

ESH
Protocol Embedded

AHA
Protocol Embedded

WatchBP[®] home **A** BT

**Accurate home blood pressure
measurements
with the WatchBP Home A BT.**

Instruction Manual

EN → 3



microlife[®]

Microlife WatchBP Home A is the world's first digital blood pressure measurement device that strictly follows European Society of Hypertension (ESH)^{1,2} and American Heart Association (AHA) recommendations for home blood pressure measurement. Using the WatchBP Home A device helps you collect accurate home blood pressure measurements your doctor can trust. This WatchBP Home A device has been clinically validated according to the ESH protocol³.

WatchBP Home A BT is the same WatchBP Home A with Bluetooth (BT) capability.

Intended use

The WatchBP Home A BT is a non-invasive digital blood pressure device using oscillometric technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures, pulse rate. The device detects the appearance of atrial fibrillation during measurement and gives a warning signal with the reading once the atrial fibrillation is detected. The device has Bluetooth capability. The memory data can be transferred to the Bluetooth enable phone by connecting wirelessly.

¹ O'Brien E, Asmar R, Beilin L, Imai Y, et al. European Society of Hypertension recommendations for conventional, ambulatory and home blood pressure measurement. European Society of Hypertension Working Group on Blood Pressure Monitoring. *J Hypertens* 2003;21:821-848.

² Stergiou GS, et al. A tool for reliable self-home blood pressure monitoring designed according to the European Society of Hypertension recommendations: The Microlife WatchBP Home monitor. *Blood press Monit.* 2007;12:127-131.

³ Stergiou GS, Giovas PP, Gkinos CP, Patouras JD. Validation of the Microlife WatchBP Home device for self home blood pressure measurement according to The International Protocol. *Blood Press Monit.* 2007;12(3):185-188.

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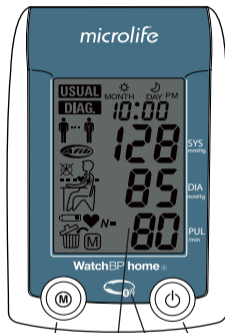
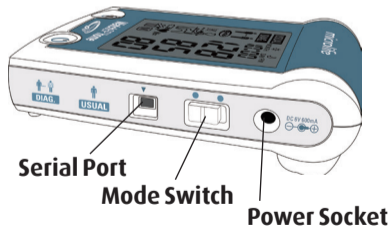
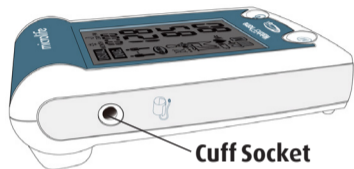
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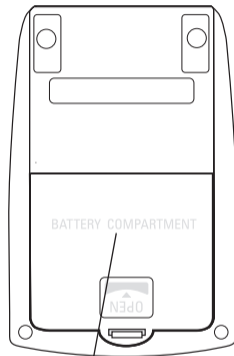


Display

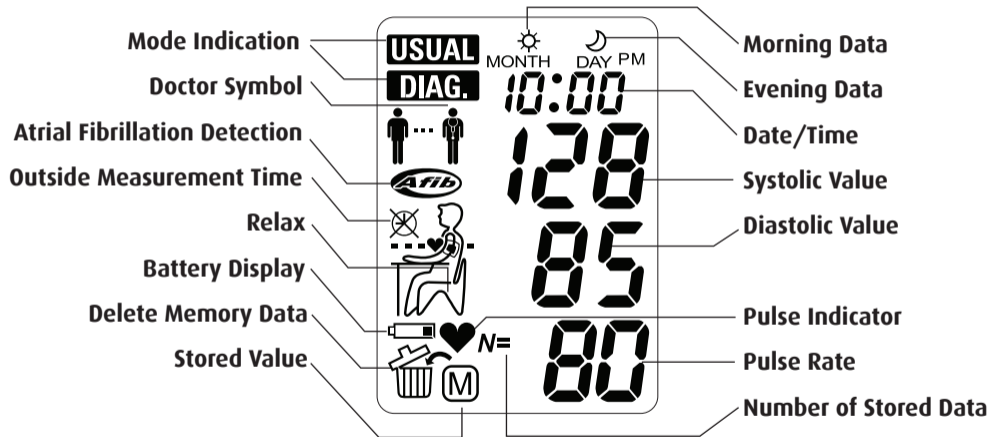
ON/OFF Button

Bluetooth symbol

M Button (Memory)



