ESH
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AHA
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WatchBP® home A BT

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

## Instruction Manual


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 protocol [3].

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

## Indications For Use

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP Home A BT (BP3MX1-3C) is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual with arm cuff circumference sizes ranging from 22 -42 cm by using a non-invasive oscillometric technique in one inflatable cuff being wrapped around the upper arm.
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 memory data can be transferred to the PC (personal computer) running the WatchBP Analyzer Home software by connecting the monitor via cable. The device can also be used in connection with smart mobile devices running the APP and via Bluetooth.
The device is intended for use by patient at home or by health care givers in primary care settings.

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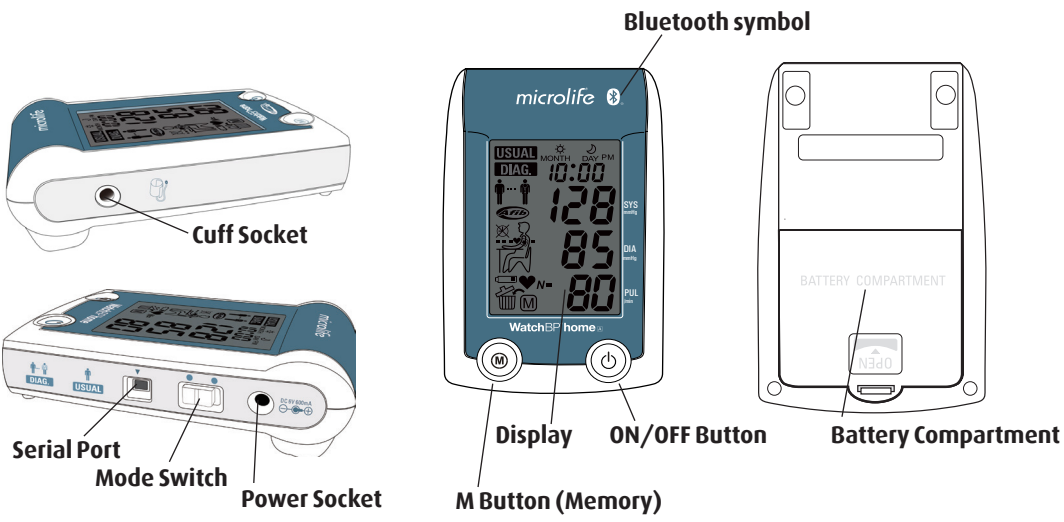
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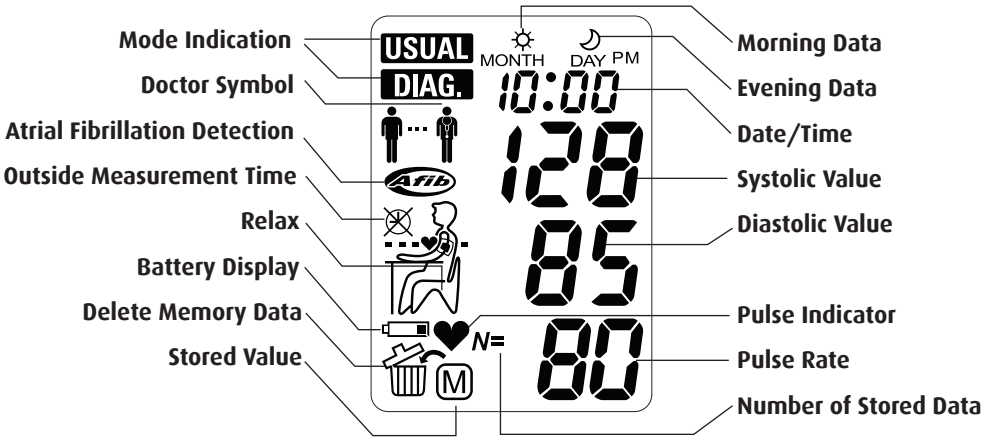
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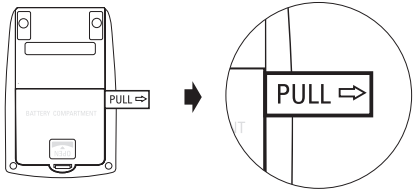
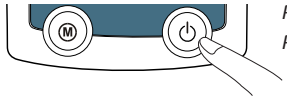
# Before using WatchBP Home A BT for the first time

## 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.

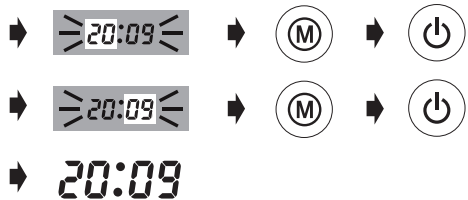



*Press M Button to make selection*
*Press ON/OFF Button to confirm*

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.

