Mucosal Integrity Testing

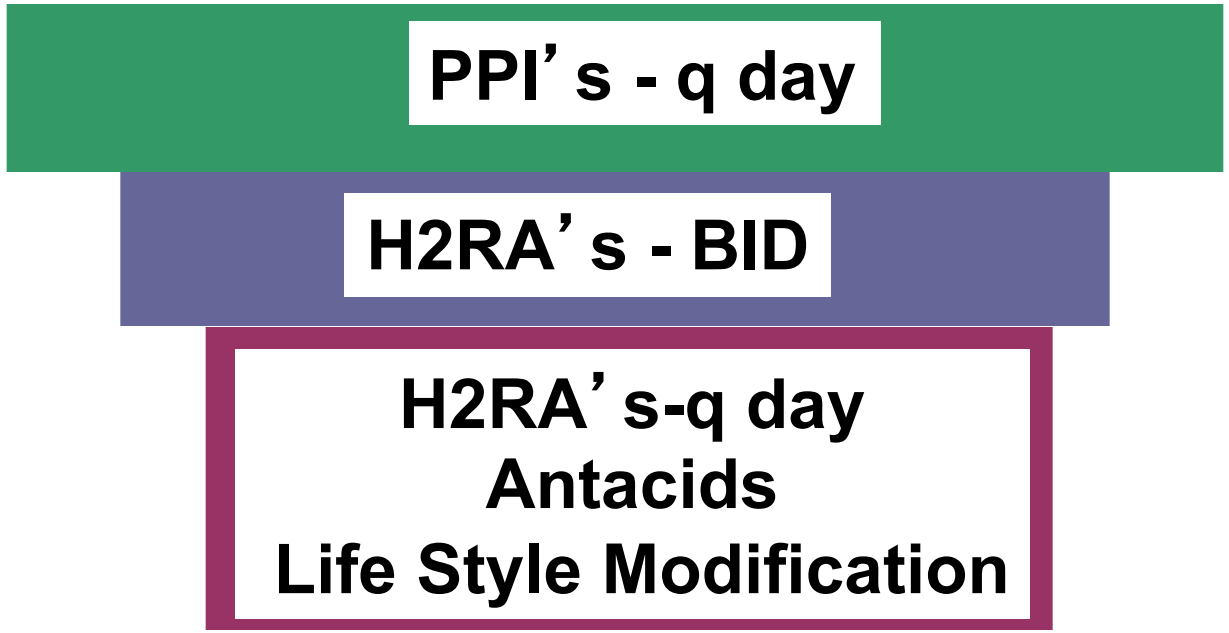
A New Diagnostic Modality
GERD and EoE

Michael F. Vaezi, MD, PhD, MSc, FACG
Professor of Medicine and Otolaryngology
Associate Chief and Clinical Director
Division of Gastroenterology, Hepatology and Nutrition
Director, Clinical Research and Esophageal Motility Center
Vanderbilt University Medical Center

Disclosures and Conflicts

- Advisory (Pharma/Device):
  - Ironwood, Phathom, ISOThrive, Sanofi, Bayer
  - Medtronic, Diversatek healthcare
- Patent:
  - Mucosal Integrity Testing (Diversatek)
- Legal:
  - Consultation in litigation relating to acid suppressive agent

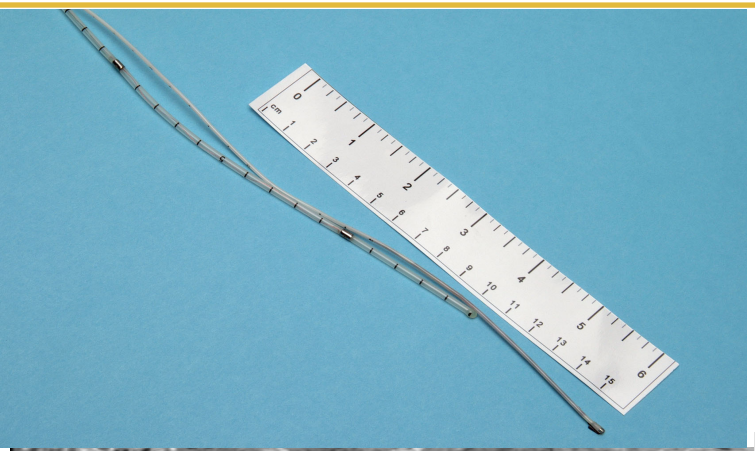
PPI Trial

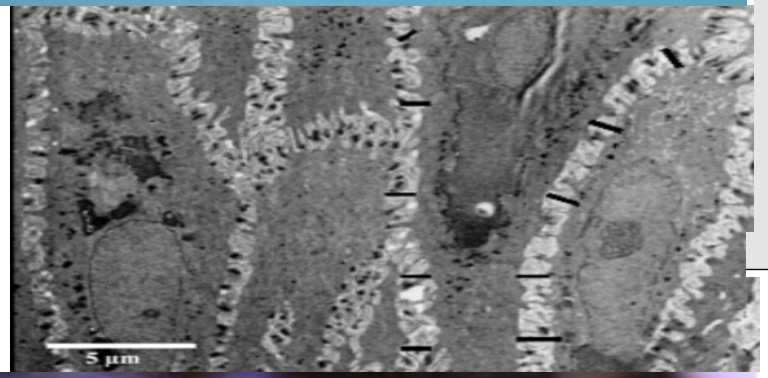

PPI's - q day
H2RA's - BID
H2RA's-q day
Antacids
Life Style Modification

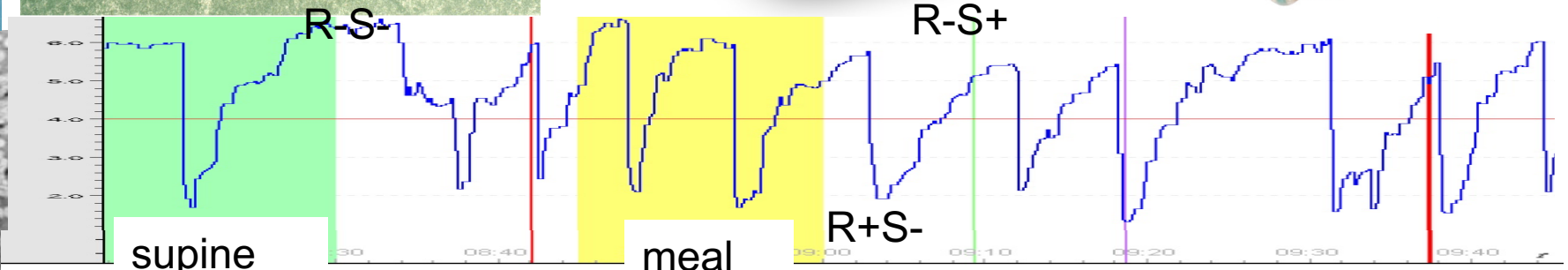
INDICATIONS FOR TESTING

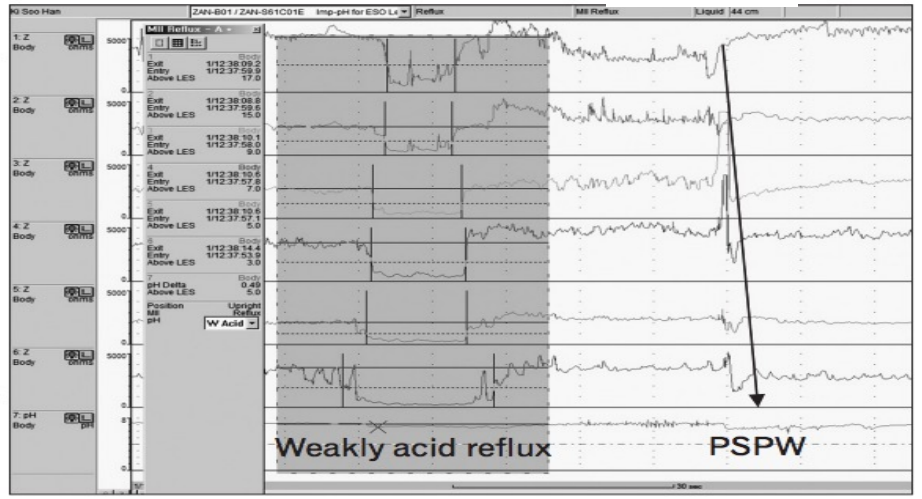
- Incomplete / lack of response to therapy.
- Prior to anti-reflux intervention.

