PURPOSE

Provide guidelines for screening and follow-up ultrasounds required by the everlinQ endoAVF EU Study protocol.

EQUIPMENT

2-D Ultrasound system
Image format: digital images for electronic transfer and/or burn to CD/DVD/flash
Acoustic gel
Tourniquet

RECORDING

All images are send to TVA Medical/VasCore Ultrasound core lab via AGMednet. Also burn a backup copy on CD and keep with patient file

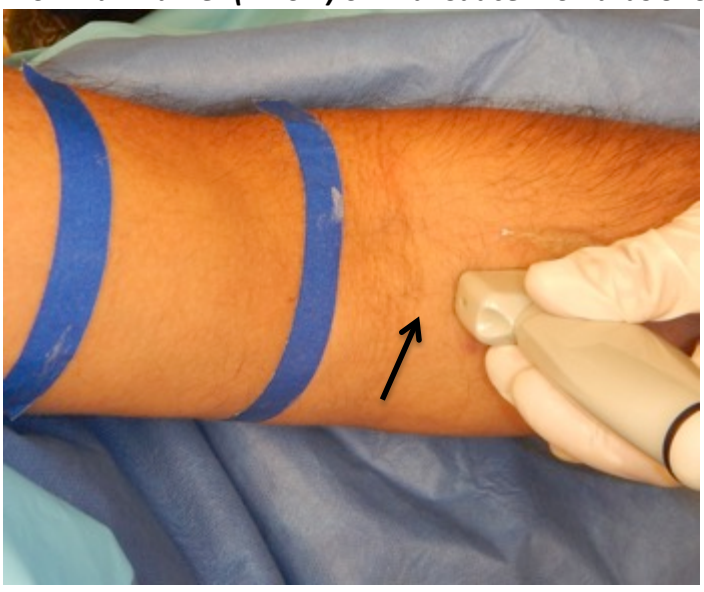
GENERAL TECHNIQUE CONSIDERATIONS

All ultrasound exams for the study should be performed the following technique for screening and follow up ultrasound exams:

- All exams will use a tourniquet applied to upper arm
- Use the "Proximal" marker towards the shoulder or head

Ultrasound Image 1

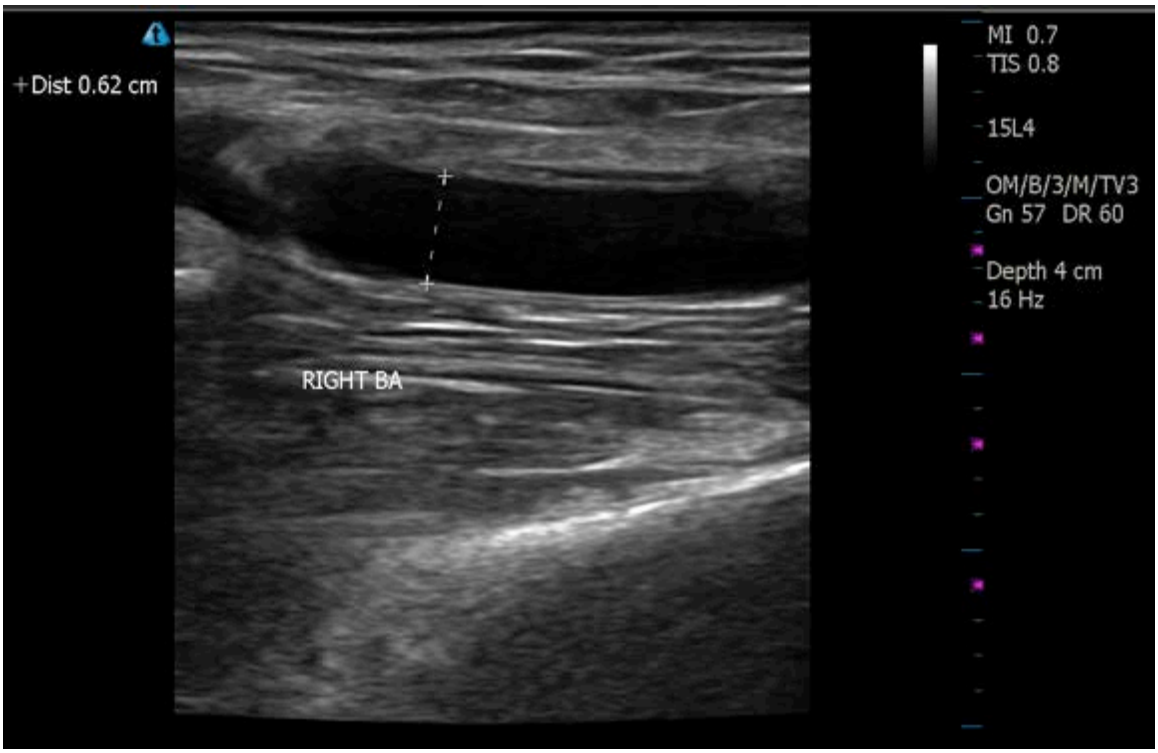
Proximal Marker (Arrow) on Transducer Towards Shoulder/Head



