Guide on Effective PAD Screening

The modern approach for early detection of Peripheral Artery Disease

Advanced Vascular Diagnostics

Rev 11-2023

SOT Medical Systems

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Any feedback, correction notes or comments are appreciated and can be sent to office@sot-medical.com with the reference “SOT Effective PAD Screening”.

DISCLAIMER:

The information is provided for educational purposes only and is not intended to be a substitute for sound clinical judgment or decision making, or professional experience relative to diagnostic and treatment options of a specific patient's medical condition. Before deciding for a potential therapy, measurement results must always be verified by an additional measurement method.

Contents

1 Peripheral Artery Disease (PAD)

Atherosclerosis is a disease in which the wall of the artery develops abnormalities, called lesions. These lesions may lead to narrowing due to the buildup of plaque. The narrowing of arteries limits the flow of oxygen-rich blood to parts of the body.

Atherosclerosis generally starts when a person is young and worsens with age. Almost all people are affected to some degree by the age of 65.

> It is the **number one cause of death** and disability in the developed world.

A common manifestation of Atherosclerosis is **Peripheral Artery Disease (PAD)**, a condition that occurs when the arteries that carry blood to the limbs (such as the legs and arms) become narrowed or blocked because of plaque buildup.

This can restrict or block the flow of blood through the arteries, which can lead to a variety of symptoms and complications.

~13%	20-50%	50%
are affected	are asymptomatic	die within 4 years
PAD affects 12-14% of the world's population.*	Up to every other PAD patient does not experience symptoms and is likely not diagnosed.*	Only 50% of PAD amputees survive more than four years.*

**Sources: WHO, 2014; AHA, 2007;*

PAD is often caused by a combination of factors, including high blood pressure, high cholesterol, smoking, and diabetes. It is more common in people who are older, obese, or who have a family history of the condition.

PAD can be diagnosed through a physical examination and may be confirmed with tests such as Pulse Wave Index (**PWI™**), an Ankle-Brachial-Index (**ABI**) or an angiogram.

1.1 Symptoms of PAD

Symptoms of PAD may include leg pain or cramping that occurs when walking or climbing stairs (called *intermittent claudication*), a decrease in pulse in the legs or feet, coldness or numbness in the legs or feet, sores on the legs or feet that are slow to heal, and a change in the color or temperature of the skin on the legs or feet.

> **Intermittent Claudication**
>
> Is a symptom that describes muscle pain on mild exertion, classically in the calf muscle, which occurs during exercise, such as walking, and is relieved by a short period of rest. It is classically associated with early-stage peripheral artery disease and can progress to *critical limb ischemia*.

PAD develops gradually, can go unnoticed for a long time and often only cause symptoms in old age. It is divided into four stages depending on the severity:

- **Stage I**: There are no symptoms yet.
- **Stage II**: Muscle pain occurs in the affected leg because of reduced blood flow. It impairs walking and requires regular breaks, giving this stage the name “intermittent claudication”. The pain improves quickly after a few minutes of rest.
- **Stage III**: The pain also occurs at rest, especially at night when lying.
- **Stage IV**: Even the smallest injuries heal only poorly, wound infections can occur. Patient may get skin changes, necrosis, or leg ulcer. In the worst case, amputation may be necessary.

Stage IV PAD with leg ulcer

1.2 Treatment of PAD

Treatment for PAD may include lifestyle changes (such as quitting smoking, eating a healthy diet, and exercising), medications to control blood pressure and cholesterol, and procedures such as angioplasty or bypass surgery to improve blood flow to the affected limb. The main aim of PAD therapy is to reduce its risk factors. The physician may apply:

- **Movement therapy**: In the early stages, structured walking and training are essential to promote the formation of new blood vessels that can bypass a blocked section of blood vessels and supply the muscles with oxygen again.
- **Drugs**: Substances that promote circulation are used to improve walking performance.
- **Invasive intervention**: It is possible to widen a narrowed or blocked artery or to create a “diversion” around the constriction.
    - *Balloon dilatation* (percutaneous transluminal angioplasty, PTA): A catheter is pushed through the constriction and a balloon is inflated, which pushes back the atherosclerotic pads and widens the vessel. A stent can also be placed to prevent the artery from reoccluding.
    - *Bypass operation*: The constriction is bypassed by a detour as part of a vascular surgery procedure.

