microlife®

WatchBP Office

Professional
Automated Office
Blood Pressure
Monitor

BP 3SK1-3B

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

The Microlife Upper Arm Automatic Digital Blood Pressure Monitor,Model WatchBP Office (BP3SK1-3B) is a non-invasive digital blood pressure device using oscillometric technique and an upper-arm blood pressure cuff to measure systolic and diastolic blood pressures, pulse rate, mean arterial pressure (MAP) for 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 and gives a warning signal together with the measured blood pressure value if atrial fibrillation is detected .

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.

The device is for hospital use only.

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 Office consists of two major parts

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

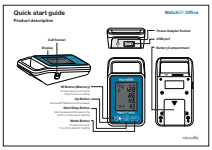
With the WatchBP Analyzer Software

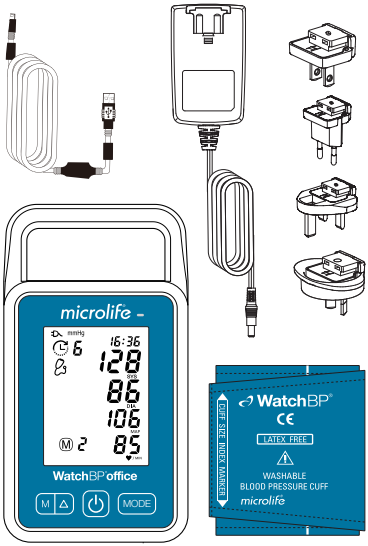
1) The device can be programmed for the blood pressure measurement procedure.
2) Measured blood pressure values can be downloaded to the PC.
3) A PDF report and Microsoft Excel spreadsheet for data analysis can be generated.

* Download the latest WatchBP Analyzer Software from the Microlife website.
https://www.microlife.com/support/software-professional-products

Contents

1. WatchBP Office Automated Office Blood Pressure (AOBP) Monitor (dependent on purchase version*)
2. WatchBP Office Cuff – Size M (22- 32cm)
3. WatchBP Office Cuff – Size L (32- 42cm)
4. Data Cable
5. Mains adapter
6. Instruction manual
7. Quick start guide





Model Type

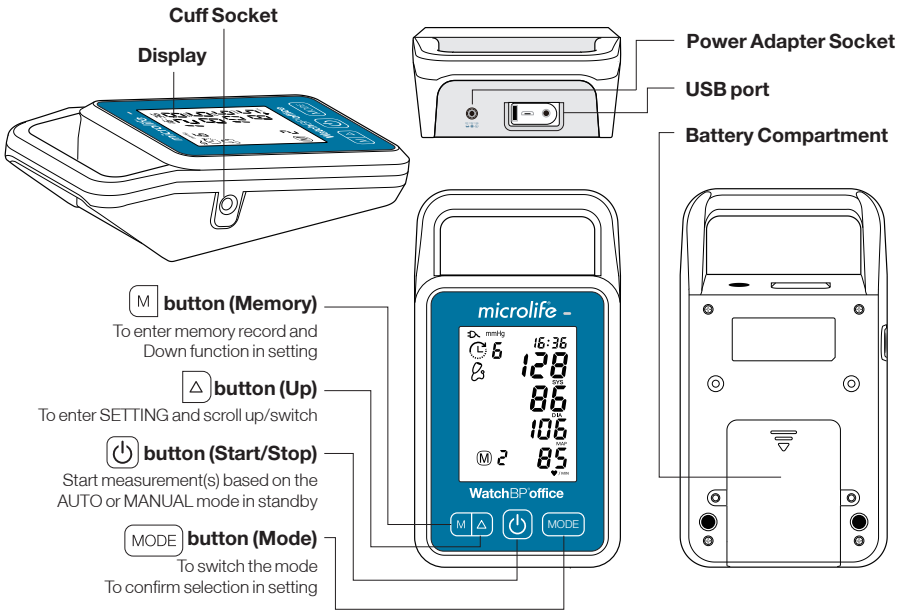
* The device can be upgraded with special features. There are three different versions of the device:

