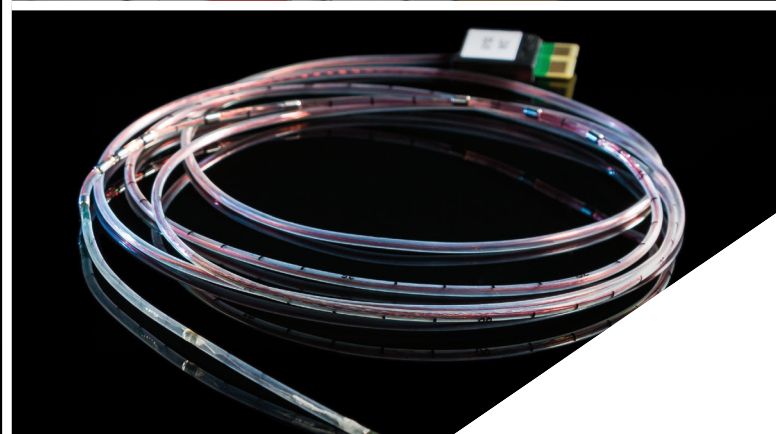
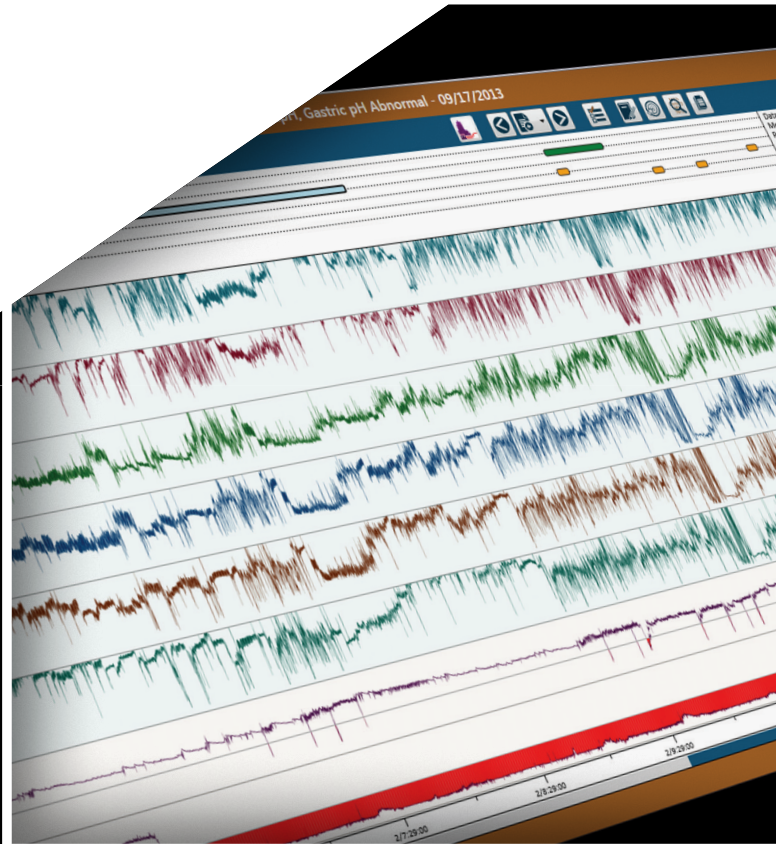


ZepHr® Guide

Reflux Analysis Guide



ZepHr®

Diversatek™
Healthcare

Table of Contents

- Select a Study
- Review and Correct Annotations
- Run AutoSCAN
- Review Study
- Create Report
- Help



Select a Study



Double click on the Zvu icon to open the Zvu® application.

The screenshot shows the 'Patient Management' window. On the left is a sidebar with a search bar and a list of patients. The main area displays patient details for 'Z/1pH' and a list of studies. The 'Z/pH 01' study is selected, showing its workflow, visit ID, facility, and other details. At the bottom right, the 'Save' button is highlighted with a red box.

Open the Study in **Patient Management**. Review and correct patient information as needed. Click **Save**.

This screenshot is identical to the one above, showing the 'Patient Management' window with the 'Z/pH 01' study selected. In this version, the 'Review Study' button at the bottom right is highlighted with a red box.

Once all corrections have been saved, the **Review Study** button will become active. Click **Review Study** to open the study.

Select a Study

Stacked View (Default View)

The study data will open in a Stacked View with all impedance waveforms stacked together and the pH separated above or below the impedance sensors.

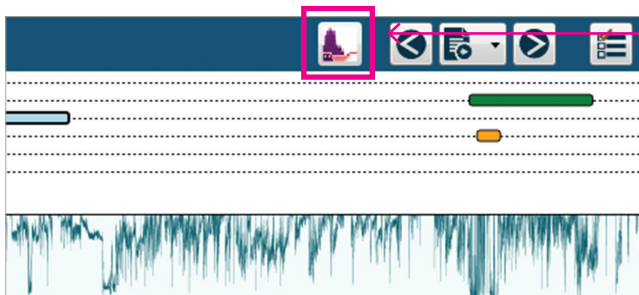
The impedance area (Z channels) are lightly shaded in green and the pH channel(s) are lightly shaded in pink. Additionally the pH channels are filled in red at any point the pH drops below a value of 4.0.



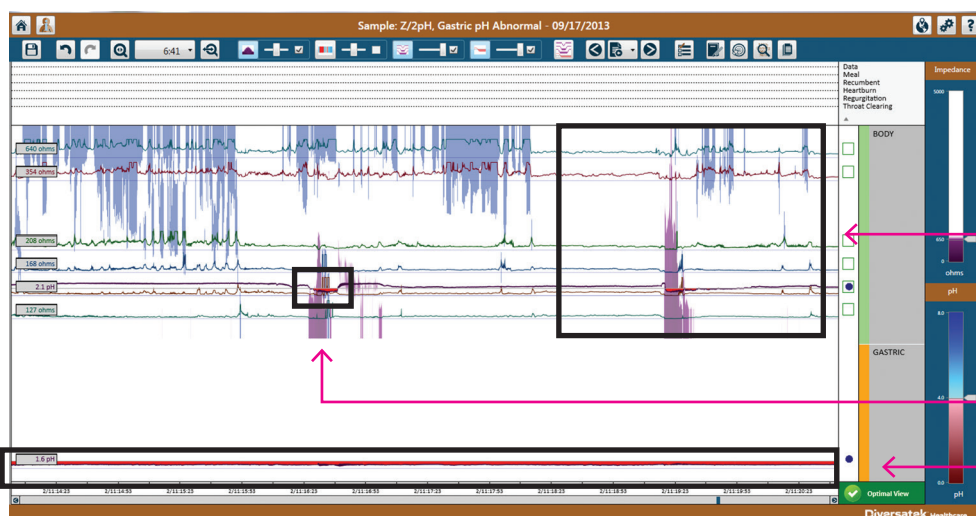
The Annotation Area located above the waveform data displays any annotations the patient has recorded during the study.

Select a Study

Fit To Probe View



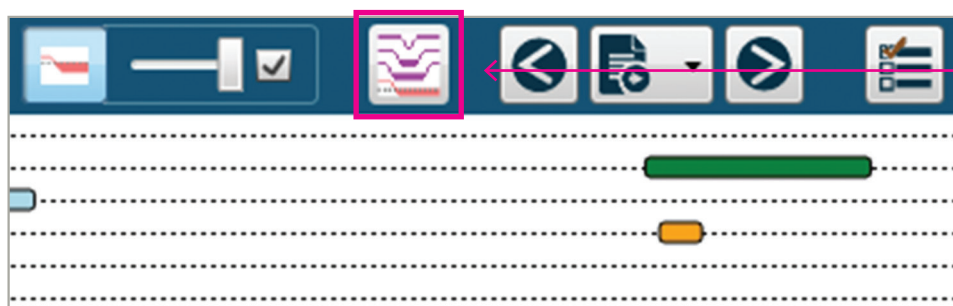
Change Data View to **Fit To Probe** View if desired. This view shows the waveforms as they appear spaced within the body. The impedance contour view is active with the purple color showing low impedance. The pH will display as waveforms filled with red where the pH value is below 4.0.



Impedance

Distal esophageal pH


Gastric pH



Change **Data View** to Stacked View if desired.

Review and Correct Annotations

Click the **Diary Editor** Button.



Diary Editor

Diary Editor

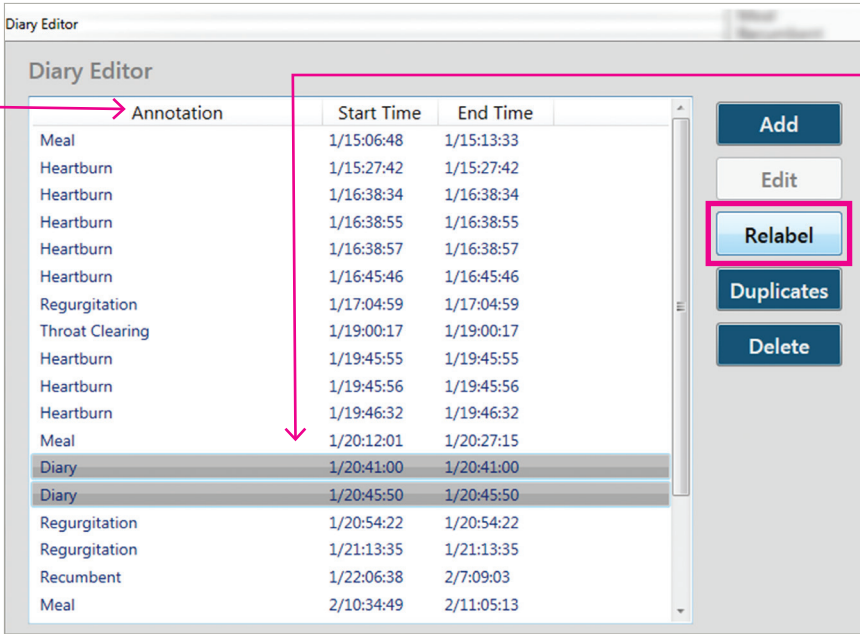
Annotation	Start Time	End Time
Meal	1/15:06:48	1/15:13:33
Heartburn	1/15:27:42	1/15:27:42
Heartburn	1/16:38:34	1/16:38:34
Heartburn	1/16:45:46	1/16:45:46
Regurgitation	1/17:04:59	1/17:04:59
Throat Clearing	1/19:00:17	1/19:00:17
Heartburn	1/19:45:55	1/19:45:55
Meal	1/20:12:01	1/20:25:45
Regurgitation	1/20:45:58	1/20:45:58
Regurgitation	1/20:54:22	1/20:54:22
Regurgitation	1/21:13:35	1/21:13:35
Recumbent	1/22:06:38	2/8:56:08
Meal	2/10:34:49	2/11:05:13
Heartburn	2/10:39:26	2/10:39:26
Regurgitation	2/11:27:28	2/11:27:28
Regurgitation	2/11:51:29	2/11:51:29
Heartburn	2/12:22:43	2/12:22:43
Meal	2/13:05:56	2/13:10:55

Buttons: Add, Edit, Relabel, Duplicates, Delete

Close

All annotations can be corrected within the **Diary Editor**.