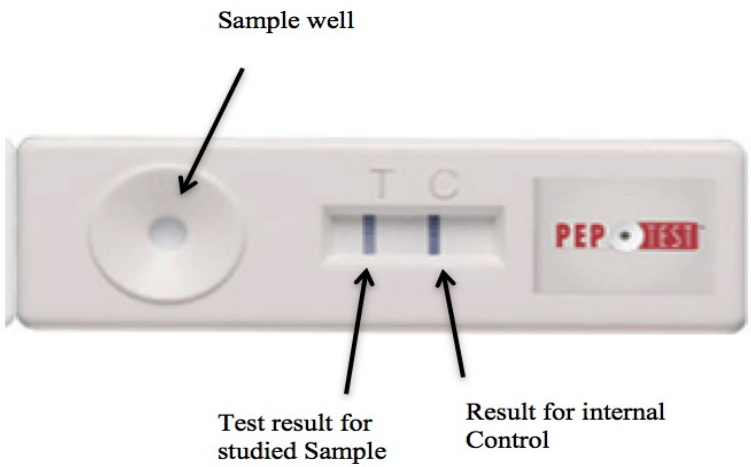
COME AND GET IT!





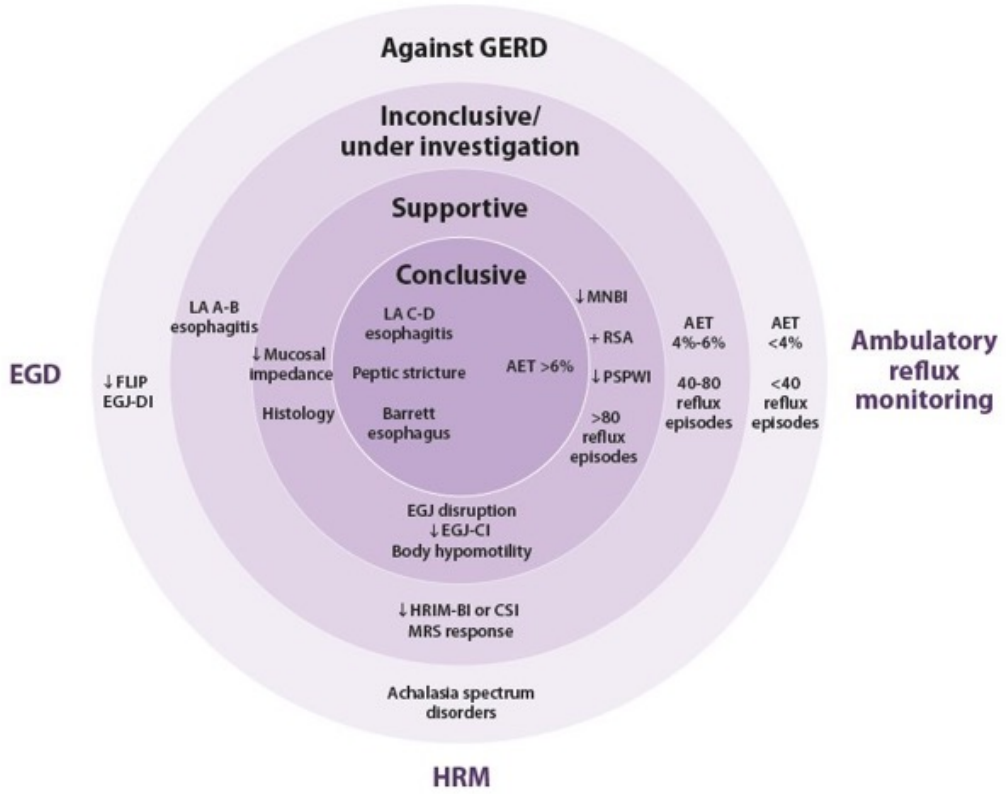




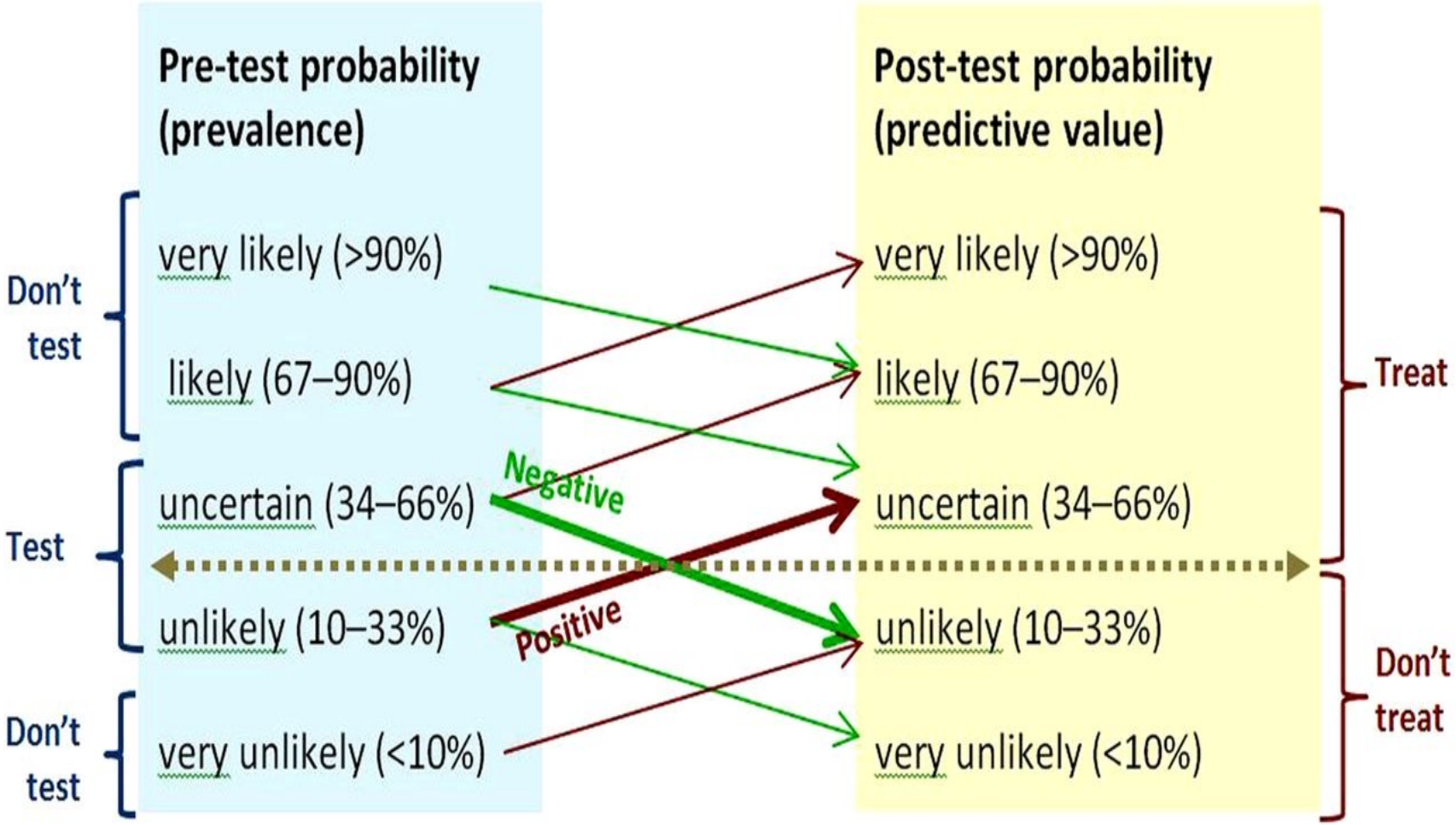


Test, Test, Test Again

- Shifting “cut-offs” of abnormalities
  - AET of >4.2%?
  - AET of >5.5%?
  - AET of >6%?
  - # of days with AET
  - AET >4.2% + MNBI?
  - MBNI+ PSPW?
  - Reflux episodes?



Cutoffs are Problematic?



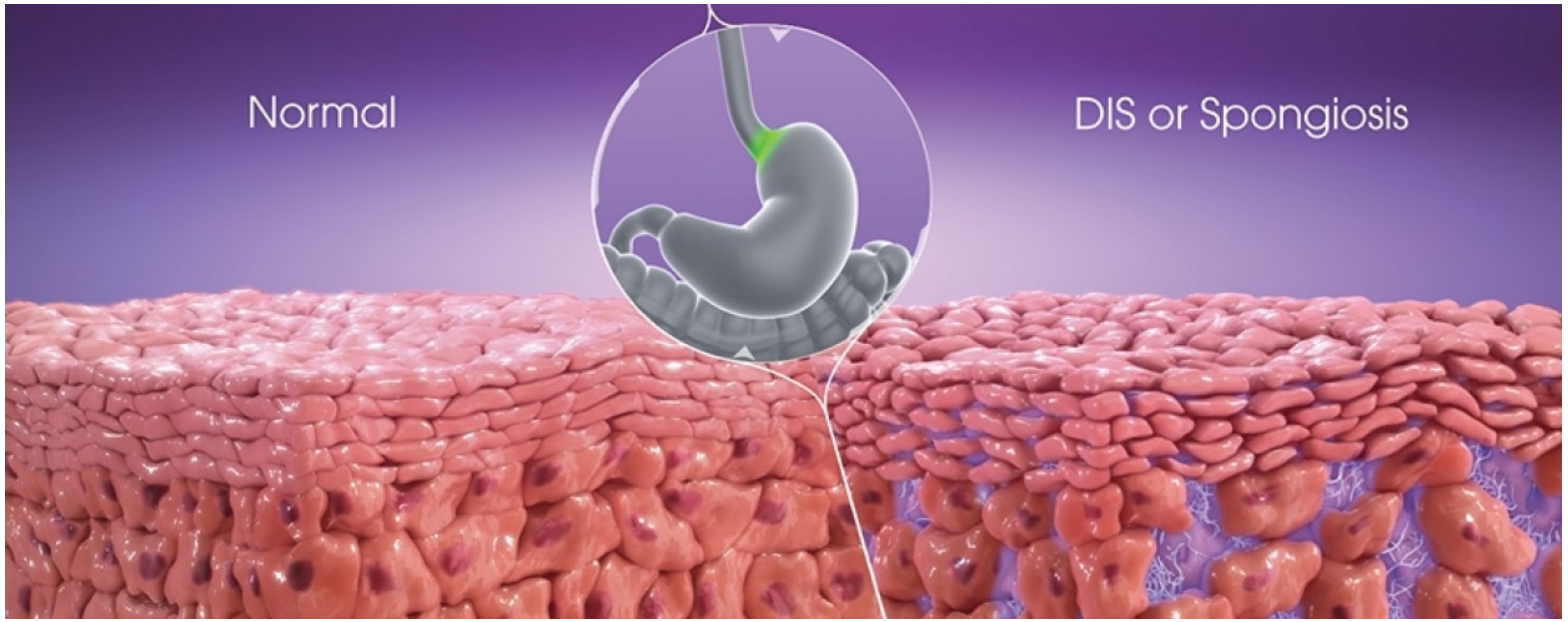
