumination field diameter, with manual override and reset feature. Automatic Iris Control
8. Automated illumination control : Should have automated illumination. Brightness control should be linked to working distance. Focus Light Link
Illumination also can be controlled by hand switch or foot switch.
9. Binocular tube : Tiltable binocular tube 10x eyepieces with +5D to -5D or more dioptre Correction
10. Suspension system Height : True overhead capability not less than 7kg. Height in stand by position should not be less than 1880mm.
11. Beam Splitter : Fully integrated beam splitter (four port)
12. Camera : FULL HD medical grade video camera so that maximum resolution will display and record.
13. Display : 24" or more FULL HD medical grade display system attached with the microscope body. (no external monitor / detachable monitor will be acceptable) .
14. Recording : FULL HD medical grade recording system integrated into microscope.
15. Face to Face attachment : Fully integrated built in face to face attachment with Stereoscopic view.
Binocular tube should have Tiltable movement.
10x eyepieces with +5D to -5D or more dioptre correction
16. Stereo co observer : Stereo co-observation tube with minimum two joints.
45 degrees inclined tube or Straight Binocular tube with PD adjustment knob.
PD adjust scale is 55 mm to 75 mm with pair of wide field push-in eyepieces 10x with sleeves with locks.
17. Fluorescence : Microscope should be ready for ICG fluorescence based vascular surgeries.

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+ Specifications for Ultrasonic Surgical Aspirator

1. The System should have expanded selection of hand pieces and surgical tips which allows the surgeon to select the most appropriate combination based on the surgical procedure.
2. The System should be compact provided with built-in integrated suction facility with vacuum pressure of -20 to -90 KPa in continuous low noise and digital display.
3. The system should be based on 4 major subsystems like Fragmentation, Cooling, Irrigation and Aspiration having user-friendly console, colour coded tubing for easy set-up of the system.
4. The system must have a feature of "Tissue Select" (Patient Safety Settings) to differentiate firm and tougher tissue barriers with a tactile feedback in the hand piece.
5. The Handpieces of having frequency 23-25 KHz and 34-36 KHz must be provided and should be based on Magneto-restrictive technology. Handpieces must be compact and Light weight with 120W of energy.
6. The system must have a feature which maintains fragmentation capability for tumor removal while maximizing selectivity for surgeon control around critical structures and can differentiate tissue barriers with a tactile feedback in the hand piece.
7. The system should have Tissue release function (automatic shutting off suction for 2 seconds after deactivation of the vibration foot switch to prevent against delicate tissue trauma.
8. The system should have various types of tips having different length and diameter to use in surgical clinical application and all tips must be removal from the handpieces.
9. The system should have 22 different types of tip to use in different clinical procedures. The hand piece tips should be from 1.57mm diameter and up to 2.64mm diameter. The Tips should be autoclavable and re-usable.
10. The hand piece must have a shear tip for Calcified fibrous tissue removal which increases the fragmentation rate by 50% than any other tip.
11. All Tips Must have Pre-aspiration Holes for cooling the tip and to avoid misting at surgical area.
12. System should have Macro, Precision & Micro Tips having different length & diameter. Tips should be autoclavable and re-usable.
13. The hand piece should have helical Bone cutting / sculpting tip with 180 degree cutting / abrasive surface to enable greater control and precise work near critical structures.
14. The hand piece must have a laparoscopic tip about 30cm in length and with reusable extended life and autoclavable.
15. For extended hours during surgeries (i.e., for more than 4 - 8 hours) the hand piece should have a built-in water cooling system to avoid overheating of the hand piece.
16. The control panel should have adjustable viewing angle for better visibility in the Operation Theatre.
17. The footswitch should have a linear operation for irrigation and operation of the hand piece.
18. Integrated Irrigation Pump, adjustable at 0-10 ml/min and fast flush 0-25ml/min.

