

ESH **AHA**
Protocol Embedded Protocol Embedded

WatchBP[®] O3

Affordable ABPM and strictly guideline-based SBPM for accurate out-of-office blood pressure measurement.

Instruction Manual



EN → 3

microlife[®]

The Microlife WatchBP O3 (Out Of Office) is designed to provide reliable and unbiased ambulatory and self blood pressure measurement results, and strictly follows European Society of Hypertension (ESH) and American Heart Association (AHA) recommendations for out-of-office blood pressure measurement ¹. The WatchBP O3 device has been clinically validated according to the ESH protocol. It shows blood pressure behaviour of individual over a 24-hour period during usual daily activities.

If the clinic blood pressure is 140/90 mmHg or higher, offer ambulatory blood pressure monitoring (ABPM) to confirm the diagnosis of hypertension.

For people identified as having a 'white-coat effect', consider ABPM as an adjunct to clinic blood pressure measurements to monitor the response to antihypertensive treatment with lifestyle modification or drugs. (BHS).

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.

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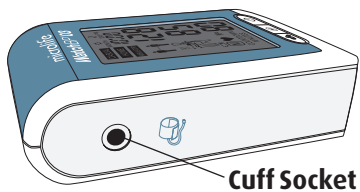
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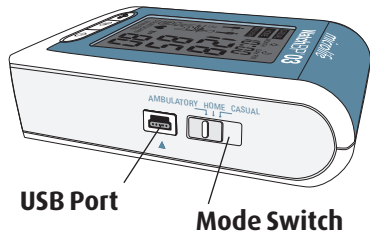
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Product description

Name of parts

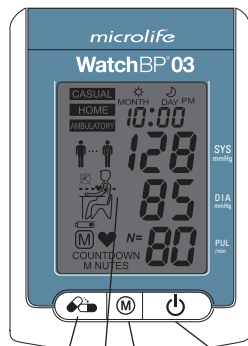


Cuff Socket



USB Port

Mode Switch

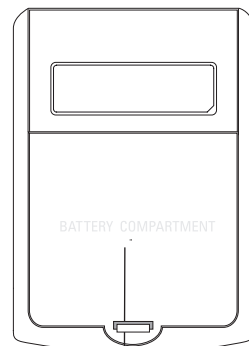


Medication Button

Display

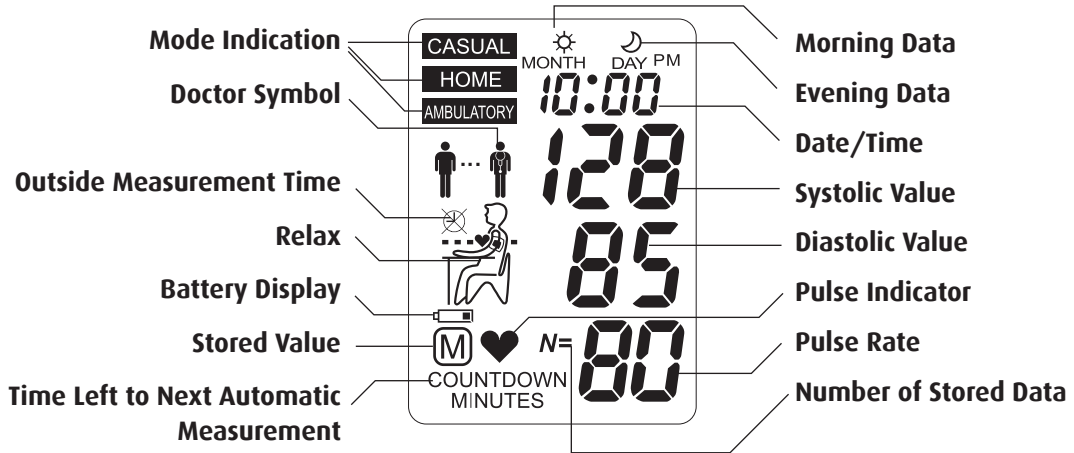
M Button (Memory)

