



PeriScan PIM 3 System

Laser Doppler Blood Perfusion Imager

The PeriScan PIM 3 System visualizes tissue blood perfusion in a wide variety of applications.

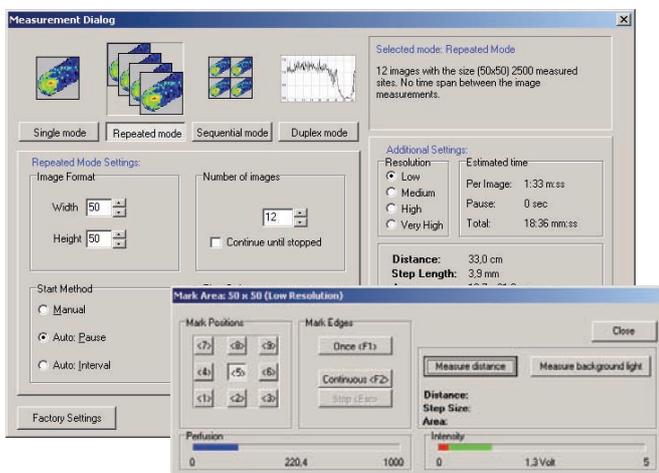
The PeriScan PIM 3 System

The PeriScan PIM 3 System is a Laser Doppler Perfusion Imaging system for non-invasive imaging of superficial tissue blood perfusion. The technique can be used to monitor microcirculatory activity in healthy and diseased tissue, and show basal values and also responses resulting from an applied physiological stimulus, a provocation. Based on the Doppler principle, two-dimensional maps (*imaging mode*) or time traces (*monitoring mode*) of the tissue blood perfusion can be created. Easy-to-use image analysis software (*LDPIwin*) assists in the evaluation of the results and in report generation. The patented stepwise laser beam movement makes it possible to read low perfused areas. Since no physical contact with the tissue is necessary, and no dyes or tracer elements are used, the influence on the perfusion can be kept to a minimum. These features also imply that repeated clinical investigations of e.g. healing wounds and leg ulcers can be performed without the additional risk of contamination, infection or discomfort to the patient.

The PeriScan PIM 3 System is flexible, small and of low weight which makes it easy to handle. The scanner head is directly connected to two USB 2.0 ports in a stationary or laptop computer. A low power laser (Class 2) means that no additional safety precautions are required. The PeriScan PIM 3 System is equipped with a digital camera for easier orientation in the images.

LDPIwin Software

The LDPIwin software runs on a PC and is used to control the PeriScan PIM 3 System and assists in evaluation. With the software it is easy to set up shape, resolution and size of the preferred measuring area.



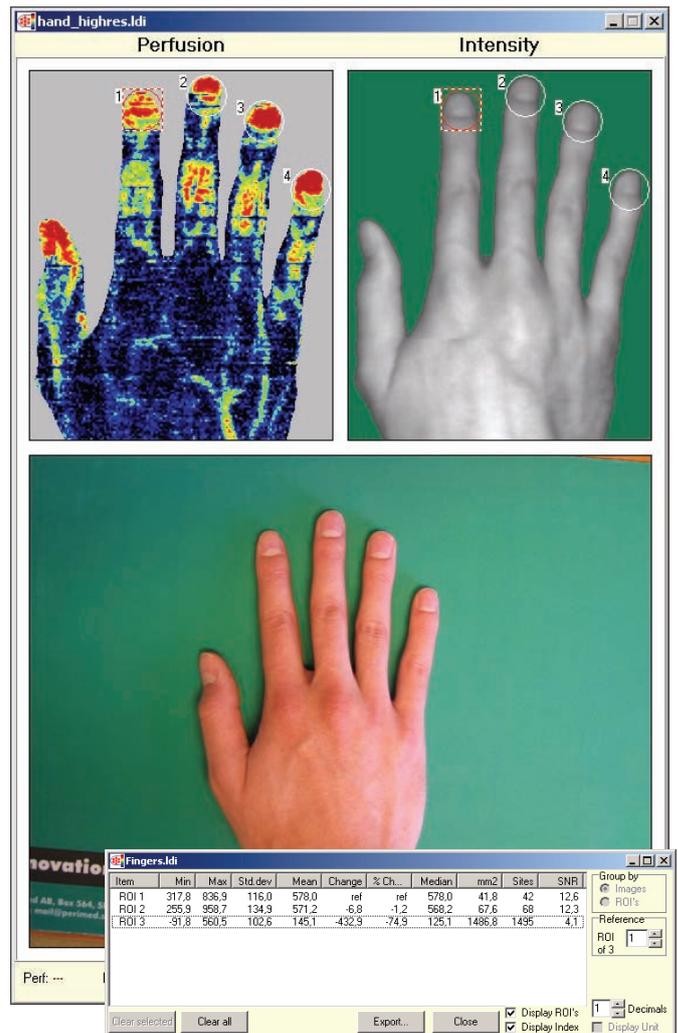
Measurement setup in LDPIwin.