Long Axis images of Brachial Artery; (1) to measure inner diameter for flow measurement (2) to identify moderate to severe plaque present (report in comments section of data collection form)

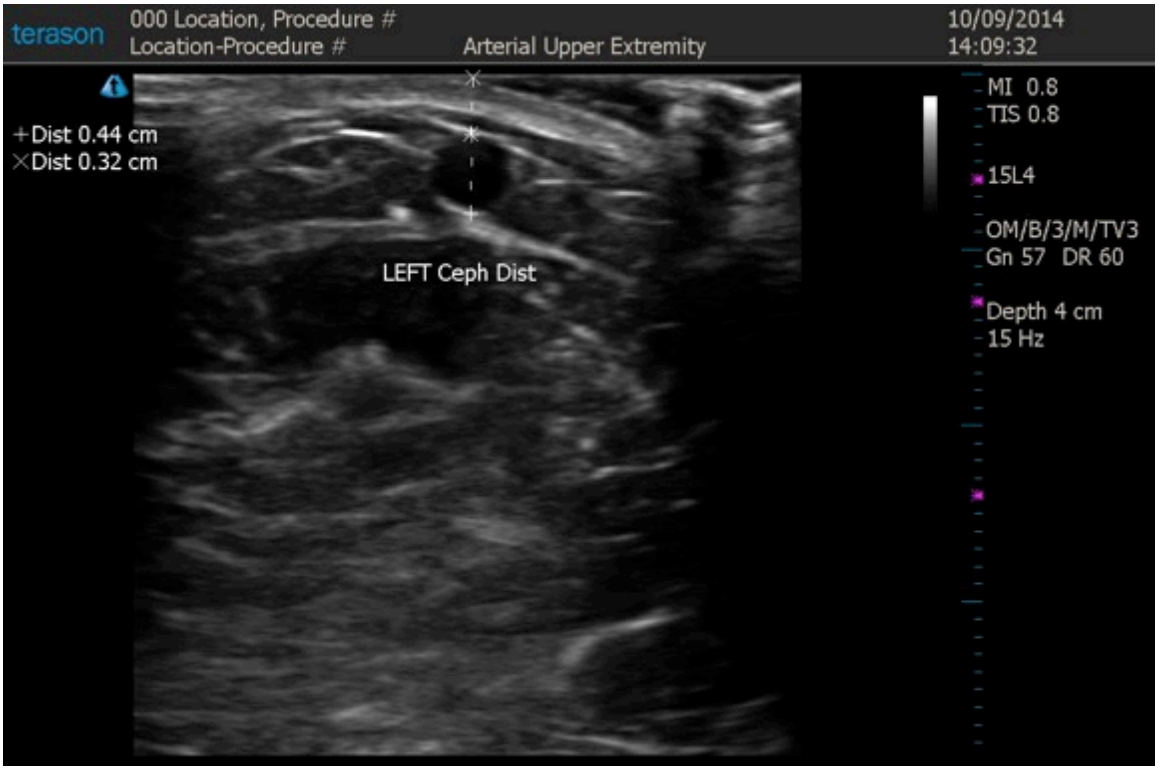
Ultrasound Image 2

Long Axis inner diameter of Brachial Artery-Due to required flow measurement



Ultrasound Image 3

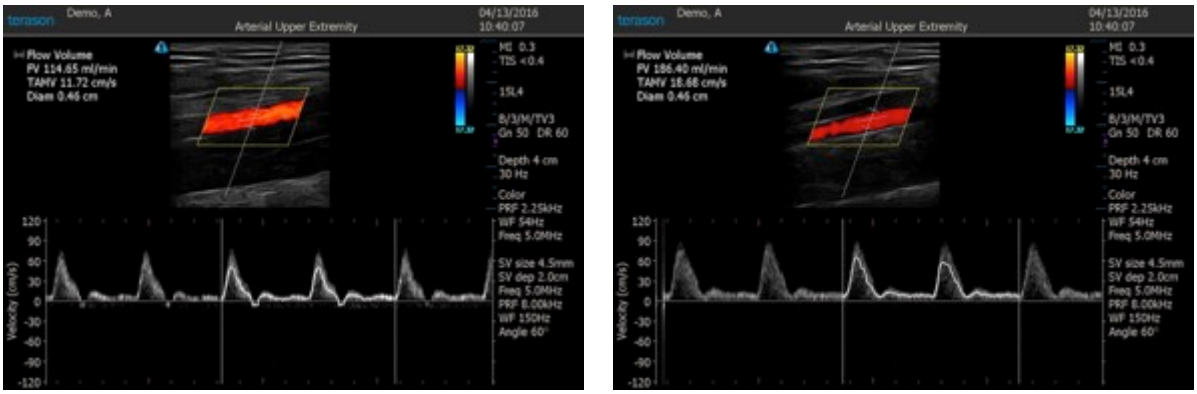
Short Axis Depth and Inner Diameter-- Vessels for potential dialysis cannulation (Upper arm Cephalic, Basilic and Median Cubital) will need to be measured in “Short Axis” for inner diameter and depth



