

SAMPLE QUALITY ASSURANCE FORMS AND REQUIREMENTS

Quality Assurance & Quality Control

CONFIRMATION AND CONFIRMATION OF RESULTS

Quality Assurance procedures will be utilized to ensure that all studies will be reviewed by a Quality Assurance meeting for review and discussion.

- Quality Assurance procedures will also be utilized to review and compare echocardiography and vascular ultrasound results in order to maintain an expected level of accuracy in our diagnostic studies. Ultimately, Quality Assurance and Quality Control procedures will improve the standards of care at our facility.
- In order to ensure accuracy in vascular ultrasound results, the results of all vascular ultrasound exams will be compared to IFA, CT, or surgical results when available. The results will be reviewed by the Technical Director or his/her designee.

- In the absence of the availability of gold standard testing and/or surgical results, vascular ultrasound exams results will be confirmed with re-examination and/or overhead results.

- In order to ensure accuracy in testing as well as the interpretation results, all bilateral internal carotid arteries from each patient of vascular ultrasound testing will be compared to the gold standard. External iliac duplex, common carotid duplex, vertebral duplex, and jugular duplex.

External iliac duplex exams will be reviewed and included under the category of arterial duplex, but must not make up more than 5% of the cases reviewed.

- Exams interpreted by the Medical Director will be randomly selected for outside review and second opinion, in order to ensure accuracy in reporting and results. This will be facilitated by the Technical Director.

There is a designated staff member who will notify the case using the quality assurance log. This staff member will notify the Quality Assurance meeting in need of a second opinion.

Quality Assurance logs will be maintained in the QA log of the information obtained during study correlations and the actions or recommendations implemented.

- Study Comparison Logs will be maintained in the Quality Assurance Manual and will reflect the full documentation recorded on the Study Comparison/Result Confirmation forms.

Completed Study Comparison/Result Confirmation forms will be maintained in the Quality Assurance Manual. When used to document a study, the staff member will sign the form within the specified time frame.

Completed Study Comparison/Result Confirmation will be reviewed by the Medical Director and disseminated to the Medical and Technical staff members.

QUALITY ASSURANCE MEETINGS

Quality Assurance meetings will be held on a regular basis. The meetings will allow for quality assurance review, peer review, in-service presented by staff members and the resolution of any other lab related issues.

- Mandatory attendance of each staff member and physician is required at fifty percent of the meetings each calendar year.

The committee will communicate results of randomly selected studies of the present facility to the medical director in their reports to the medical director. Medical Director will receive all reports presented to the committee and will be responsible for the dissemination and any actions or recommendations implemented. This information will be utilized to improve patient care and accuracy of examination results.

- Ultimately, Quality Assurance and Quality Control procedures will improve the standard of care at our facility.

QUALITY ASSURANCE PROCEDURES:

The committee will perform Quality Assurance Reviews (including Variability Analysis, Report Timeliness & Completeness and Study Correlations) The information obtained by performing these quality assurance measures will be disseminated to the Medical Director and the technical staff.

- If discrepancies are noted during the quality assurance reviews, the Medical Director will alert the technical staff and evaluate the responsibility for the discrepancy. The staff will work with the medical director to determine the specific effecting cause and corrective measures. Corrective measures will be taken to the satisfaction of the medical director and the committee.

EQUIPMENT AND INSTRUMENT MAINTENANCE:

PREVENTATIVE MAINTENANCE/SAFETY INSPECTIONS GENERAL MAINTENANCE OF INSTRUMENTS AND TRANSDUCERS:

Preventative maintenance programs will be done to insure equipment and instruments are in good working condition and are safe.

Quality assurance in the ultrasound lab requires documentation of proper equipment maintenance and safety measures. Quality Assurance procedures will be used to help ensure that the equipment utilized by our facility meets or exceeds expected standards and is functioning properly for optimal patient care.

The manufacturer's instructions, especially the imaging equipment manuals and/or other literature provided will be kept and read by the sonographer. The equipment will be inspected and maintained by the manufacturer or by a qualified technician. This will be done by scheduling permits, at a minimum of once monthly.

Documentation of equipment damage and filter cleaning will be maintained in the medical equipment log.

