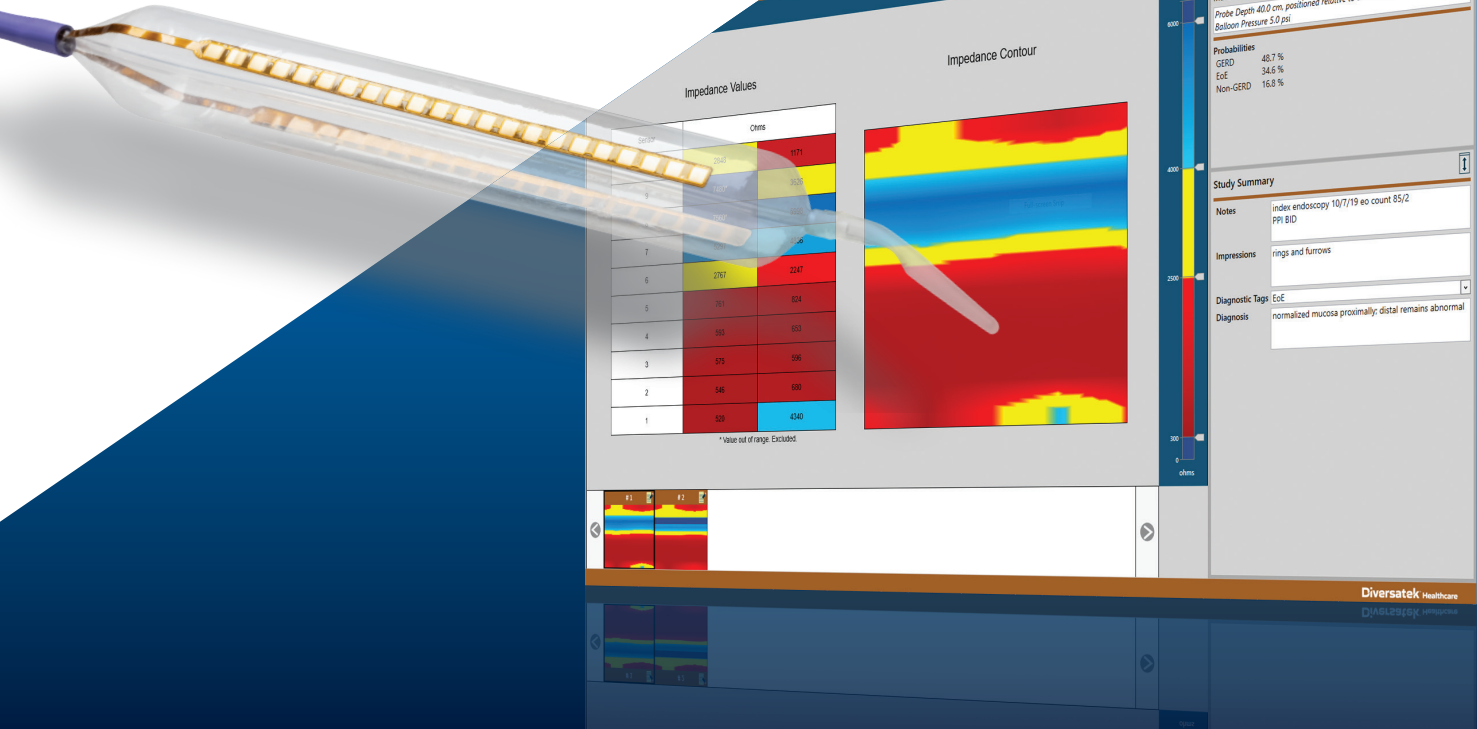


MiVu™ Mucosal Integrity Testing System



Instantly Detect GERD, EoE & Non-GERD

2 Minute Test During Endoscopy

The MiVu™ Mucosal Integrity Testing System utilizes a balloon probe and proprietary software to instantly detect changes in esophageal mucosal integrity during endoscopy – in just two minutes.

Real-Time Results

Real-time impedance values, a mucosal integrity contour pattern, and disease probability, are displayed – which distinguishes various esophageal pathologies of GERD, EoE, or Non-GERD.