Ultrasound Image 4

Brachial Artery Flow Measurements (screening and follow-up):

- Example 1 – measurement 1 = 167.90ml/min, measurement 2 = 186.40ml/min – 18.50 ml/min difference. Acceptable measurements
    - Example 2 – Measurement 1 = 114.65ml/min Measurement 2 = 186.40ml/min 171.75 ml difference
        - A third measurement is required. 3rd measurement = 167.90ml/min

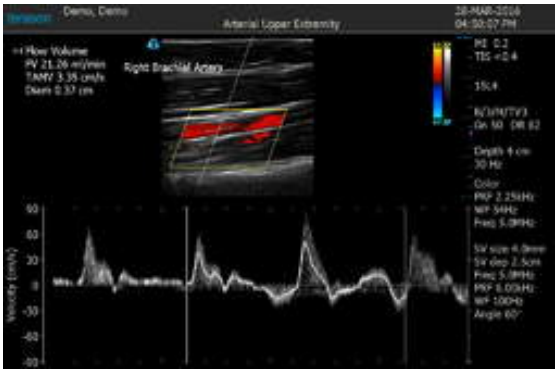


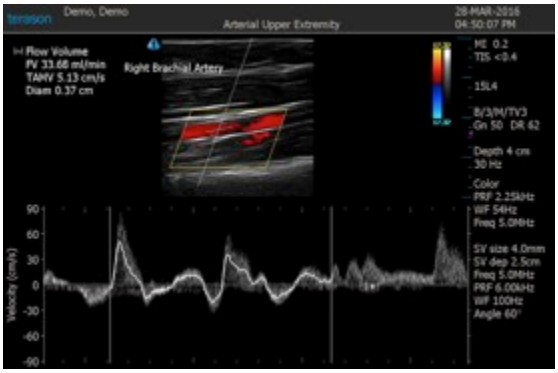
171.75ml/min Difference, NEED to measure again

