

Specifications List

Endoscopy

1. General Information

- **Equipment:** Wireless Capsule Endoscope System.
 - **Clinical Purpose:** High-resolution diagnostic imaging of the small bowel mucosa to detect obscure GI bleeding, Crohn's disease, tumors, and malabsorption syndromes.
-

2. Physical Characteristics

- **Dimensions:** Approximately 26 mm×11 mm (Length × Diameter).
 - **Weight:** ≤4 grams.
 - **Material:** Medical-grade, acid-resistant polycarbonate shell.
 - **Biocompatibility:** Must meet ISO 10993 standards for mucosal contact and transient internal transit.
-

3. Imaging and Optical System

- **Camera Type:** Ultra-low power CMOS sensor.
 - **Field of View (FOV):** Minimum 150°–170° (wide-angle).
 - **Resolution:** High-definition output (minimum 320×320 pixels).
 - **Frame Rate:** Adaptive; minimum 2 to 6 frames per second (fps) based on capsule transit speed.
 - **Illumination:** Integrated white LED array (automatic brightness adjustment).
 - **Color Imaging:** Yes; True-color rendering for pathology differentiation.
-

4. Performance & Data Management

A. Power System

- **Battery Type:** Silver oxide or specialized lithium-ion (non-toxic).
- **Battery Life:** Minimum 8–12 hours (standard small bowel transit).
- **Total Image Capture:** Capability to capture >50,000 images per study.

B. Transmission and Storage

- **Method:** Digital Radio Frequency (RF) or Human Body Communications (HBC).
 - **External Recorder:** Required (wearable sensory array/recorder unit).
 - **Data Download:** High-speed USB or proprietary docking station interface.
 - **Security:** AES-128 or higher encryption for patient data during transmission.
-

5. Software and Workstation

- **Analysis Tools:** AI-assisted detection for bleeding (Red Color Detection) and lesion identification.
 - **Localization:** Real-time tracking of the capsule's position within the GI tract.
 - **Export Formats:** JPEG, WMV, and DICOM 3.0 compatible reports.
-

6. Safety and Compliance

- **Standards:** IEC 60601-1, IEC 60601-1-2 (EMC).
 - **MRI Compatibility:** **Contraindicated (Non-MRI Compatible)** while the capsule is in the body.
 - **Ingress Protection:** IPX8 (fluid immersion resistant).
 - **Regulatory:** FDA Class II / CE Marked.
-

7. Environmental & Disposal

- **Operating Temp:** 20°C to 40°C (Optimized for internal body temp).
- **Storage Temp:** 5°C to 30°C (Store in a cool, dry place).
- **Humidity:** 10% to 90% non-condensing.

- **Disposal Method:** Single-use disposable capsule; external recorder and sensors are multi-use and must be disinfected per manufacturer guidelines.

BIOMEDICAL ENGINEERING DEPARTMENT