ESH
Protocol Embedded

AHA
Protocol Embedded

WatchBP® O3

Professional 24-hour blood pressure monitor

Instruction Manual

EN ➜ 3

microlife®

The Microlife WatchBP O3 (Out Of Office) is designed to provide reliable and unbiased ambulatory blood pressure measurement results, and strictly follows European Society of Hypertension (ESH) and American Heart Association (AHA) recommendations for ambulatory blood pressure measurement *. The WatchBP O3 device has been clinically validated according to the ESH protocol.

* O'Brien E, *et al*. European society of hypertension position paper on ambulatory blood pressure monitoring. J Hypertens, 2013; 31:1731-68.

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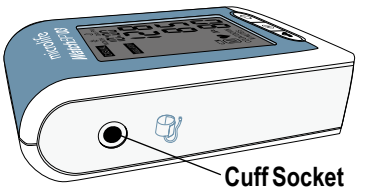
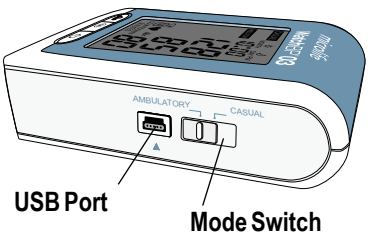
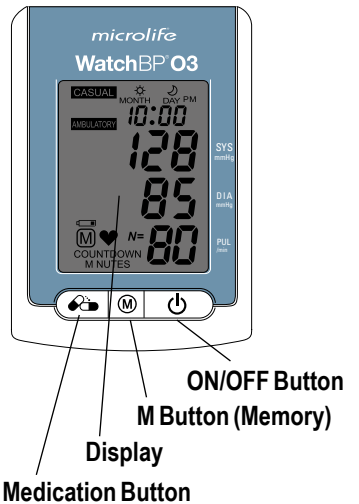
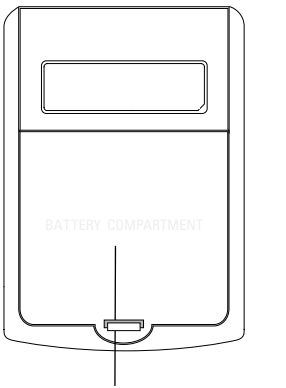
Product description

