

## TECHNICAL SPECIFICATIONS

### Temporary Percutaneous Mechanical Circulatory Support (pMCS) / Intravascular Microaxial Blood Pump System

**Department:** National Cardiac Centre (NCC), IGMH/MCGH

**Purpose:** Protected PCI and Cardiogenic Shock Program

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#### 1. SYSTEM OVERVIEW

The offered system shall be a catheter-based temporary mechanical circulatory support platform designed to provide active ventricular unloading and forward blood flow support in patients with:

1. High-risk/complex Protected Percutaneous Coronary Intervention (PCI)
2. Acute cardiogenic shock of various etiologies including:
  - Acute myocardial infarction-related cardiogenic shock
  - Acute decompensated heart failure
  - Post-cardiotomy shock
  - Myocarditis
  - Bridge to recovery
  - Bridge to decision
  - Bridge to advanced therapy

The system shall provide:

- Left ventricular support
  - Right ventricular support
  - Escalation capability for higher circulatory support when required
  - Real-time hemodynamic monitoring
  - Intelligent positioning and alarm management
  - Transport capability between ICU, cath lab, OT and imaging areas
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#### 2. CONSOLE / AUTOMATED CONTROLLER SPECIFICATIONS

The system shall include an intelligent automated controller with:

##### User Interface

- Medical-grade touchscreen display
- Minimum 10-inch color display
- Intuitive graphical user interface
- Real-time display of:
  - Pump flow
  - Pump speed
  - Motor current

- Pressure waveforms
  - Placement signals
  - Purge parameters
  - Alarm status
  - System diagnostics
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### **Power Supply**

- AC power operation
  - Integrated rechargeable battery
  - Battery backup minimum: ≥60 minutes
  - Capability for uninterrupted patient transport
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### **Data Storage**

System shall provide:

- Continuous recording of hemodynamic data
  - Minimum storage capacity: ≥24 hours
  - USB/export capability
  - Network connectivity capability
  - Remote monitoring capability
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### **Safety Features**

Automated detection of:

- Suction events
- Pump malposition
- Reduced flow
- Purge failure
- Motor malfunction
- Pressure abnormalities
- System disconnection

Alarm system shall include:

- Audible alarms
  - Visual alarms
  - Priority-based alarm hierarchy
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## **3. PUMP CATHETER SPECIFICATIONS**

System shall support multiple catheter options including:

### **Left Ventricular Support Pumps**

Must provide:

- Peak flow ≥3.5–5.5 L/min depending on model
- Active ventricular unloading

- Forward systemic circulation support
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### **Right Ventricular Support Pumps**

Must provide:

- Flow  $\geq 4.0$  L/min
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### **Pump Technology**

Pump shall include:

- Distal microaxial motor
  - Integrated impeller
  - Continuous flow mechanism
  - Flexible atraumatic distal segment
  - Radiopaque markers
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### **Catheter Characteristics**

Catheter system shall:

- Be suitable for percutaneous vascular access
  - Support femoral and/or axillary approaches
  - Include dedicated introducer kits
  - Include guidewire compatibility
  - Include hemostatic access systems
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### **Duration of Support**

System shall support:

- High-risk PCI:  $\geq 6$  hours
  - Cardiogenic shock support: up to 14 days or manufacturer's maximum approved duration
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## **4. HEMODYNAMIC INTELLIGENCE PLATFORM**

System shall provide advanced monitoring including:

### **Real-time calculations:**

- Cardiac output
  - Cardiac power output (CPO)
  - Mean arterial pressure
  - Heart rate
  - LVEDP trend
  - Flow trend analysis
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### **Smart positioning assistance:**

System shall include:

- Placement guidance
  - Position verification
  - Stability indicators
  - Automatic position monitoring
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## **5. CONSUMABLES**

Bidder shall provide sterile single-use consumables:

### **Pump Catheters**

Including:

- Standard support pump
  - High-flow pump
  - Right ventricular support pump
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### **Access Kits**

Including:

- Introducer sheaths
  - Dilators
  - Peel-away systems
  - Hemostatic valves
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### **Guidewires**

Including:

- Shapeable guidewires
  - Ventricular placement wires
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### **Purge System Components**

Including:

- Sterile purge cassette
  - Tubing
  - Accessories
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## **6. CLINICAL APPLICATIONS**

System shall be approved/indicated for:

### **Protected PCI**

Including:

- Unprotected left main intervention
- Last remaining vessel
- Severe LV dysfunction
- Complex multivessel PCI
- Atherectomy-supported procedures

- CTO interventions
  - Complex bifurcation intervention
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### **Cardiogenic Shock**

Including:

- AMI cardiogenic shock
  - Acute decompensated heart failure
  - Myocarditis
  - Bridge-to-recovery
  - Bridge-to-decision
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## **7. TRAINING REQUIREMENTS**

Vendor shall provide:

### **Clinical Training**

- Initial physician training
- Cath lab nurse training
- ICU nurse training
- CVT training
- Biomedical engineer training

Minimum:

- 5 days on-site training
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### **Proctorship Support**

Vendor shall provide:

- Initial case support
- Clinical application specialist support
- Emergency remote support

Minimum: First 5-10 cases

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## **8. WARRANTY AND AFTER-SALES SUPPORT**

Vendor shall provide:

### **Warranty**

Minimum:

- TWO-year comprehensive warranty

Covering:

- Console
  - Accessories
  - Parts
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## **Service Requirements**

- Preventive maintenance twice yearly
  - Maximum service response time: ≤24 hours
  - Availability of spare parts: Minimum 10 years
  - Local or regional technical support availability
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## **9. DOCUMENTATION REQUIREMENTS**

Bidder shall provide:

- CE and/or FDA approval
  - Product catalogue
  - Technical data sheets
  - User manuals
  - Installation requirements
  - Consumable list with item codes
  - Clinical evidence/publications
  - Regulatory certificates
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## **10. PREFERENCE**

Preference may be given for systems with:

- Ability to escalate support without console replacement
- Integrated right ventricular support platform
- Smart sensor technology
- Axillary ambulatory support capability
- Remote monitoring capability
- Established international shock program experience
- Demonstrated clinical evidence for Protected PCI and cardiogenic shock