

## Frequently Asked Questions

### MESI ABPI MD

#### Clinical Use

#### **Can MESI ABPI MD be used in case of deep vein thrombosis (DVT)?**

MESI ABPI MD is intended only to screen for blocked arteries and not as a diagnostic tool. It is not recommended to use the device on patients with DVT.

#### **Can MESI ABPI MD detect severe PAD?**

Yes, severe PAD is indicated with a warning and the PAD symbol.

If the patient has severe PAD, the pulse in the ankles is very weak. This means the ABI cannot be accurately calculated. Instead, the device will analyse the pulse waveform and indicate severe disease with a PAD symbol. In the case of a PAD result, we always recommend repeating the measurement with the device connected to the computer. This provides the full-length pulse waveform, which can be analysed to confirm the condition.

#### **Can you measure the ABI if one of the lower limbs is missing?**

If a patient has an amputated leg or is not compliant for the ABI measurement because of extensive wounds, it can be measured only on patient's left or right leg by choosing the "Amputation settings" in the device "Settings" menu.

#### **Can you measure the ABI on patients with wounds?**

If the patient can withstand a 1-minute measurement, cuffs must be protected with an impermeable dressing before they are placed on the extremities with wounds. If not, the "Amputation settings" can be chosen in the "Settings" menu and cuffs placed accordingly.

#### **Can you perform a measurement if the patient has calcified arteries?**

If arteries are calcified, the device will show the PAD message. This calls for measurement with the device connected to the computer and examining the shape of the pulse waveform. This can help you deduce, whether the arteries are just calcified or blocked as well.

#### **Can you perform a measurement if the patient has very low ankle pressure?**

The device has the unique ability to detect severe PAD. In case of severe PAD, the blood flow in the arteries is very much limited and therefore the oscillations, which are essential for the measurement of ankle pressures, might not be present. This is highly dependent on the elasticity of the arteries. If no oscillations are detected, the ABI cannot be calculated, but the device will analyse the pulse waveform and warn you about the presence of severe PAD (with the PAD message). You can confirm the result by examining the full pulse waveforms on the MESIresults report on your computer. If the blood flow is very limited, but there is enough elasticity, the device will calculate the ABI.

#### **If the patient has cardiac arrhythmia, does this affect their results?**

The device does not detect the arrhythmia per se, but the measurement can be done regardless of it. If due to the condition too many pulses are absent, the algorithm does not have enough data to calculate the ABI and it will show the "E4 error" ("an error occurred during heart rate calculation"). If the condition is not severe, the ABI is calculated as usual.

### **What are the contraindications for ABI measurement?**

- in case of the presence of intravenous cannulas or arteriovenous fistulas, the cuffs and measurement can cause injury to the limb,
- if the patient has had breast surgery/mastectomy,
- do not use the device on a patient while they are connected to a vital sign monitor,
- do not use immediately post-op following a superficial bypass graft without consulting a physician first,
- do not carry out if the patient has severe lower leg pain or severe lower leg wound pain without consulting a physician first,
- do not use for patients with dermatitis, pulmonary hypertension, severe hypertension, Parkinson's or very oedematous limbs,
- do not use with patients who have severe heart failure, gangrene or a recent skin graft on the upper or lower extremity.

### **What is Peripheral Arterial Disease (PAD)?**

PAD or LEAD (lower extremity artery disease) is the narrowing of peripheral arteries. It is caused by a build-up of plaque in the arterial walls. This means the blood flow to the limbs is restricted. The most typical symptom is leg pain which occurs during exercise and is relieved by a short period of rest, this is known as intermittent claudication. Most patients, however, do not necessarily feel the leg pain or any other symptoms or are unable to describe them to their doctor.

### **Which arteries are being measured?**

Heartbeats create oscillations on the plethysmographic signals, which are used to calculate blood pressure values from three limbs. The ankle cuffs measure oscillometric signals over the whole ankle and hence the highest systolic blood pressure of all arteries (both tibial and dorsalis pedis) within the ankle is detected. The ankle pressure is then compared to the brachial pressure to calculate the ABI.

### **Who is at risk for peripheral arterial disease (PAD)?**

People over fifty years who are diabetics, hypertensive, smokers, overweight or have high cholesterol, as well as everyone over the age of sixty-five years.

### **Cuff Positioning**

#### **Can cuffs be placed over the clothes?**

Cuffs can be placed over one layer of thin clothing. Before attaching the cuffs, any tight-fitting clothes or tightly rolled up sleeves on the upper arm should be removed.

#### **Do the cuffs come in different sizes?**

The basic MESI ABPI MD package includes a set of medium-sized cuffs for extremities with a circumference of 22-32 centimetres. An additional set of large-sized cuffs are also available for measurements on limbs with a circumference of 32-42 centimetres.