Name of parts

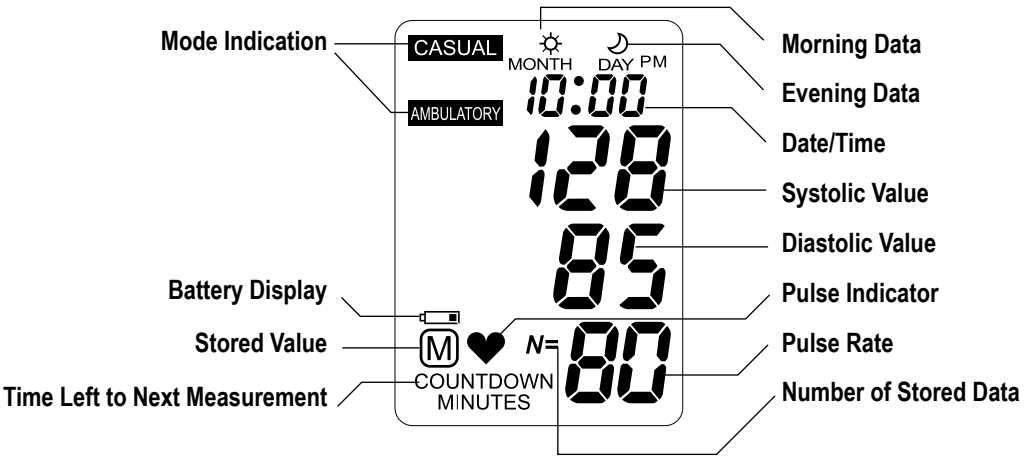








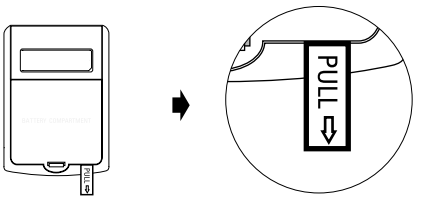
Display


Mode Indication
CASUAL
AMBULATORY
MONTH
DAY
PM
10:00
128
85
80
N=
M
COUNTDOWN
MINUTES
Morning Data
Evening Data
Date/Time
Systolic Value
Diastolic Value
Pulse Indicator
Pulse Rate
Number of Stored Data
Battery Display
Stored Value
Time Left to Next Measurement

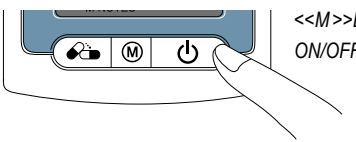
Before using the WatchBP O3 for the first time

Activating the Device

Pull out the protective strip from the battery compartment.

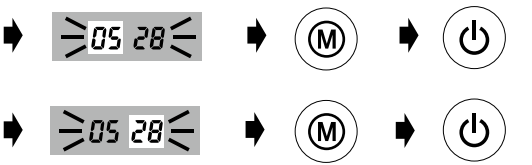


1) **Set the year** – Upon removing the protective strip or installing new batteries, the Year number flashes in the display. Use the <<M>> Button to select the Year. Press the ON/OFF Button to confirm your selection.



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

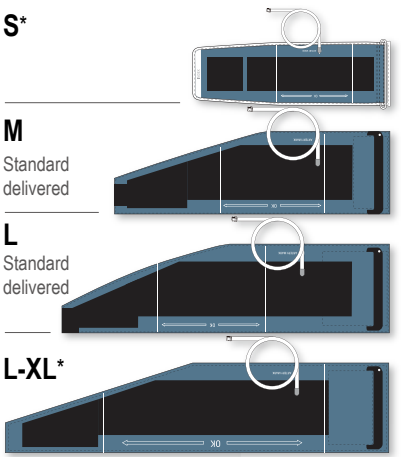
5) To change the date and time, briefly take out and put back one battery from the battery compartment. The Year number will flash. Complete the process as described above.

Confirm the cuff size

A variety of different cuff sizes are available.

☞ *Please use only Microlife cuffs!*

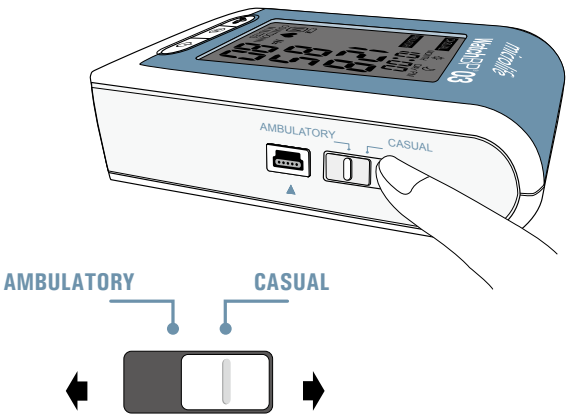
☞ *Washable cuffs available in both nylon and cotton*



☞ *S, L-XL sizes cuffs can be ordered optionally .*

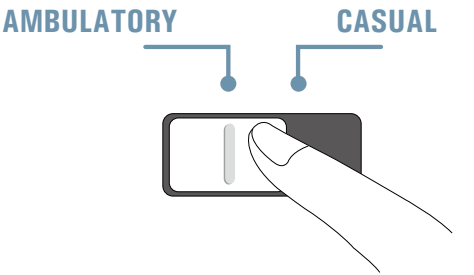
Selecting the operation mode

Prior to each measurement, use the Mode Switch on the side of the device to select the preferred measurement mode. The WatchBP O3 offers two measurement modes: «**AMBULATORY**» and «**CASUAL**» mode.



