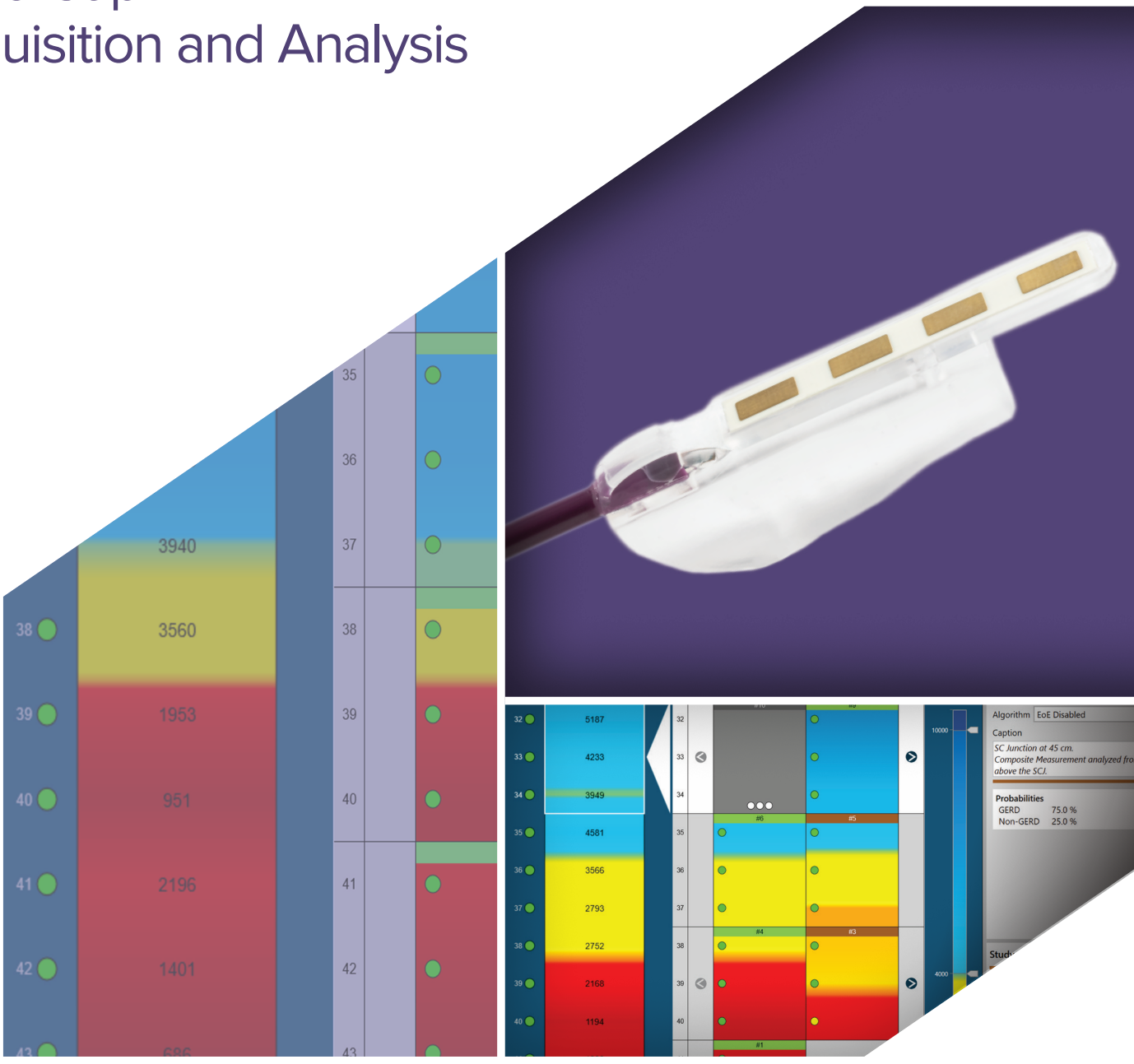
Diversatek™
Healthcare

MiVu™ Guide

Endo Cap
Acquisition and Analysis



MiVu™

Diversatek™
Healthcare

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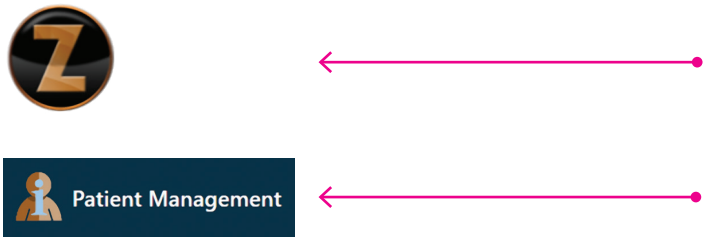
Patient Study Setup

Getting Started

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

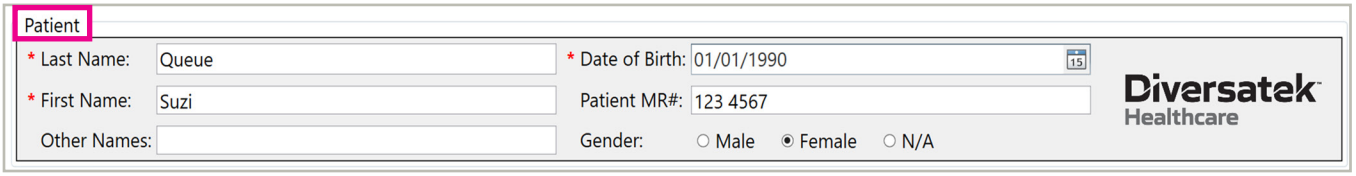


Click on **Patient Management** on the left side of the screen.

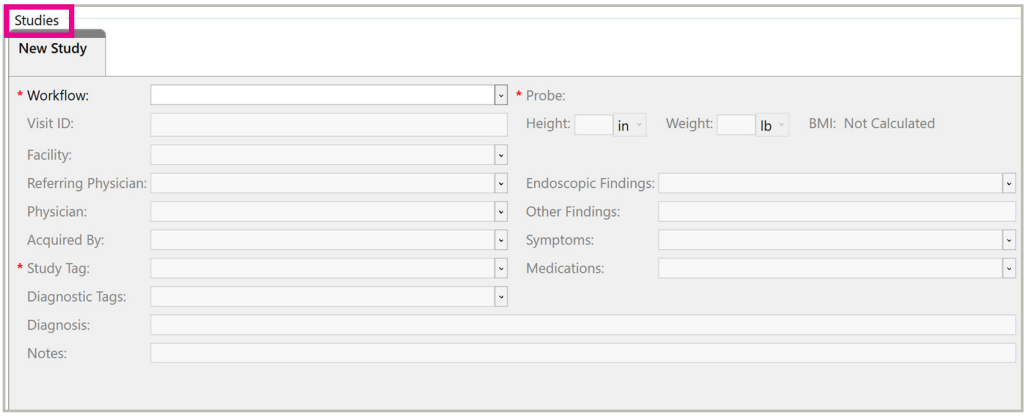
Click **New Patient** in the lower left hand corner.