ON/OFF Button



Battery Compartment

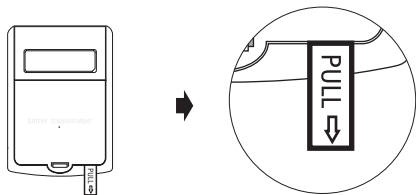
Display



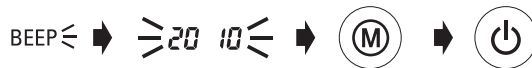
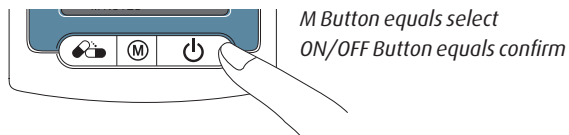
Before using WatchBP 03 for the first time

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.



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



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



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



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

Confirm cuff size

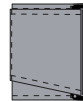
A variety of different cuff sizes are available for use with the WatchBP O3 device.

** please use only Microlife cuffs!*



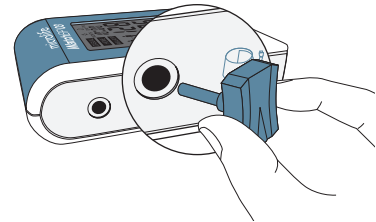
M (Medium size)

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)

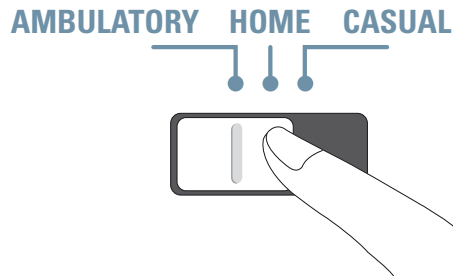
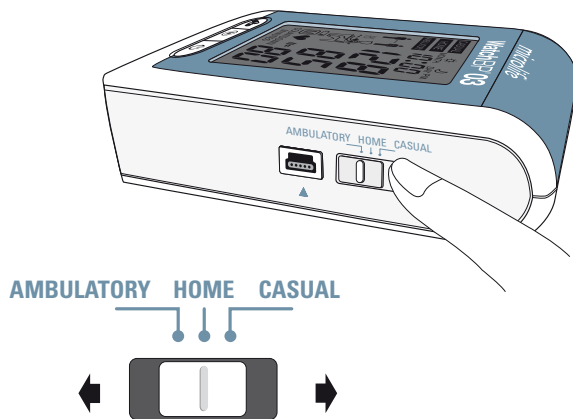


Selecting the operation mode

Prior to each measurement, use the Mode Switch on the side of the device to select the proper measurement mode. The WatchBP O3 offers three measurement modes: «**AMBULATORY**», «**HOME**» or «**CASUAL**» mode.

«**AMBULATORY**» Mode

Select «**AMBULATORY**» mode for fully programmable 24-hour patient out-of-office blood pressure measurement.



Programmable measurement intervals

The device automatically takes measurements at fixed intervals of 15, 20, 30, or 60 minutes, as programmed by the physician.

15	30	minutes
20	60	

∗ The default measurement interval is 30 minutes for the awake hours and 60 minutes for the asleep hours.

Set awake and asleep hours

To better suit each patient's lifestyle, awake and asleep hours can be programmed using the provided WatchBP O3 software. Intervals for the awake and asleep hours can also be programmed independently.

Setting Ambulatory Measurement Schedule

Awake from ~ with minutes interval

Asleep from ~ with minutes interval



Selecting the operation mode (cont.)

Two measurement periods

The awake measurement period can be programmed to start at anytime between 4AM to 10AM, and the asleep measurement period can be set to anytime between 9PM to 2AM. Measurement intervals can be set to 15, 20, 30, or 60 minutes for both awake and asleep time periods.

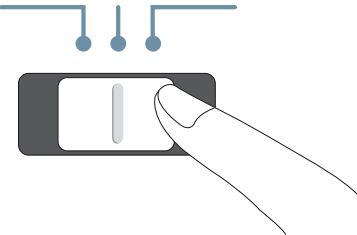


«HOME» Mode

Select «HOME» mode for patient home blood pressure measurement in accordance with the guidelines of the European Society of Hypertension (ESH) and American Heart Association (AHA).