«AMBULATORY» mode

Select «**AMBULATORY**» mode for fully programmable 24-hour ambulatory blood pressure measurement.



Selecting the operation mode : «AMBULATORY» mode

Programmable measurement intervals

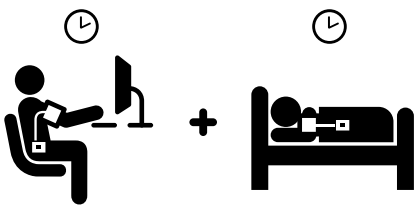
The device automatically takes measurements at fixed intervals of 15, 20, 30, or 60 minutes, as can be programmed.

15 | **30**
20 | **60**
minutes

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

Two measurement periods

The awake (day) measurement period can be programmed to start at any hour between 00 to 23, and the asleep (night) measurement period can be set to any hour between 00 to 23. Measurement intervals can be set to 15, 20, 30, or 60 minutes for both awake and asleep time periods.

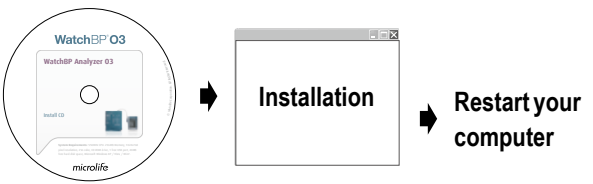


Measurement interval programming in «AMBULATORY» mode

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 provided in the installation window on the computer screen.
3) When the installation is finished, restart the computer before working with the program for the first time.

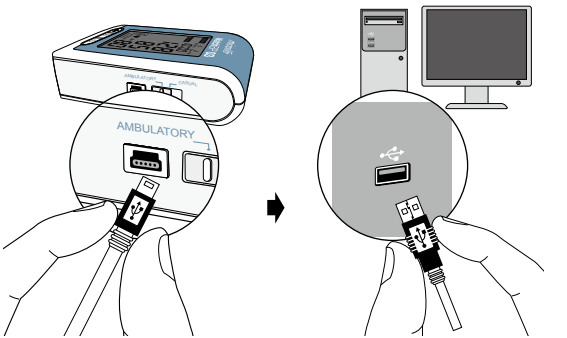
☞ Software can also be downloaded from the website **www.watchbp.com**.



☞ User manual can be found in the software by clicking on <<Help>> in the main window.

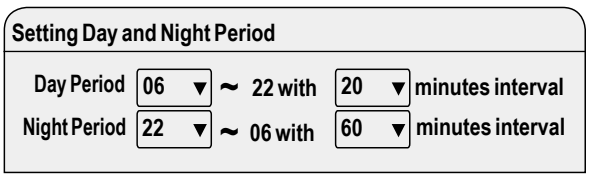
Connecting the device to a computer

1) Connect the device to the PC. 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).

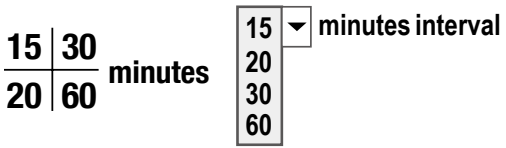


Programming the measurement procedure

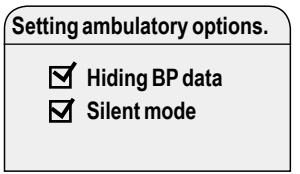
1) With “Ambulatory settings” the 24-hour measurement procedure can be programmed. Choose at what time the Day Period and Night Period starts. Using the drop-down menu on the lower-left of the screen, choose from 00 to 23 as the start of day and night periods. For instance the awake time is 06 AM and asleep time is 10PM.



2) 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.



3) Setting ambulatory options.