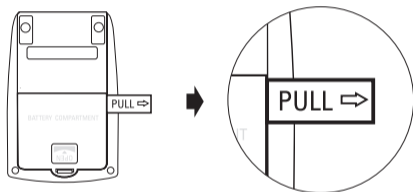
Battery Compartment



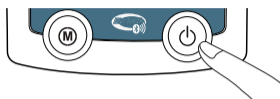
Before using WatchBP Home A BT for the first time

Activating the Device

Pull out the protective strip from the battery compartment.



1) **Set the year** – Upon removing the protective strip or installing new batteries, the Year number flashes in the display. Use the M Button to select the Year. Press the ON/OFF Button to confirm your selection.



*Press M Button to make selection
Press ON/OFF Button to confirm*



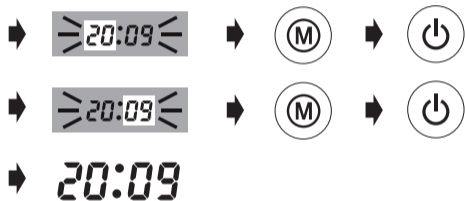
2) **Set the month** – Press the M Button to set the Month. Press the ON/OFF Button to confirm.



3) **Set the day** – Press the M Button to set the Day. Press the ON/OFF Button to confirm.



4) **Set the time** – Once you have set the Hour and Minutes and pressed the ON/OFF Button, the date and time are set, and the current time is displayed.

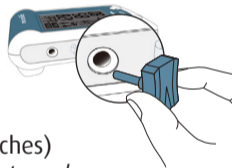


5) If you want to change the date and time, take out one battery from the battery compartment briefly and put it back. The Year number will flash. Complete the process as described above.

Selecting the correct cuff

The WatchBP Home A BT device is available with different cuff sizes. If the cuff provided with the device is an unsuitable size, please consult your doctor.

❖ *please use only Microlife cuffs!*



M (Medium size)

22 - 32 cm (8.7 - 12.6 inches)

M is the correct size for most people.



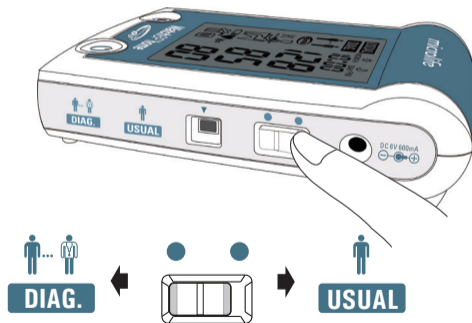
L (Large size)

32 - 42 cm (12.6 - 16.5 inches)

Taking measurements using WatchBP Home A BT

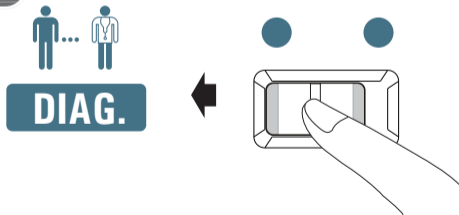
Prior to each measurement, use the Mode Switch on the right side of the device to select the proper measurement mode. The two options include:

«**DIAG.**» (Diagnostic) or «**USUAL**» (Usual) mode.



«**DIAG.**» Mode

The «**DIAG.**» mode should be selected as requested by your doctor when blood pressure is measured in accordance with the measurement guidelines of the European Society of Hypertension (ESH).



