List of equipments for the department of Blood Bank

Sl. No.	Name of Equipments
1	Deep Freezer -40 deg. C
2	Deep Freezer -80 deg. C
3	Blood Bank Refrigerator
4	Donor couch
5	Plasma Thowring bath
6	Dielectric Tube sealer
7	Blood Mixer and collector
8	Refrigerated water bath (Cryobath)
9	Automated Elisa
10	Semi Automated Reader and centrifuge for ID Gel cards

Technical specification for Blood Banks
instruments to be purchased.

Agenda Item No. 1

Review of Technical Specification of Deep Freezer -40°C

The committee approved the technical specifications of Deep Freezer -~~80°C~~ 40°C as follows:

1. Purpose of Equipment: To freeze and store Plasma
2. Type of Equipment: Compression freezer with CFC- free refrigerant
3. Capacity: As required by the blood bank (e.g. 200/400/600/900Plasma bags of 200mL. each)
4. **Construction;**
   - Internal: stainless steel(min 22g) (S.S.V2 A-1.4301)
   - External: solid outer cabinet corrosion Resistant (at least 1mm thickness)
   - CFC-free insulation
   - Design: Upright Type
   - Door: Solid door, Automatic closing of the front door below opening angle of 90°C and opening angle limited to 110°
   - Insulation and gasket should be silicone.
   - Separate inner doors to prevent cold loss
   - Drawers: Roll out type
   - Heating device on frame to avoid condensation.
5. **Electrical Characteristics:**
   - Input voltage: 220/240V 50Hz
   - A line voltage corrector of appropriate rating should form part of configuration.
6. Minimum Compressor Starting Voltage: 22% below nominal voltage
7. **Internal Temperature control:**
   - Electronic temperature control
   - Operating temperature readable lowest up to-45°C with setting accuracy of 1°C whatever the load
   - Fan air cooling
   - Automatic defrost within safe temperature range
   - Casing & door should have insulation panel with polyurethane foam> 80mm thickness.
8. **Refrigeration:**
   - Heavy duty hermetically sealed compressor air cooled cascade refrigeration system maintains inner temperature below-40°C

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- Option for duct from equipments to connect to common main duct to throw hot air out of the room.
- Refrigerant CFC free/green gas
- Optional: Access port for CO_2 backup system for refrigeration.

9. External Ambient Temperature : performs in an ambient temperature of +10 to +40°C
10. Hold over time : 2hrs at ambient temperature
11. **Cooling Down ~~Time~~** Time
    - A full load of plasma packs at +25°C takes a maximum of 5 hrs for all the packs to reach bleow-5°C
    - A full load of plasma packs at +25°C takes a maximum of 30 hrs for all the packs to reach bleow-20°C
12. **Temperature Monitoring;**
    - Digital temperature (LED) display with 0.1 °C graduation
    - Temperature recording device.
    - Microprocessor control for operation with integrated audio visual temperature alarm function with digital monitoring display. There should be a method to check alarm system.
    - Seven days inkless graphic temperature recorder with range of 0°C to-50°C with data logger, with supply of free charts for a period of warranty.
    - Battery backup for alarm and temperature recording device.
    - Provision to connect with central (temperature) monitoring system
    - Mounted on Lockable Castor wheels
    - Alarm history: Temperature maximum and minimum, average temperature during alarm period, time of duration of alarm.

Desirable:

- Noise factor should not exceed 60 decibels.
- Should have compressor running time <60to70%

13 Additional Requirements

- All equipments should specify design qualification Installation qualifications, Operational Qualifications and Performance qualifications. Validation and calibration reports should have traceability towards applicable national/international standards.
- Complete with comprehensive set of spare Parts including a spare compressor, refrigerant gas cylinder ~~tec.~~ etc. and a suitable capacity voltage stabilizer. The make rating, model, description, specifications, price quantity of each item shall be furnished separately.
- Necessary catalogues, technical write up in English shall be attached with the offer both in hard and soft copies.