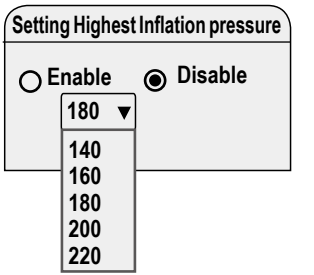


On default the blood pressure data are hidden and the device is in Silent mode. In order to show the measured blood pressure values on the LCD screen and to provide a beep before each measurement, click on the squares to the left.

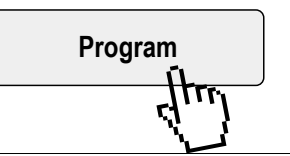
☞ *The display of blood pressure values on the LCD screen can be enabled or disabled (see P19.)*

☞ *The beeper of Ambulatory mode can be enabled or disabled (see P18.)*

4) For setting the highest inflation pressure click on the circle left to “Enable” and click on the arrow to determine the height of the inflation pressure. “Disable” means that the device will automatically search for the right inflation pressure (default)



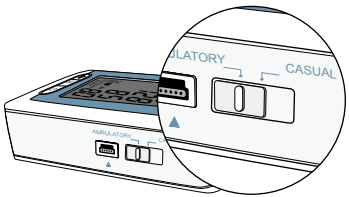
5) Once you have completed the settings, press “Program” to program the schedule into the device.



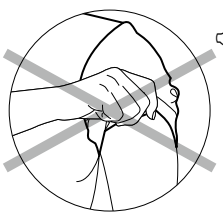
Taking blood pressure measurements in «AMBULATORY» mode

In «AMBULATORY» mode

Be sure the device is set to **«AMBULATORY» mode**.

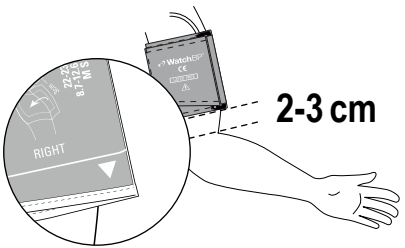


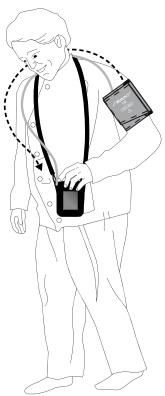
1) **Preparing measurement arm** – Remove all clothing covering or constricting the measurement arm.



☞ *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 cuff tube should point upward and be mounted over the patient's shoulder.

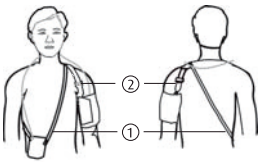




☞ *Adjust the tube holder on the belt of the pouch so it is properly positioned on the shoulder.*

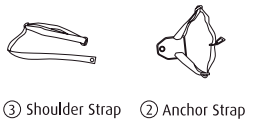
3) **Proper positioning of the cuff using the Anchor Strap**

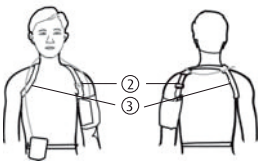
Option 1: Use the Shoulder Sling ① and the Anchor Strap ② to position the cuff as demonstrated in the diagram below.



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

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



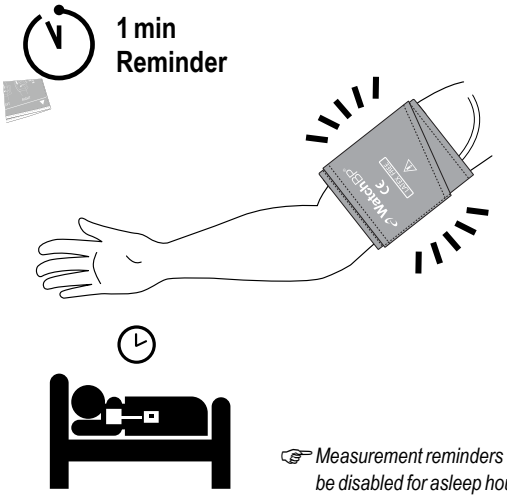


Instructions: Place the Shoulder Strap over both shoulders as demonstrated in the diagram. Connect the device to a belt. Position the device at front. Apply the Cuff to the arm. Buckle up the Anchor Strap with the Shoulder Strap. Snap the connector of the Anchor Strap into the D-ring of cuff. Adjust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

3) **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 measurement.*

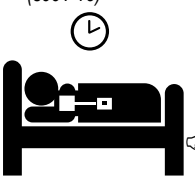
4) One minute before the next scheduled measurement, the device will partially inflate and immediately deflate the cuff to remind the patient of the upcoming measurement.