Ultrasound Image 5

Measure two to three similar complexes when possible

"Poor" Brachial Artery Complexes





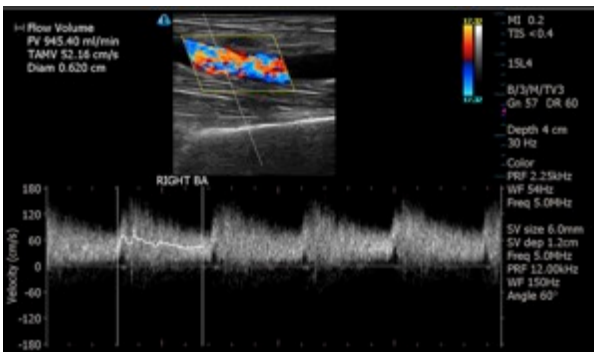
Ultrasound Image 6

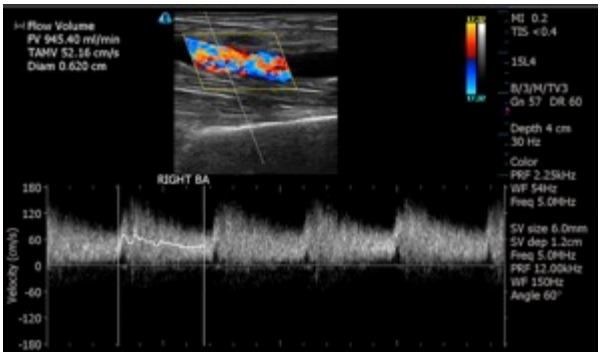
Post endoAVF Creation (study procedure)

- Note Similar Flows and same diameter

Example Post endoAVF Creation Post 24 Hours and beyond:

1st 922.96ml/min 2nd 945.40ml/min "Ideal Consistency"



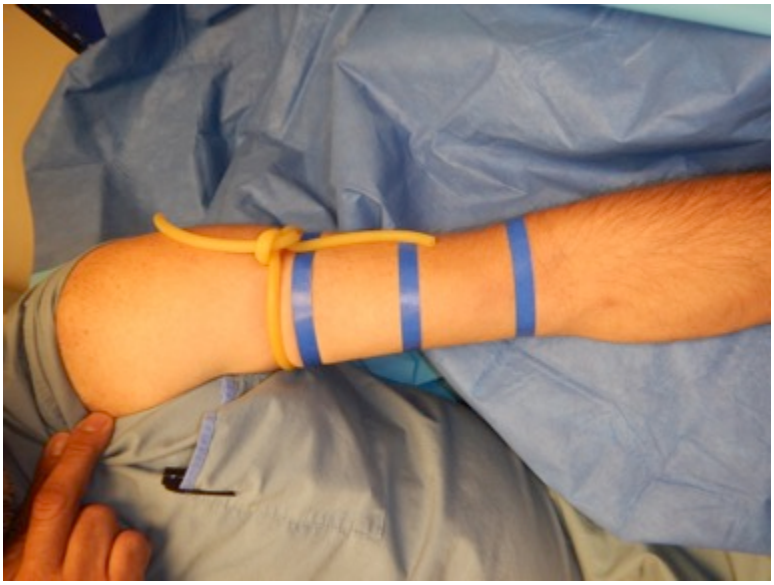


SCREENING ULTRASOUND CAPTURE SPECIFICS

Screening is in three parts with tourniquet in place – *Screening Image 1*

Screening Image 1

Tourniquet Use with Proximal (Blue Tape Shoulder), Mid and Distal (Blue Tape Elbow)



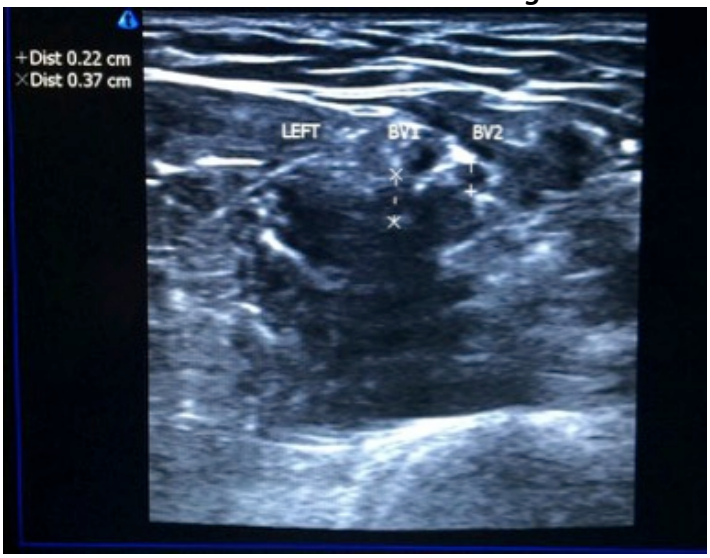
1. ACCESS

Brachial artery and juxtapose veins (Medial (BV1) and Lateral (BV2)). All vessels need to be > 2.0mm – *Screening Image 2*

