Notice Inviting e-Tender

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SUPPLY AND COMMISSIONING OF MEDICAL EQUIPMENTS (SET-I) FOR TRAUMA CARE FACILITY FOR THE HOSPITALS AND MEDICAL COLLEGES OF THE GOVT. OF WEST BENGAL

(Submission of Bid through *online*)

| Bid Reference No.: WBMSCL /NIT- 07/2018 | Dated – 18.01.2018 |
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SCHEDULE – I

The following amendments have been made in the tender document. The changes are highlighted in yellow in the document below,

Amendment – I

Revised technical specifications for 6 Otoacoustic emissions (OAE) system to be used for DEIC: Facility for doing TEOAE, DPOAE

## Otoacoustic emissions (OAE) system: Facility for doing TEOAE, DPOAE

õ TEOAE Specifications:

1. Facility of click stimulus and Tone burst stimulus
2. Configurable stimulus intensity
3. Band analysis from 1 KHz to 5 KHz or more
4. Reproducibility in half octave bands
5. Should have suppression facility
6. Full cross correlation, frequency analysis with reproducibility and signal to noise data on single test or between test pairs
7. Customized TEOAE protocol

DPOAE specifications:

1. Frequency range Minimum of 500-10,000 Hz.
2. Number of test points per octave: Minimum 30 points per octave
3. Intensity: f1 and f2 levels from 0 to 70 dB SPL.

4. Customizable measurement protocols.
5. Variable Ratio: f2/f1.
6. DP Definition Points: f2-f1; 2f2-f1; 2f1-f2; 3f1-2f2; 3f2-2f1; 4f1- 3f2; 4f2-3f1.
7. SNR assessment
8. Should supply printer for printing of reports.
9. Should have CE (European) or US FDA.

**Technical Specification for 70 OAE for SNCU follow up clinic to be set up with existing SNCUs across the State**

Facility for doing TEOAE, DPOAE

õTEOAE Specifications:

1. Facility of click stimulus
2. Configurable stimulus intensity
3. Band analysis from 1.5 KHz to 4 KHz
4. Reproducibility in half octave bands
5. Should have suppression facility
6. Full cross correlation, frequency analysis with reproducibility and signal to noise data on single test or between test pairs
7. Customized TEOAE protocol

õDPOAE specifications:

1. Frequency range Minimum of 2000-5000 Hz.
2. Number of test points per octave: Upto 30 points per octave
3. Intensity: f1 and f2 levels from 0 to 70 dB SPL.
4. Customizable measurement protocols.
5. Variable Ratio: f2/f1.
6. SNR assessment

Operating Noise should be < 50dBSPL
FDA or European CE approved equipment
Should follows IEC standard protocol which follows medical device directive
Software for data transfer to PC
Equipment can save at least 1000 patient data in the device
Thermal printer or Bluetooth printer

## SCHEDULE – II

The following amendments have been made in the tender document. The changes are highlighted in yellow in the document below,

Amendment – I

### Revised technical specifications for ABR Screener used for post newborn hearing screening diagnostic testing with Laptop facility:

### Automatic ABR Screener without disposable electrodes:

An electro acoustic instrument designed to evaluate the activity of the auditory pathway of the brain in response to an acoustic signal [auditory brainstem response (ABR)] it provides at the ear, without need of patient cooperation. The signal, detected via the device's various electrodes, is measured using computer averaging and signal processing techniques.