- **Advanced :**standard Automated Office Blood Pressure (AOBP) Monitor
- **AFIB :** standard Automated Office Blood Pressure (AOBP) Monitor with Microlife Atrial Fibrillation Detector
- **Central:** standard Automated Office Blood Pressure (AOBP) Monitor with Microlife Atrial Fibrillation Detector and Central Blood Pressure measurement

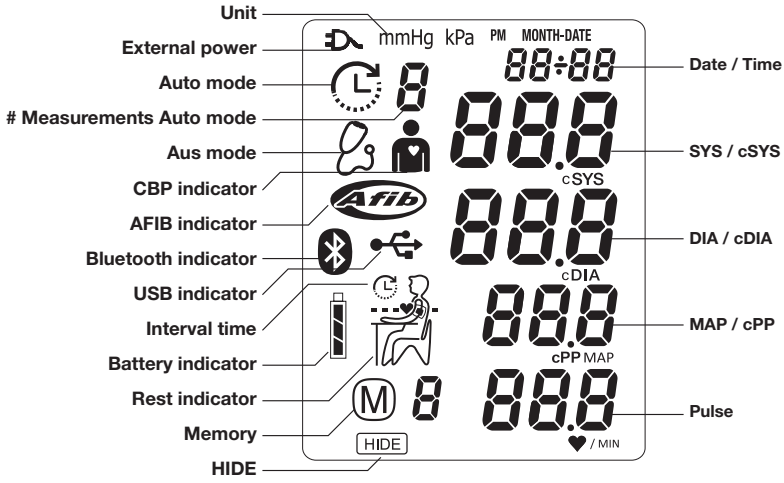
Upgrading the device

The Atrial Fibrillation Detector and Central Blood Pressure measurement of the device can be activated through the WatchBP Analyzer. An activation key is needed for activation, the activation key is specific for the device as it matches the ID. Please contact Microlife or the local distributor for additional information.

Product Overview

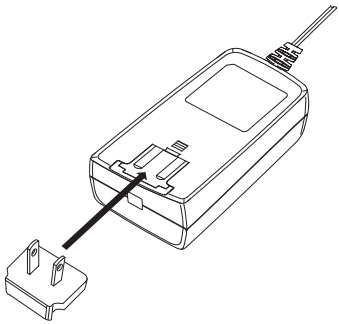


Display



Initial set up

Attaching the power plug to the power adapter
Select a suitable plug attachment and attach to the power adapter as shown here.



Charge the battery completely
When using the device for the first time, charge the battery until the recharge indicator on the device turns green.

Power ON/OFF

Press (⏻) button to switch on the device.

Press and hold (⏻) button for 3 seconds to switch off the device and turn off the LCD screen. The device displays 'oFF' before turning off.

Set the date, time and the safeguard pressure

Set the year - Press and hold the (MODE) button for 3 seconds to enter setting mode. The year number flashes in the display. Use the [△] or [M] button to select the year. Use the (MODE) button to confirm your selection and move on to month setting.

Set the month – Use the [△] or [M] button to select the month. Use the (MODE) button to confirm your selection and move on to day setting.

Set the day – Press the [△] or [M] button to select the day. Use the (MODE) button to confirm your selection and move on to time setting.

Set the time – Once you have set the hour and minutes and pressed the (MODE) button, the date and time are set, and the current time is displayed.

Set the safeguard pressure - Use the [△] or [M] button to select the highest inflation pressure or AUTO mode. Use the (MODE) button to confirm and finish the settings. Once you have finished the setting mode the current time is displayed.

