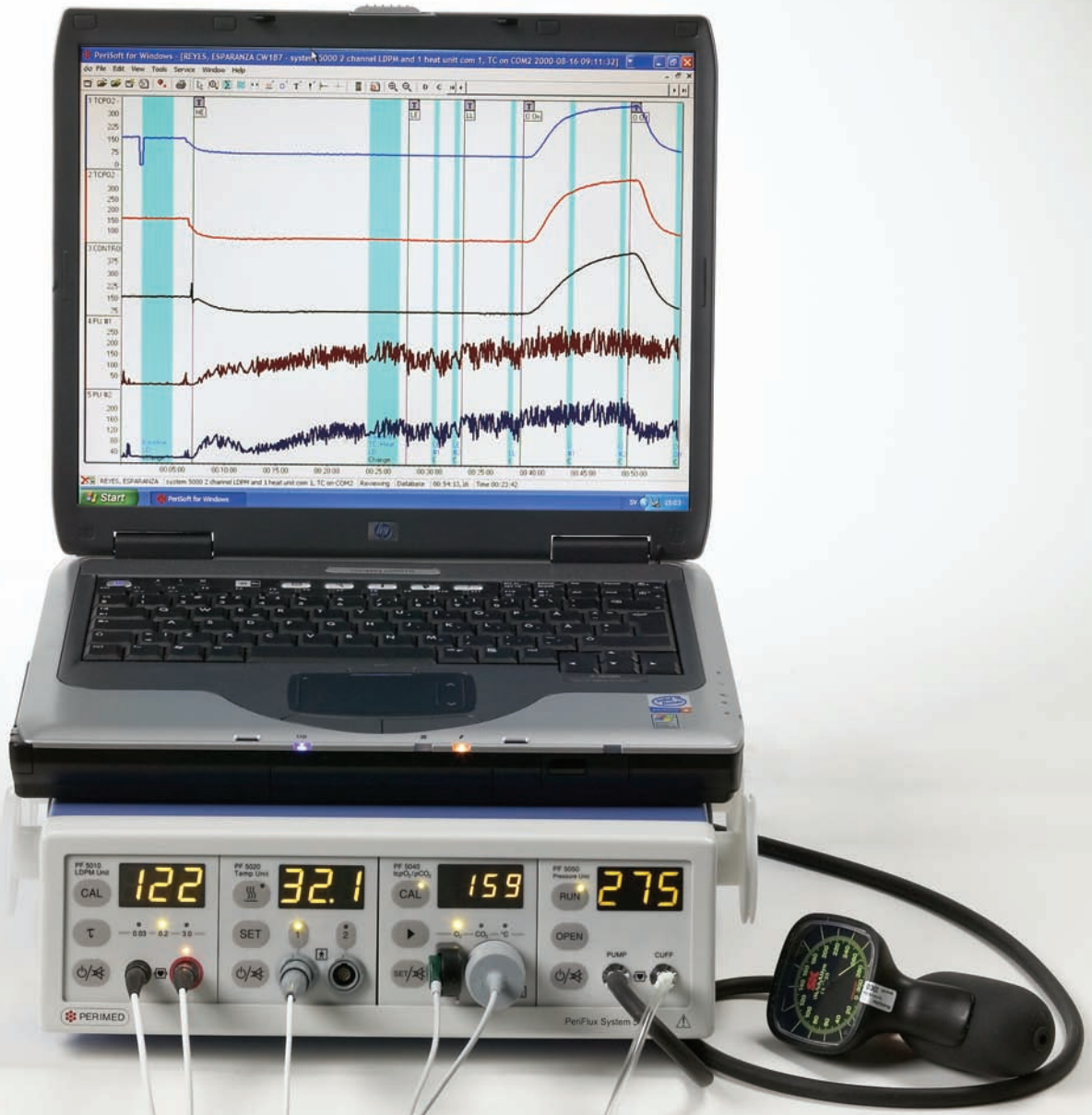


PeriFlux System 5000

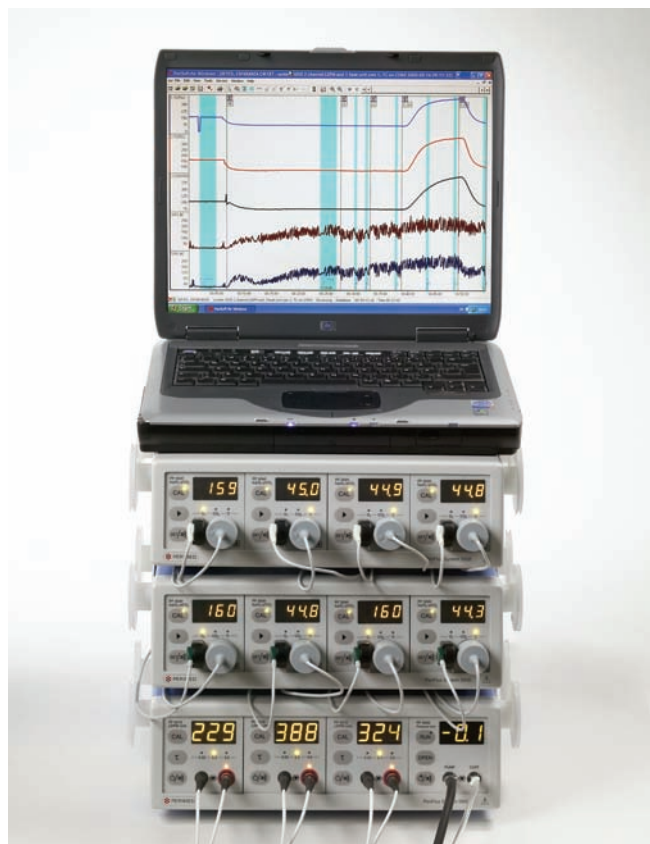
Laser Doppler Blood Perfusion Monitoring and $tcpO_2/tcpCO_2$



PeriFlux System 5000 is unique in permitting up to four channels of $tcpO_2/tcpCO_2$, toe/ankle pressure, and laser Doppler with site temperature control and heat provocation, configured to meet your exact study needs.

The PeriFlux System 5000

The PeriFlux System 5000 is the fifth generation of the Perimed PeriFlux instrument range for microvascular assessment. It is a compact, easy to use, multi-functional system that can incorporate up to four Function Units. The combination of $tcpO_2/CO_2$ and laser Doppler Function Units provides more information about tissue perfusion, oxygenation and metabolic function than the two methods individually.



Multiple PF 5000 Main units with 8 channels $tcpO_2$, 3 channels Laser Doppler and 1 channel Pressure.

Laser Doppler Perfusion Measurements

