

**ICAVL STANDARDS  
FOR ACCREDITATION IN  
NONINVASIVE VASCULAR TESTING**

**PART II  
VASCULAR LABORATORY OPERATIONS**

**PERIPHERAL ARTERIAL TESTING**

**Section 1 - Instrumentation**

**STANDARD - Instrumentation**

**1.1 Segmental systolic pressure measurements together with segmental Doppler or plethysmographic waveforms must be performed to localize and characterize peripheral arterial disease. Appropriate instrumentation must be provided.**

Measurement of systolic blood pressures at one or more levels in combination with **multi-segmental** Doppler and/or plethysmographic waveform analysis are required components of peripheral arterial testing. Duplex ultrasonography utilizing gray scale imaging with Doppler waveform analysis may be used to provide information regarding the anatomic location and severity of the disease.

- 1.1.1 **Segmental Limb Pressures:** Segmental systolic pressure measurements provide a means of assessing regional systolic blood pressure in the extremities.

**Required Instrument Characteristics**

- 1.1.1.1 Cuffs of varying width appropriate to the limb segment to be evaluated must be used.
- 1.1.1.2 Appropriate device(s) for blood flow detection must be used.
- 1.1.1.3 Pressure measurements must be recorded in mm Hg.
- 1.1.2 **Continuous Wave (CW) Doppler:** Direction sensitive CW Doppler blood flow meters provide both direct and indirect evaluation of peripheral arterial blood flow.

### **Required Instrument Characteristics**

- 1.1.2.1 Doppler transducer frequencies of 3 MHz or greater must be available.
  - 1.1.2.2 The Doppler waveform display must be capable of demonstrating bidirectional blood flow.
  - 1.1.2.3 The instrument must provide both an audible output and a permanent recording of the Doppler waveform.
- 1.1.3 **Segmental Limb Plethysmography:** Plethysmography provides a semi-quantitative method to grade the pulsatile component of regional limb blood flow.

### **Required Instrument Characteristics**

- 1.1.3.1 Instruments capable of measuring small segmental volume changes and providing permanent recordings must be used.
  - 1.1.3.2 For air plethysmography, appropriately sized pneumatic cuffs relative to segmental (limb, digit) diameter must be used.
  - 1.1.3.3 Standardization of inflation pressures for segmental air (volume pulse) plethysmography must be used.
- 1.1.4 **Duplex Ultrasonography:** Duplex ultrasonography demonstrates vessel anatomy and morphology, atherosclerotic plaque and other vascular abnormalities as well as surrounding soft tissue characteristics, and displays the Doppler spectral waveforms from selected sites. Color coded Doppler, power Doppler and other blood flow imaging techniques provide a qualitative, simultaneous display of blood flow information with the gray scale image. The use of these techniques is considered complementary.

### **Required Instrument Characteristics**

- 1.1.4.1 A range of imaging frequencies appropriate for the vessels and structures evaluated must be available.
- 1.1.4.2 Doppler transducer frequencies of at least 3.0 MHz must be available.

- 1.1.4.3 Range-gated Doppler must be provided with the ability to adjust the position of the range gate within the area of interest.
- 1.1.4.4 The Doppler angle must be measurable and adjustable.
- 1.1.4.5 The instrument must provide a visual display and an audible output as well as a permanent recording of the Doppler waveform and image.

## **1.2 Supplemental techniques may be used for appropriate clinical indications.**

**Comment:** These techniques are inadequate for use alone to diagnose and grade the severity of peripheral arterial disease.

### **1.2.1 Transcutaneous Oximetry (TcPO<sub>2</sub>)**

#### **Required Instrument Characteristics**

- 1.2.1.1 The instrumentation must be calibrated prior to use.
- 1.2.1.2 Output must be expressed in mmHg.

### **1.2.2 Photoplethysmography (PPG)**

#### **Required Instrument Characteristics**

- 1.2.2.1 The instrument must be capable of providing a permanent recording of the PPG waveform.
- 1.2.2.2 The instrument must have appropriate electrical coupling for signal display.

### **1.2.3 Laser Doppler**

#### **Required Instrument Characteristics**

- 1.2.3.1 The instrument must use appropriate frequencies / laser diodes for transillumination of the skin.
- 1.2.3.2 The instrument must have appropriate sized cuffs for coupling the probe to the limb segment under evaluation.
- 1.2.3.3 The instrument must be capable of providing a permanent recording of the data acquired.

