MESI

Simplifying Diagnostics

INSTRUCTIONS **FOR USE**

automated ABPIMD

CE 1304

ISO 9001 Q-1664
ISO 13485 M-049

automated ABPIMD

1-minute Ankle-Brachial Pressure Index

Automated Ankle-Brachial Pressure Index measuring device (MESI ABPI MD) brings fast, accurate and objective screening for Peripheral Arterial Disease (PAD) to every doctor's office. In addition to the simultaneous measurement of Ankle-Brachial Index, it also enables measurement of brachial blood pressure and heart rate. It is intended for professional use in primary healthcare and specialist clinics as a screening method for the detection of PAD.

Contents

Safety and legal recommendations

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Safety recommendations

To avoid personal injury and/or damaging the device or accessories, follow the safety recommendations given below.

1. Setup and technical personnel
The device must be set up by authorized personnel with adequate professional training and experience who are aware of all the dangers in relation to the setup of the device and its use and who will take adequate risk prevention measures for themselves, users, other personnel and devices.

2. Access to the device
Only authorized personnel may be given access.

3. Safety measures
It is required to comply with the local safety requirements, if so required by the regulations. In addition to the local safety regulations, it is also required to follow the safety instructions in this document. Should there be any conflict between the safety recommendations in this document and the recommendations stipulated by local regulations, the local regulations take precedence.

4. Information for technical personnel
The technical personnel must be given adequate technical instructions for the use and maintenance of the device.

Trademark

Manufacturer information

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1 Advantages

Objective and accurate measurement

Measurement can be carried out in 1 minute

1 min

Measurement results can be printed using the MESIresults computer application

MESIresults

Portable

Simultaneous measurement of Ankle-Brachial Pressure Index and blood pressure

2 in 1

Battery powered

Easy to use

Accessories

Technical specifications

Dimensions	Width: 25.00cm, height: 7.30cm, depth: 20.00cm, weight: 0.60kg
Display	4.3” colour LCD screen with 16-bit colour depth Resolution: 480 × 272 pixels
Power supply and battery	AC/DC power supply: FRIWO FW8001M/05 Input: 100-240V AC / 50-60Hz / 400-200mA, output: 5V DC / 3.0A Battery type: rechargeable lithium polymer Capacity: 3000mAh, number of measurements per charge: 50 Electrical specifications: 100-240V AC, 50-60Hz, 3A Type of protection against electric shock: Class II
Protection type	Compliant with standards: • EN 60601-1:2006+A1:2013 General requirements for basic safety and essential performance • EN 60601-1-2:2007 Electromagnetic compatibility – Requirements and tests • EN 80601-2-30:2010+A1:2015 Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers Flammable anesthetics: WARNING! Not suitable for use with flammable anesthetics.
Measurement types	• Ankle-Brachial Pressure Index using oscillometry and volume plethysmography, • Systolic blood presure using oscillometry and volume plethysmography • Diastolic blood pressure using oscillometry and volume plethysmography • Heart rate using oscillometry and volume plethysmography
Measurement range	• Pressure: 0 to 299mmHg • Heart rate: 30 to 199 beats per minute
Limit values of measurement errors	• Pressure: ± 3mmHg • Heart rate: ± 5% of value • Ankle-Brachial Pressure Index: ± 0.1
Cuff inflation and deflation	Automatic inflation using an air pump and deflation using an electromagnetic valve.
Temperature, humidity and atmospheric pressure range	Working environment: 10 to 40°C, 30 to 85% relative air humidity, 700 - 1060hPa air pressure, IPX0 protection. Transport and storage: 0 to 60°C, up to 85% relative air humidity, 700 - 1060hPa air pressure.

CE 1304

3 Quick guide

NOTE
Before using the device for the first time, read the instructions for use carefully and follow the recommendations and suggestions. This chapter only includes short instructions for the use of the MESI ABPI MD. For detailed descriptions of individual functions of the device, see chapter 5, Detailed instructions. Please keep for future reference.

NOTE
When using the device for taking the Ankle-Brachial Pressure Index measurement the patient must lie down and remain still.

NOTE
When using the device for measuring the upper arm blood pressure the patient must sit upright, keeping a straight back.

NOTE
The MESI ABPI MD is intended for use in medical institutions, where measurements must be carried out by adequately trained medical personnel. The MESI ABPI MD is not intended for home use.

NOTE
The MESI ABPI MD may be used on pregnant women.

NOTE
The MESI ABPI MD is not intended for use on newborns or children under the age of 10 years.

NOTE
In case of the presence of intravenous cannulas or arteriovenous (AV) fistulas, the cuffs and measurement can cause injury to the limb.

The MESI ABPI MD has two modes of operation:

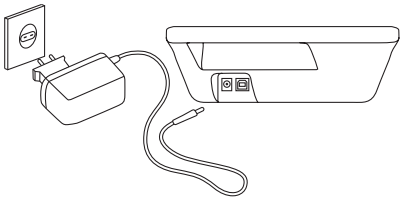
▶ The primary mode is for the **measurement of the Ankle-Brachial Pressure Index**, where you place the cuffs on the arm and the left and right ankles. The results of the

measurement are the left Ankle-Brachial Pressure Index (LEFT ABI), the right Ankle-Brachial Pressure Index (RIGHT ABI) and the upper arm blood pressure (SYS, DIA).

▶ The additional mode is for the **independent measurement of the upper arm blood pressure**. In this mode, you will only measure the upper arm blood pressure, so only place a cuff on the upper arm. The result of the measurement is the upper arm blood pressure (SYS, DIA).

Step 1

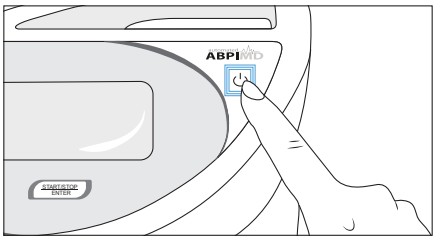
Connect the MESI ABPI MD to the mains electricity using the AC/DC power supply. The power socket is located at the back of the device and is labelled “5V DC”. Connect the cuffs to the device by inserting the tube of each cuff into the connector of the same colour on the device.



Step 2

Turn the device on using the ON/OFF button ⏻. The display will show the home screen. It is not necessary to change any settings for the basic functioning of the device.

If you are using the MESI ABPI MD device for the first time, the language, time and date menu will appear. To correctly set the menu, see section 5.1.

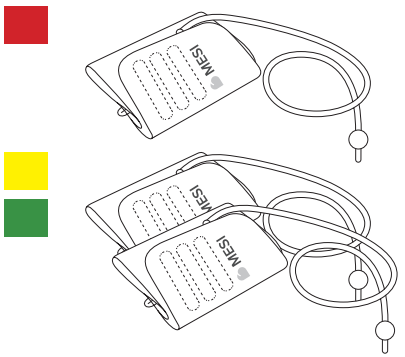


Ankle-Brachial Pressure Index measurement 3.1

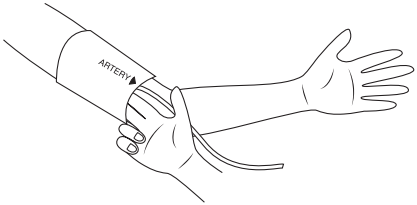
Step 3

The patient must lie down and remain still. Place the cuffs on the upper arm (cuff labeled “ARM”), the lower left leg (cuff labeled “LEFT ANKLE”) and the lower right leg (cuff labeled “RIGHT ANKLE”). Observe the following colour markings:

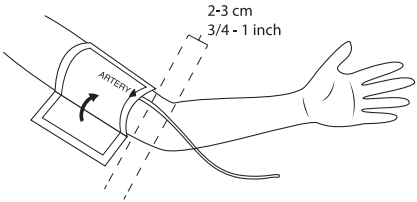
RED > left or right upper arm
YELLOW > lower left leg
GREEN > lower right leg



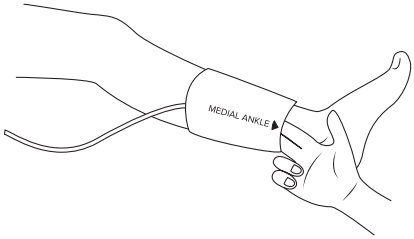
Place the cuffs so that there is a finger's width of room between the limb and the cuff.



The cuff on the upper arm must be placed so that the artery label (ARTERY) points towards the elbow. When placing the cuff, observe the image below. The cuff tube should point towards the fingers.

