

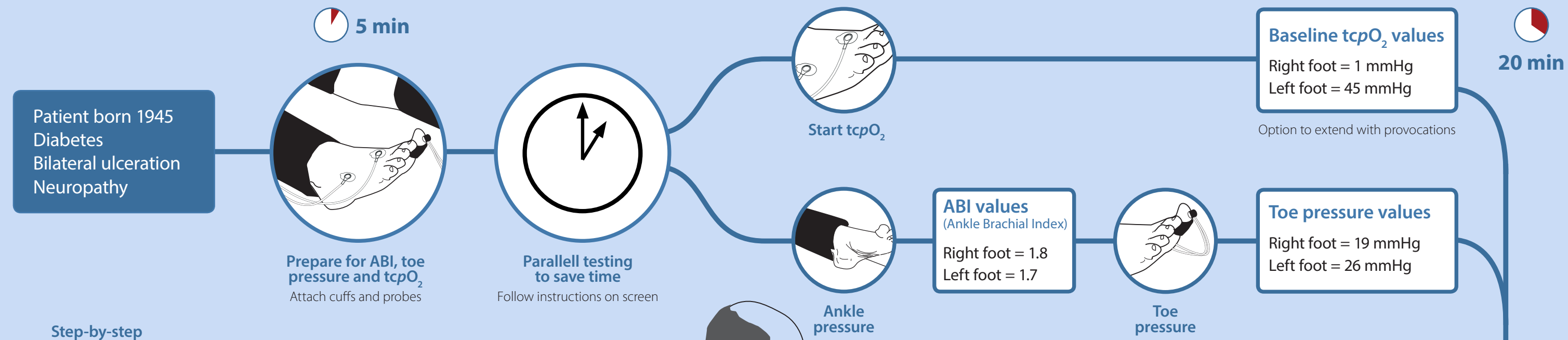
# PeriFlux 6000 | intelligence combined



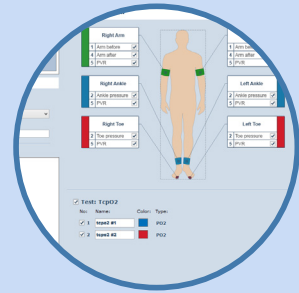
*Peripheral pressure and tcpO<sub>2</sub>*



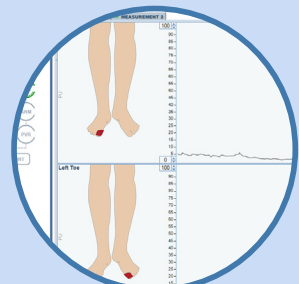
# Simultaneous assessment of limb circulation and wound healing



