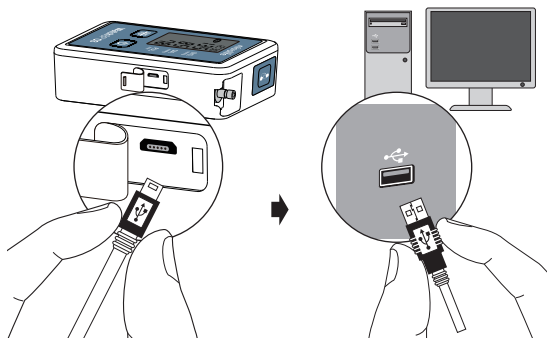


Transferring and deleting measurement data

Transferring measurement data

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



Deleting measurements

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

 See instruction manual of WatchBP Analyzer for details.

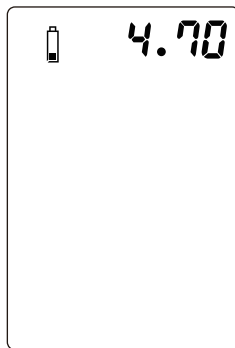
Appendix

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

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

How to replace batteries

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



-  Do not use rechargeable batteries.
-  Use 4 new, 1.5V, size AAA alkaline batteries.
-  Do not use batteries out of expiration date.
-  Remove batteries if the device will not be used for a prolonged period.

Bluetooth connectivity

Bluetooth connection of the WatchBP Analyzer supports Microsoft Windows 10

Regarding the connectivity architecture design, we used proprietary communication protocol to do data transfer process. The specific communication protocol is assured that the information (data) is correct. The program checks ACK firstly. Afterward, the program compares the received checksum with the sum of encoded raw data.

If the result is correct, the data is guaranteed during transmission. In contrast, once the device gets wrong communication command, it will not have any response. It is a data encryption and decryption architecture. We used proprietary encryption method to pack blood pressure raw data. In other word, Blood Pressure Analyzer need to use proprietary decryption method to unpack the encrypted data to get blood pressure raw data.

Pairing the device

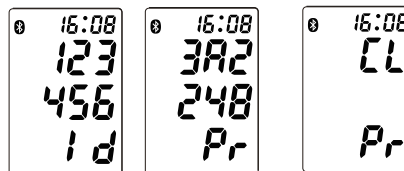
Press and hold the Start/Stop button for 7 seconds, the Bluetooth icon flashes and starts pairing mode. The unique 6-digit device ID of the unit is displayed. Connect the device and confirm pairing. The Bluetooth icon is displayed on the LCD screen of the blood pressure monitor to show the presence of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

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.

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



Safety, care, accuracy test and disposal

Safety and protection

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



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



- Ensure that children do not use the device unsupervised; some parts are small enough to be swallowed.
- Only activate the pump when the cuff is installed.
- Do not use the device if you think it is damaged or if anything appears unusual.
- Read the further safety instructions in the individual sections of the instruction manual.
- Do not connect the device to a computer until prompted to do so by the computer software.

Observe the storage and operating conditions as described in the “Technical specifications” section of this manual.

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



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



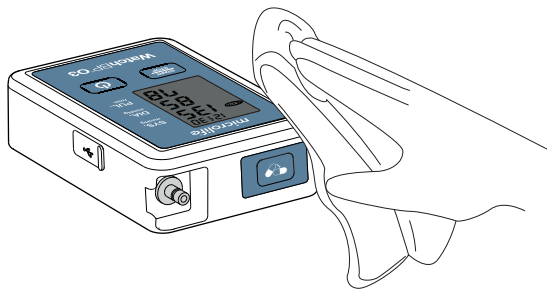
Protect the device from impact and drops

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).
- Isopropyl alcohol (70% solution).

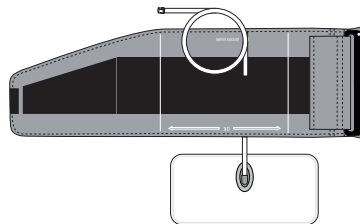
Then wipe the exterior of the device with a soft, dry cloth.



Cleaning the cuff

Take out the bladder. Fold and place the cuff cover inside a washing bag. Wash the cuff cover with warm water (43°C; 110°F) and a mild detergent in the washing machine.

Pasteurization: wash the cuff cover in 75°C(167°F) hot water for 30 minutes.



Do not iron the cuff!

Safety, care, accuracy test and disposal

Accuracy test

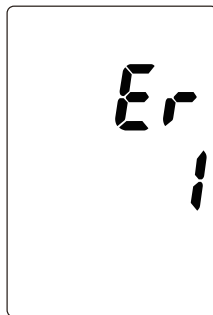
We recommend the device to be tested for accuracy every 2 years or after mechanical impact (e.g. Being dropped). Please contact Microlife to arrange an accuracy test.

Error messages

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



- The device will take another measurement automatically when an error occurs.
- Please consult your doctor, if this or any other problem occurs repeatedly.
- If you think the results are unusual, please read through the information in this instruction manual carefully.



Error	Description	Potential cause and remedy
"Er 1"	Signal too weak	The pulse signals on the cuff are too weak. Reposition the cuff and repeat the measurement.
"Er 2"	Error signal	During the measurement, error signals were detected by the cuff, caused for instance by movement or muscle tension. Repeat the measurement, keeping your arm still.