Low power laser light is transmitted to the tissue via a fiber optic probe. The returning light is processed and the relative number and velocity of the blood cells in the tissue are calculated and presented as **blood perfusion**. Laser Doppler has been extensively used for tissue evaluation on skin and most other organs (refer to Perimed Literature Reference List, or PubMed).

The technique has recently grown in importance in the diagnosis and treatment of hypoxia and ischemia-related tissue disorders. Valuable information is provided for:

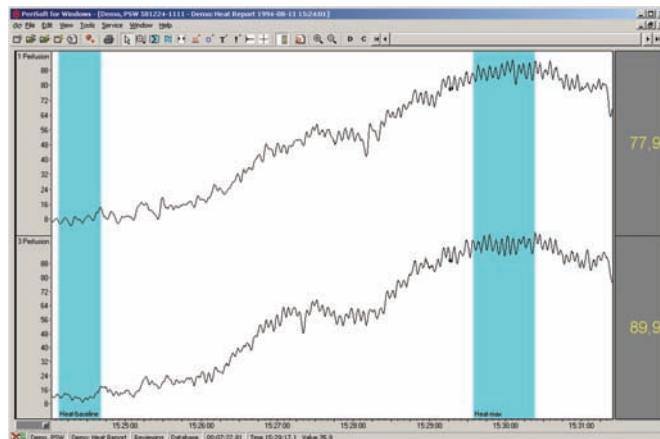
- Management of peripheral vascular disease
- Diabetes treatment
- Amputation level determination
- Monitoring therapy
- Plastic surgery (evaluation of flaps)
- Treatment of burns

Wound Healing

An excellent technique to assess the wound healing process is provided by the combination of $tcpO_2/CO_2$ and laser Doppler. The laser Doppler measures perfusion while the $tcpO_2/CO_2$ measures oxygenation and metabolic function of the tissue.

