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No. F-8() RMSC/EPM/M-2/18-19/NIB-386/ 426

Dated: 12.2.2019

CLARIFICATION/CORRIGENDUM/ADDENDUM

Sub:- Revised bid Schedule and Amended Technical Specification of the rate contract 1. OAE Analyzer 5. Impedance Audiometer 6. OAE (with BAER Technology) for under NIB No. F-8() RMSC/EPM/M-2/18-19/NIB-386/233 dated 24.01.2019

In Reference to subject cited above and NIB-386, the various representations received from the firms and issues raised by the Bidders are examined by the competent Authorities and technical committee. The following Clarification/Corrigendum/Addendum is issued for inclusion in Bid document & Technical Specification of items as below:-

Revised Technical Specification of OAE Analyzer:-

Essential

1. Power Supply: 220 Volts, - 50Hz
2. Type of OAE: TEOAEs, DPOAEs.
3. Frequency range of TEOAE should be 4000 Hz or above and for DPOAE should be 5000 Hz or above.
4. Stimulai intensity level up to 80 dB SPL for TEOAEs and 70 db SPL or above for DPOAEs.
5. Automatic F1 and F2 ratio calculation.
6. Low battery warning
7. Serviceable probes; probe mount
8. Cleaning kit
9. Printer with minimum 10 paper roll.
10. Power supply: Rechargeable Battery operated
11. Can be used as stand alone or with a PC
12. Self-calibration
13. **Separate ear tips** for infants and adults (50 no adults & 50 no. infant/pediatric).
14. Separate probe head/coupler 3 no's should be supplied free of cost with each machine.
15. Data Analysis should be fully automated (it should display cross spectrum, DP Gram, pass/Refer test report)
16. The equipment should be European CE /USFDA approved.
17. Should have safety certificate from a competent authority CE or valid detail of electrical and functional safety test. Copy of the certificate/test report shall be produced along with the technical bid.
18. Three years Guaranty to be given with the equipment.
19. Minimum of two routine maintenance services/inspections to be provided annually.
20. CMC: CMC shall be given @ 5% of net rate (excluding GST as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC may be awarded for five years (on yearly basis) after Guarantee period of three years.
21. Price quoted should be inclusive of their installation at site.
22. Final technical approval after demonstration.

Revised Technical Specification of IMPEDANCE AUDIOMETER:-

Essential

Power supply: 220 Volts, 50Hz

Probe tone: 220 or 226 Hz

Probe assembly with contralateral test facility (with supra aural earphones: TDH 39/TDH39A/TDH49/TDH49A/TDH 50 with MX 41 AR ear cushions or insert earphones (ER Tone 3A)

Test cavities (0.5, 2, 5 cc)

Separate **ear tips** for infants and adults (50 no adults & 50 no. infant/pediatric).

Printer

Tests required

- Compensated tympanometry (ear canal volume and tympanometric peak pressure)
- Ipsilateral and contralateral acoustic reflexes



Air pressure range: + 200da Pa to - 400 da Pa Stimuli for acoustic reflexes:
Type: Pure tones
Frequencies: 500Hz, 1000Hz, 2000Hz and 4000Hz
Intensity: up to 120 dB HL
Power supply: Battery operated & main
Self-calibration

- The equipment should be CE certified.
- Manufacture should have ISO 13485.
- Should have safety certificate from a competent authority CE or valid detail of electrical and functional safety test. Copy of the certificate/test report shall be produced along with the technical bid.
- Three years Guaranty to be given with the equipment.
- Minimum of two routine maintenance services/inspections to be provided ann ually.
- CMC: CMC shall be given @ 5% of net rate (excluding GST as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC may be awarded for five years (on yearly basis) after Guarantee period of three years.
- Price quoted should be inclusive of their installation at site.
- Final technical approval after demonstration.

Revised Technical Specification of OAE (with BAER Technology):-

TECHNICAL Specification of OAE (with BAER Technology)	
1.1 Technical Characteristics	<p>A. Should be a handheld unit including probe cord and Cradle</p> <p>B. Should have a Printer including power supply and power cable, Printable text file display of the acquired data, including frequency, signal, noise, response and testing parameters</p> <p>C. Probe cord for extension at least 75 cm</p> <p>D. DPOAE protocol with Fast, accurate results—in as little as 10 seconds per ear</p> <p>E. Tip should be Easy-to-clean</p> <p>F. Results should have an Objective test—no patient response required</p> <p>G. Pass/Refer result provided—No interpretation required</p> <p>H. Should operate on rechargeable battery and also in AC power</p> <p>I. At least 500-test memory</p> <p>J. Stimulus for DPOAE Frequency range - 500 to 10,000 Hz. Intensity Range - 30 to 80 dB SPL Nominal Frequencies - F 2 Artifact rejection System - (- 30 to +30) dB SPL or off DP response window - 4096 point freq response</p> <p>K. Stimulus for TEOAE Frequency range - 500 to 5500 Hz. Intensity Range - 30 to 90 dB SPL Nominal Frequency - 1 Hz Click rate - (43 - 100 Hz) Stimulus type - Non linear to linear Artifact rejection system - 0 to 60 dB SPL or off freq response window - 256 points freq response</p> <p>L. ABR Single Channel Infant Hearing Screener Channel - 3 electrode Frequency response - (0.5 - 5000) Hz. Stimuli - click range (2 KHz to 4 KHz) Level - (0-45) dB NHL Transducers - Insert Ear phone ear cups (TDH-39) Filter Setting 30Hz HPF and 1500 Hz LPF</p> <p>M. Signal input channel Facility to edit the test protocol and save Database management software</p>



