RAJASTHAN MEDICAL SERVICES CORPORATION LTD.

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No. F-8(13)RMSC/EPM/M-1/R.C.15-16/NIB-117/2015/ 2424 **Dated:** 18/12/15

CLARIFICATION/CORRIGENDUM/ADDENDUM

Subject: - Revised Bid Schedule & Amended Technical Specifications of Bid document of items (01) Refrigerated Centrifuge for Blood Components 6-8 Bags (02) Blood Cell Separation / Aphaeresis Machine (03) Blood Collection Monitor (04) Digital Hemoglobin Meter, under NIB No. F-8( ) RMSC/EPM/M-1/R. C. 15-16/NIB-117/2015/1419 Dated: 28.09.15, CLARIFICATION/CORRIGENDUM/ADDENDUM No. 1921/05.11.15 , 2105/26.11.15 , 2266/11.12.15 & 2300/15.12.15

In reference to subject cited above and NIB-117, 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) Refrigerated Centrifuge for Blood Components 6-8 Bags (02) Blood Cell Separation / Aphaeresis Machine (03) Blood Collection Monitor (04) Digital Hemoglobin Meter as below:-

(01)Amended Technical Specifications of item Refrigerated blood component centrifuge (8 Bags)

1. Purpose:

a) Medium 8 bags volume and floor standing refrigerated centrifuge for separation of components from whole blood.

2. Design and operation:

a) Stable, sturdy all-steel design with stainless steel rotor chamber, should be easy to clean corrosion resistant paintings.
b) provision of both drain and condensed water collection container.
c) Microprocessor controlled.
d) Programmable memory with temper proof program saving facility, with parallel saving atleast 9 or more programs.
e) CFC free refrigerant.
f) Various formats of Swing-out rotors with metal buckets and with and without wind shields that should be able to accommodate at least the following:

- Eight 350ml and/or 450ml single, double, triple, quadruple/quintuple blood bags with SAGM bag and empty satellite bags with In Line filter system.
- Removable plastic adapters to hold single/ double/triple/ quadruple blood bags (optional - with partition in every bucket and with provision to hold balancing weight at the sides of the adapter so that it will not come in contact with blood bags). Balancing weight should be supplied with equipment. Insert with hook adapter to spin Buffy coat or small volume of blood and balancing weights for inserts. Automatic lid lock while processing (working mode) .

3. Speed and force:

a) Maximum speed at least 4,000 rpm to 4500 rpm
b) Maximum RCF (Relative Centrifugal force) for blood bags: 5000g-6000g.
c) Acceleration and deceleration profiles should be independently adjustable with at least nine brake levels and option for free coasting.
d) Speed variation: microprocessor controlled rotor speed to within 10 rpm of set value.

4. Temperature control

a) Range at least: -0°C to +40°C.
b) Adjustable in 1°C intervals
c) Microprocessor controlled rotor temperature within 1°C of set temperature regardless of centrifuge speed.

5. Programmable centrifugation time: 0min-99min with minimum resolution of 1 minute.
6. Digital display (real time and set target) of temperature, speed and time with minimum no. of 3 digit resolution.
7. Should incorporate alarms for imbalance detection, lid interlock, over temperature, rotor over speed.
8. Motor imbalance detection: automatic shutdown of centrifuge if rotor load is out of balance with appropriate indicator.
9. Power requirement: 220/240 volts, 50 Hz. Single phase AC supply.
10. The equipment shall be suitable for operation from 0 to 40°C at 90% relative humidity. Electronic circuitry shall be tropicalised for this ambient condition.
11. Noise level within 60 decibels.
12. The equipment should come with customized castor for changing location.
13. Protection of data: in event of power interruption or complete failure, data should remain stored indefinitely.