Tissue Perfusion Capacity

To find the maximum perfusion capacity of a tissue, a combined laser Doppler and heat probe is used and the tissue is heated (e.g. 44 °C). The perfusion change from before to after the local heating is a measure of the tissue reserve capacity.



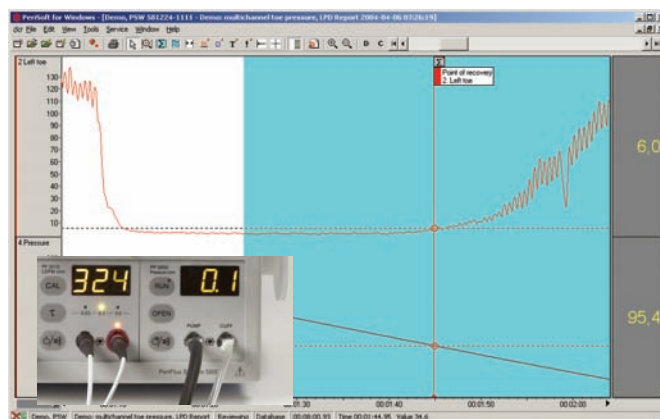
Wound healing assessment using 2 heated probes providing local heating of tissue to detect maximum dilatation.

Accurate and Reliable

The unique linearization function prevents underestimation in well-perfused tissue. Two-point calibration (using automatic zeroing and a special motility standard) ensures that all probes will provide accurate and reliable results for the best patient care. The probes are applied in seconds and results are obtained in minutes.

Toe Pressure

The Pressure Unit is a complement to the Laser Doppler Unit for performing Digital Systolic Blood Pressure (toe/finger, ankle-brachial pressure) and other measurements such as Post Occlusive Reactive Hyperemia. A laser Doppler probe is placed distal to the cuff on a digit and detects the return of the microcirculation as the cuff pressure is slowly released.



Toe Pressure: The upper curve shows the laser Doppler signal and the lower curve shows the Pressure. The point of recovery is detected automatically when the cuff pressure matches the digital systolic blood pressure - the laser Doppler signal returns. A Laser Doppler and a Pressure unit is shown in the small picture.

Oxygenation and Tissue Metabolism with $tcpO_2/CO_2$

Transcutaneous monitoring of oxygen and carbon dioxide, originally developed for neonatal use, is now used in a number of different applications, including vascular and wound care, plastic surgery, hyperbaric medicine and orthopaedic surgery.

$TcpO_2/CO_2$ Measurements

The technique is easy to use and gives accurate, reliable measurements for tissue evaluation.

It has now become a routine measurement in several clinical areas:

- Determination of peripheral vascular oxygenation
- Quantification of the degree of peripheral vascular disease
- Determination of the optimum level of amputation
- Establishing the level of tissue hypoxia in venous disease

Multichannel System

$TcpO_2$ measurements usually require at least two or three sites to provide a good picture. The more sites that are assessed, the better the oxygenation picture.

The PeriFlux System 5000 now offers the capability of measuring up to four sites on a patient from one instrument. This has several advantages over using individual single channel monitors, for example:

- Greater portability
- Saves space
- Easier identification of measurement sites
- Less risk of damage to electrodes and monitors
- Patient data from multiple sites easily downloads to a PC for storage, editing and print out of reports



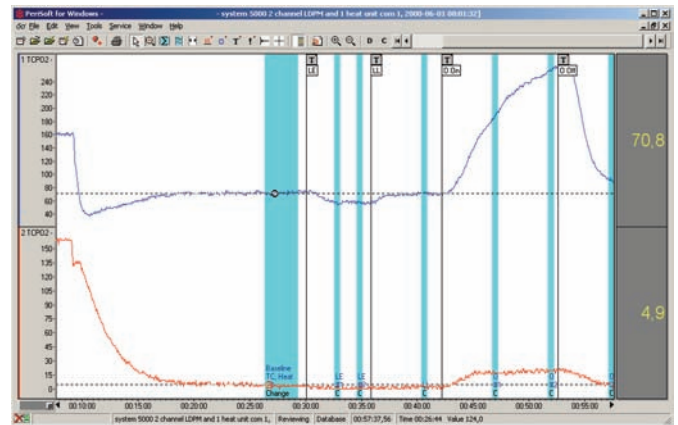
A 4-channel $tcpO_2$ system.

