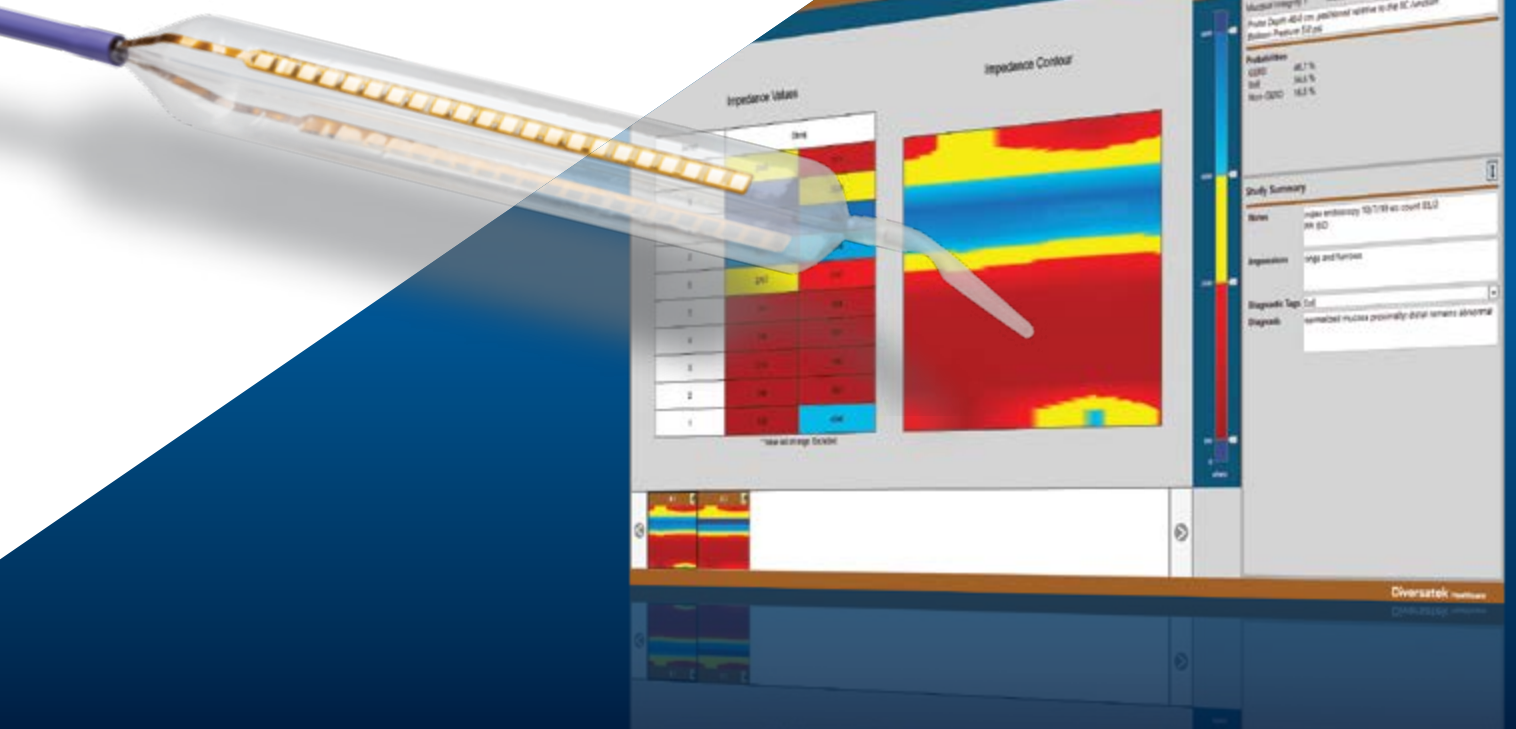


**MiVu™**

# Mucosal Integrity Testing System



## A New Approach to Assessing Esophageal Mucosal Integrity.

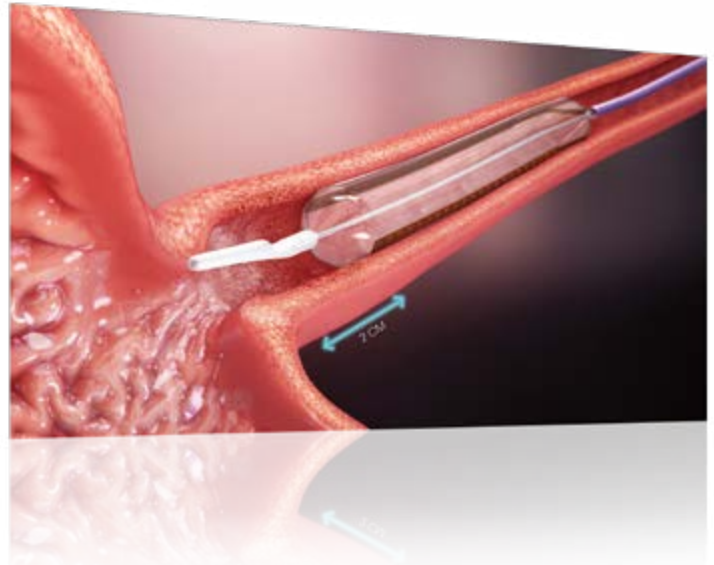
Instantly detect GERD, EoE, and Non-GERD and monitor treatment response in GERD and EoE with MiVu.™

# Mucosal Integrity Testing

Instantly detect GERD, EoE and Non-GERD.

