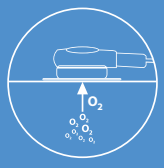
PeriFlux 6000 | tcpO_2 made intelligent



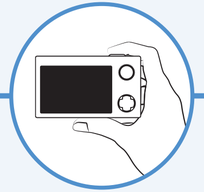
Transcutaneous oxygen

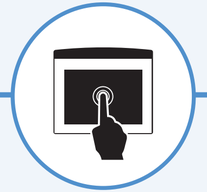
PERIMED

Reveal the wound healing capacity by performing an intelligent tc*p*O_2

Patient born 1940
Bilateral ulcerations
Unreliable ankle pressures
Suspected ischemia

Prepare for tc*p*O_2
Connect electrodes and document positioning





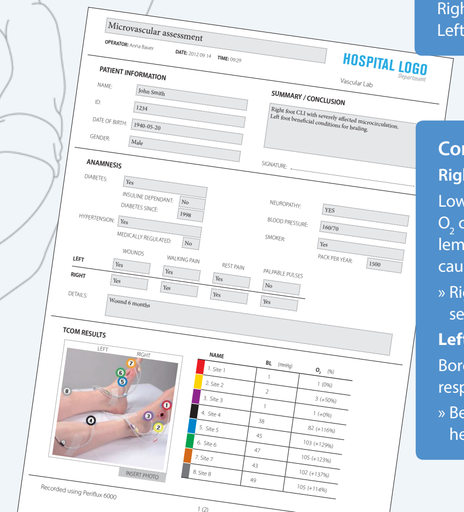
Start tc*p*O_2
Follow instructions on screen

Baseline tc*p*O_2 value
Right foot = 1 mmHg
Left foot = 45 mmHg

What does a tc*p*O_2 value < 40 mmHg indicate?
Peripheral Arterial Disease (PAD)?
Capillary impairment?
Cardiopulmonary disease?
High tissue consumption of O_2 due to infection/inflammation?

?

Extend with a provocation
10 minutes O_2 challenge
Right foot = 1 mmHg
Left foot = 103 mmHg



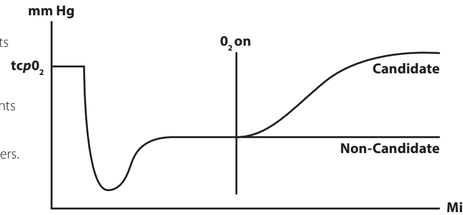
Conclusions of the examination

Right foot:
Low baseline value tc*p*O_2. No response to O_2 challenge. If no cardiopulmonary problems are present, PAD is the most probably cause.
» Right foot critical limb ischemia with severely affected microcirculation

Left foot:
Borderline tc*p*O_2 baseline value. Good response to O_2 challenge.
» Beneficial conditions for spontaneous healing

tc*p*O_2 to predict benefit from hyperbaric oxygen treatment

Hyperbaric oxygen therapy (HBOT) is a medical treatment in which the patient breathes 100% oxygen inside a pressurized chamber. The aim is to increase the general oxygen level in the tissue. It is commonly used in conditions where partial or total tissue hypoxia is present, such as diabetic foot lesions or arterial ulcers. Not all patients will benefit from HBOT. Therefore, it is often recommended to use tc*p*O_2 to qualify patients before initiating the therapy. Furthermore, tc*p*O_2 can monitor the tissue oxygenation throughout the treatment. Perimed offers a remote panel system to facilitate measurements inside a multi-place chamber. In addition, all equipment is compatible with extension cables and penetrators used in mono-chambers.



PeriFlux 6000 - tc*p*O_2 / tc*p*CO_2 monitoring

Why measure tc*p*O_2?

Peripheral Arterial Disease (PAD) will influence the outcome of wound healing. To prevent limb loss, the degree of ischemia has to be assessed at an early stage. Transcutaneous oxygen (tc*p*O_2) has proven to be a useful tool for this purpose as it reflects the metabolic state of the lower limb. tc*p*O_2 is particularly important for the assessment of wounds and prediction of amputation levels in patients with critical limb ischemia and/or diabetes, as these patients commonly also have impaired microvascular function and falsely elevated ABI values.