Ease of Use

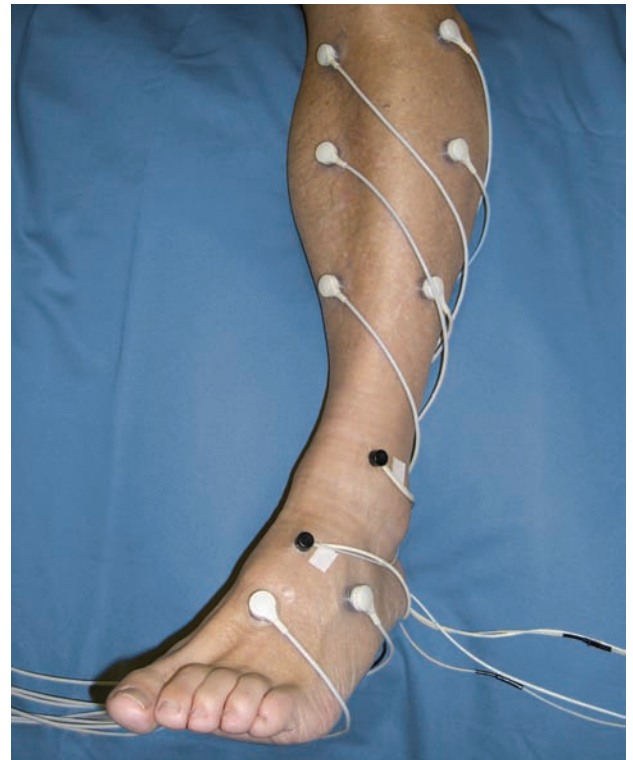
The single point calibration is typically completed in less than three minutes, making it possible to save time and costs. Attachment of the electrode takes a few seconds using rings specially designed for patient safety and reliability of measurement.

Superior Sensor Technology

The multichannel monitor utilizes Radiometer electrodes – well known for superior durability and reliability. The electrodes are safe for use in 100% oxygen at pressures up to 4 atm.



Recording of a two channel $tcpO_2$ system. Result of leg elevation and oxygen challenge. The upper trace shows the response from a healthy leg, while the lower trace shows a leg with vascular problems.



8-channel $tcpO_2$ measurement and 2 heated laser Doppler probes.

Specifications

PeriFlux 5001 Main Unit and PeriFlux 5002 Basic Main Unit

The PeriFlux 5001 Main Unit is provided with a solid state diode laser and can host up to four Function Units of different types. More channels are added using another Main Unit. The Main Unit has a digital output for connection to Perimed's PeriSoft software or a dedicated printer. It also has an analog output for connection to pen recorders or computer systems. Alternatively it can be used stand-alone, without external data acquisition systems. The PeriFlux 5002 Basic Main Unit is equivalent to the PeriFlux 5001, but is not provided with laser diode and can not host the Function Unit PF 5010 LDPM Unit.

Function Units

The Function Units are designed to meet specific needs in different applications. To optimize the system, the customer can choose the appropriate unit to meet particular requirements. Additional Function Units can be added and installed by the user.

PF 5010 LDPM Unit (Laser Doppler Perfusion Monitor)

For real-time microvascular perfusion measurements. The system uses an extensive range of laser Doppler probes to allow measurements in virtually all tissues, invasive or non-invasive.

PF 5020 Temp Unit

For local heat provocation and/or temperature measurements. During a heat provocation the microvascular response is measured with the laser Doppler. This response indicates the maximum dilatation capacity of the tissue.

PF 5040 tcpO₂/CO₂ Unit

For measurement of transcutaneous oxygen and transcutaneous carbon dioxide. tcpO₂/CO₂ is measured from a combined electrode and tcpO₂ from a single electrode. Calibration of the

O₂ electrode can be performed using atmospheric air. The CO₂ electrode requires the use of a calibration unit.