14. Should have a provision for external connectivity.
15. It shall have a security lock to prevent unintentional switch off and also unauthorized opening of the equipment.
16. A suitable stabilizer to be supplied with equipment.
17. Copper wound single phase automatic line voltage correct or conforming to IS: 9815(PLI)/94 with latest amendments or equivalent international standards fitted with a voltmeter and switch to indicate output/ input voltage.
18. Input voltage: 140-280 V,50 Hz, output voltage: 220 V ±10%.
19. Input output voltmeter and ampere meter. Protection for high low voltage cut off, overload and short circuit protection.
20. Equipment should be supplied with 2 meter cord at input and fitted with plugs of appropriate rating.
21. Certifications:

- Manufacturing should be compliant with ISO 13485 (Valid documentation should be submitted in technical bid).
- Should be compliant with European CE with notified body number or US FDA (Valid documentation should be submitted in technical bid).
- Electrical safety: Equipment meets electrical safety specifications such as that of IEC 60601-1 and 60601-1-2

22. **Additional requirements**:

a) Complete with comprehensive set of spare parts and accessories including :
Double pan balance, Balancing weights and plates, plastic inserts and spacers and hooks for adjusting to different types and sizes of bag/tubing/filter designs, and 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 repute make Free of cost with equipment. (Guarantee card with bills have to be submit with items to claim guarantee of these items).

23. **Guarantee:** Three years on equipment from the date of installation.
24. **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.
25. 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.
26. Installation will be done by supplier free of cost.
27. The service engineer should be based in Rajasthan.
28. Four Preventive Maintenance services annually during Guarantee and CMC period are essential.
29. Demonstration of equipment is must for final technical approval

(02)Amended Technical Specifications of item Blood Cell Separator/Aphaeresis machine

1. Continuous Flow latest model Blood Cell Separator.
2. Both Single & Double Needle or Only Single Needle option.
3. Built in automated protocols for at least the below procedures, which all should be US-FDA /European CE approved.

a) Leuko reduced Platelet &concurrent plasma collection (Single & Double unit)
b) Therapeutic Plasma exchange with Automated fluid balance controlled by system
c) Stem cell (MNC collection)
d) Third pressure monitoring system for LDL Apheresis & ABO Incompatibility
e) Lymphoplasma exchange optional.

4. Automatic Pump Loading & Priming of disposables sets.
5. Automated Self test to ensure maximum Donor Safety.
6. Built in Leukoreduction ($<5 \times 10^6$) for Platelets & Plasma using elutriation (eg LRS chamber) or other patented technology which is NOT based on leuko-adsorption filter.
7. Automatic Leukoreduction validation of platelets and plasma at the end of procedure.
8. Adjustable product concentration.
9. End of procedure summary screen showing Donor post Counts
10. Safety check to prevent Platelets count and hematocrit dropping below safety level for Donor .
11. Configurable maximum volume depletion levels either by weight or percentage of Total Blood Volume.
12. Configurable Product Volume, HCT & Platelet Concentration
13. Extracorporeal volume should be in range of 185ml – 250 ml in various procedures
14. Built in Access & Return Pressure sensor.
15. Built in air detectors to prevent air embolism.
16. Built in ACD Detector.
17. Built in contamination monitor for monitoring & preventing RBC contaminations in platelet collection

and plasma exchange. Should have inbuilt cuff pressure and prompt grip for donor comfort and better flow. Auto cuff mechanism for automatic inflation and deflation. Single disposable kit should be adaptable for all donors and should be self sufficient in term of collection bag, transfer pack, needles, anticouglant and normal saline, Should have automated kit loading facility.