2.	User's interface	Probe and printer
2.1	Software and/or standard of communication (where ever)	in built
3	PHYSICAL CHARACTERISTICS	
3.1	Dimensions (metric)	NA
3.2	Weight (lbs., kg)	Less than 2 kgs.
3.3	Configuration	Type: Intel Pentium P4 compatible or better; RAM: minimum 1GB; Hard disk: Minimal 5 GB free disk space Interface: USB 1.1 or 2 Display: SVGA-Color Display 800x600 or better Operating system: Windows XP SP 3 Professional Windows 7 32/64bit Professional or Ultimate
3.4	Noise (in dBA)	NA
3.5	Heat dissipation	NA
3.6	Mobility, portability	Mobile
4	ENERGY SOURCE (electricity, UPS, solar, gas, water, CO2)	
4.1	Power Requirements	220-240Vac; 50/60 HZ
4.2	Battery operated	Rechargeable battery with 2 hours backup
4.4	Protection	NA
4.5	Power consumption	as per device
5	ACCESSORIES, SPARE PARTS, CONSUMABLES	
5.1	Accessories (mandatory, standard, optional); Spare parts (main ones); Consumables / reagents (open, closed system)	Reusable ear-tips of various sizes starting from 3mm to 12 mm(each at least 10 for each size), probe cord, cradle, power cable and printer, Cleaning Kit and additional Probe Knob – 04 No., Calibration cavity for new born, infant and children
BIDDING / PROCUREMENT TERMS / DONATION REQUIREMENTS		
6	ENVIRONMENTAL AND DEPARTMENTAL CONSIDERATIONS	
6.1	Atmosphere / Ambiance (air conditioning, humidity dust ...)	Capable of being stored continuously in ambient temperature of 0 to 50 degree C and relative humidity of 15 to 90%. Capable of operating continuously in ambient temperature of 10 to 40 degree C and relative humidity of 15 to 90%.
6.2	User's care, Cleaning, Disinfection & Sterility issues	Complete unit to be easily washable and sterilizable using both alcohol and chlorine agents.
7	STANDARDS AND SAFETY	
7.1	Certificates (pre-market sanitary,.); Performance and safety standards (specific to the device type) ; Local and/or international	ISO 13485 certified manufacturer IEC 60601-1- Medical electrical equipment-Part I: General requirement for safety IEC 60645-6- Oto-acoustic emission IEC 60601-1: 2005 + CORR. 1 (2006) + CORR. 2 (2007) + AM1 (2012) or IEC 60601-1: 2012 ISO 14971 : 2007 IEC 60601-2-18



		IEC 6060-1-2 US FDA or European CE certified product
8	TRAINING AND INSTALLATION	
8.1	Pre-installation requirements: nature, values quality, tolerance	Supplier to perform installation, safety and operation checks before handover
8.2	Requirements for sign-off	Certificate of Calibration and inspection from the factory
8.3	Training of staff (medical, paramedical, technicians)	Training of users in operation and basic maintenance shall be provided
9	GUARANTEE AND MAINTENANCE	
9.1	Guarantee	Three years
9.2	Maintenance tasks	Maintenance manual detailing complete maintaining schedule
9.3	Service contract clauses, including prices	Local clinical staff to affirm completion of installation
9.4	CMC :-	CMC:- shall be given @ 5 % of net rate exclusive of GST (as applicable) and yearly escalation of 5 % on last year's CMC price. The CMC may be awarded for five years (on yearly basis) after Guarantee period of Three year
10	DOCUMENTATION	
10.1	Operating manuals, service manuals, other manuals	Advanced maintenance tasks required shall be documented User, technical and maintenance manuals to be supplied in English language. List to be provided of equipment and procedures required for local calibration and routine maintenance
10.2	Recommendations for maintenance	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided.
11	NOTES	
11.1	Service Support Contact details (Hierarchy Wise; including a toll free/landline number)	Contact details of manufacturer, supplier and local service agent to be provided
11.2	Recommendations or warnings	List to be provided of important spares and accessories, with their part numbers and cost. Certificate of calibration and inspection to be provided

Revised bid schedule:-

E-bids are invited as per following revised time schedule:-

Existing Dates			Extended Dates		
Last Date for Sale of Bid Form	Last Date of Receipt of Bid Form	Date of Opening of Technical Bid	Last Date for Sale of Bid Form	Last Date of Receipt of Bid Form	Date of Opening of Technical Bid
1	2	3	4	5	6
<u>18.02.2019</u> <u>11:00 AM</u>	<u>18.02.2019</u> <u>6:00 PM</u>	<u>19.02.2019</u> <u>11:00 AM</u>	<u>26.02.2019</u> <u>11:00 AM</u>	<u>26.02.2019</u> <u>6:00 PM</u>	<u>27.02.2019</u> <u>11:00 AM</u>

Note:- Please note that all above amendments/corrigendum in technical specifications/bid conditions is the integral part of (Section-V, Schedule of Supply, and Point no. 3) and the bid document. This corrigendum/ addendum should be signed and annexed with bid document. All other terms & conditions remains the same.

This bears an approval of Managing Director, Rajasthan Medical Services Corporation Limited, Jaipur.


Executive Director (EPM)
RMSCL, Jaipur