SPECIFICATIONS FOR DIGITAL VIDEO POLYSOMNOGRAPHY SYSTEM

The Video Polysomnography system should have at least the following essential specifications.

Should be 50 channel Polysomnography system along with a complete set of consumables and accessories, with the following specification

Hardware

1. Number of minimum EEG channels should be 25.
2. The computer should be supplied with the system, after passing the strict in-house quality checks by the manufacturer to comply with medical equipment standards. (Locally supplied PC will not be considered)
3. Should have Integrated Pulse Oximetry module.
4. Should have integrated the EtCO2 module.
5. Should have integrated pressure transducer channel
6. Should have the provision of deriving snore from either pressure channel or dedicated sensor
7. Onboard impedance measurements.
8. Body wearable, compact size.
9. System should have 16-bit ADC with a resolution of less than 97 nano volts.
10. Should be able to perform Skin electrode impedance checks at both junction box and console to give the exact impedance in numeric values.
11. Input impedance: 100 M ohms
12. Sensitivity 1 to 200 microvolt per mm
13. Noise < 1.5 microvolt Peak to peak
14. CMRR: above 105 dB
15. Should have filter settings: 0.08 Hz to 300 Hz
16. Should have internal memory for continuous recording in case internal memory

Operational requirements

1. The system should have an Ethernet interface
2. System must conform to AASM Guidelines

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP, Lko.

3. System should be able to display a full 10-20 montage EEG with
    a. EEG: 25 Channel
    b. EOG: 2 Channel
    c. EMG : 3 Channel
    d. ECG : 3 Channel
    e. PLM : 3 Channel
    f. Snore: 1 Channel
    g. RESP : 3 Channel
    h. EXTRA: 2 Bipolar Channel
    i. Integrated Airflow Pressure: 1 Channel
    j. Body position: 1 Channel
    k. Nasal pressure: 1 Channel
    l. Integrated SpO2: 1 Channel
    m. Integrated CO2: 1 Channel
    n. DC: 6 Channel
4. System must be capable of simultaneously monitoring multiple recordings
5. System should have multiple data scroll speeds
6. System should have selectable video and audio quality
7. System should have Online scoring and editing & be able to display online AHI and total sleep time &Online arousal index
8. System should have the option of Multiple recording file size choices
9. System should have multiple synchronized time base
10. System should navigate data by the graphical interface, comment query, event query, and scroll bar
11. System should have a customized event creator
12. System should have custom event trend plots and hypnograms
13. System should have the option of viewing AHI, HDI, or ADI live or at any point in the record
14. System should View AHI at every treatment level
15. System should have Automatic or custom event associations
16. System should have the option of remote access scoring

Prof. Ayinash Agrawal
MD, IDCCM, FCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP, Lko.

17. System should have a Study Creator file wizard
18. System should be able to display multiple recordings in slide show
19. System should have the option of combining fragmented recordings
20. System should have the option of creating Custom MSLT files
21. System must have Auto and manual scoring

Acquisition Software

1. It should have a facility for acquisition and review mode by split screen and at least 3 reviews simultaneously.
2. Should have user-configurable Montages
3. Should have the option of setting up three different scroll speeds for the different sets of data display. Also, have the facility for a time cursor for easy correlation among different time bases.
4. Should have an individualized set of data scoring as per user requirements.
5. Should have facility for EEG scoring & frequency detection/Classification.
6. Should have facility for creating customized events.
7. Should have facility for Single click editing
8. Should have facility for auto-updating of patient information
9. Should have facility for slide show feature for presentation.
10. Should have facility for custom workplaces for different users.
11. Should have a facility for custom channel creation for the additional parameter.
12. Should have facility for custom watermarks.
13. Should have facility for configurable keyboard and mouse keys.
14. Should have facility for edit scoring from trend plots.
15. Should have Live trending of multiple parameters.
16. Should have Selectable video and audio quality.
17. Should have Online scoring and editing.
18. Should have Online AHI and sleep time.
19. Should have an Online arousal index.
20. Should have Remote viewing of live data.
21. Should have Auto append.

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP, Lko.

22. Should have an Automatic MSLT/MWT timer and recording tool.
23. Should have Offline video monitoring.
24. Should be able to support multiple users, with individualized operational settings.
25. Should have facility for scorer comparison between two scorers.
26. Should have an option for exporting the data on CD/DVD to be able to be played on other PC without the need for additional software.
27. Should have facility for changing channel layout by single mouse drag
28. Should have Delta Analysis Summary Option for Quantitative analysis
29. Should have Power Spectrum analysis for individual wave Bands, Should also display trend plots for the same.
30. Should be able to generate a report for the EEG spectrum Analysis with detailed Epoch power analysis.
31. Should have facility for individual password protection for different users

Must be supplied with

1. Should be supplied with Desktop computer with following or better specifications
   a) Desktop PC with intel i5 processor or better
   b) 4 GB RAM or more
   c) 1 TB or More HDD
   d) DVD writer
   e) 21" monitor
   f) Laser printer
2. **Consumables**
   a) EEG electrodes-100 Nos.
   b) Conduction paste – 10 sets.
   c) Cleaning gel – 10 Nos.
   d) PSG sensor kit – 2 Nos.

