

# ZepHr™

## Tutorial Appendix



PN: S98-9528 Rev. 1.0

# ZepHr™

Definitions for the MII-pH study

MII = Multiple Intraluminal Impedance



## Definitions

- Acid reflux – drop in pH below 4.0
- Weakly Acid – drop in pH value of 1.0 pH units but pH does not drop below 4.0
  - Weakly acid reflux episodes are considered to be subset of “non-acid”
- Non-acid – pH remains above 4.0 and does not change by more then 1 pH unit



## Definitions

- **Chemical clearance – length of time from drop in pH below 4.0 until pH returns to above 4.0**
  - pH measurements are can be much longer then the corresponding impedance (bolus presence) measurements
  - The pH data is the traditional pH study
- **Bolus clearance – length of time required for a bolus to clear the esophagus (return to baseline impedance following drop in impedance caused by bolus presence).**
  - User defined channel, usually the same level as the pH clearance level (5cm above proximal LES)



## Definitions

- Bolus composition
  - Liquid
  - Mixed (Gas and liquid combined – must follow the rules for both liquid and gas)
  - GAS

NOTE: Symptoms associated with GAS reflux are not analyzed unless user defined during the AutoScan process



## Retrograde Bolus Entry Criteria

Liquid requirement:

1. 50% drop in ohms >2 seconds from pre-episode mean impedance (baseline)
2. The drop in ohms needs to be seen in **two consecutive channels of four distal channels**

Gas requires: \*\*

1. 50% rise in ohms > 2 seconds from pre episode mean impedance
2. Any two consecutive channels
3. Rapidly retrograde movement

**\*\* If desired the user can select analysis of retrograde gas movement**



## Retrograde Bolus Clearance Criteria

Liquid requires:

1. Return to pre-episode impedance baseline for > 5 seconds
2. User defined bolus clearance channel
  - Usually the channel that corresponds to the pH channel 5 cm above the proximal edge of the LES

Gas requires:

1. Clearance not quantified



## Chemical Reflux Declaration Criteria

Fall in  $\text{pH} < 4.0$  to a rise in  $\text{pH} > 4.0$  detected by the pH electrode anytime during retrograde liquid bolus movement as detected by the impedance sensors.

This gives the traditional pH data.

\*If desired, user defined AutoScan setting can be changed to allow the measurement of drops in pH below 4.0 in the absence of retrograde bolus movement



## Chemical Reflux Clearance Criteria

pH returns to  $>4.0$  for at least 5 consecutive seconds as detected by the pH electrode

Note: The Impedance-pH recorder samples 50 times a second. Traditional pH recorders sample every 5 seconds.



## Editing the Waveforms

- Review the waveforms;
  - Add/change any diary events, if needed,
  - Change any eating or body position times, if needed
  - Eliminate any areas of artifact, if needed.
    - Artifact may be at the end of the study if the probe was removed before turning off the recorder or if the probe was disconnected anytime during the procedure.



## Editing the Waveforms

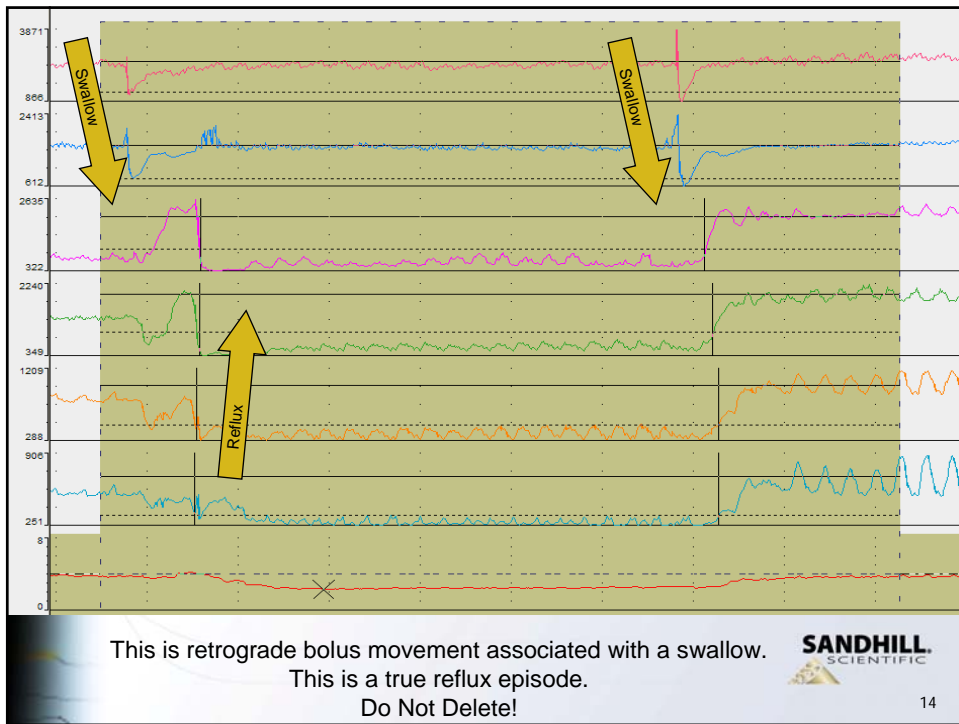
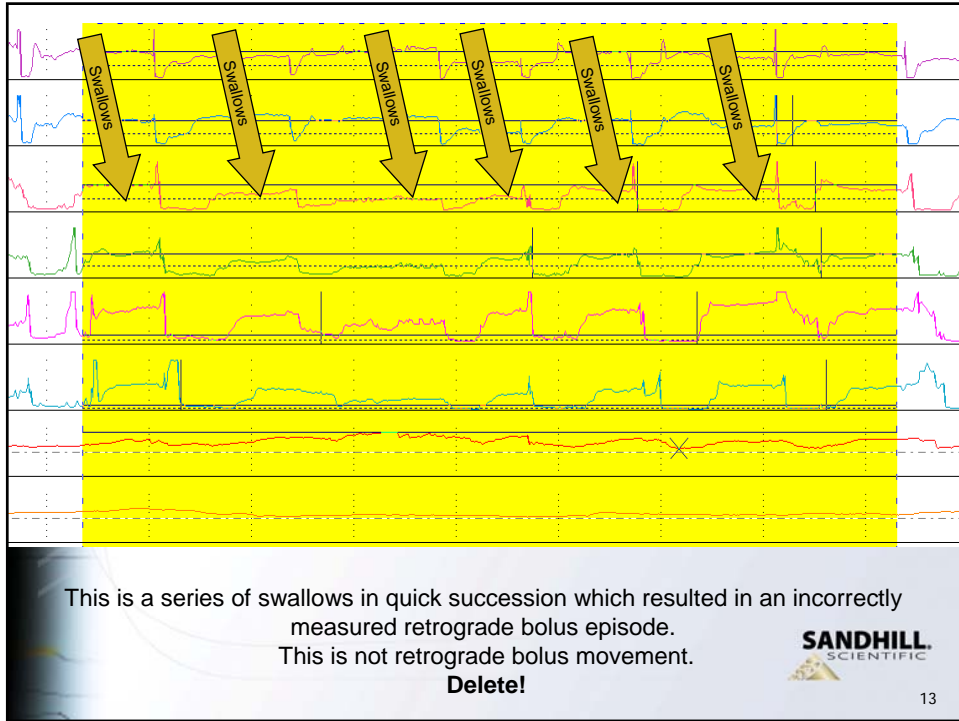
- Run AutoSCAN;
  - Software program that will identify retrograde bolus movement and place measurement box around the
    - reflux event
- **Review areas of retrograde bolus movement associated with patient documented symptoms**



