Ankle-brachial index and simultaneous dual arm measurement function for accurate office blood pressure measurement.

Instruction Manual
WatchBP Office ABI is a professional automatic office blood pressure measurement device which can determine the ankle brachial index (ABI) and inter arm difference (IAD) fast and accurately. The ABI is a measure for the assessment of peripheral arterial disease. The WatchBP Office ABI can perform automated dual-arm measurements for the most reliable IAD. In addition, the WatchBP office ABI can detect atrial fibrillation\textsuperscript{1,2} with high reliability. ABI, IAD and Afib are all important prognostic indicators for cardiovascular risk which make the WatchBP office ABI an important tool in the screening for cardiovascular risks.

\textsuperscript{1} Joseph Wiesel, Lorenzo Fitzig, Yehuda Herschman and Frank C. Messineo. Detection of Atrial Fibrillation Using a Modified Microlife Blood Pressure Monitor. \textit{American Journal of Hypertension} 2009, 22, 848–852.

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Product description

Name of parts
Display

Mean Arterial Pressure (MAP)

Pulse Pressure (PP)

Mode Indication

External Power

Atrial Fibrillation Detection

Rest and Arm Position Reminder

Supine Position Reminder

Battery Symbol

Hide Display

Memory Mode

ABI indicator and Pulse Rate

Heart Beat

L/R Cuff

Value for Left Arm

Systolic Value

Diastolic Value

Inter-arm Difference

Value for Right Arm

Systolic Value

Diastolic Value
WatchBP Office ABI, components and accessories

WatchBP Office ABI
Blood Pressure Device

AC Adaptor X1
(Input: 100-240V~50/60Hz 0.48A
Output: +7.5V 2A)

Cuff for upper arm
M size (22cm~32cm) X2
L size (32cm~42cm) X2

Serial Port Connecting Cable

Cuff for ankle
M size (22cm~32cm) X1

Instruction Manual X 1
Quick Start Guide X 1
Selective Cuffs for upper arm and ankle

For upper arm

M (Medium size, standard delivered)
22 - 32 cm (8.7 - 12.6 inches)
With air tube 130 cm

L (Large size, standard delivered)
32-42 cm (12.6-16.5 inches)
With air tube 130 cm

L-XL (Large to extra large size, to be ordered)
32-52 cm (12.6-20.5 inches)
With air tube 130 cm

For ankle

M (Medium size, standard delivered)
22 - 32 cm (8.7 - 12.6 inches)
With air tube 200 cm

L (Medium size, to be ordered)
32 - 42 cm (12.6 - 16.5 inches)
With air tube 200 cm

※ Please contact Microlife or its distributor to purchase L-XL size or other size cuffs.
Before using WatchBP Office ABI

Selecting the correct cuff
Two different sizes of cuffs for upper arms are provided with the WatchBP Office ABI: Medium and Large. Use the cuff marker to select the cuff size that best matches the circumference of the patient’s upper arm.

- **M (Medium size)**
  22 - 32 cm (8.7 - 12.6 inches)
  *With air tube 130 cm*

- **L (Large size)**
  32-42 cm (12.6 - 16.5 inches)
  *With air tube 130 cm*

Connect the cuff to the device by inserting the cuff connector into the cuff connector socket.

Fitting the cuff properly
1) Place the cuff over the left (or right) upper arm so that the air tube and artery mark arrow point toward the lower arm.
2) Lay the cuff on the arm. Make sure that the lower edge of the cuff lies approximately 2 to 3 cm ( ¾ to 1 inch) above the elbow.
3) Wrap and tighten the cuff around the arm.
4) Leave a little free space between the arm of the patient and the cuff. Two fingers should fit between the arm and the cuff. Clothing must not constrict the arm. Remove all clothing covering or constricting the measurement arm.
5) It may result in incorrect blood pressure readings if the cuffs are not fitted properly. Use a different size cuff if the range Index at the end of the cuff does not fall into the range specified by the range stripes.
6) Apply the same steps to the other arm if a double arm measurement is required.

