

RAJASTHAN MEDICAL SERVICES CORPORATION LTD.

D- Block, Swasthya Bhawan, Tilak Marg, C-Scheme JAIPUR (Raj)

Ph. No. 0141-2223887, Fax No. 0141-2228065

CIN: U24232RJ2011SGC035067

E-Mail -edepmrmsc-ri@nic.in

No. F-8(12)RMSC/EPM/M-1/R.C.15-16/NIB-116/2015/2425

Dated: 28/12/15



CLARIFICATION/CORRIGENDUM/ADDENDUM

Subject: -Revised Bid Schedule & Amended Technical Specifications of Bid document of items (01) Variable volume multichannel Micro Pipette (8 channels) (30-300 ul) (02) Sterile Connecting Device (03) Platelet Agitator and Incubator (04) pH Meter, under NIB No. F-8(12) RMSC/EPM/M-1/R. C. 15-16/NIB-116/2015/1420 Dated: 28.09.15, CLARIFICATION /CORRIGENDUM /ADDENDUM No. 1920/05.11.15 , 2104/26.11.15 & 2265/11.12.15

In reference to subject cited above and NIB-116, the representations received from the firm and issues raised by the Bidders are examined by the competent Authorities and technical committee. The following Clarification/Corrigendum/Addendum are issued for inclusion in Bid document & Technical Specification of items as below:-

01. Amended Technical Specifications of Items (01) Variable volume multichannel Micro Pipette (8 channels) (30-300 ul) (02) Sterile Connecting Device (03) Platelet Agitator and Incubator (04) pH Meter as below:-

(01) Amended Technical Specifications of item Variable volume multichannel micro pipette (8 channels) 30-300 ul

1. Variable volume multichannel micro pipette (8 channel) – Disposable Microtitre pipette. Tip 30 – 300 ul clean graduated.
2. Fully autoclavable.
3. Certification :- European CE , IVD Certified.
4. Company should have facility for in lab calibration of pipette as per NABL – ISO 17025, In India at multiple locations and should have facility for onsite calibration as per NABL guideline.
5. The company should submit technical compliance sheet as per technical specifications mentioning the make & model of quoted item along with catalogue in the Technical bid.
6. Firm should supply stand /rack to hold the pipette free cost.
7. **Guarantee:** Two years on equipment from the date of installation/supply.
8. Two Preventive Maintenance services annually during Guarantee.
9. Demonstration of item is must for final technical approval

(02) Amended Technical Specifications of item Sterile Connecting Device

1. Purpose of Equipment

1. Sterile Connecting Device is able to heat and cut two tubes and switch the connectivity of the two halves and weld them back, and do the cutting and welding in such a manner that it can be considered as sterile as fully closed process

2. Quality Standard

1. Manufacturing should be compliant with ISO 13485 (Valid documentation should be submitted in technical bid).
2. Should be compliant with European CE with notified body number or US FDA (Valid documentation should be submitted in technical bid).
3. Equipment must meet electrical safety specifications of IEC 60601-1

3. Operational requirements

- a) Should ensure sterile connection between tubing to enable transfer of fluid/ blood from one container/ bag to another by welding the tubes between them effectively as a closed system.
- b) Should be compatible with all standard tubing with an external diameter ranging from 3.9-4.5 mm & internal diameter of 2.9-3.1 mm.
- c) Should be capable of generating a temperature of upto 320 degree Centi. To prevent any type of contamination.
- d) Should have in built sensor to monitor the temperature to ensure optimal quality and strength of weld.
- e) Should be capable of welding Wet – Wet / Wet – Dry / Dry – Dry tubes
- f) Total process time should be between 20 to 30 seconds.
- g) Requirement for tube length to be welding/docking should be as small as possible

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- h) LED indicators to display the whole process with alarms.
- i) should ensure the complete sterility
- j) Should be attachable to leukocyte filters and should also be usable for plasma and platelet pooling
- k) There should be no particles or chemical residue created by welding process
- l) To be operational on 220 to 240 volts at 50 Hz. Single phase AC.
- m) Two thousand and five hundred consumables if any (eg. wafers) should be provided with instrument and cost of replacement consumables should be quoted and supply should be readily available with the vendor till the CMC period.

4. **Additional requirements**

- a) Complete with comprehensive set of spare parts and a suitable capacity voltage stabilizer.
- b) Firm should supply one desk top computer (System should have i3 processor with latest operating system, HDD 1 TB, 4GB RAM, 17" screen) with laser printer with Split AC 1.5 Ton of reputed make Free of cost with equipment. (Guarantee card with bills have to be submit with items to claim guarantee of these items)
- c) **Guarantee:** Three years on equipment from the date of installation.
- d) **CMC:** CMC will be given @ 5 % (of net rate - inclusive of Excise Duty & exclusive of VAT / CST etc.) plus service tax (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 completion of Guarantee period of three years.
- e) The company should submit technical compliance sheet as per technical specifications mentioning the make & model of quoted item along with catalogue in the Technical bid.
- f) Installation will be done by supplier free of cost.
- g) The service engineer should be based in Rajasthan.
- h) Four Preventive Maintenance services annually during Guarantee and CMC period are essential.
- i) Demonstration of equipment is must for final technical approval.
- j) **Consumable:** Consumable kit. Rate of Consumable kit should be provided by bidder in BOQ.
- k) Final rate of consumable kit after negotiation will be freezed for two years

(03) **Amended Technical Specifications of item Blood Bank Platelet agitator cum incubator**

1. **Purpose of Equipment**

- a) To continuously agitate platelet concentrate in an even suspension in a temperature controlled environment $+22\text{ }^{\circ}\text{C} \pm 2\text{ }^{\circ}\text{C}$ in standard platelet bags (random unit or aphaeresis).
- b) Must be designed specifically for blood bank use. Commercial or modified commercial incubators for other purpose are not acceptable.