## Why Edit?

- The analysis software (AutoScan) will sometimes overcall reflux,
  - It may call multiple swallows or an artifact as reflux event.
    - This is due to oscillations of the impedance signal.
  - These are called "false positives" and should be deleted.
- There also may be the occasion when the analysis software (AutoScan) did not recognize retrograde bolus movement associated with a symptom.
  - A measurement will need to be created around the retrograde bolus movement



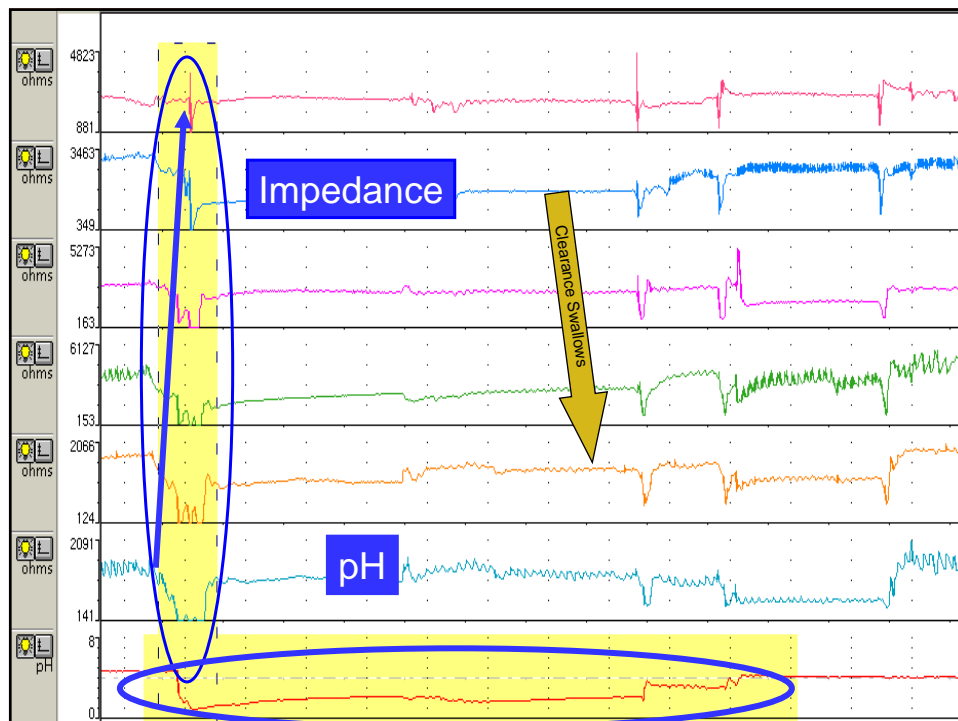


# pH measurements

- If the retrograde bolus movement is associated with a pH drop to  $< 4.0$  there will be a pH measurement separate from the associated impedance measurement.
  - This gives the traditional pH data.
- The pH measurement may often last much longer than its associated impedance measurement
  - Due to the difference in acid clearance (chemical) and bolus clearance.
  - Do not delete or change the pH measurement that is associated with a retrograde impedance measurement.
  - This is the analysis of pH based on the traditional pH study.

Note: The software will not analyze pH unless there is an associated retrograde bolus movement.