* The range index of cuff should fall into this range.
Application of the ankle cuff (in ABI mode)

1) The patient has to lie down in supine position.
2) Place the ankle cuff on the leg. Make sure the edge of the ankle cuff lies approximately 2 to 3 cm (\( \frac{3}{4} \) to 1 inch) above the ankle and notice that the artery mark is on the posterior tibial artery.

3) Wrap and tighten the cuff around the leg.
4) Leave a little free space between the leg of the patient and the cuff. Two fingers should fit between the leg and the cuff.

posterior tibial artery.
Three operation modes

Select an operation mode
The WatchBP Office ABI device includes three operation modes: «ABI», «ROUTINE», and «SCREEN» (Inter-arm difference). Use the Mode Switch to select the desired mode.

«ABI» Mode
Select «ABI» Mode for Ankle-Brachial measurement. Select the arm with the higher blood pressure value as determined with the «SCREEN» Mode.
Three operation modes (cont.)

«ROUTINE» Mode
Select «ROUTINE» Mode to perform automated duplicate measurements on the preferred arm for prompt and accurate office measurements.

Automated triple measurements
In «ROUTINE» Mode, the WatchBP Office ABI device automatically takes three consecutive measurements at 15 second intervals on default. The readings of these three measurements are averaged to produce the routine visit blood pressure measurement.

* The user can manually set measurement intervals of 15, 30, 45 or 60 seconds in ROUTINE Mode. (Please refer to special functions section page 19 “Setting measurement intervals”)

ESH Protocol Embedded
AHA Protocol Embedded
ABI ROUTINE SCREEN
«SCREEN» Mode
Select «SCREEN» Mode to complete fully-automated triple measurements on both arms according to recommended ESH/AHA blood pressure measurement protocols for a patient’s first office visit.

Simultaneous dual-arm measurements
In «SCREEN» Mode, the WatchBP Office ABI device measures the patient’s blood pressure on both arms simultaneously, which helps to determine the arm with the highest blood pressure value and reveals other potential cardiovascular risks.
Automated triple measurements

In «SCREEN» Mode, the WatchBP Office ABI device automatically takes three consecutive measurements on both arms at fixed one minute* intervals. The results of these three measurements are then averaged to conclude the blood pressure measurement.

The measuring intervals are fixed at one minute in SCREEN mode.

The arm with the higher blood pressure value should be taken for ABI measurement or future blood pressure measurements.

Determine the proper arm and inter-arm difference

If the difference of blood pressure readings between two arms is more than 20mmHg for Systolic or 10mmHg for Diastolic at all three measurements, the device indicates the arm with the higher blood pressure value by displaying L or R and the “IAD” icon. The “IAD” icon and readings of the higher arm flash to indicate that more attention is needed.
Taking measurements using WatchBP Office ABI

«SCREEN» Mode

1) **Turn on the power** – Turn on the device by switching the I/O switch at the back of the device to the ON position.

2) **Apply the cuff** – Properly fit one cuff to each of the patient’s arms.

3) **Switch to «SCREEN» Mode** – Slide the Mode Switch to «SCREEN» Mode.

4) **Inflation by fuzzy logic** – The device will adjust inflation pressure by fuzzy logic technology.

* Additional visual instruction can be found on the cuff
5) **Start measurements** – Press the Start/Stop Button to start the measurement sequence.

   ∗ A 60-second countdown will proceed the first measurement.

6) **Three consecutive measurements** – The device will take three consecutive measurements with one minute intervals between measurements.

7) **The average value of the measurements** – The average value will be displayed after the measurements. If one of the three measurements failed, a fourth measurement will be conducted.

   ∗ If the third measurements are cancelled by pressing the Start/Stop after the second measurement, the averages are calculated and saved to the memory as well.

   ∗ Please refer to special functions section page 18 “Taking less than three measurements”
**«ROUTINE» Mode**

1) **Turn on the power** – Turn on the device by switching the I/O switch at the back of the device to the ON position.

2) **Apply the cuff** – Properly fit one cuff to the preferred measurement arm.

3) **Switch to «ROUTINE» Mode** – Slide the Mode Switch to «ROUTINE» Mode.

4) **Select the inflation cuff** – Set the device to the preferred measurement side (left or right). Press and hold the M Button for 3 seconds.