Enter Study Information

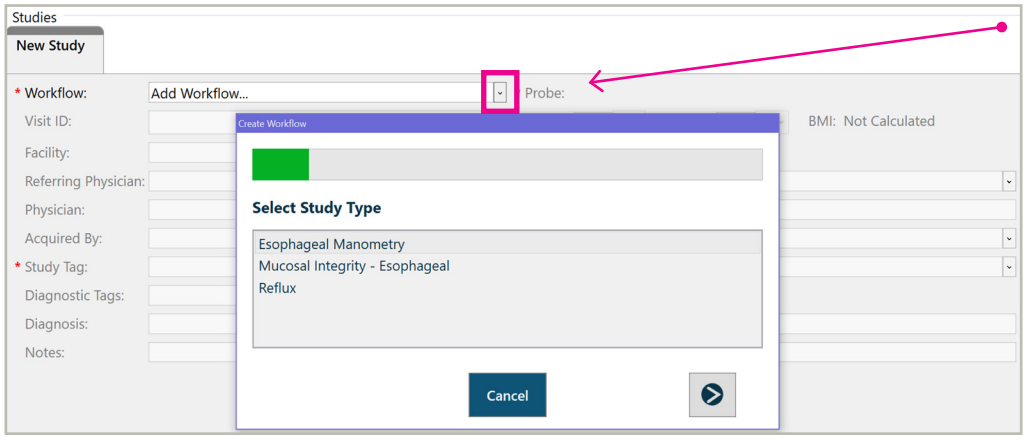
Complete the information in the **Patient** section.



Items with the asterisk (*) are required fields.

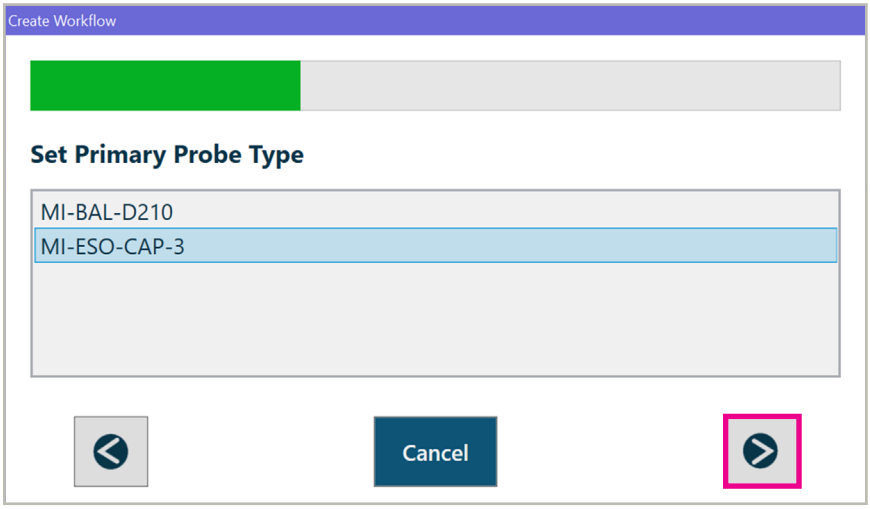


The **Studies** section allows the clinician to prepare for the Acquisition phase of the study.

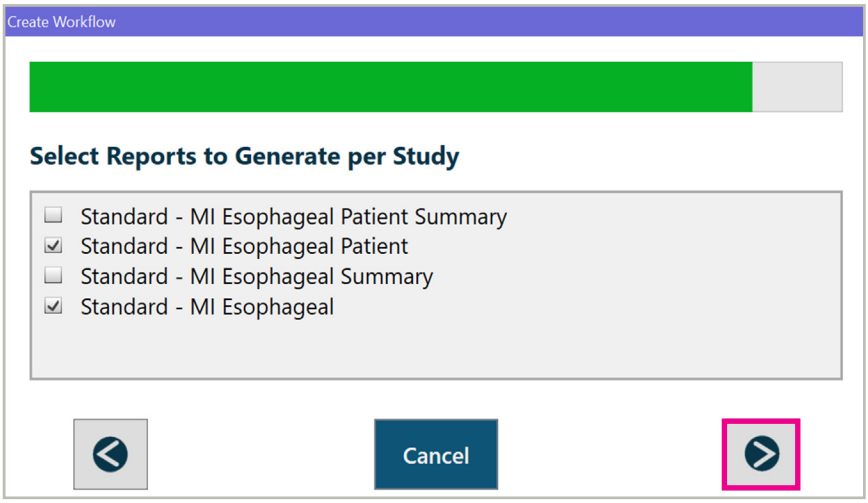


For a first-time setup, click the **Workflows** dropdown arrow and select **Add Workflow**. Once the workflow is added in the initial step, it can easily be selected from the dropdown list for future studies.

Patient Study Setup

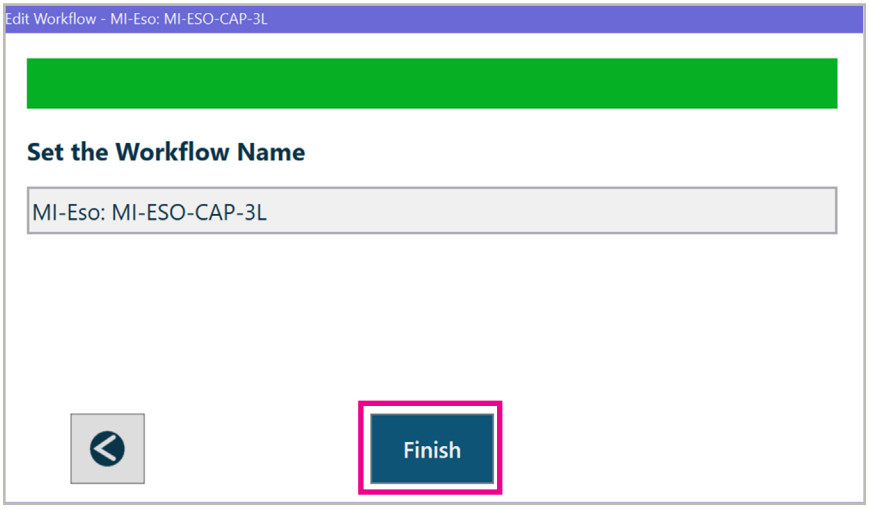


Select the Endo Cap probe and click the > button.



