

microlife®

WatchBP O3

Professional 24-hour
Ambulatory Blood
Pressure Monitor



BP 3SZ1-1

Instruction Manual

EN

ESH
Protocol Embedded

AHA
Protocol Embedded

Indications For Use

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor, Model WatchBP O3 (BP3SZ1-1) is a non-invasive 24 hour ambulatory blood pressure monitor (ABPM) using oscillometric technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures, pulse rate, mean arterial pressure (MAP) for or use in adults and pediatrics (but not neonates) with arm cuff circumference sizes ranging from 14 -52 cm.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected pre-eclampsia.

The device provides aortic blood pressure parameters, includes central systolic blood pressure (cSBP), central pulse pressure (cPP) and central diastolic blood pressure (cDBP), non-invasively through the use of a brachial cuff.

The device detects the appearance of atrial fibrillation during measurement.

The memory data can be transferred to the PC (personal computer) running the WatchBP Analyzer software by connecting the monitor via USB cable or Bluetooth.

WatchBP product support:

<https://www.microlife.com/professional-products>

WatchBP Software support:

<https://www.microlife.com/support/software-professional-products>

Developers support:

<https://www.microlife.com/developers1>

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Product description

The WatchBP O3 ABPM system consists of two major parts

- The device, cuffs and accessories.
- The WatchBP Analyzer Software.

With the WatchBP Analyzer Software

- 1) The device can be programmed for the blood pressure measurement procedure.
- 2) Measured blood pressure values can be downloaded to the PC.
- 3) A PDF report and Microsoft Excel spreadsheet (or .csv format.) for data analysis can be generated.

Model type

The device is upgradable for obtaining special features. There are three different types of the device:

- **Advanced:** advanced ABPM
- **AFIB:** advanced ABPM with Microlife Atrial Fibrillation Detector
- **Central:** advanced ABPM with Microlife Atrial Fibrillation Detector and Central Blood Pressure measurement

The Atrial Fibrillation Detector and Central Blood Pressure measurement of the device can be activated through the WatchBP Analyzer Software. Refer to **Upgrading the version of the device** for details.

Contents

1. WatchBP O3 Monitor (dependent on purchase version)
2. WatchBP O3 Cuff – Size M
3. WatchBP O3 Cuff – Size L
4. Carrying Pouch
5. Data Cable
6. AAA Alkaline Batteries x 4
7. Tube holder x 3
8. 100 cm cuff tube x 2
9. Instruction Manual
10. Patient diary
11. Quick start guide

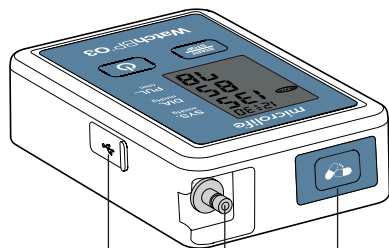


* Download the latest WatchBP Analyzer Software from the Microlife website.