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- Performance, efficiency , other factors such as distortion etc, as applicable be also furnished .
- Complete construction details in respect of material specification, thickness,
- finish etc. are to be furnished.
- Certifications:
  - Product certification CE class II A or US FDA certified
  - Quality certification : ISO certified
  - Electrical safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

Agenda Item No. 2: (13)

Review of Technical Specifications of Deep Freezer -80°C

The committee approved the technical specifications of Deep Freezer -80°C as follows:

1. Purpose of Equipment: to freeze and store plasma
2. Type of Equipment: Compression freezer with CFC-free refrigerant
3. Capacity: As required by the blood bank (e.g. 200/400/600/900 plasma bags of 200 ML. each)
4. **Construction:**
   - Internal: Stainless steel (min,22g) (s.s. V2A- 1.4301)
   - External: solid Outer cabinet corrosion Resistant (at least 1mm thickness)
   - CFC- free insulation
   - Design: Upright Type
   - Door: Solid door, Automatic closing of the front door blow opening angle of 90° and opening angle limited to 110°
   - Insulation and gasket should be silicone.
   - Separate inner doors to prevent cold loss.
   - Drawers: Roll out type
   - Heating device on frame to avoid condensation.
5. **Electrical Characteristics:**
   - Input voltage; 220/240V50Hz
   - A line voltage corrector of appropriate rating should form part of configuration.

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6. Minimum Compressor Starting Voltage: 22% below nominal voltage
7. Internal Temperature Control:
   - Electronic temperature control
   - Operating temperature reachable lowest up to -86°C with setting accuracy of
   - ± 1°C whatever the load
   - Fan air cooling
   - Automatic defrost within safe temperature range
   - Casing & door should have insulation panel with polyurethane foam > 80 mm thickness.

8. Refrigeration:

   - Heavy duty hermetically sealed compressor air cooled cascade refrigeration system, maintains inner temperature below -80°C
   - Refrigerant CFC free/green gas
   - Option for duct from equipment to connect to common main duct to throw hot air out of the room.

9. External Ambient Temperature: Performs in an ambient temperature of +10 to+40°C
10. Hold over time : 2 hrs at ambient temperature
11. Cooling Down Time:
    A full load of plasma packs at +25°C takes a maximum of 30 hrs for all the packs to reach below -20°C

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Agenda Item No: 3

Review of Technical Specifications of Blood Bank Refrigerator

The committee approved the technical specifications of Blood Bank Refrigerator as follows:

1. Purpose of Equipment: A refrigerator for storing whole blood or red cell packs in a blood bank.
2. Type of Equipment: compression type refrigerator that uses CFC- free refrigerant gas/ green gas
3. capacity: As required by the blood bank (e.g. ~~200/400/600/900~~ 500 bags blood gags of about 350/450ml.. each)
4. **Construction:**
   - Internal: Stainless steel (min.22g)
   - External: Corrosion Resistant (CR at least 1mm thickness)
   - CFC- free insulation
   - Drawer: Roll out type, Stainless steel scratch resistant material, perforated on the bottom for perfect and homogeneous distribution of cold air. The separators, if provided in the drawers, should be such that blood bags are geld in a vertical position with the label side visible.
   - Door
   - Glass door, Automatic closing of the front door below opening angle of 90° and opening angle limited to 110°
   - Insulation and gasket should be silicone.
   - Polyurethane Insulation should be minimum 80mm
   - Door opening audio and visual display alarm.
5. **Temperature range:**
   - 2·C to 6°C and adjustable with setting accuracy of ± 0. 1°C with set temperature of 4°C.
   - User Parameter settings: set point, high alarm point, low alarm point buzzer off time, C/F Temperature choice
6. **Electrical Characteristics: Input voltage:220/240V 50Hz.**
   - Equipment meets electrical safety specifications such as that of IEC (Class I).
   - A line voltage corrector of appropriate rating will form part of standard configuration
7. Minimum Compressor Starting voltage: 22% below nominal voltage
8. Internal Temperature Control:

