

1. General Information

- **Equipment:** Multi-Platform Radiofrequency (RF) Ablation Generator.
 - **Clinical Purpose:** Specialized high-frequency electrosurgical unit (ESU) designed for precise, shallow-depth coagulation of tissue.
 - **Primary Modality:** Bipolar Radiofrequency Ablation (RFA).
 - **Ablation Control:** Automated Power and Energy Density regulation.
 - **Clinical Goal:** Achievement of mucosal ablation through controlled thermal injury while strictly preserving the underlying muscularis layers.
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2. Technical Specifications

A. RF Output & Energy Delivery

Parameter	Specification Range	Unit
Operating Frequency	450 – 500 (Sinusoidal)	kHz
Maximum Power Output	40 – 300 (Application dependent)	Watts (W)
Energy Density Control	10 – 15 (Adjustable)	J/cm ²
Delivery Mode	Bipolar (Tissue-restricted current)	—
Output Waveform	Continuous Unmodulated	—

B. Intelligent Control Systems

- **Impedance Monitoring:** Real-time tracking of tissue impedance to prevent desiccation and charring. The system must automatically terminate power if impedance exceeds pre-set safety thresholds.
 - **Automatic Catheter Recognition:** The generator must automatically identify the connected catheter type (e.g., circumferential vs. focal) and load the corresponding pre-set ablation algorithms.
 - **Pulsed Delivery Option:** Capability to deliver energy in short bursts to allow for thermal relaxation of surrounding tissue, reducing the risk of transmural injury.
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3. Catheter Compatibility & Interfacing

The generator platform must support a modular suite of bipolar delivery devices:

- **Circumferential Balloon Catheter:** Designed for 360° ablation of large esophageal segments. Includes an automated inflation/deflation system integrated into the generator.
 - **Focal Catheters:** Cap-mounted or through-the-scope (TTS) electrodes for targeted treatment of residual or smaller tissue patches.
 - **Self-Sizing Logic:** For balloon-based delivery, the generator integrates with pressure sensors to automatically determine the appropriate inflation diameter for optimal tissue contact based on esophageal inner diameter.
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4. Hardware & Safety

- **User Interface:** Minimum 10-inch color LCD touchscreen displaying real-time power, energy, impedance, and procedure timers.
- **Footswitch Control:** IPX8-rated waterproof footswitch for hands-free activation.
- **Safety Cut-offs:**
 - **Timed Limit:** Automatic shut-off after a pre-defined ablation cycle (typically <1 second).

- **Thermal Guard:** Integrated software to prevent "stacked" energy delivery (repeated pulses in the same anatomical location) without a requisite cooldown period.
 - **Data Logging:** Internal memory to store up to 100 procedure logs, exportable via USB or DICOM for clinical documentation.
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5. Regulatory & Safety Standards

- **Electrical Safety:** Compliance with IEC 60601-1 (Medical Electrical Equipment).
- **HF Equipment Standard:** Compliance with IEC 60601-2-2 (Particular requirements for the basic safety and essential performance of high-frequency surgical equipment).
- **Ingress Protection:** Generator housing must meet medical-grade standards for fluid resistance in the endoscopy suite.

BIOMEDICAL ENGINEERING DEPARTMENT