* The "highest inflation pressure" can be programmed to the device. The suggested Inflation Pressure is 30 to 40 mmHg above the expected systolic value of the patient. You can select 160, 180, 200, 220 or, 240mmHg or use the default (device Displays "---') then the device will automatically inflate the cuff to the optimal cuff pressure. If the selected Highest Inflation Pressure selected is too low to measure a patient's blood pressure it may result in re-pumping or an error ("Err") will be shown.
* The date and time on the device automatically synchronizes with the date and time on the computer when connected with the WatchBP Analyzer.

Before using the device

Selecting the correct cuff

A variety of different cuff sizes are available. M and L size cuffs are provided with the device. Use the cuff marker to select the cuff size that best matches the circumference of the patient's upper arm.

Cuff Size	Circumference (cm)	Circumference (inch)
S	14-22	5.5-8.7
M	22-32	8.7-12.6
L	32-42	12.6-16.5
L-XL	32-52	12.6-20.5

* Each cuff is provided with 130 cm air tube.
* Use only cuffs provided by Microlife!
* Contact Microlife or its authorized distributor to purchase cuffs.
* M and L size cuffs are included as standard accessories.

Fitting the cuff properly

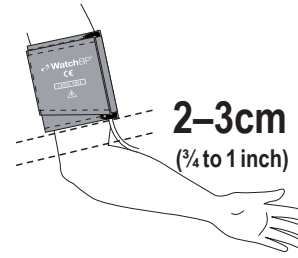
1 Place the cuff over the upper arm so that the air tube and artery mark arrow point towards the lower arm. The artery mark on the cuff must be placed over the brachial artery.

2 Lay the cuff on the arm. Make sure that the lower edge of the cuff lies approximately 2 to 3 cm (¾ to 1 inch) above the elbow.

3 Wrap and tighten the cuff around the arm.

4 Leave free space with the size of 2 fingers between the arm of the patient and the cuff. Excessive tightness may cause venous congestion and discoloration of the limb. If the cuff is wrapped too loosely, it cannot be inflated properly, and the measured values may be inaccurate. Remove all clothing covering or constricting the measurement arm. Clothing may interfere with measurement accuracy.

5 Cuffs that do not fit properly may lead to inaccurate readings. Use a different size cuff if the range index at the end of the cuff does not fall into the range specified by the range stripes.



Taking measurements in MANUAL and AUTO Mode

Turn on the power

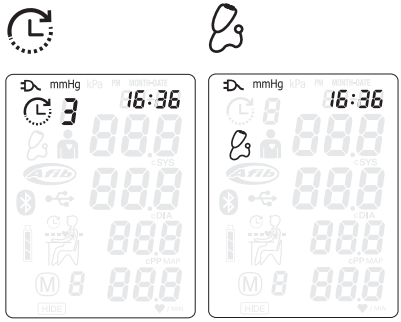
Turn on the device by pressing the ⏻ button of the device.

Connect the cuff to the device

Connect the cuff to the device by inserting the cuff connector into the cuff connector socket.

Select an operation mode

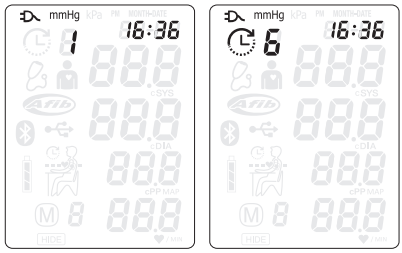
There are two measurement modes that can be used.
Press the MODE button to switch between **AUTO** or **MANUAL** Mode.



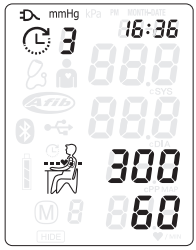
Settings of AUTO Mode

The measurement program in AUTO Mode of the device can be set, includes **Number of Measurements, Resting Time (Countdown time), Interval Time, AFIB detector, CBP measurement, HIDE and Average calculation (Discard 1st measurement).**

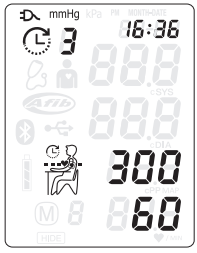
1 **Set the Number of Measurements** – Press the △ button when the device is in AUTO mode to first enter setting of **Number of Measurements**. Use the △ button to scroll up and use M button to scroll down among one to six measurements. Press MODE button to confirm the number of measurements and enter **Resting Time** setting.