- Measure and label (Left /Right) the inner diameter Brachial artery mid-distal upper arm. If High Bifurcation is found, note in Data Sheet *****
- Measure Flow and record in data sheet
- Measure inner diameter (Short Axis) and label Brachial Veins BV1, BV2
- ***High Bifurcation:** Periodically high bifurcations are encountered and can be used. First determine which branch is the Ulnar Artery and if the juxtapose veins are present at target. ALL of these vessel need to be 2.0mm or greater.

Screening Image 2

Brachial Vein measurement and labeling



Brachial Artery and Brachial Vein Zone (Mid to Distal Upper Arm)

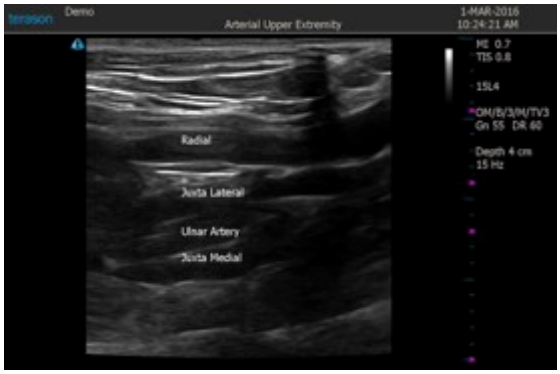
2. TARGET

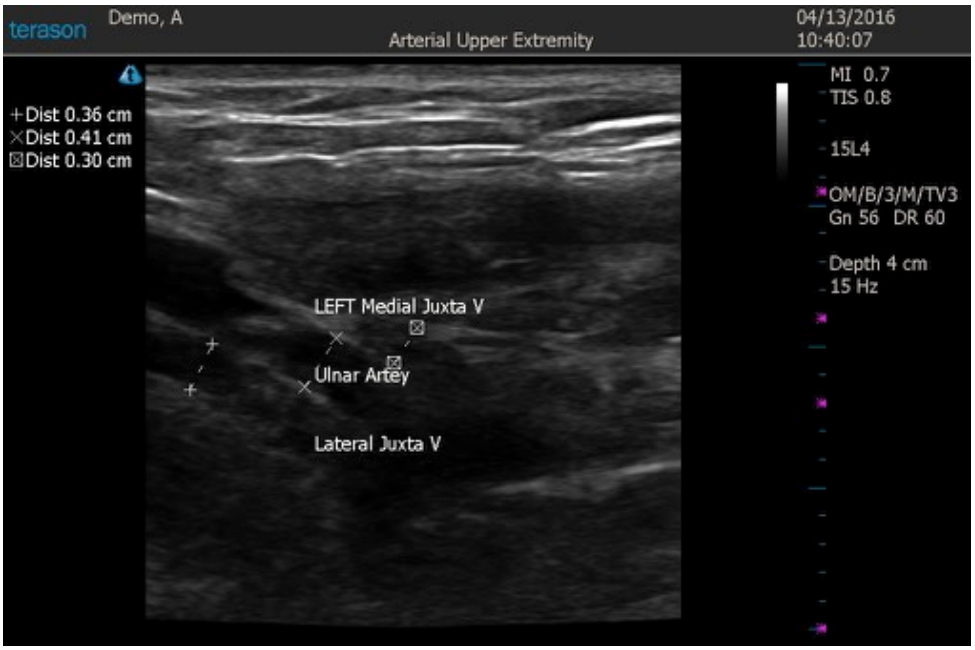
Proximal Ulnar (between brachial bifurcation and Inner Os) inner diameter (> 2mm) juxtapose medial vein and juxtapose lateral vein – *Screening Image 3*

- Measure inner diameter Proximal Ulnar Artery (Long Axis)
- Measure inner diameter juxtapose medial vein (Long Axis)
- Measure inner diameter juxtapose later vein (Long Axis)
  Note: these measurements can be verified in Short Axis
- All vessels must be 2.0 mm or greater for study inclusion
- *High Bifurcation make sure juxtapose vessels originate from upper arm