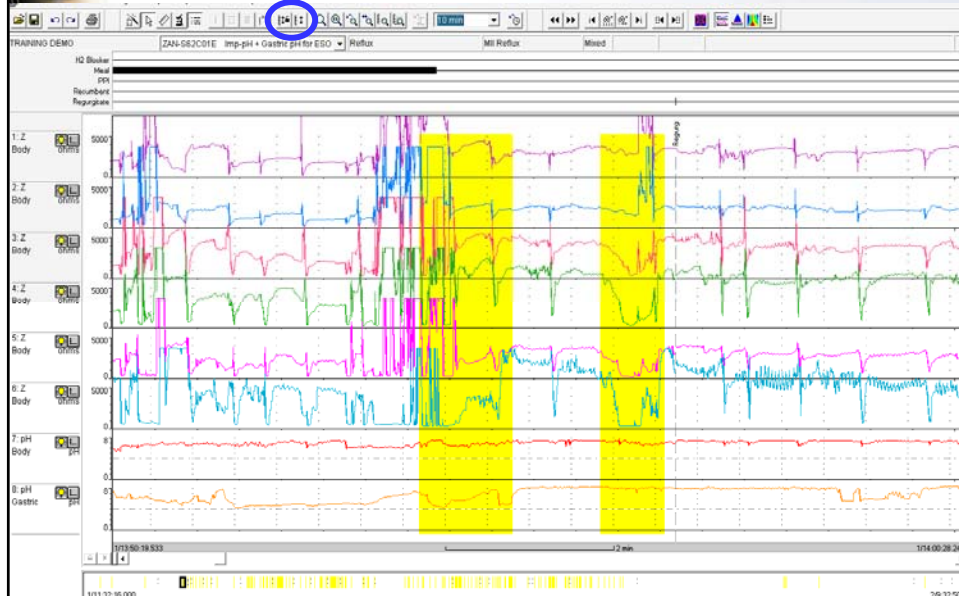
The user can select/deselect this in the AutoScan analysis process.