- The sonographer will clean transducers with anti-bacterial/anti-viral cleaning agents after each patient and will take care to clean the umbilical cables and cords. The cords and cables will be kept separate. The sonographer will inspect the probe and cables for damage and report any damage to the medical director. The medical director will be notified immediately. A report will be made of the damage and the medical director will be notified immediately. The medical director and use of equipment will be discontinued until resolution, repair or replacement of

Appropriateness of Indications for Ultrasound Examination

SAMPLE ONLY

... must be evaluated for clinical appropriateness and appropriate indications prior to completion. The performing sonographer must identify the diagnosis and indication for the ultrasound procedure from the physician orders within the patient's chart. The ordered ultrasound procedure must correlate with the diagnosis and indication for the exam(s).

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... the performing sonographer must verify that the correct exam has been ordered per the patient clinical diagnosis and indications. Patient symptoms and clinical history must accurately coincide with exam to be performed. If the indication for the ordered study does not correlate with patient clinical symptoms and diagnosis codes (refer to ICD9 coding), the ordering physician must be contacted to correct, review, and/or verify the exam(s) to be performed along with appropriate diagnosis codes and indications for the exam(s).

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Quality Assurance – Study Correlation & Confirmation of Results

Objectives

- Venous Duplex ultrasound exams will be randomly selected for comparison and correlation with gold standard modalities, including venography and MRV imaging if available, in order to ensure accuracy in testing results. Ultrasound results will also be compared with surgical results when available.

- Interpretation of the results of gold standard imaging vs surgical results, and correlation of ultrasound exams will be confirmed with alternative methods, including re-examination, clinical outcome and over-read results.

- In order to facilitate the quality assurance process, records will be maintained by referral coordinators, surgical coordinators, nurses and other ancillary staff members. Documentation will be maintained for patients scheduled for and receiving treatment, treatment within the gold standard parameters, surgical results and clinical treatment, relating to the study. A database will be developed to allow for easily retrieving patient information and making study correlation and result confirmation easily accessible.

- In order to ensure accuracy in testing as well as interpretation results, a total of 10 limbs will be compared annually. A minimum of 5 extremity comparisons will be made semi-annually and the results will be disseminated to the medical and technical staff members of the Quality Assurance Committee.

The Technical Director will be responsible for the study correlations and

confirmation of results. However at the discretion of the Technical Director, this task may be assigned to a member of the nursing and/or ultrasound staff. The majority of this task will be delegated to **INSERT NAME/TITLE HERE** with assistance from other nursing and ultrasound staff members with direct supervision and final review by the Technical Director.

The Quality Assurance Manual will be updated in the Quality Assurance Manual and will reflect the full documentation recorded on the Study Comparison/Result Confirmation forms.

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Completed Daily Comparison Result Confirmation forms will be maintained in the instrument log. The data will be used to compare our laboratory results to the reference laboratory. Accuracy statistics results will be performed and reviewed semi-annually with the medical and technical staff. Study Correlations and Confirmation of results will also be reviewed by the Medical Director.

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- Sonographer Review – Venous Duplex (minimum of 3) will be performed on a semi-annual basis. This information will be maintained on file with the QA manual.
- Physician Reviews – Venous Duplex (minimum of 3) will be performed on a semi-annual basis. This information will be maintained on file with the QA manual.

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Quality Assurance – Study Correlation & Confirmation of Results

Sample Assurance

A sample of ultrasound exams will be randomly selected for comparison and correlation with gold standard modalities, including MR/CT/Contrast Angiography, when available, in order to ensure accuracy in testing results. Ultrasound results will also be compared with surgical results, when available.

In the absence of the availability of gold standard testing against surgical results, the correlation of ultrasound examinations will be confirmed with the radiologist.

- In order to facilitate the quality assurance process, records will be maintained by referral coordinators, surgical coordinators, nurses and other ancillary staff members. Documentation will be maintained for patients scheduled for and receiving testing within the pod, including parameters and surgical procedures, allowing for correlation of cases. This will allow for easy testing patient correlation with the study care team and correlation with the pod.