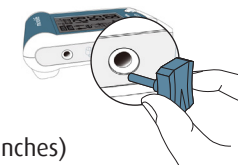



5) If you want to change the date and time, take out one battery from the battery compartment briefly and put it back. The Year number will flash. Complete the process as described above.

## 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!*



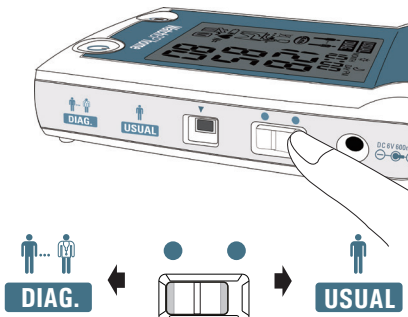
**M (Medium size)**
22 - 32 cm (8.7 - 12.6 inches)
*M is the correct size for most people.*

**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).

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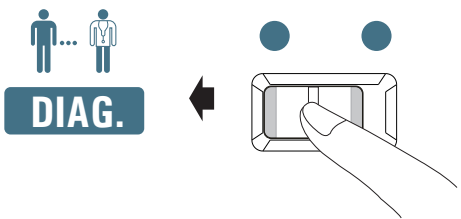


**No measurements on non-work days**

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!


**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**

## 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.

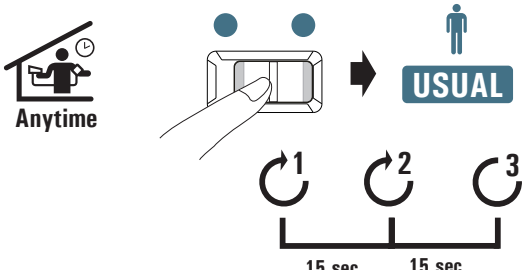
## Evaluation

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.*

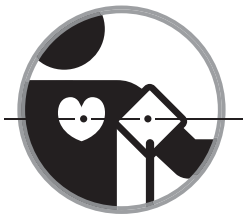
# Eight steps for measure blood pressure properly

## 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.

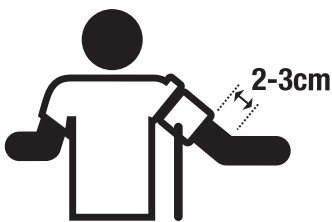

## Step 2

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*)

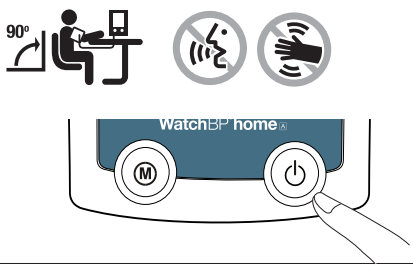



## Step 4

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

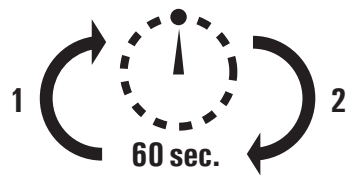
## Step 5

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. Breath 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**

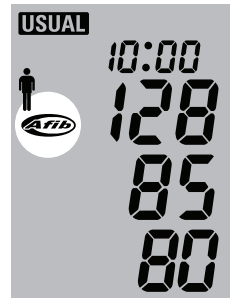
## **Step 8** (in «**DIAG.**» mode)

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.




⁂ *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.*

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

## 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.

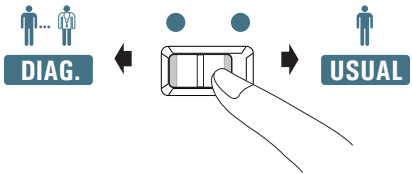
## Information for the doctor

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.

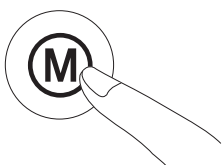
# Viewing, deleting and transferring measurements

## Viewing measurements

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

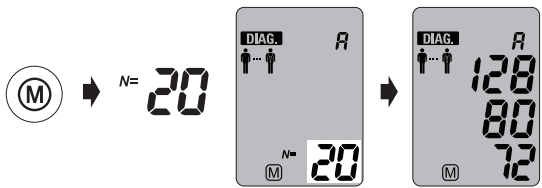



2) Then press the M Button.



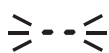

### In «DIAG.» Mode

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.

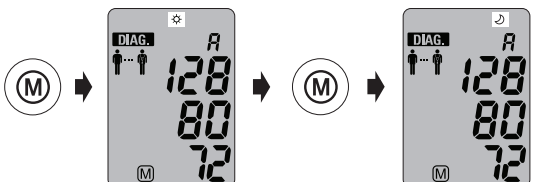



- *«A» is displayed when the number shown is the average of all data.*


- *«- -» 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.