#### 1.2.4 Treadmill Exercise / Stress Testing

**Comment:** A treadmill or other technique(s) may be used to provide stress testing for the diagnosis of lower extremity arterial occlusive disease.

##### Required Instrument Characteristics

1.2.4.1 A motorized treadmill is used to provide consistent patient workload. Other forms of standardized exercise may be used.

#### 1.2.5 Abdominal Aortic Duplex

##### Required Instrument Characteristics

1.2.5.1 As written in 1.1.4 Duplex Ultrasonography

### Section 2 - Indications

#### STANDARD - Indications

#### 2.1 Peripheral arterial testing is performed for appropriate clinical indications.

##### Required Characteristics

2.1.1 The indication for testing must be documented.

**Comment:** Generally accepted indications will vary depending on clinical considerations that are provided by the referring health care provider and in some instances can only be assessed at the time of examination. Appropriate indications for peripheral arterial examination include, but are not limited to; exercise related limb symptoms, limb pain at rest, extremity ulcer / gangrene, assessment of healing potential, follow up of limb revascularization, absent peripheral pulses, digital cyanosis, cold sensitivity, arterial trauma, aneurysms/pseudoaneurysms, follow-up of arterial reconstruction, endovascular procedures or surgical intervention.

## Section 3 - Techniques and Documentation of Examination Performance

### STANDARD - Techniques for Examination Performance

#### 3.1 Appropriate techniques must be used for evaluation of the peripheral arterial circulation to assess the presence of any abnormalities and to document their location, extent and severity.

##### Required Characteristics

##### 3.1.1 Appropriate testing modalities must be used.

3.1.1.1 The laboratory must have a written protocol to determine the anatomic extent of the study. Bilateral testing is considered an integral part of a complete examination.

3.1.1.2 Limited examinations may be performed for an appropriate or recurring indication. The reasons for a limited examination must be documented.

3.1.1.3 Both systolic blood pressures at one or more levels and **multi-segmental** Doppler and/or plethysmographic waveform analysis must be performed.

##### 3.1.1.4 Elements of study performance must include, but are not limited to:

3.1.1.4.1 Performance of the examination according to an appropriate, laboratory specific protocol

3.1.1.4.2 Proper patient positioning

3.1.1.4.3 Optimization of equipment, and when applicable gain and display settings

3.1.2 Segmental limb pressures are measured using pneumatic cuffs that are appropriately sized to the diameter of the limb segment under study and are properly positioned. The presence of arterial blood flow in the limb distal to the cuff is detected with an appropriate sensor.

##### 3.1.2.1 Elements of segmental systolic limb pressure measurement in addition must include, but are not limited to:

3.1.2.1.1 Appropriate blood flow sensor (i.e. Doppler, PPG) and pressure cuff selection and placement

- 3.1.3 Doppler waveforms are recorded from the major extremity arteries.
  - 3.1.3.1 Elements of Doppler study performance (in addition to 3.1.1.4) must include, but are not limited to:
    - 3.1.3.1.1 Appropriate Doppler transducer selection and placement
    - 3.1.3.1.2 Utilization of appropriate Doppler technique including proper Doppler transducer alignment, when applicable
- 3.1.4 Segmental limb plethysmography is done using pneumatic cuffs with sensors, which are appropriately sized to the diameter of the limb segment and are properly positioned. Plethysmographic waveforms are recorded for each limb segment.
  - 3.1.4.1 Elements of limb plethysmography study performance (in addition to 3.1.1.4) must include, but are not limited to:
    - 3.1.4.1.1 Cuff selection and placement
- 3.1.5 Duplex ultrasonography is used to evaluate the major extremity arteries and/or bypass grafts.
  - 3.1.5.1 Elements of duplex ultrasound study performance (in addition to 3.1.1.4) must include, but are not limited to:
    - 3.1.5.1.1 Appropriate transducer selection and placement
    - 3.1.5.1.2 Proper sample volume size and positioning
    - 3.1.5.1.3 An angle of 60 degrees or less with respect to the vessel wall or direction of blood flow is used.
    - 3.1.5.1.4 Proper measurement of spectral velocities

### **Supplemental Testing**

- 3.1.6 Transcutaneous oximetry calibration is carried out prior to patient measurements according to the manufacturer's directions. The electrodes are placed on the skin and measurement of oxygen values are recorded. The examination includes a measurement at a reference or baseline site.
- 3.1.7 The photoplethysmography (PPG) sensor is placed on the skin according to the manufacturer's directions and waveforms are recorded.

