



Biomedical Engineering Department
Indira Gandhi Memorial Hospital
Male', Republic of Maldives
Cryoablation System
Technical Specification

1. Equipment Description

The offered equipment shall be a complete, commercially available cryoablation system intended for minimally invasive, image-guided percutaneous tissue ablation procedures. The system shall generate controlled cryogenic temperatures through delivery of a suitable cryogenic medium (e.g., medical-grade argon gas or equivalent technology) to disposable cryoprobes, producing predictable ice-ball formation for tissue destruction using programmable freeze-thaw cycles.

The system shall be suitable for use under CT, ultrasound, and/or MRI guidance, where applicable to the offered technology.

The system shall support, at minimum, the following clinical applications:

- Renal tumor ablation
- Liver tumor ablation
- Lung tumor ablation
- Bone lesion ablation
- Soft tissue tumor ablation
- Prostate cryoablation
- Palliative pain management
- Other interventional oncology applications approved by the manufacturer

The system shall be supplied as a complete operational package including console, accessories, gas interfaces, consumables required for commissioning, and all necessary installation hardware.

2. Technical Requirements

Numeric values marked "target" in this section are institutional reference benchmarks for technical evaluation, not mandatory pass/fail thresholds. Vendors shall state actual achieved values, supported by bench or clinical data. Deviations shall be scored, not automatically disqualified, unless a clause states otherwise

2.1 Cryoablation Console

The system shall include a dedicated cryoablation console capable of independently controlling multiple cryoprobes simultaneously.

The vendor shall specify:

- Maximum number of simultaneously controlled probes
- Maximum number of independently controlled channels

- Maximum number of treatment zones that can be created simultaneously
- Physical dimensions (height × width × depth) and weight of the console
- Mobility configuration (mobile/cart-mounted vs. fixed installation) and, if mobile, castor/locking mechanism details

Power interruption behavior and backup power requirements:

- Vendor shall state whether the console incorporates internal battery backup, and if so, the minimum guaranteed runtime at typical operating load.
- Vendor shall state the console's fail-safe behavior on loss of mains power during an active freeze cycle, specifically confirming whether cryogen delivery defaults to a closed/safe state independent of any external UPS.
- Vendor shall state whether an external UPS is required or recommended for safe operation, and if so, the minimum VA/wattage rating, backup runtime, and UPS type (e.g., online double-conversion vs. line-interactive) needed to meet warranty and safety compliance.
- Vendor shall state system behavior on power restoration, including whether a full diagnostic self-test is required before the console can resume clinical use, and whether data/logs from an interrupted procedure are retained.

The console shall provide:

- Independent control of each cryoprobe
- Automatic and manual freeze/thaw operation
- Programmable treatment protocols
- User-defined treatment profiles
- Multiple sequential freeze-thaw cycles
- Adjustable freeze duration
- Adjustable thaw duration
- Active or passive thaw technology, as applicable to the offered system — vendors offering either technology shall be evaluated equally provided documented clinical performance data is supplied
- Individual probe activation/deactivation during procedures
- Minimum number of freeze-thaw cycles per probe supported without documented performance degradation: vendor to state (Target: **≥ 3 cycles** per probe within a single procedure)

2.2 Cryogenic Performance

The system shall provide:

- A minimum achievable probe-tip temperature of $\leq -140^{\circ}\text{C}$ (vendor to confirm actual value)
- Time to reach therapeutic isotherm (e.g., -20°C or -40°C , as clinically defined) at a stated radial distance from the probe: vendor to state (target: **-40°C isotherm reached at 1.0 cm within 6 minutes**)
- Uniform and reproducible ice-ball formation

- Minimum and maximum ice-ball diameter achievable per probe type, at defined freeze times (e.g., 5, 10, 15 minutes)
- Active thaw capability or equivalent passive thaw performance, with documented thaw time to probe release
- Stable cryogenic performance throughout extended procedures (vendor to state maximum continuous procedure duration supported without performance drift)

The vendor shall provide documented, third-party or manufacturer bench/clinical performance data for the above parameters.

2.3 System Monitoring

The system shall continuously monitor and display:

- Individual probe temperature, with stated measurement accuracy (target: $\pm 1.5^{\circ}\text{C}$) and update/sampling rate (target: every 2 seconds)
- Treatment duration
- Freeze/thaw cycle status
- Gas pressure, with stated normal operating range and alarm thresholds
- Gas supply status (remaining volume/time estimate, if available)
- Probe identification
- Active channels
- System status
- Alarm status

The display shall provide clear graphical representation of all active probes and their individual cycle status.