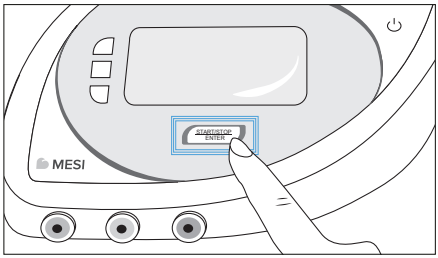


The ankle cuffs must be placed so that the ankle label (MEDIAL ANKLE) points towards the inner side of the ankle. When placing the cuff, observe the image below.

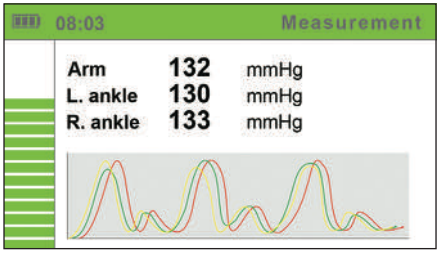


Step 4

The patient must lie still in the supine position. When you are ready, push the START button. The measurement process will begin. The patient must not move during the measurement process. The entire process takes approximately 1 minute.

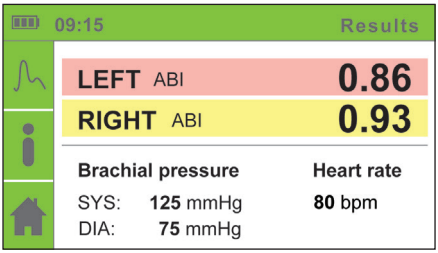


During the measurement process, the screen will display the current arterial pressures and the arterial pressures waveforms.



Step 5

When the measurement process is completed, the screen will display the results. The Ankle-Brachial Pressure Index is displayed in green, yellow or red, depending on the value. The colour scale is taken from the "*Guidelines for the Management of Patients With Peripheral Artery Disease*" published by the Journal of the American College of Cardiology.

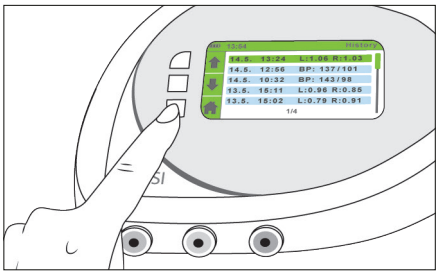


Below 0.89 – red
From 0.90 to 0.99 – yellow
From 1.00 to 1.40 – green
Above 1.41 – red

Step 6

Return to the home screen using the HOME ↵ button. From here, you can view the measurement history and change the settings.

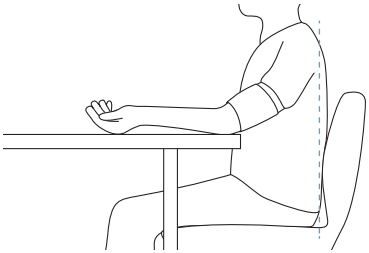
For an additional description of the specifications of the MESI ABPI MD and detailed instructions for its use, see the remaining chapters of the instructions for use.



Upper arm blood pressure measurement 3.2

Step 3

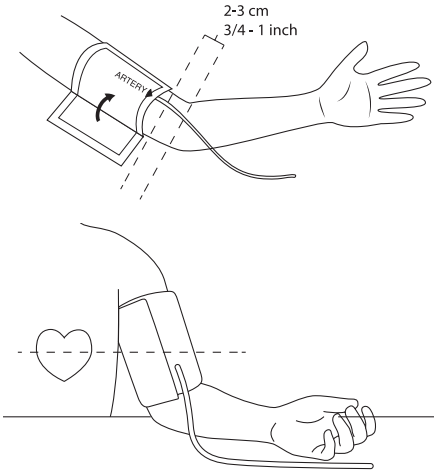
The patient must sit comfortably on a chair. They must sit upright, keeping a straight back. Only place the red upper arm cuff (cuff labeled "ARM") on the patient). In this mode of operation, the green and yellow cuffs are not placed on the patient's limbs.



Place the cuffs so that there is a finger's width of room between the limb and the cuff.

The cuff on the upper arm must be placed so that the artery label (ARTERY) points towards the elbow. When placing the cuff, observe the image below.
The cuff tube should point towards the fingers.

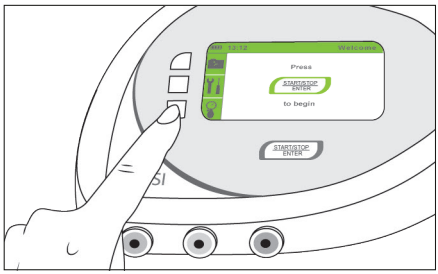
The lower arm should lie freely on a flat surface. The cuff should be level with the patient's heart.



Step 4

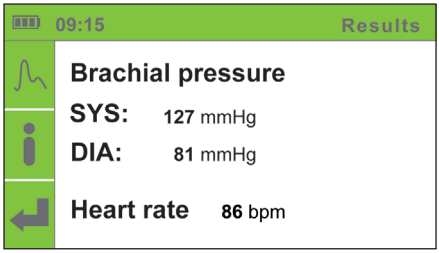
Push the BLOOD PRESSURE MEASUREMENT button to change the mode to independent blood pressure measurement.

When you are ready, push the START button. The measurement process will begin. The patient must not move during the measurement process. The entire process takes approximately 1 minute. During the measurement process, the screen will display the current arterial pressure and the arterial pressure waveform.



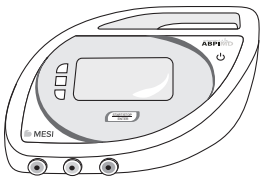
Step 5

When the measurement process is completed, the screen will display the results of the upper arm blood pressure measurement.

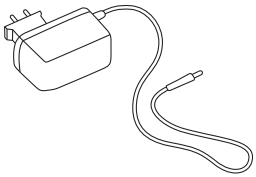


Product description

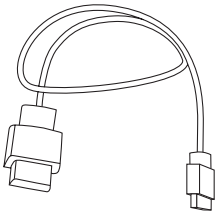
Contents of the package



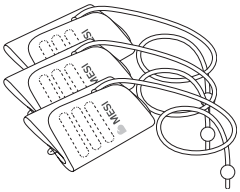
Model ABPIMDD
Description Automated Ankle-Brachial Index measuring device MESI ABPI MD



ABPIMDAAC
AC/DC power supply



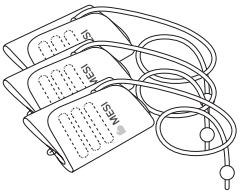
ABPIMDAUSB
Device USB cable



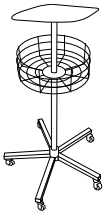
Model ABPIMDACFFSM
Description MESI ABPI MD Cuff Set M

Computer software MESIresults
Find latest version at:
www.mesimedical.com/support

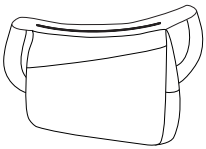
ACCESSORIES



Model ABPIMDACFFSL
Description MESI ABPI MD Cuff Set L



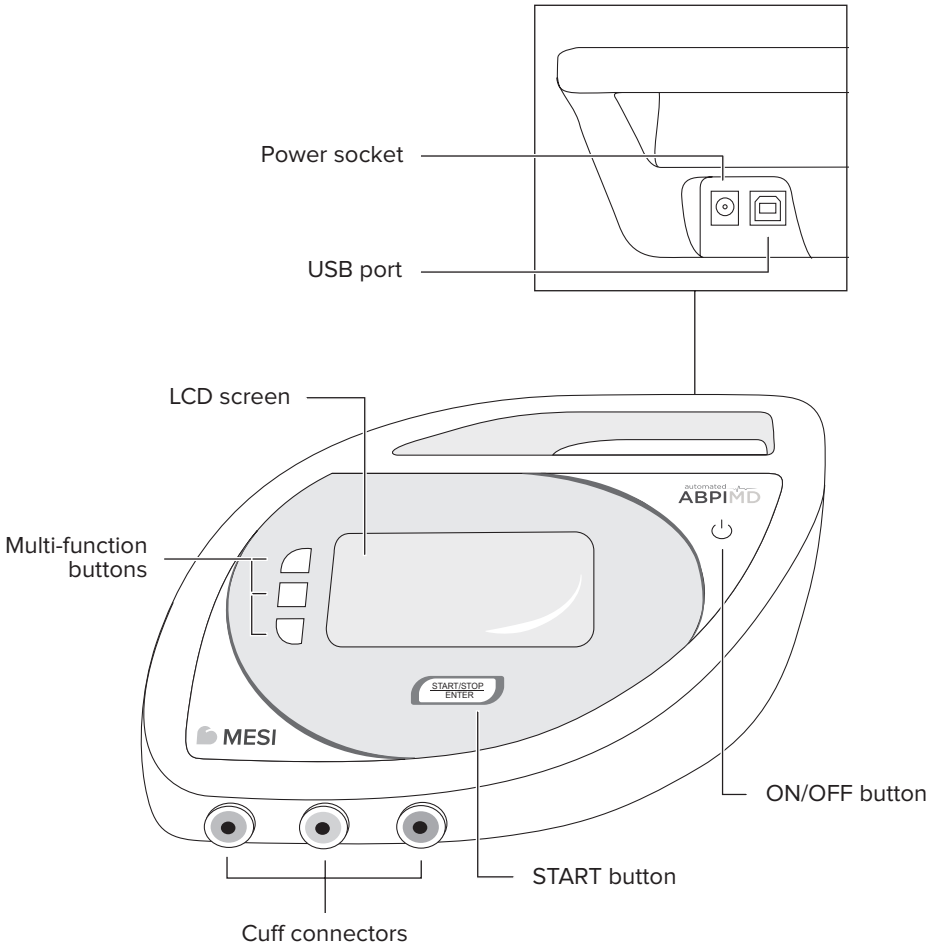
ABPIMDAST
MESI ABPI MD Stand



ABPIMDABAG
MESI ABPI MD Carry Bag

Contact your local distributor for more information.