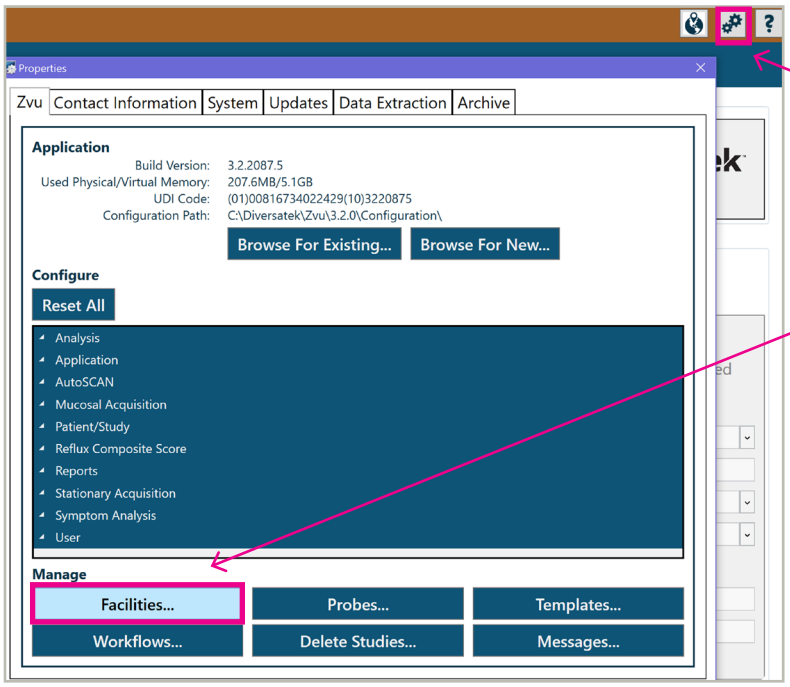
Select one or more report templates and click the > button.

The Standard – MI Esophageal Patient templates will show the composite image, but will not show the probabilities of disease.

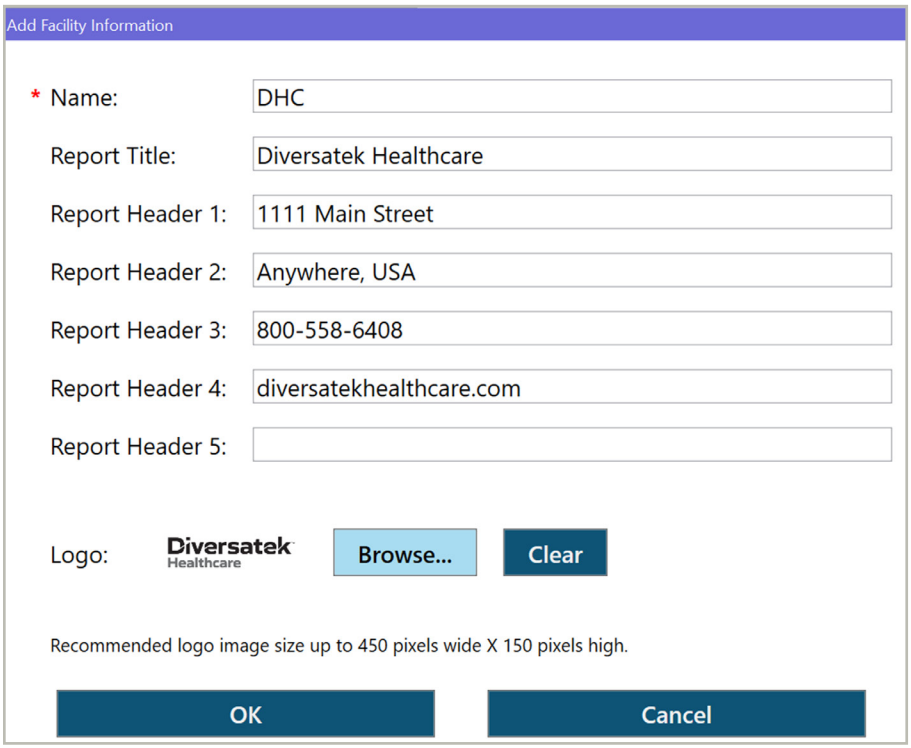


Edit the workflow name, if desired, and click **Finish**.

Patient Study Setup



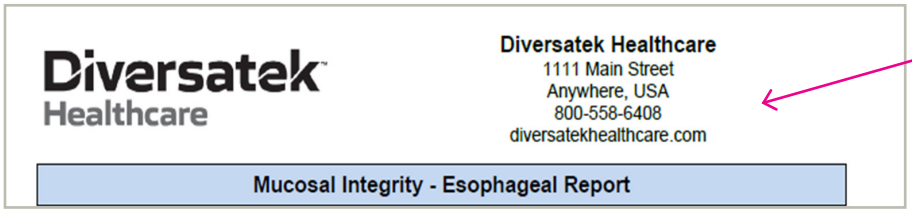
Set up the Facility for the report header by clicking the Properties page icon and the **Facilities** button to bring up the **Add Facility Information** dialog.



Use the **Name** field as a nickname or to distinguish between different locations, if applicable.

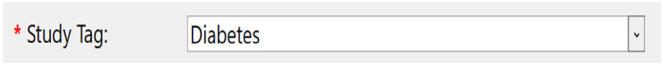
The **Header** information begins on the **Report Title** line.

Once this setup is completed on the initial setup, the added Facility can be selected from the dropdown list for future studies.



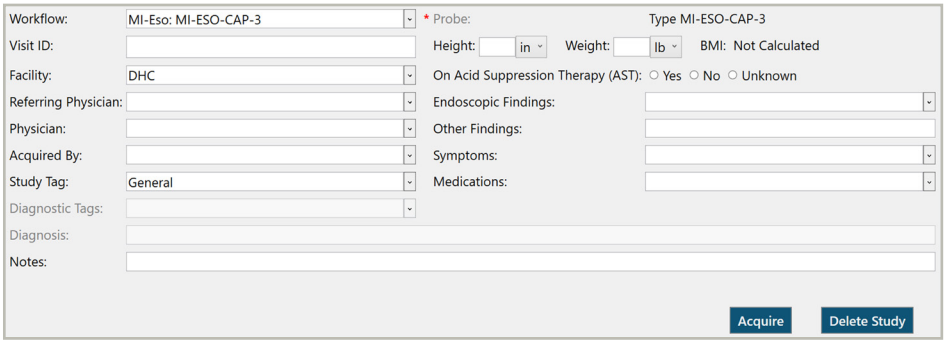
The Facility information will appear in the final report's header.

Patient Study Setup

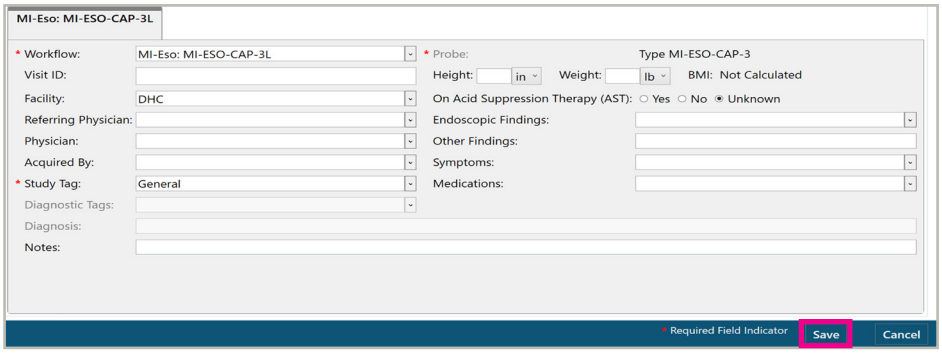


The **Study Tag** field defaults to *General*. As an option, this field can be customized. Add the Study Tag for physical attributes or other designations. Use the Study Tags to retrieve a patient list based on these custom criteria.

