

# ICAVL STANDARDS FOR ACCREDITATION IN NONINVASIVE VASCULAR TESTING

## PART II VASCULAR LABORATORY OPERATIONS

### PERIPHERAL VENOUS TESTING

At a minimum, accreditation in Peripheral Venous Testing requires that the laboratory possess a protocol and the ability to assess for deep venous thrombosis. Diagnostic venous examinations may be modified for other indications such as venous reflux and venous mapping.

#### Section 1 - Instrumentation

##### STANDARD - Instrumentation

##### 1.1 Duplex ultrasonography with color flow Doppler must be provided as instrumentation.

Duplex ultrasonography is used to assess the anatomy and physiology of the deep and superficial venous system of the upper and lower extremities. Venous hemodynamics (normal and abnormal) are evaluated using spectral Doppler analysis (at rest and during physiologic maneuvers). Gray-scale imaging is used in the detection, location and characterization of venous abnormalities. Color Doppler imaging provides a qualitative image of normal and abnormal vessel hemodynamics and is able to detect the course of blood vessels.

##### Required Instrument Characteristics

- 1.1.1 A range of imaging frequencies appropriate for the vessels and structures evaluated must be available.
- 1.1.2 Doppler frequencies appropriate for the vessels must be available.
- 1.1.3 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 The size of the range gate must be adjustable.

- 1.1.5 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 instruments may be used for appropriate clinical indications.**

### 1.2.1 Venous Plethysmography

Devices may include impedance plethysmography, strain gauge plethysmography, photoplethysmography, and air plethysmography.

#### **Required Characteristics**

1.2.1.1 All strain gauges, pneumatic cuffs, electrodes, tourniquets, and/or other devices must be applied, inflated, and/or tightened appropriately.

1.2.1.2 Sensors must be properly connected to the instrument used.

1.2.1.3 The instrument must be capable of providing a permanent recording.

## **Section 2 – Indications**

### **STANDARD - Indications**

#### **2.1 Venous 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 venous examination include, but are not limited to: evaluating suspected venous thrombosis, obstruction, or reflux; assessment of calf muscle pump function; and venous mapping.

## Section 3 - Techniques and Documentation of Examination Performance

### STANDARD - Techniques of Examination Performance

#### 3.1 Appropriate techniques must be used to assess the presence and severity of any venous abnormalities and to document their nature, location, extent and severity.

##### Required Characteristics

- 3.1.1 Duplex ultrasonography for the venous examination includes transverse gray scale imaging with transducer compressions and long axis spectral Doppler evaluation, with or without color imaging.
  - 3.1.1.1 The laboratory must have a written protocol to determine the anatomic extent of the study and when a unilateral or bilateral study is to be performed.
  - 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 gray scale imaging and Doppler information must be used to assess venous anatomy and blood flow.
- 3.1.2 Elements of a duplex study must include, but are not limited to:
  - 3.1.2.1 Performance of a duplex examination according to the written laboratory specific protocol
  - 3.1.2.2 For assessing venous patency, the entire length of the vein must be evaluated
  - 3.1.2.3 Proper patient positioning:
    - 3.1.2.3.1 For reflux examinations, patients must be evaluated in a standing or sitting position
  - 3.1.2.4 Appropriate transducer selection and placement
  - 3.1.2.5 Optimization of equipment gain and display settings
  - 3.1.2.6 Proper sample volume size and positioning

### 3.1.2.7 Appropriate indication-specific duplex techniques and measurements

#### 3.1.2.7.1 Testing for obstruction using proper transverse compression technique

#### 3.1.2.7.2 Testing for reflux using proper reflux-producing techniques

3.1.3 Elements of study performance for venous plethysmography must include, but are not limited to:

3.1.3.1 Performance of the plethysmographic examination according to the written laboratory specific protocol

3.1.3.1.1 The protocol must describe the techniques and maneuvers used to assess obstruction, reflux, calf muscle pump function, and/or any other specific venous pathology that may be evaluated using plethysmography.

3.1.3.1.2 When assessing reflux, venous refilling time is measured and recorded in response to passive emptying or calf muscle exercise.

3.1.3.1.3 If the venous refilling time is abnormal, the study may be repeated using tourniquets.

3.1.3.1.4 Occluding cuffs and/or tourniquets as well as any sensing devices must be placed appropriately on the extremity.

## **STANDARD - Documentation of Examination Performance**

3.2 Peripheral venous duplex ultrasound examinations must be comprehensive and include standard components that provide sufficient documentation for interpretation. The components of an examination vary depending upon the indication(s) for testing (e.g. evaluation for deep vein thrombosis (DVT) or obstruction, vein mapping, reflux, assessment of calf muscle pump or others). When testing is tailored to specific indications, a written protocol for evaluating each type of examination must be provided.

## Required Characteristics

3.2.1 Written protocols must be in place that define the components and documentation of the peripheral venous examination. The protocol(s) should describe how color-coded Doppler is utilized to supplement gray scale imaging and spectral Doppler. If other flow imaging modes (or plethysmography) are used, the protocol(s) should describe how they are utilized.

**3.2.1.1 Testing for DVT or obstruction: A unique protocol must be defined for the examination to evaluate for DVT or venous obstruction. Documentation of areas of suspected thrombosis must include additional representative images.**

3.2.1.1.1 Imaging (for assessing venous patency):  
Representative transverse gray scale images with and without transducer compressions (when anatomically possible or not contraindicated) must be documented as required by the protocol and must include at a minimum images of:

A.) Lower extremity:

- Common femoral vein
- Saphenofemoral junction
- Proximal femoral vein
- Mid femoral vein
- Distal femoral vein
- Popliteal vein
- Posterior tibial veins
- Peroneal veins
- When appropriate or as required by the laboratory's written protocol: common and external iliac veins, inferior vena cava, great saphenous vein, small saphenous vein, proximal deep femoral vein, and gastrocnemius, soleal, anterior tibial, and perforating veins.