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

Product description

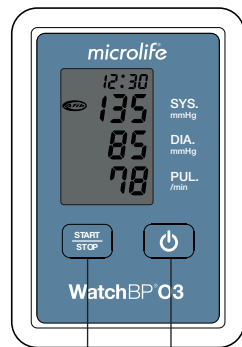
Product Overview



USB port

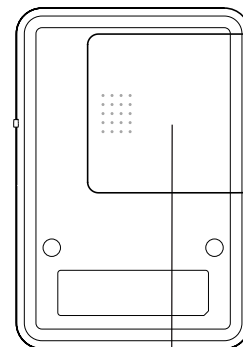
Medication button

Cuff connector

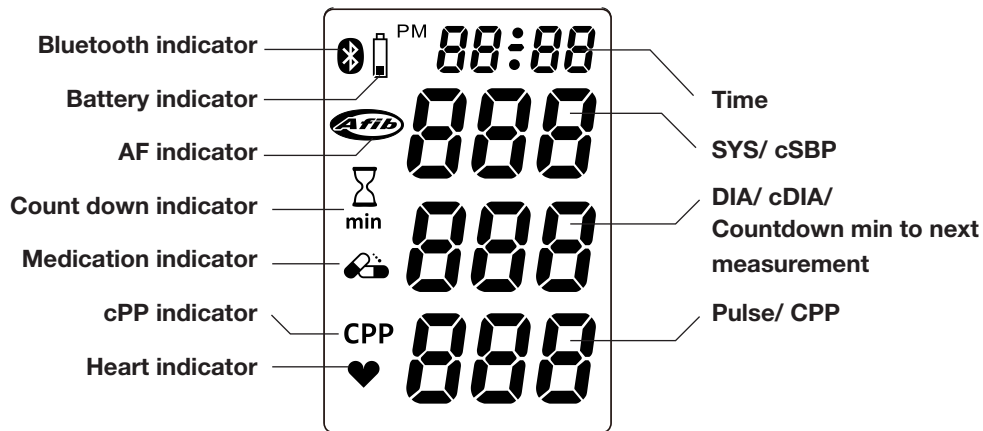


Start/Stop
button

On/Off button



Battery compartment



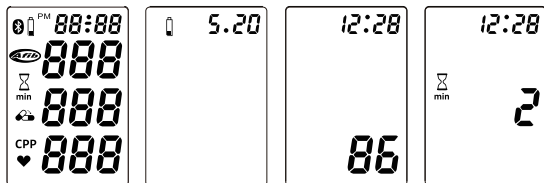
Before using the device for the first time


Activating the device

Open the battery compartment on the rear of the device and insert 4x AAA alkaline batteries according to the battery polarities (+ / -) and close the compartment.

Press the On/Off button  to activate the device.

The device displays sequentially the full screen display, the voltage of the batteries, the number of measurements stored on the device and the countdown minutes before the next measurement based on default schedule programmed on the device.



 Program the device and clear existing measurements of the device before any new patient session.

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

Using WatchBP Analyzer

The memory data can be transferred to your PC (personal computer) running the WatchBP Analyzer Software by connecting the monitor via USB cable or Bluetooth.

System Requirements for Software:

1GHz CPU. 512MB Memory, 4.5GB free hard disk space, Microsoft Windows 7 SP1 / 8 / 10

Installing the Software Program

Download the latest WatchBP Analyzer Software from the Microlife website.

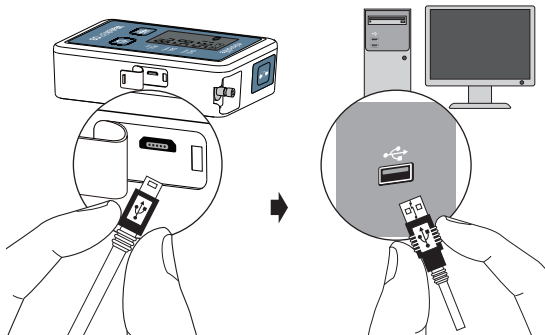
<https://www.microlife.com/support/software-professional-products>

Double click the download installer and simply follow the

Measurement programming

Connecting the Device to a Computer

Connect the device to the PC using the USB cable provided with the device.




Start the Software Program

Start the software program. The date/time on the device will sync with date/time of PC automatically when successfully connected with WatchBP Analyzer PC software.

If the device and WatchBP Analyzer software is connected successfully:

- <USB> is displayed on the LCD screen of the device.
- The device ID, model, version of the Device and batteries condition etc. are displayed on the WatchBP Analyzer software.



 See also the Instruction manual of the WatchBP Analyzer for details. The instruction manual of the WatchBP Analyzer can be found in the software by clicking <About> in the functional bar.

Measurement programming

Programmable measurement intervals

Enter name, identity number, and date of birth to create a new record (if required). Select a patient and click <Program Device>.

The device can automatically take measurements at fixed interval times of 5, 10, 15, 20, 30, or 60 minutes, as can be programmed.


Day and Night Period (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 time-intervals can be set to 5, 10, 15, 20, 30, or 60 minutes for both awake and asleep time periods.

Setting Day and Night Period

Day Period	06 ▼	~ 22 with	30 ▼	minutes interval
<input type="checkbox"/>	Central BP measurement		30 ▼	minutes interval
Night Period	22 ▼	~ 06 with	60 ▼	minutes interval
<input type="checkbox"/>	Central BP measurement		60 ▼	minutes interval

 See also instruction manual of the WatchBP Analyzer for details.

 The option of taking central blood pressure measurement is selectable if the feature of the device is activated.

Setting 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).

Setting Highest Inflation pressure

Enable Disable(auto)

180 ▼ mmHg

160

180

200

220

* "Disable" is recommended

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, tick the squares to the left.


Setting ambulatory options.

Hiding BP data

Silent mode

 The display of blood pressure values on the LCD screen can be enabled or disabled.

 The beeper can be enabled or disabled.

 Once you have completed the settings, press 'Program' to program the schedule into the device.

 For further explanation see instruction manual of the WatchBP Analyzer.