No measurements on non-work days

In «**DIAG.**» mode, blood pressure measurements are taken **on 7 consecutive working days** (or normal week days). **No readings should be taken on «non-working» days** (or particularly relaxing days) in this mode!



7 working days

Two sets of measurements per day

ESH guidelines recommend one double measurement taken in the morning between 06:00 - 09:00 and one in the evening between 18:00 - 21:00. **Always perform measurements before taking your medication, unless otherwise directed by your doctor.**



ESH Guidelines

Taking measurements using WatchBP Home A BT (cont.)

Extended measurement period

WatchBP Home A BT has an extended measurement period and allows morning measurements between 04:00 - 12:00 and evening measurements between 18:00 - 24:00.



Extended Time



Outside these times, measurements cannot be taken and the symbol on the right will be displayed on the screen.

Evaluation

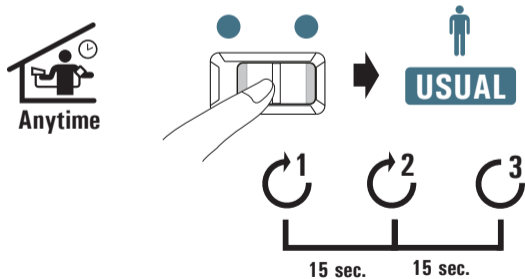
After measurements have been carried out for a total of 7 working days, take the device to your doctor for evaluation of your home blood pressure data.



When measurements have been carried out for the full 7 days, the doctor symbol will flash on the screen.

«USUAL» Mode

The «**USUAL**» mode is selected for regular blood pressure measurement with Afib detection. In «**USUAL**» mode, three consecutive measurements are taken automatically at 15 second intervals. The results are averaged and displayed. The averaged readings are automatically stored for later evaluation by your doctor.



250 measurements safely stored

The WatchBP Home A BT device can store up to 250 averaged measurement readings in «**USUAL**» mode.



- ❖ When memory is full, each new reading will automatically overwrite the earliest measurement.
- ❖ To review the last three individual measurements, press and hold the M button until a "1" is displayed on the screen. The values of the last three individual measurements are displayed sequentially.

Eight steps for measure blood pressure properly

Step 1

Avoid taking measurements directly after eating, drinking or smoking. Allow at least one hour between these activities and measurement of your blood pressure.



1 Hour Before



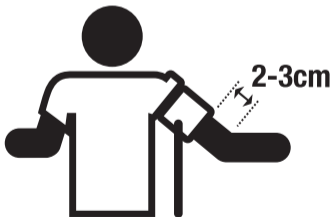
Step 2

Prepare a chair and table for the measurement. The chair should have a vertical back-rest and the table should allow your upper arm to rest at the same height as your heart.



Step 3

Remove all clothing covering or constricting the arm to be measured. Apply the cuff. Make sure the lower edge of the cuff is exactly 2–3cm from the inner fold of your arm. The tube connecting the cuff to the device should be placed on the inside of the arm. *(Additional visual instruction can be found on the cuff)*



Step 4

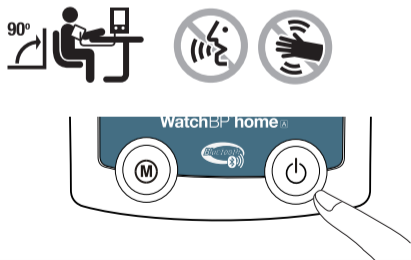
Sit down and relax for at least five minutes prior to the measurement.



Eight steps for measure blood pressure properly (cont.)

Step 5

Sit upright and lean comfortably against the chair's backrest. Press the start button. The device will initiate a 60-second countdown in «**DIAG.**» mode or a 15-second countdown in «**USUAL**» mode. During the measurement do not move, cross your legs, or tense your arm muscles. Breathe normally and do not talk.