* Additional visual instruction can be found on the cuff
5) Press the M Button to switch between left(L) and right(R). Press the Start/Stop Button to save the setting.

6) **Start measurements** – Press the Start/Stop Button to start the measurements.

7) **Three consecutive measurements** – The device will take three consecutive measurements with 15 second intervals in between on default.

8) **Inflation by fuzzy logic** – The device will adjust inflation pressure by fuzzy logic technology.

9) **The average value of the measurements** – The average values will be displayed when the measurements are completed and will be saved to the memory automatically.

※ The user can manually set the measurement intervals of 15, 30, 45 or 60 seconds in ROUTINE Mode. (Please refer to special functions section page 19 “Setting up measurement intervals”)

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Taking measurements using WatchBP Office ABI (cont.)
**Skipping the countdown time**
The 60 seconds countdown before measurement in «SCREEN» Mode and 15 seconds in «ROUTINE» Mode can be skipped by pushing the Start/Stop Button. While the Start/Stop Button is pushed, the device will immediately begin the next measurement.

![Skip the countdown time and begin measurement.](image)

* The device can be set into Stand-by Mode by pressing the Start/Stop Button after the completion of measurements. The device will automatically switch to Stand-by Mode if left unattended for five minutes.

![Stand by mode](image)

**Taking less than three measurements**
The measurement sequence can be stopped at anytime by pushing the Start/Stop Button in «SCREEN» or «ROUTINE» Mode. The device enters stand-by and the remaining measurements are cancelled. Average of the measurements is saved and can be viewed by pushing the M Button.

![Cancel remaining measurements at anytime during the measurement sequence.](image)
Taking measurements using WatchBP Office ABI (cont.)

Setting measuring intervals in «ROUTINE» Mode

1) Pressing and holding the Start/Stop Button for 3 seconds.

   Press and hold for 3 seconds...

2) Press the M Button to adjust the measurement interval, then press the Start/Stop Button to confirm, the device will go back to stand-by Mode.

   Press and hold for 3 seconds...

   15 30
   45 60

   * The default measuring interval is 15 seconds. The interval can be set as 15, 30, 45 or 60 seconds.
«ABI» Mode

1) **Turn on the power** – Turn on the device by switching the I/O switch at the back of the device into the ON position.

2) **Switch to «ABI» Mode** – Slide the Mode Switch to «ABI» Mode. The supine position reminder will display.

3) The patient has to lie down in supine position.

4) **Apply the cuff*** – Properly fit the arm cuff to the upper arm and the ankle cuff to the leg of the preferred measurement side of the body. The preferred side is determined in «SCREEN» Mode.

5) Make sure the upper arm cuff is connected to the left cuff socket and the ankle cuff is connected to the right cuff socket.

* Additional visual instruction can be found on the cuff.
Taking measurements using WatchBP Office ABI (cont.)

6) **Start measurements** – Press the Start/Stop Button to start the measurement.

7) **Inflation by fuzzy logic** – The device will adjust inflation pressure automatically by fuzzy logic technology.

8) **Display of the measurement values** – The measurement values will be displayed and the Ankle-brachial index is automatically calculated when the measurement is completed. The Ankle-brachial index and the blood pressure value display first, the brachial index value is replaced by the pulse value for 3 seconds. All the values are saved automatically.

※ There is only one set of memory capacity in the device. Only the last measurements will be saved in the memory.
※ The memory will be deleted when the power is turned off.
Special Functions

Hiding measurement values
The WatchBP Office ABI device features a Hide function in order to prevent unnecessary elevated blood pressure in patients due to nervousness triggered by visible blood pressure values.

1) Activate the «Hide» Function – Press M button; L or R flashes; keep pressing and holding the M Button for 7 more seconds until On or Off flashes.

2) Select ON or OFF – Press the M Button again to turn the “Hide” function ON or OFF.

3) Confirm – Press Start/Stop to confirm the setting.

* This feature is available in both SCREEN mode and ROUTINE mode.
* When the «Hide» function is ON, only the average values are displayed after the consecutive measurements and the Hide icon is displayed.