### Technical characteristics for automated ABER:

1. Lightweight Design
2. Inbuilt reusable electrodes make it easy to screen New Born and young Children
3. Fast and automatic ABR-screening, reliable results in short period of time
4. Integrated electrodes and should have no disposable electrodes
5. Automatic Impedance Check indicating impedance conditions
6. Stimulation level should start at 35 dBnHL and CE Chirp as stimulus.
7. No Abrasive Skin Cleaning should be required
8. No Sticking of Electrodes
9. Additional Follow-up measuring modes: Time-Step-Stimulus and Standard ABR
10. The System should have compliance to the International Regulatory Standards like CE, FDA, and ISO etc.
11. Consumables: Stainless steel electrodes (3 set of 3 pieces); Stainless steel electrodes for pre-matures (3 set of 3 pieces); Gel protection for electrodes (3 set of 3 pieces)

### Configuration of Computers for ABR+ASSR and Automated ABR (Need for both ABR+ ASSR and AABR separately:

Processor Name: Latest version of Intel (Core i5-7500 or above)
Processor Speed: 3.4 GHz or above

RAM: 8GB or above
Storage Capacity: 1 TB or above
Monitor Type: LCD Wide Screen
Screen Size: 21 inch for desktop
Operating System: Original Windows 10 (Latest version is prefarable)

## SCHEDULE – III

The following amendments have been made in the tender document. The changes are highlighted in yellow in the document below,

Amendment – I

### Revised technical specifications for Two channel pure tone clinical Audiometer

1. Frequency Range :
   Air Conduction : 125Hz to 12,000 Hz with noise free changeover between frequencies,
   Bone conduction : 250 Hz to 8,000 Hz.

2. System should have the facility for upgrading to High Frequency Testing : 8,000Hz to 20,000Hz, Intensity Range : -20 dB HL to 100 dB HL.

3. Accuracy : ≤ 2% for Earphone and ≤ 5% for Bone vibrator.

4. Intensity Range :

| | | |
|---|---|---|
| Air Conduction | : | -10 dB HL to 120 dB HL |
| Bone Conduction | : | -10 dB HL to 80 dB HL (Mastoid) |
| | | -20dB HL to 70 dB HL (Forehead) |

5. System should have the facility for Talk forward, Talk Back, Monitor and Auxilary Intercom.

6. System should have masking facility with Narrow band noise and White noise.

7. The Audiometer must have a Directional Gooseneck microphone for live voice testing and communication.

8. The Audiometer must have light pipes surrounding each parameter selection on the control panel. All recording parameters must light up and stay lit until changes are made in the test protocol. In the event of power failure, the audiometric data collected will be recovered and displayed when system is re-booted. A large easy to read color monitor must be integrated into the control panel with flexible adjustments for individual viewing preferences.

9. The audiometer must have sound field speaker output range options to include 90 dB HL,
   96 dB HL and 102 dB HL.

10. System must have the facility to perform the following tests :

i) Alternate Binaural Loudness Balance (ABLB) or Fowler Test (ALT).
- Evaluate perceived growth of loudness between ears.
- Identify Recruitment.

ii) Short-Increment Sensitivity Index (SISI).
- Present small increments of intensity change at low sensation levels.

iii) Modifications to the SISI test.

iv) Tone Decay Test (TDT).
- Measure for a rapid "abnormal auditory adaptation" in response to a continuous pure tone.
- Isolate retro-cochlear pathology of the CNVII.

v) Monaural Loudness Balance(MLB) Test.
- Evaluate perceived growth of loudness of two different frequencies in the same ear.

vi) Difference Limen Intensity (DLI).

viii) Pure Tone Stenger Test.

ix) Hearing Aid Evaluation.

ix) Speech Stenger Test.

x) Masking Level Difference (MLD).

xi) Sensorineural Acuity Level (SAL) Test. – Modification of the Rainville Method.

xii) Threshold Equalizing Noise (TEN) Test.

xiii) Quick SIN.

xiv) Lombard or Voice Reflex Test

xv) Delayed Auditory Feedback.

xvi) Staggered Spondaic Word Test (SSW).

xvii) Doerfler-Stewart Test.

xviii) Modified Doerfler-Stewart Test.

xix) Performance Intensity Phonetically Balance (PIPB) Test.

xx) Single & multi-syllabic speech normative curve.

xxi) Automated Speech Intelligibility Index (SII) Determination.

xxii) Pure Tone Audiometry (PTA) Averaging.

xxiii) Langenbeck (Tone in Noise) Test.

xxiv) BKB - SIN (Bamford-Kowal-Bench - Speech - in - Noise) Test.

xxv) Bekesy Test.

xxvi) Behavioral Observation Audiometry (BOA).

xxvii) High Frequency (Optional)
- Monitor oto-toxic effects of medical treatment plans.
- Tinnitus evaluations.