Imaging Mode

An image of the spatial distribution of the tissue perfusion is created in the imaging mode. The laser beam moves stepwise over the area to be scanned and measures the perfusion in all the different points. The perfusion over the area can be presented with its numerical values as well as a color coded image. Besides measuring the perfusion, the intensity (back-scattered light) is also recorded and used to create an intensity image (grayscale) of the scanned area for orientation purposes.

Repeated images of the same area can show variations and reactions over time and is very useful when looking at reactions to provocations.

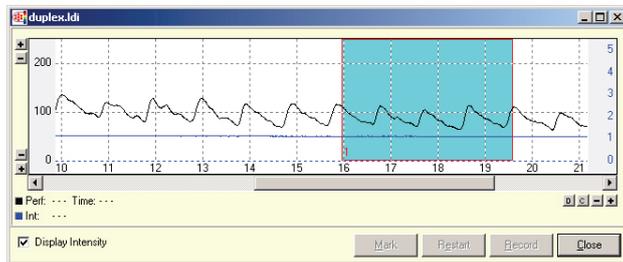
The recorded data can be easily evaluated by defining regions of interest (ROI) in the image. In the user defined ROI the software calculates parameters such as mean, maximum, minimum, % change, number of measurement sites and other values. If desired, the calculations and raw data can be exported to other programs (e.g. Excel, Word) for further evaluation.



Two-dimensional map of tissue blood perfusion in the hand, with data table from regions of interest.

Monitoring Mode

In monitoring mode (also called duplex mode), temporal variations of the tissue blood perfusion in a single site can be recorded. The LDPIwin software assists in evaluation and calculations.



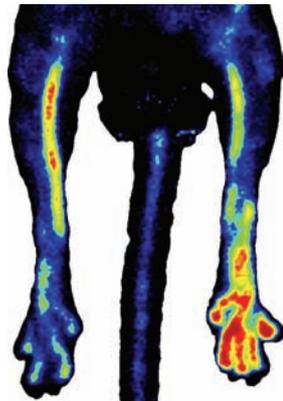
Single site tissue blood perfusion monitored over time.

Applications

The PeriScan PIM 3 System can be used for numerous different types of applications, both in clinical and in research environment. See the PeriScan Literature Reference list at www.perimed.se or search the PubMed database www.pubmed.com.

Angiogenesis and Growth Factor

The PeriScan PIM 3 System has proven very useful in different research areas, such as studying the angiogenesis process in combination with vascular growth factors. The effect of administered growth factor can be measured with the PeriScan PIM 3 System. A typical example of this kind of research is with ischemic hind limb on mice.



Ischemic hindlimb model on mouse.

Dermatology

An important clinical and research application is in the field of dermatology. Using the PeriScan PIM 3 System for Skin Allergy Patch testing allows for user-independent recording of the blood flow caused by the allergic reactions.

Malignant skin tumors have higher perfusion than benign naevus and basal cell carcinomas. Thus increasing malignancy is reflected by increased tumor circulation. When measuring the perfusion, there is a possibility to differentiate between various types of skin tumors. The PeriScan PIM 3 System is a useful tool in the research dealing with tumor growth and tumor neo-vascularization.

