



SensiLase® System

Noninvasive Micro/Macrocirculatory Assessment

Technical Specifications

Use the SensiLase System measurements to:

- Predict wound healing potential
- Determine the optimum amputation level
- Assess and diagnose peripheral arterial disease (PAD) and critical limb ischemia (CLI)
- Monitor perfusion pre/post therapy

The SensiLase System provides microvascular assessment in the most difficult situations:

- Calcified vessels
- Incompressible arteries
- Mild edema
- Necrotic tissue
- Plantar and toe wounds

The SensiLase System is easy to use and cost-effective:

- Noninvasive, at the point of care
- Familiar Windows® operating environment
- Intuitive user interface
- Fully automated
- No calibration required
- Results not operator dependent
- Minimizes need for re-testing
- Test report storage in PDF format for offline review, archiving and electronic transfer
- Minimal test time and staff training required

Measurement locations:

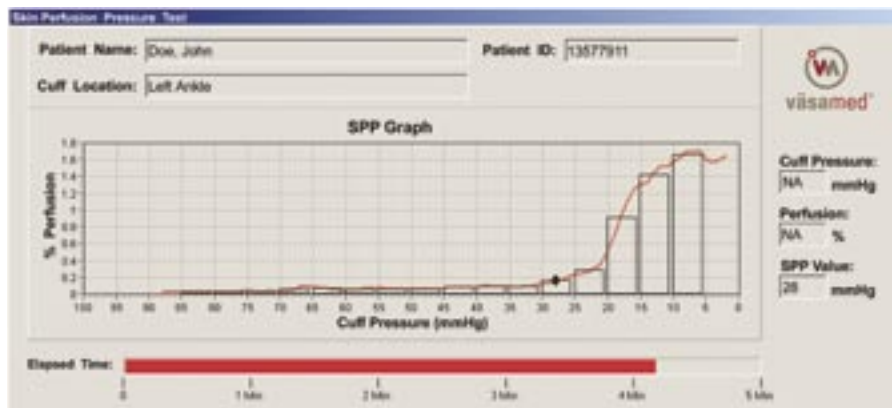
- Digits
- Dorsum and plantar aspects of the foot
- Ankle
- Calf
- Lower thighs

The SensiLase System performs Skin Perfusion Pressure (SPP) and Pulse Volume Recording (PVR) tests for micro- and macrocirculatory assessment.

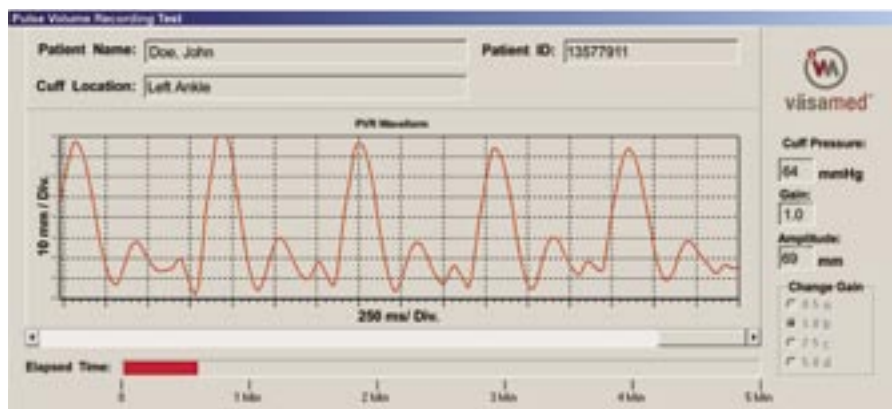
The SPP test provides a fully automated and quantitative evaluation of capillary opening pressure. During an SPP test, the pressure cuff is automatically inflated until the Laser Sensor Assembly (LSA) determines that perfusion beneath the cuff has stopped. The cuff pressure is then released at a controlled rate, and the LSA reads the point at which blood flow returns. The PVR test displays a waveform representing variations in the size of a limb when blood passes through it during each cardiac cycle. The PVR waveform provides an indication of peripheral arterial disease (PAD) and other alterations in macrocirculation, as well as an objective baseline for later comparisons.

The SensiLase System Components:

- Data Acquisition System
- SensiLase Application Software (Windows®)
- Laser Sensor Assembly (LSA)
- Pressure Cuffs (digit, foot, and leg/arm)
- Data Acquisition System AC Power Cord
- Data Port Cable
- Air Hose
- Integrated Roll Stand
- Personal Computer (laptop)
- Printer



Software screen display of SPP test graph (above,) and of PVR measurement waveform graph (below).



TECHNOLOGY

Waveform Analysis

- Skin Perfusion Pressure (SPP)
- Pulse Volume Recording (PVR)

Laser Doppler

- Power Exiting LSA: 2.3 mW, typical 3.0 mW maximum
- *Measurement Wavelength: 785 nm*
- *Invisible Laser Radiation – Must not be viewed directly with optical instruments (magnifiers)*

Equipment classification

- Laser Class I (per 21 CFR 1040.10)
- Data Acquisition System Class II (per CFR 870.21)

Signal Processing

- Noise reduction algorithm
- Programmable data acquisition settings

Reporting

- Detailed SPP report with patient information, diagnostic PVR waveform, hemodynamic parameters with normal values and comment sections
- Customizable report and notes page

Data Export

- Test report storage in PDF format for offline review, archiving and electronic transfer



User Interface

- PC keyboard
- Color graphical user interface (GUI)

Operating System

Windows XP

System Inputs/Outputs

- USB 2.0
- Ethernet
- Wi-Fi wireless network connection

Performance

- Applied Cuff Pressure: 0 to 250 mmHg
- Pressure Accuracy: ± 3 mmHg from 0 to 200 mmHg or 2% of the reading above 200 mmHg
- PVR Amplitude: Max 80 mm (3.15 inch) display, 1 to 30 Hz frequency response

Printer

Standard PC compatible (USB interface)

Electrical Power Requirements

100/120V; 50/60 Hz; 4.4 A

AC Power Cord

- 1250 Watts, 10A/125V low leakage, hospital grade, 2.434 m (8 ft.)

Environmental Range

- Operating temperature: 5 to 40° C (41 – 104° F)
- Operating humidity: 15% to 95%, non-condensing
- Transport & storage: -20 to 60° C (-4 – 140° F)

Test Platform

(Roll Stand, Acquisition System & PC)

- Size: (WDH) 66 x 74 x 99 cm (26 x 29 x 39 inches)
- Weight: 21.3 kg (47 lbs.)

Patented Technology

Sensilase System and methods are covered by the following U.S. patents and foreign equivalents: 5,654,539 and 6,178,342.

Several patent applications are pending.



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