Relabel any Diary annotations as indicated in the patient's diary.



Diary Editor

Diary Editor

Annotation	Start Time	End Time
Meal	1/15:06:48	1/15:13:33
Heartburn	1/15:27:42	1/15:27:42
Heartburn	1/16:38:34	1/16:38:34
Heartburn	1/16:38:55	1/16:38:55
Heartburn	1/16:38:57	1/16:38:57
Heartburn	1/16:45:46	1/16:45:46
Regurgitation	1/17:04:59	1/17:04:59
Throat Clearing	1/19:00:17	1/19:00:17
Heartburn	1/19:45:55	1/19:45:55
Heartburn	1/19:45:56	1/19:45:56
Heartburn	1/19:46:32	1/19:46:32
Meal	1/20:12:01	1/20:27:15
Diary	1/20:41:00	1/20:41:00
Diary	1/20:45:50	1/20:45:50
Regurgitation	1/20:54:22	1/20:54:22
Regurgitation	1/21:13:35	1/21:13:35
Recumbent	1/22:06:38	2/7:09:03
Meal	2/10:34:49	2/11:05:13

Buttons: Add, Edit, Relabel, Duplicates, Delete

Click to highlight the Diary annotation to be changed. Verify the time of the Diary annotation with the patient diary.

Click **Relabel**.

Note: To group all like annotations together, click **Annotation** at the top of the column to sort alphabetically.

*Note: If multiple diary annotations are to be relabeled to the same annotation text, then click the first Diary annotation and shift-click the last Diary annotation to select all diaries. Relabel as above and all Diary annotations will be relabeled.

Review and Correct Annotations

Example: Diaries relabeled to Cough.

Diary Editor

Diary Editor

Annotation	Start Time	End Time
Meal	1/15:06:48	1/15:13:33
Heartburn	1/15:27:42	1/15:27:42
Heartburn	1/16:38:34	1/16:38:34
Heartburn	1/16:38:55	1/16:38:55
Heartburn	1/16:38:57	1/16:38:57
Heartburn	1/16:45:46	1/16:45:46
Regurgitation	1/17:04:59	1/17:04:59
Throat Clearing	1/19:00:17	1/19:00:17
Heartburn	1/19:45:55	1/19:45:55
Heartburn	1/19:45:56	1/19:45:56
Heartburn	1/19:46:32	1/19:46:32
Nausea	1/19:46:32	1/19:46:32
Nausea	1/19:47:00	1/19:47:00
Meal	1/20:12:01	1/20:25:45
Cough	1/20:41:00	1/20:41:00
Cough	1/20:45:50	1/20:45:50
Gag	1/20:45:50	1/20:45:50
Regurgitation	1/20:45:58	1/20:45:58
Regurgitation	1/20:54:22	1/20:54:22
Regurgitation	1/21:13:35	1/21:13:35
Recumbent	1/22:06:38	2/8:56:08
Meal	2/10:34:49	2/11:05:13

Add

Edit

Relabel

Duplicates

Delete

Close

Add Annotation

Abdominal Pain

Arching

Asthma

Belch

Bloating

Bradycardia

Chest Pain

Comment

Cough

Crying

Custom Symptom

Desaturation

Start Day:

1

Start Time (hh:mm:ss):

19:47:02

Add

Done

To add annotations from the patient's diary, click **Add**. Select the desired annotation. For symptoms, enter the Start Time by day, hour and minute using a 24 hour time format.

Review and Correct Annotations

Add Annotation

Annotation added successfully.

- Abdominal Pain
- Arching
- Asthma
- Belch
- Bloating
- Bradycardia
- Chest Pain
- Comment
- Cough
- Crying
- Custom Symptom
- Desaturation

Start Day: 1

Start Time (hh:mm:ss): 18:17:02

Add Done

Multiple annotations can be added without leaving the screen. A message will appear to indicate if the annotation was added successfully.

When all annotations have been added, click **Done**.

Add Annotation

- Laryngospasm
- Meal
- Nausea
- Pain
- PPI
- Probe Depth
- Recumbent
- Regurgitation
- Sore Throat
- Sour Taste
- Spitting
- Swallow - Liquid

Start Day: 1 End Day: 2

Start Time (hh:mm:ss): 23:13:01 End Time (hh:mm:ss): 05:17:54

Add Done

Add Annotation

- Hoarseness
- Laryngospasm
- Meal
- Nausea
- Pain
- PPI
- Probe Depth
- Recumbent
- Regurgitation
- Sore Throat
- Sour Taste
- Spitting

Start Day: 1 End Day: 1

Start Time (hh:mm:ss): 18:17:02 End Time (hh:mm:ss): 18:29:34

Add Done

Add Recumbent and Meal periods if needed using a 24 hour time format. Enter both a **Start Time** and an **End Time**.

Review and Correct Annotations

Diary Editor

Diary Editor

Annotation	Start Time	End Time
Meal	1/15:06:48	1/15:13:33
Heartburn	1/15:27:42	1/15:27:42
Heartburn	1/16:38:34	1/16:38:34
Heartburn	1/16:38:55	1/16:38:55
Heartburn	1/16:38:57	1/16:38:57
Heartburn	1/16:45:46	1/16:45:46
Regurgitation	1/17:04:59	1/17:04:59
Bloating	1/18:17:02	1/18:17:02
Throat Clearing	1/19:00:17	1/19:00:17
Heartburn	1/19:45:55	1/19:45:55
Heartburn	1/19:45:56	1/19:45:56
Heartburn	1/19:46:32	1/19:46:32
Nausea	1/19:46:32	1/19:46:32
Nausea	1/19:47:00	1/19:47:00
Meal	1/20:12:01	1/20:25:45
Cough	1/20:41:00	1/20:41:00
Cough	1/20:45:50	1/20:45:50
Gag	1/20:45:50	1/20:45:50
Regurgitation	1/20:45:58	1/20:45:58
Regurgitation	1/20:54:22	1/20:54:22
Regurgitation	1/21:13:35	1/21:13:35
Recumbent	1/22:06:38	2/8:56:08

Close

Add

Edit

Relabel

Duplicates

Delete

To delete all duplicate annotations, click **Duplicates** and the Diary Editor will highlight any like symptoms occurring within 2 minutes. Click **Delete**. All highlighted symptoms will be deleted.

*Note: if deleting only specific duplicates, this must be done individually by highlighting an annotation and clicking **Delete**.

Diary Editor

Diary Editor

Annotation	Start Time	End Time
Meal	1/15:06:48	1/15:13:33
Heartburn	1/15:27:42	1/15:27:42
Heartburn	1/16:38:34	1/16:38:34
Heartburn	1/16:38:55	1/16:38:55
Heartburn	1/16:38:57	1/16:38:57
Heartburn	1/16:45:46	1/16:45:46
Regurgitation	1/17:04:59	1/17:04:59
Bloating	1/18:17:02	1/18:17:02
Throat Clearing	1/19:00:17	1/19:00:17
Heartburn	1/19:45:55	1/19:45:55
Heartburn	1/19:45:56	1/19:45:56

Close

Add

Edit

Relabel

Duplicates

Delete

Delete Confirmation

Are you sure you want to delete these annotations?

Yes

No

Delete any individual unwanted annotations. Example: Practice annotations done during patient teaching. Highlight the desired annotation and click **Delete**.

To delete several annotations in a row, Shift-Click on the first and last annotation to be removed and select **Delete**.

Whenever deleting an annotation, a **Delete Confirmation** dialog box will confirm.

When all annotation changes have been done, click Close to exit the Diary Editor.

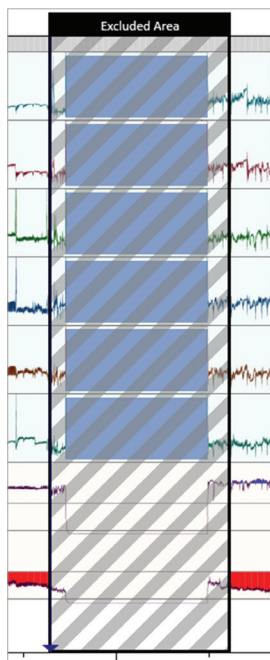
Review and Correct Annotations

Exclude artifact.

Click and drag



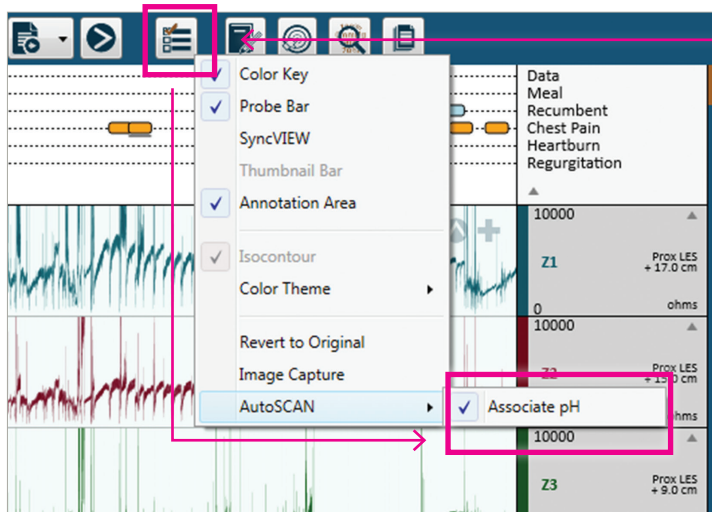
If artifact such as waveform flattening with a probe disconnect is seen in the data display area, this area can be excluded (hidden) from analysis. Right click on the tracing. Select **Add Excluded Area**. Click and drag left to right across the area of artifact.



