

MiVu™ Mucosal Integrity Testing System



Instantly Detect GERD, EoE & Non-GERD

2 Minute Test with Direct Visualization During Endoscopy

The MiVu™ Mucosal Integrity Testing System utilizes a balloon or the MiVu™ Endo Cap that attaches to the distal end of the endoscope, along with 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.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

For Use With MiVu™ Esophageal Endo Cap

MiVu™ Mucosal Integrity Testing System

Part No.	Description
PRIZMCART-II	PriZm® Gen-II Base Cart System. Includes PriZm® Gen-II Central Unit, 24" LCD medical grade monitor, computer, keyboard/mouse and printer, Zvu® and BioVIEW® Software.

MiVu™ Mucosal Integrity Upgrade Kit

Part No.	Description
PRIZMUPG-KIT	PriZm® Gen-II Base System. Includes PriZm® Gen-II Central Unit, Zvu® and BioVIEW® Software. For existing inSIGHT Ultima® Base Cart System (ULTCART) or inSIGHT Ultima® Base System (ULTSYS) users who want to perform High Resolution Manometry and have access to MiVu™ functionality with a MiVu™ Endo Cap.

MiVu™ Endo Cap & Accessories

Part No.	Description	Qty/Case
MI-ESO-CAP-3L	MiVu™ Esophageal Endo Cap. Compatible with an endoscope diameter of 9.2 - 11.2 mm (single-use, non-sterile).	1
MI-CAB-02	MiVu™ Endo Cap Cable. Connects the MiVu™ Esophageal Endo Cap to the PriZm® Central Unit.	1



Non-GERD

EoE

GERD

MiVu™ Esophageal Endo Cap
#MI-ESO-CAP-3L

MiVu™ Endo Cap Cable
#MI-CAB-02

Zvu® Software

For Use With MiVu™ Esophageal Endo Cap

GI Motility Software

Part No.	Description
ZVU-3	Zvu® Software for MiVu™ Mucosal Integrity Studies, Reflux Monitoring, and Esophageal Manometry.
ZVU-3-ZIP	Zvu® Software for MiVu™ Mucosal Integrity Studies, Reflux Monitoring, and Esophageal Manometry. Electronic delivery.

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 2022 Current Procedural Terminology (CPT®) Professional Edition. ©2022 American Medical Association. All rights reserved.

Diversatek™ Healthcare

Advancing GI care by driving science, developing and delivering solutions, and providing unmatched clinical support.

[DiversatekHealthcare.com](https://www.DiversatekHealthcare.com)

P 800.558.6408 or 414.265.7620

Corporate Headquarters
102 East Keefe Avenue
Milwaukee, WI 53212 USA
orders@diversatekhc.com
sales@diversatekhc.com

Technical Research & Training Center
9150 Commerce Center Circle, Suite 500
Highlands Ranch, CO 80129 USA
technicalsupport@diversatekhc.com
clinicalsupport@diversatekhc.com
clinicaleducation@diversatekhc.com

MiVu™ Mucosal Integrity Testing System is covered by one or more of the following patents:
US 11,291,382, US 9,814,408 and US 10,321,867.



Learn more from
your personal product
representative at
800-558-6408