2 How to assess PAD

2.1 The traditional method: Ankle Brachial Index (ABI)

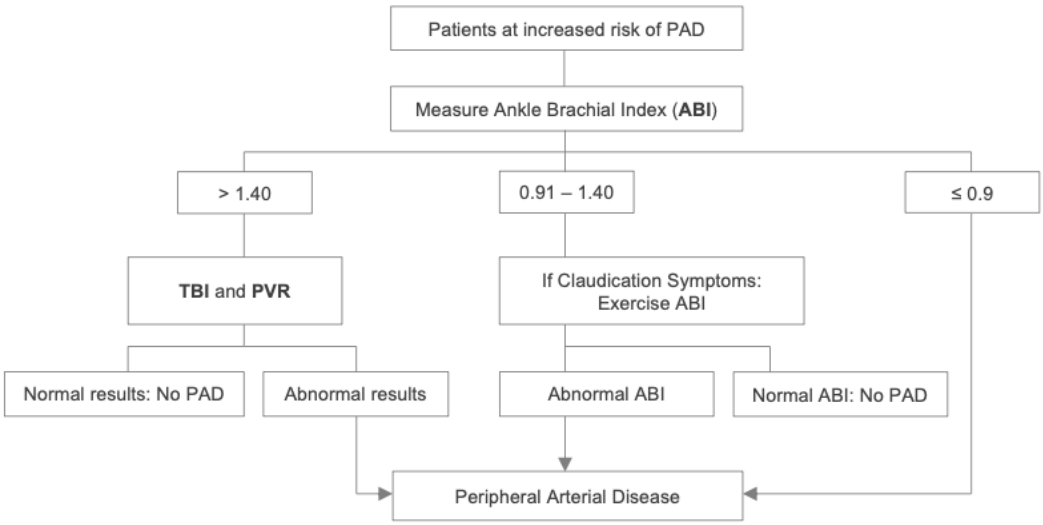
The ABI (Ankle-Brachial-Index) is an evaluation criterion of the perfusion in the extremities based on the pressures in the arteries.

According to most medical guidelines, a PAD can be assumed if an ABI ≤ 0.9 is determined on one leg. On the other hand, a resting ABI > 0.9 is not definitely a contraindication of PAD.

The 2016 AHA/ACC Guideline on the Management of Lower Extremity Peripheral Artery Disease (PAD) states:

1. *Patients at increased risk for PAD include patients aged ≥65 years, those with other risk factors for atherosclerosis (e.g., diabetes, any smoking history, hyperlipidemia, hypertension), a family history of PAD, or other known forms of atherosclerosis (e.g., coronary or carotid atherosclerosis, renal or mesenteric atherosclerosis, abdominal aortic aneurysms).*
2. *In patients with possible PAD, a resting ankle-brachial index (**ABI**), with or without segmental pressures and waveforms, is recommended to establish a diagnosis. ABI readings (the higher of each arterial pressure in each limb) are categorized as abnormal (ABI ≤0.90), borderline (ABI 0.91-0.99), normal (ABI 1.00-1.40), or noncompressible (ABI >1.40).*
3. *A toe-brachial index (**TBI**) should be measured to diagnose patients suspected of PAD when the resting ABI is >1.40. An exercise ABI should be performed in patients with exertional nonjoint-related leg symptoms and normal or borderline resting ABI (0.90-1.40).*

Essentially, a simplified depiction of the recommended and established assessment procedure may look as follows:



Several guidelines recommend an exercise ABI test to further clarify results. This is because an asymptomatic arterial lesion in the lower limbs may become visible only after induced stress.

2.1.1 Determining ABI (Ankle-Brachial-Index)

To determine the ABI, the systolic blood pressures are taken manually on each extremity individually by applying a pressure cuff to occlude the arterial blood flow and a vascular Doppler to measure the blood flow in a specific vessel. The pressure is then slowly released, e.g., using a handheld manometer. The pressure at which the blood flow resumes correlates with the systolic blood pressure in the specific vessel.

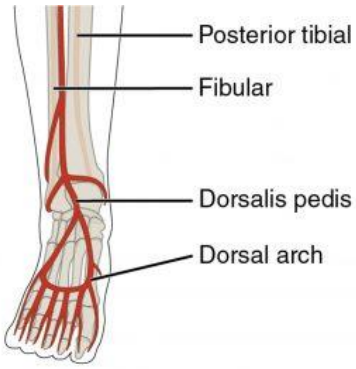
One vessel must be measured on the arm (*A. Brachialis*) and up to three vessels on the ankle (*A. Tibialis Posterior, A. Dorsalis Pedis and A. Fibularis*), on both sides of the patient.

A. Brachialis

A. Tibialis Posterior

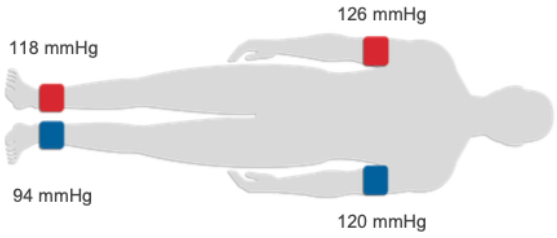
A. Dorsalis Pedis

A. Fibularis



Major leg vessels

The ABI is calculated for the right and for the left side by taking the respective systolic (or mean) arterial pressure at the ankle, divided by the higher brachial arterial systolic (or mean) pressure.



$$ABI = \frac{Systolic/Mean\ Ankle\ Pressure}{Higher\ Systolic/Mean\ Brachial\ Pressure}$$

$$ABI_R = \frac{118\ mmHg}{126\ mmHg} = 0.94$$

$$ABI_L = \frac{94\ mmHg}{126\ mmHg} = 0.75$$

Sample calculation of the Ankle-Brachial-Index

ABI readings are categorized as indicated in the table on the right.

