Notice Inviting e-Tender

West Bengal Medical Services Corporation Limited
Swasthya Sathi
GN-29, Salt Lake, Sector-V
Kolkata-700091
Phone No (033) 40340308/319
E mail: procurement@wbmsc.gov.in

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- 105/2017 Dated – 30.11.2017

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 systems used for post newborn hearing screening diagnostic testing

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 3electrodes. (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 providedthey 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% differentfrom 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. Howeveralternative calibration values should be settable by the user (administratorpermission 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 differentdepending 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 gatingenvelopes, 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 thetransducer type being used.
13. Separate output sockets for each transducer type to avoid errors associated with phone / insert / BC conflict between software calibration and actual transducer being used. It should be impossible to connect a transducer into a socket designed for a different transducer type.(Desirable)
14. 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 fieldper patient
23. Test parameters that are identical for all displayed waveforms should be listedonce rather than listed for every waveform; only those parameters with differentvalues across waveforms should be listed for every waveform, thus saving spaceand 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 parametersStimulus 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.