PF 5050 Pressure Unit

The Pressure Unit is a complement to the PF 5010 LDPM Unit and PSW that makes it easy to perform Digital Systolic Blood Pressure (toe/finger, ankle-brachial pressure), Post Occlusive Reactive Hyperemia (PORH), Skin Perfusion Pressure and Pulse Volume Recording (PVR).

Perisoft for Windows - PSW

Dedicated software for data collection, storage, analysis and printing. (See separate pamphlet).

Local Printer

For hard-copy documentation, a printer can be connected to the PF 5000, if a PC with the software PSW is not used.

Technical Specifications

PF 5001 Main Unit and PF 5002 Basic Main Unit

Type (protection against electric shock):	Class I Equipment, Type BF and/or CF depending on Function Units
Laser: (only PF 5001)	IEC 60825-1 Class 1 (CFR 1040.10 Class I) Solid-state diode laser, 780 nm wavelength. Maximum power output at probe tip 1 mW.
Mains and Power consumption:	100 - 240 VAC, 50 - 60 Hz 70 VA (with four Function Units)
Dimensions:	30 x 32 x 10.5 cm
Weight:	7.7 kg (with four Function Units)
EC Declaration of conformity:	CE approved according to MDD 93/42/EEC, Electrical Safety Standard IEC 60601-1, Class I EMC Standard IEC 60601-1-2
Operating conditions:	+10 to +35 °C at 30-85% RH
Computer: (Minimum requirements)	CPU 800 MHz, 256 MB RAM Windows 2000/XP
Output:	Digital: RS-232 output to computer or directly to printer Analog: -10 to +10 V

Output: Measured Temperature at Probe/Sensor
Heating Range: 26-44 °C; increments of 1 °C. Accuracy ±0.5 °C.
Sensor Range: 30-40 °C. Accuracy: ±0.3 °C, Repeatability ±0.1 °C. 0-30 °C and 40-50 °C, Accuracy ±0.5 °C, Repeatability ±0.1 °C

Classification: Type BF
Display: 3 digit LED display
Accessories

Probes and sensors - see separate brochure.

PF 5040 tcpO₂/CO₂ Unit

For measurement with one electrode per unit.
Output range: tcpO₂: 0-1999 mmHg (0-267 kPa), tcpCO₂: 0-200 mmHg (0-26.7 kPa)
Temp. settings 37-45 °C in increments of 0.5 °C, Temp. accuracy ±0.1 °C.
Classification: Type BF
Display: 3.5 digit LED display

Accessories

E5280 Combination electrode tcpO₂/CO₂ solid state
Response time Typical tcpO₂: 20 sec, tcpCO₂: 50 sec.
Stability Typically better than 1 mmHg/h

E5250 Electrode tcpO₂ solid state.
Response time Typical 20 sec.
Stability Typically better than 1 mmHg/h.

D280 Membraning kit for tcpO₂/CO₂ electrode.

D826 Membraning kit for tcpO₂ electrode.

TC550 Fixation kit for E5280/E5250 electrodes.

TCC3 Calibration Unit for tcpO₂/CO₂.

TC510 Calibration gas 20.9% O₂ and 5% CO₂.

TC100 Extension cable 6 m for electrode E5280/E5250.

PF 5840 Remote Panel for tcpO₂/CO₂ including cable and penetrators for hyperbaric chamber.

PF 5810 Remote Panel for LDPM and Heat incl. cable and penetrators for hyperbaric chamber.

PF 5050 Pressure Unit

For measurement and linear deflation of pressure in cuffs.
Output range: Cuff pressure 0-300 mmHg (0-40 kPa),
PVR from -2.5 to +10 mmHg (only available on digital and analog output)
Accuracy: 0-100 ±2 mmHg, 101-200 ±3 mmHg, 201-300 ±4 mmHg
Classification: Type CF
Display: 3.5 digit LED display

Accessories

PF5051 Hand pump, cuffs and tubing

Function Unit specifications

PF 5010 LDPM Unit

For one laser Doppler probe per Unit.
Outputs: Perfusion, CMBC (Concentration of moving blood cells), Velocity and TB (Total Backscattered light)

Classification: Type CF
Display: 3 digit LED display

Accessories

Probes - see separate brochure.

PF 5020 Temp Unit

For one or two Thermostatic Probes/Measurement Sensors per unit.