BP Progress BP3T01-1B

Symbols & Definitions

 Manufacturer

 Catalog Number

 Serial Number

 Caution

 Type BF Applied part

IP22 Protected against solid objects with a diameter of ≧12.5mm. ; Protected against vertically falling water drops when enclosure tilted up to 15˚

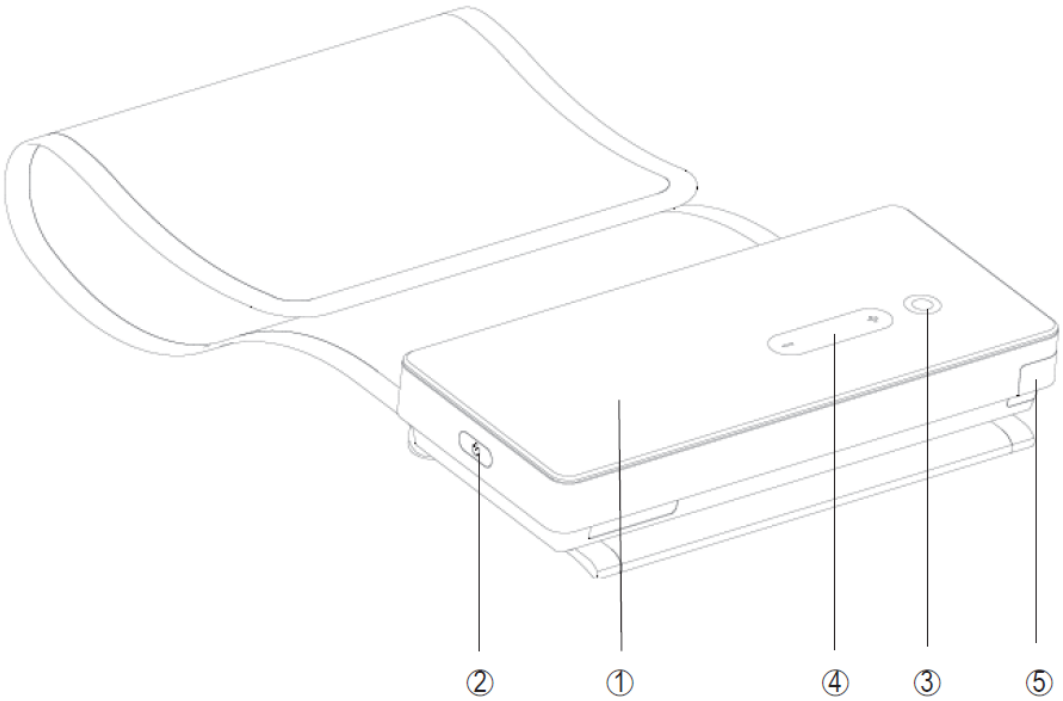
 Temperature limit

 Humidity limitation

 Follow instructions for use. This document provides important product operation and safety information regarding this device. Please read this document thoroughly before using the device and keep for future reference.

 WEEE symbol: Dispose or recycle this product in accordance with local laws or regulations that apply

Device Illustration



Device Illustration Legend

Device

1 Display

2 O/I Button

3 Select Button

4 + & - touch pad

5 Battery compartment

Important Information

 Read the important information in this Instructions for use before using this device. Follow the instructions for use for your safety and keep it for future reference.

Indication for Use

This device is a non-invasive automatic blood pressure monitor.
The intended purpose of this device is described in this section.

- This device is intended to measure blood pressure (systole and diastole) and pulse rate of an adult individual with arm circumference between 22 cm – 40 cm
- The device detects the appearance of irregular heartbeat during measurement and gives a warning signal with the reading once the irregular heartbeat is detected.
- The device is intended to be reusable: single patient multiple use or multiple patient multiple use depending on the specific variant.
- The device can be used in connection with a smart phone via Bluetooth. The measurement data can be transferred to a smart phone running the Microlife Connected Health+ mobile software (App).

Intended User, Patient, and Use Environment

This device is only intended to be used by user on patients in environments described in this section.

- The device is intended to be used by patients (self-measurement) or on a third person in a home healthcare environment (such as general household use).
- The device is intended to be operated by adult users with the vision and motor functions as well as the literacy and basic educations capable of understanding the content of this instructions for use and operating general household electrical appliances.
- The intended patients are normotensive and hypertensive adults and adolescents (aged 12 years or older) of the general population.

Indication & Clinical Benefits

This device is suitable for use for the following conditions and clinical benefits described in this section.

- The device is intended to measure human brachial blood pressure non-invasively for monitoring of the systolic and diastolic pressures, to support the diagnosis medical conditions or diseases related to blood pressure, including:
  - Diagnosis white-coat hypertension and masked hypertension and identifying white-coat effect and masked uncontrolled hypertension.
  - Evaluate blood pressure in response to treatment
  - Confirming the diagnosis of resistant hypertension
  - Detecting morning hypertension

Contra-indications

Do not use this device if the patient's condition meets the following contra-indications, to avoid inaccurate measurements or injuries.

- The device is not intended for measuring blood pressure in pediatric patients of age younger than 12 years old (children, infant, or neonates).
- Presence of significant cardiac arrhythmia during measurement may interfere with blood pressure measurement and affect the reliability of blood pressure readings. Consult with your doctor about whether the device is suitable for use in this case.
- The device is not intended for measuring blood pressure in adults with conditions of diabetes, pregnancy, or pre-eclampsia.
- The device measures brachial blood pressure using pressured cuff over upper arm. If the measuring arm suffers from injuries (for example open wounds) or under conditions or treatments (for example intravenous drip) making it unsuitable for surface contact or pressurization of the arm, DO NOT use the device, to avoid worsening of the injuries or conditions.
- Patient motions during measurement may interfere with the measurement process and influence results. Avoid taking measurements of patients with conditions, diseases, and susceptible to environment conditions that lead to incontrollable motions (e.g. trembling or shivering) and inability to communicate clearly (for example children and unconscious patients).
- The device uses oscillometric method to determine blood pressure, and requires the measured arm with normal perfusion. The device is not intended to be used on an arm with restricted or impaired blood circulation. Consult with your doctor if you severer perfusion or blood disorders before using the device.
- Avoid taking measurement on the arm on the side of a mastectomy or lymph node clearance.
- The device is not intended to measure pulse rate to check the frequency of pacemaker.
- Do not use this device in a moving vehicle (for example in a car or on an aircraft).