11. System must be able to perform recorded tests :
    - Use an external stereo tape or CD player.
    - Perform APD testing.
    - Perform Speech in Noise testing.

12. Built-in Scorer / Timer.

13. Mixing/Routing of signals to either or both ears must be possible.

14. Must hold calibration for TDH, Inserts and Bone, the supplier should provide all these transducers.

15. The audiometer must interface with 7 electronic record solutions and each must be capable of providing digital audiogram.

16. Must be able to output PDF Test Report.

17. The Audiometer must be able to operate as a standalone audiometer without a PC connection but able to communicate with computer – must have built-in display.

18. LCD display of test frequencies and intensity of test.

19. Must be Noah Compatible.

20. The system should have the Regulatory Standards such as ISO, US FDA and CE. Certificate.

The system suppliers should have Local Service support.

## SCHEDULE – IV

The following amendments have been made in the tender document. The changes are highlighted in yellow in the document below,

### Amendment – I

### Revised technical specifications for Diagnostic ABR along with ASSR systems used for post newborn hearing screening diagnostic testing along with Desktop

### General:

Conformance with IEC type 1 ABR specification.

**Number of channels:**

1. Minimum of 2 channels but able to select a single channel.
2. Able to do single channel recording for left ear and right ear assessment with 3 electrodes. (e.g. left and right mastoid and high forehead/vertex)

**EEG amplifier:**

1. Data reject levels (after filtering) ± 5µV to ± 50 µV. Steps sizes to include ± 5, 10,20, 50 or equivalent.
2. Preferences for continuous adjustment or finer data reject voltage steps. (Desirable)
3. Reject disabled period after stimulus ('blocking'). Adjustable from 0 to 15ms in1ms steps or finer.
4. EEG display to be of filtered data with rejects limits displayed.
5. Amplifier noise should be <0.5 µV RMS referred to input over bandwidth of 30 to1500 Hz.

**Filters**

Minimum of:

1. Low frequency (high pass): 20-30, 50, 100, Hz
2. High frequency (low pass): 1000, 1500, 2000, 3000 Hz

Note: The above values are the preferred values. If different values are provided they should be close to these. e.g a 1600Hz filter would be an acceptable alternative to a 1500Hz filter. Alternatives should not be more than 20% different from the preferred values.

3. User-defined non-destructive digital filter (Desirable)

**Stimulus:**

1. The click and tone pip stimulus levels should be calibrated to ISO 389-6, be expressed in units of dBnHL and be independent of repetition rate. However alternative calibration values should be settable by the user (administrator permission only).
2. If long (>20ms) tone bursts are available the stimulus levels should be calibratedto ISO 389-1/2/3 and be expressed in dBHL. (Desirable)
3. 5dB steps in stimulus level except for highest level (which may be different depending on calibration e.g. 99dBnHL).
4. 1dB steps in stimulus level (Desirable)
5. A click stimulus of 100μs duration should be provided.
6. Tone pips / tone bursts should be provided at a minimum of 500Hz, 1000Hz, 2000Hz and 4000Hz and have the option of a linear and Blackman gating envelopes, with rise, plateau and fall times as specified in IEC.
7. Stimulus polarity options should be alternating, rarefaction & compression (condensation)
8. Chirp stimuli. Bandwidth and calibration to be specified by the manufacturer.(Desirable)
9. Masking noise: contralateral unfiltered (white) noise calibrated in dBSPL when measured in an ear simulator (not a 6cc or 2cc coupler), range no less than 0-100 dBSPL. There should be a user-selected option for **synchronous** masking -changes in the stimulus level causes the noise to change by the same amount
10. Inserts: Monitoring of ear canal stimulus level and automatic pre-test stimulus level calibration.(Desirable)
11. Bone vibrator: this should be a Radioear B71 type with bone conduction BERA facility.
12. There must be a clear indication on-screen and on the printout showing the transducer type being used.
13. Should impart user training by trained application specialist trained till the satisfaction.

