MESI

Simplifying Diagnostics

3 YEAR WARRANTY

## MESI ABPI MD

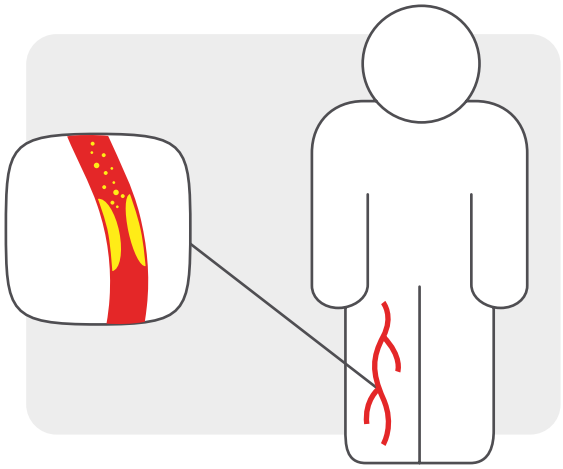
# World's fastest Ankle-Brachial Index

# What is Peripheral Arterial Disease (PAD)?

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

The **global prevalence of PAD was 5.6%** in 2015, indicating that ≒**236 million adults were living with PAD worldwide**.[1]

**The principal cause of PAD is atherosclerosis** (>90% of cases).[2] [3] Since arteries in the legs are most commonly affected, the disease is also known as **LEAD** (Lower Extremity Artery Disease).



## Risk factors

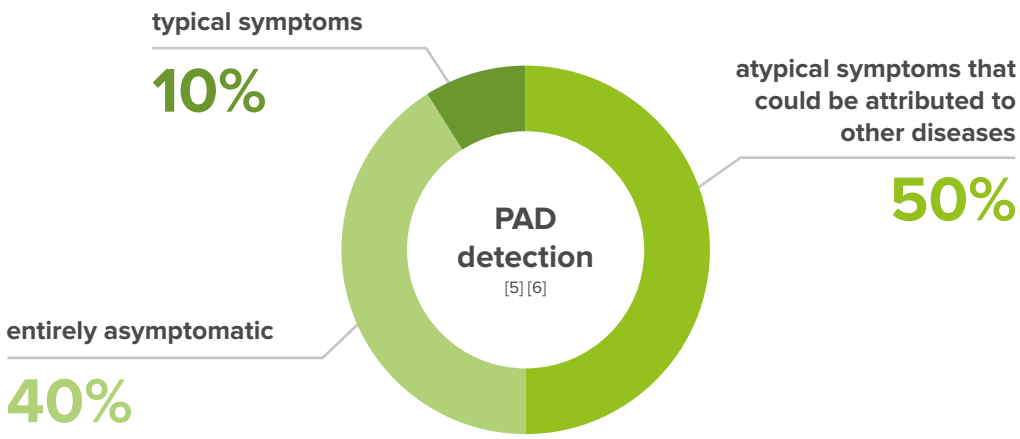
### MANAGEABLE

- Smoking
- Diabetes mellitus
- Hypertension
- Hypercholesterolemia

### NON-MANAGEABLE

- Age
- Genetic factors
- Gender
- Environment

**Under-diagnosis of PAD** in primary care may be a significant issue as **most patients with PAD do not experience typical symptoms**. The symptoms mainly appear during activities that increase energy demand.[4]



Because of the high co-occurrence of PAD with Coronary Artery Disease (CAD) and Cerebrovascular Disease (CVD), **patients diagnosed with PAD have greater chance of early diagnosis of CAD and CVD**.

**If not discovered and treated on time, PAD can lead to:**

Heart attack

Stroke

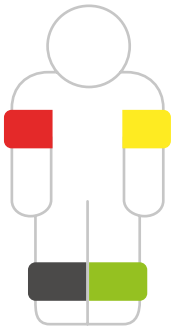
Ulcerations

Amputations

## How can PAD be detected?

**Ankle-Brachial Index (ABI)** is a reliable predictor of the occlusion of lower extremity arteries - PAD. Detection of PAD is even more important because **over 70% of the population is not aware that they have occluded arteries**.

ABI is a very simple **comparison of the blood pressures in the legs and the arms**. It is non-invasive and painless.



$$ABI = \frac{\text{SYSTOLIC BP}_{\text{ANKLE}}}{\text{SYSTOLIC BP}_{\text{ARM}}}$$

| 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** |
| Indication of PAD/ LEAD | Monitor risk factors/ symptoms | Monitor risk factors/ symptoms regularly | Indication of PAD/ LEAD | Indication of PAD/ LEAD |
| Perform advanced vascular testing or refer to a specialist | | | Perform advanced vascular testing or refer to a specialist | Perform advanced vascular testing or refer to a specialist |

Measurement of Ankle-Brachial (pressure) Index or ABI offers **great accuracy and specificity in diagnosing PAD.** It is one of the most important tools for this purpose, especially due to its **non-invasive nature and cost-effectiveness**.