Patel and Yadlapati. Gastro & Hep, 2021

MIT

- Instant diagnosis
- Comfortable (patient perspective)
- Can monitor treatment response
- Detect damage to lining of esophagus rather than “capturing” reflux event

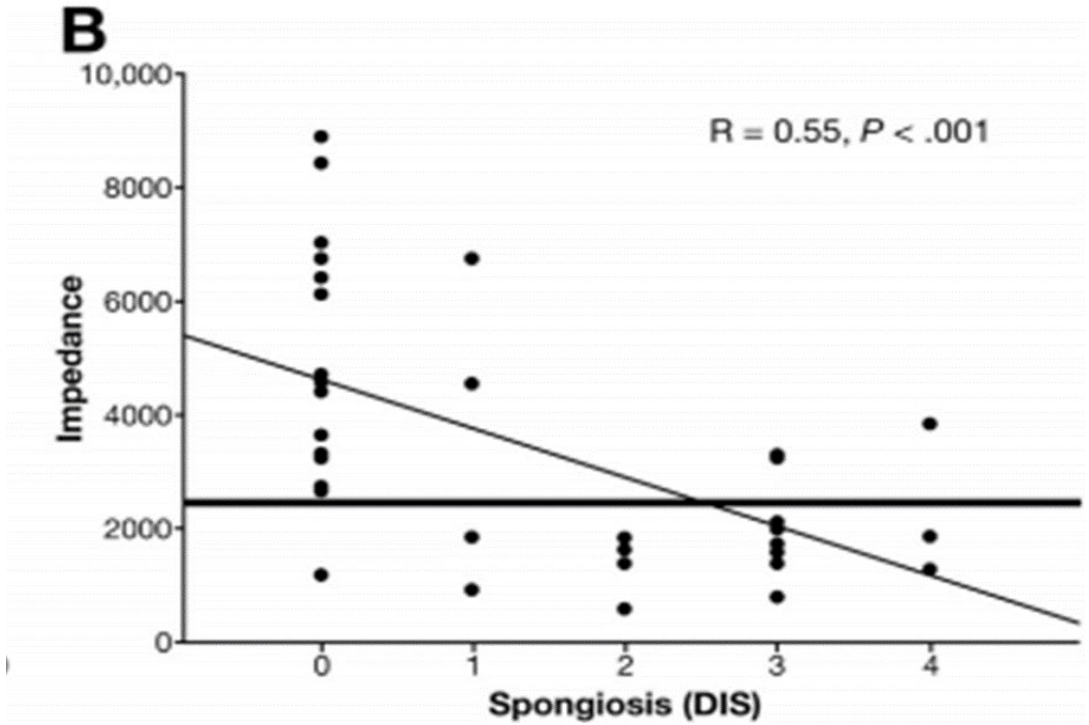
Mucosal integrity testing

- Mucosal Integrity is affected by the presence of dilated intercellular spaces (DIS) which affects paracellular permeability.