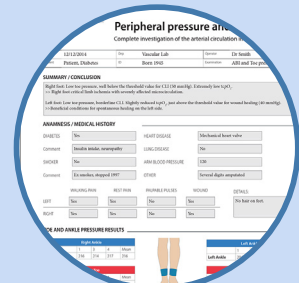
Step-by-step instructions on screen



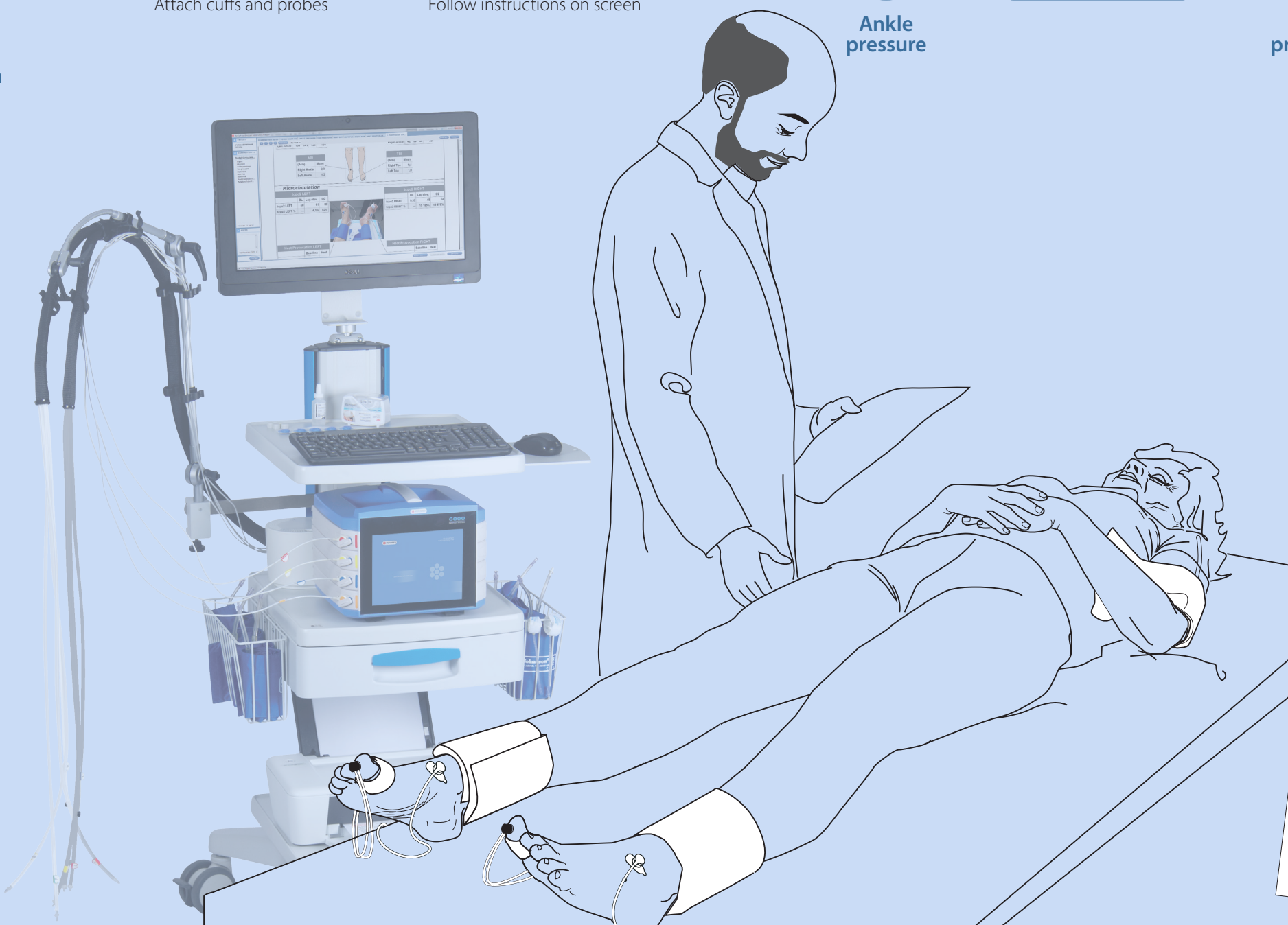
1. Setup



2. Run



3. Evaluate



**HOSPITAL LOGO**

## Peripheral pressure and tcpO<sub>2</sub>

Complete investigation of the arterial circulation in the legs

Date: 12/12/2014  
 Patient: Patient, Diabetes  
 Drp: Vascular Lab  
 ID: Born 1945  
 Doctor: Dr. Smith  
 Examination: ABI, Toe pressure and tcpO<sub>2</sub>

**SUMMARY / CONCLUSION**

Right foot: Low toe pressure, well below the threshold value for CLI (50 mmHg).  
 >> Critical limb ischemia with severely affected microcirculation in right foot.  
 Left foot: Low toe pressure, borderline CLI. Slightly reduced tcpO<sub>2</sub>, just above the threshold value for wound healing (40 mmHg).  
 >> Beneficial conditions for spontaneous healing on the left side.

**ANAMNESIS / MEDICAL HISTORY**

DIABETES: Yes  
 COMMENT: Insulin intake, neuropathy  
 SMOKER: No  
 COMMENT: Ex smoker, stopped 1997  
 HEART DISEASE: Mechanical heart valve  
 LUNG DISEASE: No  
 ARM BLOOD PRESSURE: 120  
 OTHER: Several digits amputated  
 WALKING PAIN: Yes  
 REST PAIN: Yes  
 PALPABLE PULSES: No  
 WOUND: Yes  
 DETAILS: No hair on feet.