4.2 Device description



The display screen is divided into three sections:

- ▶ title bar,
- ▶ multi-function buttons,
- ▶ active menu.

Title bar

The title bar displays the current location within the menu structure. In addition to the location within the menu structure, it also displays the time and a battery status indicator.

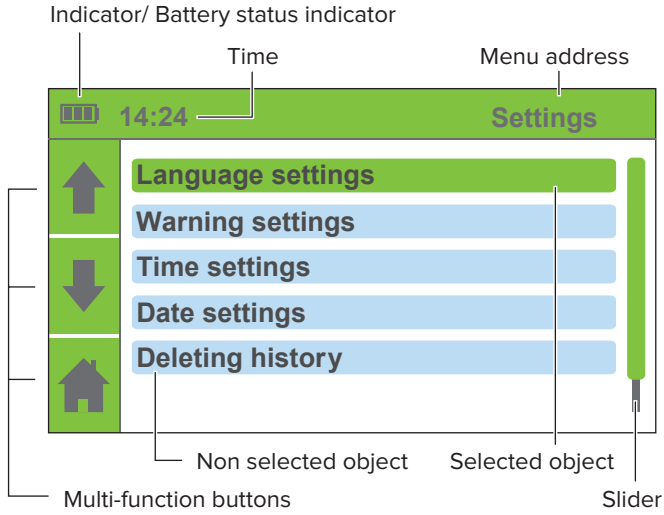
Multi-function buttons

The column on the left side of the screen is divided into three sections. They display the current functions of the three multi-function buttons located on the left of the screen. When a button is pushed, its display section turns grey.

Active menu

Most of the screen is used to display instructions, measurement results, history and other menus. The slider on the right denotes the current position of the selected element in the menu.

A pop-up window may appear in the active menu with current information, such as the battery status, errors and measurement warnings.



4.4 Graphic symbols

This chapter describes the graphic symbols. Navigation is based on a system of two fixed-function buttons and three multi-function buttons whose function changes. The current function of each of the three buttons is denoted by the icons on the left side of the screen.

Fixed-function buttons		
	START/STOP ENTER	Starts or stops the measurement process. If you are inside the menu structure, push this button to go down a level or confirm a change in the settings.
	ON/OFF	Turns the device on or off.

Multi-function buttons		
	HOME	Returns to the home screen.
	UP/DOWN	Navigation through the elements of individual menus.
	BACK	Go back up a level in the menu hierarchy.
	SETTINGS	Enter the settings menu.
	DETAILS	Display extra details about the measurement results.
	HISTORY	Display the history.
	BLOOD PRESSURE MEASUREMENT	Independent blood pressure measurement mode.
	PULSE WAVEFORM	Graphical interpretation of pulse waves.

Indicators		
	CHARGING INDICATOR	It is displayed if the AC/DC power supply is connected.
	BATTERY STATUS INDICATOR	0% | 50% | 100% battery charge

Detailed instructions

5

This chapter contains all the information required by users of the device for safe, correct and accurate measurement. This chapter includes a detailed and complete description of all the functions of the device, the safety instructions and all the information required to understand the operation of the device.

First time use 5.1

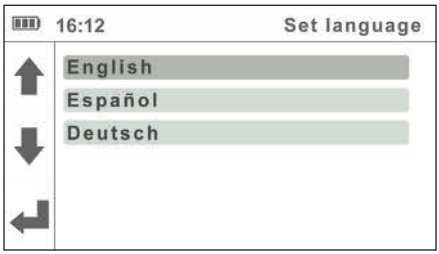
When using the MESI ABPI MD device for the first time it's necessary to set language, time and date. It is mandatory to set the exact time and date because of the effect of warnings and reminders which ensure the proper conduct or calibration of the MESI ABPI MD device.

Turn the device on using the ON/OFF button. The display will show the initial screen with a greeting. To continue press any key.

Language settings 5.1.1

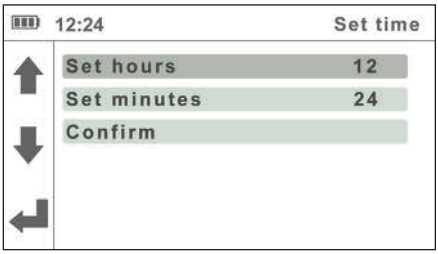
Use the UP ⬆ and DOWN ⬇ buttons to select the language. Confirm your selection using the ENTER button. The device language will be changed and the time setting menu will appear.

If you wish to return to the previous menu without confirming the changes, push the BACK button ↵.



5.1.2 Time settings

Use the UP ⬆ and DOWN ⬇ buttons to navigate through the hour and minute settings. Confirm your selection using the ENTER button.



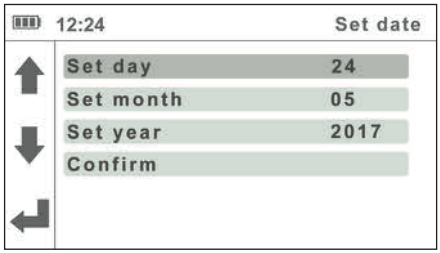
The selected field will begin to flash. Use the UP ⬆ and DOWN ⬇ buttons to set a new value and confirm it using the BACK button ↵.

If necessary, repeat the process for the other fields. When you are finished setting the time, use the UP ⬆ and DOWN ⬇ buttons to move to the Confirm field and confirm your selection using the ENTER button.

If you do not wish to apply your settings, return to the previous menu by pushing the BACK button ↵. The device time will be configured and the date setting menu will be displayed.

5.1.3 Date settings

Use the UP ⬆ and DOWN ⬇ buttons to navigate through the day, month and year settings. Confirm your selection using the ENTER button.



The selected field will begin to flash. Use the UP ⬆ and DOWN ⬇ buttons to set a new value and confirm it using the BACK button ↵.

If necessary, repeat the process for the other fields. When you are finished setting the date, use the UP ⬆ and DOWN ⬇ buttons to move to the Confirm field and confirm your selection using the ENTER button.

Before confirming, double-check the accuracy of the date because the settings will be saved after confirming and you won't be able to return to the previous menu.

The display will show a thank you note. If the incorrect date was confirmed press the ON/OFF button. To continue to the main menu, press any key.

Device setup 5.2

To ensure that the measurement accuracy is according to specifications, measurements must be carried out in an appropriate working environment. Place the device on a flat and stable surface. We recommend you to use the ABPI MD stand. During operation, the device must not be exposed to any mechanical stress or vibrations. Such disturbances can affect the measurement results, rendering the results invalid (if you set the device down on the patient's bed, you cannot ensure the validity of the results).

The device can be used at temperatures raging between +10°C and +40°C and at a relative air humidity between 30% and 85%.

AC/DC power supply and battery 5.3

The MESI ABPI MD uses the following two power sources:
- ▶ the mains electricity using an AC/DC power supply,
- ▶ battery power.

Connect the AC/DC power supply to a wall socket with a mains voltage of 100-240V at 50-60Hz and to the connector at the back of the device. The device is now ready for use.

NOTE
Only use the AC/DC power supply included with the device; FRIWO FW8001M/5. Do not use other AC/DC power supplies. Using other AC/DC power supplies can cause serious injuries to the user and/or the patient and potential damage to the device and other equipment.

The MESI ABPI MD can also function without the AC/DC power supply. When the device is not connected to the mains electricity, it is powered by a battery. The required power is provided by a high-performance lithium polymer battery. The battery is not replaceable.

NOTE
The battery inside a completely new device is most likely not completely empty and can provide enough power to start the device up. Nonetheless, connect the device to the mains electricity using the AC/DC power supply.