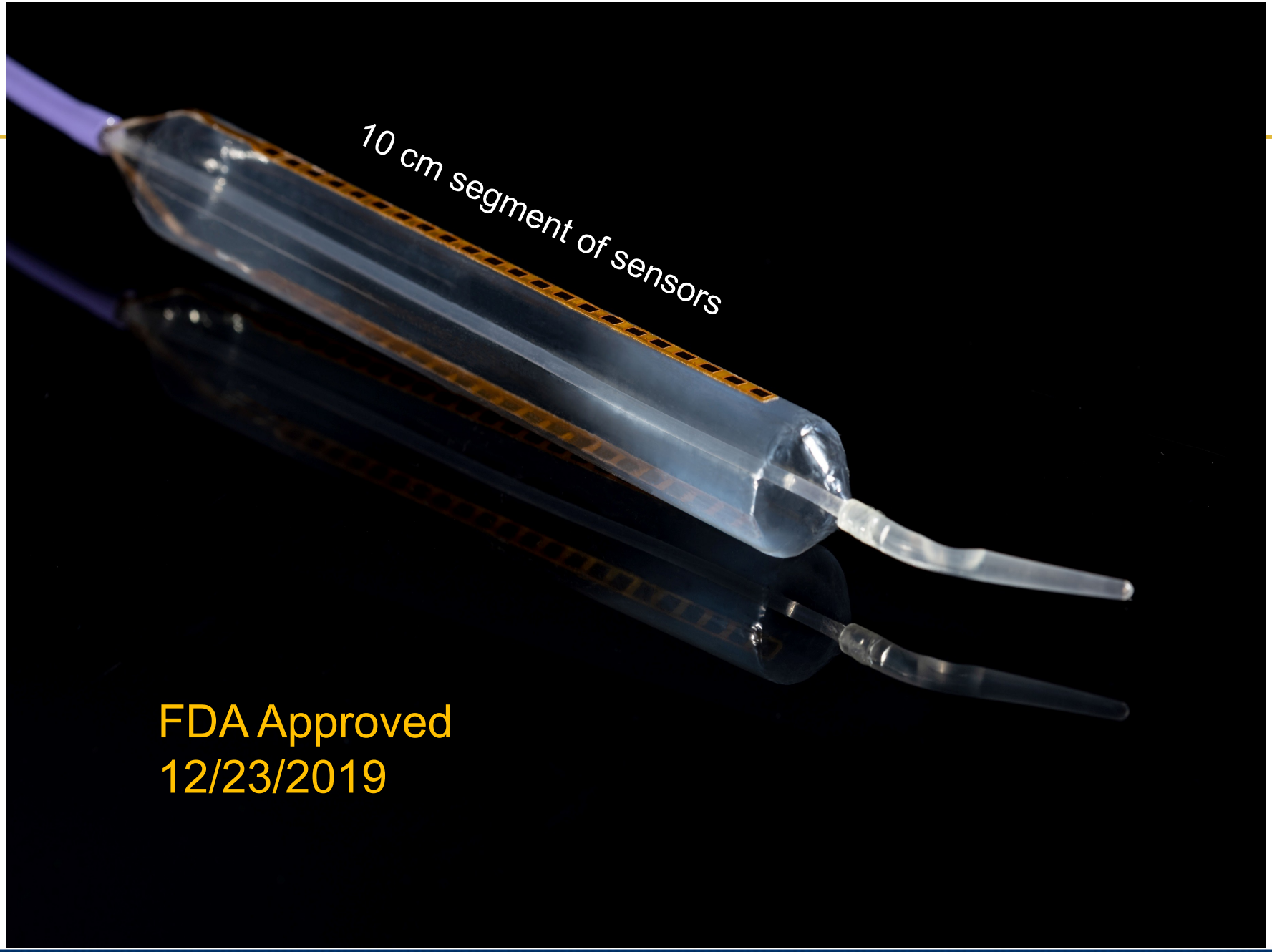


MIT vs Spongiosis

- Degree of spongiosis inversely correlates with MI measurements

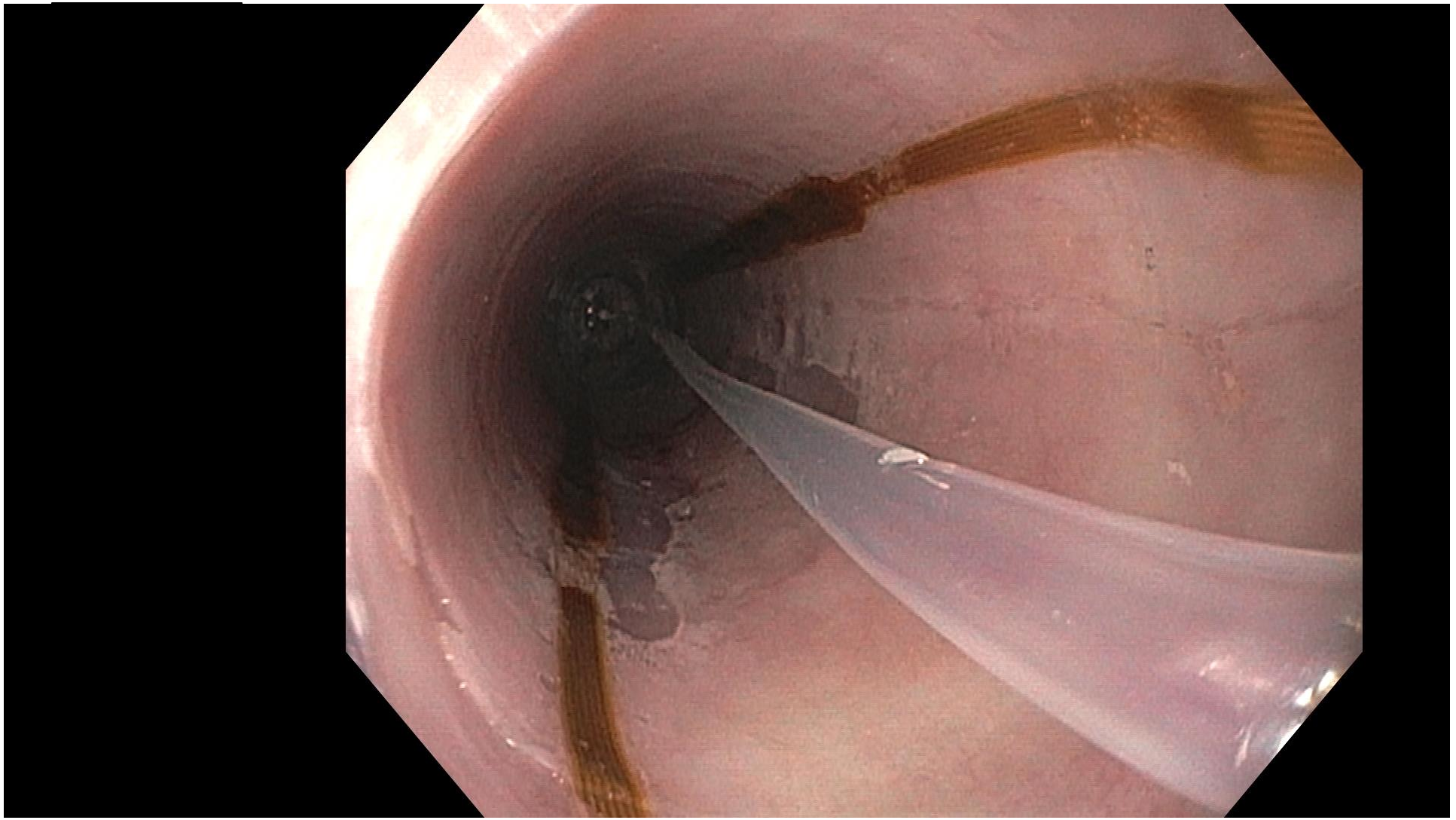


Katzka et al. CGH 2014

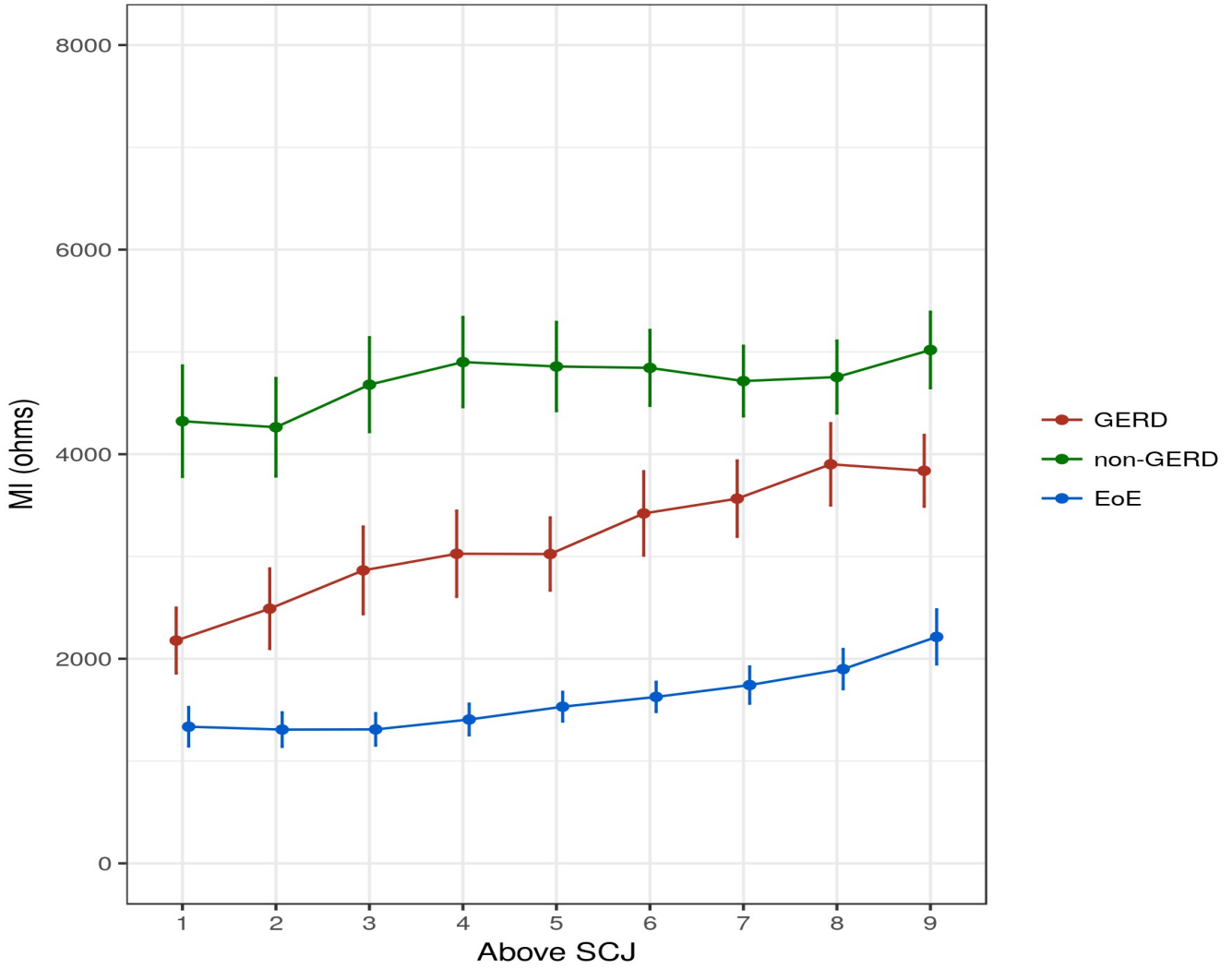


FDA Approved
12/23/2019

MI



Balloon MI Data

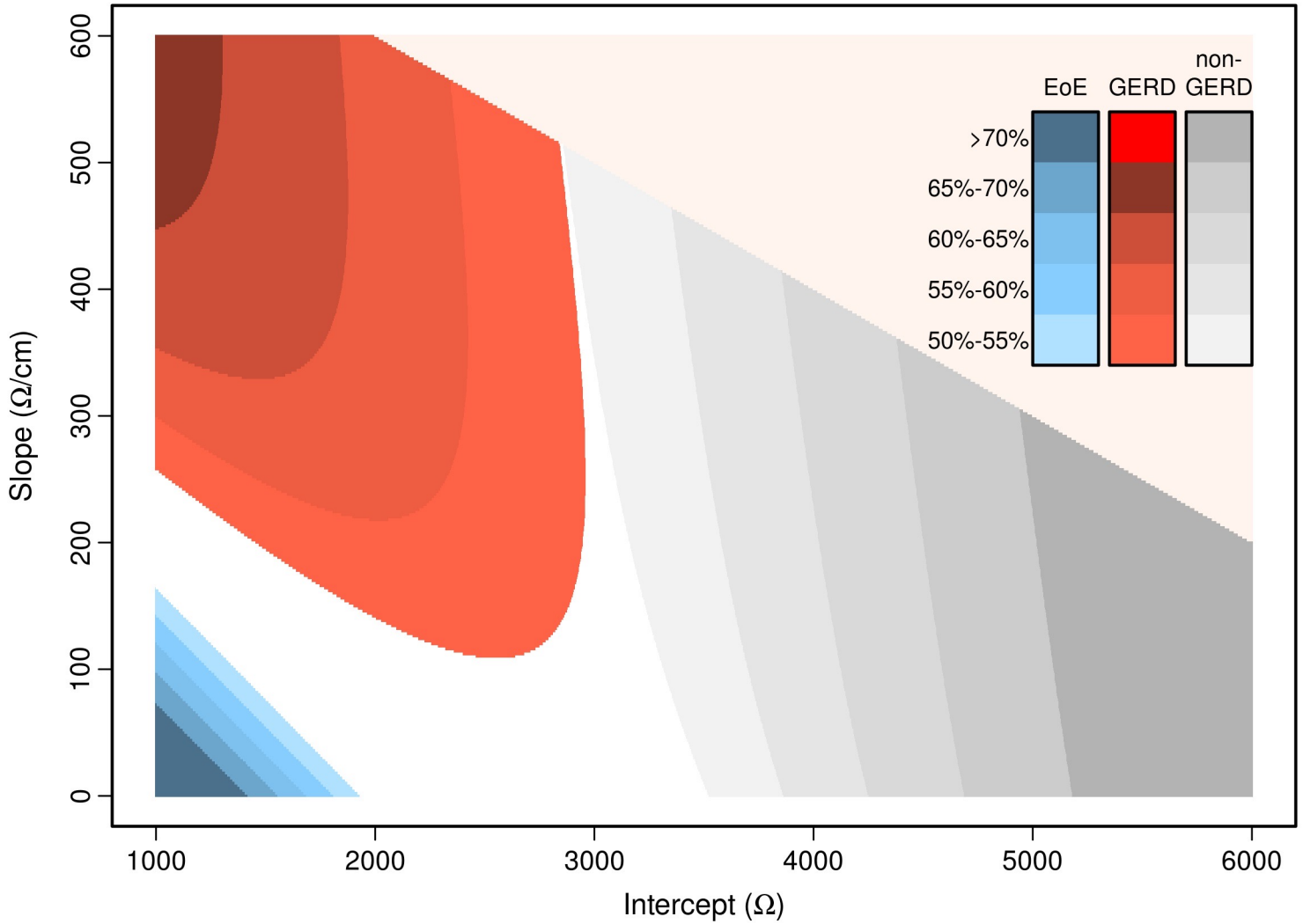


