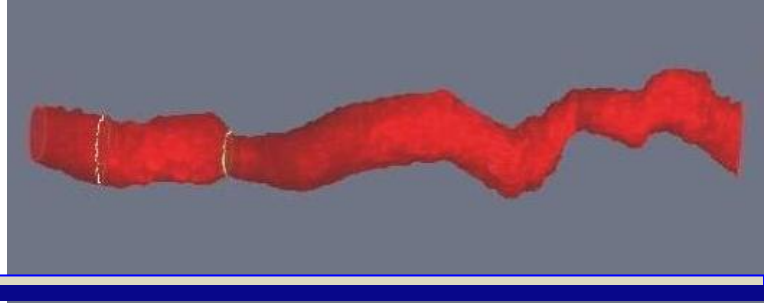
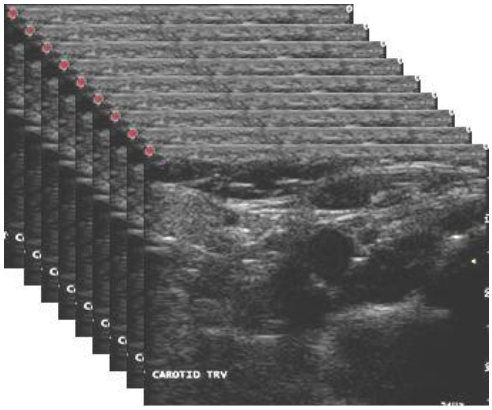
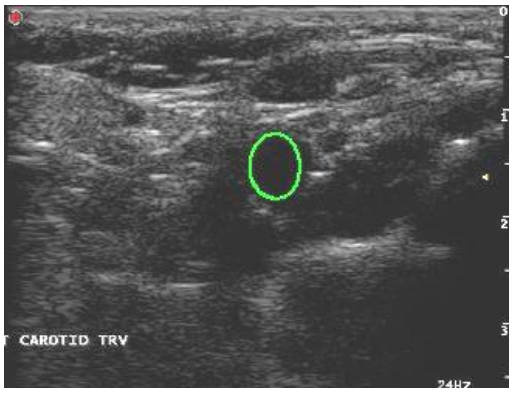
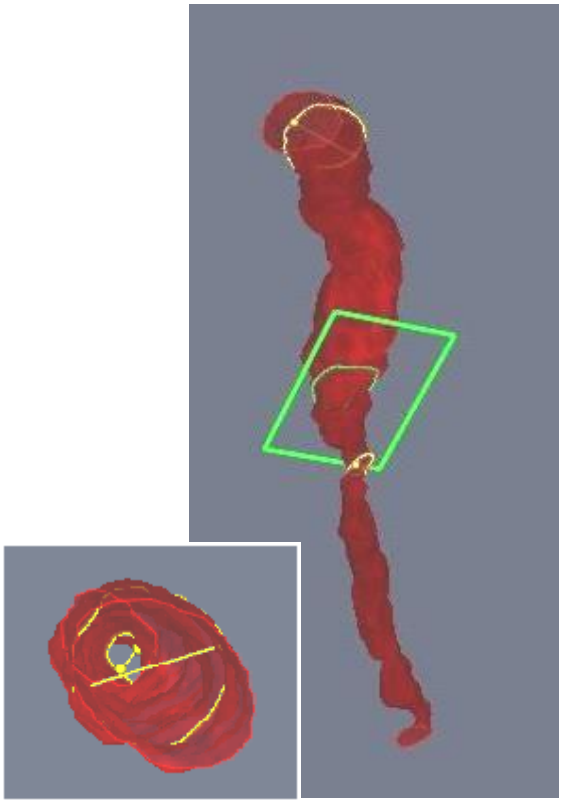
Visualize Technology









***Visualize*™ is a software algorithm provided as a service which renders The residual lumen or true lumen in 3D from the 2D frames in a cine clip. The algorithm automatically finds and measures key indicators to calculate luminal reduction – a salient point in assessing vascular health.**

The algorithm operates on DICOM B-mode gray scale data. It does not use velocities or color data that is captured in an vascular ultrasound exam. *Visualize:Vascular* provides a different perspective beyond that of Doppler Ultrasound or the information captured during the standard Duplex exam.

