


**NvisionVLE<sup>®</sup>** | Imaging System  
with Real-time Targeting<sup>™</sup>  
**See more**



# See the esophagus more completely



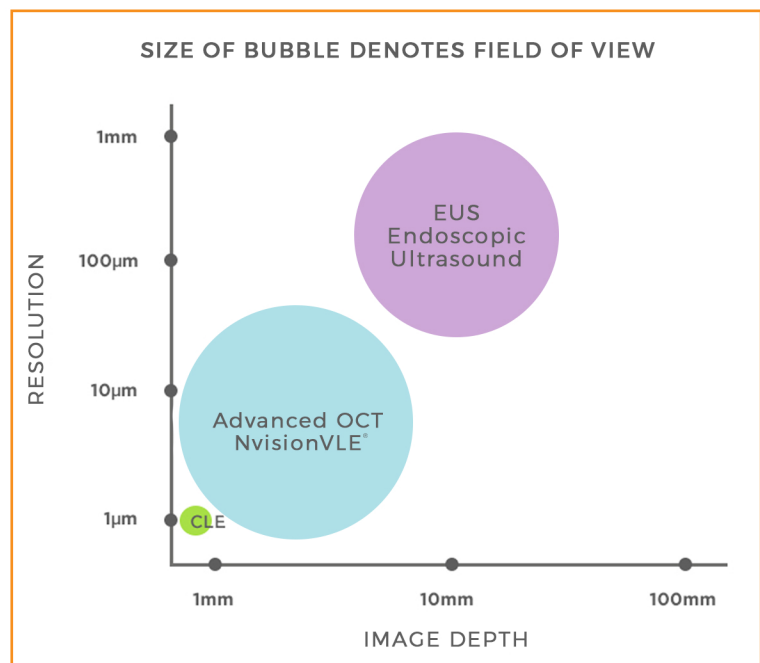
The most widely used imaging modality for standard endoscopic examination, white light endoscopy (WLE), is limited to evaluation of the surface of the esophageal tissue. It is becoming increasingly recognized that esophageal abnormalities may be present below the surface where they can't be visualized with WLE. Random biopsy is the current standard of care for diagnosing esophageal disease such as Barrett's esophagus, squamous cell carcinoma, and adenocarcinoma. However, random biopsies assess less than 3% of the esophageal surface,<sup>1</sup> leaving more than 97% of the tissue unsampled. Further, even when the tissue is targeted appropriately, biopsies have been shown to reach the lamina propria only 37% of the time.<sup>2</sup> This often is not at sufficient depth to reach the area of concern.

# Advanced OCT - filling the imaging gap

Endoscopic Ultrasound (EUS) has gained widespread adoption for esophageal imaging. Its strength is in staging existing tumors, but its lack of resolution in the first few mm of tissue makes it ill suited for evaluation of mucosal tissue microstructure. Confocal Laser Endomicroscopy (CLE) provides cellular detail, but doesn't have a wide enough field of view or depth of imaging to identify abnormalities that may be present below the surface.

The ideal imaging system for identifying and targeting abnormalities in the esophagus would optimize resolution, depth, and field of view to enable the identification and interrogation of the mucosa.

Additionally, the ideal imaging system should allow the clinician to easily target abnormal regions of concern for tissue biopsy or resection.



## NvisionVLE<sup>®</sup> | Imaging System with Real-time Targeting<sup>™</sup>

The NvisionVLE Imaging System with Real-time Targeting<sup>™</sup>, as part of the VLE procedure (Volumetric Laser Endomicroscopy), uses an optical signal acquisition and processing method to create high-resolution cross-sectional images and mark tissues – letting you evaluate:

- 100% of the tissue in a 6cm scan
- 3mm deep
- At a resolution of 7 microns

In real time. All so you can provide a more thorough evaluation – potentially leading to improved biopsy targeting for diagnosis by histopathology, and more complete information to determine the best treatment for your patients.