☞ *Measurement reminders will be disabled for asleep hours.*

5) **Measurement reminder** – Five seconds before the next measurement, the device can emit a short series of beeps to notify the patient of the coming measurement (optionally). The beep will be off on default.

☞ *The beeper of Ambulatory mode can be enabled via software setting.*
(see P15)



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

6) **During measurements** – the patient should be reminded to remain still, refrain from talking, and to breath normally during the measurement. If the patient is occupied 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.*

7) **Repeat measurements in 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.

☞ *If the repeat measurement encounters an error again, the device will take an extra measurement after a four minutes countdown. If the extra measurement is not successfully either, the device will record an error message.*

☞ *If the device stops taking measurements, the patient should return the device to the physician to determine the cause of error.*

8) **Storing measurement data** – The WatchBP O3 device can store up to 250 single measurements in **«AMBULATORY»**mode.

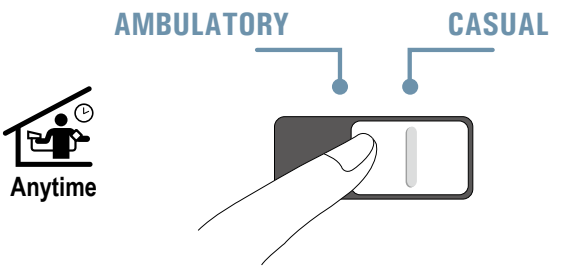
☞ *When the memory is full, each new measurement will automatically overwrite the earliest measurement.*

☞ *The display of blood pressure values on the LCD screen can be disabled in <<Ambulatory>> mode by means of software setting.*

Taking blood pressure measurements in «CASUAL» mode

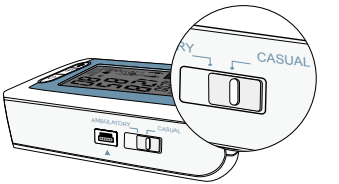
In «CASUAL» mode

In «**CASUA**L» mode, the device functions like a regular blood pressure monitor – single measurements are automatically stored and can be reviewed at a later stage. The casual mode can be used to perform a single blood pressure measurement to test if the device is functioning properly. Do not forget to put the device back in <<Ambulatory>> mode before sending away the patient for 24-hour blood pressure measurement.



Taking blood pressure measurements

Be sure the device is set to **«CASUAL»** mode.

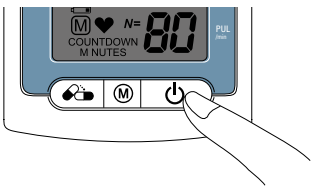


1) **Before each measurement** – Patients should be informed to avoid physical activity, eating or smoking before each measurement. The patient should sit down and relax for at least 5 minutes before the measurement.

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

2) **Applying the cuff** – 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.

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

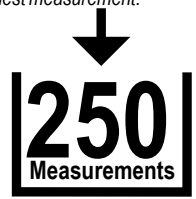


4) **During the measurement** – The cuff will inflate automatically. A single measurement will be performed by each push on the ON/OFF Button.

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

6) **250 measurements safely stored** – The WatchBP O3 device can store up to 250 single measurements in «**CASUA**L» mode.