Screening Image 3

Target Vessels



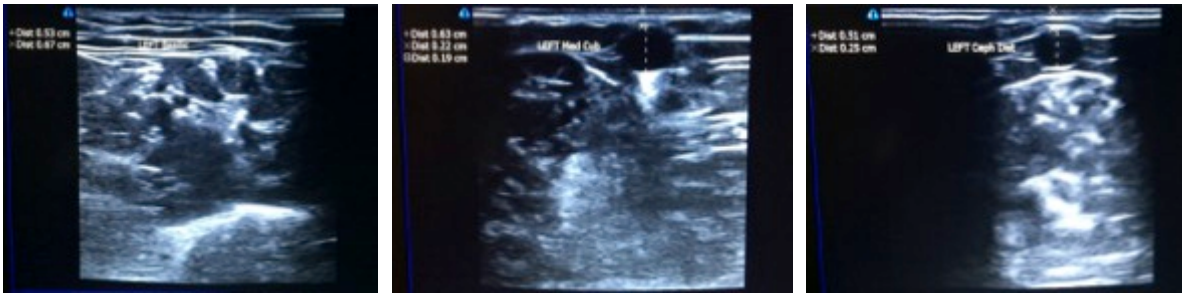


Target Zone (Fore Arm)

3. VEINS UPPER ARM (Cannulation)
Perforator (communicator between deep veins and superficial), Cephalic Vein (Distal, Mid and Proximal), Median Cubital (at Perforator Bifurcation) and Basilic Vein (Distal, id and Proximal). Patient may or may not have Cephalic vein (> 2.0mm) then concentrate on Basilic vein. – *Screening Image 4*

Screening Image 4

Veins Upper Arm



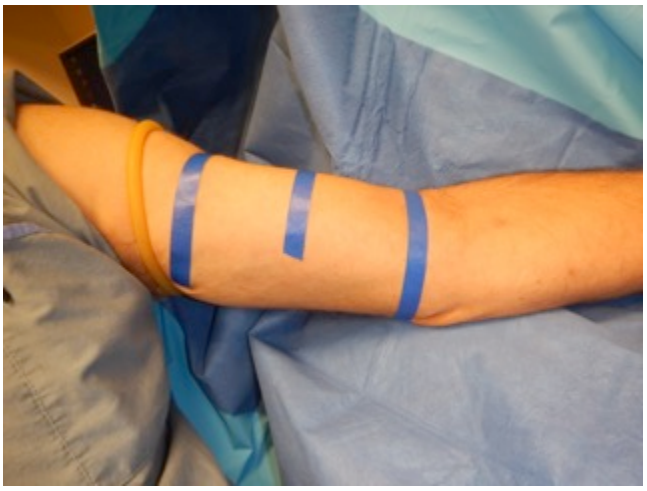
Veins Upper Arm
Measure (remove Measure and replace with identify and delete "inner diameter" we just want to identify it and see where its feeding) Perforator inner diameter (Long Axis) and try to determine what vessel it feeds (Cephalic or Basilic vein system) It is common to feed both vessel but one usually dominates.

Measure inner diameter and depth of Distal, Mid and Proximal Cephalic Vein (Short Axis). Please take care not to measure across a valve. Check the site in long axis to determine valve

location. If no Cephalic vein present, Record on Ultrasound Worksheet. Veins need to be 2.0mm or greater. – *See Veins Upper Arm Image 1.*

Veins Upper Arm Image 1

Distal (Elbow) Mid and Proximal (Shoulder)