2 **Set the Resting Time** – Press the △ button to scroll up and use M button to scroll down among 15, 30, 60, 120, 180, 240, 300 seconds of **Resting Time**. Press MODE button to confirm and enter **Interval Time** setting.

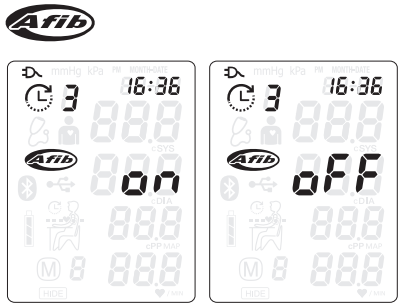


3 **Set the Interval Time** – between measurements - Press the △ button to scroll up and use M button to scroll down among 15, 30, 60, 120, 180, 240, 300 seconds of **Interval Time**. Press MODE button to confirm and enter **AFIB detector** setting.

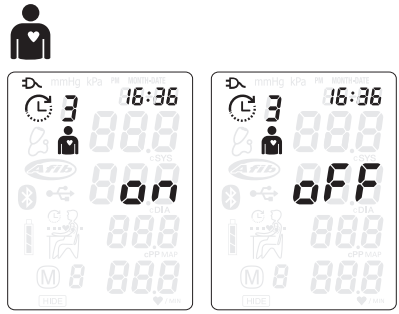


4 Set the Atrial fibrillation (AFIB) detector – Press the M or △ button to switch the **AFIB detector** ON or OFF. Press MODE button to confirm.

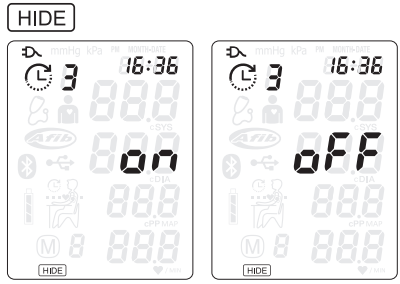
⁎ ***Set the AFIB detector option*** appears only for the device version with AFIB detector. If the device has an activated AFIB detector then it is witched on in default.



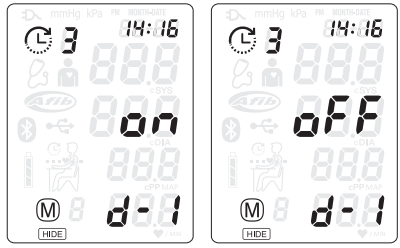
5 Set the Central blood pressure (CBP) measurement – Press △ or M button to switch ON or OFF **CBP measurement.** Press MODE button to confirm. If the device is upgraded with CBP then it is switched on in default.



6 Set the Hide function – The device features a **Hide** function in order to prevent influence on blood pressure in patients due to nervousness triggered by visible blood pressure measurements. Press △ or M button to switch ON or OFF the **Hide** Function.



7 Average calculation – The device features allow you to discard 1st measurement from averaging while the selected number of measurement is 3, 4, 5, or 6 measurements. Press △ or M button to switch ON or OFF and press MODE button to confirm the setting of **Discarding 1st measurement (d-1)** feature and finish the setting of AUTO mode . Once you go through the settings, the device returns to standby.

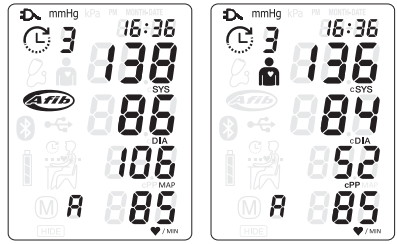


⁎ The last settings programmed to the device are the default of AUTO mode until you set the program again.