A follow-up test, such as an exercise ABI or a toe pressure test, is usually conducted to further verify results.

ABI Value	***Interpretation***
≤ 0.9	Suspected Vascular Disorder (PAD)
0.91 – 0.99	Uncertain, repeat after Exercise / Stress Test
1.0 – 1.4	Normal
> 1.4	Noncompressible

2.1.2 Disadvantages of manual ABI

Manually determining ABI by applying a pressure cuff and a handheld Doppler is accompanied by significant disadvantages, especially compared to an automated oscillography reading:

User dependent	The test must be performed by well-trained personnel capable of localizing and assigning the correct vessels while determining the slightest indication for blood flow. The test is therefore **highly user dependent**. This matter influences the method's reproducibility, as it cannot be assured that the same nurse will repeat the measurement when the patient comes back for a follow up examination.
Lengthy process	Manually obtaining the pressure readings on all relevant vessels can take **up to 15 minutes** per patient. Additionally, the more severe the patient's PAD, the more challenging it is to get accurate pressure readings.
No side comparison	Because there is no simultaneous reading, **small side deviations** between the circulation of the patient's left and right side cannot be documented. Also, variations in Blood Pressure during the measurement may affect the results.
Only one value	The traditional way is obtained by performing a simple pressure measurement. **No information on the pulse wave form**, the amplitudes or pulse wave velocity is obtained, though these are important indicators for the patient's vascular health.
Not suitable for diabetics	The method is not suitable for patients suffering from **media sclerosis**, which is very common in diabetic patients. Because of the vessels' increased stiffness, vessels will not be compressible and hence, pressure readings will be irrationally high and lead to false negative findings.

2.2 The modern approach: Pulse Wave Index (PWI™)

The modern approach is the oscillometric method, in which pressures are recorded by applying four measurement cuffs simultaneously on upper arms and ankles using an automated system. This approach is operator independent, time efficient and allows a direct side-by-side comparison of the pulse waves (where a time difference can be an indicator for an arterial occlusion). Additionally, the pulse wave shape is recorded and can be further examined.

The **PWI™ (Pulse Wave Index)** is an indicator that relies on characteristics of the pulse wave shape (pulse amplitude and rise time) rather than on pressure values, and its calculation is independent of the blood pressure. Studies suggest that it is the indicator with the highest sensitivity to determine PAD (peripheral arterial disease):

"In our study, PWI performed better than oABI and dABI. This finding is new, but not surprising as PWI is highly influenced by the time-to-peak of the volume curve. This parameter is known since long to be very sensitive for post-stenotic flow curves and tends to be less affected by vessel wall characteristics like media sclerosis." [1]

oABI = oscillometric ABI; dABI = Doppler ABI

[1] Diagnostic accuracy of ankle-brachial index by Doppler-based versus four-point oscillometry based measurements; Mayr, Hirschl, Klein-Weigel, Girardi, Kundi; Vol. 48/6 – 2019, VASA – European Journal of Vascular Medicine

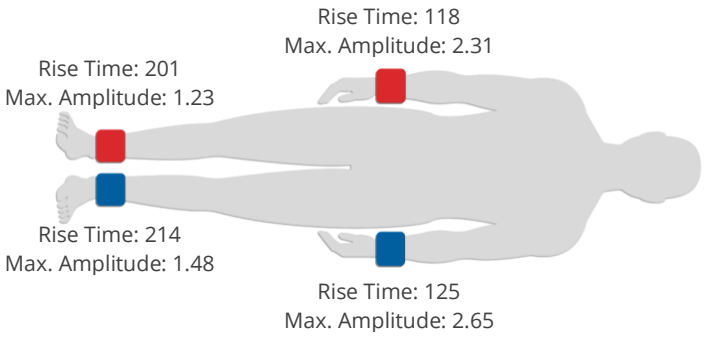
Due to the increased sensitivity of the PWI, it is possible to ascertain a pathological deviation when the body is in a state of rest already, although the ABI-value may still be normal for this patient. As it can be recorded during a regular oscillometric measurement, PWI is a time-efficient method to early detect PAD and, in addition, has a high patient acceptance. Also, the PWI acts as an indicator for a better evaluation of vascular therapies, especially before and after interventions.

During the same examination, an oscillometric ABI (**oABI**) measurement will also be conducted. This method utilizes pressure cuffs placed on the ankles and wrists (or upper arms) to record the perfusion of the vessels and register the oscillations of all underlying arterial and collateral structures in each extremity. The resulting collective pressure signals of the arteries (**mean arterial pressures**) are then utilized in the calculation of the oABI.

> This approach is considered to be more precise than traditional Doppler ABI (dABI) measurements, as it simultaneously assesses all large vessels and collaterals of the limb without a time delay in a side-by-side comparison.