- 3.1.8 The laser Doppler sensor is placed on the skin according to the manufacturer's directions and flow data are recorded.
- 3.1.9 Treadmill Exercise / Stress Testing is performed using appropriate techniques.
  - 3.1.9.1 Measurements of extremity systolic pressures are obtained at rest and at timed intervals immediately after performance of standardized exercise. Such testing will usually be performed after using a motorized treadmill, although other standardized exercise or reactive hyperemia may be used. For treadmill-based protocols, time of onset of claudication and the maximal walking time will be recorded.
- 3.1.10 Abdominal Aortic Duplex is performed using proper techniques as listed under 3.1.5.

## **STANDARD – Required Documentation of Examination**

### **3.2 Peripheral arterial examinations must be comprehensive and include standard components that provide sufficient documentation for interpretation.**

#### **Required Characteristics**

- 3.2.1 A written protocol must be in place that defines the components and documentation of the peripheral arterial examination, which must include measurement of systolic blood pressure at one or more levels in combination with either Doppler or plethysmographic waveform analysis.
  - 3.2.1.1 Examination includes bilateral sampling from three or more levels. If Doppler waveforms are used, sampling must be obtained from, but is not limited to, the common femoral artery, popliteal artery and the distal tibial arteries at the level of the ankle. If plethysmographic waveforms are used, sampling must be obtained from the thigh, calf and ankle.
- 3.2.2 A written protocol must be in place for duplex ultrasound examinations that defines the components and documentation of the complete examination. The protocol should also describe how color-coded Doppler is utilized to supplement gray scale imaging and spectral Doppler. If other flow imaging modes (e.g. power Doppler) are used, the protocol should describe how they are utilized.

**Comment:** Lower extremity duplex examinations must also include measurement and documentation of an ankle brachial index.

3.2.2.1 Gray scale - Representative gray scale images must be documented as required by the protocol with additional documentation of any abnormalities and must include at a minimum:

A.) Lower extremity:

- Common femoral artery
- Superficial femoral artery
- Proximal deep femoral artery
- Popliteal artery
- Aorta, common and external iliac arteries and tibial arteries when appropriate
- Bypass graft(s) when present, including anastomoses

B.) Upper extremity:

- Subclavian artery
- Axillary artery
- Brachial artery
- Innominate and forearm arteries when appropriate
- Bypass graft(s) when present, including anastomoses

3.2.2.2 Representative spectral Doppler waveforms must be documented as required by the protocol and must include at a minimum waveforms taken from each specified artery.

3.2.2.2.1 Documentation of areas of suspected stenosis must include representative waveforms recorded at and distal to the stenosis.

A.) Lower extremity:

- Common femoral artery
- Superficial femoral artery
- Proximal deep femoral artery
- Popliteal artery
- Tibial arteries
- Aorta, common and external iliac arteries when appropriate
- Bypass graft when present, including proximal and distal anastomoses, inflow and outflow arteries

B.) Upper extremity:

- Subclavian artery
- Axillary artery
- Brachial artery
- Radial and ulnar arteries
- Innominate artery when appropriate
- Bypass graft when present, including proximal and distal anastomoses, inflow and outflow arteries

3.2.2.3 Representative color coded Doppler images must be documented as required by the laboratory protocol.

### **Supplemental Testing**

3.2.3 A written protocol must be in place for all supplemental testing examinations that defines the components and documentation of the complete examination.

3.2.3.1 Transcutaneous oximetry includes documentation of oxygen values recorded at identified sites and includes a measurement at a reference or baseline site.

3.2.3.2 Photoplethysmography (PPG) must include hardcopy documentation of the digital waveforms.

3.2.3.3 Laser Doppler flow data is recorded.

3.2.3.4 Treadmill Exercise / Stress Testing must include documentation of pressures obtained at rest and at timed intervals immediately after performance of standardized exercise. For treadmill-based protocols, time of onset of claudication and the maximal walking time will be recorded.

### 3.2.3.5 Abdominal Aortic Duplex

3.2.3.5.1 Gray scale - Representative gray scale images of the aorta must be documented as required by the protocol with additional documentation of any abnormalities and must include at a minimum:

- Transverse views with diameter measurements proximal, mid and distal
- Longitudinal views proximal, mid and distal
- Transverse view of common iliac arteries at aortic bifurcation
- Documentation of aneurysms, if present, **must include the widest size of the aorta measured outer wall to outer wall. Additional images proximal and distal to the aneurysm must be recorded.**

3.2.3.5.2 Representative spectral Doppler waveforms of the aorta must be documented as required by the protocol and must include at a minimum waveforms taken from each specified artery.