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- Electronic temperature control, range +2 °C to °C +6 °C with setting accuracy of ±1 °C whatever the load
- Fan air cooling

9. External Ambient Temperature: Performs in an ambient temperature of +10 to +40°C
10. Hold- Over Time: A full load of blood packs at +4·C (±1 °C) takes at least 30 minutes to rise to above +6°C
11. Internal temperature hold over time in case of power failure should be at least 1.5 hours.
12. Cooling Down Time: A full load of blood packs at +25°C takes a maximum of 13 hrs for all the packs to reach below +6 °C

13. Temperature Monitoring:

- Digital temperature (LED) display with 0.1 °C graduation
- Microprocessor based temperature controller with Integrated audiovisual temperature and power alarm function with digital monitoring display.
- Independent safety thermostat to avoid negative temperatures.
- At least 2 Temperature Sensors: Sensor for temperature monitoring shown on front display, Sensor for managing use of compressor.

14. Temperature recording device

- Visual and audible alarm system indicating unsafe temperatures
- Battery backup for alarm and temperature recording device
- Facility for remote alarm contact
- Seven days graphic temperature recorder with range of - 10°Cto + 20°C with data logger, with supply of free charts for a period of warranty.
- Ideal compressor running time of 27% at room temperature.
- Interior lighting
- External ambient temperature +10 °C to +40°C
- Auto defrosting
- Cooling time – Maximum 13 hours for all the packs to reach below +6°C

15. Certifications:

- Product certification: CE Class II A or US FDA certified
- Quality Certification: ISO certified
- Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

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Agenda Item No. 9 (3)

Review of Technical Specifications of Donor couch

The committee approved the technical specifications of Donor Couch as follows:

1. Blood Donor Couch is a completely automatic enveloping, variable tilt chair and specially designed to cake blood withdrawals easier, safe and functional, and also for other diagnostic and therapeutic areas
2. Variable positioning for either arm with comfortably wide arm- rests with swinging out as well as up and down moving facility.
4. Both sides should have supporting brackets for material required for blood collection.
5. Ergonomically designed comfortable chair type for donor comfort. Mattress should be comfortably cushioned with elegantly thick washable upholstery.
6. Seat, back rest and leg rest size designed for donor comfort. It should gave step less electric remote controlled height adjustment.
7. Easily tilted to head low position, electrically operated .
8. Should be mobile with lockable wheels.
9. Comfortable working level for the operator. Lofting capacity – Approx 200 kg.

8. Certifications:

- Product certification: CE Class II A or US FDA certified
- Quality Certification: ISO certified
- Electrical safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

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Agenda Item No. 11

Review of technical specifications of plasma Thawing Bath

The committee approved the technical specifications of Plasma Thawing Bath as follows:

1. Bath is designed to safely quickly and optimally and reliably thaw fresh frozen plasma (FFP) and cryoprecipitate for the recovery of coagulation factors and cryoprecipiated antihemophilic factor (AHF). For thawing of Plasma and cryoprecipitate at required temperatures.
2. Table top with top opening
3. capacity of minimum 10 to 15 plasma bags with rack holders
4. Internal Body Material: Stainless steel (Non corrosive, Non Magnetic)
5. Having a deep thawing chamber with a stirrer and with water maintained at +37·C with pumping mechanism and in-line heating system to ensure uniform thawing.
6. Quick thawing(>20 minutes)
7. Should be a able to thaw 48 plasma bags (FFP/ cryoprecipitate/ Aphaeresis or plasma gaffs of any size).
8. Should be a water bath based system operating at a preset and precise temperature of 37 °c ± 0. 2°C
9. Should have two separate basket assemblies with built- in fingers for securely holding the plasma bags of all sizes.
10. trays with individual compartment to ensure that parts of bags may be kept above water level during the procedure .
11. Tray : Removable type stainless steel trays with partitions for holding plasma gags
12. Should give an alarm when the plasma bags are thawed.
13. Provision for programmable tine setting for length of thawing.
14. Should have digital timer clearly displaying the programmed set time or remaining cycle in minutes.
15. Should have audio visual over-temperature alarm system.
16. Should have a system to drain the chamber easily.
17. Should be supplied with a cover to keep the unit covered when not in use
18. Simple to operate, easy to read LED display
19. Drain Line with shut off calve can be connected to existing plumbing .
20. power supply: 220- 240 volts at 50Hz, single phase