See the procedural animation at [www.ninepointmedical.com/procedure](http://www.ninepointmedical.com/procedure)



# The NvisionVLE® solution

## Breakthrough Design

The NvisionVLE® Imaging System Console is designed for clinicians:

- Feature-rich user interface and hand controller for intuitive navigation and high-resolution image management
- Rapid set-up, easy mobility, and user-friendly controls
- User Interface is designed for flexibility and functionality

## High-Speed Optical Probe

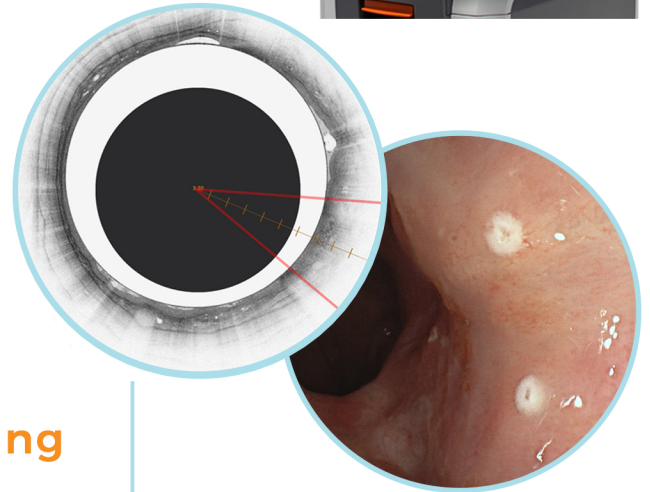
The NvisionVLE® Imaging System utilizes a single-use optical probe and lens system that rotates at high speed while retracting within the inner lumen. Plus:

- Balloon catheter facilitates optical probe positioning and centering, available in 14mm, 17mm, and 20mm
- Also available as balloon-less 7 French Low-Profile optical probe to accommodate various anatomies
- Catheter compatible with endoscope channels 2.8mm or larger

## Real-Time Image-Guided Tissue Marking

Use the Real-time Targeting™ marking laser to **target and mark** areas of suspicion that are not visible with conventional imaging modalities

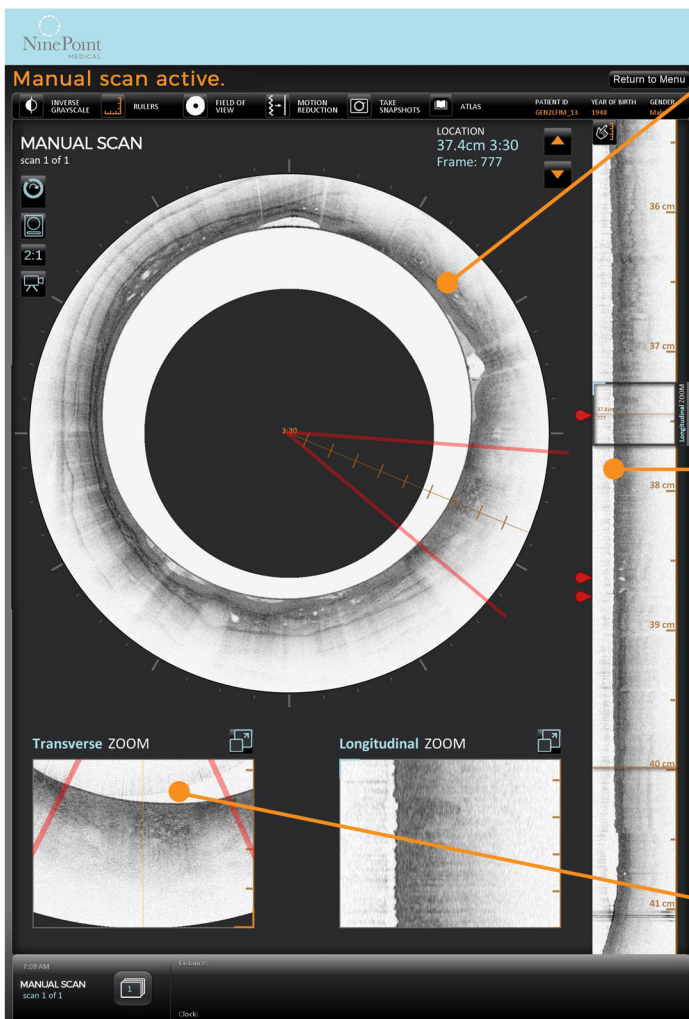
- Hand-controller allows for real-time physician control of the VLE scan and tissue marking to better evaluate areas of concern
- Active clinician-controlled workflow, tailored to the specific needs of each patient
- Single and double mark options for application flexibility



VLE was used to identify a subsurface area of suspicion. Superficial tissue laser marks were created with the Real-time Targeting™ system to target the region for biopsy. Targeted biopsy was confirmed positive for adenocarcinoma by pathology. Images from NinePoint Medical Clinical Study #15\_01.