Error messages

"Er 3"	No pressure in the cuff	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Replace the batteries if necessary. Repeat the measurement.
"Er 5"	Abnormal result	The measuring signals are inaccurate and no result can therefore be displayed. Read through the checklist for performing reliable measurements and then repeat the measurement.

"Er 11"	Signal too weak during central blood pressure measurement	The pulse signals on the cuff are too weak. Re-position the cuff and repeat the measurement.
"Er 12"	Error signal during central blood pressure measurement	During the measurement, error signals were detected by the cuff, caused for instance by movement or muscle tension. Repeat the measurement, keeping your arm still.

"Er 13"	Cuff pressure errors during central blood pressure measurement	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Check that the cuff is correctly connected and is not too loose. Replace the batteries if necessary. Repeat the measurement.
"Er 15"	Abnormal result of central blood pressure reading	The measuring signals are inaccurate and no result can therefore be displayed. Read through the checklist for performing reliable measurements and then repeat the measurement.

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

Error messages

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

Technical specification

- Operating temperature:** ● 10 - 40 °C / 50 - 104 °F
- Storage temperature:** ● -20 to 55 °C / -4 to 131 °F
● 15 - 90 % relative maximum humidity
- Weight:** ● 240g (including batteries)
- Dimensions:** ● 113 x 77.5 x 33 mm
- Measuring procedure:** ● oscillometric, corresponding to Korotkoff
- Method:** ● Phase I systolic, Phase V diastolic
- Measurement range:** ● SYS: 60~255 mmHg
DIA: 40~200 mmHg
● Pulse: 30 - 239 beats per minute
- Cuff pressure display:** ● Range: 0 - 299 mmHg
● Resolution: 1 mmHg
● Static accuracy: pressure within ± 3 mmHg
● Pulse accuracy: ± 5 % of the readout value

Power source: ● 4X1.5 V Batteries; size AAA

Expected service life: ● 2 years

Reference to Standards

Device corresponds to the requirements of the standard for non-invasive blood pressure monitor.
EN 1060-1
EN 1060-3
EN 1060-4
IEC 60601-1
IEC 60601-1-2



Type BF applied part

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

Guarantee Card

This device is covered by a two-year guarantee from the date of purchase. This guarantee is valid only on presentation of the guarantee card completed by the owner confirming date of purchase or purchase receipt. Batteries and wearing parts are not covered by this guarantee.

Name: _____

Address: _____

Date: _____

Telephone: _____

Email: _____



Product: **WatchBP O3**

Product number: **BP3SZ1-1**

Serial Number:

Date:

Distributed by:

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**Manufacturer's Declaration of the Product
(Altogether 4 pages)**

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

Row

1	Guidance and manufacturer's declaration – electromagnetic emission		
2	The model BP3SZ1-1(WatchBP O3) is intended for use in the electromagnetic environment specified below. The customer or the user of the model BP3SZ1-1(WatchBP O3) 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 BP3SZ1-1(WatchBP O3) 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. The Model BP3SZ1-1(WatchBP O3) is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
5	RF emissions CISPR 11	Class B	
6	Harmonic emissions IEC 61000-3-2	A	
7	Voltage fluctuations / flicker emissions IEC 61000-3-3	Complied	

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

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model BP3SZ1-1(WatchBP O3) are intended for use in the electromagnetic environment specified below. The customer or the user of the Model BP3SZ1-1(WatchBP O3) 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	± 6 kV contact ± 8 kV air	± 6 kV contact ± 8 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 ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	± 1 kV differential mode ± 2 kV common mode	± 1 kV differential mode ± 2 kV common mode	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	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	< 5 % UT (>95 % dip in UT) for 0.5 cycle 40 % UT (60 % dip in UT) for 5 cycles 70 % UT (30 % dip in UT) for 25 cycles < 5 % UT (>95 % dip in UT) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the models BP3SZ1-1(WatchBP O3) product name requires continued operation during power mains interruptions, it is recommended that the models BP3SZ1-1(WatchBP O3) be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	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 – for ME EQUIPMENT and ME SYSTEMS that are not LIFE-SUPPORTING

Guidance and manufacturer's declaration – electromagnetic immunity			
The BP3SZ1-1(WatchBP O3) is intended for use in the electromagnetic environment specified below. The customer or the user of the BP3SZ1-1(WatchBP O3) 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	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the Models BP3SZ1-1(WatchBP O3), including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3,5}{V_1} \right] \sqrt{P}$ $d = \left[\frac{3,5}{E_1} \right] \sqrt{P} \quad 80 \text{ MHz to } 800 \text{ MHz}$ $d = \left[\frac{7}{E_1} \right] \sqrt{P} \quad 800 \text{ MHz to } 2,5 \text{ GHz}$ 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	3 V/m 80 MHz to 2.5 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 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 Model BP3SZ1-1(WatchBP O3) are used exceeds the applicable RF compliance level above, the Model BP3SZ1-1(WatchBP O3) should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model BP3SZ1-1(WatchBP O3).			
^b 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 -
for EQUIPMENT and SYSTEMS that are not LIFE-SUPPORTING**

Recommended separation distances between portable and mobile RF communications equipment and the model BP3SZ1-1(WatchBP O3)			
The Model BP3SZ1-1(WatchBP O3) is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model BP3SZ1-1(WatchBP O3) can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model BP3SZ1-1(WatchBP O3) 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 2.5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
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.			