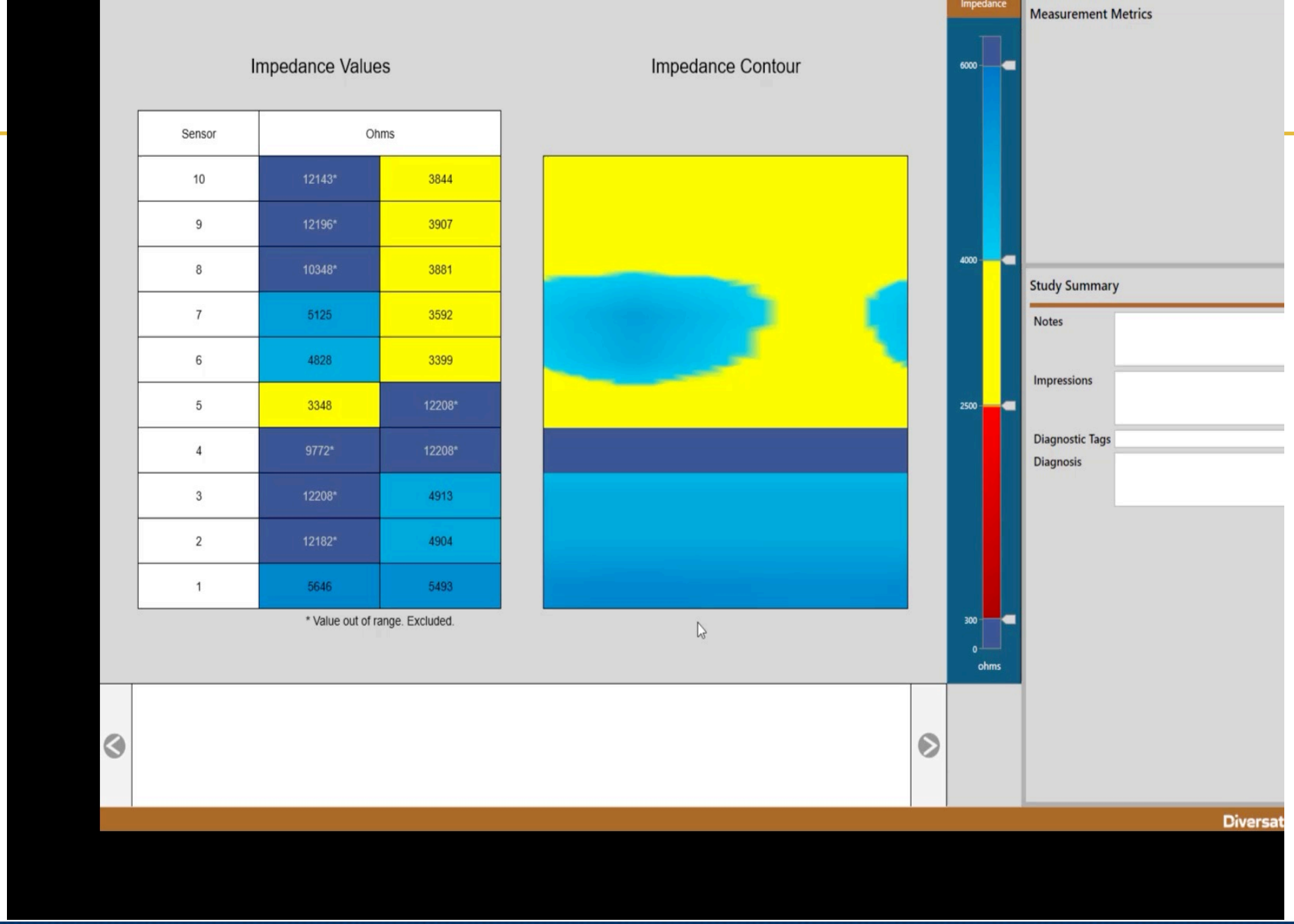
MI Pattern

Normal

GERD

Balloon MI Data




Impedance Values
Impedance Contour
Sensor
Ohms
10 12143* 3844
9 12196* 3907
8 10348* 3881
7 5125 3592
6 4828 3399
5 3348 12208*
4 9772* 12208*
3 12208* 4913
2 12182* 4904
1 5646 5493
* Value out of range. Excluded.
Impedance
6000
4000
2500
300
0
ohms
Measurement Metrics
Study Summary