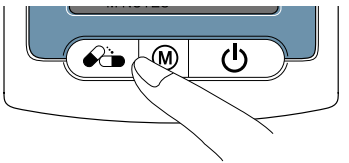
☞ *When the memory is full, each new measurement will automatically overwrite the earliest measurement.*



Recording the taking of medication

Medication record

The patient can record the time of medication intake by pressing the Medication Button.



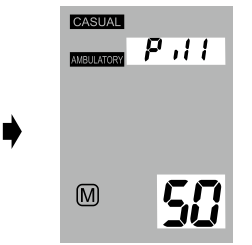
1) Press and hold the Medication Button for 2 seconds and the Pill icon will appear.

➧ **Press and hold for 2 Seconds...** ➧ P.11

☞ *A Medication record can be recorded in both modes.*

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

➧ **Press and hold**



➧ P.11 10:00

3) Medication record is saved after the beep sound.

BEEP ➧ **Saved**

☞ *The beeper can be disabled via software setting.*

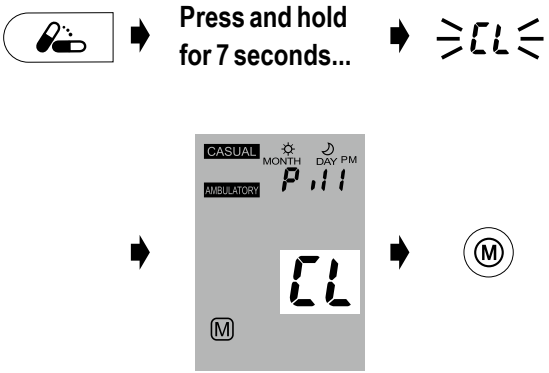
50 records safely stored

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 the ON/OFF button to cancel the deletion .



☞ *Pressing the <<M>> Button to delete data will erase all medication recordings in the selected mode.*

Special Function: atrial fibrillation (Afib) detection

Appearance of atrial fibrillation for early detection

The device is designed to detect atrial fibrillation during blood pressure measurements in the «**AMBULATORY»** mode. This device is able to detect atrial fibrillation with high accuracy: a sensitivity of 97% and a specificity of 89%*. If the atrial fibrillation icon is displayed after the measurement, it is recommended to visit a doctor.

Afib Detector

The device can screen for atrial fibrillation during blood pressure measurement.

Occasionally, 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 to keep the arm still during the measurement.

2) Some arrhythmia (irregular heart beat) other than atrial fibrillation might be present. In such case it may still be useful to pay a visit to the doctor.

* Wiesel J, *et al.* Detection of atrial fibrillation using a modified microlife blood pressure monitor. Am J Hypertens, 2009; 22: 848-52.
* Stergiou GS, *et al.* Diagnostic accuracy of a home blood pressure monitor to detect atrial fibrillation. J Hum Hypertens, 2009; 23: 654-8..

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

☞ *This device may not detect atrial fibrillation in people with pacemakers or defibrillators.*

About atrial fibrillation

Atrial fibrillation is a common heart rhythm problem. It affects more than 2 million people in North America. It is more common in older age and it is found in 18% individuals aged 85 years and older. It is a common cause of major strokes. About 15% of all strokes are caused by atrial fibrillation.

The elderly, or those with high blood pressure, diabetes or heart disease are more likely to get a stroke if they have atrial fibrillation.

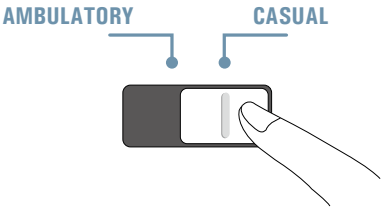
Atrial fibrillation is a rhythm problem that can last from a few minutes, to days or weeks and even years. Atrial fibrillation can cause blood clots in the upper chambers of the heart (the atria). These clots can break off and flow to the brain causing a stroke.

With the right treatment the chance of stroke can be reduced by two-thirds.