Step 6 (in «**DIAG.**» mode)

One measurement cycle includes two measurements. Once the first measurement is complete, continue to relax as you wait for the second measurement. The second measurement will start after 60-seconds. During this time avoid any movement.



Step 7 (in «DIAG.» mode)

Once the two readings are complete, measurement data is automatically stored for future reference by your doctor. If an error displays after the readings, please repeat the first six steps once again.



Automatically stored


Step 8 (in «DIAG.» mode)

When seven days of measurements have been collected, the Doctor Symbol will flash on the display. Do not forget to take your WatchBP Home A BT device with you on your next visit to the doctor. (*Note: the doctor symbol is only displayed for measurements in «DIAG.» Mode.*)



Special Function

Atrial fibrillation detection

This device is designed to screen for atrial fibrillation during blood pressure measurements both in «**USUAL**» Mode and «**DIAG.**» Mode. If atrial fibrillation is detected during all readings of the triple measurements in usual mode or all four readings of one day in diagnostic mode, the Afib icon  is displayed. If the Afib icon is displayed after a blood pressure measurement follow the instructions on page 21.

❖ *Joseph Wiesel, et al. Detection of Atrial Fibrillation Using a Modified Microlife Blood Pressure Monitor. American Journal of Hypertension 2009; 22, 8, 848-852.*



- ❖ *Atrial fibrillation, a major cause of stroke can be detected by this device. However, 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. People with pacemakers or defibrillators should therefore not use this device to detect atrial fibrillation.*

About Atrial Fibrillation

Atrial fibrillation is a common heart rhythm problem and a common cause of major strokes. It affects more than 2 million people in North America. It is more common in old age and found in 10% of people over 80 years old. About 20% 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 lead to the formation of blood clots in the upper chambers of the heart (the atria). These clots can break off and flow to the brain causing stroke. The use of blood thinners, such as warfarin , can lower the risk of stroke in patients with atrial fibrillation.

A doctor can confirm the presence of atrial fibrillation by using an EKG. Atrial fibrillation can sometimes come and go. So a doctor may not see its symptoms on regularly scheduled visits.

One sign of atrial fibrillation is palpitations. But, many people don't feel anything. These people can still get a stroke and should be checked for atrial fibrillation regularly. Diagnosing atrial fibrillation earlier and followed by treatment can lower the chances of getting a stroke.

Atrial Fibrillation Detector

The WatchBP home A can screen for atrial fibrillation during blood pressure measurement.

Some people may have atrial fibrillation occasionally that lasts longer than a day. In this situation the WatchBP Home A allows frequent screening on multiple days for optimal diagnosis of atrial fibrillation.

Sometimes the device might falsely detect atrial fibrillation which can have two causes:

- 1) The arm has moved during blood pressure measurement. For this reason it is of essential importance that the arm is kept still during the measurement.
- 2) Some arrhythmia (irregular heart beat) other than atrial fibrillation might be present. In such a case it is still recommended to pay a visit to the doctor.

For people with pacemakers or defibrillators it is not recommended to use the WatchBP Home A for diagnosing atrial fibrillation.

Measurement

If atrial fibrillation is detected during all readings of the triple measurements in «**USUAL**» Mode or all four readings of one day in «**DIAG.**» Mode then atrial fibrillation is most likely present.

Since atrial fibrillation sometimes lasts for only a few minutes. It is recommended to perform another measurement session one hour later. If this also shows the presence of atrial fibrillation then a doctor should be seen. It is recommended to take the device when visiting the doctor.

Atrial fibrillation detection instructions

- Use this device regularly, once per week, or once per month to screen for atrial fibrillation.
- If atrial fibrillation is detected during all readings of the triple measurements, another measurement session should be done approximately one hour later.
- If this last reading shows atrial fibrillation contact your doctor.
- Take this device with you when you see the doctor.