#### **How can cuffs be cleaned and protected?**

As stated in the Instructions for use, they should not be soaked in disinfectant, machine-washed or submerged in water at any time. The use of disinfectants should not contain industrial solvents or whitening agents since this can cause cuff discoloration. The majority of standard disinfectants can be used. In the case of patients with lower extremity wounds, we recommend protecting them with

a protective sleeve or a different impermeable dressing, which also protects cuffs against cross-contamination.

### **How can I be sure that cuffs have been placed correctly?**

Each cuff is clearly labelled and includes a diagram to ensure correct placement. When fastening, make sure that cuffs are wrapped around the extremity as tight as possible, while ensuring the patient is comfortable. For exact placing instructions, refer to the “Instructions for use”.

### **How sensitive are cuffs to movements?**

During the measurement, the patient must lie completely still, must be relaxed and must not talk. They must not cross their legs. As the plethysmography sensors detect even the smallest changes in volume, cuffs are highly sensitive to movement during the measurement process.

### **How to place cuffs in case the patient has smaller ankles and larger calves?**

Make sure you place cuffs so they follow the calf's shape and form a conical figure.

Do not leave any space between the limb and the cuff in order to avoid measurement errors.

### **Is it important which cuff is placed on which extremity?**

Each cuff is intended for placement on a specific limb. By placing the cuff on the wrong limb, the accuracy of the measurement results can be affected. The red cuff is intended for the upper arm, the yellow cuff for the lower left leg and the green cuff for the lower right leg.

### **Is it possible with MESI ABPI MD to place a larger cuff only on one of the extremities and medium cuffs on the rest?**

Yes, large and medium cuffs are interchangeable. A combination of cuffs with different circumferences can be used during the same measurement. Due to their conical shape, the appropriately-sized cuffs must be used at all times in order to ensure the perfect fit to the extremities and prevent any errors.

### **Should the arm cuff be placed on the left or on the right arm?**

It is advised to perform the measurement on the right arm, due to lower incidence of subclavian stenosis. When a difference in the arm blood pressures is suspected, it is recommended to place the arm cuff on the other arm and repeat the measurement. The result considered should be the lowest ABI of the two.

### **What can I do if cuffs do not inflate?**

Make sure that:

- cuffs are plugged into the device correctly,
- cuffs are plugged into plugs of a matching colour,
- bladders in cuffs are not tangled or damaged in any other way.

### **Why three cuffs and not four?**

MESI ABPI MD utilizes a unique simultaneous measurement, where the cuffs are positioned on three limbs at the same time. A simultaneous measurement is essential for the accuracy of the ABI, as it eliminates measurement error due to the natural changes in human blood pressure. Simultaneous

inflation and deflation of four cuffs instead of three would increase the risk for cardiac overload (it is not advisable to obstruct all four extremities at the same time).

## **Device Operation**

### **Can the measurement report be customized?**

MESResults application enables customization of a report by entering the patient's information, as well as equipping it with the logo and name of the healthcare institution. You can customize your report in MESResults under "Settings". You can also add or remove the ABI reference scale.

### **Do I need a computer to use MESI ABPI MD?**

MESI ABPI MD is portable and can be used as a standalone device. It is equipped with a long-lasting rechargeable battery and a measurement history, which stores the results. The measurements saved on the device can be transferred to a computer at a later time.

### **Does device position affect the measurement results?**

The device position should not significantly affect the measurements, however, as per instructions for use, the device should be placed on a flat surface. It is possible that moving the device during the measurement may cause obstruction of other parts (tubes, for example), or prompt the patient's movement, resulting in the need for repeating the measurement.

### **How many measurements can MESI ABPI MD store?**

MESI ABPI MD can store approximately 40 measurements. The oldest measurements are automatically deleted for each additional measurement, so we recommend transferring them regularly to your computer using the MESResults application.

### **My computer does not recognize the MESI ABPI MD device. What can I do?**

- check your Windows version (it needs to be Windows XP or newer),
- check if the USB cable port is damaged and try using another one,
- try using a different computer.

### **The calibration reminder appears on the MESI ABPI MD device. What can I do?**

To ensure the device is functioning properly, we recommend an annual calibration. The date of the last calibration can be found in the "About" section.

The calibration reminder pops up on the device when THE TWO of the following criteria are fulfilled:

- if the difference between the current time and date of calibration is more than one year,
- if the difference between current time and the first use date is more than one year,

### **What are MESI ABPI MD's modes of operation?**

MESI ABPI MD device has two modes of operation.

