

TECHNICAL SPECIFICATION

Intravascular Extracorporeal Membrane Oxygenation (ECMO/ECLS) System
National Cardiac Centre (NCC) – IGMH
For Protected PCI, Cardiogenic Shock, and Cardiothoracic Surgery Support

1. Purpose

The proposed system shall provide temporary extracorporeal life support (ECLS)/ECMO support for:

1. Cardiogenic shock (AMI-CS, decompensated heart failure, myocarditis, refractory VT/VF)
 2. Protected high-risk PCI
 3. Post-cardiotomy cardiogenic shock
 4. Respiratory failure requiring VV ECMO
 5. Bridge to recovery
 6. Bridge to decision
 7. Bridge to advanced therapies
 8. Intra- and inter-hospital transport
 9. Future cardiothoracic surgery program support
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2. General Requirements

The offered system shall:

- Be FDA and/or CE approved
 - Be a commercially available latest-generation ECMO system
 - Be capable of both VA and VV ECMO configurations
 - Support adult and pediatric applications
 - Include integrated centrifugal pump technology
 - Support prolonged extracorporeal support (>14 days)
 - Be suitable for ICU, Cath Lab, OT, Emergency Department, and transport environments
 - Include all hardware/software licenses required
 - Include future upgrade capability
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3. Console Requirements

The system shall include:

Base Console

- Compact portable design

- Weight ≤ 12 kg including main operating components
 - Integrated carrying handle
 - Transport-capable design
 - Color touchscreen display ≥ 7 inches
 - Intuitive graphical user interface
 - Touchscreen and rotary controller operation
 - User-guided setup workflow
 - Stepwise priming guidance
 - Expert mode and simplified mode
 - Multi-language interface
 - Internal data storage
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4. Pump System

The system shall:

- Utilize magnetically levitated centrifugal pump technology
 - Blood flow range: ≥ 0.5 – 7.0 L/min minimum
 - Pump speed range suitable for full cardiopulmonary support
 - Automatic flow calculation
 - Continuous display of:
 - RPM
 - Blood flow
 - Pressure values
 - Temperature
 - Alarms
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5. Oxygenator Requirements

The offered oxygenator shall:

- Be integrated with pump system
- Support prolonged use
- Have low priming volume
- Have low resistance/pressure drop
- Have biocompatible coating
- Support blood flow up to ≥ 7 L/min
- Include integrated heat exchanger
- Support:
 - Adult ECMO
 - Pediatric ECMO

6. Monitoring Requirements

The system shall provide integrated monitoring for:

Hemodynamic parameters

- Venous pressure
- Arterial pressure
- Circuit pressure
- Transmembrane pressure
- Blood flow

Blood parameters

- Venous saturation (SvO₂)
- Hemoglobin
- Hematocrit
- Blood temperature

Tissue perfusion monitoring

- Regional tissue oxygenation (rSO₂/NIRS)

Trend monitoring

- Trend display of all parameters
- Real-time graphical analysis
- Historical data review

Integrated venous blood parameter monitoring and NIRS capability are optional.

7. Safety Features

The system must include:

Air detection

- Venous air detection
- Arterial air detection

Pressure safety

- High-pressure alarms
- Low-pressure alarms
- Backflow detection

Emergency functions

- Emergency drive capability
- Manual/emergency mode operation
- Alarm troubleshooting guidance

Battery backup

- Internal battery operation

Minimum battery life: ≥90 minutes

Alarm system

Visual and audible alarms for:

- Flow abnormalities
 - Pressure abnormalities
 - Pump malfunction
 - Gas supply failure
 - Temperature deviation
 - Air embolism detection
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8. Gas Management

System should include:

- Integrated gas blender
- Oxygen and air mixing capability
- Adjustable sweep gas flow
- FiO₂ adjustment: 21–100%
- Gas consumption monitoring

Electronic gas blending functionality would be preferred in transport-capable systems.

9. Connectivity and Data Management

The system shall include:

- Ethernet connectivity
 - Wireless capability (preferred)
 - EMR/HIS integration capability
 - Exportable data storage
 - USB export
 - Remote monitoring capability
 - Cloud connectivity (optional)
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10. Mobility and Transport Requirements

System shall:

- Be transport approved
 - Be suitable for:
 - Ambulance transport
 - Air transport
 - Intra-hospital transport
 - Include compact mounting system
 - Include transport trolley
 - Include gas cylinder holder
 - Include IV pole attachment
 - Include shock-resistant design
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11. Consumables - negotiable

Vendor shall provide:

Initial consumables

Minimum:

- Adult ECMO sets × 20
 - Pediatric ECMO sets × 10
 - Cannulation kits × 20
 - Tubing sets × 20
 - Oxygenators × 20
 - Heat exchanger accessories × 20
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12. Accessories Included

Vendor shall supply:

- Transport cart
- Heater-cooler integration accessories
- Pressure sensors
- Flow sensors
- NIRS interface capability
- Emergency hand crank/drive
- Battery system
- Gas blender

- Mounting accessories
 - UPS compatibility accessories
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13. Installation and Training

Vendor shall provide:

Installation

- Complete installation and commissioning

Training

On-site structured training for:

- Interventional cardiologists
- Cardiac surgeons
- Intensivists
- Perfusionists
- ICU nurses
- Cath lab nurses
- Biomedical engineers

Minimum:

- Initial training: 5 days
 - Refresher training: twice yearly
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14. Warranty and Service

Vendor shall provide:

- Minimum warranty: 2 years comprehensive
 - Preventive maintenance: Minimum twice yearly
 - Breakdown response: Within 24 hours
 - Spare parts availability: ≥ 10 years
 - Remote technical support
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ECMO system should support future hybrid MCS strategy (ECPELLA, ECMO + IABP, ECMO + Impella, LV unloading strategies) for National Cardiogenic Shock Program development.