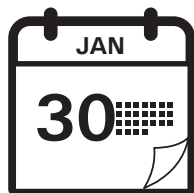
ESH Protocol Embedded AHA Protocol Embedded

AMBULATORY HOME CASUAL



No measurements on non-work days

The patient should carry out readings 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

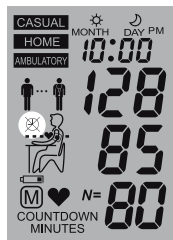
ESH guidelines recommend one double measurement be taken in the morning between 06:00 - 09:00 and one double measurement taken in the evening between 18:00 - 21:00.



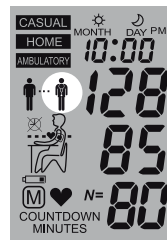
Selecting the operation mode (cont.)

Extended measurement period

The WatchBP O3 device offers an extended measurement period and allows morning measurements between 04:00 - 12:00 and evening measurements between 18:00 - 24:00.



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



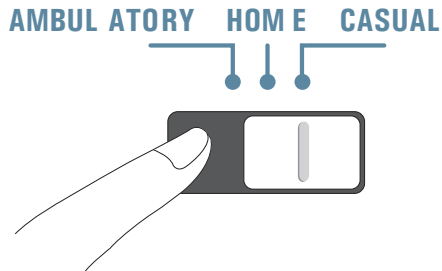
When measurements have been carried out for the full 7 days, the doctor symbol will flash on the screen.

Evaluation

After measurements have been carried out for a total of 7 working days, patients return to the office with the WatchBP O3 device for an evaluation of their home blood pressure measurement data.

«CASUAL» Mode

In «CASUAL» mode, the device functions like a regular blood pressure monitor – single measurements are automatically stored and can be reviewed by the physician at a later date.



250 measurements safely stored

The WatchBP 03 device can store up to 250 single measurements in «CASUAL» mode.

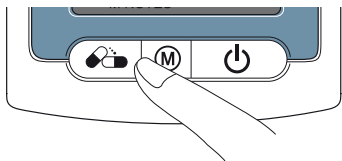
** When memory is full, each new measurement will automatically overwrite the earliest measurement.*



Recording the taking of medication

Medication record

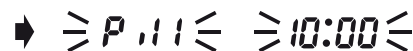
The patient can record the time medication is taken by pressing the Medication Button.



1) Press and hold the Medication Button for 2 seconds and the Pill icon will appear.



2) Release the Medication Button and the Pill icon will flash in alternation with the recorded time.



3) Medication record is saved after the beep sound.



* A Medication record can be recorded in any of the three modes.

* The beeper can be disabled via software setting.

50 records safely stored

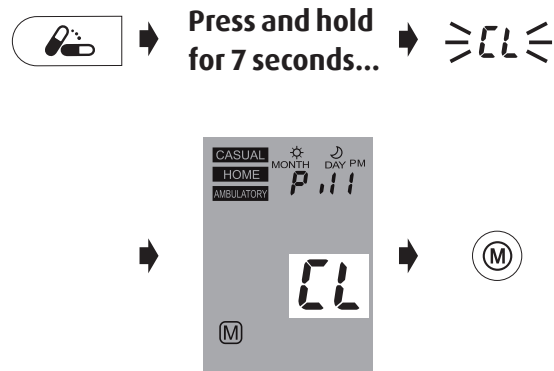
The WatchBP O3 device can store up to 50 medication records.

* *When the memory is full, the device will display Full.*



Delete stored medication records

To clear the memory of all medication records, press and hold the Medication Button for 7 seconds. The “CL” symbol will flash. Press M to delete the memory or ON/OFF to cancel the deletion .