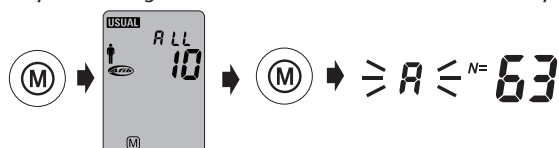

3) Press the M Button repeatedly to review all the individual readings one by one.

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.



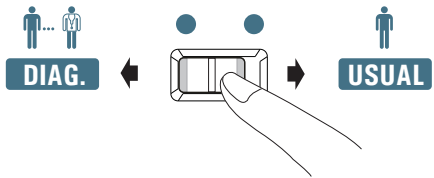

3) All individual readings can be viewed by repeatedly pressing the M Button.

## Deleting measurements

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


⁂ *Only delete the stored measurements when you are sure that you no longer need the data.*

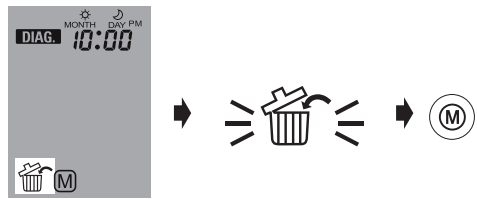
1) Use the Mode switch to select the mode of measurements you want to delete.




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

Ⓜ ➧ **Press and hold for 7 seconds...**

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.*

## Installation of the software program

The latest WatchBP Analyzer Home Software is available from the Microlife website.

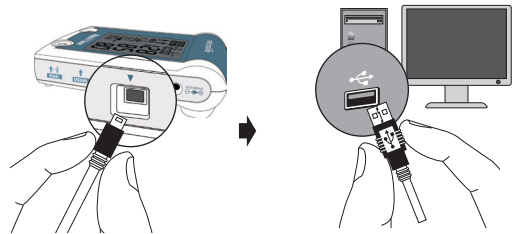
https://www.microlife.com/support/softwareprofessional-products

Double click the download installer and simply follow the instructions provided in the installation window on the PC screen.

⁘ *System Requirements for Software: 1GHz CPU. 512MB Memory, 4.5GB free hard disk space, Microsoft Windows 7 SP1 / 8 / 10*

## Transferring data to the computer

1) Start the software program and connect the device to the computer using the cable supplied.
2) The date and time on the device automatically synchronize with the date and time on the PC when successfully connected with WatchBP Analyzer Home PC software.
3) Click <**Download**> button in the WatchBP Analyzer Home to transfer the measurement data on the device to a PC.

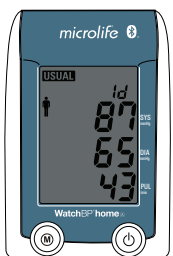


※ *See instruction manual of the WatchBP Analyzer Home for details.*

## Bluetooth connectivity

The measurement data in «**DIAG.**» and «**USUAL**» can be transferred to a Bluetooth enabled cell phone (android, iphone). Make sure that the phone has Bluetooth turned on before transferring measurements. Before connecting with the phone, please check if Bluetooth pairing is necessary.

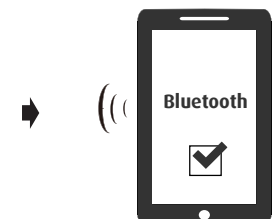
*Please download the «Microlife WatchBP Home» App. (referred to as App in this document) from Apple's App Store® or Google Play® before connecting your devices.*




Press and hold the M button for around 5 seconds,the unique 6-digit device ID of the unit is displayed.Open the «Microlife WatchBP Home» app on your smartphone. Go to «Dashboard». Click «Sync data» icon. Connect the device and confirm pairing. The measurement data on the device will upload to smartphone automatically when the connection is established.

**WatchBP Home App Compatibility:**

iPhone 6 or above running iOS 12.0 or higher. Android phones running Android 8 or above.




*Questions?*

*To access the tutorial, go to the App home screen (Microlife WatchBP Home) and press the "Settings and & help" button.•Press "Tutorial" and select your topic.*

After the finish of a blood pressure measurement, the Bluetooth also turns on and displays the 6-digit device ID awaiting the connection.

The screen will show “FL” if the connection fails.