Preparing for a blood pressure measurement

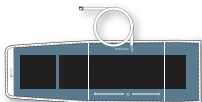
Confirm the cuff size

A variety of different cuff sizes are available.

 *Only use Microlife cuffs!*

 *Washable cuffs are available in both nylon and cotton.*

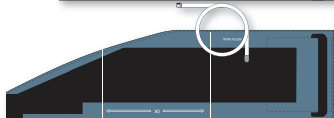
S 14 - 22 cm
(5.5 - 8.7 inches)



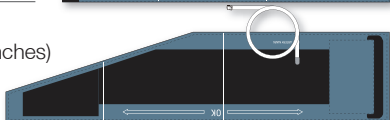
M 22 - 32 cm
(8.7 - 12.6 inches)



L 32-42 cm
(12.6-16.5 inches)



XL 32-52 cm
(12.6-20.5 inches)

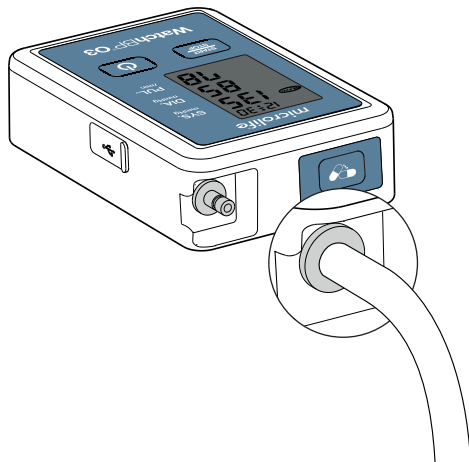


 *S, XL size cuffs can be ordered optionally.*

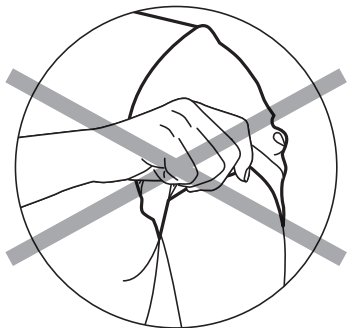
 *M & L size cuffs are supplied as standard with the device.*


Connecting the cuff tube to the device

Push the end of the tube firmly onto the metal cuff connector on the device.

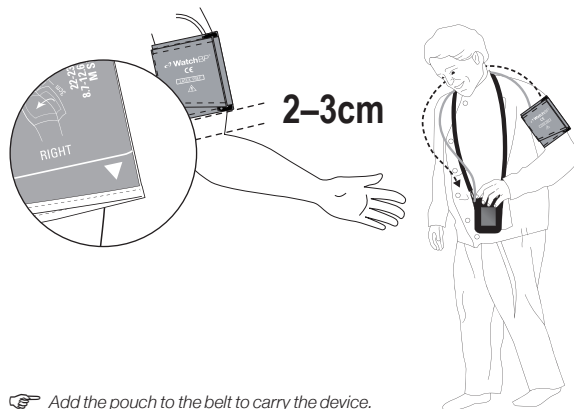


Preparing the measurement arm – Remove all clothing covering or constricting the measurement arm.




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

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 upwards and should be mounted over the patient's shoulder to the other site of the body.



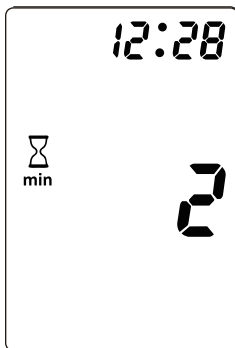
 Add the pouch to the belt to carry the device.

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

Taking blood pressure measurement

Next measurement indicator

The device will display the next measurement time, indicated by a countdown in minutes on the display.

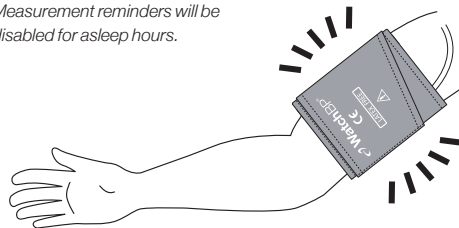


 The example shows countdown 2 minutes to the next measurement.

Measurement reminder

One minute before the next scheduled measurement, the device will partially inflate to approximately 50 mmHg and immediately deflate the cuff to remind the patient of the upcoming measurement.

 Measurement reminders will be disabled for asleep hours.



