microlife



Professional Automated Office Blood Pressure Monitor



BP 3SK1-3B

Instruction Manual



Preface

Microlife WatchBP Office (BP3SK1-3B) is an Automated Office Blood Pressure (AOBP) Monitor.

The device 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 pediatric and adult populations with arm cuff circumference sizes ranging from 14-52 cm.

The device can be connected to a computer (PC) running the WatchBP Analyzer software. The measured patient data can be transferred from the blood pressure monitor to the PC by means of a USB cable connection or Bluetooth connection. The Bluetooth 4.2 connectivity allows data transferring from the device to PC, smartphones or tablet.

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 (optional).

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

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 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



Model Type

- * The device can be upgraded with special features. There are three different types of the device:
- Advanced: advanced AOBP Monitor
- AFIB: advanced AOBP Monitor with Microlife Atrial Fibrillation Detector
- **Central:** advanced 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 \triangle 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 \triangle or \bigcirc button to select the month. Use the \bigcirc button to confirm your selection and move on to day setting.

Set the day – Press the \triangle or \bigcirc button to select the day. Use the \bigcirc 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 \triangle or \bigcirc button to select the highest inflation pressure or AUTO mode. Use the \bigcirc 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
м	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 0 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.







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- 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 (b) 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 (b) 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



Taking measurement in MANUAL mode

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 – 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 (\underline{O}) 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 \triangle 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 \mathbb{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 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.
- 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

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 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.

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.

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Bluetooth connectivity

Pairing the device

Press and hold the MODE button for around 7 seconds, until 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.



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.







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Using a power adapter

Only use the Mains Adapter 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.



 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.



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

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.



Disposal

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





Do not iron the cuff!

Error messages and Troubleshooting

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

Er

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.

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"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/ • 10 to 40 °C (50 to 104 °F)/ 15 - 90 % relative maximum humidity 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:	 60 - 255mmHg - systolic blood pressure; 30 - 200mmHg - diastolic blood pressure; 30 - 239 beats per minute - pulse 	
Cuff pressure display:	 Range: 0 - 299 mmHg; Resolution: 1 mmHg; Static accuracy: pressure within ± 3 mmHg; 	
Pulse accuracy:	• ±5 % of the readout value	
Power source:	 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: 2005+A1:2012 IEC 60601-1-2 2014 ANSI/AAMI/ISO 81060-2 ANSI/AAMI/IEC 80601-2-30 	
Electromagnetic Compatibility:	• Device fulfills the stipulations of the standard IEC 60601-1-2.	
C€ 0044	The stipulations of the EU Directive 93/42/EEC for Medical Devices Class IIa have been fulfilled.	
†	Type BF applied part	
	Microlife reserves the right to alter technical specifications without prior written notice.	

Guarantee Card

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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.

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