

PeriFlux 6000 | intelligent peripheral vascular diagnosis

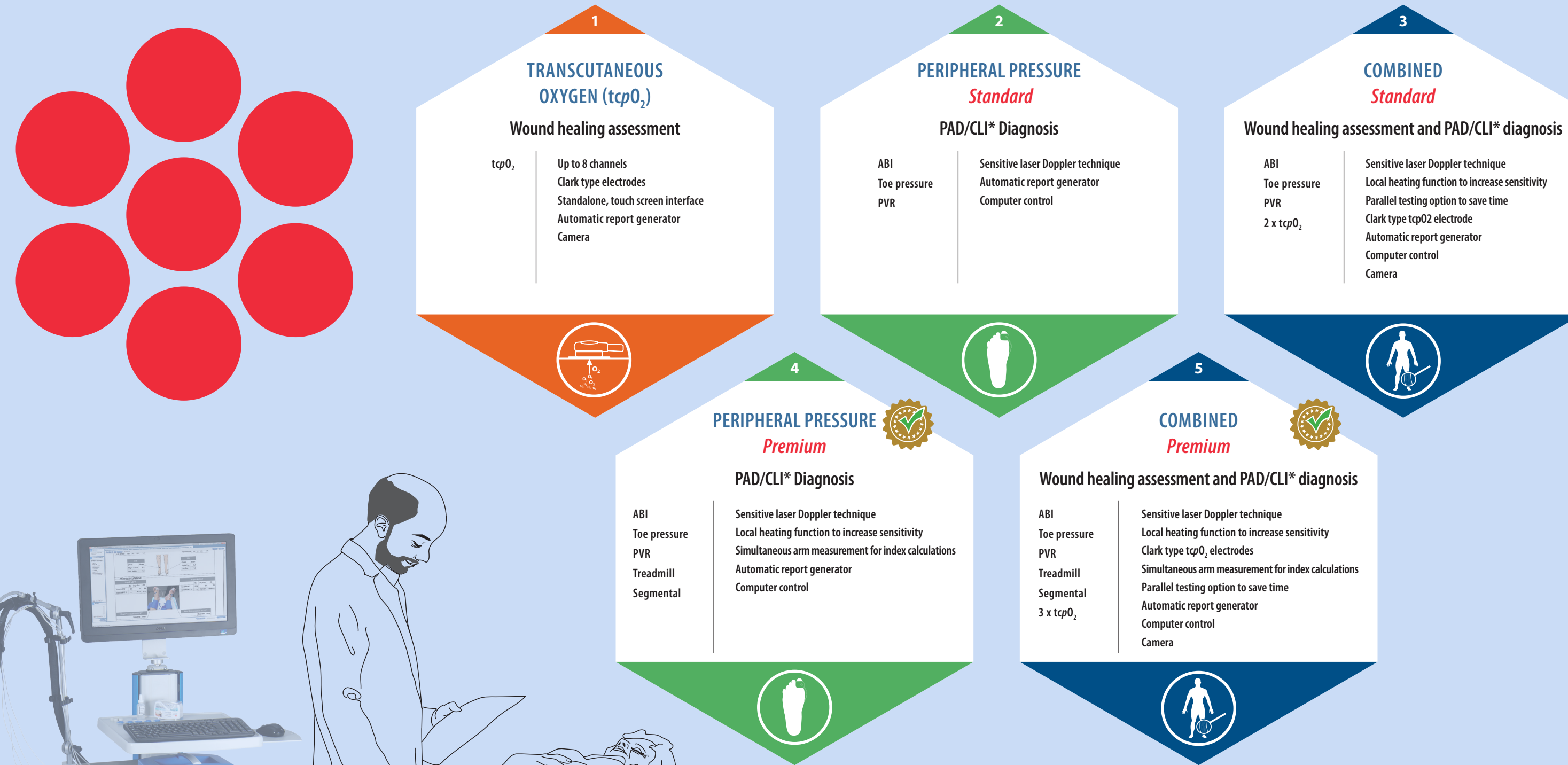


Product brochure



PeriFlux 6000 - a flexible system that grows with your needs

Tailor PeriFlux 6000 to your specific diagnostic challenge



	1 tcpO ₂	2 PRESSURE Standard	3 COMBINED Standard	4 PRESSURE Premium	5 COMBINED Premium
DICOM	○	○	○	○	○
DICOM and HL7	○	○	○	○	○
Local heating function	—	○	●	●	●
Treadmill kit	—	○	○	●	●
Segmental kit	—	○	○	●	●
Finger pressure kit	—	○	○	○	○
Hyperbaric kit	○	—	○	—	○
O ₂ challenge kit	○	—	○	—	○
Camera	●	○	●	○	●
Cart	○	●	●	●	●
Computer	○	●	●	●	●

○ Available ● Included — Not applicable

Please note that it is always possible to upgrade from STANDARD to PREMIUM, or from tcpO₂ to COMBINED. In addition, channels can be added to increase the number of measurement sites.

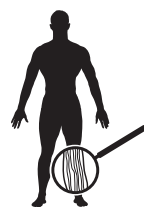
* **Peripheral Arterial Disease (PAD):** PAD is a condition caused by obstruction of the peripheral arteries, leading to an increased risk for cardiovascular events. The classical PAD symptom is intermittent claudication (walking pain), but notably two-thirds of all patients are asymptomatic. PAD is often more aggressive in diabetics, with a higher risk of major amputations. PAD should always be confirmed using objective vascular tests.

