Technical Specifications

3D Electrophysiology Mapping System with Radiofrequency Ablation (RFA) Platform (Equivalent to EnSite™ X EP System or Higher)

Prepared for: National Cardiac Centre / National Centre for Cardiovascular Sciences (NCCS)
Purpose: procurement for advanced cardiac electrophysiology mapping and arrhythmia ablation services.
Reference technical capabilities derived from EnSite™ X EP System brochure.

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1. GENERAL REQUIREMENTS

1. The offered system shall be a latest-generation 3D electro-anatomical cardiac mapping and radiofrequency ablation platform intended for diagnosis and treatment of:
    - Atrial fibrillation (AF)
    - Atrial flutter
    - SVT
    - AVNRT
    - AVRT
    - Ventricular tachycardia (VT)
    - PVCs and complex ventricular arrhythmias
2. The system shall support:
    - High-density electro-anatomical mapping
    - Contact-force guided RF ablation
    - Real-time catheter visualization
    - Advanced activation and voltage mapping
    - Integration with fluoroscopy and intracardiac echocardiography (ICE)
3. The offered system shall be FDA approved and/or CE certified.
4. The manufacturer shall have a proven international track record in electrophysiology systems.
5. Vendor shall provide:
    - Installation
    - Commissioning
    - Clinical application support
    - Biomedical training
    - Physician training
    - Warranty and annual maintenance support

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2. ELECTROPHYSIOLOGY MAPPING SYSTEM

2.1 Core Mapping Platform

1. System shall provide advanced 3D electro-anatomical mapping.
2. System shall support both:
    - Impedance-based localization
    - Magnetic-based localization
3. System shall allow creation of high-density cardiac chamber geometry.
4. System shall support simultaneous visualization of multiple catheters.
5. System shall provide real-time dynamic cardiac mapping.
6. System shall support acquisition and display of:
    - Activation maps
    - Voltage maps
    - Propagation maps
    - Fractionation maps
    - Scar maps
7. System shall support mapping of:
    - Right atrium
    - Left atrium
    - Right ventricle
    - Left ventricle
    - Coronary sinus
    - Pulmonary veins
8. System shall support point acquisition of at least 1,000,000 mapping points.
9. System shall provide beat-to-beat visualization capability.
10. System shall support automated high-density mapping.

2.2 Omnipolar / Advanced Signal Technology

1. System should support omnipolar or equivalent advanced mapping technology capable of:
    - Direction-independent signal analysis
    - Wavefront orientation-independent electrogram interpretation
    - High-fidelity local electrogram analysis
2. System should provide:
    - Real-time activation vectors
    - Dynamic wavefront propagation display
    - Instantaneous voltage mapping
3. System should support 360-degree signal acquisition capability.
4. System should provide enhanced signal-to-noise ratio with low-noise acquisition capability.
5. System should support ultra-high-density mapping catheter integration.

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3. MAPPING CATHETERS

1. System shall support sensor-enabled high-density mapping catheters.
2. Mapping catheter should preferably have:
    - Grid-based or equivalent multipolar electrode design
    - Small electrode spacing
    - Flexible atraumatic shaft
3. Mapping catheter shall support:
    - High-density activation mapping
    - Voltage mapping
    - Scar characterization
    - Fractionation mapping
4. System shall support automatic acquisition and annotation of mapping points.
5. Mapping catheter shall be compatible with both atrial and ventricular arrhythmia mapping.

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4. RADIOFREQUENCY ABLATION SYSTEM

4.1 RF Generator

1. Vendor shall provide advanced RF ablation generator.
2. Generator shall support:
    - Temperature-controlled ablation
    - Power-controlled ablation
    - Irrigated ablation
3. Generator shall provide:
    - Adjustable power settings
    - Adjustable irrigation flow
    - Real-time impedance monitoring
    - Real-time temperature monitoring
4. RF generator shall support:
    - Standard RF ablation
    - High-power short-duration ablation (preferred)
5. Generator shall support integration with the mapping platform.

4.2 Ablation Catheters

1. System shall support sensor-enabled irrigated RF ablation catheters.
2. Ablation catheter shall preferably support:
    - Contact force sensing
    - Real-time force vector visualization
    - Lesion indexing technology
3. Catheter shall support:
    - Atrial ablation
    - Ventricular ablation

    - Complex substrate modification
4. Vendor shall provide compatible steerable sheaths.
5. Catheters shall be FDA and/or CE approved.