**TOE AND ANKLE PRESSURE RESULTS**

Right Ankle					Left Ankle				
	1	2	3	Mean		1	2	3	Mean
Right Ankle	216	214	217	216	Left Ankle	204	203	205	204

Right Toe					Left Toe				
	1	2	3	Mean		1	2	3	Mean
Right Toe	30	29	31	19	Left Toe	24	20	25	20

**ABI**

(Arm)	Right Ankle	Mean
Right Ankle	1.8	
Left Ankle	1.7	

**TCPO<sub>2</sub> RESULTS**

tcpO <sub>2</sub> Right		tcpO <sub>2</sub> Left	
BL	Mean	BL	Mean
tcpO <sub>2</sub>	1	tcpO <sub>2</sub>	45

# PeriFlux 6000 - Peripheral pressure and tcpO<sub>2</sub>

Why evaluate both macrocirculation and microcirculation?

Diabetic foot ulcers

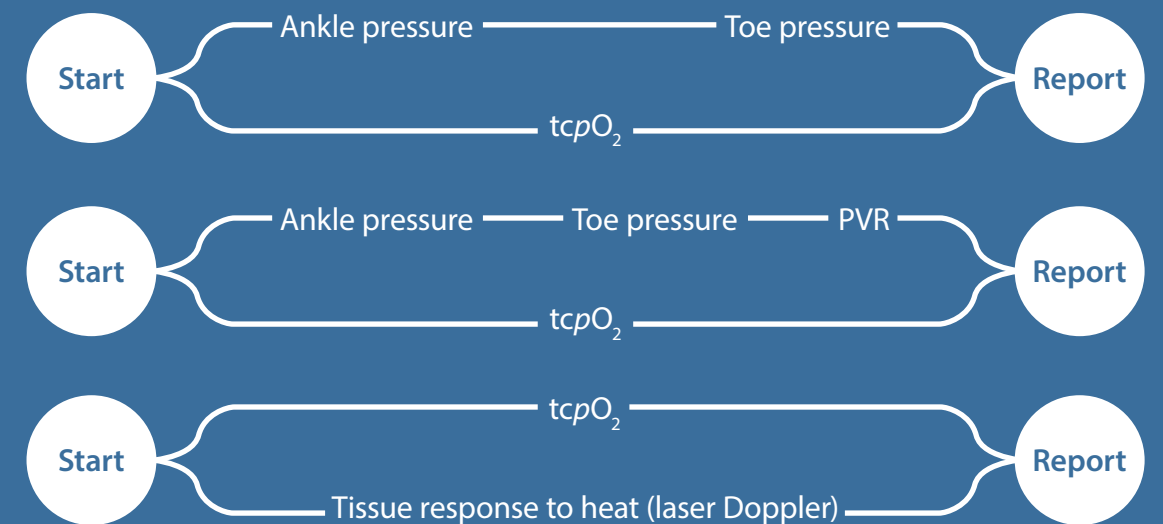
Peripheral Arterial Disease (PAD) is often more aggressive in diabetics, with a higher risk of major amputations. Both macrovascular disease and microvascular dysfunction impair the perfusion in the diabetic foot. Once diagnosis of PAD has been established, an estimate of the wound healing potential will help to identify the correct management strategy for each patient. ABI values or ankle pressure values provide limited information about the wound healing potential. It can therefore be useful to perform additional microvascular evaluations. One well established method is transcutaneous oximetry (tcpO<sub>2</sub>). It measures the tissue oxygenation at the wound site, showing the ability to deliver oxygen and nutrients to the area, reflecting wound healing potential. Other methods include tissue response to local heating and Skin Perfusion Pressures (SPP). The PeriFlux 6000 offers the option to perform any of these methods. To save time, the PeriFlux 6000 offers parallel testing of tcpO<sub>2</sub> and peripheral pressures (toe and ankle pressures).