1. The primary mode is for the measurement of the ankle-brachial index (ABI), where you place cuffs on the arm and on the left and right ankles.
2. The additional mode is for an independent measurement of the upper arm blood pressure. In this mode, you will only measure the upper arm blood pressure, so only place the cuff on the upper arm.

### **What does the clock battery serve for?**

The clock battery saves the set time on the device when the main battery is completely empty. If the device is charged regularly, the clock battery will have a much longer life and won't cause any issues. If not, it can cause issues the next time the device is charged.

If the device is not in use very often, it is recommended to charge it at least once a month.

### **What does the measurement process look like and how long does it take?**

The measurement process consists of four simple steps:

- correctly placing the arm cuff,
- correctly placing the ankle cuffs,
- running the measurement,
- receiving the results.

The calculation of the measurement results takes a couple of seconds, while the entire measurement process takes approximately a minute.

### **What happens if an error occurs during or after the measurement?**

Thanks to a unique error detection system, MESI ABPI MD will alert the operator of any irregularities. The device can identify two types of errors: measurement and calculation errors. Instead of a false result, a warning message is displayed on the screen along with further instructions. For detailed error descriptions, please check the "Instructions for use".

### **What is the best way to clean MESI ABPI MD?**

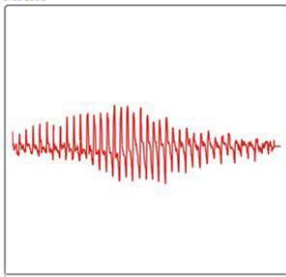
The "Instructions for use" state that the device can be wiped down using a damp cloth or a disinfectant that does not contain thinners or similar solvents. The same as cuffs, it should not be soaked in liquid at any time.

### **What is the difference between using MESI ABPI MD as a standalone device or connected to the computer?**

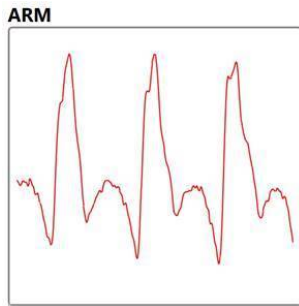
The pulse waveform on the report in MESIresults will look different.

If the measurement is performed with the device connected to the computer and the MESIresults software running, the pulse waveforms are recorded during the entire duration of the measurement. Using MESIresults, the users can zoom in to see the details of the waveform.

ARM



If the measurement is performed while the device is not connected to the computer and the results are transferred to the computer later, the device will only record 5 to 6 seconds of the pulse wave, which can be inspected on the device or in MESIresults.



Both use cases are correct, however using the device connected to the computer provides more information, as it records the full pulse waveform.

#### **What kind of power supply does MESI ABPI MD use?**

MESI ABPI MD uses the following two power sources:

- the mains electricity using an AC/DC power supply,
- battery power.

When fully charged, the battery capacity is sufficient for up to 50 measurements. **Only the original power supply should be used for charging the device to avoid any damage.**

#### **Where can I find my offline key?**

Visit [mrecords.mesimedical.com](https://mrecords.mesimedical.com) and log in using your MESIresults username and password. Click on the menu in the top right corner and select "Profile settings". Scroll to the bottom of the "Personal data" section and find your "Offline key". Copy it and return to the MESIresults application. Open the MESIresults app and click on "I don't have an internet connection". Use your email address and the offline key to access your account.

#### **Why is the device's screen blank, even if the green/red light is switched on?**

If the device's light indicator is green and red light when turned on, but the screen is completely blank, it most likely means that the cable between the display and the circuit is broken. The device needs to be checked and serviced by the MESI Service team.

#### **MESIresults Software**

##### **Can I use the MESIresults app without creating an account?**

Unfortunately, this is not possible due to regulations on patient data protection.

##### **Can I use the MESIresults app without internet connection?**

Yes, you can use the application in the offline mode. For further instructions see the "Where can I find my offline key?" section.

### **How are the measurement results transferred to the computer?**

The MESIresults application comes free with each device. MESI ABPI MD can be connected to a computer via the enclosed USB cable. Once the application is installed, the results are transferred automatically when the device is connected to the computer. Creating a username and password for accessing reports provides the highest level of security.

### **How can I create my MESIresults account?**

Open MESI results, click on “Register a new account”. You will be taken to [mrecords.mesimedical.com/register](https://mrecords.mesimedical.com/register) where you can create your account. Simply fill in the necessary information and click “Register”. **You will then receive an email message to confirm your email address. Please make sure to confirm your email address within 24 hours.** If you don’t receive the email, please make sure to check your spam folder. If you are unable to locate the email message, please contact MESI Support.