Diabetes

Another important clinical application is the assessment of the skin blood flow response to a provocation in diabetic patients. Already in its early stages, the diabetic disease impairs the sympathetic nervous system, which controls skin blood flow. Stimulating the microcirculation, either by a drug or tempera-

ture provocation, and then measuring the vascular response with the PeriScan PIM 3 System allows for a quantification of the autonomic control function.

Raynauds Syndrome

Assessment of Raynauds syndrome and vibration syndrome is performed using temperature provocations, usually cold exposure. The response from the provocation can then be quantified by using the PeriScan PIM 3 System.

Wound Healing

Measuring perfusion in and around wounds is useful for several disciplines, such as diabetes care, vascular surgery, orthopedics and geriatric medicine. Infections and inflammation of the wound increases the perfusion and impaired micro-circulation causes ischemic areas. These high and low perfused tissues can be detected by the PeriScan PIM 3 System and quantified in ROI. Leg ulcers and wounds can be monitored without physical contact, which is a benefit regarding contamination and discomfort issues.

Visceral Surgery

During visceral operations intestinal blood perfusion is recorded with the PeriScan PIM 3 System. Information about the perfusion is valuable for the surgeon before operation as well as checking the anastomosis after surgery.

Brain

With open skull a visualization and evaluation of the brain blood perfusion in animal as well as human can be performed.

Nerves

Local stimulations (e.g. drugs, temperature or electrical) of nerves resulting in blood perfusion changes can be assessed.

Burns, Plastic Surgery and Transplantations

Superficial burns with increased perfusion and deep burns with apparent tissue necrosis are both easily classified by visual inspection. However, deep partial thickness burns can be difficult to identify visually. Measuring the blood perfusion helps to diagnose the actual severity and depth of the burn and can show if the burn will heal spontaneously (high perfusion) or if it is necrotic (low perfusion).

In plastic and reconstructive surgery - flap surgery - it is of fundamental importance that the perfusion in the flap is adequate. Using the PeriScan PIM 3 System, a perfusion image of the flap can be recorded at the end of the procedure to give valuable information about the microvascular condition of the flap. For long term monitoring, see also PeriFlux System 5000.

Iontophoresis

Iontophoresis can be used to transport drugs in ionic form through intact skin. The technology is based on the principle that an electric potential will cause ions in solution to migrate according to their electrical charges. The quantity and distribution of a drug delivered by Iontophoresis are dependent on the charge of the ion, the size of the ion (molecular weight), the strength of the electrical current being applied, the duration of the current flow and numerous other factors. The drugs being administered by Iontophoresis can cause changes in the blood flow. The vascular response is then assessed by the PeriScan PIM 3 System.

Perilont for PeriScan

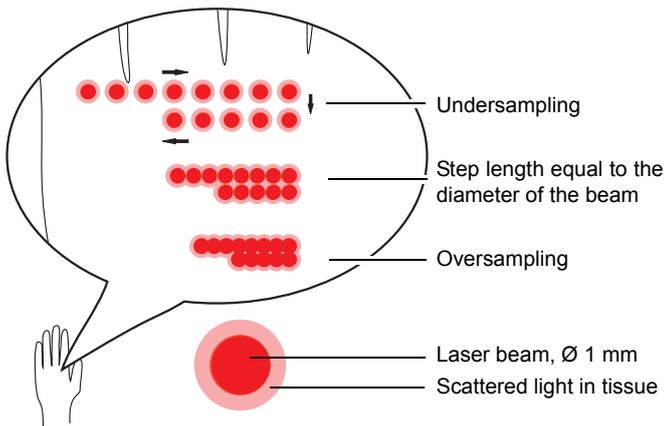
Perilont has a disposable Drug Delivery Electrode. This minimizes the risk of spillage, drug contamination between tests

and cross-infection between subjects. This design is unique and differs from the present technique of Iontophoresis which utilizes reusable electrodes. The Drug Delivery Electrode and a Dispersive Electrode are connected to the constant Current Power Supply. The PeriScan PIM 3 System reads the vascular response through the transparent lid of the Drug Delivery Electrode.

