Specifications of Intra Aortic Balloon Pump (Fully Automatic Fiber Optic)

A. Description of Functions: Intra-aortic balloon pump (IABP) is a mechanical device that is used to decrease myocardial oxygen demand while at the same time increasing cardiac output. By increasing cardiac output it also increases coronary blood flow and therefore myocardial oxygen delivery.

B. Technical Specifications

1. Latest generation IABP system.
2. Transportable, Compact IABP system with minimum 2 Hours of Battery Backup.
3. Fast Pneumatics to provide accurate & reliable ventricular support enhancing augmentation & improved after-load reduction.
    a. Driver System: Stepper motor driven bellows /compressor based system
    b. Drive Gas: Helium.
4. System should be based on state of the art, latest technology namely Fibre Optic Technology for long endurance trouble free maintenance and artifact less signals.
5. Should have 3 modes of Operation, 1) Automatic, 2) SemiAutomatic, 3) Manual.
6. System should be capable of automatically selecting appropriate Trigger i.e ECG or Pressure and also accurately select the Inflation and Deflation points, in Automatic mode.
7. In Automatic mode of Operation user should be in control of the deflation point.
8. In Automatic and Semiautomatic Mode, Single ECG Trigger should be able to track various Ventricular and Atrial Arrythmia including VE's, Bigeminy, Trigeminy, Couplets etc and Atrial Fibrillation, without any user intervention, and still give optimal performance.
9. In Automatic and Semiautomatic Mode, Advance Software should automatically adapt the timings for various rhythms and rate variations, without any user intervention
10. In Automatic and Semiautomatic Mode, it should automatically identify Atrial Fibrillation & adopt R-Wave deflation mode for better patient support, without any user intervention
11. Should be able to trigger on minimum of 7mmhg of Pulse Pressure when used in Pressure Trigger mode
12. Single Key Start-up to make it fast, user friendly and easy to use
13. Should be able to display at least 3 waveform as ECG, Invasive Pressure and Balloon Pressure waveform

14. Large Detachable Display for brighter & very good visibility from a distance in any lighting conditions
15. On screen indication for Helium level in the cylinder & Battery level for timely intervention and correction
16. ECG Inflation marker to indicate inflation period on ECG which can be useful when arterial pressure waveform is not available
17. On screen indication of standby time and should give alarm after 20 mins, to draw user's attention on the system being on standby.
18. Optical Blood back detect for early indication of blood coming into the balloon lumen due to IABC leak
19. Should have extensive Help Text available during startup to make the system easy to use even for new users
20. Should give extensive Help messages to correct the alarm conditions that are specific to the alarm condition. This should help the user to overcome the alarm problems immediately and with ease.
21. Should have Peripheral Vascular Doppler for checking Limb Ischemia, which is tethered to the main equipment
22. In-built Comprehensive Service Diagnostics to help the technician to locate the fault immediately.
23. System should be supplied with the following:
    a. ECG Cable with Lead wires: 02 sets
    b. Reusable Invasive Blood Pressure Transducer: 3 Nos.
    c. Refillable Helium Cylinder compatible with the IABP system Qty: 2 Nos
    d. Intra Aortic Balloon F/o Catheter for Adult, size 30-35 cc Qty: 03 nos.
    e. Intra Aortic Balloon F/o Catheter for Adult, size 40cc Qty: 03 nos.

C. Environmental factors

1. Shall meet IEC-60601-1-2:2001(Or Equivalent BIS) General Requirements of Safety for Electromagnetic Compatibility. Or should comply with 89/366/EEC; EMC directive.

2. The unit shall be capable of being stored continuously in ambient temperature of 0 -50deg C and relative humidity of 15-90%

3 The unit shall be capable of operating continuously in ambient temperature of 10 -40 deg C and relative humidity of 15-90%.

D. Power Supply

1. Power input to be 170-270 V AC, 50Hz fitted with Indian plug.

E. Standards, Safety and Training

1. Should be Indian regulatory body certified/CDSCO/BIS/ US FDA / European-CE approved product
2. Manufacturer/Supplier should have ISO certification for quality standards.

F. Documentation

1. User/Technical/Maintenance manuals to be supplied in English.
2. Certificate of calibration and inspection should be supplied.
3. Log book with instructions for daily, weekly, monthly and quarterly maintenance checklist. The job description of the hospital technician and company service engineer should be clearly spelt out.
4. List of Equipments available for providing calibration and routine maintenance support as per manufacturer documentation in service / technical manual.
5. List of important spare parts and accessories with their part number and costing.

G. Other requirements

1. Model should be of latest generation**.**
2. Should have local service facility.
3. Comprehensive warranty for 5 years and CMC for next five years post warranty**.**
4. Availability of spares & consumables to be ensured for minimum 10 years period.