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19. System must have a feature of "Lap Mode" which facilitates to stop the continuous suction completely and the suction gets only activated by pressing the foot switch for fragmentation.
20. Hand piece / Probes:-
For integrated hand pieces/Probes and reusable tips.
- i. One 34-36 KHz Angled Micro hand piece with Tip: micro tip. Approx 1.5mm, long
 - ii. One 34-36 KHz Straight Hand piece with Tip diameter <1.2mm
 - iii. Two 34-36 KHz Handpieces/Probes for Transphenoidal surgeries (Min. Tip Length: 19 cm)
 - iv. One 23-25 KHz Angled Macro hand piece with tip. (ID approx 2mm or more, short)
 - v. One 23-25 KHz Straight, Micro hand piece with tip . (ID approx 1.5mm or more, short)
 - vi. One 23-25 KHz Laparoscopic Hand piece with Reusable Tip.
 - vii. Two Bone sculpting Hand piece with tip for bony lesion removal.

OR

For universal hand pieces/probes and disposable tips.

- i. One hand piece/probe each in each frequency range with detachable reusable/disposable Straight, Micro, Micro Plus, Macro, bone removal tips & laparoscopic tips.
21. Minimum consumables for 100cases (Tubing Set, Micro tips, Macro tips, laparoscopic tips as required for the system) should be provided and easily available thereafter (mention the name of consumable i.e tubing set, tips (Straight/angular, short/long etc.)
22. Cost of consumables should be quoted separately and quantity required for 100 cases from each category should clearly mentioned in the technical bid and cost of consumables for 100 cases per year for 10 years will be taken for price evaluation /ranking.
23. There must have an option to attach the handpiece to existing electro surgery unit in hospital OT to do the coagulation with the same tip including laparoscopic tips and parts required to attach must be provided. The coagulation effect should be achieved simultaneously along with fragmentation or independently. All the handpieces must have Coagulation facility.
24. Each hand piece to be provide with container from OEM for safe storage and autoclaving
25. The system along with all the subsystems should be based on integrated robust mobile cart including suction canister.
26. The system should be in use in at least 10 major hospitals and to provide at least 3 satisfactory certificates of the users.
27. Local service facility should be in Manipur.
28. System should have CE & US FDA approval.

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Technical Specification for 32 Channel Intra-Operative Monitoring (IOM) system

1. System should have minimum 32 channels of data acquisition with atleast 64 inputs that are software configurable.
2. Should have facility to display upto 128 channels.
3. All channels must be sampled simultaneously at 60 KHz.
4. System should have 18 programmable electrical stimulus outputs.
5. Should be provided with extremely durable, locking LEMO connectors.
6. System should be capable of accommodating simultaneous remote monitoring of upto 15 acquisition systems.
7. Should provide true IP-based peer-peer connectivity for remote monitoring.
8. System should have a test creation wizard to make individual monitoring protocols.
9. Should have NIM-like free running and stimulated EMG monitoring feature incorporated in the system.
10. Should have special chime function to indicate successful and unsuccessful stimulus delivery in the beginning of stimulus train.
11. Should be able to stimulate upper SSEP, lower SSEP, and auditory EP at independent rates within the same test protocol.
12. System should have special pedicle screw stimulation program.
13. System should be capable of monitoring upper and lower SSEP with MEP.
14. System should provide flexible and programmable TCeMEP stimulation of upto 1000V & 1500mA.
15. Additionally system should be able to monitor EEG, AEP, VEP, EMG etc. simultaneously as multi-modality feature.
16. Facility should be there for CSA & DSA plots.
17. System should have history window, event log and reporting capabilities.
18. Should be able to automatically detect use of electrosurgical devices, mute audio and protect averages (ESU Detection).
19. History window must display special notes in it.
20. System should be provided with the required set of electrodes and consumables.

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- 21. The system should have Regulatory Standard like US FDA Certificate, etc.
- 22. System should work based on PC (Laptop) interface that works under Windows platform with reporting facility.
- 23. Should be supplied with latest specification of laptop having configuration of 15.6" Screen, 1TB Hard disk, 4 GB RAM, Wireless Mouse, Speaker, B/W Laserjet Printer & Trolley.
- 24. Should have a local service support in Manipur.

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