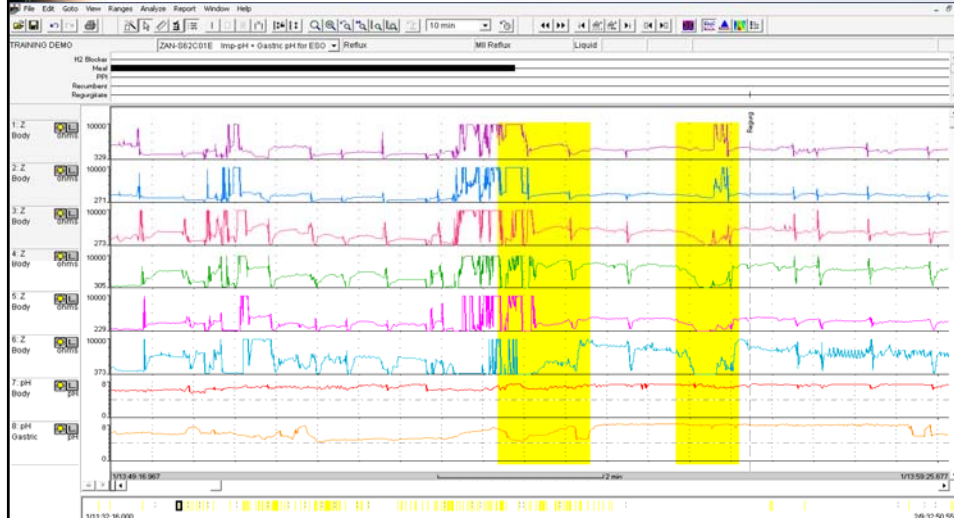
# Range Function



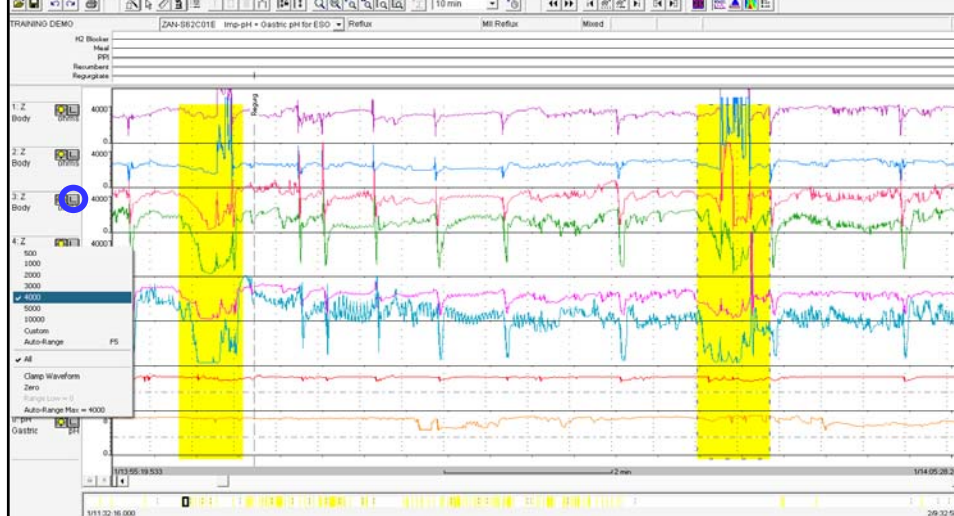
# Impedance Waveform "Range" Function



# Impedance Waveform "Range" Function

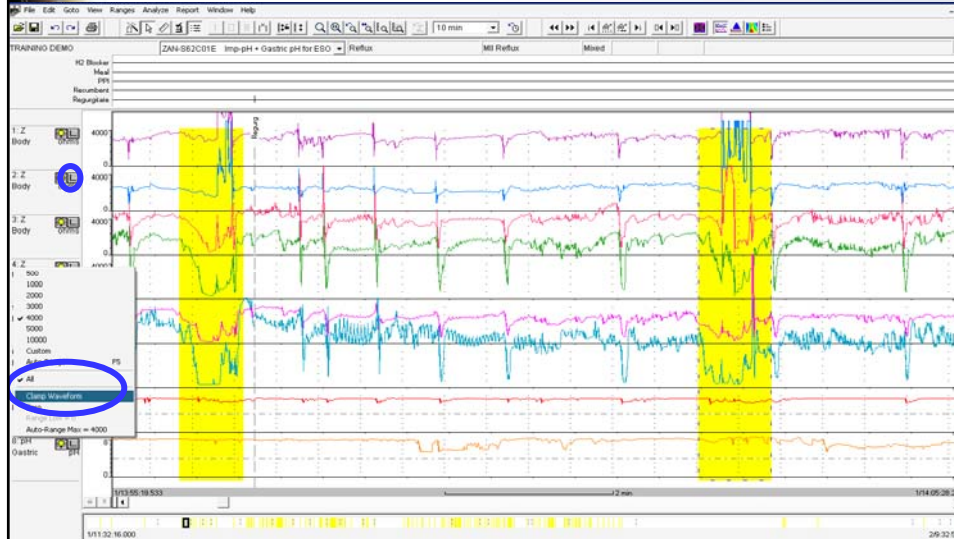