*Bluetooth is not active when the blood pressure monitor device is recording data. The blood pressure monitor device will not sound any alarm with or without Bluetooth. The Bluetooth is used only to transfer data from point A to point B.*

# Batteries and power adaptor

## Battery indicator

When the batteries have ¼ 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, 1.5V,size AA alkaline 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

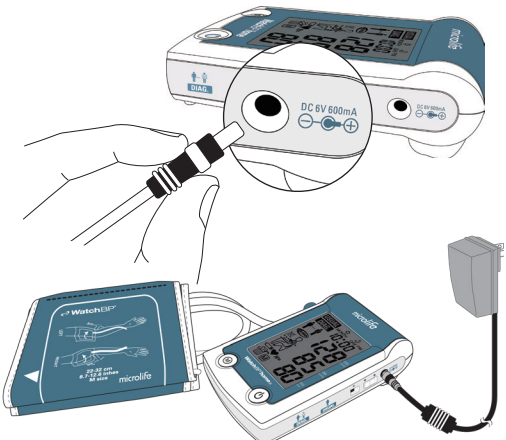
The WatchBP Home A BT device can also be operated using a Microlife power adaptor (DC 6V, 600mA).

⁘ *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

Follow Instructions for Use. This document provides important product operation and safety information. Please read this document thoroughly before using the device and keep for future reference.

## 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.

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

- 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.** |

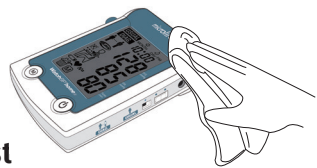
## Device cleaning and disinfecting

Use a soft cloth with one of the following recommended cleaning solutions to wipe the exterior of the device:

· Ethyl or isopropyl alcohol (70% solution)

· Hydrogen peroxide 7.5% solution

· Sodium hypochlorite solution (5.25-6.15% household bleach diluted 1:500 provides >100 ppm available chlorine)



## 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 cleaning and disinfecting

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

Wipe the cuff with 70% ethyl or isopropyl alcohol. Do not immerse hose. Allow to air-dry thoroughly before next use.

**Do not wash the cuff!**

**Do not iron the cuff!**

## Disposal

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

# Error messages

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

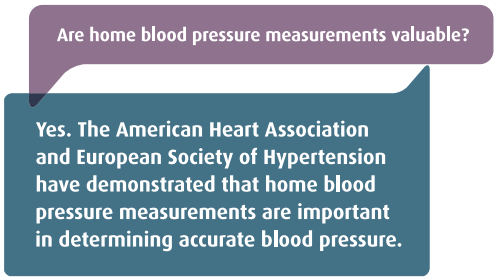

- *Please consult microlife, if this or any other problem occurs repeatedly.*
- *If you think the results are unusual, please read through the information in this instruction manual carefully.*


| 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




- **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:** | • 10 to 40 °C (50 to 104 °F)<br>• 15 - 90 % relative maximum humidity, Air pressure 700 to 1040 hPa. |
| **Storage condition.** | • -20 to 55 °C (-4 to 131 °F)<br>• 15 - 90 % relative maximum humidity |
| **Weight:** | • 385 g (including batteries) |
| **Dimensions:** | • 150 x 100 x 50 mm |
| **Measuring procedure:** | • Oscillometric, corresponding to Korotkoff |
| **Method:** | • Phase I systolic, Phase V diastolic |
| **Measurement range:** | • 30 - 280 mmHg – blood pressure<br>• 40 - 200 beats per minute – pulse |
| **Cuff pressure display:** | • Range: 0 - 299 mmHg<br>• Resolution: 1 mmHg<br>• Static accuracy: pressure within ± 3 mmHg<br>• Pulse accuracy: ± 5 % of the readout value |
| **Voltage source:** | • 4 x 1.5 V Batteries; size AA<br>• Mains adapter DC 6V, 600 mA (optional) |
| **Battery life:** | Approximately 250 measurements |
| **Reference to standards:** | • Device corresponds to the requirements of the standard for noninvasive blood pressure monitor.<br>IEC 60601-1; IEC 60601-1-2; IEC 60601-1-11,<br>ANSI/AAMI/ISO 81060-2<br>ANSI/AAMI/IEC 80601-2-30 |
| **Electromagnetic compatibility:** | • Device fulfills the stipulations of the standard IEC 60601-1-2. |
| **Expected service life:** | • 5 years or 10,000 measurements (batteries and cuff are not included. |
| **Cuff service life:** | • Approximately 2 years |

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:** _____

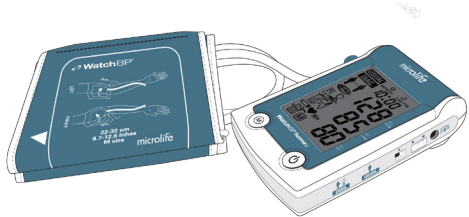
**Telephone:** _____

**Email:** _____

**Model:** WatchBP Home A BT

**ERP Model Number:** BP3MX1-3C

**Date:**



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