The **Excluded Area** will appear as a diagonal hash mark box over the data. The recorded data are not erased but will be ignored during analysis including any annotations the patient recorded.

Run AutoSCAN

Change pH association if desired.

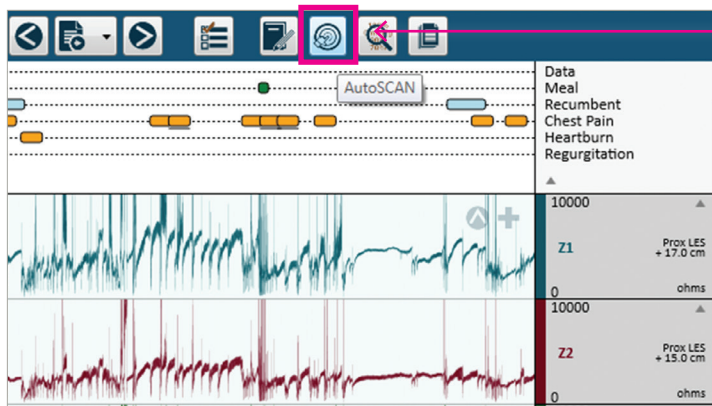


AutoSCAN will analyze a drop in the pH when associated with an impedance-identified reflux episode by default in all but infant studies.

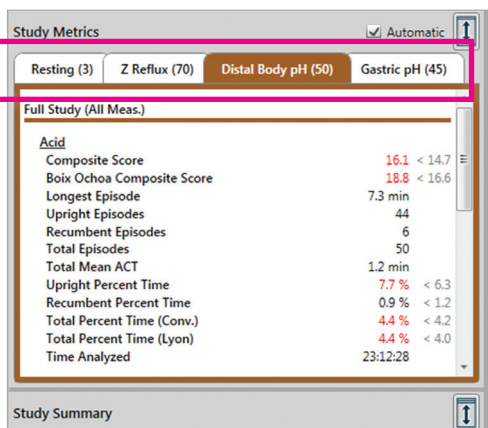
To change this feature, click the **Options** button. Hover or click on **AutoSCAN**. Select or deselect **Associate pH** as desired.

In infant studies, all drops in pH below 4 will be analyzed regardless of changes in impedance.

Run AutoSCAN.



Click the **AutoSCAN** button on the toolbar. **AutoSCAN** scans through the study identifying and measuring retrograde bolus movement utilizing the impedance data, and creating Z reflux measurements. When **Associate pH** is selected, a pH reflux measurement will be created only if impedance identifies reflux in the same time period, and the pH is below 4.0 for at least 5 seconds. If **Associate pH** is not selected, all pH below a value of 4.0 for at least 5 seconds will be measured.



When **AutoSCAN** is complete, measurement boxes will be created wherever reflux is found. The **Study Metrics** tabs will indicate the type and number of impedance and pH measurements identified in the study period. Impedance and esophageal pH data are not analyzed under meal periods by default.

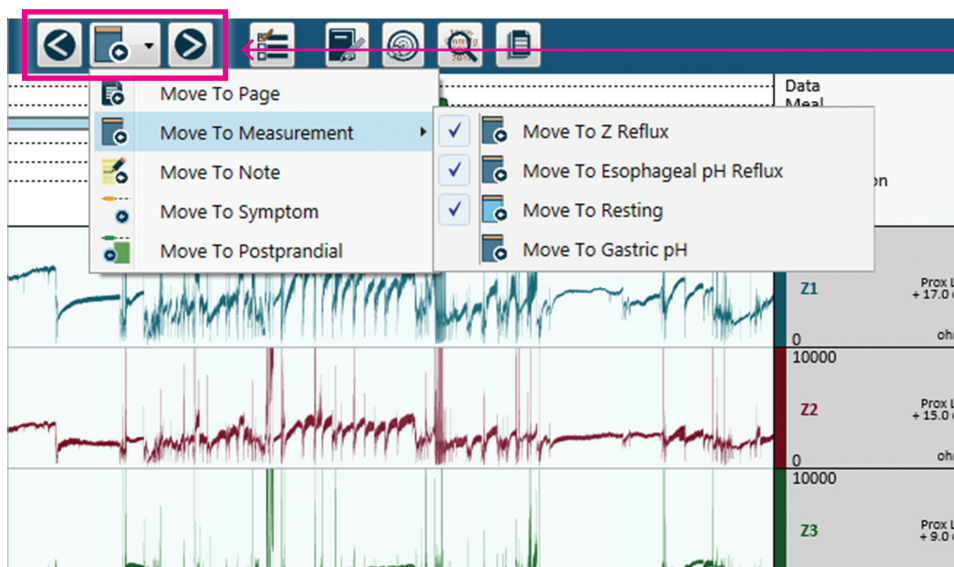
Review Study

Select the desired time scale.



Click the down arrow next to the time scale and select the desired time window.

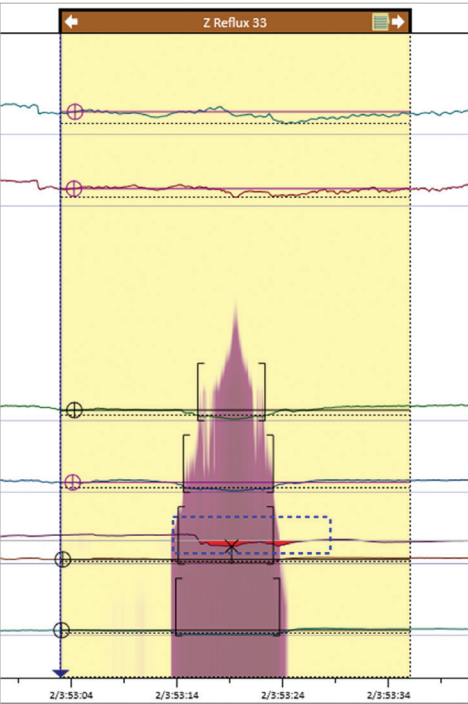
Select the desired method to navigate through the study.



Click the down arrow for the **Move To** button and select the desired method for review. The forward and backward arrows will navigate as selected.

Review Study

Acid Reflux Example



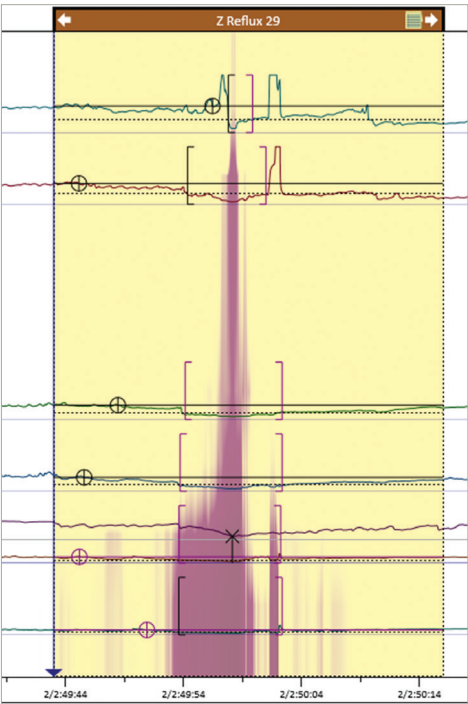
Fit-to-Probe View



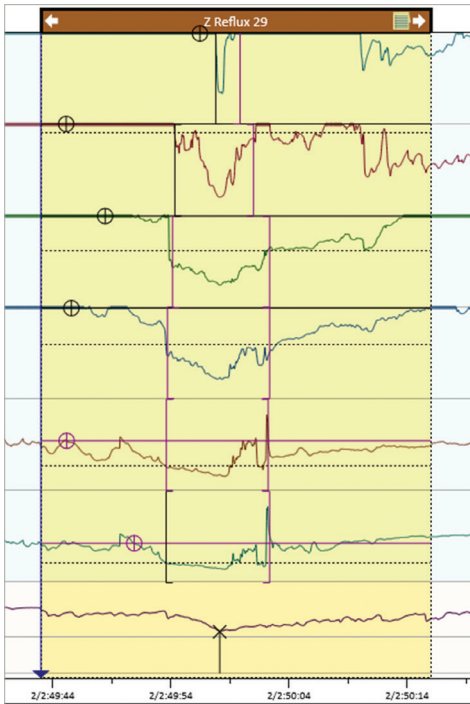
Stacked View

Retrograde bolus movement identified by impedance is qualified as an acid reflux episode if the distal esophageal pH drops below 4.0 concurrently.

