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

Technical Specification for Equipment

Technical Specification: Radiofrequency (RF) Ablation System

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1. Equipment Description

- Complete Radiofrequency Ablation System suitable for minimally invasive thermal ablation procedures.
- The system shall be designed for controlled delivery of radiofrequency energy to create localized tissue ablation zones under image-guided clinical procedures.
- The system shall support clinical applications including but not limited to:
    - Tumor ablation procedures.
    - Liver, kidney, bone, and soft tissue ablation applications.
    - Other interventional RF ablation procedures as required by the clinical department.

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2. System Technical Requirements

2.1 RF Ablation Generator Unit

- Dedicated radiofrequency energy generator system.
- Adjustable RF power output suitable for clinical ablation procedures.
- Controlled energy delivery with automatic impedance monitoring.
- Real-time monitoring of:
    - Tissue impedance.
    - Delivered power.
    - Treatment duration.
    - Ablation parameters.
- Automatic adjustment of energy delivery based on tissue response.
- Digital display with clear visualization of:
    - Power settings.
    - Ablation time.
    - System status.
    - Error/alarm indications.
- Audible and visual alarms for abnormal conditions.
- Emergency stop function.
- User-friendly interface with programmable treatment settings.
- Self-test and system diagnostic functions.

2.2 Electrode System Compatibility

- The system shall support expandable RF ablation electrodes capable of creating controlled ablation zones.
- Required electrode compatibility:

Standard RF Ablation Electrodes

- Electrode diameter: 4.0 cm
- Electrode length: 15.0 cm

Standard RF Ablation Electrodes

- Electrode diameter: 3.5 cm
- Electrode length: 15.0 cm

Slim RF Ablation Electrodes

- Electrode diameter: 2.0 cm
- Electrode length: 15.0 cm

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3. Consumables Requirements

- The vendor shall provide all necessary disposable consumables required for safe and complete operation of the system.
- Consumables shall include:

- RF ablation electrodes/needles compatible with the supplied system.
- Patient grounding/return electrodes if required.
- Connecting cables and adapters (if applicable).
- Sterile disposable accessories required for each procedure.
- Any additional procedure-specific consumables required for operation.
- Vendor shall provide a detailed consumable list with:
    - Item description.
    - Catalogue/reference number.
    - Unit price.
    - Estimated annual consumption cost.
    - Shelf life and storage requirements.

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4. Safety Requirements
- The system shall comply with applicable international medical electrical equipment safety standards.
- Electrical isolation and patient safety protection features shall be incorporated.
- The system shall include:
    - Over-temperature protection.
    - Over-current protection.
    - Fault detection.
    - Alarm notification system.
- All patient-contact components shall be biocompatible and suitable for intended clinical use.

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5. Environmental Conditions
- The system shall operate reliably under the following environmental conditions:

Operating Conditions
- Ambient temperature:
    - 10°C to 40°C
- Relative humidity:
    - 30% to 75% (non-condensing)
- Atmospheric pressure:
    - 700 hPa to 1060 hPa

Storage and Transportation Conditions
- Temperature:
    - -20°C to 60°C
- Relative humidity:
    - 10% to 90% (non-condensing)

Installation Environment
- Indoor hospital environment.
- Clean and dust-controlled clinical area.
- Stable electrical supply with proper grounding.
- Protection from excessive vibration and electromagnetic interference.
- Suitable space for:
    - Equipment operation.
    - Maintenance access.
    - Cable management.
    - Patient safety.

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6. Power Requirements
- Voltage requirement. 230V +/- 10V, BS 1363
- Frequency requirement. 50 Hz
- Recommended electrical protection.
- Equipment shall be compatible with hospital electrical infrastructure.
- Proper earthing/grounding requirement shall be provided.

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7. Installation and Commissioning
- The vendor shall:
- Perform complete installation and setup of the system.
- Verify system functionality before clinical use.
- Perform operational and safety checks.
- Configure system according to hospital requirements.
- Provide installation and commissioning report including:
    - Installation date.

    - Equipment details.
    - Testing results.
    - Safety verification.
    - Acceptance confirmation.

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8. Warranty Requirements

- Minimum warranty period:
    - 2 years from successful installation and commissioning.
- Extended warranty coverage is preferred.
- Warranty shall include:
    - Complete system coverage.
    - Replacement of defective parts.
    - Technical troubleshooting.
    - Preventive maintenance support.

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9. Service and Technical Support Requirements

- The vendor shall provide:
- Local technical support capability.
- Local maintenance and troubleshooting support.
- 24 × 7 technical support availability until system decommissioning.
- Response time commitment for:
    - Critical system failures.
    - Clinical downtime situations.
- Preventive maintenance services according to manufacturer recommendations.
- Corrective maintenance support.
- Availability of trained service engineers.

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10. User Training Requirements

- Vendor shall provide on-site training for:

Clinical Users

- Training shall include:
- System operation.
- RF ablation procedure workflow.
- Safety precautions.
- Consumable handling.
- Alarm/error interpretation.
- Basic troubleshooting.

Biomedical Engineering Staff

- Training shall include:
- System operation principles.
- Preventive maintenance procedures.
- Routine inspection requirements.
- Error handling and troubleshooting.
- Safety checks.
- Basic performance verification.
- Good maintenance practices.
- Training completion certificates shall be provided.

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11. Spare Parts Requirements

- Vendor shall provide:
- Essential spare parts buffer stock recommendation.
- List of major spare parts required for system maintenance.
- Estimated spare part pricing.
- Recommended replacement intervals.
- Availability timeline for spare parts.
- Spare parts documentation shall include:
- Part description.
- Part number/reference.
- Estimated cost.
- Expected availability.

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12. Documentation Requirements

- Vendor shall provide:
- User operation manual.
- Service manual (for Biomedical Engineering department).
- Preventive maintenance checklist.
- Electrical safety testing procedure.
- Troubleshooting guide.
- Consumable catalogue.
- Warranty certificate.
- Installation and commissioning report.
- Training records.

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13. Vendor Compliance Requirement

- The vendor shall confirm compliance with all technical specifications and provide a compliance statement with the quotation.

End of Specification