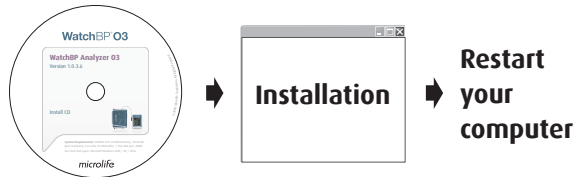


✳ *Pressing the M Button to delete data will erase all medication record data in the selected mode.*

Measurement interval programming

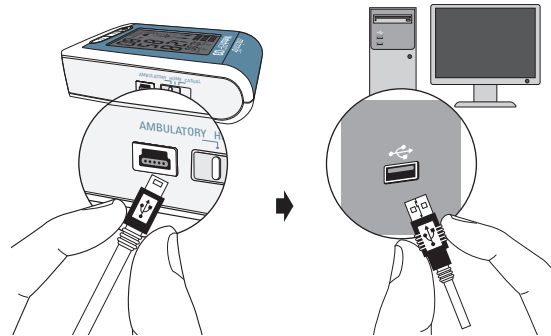
Installing the software program

- 1) Put the CD in the CD-ROM drive of your computer.
Alternatively click on «**setup.exe**» in the CD's directory.
- 2) Simply follow the instructions provide in the installation window on the computer screen.
- 3) When installation is finished, be sure to restart the computer before working with the program for the first time.



Connecting the device to a computer

- 1) Connect the device to computer. A successful connection is displayed by «**PC**» on the device.
- 2) Start the software program.
- 3) Enter name, identity number, and date of birth to create a new record (if required).



Programming the interval schedule

- Using the drop-down menu on the lower-left of the screen, choose from 4AM to 10AM as the start of the awake hours.

Awake from **06 AM** ▼ ~ **10 PM**

- Using the drop-down menu on the lower-left of the screen, choose from 9 PM to 2 AM as the start of the asleep hours.

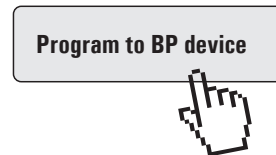
Asleep from **10 PM** ▼ ~ **06 AM**

- Assign the measurement intervals for the awake and asleep hours by using the drop-down menu to choose from 15, 20, 30, and 60 minutes as the measurement interval.

15	▼	minutes interval
20		
30		
60		

15	30	minutes
20	60	

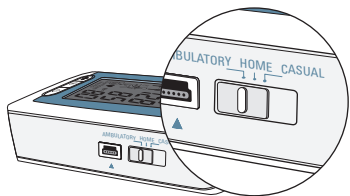
- Once you have completed the settings, press “Program to BP device” to program the schedule into the device.



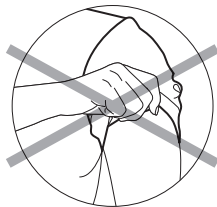
Taking blood pressure measurements

In «AMBULATORY» mode

Be sure the device is set to «AMBULATORY» Mode.

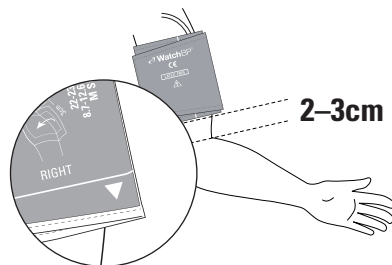


- 1) **Preparing measurement arm** – Remove all clothing covering or constricting the measurement arm.



❖ *Avoid rolling up long sleeves, as this may lead to constriction of blood flow to the measurement arm.*

- 2) **Positioning the cuff and device** – Fit the cuff closely, but not too tight. Make sure that the cuff is 2~3 cm (1 inch) above the elbow with the tube on the inside of the arm. The measurement tube should point upward and be mounted over the patient's shoulder.

