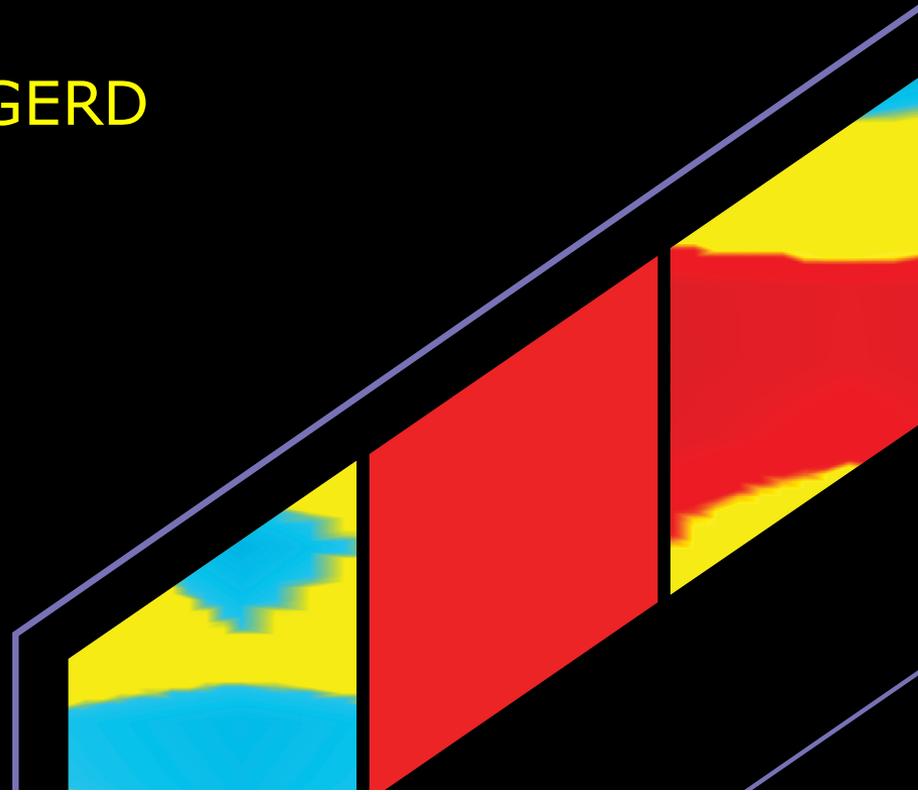
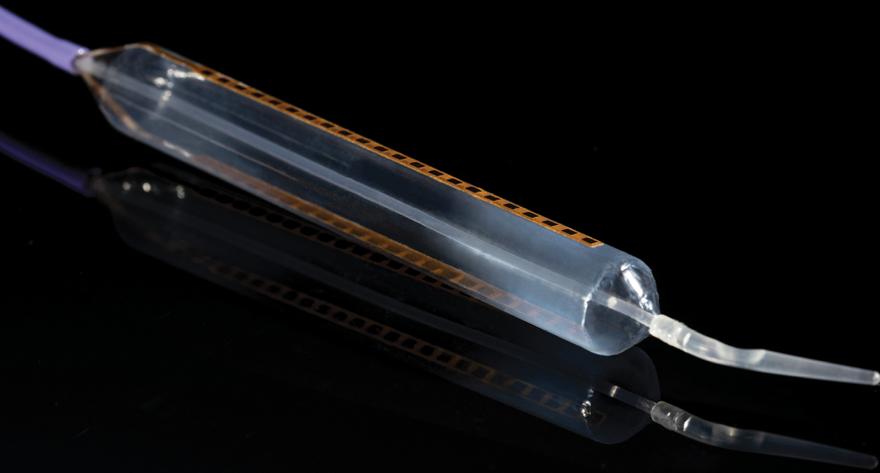


MiVu™

A Better Way to Diagnose GERD
& Eosinophilic Esophagitis



MiVu™ Mucosal Integrity Conductivity Test

MiVu is a minimally invasive, short-duration MI technique for detecting esophageal mucosal changes due to chronic GERD without the need for 24- to 48-hour ambulatory impedance pH catheter placement.

Published clinical data show MiVu is:

1. An innovative method for differentiating the mucosal pattern in GERD compared with non-GERD,
2. Recovery of GERD-related MI changes with PPI therapy,
3. Distinction of the MI pattern from EoE, and
4. Favorable detection of GERD compared with pH monitoring.

MiVu significantly improves the ability to diagnose GERD.

Limitations of Diagnostic Tests

Current diagnostic testing suboptimal:

- Limited sensitivity and/or specificity
 - Less than 30% of patients are positive for GERD upon endoscopic evaluation
 - Current technology has a false negative rate of 30%
- Constrained by measuring reflux
 - Single time point (1- or 2-day duration)
 - Specific location (5-cm above LES)
 - For an effective study, patient compliance is required
 - Timely analysis and editing required for report
 - What to do with $4\% < \text{AET} < 6\%$, 17-25 Demeester

Dent J. Gastro-oesophageal reflux disease. *Digestion* 1998;59: 433–445.