* The default setting of “Hide” is set at “ON” in both «SCREEN» Mode and «ROUTINE». 
Special Function (cont.)

MAP (Mean Arterial Pressure)
The WatchBP Office ABI device measures the true mean arterial pressure (MAP) of the patient. Each measurement includes a single MAP value. The average measurement will display the average MAP value. When viewing in Memory mode, the MAP value will be displayed with the systolic and diastolic pressure once every 5 seconds.

PP (Pulse Pressure)
The WatchBP Office ABI device provides the pulse pressure (PP) of the patient: pulse pressure = systolic - diastolic pressure. Each measurement includes the calculation of a single PP value. The average measurement will display the average PP value. When viewing in Memory mode, the PP value will be displayed with the systolic/diastolic pressure once every 5 seconds.

* The Mean Arterial Pressure (MAP) in this device is determined from the maximum peak of the oscillometric envelope curve.
Appearance of the atrial fibrillation indicator for early detection
The WatchBP Office ABI is designed to detect asymptomatic atrial fibrillation during blood pressure measurements in the «SCREEN» and «ROUTINE» Mode. If two out of three measurements detect atrial fibrillation, the Afib icon is displayed. This device is able to detect atrial fibrillation with high accuracy: a sensitivity of 97% and a specificity of 89%.* If the atrial fibrillation icon is displayed after the measurement, it is recommended to visit a doctor.


* This device detects atrial fibrillation, a major cause of stroke. Not all risk factors for stroke, including atrial flutter, may be detected by this device.

* This device may not detect atrial fibrillation in people with pacemakers or defibrillators.
About Atrial Fibrillation

Atrial fibrillation is a common heart rhythm problem. It affects more than 2 million people in North America. It is more common in older age and it is found in 18% individuals aged 85 years and older. It is a common cause of major strokes. About 15% of all strokes are caused by atrial fibrillation. The elderly, or those with high blood pressure, diabetes or heart disease are more likely to get a stroke if they have atrial fibrillation.

Atrial fibrillation is a rhythm problem that can last from a few minutes, to days or weeks and even years. Atrial fibrillation can cause blood clots in the upper chambers of the heart (the atria). These clots can break off and flow to the brain causing a stroke.

The use of blood thinners, such as warfarin, can lower the risk of a stroke in patients with atrial fibrillation.

A doctor can confirm the presence of Afib by using an ECG. Sometimes Afib is present incidentally. Therefore, a doctor may not see it on regularly scheduled visits.

One method of detecting Afib is by mean of palpations. This method is not very reliable. Failure of detecting Afib may lead to the occurrence of a stroke in the end; whereas early detection may lead to early treatment that can significantly reduce the chances of a stroke.
**ABI (Ankle Brachial Index)**

The systolic blood pressure values of a person’s arm and leg need to be measured in order to determine ABI (Ankle Brachial Index).

The ankle-brachial index (ABI) is then calculated using the quotient of the systolic pressure from the leg measurement and the systolic pressure from the arm measurement.

A low ankle-brachial index (ABI) is indicative of systemic vascular disease, and should place a patient in the high-risk category.
Viewing and transferring measurement readings

«ROUTINE» and «SCREEN» Mode

1) **Switch the mode switch** – The M Button can be pressed in either the «ROUTINE» or «SCREEN» mode to retrieve the last set of readings from the measurements.

2) **Viewing the average of all measurements** – At first an “A” will be displayed, followed by an average of all measurements taken in the last sequence of measurements.

3) **Viewing MAP and PP values** – Ten seconds after the display of the average blood pressure, the device will display values for Pulse Pressure (PP) and Mean Arterial Pressure (MAP).

4) **Viewing individual measurements** – Press the M Button once again to view individual measurements. The display will flash a number “3” indicating the third measurement.
5) Values of the third measurement (including PP and MAP values) will be displayed in the order listed in step 3.

6) Press the M Button to retrieve values for second and first measurements from the last completed set of measurements.

«ABI» Mode

1) **Switch the mode switch** – Select the slide switch to «ABI» Mode then press M button to retrieve the last sets readings of the measurements.

2) **Viewing the Ankle-brachial index (ABI)**
   At first the INDEX icon, the ABI and the blood pressure values will be displayed.