Notes
Impressions
Diagnostic Tags
Diagnosis

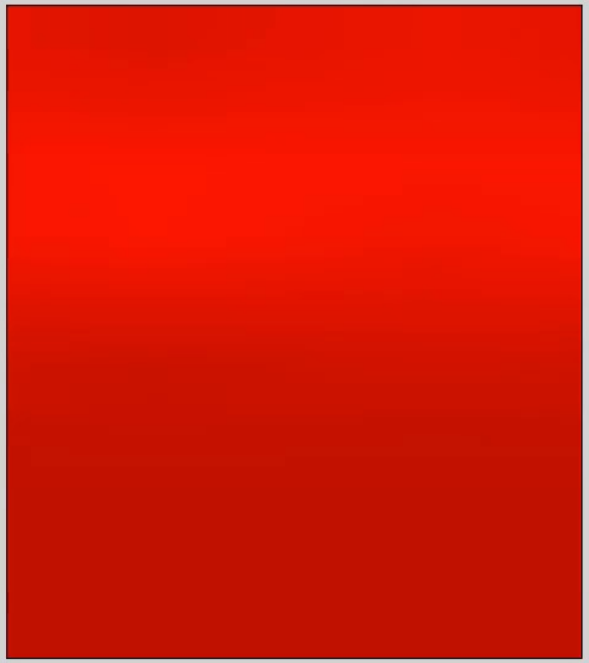
VUMC 2039 Johnson, Savannah -

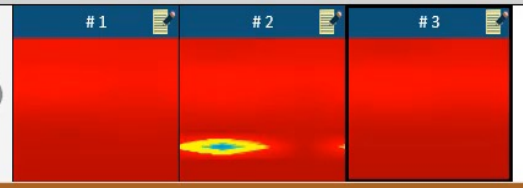
Impedance Values

Sensor	Ohms	
10	1196	1550
9	1529	1640
8	1931	1857
7	1922	1666
6	1343	1290
5	786	957
4	749	711
3	12208*	617
2	12208*	617
1	12208*	568

* Value out of range. Excluded.