Side Effects

Use of the device may be accompanied by minor side effects.

- In some cases, slight bruising may result after measurement due to pressurization of the arm.

Warning

Indicates a potentially hazardous situation, which if not avoided, could result in death or serious injury.

- A self-measurement reading is not a medical diagnosis or treatment. Always consult with your physician. Under no circumstances should you diagnose or alter your prescribed medication by yourself.
- Consult your physician before using this device if any of the following or similar conditions are present: arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, pregnancy, preeclampsia, or renal diseases.
- Motion during measurement, including trembling or shivering may affect the measurement. Keep the device away from children! The device and its accessories contain small parts, tubes and cables. Beware of the risks of accidental strangulation or swallowing of small parts by children.
- DO NOT use this device on infants, children, and people unable to clearly communicate.
- DO NOT Use the displayed pulse for checking the frequency of heart pacemakers as this device is not suitable for this action.
- DO NOT Place the Cuff over a wound as this may cause further injury.
- DO NOT Place and pressurize the Cuff over/near any present intravascular access or therapy, or arteriovenous shunt, as this may cause blood flow interference and result in harmful injury.
- DO NOT Place and pressurize the Cuff over a limb near the side of a mastectomy as this may cause harmful injury.
- DO NOT use this device for purposes beyond described in this Instructions for Use. The manufacturer cannot be held liable for damage caused by incorrect application.
- DO NOT change the patient medication and treatment based the result of one or multiple measurements. Treatment and medication changes should be prescribed only by a medical professional.
- Inspect the device, cuff, and other parts for damage. DO NOT use the device, cuff or parts if they appear damaged or operating abnormally.
- Blood flow of the arm is temporarily interrupted during measurement. Extended interruption of blood flow reduces peripheral circulation and may cause tissue injury. Beware of signs (for

example tissue discoloration) of impeded peripheral circulation if taking measurements continuously or for an extended period of time (for example more than 30 minutes).

- Prolonged exposure of the arm to cuff pressure will reduce peripheral perfusion and may lead to injury. Avoid situations of extended cuff pressurization beyond normal measurements. In the case of abnormally long pressurization, abort the measurement, loose the cuff, or disconnect the cuff from device to depressurize the cuff.
- DO NOT use this device in oxygen rich environment or near flammable gas.
- The device is not waterproof. DO NOT immerse the device in water or other liquids.
- DO NOT dissemble or attempt to service the device, accessory and parts, during use or in storage. Access to the device internal hardware and software is prohibited. Unauthorized access and servicing of the device, during use or in storage, may compromise the safety and performance of the device.
- DO NOT dissemble or attempt to service the device, accessory and parts, during use or in storage. Access to the device internal hardware and software is prohibited. Unauthorized access and servicing of the device, during use or in storage, may compromise the safety and performance of the device.

Caution

Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient, or cause damage to the device or other property.

- To avoid inaccurate measurements and to lessen any discomfort from Cuff pressure, ensure the Cuff is placed correctly on the limb and fits correctly when snug (not tight), as indicated by markings with the Cuff.
- Consult your physician in cases of frequent irregular heartbeat detections.
- The Traffic Light Indicator feature provides a general reference of self-measurement blood pressure classification based on the clinical guideline of American College of Cardiology. The MyCheck feature provides a qualitative comparison of the current measurement reading versus the average reading of the past 4 weeks. MyBP feature provides a blood pressure average based on principles of clinical guidelines. Beware these features are not diagnosis and do not replace professional medical consultation. Do not diagnose or treat yourself based on the results of these features. Always consult with your physician.
- DO NOT Drop this device or expose it to strong vibrations; sensitive components may be affected resulting in inaccuracies and/or operational issues.
- DO NOT Use this device in a moving vehicle; inaccurate measurements may result. Only use this device in a home healthcare environment.
- The device is intended only for measuring blood pressure at upper arm. DO NOT measure other

sites because the reading does not reflect your blood pressure accurately.

- Overly frequent measurement within a short time (for example 5 – 10 minutes) may reduce peripheral perfusion and cause injury. After a measurement is completed, loosen the cuff and rest the arm for a few minutes to restore limb perfusion, before taking another measurement.
- DO NOT use this device with other medical electrical (ME) equipment simultaneously. This may cause device malfunction or measurement inaccuracies.
- DO NOT use this device in proximity of high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) equipment, and computerized tomography (CT) scanners. This may cause device malfunction and measurement inaccuracies.
- Avoid kinking, pressing, and moving of the cuff tube during device operation, as this affects reading reliability and may cause injury if the device deflation is interrupted.
- Use this device only with compatible accessory and parts from Microlife, including cuffs, connectors, and adaptors. Using non-compatible accessories may compromise the safety and performance of the device.
- Use and store the device, cuff and parts in temperature and humidity conditions specified in the Technical Description. Usage and storage of the device, cuff and parts in conditions outside ranges given in the Technical Description may results in device malfunction and the safety of usage.
- Protect the device & accessories from the following to avoid damaging the device:
  - Water, other liquids, and moisture
  - Extreme temperatures
  - Impacts and vibrations
  - Direct sunlight
  - Contamination and dust
- Always use the arm cuff of range appropriate for the mid arm circumference of the patient.
- Stop using this device and cuff and consult with your doctor if you experience skin irritation or discomfort.
- DO NOT use this device, cuff or parts after the expiration of its stated service life.