Patel DA, Vaezi MF. Utility of esophageal mucosal impedance as a diagnostic test for esophageal disease. *Curr Opin Gastroenterol* 2017;33:277–284.

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.

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.

What is Mucosal Integrity?

Esophageal epithelial integrity is affected by the presence of dilated intercellular spaces (DIS), or spongiosis (intercellular edema), which affects paracellular permeability of the esophageal lumen.

DIS is an important histologic feature in GERD and EoE which inversely correlates with MI measurements (i.e. lower impedance values with increasing DIS).

The degree of dilation of intercellular spaces is shown to inversely correlate with MI measurements in adult¹ and pediatric populations², showing that MI could serve as a surrogate marker of histologic changes in these patients³.

1 Katzka DA, Ravi K, Geno DM, et al. Endoscopic mucosal impedance measurements correlate with eosinophilia and dilation of intercellular spaces in patients with eosinophilic esophagitis. Clin Gastroenterol Hepatol 2015;13:1242–1248 e1

2 Lowry MA, Vaezi M, Correa H, et al. 704 An innovative mucosal impedance device differentiates active eosinophilic esophagitis from inactive disease, NERD and controls. Gastrointest Endosc 2016;83:AB166

3 Development and Validation of a Mucosal Impedance Contour Analysis System to Distinguish Esophageal Disorders. Patel DA, Higginbotham T, Slaughter JC, Aslam M, Yuksel E, Katzka D, Gyawali CP, Mashi M, Pandolfino J, Vaezi MF, Gastroenterology (2019), doi: <https://doi.org/10.1053/j.gastro.2019.01.253>.

Clinical Advantages of MiVu

Eliminates:

1. The need for hours of prolonged, uncomfortable ambulatory monitoring in GERD diagnosis, and
2. The need for multiple invasive biopsies to monitor response to treatment in EoE, saving both time and money¹.
3. The need for patient compliance
4. The need for multiple visits, reducing diagnostic and treatment latency.

¹ Mucosal Impedance: a New Approach to Diagnosing Gastroesophageal Reflux Disease and Eosinophilic Esophagitis. Barrett C, Choksi Y, Vaezi MF. Curr Gastroenterol Rep. 2018 Jun 9;20(7):33. doi: 10.1007/s11894-018-0639-4. Review.

Clinical Advantages of MiVu

- Provide superior values compared to current technology for patients with nonerosive disease who had abnormal reflux by pH monitoring with a specificity of 95% and positive predictive value of 96% compared to 64% and 40% respectively.
- Predict EoE with a sensitivity of 100% and specificity of 96% without the need for histology.

References:

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.

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.

MiVu Procedure

- A flexible endoscope is introduced (CPT code 43235 or 43239) and then the MiVu balloon probe is inserted and advanced to 2 cm above the squamocolumnar junction (SCJ).
- Data acquisition occurs over 6 inflation/deflation capture cycles. Each cycle includes a MiVu™ Mucosal Integrity Balloon Probe balloon inflation, measurement capture, and deflation of the MiVu™ Mucosal Integrity Balloon Probe.
- Once confirmation of successful impedance data acquisition is completed, the MiVu™ Mucosal Integrity Balloon Probe is removed.
- After the MiVu test, if the physician may do a brush, wash or biopsy.

MiVu Cost per Vanderbilt University

- Below is the cost of performing MiVu and an EGD.
- Using a CCR of 0.222 the total cost is: \$3,543.78

(40) Revenue Code	(43) Description	(44) HCPCS	(45) Service Units	(47) Total Charges	(48) Non- Covered Charges
0250	DRUGS GENERAL		450	\$1,192.50	
0253	DRUGS TAKE HOME		10	\$18.98	\$18.98
0259	OTHER PHARMACY		4	\$38.37	
0272	SUPPLIES - STERILE		6	\$2,935.00	
0272	SUPPLIES - MUCOSAL INTEGRITY BALLOON PROBE		1	\$2,600.00	
0361	OPERATING ROOM MINOR PROCEDURE	43499	38	\$7,999.11	
0372	ANESTHESIA INCIDENT TO DIAGNOSTIC SVCS		38	\$655.00	
0710	RECOVERY - FIRST 30 MINS		1	\$543.00	
		TOTALS		\$15,981.96	\$18.98

Request to CMS

We request C9777 be grouped into APC 5303, Level 3 Upper GI Procedures, which has a proposed 2022 payment rate of \$3160.76 which would include the EGD (CPT codes 43235 or 43239).