

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.

1. GENERAL REQUIREMENTS

1. The system offered 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 system offered 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

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.
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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.
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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.

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

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.

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

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

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