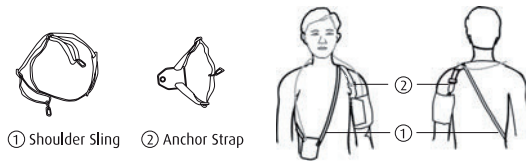


❖ *Adjust the tube holder on the belt of the pouch so it is properly positioned on the shoulder. Attach the tube to the holder so the tube goes up over the shoulder to the other side of the body. An alternative method is to use a waist belt.*



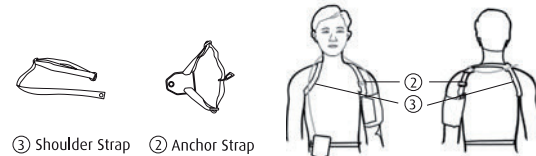
3) Proper Positioning the cuff using Anchor Strap

Option 1: Use the Shoulder Sling ① and Anchor Strap ② to position the cuff as demonstrated in the diagram below.



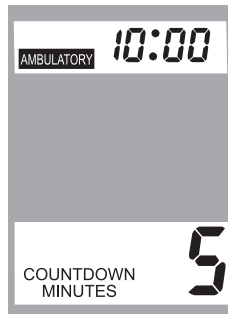
Instructions: Place the Shoulder Sling over the left shoulder. Insert the device into the holster. Position the device at front. Apply the Cuff to the arm. Buckle up Anchor Strap with Shoulder Sling. Snap the connector of Anchor Strap into D-ring of cuff. Adjust length for fit and comfort.

Option 2: Use the Shoulder Strap ③ and Anchor Strap ② to position the cuff as demonstrated.



Instructions: Place the Shoulder Strap over both shoulders as demonstrated in the diagram. Connect the device to a belt. Position the device at front. Apply the Cuff to the arm. Buckle up Anchor Strap with Shoulder Strap. Snap the connector of Anchor Strap into D-ring of cuff. Adjust length for fit and comfort.

- 4) **Next measurement indicator** – The device will display the next measurement time, indicated by a countdown in minutes on the display.

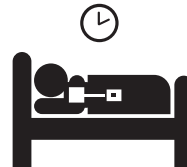
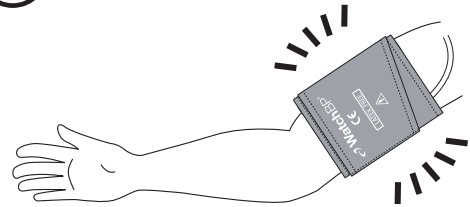


❖ The screen will display X countdown minutes to indicate the time to the next automatic measurement.

- 5) **Measurement reminder** – One minute before the next scheduled measurement, the device will partially inflate and immediately deflate the cuff to remind the patient of the next measurement.



**1 min
Reminder**



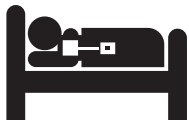
❖ Measurement reminders will be disabled for the asleep hours.

Taking blood pressure measurements (cont.)

6) **Measurement reminder** – Five seconds before the next measurement, the device will emit a short series of beeps to notify the patient of the coming measurement.



* The beeper of Ambulatory Mode can be disabled via software setting.



* The device will not beep prior to asleep measurement in «AMBULATORY» mode.

7) **During measurements** – the patient should be reminded to remain still, refrain from talking, and to breath normally during the measurement. If driving or operating equipment when a measurement begins, the patient should, when safe, relax the measurement arm.



* The patient can stop any single measurement at anytime by pressing the ON/OFF Button.

- 8) **Repeat measurements in the case of an error** – The device will automatically repeat the measurement after a two minute countdown should an error occur during measurement.



➔ **A repeat measurement is performed automatically if an error occurs.**

- 9) **Storing measurement data** – The WatchBP 03 automatically stores each measurement result, along with the measurement date and time. A total of 250 measurements can be stored in «**AMBULATORY**» mode.



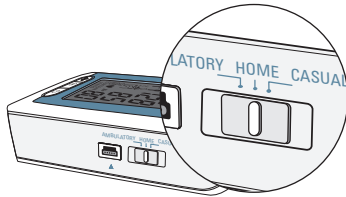
- ❖ *The display of BP reading and memory of Ambulatory Mode can be disabled via software setting.*

❖ *If the repeat measurement encounters an error, the device will stop taking measurements. The patient should return the device to the physician to determine the cause of error.*

Taking blood pressure measurements (cont.)