18. Audio visual alarms.
19. Built-in Colour Graphic LCD Screen
20. Periodic Instrument Calibration certificate for the various parameters and QC of the products should be provided/maintained by the vendor
21. European CE with notified body number approved or US-FDA approved. CDSCO (Central Drug Standard Control Organization) approval & registration certificates for various Disposable sets & kits should be attached (Valid documentation should be submitted in technical bid).
22. Additional accessories to be provided

a. 30 (Demo) disposables kits should be provided after license recieval of Apheresis. Bidder should submitted affidavit for the same at the time of Rate Contract.
b. Fully automated Blood Donor Couch (electrically operated) – 01No. **(as per technical specification given below)**
c. All consumables required for installation and standardization of system to be given free of cost.
d. Complete with comprehensive set of spare parts and a suitable capacity UPS with maintenance free batteries for minimum one-hour back-up.
e. 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 2 Ton of repute make Free of cost with equipment. (Guarantee card with bills have to be submit with items to claim guarantee of these items).
f. One LED TV of 32" should be supplied with the system free of cost.

23. **Guarantee:** Three years on equipment from the date of installation.
24. **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.
25. 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.
26. Installation will be done by supplier free of cost.
27. The service engineer should be based in Rajasthan.
28. Four Preventive Maintenance services annually during Guarantee and CMC period are essential.
29. Demonstration of equipment is must for final technical approval.
30. Consumable: Consumable kit. Rate of Consumable kit should be provided by bidder in BOQ.
31. Final rate of consumable kit after negotiation will be freezed for two years.

Technical Specifications of item fully Automated Deluxe Donor Couch :

1. It should have electrically operated functions operated by wire connected remote Control with single motor chair.
2. Arm rest should have swing out as well as up and down movement along with arm rest height adjustment.
3. It should be easily convertible in head down foot up position.
4. Should have lifting capacity at least 350 Lbs / 150 kgs. (donor weight).
5. The frame of the Recliner is constructed of High grade Steel duly epoxy powder-coated.
6. The base is covered with smooth and elegant finish polymer molded which is rust-free, scratch resistant and easy to clean and should have wheels to move the couch.
7. The Recliner is fitted on heavy duty maneuvering heavy duty Castors with brakes.
8. It should has a three sectional top duly covered with Elegant upholstered high density, max. Comfort Foam Padding.
9. To have attached or detachable tray& stands for keeping all blood collection associate accessories like - blood Collection Monitors Tray, BP. Apparatus Tray and Tray for other accessories and telescopic IV Stand.
10. The system should be CE approved (Valid documentation should be submitted in technical bid).
11. Manufacturing should be compliant with ISO 13485 (Valid documentation should be submitted in technical bid).
12. **Guarantee:** Three years on equipment from the date of installation.

13. **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.
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 during Guarantee and CMC period are essential.
18. Demonstration of equipment is must for final technical approval.

(03)Amended Technical Specifications of item Blood Collection Monitor

Bag holder tray suitable for all types of blood Bags. Magnetic removable cradle Tray for easy cleaning

1. Should have facility to preset total volume of blood to be collected and accordingly monitor and display amount collected. It should have facility to clamp to stop the collection of blood as soon as preset volume is collected and not allow over collection.
2. Battery backup should be > 8 hours (12VDC) with continuous workload(rechargeable battery)
3. Battery charger should be inbuilt.
4. Should be portable (Suitable for outdoor blood donation camps).
5. Should have standby / pause mode Manual clamp facility to abort collection Automatic Release of Clamp when the Bag is lifted.
6. Should be able to operate at Temperature of +5° to +45° C and relative humidity (RH) of 5 to 95 %
7. There should be continuous digital display of preset volume, Blood flow rate and total time taken at the end of collection.
8. Oscillation: 12 ± 2 rpm
9. Should mix the blood with anti – coagulant solution during Collection and ensure that only correct amount of blood is collected
10. There Should be Visual display and audible alarm:
    (i) when flow rate goes below 20 ml /min or high flow rate above 180 ml / min
    (ii) at the end of collection
    (iii) when battery low
    (iv) during pause function
    (v) any abnormal condition
11. **Quality Standard**
    a) Manufacturing should be compliant with ISO 13485 (Valid documentation should be submitted in technical bid).
    b) Should be compliant with European CE or US FDA (Valid documentation should be submitted in technical bid).
    c) Equipment must meet electrical safety specifications of IEC 60601-1 and 60601-1-2 (as relevant)
12. Every Bio-mixer should be provided with carry box with handle
13. Firm should supply the relevant calibration certificate for the equipment from NABL accredited Lab.
14. User's list should be provided with satisfactory report for the last three years from three Licensed Blood Banks with contact details.
15. Original literature of equipment should be submitted.
16. Electrical: The equipment should be able to run on the existing Electrical provision.
17. **Broad specifications are:**
    Automatic Type Input 150-280V, Output 220 V +/- 7 %, 50 Hz /60 Hz.
    Single phase, AC with automatic 2-4 sec Cut Off and 6-9 minutes
    Restart delay. Quick start arrangements for bypassing the start
    delay. Suitable MCB on input voltmeter and indicators on Front
    Panel. Input Power Cable with 15 A Plug and six way output
    Terminal strip for two outlets
18. **Accessories:-**
    – Floor stand
    – Transport case with built-in charger
    – Suitable Calibration weight
19. **Guarantee:** Two years on equipment from the date of installation.
20. **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 two years.