# Impedance Waveform "Range" Function The clamp function



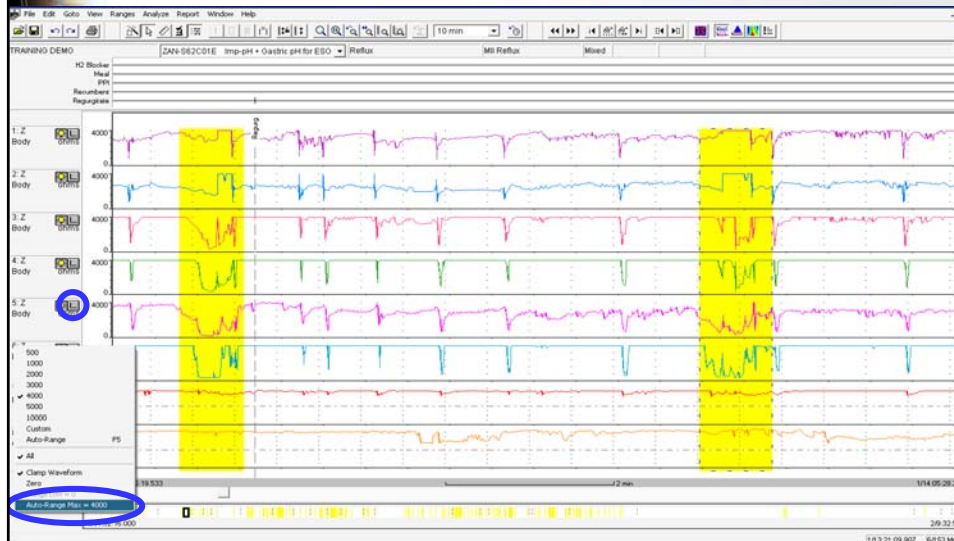
# Impedance Waveform "Range" Function

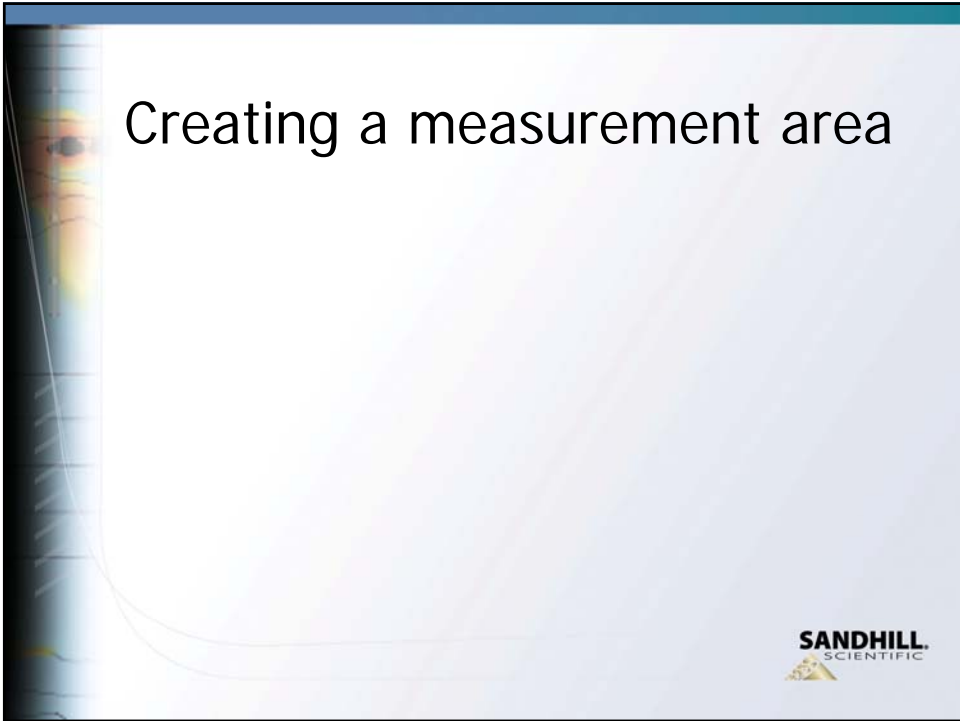
## The clamp function

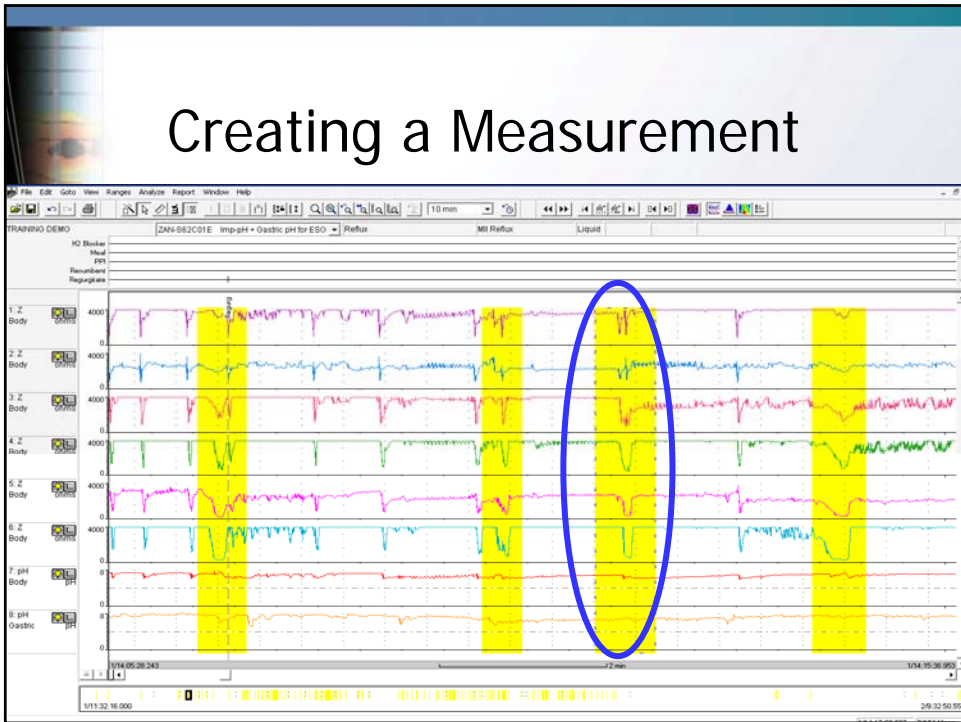
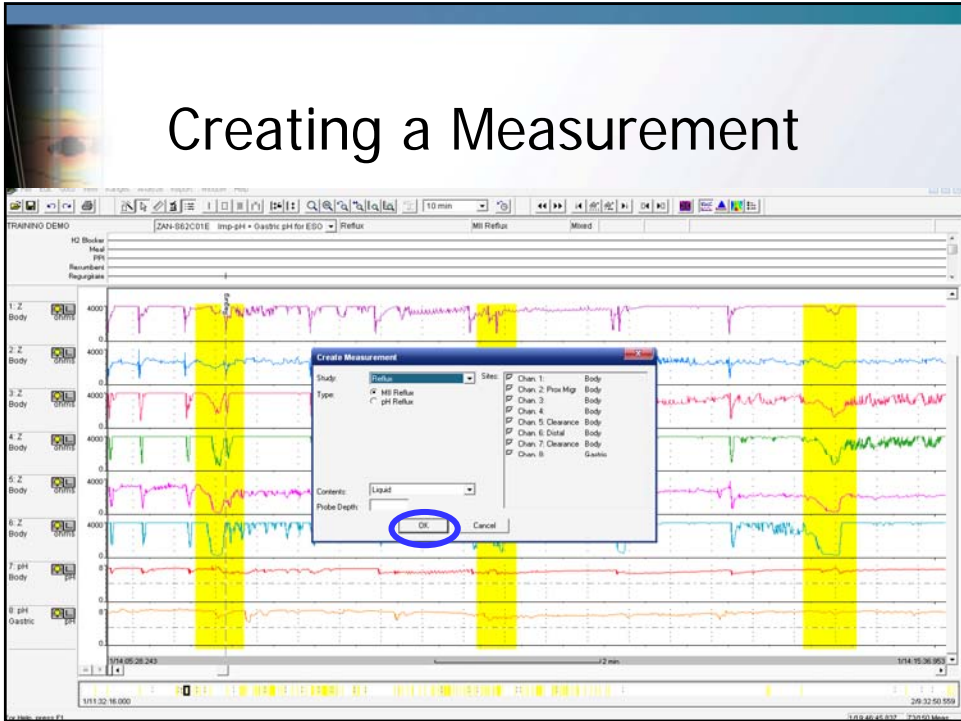