- In order to ensure accuracy in testing as well as interpretation results, a total of 10 limbs will be compared annually. This task will be performed on a semi-annual basis with a minimum of 5 extremity correlations. Results will be disseminated to the medical and pod staff at semi-annual Quality Assurance (QA) meeting.

Pod staff members will be responsible for the correlation of results; however at the discretion of the Technical Director, this task may be assigned to a member of the nursing and/or ultrasound staff. The majority of this task will be delegated to **INSERT NAME/TITLE HERE** with assistance from other nursing staff members with direct supervision and final review by the Technical Director.

- Pod staff members will be trained in the quality assurance process and will be responsible for documenting the correlation on the Study Comparison/Result Confirmation forms.

- Completed Study Comparison/Result Confirmation forms will be maintained in the Quality Assurance Manual and will be used to document accuracy in vascular lesions and stenosis detection results with the laboratory's secondary test results which are then reviewed periodically with the laboratory. The Study Comparison/Result Confirmation of results will also be reviewed by the Medical Director.

- Sonographer Reviews – Peripheral Arterial (minimum of 3) will be performed on a semi-annual basis. This information will be maintained on file within the QA manual.
- Peripheral Venous (minimum of 3) will be performed on a semi-annual basis. This information will be maintained on file within the QA manual.

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Quality Assurance – Study Correlation & Confirmation of Results

Carotid

- Carotid duplex ultrasound exams will be randomly selected for comparison and correlation with gold standard modalities, including MR/CT/Contrast Angiography, when available, in order to ensure accuracy in testing results.

Vascular ultrasound results will also be compared with surgical results, when available.

When the gold standard is available and/or surgical and/or surgical results, carotid duplex ultrasound exams results will be confirmed with re-examination and over-read results.

- In order to facilitate the quality assurance process, records will be maintained by referral coordinators, surgical coordinators, nurses, and other ancillary staff members. Documentation will be maintained for patients who are referred for carotid duplex ultrasound to the general radiology department and for patients who are referred for carotid duplex ultrasound to the vascular laboratory. This will allow for easily retrieving patient information and making study correlation and result confirmation easily accessible.

- In order to ensure accuracy in testing as well as interpretation results, a minimum of 10 case studies will be compared and confirmed annually. This task will be completed by the research assistant with a minimum of two case reviews. The results of the study correlation will be presented to the medical and technical staff at semi-annual Quality Assurance (QA) meetings.

- The Technical Director will be responsible for the study correlations and confirmation of results. However at the discretion of the Technical Director, this task may be assigned to a member of the nursing or ultrasound staff. The majority of this task will be delegated to the research assistant with a minimum of two nursing or ultrasound staff members. The results of the study correlation will be presented to the Technical Director.

- Study Comparison Logs will be maintained in the Quality Assurance Manual and will reflect the full documentation recorded on the Study Comparison/Result Confirmation forms.

SAMPLE ONLY

- Completed Study Comparison Result Confirmation forms will be maintained in the Quality Assurance Manual and will be used to determine accuracy of vascular reports. The results of the laboratory work and abnormal results will be performed and reviewed semi-annually with the medical and technical staff. Study Correlations and Confirmation of results will also be reviewed by the Medical Director.

SAMPLE ONLY

- Sonographer Reviews – Carotid Duplex (minimum of 3) will be performed on a semi-annual basis. This information will be maintained on file within the QA manual.
- Sonographer Reviews – Carotid Duplex (minimum of 3) will be performed on a semi-annual basis. This information will be maintained on file within the QA manual.

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Quality Assurance – Study Correlation & Confirmation of Results