21. 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.
22. Installation will be done by supplier free of cost.
23. The service engineer should be based in Rajasthan.
24. Two Preventive Maintenance services during Guarantee and CMC period are essential.
25. Demonstration of equipment is must for final technical approval

(04) Amended Technical Specifications of item Hemoglobin Meter (Digital Microprocessor Based)

1. Device should based on broad spectrum photometric/isobestic points working on cyanmethhaemoglobin/ azidmeth or imidazole methemoglobin hemoglobin method.
2. Device should Color/ black and white LCD Display
3. Device should measure Hb within 60 seconds
4. Should in built with Li-Ion battery/power backup with AA or AAA batteries, over 40 hours usage with a fully charged battery
5. Device Should programmed with Automatic cuvette holder/ strip, ejects the cuvette after measurement
6. Should always ready for measurement, even in standby mode
7. Device should also display Hct value is optional.
8. There should no reagent in the cuvette/strip and reaction should taken place in cuvette/strip
9. Shelf life of the cuvettes / strip must be more than 1 years
10. Cuvette/ strip must be reagent free.
11. Cuvettes/strip must be insensitive to humidity and/or temperature, operating temperature range 5 - 40°C.
12. Measurement accuracy +/- 0.3 g/dL for 0-20 g/L, +/- 0.7 g/dL for > 20 g/dL, compared to HiCN , ICSH
13. Measuring range 0–24 g/dL.
14. Power supply 100–240 V AC , 50–60 Hz
15. Approx. 40 hrs continuous, with a fully charged battery.
16. ~~Certification:- European CE with notified body number /US FDA and IVD approved.~~
17. Transport Box should be supplied with Equipment.
18. Quality control has to be run quarterly free of cost by the firm with minimum 3 levels.
19. Rate of Consumable item should be provided by bidder in BOQ.
20. Final rate of consumable kit after negotiation will be freezed for two years.
21. 200 cuvvett /strips should be supplied free of cost with Equipment.
22. 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.
23. Demonstration of equipment 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
19.12.2015	02.01.2016	02.01.2016	02.01.2016
11.00 AM	02.00 PM	02.00 PM	03.30 PM

(03) It is clarified that previous Amendment in Bid Condition SECTION III: QUALIFICATION AND EVALUATION CRITERIA Clause No.2- Contractual experience & SECTION VI B: SPECIAL CONDITIONS RATE CONTRACT (SCC) Clause No.11 regarding Past Performance vide CLARIFICATION/CORRIGENDUM/ADDENDUM No. 2300/15.12.15, is only applicable for item Hemoglobin Meter (Digital Microprocessor Based)

It is also clarified that information of award of contract shall be communicated to all participating bidders on the website www.rmsc.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