Superior Specificity & Positive Predictive Value

Current diagnostic testing in GERD is suboptimal and can have false-negative rates of nearly 30% in patients that have endoscopic esophagitis.^{i,ii}

MI was superior in predicting erosive reflux when compared to pH monitoring, with a specificity of 95% and positive predictive value of 96% compared to 64% and 40%, respectively.ⁱⁱⁱ MI also accurately predicted EoE during endoscopy with a sensitivity of 100% and specificity of 96% without the need for histology.^{iv}

Decreased Treatment Latency

Detection is instant during routine endoscopy, potentially obviating the need for 24- to 48-hour ambulatory pH monitoring or esophageal biopsies for histopathology, reducing both diagnostic and treatment latency.^v

CPT^{vi} Code: C9777

Effective January, 2022, the US Centers for Medicare & Medicaid Services (CMS) has assigned C9777 to APC 5303 (Level 3 Upper GI Procedures) and changed the Status Indicator to J1 in Hospital Outpatient setting, and J8 in the Ambulatory Surgery Center setting.

C9777 Descriptor: Esophageal mucosal integrity testing by electrical impedance, transoral, includes esophagoscopy or esophagogastroduodenoscopy.

MiVu™ Mucosal Integrity Testing



Non-GERD



EoE



GERD

MiVu™ Mucosal Integrity Testing System

Choose a Base Design:

Part No.	Description	Qty/Case
PRIZMCART	PriZm® Base Cart System includes PriZm® Central Unit, 24" LCD medical grade monitor, computer, keyboard/mouse and printer, Zvu® and BioVIEW® Software. • Motility Cart with isolation transformer. • Training for High Resolution Esophageal Manometry, Reflux Monitoring, and High Resolution Anorectal Manometry included (#DEN-FGID)—US customers only. Training for MiVu™ Mucosal Integrity Studies is included and performed during installation.	1

Upgrade Kit for MiVu™ Mucosal Integrity

Part No.	Description	Qty/Case
PRIZM-KIT	PriZm® Upgrade Kit. For customers with an existing Ultima® Base Cart System (ULTCART) or existing Ultima® Base System (ULTSYS) to perform MiVu™ Mucosal Integrity Studies. • Includes a PriZm® Central Unit, MiVu™ Cable, MiVu™ Regulator. Includes Zvu® Software.	1

Starter Kit for MiVu™ Mucosal Integrity

Part No.	Description	Qty/Case
MIVU-KIT	MiVu™ Mucosal Integrity Starter Kit. Includes MiVu™ Cable, MiVu™ Regulator. Includes Zvu® Software.	1

MiVu™ Mucosal Integrity Balloon Probes & Accessories

Part No.	Description	Qty/Case
MI-BAL-01	MiVu™ Mucosal Integrity Balloon Probe with Inflation Syringe and Extension Tubing. Single-use, Non-sterile.	1
MI-CAB-01	MiVu™ Cable. Connects the MiVu™ Mucosal Integrity Balloon Probe to the Regulator and to the inSIGHT Ultima® Central Unit.	1

MiVu™ Mucosal Integrity Testing System is covered by one or more of the following patents: US9, 814, 408 and US10, 321, 867.

GI Motility Software

Part No.	Description	Qty/Case
ZVU-3	Zvu® Software for Mucosal Integrity Studies, Reflux Studies, and Esophageal Manometry.	1

¹ Wenner J, Johansson J, Johnsson F, et al. Optimal thresholds and discriminatory power of 48-h wireless esophageal pH monitoring in the diagnosis of GERD. Am J Gastroenterol 2007;102:1862–1869.

² Kessels SJM, Newton SS, Morona JK, et al. Safety and efficacy of wireless pH monitoring in patients suspected of gastroesophageal reflux disease: a systematic review. J Clin Gastroenterol 2017;51:777–788.

³ Caroline Barrett & Yash Choksi & Michael F. Vaezi, Mucosal Impedance: a New Approach to Diagnosing Gastroesophageal Current Gastroenterology Reports (2018) 20:33 Reflux Disease and Eosinophilic Esophagitis.

⁴ Choksi Y, Lal P, Slaughter JC, et al. Esophageal mucosal impedance patterns discriminate patients with eosinophilic esophagitis from patients with GERD. Clin Gastroenterol Hepatol 2018;16:664–671 e1.

⁵ Dhyanes A. Patel, Tina Higginbotham, James C. Slaughter, Muhammad Aslam, Elif Yuksel, David Katzka, C. Prakash Gyawali, Melina Mashi, John Pandolfino, and Michael F. Vaezi, Development and Validation of a Mucosal Impedance Contour Analysis System to Distinguish Esophageal Disorders, Gastroenterology 2019;156:1617–1626.

⁶ 2021 Current Procedural Terminology (CPT®) Professional Edition. ©2020 American Medical Association. All rights reserved.

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