Impedance Contour





Measurement Metrics

Mucosal Integrity 3 Mucosal Integrity

Probe Depth 40.0 cm
Balloon Pressure 5.0 psi

Probabilities

GERD	18.6 %
EoE	75.8 %
Non-GERD	5.7 %

Study Summary

Notes r/o eoe

Impressions

Diagnostic Tags

Diagnosis

Diversatek Healthcare

Vanderbilt Digestive Disease Center

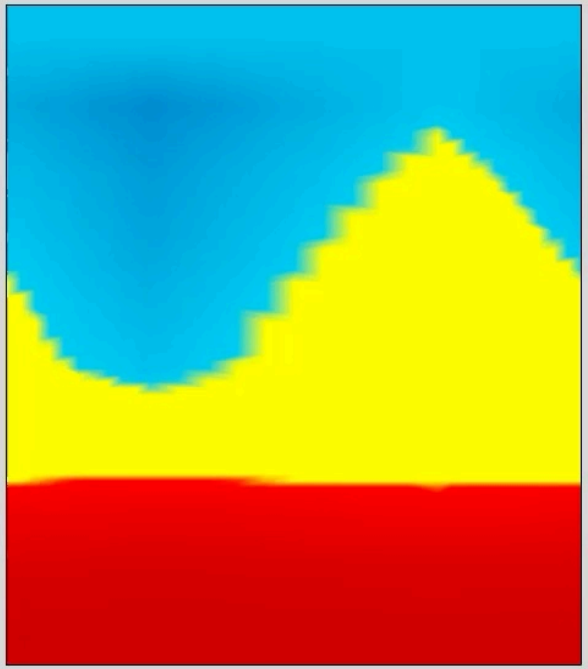
VUMC 2038 Anderson, Evan -

Impedance Values

Sensor	Ohms	
10	6004*	4304
9	5563	4151
8	5195	3724
7	4964	3386
6	4644	3074
5	4263	3243
4	3361	3183
3	2042	2309
2	1332	1462
1	1163	1166

* Value out of range. Excluded.

Impedance Contour



Impedance

Measurement Metrics

Mucosal Integrity 1 Mucosal Integrity

Probe Depth 41.0 cm
Balloon Pressure 5.0 psi

Probabilities

GERD	63.5 %
EoE	10.7 %
Non-GERD	25.8 %

Study Summary

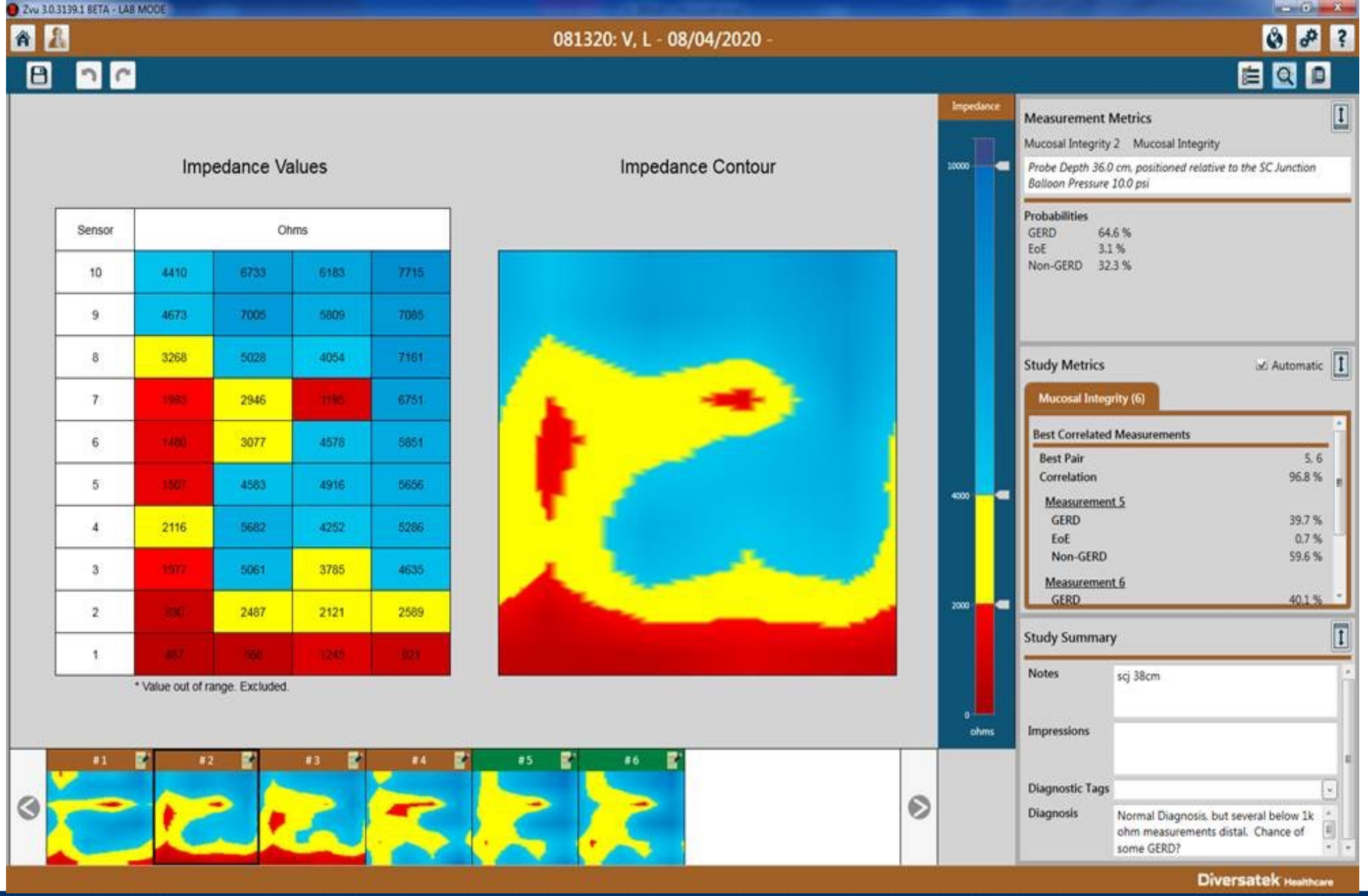
Notes r/o eoe

Impressions

Diagnostic Tags

Diagnosis

Diversatek Healthcare


Zvu 3.0.3139.1 BETA - LAB MODE
081320: V, L - 08/04/2020 -
Impedance Values
Impedance Contour
Sensor
Ohms
10 4410 6733 6183 7715
9 4673 7005 5809 7085
8 3268 5028 4054 7161
7 2946 6751
6 3077 4578 5851
5 4583 4916 5656
4 2116 5682 4252 5286
3 5061 3785 4635
2 2487 2121 2589
* Value out of range. Excluded.
Impedance
10000
4000
2000
0
ohms
Measurement Metrics
Mucosal Integrity 2 Mucosal Integrity
Probe Depth 36.0 cm, positioned relative to the SC Junction
Balloon Pressure 10.0 psi
Probabilities
GERD 64.6 %
EoE 3.1 %
Non-GERD 32.3 %
Study Metrics
Automatic
Mucosal Integrity (6)
Best Correlated Measurements
Best Pair 5, 6
Correlation 96.8 %
Measurement 5
GERD 39.7 %
EoE 0.7 %
Non-GERD 59.6 %
Measurement 6
GERD 40.1 %
Study Summary
Notes scj 38cm
Impressions
Diagnostic Tags
Diagnosis Normal Diagnosis, but several below 1k ohm measurements distal. Chance of some GERD?
#1
#2
#3
#4
#5
#6
Diversatek Healthcare