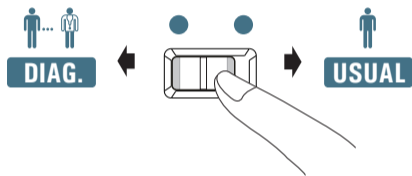
Information for the doctor

This device is designed to detect atrial fibrillation and false negative readings are very rare. Though it is programmed to specifically detect atrial fibrillation, frequent premature beats, marked sinus arrhythmia or other rhythm abnormalities might cause false positive readings. If atrial fibrillation is detected by the device at home, we suggest another reading done in the doctor's office. If the atrial fibrillation icon is not displayed then the previous abnormal readings may have been due to transient atrial fibrillation. If the atrial fibrillation icon is displayed then it is suggested to perform an EKG to determine the exact rhythm abnormality.

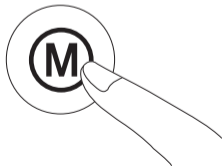
Viewing, deleting and transferring measurements

Viewing measurements

- 1) Use the Mode switch to first select the type of measurements you wish to view.

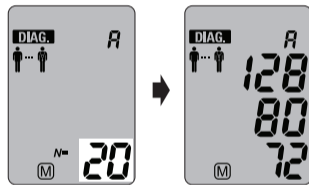


- 2) Then press the M Button.



In «DIAG.» Mode

- 1) When the M Button is pressed, it briefly displays the total number of measurements stored, e.g. N=20 and then switches to the average of all readings.



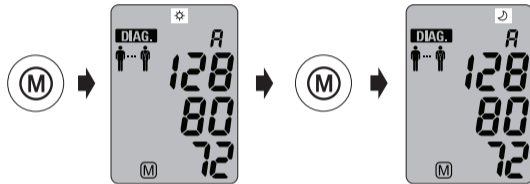
❖ «A» is displayed when the number shown is the average of all data.



❖ «- -» will display when the number of measurements is less than 12.



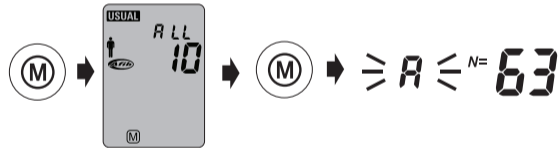
- 2) Press the M Button again to display the average of all morning data. Press the M Button once again to show the average of all evening data.



- 3) Press the M Button repeatedly to review all the individual readings one by one.
4) The daily average is displayed after the individual readings of the day.

In «USUAL» Mode

- 1) When the M Button is pressed, the number of readings detected with Afib are displayed.
2) Press M Button again, the number of total readings stored, e.g. N=63, is displayed; followed immediately by the average of all measurements stored in memory.



- 3) All individual readings can be viewed by repeatedly pressing the M Button.



Viewing, deleting and transferring measurements (cont.)

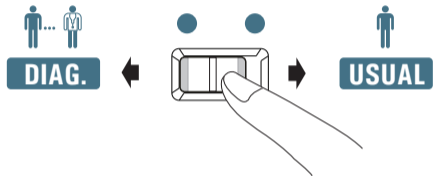
Deleting measurements

Data from «**DIAG.**» and «**USUAL**» can be deleted independent of each other.

❖ *Before deleting data, be sure to ask your doctor if the measurement data is still required. Only delete the stored measurements when you are sure that you no longer need the data.*



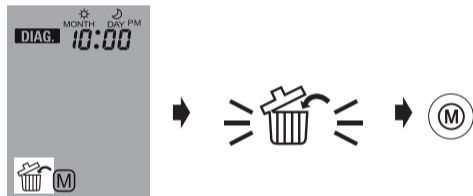
1) Use the Mode switch to select the mode of measurements you want to delete.



2) Press the M Button and hold it for 7 seconds until the delete symbol flashes.



3) Release the M Button and press it once more while the delete symbol flashes. The deleting is confirmed by the beep sound.



❖ *Only measurements in the selected mode will be deleted.*

Viewing, deleting and transferring measurements (cont.)

