

1. General Information

- **Equipment:** Magnetic Endoscope Positioning and Navigation System.
 - **Intended Use:** Real-time 3D visualization of the endoscope's insertion path, shape, and spatial orientation during gastrointestinal procedures.
 - **Clinical Use:** Identification and resolution of loops during colonoscopy, assisting in deep small bowel enteroscopy, and training for endoscopists.
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2. Physical Characteristics

- **Dimensions (W × H × D):** * **Processor Unit:** Approx. 450×150×450 mm.
 - **Magnetic Generator (Dish/Plate):** Approx. 600×600×100 mm.
 - **Weight:** Processor ≈15 kg; Magnetic Generator ≈10–20 kg.
 - **Housing:** Medical-grade, non-ferromagnetic shielded enclosure.
 - **Cooling:** Low-decibel internal fan cooling (<45 dB).
 - **Electrical Rating:** 220-240 VAC, 50 Hz.
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3. Safety & Standards

- **Electromagnetic Safety:** Must comply with IEC 60601-1-2 (EMC). The magnetic field generated must be low-intensity and non-ionizing.
 - **Regulatory Compliance:** CE Class IIa / FDA 510(k) cleared for use in clinical environments.
 - **Patient Safety Features:** * **Pacemaker/ICD Safety:** The system must specify a safe distance for patients with implanted electronic devices (typically >30 cm).
 - **Continuous Monitoring:** Real-time detection of external magnetic interference with automated visual warnings.
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4. Connectivity & Integration

- **Video Signal Inputs:** Support for DVI, HDMI, or HD-SDI to allow "Picture-in-Picture" (PiP) display on the primary endoscopy monitor.
 - **Magnetic Field Standards:** Utilization of low-frequency magnetic induction (typically $<100\mu\text{T}$) to ensure no interference with standard theater equipment.
 - **Scope Compatibility:** Must integrate with endoscopes containing internal magnetic sensor coils or support a "through-the-channel" magnetic probe. **MUST BE COMPATIBLE WITH THE EXISTING OLYMPUS SCOPES UTILIZED IN THE ENDOSCOPY DEPARTMENT**
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5. Operating Conditions

- **Operating Temperature:** 10°C to 35°C.
 - **Operating Humidity:** 30% to 85% non-condensing.
 - **Consumables: * Chemical Consumption:** Zero (Dry system).
 - **Water Consumption:** Zero.
 - **Storage:** Must be stored away from large ferromagnetic structures to maintain calibration accuracy.
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6. Functional Capabilities

- **Loop Identification:** Software-driven 3D rendering to clearly distinguish between "Alpha," "N," and "Deep" loops.
- **Position Reset:** Single-touch recalibration to align the 3D model with the anatomical patient position.
- **View Rotation:** Ability to rotate the 3D model 360° via footswitch or touchscreen to view the loop from different sagittal and coronal planes.