2.4 User Interface

The console shall include:

- High-resolution colour touchscreen display (minimum screen size: ≥ 12 -inch diagonal)
- Intuitive graphical user interface
- Treatment protocol library
- User-programmable protocols
- Password-protected configuration settings
- Treatment summary display, exportable at end of procedure

2.5 Image Guidance Compatibility

The system shall be suitable for use with image-guided interventions using:

- CT
- Ultrasound
- MRI (where applicable to the offered system; vendor to state MRI-conditional status and field strength limitations, if any)

The vendor shall specify all imaging compatibility limitations, including any restrictions on simultaneous imaging during active freeze/thaw.

2.6 Cryogen Supply

The vendor shall specify:

- Cryogenic medium used and required purity grade
- Cylinder size and capacity
- Cylinder connection/fitting standard (e.g., CGA type or equivalent)

- Regulator and gas manifold requirements
- Required supply pressure (operating range)
- Gas consumption per procedure, expressed in standard comparable units (e.g., liters or kg per full freeze cycle, per probe)
- Estimated number of procedures per cylinder, at stated typical protocol settings
- Storage requirements (temperature, ventilation, segregation from other gases)
- Ventilation and exhaust requirements for the procedure room
- Safety precautions specific to the cryogenic medium used (e.g., asphyxiation risk in poorly ventilated spaces)
- Cylinder structural/floor-loading considerations, if relevant to the installation site

Any required gas supply infrastructure (manifolds, piping, cylinder storage racks) shall be included in the quotation, with associated installation costs itemized separately.

2.7 Cryoprobes

The offered system shall support a range of disposable, sterile cryoprobes suitable for different clinical applications and anatomical access requirements.

Available probe configurations shall include, at minimum:

- A straight-tip needle probe
- A 90° angled-tip needle probe
- Both standard and extended-shaft-length variants of the angled-tip probe, to accommodate varying depth/access requirements

For each probe type offered, the vendor shall specify:

- Probe diameter/gauge
- Overall shaft length
- Active tip length
- Expected ice-ball dimensions at stated freeze times (see 2.2)
- Freeze performance (time to target isotherm)
- MRI compatibility/conditional status, if applicable
- Single-use or reusable status, and if reusable, reprocessing/sterilization requirements

All probes offered shall be fully compatible with the supplied console without requiring third-party adapters. Vendors shall map their available probe range against the tip geometries and shaft-length ranges required by the purchasing institution's clinical use cases.

3. Consumables

The vendor shall provide a complete consumables list including:

- Cryoprobes (all configurations offered)
 - Extension cables
 - Gas hoses/lines
 - Sterile disposable accessories
 - Procedure kits
 - Filters
 - Adapters (if genuinely required for any listed accessory, not for core probe compatibility)
 - Any additional consumables required for clinical operation
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The quotation shall include, per item:

- Catalogue number
- Description
- Unit price
- Estimated annual consumption (based on estimated case volume, to be confirmed with purchasing institution)
- Shelf life
- Storage conditions

4. Safety Requirements

The system shall comply with applicable IEC and ISO standards for medical electrical equipment, including but not limited to:

- IEC 60601-1 (general safety and essential performance)
- IEC 60601-1-2 (electromagnetic compatibility)
- IEC 60601-1-8 (alarm systems)
- IEC 62366-1 (usability engineering)
- IEC 62304 (medical device software lifecycle, if applicable) — vendor to state the software safety classification (Class A/B/C) of the console software
- IEC 62353 (recurring/periodic electrical safety testing, for ongoing biomedical maintenance)
- ISO 14971 (risk management) — vendor to provide a summary risk management report or equivalent evidence
- ISO 13485 (manufacturer's quality management system) — vendor to provide current certification

The system shall include:

- Automatic self-test prior to procedure start
- Over-pressure protection
- Over-temperature protection
- Under-temperature protection
- Gas leak monitoring
- Low gas supply alarm
- High pressure alarm
- Probe fault detection
- System diagnostics
- Audible and visual alarms, distinguishable by severity
- Emergency stop function with immediate cessation of cryogen delivery
- Electrical isolation
- Patient leakage current protection

Cryoprobes and all patient-contact components shall be biocompatible (per ISO 10993 or equivalent) and supplied sterile.

The vendor shall describe its post-market surveillance and vigilance process, including notification timelines for field safety corrective actions (FSCAs) or recalls affecting the installed system.

5. Data Management and Connectivity

The system should provide:

- Internal treatment data storage
- Treatment log generation
- Procedure summary reports
- USB data export
- Ethernet connectivity
- DICOM compatibility (preferred, not mandatory)
- Hospital network connectivity (preferred, not mandatory)

Absence of networking/DICOM features shall not constitute non-compliance but may be scored during technical evaluation. The vendor shall specify available software options, licensing requirements, and any recurring software subscription costs.