The battery charging system works automatically. The battery begins to charge when the AC/DC power supply is connected, which is indicated by the battery status indicator. When the battery is charged, the charging process stops and the title bar displays the battery status indicator and the charging indicator.

The battery status indicator is displayed in the upper left corner of the screen:

 Battery empty

 Battery at 50%

 Battery at 100%

The battery capacity is sufficient for approximately 50 measurements.

Power indicator light
Power indicator is a small LED positioned next to the ON/OFF button (see p.14). It indicates the power status of the MESI ABPI MD device. Possible statuses are shown in the table below.

Power indicator status	Power indicator light color
The MESI ABPI MD device is turned off + The battery is not charging	No light
The MESI ABPI MD device is turned off + The battery is charging	Red light
The MESI ABPI MD device is turned on + The battery is not charging (It means that the device is fully charged or the device operates on battery)	Green light
The MESI ABPI MD device is turned on + The battery is charging	Orange light

5.4 Cuff setup

When the MESI ABPI MD is positioned correctly, i.e. on flat surface, you can connect the cuffs and begin the measurement. The cuffs, tubes and connectors are of different colours to enable the correct placement and connection of the cuffs. For a successful and correct measurement, all three cuffs must be connected and placed correctly on all three limbs in accordance with the instructions for use.

Colour markings on individual cuffs:
RED > left or right upper arm
YELLOW > lower left leg
GREEN > lower right leg

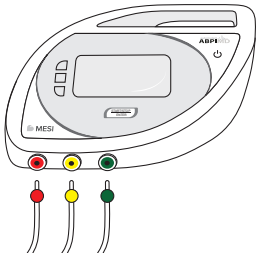
The proper placement of the cuffs is of vital importance to ensure valid measurement results.

NOTE
Use moderate force to attach and remove the cuffs.

NOTE
When you connect the tubes of the cuffs, make sure that the air flow is not obstructed in any way. Obstructing the air flow is as easy as accidentally placing an object on the tube.

Before using the cuffs, check the following:
- the inflatable pocket must be fitted in the cuff correctly;
- the inflatable pocket is not twisted or turned the wrong way;
- the tube of the cuff is not twisted or otherwise inappropriately bent.

Connect each cuff to the device by connecting the plug on the tube to the corresponding socket. Remove it by pulling it out of the device – be careful to pull it by the plug, and not by the tube.



Choosing the appropriate cuff 5.5

The basic package includes three different cuffs for placement on the upper arm and the lower left and right legs.

Model	Description	Limb circumference
ABPIMDACFFSM	MESI ABPI MD Cuff Set M	22–32 cm

Additional cuffs are also available for measurement on limbs with a larger circumference. They are available only together in a set. It is possible to choose between different cuff model numbers.

Model	Description	Limb circumference
ABPIMDACFFSL	MESI ABPI MD Cuff Set L	32–42 cm

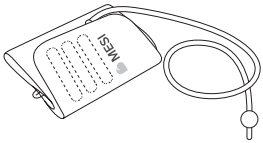
Check the markings on the cuffs to choose the correct cuff size. The cuff will fit the limb if the INDEX mark is within the area delineated by the arrows. If the cuff size is incorrect, choose a more appropriate size from the list above.

NOTE
Each cuff is intended for placement on a specific limb. By placing a cuff on the wrong limb, you can affect the accuracy of the measurement results.

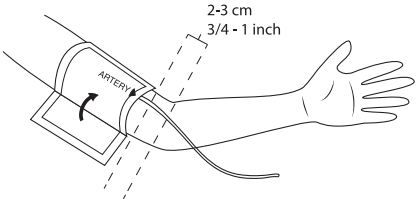
5.6 Arm cuff

Ensure that the cuff fits by choosing the appropriate cuff size according to the circumference of the patient's arm. Use the table in Chapter 5.5 *Choosing the appropriate cuff.*

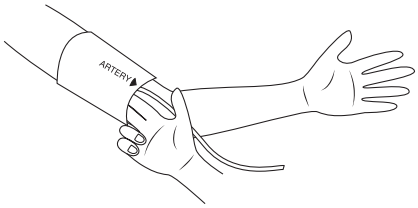
Choose a cuff labelled ARM CUFF of the appropriate size. Check that you have chosen the correct size using the INDEX marking and the OK area on the cuff.



Place the cuff on the upper left or right arm. Make sure that the arrow-shaped artery marking is in line with the brachial artery. The cuff tube should point towards the fingers.



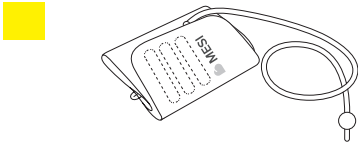
Wrap the cuff around the arm and fasten it. Make sure that the lower edge of the cuff is approximately 2 to 3 cm above the elbow. The cuff must not be obstructed by clothing. When fastening the cuff, make sure that there is a finger's width of room between the cuff and the arm.



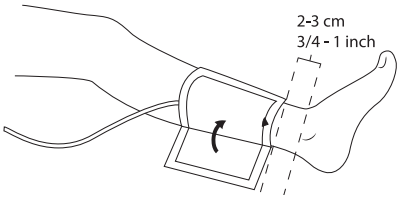
Left ankle cuff 5.7

Ensure that the cuff fits by choosing the appropriate cuff size according to the circumference of the patient's lower left leg. Use the table in Chapter 5.5 *Choosing the appropriate cuff.*

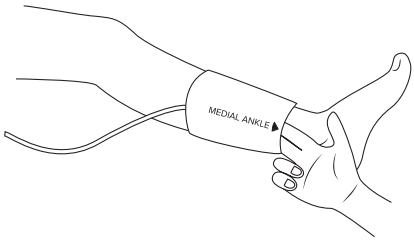
Choose a cuff labeled LEFT ANKLE CUFF of the appropriate size. Check that you have chosen the correct size using the INDEX marking and the OK area on the cuff.



Place the cuff on the lower left leg. Make sure that the arrow-shaped MEDIAL ANKLE marking points towards the inner side of the ankle. The cuff tube should point towards the knee.



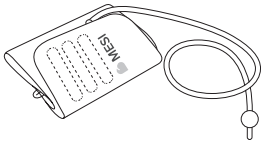
Wrap the cuff around the ankle and fasten it. Make sure that the lower edge of the cuff is approximately 2 to 3 cm above the ankle. The cuff must not be obstructed by clothing. When fastening the cuff, make sure that there is a finger's width of room between the cuff and the leg.



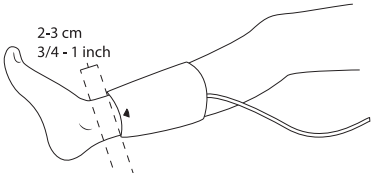
Right ankle cuff 5.8

Ensure that the cuff fits by choosing the appropriate cuff size according to the circumference of the patient's lower right leg. Use the table in Chapter 5.5 *Choosing the appropriate cuff.*

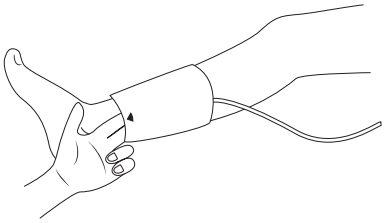
Choose a cuff labelled RIGHT ANKLE CUFF of the appropriate size. Check that you have chosen the correct size using the INDEX marking and the OK area on the cuff.



Place the cuff on the lower right leg. Make sure that the arrow-shaped MEDIAL ANKLE marking points towards the inner side of the ankle. The cuff tube should point towards the knee.



Wrap the cuff around the ankle and fasten it. Make sure that the lower edge of the cuff is approximately 2 to 3 cm above the ankle. The cuff must not be obstructed by clothing. When fastening the cuff, make sure that there is a finger's width of room between the cuff and the leg.



5.9 Ankle-Brachial Pressure Index measurement

NOTE
It is recommended for the patient to lie still for at least 5 minutes before starting the measurement process. During measurement, the patient must lie completely flat, must be relaxed and must not talk. They must not cross their legs.

NOTE
The person carrying out the measurement should remain by the patient's side at all times and closely monitor the measurement process.

NOTE
The measurement of the Ankle-Brachial Pressure Index can be affected by the placement of the cuffs, the position of the patient and their physical condition. The functioning of the device can also be affected by high temperatures, humidity and altitudes.

NOTE
If the results of the Ankle-Brachial Pressure Index measurement are very unusual, repeat the measurement three times.