Five seconds before the next scheduled measurement, the device can emit a short series of beeps to notify the patient of the coming measurement (optionally). The beep is switched off by default and can be enabled via software setting. (See instruction manual of the WatchBP Analyzer)


 The beep sound is disabled for asleep measurement


During blood pressure measurements

The patient should be reminded to remain still, refrain from talking, and to breathe normally during the measurement. If the patient is occupied at the start of a measurement, the patient should, where possible, try to relax the measurement arm.

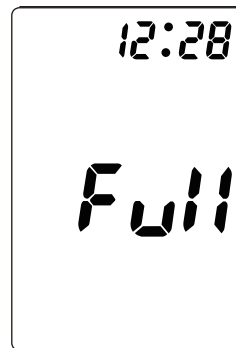
 *At any time, a single measurement can be stopped by pressing the Start/ Stop or ON/OFF button.*


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

 *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 successful either, the device will record an error message.*

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


Storing measurement data – The device can store up to 330 memories, which includes measurements, medication records, errors and start/ stop events.




 *When the memory is full the LCD screen of the device displays 'Full' and no further measurements or medication records can be performed. Upload the measurement data and clear the memory to reset the device.*

Initiating blood pressure measurement manually

Press the Start/Stop button during standby to start a measurement. Once the measurement is complete, the measurement value is automatically stored and can be checked with the software.

 Before starting a measurement, make sure the correct cuff size is used and is properly positioned on the arm.

 If 'Highest Inflation Pressure' is enabled (on default it is disabled), the selected 'Highest Inflation Pressure' is displayed on the device before starting the measurement.


Setting Highest Inflation pressure

Enable Disable(auto)


180 ▼ mmHg

* "Disable" is recommended



 Readings are displayed at the end of the manually initiated blood pressure measurement.



 When a central blood pressure measurement is performed. The LCD screen switches every 2 seconds after the measurement to display both central and brachial (peripheral) blood pressure values.



Special functions

Screening for atrial fibrillation during blood pressure measurement

The device is designed to screen for atrial fibrillation during blood pressure measurements with high accuracy: a sensitivity of 98% and a specificity value of 92%*. If atrial fibrillation is detected this will be shown in the report.

About Atrial Fibrillation

Atrial fibrillation is a common heart rhythm problem and a common cause of major strokes. It affects 8% of those 65 years and older and about 20% of all strokes are caused by 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 heart. These clots can break off and flow to the brain causing stroke. One sign of atrial fibrillation is palpitations. However, many people have no symptoms and therefore may remain undetected whereas diagnosing atrial fibrillation early followed by adequate treatment can largely reduce the chance of getting a stroke.

* Verberk et al. Screening for atrial fibrillation with automated blood pressure measurement: Research evidence and practice recommendations. *Int J Cardiol* 2016: 465–473

Central blood pressure parameters

The device is designed to take central blood pressure parameters .

Central blood pressure is the pressure in the ascending aorta, the largest artery that originates from the left ventricular of the heart and from where oxygen is distributed to all parts of the body through the systemic circulation. Central Systolic Blood Pressure and Central Pulse Pressure by this monitor is determined directly through pulse volume plethysmography (PVP) waveform analysis. Central Diastolic Blood Pressure by this monitor is calculated by subtraction of Central Systolic Blood Pressure and Central Pulse Pressure.

Special functions

How is central blood pressure measured?

The device measures brachial systolic and diastolic blood pressure as usual. However, where the cuff normally totally deflates after the blood pressure measurement, the cuff now stops deflating at approximately 60 mmHg cuff pressure to keep a stable pressure on the brachial artery for approximately 10 seconds which is needed to acquire brachial pulse volume plethysmography (PVP) waveforms (pulse volume recording). During these 10 seconds approximately 10 PVP waveforms are recorded from which one average PVP waveform is determined and analysed. From the average PVP waveform, some characteristic points (parameters) are identified that are directly related to arterial compliance (stiffness) and wave reflections. With these parameters and previously measured peripheral (regular) blood pressure the central systolic blood pressure value and the central pulse pressure value are then determined¹.

The time that is needed to determine the central blood pressure value may vary among patients; i.e. with faster heart rate, less time is required for collecting the number

of required PVP waveforms. It is very important to keep the arm still during the time the PVP waveforms are collected.

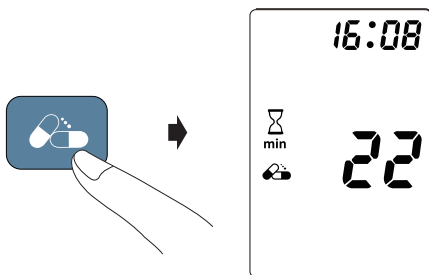
Accuracy of the central blood pressure parameters

The accuracy of central blood pressure parameters performed with this device can only reliably be determined against intra-arterial blood pressure measurement. The device is a certified equivalence with the WatchBP Office Central that has been validated against simultaneous recorded intra-arterial blood pressure measurement in 85 subjects and showed high accuracy².