2.2.1 Calculation of PWI™

PWI is calculated as the higher maximal pulse amplitude of the upper extremity (left or right wrist) divided by the maximal pulse amplitude measured at the respective lower leg (left or right ankle) and then multiplied by the respective ankle rise time of the pulse wave.



$$PWI_R = \frac{2.65\ mmHg}{1.23\ mmHg} * 201\ ms = 433$$

$$PWI_L = \frac{2.65\ mmHg}{1.48\ mmHg} * 214\ ms = 383$$

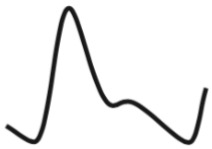
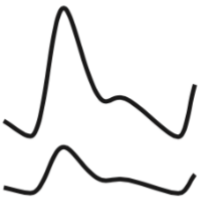
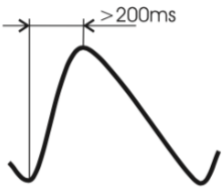
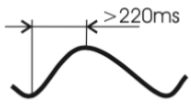
$$PWI = \frac{Higher\ Pulse\ Amplitude\ Wrist\ (mmHg)}{Pulse\ Amplitude\ Ankle\ l/r\ (mmHg)} * Rise\ Time\ Ankle\ l/r\ (ms)$$

The result of the calculation is a numerical index, which is interpreted as indicated in the table. The higher the PWI, the more likely the patient is affected by a circulatory disorder in the respective leg.

PWI Value	Interpretation
> 220	Pathologic
180 - 220	Uncertain
< 180	Normal

2.2.2 Classification of Pulse Wave Quality

The shape of the pulse wave (amplitudes and rise times) has a significant influence on the PWI and should be evaluated and compared carefully to detect pathologic patterns. The following table describes possible occurring waveforms.

Normal Pulse Wave		• Short Rise Time (<200ms) • Well observable dicrotic wave • Rise-to-fall ratio < 30%
Differences in Rise Time		• Side difference of Rise Time • Rise time difference > 40ms
Differences in Amplitude		• Difference in amplitude > 40% indicates pathologic change of the vessel system.
Slightly pathologic		• Elongated Rise Time (>200ms) • Missing dicrotic wave
Severe pathologic		• Elongated Rise Time (>220ms) • Missing dicrotic wave • Nearly equal-sided shape • Clearly reduced amplitude
Arterial Spasm		• Oscillation with small saw tooth shapes in the declining edge of the pulse wave.
Anarchic Pulse Wave		• Arbitrary oscillations • No recognizable regularity
No Pulse Wave		• No pulsation detectable (not even at the highest amplification)

3 Vascular Screening with the TOPP-Method

TOPP is a standardized 3-minute test method that provides information of pedal (i.e., foot area) macrocirculation and microcirculation, which cannot be achieved by ABI analysis alone.

TOPP-ABI includes simultaneous automated oscillometric ABI (oABI) and PWI determination together with the systolic tissue optical perfusion pressure (TOPP) at the far end of microperfusion at the toe in a single 3-minute test.

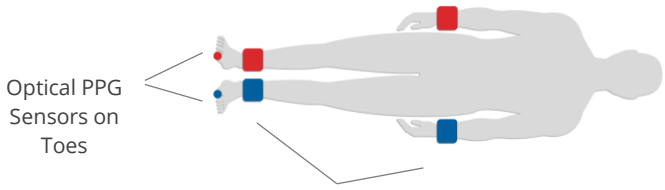
"Critical limb ischemia with consecutive foot ulcers and minor amputations are below the measuring thresholds of ABI. Since peripheral interventions enter the region of the pedal arteries, additional criteria determining the improvement of macrocirculatory and microcirculatory hemodynamics are of utmost interest."[2]

> In other words, this standardized 3-minute method combines ABI with toe and forefoot circulation to detect even the slightest indications of circulatory disorders. An approach that is especially important for **diabetic** patients, as they tend to develop the vascular disease in toes and forefeet first. Further, their often calcified vessels make regular pressure readings inaccurate.

With TOPP plus oscillometric ABI (TOPP-ABI) used as a single-test screening method, patients with unknown or unconfirmed PAD are sooner diagnosed and treated earlier to slow down disease progression.

3.1 Measurement Principle

After applying the cuffs on ankles and wrists, as well as the optical sensors on the toes, the system applies a pressure of 180mmHg to all cuffs, that is decreased by steps of 10mmHg.



By recording the optical sensors, the examiner can immediately determine the pressure step at which the patient's toes show the first pulsations. Different key indicators, like the oscillometric ABI, the PWI, the amplitude or the rise time of the pulse wave, are recorded simultaneously.

In addition, important indicators for foot blood circulation, such as the toe waveforms, are collected within the same measurement.

