microlife®

WatchBP O3

Professional 24-hour Ambulatory Blood Pressure Monitor

BP 3SZ1-1

Instruction Manual

ESH Protocol Embedded

AHA Protocol Embedded

Federal Communications Commission (FCC) Statement
changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) this device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.
Note: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy, and if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
– Reorient or relocate the receiving antenna.
– Increase the separation between the equipment and receiver.
– Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
– Consult the dealer or an experienced radio/TV technician for help.
– This device complies with FCC radiation exposure limits set forth for an uncontrolled environment. End users must follow the specific operating instructions for satisfying RF exposure compliance.)

Indications For Use
Microlife WatchBP 03 (BP3SZ1-1) Ambulatory Blood Pressure Monitor is designed to measure systolic and diastolic blood pressure, Mean Arterial Pressure (MAP) and pulse rate using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm. The WatchBP O3 device has been clinically validated according to the ESH and ISO 81060-2: 2013 protocol (equivalence).

Function for Options:
AFIB Version: The device can detect atrial fibrillation if present during blood pressure measurement.
CBP Version: The device can determine ascending aortic blood pressure values and related parameters during regular brachial cuff blood pressure measurement.

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

Table of Contents

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.

Device Version

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 Software. Refer to **Upgrading the version of the device** for details.

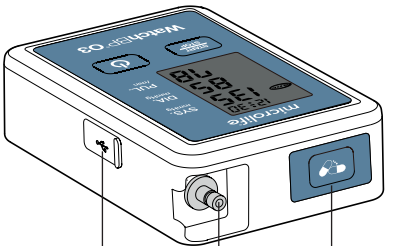
Contents

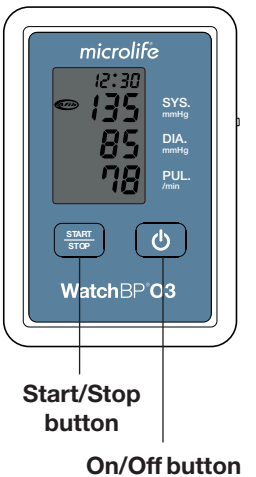
1. WatchBP O3 Monitor (dependent on purchase version)
2. WatchBP O3 Cuff – Size M
3. WatchBP O3 Cuff – Size L
4. Carrying Pouch
5. Data Cable
6. AAA Alkaline Batteries x 4
7. Tube holder x 3
8. 100 cm cuff tube x 2
9. Instruction Manual
10. Patient diary
11. Quick start guide

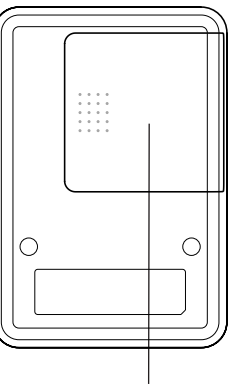
* *Download the latest WatchBP Analyzer Software from the Microlife website.*

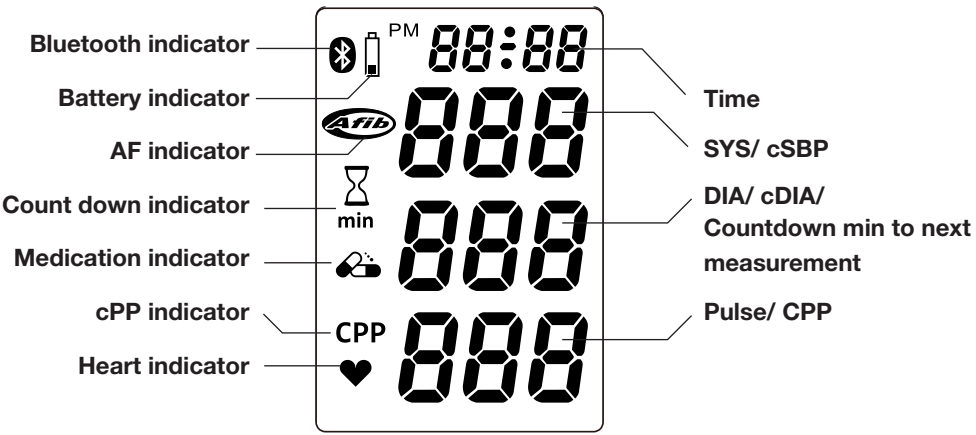
https://www.microlife.com/support/softwareprofessional-products