Nonacid Reflux Example



Fit-to-Probe View

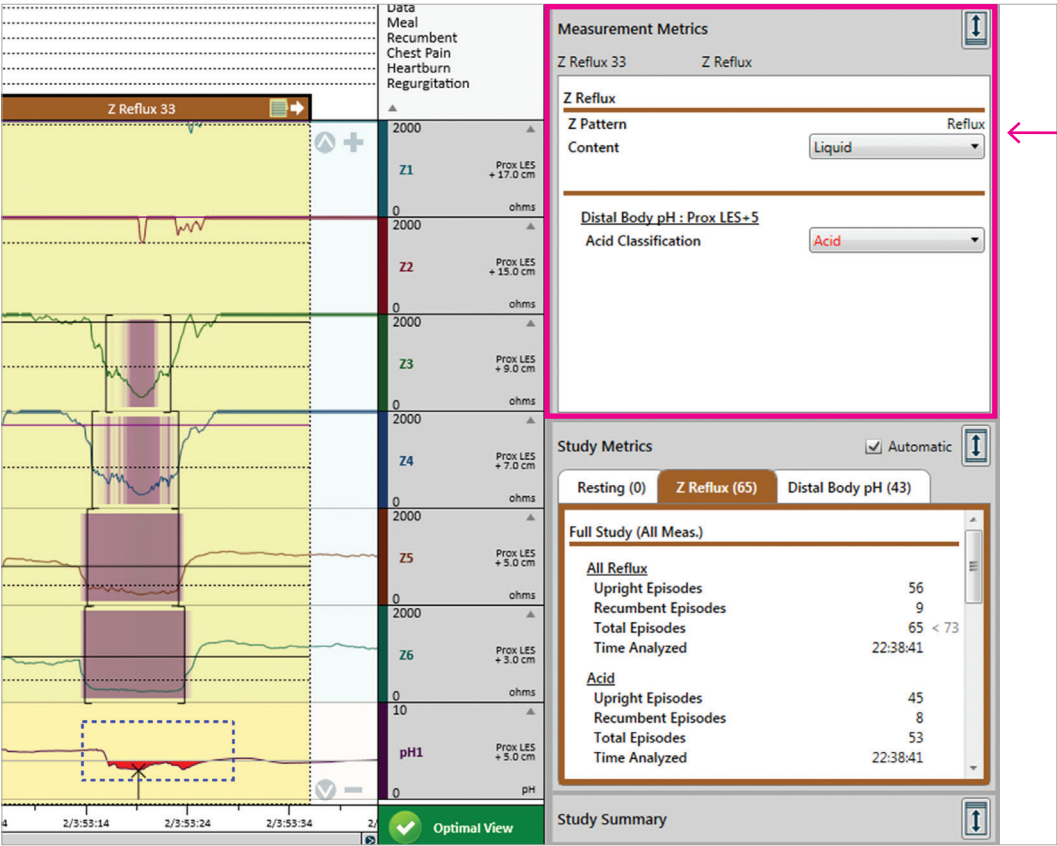


Stacked View

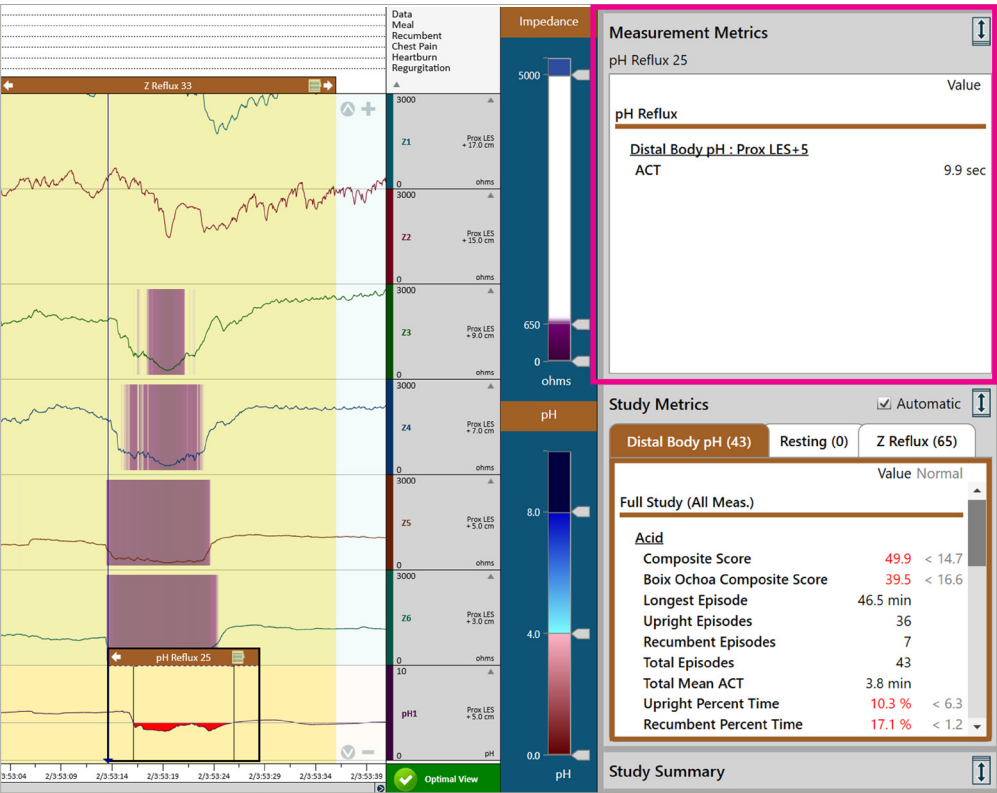
Retrograde bolus movement identified by impedance is qualified as a nonacid reflux episode if the distal esophageal pH remains above 4.0.

Review Study

Review reflux measurement data.

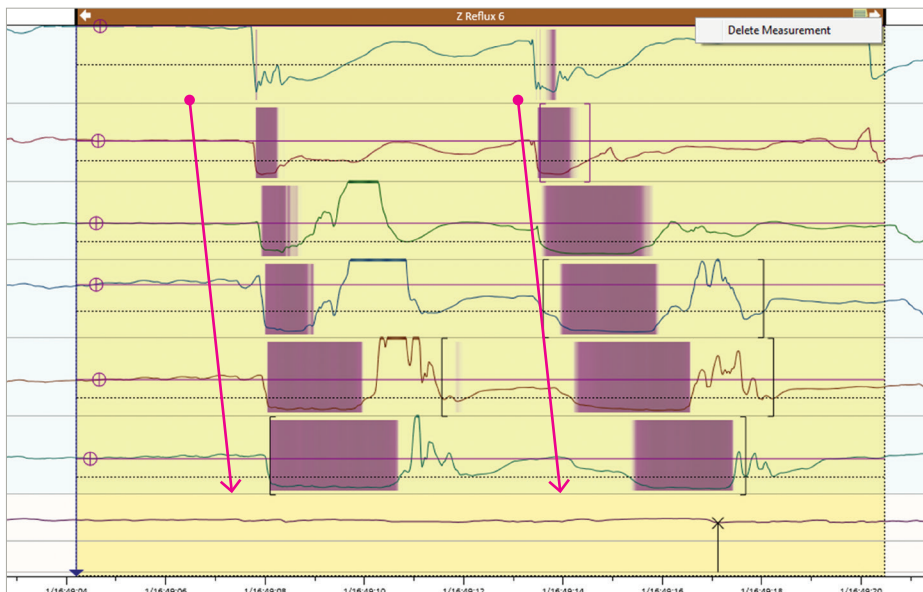


Review measurement data as needed in the **Measurement Metrics** section.



Review Study

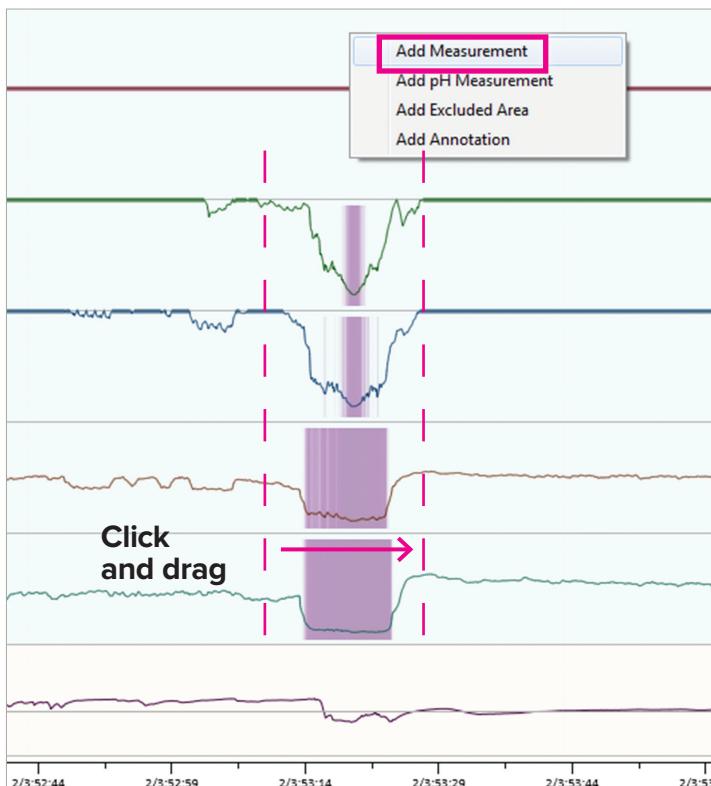
Delete false positives.



Delete any measurements where reflux is not true. Right click on the measurement title bar and select **Delete Measurement**.

Multiple Swallows

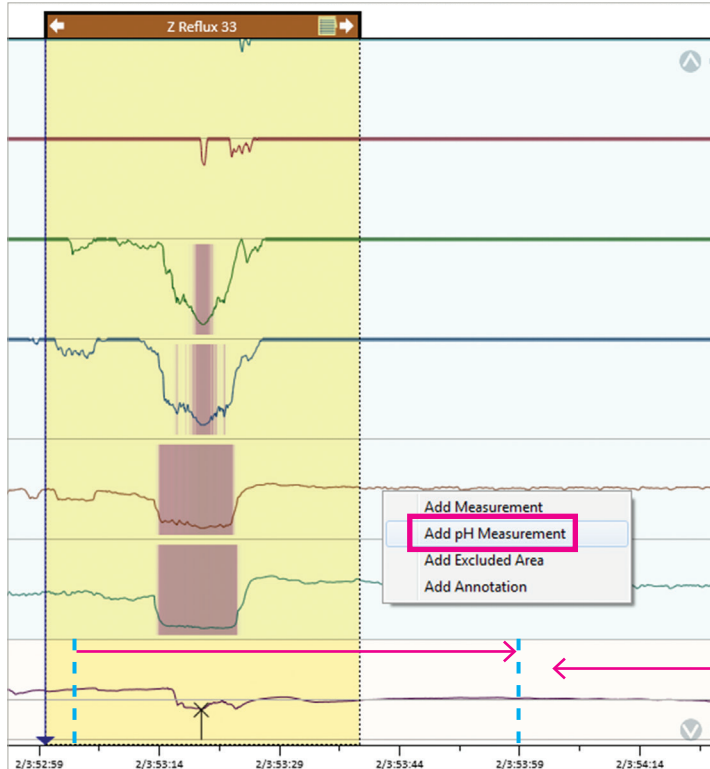
Manually add Impedance Reflux Measurement.