B.) Upper extremity:

- Internal jugular vein
- Subclavian vein
- Axillary vein
- Brachial veins
- Basilic vein
- Cephalic vein
- When appropriate or as required by the laboratory's written protocol: Jugular/ subclavian vein junction, brachiocephalic (innominate) and forearm veins.

3.2.1.1.2 Doppler (for assessing venous patency):

Representative spectral Doppler waveforms showing variations with respiration and/or manual flow augmentation must be documented as required by the protocol and include at a minimum the following vessels:

A.) Lower extremity:

- Common femoral vein  
**Comment:** If a unilateral study is performed, a contralateral common femoral venous spectral waveform must be documented.
- Popliteal vein
- When appropriate or as required by the laboratory's written protocol: common and external iliac veins, inferior vena cava, femoral vein, proximal deep femoral vein, deep calf veins, great saphenous vein and small saphenous vein.

B.) Upper extremity:

- Internal jugular vein
- Subclavian vein  
**Comment:** If a unilateral study is performed, a contralateral subclavian vein spectral waveform must be documented.
- Axillary vein
- When appropriate or as required by the laboratory's written protocol: jugular-subclavian confluence, brachiocephalic (innominate) vein, brachial vein, basilic vein, cephalic vein and forearm veins.

3.2.1.1.3 Plethysmography

- Plethysmographic tracings showing baseline and response to appropriate maneuvers must be documented.

### 3.2.1.2 Testing for lower extremity reflux

#### 3.2.1.2.1 Imaging (for assessing venous patency):

Representative gray scale images with and without transverse transducer compressions (when anatomically possible or not contraindicated) must be documented as required by the protocol and must include at a minimum images of:

- Common femoral vein
- Saphenofemoral junction
- Mid femoral vein
- Great saphenous vein
- Popliteal vein
- Small saphenous vein
- When appropriate or as required by the laboratory's written protocol: common and external iliac veins, inferior vena cava, proximal deep femoral vein, deep calf veins, and perforating veins.
- When appropriate or required by the laboratory's written protocol, measurements must be recorded.

#### 3.2.1.2.2 Doppler (for assessing venous reflux):

The protocol should describe how color-coded Doppler is utilized to supplement gray scale imaging and spectral Doppler. **Documentation of areas of suspected reflux must include spectral Doppler.** Representative spectral Doppler waveforms and/or color Doppler must be documented at baseline and during reflux producing maneuvers as required by the protocol and include at a minimum the following vessels:

- Common femoral vein
- Sapheno-femoral junction
- Great saphenous vein
- Femoral vein
- Popliteal vein
- Small saphenous vein
- When appropriate or as required by the laboratory's written protocol: common and external iliac veins, inferior vena cava, proximal deep femoral vein, deep calf veins, perforating veins, and other accessory venous tributaries.

3.2.1.2.3 If plethysmography is used, a written protocol must be in place that defines its components, including its use in conjunction with duplex scanning

- Plethysmographic tracings showing baseline and response to appropriate maneuvers must be documented.

3.2.1.3 Vein mapping

Representative transverse gray scale images must be documented according to the laboratory's written protocol. Areas of abnormality should be documented with additional images.

3.2.1.3.1 The veins of interest should be assessed for size and patency.

3.2.1.4 Other venous testing (e.g. assessment of the calf muscle pump)

3.2.1.4.1 If other venous testing is done, a written protocol must be in place that defines its components.

- Representative gray scale images must be documented as required by the protocol
- Representative spectral Doppler waveforms must be documented as required by the protocol
- Any other venous testing component used (e.g. color Doppler or plethysmography) must be documented as required by the protocol

## Section 4 - Diagnostic Criteria and Interpretation

### STANDARD - Diagnostic Criteria

**4.1 Interpretation of venous duplex and venous plethysmography examinations must use validated diagnostic criteria to assess the presence and extent of venous thrombosis, vessel patency, valvular competency, and/or calf muscle pump function.**

#### Required Characteristics

- 4.1.1 Diagnostic criteria must be laboratory specific and documented. These criteria can be based on published reports or internally generated and internally validated data, as outlined in Section 6.
- 4.1.2 When assessing for obstruction, there must be criteria for interpretation of imaging, transverse compression, and Doppler waveforms.
- 4.1.3 When assessing for reflux, there must be criteria for interpretation of venous reflux and valve function.
- 4.1.4 When mapping veins, there must be criteria for interpretation of vein size, patency, compressibility and course.
- 4.1.5 If venous plethysmography is used, there must be criteria for interpretation of obstruction and/or reflux.

### STANDARD - Interpretation

**4.2 The interpretation and report 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, severity, and (in the case of venous thrombosis) age when possible.**

**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 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. These 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 Venous duplex examinations must be regularly correlated.

#### Required Characteristics

- 6.1.1 The laboratory must have a written procedure for regular correlation of venous duplex examinations. Acceptable methods for correlation include, **but are not limited to:** repeat examination by a second examiner at the same setting, clinical outcome, over-reading of the final interpretation, and comparison with venography or surgical pathology.
- 6.1.2 A minimum of 30 limbs must be correlated every three years. These correlations must reflect a mix of upper and lower extremities as performed by the laboratory. These studies must have been done within the three years preceding the submission of the application.
- 6.1.3 Documentation of correlation must be maintained.
- 6.1.4 The correlation should demonstrate greater than 70% agreement.
- 6.1.5 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*.