Transferring measurements

Installation of the software program

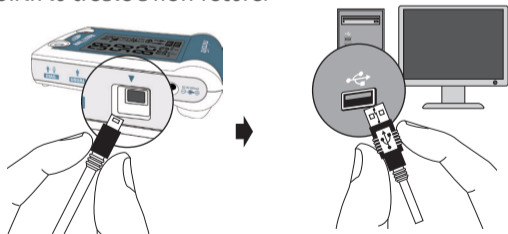
- 1) Put the CD in the CD-ROM drive of your computer.
Alternatively click on «**setup.exe**» in the CD's directory.
- 2) Follow the instructions provided in the installation window on the computer screen.
- 3) When the installation is finished, be sure to restart the computer before using the program.



- ❖ *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 XP / Vista / Win7*
- ❖ *Or download the latest version from <http://www.watchbp.com>*

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 name, identity number (if required), and date of birth to create a new record.



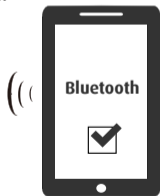
| Software commands | Refer to the software user manual for detailed information and instructions. |
|------------------------------------|--|
| Transfer «DIAG.» mode data | Click «Download» |
| Corresponding value | You can remove the check mark and the corresponding value will not be used to calculate the average. |
| Store data | Click «Save», the file name is formed automatically from the patient's identity number and the suffix «Dmode.xls». |
| View the data | Click «Patient Files» |
| Store the «USUAL» mode data | Click «Download Usual Mode Data», the file name is formed automatically from the patient's identity number and the suffix «Umode.xls». |
| Print the data sheet | Click «Print» |
| Delete the memories | Click «Clear Memory» |
| Close the program | Click «Exit» |

❖ Please store the data before using «Clear Memory» or «Exit».

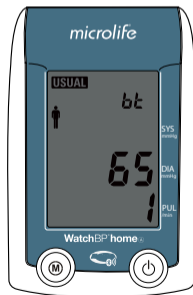
Viewing, deleting and transferring measurements

Transferring measurements

The measurement data in «**DIAG.**» and «**USUAL**» can be transferred to Bluetooth enabled phone. Make sure that the phone has Bluetooth turned on before transferring measurements. Before connecting with the phone, please check if Bluetooth pairing is necessary. Pressing the M button 3 second, the screen will show “PA” means Bluetooth enter the pairing mode.



When you press the start button to take the measurement, the Bluetooth also turn on and enter standby mode waiting the connection. The screen will show the “bt” and time alternatively.



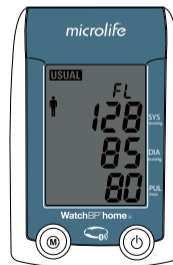
❖ *The Bluetooth pairing PIN code is 4103, if Bluetooth pairing is necessary.*

Connecting and receive the data

1. Start the application on your phone.
2. Connecting with this device and phone via a specified application. The screen will show "Cn" and time
Alternatively, once the connection is built successfully.
3. The measurement data will transfer to the application automatically when the measurement is completed.



The screen will show "FL" if the connection fails.



Batteries and power adaptor

Battery indicator

When the batteries have $\frac{1}{4}$ power supply left, the Battery Symbol will flash each time the device is switched on.



Replacing low batteries

When the batteries need to be replaced, the Battery Symbol will flash each time the device is switched on.

- 1) Open the battery compartment at the back of the device.
- 2) Replace the batteries – ensure correct polarity as shown by the symbols in the compartment.
 - ✦ Use 4 new, long-life 1.5V, size AA batteries.
 - ✦ Do not use batteries beyond their date of expiry.
 - ✦ Remove batteries, if the device will not be used for a prolonged period.