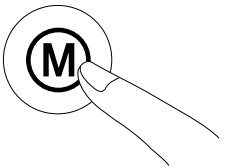
Viewing, deleting and transferring measurement data

Viewing measurement data

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

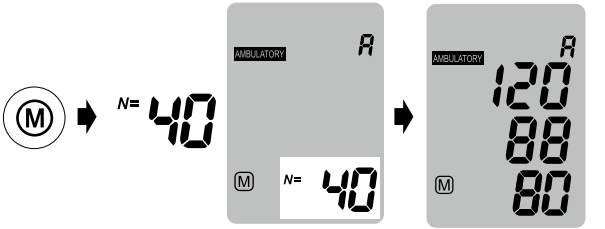


2) Then press the <<M>> Button



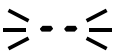
In «AMBULATORY» mode

1) When the <<M>> Button is pressed, it briefly displays the total number of measurements stored, e.g. N=40, followed immediately by the average of all measurement data stored in memory.



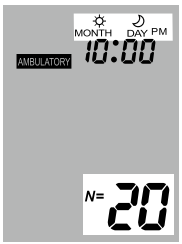
☞ *«A» is displayed when the number shown is the average of all data.*

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



Viewing, deleting and transferring measurement data (cont.)

2) Pressing the <<M>> Button again displays the average of all awake hours.



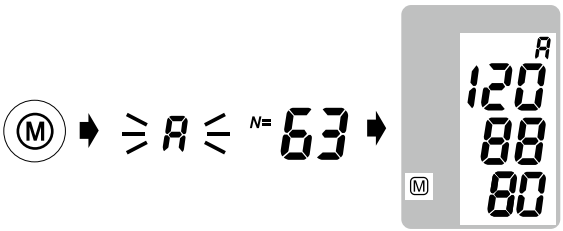
3) Pressing <<M>> Button once again shows the average of all night hours.

☞ *All individual readings can be viewed by repeatedly pressing the <<M>> Button.*

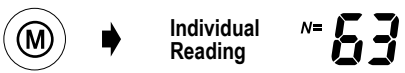
☞ *The display of BP reading and memory of Ambulatory Mode can be disabled via software setting.*

In «CASUAL» mode

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



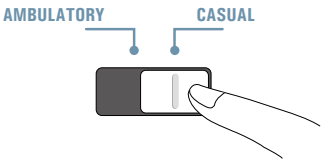
2) All individual readings can be viewed by repeatedly pressing the <<M>> Button.



Deleting measurements

Data from «**AMBULATORY**» 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.

Ⓜ ➧ **Press and hold** ➧ CL

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

➧ Ⓜ

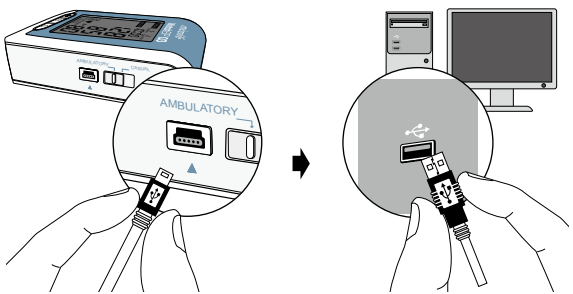
➧ **Standby mode**

☞ *Each deletion will erase entire records of each mode.*

Viewing, deleting and transferring measurement data on the PC. (cont.)

Transferring measurement data

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



☞ *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.*

Software commands	
Store data	Click «Save Excel report» or «Save PDF report», the file name is formed automatically from the patient's identity number and the suffix «WatchBPO3_(date).xls». or WatchBPO3_(date).pdf»
View the data	Click <<Open 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 to do so.*

☞ *The program will prompt to synchronize the date/time of the device to that of the PC.*

☞ *Before using <<Clear Memory>> or <<Exit>> make sure the data are stored.*

☞ *Press <<Help>> to open user manual of software*

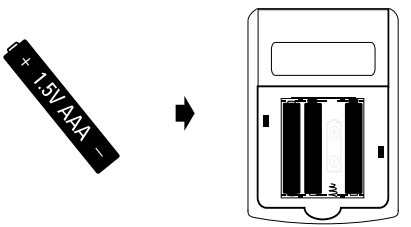
Appendix

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 device is connected to a computer, the pump runs for 1 second instantaneously and “Pc --“ is displayed together with voltage of the batteries on the PC screen. If the voltage is low, the buzzer of the device beeps. The battery icon and voltage number are also displayed on the screen of the device. It is a reminder for replacing new batteries.The buzzer keeps beeping until the batteries are replaced.