Electromagnetic Compatibility Information

- This device is compliant with IEC 60601-1-2 Electromagnetic Disturbances standard.
- This device is not certified to be used in vicinity of medical equipment including high frequency (HF) surgical equipment, magnetic resonance imaging (MRI) and computerized tomography (CT) instruments.
- DO NOT use this device close to strong electromagnetic fields and portable radio frequency communication devices (for example microwave oven and mobile devices). Keep a minimum

distance of 0.3 m from such devices when using this device.

- This device features Bluetooth(R) that emits radio frequency (RF) in the 2.4GHz band. Do not use this device in locations where RF is restricted (for example, on a aircraft). Turn off the device and remove the power source if necessary when in RF restricted locations.
- This device operates in an unlicensed ISM bad at 2.4GHz. In case this device is used near other wireless devices (for example wireless LAN) which operates on the same frequency band as this device, there is a possibility that interference may occur. If interference occurs, stop the operation of other devices or relocate this product away from other wireless devices before using it.

MR Unsafe

Data Transmission

- This product emits radio frequencies (RF) in the 2.4 GHz band. DO NOT use this product in locations where RF is restricted, such as on an aircraft or in hospitals. Turn off the Bluetooth® feature in this monitor, remove batteries when in RF restricted areas. For further information on potential restrictions refer to documentation on the Bluetooth usage by the FCC.

FCC

- 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. Changes or modifications to the product are not approved by Microlife USA and could void the user's authority to operate the equipment under FCC jurisdiction.
- 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: 1) Reorient or relocate the receiving antenna. 2) Increase the separation between the equipment and receiver. 3) Connect the equipment into an outlet on a

circuit different from that to which the receiver is connected. 4) 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.

Trademark Usage:

Apple, the Apple logo, iPad, and iPhone are trademarks of Apple Inc., registered in the U.S. and other countries. App Store is a service mark of Apple Inc.

Android and Google Play are both trademarks of Google Inc.

The Bluetooth® word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks in this Blood Pressure Monitor is under license. Other trademarks and trade names are those of their respective owners.

Important Information about Blood Pressure – for Patients

- This device is clinically validated for blood pressure measurement in adults and adolescents. [1]
- Blood pressure is a dynamic vital sign and its level is influenced by the patient and the environment during the measurement. Individual blood pressure reading can be affected by measurement site, patient's body position, and patient's physiological conditions and health (e.g. cardiovascular or renal diseases, trembling, and pregnancy). It's recommended to always take measurements at the same measurement site with the same body position, under similar physiological conditions at the same time of the day, to ensure the reliability of the blood pressure values.
- The measurement result of the device is not a diagnosis, and a single measurement is not representative of the health condition. Consult with your doctor for any questions related to the diagnosis and treatment of your conditions or disease. Under no circumstances should you alter the dosages of drugs or initiate a treatment without consulting your doctor.
- Deviations between measurements taken by your doctor or in the pharmacy and those taken at home are quite normal, as these situations are completely different and the white coat effect may lead to different values.
- If you are entering pregnancy, you should monitor your blood pressure regularly as it can change drastically throughout the pregnancy.

Important Information about Irregular Heart Beat (IHB) - for Patients

- An Irregular Heartbeat (IHB) occurs when an irregular interval between heart beats is detected during measurement.

- Presence of IHB may affect blood pressure measurement; it's recommended to retake measurement if IHB is detected, to ensure reliability of blood pressure reading.
- Occasional IHB detection is no cause for concern. Consult with your doctor if IHB is detected frequently (e.g. in majority of measurements).

Important Information about Irregular Heart Beat (IHB) – for Doctors

- Irregular Heart Beat (IHB) is defined a beat-to-beat interval that is 25% faster or 25% slower than the average pulse interval detected during the measurement.

Adverse Events & Reporting

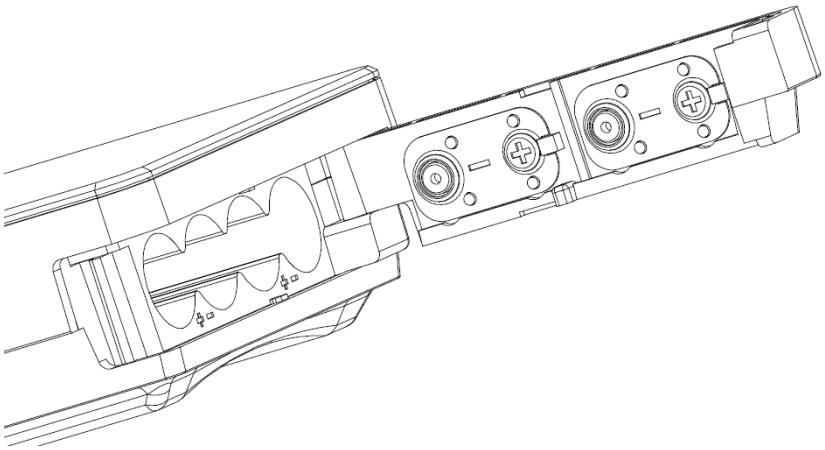
- In case of an adverse event, please contact your local Microlife distributor, the manufacturer, and the competent authority of the Member State.

Table of Contents

1. Using the device for the first time

Inserting the batteries

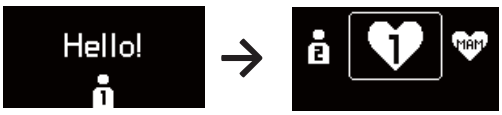
After unpacking your device, open the battery compartment 5 and insert batteries. The battery compartment 5 is located to the right side of the device. Insert the batteries (4 x 1.5 V, size AAA) in the orientations following the polarity symbols marked on the battery compartment (see the below picture) to put batteries by correct orientation.