- One site in the aorta as described in the laboratory protocol
- Other aorto-iliac sites as appropriate

3.2.3.5.3 Representative color coded Doppler images must be documented as required by the laboratory protocol.

## Section 4 - Diagnostic Criteria and Interpretation

### STANDARD - Diagnostic Criteria

**4.1 Interpretation of the peripheral arterial examination must use validated diagnostic criteria to assess the presence of disease, and to document its location, etiology, extent and severity.**

**Comment:** Peripheral arterial testing requires two or more testing modalities as a minimum component. It is necessary to have a diagnostic algorithm that defines the weighting of each component in arriving at the final interpretation, particularly when discordant results are found. Diagnostic criteria must be laboratory specific and documented. These criteria can be based on published reports or internally generated and internally validated as outlined in Section 6.

## Required Characteristics

- 4.1.1 There must be criteria for interpretation of Segmental limb pressures and must be compared to the adjacent ipsilateral segments, to the contralateral-paired segment, and to the greater of the two brachial systolic pressures.
- 4.1.2 There must be criteria for interpretation of CW Doppler waveform changes related to the anatomic site and hemodynamic severity of disease.
- 4.1.3 There must be criteria for interpretation of air plethysmographic waveform changes related to the anatomic site and hemodynamic severity of disease.
- 4.1.4 There must be criteria for interpretation of gray scale images, spectral Doppler and when reported, plaque morphology, and color-coded Doppler images related to the anatomic site and hemodynamic severity of disease.
- 4.1.5 There must be criteria for interpretation of transcutaneous tissue oxygen pressure related to the degree of local tissue ischemia. Extremity measurements must be compared to a reference site.
- 4.1.6 There must be criteria for interpretation of the photoplethysmographic (PPG) signal amplitude and waveform shape may be made to assess the degree of local ischemia. Testing conditions, which might produce waveform artifacts, must be noted.
- 4.1.7 There must be criteria for interpretation of the laser Doppler data to assess the degree of local ischemia. Testing conditions, which might produce signal artifacts, must be noted.
- 4.1.8 There must be criteria for interpretation of exercise stress testing comparing the changes in extremity systolic pressure after exercise with those pressure values obtained at rest.
- 4.1.9 There must be criteria for interpretation of aortic duplex examination (i.e. aneurysm and stenotic disease).

## **STANDARD – Interpretation**

- 4.2 The interpretation and report that is generated from the examination findings and diagnostic criteria must state the absence or presence of abnormalities in the vessels that were investigated. Disease, if present, must be characterized according to its location, extent and severity.**

**Comment:** For the required characteristics of interpretation/final report, refer to Section 4 of the *ICAVL Standards, Part I: Vascular Operations – Organization*.

## **Section 5 - Procedure Volumes**

### **STANDARD - Procedure Volumes**

- 5.1 The annual procedure volume must be sufficient to maintain proficiency in examination techniques and interpretation.**

**Comment:** In general, a laboratory should perform a minimum of 100 complete primary examinations annually. In some settings, laboratories may perform quality examinations with lower volumes. These laboratories will be required to demonstrate competence through the submission of additional case studies as required by the ICAVL accreditation application.

### **Required Characteristics**

- 5.1.1 Records must be maintained that permit evaluation of annual procedure volumes. The records must include information on the indication, test(s) performed and the findings.

## **Section 6 - Quality Assurance**

### **STANDARD - Correlation and Confirmation of Results**

- 6.1 Results of peripheral arterial examinations are regularly correlated with angiographic findings.**

## Required Characteristics

- 6.1.1 The laboratory must have a written procedure for regular correlation of peripheral arterial examination results with angiographic findings produced by digital subtraction arteriography, contrast-enhanced computed tomography, magnetic resonance angiography or surgery. The correlation must be reported using the comparison of the results of the arterial examination and the results of the validating study with regard to the location and severity of disease as defined by the diagnostic criteria utilized by the laboratory.
- 6.1.2. A minimum of 30 extremities must be correlated every three years. These studies must have been done within the three years preceding submission of the application.
  - 6.1.1.2 The correlation matrix should demonstrate greater than 70% agreement.
- 6.1.3 Documentation of correlation must be maintained.

**Comment:** If the laboratory is unable to obtain the minimum number of correlations, alternative methods for QA may be considered.
- 6.1.4 Procedures must be in place for ongoing dissemination of information to both medical and technical personnel of the laboratory as required in Section 6 of the *ICAVL Standards, Part I: Vascular Operations – Organization*.