

# 1. General Information

- **Equipment:** High-Resolution Manometry (HRM) and pH-Impedance System.
  - **Clinical Purpose:** To quantify the muscular activity (motility) of the esophagus and anorectum and to monitor gastroesophageal reflux (GERD).
  - **Clinical Use:** Gastroenterology labs, motility clinics, and pre-surgical evaluation for anti-reflux surgery.
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# 2. Technical Specifications: Acquisition Station

- **Pressure Sensing:** High-resolution acquisition supporting at least 32–36 pressure channels.
  - **Sampling Rate:** Minimum 50 Hz per channel for smooth pressure topography.
  - **Software Analysis:** \* **Esophageal:** Automated calculation of Chicago Classification metrics (e.g., IRP, DCI, DL).
    - **Anorectal:** Automated calculation of London Classification metrics (e.g., Resting Pressure, RAIR).
  - **Visualization:** Real-time Pressure Topography (Contour Maps/Clouse Plots) and traditional line tracings.
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# 3. Hardware & Catheter Components

The system must include the following solid-state transducers and recording hardware:

Item	Specification	Quantity
<b>Solid-State Esophageal Catheter</b>	36 circumferential pressure sensors at 1 cm intervals; Diameter $\leq$ 12 Fr.	2 Units
<b>Solid-State Anorectal Catheter</b>	Minimum 12 sensors with 3D or high-resolution longitudinal array; Diameter $\leq$ 14 Fr.	1 Unit
<b>Ambulatory pH-Impedance Recorder</b>	Lightweight, wearable device for 24-hour monitoring; digital symptom markers.	1 Unit

<b>pH-Impedance Electrodes</b>	6 Impedance channels + 1 Antimony pH sensor; Adult 6 Fr; Single-use.	20 Units
<b>pH Calibration Kits</b>	Dual-point calibration kit: Includes pH 4.0 and pH 7.0 buffer solutions (>50 ml bottles) and calibration stand/test tubes.	10 units
<b>Rectal Balloons</b>	Non-latex, high-compliance silicone or PVC; integrated with inflation port for RAIR and Balloon Expulsion tests.	50

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## 4. Required Clinical Accessories

- **Rectal Balloons:** High-compliance, non-latex balloons for Anorectal Manometry (Sensory testing and Balloon Expulsion Test).
- **pH Calibration Kit:** Buffer solutions (pH 4.0 and 7.0) for pre-procedure electrode calibration (10-bottle set).
- **Pressure Calibration Chamber:** Dedicated hardware for verifying the accuracy of solid-state sensors.
- **Connectivity:** USB/LAN for workstation data transfer; DICOM/HL7 compatibility for hospital EMR integration.

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## 5. Performance Characteristics

- **Pressure Range:** -20 mmHg to 300 mmHg (Accuracy:  $\pm 2$  mmHg).
- **Impedance Range:** 0 to 10,000  $\Omega$  for bolus transit detection.
- **pH Accuracy:**  $\pm 0.1$  pH unit within the clinical range.
- **Cleaning Compatibility:** Solid-state catheters must be compatible with High-Level Disinfection (HLD) solutions (e.g., CIDEX, Peracetic Acid).

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## 6. Safety & Standards

- **Classification:** Class IIa Medical Device.
- **Safety Standards:** IEC 60601-1 (Electrical Safety) and IEC 60601-1-2 (EMC).
- **Biocompatibility:** Catheters and electrodes must meet ISO 10993 for mucosal contact.
- **Data Security:** HIPAA-compliant patient data management and encryption.

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