⚠Caution**:** Inserting the batteries in incorrect polarity orientations may lead to short circuiting and damage the device!

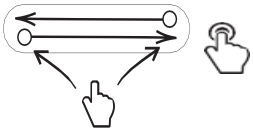
Power-on the device

Press the O/I button 2 to power-on the device. The display 1 will activate, displays greeting message, currently selected users, date & time, then display the device function main menu.



Navigate the device function main menu

When the main menu is shown on display 1, press the + & - touch pad 4 or swipe your finger left and right on the + & - touch pad 4 to navigate the menu to select different functions.



There are 5 functions on the main menu

1. User Settings 2. Standard mode - Single Measurement


3. MAM mode - Microlife Average Mode (MAM) Measurement

4. User Data Memory 5. Device Settings

The function currently selected on the main menu is positioned in the center of the display, indicated by a rectangular box. To confirm function selection and activate or enter the selection function, press the Select button 3. To return to the main menu, press the O/I button 2 to exit individual function and return to the main menu.

Setting the user

Select User Settings on the main menu and press the Select button 3 to enter User Settings. You can choose between User 1, User 2, and Guest User by pressing + and – or swiping left or right on the + & - touch pad 4; the user selected is positioned in the center of the display 1 and indicated inside a rectangular box.

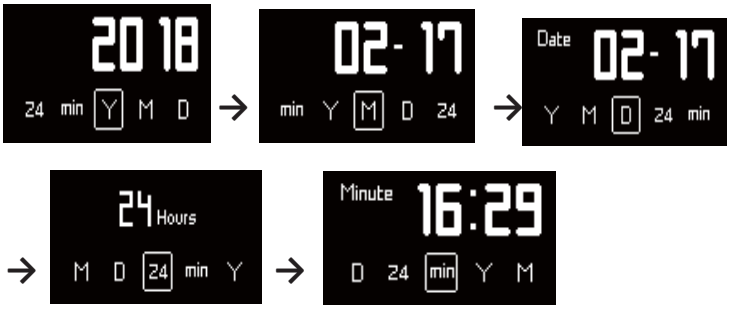
To confirm user selection, press the Select button 3. Once user selection is set you will return to the main menu, where the selected user (1, 2, or guest) is indicated.

Note: When guest user is selected, measurement can be taken but the results are not saved in device memory and cannot be transferred via Bluetooth.

Setting the date and time

Select Device Settings on the main menu and press the Select button 3 to enter Device Settings. Select Date & Time setting in the Device Settings menu and press the Select button again to open the adjustment function.

In the date & time adjustment menu, press “Select” 3 to change the settings. Press “+” and “-“ of + & - touch pad 4 to adjust the values of year, month, day, hour, hour format, and minute; press “Select” 3 to confirm the adjustment and proceed to the next item.



After completing all date & time adjustments, the display will show the current date & time momentarily, then return to the Device Settings menu.

Set up Bluetooth® pairing with your mobile phone

Use the Bluetooth function to transfer data to <Microlife Connected Health+> App on a smartphone (Android OS or iOS). Information available on:

Please check mobile software OS Compatibility with Apps by the following link:

Android:

IOS:

When using the device with mobile phone for the first time, Bluetooth pairing process needs to be completed, so the device recognizes user's mobile phone. Select Device Settings on the main menu and press the "Select" button (3) to enter Device Settings. Select the Bluetooth® icon to activate the Bluetooth function, and the device will search for recognizable mobile phone (with companion mobile app open) in the vicinity.

If the mobile device and the companion mobile App is near-by and activated, the device should find and establish connection with the mobile phone automatically, and trigger the Bluetooth pairing process. During Bluetooth pairing, a 6 digit pairing code is displayed on the device display. Check if the pairing code matches the pairing code on the mobile phone; confirm executing of pairing if pairing codes are consistent on device and mobile phone. After the pairing process is completed, the device will power-off automatically.

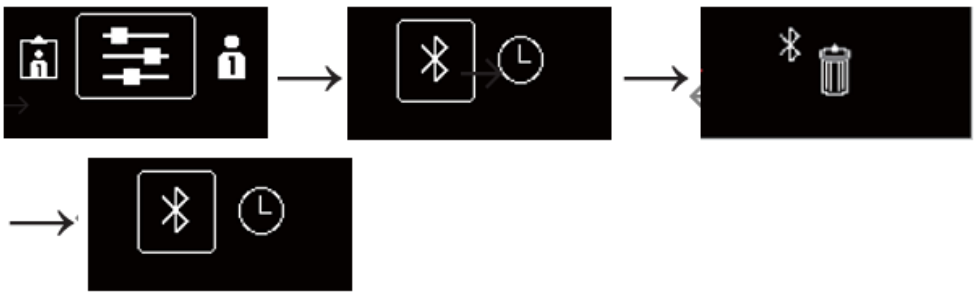
If the Bluetooth pairing is not successfully complete or interrupted, please repeat the Bluetooth pairing process with the mobile phone.

Resetting Bluetooth pairing with your mobile phone

In case the Bluetooth pairing between the device and mobile phone needs to be cleared or reset, please follow the instructions:

Device:

Select Settings on the main menu to enter the settings interface. In the settings menu, select Bluetooth function (indicated by the box) and press and hold the "O/I " button 2 for longer than 3 seconds to clear all Bluetooth pairing settings on the device. A garbage bin icon will appear to indicate that the pairing record is successfully cleared.



Mobile Phone:

In the Bluetooth settings of the mobile phone (usually found in settings), select the device name “Progress”, then select “forget this device” to erase the device pairing record on the mobile phone.