1. Sung, S.H., et al., *Measurement of central systolic blood pressure by pulse volume plethysmography with a noninvasive blood pressure monitor. Am J Hypertens*, 2012. 25: 542-8.
2. Cheng, H.M., et al., *Measurement accuracy of a stand-alone oscillometric central blood pressure monitor: a validation report for Microlife WatchBP Office Central. Am J Hypertens*, 2013. 26: 42-50.

Recording intake medication

The patient can record the time of medication intake by pressing and holding the medication button for 2 seconds. The pill icon flashes twice and displays for 1 min before the LCD screen returns to display the count down time (min) to next measurement.



Upgrading the version of the device

The device is upgradable for obtaining special features. There are three different versions of the device:

- Standard version: standard ABPM
- AFIB version: standard ABPM with Microlife Atrial fibrillation Detector
- CBP version: standard ABPM with Microlife Atrial fibrillation Detector and Central Blood Pressure measurement

The Atrial Fibrillation Detector and Central Blood Pressure measurement of the device can be activated through the WatchBP Analyzer. A 16-digit activation key is needed specifically to match the device ID for activation. Please contact Microlife or the local distributor for additional information.

About

WatchBP Analyzer: Version 1.0.0.2

Device ID: 112233445566

Firmware version: RE1.2018.10.07

Options:

AFIB

Central BP

Please consult Microlife or local distributor on the options activation

Central BP Activation

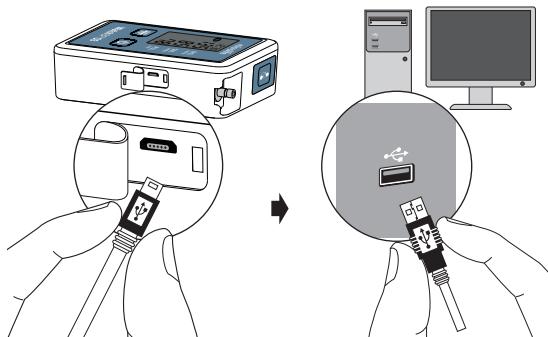
Device ID: 112233445566

Please insert a 16-digit activation key

Transferring and deleting measurement data

Transferring measurement data

Connect the device to the PC. Start the software program. Click **<Download>** and follow the procedure of the WatchBP Analyzer to transfer the measurement data to a computer.



Deleting measurements

The measurement data on the device will be automatically deleted after clicking **<Program Device>** in the WatchBP Analyzer software to program a measurement schedule for the next patient.

 See instruction manual of WatchBP Analyzer for details.

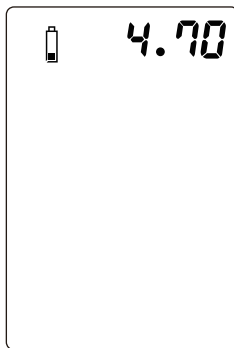
Appendix





“AAA” alkaline batteries are the main power source of the device.

If the voltage is low, the buzzer of the device beeps in order to remind the user that the batteries need to be replaced. The buzzer keeps beeping until the batteries are replaced. The battery icon and voltage number are also displayed on the LCD screen of the device.

How to replace batteries

Open the battery compartment at the back of the device. Replace the batteries – ensure correct polarity as shown by the symbols in the compartment.



-  Do not use rechargeable batteries.
-  Use 4 new, 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.

Bluetooth connectivity

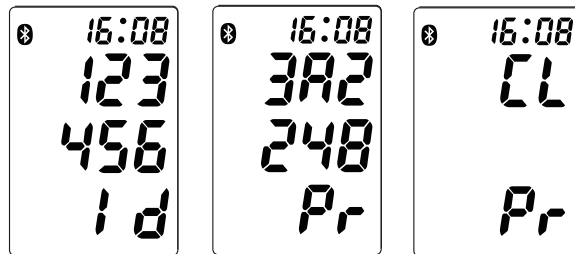
Bluetooth connection of the WatchBP Analyzer supports Microsoft Windows 10

Regarding the connectivity architecture design, we used proprietary communication protocol to do data transfer process. The specific communication protocol is assured that the information (data) is correct. The program checks ACK firstly. Afterward, the program compares the received checksum with the sum of encoded raw data. If the result is correct, the data is guaranteed during transmission. In contrast, once the device gets wrong communication command, it will not have any response.