# See more **deeply**



## ● **Cross-Sectional View**

Explore the entire targeted segment of the esophagus in real time:

- Collect 1,200 cross-sectional images
- Across a targeted segment of 6cm
- Penetrating approximately 3mm into esophageal tissue

## ● **Longitudinal View**

Examine the plane of the esophagus perpendicular to its cross-section:

- View the esophageal wall along the axis of the organ
- With over 4,000 longitudinal images of the esophagus

## ● **Zoom View**

For close examination of a particular area of interest, either within the cross-sectional or longitudinal views, these windows provide a zoomed-in view.

The NvisionVLE® Imaging System is indicated for use as an imaging tool in the evaluation of human tissue microstructure, including esophageal tissue microstructure, by providing two-dimensional, cross-sectional, real-time depth visualization and may be used to mark areas of tissue. The safety and effectiveness of this device for diagnostic analysis (i.e. differentiating normal versus specific abnormalities) in any tissue microstructure or specific disease has not been evaluated.

## **All Views**

As you manipulate the cross-sectional or longitudinal views on the NvisionVLE® touch-screen monitor or hand controller, each of the corresponding views update smoothly, and in real time.

# See the difference

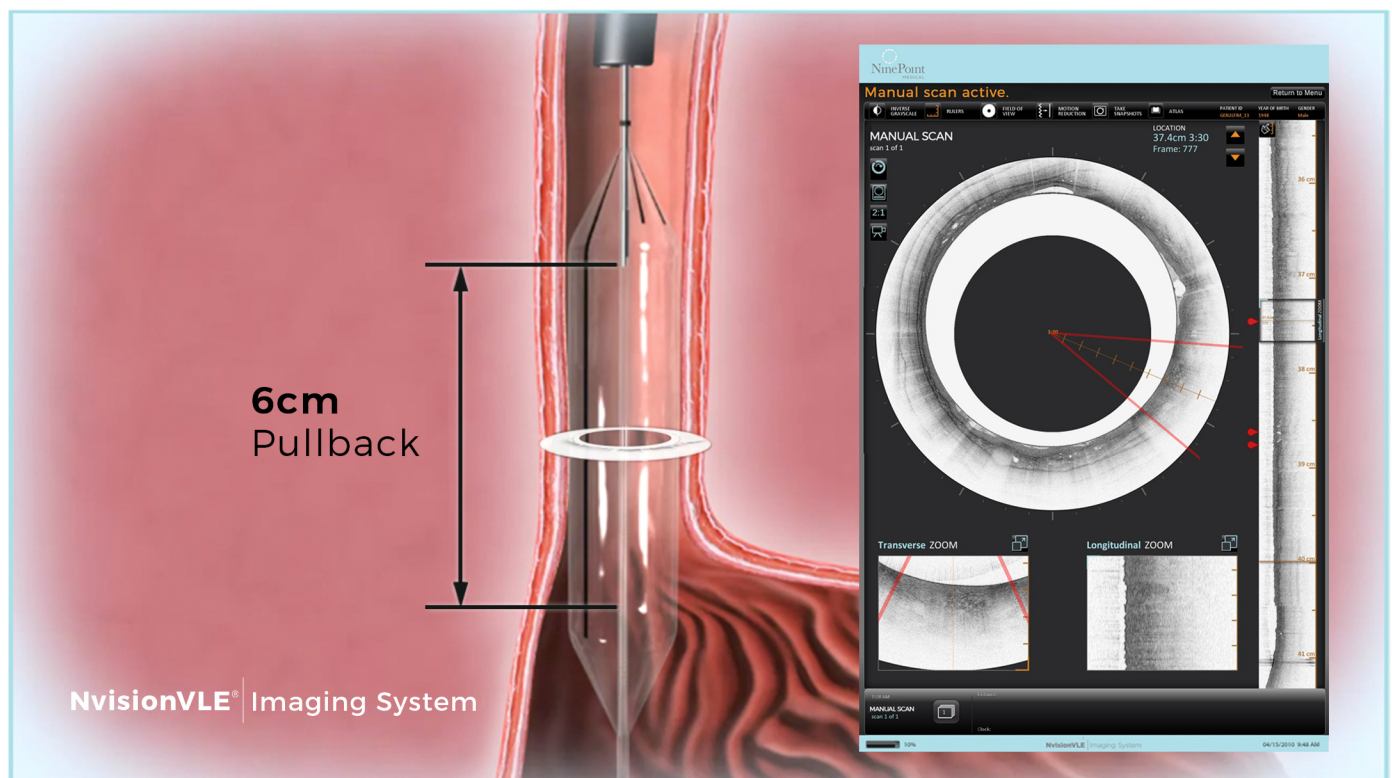
## NvisionVLE® Imaging System Advantages - what sets it apart