# Impedance Waveform "Range" Function

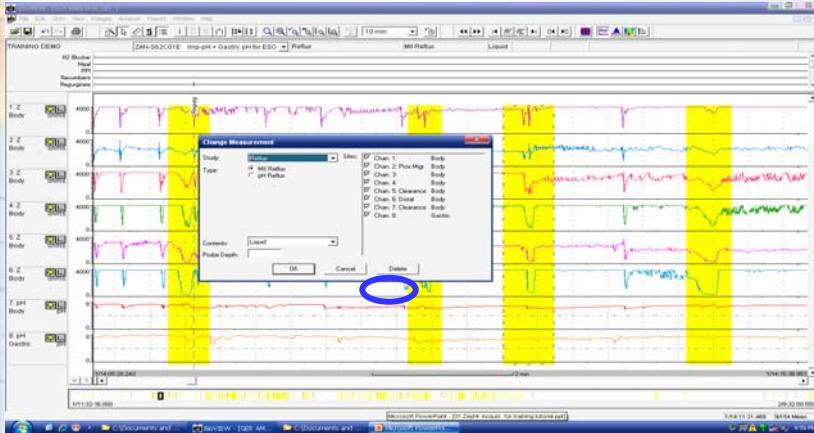
## The clamp function





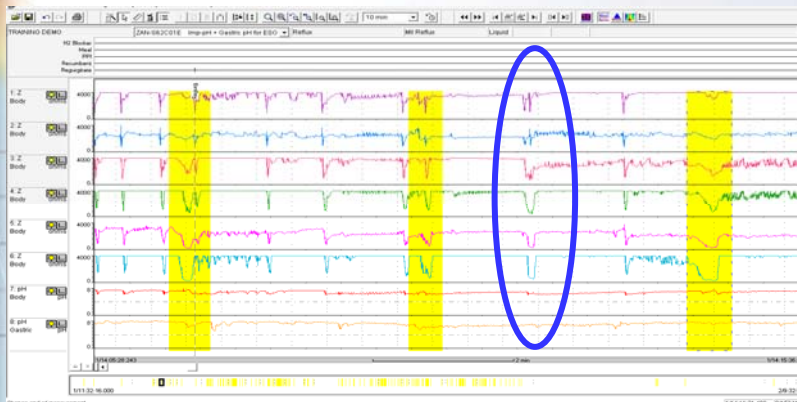


# Deleting a measurement



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# Deleting a measurement



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# Analysis Marks

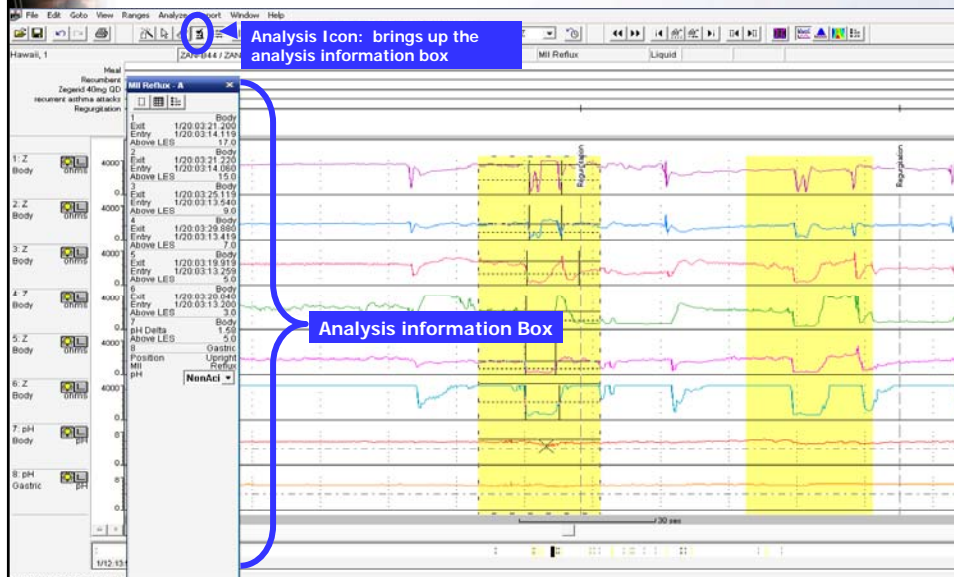
The analysis marks in a measurement do not usually need to be changed.

If changes are made they are usually:

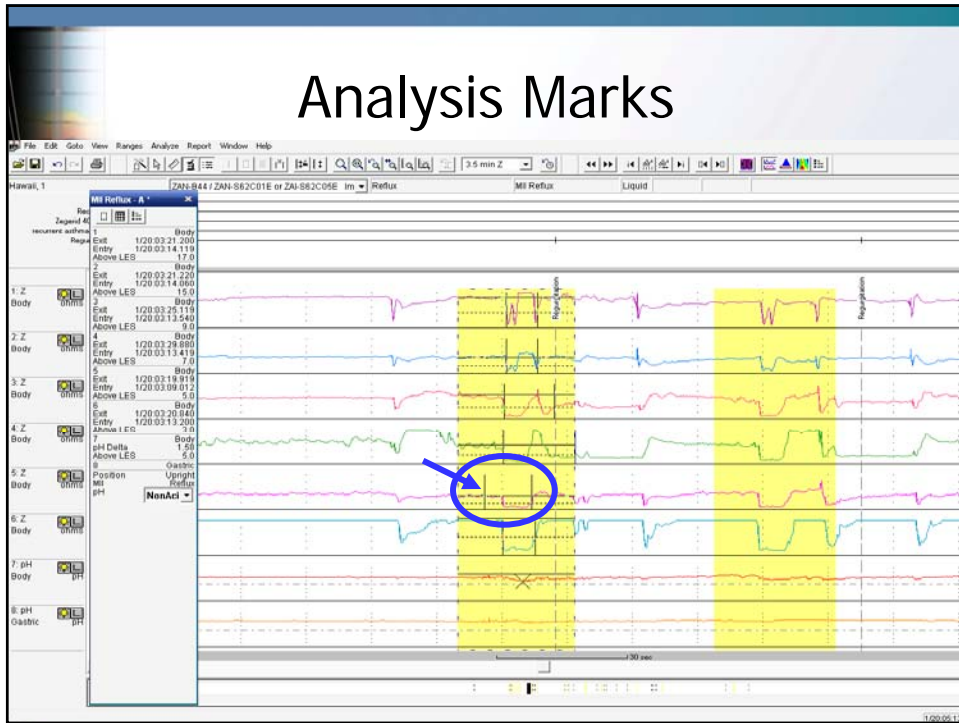
- moving entry or exit marks
- adding entry or exit marks