3) **Viewing MAP and PP values** –
   Ten seconds after the display of the ABI, the values of Pulse Pressure (PP) and Mean Arterial Pressure (MAP) will be displayed.
Transferring measurements

Installation of the software program

1) Put the CD in the CD-ROM drive of your computer or click on «setup.exe» in the CD’s directory alternatively.

2) Follow the instructions provided in the installation window on the computer screen.

3) When installation is finished, be sure to restart the computer before you start working with the program.

Transferring data to the computer

1) Start the software program and connect the device to the computer using the cable supplied.

2) A successful connection is displayed by «Connected» on the computer screen.

3) Enter identity number, Patient Name and Surname to create a new record.

※ System Requirements:
550MHz CPU. 256MB Memory, 1024x768 pixel resolution, 256 color, CD-ROM drive, 1 free USB port, 40MB free hard disk space, Microsoft Windows 7/8/10.
**Software commands**

<table>
<thead>
<tr>
<th>Command</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Perform a measurement</td>
<td>Click «Measure»</td>
</tr>
<tr>
<td>Stop a measurement</td>
<td>Click «Stop»</td>
</tr>
<tr>
<td>Store data</td>
<td>Click «Save»</td>
</tr>
<tr>
<td>Close</td>
<td>Click «Close»</td>
</tr>
</tbody>
</table>

*Please read the software manual to know more details of the software operation commands.*
Appendix

Rechargeable Battery
WatchBP Office ABI equips with a built-in, rechargeable Ni-MH battery pack which delivers up to 400~500 measurement cycles. The batteries can be recharged while the power adaptor is plugged in. It doesn’t affect the measurement.

Using a power adaptor
Please only use the Microlife adaptor supplied with the WatchBP Office ABI to recharge the device.
1) Plug the adapter cable into the Power Plug of the WatchBP Office ABI device.
2) Plug the adaptor plug into the wall socket. When the power adaptor is connected, no battery power is consumed.

*A First time use, charge the batteries until the recharge indicator turns to green
*A An orange recharge indicator means recharge in progress.
*A A green recharge indicator means recharge is completed.
## Troubleshooting

<table>
<thead>
<tr>
<th>Problem</th>
<th>Possible cause</th>
<th>How to make correction</th>
</tr>
</thead>
<tbody>
<tr>
<td>No power (No LCD display)</td>
<td>Power supply is not properly plugged in</td>
<td>Plug power supply into wall socket.</td>
</tr>
<tr>
<td></td>
<td>Battery is fully discharged</td>
<td>Recharge the rechargeable battery by plugging in the power supply.</td>
</tr>
<tr>
<td>Cuff does not inflate properly</td>
<td>Loose connection of the tube</td>
<td>Make sure the tube of the cuff is securely connected to the device.</td>
</tr>
<tr>
<td></td>
<td>Leakage of the tube or bladder</td>
<td>Check for cracks on the tube or the bladder. Please contact Microlife customer service for this issue.</td>
</tr>
<tr>
<td>No result displayed between measures</td>
<td>The Hide function is activated</td>
<td>Disable “hide” function, or use «ROUTINE» mode to measure the blood pressure.</td>
</tr>
</tbody>
</table>
If an error occurs during measurement, the measurement is interrupted and an error message «Err» is displayed.

- Please contact your local Microlife service center if the error persists.
- If you think the results are unusual, please read through the information in this instruction manual carefully.