- Venous Duplex ultrasound exams will be randomly selected for comparison and correlation with gold standard modalities, including venography and MRV imaging if available, in order to ensure accuracy in testing results. Ultrasound results will also be compared with surgical results when available.
- Correlation of the results of gold standard testing with surgical results, including re-examination of gold standard exams, will be confirmed with alternative methods, including re-examination, clinical outcome and over-read results.
- In order to facilitate the quality assurance process, records will be maintained by referral coordinators, surgical coordinators, nurses and other ancillary staff members. Documentation will be maintained for patients scheduled for and receiving endovascular treatment within the gold standard parameters surgical treatment and clinical treatment including treatment of the lower extremities. The staff will follow for easily retrieving patient information and making study correlation and result confirmation easily accessible.
- In order to ensure accuracy in testing as well as interpretation results, a total of 10 limbs will be compared annually. A minimum of 5 extremity comparisons will be made annually and the results will be disseminated to the medical and technical staff for internal quality assurance purposes.
- The Technical Director will be responsible for the study correlations and confirmation of results. However at the discretion of the Technical Director, this task may be assigned to a member of the nursing and/or ultrasound staff. The majority of this task will be delegated to **INSERT NAME/TITLE HERE** with assistance from other nursing and ultrasound staff members with direct surgical responsibilities by the Technical Director.
- The results of the study will be documented in the quality assurance Manual and will reflect the full documentation recorded on the Study Comparison/Result Confirmation forms.

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• Completed Daily Duplex or Result Confirmation forms will be maintained in the quality manual. The results will be used to determine accuracy of the laboratory. Accuracy statistics results will be performed and reviewed semi-annually with the medical and technical staff. Study Correlations and Confirmation of results will also be reviewed by the Medical Director.

SAMPLE ONLY

- Sonographer Review – Venous Duplex (minimum of 3) will be performed on a semi-annual basis. This information will be maintained on file within the QA manual.
- Physician Reviews – Venous Duplex (minimum of 3) will be performed on a semi-annual basis. This information will be maintained on file within the QA manual.

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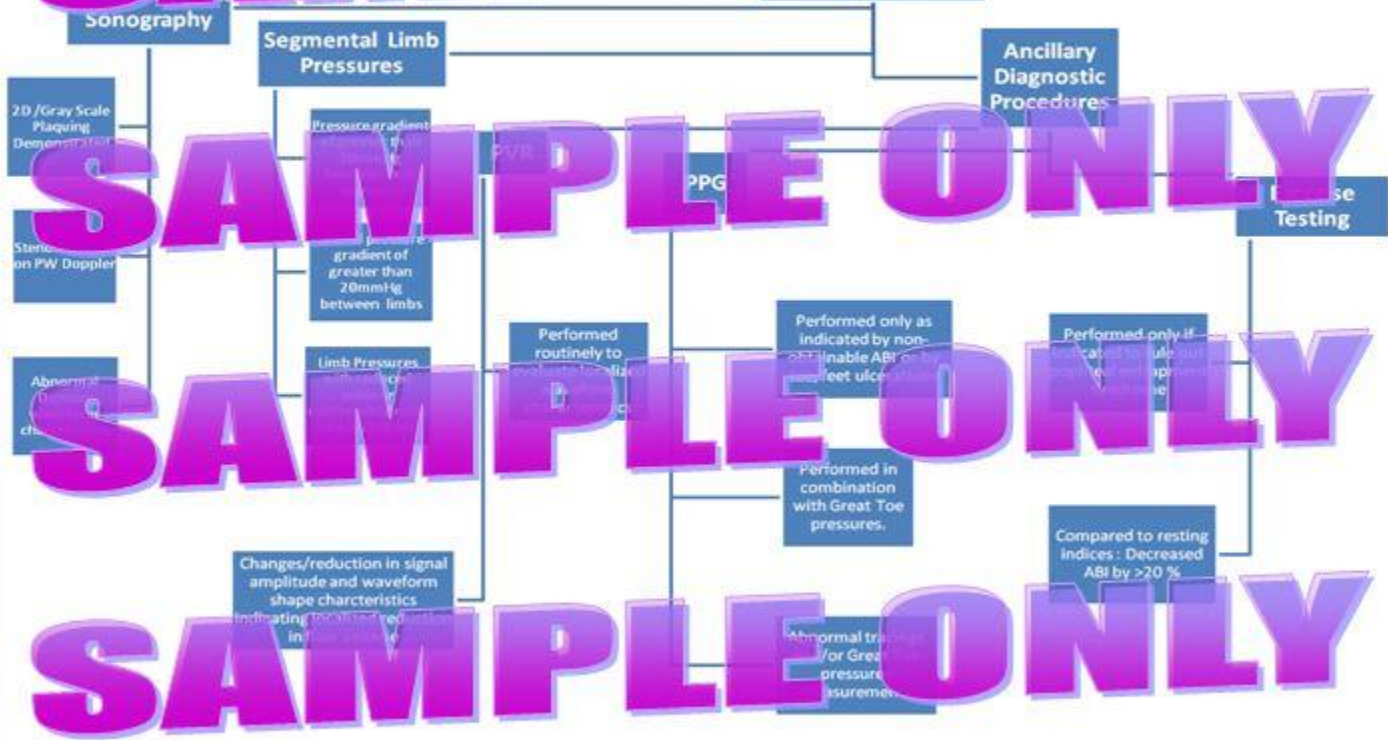
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DIAGNOSIS OF PERIPHERAL ARTERIAL DISEASE

