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Microwave Ablation System

Technical Specification

1. Equipment Description

The offered equipment shall be a complete, commercially available microwave ablation system intended for minimally invasive, image-guided percutaneous and/or intraoperative tissue ablation procedures.

The system shall generate controlled microwave energy, delivered via disposable antennas, to produce predictable, reproducible thermal ablation zones in target tissue through controlled power and time delivery.

The system shall be suitable for use under CTand ultrasound and shall also support intraoperative/laparoscopic use where applicable.

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

- Liver tumor ablation (primary and metastatic)
- Kidney tumor ablation
- Lung tumor ablation
- Bone lesion ablation
- Soft tissue tumor ablation
- Other interventional oncology applications approved by the manufacturer

The system shall be supplied as a complete operational package including generator, antennas/cabling required for commissioning, coolant delivery system (if applicable), and all necessary installation hardware.

2. Technical Requirements

2.0 Interpretation of Target Values

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

2.1 Microwave Generator Unit

The system shall include a dedicated microwave generator capable of delivering controlled energy to one or more antennas.

The vendor shall specify:

- Generator cooling method (air-cooled, forced-air, liquid-cooled).
- Operating frequency (e.g., 902–928 MHz and/or 2450 MHz band, as applicable to the offered technology)

- Frequency stability and tolerance throughout microwave energy delivery.
- Continuous duty cycle at maximum power output (Watts) and adjustable power range
- Maximum number of antennas that can be simultaneously energized from a single generator
- Whether simultaneous multi-antenna activation uses independent, individually controlled channels or power-shared/multiplexed delivery, and the clinical implications of the offered method
- Physical dimensions (height × width × depth) and weight of the generator
- Mobility configuration (mobile/cart-mounted vs. fixed installation) and, if mobile, castor/locking mechanism details

The generator shall provide:

- Programmable power and time settings per antenna
- Pre-set and user-programmable ablation protocols
- Independent or synchronized control of multiple active antennas
- Automatic power adjustment or cutoff in response to fault conditions (e.g., antenna disconnection, coolant failure, excessive reflected power)
- Real-time display of delivered power, elapsed time, and antenna status per channel

The vendor shall state the manufacturer-defined essential performance and single-fault safe-state behavior of the generator, per IEC 60601-1.

Power interruption behavior and backup power requirements:

- Vendor shall state whether the generator incorporates internal battery backup, and if so, the minimum guaranteed runtime at typical operating load.
- Vendor shall state the generator's fail-safe behavior on loss of mains power during an active ablation, specifically confirming whether microwave energy delivery ceases immediately and safely without operator intervention.
- 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 generator can resume clinical use, and whether data/logs from an interrupted procedure are retained.

2.2 Ablation Performance

The system shall provide:

- Predictable, reproducible ablation zone dimensions per antenna type and power/time setting
- Documented ablation zone size and shape (including sphericity/eccentricity characteristics) at stated power and time combinations (institution reference example: 100 W for 10 minutes producing an ablation zone of approximately 5 × 3 cm; vendor to state actual values per antenna type offered, see Clause 2.0)
- The vendor shall provide ablation zone performance data (size, shape, time-to-target) separately for each clinical application listed in Section 1 for which antennas are offered, rather than a single generalized figure
- Minimal antenna shaft/back-heating, with vendor-stated data demonstrating control of proximal thermal spread
- Stated maximum single-antenna ablation zone diameter, and stated maximum achievable zone diameter using simultaneous multi-antenna activation
- Stated time to reach a defined ablation zone size at maximum rated power, for each antenna type offered

The vendor shall provide documented, third-party or manufacturer bench/animal/clinical performance data for the above parameters, and shall reference any peer-reviewed clinical publications supporting the stated ablation zone performance of the offered antennas.

2.3 System Monitoring

The system shall continuously monitor and display, per active channel:

- Delivered power (Watts)
- Reflected power / impedance-related fault indication, if applicable to the offered technology
- Treatment/ablation duration
- Antenna connection/fault status
- Coolant flow/pressure status (if internally cooled antennas are offered)
- System status
- Alarm status

The display shall provide clear graphical or numerical representation of all active channels simultaneously.