[2] Tissue optical perfusion pressure: a simplified, more reliable, and faster assessment of pedal microcirculation in peripheral artery disease; Horstick, Messner, Grundmann, Yalcin, Weisser, Espinola-Klein; Vol. 319: H1208–H1220, 2020, AJP Heart – American Physiological Society

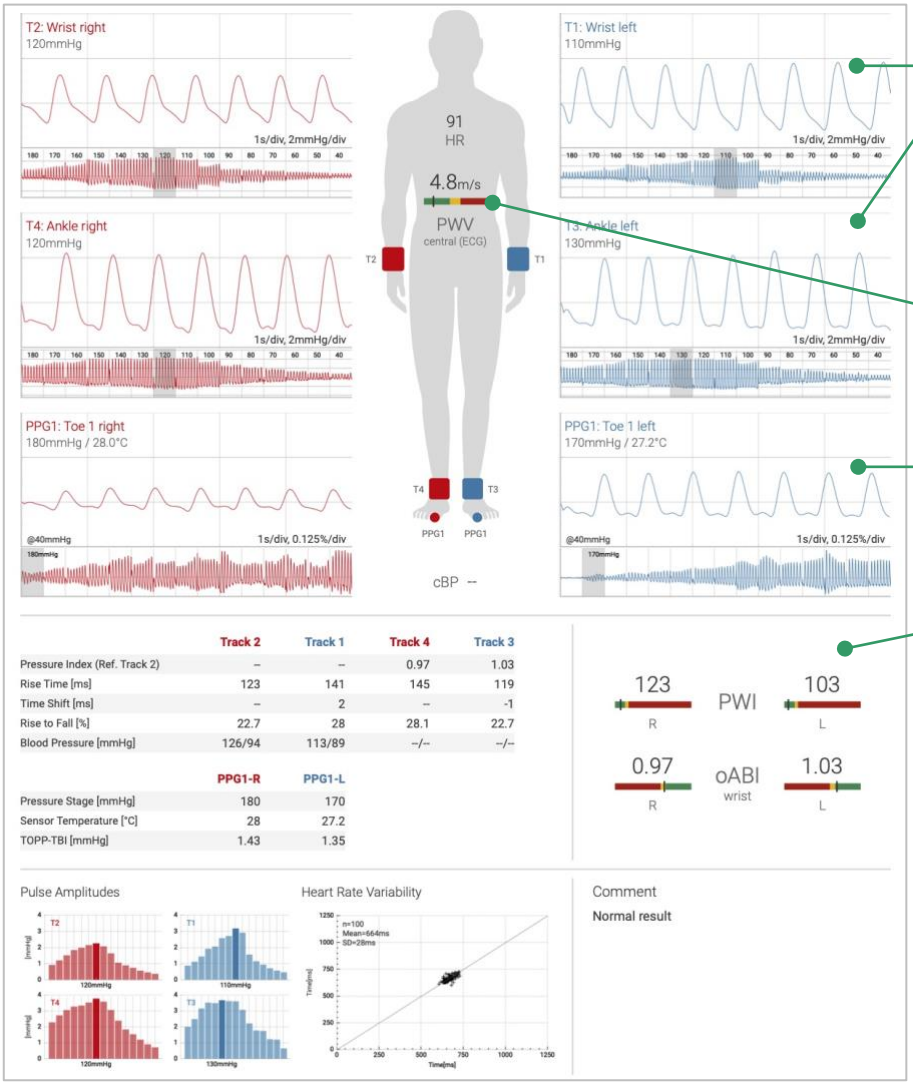
3.2 Obtained Parameters

A vascular screening with the TOPP-method will produce the following parameters within one single standardized test in just under three minutes:

Parameter	Name / Unit	Description
PWI™	Pulse Wave Index	Maximal amplitude of the upper extremity (wrists) divided by the maximal pulse amplitude measured at the respective lower leg (ankles) and then multiplied by the respective ankle rise time of the pulse wave. Values above 220 are considered abnormal.
oABI	Oscillometric Ankle-Wrist-ABI	Mean arterial pressure of the ankle related to the mean arterial pressure of the wrist; values ≤ 0.9 indicate a vascular disorder.
HRV	Heart-Rate-Variability	Heart rate variability (HRV) is the physiological phenomenon of variation in the time interval between heartbeats. It is measured by the variation in the beat-to-beat interval or by including the ECG trigger. The ideal HRV varies over age and is individual to each patient.
PWV	Pulse-Wave-Velocity [m/s]	PWV is the velocity at which the blood pressure pulse propagates through the circulatory system and should generally be ≤10 m/s. It is used clinically as a measure of *arterial stiffness*.
Time Shift	ms	The time shift, measured between the start point of both pulse waves, shows the propagation time difference between the left and the right extremity. Values above 50 milliseconds are considered abnormal.
Amplitude	mmHg	The height from the beginning of the steepest rise to the highest point of the pulse curve is the amplitude.
Rise Time	ms	The rise time marks the time interval of the steepest rise to the highest point of the pulse curve. It should be < 200 milliseconds for healthy subjects.
Rise to Fall	%	The quotient, stated in percentage, of rise time and fall time. It should be < 33% for normal values.
Oscillometric Index	mmHg	The oscillometric index marks the pressure stage where the highest amplitude was measured and is comparable to the *mean arterial pressure*. Values higher than 120 mmHg are considered abnormal.
Skin TEMP	Skin Temperature [°C]	Skin temperature on toes recorded by the probes on the optical sensors. Side differences of more the 3 °C should be observed.

