Indira Gandhi Memorial Hospital

Indira Gandhi Memorial Hospital
Male', Republic of Maldives
Biomedical Engineering Department

Technical Specification for Equipment

Technical Specification: Double Door H_2O_2 Plasma Sterilizer

1. General Description
   - The system shall be a double-door, pass-through type H_2O_2 plasma sterilizer, designed to ensure effective sterilization of heat- and moisture-sensitive medical instruments and materials.
   - It shall utilize low-temperature hydrogen peroxide plasma technology, providing a residue-free sterilization process safe for instruments and users.
   - The sterilizer shall ensure complete separation between clean and sterile areas, supporting hospital infection control standards.
   - Operation shall be fully automated and microprocessor-controlled with user-friendly graphical interface and data logging capability.

2. Chamber and Construction
   - Chamber Material: High-quality stainless steel (minimum grade SUS 316L).
   - Chamber Capacity: Suitable for medium to large instrument loads (approx. 100–150 L).
   - Door Configuration: Electrically or pneumatically operated double door with interlock system preventing simultaneous opening.
   - Door Gasket: Durable silicone gasket ensuring airtight sealing.
   - Chamber Design: Smooth internal surfaces and rounded edges to facilitate easy cleaning and prevent residue accumulation.
   - Observation Window: Safety glass window for process monitoring (if applicable).

3. Sterilization Technology and Process
   - Sterilization Method: Hydrogen Peroxide Plasma process using diffusion and plasma phases.
   - Operating Temperature: ≤ 60°C (low temperature sterilization).
   - Sterilant Concentration: 58–60% aqueous hydrogen peroxide.
   - Cycle Types:
     - Standard cycle for general instruments.
     - Fast cycle for light loads.
     - Flexible or custom cycle based on instrument type.
   - Cycle Duration: Typically 45–60 minutes depending on load and cycle type.
   - Sterilization Verification:
     - The system must have a dedicated sterilization test cycle and indication system to validate sterilization efficiency (using chemical and biological indicators).
     - The system must automatically log sterilization data for each cycle for record-keeping and validation.

4. Control and User Interface
   - User Interface: High-resolution touchscreen control panel with intuitive menus.
   - System Monitoring: Continuous monitoring of temperature, pressure, and hydrogen peroxide concentration.
   - Data Storage: Minimum of 500 cycle records, exportable via USB or LAN.
   - Safety Features:
     - Automatic abort function for any abnormal condition.
     - Door interlock to prevent opening during operation.
     - Audible and visual alarms for cycle faults or system errors.

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5. Consumables

- Hydrogen Peroxide Cartridges / Cassettes:
  - Single-use cartridges containing stabilized H_2O_2 solution.
  - Cartridges designed for safe handling and easy loading.
  - Each cartridge supports a defined number of sterilization cycles (vendor must specify cycle count per cartridge).
- Shelf Life: Minimum 12 months under standard storage conditions.
- Consumable Storage:
  - If special storage conditions are required (e.g., temperature-controlled storage or dedicated containment), the vendor must provide full details and supply the necessary storage containers or cabinets.
- Other Consumables:
  - Replacement HEPA filters (if applicable).
  - Door seals and maintenance kits.
  - Approved cleaning and calibration materials.
- The vendor shall provide initial consumables sufficient for a minimum of 100 sterilization cycles at installation.

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6. Environmental Conditions

- Operating Temperature: 18°C – 30°C.
- Relative Humidity: 30% – 70% (non-condensing).
- Dimension: (L-2000mm x W- 1100mm x H-2200mm)
- Altitude: Up to 2000 meters above sea level.
- Power Supply: 220–240 V AC, 50 Hz, single or three-phase (as specified).
- Ventilation: Adequate air circulation; exhaust connection to the ventilation system if required by safety regulations.
- Noise Level: ≤ 65 dB during operation.
- Ambient Conditions: Must operate safely under standard hospital CSSD environmental conditions.

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7. Installation and Commissioning

- The vendor must proceed with full installation setup, including electrical, mechanical, and safety connections.
- Vendor shall provide site preparation details in advance (power, ventilation, and space requirements).
- Commissioning:
  - The system must undergo installation qualification (IQ) and operational qualification (OQ) tests.
  - A detailed installation and commissioning report must be provided upon completion.
- The vendor shall also provide all documentation including:
  - Operation manuals.
  - Service manuals.
  - Technical manuals and wiring diagrams.
  - Training materials.
  - Calibration and test certificates.

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8. Training

- User Training: On-site training for clinical and CSSD staff on routine operation, loading techniques, safety procedures, and cycle selection.
- Technical Training:
  - Vendor must provide technical training for biomedical staff conducted by a certified trainer.
  - Training must include system principles, good operational practices, preventive maintenance, troubleshooting, and error handling.

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9. Service and Support

- Warranty: Minimum 2 years comprehensive warranty (extendable preferred).
- Service Support: Local technical support and maintenance capability must be available within the region.

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- Technical Support: 24×7 technical support must be provided by the vendor until system decommissioning.
- Preventive Maintenance: Vendor to perform scheduled preventive maintenance visits during warranty and support periods.
- Spare Parts:
    - Vendor must provide essential spare part buffer stock or one annual maintenance kit at installation.
    - Vendor must also provide a major spare parts list with estimated price list for 5 years post-warranty.
    - All spare parts must be genuine and compatible with the supplied system.

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10. Compliance and Safety
    - The sterilizer shall comply with relevant international standards, including but not limited to:
        - ISO 14937: Sterilization of health care products – General requirements.
        - ISO 13485: Medical devices – Quality management systems.
        - IEC 61010: Safety requirements for electrical equipment.
        - ISO 11140: Chemical indicators for sterilization processes.
    - Must possess CE certification or equivalent regulatory approval.
    - The system must ensure safety for operators, patients, and the environment with no toxic or corrosive residues after sterilization.

End of Specification

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