1 Introduction

Indications for Use

The SensiLase PAD-IQ® provides a noninvasive measurement of Skin Perfusion Pressure (SPP) and Pulse Volume Recording (PVR) on extremities of patients.

Contraindications

There are no known contraindications for the SensiLase PAD-IQ.

Document Application

This Operator's Manual applies to SensiLase PAD-IQ software version 2.08 (June 2016). A current revision of the SensiLase PAD-IQ Operator's Manual is included and installed with each software update. The SensiLase PAD-IQ Operator's Manual can be viewed or printed from the SensiLase PAD-IQ. Contact Customer Service if the Operator's Manual is not in agreement with the software version for your SensiLase PAD-IQ.

2 Principles of Operation

Skin Perfusion Pressure (SPP)

The SPP test provides a fully automated and quantitative evaluation of microcirculatory perfusion in the skin. The SPP test measures skin perfusion using a laser Doppler sensor (the Laser Sensor Assembly) and a pressure cuff to evaluate reactive hyperemia. This type of provocative functional maneuver requires that the pressure cuff is first automatically inflated to occlude arterial bed blood flow; this is verified by the SensiLase PAD-IQ which determines that perfusion has stopped. The pressure is then automatically released at a controlled rate while the cuff pressure and skin perfusion are measured. A graph displays pressure and perfusion during cuff deflation and indicates the pressure at which skin perfusion is found to return. Additional information observable from the graph includes percentage perfusion increase above baseline, total response time, perfusion reappearance time, and perfusion contour.

SPP as a perfusion measurement with reactive hyperemia can be useful in identifying patients with peripheral arterial disease (PAD) and alterations in microcirculation. The SPP test can also be used as an aid in the determination of optimum clinical treatment for patients with intractable wounds. Patients with chronic foot ulcers, diabetes, and candidates for amputation often have serious alterations in circulation. Clinical studies have demonstrated that the SPP test is not affected by edema, anemia or medial calcification. Clinical studies have also demonstrated that tests involving provocative functional maneuvers to mimic exercise blood flow requirements (e.g. postural provocation and reactive hyperemia) are useful in patients with PAD and alterations in microcirculation.

Pulse Volume Recording (PVR)

The PVR test measures and displays a waveform representing variations in the volume of blood passing through a limb during each cardiac cycle. The PVR test is fully automated and uses a partially inflated pressure cuff to apply slight pressure to the limb. The impact of blood passing through the limb is transferred to the pressure cuff where it is measured as small changes in cuff pressure. The changes are displayed as a PVR waveform. A user may elect to stop the PVR test when a satisfactory waveform is achieved, usually about thirty seconds after test initiation, or wait for the test to timeout in five minutes. The PVR test is sometimes referred to as air plethysmography or volume plethysmography.

The PVR test can be useful in providing an indication of peripheral arterial disease (PAD) and other alterations in macrocirculation. The PVR test can also be used as an aid in determination of optimum clinical treatment. Examination of amplitude, frequency, and pulse contours allows an interpretation of intraluminal changes in connection with occlusive disease. The PVR waveform can be used as a measure of functional severity of the occlusive disease and as an objective baseline for later comparison.

PVR-IQ is a feature unique to PAD-IQ that ensures PVR tests are not biased by the fit (too tight or too loose) with which a pressure cuff is wrapped. The cuff should be snug but not too tight since the tightness with which a pressure cuff is wrapped on a limb affects the air volume in the filled cuff. With other devices that perform PVR tests cuff wrap fit can affect the PVR waveform and amplitude. PVR-IQ addresses this potential for operator error by measuring cuff air volume during the PVR test and then adjusting the PVR waveform and amplitude appropriately.

Pressure Assist

The PAD-IQ can be used to fill and empty pressure cuffs to assist in acquiring pressure values for calculating ankle brachial index (ABI). ABI can be useful in providing an indication of PAD depending

on both the methodology and technology used to detect the return of arterial pressure following controlled occlusion and release of arterial flow.