A new way of looking at esophageal mucosa and targeting tissue

- Uses Advanced OCT to capture images up to 3mm beneath the mucosa at 7 micron resolution in real time—unlike white light endoscopy, which can only image surface detail
- Lets you evaluate 100% of the tissue in a 6cm scan to better inform your evaluation
- Offers a full-field view (~10,000mm<sup>2</sup>), as opposed to a “point” image typically obtained with confocal microscopy (0.25mm<sup>2</sup>)
- Advanced OCT imaging delivers up to 25X higher resolution than endoscopic ultrasound
- Provides a dramatic increase in imaging speed and improved image resolution, compared to first-generation OCT systems
- Creates tissue laser marks visible under white light endoscopy, designed to help clinicians target biopsies at a site of interest that may not be visible with other imaging modalities

It all translates to a more confident assessment, and more informed course of treatment.

See more completely.



# See for yourself

Seeing is believing. Get a demonstration of the NvisionVLE® Imaging System with Real-time Targeting™. You'll find our contact information on the back cover and product codes below.

## Ordering Information

Item Name	Order Code	
<b>NvisionVLE® Imaging Console with Real-time Targeting™</b>	94301-M	
<b>NvisionVLE® Probe</b>	<b>Optical Probe</b>	<b>With Marking</b>
20mm Balloon	95101-20	95301-M-20
17mm Balloon	95101-17	95301-M-17
14mm Balloon	95101-14	95301-M-14
Low-Profile Balloon-less	95501-LP	N/A
<b>NvisionVLE® Probe - Box of 5</b>	<b>Optical Probe</b>	<b>With Marking</b>
20mm Balloon (Box of 5)	95101-20-5	95301-M-20-5
17mm Balloon (Box of 5)	95101-17-5	95301-M-17-5
14mm Balloon (Box of 5)	95101-14-5	95301-M-14-5
Low-Profile Balloon-less	95501-LP-5	N/A
<b>NvisionVLE® Inflation System - Box of 5</b>	96101-60-5	

## Reimbursement

For current information regarding reimbursement of the VLE procedure, please visit [www.ninepointmedical.com/#reimbursement](http://www.ninepointmedical.com/#reimbursement) or contact [Reimbursement@NinePointMedical.com](mailto:Reimbursement@NinePointMedical.com)

## Regulatory

The NvisionVLE® Imaging System has been cleared by the U.S. FDA with 510k #K143678 and #K153479, under the classification regulation for Ultrasonic Pulsed Echo Imaging Systems, 21 CFR 892.1560, Product Code NQQ.

## References

<sup>1</sup> PT Chandrasoma and TR DeMeester. GERD: Reflux to Esophageal Adenocarcinoma. Academic Press. 2010.

<sup>2</sup> N Gupta et al. Adequacy of esophageal squamous mucosa specimens obtained during endoscopy: are standard biopsies sufficient for postablation surveillance in Barrett's esophagus? Sharma Dumot Adequacy of biopsies for Barrett's. 2012.







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