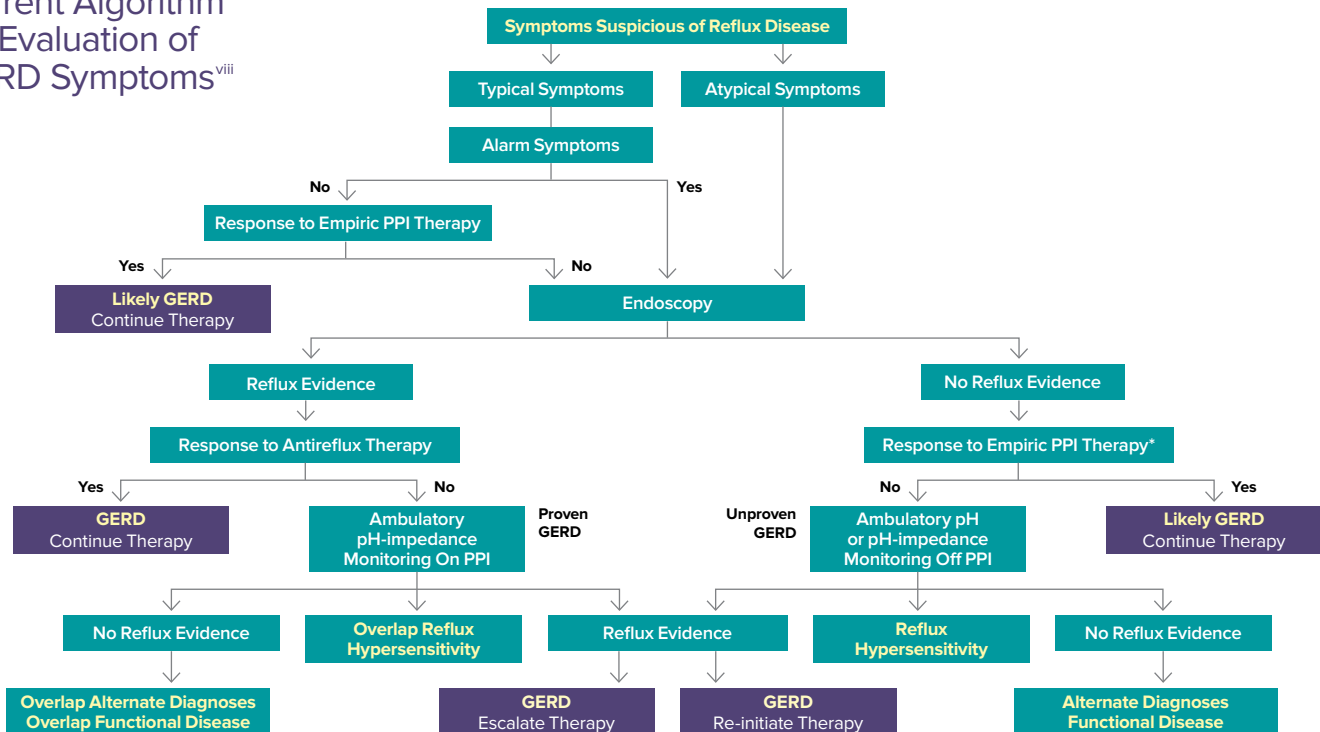
## Current Testing.

Primary diagnostic tools used in practice today for suspected GERD include endoscopy and ambulatory reflux monitoring. These commonly used tools have significant limitations, resulting in many tested patients having a vague, questionable diagnosis that is not an effective guide for therapy. Esophageal mucosal injury detected by endoscopic evaluation is present in less than 30% of patients.<sup>i</sup> Currently available pH technology only measures the acidity of



refluxed material at a single point along the esophagus. Furthermore, these tests fail to account for day-to-day variability of reflux, as they only provide a 24- to 48-hour snapshot of a disease process that is chronic in nature.<sup>ii</sup> Thus, current diagnostic testing in GERD is suboptimal and can have false-negative rates of nearly 30% in patients that have endoscopic esophagitis.<sup>iii iv</sup>

## Current Algorithm for Evaluation of GERD Symptoms<sup>viii</sup>



<sup>i</sup> Dent J. Gastro-oesophageal reflux disease. Digestion 1998;59: 433–445.

