

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/or 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.
 - Adjustable **vacuum control** suitable for high-efficiency nucleus removal.
 - Adjustable **aspiration flow rates** with fast response time.
 - Multiple ultrasound power modulation modes, such as:
 - Continuous
 - Pulse
 - Burst
 - Occlusion-based or equivalent intelligent modulation
 - **Integrated anterior vitrectomy** function.
 - **Programmable surgeon footswitch** with multiple control functions.
 - **Touchscreen user interface** with surgeon-specific presets and memory for customized case parameters.
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3. Performance Requirements

- **Phaco frequency**: Approximately **28–45 kHz**.
- **Maximum vacuum**: ≥ 600 mmHg.
- **Maximum aspiration flow rate**: ≥ 35 cc/min.
- **Infusion control**: Ability to set and maintain a target **intraocular pressure (IOP)**.
- **Vitrectomy cut rate**: Minimum **800 cuts/min**.

4. Safety Features

The system shall incorporate the following safety mechanisms:

- Continuous monitoring of **infusion, aspiration, and chamber stability parameters**.
- Automatic **surge suppression** and occlusion management.
- **Thermal protection system** with temperature monitoring and automatic shutdown to prevent tissue injury.
- **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.
- If the offered system utilizes **reusable anterior vitrectomy probes**, the supplier shall provide the probe along with all required accessories and connections
- Compatible **irrigation/aspiration handpieces**.
- All consumables and accessories shall be **original, manufacturer-approved**.

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** (or equivalent international regulatory certification).
- Manufacturer shall be compliant with **ISO 13485** quality management standards.

- Device shall comply with applicable **IEC 60601 series** medical electrical equipment standards.
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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.
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11. Deliverables from Supplier

- Complete **technical datasheet** with detailed performance specifications.
- **List of consumables and accessories**, including estimated cost per procedure.
- User manuals, service manuals, and training documentation.
- Regulatory compliance certificates and quality system documentation.