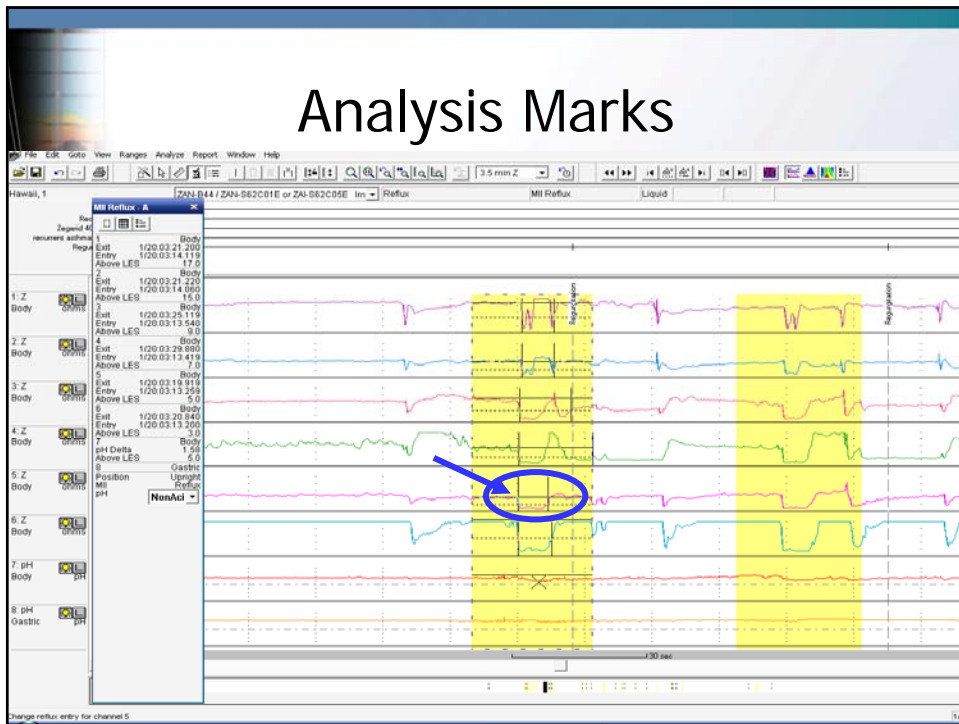
# Analysis Marks



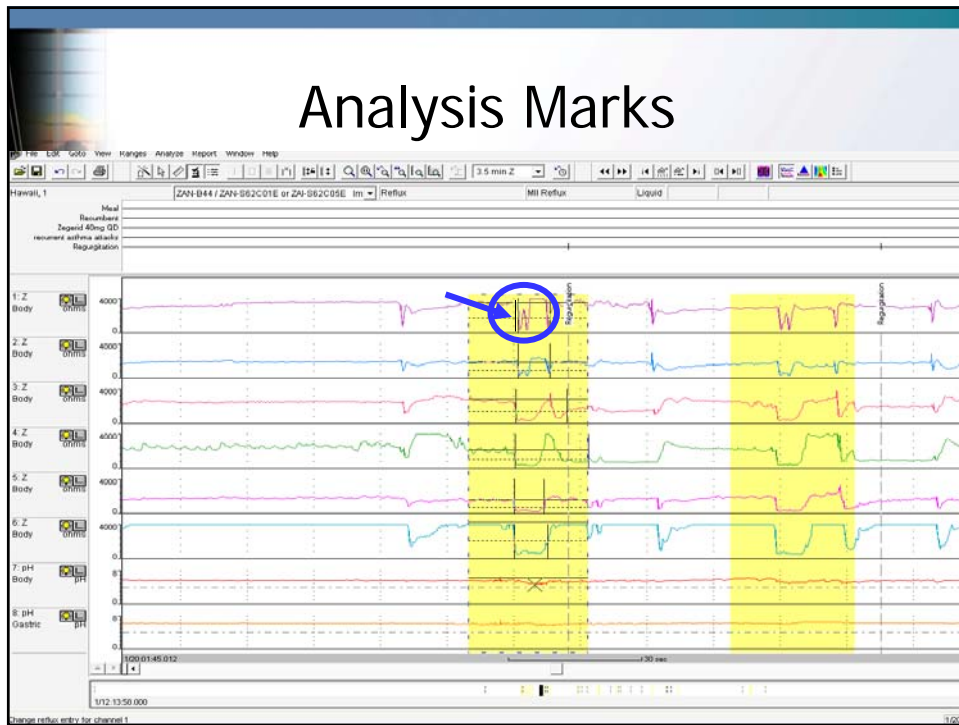
# Analysis Marks



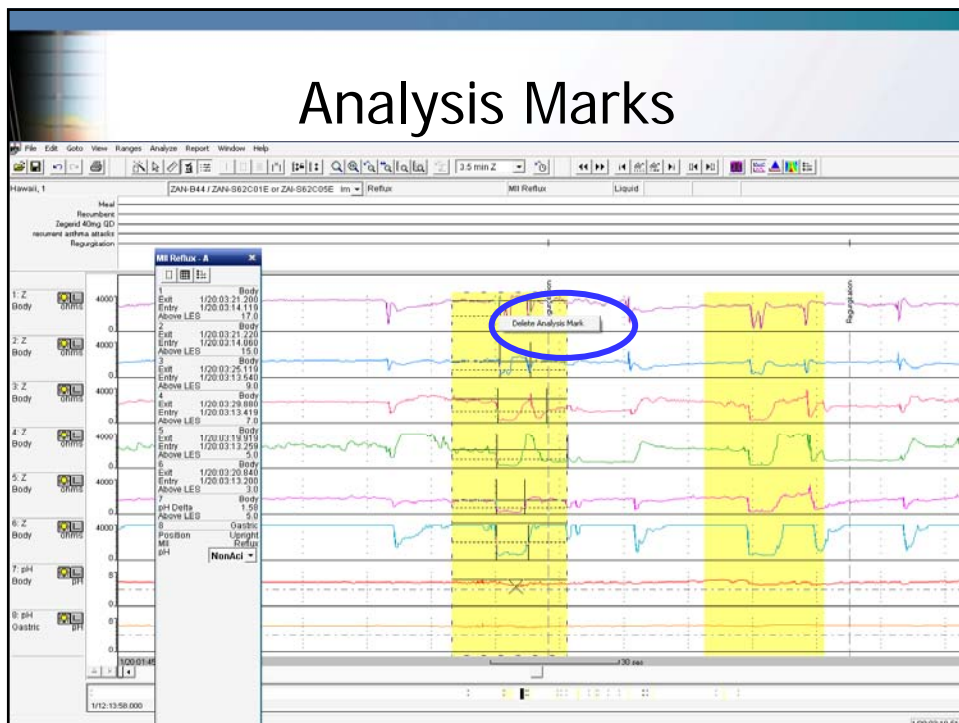
# Analysis Marks



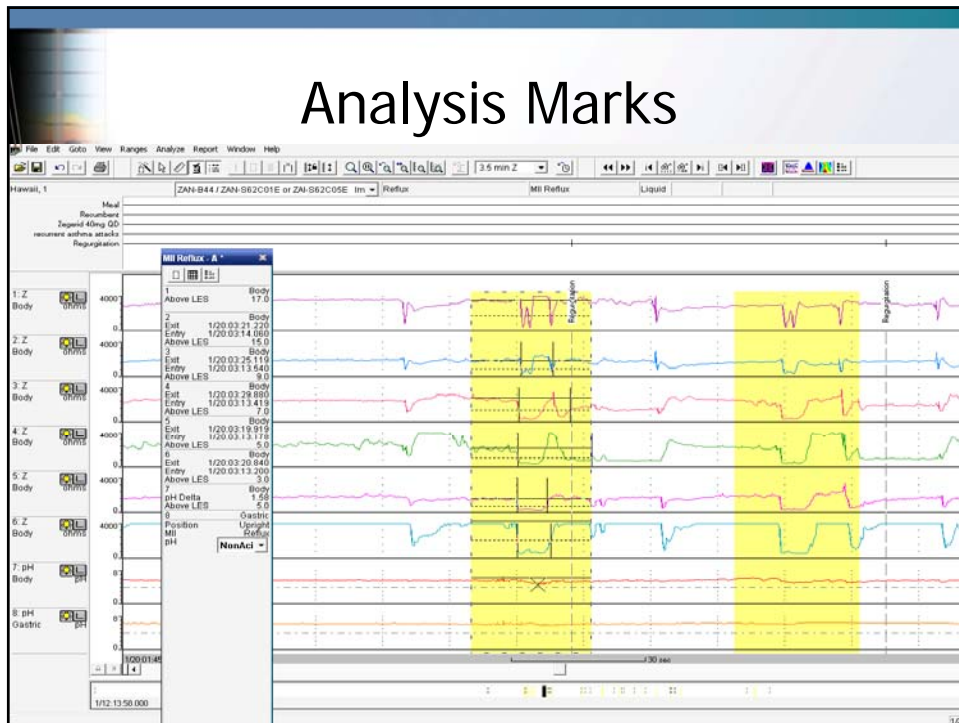
# Analysis Marks



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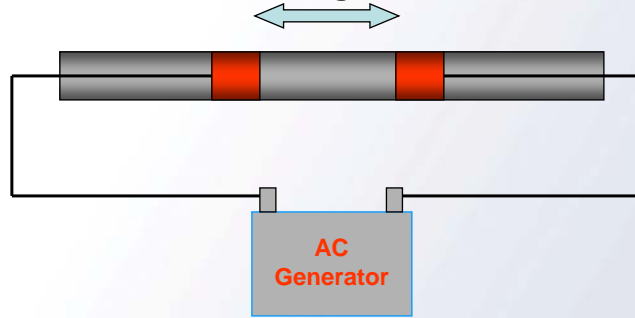


## WHAT IS IMPEDANCE (Z) ?

“Opposition to Current Flow”

# The Impedance Circuit

Voltage is Applied Across the Impedance Ring Set

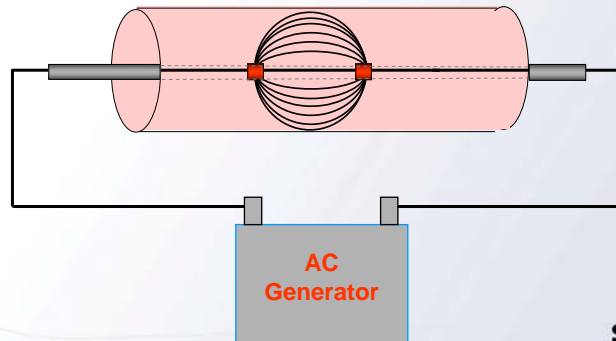


The Impedance-pH probe has 6 Impedance Ring Sets.  
Multiple Intraluminal Impedance = MII



# The Impedance Circuit

Intraluminal Ions Support the Current Flow:  
