All-India Institute of Medical Sciences Ansari Nagar, New Delhi-29. (RESEARCH SECTION)

Ref. No.05/Stores/NM/MT/2014-15/RS

Dated: 23.07.2104

Subject: Purchase of equipments required for Video PSG-EEG Machine for the department of Nuclear Medicine at AIIMS, New Delhi-29 on proprietary basis- <u>Inviting comments</u> thereon.

The request has been received from Dr. Madhavi Tripathi, Deptt. of Nuclear Medicine, AIIMS to purchase the subject item from M/s Rohanika Electronics & Medical Systems (Mfd. By M/s Somno Medics Gmbh, Germany) on proprietary basis. The proposal submitted by M/s Rohanika Electronics & Medical Systems. and PAC certifications 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 issue of 15 days giving reference **No. 05/Stores/NM/MT/2014-15/RS**. The comments should be received by office of Stores Officer (RS), Research Section at AIIMS on or before **08.08.2014 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.

STORES OFFICER (RS)

Encl: Related documents enclosed.

- 1. PAC Certificate enclosed.
- 2. Specification of equipment.

Medizinische Geräte für Schlafdiagnostik und Therapie



SOMNOmedics GmbH · Am Sonnenstuhl 63 · D-97236 Randersacker

SOMNOmedics GmbH Am Sonnenstuhl 63 D-97236 Randersacker Telefon 0049(0) 931-359094-0 Telefax 0049(0) 931-359094-49 www.somnomedics.de info@somnomedics.de

10.06.2014

Proprietary Certificate

We Somnomedics GmbH manufacture portable Polysomnography units (weight 220 gms up to 58 channels) that give full mobility to the patient with wireless data transfer up to 100 metres. It has battery backup of up to 14 hours during Online Monitoring and up to 33 hours for ambulatory PSG. Our unit also measure beat to beat Blood Pressure Monitoring (both Systolic & Diastolic) through PTT without inflation of cuff.

All the features combined (Portability, Battery back, wireless capability and BP Monitoring) make our system unique and proprietary in nature.

For Somnomedics GmbH

Stahn Anja

International Sales

ПГ SOMM medics SOMNOmedics GmbH

SOMNOmedics GmbH Am Sonnenstuhl 63 · D=97236 Randersaeker Telefon 0049(0) 9 31-35 90 94-0 Telefax 0049(0) 9 31-35 90 94-49

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Sitz der Gesellschaft: Randersacker Geschäftsführer: Dr. Gert Küchler Betriebs-Nr.: 13012621 Registergericht: Würzburg / HRB 7171 IK: 590961172 / Zoll-Nr.: 4954211 UST-ID: DE 814687575 Raiffeisenbank Höchberg eG BIC-Code: GENODEF1HBG IBAN-Nr.: DE31790631220100213713 Sparkasse Mainfranken Würzburg BIC-Code: BYLADEM1SWU IBAN-Nr.: DE28790500000043207026 Deutsche Bank PGK Würzburg (USD-Konto) BIC-Code: DEUTDEDB790 IBAN-Nr.: DE63 7907 0024 0130 0755 01

ALL INDIA INSTITUTE OF MEDICAL SCIENCES ANSARI NAGAR: NEW DELHI: 110 029

Name of the Item: Purchase of Portable Video PSG-EEG Machine (01 Nos.)

TECHNICAL SPECIFICATION:

Technical specifications for Portable Video Polysomnography – 1 no.

Hard ware Specifications for **Portable Video-PSG–EEG machine** facility to record up to 58 channels 1. Should have following Channels:-

EEG- compatible with acquisition in PET/CT and PET-MRI environment

ECG- compatible with acquisition in PET/CT and PET-MRI environment

EOG

EMG Nasal pressure transducer

Thermistor - RIP Respiratory Effort - RIP

Snoring Body Position CPAP Pressure

Limb Movement SaO2 Pulse Rate

2. The system must have

a. Amplifier must be compact, body wearable and light weight approximately <1000 gms

b. Referential Channels at least 25

(Possible to configure all Referential Channels for

EOG, EEG & EMG, as per requirement.

c. Bipolar Channels - at least 6

d. Additional DC Channels - at least 8

(For External Peripherals like Capnography, PH, Oesophageal monitoring, etc.)

Should have ability for re-referencing, re-montaging and re-filtering at any time or even after the study has been recorded

e. The system should be able to record Systolic and Diastolic BP either from PTT signal or from 3rd party standalone system offering NIBP measurement from non-inflating soft finger cuffs that can directly be interfaced with the machine.

f. Should have and additional feature of FFT Analysis of all EEG waveforms and capability to record Heart Rate Variability. Should have adjustable low and high pass filters to have clear view of EEG, Should have sampling rate of 4 to 512 samples/sec. Should have an ECG Elimination filter for EEG. Also should have facility of Brain mapping.

