microlife®

BP M1

Automated Office Blood Pressure Monitor

BP 3SK1-3B

Instruction Manual

EN

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 BP M1 (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 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. (Active only in AFIB mode)

The memory data can be transferred to the smart device running the Microlife MultiCare software by connecting the monitor via Bluetooth.

The device is for hospital use only.

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Product description

The BP M1 consists of two major parts

- The device, cuffs and accessories.
- The Microlife MultiCare Software.

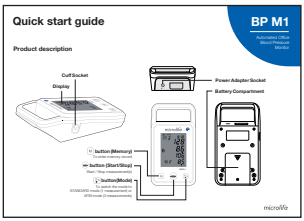
With the Microlife MultiCare Software

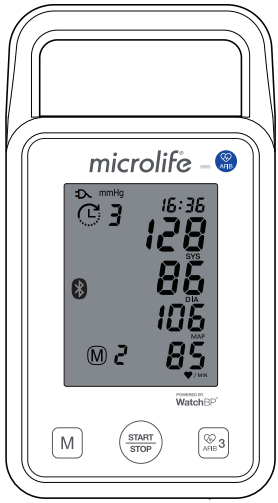
Measured blood pressure values can be transfer to the smart device.

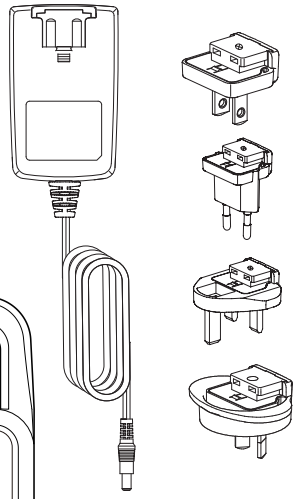
* *Download the latest Microlife MultiCare from the Microlife website.*

Contents

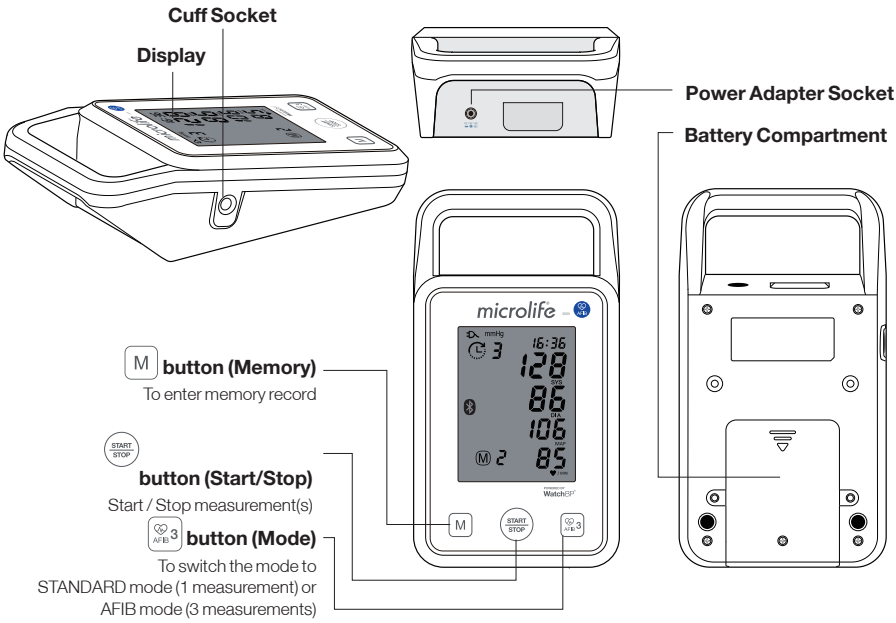
1. BP M1 Automated Blood Pressure Monitor
2. Cuff – Size - S (14- 22cm)
3. Cuff – Size - M (22- 32cm)
4. Cuff – Size - L (32- 42cm)
5. Mains adapter
6. Instruction manual
7. Quick start guide