After clearing the Bluetooth pairing records on both the device and mobile phone, Bluetooth pairing will need to be be completed next time the device connects to mobile phone via Bluetooth.

Selecting Standard mode or MAM mode for measurement

Select standard mode on the main menu to initiate one measurement.

Select MAM measurement mode to initiate automatic consecutive measurements with average.

⚠**Caution:** In MAM mode, if one of the individual measurements was questionable, the device automatically takes an additional measurement.

2. Checklist for taking a reliable measurement

Patient Preparations of Measurement

⚠Caution**:** Follow these steps to obtain reliable blood pressure reading. Lack of rest, incorrect body posture, arm position, and improper cuff fitting may lead to inaccurate blood pressure reading!

Prior to Taking a Measurement

- It is recommended that doctors perform double arm measurements on a patient's first visit in order to determine which arm to measure in the future. The arm with the higher blood pressure should be measured.
- Avoid exercising, bathing, eating, drinking, and smoking, 30 minutes prior to measurement.
- Empty your bladder prior to measurement.
- Sit down on a back-supported chair, keep the feet flat on the floor, and do not cross your legs.
- Sit down on a Relax for at least 5 minutes before taking measurement.

Correct Cuff Fitting and Posture for Taking a Measurement

- Remove thick clothing and close-fitting garments from the upper arm. To avoid constriction, shirt sleeves should not be rolled up - they do not interfere with the cuff if they are laid flat.
- Always ensure that the cuff size is suitable for your arm circumference (22 – 40cm)
  - Fit the cuff on your arm snugly without overly tight.
  - Make sure that the device and cuff is positioned 2cm above the elbow.
  - Ensure that the device is over your (brachial) artery which runs down the inner side of the arm.
  - Support your arm so it is relaxed.
  - Ensure that the cuff is at the same height as your heart.

3. Taking a Blood Pressure Measurement

Starting measurement

1 Check to make sure the cuff is secured with the D-ring

2. With the O/I button of the device facing you, gently place your measurement arm inside the cuff, then position the device on upper arm, with the edge of the cuff about 1 to 2 cm from the elbow.

3. Make sure the centerline of the device is aligned with your arm, then secure the device by pulling and tightening the cuff and hold it with the cuff Velcro.

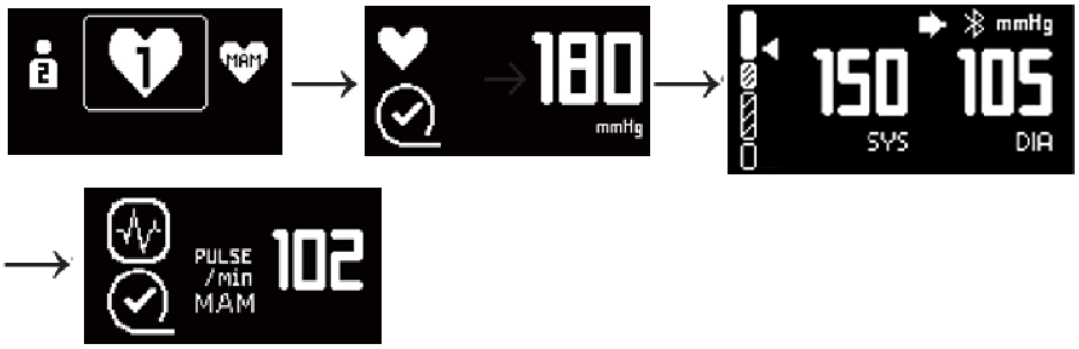
4. Turn on the device using O/I button.

5. Select standard (single measurement) or MAM mode (automatic triple measurement): see details in chapter 1.

6. Press the “Select” button 3 to start the measurement.

7. The cuff will now pump up automatically. Relax, do not move and do not tense your arm muscles until the measurement result is displayed. Breathe normally and do not talk.

⚠Caution**:** Remain still and do not move or talk during measurement. Motions caused by talking, moving, trembling and other vibrations may interfere with the measurement and affect the measurement accuracy!



8. The cuff fit check on the display indicates the cuff is perfectly placed. If the icon below appears, the cuff is fitted sub-optimally, but it is still ok to measure.

Cuff Fit OK:

Cuff Fit Sub-optimal:

9. The measurement is performed during the inflation. The inflation speed may vary, this is a normal occurrence.

10. During the measurement, the pulse indicator flashes in the display.

11. The result, comprising the systolic, the diastolic and the pulse rate is displayed. Note also explanations on further display symbols in this booklet.

Aborting measurement (Emergency Stop)

⚠**Caution:** You can stop the measurement at any time by pressing the ON/OFF button, disconnecting the cuff, and by opening the cuff. (E.g. if you feel uneasy or an unpleasant pressure sensation).

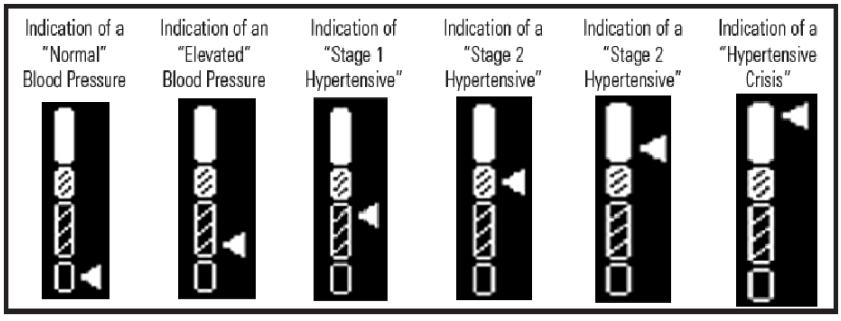
How do I evaluate my blood pressure?