Distal Cephalic and Basilic Zone

Mid Basilic and Cephalic Zone

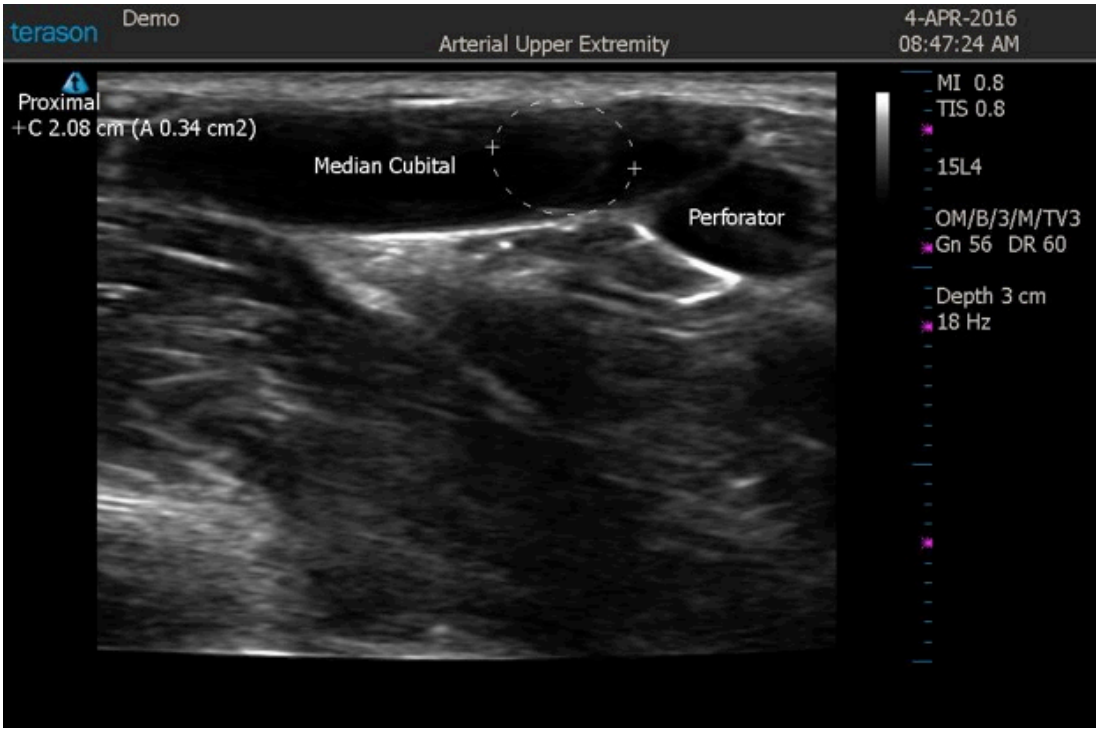
Proximal Cephalic and Basilic Zone

Measure inner diameter and depth of Median Cubital vein just proximal to Perforator *Veins Upper Arm Image 2 -*

Veins Upper Arm Image 2

Median Cubital position to Perforator

The Segmented Circle. Demonstrates the Ideal area to measure Diameter and flow



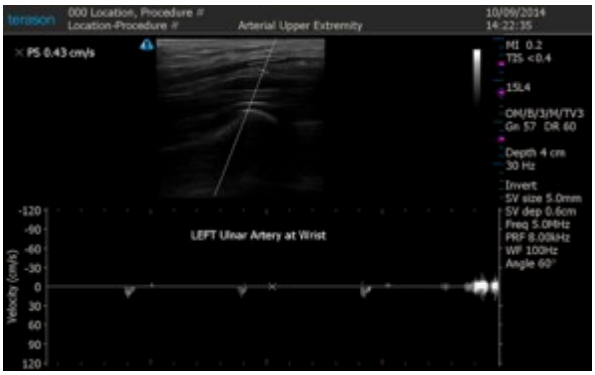
Perforator Zone

Additional Measurement

Radial and Ulnar Artery flow at the wrist with pulse wave to demonstrate flow at the wrist.
Additional Measurement Image 1