For reflux episodes identified by the user but not marked by AutoSCAN, right click on the tracing and select **Add Measurement**. Click and drag left to right across the identified reflux episode. Make sure to include at least 3 seconds before and 5 seconds after the reflux episode.

Review Study

Manually add pH Measurement.

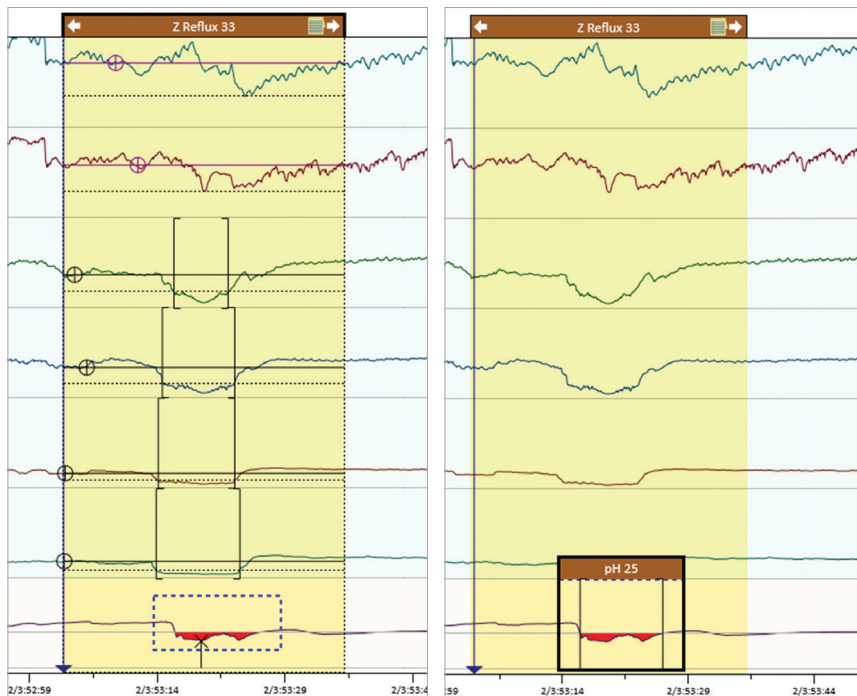


For any added Z reflux measurements with a pH below 4.0 for at least 5 seconds, a separate pH measurement must be created. Right click on the tracing and select **Add pH Measurement**.

Click and drag left to right across the desired pH waveform where acid reflux is seen. Make sure to include at least 3 seconds before and 5 seconds after the acid episode.

Only pH drops below 4.0 for at least 5 seconds will show a value in the Metrics and be reported in the Acid Exposure section of the report.

Below is the corrected measurement.



Z Reflux Measurement Active pH Reflux Measurement Active

Review the complete study adding and deleting measurements if needed.

Review methods:

- Page by Page
- Symptom by Symptom

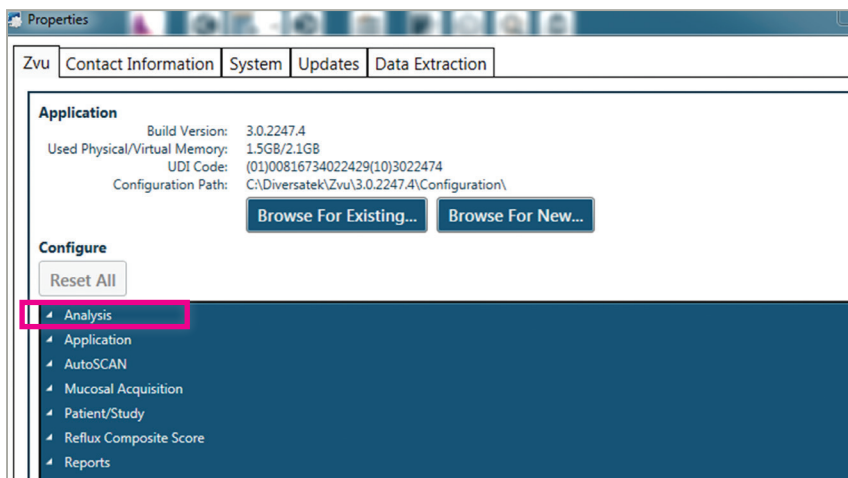
To activate the pH reflux measurement for review, click within its dashed blue lines.

Review Study

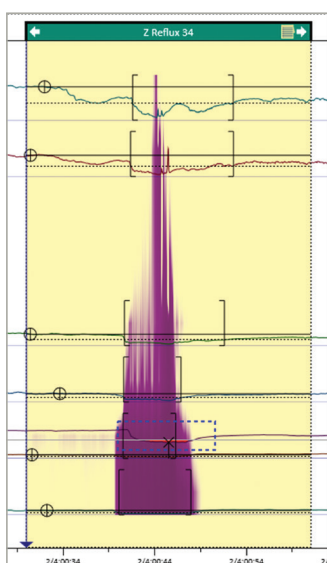
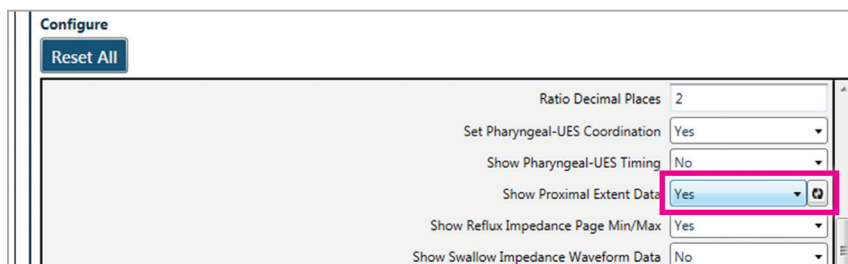
Proximal Extent when using a Standard Configuration Probe (non-LPR)



AutoSCAN can identify Proximal Reflux Episodes if this feature is enabled. Click on the **Properties** (gears) icon above the tool bar from any Zvu page.



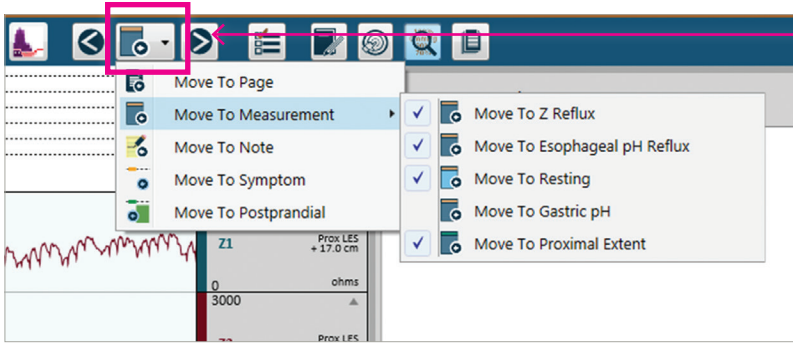
Select **Analysis**. Select Yes next to Show Proximal Extent Data. X-out of the Properties Page. Re-run **AutoSCAN** if needed. This selection will apply to all standard Z/pH study analyses.



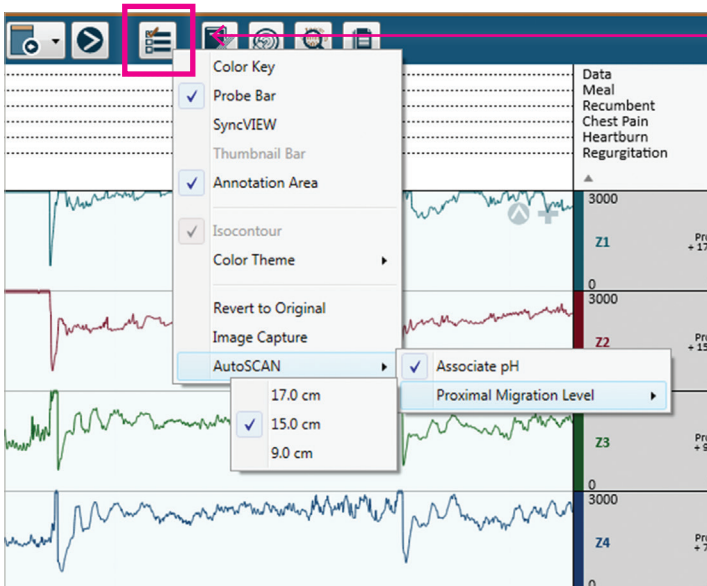
- ← Reflux height 17cm above the LES
- ← Migration level 15 cm above the LES reached

Impedance measurements in which retrograde bolus movement reached the designated proximal migration level will have a green title bar.

Review Study

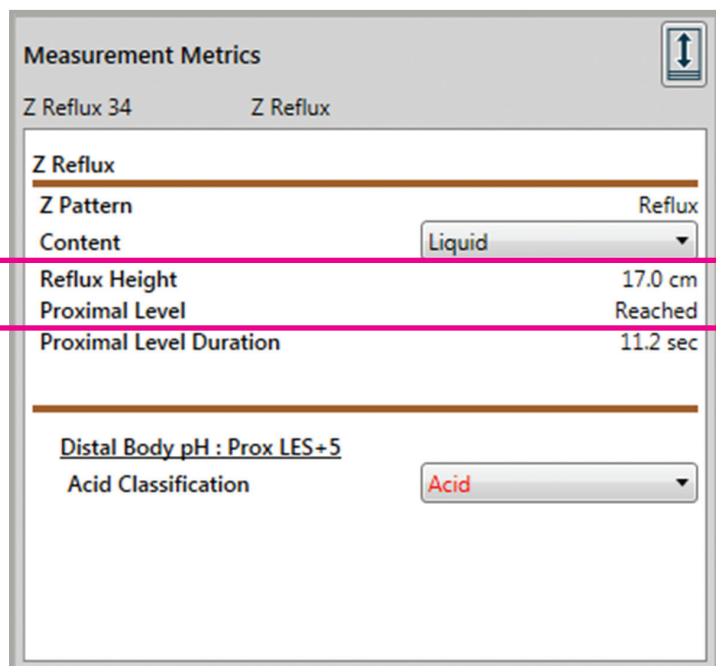


Each measurement should be checked for proximal level accuracy. The **Move To Measurement** feature can be set to Proximal Extent to aid in this review.