The triangle on the left-hand edge of the display points at the range within which the measured blood pressure value lies. The pattern indicator on the left-hand edge of the display has been designed to provide a quick visual representation of your blood pressure. Once a measurement has been completed, a triangle will display on screen next to the pattern hypertension indicator. The height of the black triangle will show if the measurement is within the normal (the bottom pattern), borderline (From top to bottom, the second and the third pattern. or danger (the top pattern) range.

This classification is based on standards established by the American Heart Association (AHA) and American College of Cardiology (ACC) in 2017.

If the black triangle is in the:

- •The bottom pattern zone, your measurement is "Normal."
- •lower the third pattern zone, it is "Elevated."
- •upper the third pattern zone, it is "Stage 1 Hypertensive."
- •The second pattern zone, it is "Stage 2 Hypertensive."
- •lower the top pattern zone, it is "Stage 2 Hypertensive."
- •upper the top pattern zone, it is "Hypertensive Crisis."0



⚠**Caution:** The blood pressure classification is a general guide of blood pressure levels, but

diagnosis of hypertension should be made by a healthcare profession based on specific conditions of the patient. Consult with your doctor for questions about the interpretation and classification of your blood pressure values.

Average Indicator «MyCheck»

The symbols indicates after each measurement, if the most recent measured value lies below, above or on the same level as your stored average value .

If the measured Systole or Diastole is more than 5mmHg higher than the stored average, the arrow shows upwards.

If the measured Systole or Diastole is more than 5mmHg lower than the stored average, the arrow shows down- wards.

If the measured Systole and Diastole do not differ by more than 5mmHg from the stored average, the arrow shows straight on.

If the measured systole and diastole differ in different directions from the stored average, this is indicated first with the systole figure flashing, together with the up or down arrow for two seconds. Thereafter, the diastole figure flashes with the arrow pointing up or down for two seconds.

Appearance of the Irregular Heartbeat (IHB)

This symbol indicates that an irregular heartbeat was detected during the measurement.

Caution: When IHB is detected, the result may deviate from your normal blood pressure. It is recommended to repeat the measurement, with MAM mode if possible.

4. Data Memory

Measurement memory function

This device automatically stores the last 120 measurement values of each user in memory for review. Memories are not stored in guest mode.

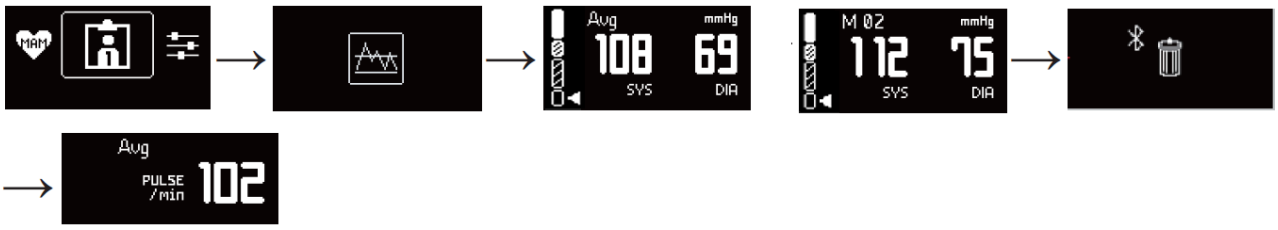
Select the intended user (user 1 or user 2 or guest) by pressing the User indicator button.

Viewing the stored values in memory

Select memory on the main menu interface and press “Select” button 3 to enter the memory interface. Make sure the correct user is selected.

If there is no data in the memory, “0” will be displayed.

If there are values in the memory, the average of one month stored values will be displayed first upon entering the memory interface. To skip the average blood pressure views, press “Select” button 3 once. To extend the display of average blood pressure view, press and hold “Select” button 3.



Individual measurement results will be accessible after display of the average blood pressure. The newest measurement will be displayed first. Use “+” and “-“ + & - touch pad 4 to navigate the memory to view older measurement records. To view the date and time of a specific measurement record, press and hold “Select” button 3 while the record is displayed. The date and time of the measurement will appear for 3 seconds.

Press “O/I” button (1) to exit memory mode and return to main menu.

Note

Blood pressure readings with suboptimal cuff fit are not considered in the average value.

Memory full

Pay attention that the maximum memory capacity of 120 memories is not exceeded. When the 120 memory is full, the oldest value is automatically overwritten with the 121st value.

Values should be evaluated by a doctor before the memory capacity is reached – otherwise data will be lost.

Clearing all values in memory

Make sure the correct user is selected.

If you are sure that you want to permanently remove all stored values, press and hold O/I button 1 for longer than 3 seconds to activate memory deletion function, a garbage bin icon will appear and flashes. Press “Select” button 3 to confirm the deletion, the garbage bin icon will stop flashing. Press “O/I” button 1 to cancel deletion.

5. Bluetooth function and data transfer

Please note the following:

Wireless communication interference

This product operates in an unlicensed ISM band at 2.4 GHz. In the event this product is used near other wireless devices such as microwave and wireless LAN, which operate on the same frequency band as this product, there is a possibility that interference may occur. If interference occurs, stop the operation of the other devices or relocate this product away from other wireless devices before attempting to use it.

Medical Device Data System

The Bluetooth® of this monitor is a medical device data system (MDDS) as its only function is for transfer of records and no additional functions. The Bluetooth® is not active when the monitor is recording data or during blood pressure measurement. The monitor will not sound any alarm with or

without Bluetooth®. The Bluetooth® is used only to transfer data from point A to point B. The App on your smart devices cannot be used to start or stop the monitor, nor update the firmware of monitor via Bluetooth®.

Automatic data transfer after measurement

This device can be used in conjunction with a mobile phone running the companion app. The Bluetooth function is automatically activated after the completion of measurement, indicated by a blinking Bluetooth® icon on the display.