Product Overview








Bluetooth indicator
Battery indicator
AF indicator
Count down indicator
Medication indicator
cPP indicator
Heart indicator
PM
88:88
AFib
min
CPP
Time
SYS/ cSBP
DIA/ cDIA/
Countdown min to next
measurement
Pulse/ CPP

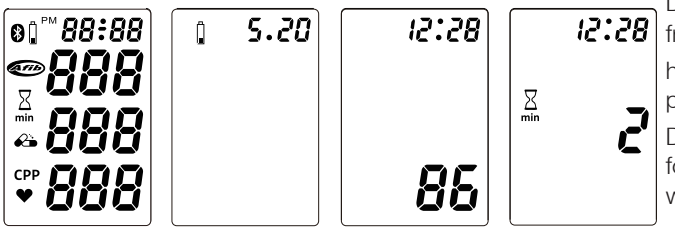
Before using the device for the first time

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.

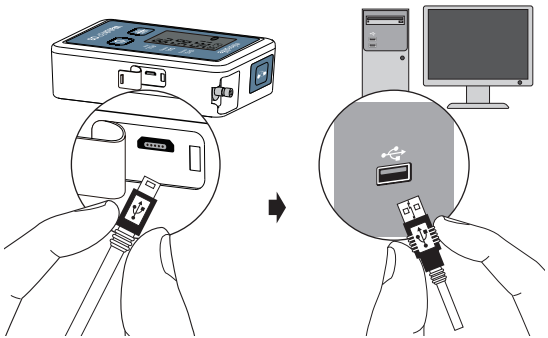
https://www.microlife.com/support/software-professional-products

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

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 WacthBP 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.*

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

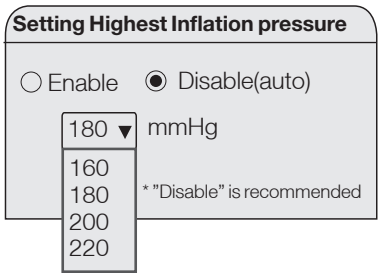
Day Period	06 ▼	~ 22 with	30 ▼	minutes interval
☐	Central BP measurement		30 ▼	minutes interval
Night Period	22 ▼	~ 06 with	60 ▼	minutes interval
☐	Central BP measurement		60 ▼	minutes interval

☞ *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.*

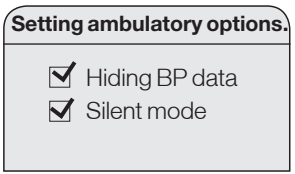
Setting highest inflation pressure

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 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.



☞ *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!*

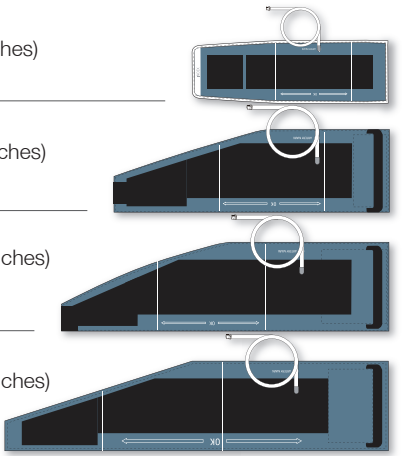
☞ *Washable cuffs are available in both nylon and cotton.*

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)