Additional Measurement 1

Radial and Ulnar arteries at wrist

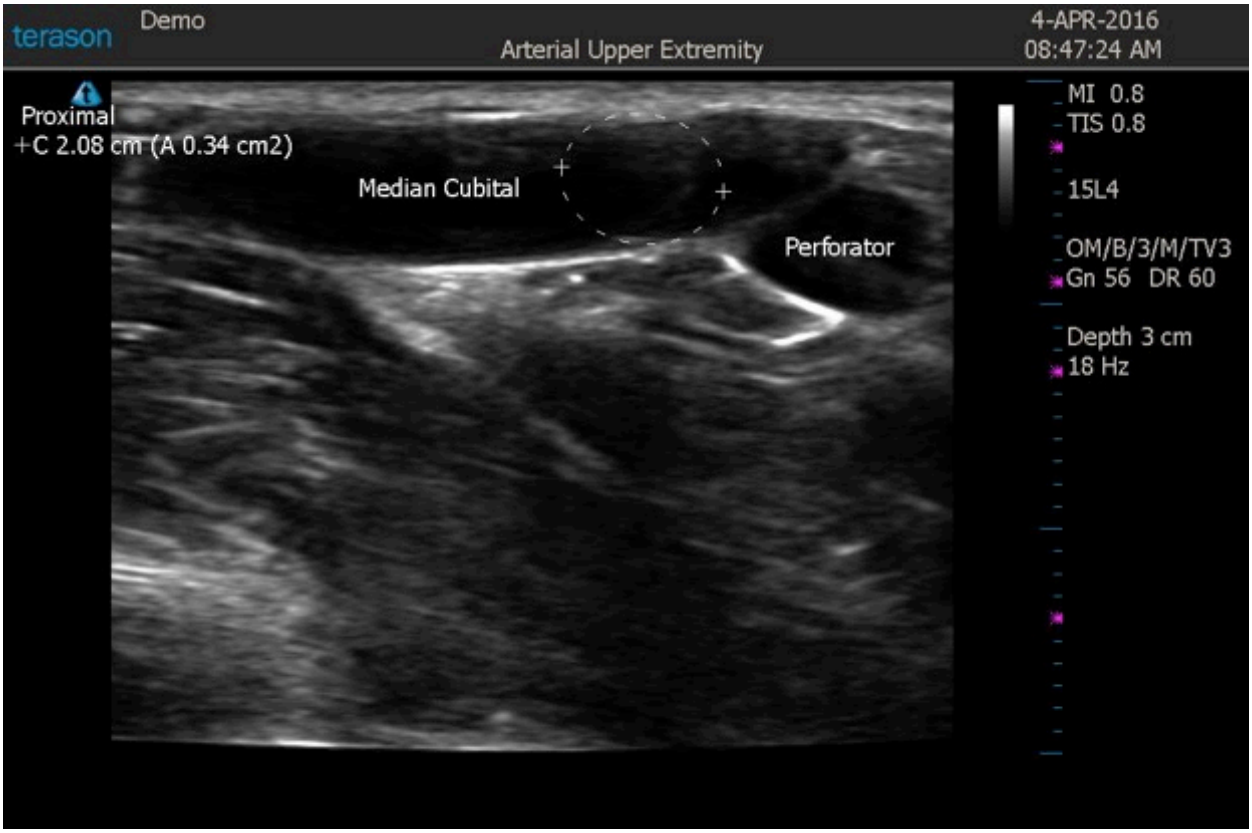


FOLLOW-UP ULTRASOUND CAPTURE

- Study required follow-up visits
  - 0-7 Days, 30-45 Days, 3 months, 6 months, 12 months
  - Unscheduled Visits
- All measurements should be recorded on the follow-up worksheet
- All flow measurements require at least 2 measurements
  - If measurement 1 and measurement 2 are >100 ml/min apart, a 3rd measurement is required.
- endoAVF flow maturation is determined by Brachial Artery Flow. Success with this protocol is flows 500ml/min or greater.
- Label and measure Brachial Artery Flow in long axis with color Doppler to demonstrate direction.
- Label and Measure flow in Distal, Mid and Proximal Cephalic Vein (Long Axis). Measure using color Doppler to determine direction. Then Measure depth and inner diameter.
- Label and measure flow in Distal, Mid and Proximal Basilic Vein (Long Axis).Measure using color Doppler to determine direction. Then Measure depth and inner diameter.
- Label and measure flow Median Cubital Vein (Long Axis). This location is just proximal to Perforator bifurcation. Measure using color Doppler to determine direction. Then Measure depth and inner diameters. *See Follow-up Image 1*

Follow-up Image 1

MC. Segmented Circle is Ideal



- Label and Measure Brachial Veins. There is a very good chance one of these Brachial Veins was “coiled” (Coil= embolization coil). A long axis image with color Doppler to demonstrate occlusion should suffice. *See Follow-up Image 2*

Follow-up Image 2

Embolizing Coil (Blue Arrow)