Blood pressure cuffs are placed bilaterally on the upper arm (brachial pressure), and at the ankles just above the medial malleolus. Following manufacturer's instructions for use, any Doppler ultrasound transducer can be used to locate the arterial Doppler signal distal to the blood pressure cuff. The Doppler signal from the brachial artery is used to obtain the systolic arm pressure and the Doppler signal from the Posterior Tibial (PT) and/or Dorsalis Pedis (DP) arteries are used to obtain the systolic ankle pressure. At each location, the blood pressure cuff is inflated above systolic pressure so that the audible arterial Doppler signal disappears. The blood pressure cuff is slowly deflated, and the operator notes the pressure at which the audible arterial Doppler signal returns. The higher of the two systolic arm pressures is used in conjunction with the higher of the two systolic ankle pressures (either the PT or DP) for the right and the left leg to calculate a right and left leg ABI.

3 Safety Information

This section contains important safety information related to the general use of the SensiLase PAD-IQ. Before use, carefully read this manual, any instructions for use provided with single use accessories, all warnings, cautions, notes, and specifications.

Warnings and cautions are identified by this symbol. A **warning** designates a possibly dangerous situation. Non-observance may lead to death or injuries. A **caution** designates a possibly harmful situation. Non-observance may lead to damage to the product or the environment.

Warnings

- **This product emits invisible laser radiation from the distal end of the laser cable and is designated a Class 1 laser product per IEC 60825:2007.**
- **To avoid the risk of electric shock this equipment must be connected to a supply mains with protective earth.**
- **Operate the instrument by battery if the protective earth arrangement of the mains supply is in doubt.**
- **This product complies with IEC 60601-1-2:2007. These tests demonstrate the device provides reasonable protection against electromagnetic interference in a typical medical installation. However, there is no guarantee that interference will not occur in a particular installation. If this equipment causes interference to, or is negatively impacted by, other devices, the user is encouraged to try to correct the interference by one or more of the following measures:**
    - **Reorient or relocate the devices.**
    - **Increase the separation between the devices.**
    - **Connect the equipment to an outlet on a different circuit.**
    - **Consult the manufacturer for assistance.**
- **The SensiLase PAD-IQ instrument must be powered with the supplied AC power cord or with a replacement AC power cord that meets specification.**
- **If the instrument will not be used for two (2) months or longer, remove the instrument battery pack prior to storage.**
- **Periodically operate the instrument on battery power to ensure battery is in proper operating order. Replace battery if instrument reports battery failure.**
- **The battery is charged by the PAD-IQ instrument. The battery should not be charged by any other charger.**
- **If the equipment is modified, appropriate inspection and testing by qualified personnel must be conducted to ensure continued safe use of the equipment.**
- **When located in the patient environment, do not connect equipment that is not identified as part of the SensiLase PAD-IQ.**
- **SensiLase PAD-IQ is designed to print by wireless connection when printing within the patient environment. When removed from the patient environment, SensiLase PAD-IQ may print by Ethernet or USB connection.**

- **SensiLase PAD-IQ may print by Ethernet or USB connection within the patient environment only when complying with requirements of IEC 60601-1.**
- **When using the SensiLase PAD-IQ in the patient environment, do not connect any items, such as other cables or devices that are not identified as components of the SensiLase PAD-IQ.**
- **Explosion hazard. Do not use the SensiLase PAD-IQ in the presence of flammable anesthetics or gases.**
- **In the event fluids are accidentally spilled on the equipment, take the equipment out of service and contact Customer Service.**
- **For continued safe use of this equipment, the listed instructions must be followed. However, instructions listed in this manual do not supersede established medical procedures concerning patient care.**
- **Do not kink or crush the air hose. A damaged air hose can cause continuous cuff pressure and result in restricted blood flow and injury to a patient, inaccurate values or an error message.**
- **Do not kink or crush the laser cable. A damaged laser cable can cause inaccurate values or an error message.**
- **To maintain proper ventilation and ensure proper cooling, place the instrument on a hard, flat surface. Do not set the instrument on bedding. Do not allow the instrument vents to be covered.**
- **The installation options described assume that any piece of information technology equipment connected to the SensiLase PAD-IQ meets standards for that equipment (IEC 60950 for the case of information technology equipment).**
- **Do not place the SmartGuide directly onto a wound bed.**
- **Do not wrap the pressure cuff around an open wound or any site with obvious compromised tissue (skin).**
- **Solutions used to clean the SensiLase PAD-IQ instrument or components should be used in accordance with the manufacturer's instructions.**