It is a data encryption and decryption architecture. We used proprietary encryption method to pack blood pressure raw data. In other word, Blood Pressure Analyzer need to use proprietary decryption method to unpack the encrypted data to get blood pressure raw data.

Pairing the device

Press and hold the Start/Stop button for 7 seconds, the Bluetooth icon flashes and starts pairing mode. The unique 6-digit device ID of the unit is displayed. Connect the device and confirm pairing. The Bluetooth icon is displayed on the LCD screen of the blood pressure monitor to show the presence of Bluetooth connection.



 Press and hold the Start/Stop button for 5 seconds to clear the connection.

See the instruction manual of WatchBP Analyzer for details.

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.

Safety, care, accuracy test and disposal

Safety and protection

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



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



- 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 as 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



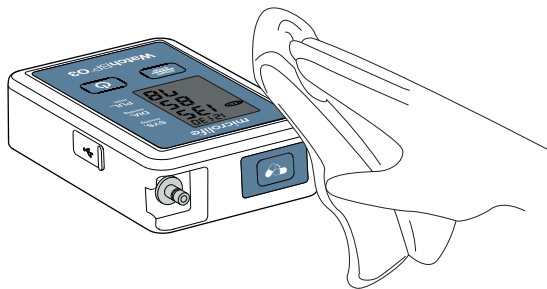
Protect the device from impact and drops

Device 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)

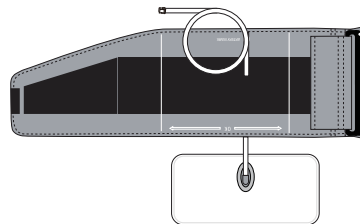
Then wipe the exterior of the device with a soft, dry cloth.



Cuff cleaning and disinfecting

Take out the bladder. Fold and place the cuff cover inside a washing bag. Wash the cuff cover with warm water (43°C; 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!

Safety, care, accuracy test and disposal

Accuracy test

We recommend the 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.

Disposal



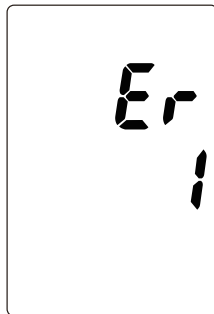
Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, and not as domestic waste.

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. Reposition 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.

Error messages

"Er 3"	No pressure in the cuff	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Replace the cuff 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.

"Er 11"	Signal too weak during central blood pressure measurement	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.
"Er 12"	Error signal during central blood pressure measurement	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 13"	Cuff pressure errors during central blood pressure measurement	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Check that the cuff is correctly connected and is not too loose. Replace the batteries if necessary. Repeat the measurement.
"Er 15"	Abnormal result of central blood pressure reading	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.

"Er F"	The device has gone into "single fault condition"	Single fault condition means that the measurement is aborted to protect the patient from being harmed or the device from being damaged. Re-position the cuff and repeat the measurement. Replace the batteries if necessary. If the error persists, contact microlife or the local distributor.
"Er A"	Flash memory error	Possible hardware fault. Try again. If the error persists, contact Microlife or the local distributor.

Error messages

"HI"	Pulse or cuff pressure too high	The pressure in the cuff is too high (over 299 mmHg) OR the pulse is too high (over 239 beats per minute). Relax for 5 minutes and repeat the measurement.
"LO"	Pulse too low	The pulse is too low (less than 30 beats per minute). Repeat the measurement.

Technical specifications

- Operating temperature:** ● 10 - 40 °C / 50 - 104 °F
- Storage temperature:** ● -20 to 55 °C / -4 to 131 °F
● 15 - 90 % relative maximum humidity
- Weight:** ● 240g (including batteries)
- Dimensions:** ● 113 x 77.5 x 33 mm
- Measuring procedure:** ● oscillometric, corresponding to Korotkoff
- Method:** ● Phase I systolic, Phase V diastolic
- Measurement range:** ● SYS: 60~255 mmHg
DIA: 40~200 mmHg
● Pulse: 30 - 239 beats per minute
- 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
- Expected service life:** ● 2 years
- Electromagnetic compatibility:** ● Device fulfills the stipulations of the standard IEC 60601-1-2.

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

CE 0044

The stipulations of the EU Directive 93/42/EEC for Medical Devices Class all 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: _____

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Product: **WatchBP O3**

Product number: **BP3SZ1-1**

Serial Number:

Date:



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