Critical Limb Ischemia

Critical Limb Ischemia (CLI) is a severe form of PAD with arterial lesions impairing the blood flow to such an extent that that nutrient flow to the tissue is critically disturbed. As patients with CLI have a poor prognosis, it is important to choose the correct treatment option at an early stage. Amputations are often required and the optimal level needs to be defined. For these cases, tcpO<sub>2</sub> has proven to be a better option for amputation level determination than peripheral pressures. The PeriFlux 6000 offers the unique possibility to combine both ABIs and toe pressures with tcpO<sub>2</sub>. This provides an excellent overview of the entire limb circulation, aiding clinical decision making.

Combining vascular tests using the PeriFlux 6000





# A unique combination of simultaneous vascular tests to speed up your diagnosis

## 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)

### PF 6040 tcpO<sub>2</sub>/tcpCO<sub>2</sub> Unit

One electrode per unit  
 Measured parameters: tcpO<sub>2</sub>, tcpCO<sub>2</sub>  
 Measurement ranges: tcpO<sub>2</sub> = 0 to 1999 mmHg (0–267 kPa), tcpCO<sub>2</sub> = 5 to 200 mmHg (0.67–26.7 kPa)  
 Accuracy: tcpO<sub>2</sub> < ±5 mmHg from 0 to 20.9 % O<sub>2</sub> and < ±10 % of reading from 21% to full scale  
 tcpCO<sub>2</sub> ±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<sub>2</sub> sensor  
 E5280: Combined pO<sub>2</sub> / pCO<sub>2</sub> 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<sub>2</sub> / tcpCO<sub>2</sub>, TC 555 Fixation Rings Extra Strength Adhesive for tcpO<sub>2</sub> / tcpCO<sub>2</sub>  
 Contact liquid (20 ml): TC 560 Contact Liquid  
 Membraning kit: D826 Membraning Kit tcpO<sub>2</sub>, D280 Membraning Kit tcpCO<sub>2</sub>  
 Calibration unit for CO<sub>2</sub>: TC 600 Calibration Unit  
 Calibration gas (CO<sub>2</sub>): 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.

### 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	-	○	○	●	●

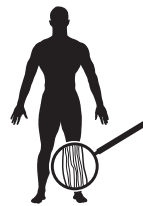
○ Available ● Included - Not applicable

### For more information please contact Perimed AB

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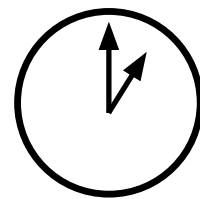


www.perimed-instruments.com



### Accurate vascular assessment

The PeriFlux 6000 offers the unique possibility to combine macrovascular and microvascular measurements in the limb. Using the same instrument and software, high-quality diagnosis of Peripheral Arterial Disease (PAD) and assessment of the wound healing potential is obtained.



### Time saving

The proprietary PSW ExM software streamlines the workflow and guides the user through the procedure. To save time, several vascular tests may be performed in parallel. As an example, toe and ankle pressures measured at the same time as a baseline tcpO<sub>2</sub> is being recorded.



### 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.

### 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.

### Available vascular tests

Available vascular tests include ankle pressure/ABI, toe pressure/TBI, Pulse Volume Recording (PVR), segmental pressures, transcutaneous oximetry (tcpO<sub>2</sub>), Skin Perfusion Pressure (SPP) and tissue response to heat.

### Billing and reimbursement codes

Use CPT codes 93922 and 93923 for billing and reimbursement.

### References

1. International Consensus on the Diabetic Foot and Practical Guidelines on the Management and Prevention of the Diabetic Foot, International Working Group on the Diabetic Foot, 2012
2. European Society for Vascular Surgery, CLI Guideline Committee Guidelines for Critical Limb Ischaemia and Diabetic Foot, 2011
3. Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASCII). Eur J Vasc and Endovasc Surgery, Vol 33 suppl 1 2007
4. Wound Care Practice. Edited by P.J. Sheffeld *et al.*, Best Publishing Company, 2004, p117-156
5. The correlation between three methods of skin perfusion pressure measurement: Radionuclide washout, laser Doppler flow, and photoplethysmography. Trivino *et al.* J Vasc Surg, 15:823-30, 1992