Specification for Low Temperature Hydrogen Peroxide Gas Plasma Sterilizer 90-120 litres

1. The Sterilizer should use Low Temperature H_2O_2 Gas Plasma for sterilization with plasma energy generated inside the sterilization chamber using RF energy/DBD Plasma for better efficacy and avoid the residual hydrogen peroxide for the safety of user and instruments.
2. Shape of sterilization chamber should be Rectangular.
3. Type of Hydrogen Peroxide Gas Sterilization technology used should be plasma technology Generated inside/outside the chamber.
4. Sterilizer should have chamber temperature of 50 - 56^0 C at all the time during the cycle.
5. Sterilizer should have usable volume 90-120 liters or more
6. Sterilizer should be mobile, no civil work should be required while installation. It should run on single phase/ three phase supply.
7. Shelf size should be of minimum 70 cm depth so that robotic trays can be sterilized easily. It should be able to sterilize 2 Trays in one cycle. [Each Tray of size 20 - 23inch x 8 – 10 inch x 2 -3 inch]
8. Sterilizer should have process certificate ENISO 14937.
9. The quoted model should be certified for sterilization of metal and non-metal medical devices by USFDA/European CE/BIS and CDSCO certificate.
10. The sterilizer should have 15 minutes or less readout time biological indicator system and BI should be approved as PCD for highest level of resistance. Reader and biological indicator should be from same sterilizer company to assure proper validation if reader is from different company, it should come along with the traceability certificate from the authorized NABL labs and this validation to be repeated every year as part of annual maintenance.
11. Sterilizer should have facility to completely monitor its operation with audiovisual alarms and alarm history.
12. Should have built in facility for recording and printing cycle details and smart information technology device for automatic collection, reconciliation & communication of sterilization records.

13. Sterilizer should have preprogrammed cycles without any room for human error due to manual programming. Fastest cycle time should be less than 30 minutes and longest cycle should be less than 50 min with automated moisture check cycle before the start of the cycle to reduce cycle cancellation and wastage of sterilant and time. There should be separate cycle for non- lumen/lumened instruments.

14. The leading/reputed device manufacturers should clearly specify in their instruments IFU (Instructions for Use) that the sterilizer brand as a validated method for reprocessing/ sterilizing Telescopes, Camera head, Fiberoptic Cables, Laparoscopes, robotic instruments etc. present in the hospital. Validation Documents from at-least two of these companies mentioned above needs to be submitted. No third party/self-declaration will be valid.

15. The By-products of the sterilizer should be non-toxic and eco-friendly. The OEM should provide EPA certificate/or environment safety document for the safety of the user and environment.

16. Sterilant cassette should be storable at room temperature and should have cassettes/ cartridges ONLY to release calibrated sterilant for every Sterilization cycle.

17. Sterilant (H_2O_2 concentration >= 55%) should be in cassette/cartridges form with leak proof indicator to avoid exposure of concentrated H_2O_2. The concentration of H2O2 should not be 59%-60%. And used volume should not exceed 12ml in each cycle.

18. Original Manufacturer or their subsidiary or authorized Dealer who is quoting should be present in India having Plasma Sterilizer selling experience of more than 5 years and installations.

19. The bidder/ OEM should have their service team based at the location of installation. With service center Help lines numbers.

20. The sterilizer should have a provision for connecting a smart information technology device to connect, correlate & communicate cycle data and BI result across multiple sterilizers on hospital information network through cloud, desktop & smartphone access. To have the live data access of the machine. User should be notified through email and message alerts It should do automatic reconciliation of data to track the sterilized instruments and provided with bar code scanner and printer.

21. Sterilizer should be able to process 40 Stainless Steel lumens in single cycle and reprocess the same in less than 50 minutes.

22. It should have communication protocol for Instrument tracking system(ITS) for the instrument tracking in case of sterilization failure and call back.

23. The system should come with suitable H2O2 concentration monitor to continuously check the concentration of H2O2 and the emission level should not be more than 1PPM as per OSHA guidelines for the safety of user.

24. Sterilizer should have capability of upgrading the new cycles in future.

25. It should be able to sterilize flexible lumen instruments with inside diameter of 1 mm and length up to 850mm, polyethylene and Teflon Tubing 1mm and upto 1000mm and rigid stainless steel lumen instruments with inside diameter of >0.7 mm and length of 500mm backed by clinical trials.

26. It should be able to sterilize minimum 2 flexible endoscope in single cycle.

27. Machine should come with UPS with 30 min backup and heat sealing machine.

28. Consumables should be supplied with each sterilization unit.

29. Warranty of the sterilizer should be for five years. CMC for next five years after warranty to be quoted.

30. Sterilizer should be supplied with dedicated online UPS with 5 Years warranty.

31. **Demonstration (physical) of the quoted model at the site is must at the stage of technical evaluation**