Taking measurement in AUTO Mode

Select AUTO mode. Press the ⏻ button to perform automatic measurements based on the settings of AUTO mode. The device shows all the settings and then starts counting down the Resting Time before the first measurement. The average measurement reading is displayed and saved after the measurements are complete.

The device switches the display for the average Systolic Blood Pressure (SYS), Diastolic Blood Pressure, Mean Arterial Pressure (MAP), central Systolic Blood Pressure (cSYS), central Diastolic Blood Pressure, and central Pulse Pressure (cPP) automatically if central blood pressure measurement is enabled.



* If CBP measurement is enabled, the cuff pressure is held at around 60 mmHg for around 10 seconds to collect sufficient pulse waves.
* Press ⏻ button during countdown to skip the countdown.
* Press ⏻ button to cancel remaining measurements at anytime during the measurement sequence. Display the results (average) if available.

Viewing stored values

The device stores blood pressure values of the last measurement procedure in AUTO mode.

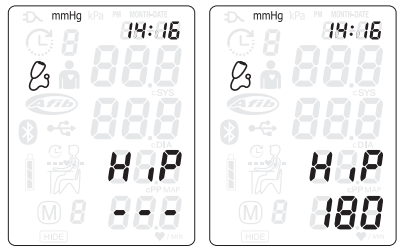
Press the M button to reveal the average of the measurements of AUTO mode. Continue pressing the M button to review individual measurements.

* The device switches the display for values of the individual measurement (including SYS, DIA, MAP, cSYS, cDIA and cPP values) if central blood pressure measurement is enabled.

MANUAL Mode Settings

The measurement program in MANUAL mode can be set to preferences. The program includes setting the **Highest Cuff Pressure** and **Hide Cuff Pressure** during deflation.

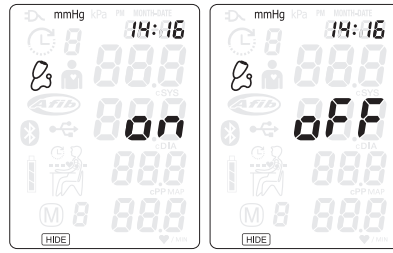
Set Highest Inflation Pressure – press △ button when the device is in MANUAL mode to enter setting of **Highest Cuff Pressure**. Use △ button or M button to scroll among 160, 180, 200, 220, 240 mmHg and auto '- - -'. Use the MODE button to confirm and move to **HIDE Pressure** setting.



* When auto '---' is selected, the device automatically inflates the cuff to the correct cuff pressure.
* The Highest Inflation Pressure is considered as a safeguard pressure. The device automatically inflates the cuff to the optimal cuff pressure but not higher than the selected Highest Cuff Pressure.

Hide Cuff Pressure during deflation

– This option helps you to determine Korotkoff K1 and K5 sound readings without digit preference. To use the HIDE function in MANUAL mode, push △ button to select the setting of HIDE function and confirm the selection by MODE button and finish the setting of MANUAL mode.



Taking measurement in MANUAL mode

Use a stethoscope to perform measurement.

Select the MANUAL mode if auscultatory blood pressure measurement is preferred above oscillometric blood pressure measurement. In MANUAL mode, the device serves as a pressure gauge. No oscillometric measurements will be taken. Systolic and diastolic Korotkoff sounds are determined by the physician using a stethoscope placed over the brachial artery.

Start inflation – Press the ⏻ button to start cuff inflation. When the maximum inflation pressure is reached, the device will automatically begin a linear deflation at a rate of 3 mmHg/sec as is recommended by the guidelines.

Assess the Korotkoff K1 and K5 sound with stethoscope – when pushing the MODE button during cuff deflation the cuff pressure at the time of pushing is temporarily stored so that the systolic (K1) and diastolic (K5) pressures can be seen afterwards. The device can store up to 4 pressures.