☞ *Caution: do not use rechargeable batteries.*

☞ *Use 4 new, long-life 1.5V, size AAA alkaline batteries.*

☞ *Do not use batteries out of expiration date.*

☞ *Remove batteries if the device will not be used for a prolonged period.*

Safety, care, accuracy test and disposal

Safety and protection

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

- Ensure that children do not use the device unsupervised; some parts are small enough to be swallowed.
- Only activate the pump when the 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

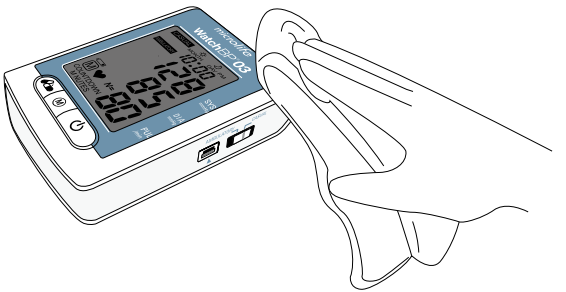
Avoid proximity to electromagnetic fields, such as those produced by mobile phones

Never open the device

Protect the device from impact and drops

Device care

Clean the device with a soft, dry cloth.

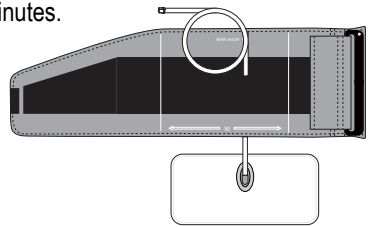


Accuracy test

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

Cleaning the cuff

Take out the bladder. Fold and place the cuff cover inside a washing bag. Wash the cuff cover with warm water (43 °C; i.e. 110 °F) and a mild detergent in the washing machine.
Pasteurization : wash the cuff cover in 75 °C (167 °F)hot water for 30 minutes.



Do not iron the cuff!

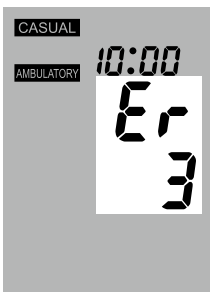
Disposal

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.

- *The device will take another measurement automatically when an error occurs.*
- *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 - 40 °C / 50 - 104 °F

Storage temperature:
- -20 - +55 °C / -4 - +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 corresponds to the requirements of the standard for non-invasive blood pressure monitor.

EN 1060-1
EN 1060-3
EN 1060-4
IEC 60601-1
IEC 60601-1-2

Electromagnetic compatibility:
- Device fulfills the stipulations of the standard IEC 60601-1-2.

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

CE 0044

Type BF applied part

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

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: _____

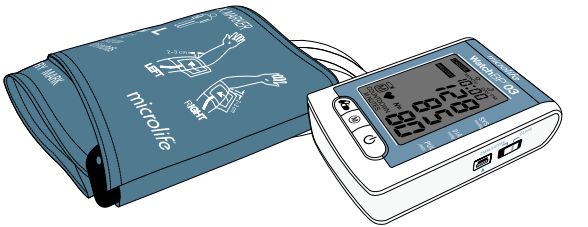
Email: _____

Product: WatchBP O3

Product Number: BP3MZ1-1

Serial Number:

Date:



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CE 0044

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

IB WatchBP O3 BP3MZ1-1 EN 0117