If a mobile phone with the companion mobile app opened is near-by, the device will automatically find the mobile phone and establish Bluetooth connection for data transfer. A connection icon will appear when the device has successfully connected to a mobile phone. Data transfer will execute automatically and the device will display a 6-digit code for identification. After completion of data transfer, the device will automatically terminate the Bluetooth connection and power-off.

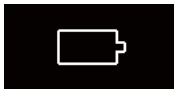
Manual data transfer

To manually activate the Bluetooth function of the device for data transfer, select Bluetooth function in the settings menu and press “Select” button 3 to turn on Bluetooth. For data transfer, please open the companion app.

Battery Indicator and Battery Replacement

Flat battery and replacement

When the batteries are flat (battery voltage is low), the low battery will flash as soon as the device is switched on (flat battery displayed). You cannot take any further measurements and must replace the batteries.



1. Open the battery compartment 5.
2. Replace the batteries – ensure correct polarity as shown by the symbols in the compartment.
3. Following battery replacement, device date and time must be re-set. Refer to chapter 1.

Batteries

1. Use 4 new 1.5 V, size AAA alkaline batteries. Do not use expired batteries or mix new and used batteries together.
2. Inserting the batteries in incorrect polarity orientations may lead to short circuiting and damage the device!
3. Remove batteries if the device is not going to be used for a prolonged period.

Using rechargeable batteries

You can also operate this device using rechargeable batteries.

- Only use NiMH type rechargeable batteries.
- Batteries must be removed and recharged when the flat battery symbol appears. They should not remain inside the device as they may become damaged (total discharge as a result of low use of the device, even when switched off).
- Always remove the rechargeable batteries if you do not intend to use the device for a week or more.
- Batteries cannot be charged in the blood pressure monitor. Recharge batteries in an external charger and observe the information recharging the charging and care of the batteries from the battery manufacturer.

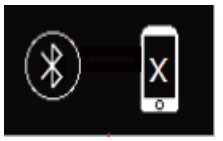
Spare Parts

Batteries

- Use 4 new 1.5 V, size AAA alkaline batteries. Do not use expired batteries or mix new and used batteries together.
- Inserting the batteries in incorrect polarity orientations may lead to short circuiting and damage the device!
- Remove batteries if the device is not going to be used for a prolonged period.
- The device can be used with rechargeable batteries. Rechargeable batteries cannot be charged in the device. Batteries must be removed and recharged when the flat battery symbol appears.

7.Error Messages

If an error occurs during the measurement, the measurement is interrupted and an error message, e.g. «Err 3», is displayed.

Error	Description	Potential cause and remedy
«**Err 1**» 	Signal too weak	The pulse signals on the cuff are too weak. Re-position the cuff, ensure a tight, snug fit, and repeat the measurement.*
«**Err 2**» 	Error signal	During the measurement, error signals were detected by the cuff, caused for instance by movement or muscle tension. Repeat the measurement, while keeping your arm and body still and refrain from speaking.
«**Err 3**» 	Abnormal cuff pressure	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.
«**Err 5**» 	Abnormal result	The measuring signals are inaccurate and no result can therefore be displayed. Read through the checklist for taking reliable measurements and then repeat the measurement. *
«**Err 6**» 	MAM Mode	There were too many errors during the measurement in MAM mode, making it impossible to obtain a final result. 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 200 beats per minute). Relax for 5 minutes and repeat the measurement. *
«**LO**» 	Pulse too low	The pulse is too low (less than 40 beats per minute). Repeat the measurement. *
	Problem with Bluetooth® connection	If any problem occurs with the Bluetooth connection, Bluetooth error symbol will appear and then device will power off.

Touch Error 	Touch pad error	Touch pad self-test error; device will power off automatically. Please contact your local Microlife customer service.

* Please immediately consult your doctor, if this or any other problem occurs repeatedly.

8.Maintenance, Service, and Disposal

Maintenance

When not in use:

- Keep the device and accessories in a dry, cool place away from sunlight, with ambient conditions within the temperature and humidity ranges described in the Technical Description.
- Remove the batteries from the device if the device will not be used for an extended period.

⚠**Caution:** Storing the device disuse for an extended period without removing batteries increases the chance of battery fluid leakage, which may lead to device damage and skin irritation when in contact. If your eye or skin is exposed to battery fluid, wash the exposed part immediately with ample clean water. Consult a doctor if irritation or discomfort persists.

Cleaning

The device can be cleaned when necessary (e.g. between uses by different patients).

Use a soft cloth, dry or wet with detergent, to gently wipe the exterior of the device remove dusts or stains.

⚠**Caution:** Do not machine wash the cuff and do not use fabric softener.

⚠**Caution:** Do not dry tumble dry or iron the cuff cover

⚠**Caution:** Do not use gasoline, thinners or similar solvents.

Service & Calibration

We recommend this device is tested by trained personnel of Microlife distributor for accuracy every 2 years. Please contact your local Microlife Service to arrange the test (see foreword).

⚠Caution**:** The device and accessories can only be serviced (tested & calibrated) by a trained personnel qualified for servicing Microlife products. Do not attempt to service or calibrate the device and accessories yourself.

Disposal (Waste Electrical and Electronic Equipment)

This device is an electronic device. The device and batteries must be disposed of in accordance with the locally applicable regulations, not with domestic or commercial waste.

Guarantee

The guarantee is valid only on presentation of the guarantee card completed by the dealer (see back) confirming date of purchase or the receipt.

- This device is covered by a guarantee of 10,000 measurements or 5 years, whichever occurs earlier, from the date of purchase.
- The cuff has a functional guarantee (bladder tightness) of 5,000 measurements or 2 years, whichever occurs earlier.
- Batteries and parts that become worn with use are not included.
- Opening or altering the device invalidates the guarantee.
- The guarantee does not cover damage caused by improper handling, discharged batteries, accidents or non-compliance with the operating instructions.