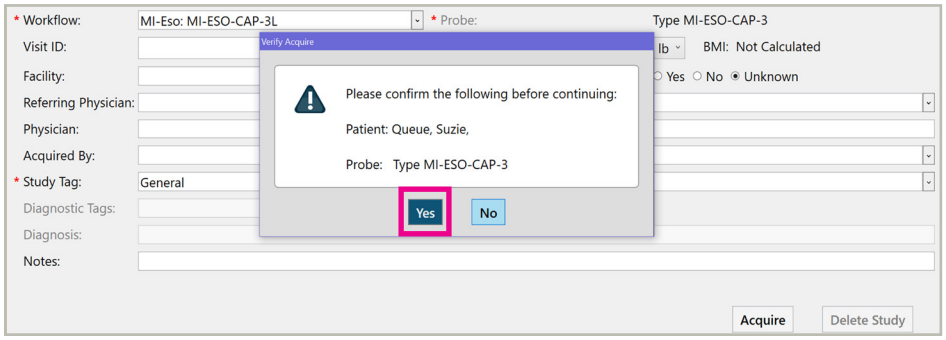
The remaining fields are optional and can be completed at any time during the Analysis phase.



Click the **Save** button in the lower right corner.



The **Acquire** button will appear. Click the **Acquire** button in the lower right-hand corner.



A confirmation screen will appear that includes the patient's name and probe type.

Click **Yes** if you are ready to proceed with acquiring the study.

Note: It is recommeded to have two (2) people available to perform this type of study – one to perform the endoscopy maneuvers and one to operate the software.

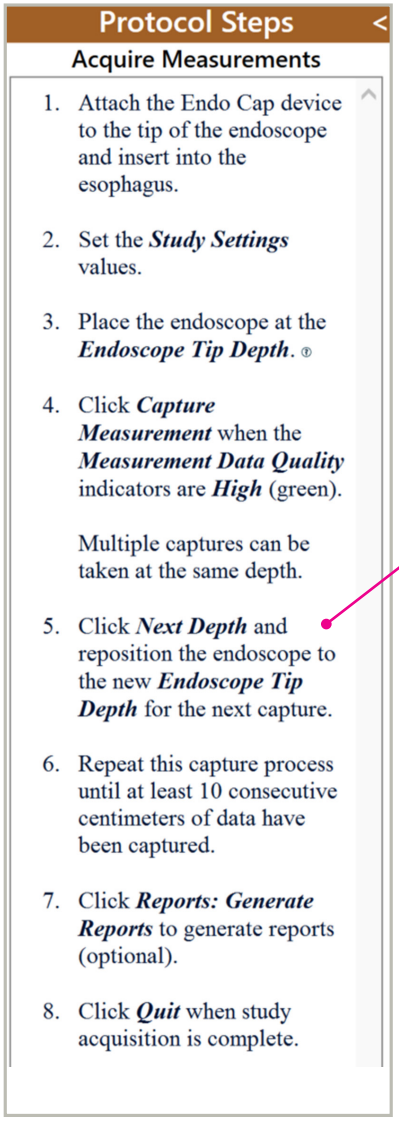
Acquisition

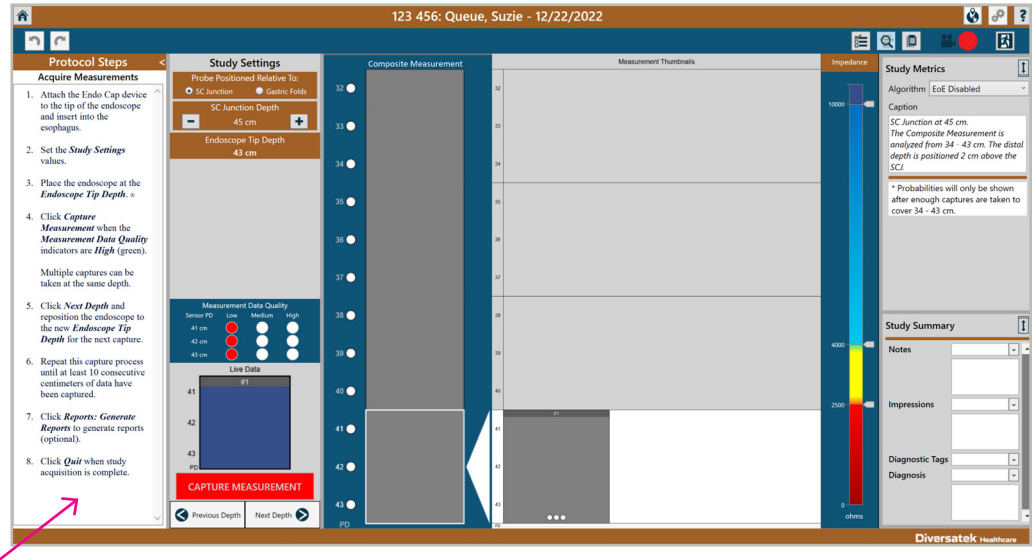
Note: The MiVu Endo Cap device utilizes a security feature that limits the device to a singe use. When the **Acquire** button in Zvu is first clicked, while using the MiVu Endo Cap, the device has a one-hour period during which it must be used.

During this period, Zvu will allow a study to be restarted in case there are unforseen interruptions, such as a loss of power or a device disconnection.

After the one hour period, if a study acquisition is attempted using the same device, Zvu will report that the device has been used and will not allow the sudy acquistion to begin.

After the Acquire button is pressed and confirmed on the Patient Management page, the **Mucosal Integrity Acquisition** screen will appear.





The **Protocol Steps** appear on the left side of the screen, which provide a stepwise guide to walk the user through the acquisition protocol.

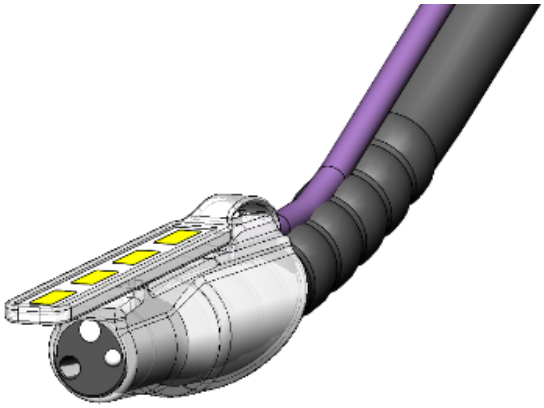
Acquisition

The MiVu™ Esophageal Endo Cap is a single-use, non-sterile device that does not require cleaning before use.