The ohms will drop (no resistance)

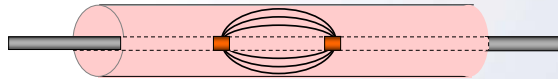


Note: ohms = the measurement for impedance

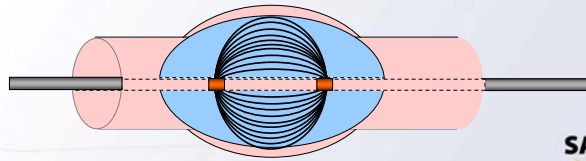


## WHY DOES THE IMPEDANCE WAVEFORM CHANGE?

**No bolus = high impedance** (No decrease in ohms)

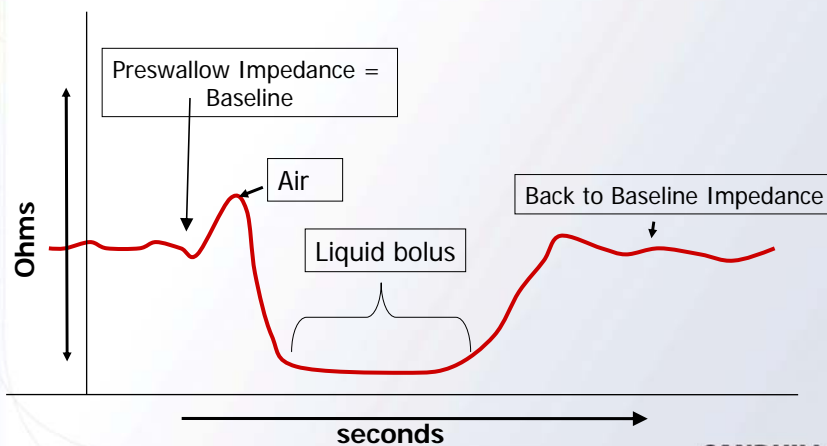


**Bolus present = low impedance** (ohms decrease)



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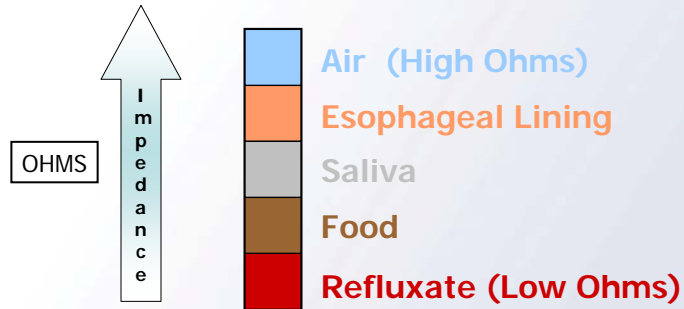
## Intraluminal Impedance



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# Impedance Range

Low Conductivity = High Impedance



High Conductivity = Low Impedance



MII=Multi Intra-luminal Impedance:  
MII will show direction of bolus movement