2.4 User Interface

The generator shall include:

- High-resolution colour touchscreen display (institution reference target: ≥ 12-inch diagonal; vendor to state actual value, see Clause 2.0)
- Intuitive graphical user interface
- Treatment protocol library, organized by clinical application/organ and target ablation zone size
- User-programmable protocols
- Password-protected configuration settings
- Treatment summary display, exportable at end of procedure
- Available interface language(s); vendor to confirm availability in the language(s) required by the purchasing institution

The vendor shall provide a summary of the usability engineering evaluation performed on the generator interface (per IEC 62366-1), addressing use-error risks relevant to protocol selection and antenna activation, particularly for multi-antenna simultaneous procedures.

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 per ASTM F2503, including field strength limitations and any spatial gradient or RF exclusion requirements, if any)

The vendor shall specify all imaging compatibility limitations, including any electromagnetic interference considerations affecting real-time ultrasound visualization during active microwave delivery.

2.6 Antenna Cooling System (where applicable)

Where the offered antennas are internally cooled, the vendor shall specify:

- Manufacturer-approved coolant.
- Coolant delivery mechanism (e.g., peristaltic pump, pressurized cartridge)
- Coolant reservoir/bag size and estimated consumption per procedure

- Coolant flow rate (operating range) and pressure monitoring/alarm thresholds
- Coolant line priming and setup time
- Any coolant temperature control/chiller requirements

Any required coolant supply infrastructure (pumps, tubing sets, chillers) shall be included in the quotation, with associated installation costs itemized separately.

2.7 Antennas (Applicators)

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

Available antenna configurations shall include, at minimum:

- Standard-length antennas
- A range of antenna gauges/diameters
- A range of active tip / radiating section lengths suitable for the clinical applications listed in Section 1
- Antennas suitable for percutaneous and, where applicable, laparoscopic/intraoperative use
- Antenna gauge/diameter options shall include, at minimum, 15G and/or 17-18G, in addition to any other gauges offered, to accommodate varying lesion sizes and anatomical access requirements.
- Automatic antenna recognition by the generator (where supported).

For each antenna type offered, the vendor shall specify:

- Antenna diameter/gauge
- Overall shaft length
- Active tip / radiating section length
- Whether internally cooled or non-cooled design
- Expected ablation zone dimensions at stated power/time settings (see 2.2)
- MRI compatibility/conditional status, if applicable
- Single-use status (reusable antennas are not typically applicable to this technology; vendor to confirm)
- Unique Device Identification (UDI) compliance status

All antennas offered shall be fully compatible with the supplied generator without requiring third-party adapters. Vendors shall map their available antenna range against the gauge, length, and radiating-section options required by the purchasing institution's clinical use cases.

3. Consumables

The vendor shall provide a complete consumables list including:

- Antennas (all available options to be specified)
- Coaxial cables/feedlines
- Coolant tubing sets/circuits (if applicable)
- Sterile disposable accessories
- Procedure kits
- Sterile probe/transducer covers (for image-guidance equipment used alongside the system)
- Console keyboard/touchscreen protective covers (single-use or reusable, for infection control)
- Any additional consumables required for clinical operation

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
- UDI/traceability identifier

4. Accessories

The system shall be supplied with:

- Generator
- Footswitch (if applicable)
- Power cord
- Cooling system (if applicable)
- Initial antenna(s) for commissioning (15G and 18G)
- Connecting cables
- Equipment trolley/cart (if applicable)
- Operator manuals
- Service manuals

5. 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 60601-2-2 (particular requirements for high-frequency surgical/ablation equipment, as applicable)
- 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 generator 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
- Antenna fault/disconnection detection
- Coolant flow failure detection (where applicable), with automatic power reduction or cutoff
- Over-temperature protection at the generator and antenna connection points
- System diagnostics
- Audible and visual alarms, distinguishable by severity, per IEC 60601-1-8
- Emergency stop function with immediate cessation of microwave energy delivery
- Electrical isolation
- Patient leakage current protection

The vendor shall confirm whether the offered technology requires a patient return/grounding electrode; if not required, this shall be explicitly stated as a design characteristic of the offered system.

Antennas and all patient-contact components shall be biocompatible (per ISO 10993 or equivalent) and supplied sterile. The vendor shall submit the ISO 10993 biocompatibility test summary/report (or equivalent regulatory evidence) for all offered patient-contact components as part of the technical submission.

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.

6. 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)
- HL7 / Modality Worklist (MWL) integration (preferred, not mandatory)
- Hospital network connectivity (preferred, not mandatory)

Absence of networking/DICOM/HL7 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.