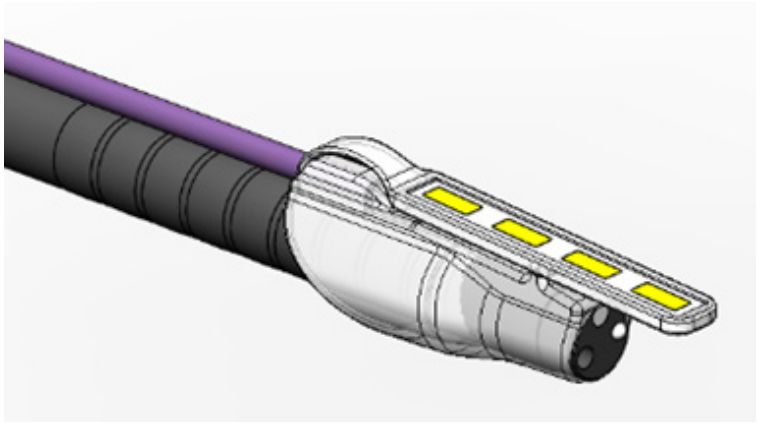
In a typical study, the MiVu Esophageal Endo Cap device is installed over the end of an endoscope prior to scope insertion. The tubular design of the device allows for the lighting, optics and working channel of the endoscope to be used unimpeded. The sensor area of the device is denoted by a small protrusion that is visible with the endoscope camera to aid in locating the sensors against the esophageal tissue.

Placement of the Endo Cap Device

- Apply a small amount of lubricant on the sides of the endoscope tip.
- Slide the Endo Cap onto the working end of the endoscope as shown in the image below.



- The sensors should be aligned at the 12 o'clock position, as controlled by the big wheel of the endoscope.

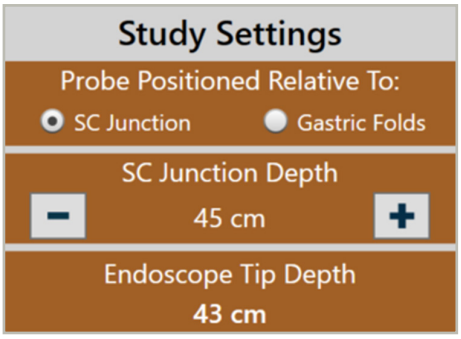


- Make sure the face of the endoscope end is flush with the opening of the Endo Cap device.
- The device should have a snug fit on the endoscope.

Insertion of the Endoscope with an Endo Cap Device Affixed to the End

- Begin the upper endoscopy procedure.
- As the endoscope passes through the oral cavity, the sensor surface should be in contact with the patient's tongue.
- As the endoscope approaches the larynx and the esophageal inlet, the sensor surface is oriented anteriorly.
- Gently introduce the tip of the Endo Cap posterior to the arytenoids, into the esophageal inlet, avoiding contact with the larynx. Do not use excessive force.
- Rinse and suction the esophagus as needed to remove excess fluid or foam.

Note: Perform the mucosal impedance study before taking biopsies of tissue so the compromised tissue and the presence of blood does not impact the mucosal impedance readings.



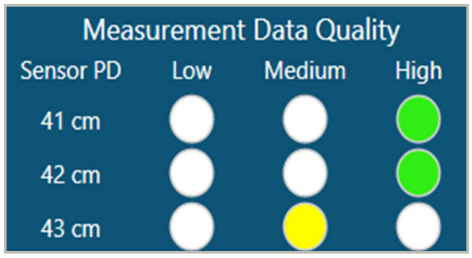
Mark the **Probe Positioned Relative To** option and define the endoscopic probe depth of the chosen option.

The software will automatically set the **Endoscopic Tip Depth** at 2 cm above the selected probe reference depth, indicating where to initially place the endoscope to begin the Endo Cap study.

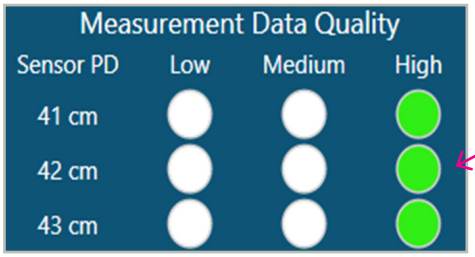
While visually observing the video endoscopic image on the monitor, rotate the Endo Cap sensor surface to between the 6 o'clock and 9 o'clock positions.

When properly placed, the physician will rotate the tip of the scope into the esophageal wall by turning the big wheel of the endoscope. The light pressure will cause the proximal end of the Endo Cap to pivot into the esophageal mucosa, providing a constant pressure along the measurement region. Any luminal air or liquid between the sensors and mucosal tissue will be pressed away from the tissue being measured.

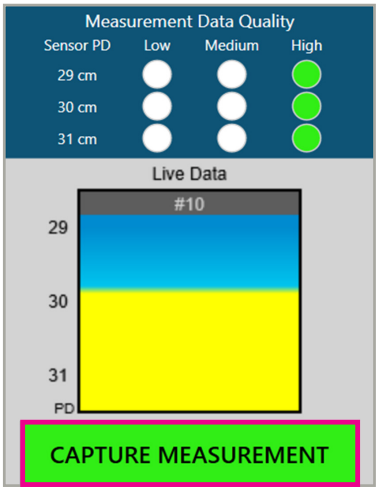
Acquisition



The status or stability of the data measured by the three (3) Endo Cap sensors is displayed in real time. The clinician can choose when the data is optimal or make position adjustments before capturing a measurement.



The goal is to capture a measurement when all three (3) sensor indicators are green.

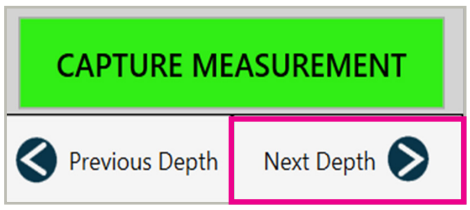


Real-time data is displayed in a contour view in the Live Data window. The **Capture Measurement** button changes color in conjunction with the Measurement Data Quality status, to give a visual cue for when to capture the measurement.

When the **Capture Measurement** button is pressed, an audible "positive" tone will be played if the captured measurement's data is high quality; and, a "negative" tone is played if the measurement quality is less than high. These tones will alert the physician as to when the capture was made and to the quality of the measurement.

Acquisition

Often, after the sensors have pivoted up against the esophageal mucosa, they can remain in this position as the scope is pulled proximally in 3 cm increments as measurements are acquired.