Push the ⏻ button at any time to start fast deflation and finish the measurement of MANUAL mode and show the pressure you have marked. Alternatively, the device quickly deflates and shows the pressures after having pushed the button 4 times, or the cuff pressure has reached 20mmHg during the deflation cycle.

After the measurement in MANUAL mode, the device displays all marked cuff pressures for one minute.

Re-inflate – Push and Hold the Up △ button during deflation to re-inflate for as long as the button is held up to a max of 299mmHg. Release the button to continue deflation. Exceeding 299 mmHg will result in an immediate release of cuff pressure and a 'HI' Error message.

Deflate faster – Push and hold the M button during deflation to release the pressure in the cuff faster, at around 8 -12 mmHg/second.

* The recommended deflation rate for auscultation is 2-3 mmHg per second. Do not assess K1 or K5 sound while holding the M button.
* If HIDE in MANUAL mode is selected, the cuff pressure during deflation will not be displayed. The display shows "---" during cuff deflation.

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.

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

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.

Central blood pressure parameters

The device is designed to assess 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 provided by this monitor are 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 analyzed. 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].

☞ 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.

☞ 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.

MAP (Mean Arterial Pressure)

The device measures the true mean arterial pressure (MAP) of the patient. Each measurement includes a single MAP value. The MAP value will always be displayed together with the systolic and diastolic blood pressure value.

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

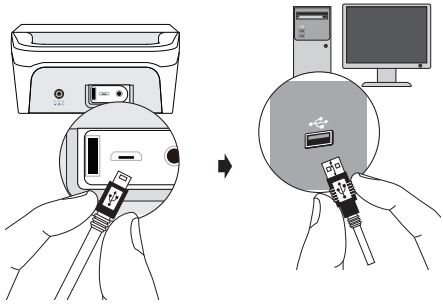
The latest WatchBP Analyzer Software is available from the Microlife website.

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.

Connecting the Device to a Computer

It is important to only use the USB cable provided.



Start the Software Program

Start the software program. The date and time on the device automatically synchronizes with the date and time on the computer 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.

Transferring measurement data

Connect the device to the PC. Start the WatchBP Analyzer software program.

Click <**Download**> button of the WatchBP Analyzer to transfer the measurement data on the device 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.

* Press and hold M button of the device for 7 seconds displays CL, presses M button again to clear the memory

☞ See instruction manual of WatchBP Analyzer for details.

Bluetooth connectivity

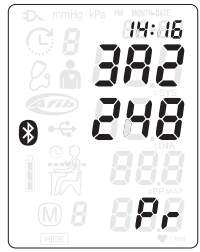
Bluetooth connection of the WatchBP Analyzer supports Microsoft Windows 10

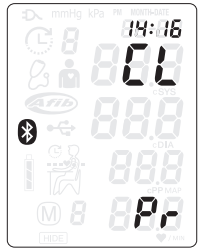
Regarding the connectivity architecture design, we used proprietary communication protocol to do data transfer process. The specific communication protocol is assured that the information (data) is correct. The program checks ACK firstly. Afterward, the program compares the received checksum with the 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 MODE button for around 7 seconds, untill 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 device to show the presence of Bluetooth connection.





☞ Press and hold the ⏻ button for 5 seconds to clear the connection.

☞ See the instruction manual of WatchBP Analyzer for details

Please note the following:

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.

Rechargeable battery and power adapter

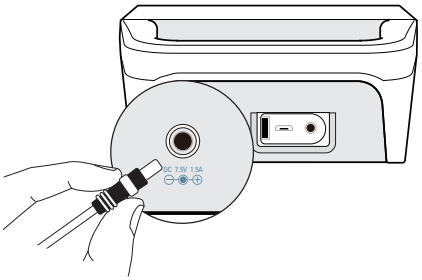
Rechargeable Battery

The device has a built-in, rechargeable Ni-MH battery pack that can perform up to 400 measurement cycles on a full charge. The battery can be recharged with the power adapter provided with the device. The empty battery indicator is displayed when the battery is low.