7. Environmental Requirements

Operating Conditions

- Temperature: 10°C–40°C
- Relative Humidity: 30%–75%, non-condensing
- Atmospheric Pressure: 700–1060 hPa

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 generator, antennas, and coolant system components; deviations shall not constitute automatic non-compliance provided justification is supplied

Acoustic Performance

The vendor shall state the maximum sound pressure level (dB) generated by the system during operation (e.g., coolant pump noise), measured at 1 meter, given potential procedure-room noise limits.

Facility Fit

Installation shall be suitable for indoor hospital use with adequate space for the generator, coolant pump/reservoir (if applicable), cable management, maintenance access, and patient safety. The vendor

shall confirm any minimum room dimensions, doorway clearance, or floor-loading requirements necessary for delivery and installation.

8. Electrical Requirements

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

9. Installation and Commissioning

The vendor shall perform:

- Complete installation
- Coolant system installation and priming (if applicable)
- System configuration
- Functional testing
- Safety testing
- Ablation performance verification (against parameters stated in Section 2.2)
- Acceptance testing
- Clinical readiness verification

The vendor shall state the expected delivery timeline from order confirmation to completed installation, and shall clarify responsibility for import, customs clearance, and transport insurance where applicable.

Installation documentation shall include:

- Installation report
- Acceptance certificate
- Safety test results
- Functional test results
- Commissioning checklist

10. 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.

11. Service Requirements

The vendor shall provide:

- Local technical support
- Factory-trained engineers
- Preventive maintenance, per manufacturer-recommended schedule
- Calibration or performance verification schedule, as recommended by the manufacturer.
- Emergency breakdown service
- Telephone support
- Remote technical support, where available
- All required consumables must be available for purchase for at least 5 years from the commissioning of the device. Buffer stock for antennas to be kept as per requirement of user department, available for purchase

The vendor shall state:

- Response time commitment for critical failures
- Typical repair/resolution time
- Guaranteed system uptime (%), if offered, and any penalty/remedy provisions for failure to meet response or repair commitments
- Preventive maintenance schedule and scope
- Expected service life of the generator
- Backup/loaner unit policy in the event the generator is non-operational beyond a stated number of days
- Expected product end-of-life/discontinuation notice period (minimum advance notice the vendor commits to providing before discontinuing support)
- Detailed spare parts lead times and pricing — see Section 12

The vendor shall state the expected minimum availability period for consumables (antennas) 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.

12. Training

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

End-user (clinical) training shall be included as part of the base equipment package at no additional cost, covering all clinical staff who will operate the system

Clinical Staff

- System operation
- Procedure setup
- Antenna selection
- Protocol selection and power/time programming
- Single- and multi-antenna simultaneous ablation workflow
- Image-guided workflow
- Safety precautions
- Alarm interpretation

- Basic troubleshooting

Biomedical Engineering Staff

- System architecture
- Coolant system (if applicable)
- Preventive maintenance
- Routine inspection
- Performance verification
- Calibration procedures
- Safety testing (including periodic electrical safety testing per IEC 62353)
- Fault diagnosis
- Basic repairs
- Service documentation

Training completion certificates shall be provided for all attendees.

13. 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
- Unit pricing

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

14. 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 generator and all offered antennas.

The vendor shall provide:

- User Manual
- Service Manual
- Installation Manual
- Preventive Maintenance Manual
- Calibration Manual/Procedure
- Electrical Schematics (where available)
- Parts Catalogue
- Troubleshooting Guide
- Safety Manual
- Consumables Catalogue
- Warranty Certificate

- Installation Report
- Acceptance Test Report
- Training Records
- Certificate(s) of Conformity / Regulatory Clearance
- ISO 13485 certification (manufacturer's quality management system)
- ISO 14971 risk management summary or equivalent
- ISO 10993 biocompatibility test summary/report for all offered patient-contact components

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

15. Disposal and Decommissioning

The vendor shall specify:

- Any special disposal requirements for used antennas and other single-use consumables
- Coolant/waste fluid disposal considerations, if applicable
- Any environmental or regulatory disposal considerations specific to the offered technology
- Generator decommissioning/disposal guidance at end of service life

16. Total Cost of Ownership

The vendor shall provide a structured cost breakdown over a five (5) year horizon (or purchasing institution's preferred period), including:

- Capital equipment cost
- Annual service contract cost (post-warranty)
- Estimated annual consumables cost, based on stated or estimated case volume
- Any recurring software licensing/subscription costs
- Extended warranty cost, if applicable

This breakdown is intended to support lifecycle cost comparison across vendors, in addition to capital price comparison.

17. 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