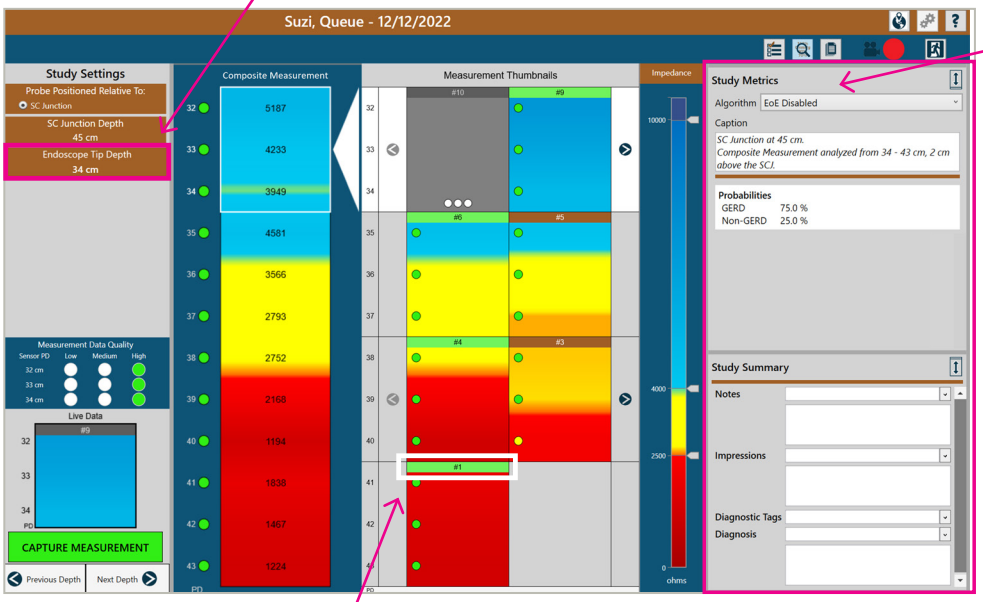


Once all desired measurements have been captured at a certain depth, the **Next Depth** button can be pressed.

Note: It is critical that the probe depth matches the probe depth currently displayed by the software. Should a measurement be captured at the wrong depth, it can be moved to the correct position.

Failure to accurately locate measurement locations will adversely affect the procedure results.

Under the **Endoscope Tip Depth** field, the value will change by 3 centimeters. The probe can be adjusted to this new depth and measurements taken on a new row.



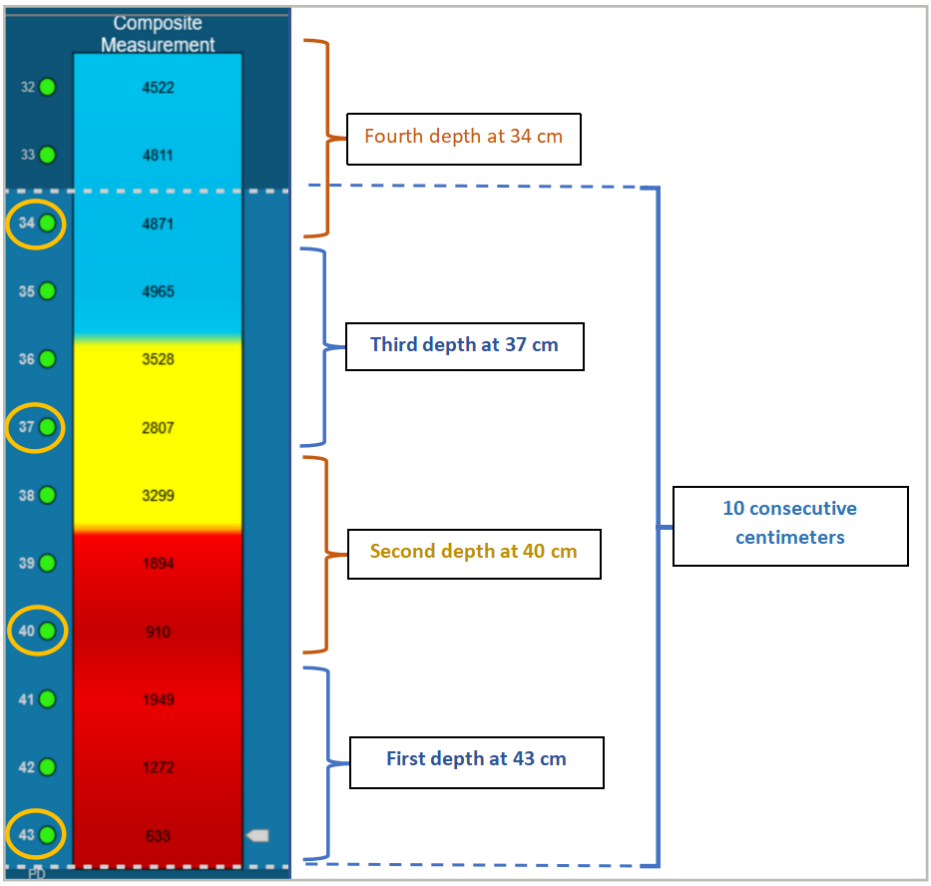
The **Study Metrics** require data spanning 10 consecutive centimeters. Each measurement capture will span 3 cm, and a minimum of 4 measurements spanning 10 cm are required. Once measurements have been captured at 4 depths, the metrics will populate. Four depths with 3 sensors each will give 12 sensors' worth of data. The data for the distal 10 sensors will be analyzed.

One measurement will be selected at each 3 cm depth. By default, the measurement on the left of each row, which was the last acquired measurement at that depth will be marked as the selected measurement.

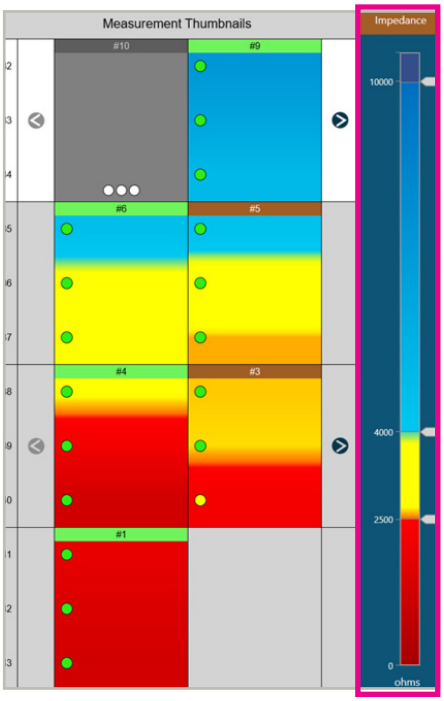
The selected measurement at each depth is marked by a green title bar.

Acquisition

The **Composite Measurement** builds from the bottom up as measurements are captured at higher or more proximal depths. The Composite Measurement shows the data from the selected measurement at each measurement capture position.