6. Environmental Requirements

Operating Conditions

- Temperature: 10°C–40°C
- Relative Humidity: 30%–75%, non-condensing

Storage Conditions

- Temperature: –20°C to +60°C
- Relative Humidity: 10%–90%, non-condensing
- Vendor shall confirm actual storage specifications per manufacturer datasheet for the offered console, probes, and accessories

Acoustic Output

The vendor shall state the maximum sound pressure level (dB) generated by the console during active cryogen delivery, measured at 1 meter, given the potential for procedure-room noise limits.

Installation shall be suitable for indoor hospital use with adequate ventilation, cryogen exhaust, grounding, gas cylinder storage, maintenance access, and cable management.

7. Electrical Requirements

- Supply Voltage: 230 VAC $\pm$ 10%
- Frequency: 50 Hz
- Plug: BS 1363
- Medical-grade grounding
- Hospital-compatible electrical protection

8. Installation and Commissioning

The vendor shall perform:

- Complete installation
 - Gas supply installation
 - System configuration
 - Functional testing
 - Safety testing
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- Cryogenic performance verification (against parameters stated in Section 2.2)
- Acceptance testing
- Clinical readiness verification

Installation documentation shall include:

- Installation report
 - Acceptance certificate
 - Safety test results
 - Functional test results
 - Commissioning checklist
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9. Warranty

Minimum warranty:

- Two (2) years comprehensive, from date of successful installation and commissioning

Warranty shall include:

- Labour
- Travel
- Parts
- Software updates (where applicable)
- Preventive maintenance
- Corrective maintenance

Extended warranty options shall be quoted separately, with per-year pricing.

10. Service Requirements

The vendor shall provide:

- Local technical support
- Factory-trained engineers
- Preventive maintenance, per manufacturer-recommended schedule
- Emergency breakdown service
- Telephone support
- Remote technical support, where available

The vendor shall state:

- Response time commitment for critical failures
- Typical repair/resolution time
- Preventive maintenance schedule and scope
- Expected service life of the console
- Detailed spare parts lead times and pricing — see Section 12

The vendor shall state the expected minimum availability period for consumables (cryoprobes) and spare parts following installation. Longer stated availability periods may be scored favorably during technical evaluation but shall not constitute a mandatory pass/fail requirement.

11. Training

Comprehensive onsite training shall be provided for both clinical users and Biomedical Engineering personnel.

Clinical Staff

- System operation
- Procedure setup
- Probe selection
- Freeze-thaw programming
- Image-guided workflow
- Safety precautions
- Alarm interpretation
- Basic troubleshooting

Biomedical Engineering Staff

- System architecture
- Cryogenic gas system
- Preventive maintenance
- Routine inspection
- Performance verification
- Safety testing
- Fault diagnosis
- Basic repairs
- Service documentation

Training completion certificates shall be provided for all attendees.

12. Spare Parts

The vendor shall provide:

- Recommended spare parts list
- Preventive maintenance parts list
- Critical spare parts list
- Recommended replacement intervals
- Lead times per part
- Pricing per part

The vendor shall state the expected availability period for spare parts following installation (see also Section 10).

13. Regulatory and Documentation Requirements

The vendor shall provide evidence of regulatory clearance/certification applicable to the country of installation (e.g., CE marking, FDA 510(k) or equivalent, or local regulatory authority approval), for both the console and all offered cryoprobes.

The vendor shall provide:

- User Manual
- Service Manual
- Installation Manual
- Preventive Maintenance Manual
- Electrical Schematics (where available)
- Parts Catalogue

- Troubleshooting Guide
- Safety Manual
- Cryogen Handling and Storage Manual
- Consumables Catalogue
- Warranty Certificate
- Installation Report
- Acceptance Test Report
- Training Records
- Certificate(s) of Conformity / Regulatory Clearance

Documentation shall be supplied in English, in both printed and electronic formats.

14. Disposal and Decommissioning

The vendor shall specify:

- Any special disposal requirements for used cryoprobes and other single-use consumables
- Cryogen cylinder return/exchange procedures, if applicable
- Any environmental or regulatory disposal considerations specific to the offered technology

15. Vendor Compliance

The vendor shall submit a detailed, clause-by-clause compliance statement against this specification, explicitly stating "Comply," "Partially Comply" (with explanation), or "Do Not Comply" for each numbered requirement.

Any deviations shall be clearly identified and justified.

The quotation shall include manufacturer brochures, technical data sheets, and supporting documentation (including third-party performance data where available) demonstrating compliance with the offered system.

End of Specification