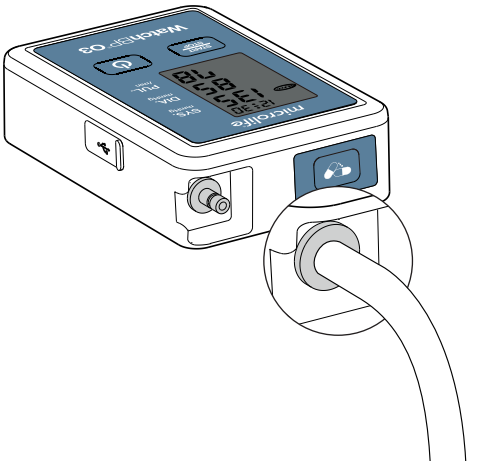


☞ *S, XL size cuffs can be ordered optionally.*

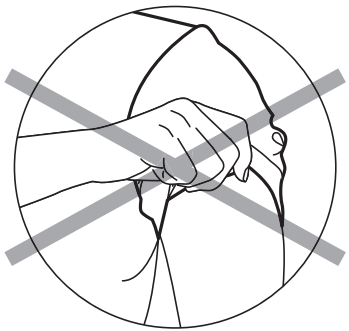
☞ *M & L size cuffs are supplied as standard with the device.*

Connecting the cuff tube to the device

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

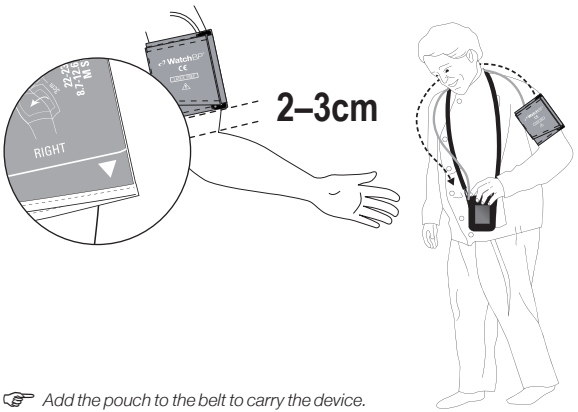


Preparing the measurement arm – Remove all clothing covering or constricting the measurement arm.



☞ *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.



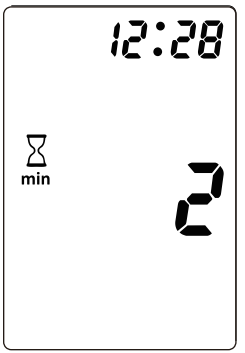
☞ *Add the pouch to the belt to carry the device.*

☞ *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.

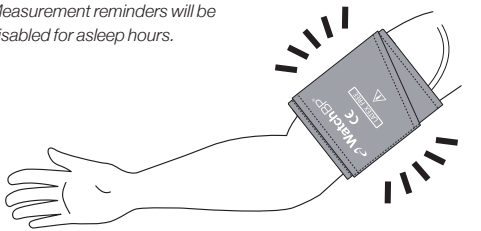


☞ *The example shows countdown 2 minutes to the next measurement.*

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.

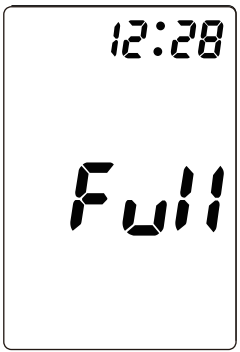
☞ *At any time, a single measurement can be stopped by pressing the Start/ Stop or ON/OFF button.*

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.*

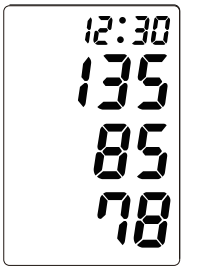
Setting Highest Inflation pressure

○ Enable ◉ Disable(auto)

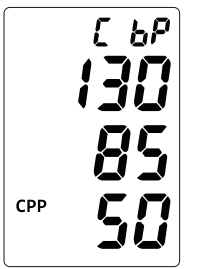
180 ▼ mmHg

* "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 (optional) 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 (optional).

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.

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 determined[1].

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.

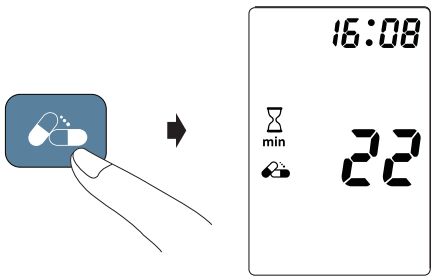
Accuracy of the central blood pressure parameters

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 accuracy[2] .

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.