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Peripheral Arterial Diagnosis



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VASCULAR QUALITY ASSURANCE WORKFLOW



Diagnostic Criteria: Peripheral Arterial Duplex Ultrasound Assessment

Level of disease	Flow pattern	Distal brachial index	Waveform of proximal
Normal	Triphasic	Absent	No change
Mild 1%-19%	Triphasic	Present	<2:1
Moderate 20%-49%	Biphasic	Present	<2:1
Severe 50%-99%	Monophasic	Present	>2:1
Occluded	None	None	None

Distal brachial index >1.6 suggests >75% stenosis, >7:1 suggests >90% stenosis.

Reference:

Table 15 Diagnostic criteria for peripheral arterial diameter reduction. Guidelines for Noninvasive Vascular Laboratory Testing: A Report from the American Society of Echocardiography and the Society of Vascular Medicine and Biology. Journal of the American Society of Echocardiography, August 2008.

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Diagnostic Criteria: Peripheral Arterial Segmental Limb Pressure Assessment

Level of disease	Findings
Aortoiliac	High thigh/brachial index <0.9 bilaterally
Distal aortoiliac	High thigh/brachial index <0.9 bilaterally
Distal femoral	High thigh/brachial index <0.9 bilaterally
Distal SFA/popliteal	Gradient between thigh cuff and calf cuff
Infrapopliteal	Gradient between calf and ankle cuffs

Pressure readings are <90 mmHg considered abnormal. Pressure readings are >90 mmHg considered normal.

SFA = Superficial femoral artery.

Reference:

Table 10 Criteria for abnormal segmental pressure study. Guidelines for Noninvasive Vascular Laboratory Testing: A Report from the American Society of Echocardiography and the Society of Vascular Medicine and Biology. Journal of the American Society of Echocardiography, August 2008.

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Diagnostic Criteria: Peripheral Arterial PVR Assessment

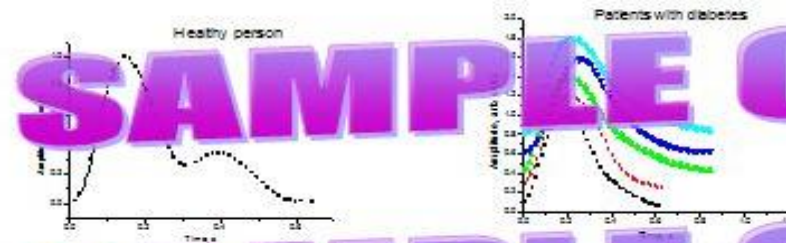


Recording order with increasing vascular disease severity

Guidelines for Noninvasive Vascular Laboratory Testing: A Report from the American Society of Echocardiography and the Society of Vascular Medicine and Biology. *Journal of the American Society of Echocardiography*, August 2006.

Diagnostic Criteria: Peripheral Arterial Photoplethysmography Assessment

A PPG waveform consists of a systolic part or a sharp upstroke, a diastolic part or a sharp downstroke, and a systolic-diastolic interval or a sharp downstroke. The upstroke and downstroke represent the stretching of blood vessel walls under the increased blood pressure after each heartbeat, and diastole – relaxation processes of the blood vessel walls in-between.



Potential of advanced photoplethysmography sensing for non-invasive vascular diagnostics and early screening.

3. RESULTS OF THE CLINICAL TEST MEASUREMENTS

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Diagnostic Criteria: Additional Arterial Testing Parameter Assessment

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ABI, Ankle-brachial index; PAD, peripheral arterial disease.

