

BIO-MEDICAL ENGINEERING SECTION

Addu Equatorial Hospital

TECHNICAL SPECIFICATION

TECHNICAL SPECIFICATION – PHACOEMULSIFICATION MACHINE

Quantity: 1 No.

1. Intended Use

A microprocessor-controlled ophthalmic surgical system intended for **cataract extraction and anterior segment procedures**, providing **phacoemulsification with irrigation/aspiration**, with provision for **anterior vitrectomy**.

2. Minimum Functional Requirements

The system shall provide the following minimum functionalities:

- Ultrasound phacoemulsification with **longitudinal and non-longitudinal ultrasound modes** (e.g., torsional, oscillatory, transversal, or equivalent).
- Integrated **fluidics management system** capable of maintaining a **stable anterior chamber** during aspiration, occlusion, and occlusion break.
- The system shall provide automated control of irrigation pressure through motorised bottle height adjustment or equivalent fluidics technology.
- Adjustable **vacuum control** suitable for high-efficiency nucleus removal.
- Adjustable **aspiration flow rates** with fast response time.
- **Integrated anterior vitrectomy** function.
- **Programmable surgeon footswitch** with multiple control functions.
- **Touchscreen user interface** with surgeon-specific presets and memory for customized case parameters.

3. Performance Requirements

- **Phaco frequency:** Approximately **28–45 kHz**.
- **Vacuum:** Minimum **600 mmHg**.
- **Aspiration flow rate:** Minimum of **35 cc/min**.
- **Vitrectomy cut rate:** Minimum **1000 cuts/min**.

4. Safety Features

The system shall incorporate the following safety mechanisms:

- Continuous monitoring of **infusion, aspiration, and chamber stability parameters**.

- **Audible and visual alarms** for abnormal operating conditions.

5. Consumables & Accessories

- System shall utilize **single-use disposable cassettes or tubing sets** with defined shelf life.
- Compatible **phaco handpieces**, including standard and micro-incision tips with sleeves.
- Compatible **irrigation/aspiration handpieces**.
- The bidder shall include in the quotation all machine-specific consumables, reusable instruments, accessories, and standard operating items required for the complete operation of the offered system

6. Ergonomics & Usability

- Large **color touchscreen display** with intuitive user interface.
- **Multidirectional programmable footswitch**.
- Compact, mobile design with **lockable castors** for easy movement within OT.

7. Connectivity & Data Management

- USB and/or Ethernet interface for:
 - Export of case logs
 - Export of system parameters
- Optional integration with **OT / hospital data management systems** preferred.

8. Power & Environmental Requirements

- **Power supply:** 100–240 V AC, 50/60 Hz.
- **Operating temperature:** 15–30 °C.
- **Relative humidity:** 20–80%, non-condensing.

9. Regulatory & Standards Compliance

- Device shall be **CE marked or FDA approved**
- Manufacturer shall be compliant with **ISO 13485** quality management standards.
- Device shall comply with applicable **IEC 60601 series** medical electrical equipment standards.

10. Warranty & Service Support

- **Warranty:** Minimum 1 years (comprehensive – parts & labor).
- **Service support:** Local authorized service support with **maximum response time of 48 hours**.
- **Training:** On-site installation, clinical user training, and basic preventive maintenance

training shall be included.

11. Deliverables from Supplier

- Complete technical datasheet with detailed performance specifications.
- The bidder shall provide a comprehensive list of all proprietary consumables, accessories, and reusable instruments required for routine operation, indicating the item description, manufacturer part number/catalogue number, unit of supply, and current unit price to facilitate future procurement.
- User manuals, service manuals, and training documentation.
- Regulatory compliance certificates and quality system documentation.