***Visualize's* algorithms require the use of a special scanning protocol. The probe is turned 90° from longitudinal scanning to specifically capture a set of 2D transverse frames in a movie clip or cine loop format. Thus acquiring the frames as parallel slices through the vessel which is very similar to the way that CT or MRI data is captured.**

A 10 second clip yields about 300 frames or slices in the cine clip as the probe is moved along the vessel.

***Visualize* uses the gray scale data to find the transition between the lumen and the trapped matter on the edges of a vessel to select the residual lumen as the area of interest. It then continues on to find that same edge of the true lumen on all of the frames in the sequence.**

The algorithm pulls this area of interest out from the surrounding image and reconstructs it in 3D, isolating just the area of interest which is the residual lumen or true lumen. The green slice on the 3D rendering corresponds to the frame in the ultrasound cine shown above.

***Visualize:Vascular* renders 3D from a set of 2D images.**

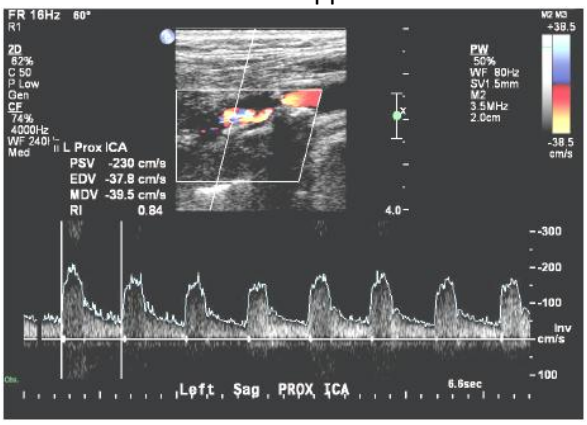
The algorithm automatically continues on to find the maximal and minimal diameter 360° around the center as shown in yellow. Looking down the artery, the yellow lines show the maximal and minimal diameters. Luminal reduction is calculated using these dimensions.

The algorithm can use cross sectional area to find the maximal and minimal points as an alternative to the diameter method. The diameter method is based on the NASCET methodology and criteria. There is no clinical trial which utilizes cross sectional area to date.

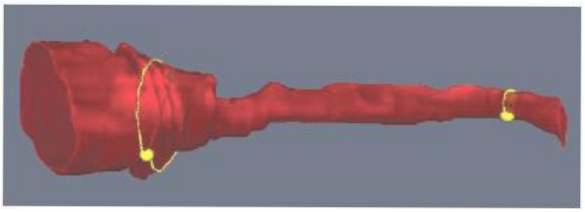
The 3D object can be turned to view it from any direction or tipped on end to look down the inside of the vessel.

Visualize

Color Doppler



Visualize:Vascular 3D



MRA

Doppler is the primary diagnostic test for vascular concerns. If one of the abnormal conditions listed below is found during the Doppler exam, then 3D rendering can be performed as a secondary diagnostic test in addition to the Doppler exam. 3D rendering is a separate exam. Several white papers have shown that the following criteria is appropriate for medical necessity:

- **Visible plaque**
- **Tortuosity**
- **Higher grade Stenosis (>50%) or Velocity (PSV > 135)**
- **Surgical follow-up**

In clinical use, 3D results vary from Doppler results on about 25% of exams. Studies have shown that *Visualize:Vascular* results compare well to magnet resonance angiography (MRA) and are effective in situations where Doppler imaging can have difficulty: tortuosity and calcific plaque. Doppler results can show very high velocities in tortuous patients. The turns and bends in a tortuous artery increase velocities when there may be no plaque present. Equally, top side calcific plaque shadows the artery below making it difficult to obtain velocities due to color drop-out. Visualize agrees well with MRA, while the Doppler results are affected by calcific shadowing.

***Visualize* does not replace Doppler. It is performed in addition to Doppler. *Visualize* does not replace MRA. *Visualize* provides critical detail in a focused area of interest to provide the salient detail in determining patient planning.**

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