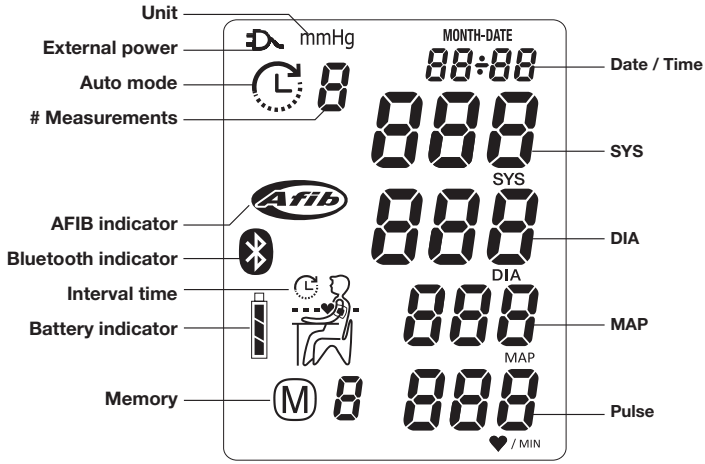




Product Overview

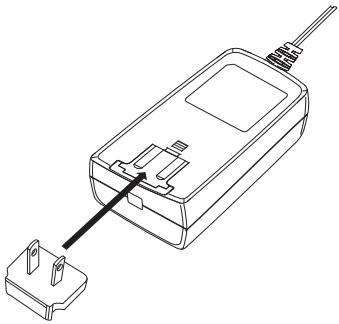


Display



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 (START/STOP) button to switch on the device.

Press and hold (START/STOP) 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
The date and time on the device automatically synchronizes with the date and time on the smart device when connected with the Microlife MultiCare software.

Before using the device

Selecting the correct cuff

A variety of different cuff sizes are available. S, 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.*
* *S, M and L size cuffs are included as standard accessories.*

Fitting the cuff properly

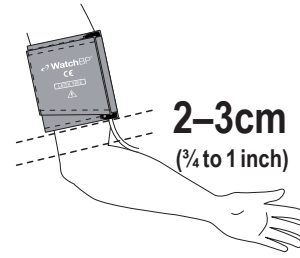
1 Place the cuff over the upper arm so that the air tube and artery mark arrow point towards the lower arm. The artery mark on the cuff must be placed over the brachial artery.

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 STANDARD and AFIB Mode

This device is able to detect atrial fibrillation (Active only in AFIB mode). This AFIB symbol indicates that atrial fibrillation was detected during the measurement. Please refer to the next paragraph for information regarding the consultation with your doctor.

Turn on the power

Turn on the device by pressing the START/STOP 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 AFIB button to switch between **STANDARD** or **AFIB** Mode.

Settings of STANDARD Mode

Press the AFIB button to switch to **STANDARD** mode with digital 1 showing on the display.
Press the START/STOP button to turn to standby.

Taking measurement in STANDARD Mode

Select **STANDARD** mode. Press the START/STOP button to perform automatic measurement. The device shows all the settings and then starts the measurement. The measurement reading is displayed and saved after the measurement is complete.

* *Press ⏻ button to cancel remaining measurements at anytime during the measurement sequence.*

Settings of AFIB Mode

Press the AFIB button to switch to **AFIB** mode with digital 3 showing on the display.

Press the START/STOP button to turn to standby.

Taking measurement in AFIB Mode

Select **AFIB** mode. Press the START/STOP button to perform automatic measurement. The device shows all the settings and then starts the measurement. Three consecutive measurements are taken automatically at 60 second intervals. The average measurement reading is displayed and saved after the measurements are complete.

* *Press Start/Stop to cancel remaining measurements at anytime during the measurement sequence. Display the results (average) if available.*

* *Press Start/Stop during countdown to skip the countdown.*

* *If there is an error in taking the measurement, the device will automatically start the next measurement. The device terminates the measurement if there are errors twice.*

* *Afib detection is only activated in AFIB mode. Afib is displayed by 2 out of 3 measurement*

Viewing stored values

The device stores blood pressure values from the last measurement.

Press the M button to reveal the average of the measurements in **AFIB** mode. Continue pressing the button to review individual measurements. If the latest measurement is in **STANDARD** mode, the value is only one measurement.