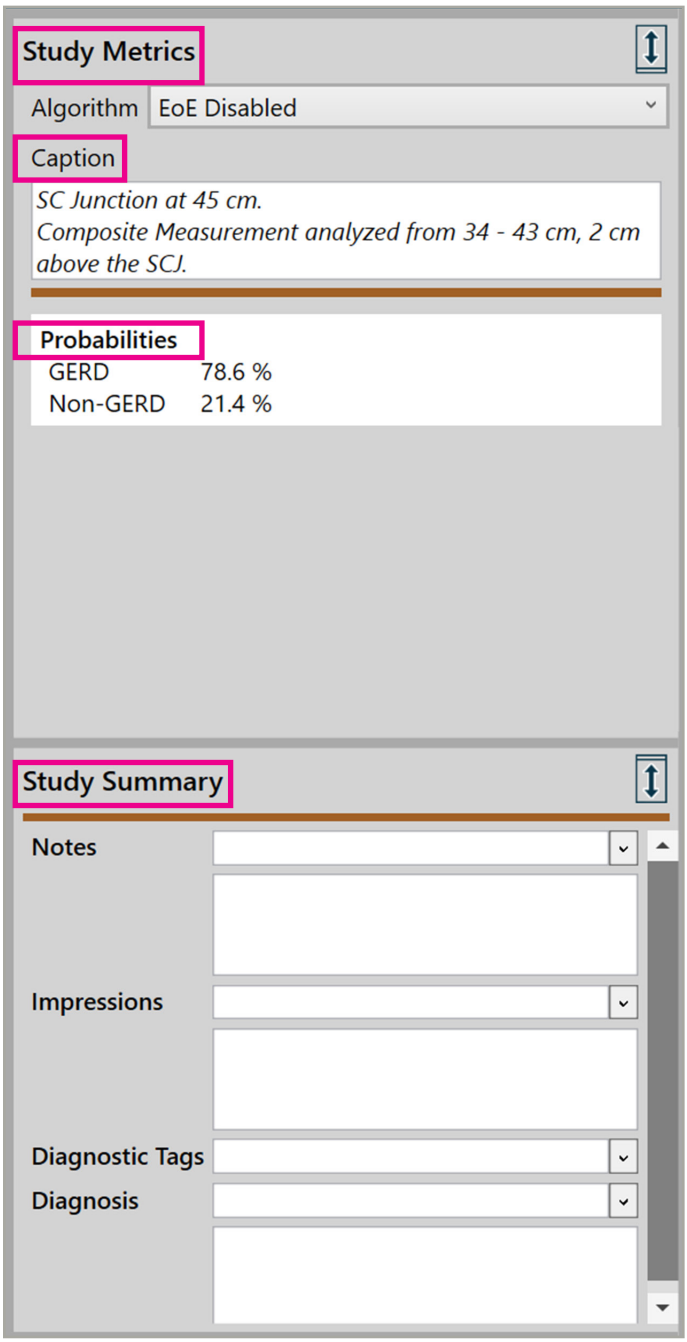
The displayed metrics come from the Composite Measurement. These metrics and the Composite Measurement will appear on the report.



The **Color Key** indicates the values in ohms represented by the colors in the individual measurements and the Composite Measurement.

Analysis and Reporting

Data Analysis During Acquisition



The **Study Metrics** and **Study Summary** are located on the right-hand side of the Acquisition screen.

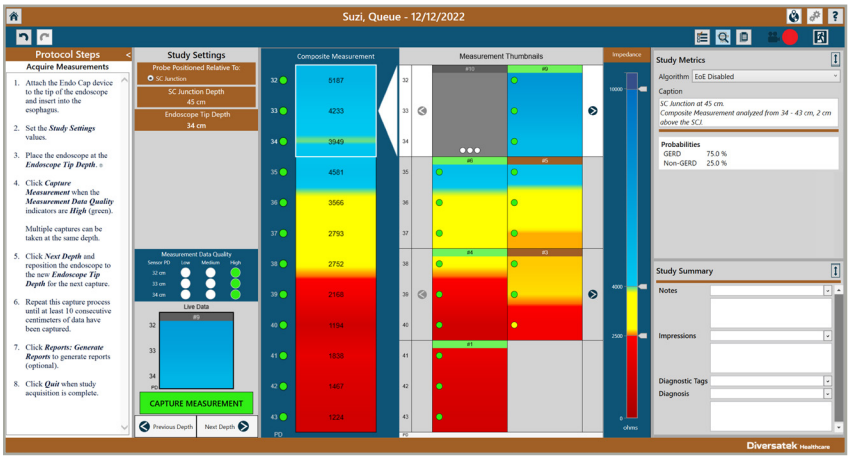
Study Metrics include a dropdown selection for the algorithm to be used in the analysis of the data. The default setting is for EoE analysis to be disabled.

The **Caption** includes the **Probe Position** and **Analyzed Heights**.

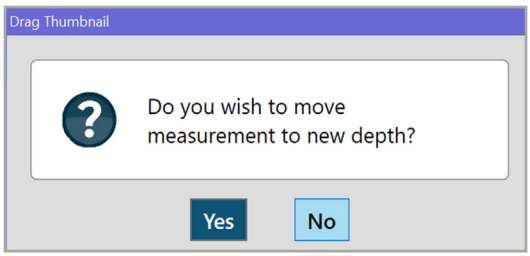
Once 10 centimeters worth of consecutive data have been acquired, the **Probabilities** of disease will be displayed. These probabilities will update if different measurements are selected. To select a different measurement, double click on it. The measurement title bar will change from brown to green. The Composite Measurement and associated probabilities will update accordingly.

The **Study Summary** gives the clinician the ability to insert **Notes**, **Impressions**, a **Diagnostic Tag** as well as a **Diagnosis**. This information, except for the Diagnostic Tag, will be displayed on the final report.

Analysis and Reporting

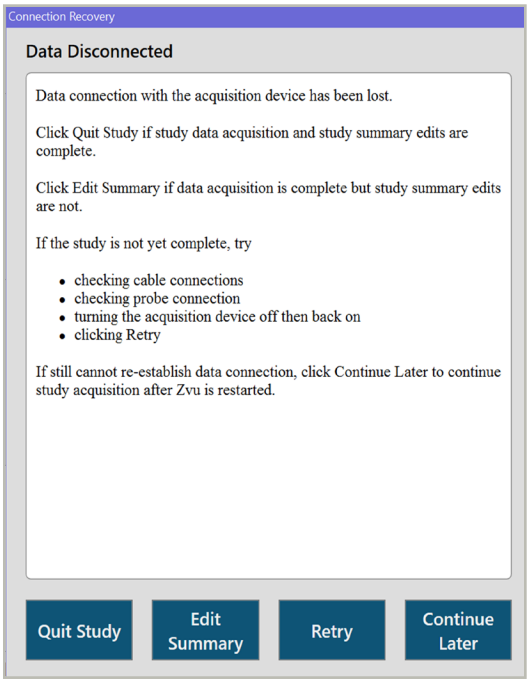


Changes can be made in the text fields of the **Study Metrics** or **Study Summary** sections. Reports can be generated during study acquisition or during an optional post-study analysis by selecting the **Review Study** button from the Patient Management screen.



Measurements can be moved to different rows with a simple drag and drop.