3.3 Interpretation Example

Normal TOPP-Test



Wrist and Ankle Pressure Tracks

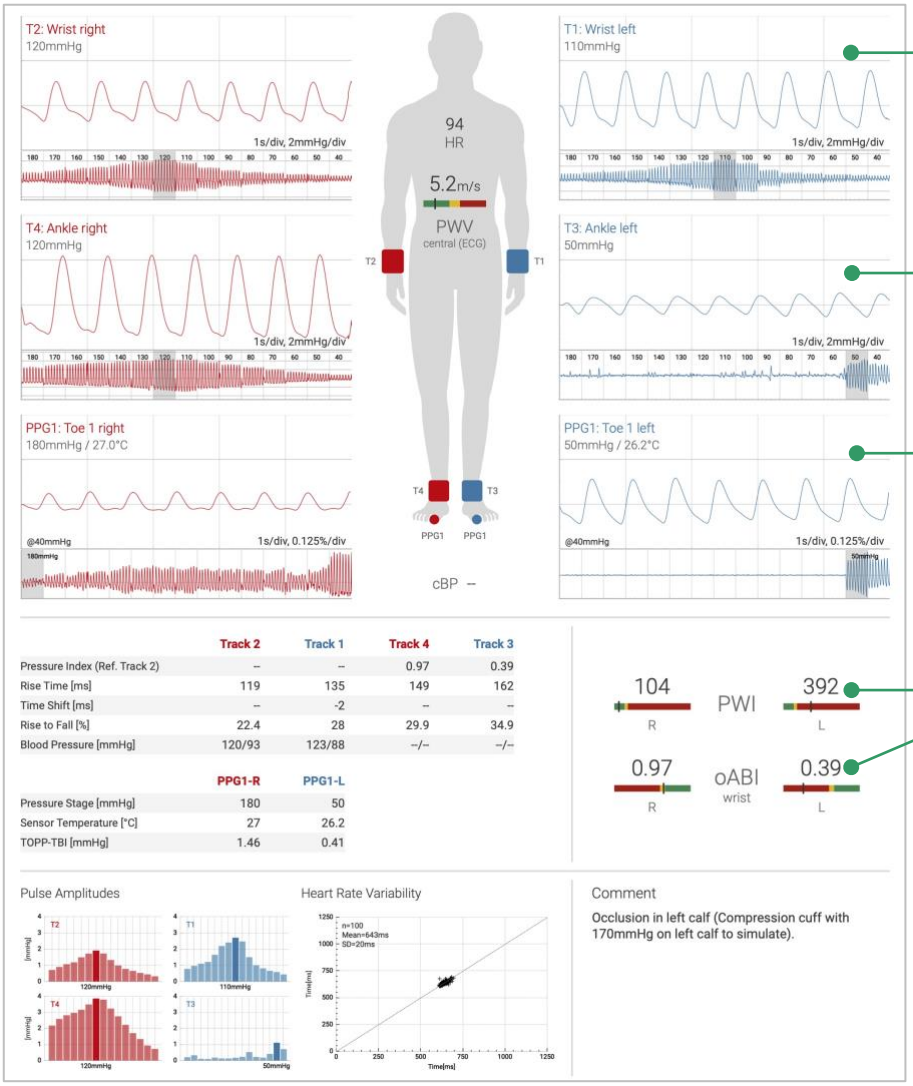
Central Pulse Wave Velocity (PWV) and Heart Rate (HR)

Optical Pulse Oscillography on Toes (APPG)

Result Table with PWI, oABI, Amplitudes and Rise Times

Interpretation Criteria					
Side Difference	There are no significant side differences regarding amplitudes, mean arterial pressures or time values of the pulse waves.				
Pulse Wave	The pressures reach the toes from the beginning. The pulse waves ascend steeply, the dicrotic wave is visible and the height of the amplitude is normal. The **PWI** describes a healthy vascular state.				
APPG Difference	However, the first amplitudes at the toes appear at a very high-pressure step (very far left), which indicates that circulation is good in both sides. As for temperature, there is only a small difference between left and right toe (< 3 °C).				
PWI™	< 180	Time Shift and Rise Time	Both within reference range.	Pulse Wave Velocity	≤ 10 m/s
oABI	> 0.9				

Pathologic TOPP-Test



Wrist pressure tracks show normal amplitudes.

Left ankle has reduced amplitudes starting at 50 mmHg only.

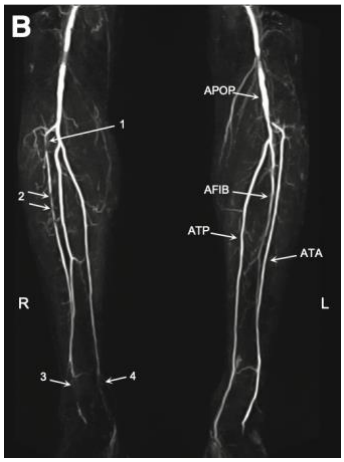
Optical Pulse Oscillography on toes shows significant side differences.