Interpretation criteria for arterial stenosis after revascularization

SAMPLE ONLY

PSV, Peak systolic velocity.

Criteria for diagnosis of pseudoaneurysm sac

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Diagnostic criteria for abdominal aortic aneurysm and endoleak

- Aneurysm: diameter > 3.0 cm
- Endoleak: flow outside of the aortic endograft, and within the aneurysm sac
- Dissection: true and false lumen present

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Diagnostic Criteria: Interpretation of Arterial Bypass Graft

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Exceptions to using distal-to-proximal PSV ratio include cases with a diameter mismatch in the graft or proximal tandem lesions. In these cases a distal PSV can be used instead of the PSV ratio. Doubling of the velocity PSV ratio indicates significant graft stenosis of greater than 50%, with sensitivity of 95% and specificity 100%. Severe or high-grade lesions warrant intervention. Low velocities indicate poor arterial inflow, proximal stenosis, or large graft diameter. The presence of a parvus et tardus waveform indicates inflow disease or proximal stenosis. In addition a PSV less than 45 cm/s within a graft indicates that the graft is not functioning. The following criteria for flow velocities help to determine the degree of stenosis: flow velocities < 45 cm/s or ratios greater than 2 indicate up to 50% stenosis; low-flow states (<45 cm/s) indicate increased propensity for graft failure; and changes in waveform shape and velocity measurements on serial examinations warrant close follow-up/possible revision.

Diagnostic criteria for vein graft lesions using peak systolic velocity

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Mild stenosis:	50% with PSV ratio <1.5 and a PSV <125 cm/s
Severe stenosis:	50% to 75% with PSV ratio 1.5 to 2.4 and a PSV <180 cm/s
High-grade stenosis:	>75% with PSV ratio >4 and PSV >300 cm/s

PSV, Peak systolic velocity.

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Diagnostic Criteria: Extracranial Duplex

Degree of Stenosis	Peak Velocity (cm/s)	Plaque Estimate %	ICA EDV (cm/s)	ICA/CCA PSV Ratio (PSV Ratio)
Normal	<125	0	<40	<2
<50%	<125	<50%	<40	<2
51-70%	>125	>50%	>40	>2
>70%	>230	>50%	>100	>4
Sub-Total Occlusion	variable	>50% Narrow Lumen	>0	Variable
Total Occlusion	0	>50%	0	<1

CCA = common carotid artery; ICA = internal carotid artery; PSV, peak systolic velocity.

References:

Table 3 Criteria for classification of internal carotid artery disease by duplex scanning with spectral waveform analysis of pulsed Doppler signals.

Guidelines for Noninvasive Vascular Laboratory Testing: A Report from the American Society of Echocardiography and the Society of Vascular Medicine and Biology. *Journal of the American Society of Echocardiography*, August 2006.

Diagnostic Criteria: Extra-cranial Duplex

PSV is the primary parameter which is relied upon for diagnosis of the percent of stenosis of the vessel.

Considerations are taken for vessel anatomy, specifically tortuosity, which may cause an increase in PSV velocity without the presence of a true stenosis.

- Considerations are also taken for the presence of plaque within the vessel.
- EDV measurements are performed and reviewed. These measurements are taken into consideration for the overall diagnosis. However they are not typically used as a primary diagnostic parameter in evaluation for ICA stenosis in this lab.
- ICA/CCA ratio is also reviewed. However careful interpretation is required.
- Color Doppler is performed. This diagnostic information is utilized in conjunction with PSV measurements to gain an overall review of the stenosis and to diagnose an accurate percentage of occlusion.

- Additional reporting is performed to include the characterization and description of plaque formations within the CCA, ICA and Vertebral arteries. Plaque formation is documented by location, 2D ultrasound characteristics as well as velocity ratios if appropriate.
- Velocity ratio indices may be performed for any stenosis within an extra-cranial vessel. This is performed as long as the vessel is a primary vessel. If a branch vessel, the reporting of this stenosis ratio will be performed as indicated.