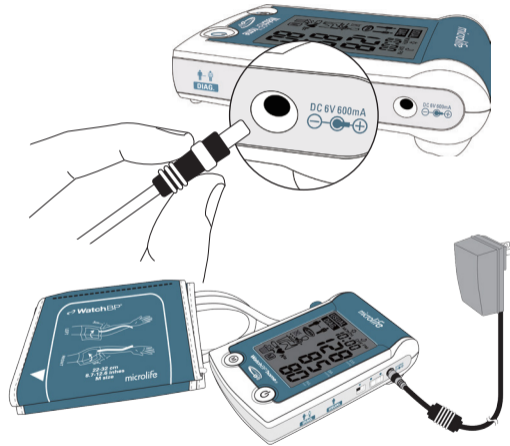
Using a power adaptor

The WatchBP Home A BT device can also be operated using a Microlife power adaptor (DC 6V, 600mA).

❖ *Only use Microlife branded power adaptors.*

- 1) Plug the adaptor cable into the Power Plug in the WatchBP Home A BT device.
- 2) Plug the adaptor plug into the wall socket. When the power adaptor is connected, no battery power is consumed.

❖ *External power adaptor shall be fulfilled in compliance with the requirements of IEC 60601-1:2005.*



Safety, care, accuracy test and disposal



“Read the instruction manual carefully before using this device, especially the safety instructions, and keep the instruction manual for future use.”

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.



- Strangulation due to cables and hoses, particularly due to excessive length. Inhalation or swallowing of small parts, if 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



Do not use this device close to strong electromagnetic fields such as mobile telephones or radio installations. maintain a minimum distance of 3.3m from such devices when using this unit.



Never open device



Protect device from impact and drops

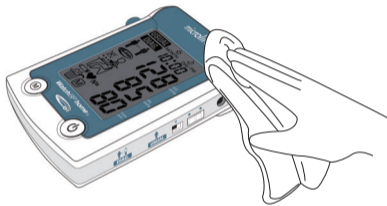


Keep dry

IP20: Protected against solid foreign particles with a diameter of more than 12.5 mm, no protection against water, please do not drop water on device for avoid performance influence.

Device care

Clean the device with a soft, dry cloth.



Accuracy test

We recommend the WatchBP Home A BT 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.

Cuff care

DO NOT wash the cuff. DO NOT iron the cuff cover.



Do not wash the cuff!



Do not iron the cuff!

Disposal



Batteries and electronic devices must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

Error messages

If an error occurs during measurement, the measurement is interrupted and an error message «Er» is displayed.



- *Please consult microlife, if this or any other problem occurs repeatedly.*
- *If you think the results are unusual, please read through the information in this instruction manual carefully.*



| Error | Description | Potential cause and remedy |
|--------|------------------------|---|
| «Er 1» | Signal too weak | The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement. |
| «Er 2» | Error signal | 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. |

| | | |
|--------|--------------------------------|---|
| «Er 3» | No pressure in the cuff | An adequate pressure cannot be generated in the cuff. A leak may have occurred. Replace the batteries if necessary. Repeat the measurement. |
| «Er 5» | Abnormal result | 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. |

| | | |
|------|--|--|
| «HI» | Pulse or cuff pressure too high | 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. |
| «LO» | Pulse too low | The pulse is too low (less than 40 beats per minute). Repeat the measurement. |

Important facts about blood pressure and home measurements

Are home blood pressure measurements valuable?

Yes. The American Heart Association and European Society of Hypertension have demonstrated that home blood pressure measurements are important in determining accurate blood pressure.

- **Blood pressure** is the pressure of the blood flowing in the arteries generated by the pumping of the heart. Two data readings, the **systolic** (upper) value and the

diastolic (lower) value, are always measured.

- The **pulse rate** is the number of times the heart beats in a minute.
- **Permanent high blood pressure can damage your health and therefore must be treated!**
- Always discuss your home blood pressure measurement data with your doctor and tell him/her if you have noticed anything unusual or feel unsure. **Never rely on single blood pressure readings.**
- There are many causes of excessively **high blood pressure**. Your doctor will explain them in more detail and offer treatment when appropriate.
- Blood pressure is subject to wide fluctuations as the day progresses, and can be impacted by emotions, physical exertion and other conditions .