# Areas of use

## First-contact care and cardiovascular disease assessment

Every patient at risk for Peripheral Arterial Disease regardless of the presence of symptoms. ESC guidelines recommend early ABI measurement for the three groups listed below.

### Patients with clinical suspicion for LEAD

- Unnoticeable pulse
- Claudication or symptoms suggestive of LEAD
- Non-healing wound

### Patients with clinical conditions increasing LEAD risk

- CAD
- Heart failure
- Abdominal Aortic Aneurysm
- CKD

### Asymptomatic individuals at risk for LEAD

- < 65 years with cardiovascular risk factors
  - Diabetes
  - Hypertension
  - Smoking
  - Dyslipidaemia
- < 50 years with family history of LEAD
- Everyone > 65 years

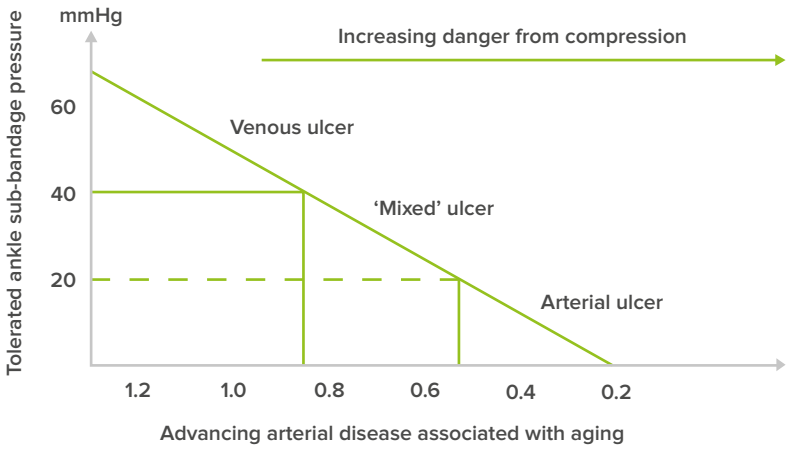
## Compression therapy and wound care

Ankle-Brachial Index is a crucial measurement in wound care management and compression therapy.

### ABI measurement should be performed to:

- Determine adequate arterial blood flow prior to compression therapy
- Rule out PAD/LEAD with a lower extremity wound
- Assess wound healing potential
- Evaluate therapeutic outcome
- Determine safe level of compression

**RELATIONSHIP BETWEEN ABI AND COMPRESSION APPLIED** [7]




## Chronic disease management: Diabetes, Chronic kidney disease

Cardiovascular risk factors affect the onset of PAD differently, but always significantly. PAD is present in as many as **50% of patients** with diabetic foot ulceration (DFU).

DFU combined with PAD makes the wound **less likely to heal and more likely to require amputation** compared to patients without PAD.

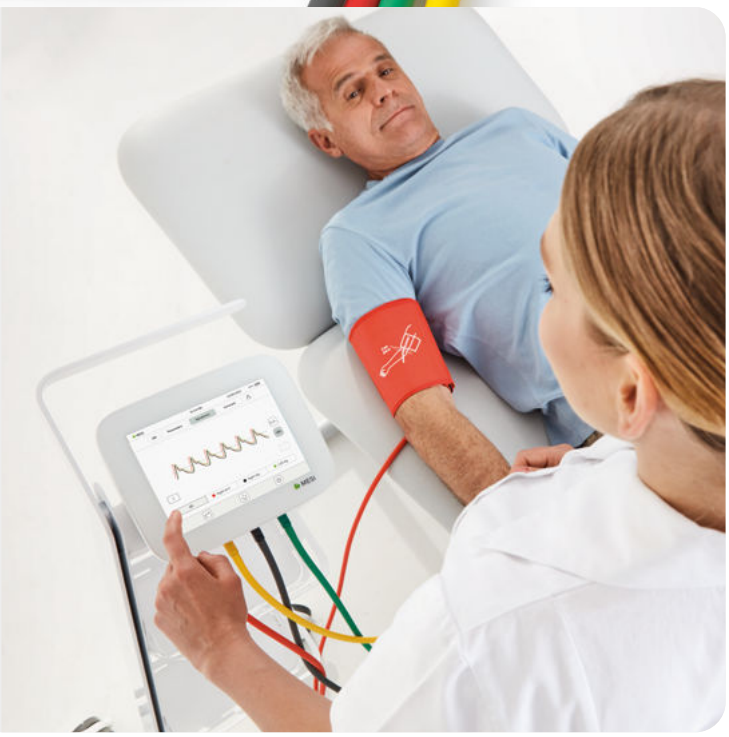
Patients with impaired renal function have **greater than two-fold risk of developing PAD**. PAD is usually not prognosed well and often coexists with other conditions like CAD and diabetes. In end-stage renal disease, **diabetes is the most common factor** for PAD risk and outcomes.