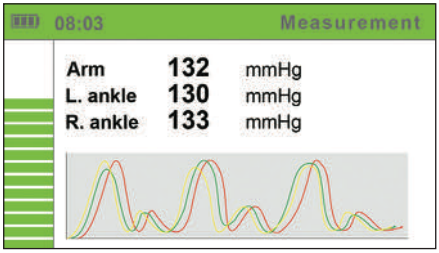
You can begin measuring the Ankle-Brachial Pressure Index when the cuffs are correctly positioned on the patient lying down and when the connections have been checked and any potential air flow obstructions in the tubes have been eliminated.

Turn the device on. The display will show the home menu. If the home menu is not displayed or if another menu is displayed, push the BACK ↵ or the HOME 🏠 button until you get to the Start menu (right image). To begin the measurement process, push the START button.

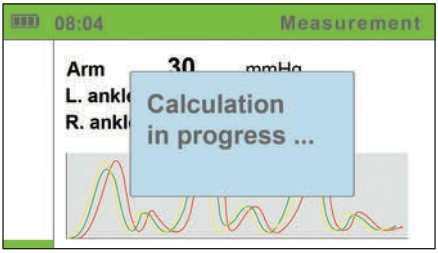
NOTE
If the measurement process must be interrupted for any reason (e.g. the patient is not feeling well), push the START/STOP button immediately. The measurement process will be stopped and the cuffs will be deflated. If the cuffs are not deflated despite the process being stopped, immediately disconnect the cuffs tubes from the device.

NOTE
Maximum allowed measurement time before displaying an error message is 180s.

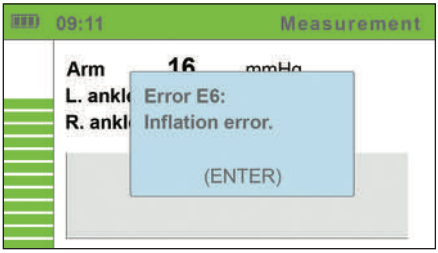
During measurement, the screen displays the current pressure in the cuff for each limb separately and the pressure waveforms on which the red curve shows the oscillation of pressure in the upper arm, the green curve shows the oscillation of the right ankle and the yellow curve shows the oscillation of the left ankle. The left side of the screen displays a bar with a timer which displays the remaining measurement time.



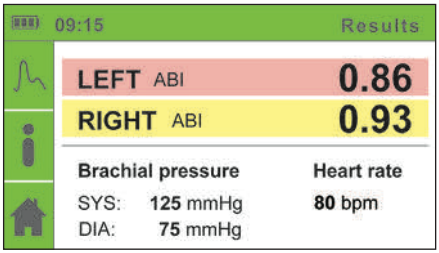
The device will determine the upper limit pressure for cuff inflation on the basis of the monitoring of the pressure dynamics during inflation. As pressure data is actively captured while the cuffs are deflated, the patient must remain still. The measurement result processing begins when the cuffs are deflated, i.e. when the screen displays the corresponding message (right image).



During measurement or when the results are displayed, a warning can be displayed on the screen. If an error occurs during the measurement process, a warning will be displayed in a blue box and the measurement will stop automatically. The box will display the name of the warning or error with a short description. For detailed descriptions of warnings and errors, see Chapter 5.13 *Error messages*.

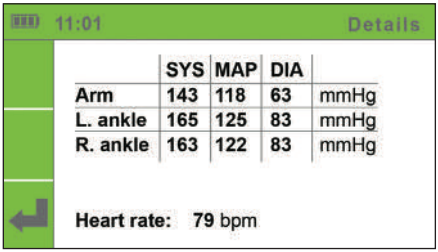


You may now remove the cuffs. The patient may move freely now. The calculation of the measurement results takes a couple of seconds, while the entire measurement process including the calculation process takes approximately a minute. After the calculation is completed, the device displays the results on the screen: the left and the right Ankle-Brachial Pressure Index, the upper arm pressure and the heart rate.



To prepare the device for further measurement, push the HOME button, or push the START button to immediately start a new measurement. The device stores the measurement data in its memory, and you can see it using the HISTORY menu.

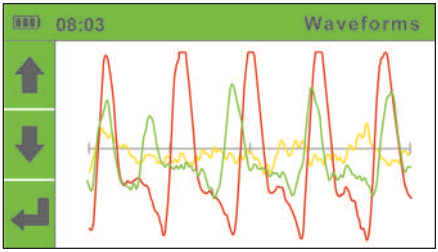
In case of "Abnormally weak pulse" result, or in case of a calculation error, a warning will be displayed along with the measurement results. For a detailed description of the detection of severe PAD or incompressible arteries (medial calcinosis), please see chapter 5.9.1 *Detection of severe PAD and incompressible arteries* on page 27.



For a detailed description of warnings and errors, see Chapter 5.13 *Error messages*.

For additional information on the measurement results, push the DETAILS button.

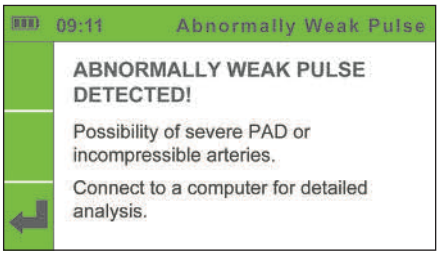
To display the pulse waveforms, push the PULSE WAVEFORM button.

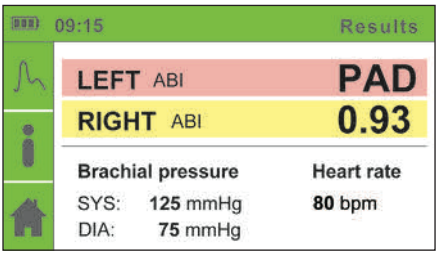


Detection of severe PAD and incompressible arteries

5.9.1

When the result “Abnormally weak pulse” is displayed, there is a high probability of severe Peripheral Arterial Disease (PAD) or incompressible arteries (Medial Calcinosis).





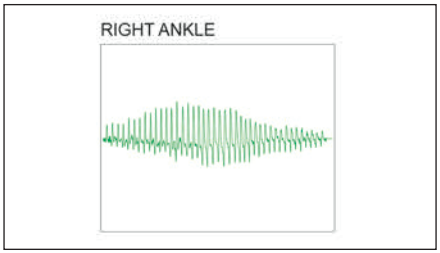
NOTE
The majority of the “Abnormally weak pulse” results describe the patients with ABPI around or lower than 0,5.

NOTE
If an “Abnormally weak pulse” message is displayed, it is recommended to repeat the measurement with the device connected to the computer using MESIresults software (see page 13). Such use will allow for an interpretation of full pulse waveforms (See example below).

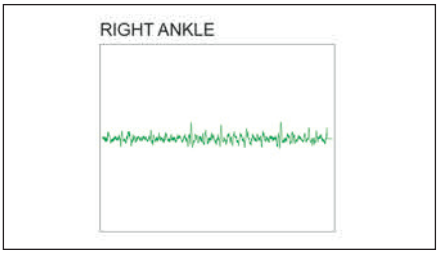
NOTE
In case of Medial Calcinosis, the arteries cannot be compressed due to stiff arterial walls. The measurement of Blood Pressure with cuffs is not possible, and therefore the ABPI cannot be reliable. The patient should be referred for a Toe Brachial Index measurement.

Pulse waveform example:

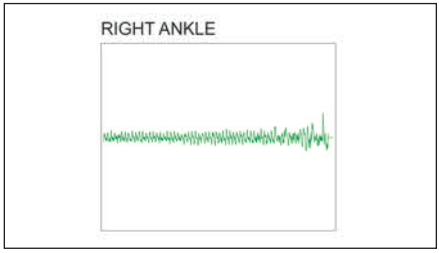
1. Normal pulse waveform example:



2. Severe PAD pulse waveform example:



3. Incompressible arteries pulse waveform example:



5.9.2 Simultaneous measurement

MESI ABPI MD utilizes a unique “simultaneous measurement”, where the cuffs are positioned on three limbs at the same time. The cuffs inflate and deflate simultaneously, in order to capture the blood pressure in all extremities in a specific moment.

NOTE
Simultaneous measurement with four cuffs instead of three would increase the risk for cardiac overload. (It not advisable to obstruct all four extremities at the same time.)

Three-cuff measurement is provided to allow safe simultaneous measurement of Ankle-Brachial Pressure Index.
Simultaneous measurement is essential for the accuracy of the ABPI, because it eliminates the measurement error due to the natural change in human blood pressure.

NOTE
For general population, performing a three-cuff measurement is sufficient. When a difference in the arm blood pressures is suspected, it is advised to place the arm cuff on the other arm and repeat the measurement. The result considered should be the lowest ABPI of the two.

NOTE
It is advised to perform the measurement on the right arm, due to lower incidence of subclavian stenosis.

NOTE
It is recommended that the patient sit still for at least 5 minutes before starting the measurement process.