Evaluating blood pressure data

The table on the right classifies blood pressure data for adults in accordance to the guidelines of the European Society of Hypertension (ESH). (Data in mmHg)

The higher value is the one that determines the evaluation. Example: a readout value between **150/85** or **120/98** mmHg indicates «Grade 1 Hypertension».

| Category | Systolic | Diastolic |
|--------------------------------|-----------|-----------|
| Optimal | < 120 | < 80 |
| Normal | 120 - 129 | 80 - 84 |
| High normal | 130 - 139 | 85 - 89 |
| Grade 1 Hypertension | 140 - 159 | 90 - 99 |
| Grade 2 Hypertension | 160 - 179 | 100 - 109 |
| Grade 3 Hypertension | ≥ 180 | ≥ 110 |
| Isolated Systolic Hypertension | ≥ 140 | < 90 |

Technical specifications

| | |
|-------------------------------|---|
| Operating condition: | <ul style="list-style-type: none">• 10 to 40 °C (50 to 104 °F)• 15 - 90 % relative maximum humidity, Air pressure 700 to 1040 hPa. |
| Storage condition. | <ul style="list-style-type: none">• -20 to 50 °C (-4 to 131 °F)• 15 - 90 % relative maximum humidity |
| Weight: | <ul style="list-style-type: none">• 385 g (including batteries) |
| Dimensions: | <ul style="list-style-type: none">• 150 x 100 x 50 mm |
| Measuring procedure: | <ul style="list-style-type: none">• Oscillometric, corresponding to Korotkoff |
| Method: | <ul style="list-style-type: none">• Phase I systolic, Phase V diastolic |
| Measurement range: | <ul style="list-style-type: none">• 30 - 280 mmHg – blood pressure• 40 - 200 beats per minute – pulse |
| Cuff pressure display: | <ul style="list-style-type: none">• Range: 0 - 299 mmHg• Resolution: 1 mmHg• Static accuracy: pressure within ± 3 mmHg• Pulse accuracy: ± 5 % of the readout value |
| Voltage source: | <ul style="list-style-type: none">• 4 x 1.5 V Batteries; size AA• Mains adapter DC 6V, 600 mA (optional) |
| Battery life: | <ul style="list-style-type: none">• Approximately 250 measurements |

| | |
|---------------------------------------|---|
| Reference to standards: | <ul style="list-style-type: none">• Device corresponds to the requirements of the standard for noninvasive blood pressure monitor. EN 1060-1; EN 1060-3 ; IEC 60601-1 IEC 60601-1-2; IEC 60601-1-11, ESH protocol |
| Electromagnetic compatibility: | <ul style="list-style-type: none">• Device fulfills the stipulations of the standard IEC 60601-1-2. |
| Expected service life: | <ul style="list-style-type: none">• 5 years or 10,000 measurements (batteries and cuff are not included). |
| Cuff service life: | <ul style="list-style-type: none">• Approximately 2 years |

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The stipulations of the EU Directive 93/42/EEC for Medical Devices Class IIa have been fulfilled.



Type BF applied part

Microlife reserves the right to alter technical specifications without prior written notice.

Guarantee card

This device is covered by a five-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. Batteries, cuff and wearing parts are not covered by this guarantee.

Name: _____

Address: _____

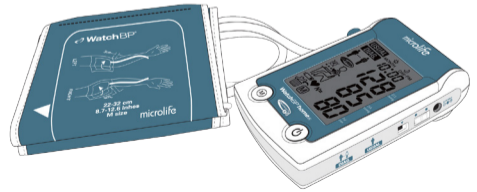
Date: _____

Telephone: _____

Email: _____



Model: WatchBP Home A BT
ERP Model Number: BP3MX1-3C
Date:



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