Easy and automatic vascular analysis for diagnosing PAOD and arterial stiffness.

**Pulse Wave Velocities (PWV)**

Automatic measurement and determination of central and central-peripheral pulse wave velocities using blood pressure cuffs
- \( PWV_{ao} \) (aortic) using the reflection method under brachial stop-flow conditions
- \( PWV_{cf} \) (carotid-femoral) calculated from the \( PWV_{ao} \)
- \( PWV_{ba} \) (brachial-ankle) by means of simultaneous cuff measurements on upper arm and ankle

**Augmentation Index (Alx)**

- Determination of the brachial Alx and approximation of the aortic Alx at suprasystolic pressure according to the stop-flow method (brachial)

**Aortic Blood Pressure**

- Determination of the central blood pressure from the brachial values by applying a transfer function

**Ankle–Brachial Index (ABI)**

- Measurement of peak vascular occlusion pressures on all four extremities using a new measuring method (cuffs equipped with photoplethysmographic sensors)
- Precise measurement of ABI – Clinically validated
- Strongly correlated with the gold standard of Doppler method, especially in PAOD patients
PULSE WAVE VELOCITIES (PWV) AND AUGMENTATION INDEX (AIX)

As measurement of arterial stiffness one can determine the brachial and the aortic (converted using a transfer function) augmentation index (AIx) as well as different pulse wave velocities (PWV) and the central blood pressure.

The PWV\textsubscript{ba} (brachial-ankle) is determined by simultaneous cuff measurements on upper arm and ankle on a diastolic pressure level (the time difference of both pressure waves in a base point to base point - measurement); the PWV\textsubscript{ao} (aortic) is determined by using the reflection method under stop-flow conditions (time offset between direct and reflected pulse waves in a base point to base point – measurement) as well as the PWV\textsubscript{cf} (carotid-femoral) by calculations from PWV\textsubscript{ao}.

Fig. 1: AIx|PWV-diagnosis and display of central blood pressure

At the same time the AIx is measured through the use of the brachial cuff in combination with a highly sensitive vibration sensor. Oscillations generated by the pulse wave at diastolic and supra systolic pressure levels are recorded in this process. The first peak (P1) is a result from the ejection of blood from the heart. This wave is reflected, primarily at the aortic bifurcation, in branches and constrictions, which is indicated by the second peak (P2). The figures show that the curve changes with advancing age. This change is a result of increased arterial stiffness. The stiffer the arteries the faster the pulse wave is propagated in the vessel, which causes the reflected wave to occur earlier in P1. Therefore reduced arterial elasticity can be assumed when positive augmentations occur in adults.

Fig. 2: Pressure curves at different stages of life: Top graphic: Normal pressure curve in adults; Bottom graphic: Pressure curve in a later stage of life

The augmentation index represents the ratio of augmentation to pulse pressure. Augmentation as a function of pulse wave reflection is largely dependent on the pulse wave velocity, which in turn is dependent on arterial elasticity.

Age Graphs

Additionally to the analysis of the existing parameters central pulse wave velocity, brachial – ankle pulse wave velocity and central augmentation index as bar graph with standard ranges, the patients’ results are shown in an age graph.

Fig. 3: Age graphs of aortal pulse wave velocity, augmentation index as well as brachial-ankle pulse wave velocity.

By means of these age graphs a fast and clear assessment of the patients’ vessel results is possible, meaning if this patient has pertinent arteries for his age.

Therefore the biological age of the vessels can be illustrated with reference to the real age!
The age-dependent standard values were extracted from the following references and converted to internal graphs:


Determining seated PWV und AIx

The study results show:

- Only a slight variability between supine and seated measurements!
- Measurements can also be taken whilst seated!

Fig. 4: Evaluation of Pulse Wave Velocity and Augmentation Index in supine and sitting position; J. Nürnberg et al; Artery 2009.

Aortic values such as blood pressure, pulse wave velocity and augmentation index can be measured using just one blood pressure cuff on the left or right upper arm.

**BRACHIAL AND AORTIC BLOOD PRESSURE**

During the examination of pulse wave velocity the blood pressure on the arm is automatically ascertained. These values are needed for the determination of the central blood pressure afterwards. The central blood pressure is calculated based on a transfer function.

**Graphical Evaluation of Blood Pressure Measurements**

According to the WHO-guidelines the blood pressure values from the arm cuff are displayed in a colored diagram.

With this colored classification the doctor can decide faster on a possibly necessary therapy or the therapeutic success. In a doctor-patient dialog the results are easily conveyed to the patient and descriptive as well.

**ANKLE-BRACHIAL-INDEX (ABI)**

Automatic and precise determination of ABI for diagnosing PAOD and peripheral arteriosclerosis based on vascular occlusion pressures.

Fig. 6: Photoplethysmographic ABI-determination

The system features a new and reliable measuring procedure for determining vascular occlusion pressures based on the simultaneous recording of a pressure curve and a distal plethysmogram. In terms of precision, this measuring method is equivalent to the gold standard (manual determination of the vascular occlusion pressure using Doppler method), but can be run significantly faster, automatic and objective.
In our own study of PAOD patients, the correlation coefficient for ABIs measured by this method and the gold standard of Doppler pressure or Doppler ABI was 0.93. Thus, we were able to reproduce results comparable to those of studies published by other groups. It was also confirmed that the correlation of ABIs based on normal, oscillometrically measured systolic blood pressures was significantly lower, especially for PAOD patients (the literature cites correlation coefficients of 0.4-0.6 for PAOD patients compared to Doppler ABI).