# MESI ABPI MD

The MESI ABPI MD device is an **automated Ankle-Brachial Index system.** With its **3CUFF™ technology**, it allows simultaneous measurement of brachial and ankle pressures. It also incorporates the **PADsense™ algorithm** for the detection of severe Peripheral Arterial Disease.


## Highlights of MESI ABPI MD:

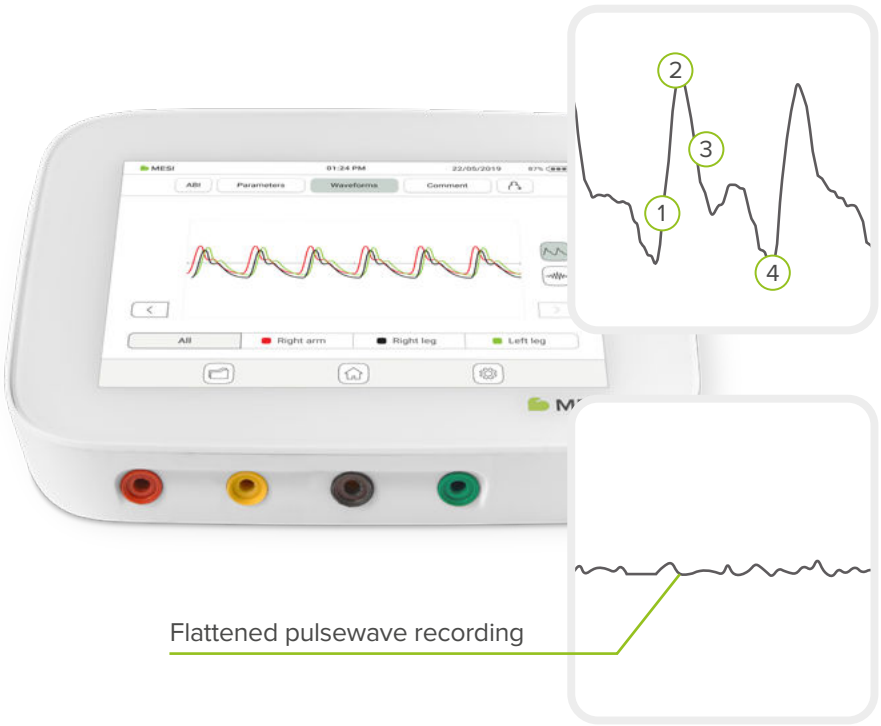
- Guided measurement procedure on the device screen
- SmartArm™ detection – to determine the higher blood pressure of the two
- Automated, 3-cuff simultaneous measurement
- Multiple cuff sizes and ability to mix-and-match different size cuffs during one measurement
- Discovers blocked arteries in 1 minute
- Pulse waveforms and oscilation graphs
- Advanced review and alerts thanks to PADsense™ algorithm



# Pulse waveforms and oscillation graphs

The MESI ABPI MD uses the PADsense™ pattern recognition algorithm to **automatically interpret the acquired pulse waveform** and calculate the ABI with the result.

Combining the ABI result and pulse waveform represents **the best practice in evaluating the presence and severity** of Peripheral Arterial Disease (PAD).




## NORMAL RESULT

1. A rapid rise in the upstroke during systole
2. A very sharp peak
3. A gradual downstroke
4. A presence of dichrotic notch

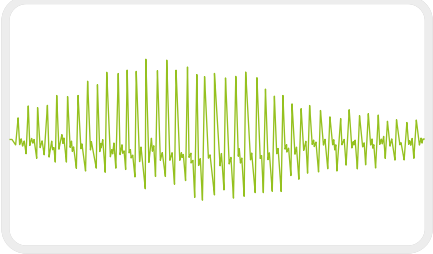
## ABNORMAL RESULT

A flattened pulsewave recording or one without the typical lemon shape is an indicator of severe PAD.