- When using the device for the first time, charge the battery until the recharge indicator turns to green.
- The orange recharge indicator indicates that the recharge is in progress.
- A green recharge indicator indicates that the recharge is completed.
- A green and orange changing recharge indicator, means that there is a charging error. Make sure that the correct Mains Adapter is used. If the condition persists, contact Microlife or the local distributor.

Using a power adapter

Only use the Mains Aadapter supplied with the device to recharge the device.



1) Plug the adapter cable into the power socket of the device.
2) Plug the adapter plug into the wall socket. The battery will be recharged if the device is attached to an AC power source. After the battery is fully recharged, the charging will stop. No battery power will be used if the adapter is plugged in. The battery must always remain within the device even when using AC power.
3) If the battery starts losing capacity, contact your local dealer for replacement battery. The battery can be replaced.

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.

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

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.

- Only activate the pump when the cuff is connected to the device.
- 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.

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

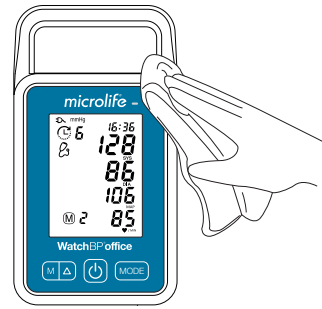
Protect the device from impact and drops

Do not use the device in the MRI environment.

Device care

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

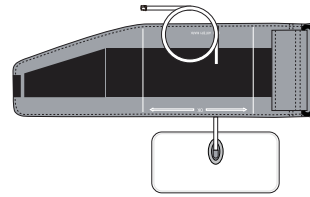
- Mild soap and water.
- Hydrogen peroxide solution (3% diluted with water).
- Sodium hypochlorite solution (1:10 dilution of household chloride bleach in water).



Cleaning the cuff

Remove 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.



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.

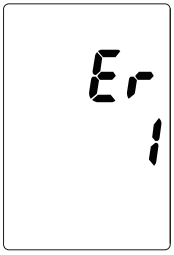
Do not iron the cuff!

Disposal

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

Error messages and Troubleshooting

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



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.
“Er 3”	**No pressure in the cuff**	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Replace the blood pressure cuff if necessary. Repeat the measurement.
“Er 5”	**No valid results**	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, when keeping the 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 if the cuff is correctly connected and is not too loose. Replace the blood pressure cuff if necessary. Repeat the measurement.

"Er 15"	**Abnormal result of central blood pressure reading**	The measuring signals are inaccurate so that no result can 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.
"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.

Troubleshooting

Problem	Possible cause	Solutions
No power (No LCD display)	**Power supply is not properly plugged in**	Plug the power supply into the wall socket.
	Battery is fully discharged	Recharge the rechargeable battery by plugging in the power supply.
Cuff does not inflate properly	**Loose connection of the tube**	Make sure the tube of the cuff is securely connected to the device.
	Leakage of the tube / bladder	Check for cracks on the tube or the bladder. Replace the blood pressure cuff if necessary.
No result displayed after measurements	**Device is in MANUAL mode**	Switch to AUTO Mode and repeat the measurements.

Technical specifications

Operation temperature/ humidity:	• 10 to 40 °C (50 to 104 °F)/ 15 - 90 % relative maximum humidity
Storage temperature/ humidity:	• -20 to 55 °C (-4 to 131 °F)/ 15 - 90 % relative maximum humidity
Weight:	• 620g (including rechargeable battery pack)
Dimensions:	• 220.4 x 121.7 x 63.3 mm
Measuring method:	• Oscillometric, Systolic blood pressure = K1; Diastolic blood pressure = K5
Measurement range:	• SYS/DIA:30-280mmHg Pulse: 40-200 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:	• Rechargeable battery pack; 4.8V 2400 mAh; Mains power supply DC 7.5V, 1.5 A
Expected service life:	• 2 years
Reference to Standards:	• Device corresponds to the requirements of the standard for non-invasive blood pressure monitor. IEC 60601-1 IEC 60601-1-2 ANSI/AAMI/ISO 81060-2 ANSI/AAMI/IEC 80601-2-30
Electromagnetic Compatibility:	• Device fulfills the stipulations of the standard IEC 60601-1-2.
	Type BF applied part