Safety requirements

1. The manufacturer must be ISO 13485 certified facility & product quoted must have passed at least the following certifications:-

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP, Lko

2. The offered system must be USFDA approved
3. IEC60601-1 Amnd. safety for EEG equivalent.
4. IEC60601-1 Amnd. 2 (1995),
5. IEC60601-2-26 (1994)
6. IEC60601-1 (1988)
7. CE certification with notified body approval having a four-digit approval number.
8. Class 2B Medical Device Directive for compliance to 93/42/EEC as amended up to date.

Conditions for tenderer:

1. All accessories should be from the same Original Equipment Manufacturer for the main unit.
2. Instruments must be ISO certified and a copy should be enclosed. (The ISO Certificate must be issued by any organization accredited by the Bureau of Indian Standard or accredited by the international accrediting forum "IAF" (Certificate to be attached).
3. Should be USA FDA and/ orEuropean CE be approved by 4 digits notified body.
4. Other necessary certifications if any required will be provided by the bidder for the smooth functioning of the machine.
5. Installation process should be performed by O.E.M trained service engineers/ service representatives on OEM letterhead or Service Report within 15 days of supply, with the mandatory provision of providing preventive services visit of OEM trained Service Engineer/ Service Representative quarterly per year till the completion of warranty period (i.e., 20 visits for the first 05 years) & further quarterly visits (04 visits/year) year till the completion of CMC period.
6. The equipment should have a Brand name/ Model Number embossed/etched on the equipment.
7. All the technical specifications in the compliance statement must be supported by Original Literature from the firm/ O.E.M with highlighting Numbering & flagging of all technical certificates.
8. Offered Equipment should have a strong Government Installation base.
9. Offered Equipment should have a Regional Sales Service Centre of the Original Equipment Manufacturer in the region for a 95 % uptime guarantee.
10. For the offered main unit, the essential, optional required consumables'/accessories' shelf

life should be declared on the Original Equipment Manufacturer's letterhead.

11. In case of technical snag/failure/breakdown the response time for the inspection should be within 24 hours and repair within 05 days otherwise provide a service machine/ alternate arrangement to be made till the period of recovery of the breakdown of the unit, failing which attracts penal action as per the decision of institute/ hospital.
12. For offered equipment the Training of technical staff and users should be performed by Original Equipment Manufacturer trained Service Engineers at the proper designated place- at bidders' cost.
13. Company should quote their latest model and need to provide an affidavit for the same.
14. As a tendering process the Demonstration of the offered Equipment is Mandatory at hospital/institute premises or other designated places at the bidder's cost.
15. The bidder must comply with the General Financial Rules and their modifications if any issued by the Government of India- 2017.
16. Any bidder from a country that shares a land border with India will be eligible to bid in the tender only if the bidder is registered with the Competent Authority (i.e., Registration certificate issued by the Ministry of Commerce and Industry (Department for Promotion of Industry and Internal Trade- DPIIT after October 2020). If any such bidder is not registered with DPIIT they will be liable for technical disqualification.
17. Principal (OEM) must authorize only one agent to be quoted in the bid otherwise multiple quotes through different agents in the same bid will be canceled.
18. The Bidder and its OEM both have to submit a notarized affidavit on the Indian Non-Judicial Stamp Paper of Rs.100/- that the bidder has not quoted the price higher than the current financial year and last financial year supplied to any government Institute/ Organization/ reputed Private Organization. OEM also has to submit that the price quoted by the bidder in the bid is on its behalf and the lowest in the current and last financial year in the country. Therefore, if at any stage it has been found that the supplier and its OEM have quoted lower rates than those quoted in this bid; the Institute (the purchaser) would be given the benefit of lower rates by the Supplier and any excess payment if any, will become immediately payable to the Institute (the purchaser). If such an affidavit is not submitted, the bid will be outrightly rejected. (Part of technical bid).

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP, Lko.

19. Guarantee / Warranty Period: Separate offers of Comprehensive Maintenance Contract (CMC on main equipment) and Annual Maintenance Contract (AMC on main equipment) for further 5 years after expiry of 5 years of warranty (i.e., 6^{th}, 7^{th}, 8^{th}, 9^{th} and 10^{th} years) in rupees only (and on basis of percentage of price) should be included in a financial bid in the absence of which the offer is liable to be rejected. Payment for CMC/AMC shall be made only after the expiry of the warranty of 5 years, in case the Institute (the purchaser) decides for availing of CMC/AMC services. Contract for CMC/AMC shall be decided on expiry of warranty but rates (not more than 5% inclusive of all taxes for 6^{th} to 10^{th} year) will be frozen at the price of an issued purchase order before the release of payment by the Institute (the purchaser). However, the Institute (the purchaser) may decide not to enter into any CMC/AMC contract without assigning any reason for the same, which shall be binding upon the bid.
20. Should provide 5-year CMC. CMC cannot be more than 5% of the contract value.
21. System configured application-specific educational video tutorials shall be provided as standard with the system.
22. Details of service outlet in India to render services during 5 years warranty period.
23. The principals must give a certificate if the supplier/vendor is changed during the course of the guarantee/warranty period, the principals would be responsible for the upkeep/maintenance of the quote/supplied equipment, besides honouring all the terms and conditions of CMC/AMC in letter and spirit.

Prof. Avinash Agrawal
MD, IDCC, IFCCM, FICCM, FIACCM, FCCP (USA)
Head, Department of Critical care,
King George's Medical University, UP, Lko.