<table>
<thead>
<tr>
<th>Error</th>
<th>Description</th>
<th>Potential cause and remedy</th>
</tr>
</thead>
<tbody>
<tr>
<td>«Err 1»</td>
<td>Signal too weak</td>
<td>The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.</td>
</tr>
<tr>
<td>«Err 2»</td>
<td>Error signal</td>
<td>During the measurement, error signals were detected by the cuff, caused for instance by movement or muscle tension. Repeat the measurement, keeping your arm still.</td>
</tr>
<tr>
<td>«Err 3»</td>
<td>No pressure in the cuff</td>
<td>An adequate pressure cannot be generated in the cuff. A leak may have occurred. Replace the batteries if necessary. Repeat the measurement.</td>
</tr>
<tr>
<td>----------</td>
<td>-------------------------</td>
<td>---------------------------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>«Err 5»</td>
<td>Abnormal result</td>
<td>The measuring signals are inaccurate and no result can therefore be displayed. Read through the checklist for performing reliable measurements and then repeat the measurement.</td>
</tr>
<tr>
<td>«HI»</td>
<td>Pulse or cuff pressure too high</td>
<td>The pressure in the cuff is too high (over 300 mmHg) OR the pulse is too high (over 200 beats per minute). Relax for 5 minutes and repeat the measurement.</td>
</tr>
<tr>
<td>«LO»</td>
<td>Pulse too low</td>
<td>The pulse is too low (less than 40 beats per minute). Repeat the measurement.</td>
</tr>
</tbody>
</table>
Safety, care, accuracy test and disposal

Safety and protection
This device may be used only for the purpose described in this booklet. The device comprises of sensitive components and must be treated with caution. The manufacturer cannot be held liable for damage caused by incorrect application.

- Ensure that children do not use the device unsupervised; some parts are small enough to be swallowed.
- Only activate the pump when cuff is installed.
- Do not use the device if you think it is damaged or if anything appears unusual.
- Read the further safety instructions in the individual sections of the instruction manual.
- Do not connect the device to a computer until prompted to do so by the computer software.

Observe the storage and operating conditions described in the “Technical specifications” section of this manual.

- Protect the device from water and moisture
- Protect the device from direct sunlight
- Protect the device from extreme heat and cold
- Avoid proximity to electromagnetic fields, such as those produced by mobile phones
- Never open device
- Protect device from impact and drops
Device care
Clean the device with a soft, dry cloth.

Accuracy test
We recommend the WatchBP Office ABI device be tested for accuracy every 2 years or after mechanical impact (e.g. being dropped). Please contact Microlife to arrange for an accuracy test.

Cleaning the cuff
Take out the bladder. Fold and place the cuff cover inside a washing bag. Wash cuff cover with warm water and a mild detergent in washing machine. Air dry the cuff. DO NOT iron the cuff cover.

Disposal
Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, and not as domestic waste.
## Technical specifications

**Operation temperature/humidity:**
- 10 to 40 °C (50 to 104 °F)

**Storage temperature/humidity:**
- -20 to 55 °C (-4 to 131 °F)
- 15 - 90 % relative maximum humidity

**Weight:**
- 1100 g (including rechargeable battery pack)

**Dimensions:**
- 200 x 125 x 90 mm

**Measuring method:**
- Oscillometric, corresponding to Korotkoff

**Measurement range:**
- 30 - 280 mmHg – blood pressure
- 40 - 200 beats per minute – pulse

**Cuff pressure display:**
- Range: 0 - 299 mmHg
- Resolution: 1 mmHg
- Static accuracy: pressure within ± 3 mmHg
- Pulse accuracy: ±5 % of the readout value

**Voltage source:**
- Rechargeable battery pack; 4.8V C3500 mAh
- Mains adapter DC 7.5V, 2 A

**Reference to Standards:**
- Device corresponds to the requirements of the standard for non-invasive blood pressure monitor.
  - EN 1060-1
  - EN 1060-3
  - EN 1060-4
  - IEC 60601-1
  - IEC 60601-1-2

**Electromagnetic compatibility:**
- Device fulfills the stipulations of the standard IEC 60601-1-2.
- The stipulations of the EU Directive 93/42/EEC for Medical Devices Class IIa have been fulfilled.

**CE 0044**

Type BF applied part

Microlife reserves the right to alter technical specifications without prior written notice.
This device is covered by a two-year guarantee and accessories are covered by a one-year guarantee from the date of purchase. This guarantee is valid only on presentation of the guarantee card completed by the owner confirming date of purchase or purchase receipt.

**Product:** WatchBP Office ABI

**Product Number:** TWIN200 ABI

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**Name:**

**Address:**

**Date:**

**Telephone:**

**E-mail:**
Read the instructions carefully before using this device.

Caution: Federal law restricts this device to sale by or on the order of a physician.