3. There should be two integrated Pressure Transducers:

a. To measure direct CPAP Pressure (Facility to interface any make of CPAP with the system)

b. To measure Nasal Pressure to assess Nasal Airflow without Nasal thermistor.

4. Should have Integrated Pulse Oximeter, body position sensor, light sensor and movement detection sensor.

5. Should have Integrated Bed side and on screen impedance check & self-calibration.

6. Should have adjustable gain and notch filters.

7. Should have fully compressed raw data stored on all channels.

8. Easy interface with CPAP machines of various make should be possible, with ease in PAP titration.

There should be provision for automatic calculation and display of apnoea- hypopnea index as well as other parameters like desaturation index, live during recording of titration studies.

9. Should have synchronized digital video with camera and infrared source. Video camera with high audio quality without external microphone (best available commercially).

10. Should have provision for power backup for at least 12 hrs and ups for camera & computer.

11. Ability for wireless acquisition and transmission of PSG data - means full mobility to the patient

12. The unit should have facility to store data on Flash card and simultaneously transmit the data to the Base station/PC. Data Storage on high speed compact flash card with up to 2 GB capacity or up to minimum of 50 hours of PSG recording time.

13. Should have continuous signal check on display or at the patient bedside.

14. The system should have the ability to work on battery so that there is no electrical interference coming to EEG signals.

Software Specifications:

1. Should have provision for Real Time Access to studies for analysis of data currently being recorded from the review/ recording station.

2. Should be interfaced to PC via interface for data acquisition.

3. The system should be compact & modular in design and should have facility to hook-up directly to any LAN port on the network and the data should acquired on sleep station fixed too.

4. Should have user definable Montage changes.

5. Should have independent, Selectable time basis for upper & Lower portions of the screen enabling review of fast moving traces like EEG in one half and slower Respiratory Waveforms on the other half, simultaneously.

6. Should have sleep staging options for Adult and Paediatric populations, configured according to latest AASM 2013 criteria.

7. Should have scoring comparison (quality control) feature which will allow comparison between scoring by different users, including sleep stages, respiratory events and AHI, arousals and limb movements, with provision for calculation of percentage agreement between different reviewers/ scorers.

8. Should have capability to export and import the complete study in EDF Format, exe format, and reports can be exported to Excel and PDF format

9. Software should have the capability to display and analyze respiratory events linking with arousals, periodic limb movements and desaturations.

10. Should have the capability for periodic limb movement display and analysis with linking of individual limb movements with apnea/hypopnea and with arousals.

11. Software for cyclic alternating pattern analysis should be made available.

12. It should have an integrated display the detailed sleep apnea treatment steps for all modalities (CPAP, bi-level PAP (different modes), Adaptive servo ventilation and oxygen supplementation)

13. Antivirus security till the AMC or CMC (not free or trial version) - upgradable every year, should be made available with each system.

Review Station

1. Highest configuration windows based 'all-in-one' laptop computer with at least 3rd Generation Intel Core tm i7 Processor, 8 GB RAM or highest available, 18-21" LED color monitor, DVD R/W, Mouse.

2. Online PSG viewing software (1 no.)

3. Licenses for review and analysis software for PSG equipment (2 nos.)

4. Software for networking all existing PSG systems with the review room.

Wireless access points

Access switches-2

Server: External hard drive 3 TB capacity

6. Archiving facilities: 1 high capacity servers each with 10 TB capacity each

7. High speed wireless internet connectivity with advanced security-

Camera: The system should be provided with High end HD camera which can be synchronized with the raw data and audio recordings. Playback at different frame speeds (1-100 times).

The camera should have capability of more than 8X optical zoom and 12 X digital zoom for detailed analysis.

It should have good recording in dark also (infrared).

Camera should be controlled directly via Software with capability of color recording with IR capability and be supportable on a portable sturdy tripod/stand.

Actigraphy: 1 in number to be provided with the latest AASM requirement.

Treatment facilities to be supplied with the system:

1. Multimodality titration equipment (enabled to titrate CPAP, Bi-level, and ASV)

2. Capability to remotely control PAP treatment parameters live, from the review station, without entering patients' cubicles.

3. Multiple types of masks of different sizes pediatric and adult.

4. The suitable rating UPS to be provided for recording for 1 -2 hrs for both raw data and video.

5. The system quoted should be warranted as per AIIMS research section rules.

6 sets of accessories should be supplied along with the system,

Along with price list of all accessories.

6. Periodic maintenance and Annual maintenance contract must be provided as per AIIMS rules.

7. It should be certified by European (EC) & American Standards (FDA)