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5. CONTACT FORCE TECHNOLOGY

1. System shall support real-time contact force measurement.
2. Contact force display shall include:
    - Gram force display
    - Force vector direction
    - Stability indicators
3. System should support lesion quality indices such as:
    - Lesion Size Index (LSI)
    - Force-Time Integral (FTI)
    - Equivalent validated lesion metrics
4. System should provide lesion tagging and lesion continuity assessment.

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6. INTEGRATION REQUIREMENTS

1. System shall integrate with:
    - Fluoroscopy systems
    - Hemodynamic monitoring systems
    - Intracardiac echocardiography (ICE)
    - EP recording systems
2. System should support DICOM compatibility.
3. System should support CT/MRI image integration.
4. System should support export of procedural data and maps.
5. System shall support network connectivity and PACS integration.

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7. RECORDING SYSTEM

1. Vendor shall provide integrated electrophysiology recording system.
2. Recording system shall support:
    - Surface ECG recording
    - Intracardiac electrogram recording
    - Digital signal storage
    - Real-time display
3. Recording system shall support:
    - At least 48 intracardiac channels
    - Adjustable filter settings
    - Stimulator integration
4. System shall support data archival and retrieval.

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8. WORKSTATION & SOFTWARE

1. System shall include dedicated workstation(s) with high-resolution monitors.
2. Software shall support:
    - Real-time mapping
    - Automated annotation
    - Propagation mapping
    - Dynamic activation analysis
3. System should support:
    - Respiratory compensation algorithms
    - Motion compensation
    - Catheter stability tracking
4. System should include cybersecurity protection and access control.
5. Vendor shall provide latest software version at installation.

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9. ACCESSORIES & CONSUMABLES

Vendor shall quote separately for compatible:

- Diagnostic EP catheters
- Coronary sinus catheters
- Decapolar catheters
- Circular mapping catheters
- High-density mapping catheters
- Contact force RF ablation catheters
- Steerable sheaths
- Transseptal needles
- Introducers
- Surface patches
- Irrigation tubing sets

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10. INSTALLATION REQUIREMENTS

Vendor shall provide:

- Site planning
- Electrical requirements
- UPS compatibility
- Installation drawings
- Environmental specifications

Vendor shall confirm compatibility with existing cath lab fluoroscopy system.

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11. TRAINING REQUIREMENTS

Vendor shall provide:

- On-site physician training

- EP technologist training
- Biomedical engineer training
- Nursing training
- Clinical application specialist support during initial procedures

Minimum:

- 5 working days application training
- Support during first 10 EP cases

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12. WARRANTY & SERVICE

1. Minimum warranty period:
    - 2 years comprehensive warranty
2. Vendor shall provide:
    - Preventive maintenance
    - Software upgrades
    - Remote diagnostics
    - On-site support
3. Breakdown response time:
    - Within 24 hours
4. Uptime guarantee:
    - Minimum 95%
5. Vendor shall provide availability of spare parts for minimum 10 years.

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13. PREFERRED FEATURES

Preference may be given to systems offering:

- Omnipolar mapping technology
- Ultra-high-density mapping
- AI-assisted mapping workflows
- Dynamic activation vector display
- Contact-force lesion optimization
- Integration with pulsed field ablation (PFA) platforms
- Zero or low fluoroscopy workflow capability
- Advanced VT mapping tools
- Remote support capability

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14. COMPLIANCE STATEMENT

Vendor must submit:

- Detailed compliance sheet
- Point-by-point response
- Original product brochures
- Regulatory certificates

- List of installed sites in region
- Warranty declaration
- Consumable price list
- Optional accessories list

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15. SYSTEM CONFIGURATION (MINIMUM)

The offered package should include minimum:

- 01 x 3D EP Mapping System
- 01 x RF Ablation Generator
- 01 x EP Recording System
- 01 x Workstation with monitors
- 01 x Contact force module
- 01 x High-density mapping module
- 01 x Respiration compensation module
- Required software licenses
- Required cables and interface modules
- UPS compatibility
- Starter consumables package

Equivalent or superior systems from internationally recognized manufacturers may be accepted provided all specifications are met or exceeded.

Examples include:

- Abbott EnSite™ X EP System
- Biosense Webster CARTO™ platform
- Boston Scientific RHYTHMIA™ HDx platform