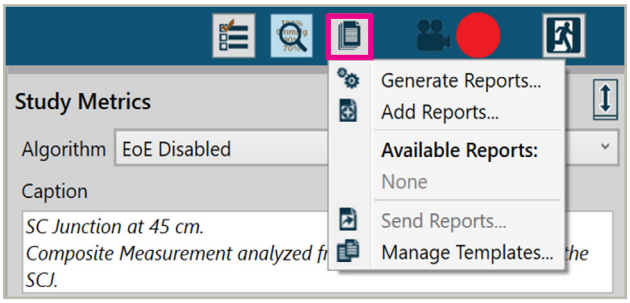
Post-Procedure

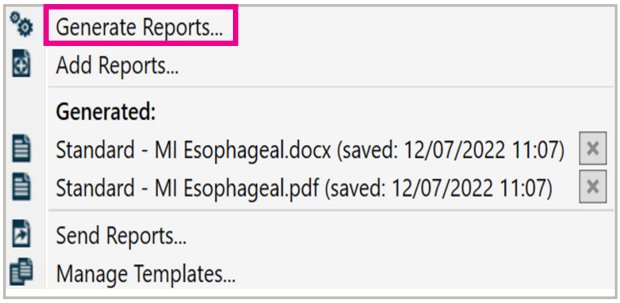


- After all measurements are taken, gently withdraw the endoscope. Should the Endo Cap device appear to be moving off the endoscope, gently pull the Endo Cap conduit tubing to keep it from slipping further. Stop the extraction if there is any resistance that might lead to patient injury.
- Remove the MiVu Esophageal Endo Cap tip from the end of the endoscope.
- After use, this device must be disposed of according to local or facility regulations pertaining to biohazardous disposable medical devices.
- The MiVu Esophageal Endo Cap is a single-use device and must not be re-used.

Note: When the Endo Cap device is disconnected from the MiVu Endo Cap Cable, the system will detect the disconnection and Zvu will display the message shown above if it is still on the Acquisition screen. If the study data are acquired and the study edits are complete, click the **Quit Study** button to save the acquired data and close the study. If the study data are acquired but the study summary requires editing, click the **Edit Summary** button.

Analysis and Reporting

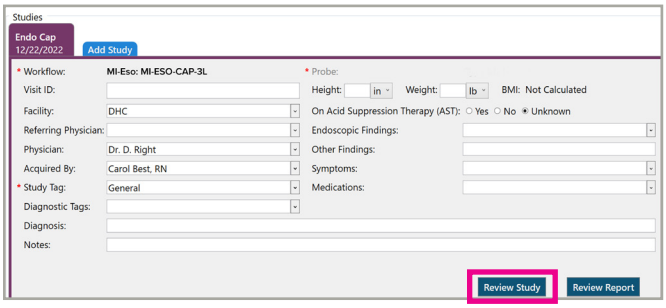




After all updates are complete, click the **Reports** icon and select **Generate Reports** from the menu. The reports can be generated in .doc, .pdf, or .rtf file formats.

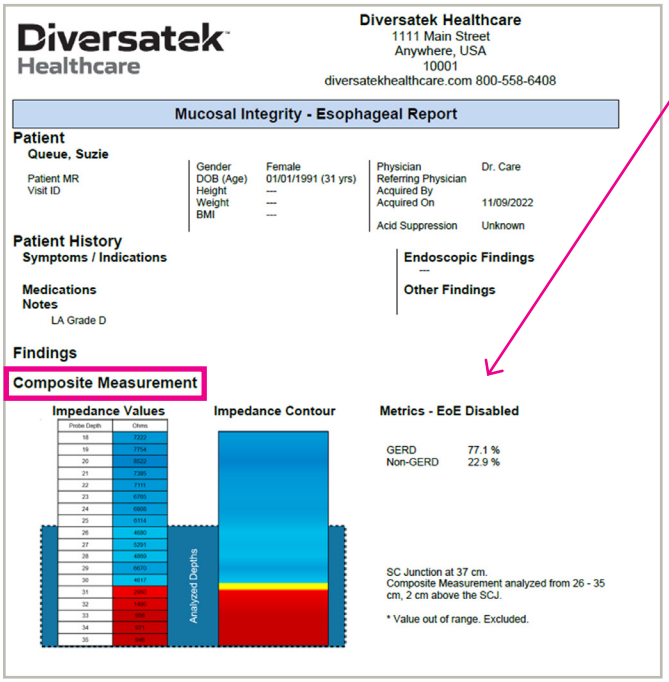
Once **Quit** is clicked to end the study, a message will show that if **Yes** is clicked, this study cannot be resumed and the probe cannot be used for another study.

Editing Post-Acquistion

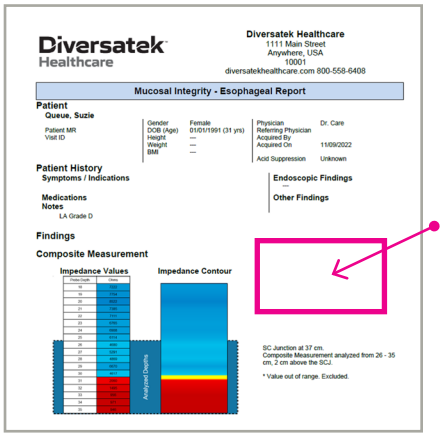


Optionally, the study can be opened in Analysis, and changes can be made, as well as reports regenerated.

Final Reports



The final full report includes the information from the **Patient Management** screen as well as the **Composite Measurement** and the associated disease probabilities.



No disease probabilities on patient's report copy.

Innovations in Clinical Education

Diversatek University Online

Our online training platform contains free content on esophageal and anorectal manometric studies, as well as impedance/pH reflux monitoring studies. Included are tutorials providing step-by-step guidance to develop skills in data acquisition, study review and report generation. Simply go to **DiversatekHealthcare.com** to request log-in information.

Denver Training Center

Our Technical Research & Training Center offers a number of product training courses to provide clinical users with the knowledge and skills necessary to effectively acquire and analyze High Resolution Impedance manometry studies, impedance/pH reflux monitoring studies and High Resolution Anorectal manometry studies. Email us at **clinicaleducation@diversatekhc.com** or visit us online to learn more about our Denver course offerings.

Webinars

Diversatek Healthcare is proud to present a series of live, interactive discussions on topics related to esophageal function testing, impedance/pH reflux monitoring studies and anorectal manometry. Each webinar includes a didactic session followed by an open discussion. All webinars are recorded and posted to the Diversatek U online portal for easy reference. Access **DiversatekHealthcare.com** for upcoming webinar announcements.

Personalized Clinical Support

Onsite Training

Diversatek Healthcare Clinical Specialists deliver product support to suit your specific needs—on your schedule. Specialists are onsite at your facility to train and support you on your Diversatek Healthcare manometry or reflux monitoring equipment as you work through patient cases, acquire and analyze patient data, and create patient reports.

Virtual Coaching

Online and in real-time, Diversatek Healthcare Clinical Specialists work with you via screen sharing to provide study-specific data review and report generation coaching for your more difficult studies. Email us at **clinicalsupport@diversatekhc.com** to schedule a one-on-one session.

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