To change the migration level, click the Options icon, click on AutoSCAN, and then click on **Proximal Migration Level**. The default level is the height of the second impedance sensor (Z2). The migration level can be changed to the waveform above or below this default.

Review Study



Measurement Metrics

Z Reflux 34 Z Reflux

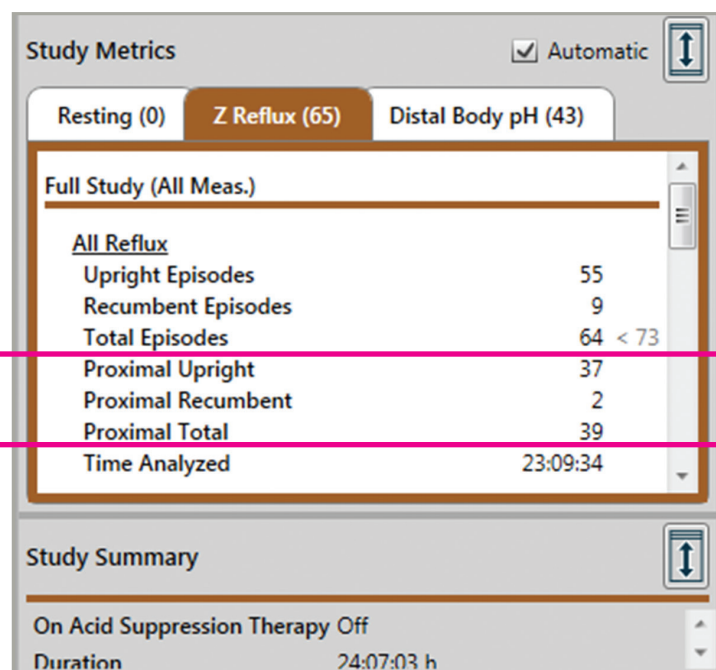
Z Reflux

Z Pattern	Reflux
Content	Liquid
Reflux Height	17.0 cm
Proximal Level	Reached
Proximal Level Duration	11.2 sec

Distal Body pH : Prox LES+5

Acid Classification	Acid
---------------------	------

The Measurement Metrics will reflect the height of the reflux episode and whether or not it reached the proximal migration threshold which will designate the reflux as a proximal episode.



Study Metrics ☒ Automatic

Resting (0) **Z Reflux (65)** Distal Body pH (43)

Full Study (All Meas.)

<u>All Reflux</u>	
Upright Episodes	55
Recumbent Episodes	9
Total Episodes	64 < 73
Proximal Upright	37
Proximal Recumbent	2
Proximal Total	39
Time Analyzed	23:09:34

Study Summary

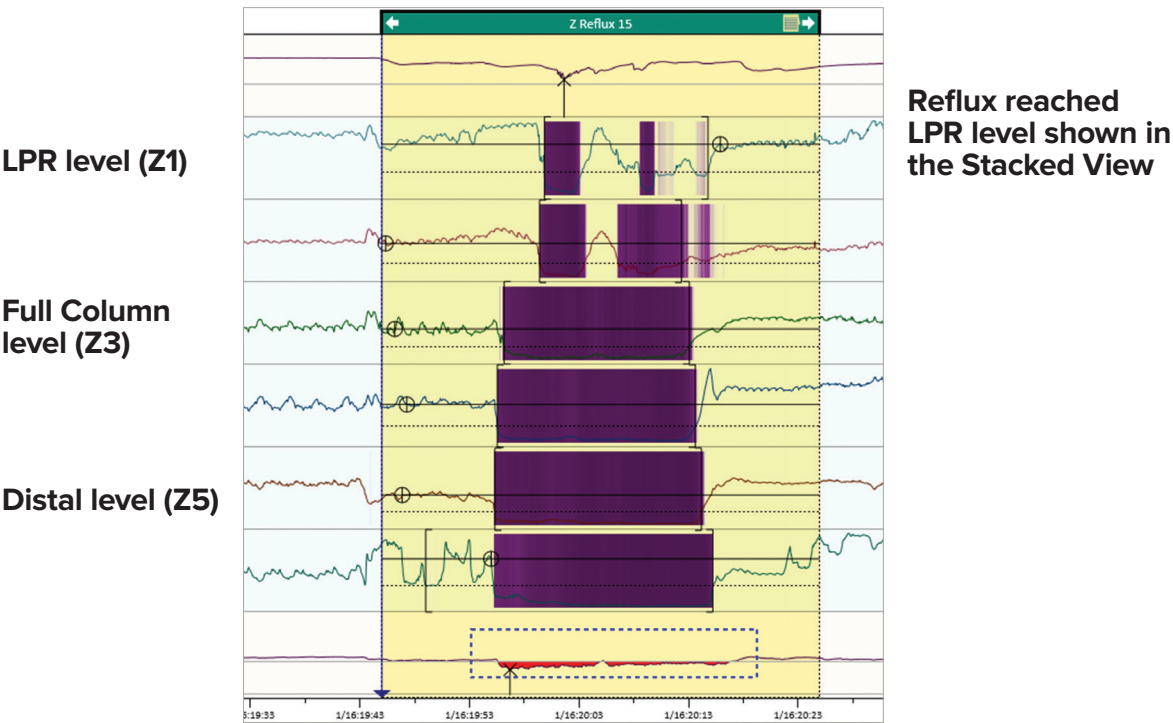
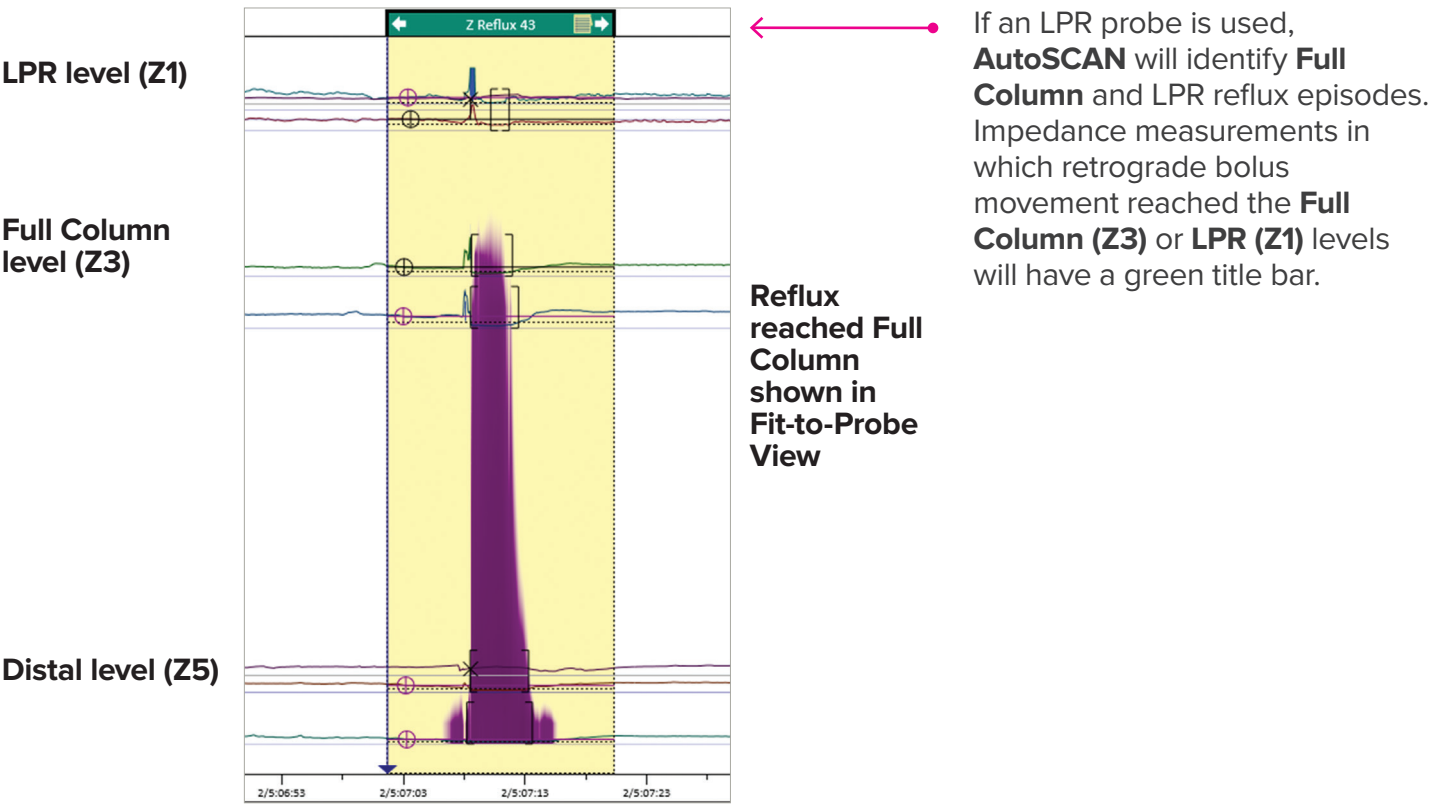
On Acid Suppression Therapy Off

Duration 24:07:03 h

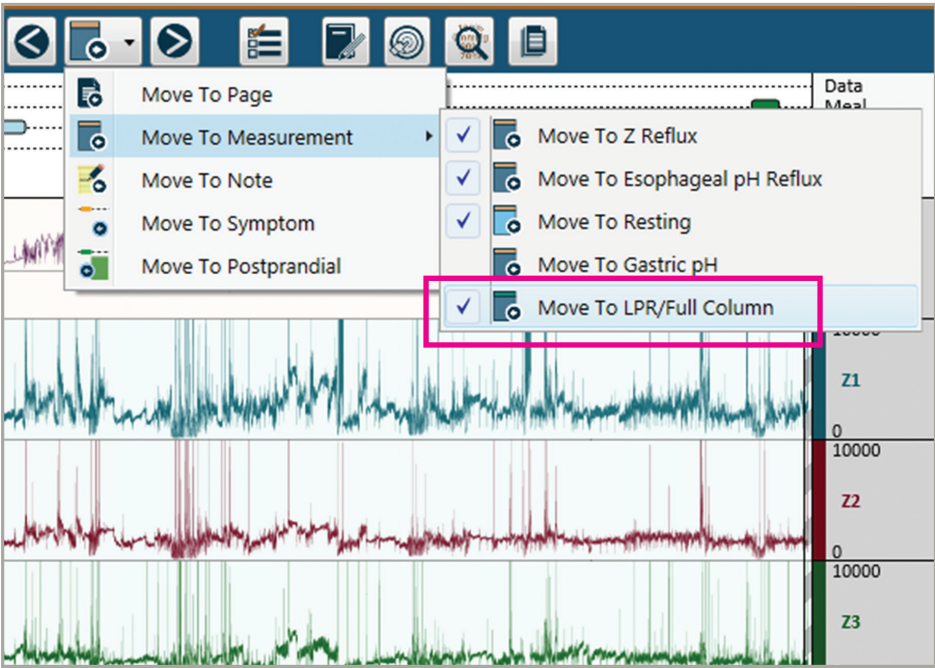
The Study Metrics and report will indicate how many episodes reached the proximal migration level.