NOTE
The person carrying out the measurement should remain by the patient's side at all times and closely monitor the measurement process.

NOTE
The measurement of the upper arm blood pressure can be affected by the placement of the cuff, the position of the patient and their physical condition. The functioning of the device can also be affected by high temperatures, humidity and altitudes.

NOTE
If the results of the upper arm blood pressure measurement is not as expected, repeat the measurement three times.

NOTE
Before attaching the cuff, remove any tight-fitting clothes or tightly rolled up sleeves on the upper arm. Do not place the cuff on top of thick clothing.

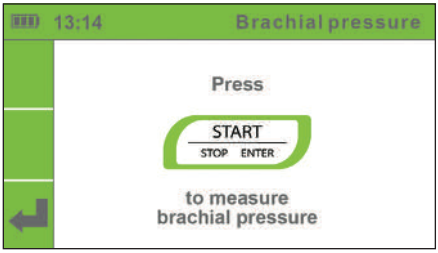
You can begin measuring the upper blood pressure when the cuff is correctly positioned on the sitting patient and when the connections have been checked and any potential air flow obstructions in the tubes have been eliminated.

During the measurement, the patient must be correctly seated so that:
- They are sitting on a chair with their feet resting flat on the floor.
- They are sitting upright, keeping a straight back.
- The cuff must be level with the patient's heart.

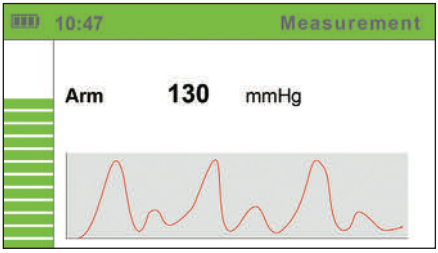
For details on the placement of the cuff, see Chapter 5.6 *Arm cuff*.

NOTE
In the independent blood pressure measurement mode, only place the arm cuff on the patient. The other cuffs must not be attached.

Turn the device on. The display will show the home menu. For upper arm blood pressure measurement, change the operating mode by pushing the BLOOD PRESSURE MEASUREMENT button. A menu will be displayed as in the image below.



To begin the measurement process, push the START button. During measurement, the screen displays the current pressure in the cuff and the pressure waveform graph. The left side of the screen displays a bar with a timer which displays the remaining measurement time.



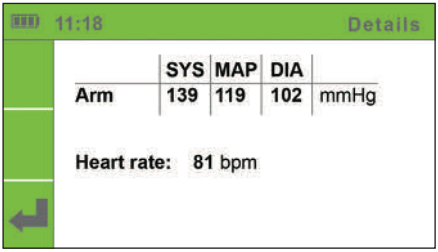
The device will determine the upper limit pressure for cuff inflation on the basis of the monitoring of the pressure dynamics during inflation. As pressure data is actively captured while the cuff is deflated, the patient must remain still. The measurement result processing begins when the cuff is deflated, i.e. when the screen displays the corresponding message.

You may now remove the cuffs. The patient may move freely now. The calculation of the measurement results takes a couple of seconds, while the entire measurement process including the calculation process takes approximately a minute.

After the calculation is completed, the device displays the upper arm blood pressure and heart rate on the screen.

For additional information on the measurement results, press the DETAILS button.

To display the pulse waveforms, press the PULSE WAVEFORM button.



NOTE
If the measurement process must be interrupted for any reason (e.g. the patient is not feeling well), push the START button immediately. The measurement process will be stopped and the cuff will be deflated. If the cuffs are not deflated despite the process being stopped, immediately disconnect the cuff tubes from the device.

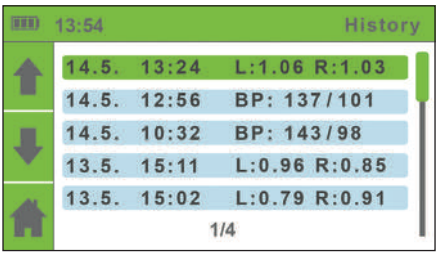
Measurement history 5.11

In the History menu, you can view the last measurements. To view the measurement history, push the HISTORY button .

▶ Use the UP and DOWN buttons to navigate through the measurement history and choose the measurement you wish to view.
▶ Push the ENTER button for details on the selected measurement.
▶ Push the BACK button to return to the history selection menu and the HOME button to return to the home screen.

The History menu stores the Ankle-Brachial Index and upper arm blood pressure measurements:

L: 1.06 **R:** 1.03 - ankle brachial pressure index measurements;
BP: 137/101 - upper arm blood pressure measurements.



NOTE
The Measurement History memory can store approximately 30 measurements. The oldest measurements are automatically deleted for each additional measurement.

5.12 Changing device settings

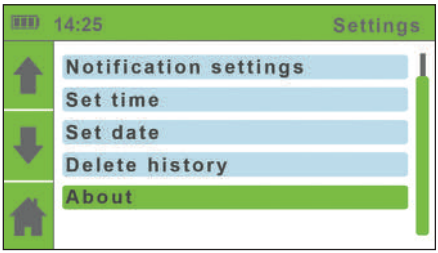
You can access the Settings menu from the home menu.

To change the settings of the device, push the SETTINGS button . The settings menu will be displayed.

▶ Use the UP and DOWN buttons to select a setting. The selected settings menu will turn green.

▶ Push the ENTER button to enter the selected menu. For descriptions of individual settings, see the chapters below.

▶ To return to the home screen, push the HOME button .

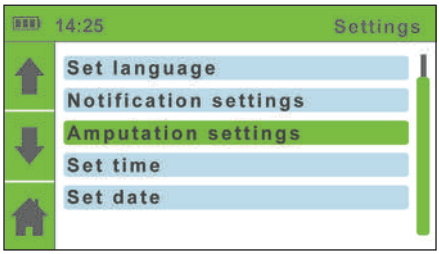


5.12.1 Amputation Settings

If the patient has an amputated leg or is not compliant for ABPI measurement due to a presence of severe and/or painful wounds, the ABPI can be measured only on patient's left or right leg.

Use the UP and DOWN buttons to select the amputation settings. Confirm your selection using the ENTER button. Select the leg that you will not be placing the cuff on. Confirm your selection using the ENTER button.

If you wish to return to the previous menu without confirming the changes, push the BACK button .

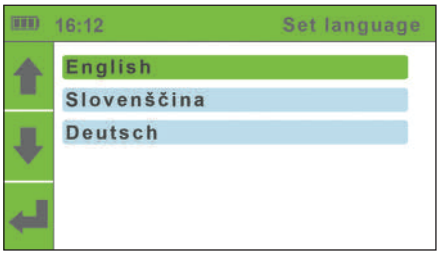


NOTE
Only one of the leg cuffs (either green - right, or yellow - left) should be used, when the amputation setting is selected.

Language settings

5.12.2

Use the UP ⬆ and DOWN ⬇ buttons to select the language. Confirm your selection using the ENTER button. The device language will be changed and you will return to the previous menu. If you wish to return to the previous menu without confirming the changes, push the BACK button ↵.



Time settings

5.12.3

Use the UP ⬆ and DOWN ⬇ buttons to navigate through the hour and minute settings. Confirm your selection using the START button.

The selected field will begin to flash. Use the UP ⬆ and DOWN ⬇ buttons to set a new value and confirm it using the BACK button ↵.

If necessary, repeat the process for the other fields. When you are finished setting the time, use the UP ⬆ and DOWN ⬇ buttons to move to the Confirm field and confirm your selection using the ENTER button.

If you do not wish to apply your settings, return to the previous menu by pushing the BACK button ↵.

Date settings

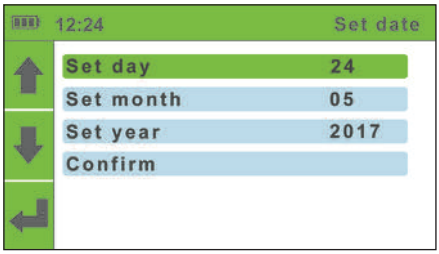
5.12.4

Use the UP ⬆ and DOWN ⬇ buttons to navigate through the day, month and year settings. Confirm your selection using the ENTER button.

The selected field will begin to flash. Use the UP ⬆ and DOWN ⬇ buttons to set a new value and confirm it using the BACK button ↵.

If necessary, repeat the process for the other fields. When you are finished setting the date, use the UP ⬆ and DOWN ⬇ buttons to move to the Confirm field and confirm your selection using the ENTER button.

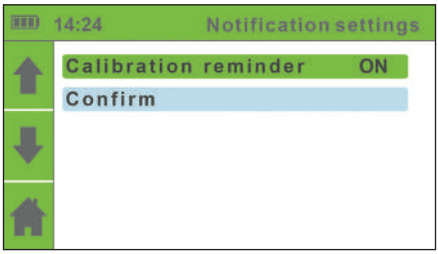
If you do not wish to apply your settings, return to the previous menu by pushing the BACK button ↵.