21. Accessories:

1. Reusable wrap bag- 8 numbers

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2. Frozen plasma bag holder
3. Compression rack holder
4. Reference thermometer

22. Certifications:

Product certification: CE Class II A or US FDA certified
Quality certification ISO certified
Electrical Safety: Equipment meets electrical safety specifications such as that of IEC (Class I)

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Agenda Item No. 12.

Review of Technical specifications of Dielectric Tube Sealer.

The committee approved the technical specifications of Dielectric Tube sealer as follows:

1. Blood Bag tube Sealer id a compact equipment to seal the Blood bag pilot tubing.
2. The system should be heavy duty and be able to seal the blood bag etc quickly and effectively.
3. Should be simple to handle
4. System should gently seal the tubing with no hemolysis using radio frequency.
5. Should be capable of making wide seal of 2 mm thickness.
6. Should be for bench-top use.
7. The sealing time should not be more then 2 seconds .
8. Sealing trigger should be automatic
9. Should also have extended portable hand unit sealing hand should be with coaxial cable of 1.5-2.0 meter.
10. Should have indication lamps for sealing "process" on handle as well as main unit.
11. No warm-up time should be required.
12. Should ensure easy separation of tube segments after the sealing
13. System should run on both mains and battery (mort than 10 hrs. back up and charger).
14. Back up battery should seal more than 500 seals on PVC – tubes in continuous mode.

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15. The unit shall be capable of operating continuously in ambient temperature of 10-40°C and relative humidity of 15-90%
16. Power input 220-240V/50Hz AC dingle phase or 380-400VAC 50Hz Three phase fitted with appropriate Indian plugs and sockets.
17. Suitable Auto voltage corrector with spike protector should be available.
18. Electrodes should be well protected by a cover
19. Certifications

    Product certification: CE Class II A or US FDA certified

    Quality certification: ISO certified

    Electrical safety: Equipment meets electrical safety specifications such as that Of IEC (Class I) or Class Ii type- B device to protect against electric shock. Shall meet IEC-60601-1-2-2001(or Equivalent BIS) General Requirements of safety for Electromagnetic Compatibility

Agenda Item No. 13. (v)

Review of Technical Specifications of blood Mixer and Collector

The committee approved the technical specifications of Blood Mixer and collector as follows:

1. The system is used to collect donated blood from the donor at the same time mixing the blood for quality collection of blood.
2. It is meant for stationary and mobile use. Gentle end to end mixing and control of collection time to give high quality Blood suitable for all blood bags.
3. Volume setting: pre-selection of volume to be collected. Tarring of bag volume before collection. Tarring range: 0 -600 g. Automatic storage and recall of set volume. Measure volume with best accuracy.
4. LED indication on commencement of collection.
5. LED indication and audible alarm at the end of collection.
6. Indication of time taken for collection.
7. Indication of blood flow with audio alarm when blood flow is higher or lower than desired.
8. Continuous display of collected volume, flow and time during collection
9. Automatic clamping at termination of preset volume collection.
10. Automatic release of bag when lifted.
11. Continuous agitation of blood bags during collection: 12-16 rpm.