Scanning, Physiological Information

The figure below shows how the laser beam moves during a typical scan. The distance between two measuring points depends on the distance between the scanner head and the measurement object, but can also be adjusted in the software. The laser beam light scatters in the tissue. This results in that a slightly larger area than that of the laser beam contributes to the measured signal.

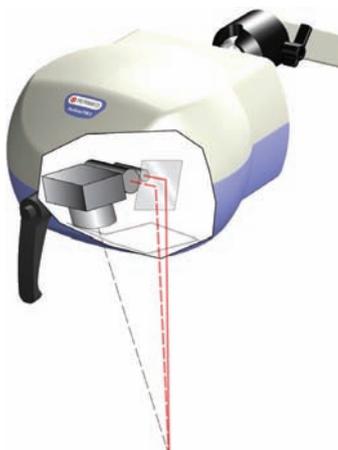
When making a scan it is important to select the number of measuring points carefully. It is often important to minimize the time that it takes to make a scan, but it is also important to have enough measuring points so that all physiological information is collected. This is best achieved if the step length is equal to the diameter of the laser beam. For step lengths smaller than the beam diameter the same physiological information is partly collected by neighboring measurements (oversampling). This takes extra time and does not add any additional information.



Laser beam movement.

Technology

A low power laser beam successively scans the tissue recording up to 255x255 measurement points. In the tissue, the laser light is scattered and changes wavelength when it hits moving blood cells (Doppler shift).



Principle of PeriScan PIM 3 System.

A fraction of the backscattered light is detected by a photo detector and the data is recorded and processed by software. The *Perfusion* is defined as *Concentration of Moving Blood Cells × Mean Velocity of these blood cells*. The concentration is related to the magnitude of the Doppler signal and the velocity is related to the frequency shift.

Mobile Carrier Option

The PeriScan PIM 3 System can be mounted on a mobile carrier for easy transportation between rooms. Chassis runners allow the scanner head and adjustable arm to be positioned at an operating height from 35 - 115 cm.

Technical Specifications

| | |
|--|--|
| Type (protection against electric shock): | Class I Equipment, Type B |
| Laser: | EN 60825-1 Class 2 Wavelength: 670-690 nm Max output power: 1 mW Beam diameter: 1 mm |
| Camera: | CMOS, 1280x1024, color, digital zoom |
| Mains and Power consumption: | 100 - 240 VAC, 50 - 60 Hz 35 VA |
| Dimensions Scanner head: | 22 x 15 x 20 cm |
| Weights Scanner head: Arm and stand: | 2.0 kg 7.4 kg |
| EC Declaration of conformity: | MDD 93/42/EEC |
| Operating conditions: | Normal ambient light, +15 to +30 °C at 30-75% RH Atmospheric pressure between 700 mbar and 1600 mbar |
| Computer requirements: (Minimum requirements) | CPU 1.5 GHz, 256 MB RAM 2 x USB 2.0 ports Windows XP (Service Pack 2) |
| Area and distance measurements: | The size of the area to be scanned, the distance to the object, and the area of the ROI:s are measured |
| Max scan area: | Approximately 50 x 50 cm, depending on distance to object |
| Measuring depth: | Approximately 0.5-1 mm, depending on tissue properties |
| Measuring units: | Perfusion Units (arbitrary units) |

| | Area | Time | Image format |
|---|------------|------------|----------------|
| Scan times/sizes: (approx. 25 cm from object, low resolution) | 2.7x2.9 cm | 4 s | (10x10 points) |
| | 5.7x6.1 cm | 15 s | (20x20 points) |
| | 15x16 cm | 1 min 30 s | (50x50 points) |
| | 26x29 cm | 4 min 29 s | (85x85 points) |

| | | | | |
|--|------|--------|------|-----------|
| Resolution: | Low | Medium | High | Very high |
| Step length: (approx. 25 cm from object) | 3 mm | 2 mm | 1 mm | 0.5 mm |