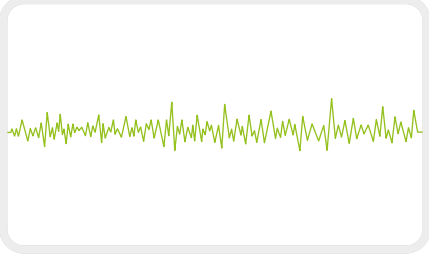
The absence of the pulsations caused by occlusions in the artery makes it impossible to calculate the ankle pressures. Instead of the ABI value, the device will display a “PAD” result.

The measurement of the Ankle-Brachial Index also provides **oscillation graphs, which provide the analysis of the entire deflation portion** of the measurement.

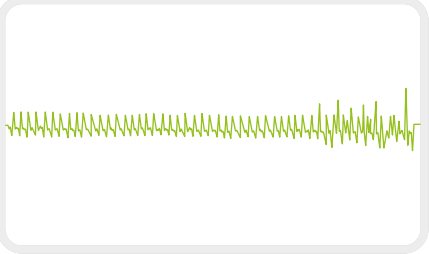
The oscillation graph in a healthy patient has its **easily recognizable lemon shape, which shows the arteries are elastic**. If the patient has PAD or incompressible arteries, the graph will reflect the condition.

**Normal oscillation graph**



**Severe PAD oscillation graph**



**Incompressible arteries oscillation graph**

# Technical specifications

| Measurements |
| --- |
| Ankle-Brachial Pressure Index using improved oscillometric method and plethysmography, with PADsense™ algorithm |
| Heart rate and systolic, diastolic, and mean blood pressure using an improved oscillometric method and plethysmography |

| Measurement extensions |
| --- |
| Blood pressure |
| Pulse wave velocity* |

*Available with MESIresults software

| Device dimensions |
| --- |
| Width: 223 mm / 8.78 in |
| Depth: 174 mm / 6.85 in |
| Height: 86 mm / 3.38 in |
| Weight: 1000 g / 2.2 lbs |

| Power & battery |
| --- |
| Battery type: Rechargeable lithium-polymer battery |
| Capacity: 4400 mAh |
| AC/DC adaptor: FRIWO FW8030M/05 or FOX NEO30-XM |
| Input: 100-240 V AC / 50-60 Hz / 600-300 mA |
| Output: 5V DC / 3.0 A |
| Examinations per battery charge: > 100 |
| Charge time for depleted battery: 2 hrs |

| Touchscreen display |
| --- |
| Diagonal size: 8” |
| Resolution: 800 x 600 pixels |
| Color depth: 16-bpp |

| Cuffs |
| --- |
| Medium size cuffs (circumference: 22-32 cm / 6.7-12.6 in) |
| Large size cuffs: (circumference: 32-42 cm / 12.6-16.5 in) |

| Measurement range & Accuracy |
| --- |
| ***Measurement range:*** |
| Pressure: 0 to 299 mmHg |
| Pulse rate: 30 to 199 beats per minute |
| ***Accuracy:*** |
| Pressure: ± 3 mmHg |
| Heart rate: ± 5% of value |
| Ankle-Brachial Pressure Index: ± 0.1 |

| Data backup and management |
| --- |
| MESIresults software |

| Protection Classification |
| --- |
| Protection against electric shock: Class II |
| Medical device classification: Class IIa |
| Applied parts (cuffs for arms and ankles): Type BF Applied part |
| Software classification: Class A |
| RF emissions (CIPSR 11): Group 1. Class A |
| Ingress protection: IP2X |

| Applied Standards |
| --- |
| EN 60601-1:2006+A1:2013 General requirements for basic safety and essential performance |
| EN 60601-1-2:2015+A1:2021 Electromagnetic disturbances - Requirements and tests |
| EN 80601-2-30:2019 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers |

| Operating Conditions |
| --- |
| Temperature, operating: 10° to 40°C (50° to 104°F) |
| Relative humidity: 30 to 80% (no condensation) |
| Pressure during operation: 700 to 1060 hPa |

| Transport & Storage Conditions |
| --- |
| Temperature: 0° to 40°C (32° to 104°F) |
| Relative humidity: 15 to 85% |
| Pressure during storage: 700 to 1060 hPa |

# Measure ABI with MESI ABPI MD in three simple steps

Place the colour-coded cuffs on the arms and ankles **1**

**2** Press the START button for the measurement to begin

Analyse the pulse waveforms and read the ABI results **3**

## References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ISO 13485 M-049

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