Specification – Intra Aortic Balloon Pump Machine.

1. Should be Touch screen IABP System, with touch access control.
2. Transportable, Compact IABP System with minimum 90 Min -180 mins of battery Backup.
3. The equipment shall have min. 2 Lithium Ion batteries for portable operation (patient transport), with LED indicators.
4. Fast Pneumatics to provide accurate & reliable ventricular support enhancing augmentation& improved After-load reduction. Preferably a stepper motor Driven Bellows (or) Safety Disk system.
5. System should be capable of using fibre optic Balloon and conventional balloons.
6. Automatic in-vivo calibration function, when Fiberoptic balloon is in use
7. Automatic in vivo recalibration every 2 hours or sooner should patients or environmental conditions change when Fiberoptic balloon is in use
8. Should have 1).Automatic. 2.) Operator Modes/Semi Automatic Mode of operation.
9. System should be able to Trigger on Pulse Pressure as low as 3 mmhg (or) 3/8 of the systolic pulse height, 7mmHg minimum.
10. Fill system shall ensure a pressure controlled measurement of catheter and tubing volume and calculate a targeted fill pressure based on that volume.
11. System should not require any connector for balloon connection or volume detection.
12. System should stop shuttling of gas in case of balloon rupture and avoid chances of blood leak to machine (with Alarm).
13. Should be capable of removing Condensation automatically without interrupting the therapy. Condensation Removal System shall utilize technology for continuous water vapour removal with each inflation and deflation cycle.
14. System should be capable of automatically selecting appropriate trigger that in Automode.
15. In automatic and operator mode single ecg trigger should be able to track various ventricular and atrial arrhythmia including VE‘s bigeminy , Trigeminy, Couplets etc and atrial fibrillation, without any user intervention and still give optimal performance.
16. In automatic mode, advanced software should automatically adapt the Timings for various rhythms and rate variations, without any user intervention.

17. In automatic mode it should automatically identify atrial fibrillation and adopt r-wave deflation mode for better patient support without any user intervention.
18. Single key start up to make it fast, user friendly and easy to use.
19. Should be able to display at least 3 wave form as ECG, Invasive Pressure and balloon pressure Wave form.
20. Large display for brighter and very good visibility from a distance in any lighting conditions.
21. On screen indication for helium level in the cylinder and battery level for timely intervention and correction.
22. ECG Inflation marker to indicate inflation period on ECG which can be usefully when atrial pressure wave form is not available.
23. On screen indication of stand by time and should give alarm after 20 mts to draw user's attention on the system being on standby.
24. Should give extensive help message to correct the alarm conditions that are specific to the alarm conditions, this should help the user to overcome the alarm problem immediately and with ease.
25. In built comprehensive service diagnostics to help the technician to locate the faults immediately.
26. System should be supplied with the followings.
    - ECG cable with lead wires 01 Nos.
    - Compatible Pressure transducer cable -01 Nos.
    - Refillable helium cylinder compatible with the iabp system helium (or other) gas cylinders 2 Nos. certificate from explosives dept.
27. Entire unit should be mounted on cart with max < 55 kg weight, for Easy transport.
28. Should have an easy and quick set up transport configuration with light weight of 25kg for total transport console.
29. Internal Helium tank for transport situation with smaller size and lighter for proper transport handling - located inside the unit.
30. It should be US FDA/CE certified.

GENERAL SPECIFICATIONS

- Three years comprehensive warranty be followed by **7 years CMC**. Technical support, required spares and consumables should be assured for two years after initial 3 + 7 years period is over.

- It should be **CE Certified** by European Notified Body (under MDD/MDR) along with declaration of conformity or US FDA approved for offered model and accessories.

In case of CE (Class-I) following documents are required to be enclosed:
a) Declaration of conformity by manufacturer or EU representative of manufacturer for the quoted model.
b) Documentary evidence regarding firm registered with EEA (European Economic Area) competent authority is required. OR
European Representative registered with EEA (European Economic Area) competent authority appointed by firm is required. OR
Other documents like certificates from notified body along with declaration of conformity.

- Demonstration of quoted model is compulsory.

- Power supply: 230 V ±15%, 50 Hz ±3%.

- Service training to MEC Engineers and operational training to user department.

- Operating and detailed service manual should be provided.

- Third party inspection certificate should be applied from port of origin of shipping of equipment (from parent company's country of origin).

- Tropicalization:

• Operating Temperature: 40°C
• Storage Temperature: 60°C
• Relative Humidity: Up to 90% non-condensing