

World's Fastest Ankle-Brachial Index Screening Device



Accurate and objective Peripheral Arterial Disease diagnosis

From secondary to primary healthcare with the help of technology.



MESI founders identified the need of primary healthcare for more simple and reliable diagnostic technology.

Cardiovascular diseases cause 35% of deaths globally. Efficient diagnostics is the only way to lower this number.

With early diagnosis of Peripheral Arterial Disease, the Automated Ankle-Brachial Index Measuring Device – MESI APBI MD, could help more than 200 million people.



Jakob Šušterič CEO, co-founder

MESI ABI MD is extremely time-saving, improves productivity, as well as increases the patient's and doctor's satisfaction.





Tomo Krivc CTO, co-founder

We collected over 1000 feedbacks from doctors and developed a complete diagnostic solution based on their needs: automated, simple to use, reliable and more affordable than ever.

NOVAK



Matjaž Špan CV surgeon, co-founder

In five years, our goals are to decrease the number of people, who are not aware of Peripheral Arterial Disease, by 50% and bring automated ABI technology to every physician to enable on-time screening of all patients in the risk group.

What is Peripheral Arterial Disease (PAD)?

PAD is a circulatory problem where narrowed arteries reduce blood flow to your limbs.

Healthy arteries.

Arteries are narrowed by build-up of plaque in the walls. The blood flow is partially restricted. The patient does not feel leg pain or other symptoms.

Arteries are clogged. The flow of oxygen rich blood is heavily restricted, leading to possible heart attack, stroke, gangrene, amputation and ulcerations.

When PAD develops, your extremities — usually your legs — don't receive enough blood flow to keep up with demand. This causes symptoms, most notably leg pain when walking (intermittent claudication).

Over 70% of patients do not know about the disease because they do not feel or recognise the symptoms until severe complications occur.

PAD is likely to be a sign of a more widespread accumulation of fatty deposits in your arteries (atherosclerosis). This condition may be reducing blood flow to your heart and brain, not only to your legs.

With early diagnosis, your physician will help you to determine the best treatment.

Early diagnosis of PAD in primary healthcare is crucial.

Who must be diagnosed for PAD or LEAD?

LEAD risk group

1. Patients with clinical suspicion for LEAD:

- → Unnoticeable pulse in lower extremities and/or arterial bruit
- → Typical intermittent claudication or symptoms suggestive for LEAD
- ightarrow Non-healing lower extremity wound

3. Asymptomatic individuals at risk for LEAD

2. Patients with clinical conditions which may cause a risk for LEAD:

- → Atherosclerotic diseases: CAD, any PADs
- ightarrow AAA, CKD, heart failure

Everybody in the risk group should be screened for PAD/LEAD.

<65

 \bigcup

Individuals younger than 65 years with cardiovascular risk factors

| (ju) | |
|------|--|
| • | |

DIABETES







SMOKING





50+

65

individuals older than 50 years with family history for LEAD

HYPERTENSION

Everyone older than 65 years

AAA – abdominal aorta aneurysm CAD – coronary artery disease CKD – Chronic kidney disease CV – cardiovascular LEAD – lower extremity arterial disease PADs – peripheral arterial diseases

PAD Disease prevalence

15-20% of people over 60 years old have PAD.

70% of patients with PAD experience no symptoms and are not diagnosed. Cardiology associations recommend Ankle-Brachial Index screening on the complete PAD risk group for early detection of the disease.

> Source: Inter-Society Consensus for the Management of Peripheral Arterial Disease (TASC II). * Source: 2017 ESC Guidelines on the Diagnosis and Treatment of the PAD.

ANKLE-BRACHIAL INDEX MEASUREMENT Simple solution for diagnosing PAD

Ankle-Brachial-Pressure Index (ABI) is a very simple comparison of blood pressure in the arm and legs. It is non-invasive and painless. With MESI ABI MD, the procedure becomes reliable, objective and even possible to be performed as a screening device in primary healthcare. ABI screening is incredibly important for at least two reasons:

- It is a reliable predictor of the occlusion of lower extremity arteries - PAD. Detection of PAD is even more important when we know, that over 70% of the population is not aware that they have occluded arteries.
- Because of the high correspondence of PAD with Coronary Artery Disease (CAD) and Cerebrovascular Disease (CVD), patients diagnosed with PAD have a greater chance of early diagnosis of CAD and CVD.

ABI screening reference scale

| 1.41 or more | 1.40 - 1.00 | 0.99 - 0.91 | 0.90 - 0.51 | 0.50 or less |
|------------------|-------------|-------------|-------------|--------------|
| non-compressible | normal | borderline | abnormal | severe |
| | | | | |



MESI ABI MD World's fastest ABI screening device

Compared to the handheld Doppler probe, MESI ABI MD performs an automated ABI measurement. Innovative technology enables the device to provide accurate and objective results, from which clinician's can determine the safety and suitability for compression.

Advanced error detection system

Smart software prevents false results even in the case of critical ischemia or medial calcinosis, and gives physicians all the confidence they need.