9. Technical Specification

Product Category: Non-invasive oscillometric blood pressure gauge

Product Description: Upper arm automatic blood pressure monitor

Model Number: BP3T01-1B

Operation Conditions: 10 – 40℃, 15 – 90% relative humidity, 700hPa – 1060hPa

Storage & Transport Conditions: -20 - +55℃,15 – 90% relative humidity

Weight: 340g (including batteries)

Dimensions: L: 145mm, W: 67mm, H: 28mm

Measurement Method: Oscillometric method, corresponds to Korotkoff method:

Phase I systolic / Phase V diastolic

Cuff range: 22 cm – 40 cm

Pressure Resolution: 1mmHg

Cuff Pressure Display Range: 0 – 299 mmHg

Measurement Ranges:

Systole: 60 – 255 mmHg

Diastole: 40 – 200 mmHg

Pulse: 40 – 199 beats / minute

Accuracy – Static Pressure: ±3 mmHg

Accuracy - Pulse: ±5% of readout value

Wireless Communication: Bluetooth® Low Energy

Wireless communication: Frequency range: 2.4 GHz (2400 - 2483.5 MHz)

Modulation: GFSK

Effective radiated power: < 20 dBm

Power Source – 4 x 1.5V LR3(AAA) batteries

IP Rating: IP22: Protected against solid objects with a diameter of ≧12.5mm. ; Protected against vertically falling water drops when enclosure tilted up to 15˚

Applied Part Type Reference: Type BF 

Service Life - Device: 10,000 measurements or 5 years, whichever occurs earlier

Service Life – Cuff: 5,000 measurements or 2 years, whichever occurs earlier

Battery Life: Approx. 900 measurements (new Alkaline LR6 batteries)

This medical device is compliant with:

- Medical device and non-invasive blood pressure monitor standards IEC 60601-1, IEC 60601-1-2, IEC 60601-1-11, and AAMI/ANSI/IEC 80601-2-30
- Electromagnetic standards IEC 60601-1-2, along with FCC Part 15
- Clinical Testing per standard ISO 81060-2:2013 was conducted on blood pressure device using the same measurement technology.

Appendix

Guidance and manufacturer's declaration – Electromagnetic emissions		
The BP3T01-1B is intended for use in the electromagnetic environment specified below. The customer or the user of the BP3T01-1B should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR11	Group 1	The BP3T01-1B use 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.
RF emissions CISPR11	Class B	The BP3T01-1B is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplier buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage Fluctuations/flicker emissions IEC 61000-3-3	Compliance	

Guidance and manufacturer's declaration – Electromagnetic immunity			
The BP3T01-1B is intended for use in the electromagnetic environment specified below. The customer or the user of the BP3T01-1B should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	**Electromagnetic environment - guidance**
Electrostatic discharge(ESD) IEC61000-4-2	±8 kV contact ±15 kV Air	±8 kV contact ±15 kV Air	Floor should be wood, concrete or ceramic tile, If floor are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/burst IEC61000-4-4	±2kV for power supply lines ±1kV for input/output lines	±2kV for power supply lines Not applicable	Mains power quality should be that of a typical commercial or hospital environment.
Surge	±1kV line(s) to	±1kV differential	Mains power quality should

IEC61000-4-5	line(s) ±2kV line(s) to earth	mode Not applicable	be that of a typical commercial or hospital environment.
Voltage Dips, short interruptions and Voltage variations on power supply input lines IEC61000-4-11	＜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 s	＜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 s	Mains power quality should be that of a typical commercial or hospital environment, If the user of the BP3T01-1B requires continued operation during power mains interruptions, it is recommended that the BP3T01-1B be powered from an uninterruptible power supply or a battery.
Power frequency(50.60HZ) Magnetic field IEC61000-4-8	30 A/m, 50Hz	30 A/m, 50Hz	The BP3T01-1B 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			
The BP3T01-1B is intended for use in the electromagnetic environment specified below. The customer or the user of the BP3T01-1B should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	**Electromagnetic environment - guidance**
Conducted RF IEC61000-4-6 Radiated RF IEC61000-4-3	3 Vrms 150KHz to 80MHz 10 V/m 80MHz to 2.7GHz	3 Vrms 150KHz to 80MHz 10 V/m 80MHz to 2.7GHz	Portable and mobile RF communications equipment should be used no closer to any part of the BP3T01-1B including cables, than the recommended separation distance calculated from the equation applicable to the

			frequency of the transmitter. Recommended separation distance: d=1.2 $\sqrt{P}$ d=1.2 $\sqrt{P}$ 80MHz to 800MHz d=1.2 $\sqrt{P}$ 800MHz to 2.7GHz 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 meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic sites survey, [a] each frequency range [b] Interference may occur in the vicinity of equipment marked with the following symbol 

NOTE1: At 80MHz and 800MHz, the higher frequency range applies.

NOTE2: 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 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 BP3T01-1B is used exceeds the applicable RF compliance level above, the BP3T01-1B should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the BP3T01-1B.

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

Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications device						
Test frequency (MHz)	**Band (MHz)**	**Service**	**Modulation**	**Maximum power (W)**	**Distance (m)**	**IMMUNITY TEST LEVEL (V/m)**
385	380 to 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
450	430 to 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710, 745, 780	704 to 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
810, 870, 930	800 to 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
1720, 1845, 1970	1700 to 1990	GSM 1800;CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	2	0.3	28
2450	2400 to 2570	Bluetooth, WLAN, 802.11 b/g/n , RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
5240, 5500, 5785	5100 to 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9

Back Cover

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