In «HOME» mode

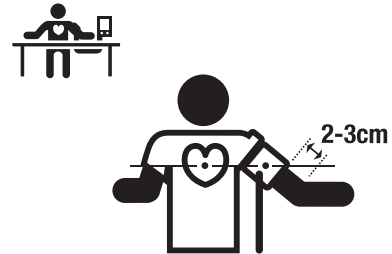
Be sure the device is set to «HOME» Mode.



1) **Before the measurement** – Patients should be informed to avoid physical activity, eating or smoking before each measurement. The patient should sit down for at least 5 minutes before the measurement and relax.

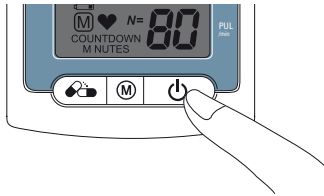


2) **Applying the cuff** – Patients should be trained on how to properly fit the cuff to their own arm. The cuff should fit closely around the arm, but not too tight, and be placed 2~3cm above the elbow with the tube on the inside of the arm. The patient should support the arm at the same height as the heart during measurement.

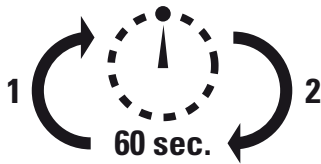


** Additional instructions on taking proper blood pressure measurement can be found on the www.watchbp.com website.*

- 3) **Start the measurement** – Press the ON/OFF Button to start measurement.

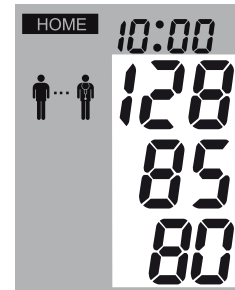


- 4) **During the measurement** –The cuff will inflate automatically. One measurement cycle includes two measurements. Once the first measurement is complete, the second measurement will begin after 60-seconds.



- 5) **Finishing the measurement** – Once the two measurements are complete, measurement data is automatically stored for later reference by the physician. If an error displays after the measurements, the process should be repeated once again.

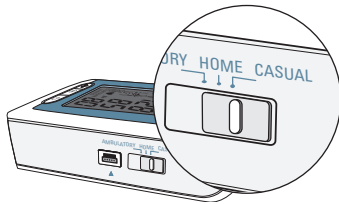
BEEP ≡ →



Taking a blood pressure measurements (cont.)

In «CASUAL» mode

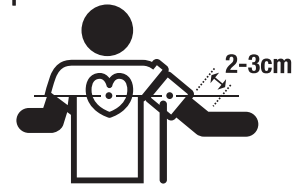
Be sure the device is set to «CASUAL» Mode.



- 1) **Before each measurement** – Patients should be informed to avoid physical activity, eating or smoking before each measurement. The patient should sit down for at least 5 minutes before the measurement and relax.

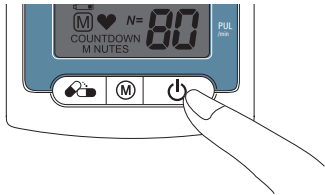


- 2) **Applying the cuff** – Patients should be trained on how to properly fit the cuff to their own arm. The cuff should fit closely around the arm, but not too tight, and be placed 2~3cm above the elbow with the tube on the inside of the arm. The patient should support the arm at the same height as the heart during measurement.



* Additional instructions on taking proper blood pressure measurement can be found on the www.watchbp.com website.

- 3) **Start the measurement** – Press the ON/OFF Button to start measurement.

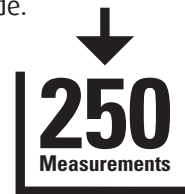


- 4) **During the measurement** –The cuff will inflate automatically. A single measurement will be completed for each push of the ON/OFF Button.



- 5) **Finishing the measurement** – Once the measurement is complete, measurement data is automatically stored for later reference by the physician. If an error displays after the measurements, the process should be repeated once again.