2. **Type of Equipment**

- a) Flatbed agitator fitted inside a temperature controlled incubator that uses CFC-free refrigerant and CFC free insulation material

3. **Quality Standard**

- a) Should have micro processed controlled LED/LCD display, temperature graph display & digital sensor probe.
 - b) Should have provision for 6" 7 day inkless chart recorder with battery back of 24 hours for continuous operation during power failure.
 - c) Manufacturing should be compliant with ISO 13485 (Valid documentation should be submitted in technical bid).
 - d) Should be compliant with European CE or US FDA (Valid documentation should be submitted in technical bid).
 - e) Equipment must meet electrical safety specifications of IEC 60601-1
4. SMS alerts to user defined recipients in case of any deviation in temperature, break down and power failure with provision to connect with central (Temperature) monitoring system / facility of wireless data transfer facility & storage of temp. data on cloud, with continuous accessibility of data on PC or laptop and on smart phones with internet facility

5. **Capacity**

- a) At least 50-60 standard random platelet unit bags.

6. **Construction**

- a) Outside C. R. (Corrosion Resistant) sheet preferably coated with bacteria resistant material
- b) Inside stainless steel.
- c) Insulation foaming agent CFC free

7. **Drawers and agitator**

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- a) Nonslip corrosion resistant drawers coated with bacteria resistant material.
- b) Drawers perforated to ensure good air circulation.
- c) The agitator holding the shelves is suspended in such a way as to ensure minimum noise for the life of the agitator.
- d) Gentle side to side agitation at 1.5 inch (3.6-4 cm) and 60-70 strokes/min.
- e) Heavy duty ball bearing gear motor for noiseless and continuous operation for 24 hours a day 365 days a year.
- f) Auto-pause of agitator on opening door.
- g) Push button switch to pause agitator.
- h) Should have Alarm for power failure and LED indication would be an extra advantage.

8. Door

- a) Glass door with full visibility of units without opening door.
- b) Door lock should be available

9. Electrical characteristics

- a) Compatible with Input 240V 50 Hz Single phase AC
- b) Should have an integrated voltage stabilizer or external stabilizer of appropriate ratings meeting ISI Specifications (Input 160-260 V and output 220-240 V and 50 Hz).

10. Internal Temperature

- a) Forced air circulation method for the uniformity of the temperature at all sides of incubator
- b) Platelet incubator should have inside temperature range of 20°C - 24°C
- c) Whatever the load, setting accuracy less than or equal to 0.5°C (preferably 0.1°C).
- d) Should ensure frost free performance thereby avoiding either freezing or heating. If defrosting function used, temperature should not go outside range specified above

11. Guarantee: Three years on equipment from the date of installation.

12. CMC: CMC will be given @ 5 % (of net rate - inclusive of Excise Duty & exclusive of VAT / CST etc.) plus service tax (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 completion of Guarantee period of three years.

13. The company should submit technical compliance sheet as per technical specifications mentioning the make & model of quoted item along with catalogue in the Technical bid.

14. Installation will be done by supplier free of cost.

15. The service engineer should be based in Rajasthan.

16. Four Preventive Maintenance services annually during Guarantee and CMC period are essential.

17. Demonstration of equipment is must for final technical approval

(04) Amended Technical Specifications of item pH Meter

Type: Digital electronic pH Meter with combination pH electrodes

1. pH Range: 0.0 to 14.0 pH with 3 ^{1/2} digital display
2. Mill volt Range: 0.0 to 1999 mv
3. Accuracy, repeatability and resolution: 0.01 pH
4. Calibration solution should be provided
5. Temperature compensation & pH standardization: 0^o to 100^oC(manual)
6. Electrical Power supply: 220 -240 volts at 50 Hz, single phase
7. Ambient Temperature: 0^o to 40^oC. 40^oC at 95% RH
8. Equipment shall have suitable, rechargeable battery with a battery charger.
9. Type and details of battery being supplied shall be clearly indicated e.g. V, AH, number etc.
10. A suitable battery charger shall also be supplied so that charging batteries continue when the equipment on main.
11. Equipment shall be supplied in suitable case.
12. Technical literature: The firm shall positively submit printed illustrated literature/leaflet, indicating the model quoted by the firm. If quoted model is a modified version of their any standard product that also be indicated in the offer.
13. **Guarantee:** one year on equipment from the date of installation.
14. The company should submit technical compliance sheet as per technical specifications mentioning the make & model of quoted item along with catalogue in the Technical bid.
15. Installation will be done by supplier free of cost.
16. The service engineer should be based in Rajasthan.
17. Two Preventive Maintenance services annually during Guarantee and CMC period are essential.
18. Demonstration of item is must for final technical approval

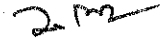
(02) Revised bid schedule:-

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

Bid Submission Start	Last date & time for sale of bid form	Last date & time of receipt of bid form	Date & time of opening of technical bid
<u>19.12.2015</u> 11.00 AM	<u>02.01.2016</u> 02.00 PM	<u>02.01.2016</u> 02.00 PM	<u>02.01.2016</u> 03.30 PM

It is also clarified that information of award of contract shall be communicated to all participating bidders on the website www.rmso.nic.in and sppp.raj.nic.in. Please note that individual bidder will not be intimated."

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 the approval of M.D., RMSCL, Jaipur.



Executive Director (EPM)
RMSCL, Jaipur