**Data averaging and editing:**

1. Time base (window) options: a minimum of 10ms, 20ms, 25ms (all ±2ms)
2. Time base (window) length set table in 1ms steps.(Desirable)
3. For alternating stimuli the average should contain an equal number of sweeps with rarefaction and compression stimuli.

**Objective scoring/residual noise:**

1. At least one validated measure of confidence in the presence of a response. e.g. Fsp, correlation. Validation should be published evidence of efficacy in a peer reviewed journal. Full details of the algorithm used to calculate the measure should be provided.
2. At least one validated measure of residual noise. Full details of the algorithm used to calculate the measure should be provided.
3. Confidence and residual noise measures should be displayed on-screen and updated every 1 second or less.(Desirable)
4. The data window start and end time used for the measurement of the confidence in the result should be settable in 1ms steps or less.

5. Waveforms should be exportable for validation of these objective measures in a format that can be imported into Excel. They should include sufficient details of test subject and test parameters so that the waveforms can be correctly identified.
6. Confidence and residual noise measures should be provided for any number of Sweeps (Desirable)
7. Auto stop features based on confidence and residual noise (Desirable)

**Display / waveform manipulation:**

1. Option of automatic super imposition of traces by stimulus level
2. Super imposition should be optimal (excluding any stimulus artifact, the difference between the traces summed over the recording window should on average be zero).
3. Option to manually position traces on screen. Position should remain upon completion of a new average unless method of display is changed.
4. User defined display scales to include scales within the range defined in the NHSP ABR Guidance (2010).
5. Options to add (weighted add) and subtract (un-weighted) pairs of waveforms.
6. User-defined waveform peak markers capable of on-screen and printed absolutelatency, inter-peak latency difference and inter-peak amplitude difference.
7. Option to display horizontal & vertical gridlines at intervals equal to axis tick Marks
8. Display scale tick marks at standardized numbers of ms/uV. E.g. 2ms on the x axis and 0.1uV (100nV) on y axis.(Desirable)
9. Average display update at least every one second.(Desirable)
10. Optional separate display of rarefaction and compression averages when using alternate stimuli.(Desirable)
11. Rarefaction and compression averages, when using alternating stimuli, to be optimally superimposed for the purposes of assessing replication.(Desirable)
12. Some means should be provided that allows up to 4 superimposed waveforms at the same stimulus level to be distinguished from each other (using colour or linetype) (Desirable)
13. Provision of waveform baselines (zero voltage line) to aid / check optimal manual superposition of replications (Desirable)

**Printout:**

1. The waveform aspect ratio on the printout should be the same as that on the screen.
2. There should be an option of print to file in a recognized format (e.g. pdf, xps).
3. There should be an option to print to paper or file in an anonymised version i.e. with no patient, site or tester information.
4. Clear vertical and horizontal scales should be provided
5. Any non- original e.g. calculated /modified waveforms should to be identified assuch

**The printout should include :**

1. Date of test (date format must be selectable or be dd/mm/yyyy)
2. Patient Name

3. Patient Identifier
4. Patient date of birth (date format must be selectable or be dd/mm/yyyy)
5. The following data should be given for each waveform.
6. Number of sweeps accepted
7. Number (or %) of sweeps rejected
8. Filter setting low frequency (high pass)
9. Filter setting high frequency (low pass)
10. Data reject level in ±µV
11. Notch filter enablement
12. Transducer type*
13. Stimulus level*
14. Stimulus type*
15. Frequency of stimulus (if applicable)*
16. Stimulus plateau cycles
17. Stimulus rate
18. Stimulus polarity
19. Masking level (if masking is not enabled then this should be indicated)
20. Validated objective score e.g. Fsp, correlation
21. Validated residual noise measure.
22. User-defined comment fields: one per level (or waveform) plus one multi-line field per patient
23. Test parameters that are identical for all displayed waveforms should be listed once rather than listed for every waveform; only those parameters with different values across waveforms should be listed for every waveform, thus saving space and aiding review (Desirable)
24. Some means should be provided that allows up to 4 superimposed waveforms tobe distinguished from each other (preserved when copied in monochrome)(Desirable)