What is tc*p*O_2 and tc*p*CO_2?

Transcutaneous oxygen, tc*p*O_2 or TCOM, is a local non-invasive measurement reflecting the amount of O_2 that has diffused from the capillaries, through the epidermis, to a Clark-type electrode at the measuring site. It provides instant, continuous information about the body's ability to deliver oxygen to the tissue. Any impairment in the ability to deliver oxygen to the tissue will be revealed immediately since the skin is ranked very low in the body's system of oxygenation priority. tc*p*O_2 measurements usually require at least 2-3 sites, preferably 4 or more, to provide a good picture of the oxygenation status of the skin.

Transcutaneous carbon dioxide (tc*p*CO_2) is the local carbon dioxide tension in the skin. The carbon dioxide level is affected by both the local metabolic processes and the blood perfusion ability to remove carbon dioxide.

Reference values tc*p*O_2

50-70 mmHg	Normal
< 40 mmHg	Impaired wound healing
< 30 mmHg	Critical Limb Ischemia

Interpreting results

As a tc*p*O_2 value can be influenced by many factors, extending the baseline with provocations, or including a reference electrode, may prove valuable for the clinical decision making.

Oxygen challenge (tc*p*O_2 measurement during 100 % oxygen inhalation) will distinguish low values due to a barrier to oxygen diffusion (edema and/or inflammation) from macrovascular disease (PAD).

Leg elevation for a duration of 5-15 minutes may be used to confirm macrovascular disease. Other methods to confirm macrovascular disease include toe and ankle pressure.

Reference electrode or oxygen saturation (pulse oximeter) will rule out arterial hypoxemia (due to pulmonary disease, for example).

PeriFlux 6000 is the latest generation transcutaneous O_2 and CO_2 equipment from Perimed

1 - 2 - 3

Compact and elegant solution

The PeriFlux 6000 is operated using a touch screen interface. It can be equipped with up to 8 channels of tcpO_2 allowing for accurate mapping of the extremity. It is small, portable and can be mounted on an arm or stand.

Step-by-step-instructions

The user is guided throughout the procedure by simple instructions displayed on the screen. Different tests may be implemented, including exam room and in-chamber measurements.

Automatic report generator

All test results, including the site positioning photo, are displayed in an automatically generated report that may be printed or exported as a PDF file. The report template can be customized according to the requirements of the user.

HIPAA compliant

For patient security the PeriFlux 6000 is HIPAA compliant.

Billing and Reimbursement

Use CPT codes 93922 and 93923 for billing and reimbursement of tcpO_2 measurements.

Connection to PC

Data from the PeriFlux 6000 can be transferred to a PC. The PeriFlux Configuration Software (PCS) also makes it possible to review generated data on a PC.

References

1. European Society for Vascular Surgery, CLI Guideline Committee Guidelines for Critical Limb Ischaemia and Diabetic Foot, 2011

2. Transcutaneous Oximetry in Clincal Pratice: Consensus statements from an expert panel based on evidence. Fife, Smart, Sheffield, Hopf, Hawkins and Clarke. UHM 2009, Vol. 36, No. 1.

PeriFlux 6000 Specifications

Start-up time:	Maximum 60 seconds
Automatic calibration:	In air (tcpO_2) / with TC 600 (tcpCO_2), 8 electrodes simultaneously
Memory storage capacity:	2 GB
Alarm:	Visual and audible
Dimensions:	W=28 cm, H=22 cm, D=25 cm
Weight:	4.9 kg (equipped with 8 PF 6040 units)
Display:	Touchscreen: 8.4" color TFT-LCD, Resolution: 800x600 px
Power consumption:	100 to 240 VAC, 50 or 60 Hz, 65 VA
Operating conditions:	Temp.: +15 to +35 °C at 10 to 85 % RH, Environmental pressure: 70 to 110 kPa / 700 to 1100 mbar
External connections:	2 USB hosts (for connecting printer, camera, keyboard, pointer device, etc.), 1 USB device (for connecting PC)
Humidity sensor:	Range: 10 to 85 % RH, Accuracy: ± 4 % RH