5.12.5 Notification settings

Push the ENTER button to turn the calibration reminder on or off.
When you are finished changing the setting, use the UP ⬆ and DOWN ⬇ buttons to move to the Confirm field and confirm your selection using the ENTER button.

If you do not wish to apply your settings, return to the previous menu by pushing the BACK button ↵.

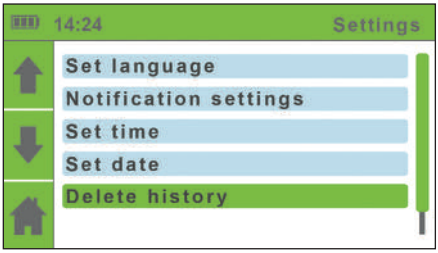


NOTE
Calibration reminder appears one year after first use. If date is not correctly set, reminder may not appear correctly.

5.12.6 Deleting history

Use the UP ⬆ and DOWN ⬇ buttons to move to the “Delete History” entry.

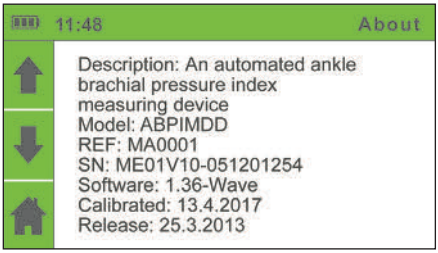
To delete the entire measurement history, push the ENTER button.



5.12.7 Device information

Use the UP ⬆ and DOWN ⬇ buttons to move to the “Device Information” entry and confirm your selection by pushing the ENTER button.

To return to the home screen, push the HOME button ⌂.



You can view information about the device (Description, Model, REF, SN), information on the software version (Software), the date of the last device calibration (Calibrated) and the issue date of the device (Issue), which denotes the date of manufacture of the device.

Error messages 5.13

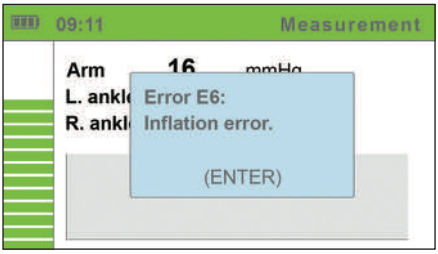
During measurement, the device can identify two types of errors:
▶ measurement errors (a warning is displayed during measurement and the measurement is stopped) and
▶ calculation errors (a warning is displayed along with the measurement results).

Measurement errors 5.13.1

A warning is displayed in the form of a blue pop-up window during the inflation and deflation of the cuffs.

The measurement is automatically stopped.

To return to the home screen, push the ENTER button.



Error	Description	Solution
ERROR 6	Inflation error.	Check the placement of the cuffs and repeat the measurement.
ERROR 7	Deflation too fast.	The cuff is not attached or is not attached correctly. Attach the cuff correctly and repeat the measurement.

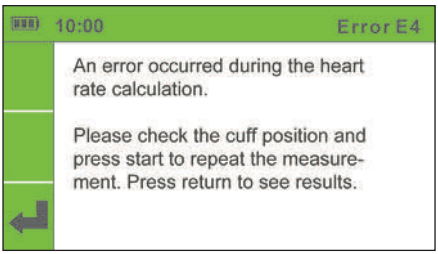
NOTE
If an ERROR message is displayed, it is recommended to repeat the measurement with the device connected to the computer using MESIresults software (See page 13). Such use will allow for an interpretation of full pulse waveforms.

Calculation errors 5.13.2

A warning appears in a separate window when the measurement results are displayed.

To view the measurement results, push the BACK button ↵.

The error identification number is displayed instead of the measurement results.



Error	Description	Solution
ERROR 2	An anomaly has been detected. The patient may have moved during the measurement process.	Remind the patient to remain still during measurement, and repeat the measurement.
ERROR 3	The cuff was insuficiently inflated.	Check the placement of the cuffs and repeat the measurement.
ERROR 4	An error occurred during heart rate calculation.	Repeat the measurement. If the error is repeated, the measured value is outside the measurement range of the device.
ERROR 5	An error occurred during Ankle-Brachial Pressure Index calculation.	Repeat the measurement. If the error is repeated, the measured value is outside the measurement range of the device.
ERROR 8	An error occurred during systolic pressure calculation.	Repeat the measurement. If the error is repeated, the measured value is outside the measurement range of the device.
ERROR 9	An error occurred during diastolic pressure calculation.	Repeat the measurement. If the error is repeated, the measured value is outside the measurement range of the device.
ERROR 10	An error occurred during mean pressure calculation.	Repeat the measurement. If the error is repeated, the measured value is outside the measurement range of the device.
ERROR 11	A large pressure fluctuation was detected. The patient may have moved.	The results may be incorrect. Repeat the measurement.

NOTE
For “Abnormally weak pulse” message, please see chapter 5.9.1 on page 27.

General warnings and precautionary measures

WARNING! Before using the device for the first time, read the instructions for use carefully and follow the recommendations.

WARNING! The MESI ABPI MD device users must be adequately educated to use the device. The education must be performed by the trained MESI representative. Before the first use of the device, users must read the entire instructions for use carefully and follow the instructions for the use of the connected equipment.

WARNING! It is mandatory to have the device calibrated once per year to ensure the correct functioning and accuracy. Contact your dealer or the manufacturer about calibrating the device.

WARNING! If the device is used or stored outside the specified temperature range and air humidity, the accuracy specified within the technical specifications of the device is not guaranteed.

WARNING! Do not use the device when it is wet. After cleaning the device with a damp cloth, wait for it to dry. Only use the device when it is completely dry.

WARNING! Do not dispose of the device as unsorted municipal waste. Prepare it for recycling or separate waste collection in accordance with Directive 2002/96/EC on scrap electrical and electronic equipment (WEEE).

WARNING! To prevent electric shock hazard due to leakage current, only use AC/DC power supplies which are compliant with the technical specifications of the device.

WARNING! Only use non-aggressive cleaning agents to clean the device. The device may be wiped with a damp cloth.

WARNING! Make sure that the device does not come into contact with an electrical current while it is being cleaned.

WARNING! The device may only be used by professional medical personnel. The device is class A equipment and can cause radio interference or even cause nearby devices to cease to function. It may be necessary to reposition the MESI ABPI MD or protect the room containing the device from electromagnetic radiation.

WARNING! Do not open the device. The device does not contain any parts which can be replaced by a user. Do not alter or adapt the device.

WARNING! Protect the device from moisture and liquids and extremely high/low temperatures. Also protect the device from mechanical stress and do not expose it to direct sunlight, as this can cause the device to not function properly.

WARNING! A twisted or bent tube can cause high pressure in the cuff, which may result in injury to the patient.

WARNING! Consecutively carrying out too many measurements may result in injury to the patient.

WARNING! Do not place the cuffs on wounds, as this may cause additional injury. Only place the cuffs on the upper arms and lower legs.

WARNING! Be carefull when folding the cuffs and tubes. Do not fold them too tightly.

WARNING! In case of the presence of intravenous cannulas or arteriovenous (AV) fistulas in the limbs, the cuffs and measurement can cause injury to the limb.

WARNING! If the patient has had breast surgery, do not place the arm cuff on the side which has been operated on.

WARNING! Do not use the device on a patient while they are connected to a vital sign monitor.

WARNING! Never carry out repairs of any kind yourself. If a defect occurs, consult your dealer or distributor.

WARNING! When moving the MESI ABPI MD stand, be sure to push the rack and not the device.

WARNING! Check the pressure in the cuff several times during measurement. If the cuff puts pressure on the limb for too long, it can impair the blood flow.

WARNING! The MESI ABPI MD is not intended for use in conjunction with high-frequency surgical equipment.

WARNING! The MESI ABPI MD is intended for Ankle-Brachial Pressure Index measurement. Upper arm blood pressure measurements are for informational purposes only.

WARNING! The AC/DC power supply must be connected to an easily accessible socket (the AC/DC power supply also serves for galvanic isolation).

WARNING! The MESI ABPI MD must not be used in an oxygen-rich environment.

WARNING! When repeating the Ankle-Brachial Pressure Index measurement or Blood Pressure measurement for several times a slight pain may appear at the measurement location. Other effects are excluded.

WARNING! The cables and accessories may negatively affect the EMC performance. The device while operated should not be stacked closer than 30cm from another medical device.