* Each waveform label should contain information on these parameters Stimulus rise and fall cycles or total cycles (Blackman)

**Electronic record for review/audit:**

The facility to export the records and traces of an individual patient (option of agroup of patients desirable) in a format suitable for review on a computer loaded with the appropriate software.

Configuration of Computers:

Processor Name: Latest version of Intel (Core i5-7500 or above)
Processor Speed: 3.4 GHz or above
RAM: 8GB or above
Storage Capacity: 1 TB or above
Monitor Type: LCD Wide Screen
Screen Size: 21 inch for desktop
Operating System: Original Windows 10 (Latest version is prefarable)

## SCHEDULE – V

The following amendments have been made in the tender document. The changes are highlighted in yellow in the document below,

### Amendment – I

### Revised technical specifications for Diagnostic Tympanometer (Middle Ear Analyzer)

1) The system should have the capacity to perform the following tests:
   - Diagnostic Tympanometry,
   - Acoustic Reflex Threshold,
   - Reflex Decay,
   - Eustachian Tube Function ( Intact & Perforated),

   **Special Tests** like:
   - **Two-Component Tympanometry,**
   - **Multiple Frequencies Tympanometry,**

2) The Tympanometry should have the following protocols like Diagnostic, Screening and should be User Defined.

3) The System must have pre-programmed testing protocols with ultra-light probe.

4) System should have the facility for storing upto 26 test results in its internal memory.

5) The system should have the following Specification :

   a) **Probe Tone :** 226 Hz (85 dB SPL ± 1.5 dB)
   **678 Hz (85 dB SPL ± 3.0 dB)**
   **1000 Hz (75 dB SPL ± 3.0 dB)**
   Accuracy : ± 1%
   Harmonic Distortion : Less than 5%

   b) **Admittance Measurements :**
   - Range : 226 Hz (-1.0 to+ 7.0)
     678 Hz (-5.0 to+ 25)
     1000 Hz (-5.0 to+ 30)
   - Sensitivity Scale : Auto Scales to Appropriate Range, Manual Selection also possible in Reflex modes only.
   - Accuracy (226 Hz) :
     Tymp Mode : ± 5 % of Reading or ± 0.1 ml, whichever is greater.
     Reflex Mode : ± 5 % of Reading or ± 0.2 ml, whichever is greater.

   c) **Pressure Measurements** (Load Volume of 0.2 to 7.0 ml) **:**

- Range : Normal = +200 to -400 da Pa
  Wide = +400 to -600 da Pa
- Accuracy : ± 10 % of reading or ± 10 da Pa, whichever is greater.
- Sweep Rate : 12.5, 50.0 and 600/200 da Pa/sec, 200 daPa/Sec.
- Sweep Accuracy : 10 % of nominal rate.
- Maximum limits (in 0.5 cc Cavity) : -800 da Pa and + 600 da Pa.

d) **Reflex Measurements :**

- Stimuli : 250,500, 1K, 2 K, 4K, BBN, LBN & HBN,
  Click (100 microseconds pulse), External Input,
  Non –acoustic.
- Frequency Accuracy : ± 3 %
- Harmonic Distortion (THD) : Less than 5 % (measured acoustically)
- Noise Signals : (3 dB band widths)
- Low Band (LBN) : 125 - 1,600 Hz
- High Band (HBN) : 1,600 - 4,000 Hz
- Broad Band (BBN) : 125 - 4,000 Hz
- Intensity Range : 35 to 120 dB HL
- Step Size : 1dB, 2dB, 5 dB
- Calibration Accuracy : ± 3 dB
- Step Accuracy : ± 0.5 dB
- ON/OFF Ratio : 70 dB minimum

6) System should have built in Large and clear LCD Display with contrast adjustment knob for Displaying Tympanometry Results.