Both PWI and oABI are indicated pathologic for left side.

Interpretation Criteria

Side Difference	Significant visible differences of the amplitude height between left and right ankle were measured.				
Pulse Wave	The averaged pulse wave on the left lower extremity has a slow and flat increase and hardly a dicrotic wave. Also, the heights of the amplitudes in the lower left limb are low. The **PWI** value describes the pathologic state of the left side.				
APPG Difference	The first oscillations in the toes are at a much higher pressure in the right toe than in the left toe. That means, the probability of a severe blood flow disorder is high in the left leg. The pressure in the left leg is very low. No significant difference in temperatures.				
PWI™	> 220 (left)	Time Shift and Rise Time	The Rise Time on the left side is clearly higher, an indicator for an arterial problem.	Pulse Wave Velocity	Value within range but might be falsified due to potential occlusion.
oABI	< 0.9 (left)				

3.4 Case Study with Angiography[3]



Example of a patient with peripheral artery disease (PAD) and severely hindered pedal perfusion at the level of the right ankle before and after intervention (chronic total occlusion of the arteria tibialis anterior).

B: MRI lower legs before intervention:

1: Chronic total occlusion (CTO) of the ATA with collateral arteries

2: Stenosis

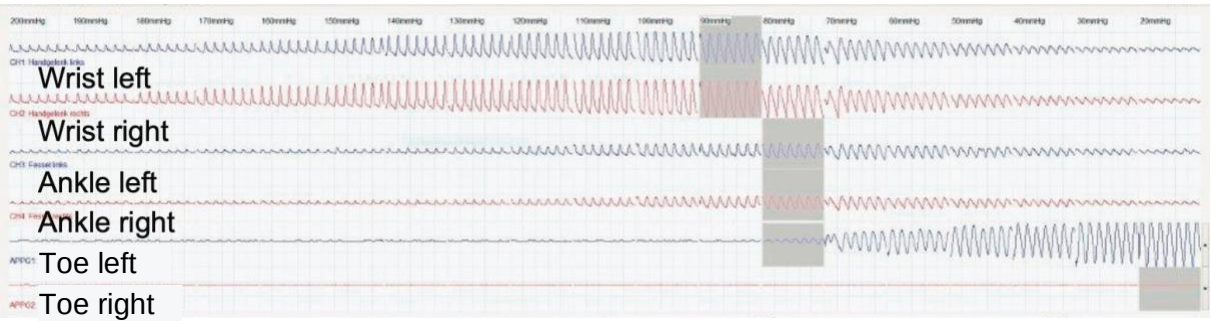
3: ATA - Chronic total occlusion (CTO)

4: ATP - Chronic total occlusion (CTO)

ATA, arteria tibialis anterior; AFIB, arteria fibularis; ATP, arteria tibialis posterior.

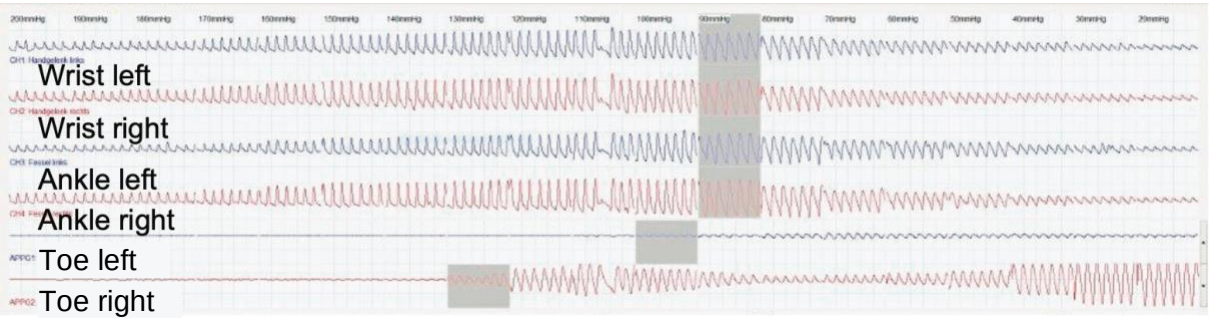
Before intervention

TOPP-test and angiography of distal lower leg and ankle before recanalization.
Ankles: no difference. Toe left: reduced pressure. Toe right: no detectable circulation.



After intervention

TOPP-test and angiography of distal lower leg and ankle 1 day after recanalization.
Toe right: significantly improved circulation.



[3] Cf.: Tissue optical perfusion pressure: a simplified, more reliable, and faster assessment of pedal microcirculation in peripheral artery disease; Horstick et.al., 2020, AJP Heart – American Physiological Society

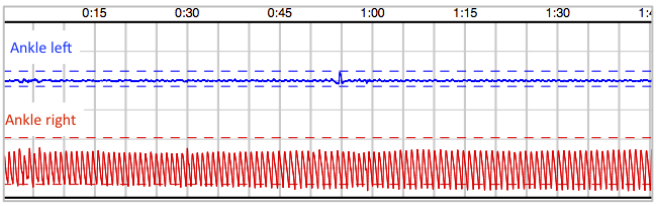
4 Bonus: Exercise Stress Test

Several guidelines recommend an “exercise stress test” or “Exercise ABI” to clarify results. This is because an asymptomatic arterial disorder in the lower limbs may become symptomatic after induced stress.

