

## TECHNICAL SPECIFICATIONS

### Optical Coherence Tomography (OCT) System – Advanced Coronary Imaging Platform - ULTREON 2.0

#### 1. Scope of Supply

The bidder shall provide a **complete, fully integrated Optical Coherence Tomography (OCT) system** for intracoronary imaging, including:

- Imaging console with AI-assisted software
  - Pullback device and interface
  - Compatible OCT catheters (disposable)
  - Workstation with analysis software
  - Data storage and reporting system
  - Integration with cath lab imaging systems (DICOM/PACS)
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#### 2. System Overview Requirements

The system must:

- Be based on **Frequency Domain OCT (FD-OCT)** technology
  - Provide **high-resolution intracoronary imaging** for:
    - Lesion morphology
    - Plaque characterization
    - Stent optimization
  - Be suitable for:
    - Complex PCI (left main, bifurcation, calcific disease)
    - Imaging-guided interventions
    - Research and registry use
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#### 3. Imaging Performance Specifications

##### 3.1 Resolution

- Axial resolution:  $\leq 15 \mu\text{m}$
- Lateral resolution:  $\leq 20\text{--}40 \mu\text{m}$

### 3.2 Imaging Speed

- Pullback speed:  $\geq 20\text{--}40 \text{ mm/sec}$
- Frame rate:  $\geq 150 \text{ frames/sec}$

### 3.3 Imaging Length

- Minimum pullback length:  $\geq 70\text{--}100 \text{ mm}$

### 3.4 Blood Clearance

- Compatible with contrast and/or low-viscosity flushing media
- Efficient lumen clearing with minimal contrast use

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## 4. AI-Enabled Imaging & Analysis (Critical Requirement)

System must include **AI-assisted automated analysis capabilities**, including:

- Automatic lumen contour detection
- Automated:
  - Minimum lumen area (MLA)
  - Reference vessel diameter
  - Lesion length
- Calcium characterization:
  - Arc
  - Thickness
  - Length
- Stent analysis:
  - Expansion
  - Apposition
  - Edge dissection detection

Must provide **real-time decision support for PCI optimization**

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## **5. Software & Clinical Decision Support**

### **Mandatory Features:**

- Pre-PCI lesion assessment module
- Stent sizing recommendation tool
- Post-PCI optimization module
- Automated report generation

### **Advanced Features:**

- Co-registration with angiography
  - Longitudinal vessel mapping
  - Frame-by-frame analysis
  - Side branch visualization support
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## **6. Catheter Requirements**

- Rapid-exchange OCT imaging catheters
  - Compatibility with **6 Fr guide catheters**
  - Trackable in tortuous and calcified vessels
  - Radiopaque markers for positioning
  - Sterile, single-use
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## **7. System Integration**

System must integrate with:

- Cath lab angiography system (Philips / GE / Siemens compatible)
- PACS (DICOM compliant)
- Hospital EMR (optional but preferred)

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## 8. Hardware Requirements

- Medical-grade imaging console
- Touchscreen or dual-monitor display
- High-speed processor for real-time rendering
- Storage:
  - Minimum **5–10 TB local storage**
  - External backup support

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## 9. Reporting & Data Management

- Automated structured reporting
- Export formats:
  - PDF
  - DICOM
- Capability for:
  - Registry data export (Excel/CSV)
  - Research database integration

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## 10. Safety & Compliance

- CE / FDA approved system
- Electrical safety compliant (IEC standards)
- Radiation-safe integration with cath lab
- Infection control compatible with sterile cath lab workflow

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## 11. Training & Support

Vendor must provide:

- On-site installation and commissioning
  - Initial clinical training (minimum 3–5 days)
  - Advanced training for:
    - Complex PCI imaging
    - AI-guided interpretation
  - Ongoing:
    - Technical support (24–48 hr response)
    - Software updates
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## **12. Warranty & Service**

- Minimum **3-year comprehensive warranty**
  - Preventive maintenance: **2–3 visits/year**
  - Availability of spare parts locally or regionally
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## **13. Consumables & Cost Transparency**

Vendor must provide:

- Cost per OCT catheter
  - Shelf life of consumables
  - Annual projected consumable cost
  - Bulk pricing options
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## **14. Add-ons required:**

- Angio-OCT co-registration module
  - Cloud-based data storage
  - Remote case review capability
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## **15. Compliance Statement**

Vendor must submit:

- Full technical compliance sheet
- Deviations (if any)
- List of installations in similar tertiary centers
- References in South Asia / similar healthcare settings