Two different metrics of GERD

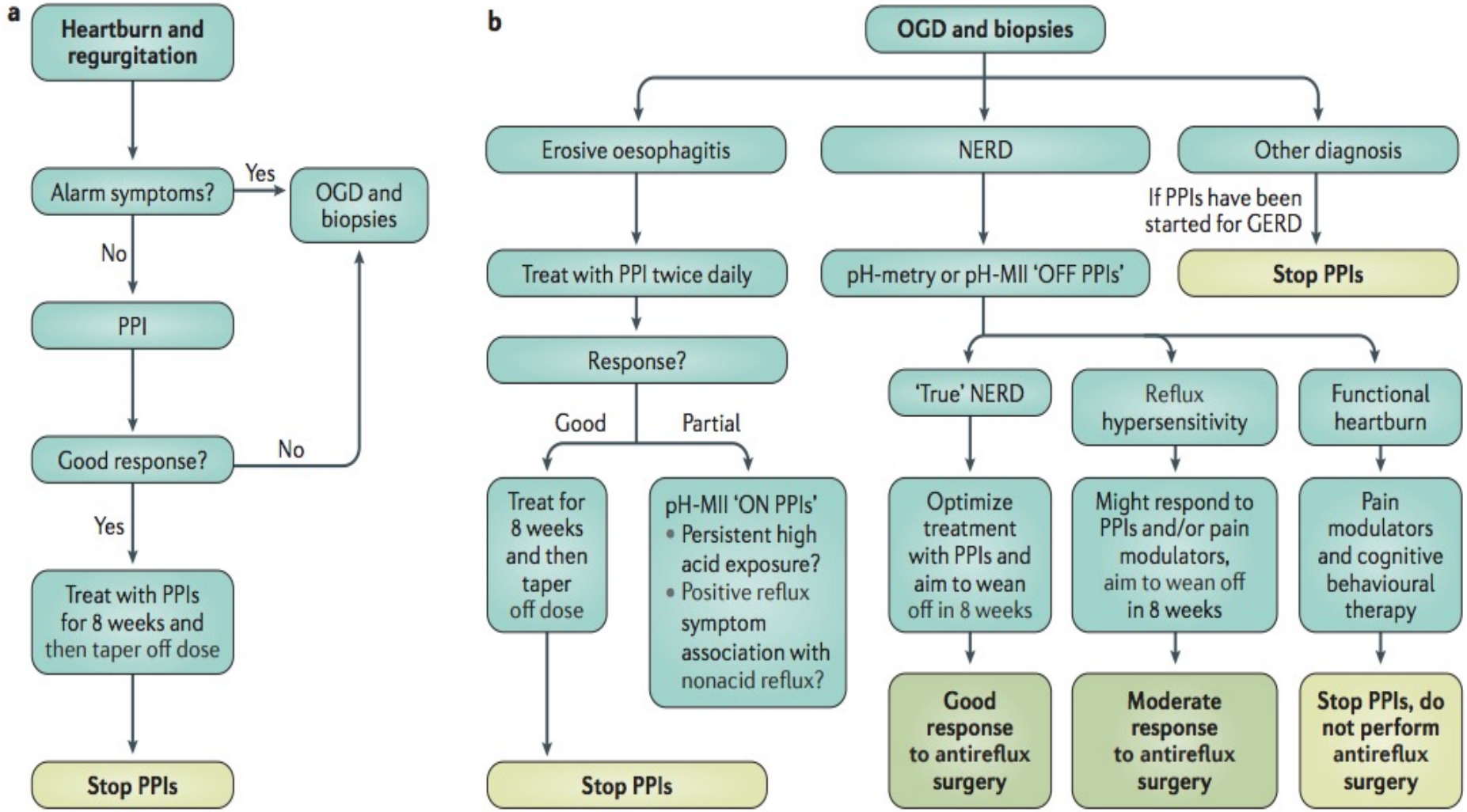
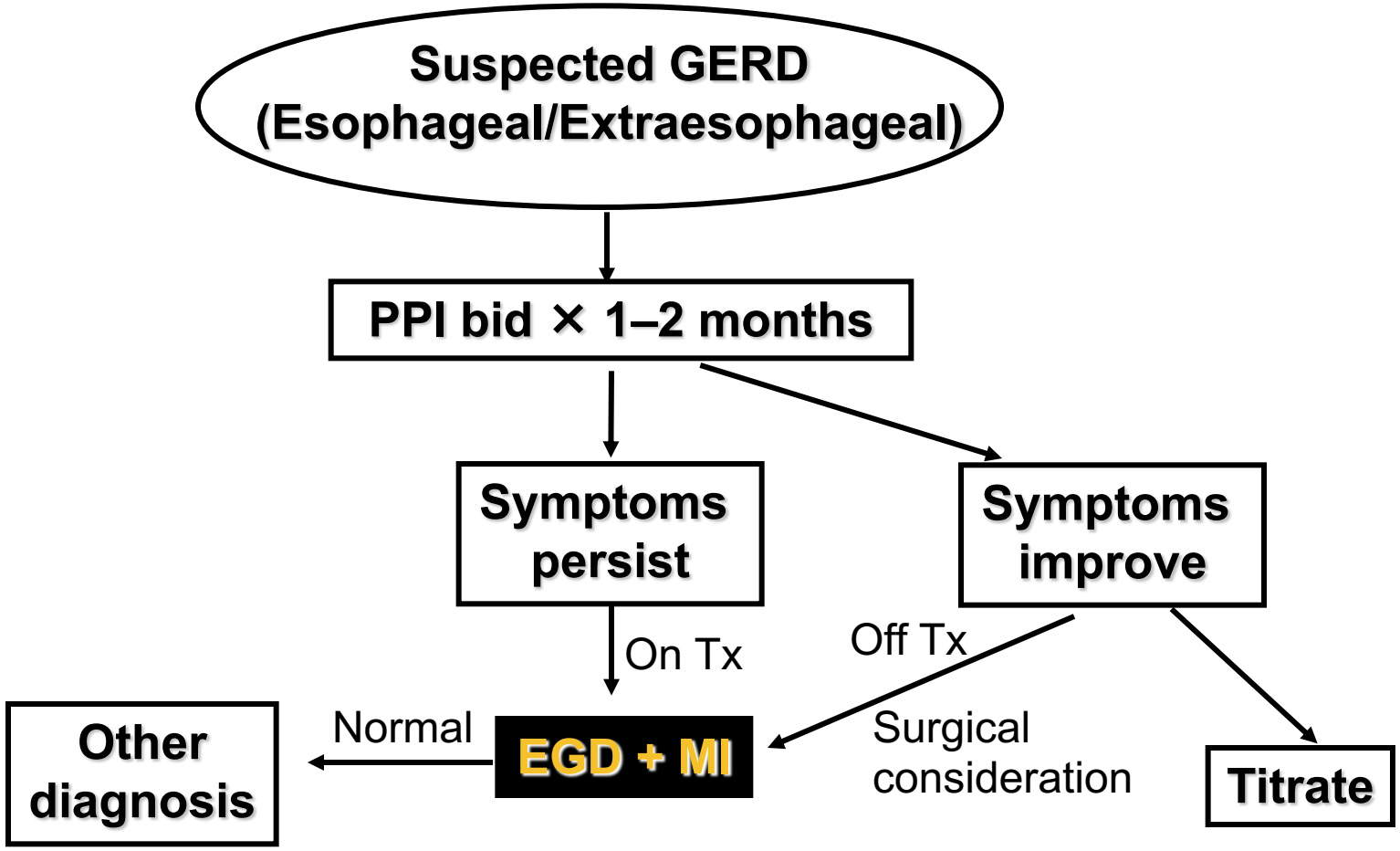
pH Testing

- Captures episodes of refluxate at a point in the esophagus (5 or 6 cm above GEJ)
- Susceptible to day-to-day variability of reflux patterns
- Susceptible to patient behavior

Mucosal Integrity Testing

- Captures “end-result” of reflux on the esophageal mucosa
- Can detect changes on 10 cm area of the esophagus

Can We Simplify Algorithms?



Future State Algorithm