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12. Equipments carry case for BCM should be provided for portability.
13. Should operate on mains as well as rechargeable battery. On battery it should operate for a minimum of 5-8 hours.
14. The unit shall be capable of operating continuously in ambient temperature of 10-40°C and relative humidity of 10-90%
15. Power input to be 220-240 VAC, 50Hz/ 440V3 phase as appropriate fitted with Indian plug.
16. Resettable over current breaker shall be fitted for protection
17. Suitable Automatic Voltage regulator/stabilizer meeting ISI specifications should be supplied. Broad specifications are: Automatic Type Input 150-280V output 220V+/-7%, 50Hz . single phase, AC with automatic 2-4 sec Cut Off and 6-9 minutes restart delay. Quick start arrangements for by passing the start delay. Suitable MCB on input voltmeter and indicators on front panel.
    Input pore cable with 15 A plug and six way output terminal strip for two outlets.

18. Certifications:

Product certification: CE Class II A or US FDA Certified
Quality Certification: ISO certified
Electrical safety; Equipment ,meets electrical safety specifications as that of IEC (Class I) or Class II type-B device to protect against electric shock.
Shall meet IEC-60601-1-2; 2001 9 Or Equivalent BIS) General Requirements of safety for Electromagnetic Compatibility

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Agenda Item No-17 (11)

17. Review of Technical Specifications of Refrigerated water bath (Cryobath)

The committee approved the technical specification of Refrigerated water bath (Cryobath) as follows:

1. For uniform thawing of plasma bags at preset temperature of 4· ± 0, 2°C
2. High capacity pump to facilitate optimum and uniform thawing of plasma.
3. Capacity: 10-12 bags per run or per one cycle.
4. System to prevent contamination of individual ports during thawing.
5. Microprocessor based controller for precise monitoring and controlling of temperature at 4·± 0. 2°C
6. Other requirements:

a) Input Power supply: 230 + 10%V, 50Hz, 15A Single phase AC
b) Power consumption: Maximum 1600w
c) Operating temperature: 3.5°C – 4.5° C
d) Programmable temp. range: 3° C - 50°C
e) Display resolution: 0. 1°C
f) Temp. controller: Microprocessor based digital controller
g) Stainless steel tank of 22 guage & stainless steel lid of at least 20 guage.
h) Time taken for one process: Not more than 2 hours for plasma bags store at -40°C.
i) Tray: Stainless steel, removable tray of individual compartments for holding plasma bags.
j) External dimension (WxDxH): should be les than 850 x 500x 800 mm (± 10%).
k) Castor wheels: Mounted on lockable castor wheels.
l) Temp. sensing method: sealed sensor dipped directly in the water.
m) weight: Less than 70 Kg
n) Drain line with shut off valve can be connected to existing plumbing.

7. **Certifications:**

- Product certification: CE Class II A or US FDA certified
- Quality Certification: ISO certified
- Protection against electric mechanical hazards: Preferably having imitational safety requirements of EN6 1010-1.

The representations/ complaints received from the manufactures during the pre-bid meetings for past 5 years have also been examined while finalizing these technical specifications and wherever found necessary suitable modifications have been incorporated.

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[redacted] - Specifications For Automated ELISA