PF 6040 tcpO_2/tcpCO_2 Unit

One electrode per unit	
Measured parameters:	tcpO_2, tcpCO_2
Measurement ranges:	tcpO_2 = 0 to 1999 mmHg (0–267 kPa), tcpCO_2 = 5 to 200 mmHg (0.67–26.7 kPa)
Accuracy:	tcpO_2 < ±5 mmHg from 0 to 20.9 % O_2 and < ±10 % of reading from 21% to full scale tcpCO_2 ±5 mmHg over measurement range (5 to 100 mmHg)
Temperature settings:	Range: 37 to 45 °C, set in steps of 0.5 °C, Accuracy: 0.5 °C
Built-in barometer:	Range: 225 to 825 mmHg, Accuracy: ± 3.0 mmHg
Classification type:	BF (body floating)

Electrodes:

E5250:	pO_2 sensor
E5280:	Combined pO_2 / pCO_2 sensor

Compliance:

HIPAA compliant

MDD 93/42/EEC, WEEE 2002/96/EG, ROHS 2002/95/EG, EN60601-1:2006 (Third edition), EN60601-1-2:2007, EN60601-1-6:2010, ASTM D4169:2009, EN ISO10993-1:2009, EN62304:2006, 21 CFR 800-1299:2008, ANSI/AAMI ES60601-1:2005, CMDR, 2010, CAN/CSA-C22.2 No. 60601-1:08, IEC60601-2-23:2011, EN60601-1-8:2007 (Second edition), NFPA 99:2012,GB 18455-2001, SJ/T 11363-2006, SJ/T 11364-2006, EN 980:2008, ISO15223-1:2007 (First edition), EN62366:2008, EN 1041:2008, MEDDEV. 2.7.1 Rev.3, EN ISO 14971:2012

Accessories and Consumables:

Fixation rings:	TC 550 Fixation Rings for tcpO_2 / tcpCO_2, TC 555 Fixation Rings Extra Strength Adhesive for tcpO_2 / tcpCO_2
Contact liquid (20 ml):	TC 560 Contact Liquid
Membraning kit:	D826 Membraning Kit tcpO_2, D280 Membraning Kit tcpCO_2
Calibration unit for CO_2:	TC 600 Calibration Unit
Calibration gas (CO_2):	TC 510 Calibration Gas
Remote panel:	PF 5840 TC Remote Panel
Cables for remote panels:	PF 5841 Extension Cable 3 m, PF 5842 Extension Cable 6 m
Color coded labels:	PF 6103 Color Coded Labels
Camera:	PF 6113 Camera

System carts
Foot pedal
Demand valve EASE II 03 3M SS/DIN 120 and range of different sized masks
Medical isolation transformer, Network isolator

Due to Perimed's commitment to continuously improve our products, all specifications are subject to change without notice.
The 510(k) approval for the PeriFlux 6000 does not yet cover the modules PF 6010 and PF 6050.

Standard PeriFlux 6000 configurations:

	tc$p0_2$	PRESSURE *Standard*	COMBINED *Standard*	PRESSURE *Premium*	COMBINED *Premium*
Toe pressure, ABI and PVR	-	●	●	●	●
tcpO_2	**1 - 8**	-	**2**	-	**3**
Treadmill	-	○	○	●	●
Segmental pressure	-	○	○	●	●

○ Available ● Included - Not applicable

For more information please contact Perimed AB

Perimed AB, Datavägen 9A, SE-175 43 Järfälla-Stockholm, Sweden | Tel: +46-8-580 119 90 Fax: +46-8-580 100 28
E-mail: mail@perimed-instruments.com | Website: www.perimed-instruments.com

Part. No. 44-00284-03

PERIMED

www.perimed-instruments.com