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

Annex

Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Row			
1	Guidance and manufacturer´s declaration – electromagnetic emission		
2	The model BP3SK1-3B is intended for use in the electromagnetic environment specified below. The customer or the user of the model BP3SK1-3B should assure that it is used in such an environment.		
3	Emissions test	Compliance	Electromagnetic environment – guidance
4	RF emissions CISPR 11	Group 1	The Model BP3SK1-3B uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
5	**RF emissions CISPR 11**	Class A	The BP3SK1-3B is suitable for use in all establishments, other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
6	**Harmonic emissions IEC 61000-3-2**	Not applicable	
7	**Voltage fluctuations / flicker emissions IEC 61000-3-3**	Not applicable	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic immunity			
The Model BP3SK1-3B are intended for use in the electromagnetic environment specified below. The customer or the user of the Model BP3SK1-3B should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	± 8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines 100 kHz repetition frequency ± 1 kV for input/output lines	± 2 kV for power supply lines 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 0.5 kV, ± 1 kV differential mode line-line	± 0.5 kV, ± 1 kV differential mode line-line	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	0 % UT (100 % dip in UT) for 0.5 cycle at 0°, 45°, 90°, 135°,180°, 225°, 270°, and 315° 0 % UT (100 % dip in UT) for 1 cycle at 0° 70 % UT (30 % dip in UT) for 25/30 cycles at 0° 0 % UT (100 % dip in UT) for 250/300 cycle at 0°	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models BP3SK1-3B product name requires continued operation during power mains interruptions, it is recommended that the models BP3SK1-3B be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE: UT is the a. c. mains voltage prior to application of the test level.			

Guidance and MANUFACTURER'S declaration – electromagnetic IMMUNITY

Guidance and manufacturer's declaration – electromagnetic immunity			
The BP3SK1-3B is intended for use in the electromagnetic environment specified below. The customer or the user of the BP3SK1-3B should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	3 Vrms 150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bandsa	Portable and mobile RF communications equipment should be used no closer to any part of the Models BP3SK1-3B, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = [\frac{3,5}{V_1}]\sqrt{P}$ $d = [\frac{3,5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d = [\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2,5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range b Interference may occur in the vicinity of equipment marked with the following symbol: 
Radiated RF IEC 61000-4-3	3V/m 80 MHz to 2.7 GHz	3 V/m	
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the BP3SK1-3B is used exceeds the applicable RF compliance level above, the BP3SK1-3B should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BP3SK1-3B.

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM

Recommended separation distances between portable and mobile RF communications equipment and the model BP3SK1-3B			
The Model BP3SK1-3B is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model BP3SK1-3B can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model BP3SK1-3B as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}]\sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.04	0.07
0.1	0.37	0.12	0.23
1	1.17	0.35	0.7
10	3.7	1.11	2.22
100	11.7	3.5	7.0
For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

Recommended separation distances between RF wireless communications equipment

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment.

Frequency MHz	Maximum Power W	Distance	IEC 60601 Test Level	Compliance Level	Electromagnetic Environment - Guidance
385	1.8	0.3	27	27	RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol: 
450	2	0.3	28	28	
710	0.2	0.3	9	9	
745					
780					
810	2	0.3	28	28	
870					
930					
1720	2	0.3	28	28	
1845					
1970					
2450	2	0.3	28	28	
5240	0.2	0.3	9	9	
5500					
5785					

Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

WARNINGS!

·This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.

·The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

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 Office**

Product number: **BP3SK1-3B**

Date:

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