### **How can I transfer the measurement results to the computer?**

You can transfer the measurements to the computer using a USB cable and the MESIresults application. The application comes with the device free of charge. You can install it by downloading the newest version from [mesimedical.com/support](https://mesimedical.com/support).

Once the application is installed, you can create your user account and start using the application. When the device is connected to the computer, measurements will transfer automatically.

### **How often is the software updated?**

The software is updated approximately every 2 months. The MESIresults software notifies you of any updates automatically via a pop-up window.

### **I forgot the password for my MESIresults account. What can I do?**

Open MESIresults and click on “Forgot password?”. You will be taken to [mrecords.mesimedical.com/forgot\\_password](https://mrecords.mesimedical.com/forgot_password). Please enter your email address and click on “Request a new password”. You will receive an email with a link. Please click on the link and create a new password.

### **Is MESI ABPI MD a Doppler?**

No, MESI ABPI MD is not a Doppler. Doppler is an ultrasound probe, while MESI ABPI MD uses volume plethysmography to measure the ABI. It is much faster and more objective in detecting and identifying patients with PAD.

The accuracy of MESI ABPI MD was confirmed with several clinical studies (85 % sensitivity and 96 % specificity to detect ABI lower than 0.9 was proven). As the device is automated, it eliminates human error that can occur during the standard handheld Doppler measurement. Pressures on the arms and both ankles are measured completely simultaneously, which eliminates error due to blood pressure drift.

### **The measurement history is not transferring to the computer. What can I do?**

First, make sure that you are using the latest version of MESIresults. You can download it here: [mesimedical.com/support](https://mesimedical.com/support). Then, connect the device to the computer and switch it on. In the lower right corner, a “Connected” text should be displayed, and the device should show a message

“Transferring history”. If not, check the “History” section, whether the device contains any measurements.

**If you continue experiencing issues, try also:**

- performing a measurement with the device connected to the computer,
- connecting the device to the computer and running MESI results afterward,
- switching the device on and off while connected to MESI results.

**What are the software system requirements?**

At least 100 MB disk space, 1 GB RAM, Windows XP or newer.

Our MESIresults software offers connectivity with any GDT compatible hospital system. All MESIresults GDT settings can be found in the MESIresults application under the “Settings” left-hand side tab and then under the “GDT” subtab at the top of the page.

There are three steps:

- enter input file (the file in which you GDT enabled software will deposit a measurement request)
- enter output file (the file in which you will deposit the created measurement data)
- enable GDT (checking this will enable the MESIresults GDT communication pipeline)

The standard workflow is:

- a GDT 2.1 compliant service must be configured to deposit measurement requests into a common folder with a specific name, for example: “E:\GDTComms\gdt”
- the MESIresults “Input file” setting is set to the same file, so “E:\GDTComms\gdt” in our example; this tells MESIresults to wait for a file in that location and propose a measurement with the data contained in that file once found
- create a measurement by following the on-screen instructions; MESIresults will deposit a GDT measurement results into the file set under “Output file” in the settings
- configure your GDT compliant software to wait for the above file to appear, upon which your result will appear at your GDT enabled software

**Pulse Waveform**

**The graph is showing pulse waveform in halved and not full »lemon« shape. What could be the reason?**

When the oscillations on the graphs do not appear in full “lemon” shape, but halved, it implies that the (leg) cuffs did not inflate sufficiently (showing errors E8 and E10). It can result in systolic and diastolic pressures not being reliably measured.

Combination of these kinds of graphs in the legs and a normal graph in the arm, usually appear when:

- the patient is not in a completely supine position
- the cuffs on the legs are not sufficiently tightened
- the leg pressures are significantly higher than the arm pressure (note that the device takes the arm pressure into consideration when defining the maximum pressure during the inflation)



We suggest you check the patient's and cuffs' position again and then repeat the measurement.

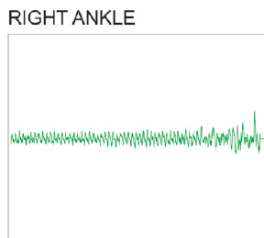
**What does a normal pulse waveform look like?**

Full lemon shape, clearly visible oscillations with high amplitudes



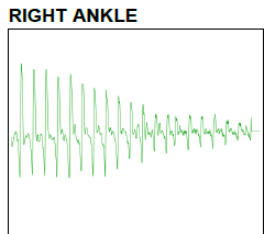
**What does a pulse waveform indicating incompressible arteries look like?**

A flattened shape, oscillations with low amplitudes



**What does a pulse waveform indicating leg cuffs not inflated sufficiently look like?**

Halved lemon shape



**What does a pulse waveform indicating severe PAD look like?**

No typical shape, oscillations almost invisible (noise)