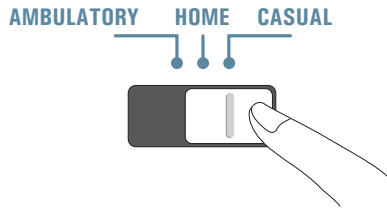
- 6) **Storing measurement data** – The WatchBP 03 automatically stores each measurement result, along with the measurement date and time. A total of 250 measurements can be stored in «CASUAL» mode.



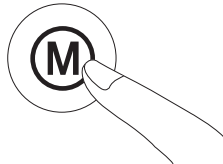
Viewing, deleting and transferring measurements

Viewing measurements

1) Use the Mode switch to first select the type of measurements wished to be viewed.



2) Then press the M Button.



In «AMBULATORY» mode

1) When the M Button is pressed, it briefly displays the total number of measurements stored, e.g. N=20.



* «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) Pressing the M Button again displays the average of all awake hours.



- 3) Pressing M Button once again shows the average of all night hours.



- ❖ All individual readings can be viewed by repeatedly pressing the M Button.
- ❖ The display of BP reading and memory of Ambulatory Mode can be disabled via software setting.

In «Home» mode

- 1) When the M Button is pressed, it briefly displays the total number of measurements stored, e.g. N=20.



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



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



Viewing, deleting and transferring measurements (cont.)

2) Pressing the M Button again displays the average of all morning data.



3) Pressing M Button once again shows the average of all evening data.



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

In «CASUAL» mode

1) When the M Button is pressed, it briefly displays the total number of measurements stored, e.g. N=63, followed immediately by the average of all measurements stored in memory.



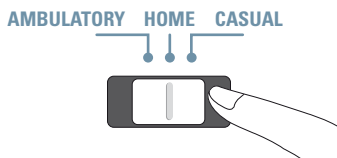
2) All individual readings can be viewed by repeatedly pressing the M Button.



Deleting measurements

Data from «**AMBULATORY**», «**HOME**» and «**CASUAL**» mode measurements can be deleted independent of each other.

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



- 2) Press the M Button and hold it until the CL symbol flashes.



- 3) Release the M Button and press it once more while the delete symbol flashes.



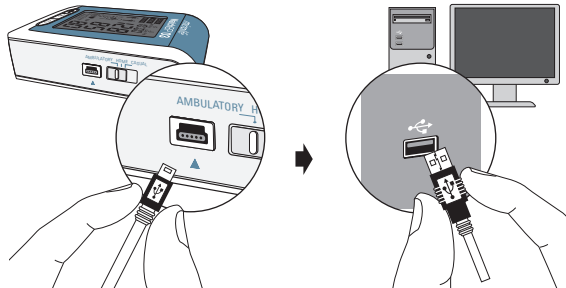
Stand by mode

* Each deletion will erase entire records of each mode.

Viewing, deleting and transferring measurements (cont.)

Transferring measurements

- 1) Connect the device to computer. A successful connection is displayed by «PC» on the device.
- 2) Start the software program.
- 3) To transfer the data in all three modes and the medication compliance record, click «Download BP data to PC».



Software commands	
Store data	Click «Save», the file name is formed automatically from the patient’s identity number and the suffix «WatchBP03_(date).xls».
View the data	Click <<Open excel file>>
Delete the memories	Click «Clear Memory»
Close the program	Click «Exit»

- * Please unplug and re-plug the USB cable to the PC if the software instructs you to do so.
- * The program will prompt to synchronize the date/time of the device to that of the PC.
- * Stored your data before using «Clear Memory» or «Exit».
- * 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.

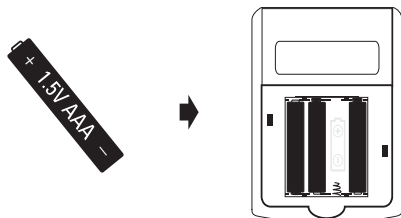
Appendix

Ensure using new batteries

New batteries should be used for each patient monitoring session. “AAA” alkaline batteries are the main power source of watchBP O3.