WARNING! Important information on electromagnetic compatibility (EMC). As the number of electronic devices such as computers and mobile phones in the room increases, medical devices can become sensitive to the electromagnetic influences of other devices. Electromagnetic interference can cause medical devices to malfunction, which can potentially lead to dangerous situations. Furthermore, medical devices must not interfere with other devices. The IEC/EN 60601-1-2 standard was introduced due to the necessity to establish electromagnetic compatibility (EMC) requirements for the prevention of dangerous situations in the use of medical devices. The standard defines the level of resistance to electromagnetic interference for medical devices. This medical device is compliant with the IEC/EN 60601-1-2 standard in terms of resistance to electromagnetic interference and electromagnetic emissions. Nevertheless, do not use mobile phones and similar devices which create strong electromagnetic fields in the vicinity of the device. This can cause the device to malfunction, which can potentially cause a dangerous situation.

Important labels 6.1

The symbols on the labels on the bottom of the device, the packaging and the instructions provide important information about the device. The symbols are described below.

	MANUFACTURER		TYPE BF APPLIED PART
REF	REFERENCE NUMBER	CE 1304	CE MARKING
SN	SERIAL NUMBER		WARNING
	SEE THE INSTRUCTIONS FOR USE		REFER TO INSTRUCTIONS FOR USE

6.2 Standard compliance

The provisions of the Council Directive 93/42/EEC concerning medical devices were complied with. The standards in the table below were complied with.

Reference mark (ID:year)	Description
EN 60601-1:2006+A1:2013	Electrical medical equipment – Part 1: General requirements for basic safety and essential performance
EN 60601-1-2:2015	Electrical medical equipment – Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic compatibility – Requirements and tests (IEC 60601-1-2:2007, modified)
EN 60601-1-6:2010+A1:2013	Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability
EN 80601-2-30:2010+A1:2015	Electrical medical equipment – Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
EN 60601-2-30:2000	Electrical medical equipment – Part 2-30: Particular requirements for the safety, including essential performance, of automatic cycling non-invasive blood pressure monitoring equipment
EN 1060-1:1995+A2:2009	Non-invasive sphygmomanometers. Part 1: General requirements
EN 1060-3:1997+A2:2009	Non-invasive sphygmomanometers – Part 3: Supplementary requirements for electromechanical blood pressure measuring systems
EN 1060-4:2004	Non-invasive sphygmomanometers – Part 4: Test procedures to determine the overall system accuracy of automated non- invasive sphygmomanometers
EN ISO 14971:2012	Medical devices – Application of risk management to medical devices
EN ISO 10993-1:2009	Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process
ISO 15223-1:2016	Symbols for use in the labelling of medical devices
EN ISO 13485:2016	Medical devices – Quality management systems Requirements for regulatory purposes
EN 62304:2006+A1:2015	Medical device software - Software life cycle processes

Maintenance

7

7.1 Charging the battery

If you wish to use the device on battery power, you must ensure that the battery is charged regularly. One battery charge is sufficient for approximately 50 measurements.

If the capacity of the battery is significantly decreased after a certain period of intensive use, the battery is most likely spent and you should replace it. As the device does not contain any parts which can be replaced by a user, you should contact your dealer or the manufacturer about replacing the battery.

7.2 Cleaning instructions

It's recommended to clean the device regularly with a soft, dry or damp cloth. Do not use aggresive cleaning agents, volatile liquids or excessive force when cleaning the device.

Do not wash the cuffs or immerse it in water. Also do not use petrol, thinners or similar solvents to clean the cuffs. To adequately clean the cuffs use a soft, moistened cloth and soap.

Recommendations for service and maintenance intervals 7.3

It is mandatory to calibrate the device once per year. Contact your dealer or the manufacturer about calibrating the device.

Product life and storage 7.4

If correctly used, maintained and regularly calibrated, the device will have a minimum service life of 5 years.
You can store the device in suitable conditions for a maximum of 5 years.

When using the device after storage, we recommend you to subject the device to a thorough maintenance check and calibrate it.

Protecting the cuffs 7.5

In case of open wounds, protect the wounds with adequate impermeable dressing prior to applying the cuffs. Use of protective sleeves is recommended.

NOTE! Do not wash the cuffs in a washing machine or iron them.

NOTE! In the event of mechanical stress, the device must be calibrated!

NOTE! In the event of contact with infected body fluids, the device should be cleaned with non-aggressive cleaning agents and the cuffs should be immediately replaced with new. To avoid replacing the cuffs, use the cuff protection paper.

NOTE! It is mandatory to have the device calibrated once per year to ensure the correct functioning and accuracy. Contact your dealer or the manufacturer about calibrating the device.

8 Troubleshooting

Issue	Possible cause	Possible solution
The device does not turn on, but the green light comes on.	The battery is empty.	Plug in the AC/DC power supply.
The cuffs do not inflate.	Possible air leakage.	Check the cuffs, the air tubes and the connectors and replace them if necessary. If you cannot fix the issue yourself, consult your dealer or the manufacturer.
Hissing noises.		
Unexpected result.		
Unexpected result.	Incorrect cuff placement.	Reread the instructions for use and place the cuffs correctly.
	Patient moving during measurement.	Repeat the measurement process.
	Wrong cuff size used.	Use cuffs of the correct size.
Audible stretching of the fastening tape.	Incorrect cuff placement.	Reread the instructions for use and place the cuffs correctly.
	Wrong cuff size used.	Use cuffs of the correct size.

Warranty information

A warranty period of three years applies to the device, starting from the date of purchase (delivery date shown on the invoice). Warranty claims will only be valid if accompanied by the purchase receipt.

More details about the warranty can be found in the warranty booklet attached to the given instructions for use.

For inquiries about servicing, contact:

Help and support	☎ +386 (0)1 620 34 87
	info@mesimedical.com

10 MESI ABPI MD stand

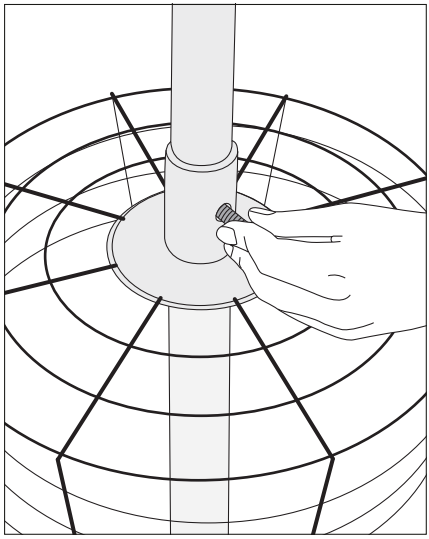
During measurement, the device must be placed on a flat and stable surface. The best option is to use the MESI ABPI MD stand, which ensures the best possible placement of the device in the clinic, as it can also be used for storing the device when it is on standby and for storing accessories (cuffs, AC/DC power supply).

The MESI ABPI MD stand ensures the mobility and stability of the device. The round basket is intended for the storage of accessories (cuffs, AC/DC power supply) and the flat surface on the top holds the device – the device is simply placed on the magnetic plate, which ensures its stability. A small amount of force is required to remove the device from the plate.

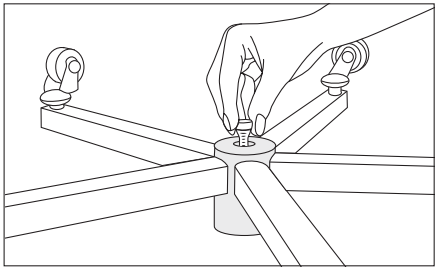
NOTE
Medium-intensive or intensive mechanical influences can lead to discontinuation of stable position of the stand. Device can damage after a fall.

10.1 Stand assembly

Insert the rod through the ring on the basket. Align the openings on the basket ring and the rod and secure the basket ring and the pipe together using screw A.



Insert the rod into the opening in the base. Use screw B to attach the rod to the base.



Using the stand 10.2

Place the MESI ABPI MD on the magnetic plate. The device will remain stable in this position. Place the cuffs and other accessories in the basket. Removing the device requires a small amount of force necessary to overcome the magnetic forces which keep the device in a stable position on the plate.

Clean the stand with a damp cloth or non-aggressive cleaning agents.

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MESI

Simplifying Diagnostics

INSTRUCTIONS **FOR USE**

automated ABPIMD

CE 1304

ISO 9001 Q-1664
ISO 13485 M-049

automated ABPIMD

1-minute Ankle-Brachial Pressure Index

Automated Ankle-Brachial Pressure Index measuring device (MESI ABPI MD) brings fast, accurate and objective screening for Peripheral Arterial Disease (PAD) to every doctor's office. In addition to the simultaneous measurement of Ankle-Brachial Index, it also enables measurement of brachial blood pressure and heart rate. It is intended for professional use in primary healthcare and specialist clinics as a screening method for the detection of PAD.