Unique algorithm for ankle blood pressure calculation

It is not possible to measure blood pressure in ankles with a brachial blood pressure device. Therefore, our algorithm is different, developed with human ankle anatomy in mind.

Cuff-based technology

Plethysmography sensors detect the smallest changes in volume. Ease-of-use excludes the possibility of human error. Minimal training is required; simply place three cuffs as described, press 'Start' and wait one minute for the results.

Simultaneous measurement

Because blood pressure is constantly changing, simultaneous measurement is crucial to avoid error from blood pressure drift.

| | DOPPLER PROBE | MESI ABI MD | MESI ABI MD USE ARGUMENTS |
|-------------------------|----------------------------|------------------|---|
| Measurement duration | 30 min | 1 min | Plethysmographic method |
| Pre-measurement resting | 10-20 min | 0 min | Eliminates blood pressure |
| Measuring process | One extremity at a time | Simultaneous | time-saving |
| Additional education | YES | NO | Medical staff are familiar with the cuffs |
| Calculations | Manually | Automatic | Instant left and right ABI and more accuracy |
| Measurement report | NO | Automatic via PC | For the patient record and insurance billing |
| Clothes removal | YES | NO | Increased patient |
| Gel application | YES | NO | comfort |

Accuracy is key

Unique error detection without false results

Thanks to a unique error detection system, MESI ABI MD will alert the operator to any irregularities which occur during the measurement process.

If the cuffs have been poorly placed or if the patient has moved during the measurement, the error message will be displayed on the screen.

A description of the problem / cuff in question can be found by pressing the 'return' key at this stage. A description of the problem / cuff in question can be found by pressing the 'return' key at this stage.



Reliable even in the case of critical ischemia and medial calcinosis

Our improved plethysmographic sensors detect critical ischemia and medial calcinosis even when pressure oscillations are not available due to heavy occlusion.

Every measurement with MESI ABI MD provides sufficient information for further actions.



While performing the measurement on a patient with severe PAD, it is possible that no pulse is detected. The obstruction of the artery is heavy, resulting in weak blood flow after the obstruction. The pressure is supressed and the difference between systolic and diastolic pressure vanishes.

PAD increases the risk of heart attack or stroke!

Elimination of blood pressure drift error



It is crucial to eliminate the delay between separate measurements on each extremity to achieve maximum ABI accuracy.

MESI ABI MD conducts simultaneous blood pressure measurements on one arm and both ankles.

Simultaneous cuff inflation. Red line for the cuff on the upper arm, green for the cuff on the right ankle and yellow for the cuff on the left ankle.

Cuffs are essential for ABI measurement



The conical shape of the cuffs provides perfect fitting to the patient's extremities, providing the best accuracy.

Different colours indicate where to place each cuff.

The red cuff should be positioned on the upper arm, the green on the right and the yellow on the left ankle.

Each cuff is clearly labelled and includes a diagram to ensure correct placement. No training is needed as comprehensive guidelines are provided.

Cuffs are available in medium and large sizes.

Low ABI indicates narrowed arteries and reliably predicts PAD.

2 in 1: ABI, BP measurements and Pulse Waveform Recording



Expertly developed MESI ABI MD enables:

- Simultaneous measurement of left ABI, right ABI, brachial pressure and heart rate.
- Stand-alone measurement of brachial blood pressure and heart rate.
- Recording of Pulse Waveform, providing big advantage in ABI interpretation.

Stand supplements MESI ABI MD

A wheeled stand is available with a magnetic base that is designed to hold both - the device and the cuffs.

Long lasting battery for maximum portability

During the measurement, the patient needs to be lying down.

The MESI ABI MD is equipped with a long-lasting rechargeable battery. 30-50 readings can be taken on one full charge thereby aiding mobile use.



Save ABI measurement with MESIresults

MESIresults application comes free with the device. MESI ABI MD can be connected to a computer to provide an electronic copy or a printout of the ABI result.

MESIresults also enables information such as the name, address and logo of the healthcare institution to be imported into every measurement report.

| utf | Fill in the data for display in the handout | _ |
|----------|---|---|
| | New Concern | |
| | | |
| <u>M</u> | | |
| (i) | | |
| 100 | | |
| | | |
| | | |
| | | |
| | 2 | |

ABI should be measured in primary healthcare as a standard method of diagnosing and monitoring PAD.

Simple ABI measurement procedure



Step 1: Place the arm cuff.



Step 3: Press the Start button to run the measurement.



Step 2: Place the ankle cuffs.



Step 4: See the result.

Added value of MESI ABI MD







1 minute measurements



error

Healthcare staff friendly



Report printout



MESI, development of medical devices, Ltd.

T: +386 1 620 34 87 E: info@mesimedical.com www.mesimedical.com



MESI Ltd. reserves the rights to make any changes in specifications and/or to discontinue any product at any time without notice or obligation and will not be liable for any consequences from the use of this publication.

October 2017

European production and development

CE 1304, ISO 9001 and ISO 13485 certified