Critical Limb Ischemia (CLI): CLI is a severe form of PAD with high incidence of amputation and mortality. The distal blood flow and microcirculatory function are severely compromised resulting in rest pain, ischemic ulcers and gangrene. CLI is a clinical diagnosis, but should be supported by objective tests.



PeriFlux 6000

intelligent diagnosis of patients with peripheral vascular disease



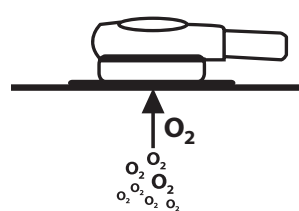
Accurate vascular assessment

PeriFlux 6000 offers a unique combination of vascular tests. Using the same instrument and software, high-quality diagnosis of Peripheral Arterial Disease (PAD) and assessment of the wound healing potential is obtained.



ABI and toe pressure

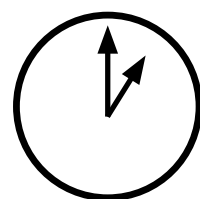
Accurate toe pressure measurements require precise techniques. PeriFlux 6000 uses sensitive laser Doppler technique for detection. Accuracy is further improved with local heating at the measurement point, enhancing the detection on cold ischemic feet.



Microvascular tests – tcpO₂

Transcutaneous oxygen monitoring (TCOM / tcpO₂) is a non-invasive way to evaluate the microvascular status of the patient. Today, TCOM / tcpO₂ is commonly used in clinical applications such as wound healing assessment, hyperbaric medicine, amputation level determinations and more.

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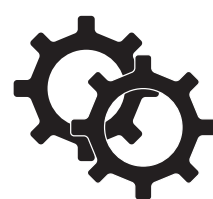


Step-by-step instructions

The user is guided throughout the procedure by clear instructions available in several languages. The operator independent workflow provides reliable results at any time. The instrument can be managed by a nurse or technician.

Parallel testing to save time

To save time, several vascular tests maybe performed in parallel. As an example, toe and ankle pressures are measured at the same time as a baseline tcpO₂ is being recorded.



Adaptable tests and workflows

Each examination can be streamlined according to the individual patient. For example, a patient with a diabetic foot ulcer should be evaluated using toe pressure and tcpO₂ measurements. Whereas a patient with walking pain should be examined using ABI and toe pressure.

PeriFlux 6000 Specifications

Start-up time: Maximum 60 seconds
 Automatic calibration: In air (tcpO₂) / with TC 600 (tcpCO₂), 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 6010 LDPM/Temp Unit

One laser Doppler probe per unit
 Outputs (LDPM): Perfusion, CMBC (Concentration of Moving Blood Cells), Velocity and TB (Total Backscatter)
 Outputs (Temp): Measured temperature at probe site
 Perfusion range: 0 to 1999 PU
 Heating range: +26 to +44 °C, Increments: 0.5 °C, Accuracy: ± 0.5 %
 Classification type: BF (body floating)

PF 6050 Pressure Unit:

Six pressure outlets per unit
 Output range: Cuff pressure 0 to 300 mmHg
 Accuracy: 0 to 150 mmHg: ± 3 mmHg, 151 to 300 mmHg: ± 2 %
 Classification type: BF (body floating)

PF 6040 tcpO₂/tcpCO₂ Unit

One electrode per unit
 Measured parameters: tcpO₂, tcpCO₂
 Measurement ranges: tcpO₂ = 0 to 1999 mmHg (0–267 kPa), tcpCO₂ = 5 to 200 mmHg (0.67–26.7 kPa)
 Accuracy: tcpO₂ < ±5 mmHg from 0 to 20.9 % O₂ and < ±10 % of reading from 21% to full scale
 tcpCO₂ ±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: pO₂ sensor
 E5280: Combined pO₂ / pCO₂ 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 tcpO₂ / tcpCO₂, TC 555 Fixation Rings Extra Strength Adhesive for tcpO₂ / tcpCO₂
 Contact liquid (20 ml): TC 560 Contact Liquid
 Membraning kit: D826 Membraning Kit tcpO₂, D280 Membraning Kit tcpCO₂
 Calibration unit for CO₂: TC 600 Calibration Unit
 Calibration gas (CO₂): 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
 Calibration LDPM: PF 1000 Calibration Device
 Camera: PF 6113 Camera
 Double-sided tape strips: PF 105-3 Double-Sided Tape Strips (100 pcs)
 Range of different sized pressure cuffs
 Range of different laser Doppler probes
 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.

	tcpO ₂	PERIPHERAL PRESSURE <i>Standard</i>	COMBINED <i>Standard</i>	PERIPHERAL PRESSURE <i>Premium</i>	COMBINED <i>Premium</i>
PF 6010	-	2	2	3	3
PF 6050	-	1	1	1	1
PF 6040	1-8	-	2	-	3
PROBE 457	-	-	2	3	3
PROBE 407	-	2	-	-	-
E5250	1-8	-	2	-	3
Pressure cuffs	-	yes	yes	yes	yes
PSW ExM software	-	1	1	1	1
Cart	-	1	1	1	1
Computer	-	1	1	1	1
Foot pedal	-	1	1	1	1
Camera	1	-	1	-	1
Medical isolation transformer	-	1	1	1	1

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. 44-00313-01



www.perimed-instruments.com