7) The system must have the following features :
   a) Pre-programmed default parameters for each test mode.
   b) Ability to change default parameters.
   c) Ability to set-up parameters for multiple users.
   d) Automated sequence programmability or manual sequencing.
   e) The Sensitivity Scales must automatically be determined based on peak amplitude.
   f) The Test tracings, ECV and Pressure Meter are displayed in real-time on the monitor.
   g) Ability to overlay multiple (upto three) tracings.
   h) Ability to choose between automatic or manual time tones presentations.

i) To Display the time interval between onset of acoustic stimulus and onset of stapedius contraction.0
j) Peak Pressure value from the tympanogram must be maintained for Reflex Testing & also must be capable for the manual adjustment.
k) Able to automatically (or) manually seek and mark the threshold level.
l) To use in pre-operative and post-operative evaluations:
    - Two-component Tympanometry.
    - View tracings in B/G format for each frequency.

8) The System should have NAOH-Compatibility for easy data management.

9) The System should have Continuous Strip Printer.
10) The System should have compliance to the International Regulatory Standards like CE, FDA, ISO etc.

## SCHEDULE – VI

The following amendments have been made in the tender document. The changes are highlighted in yellow in the document below,

### Amendment – I

### Revised technical specifications for Pedo Dental chair and dental X-ray

### Dental Chair Specification – Paediatric

1. High speed hand piece tie in (2 hole) / (4 hole)
2. Low speed hand piece tie in (2 hole) / (4 hole)
3. 3 way syringe 1 set
4. All directional Head Rest 1 set
5. X-Ray image viewer – 1
6. Saliva ejector – 1 set
7. Outlet pure water bottle – 1 set
8. Movable dental unit
9. Double arm rest
10. Completely seamless back rest
11. Dentist Stool – 1 pc

12. Lower chair frame
13. Stain resistant ceramic bowl
14. Ceramic spittoon
15. Velcro straps
16. LED/ Halogen light

## X-Ray Unit

1. X-Ray tube current minimum 7/8/10 Ma and 60/65/70 KV
2. Constant potential minimum 20 KHz frequency DC X-Ray.
3. Exposure timer of minimum 0.02 to 2 seconds
4. Focal spot size should not exceed 0.8 X 0.8 mm
5. Compatible for digital Radiography
6. Swing angulation of at least $290^0$ in vertical plane and $360^0$ continuous rotating in the horizontal plane.
7. Should work on 200-240 Vac / 50Hz
8. Should be AERB type approved and relevant copies of certificate should be present
9. Should have safely certificate from a competent authority
10. Mobile floor unit model
11. CE (European) / US FDA

## Compressor:

It should be provided with 0.75 -2 HP and also oil free, noise free and maintenance free.

## Suction Machine:

Should have both the facility of high and low suction and outlet part should be automatic controlled.

## Specification of Lead Apron

1. AERB approved
2. Light weight 0.5mm Lead equivalent
3. Hook and loop type
4. Supplied along with Thyroid gland collar

## SCHEDULE – VII

The following amendments have been made in the tender document. The changes are highlighted in yellow in the document below,

### Amendment – I

### Revised technical specifications for Radio visiography (RVG)

1. CCD / Super CMOS Technology
2. Sensor size 1 universal comfortable for paediatric
3. Number of pixels minimum 20 lacs/nm (Tube resolution)
4. Pixel size in range of 18.5 X 18.5 microm to 20 X 20 microme
5. Exposure light should be minimum 4 lacs
6. Sensor cable length should be minimum 2 meter
7. Laptop with LASER printer (Black & White) and should provide 1TB external hard disk.
8. CE (European) / US FDA

Should be supplied with adequate and compatible computer system with latest operating system.