Diagnostic Criteria: Venous Duplex

Diagnosis of venous thrombosis is based on the following criteria:

• Diagnosis of age of thrombus

- Vessel Patency
- Valvular Insufficiency

Criteria for diagnosis of vessel patency and

assessment of the thrombus age

Diagnosis of vessel patency and assessment of the thrombus age will be assessed by 2D imaging with compression maneuvers to collapse the vessel, or prove non-coaptation of the vessel walls, therefore allowing for the diagnosis or exclusion of DVT.

- Signs of fresh/acute DVT of the leg are pronounced dilatation of the vein and good delineation of the homogeneous, often hypoechoic, intraluminal thrombus lumen from perivascular connective tissue.

Chronic thrombosis is associated with shrinkage of the lumen relative to the compression point (normal vein lumen position) and with fresh thrombus.

Diagnosis of DVT or superficial thrombosis will be based on compression ultrasound technique.

- Chronic DVT and/or superficial thrombosis may be characterized by recanalization of flow. This can be diagnosed by the utilization of Color Doppler.

Reference: Ultrasonography in Vascular Diagnosis, W. Schaefer, 333 Atlas Periphoral Veins, pp. 147

Criteria for diagnosis of valvular insufficiency:

- Valvular incompetence/insufficiency is primarily diagnosed with PW Doppler waveforms, which assess flow characteristics in response to compression and decompression augmentation maneuvers, as well as respiratory variances and particularly the Valsalva maneuver.

True valvular insufficiency must be distinguished between distal or locally sclerosed veins in cases with history of chronic thrombosis.

Flow velocity measurements by color duplex imaging to document the severity of reflux and the venous outflow reflux is also useful to document the severity of reflux at the venous confluence.

References:

Ullrich NP, et al. Vascular Dementia. *N Engl J Med*. 1991;325:1068-75.
Aronson GR, et al. *Stroke*. 1984;15:140-4.
Wright J, et al. *Stroke*. 1984;15:140-4.
New, MD, Resident, Department of General Surgery, University of Southern California; Fred A Weaver, MD, Professor of Surgery, University of Southern California; Chief, Division of Vascular Surgery, Director of Noninvasive Vascular Laboratory, Program Director of Vascular Surgery, University of Southern California University Hospital; Craig P. Feist, MD, FACS, FASEP, FACP, Professor of Emergency Medicine, Georgia Institute of Technology School of Medicine, General Vascular and Endovascular Hospital Group. *Stroke*. 1984;15:140-4.

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Physician / Final Report Review

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Reviewer : _____ Date of Review _____

	Study # 1	Study #2	Study #3
Interpretation			

Interpretation Scoring: No Discrepancies=1 | Minor Discrepancies=2 | Major Discrepancies=3

Report Scoring: Accurate/Complete=1 | Minor Inconsistencies=2 | Major Inconsistencies=3

Overall Comments:

SAMPLE ONLY

Study #2:

SAMPLE ONLY

Study #3:

Technologist / Sonographer Exam Review

Type of No. _____ Date: _____

Technologist: _____

Reviewer: _____ Date of Review: _____

Criteria	Study #1	Study #2	Study #3
Type of animal			
Adherence of protocol			
Scan is complete and thorough			
Waveform quality (CW Doppler, PR, DE, etc. PWT)			
Image quality (if applicable)			
Overall technical quality (system settings, accurate measurements and angle technique)			

Criteria: Score 1: 5, Score 2: 4, Score 3: 3, Score 4: 2, Score 5: 1, Unacceptable=0

Review Comments:

Study #1: _____

Study #2: _____

Study #3: _____

Preliminary/STAT Results

SAMPLE ONLY
Time: _____

Patient Name: _____

Exam Performed: _____

SAMPLE ONLY
Results called by: _____
Date/Time: _____

Summary of Results: _____

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TIMELINESS/COMPLETENESS OF REPORTS

REVIEWER: _____

	PATIENT	TEST	INTERPRETATION	DATE	TIME	MEASUREMENT	REASON FOR TEST	DATE	TIME	PERIOD	AO
1.						Y/N					
2.						Y/N					
3.						Y/N					
4.						Y/N					
5.						Y/N					
6.						Y/N					
7.						Y/N					
8.						Y/N					
9.						Y/N					
10.						Y/N					