1. CE & US FDA Approved Fully Automated Walk away Micro plate ELISA System
2. CAP(College of American Pathology) listed system
3. Sample capacity- 190/ Batch
4. Independent racks for sample loading(12 Racks) which can accommodate different type of sample tubes varying from 1.5 ml Eppendorf tubes to sample tubes of 10 to 16 mm in diameter
5. Multi tasking modular system (simultaneous functioning of different processing steps)* like Sample pipetting, Incubating, washing, and Reading
6. Assay Optimization to reduce the total turnaround time for faster throughput.
7. Triple technology liquid detection system (capacitance, Air pressure & Colorimetric)
8. QC software inbuilt with Westgard Rules.
9. Original kit vial loading facility(direct loading of reagent vials irrespective of the manufacturer)
10. Should be a Singe probe system to avoid repeated breakdowns
11. Dual Robotic arm- one for Sample/reagent dispensing and the other for Micro plate transporter
12. Carbonized disposable tips for reagent dispensing & sample dispensing
13. Should have Primary Tube sampling facility
14. Parallel Sample dispensing
15. Aspiration Pressure monitoring facility
16. Sample dilutions - 1 to 1:10000
17. Should have option for Plate dilution, in tip dilution as well as tube dilution
18. Should be able to process up to 7 micro plates at a time with minimum of 4 plates with any assay protocol (4 incubators at RT and 4 with temp options from RT to 47^{0}C)
19. Should have Clot detector
20. On board capacity of 480 Sample/ Reagent Tips
21. Should have at least 24 position for reagents and 20 positions for control.
22. Automatic sample, Reagent, and Micro plate bar-code reader.
23. 8 Channel washer manifold with spot light and Cross well aspiration.
24. 8 filter positions (pre installed 6 filters with a range of 405-690 nm and 2 optional).
25. Bi-directional interface.
26. Start up time – less than 10 minutes.
27. Option for performing individual modular functions (Washing, reading, incubation and sample addition.)
28. 24 Hrs service support with toll free Number.
29. [redacted] worldwide.
30. Installation references from reputed Govt. Institution.
31. Should have more than 15 installations in India at Blood Banks, Laboratories and Clinical research Organizations
32. Reagent lot Tracking
33. Should have Software for Multiple system configurations Software should have option for generating different type of patient report

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Specifications for Semi-Automated Raeder and Centrifuge for ID Gel cards ([redacted] ID Reader)

Semi-automated Immunohematology analyser able to perform centrifugation, reading and interpretatio of all the tests based on Sephadex Gel Technology for Cross Matching on coombs and enzyme phase t pick both IgG & IgM Antibodies, Blood Grouping, partial D typing, Antibody screening & Identification.

1. Equipment should Centrifuge, Read and Interprets ID Gel Cards in one working step.
2. Equipment must centrifuge cards for the test require incubation at 4°C or 37°C at one run.
3. Capacity for 24 ID-Cards with 6 "V" bottom shaped tubes based on Gel technology.
4. Centrifugation time should be 10 minutes with 85g force.
5. The rpm of instrument should be 910± 5.
6. The instrument should read 24 cards within 4 minutes.
7. The total cycle time for centrifugation and reading of the cards should be less than 15 minutes.
8. It should be able to do full positive identification of the Cards.
9. It should give easy interpretation with clear colour images of the test results with CCD camera
10. The instrument should be able to validate, store, print and sent the results to host computer..
11. There should be complete traceability of tests, results and operator.
12. All operations are monitored by Maestro Master Software.
13. Instrument should be able to perform more than 50 different kind of test including specialised tests like Partial RhD testing, D^{weak}, Single Rare antigens, PNH, Heparin/PF4 Ab Test (HIT) etc.
14. Exhibit different gradation of reaction (4+, 3+, 2+, 1+ & -ve).
15. Dimensions (w/h/d): 53.2 cm / 38.8 cm / 52.4 cm (Approx)
16. Weight: 25 kg (Approx)
17. Power requirements: 100 V - 230 VAC
18. Frequency: 50 Hz - 60 Hz
19. CE compliant according to IVD Directive 98/79/EC.

The company should have the following combinations of cards/Reagents:

1) Sephadex Gel based LISS/Coombs cards with 6 'V' bottom shaped micro tubes containing polyspecific AHG (rabbit anti-IgG, monoclonal anti-C3d, clone no C139-9) For Coomb's Cross-match, IAT, DAT.

2) Sephadex Gel based PNH Test with Anti-DAF & Anti-MIRL Antigens.

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3) Sephadex Gel based Heparin /PF4 Ab test (HIT)

4) Gel based Anti-IgA antibody test.

5) Gel based Forward/Reverse Blood grouping cards with 6 'V' shaped bottom tubes.

6) The company should offer complete panel of ready to use liquid red cell reagents for antibo screening & identification, including the Anti-D prophylaxis panel for Rh negatives.

7) The satisfactory user list of at least 200 customers using Sephadex Gel technique based System.

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