

# PeriFlux 6000 | peripheral pressure made intelligent



*ABI and toe pressure*



# Assess limb circulation by performing an intelligent PAD diagnosis

## Example: Toe and ankle pressure workflow

Patient born 1950  
Diabetes  
Suspected ischemia



**Prepare for ABI and toe pressure**  
Attach cuffs and probes



**Start pressure measurements**  
Follow instructions on screen

**ABI values**  
(Ankle Brachial Index)  
Right foot = 2.1  
Left foot = 2.1

**Suspected medial sclerosis**  
Falsely high ABI due to arterial calcification?  
» Extend with toe pressure measurement

**Toe pressure values**  
Right foot = 25 mmHg  
Left foot = 29 mmHg

**Conclusions of the examination**  
ABI values > 1.4 indicate incompressible arteries in both legs. Toe pressure values below threshold value for critical limb ischemia (< 50 mmHg).  
» Patient with Critical Limb Ischemia

**Customized workflows and reports**  
» Step-by-step instructions  
» Automatic calculation of, ABI and TBI, for example  
» Adaptable report

**Laser Doppler probes for detection**  
» Excellent sensitivity, no need for pulsatility  
» Unique local heating feature to dilate vessels in cold feet  
» Small and easy to affix on all digits

**Up to 12 independent pressure channels**  
» Possibility to set individual pressures  
» Several deflation rates  
» Built-in pump

**Extendable with tcpO<sub>2</sub> modules**

### Why measure tcpO<sub>2</sub>?

Transcutaneous oxygen monitoring (TCOM / tcpO<sub>2</sub>) is a non-invasive way to evaluate the microvascular status of the patient. Today, TCOM / tcpO<sub>2</sub> is commonly used in clinical applications such as wound healing assessment, hyperbaric medicine, amputation level determinations and more.

The number of pressure cuffs illustrated on the patient does not correspond to the number necessary in the workflow example.

# PeriFlux 6000 - Peripheral pressure

## Why diagnose Peripheral Arterial Disease with objective tests?

Two thirds of all patients with PAD are asymptomatic. Diabetics have reduced pain perception due to neuropathy. Neuropathy may also result in relatively warm feet (atypical for ischemic feet), due to the increased arteriovenous shunt blood flow. Many patients with PAD are sedentary, and do therefore not experience typical symptoms of claudication. Palpable pedal pulses tend to overestimate PAD. It is therefore recommended to use objective vascular tests to verify and confirm the diagnosis of PAD.<sup>1-3</sup>

## Objective vascular tests available using the PeriFlux 6000

### ABI/Ankle pressure

Ankle pressure and the Ankle Brachial Index (ABI) are the most common vascular tests used to diagnose PAD. Its diagnostic accuracy is unfortunately limited in patients with incompressible arteries (diabetes, end-stage renal disease, Critical Limb Ischemia), resulting in falsely elevated ABI values.<sup>1-3</sup> The PeriFlux 6000 offers straight forward solutions to combine ABI tests with toe pressure measurements to improve the PAD diagnosis in these patients.

### Toe pressure

"Trust ABI when low but not when high."<sup>1</sup> Toe pressures have proven to be an excellent option for the diagnosis of PAD in patients at risk for falsely elevated ABI values. The digital vessels are not as affected by calcifications. Accurate detection of toe pressures requires careful techniques. The PeriFlux 6000 uses laser Doppler for detection and includes an unique local heating feature, assuring excellent sensitivity.<sup>4</sup> Different sized cuffs and small probes make it possible to measure on all toes.

### Treadmill

A treadmill exercise test is performed on patients with typical symptoms of PAD, but with a normal ABI. ABI values at rest are compared to values during exercise.<sup>3</sup> Tailored treadmill protocols are available in the PeriFlux 6000 software.

### PVR

Pulse Volume Recording (PVR) reflects arterial pulsatility and can be used to localize significant occlusive lesions. Arterial calcifications will not result in false PVR interpretations, but accuracy is still limited.<sup>1,3</sup>

### Segmental pressures

Segmental pressures can provide an initial indication on the localization of the occlusive lesion. Values are affected by several factors, such as arterial calcifications, and are therefore often combined with PVR.<sup>2</sup>