The ABI is the general practioner’s method of choice for diagnosing and screening off PAOD:

- The normal value is between 0.90 - 1.30.
- Mild PAOD is present at an ABI of 0.75 – 0.90.
- Moderate PAOD is present at an ABI of 0.50 - 0.75.
- Severe PAOD is present when the ABI is less than 0.50.

Diabetics represent an exception. Because media sclerosis reduces or prevents compressibility of the arteries, the measured ankle artery pressures are very high. Therefore, at an ABI higher than 1.3, the tentative diagnosis of media sclerosis can be rendered. Patients with chronic renal insufficiency also frequently have medial sclerosis.

RESEARCH AND CLINIC MODES

The software features two viewing modes. Users themselves decide which mode they want to work in. The research mode offers the user a detailed report on all the parameters and values measured and used for analysis. This mode is particularly suitable for clinical studies and research work.

The clinical mode is ideal for use in everyday clinical practice in hospitals and doctor’s practices because the display is limited to the patient’s most important parameters, displaying them in a clear and concise way.

This is very helpful for the doctor’s consultation with the patient.

Users can toggle between the two modes and therefore alternate the findings' illustrations.

OTHER FUNCTIONS

- Export of Data to an Excel-Document
  Automatic and/or manual export of patient and examination data into an excel-file. Data can be added to the document line by line at any time. (Optionally available)

- Easily Created PDFs from Defined and Freely Chosen Software Views
  In addition to a standardized connection to a Windows-printer, results, predefined and/or freely chosen Software views can be saved as a PDF-file with just one click.

- Connection to a Doctor’s Office EDP System
  With a GDT interface at the office our product can be integrated easily into the EDP system. This way patient data can be imported easily. The results are transferred to the office’s data base and therefore related to the patient.

- Connection to a Hospital Information System (HIS)
  With a HL7 interface our product can be integrated easily to the HIS. This way patient data can be imported easily. The results are transferred to the HIS and related to the patient. (Optionally available)
Case Report I

Female Patient with Stiff Arteries and Hypertension

The reflected pulse wave P2 is superimposed on the ejection wave P1. Therefore a pathologic augmentation index is the result.

The pathological results are shown in the red area of the bar graph. Also, the pulse wave velocity is elevated at 10.6 m/s. This is a symptom for stiff arteries.

Case Report II

Patient with Hypertension at an Early Stage

The blood pressure results of this patient are slightly elevated. This could be the result from the also elevated augmentation index. This relation is defining for the choice of hypertension therapy.

At a real age of 47 the estimated arterial age correlates to that of a man of 59 years. Therefore the patient shows an elevated potential of cardiovascular risk.
**Case Report III**

**Female Patient with PAOD**

![Fig. 14: Recorded plethysmogram](image)

The ABI on both sides shows a moderately severe PAOD. The occlusion pressure is at 105 mmHg in the right leg and at 110 mmHg in the left.

![Fig.:15: Detailed image of the occlusion pressure in the left leg](image)

The systolic and diastolic blood pressure as well as the occlusion pressure is depicted for each extremity. The ABI left and right can be read in the bar graph.

**Fig. 16: Findings of ABI**

**Technical Data**

- 2 blood pressure channels (NIBP):
  - Oscillometric measuring method, pressure range of 0-300 mmHg, typical accuracy of ± 5 mmHg
- 2 plethysmography channels:
  - Resolution: 24 bit; scanning frequency: 50 Hz
  - SPO2 45-100% (accuracy ± 1.5%)
- PC interface: USB 2.0
- Power supply: 6V / 4,16 A (med. power supply)
- Size: 200 x 150 x 69 mm (LxWxH)
- Weight: 650 g
- Classification: IIa 93/42/EEC

**Minimal Requirements**

- Microsoft® Windows XP
- Minimum screen resolution: 1024 x 768 pixels
- CPU: Intel i3
- RAM: 3 GB
- Graphic Intel HD
- One free USB-Port (2.0)
- Other interface for License dongle (USB-Port or SD-card)
- CD / DVD-drive for Installation by CD

**Standard Delivery Contents**

- VASCULAR EXPLORER
  - incl. Basic-Software „ABI+Alx“
- Patient data management (PATIENT EXPLORER)
- User manual (digital)
- 2 photoplethysmographic sensors
- 2 NIBP cuffs with extension
- Medically approved power supply
- USB cable (with ferrite core)
- Installation CD
- License dongle
- Tape measure roll

**Accessories (optional)**

- NIBP cuffs (different sizes and shapes)
- Photoplethysmographic sensors (specifically for attaching to fingers or toes)
- Equipment trolley (COACH EXPLORER light) with various accessories, e.g. insulating transformer Kabelarm etc.

**In Conformity with Standards and Regulations**

- DIN EN 60601-1, DIN EN 60601-1-2