Review Study

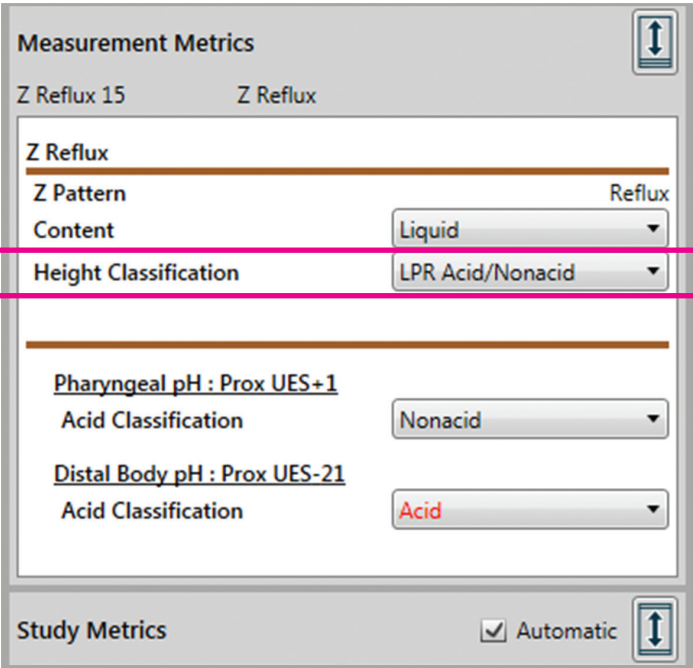
Full Column and LPR (Laryngopharyngeal Reflux) when using an LPR Probe



Review Study

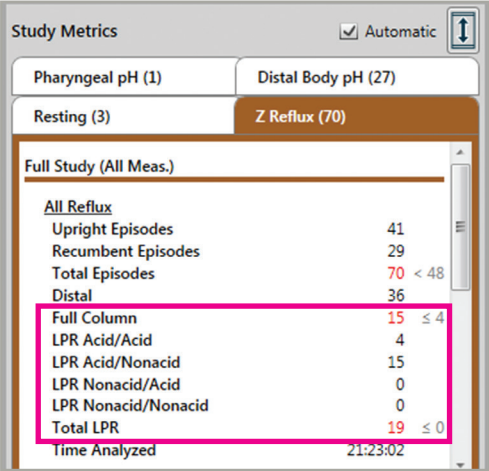


Each measurement should be checked for level accuracy. The **Move To Measurement** feature can be set to LPR/Full Column to aid in this review.



The **Measurement Metrics** will designate the level reached by the reflux episode as Distal, Full Column or LPR. If the episode reaches the LPR level, it will further be described based on the pH data. LPR Acid/Nonacid would be the label for an episode that reached the LPR level of Z1 with pH below 4.0 at the distal sensor and pH above 4.0 at the pharyngeal sensor.

Review Study



The **Study Metrics** and report will indicate the number of Full Column and LPR episodes in the study with the LPR episodes further defined by pH.

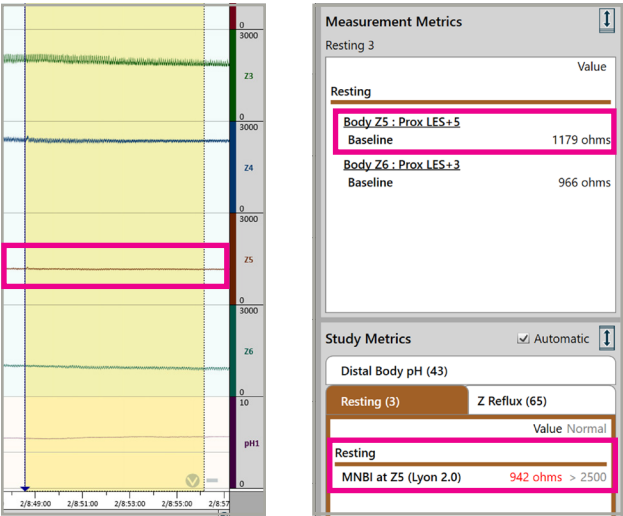
Reflux Episode Activity (Liquid Impedance)				
	Upright	Recumbent	Total	Total Normal
All Reflux (Conv.)	41	29	70	≤ 48
All Reflux (Lyon)*	41	29	70	≤ 40
Distal	20	16	36	
Full Column	9	6	15	≤ 4
Total LPR	12	7	19	≤ 0
LPR Acid/Acid	3	1	4	
LPR Acid/Nonacid	9	6	15	
LPR Nonacid/Nonacid	0	0	0	

* Pathologic > 80 supportive of diagnosis of GERD; 41-80 is borderline, needs alternate evidence for conclusive diagnosis of GERD

Symptom Correlation to Reflux (Impedance)					
Symptom	Count	Distal SI	Full Column SI	LPR SI	All Reflux SI
Cough	12	16.7 %	25.0 %	25.0 %	50.0 %

More LPR data are detailed in the report.

Mean Nocturnal Baseline Impedance (MNBI)



AutoSCAN will create three 10-minute Resting measurements around 1 A.M., 2 A.M. and 3 A.M. if the patient is marked as recumbent. The software will keep the measurement away from reflux episodes. The reviewer may need to move the measurements away from swallow activity. In each Resting measurement, the average ohms in Z5 are given as a baseline value. The three baseline values are averaged to obtain the MNBI value. The MNBI value is displayed under the Resting tab in the Study Metrics and in its own section on the report.

Average baseline ohms measured in Z5

Review Study

MNBI Analysis Level

Z5

Both

Z5

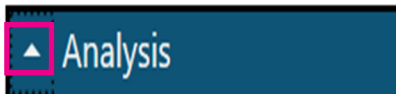
Z6

Some may choose to view the MNBI calculation from the Z6 level, or from both Z6 and Z5 for comparison purposes. To change which level is analyzed, displayed and reported from the MNBI metric,

- Navigate to the Properties page,



- Expand the Analysis section,



- Select the MNBI level or levels of choice.

Measurement Metrics

Resting 3

	Value
Resting	
Body Z5 : Prox LES+5	
Baseline	841 ohms
Body Z6 : Prox LES+3	
Baseline	581 ohms

Study Metrics

☒ Automatic

Distal Body pH (43)

Resting (3)Z Reflux (65)

	Value	Normal
Resting		
MNBI at Z5 (Lyon 2.0)	816 ohms	> 2500
MNBI at Z6	779 ohms	

MNBI calculated and displayed at both levels in the Study Metrics once enabled.

If a report was previously generated before a change in the MNBI setting, regenerate the report to include the new data.

MNBI at Z5 (Lyon 2.0)*	Value	Normal
MNBI at Z6	816 ohms	> 2500
	779 ohms	

MNBI data for both Z6 and Z5 included in the report.

Create Report

Review Study Metrics.

Study Metrics

☒ Automatic

Resting (0)

Z Reflux (65)

Distal Body pH (43)

Full Study (All Meas.)

All Reflux

Upright Episodes56

Recumbent Episodes9

Total Episodes65 < 73

Time Analyzed22:38:41

Acid

Upright Episodes45

Recumbent Episodes8

Total Episodes53

Time Analyzed22:38:41

Nonacid

Upright Episodes11

Recumbent Episodes1

Total Episodes12

Time Analyzed22:38:41

The **Study Metrics** are located on the right side of the study tabulating all data during the study period.

Enter Study Summary Data.

Study Metrics

☒ Automatic

Study Summary

On Acid Suppression Therapy Off

Duration24:07:03 h

Upright Time Analyzed16:45:35 h

Recumbent Time Analyzed5:53:05 h

Total Time Analyzed22:38:41 h

NotesStudy done for pre-op evaluation.

Impressions

Diagnostic Tags

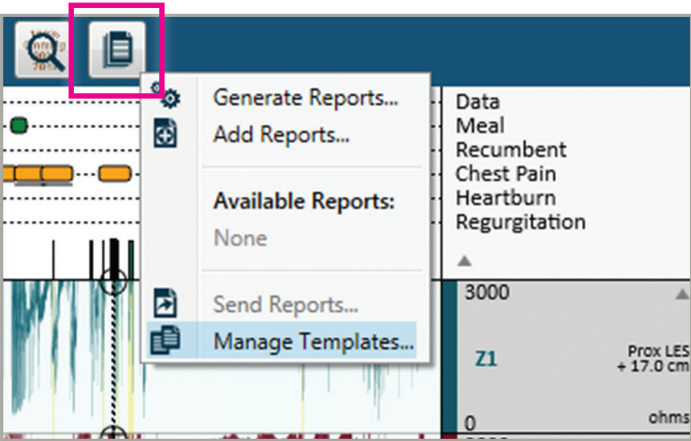
Diagnosis

The Study Summary section below the Study Metrics provides fields to enter any **Notes** related to the study. Physicians can enter Impressions and Diagnostic information to be included on the final report.