### SPP

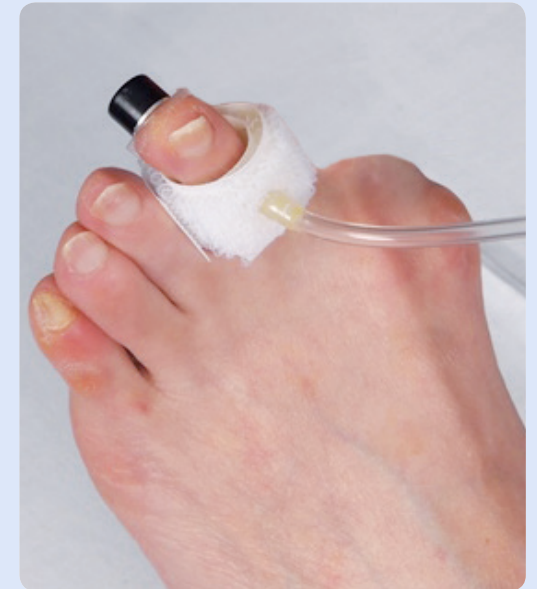
Skin Perfusion Pressure (SPP) measures the local pressure of the skin microcirculation.<sup>7</sup> It has been successfully employed for amputation level determination, in particular major amputations. SPP measurements are performed in a similar way as toe pressure measurements but with the probe located underneath the pressure cuff.

### Tissue response to local heating

Tissue response to local heating gives valuable information about the status of the microcirculation and reflects the endothelial function as a response to local heating.<sup>5</sup> Must be used in conjunction with laser Doppler measurement.

### Finger pressure

Probes and pressure cuffs may be attached to the digits to measure systolic finger pressures. The Perimed probes are water resistant and may be submerged into cold water, when, for example, evaluating hand-arm vibration syndrome (HAVS).



**HOS PERIPHERAL PRESSURE TEST**  
Bilateral investigation of the arterial circulation in the legs

Date: 12/12/2014  
Patient: Patient, Diabetes  
Dep: Vascular Lab  
Operator: Dr Smith  
Born 1950  
Examination: ABI and Toe pressure

**SUMMARY / CONCLUSION**  
ABI values > 1.4 indicate incompressible arteries in both legs.  
Toe pressure values below threshold value for critical limb ischemia (< 50 mmHg).

**ANAMNESIS / MEDICAL HISTORY**

DIABETES: Yes  No

HEART DISEASE: Yes  No

COMMENT: Insulin intake

LUNG DISEASE: Yes  No

SMOKER: Yes  No

ARM BLOOD PRESSURE: 120

COMMENT: 100 pack/year

OTHER:

WALKING PAIN: Yes  No

REST PAIN: Yes  No

DISCOLORATION: Yes  No

PALPABLE PULSES: Yes  No

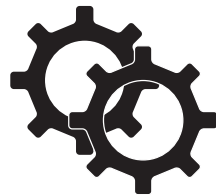
WOUND: Yes  No

**TOE AND ANKLE PRESSURE RESULTS**

	1	2	3	Mean
Right Ankle	248	250	249	249
Left Ankle				



# Streamline your workflow to secure accurate vascular diagnosis



## Excellent toe pressure detection

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

## HL7 and DICOM compatible

The PSW ExM software is DICOM (Digital Imaging and Communication in Medicine) and HL7 (Healthcare Language Level 7) compatible. Patient information (worklists) may be imported and data exported automatically.

## Configurable examinations

The PeriFlux 6000 is operated using the PSW ExM application software. Examinations and workflows are adapted to specific needs. A toe and ankle pressure measurement may, for example, be preceded by pulse volume recording.

## Extend with tcpO<sub>2</sub> modules

The PeriFlux 6000 has a modular design and is easily extended with transcutaneous oximetry (tcpO<sub>2</sub>). The tcpO<sub>2</sub> test provides useful information for wound healing prediction, as it reflects the metabolic state of the limb.

## Automatic report generator

All test results 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 user requirements.

## Billing and reimbursement codes

Use CPT codes 93922 and 93923 for billing and reimbursement.

## PeriFlux 6000 Specifications

Start-up time:	Maximum 60 seconds
Automatic calibration:	In air (tcpO <sub>2</sub> ) / with TC 600 (tcpCO <sub>2</sub> ), 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)

### 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:

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	
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:

	tcpO <sub>2</sub>	PRESSURE Standard	COMBINED Standard	PRESSURE Premium	COMBINED Premium
Toe pressure, ABI and PVR	-	●	●	●	●
tcpO <sub>2</sub>	1 - 8	-	2	-	3
Treadmill	-	○	○	●	●
Segmental pressure	-	○	○	●	●

○ Available ● Included - Not applicable

## For more information please contact Perimed AB

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