How to Replace batteries

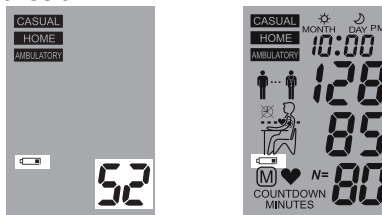
- 1) Open the battery compartment at the back of the device.
- 2) Put in the batteries – Be sure to have correct polarity as shown by the symbols in the compartment.



Battery indicator

When the batteries are placed into battery compartment, the battery and the number indicating battery power will be displayed. Do not use the batteries if the number is equal or lower than 50.

When the batteries have ¼ power supply left, the battery symbol will flash each time when the device is switched on.



- ⚠ *Caution: do not use rechargeable batteries.*
- ⚠ *Use 4 new 1.5V, size AAA alkaline batteries.*
- ⚠ *Do not use batteries out of their expiration date.*
- ⚠ *Remove batteries if the device will not be used for a prolonged period.*

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.



- 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



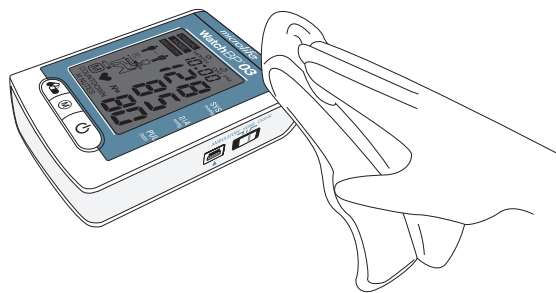
Never open device



Protect device from impact and drops

Device care

Clean the device with a soft, dry cloth.



Accuracy test

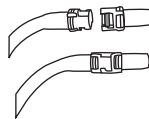
We recommend the WatchBP O3 device be tested for accuracy every 2 years or after mechanical impact (e.g. being dropped). Please contact Microlife to arrange for an accuracy test.

Cleaning the cuff and straps

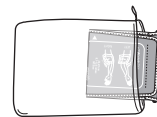
Use a mild disinfectant solution to clean the pouch, straps, sling and belt. To wash these items and cuff in washing machine, use a cuff plug (article #90-273MZ11-004) to keep the inside of the bladder dry. Fold and place the cuff inside a washing bag. Wash these items using warm water and a mild detergent. Air dry the cuff. DO NOT iron the cuff cover.



Do not iron the cuff!




Seal the tube of cuff with a plug



Fold and place the cuff inside a washing bag.

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.

≡ Er ≡

- Please consult your doctor, 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.

Technical Specifications

- Operating temperature:**
- 10 to 40 °C (50 to 104 °F)
 - 15 - 85 % relative maximum humidity
- Storage temperature:**
- -20 to 55 °C (-4 to 131 °F)
 - 15 - 90 % relative maximum humidity
- Weight:**
- 260g (including batteries)
- Dimensions:**
- 115 x 80 x 35 mm
- Measuring procedure:**
- 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
- Power source:**
- 4X1.5 V Batteries; size AAA

- Reference to standards:**
- Device standard: Device corresponds to the requirements of the standard for non-invasive blood pressure monitor.
EN 1060-1
EN 1060-3
EN 1060-4
EN 60601-2-30
IEC 60601-1
IEC 60601-1-2
 - Device fulfills the stipulations of the standard IEC 60601-1-2.
- Electromagnetic compatibility:**

CE 0044

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 two-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 and wearing parts are not covered by this guarantee.

Name: _____

Address: _____

Date: _____

Telephone: _____

Email: _____

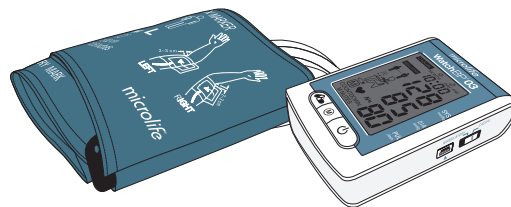


Product: WatchBP O3

Product Number: BP 3MZ1-1

Serial Number:

Date:



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