Editing can also be done directly on the report. Once the report is saved outside of Zvu, it can be added back to the study.

Create Report

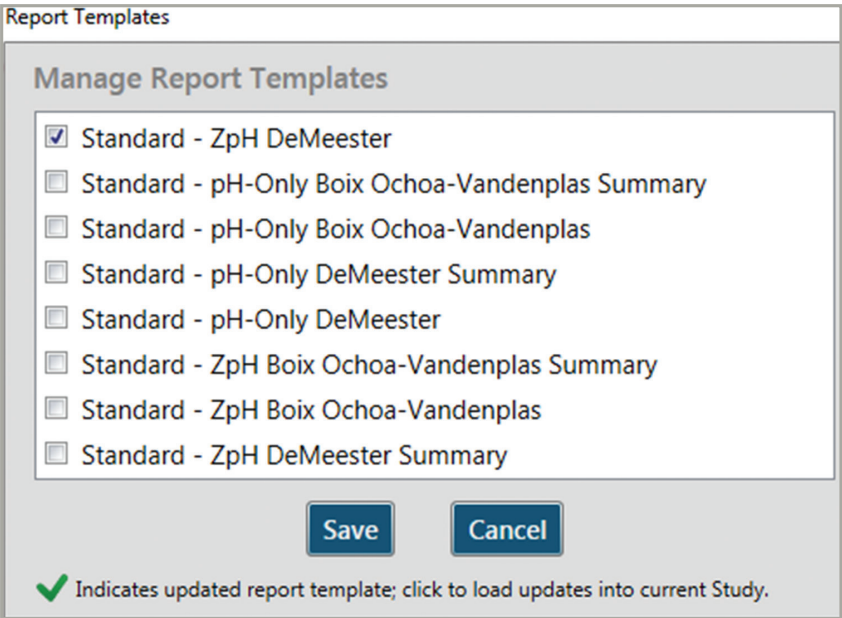
Create Report.



Click on the **Reports** icon on the toolbar and select **Generate Reports** to create the report(s) that were selected in the workflow.

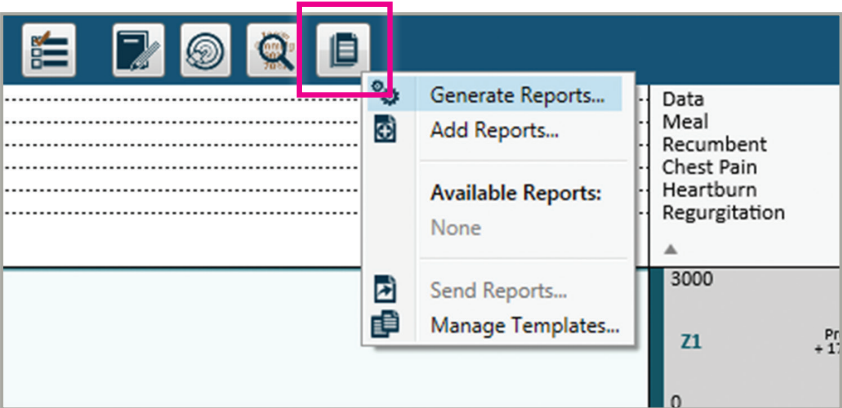
To change the designated report template, select **Manage Templates**.

Select Template.



Once the desired template is selected, click **Save**. Report templates will reflect normal values based on the age of the patient and the selection for Acid Suppression Therapy set for the study on the **Patient Management** screen.

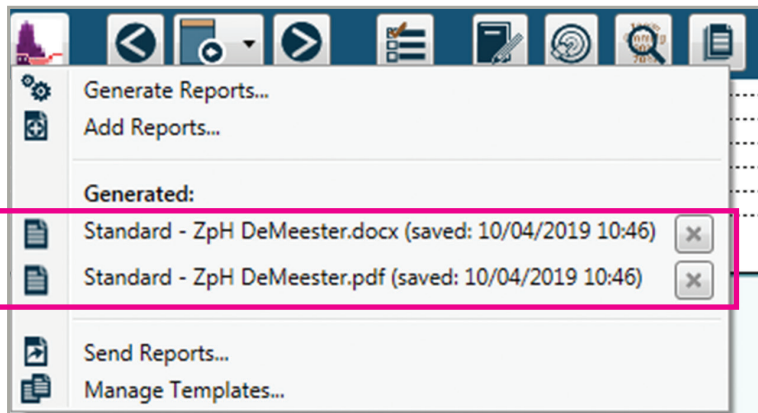
Generate Report.



After a review or change has been made under Manage Templates, select **Generate Reports**.

Create Report

Report Format.



A report pop up menu will open when reports are generated. Select a report from the **Generated** list and review data.

Review Data.

Diversatek Healthcare

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Highlands Ranch, CO, 80129
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Reflux Monitoring Report

Patient
Z/1pH, Abnormal
Patient MR Sample
Visit ID

Patient History
Symptoms / Indications
Medications
Notes
GER Z Challenge 01 probe 09-10-2007 00

Findings
Acid Exposure

	Upright	Upright Normal	Recurrent	Recurrent Normal	Total	Total Normal
Distal Body pH: Prox LES+5	10.3 %	< 6.3 %	17.1 %	< 1.2 %	12.0 %	< 4.2 %
% Exposure Time (Conv.)	10.3 %	< 6.3 %	17.1 %	< 1.2 %	12.0 %	< 4.0 %
% Exposure Time (Lyon 2.0)*	10.3 %	< 6.3 %	17.1 %	< 1.2 %	12.0 %	< 4.0 %

* Pathologic > 6 % is conclusive for pathologic GERD; 4-6 % is borderline, needs alternate evidence for conclusive diagnosis of GERD

Composite Score (normalized for 24 hours)

DeMeester	Score	Normal
	63.9	< 14.7

Reflux Episode Activity (Liquid Impedance)

	Upright	Recurrent	Total	Total Normal
All Reflux (Conv.)	56	9	65	< 73
All Reflux (Lyon 2.0)*	56	9	65	< 40

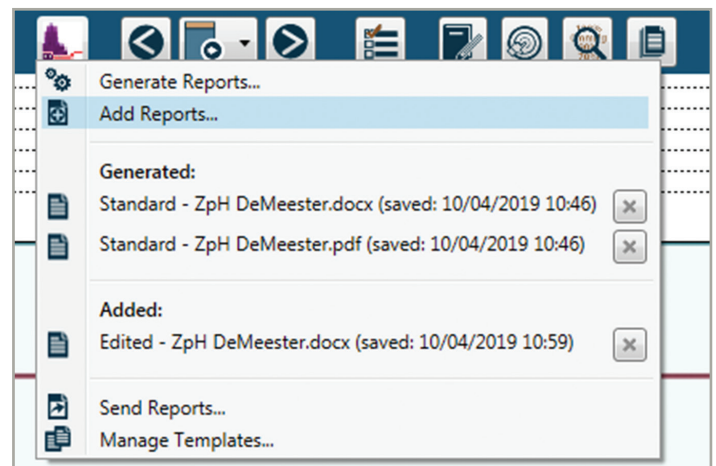
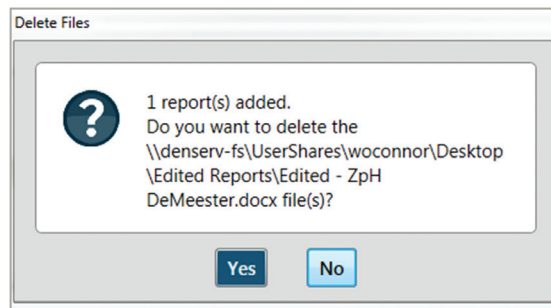
* Pathologic > 80 is adjunctive evidence of objective GERD; 40-80 is inconclusive for GERD as a stand-alone metric

Symptom Correlation to Reflux (Impedance)

Symptom	Count	Acid Related	Nonacid Related	All Reflux Related	All Reflux SI	All Reflux SAP
Chest pn	22	6	0	6	27.3 %	87.7 %
Heartburn	1	1	0	1	100.0 %	90.7 %
Regurg	1	1	0	1	100.0 %	90.7 %

Mean Nocturnal Baseline Impedance

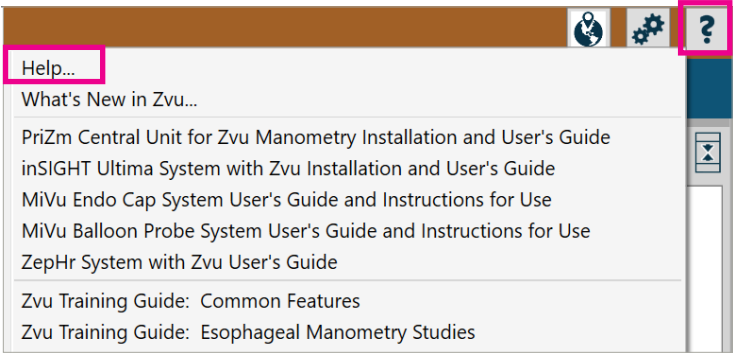
	Value	Normal
MNBI at Z5 (Lyon 2.0)*	815 ohms	> 2500
MNBI at Z6	778 ohms	



If editing directly on the report, **first Save** the doc file to a desktop folder, then proceed with edits. End with a final **Save**. After exiting the report, click on the **Reports** icon again and select **Add Reports** to bring the edited report back into the study.

If the report is edited and saved by the user, the saved report will contain patient identifying information. The report should be added back to the study so that the software can encrypt the information. It is recommended that the saved unencrypted copy should be deleted once the report is added into the study to protect the patient's data.

Help



For additional details click the ? icon on the right end of the toolbar to access **Help**.



The **Annotated Index** will navigate to the full **Help** list.



This image shows a single sheet of white paper with horizontal ruling lines. The lines are evenly spaced and run across the width of the page. There are no margins, text, or other markings on the paper.

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Diversatek Healthcare offers a variety of sources to learn more about our technology, covering:

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- Zvu® Esophageal Manometric Studies
- BioVIEW® Anorectal Manometric Studies
- Zvu® Impedance/pH Reflux Monitoring Studies



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