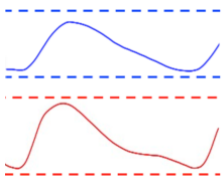
Before performing the exercise, a regular Vascular Screening test with TOPP should be conducted on the patient to acquire reference values. After completion, the patient is asked to perform specific movements, such as toe tip stands (calf indication), knee bends (thigh and hip indication) or treadmill (for additional determination of the walking distance).

> The exercise must be performed under medical guidance and should provoke the physical complaint.

After the exercise, the patient takes a lying position with the measurement cuffs applied on the ankles. On the measurement screen, a dotted line marks the amplitudes before exercise, which the patient should recover to. Once the initial pulse wave amplitudes are reached, the test can be completed, and the recovery time is documented.



Pulse wave recording during recovery



Stabilization of the amplitude

The recovery time can be interpreted as follows:

Amplitudes within 20 to 30 seconds	No indication for PAD
No initial amplitudes but recovery within 1 minute	Good compensation of a potential occlusion
No initial amplitudes and no recovery within 2 to 3 minutes	Bad but sufficient compensation of a possible occlusion
Recovery time of more than 5 minutes	Insufficient compensation of a possible occlusion

For patients with limited mobility, a *passive stress test* can be conducted by performing a suprasystolic compression on thighs in lying position for three minutes. Afterwards, recovery time can be determined.

References

Tissue optical perfusion pressure: a simplified, more reliable, and faster assessment of pedal microcirculation in peripheral artery disease; Horstick, Messner, Grundmann, Yalcin, Weisser, Espinola-Klein; Vol. 319: H1208–H1220, 2020, AJP Heart – American Physiological Society

Diagnostic accuracy of ankle-brachial index by Doppler-based versus four-point oscillometry based measurements; Mayr, Hirschl, Klein-Weigel, Girardi, Kundi; Vol. 48/6 – 2019, VASA – European Journal of Vascular Medicine

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Guide on Arterial and Venous Diagnostics

Get the full guide.

Download our guide to arterial and venous measurement applications and their interpretation, together with parameters, reference values, normal and pathological test examples here.

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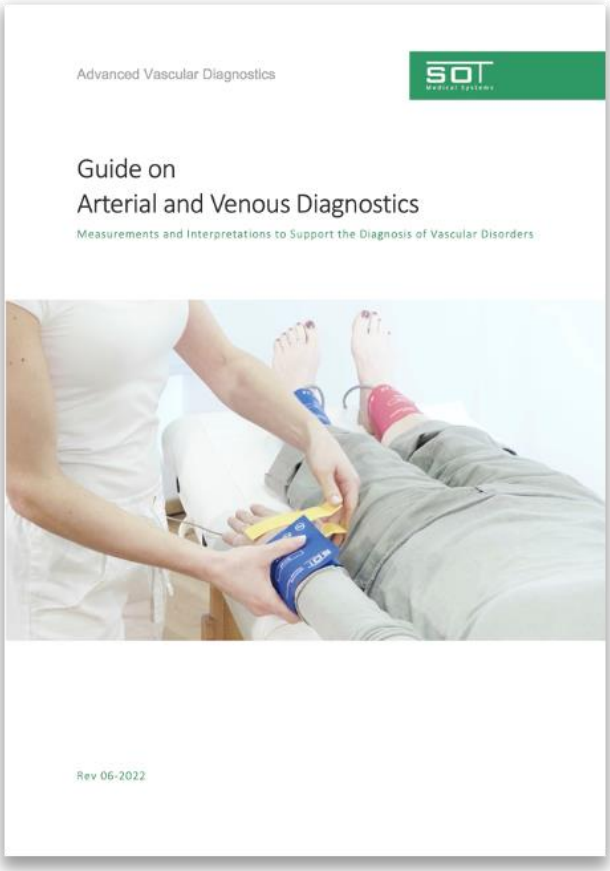
www.sot-medical.com/guide-on-vascular-diagnostics



The guide contains information on measurement principles, parameters (with reference values) and normal vs. pathological test examples on the following topics:

Arterial tests

- PVR – Pulse Wave Recording (4 and 8 channels)
- TOPP Method (Tissue Optical Perfusion Pressure)
- OPO – Optical Pulse Oscillography
- OAP – Optical Arterial Pressure
- Exercise Test
- TOS Test (Thoracic Outlet Syndrome)

Parameters and indicators

- ABI – Ankle Brachial Index
- TBI – Toe Brachial Index
- PWI™ – Pulse Wave Index
- Finger/toe pressure and more

Venous tests

- D-PPG Muscle Pump Test (Venous Reflux)
- VOP – Venous Occlusion Plethysmography

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