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

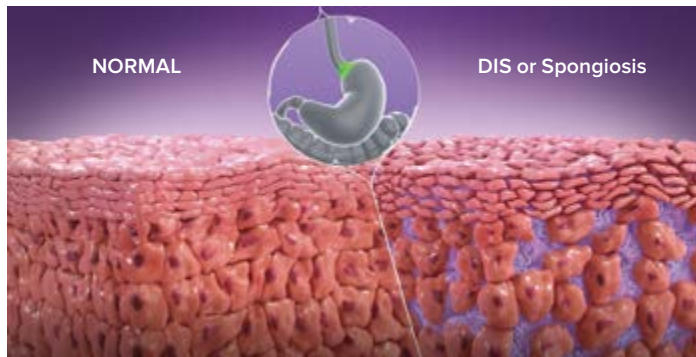
<sup>iii</sup> Wenner J, Johansson J, Johansson F, et al. Optimal thresholds and discriminatory power of 48-h wireless esophageal pH monitoring in the diagnosis of GERD. Am J Gastroenterol 2007;102:1862–1869.

<sup>iv</sup> 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 Testing (MI)?

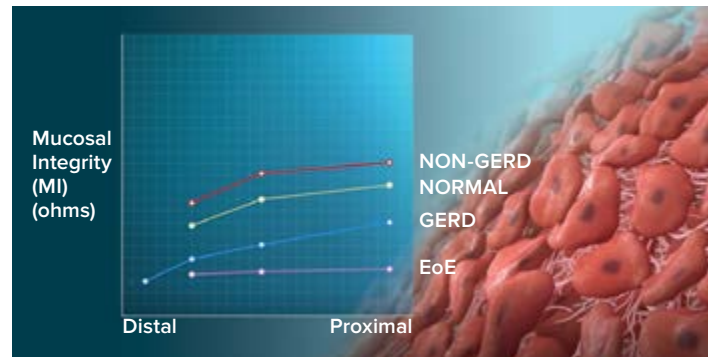
Mucosal Integrity is affected by the presence of dilated intercellular spaces (DIS), or spongiosis, which affects paracellular permeability of the esophageal lumen. DIS is an important histologic feature in GERD and eosinophilic esophagitis (EoE) where the degree of dilation inversely correlates with MI measurements (i.e., lower impedance values occur with increasing DIS).

**Mucosal Integrity correlates inversely with spongiosis, differentiates esophageal disorders, and monitors treatment response in GERD.**



## How is Mucosal Integrity Measured?

Diversatek Healthcare developed the MiVu™ Mucosal Integrity Testing System, which utilizes a balloon probe and proprietary software to instantly detect changes in esophageal mucosal integrity during endoscopy—in just two minutes. The MiVu™ Balloon Probe incorporates both radial and axial sensors mounted at 180-degree intervals along a 10 cm segment of the esophagus to measure esophageal mucosal integrity. Real time impedance values, a mucosal integrity contour pattern, and disease probability, are displayed which distinguishes various esophageal pathologies (GERD, EoE, or Non-GERD).



## Why MiVu?

Using esophageal mucosal integrity measurements, clinicians are able to easily differentiate certain esophageal disorders and monitor treatment response in GERD.

In those patients with nonerosive disease who had abnormal reflux by pH monitoring, MI values were similar to those with erosive esophagitis. 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.<sup>v</sup> Despite the lack of obvious mucosal changes at endoscopy, MI can differentiate those with abnormal reflux pattern from those with normal reflux parameters.

MI also accurately predicted EoE during endoscopy with a sensitivity of 100% and specificity of 96% without the need for histology.<sup>vi</sup> Our findings support the possibility that in vivo measurement of esophageal mucosal impedance may be an accurate means of assessing activity in a patient with EoE without the need for obtaining esophageal biopsy specimens.

MiVu™, only from Diversatek Healthcare, detects esophageal mucosal changes due to chronic GERD and EoE, and as importantly, MiVu provides objective evidence of no inflammatory disease. 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.<sup>vii</sup>



<sup>v</sup> 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.

<sup>vi</sup> 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.

<sup>vii</sup> Dhyanesh 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.

<sup>viii</sup> Savarino, E., Bredenoord, A., Fox, M. et al. Advances in the physiological assessment and diagnosis of GERD. Nat Rev Gastroenterol Hepatol 14, 665–676 (2017). <https://doi.org/10.1038/nrgastro.2017130>

# Mucosal Integrity

## MiVu™ Mucosal Integrity

### 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
PRIZMSYS	PriZm® Base System includes PriZm® Central Unit plus isolation transformer, Zvu® and BioVIEW® Software. • 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
MI-REG-01	MiVu™ Regulator. Regulates inflation for the MiVu™ Mucosal Integrity Balloon Probe.	1
MI-SYR-01	MiVu™ Inflation Syringe and Extension Tubing. Single-use, Non-sterile.	5

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. Recommended Requirements for Host Computer: PC Processor: Intel 64-bit processor, 2 GHz or faster with 4 cores Operating System: Windows® 10 Professional Graphics: DirectX-11 device with Feature (DDI) level 11 or higher (includes Intel HD2500) Memory: 4 GB Hard Drive: 200 GB Monitor: Full HD 1080 p (1920 x 1080 resolution) USB Ports: 4 available USB 2.0 ports for: • PriZm® Central Unit • Mouse • Card Reader • Printer	1



**MiVu™**

# Diversatek™ Healthcare

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

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