After 60 seconds without any operation, the device returns to standby.

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.

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 Microlife MultiCare

The memory data can be transferred to smart device running the Microlife MultiCare Software by connecting the monitor via Bluetooth.

Transferring measurement data
Automatically upload the result to APP through Bluetooth after each measurement.

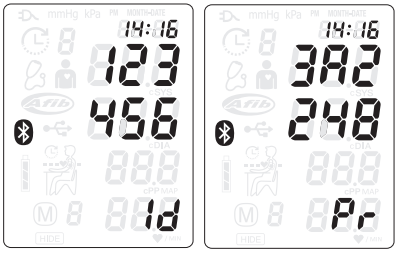
Bluetooth connectivity

Bluetooth connection of the Microlife MultiCare

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, **Microlife MultiCare** needs to use proprietary decryption method to unpack the encrypted data to get blood pressure raw data.

Pairing the device
Press and hold the M button for around 3 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 M button and AFIB button together for 5 seconds to clear the connection.*

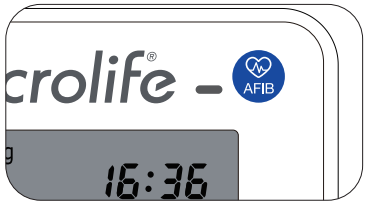
☞ *See the instruction manual of Microlife MultiCare for details.*

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

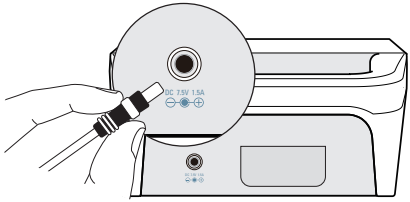
Rechargeable Battery



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 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.
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.

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

Do not use the device in the MRI environment

Avoid proximity to electromagnetic fields, such as those produced by mobile phones

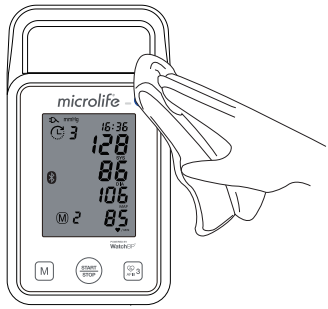
Never open the device

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:

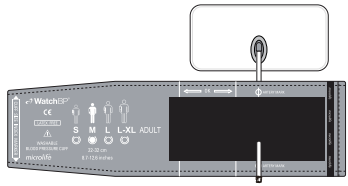
- Mild soap and water.
- Hydrogen peroxide solution (3% diluted with water).
- Sodium hypochlorite solution (1:10 dilution of household chloride bleach in water).



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.



Do not iron the cuff!

Accuracy test

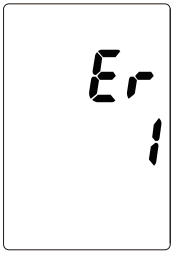
We recommend the device to be tested for accuracy every 2 years or after mechanical impact (e.g. Being dropped). Please contact Microlife to arrange an accuracy test.

Disposal

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

Error messages 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.
"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.

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: 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.
	Type BF applied part

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

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Intertek
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CONFORMS TO AAMI STD ES 60601-1, IEC STD. 60601-1-6, IEC STD. 80601-2-30
CERTIFIED TO CSA STD C22.2 NO. 60601-1, NO. 60601-1-6

Annex

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

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 mode BP3SK1-3B should assure that it is used in such an environment.		
3	missions test	missions test	Electromagnetic environment – guidance
4	RF emissions CISPR 11	Group 1	An adequate pressure cannot be generated in the cuff. A leak may have occurred. Replace the blood pressure cuff if necessary. Repeat the measurement.
5	No valid results	Class B	The Model BP3SK1-3B 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.
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 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.			
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 BP3SK1-3Bproduct name requires continued operation uring 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	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 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		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 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	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 BP3SK1-3B are used exceeds the applicable RF compliance level above, the Model 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 Model BP3SK1-3B. [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 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 2.5 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.			

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: **BP M1**

Product number: **BP3SK1-3B**

Date:

microlife®

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