Cautions

- **Federal law (USA) restricts this device to sale by or on the order of a physician.**
- **Test results should be used in combination with other clinical information.**
- **There are no user serviceable parts inside the instrument. The cover of the instrument can only be removed by authorized service personnel.**
- **Use of controls or adjustments or performance of procedures other than those specified herein may result in hazardous radiation exposure.**
- **For SPP, PVR and ABI testing, it is recommended the patient be positioned supine and lying comfortably.**
- **The patient should remain still during SPP, PVR and ABI tests. Any type of patient movement, including talking, may result in incorrect test results or cause the measurement to time out. Results may also be affected by movement of the laser cable or air hose.**
- **Stay with the patient during the SPP, PVR and ABI test.**
- **When performing an SPP test, do not place the laser cable directly over a bone, tendon, scar, callous or wound.**
- **Wrap the pressure cuff securely around the patient's extremity being careful not to obstruct blood flow.**
- **If the SensiLase PAD-IQ instrument or other components are stored outside the operating temperature range (5° to 40° C), make sure the instrument or components return to operating temperature before use.**
- **Before use, check the SensiLase PAD-IQ and all components for signs of wear and fatigue.**
- **Do not spray, pour, or spill any liquid on the SensiLase PAD-IQ instrument, connectors, switches, or openings in the instrument chassis.**

- **Do not use wax based cleaners, abrasives, solvents, including acetone, ketone or Betadine.**
- **Ensure all components are clean and properly disinfected prior to use.**
- **The SensiShield Cuff Liner and SmartGuide are intended for single patient use only. Do not attempt to reuse, reprocess or alter the SensiShield Cuff Liner or SmartGuide in any way. Please discard appropriately after use.**
- **SensiLase pressure cuffs and laser cable should be cleaned between patients in accordance with facility guidelines for cross contamination prevention.**
- **Contact Customer Service if service of the SensiLase PAD-IQ is required. Service should not be attempted by anyone other than authorized personnel.**

4 System Components

Product Description and Components

The SensiLase PAD-IQ consists of the components listed below. A brief description of each component is provided.

SensiLase PAD-IQ instrument – The instrument (Figure 1 and Figure 2) has two laser cable ports, two air hose ports, an integrated touch screen display, and communication ports.

Laser Cable (2) – The laser cable (Figure 3) transmits and receives light during an SPP test. The integrated air hose enables the instrument to control cuff pressure. The laser cable and air hose plug into the optic cable and air hose ports on the front of the instrument.

Pressure Cuffs – Four pressure cuff sizes are available (Figure 4). The cuff applies pressure to the area being tested. Follow the procedure to select the correct cuff size (Section 5.3).

SensiShield Cuff Liner – The Cuff Liner is a non-sterile, single use patient testing tool that supports an institution's cross contamination initiatives.

SmartGuide – The SmartGuide is a non-sterile, single use patient testing tool that protects the laser cable and aids in the secure placement of the SensiLase laser cable for an SPP test.

AC Power Cord – The AC power cord supplies power to the instrument.

Battery – A system is equipped to function on one or two batteries. Two batteries provide extended run time when AC power is unavailable.

SensiLase PAD-IQ® Studycast® Service – A web-based medical reporting service for the SensiLase PAD-IQ instrument. This feature is installed on some instruments. See SensiLase PAD-IQ Studycast Operator's Manual.

Wound Imaging – Wound Imaging is an optional software component for import of wound images and calculation of wound surface area.

Note: Contact Customer Service if you require the large cuff.

Note: Contact Customer Service for replacement components and single use accessories.