
AM
8:00
My Trend Average
115
75
68
Pulse
2 wks ago
120
SYS
mmHg
80
DIA
mmHg
70
Pulse
/min
microlife
SET
START/STOP
M

BPHJE2-D

Symbols & Definitions

 Manufacturer

 Caution

 Type BF Applied part

IP21 Protected against solid objects with a diameter of ≧12.5mm. ; Protected against vertically falling drops of water, e.g. condensation.

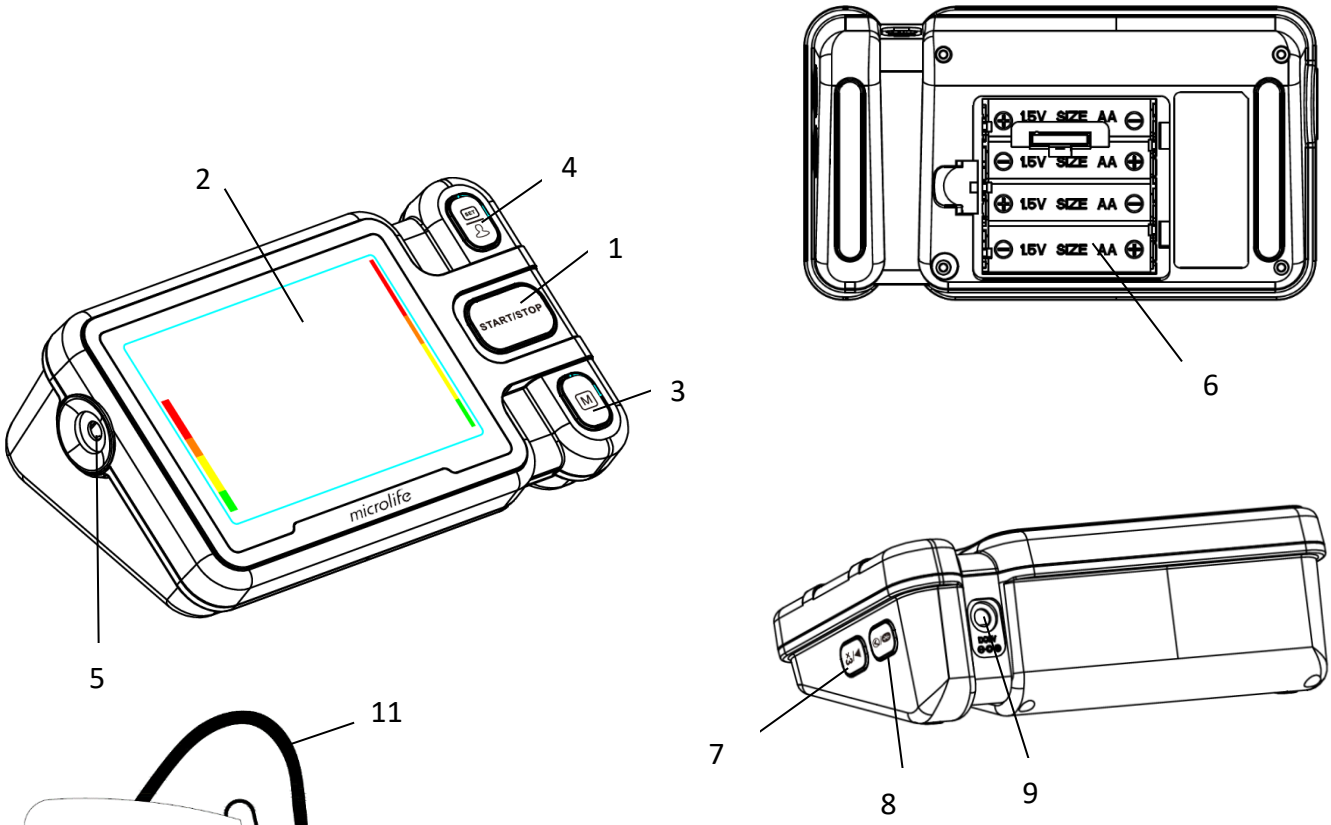
 Keep Dry

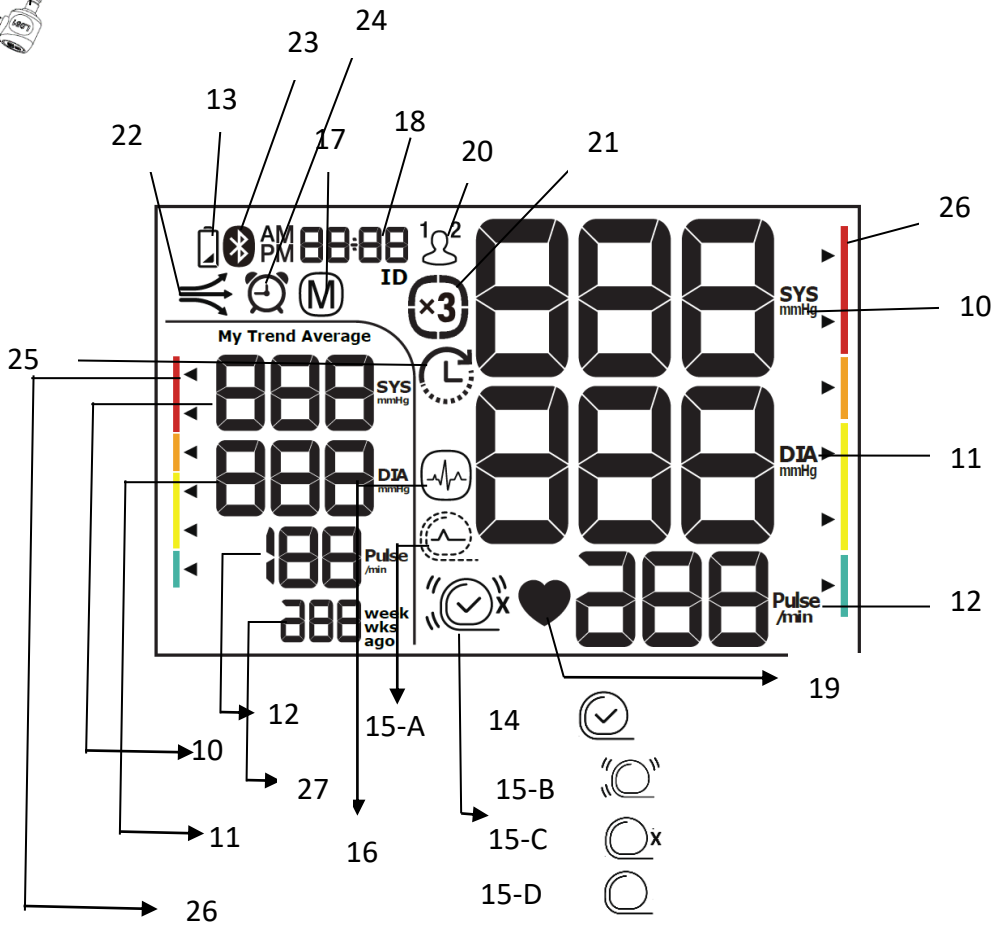
 Temperature limit

 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.

Device Illustration





Device Illustration Legend

Device

1 START/STOP button

2 Display

3 M-button (memory)

4 SET/USER Button

5 Cuff Socket

6 Battery Compartment

7 MAM/NEXT button

8 BT/CONFIRM button

9 Mains Adapter Socket

10 Cuff

11 Cuff Tube

12 Cuff Connector

Display

10 Systolic Value

11 Diastolic Value

12 Pulse Rate

13 Battery Display

14 Cuff Fit OK

15-A: Cuff Signal Indicator «Err 1»

15-B: Arm Movement Indicator «Err 2»

15-C: Cuff Pressure Check «Err 3»

15-D: Suboptimal Cuff Fit

16 Irregular heartbeat (IHB) symbol

17 Stored values

18 Date/Time

19 Pulse indicator

20 User indicator

21 MAM Mode

22 Average Indicator «MyCheck»

23 Active Bluetooth®

24 Alarm

25 Count Down Mode

26 Traffic light display

27 Average Period

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.

Intended Purpose

Indication for Use

The Upper Arm Blood Pressure Monitor, Model BPHJE2-D is a device intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive oscillometric technique in which an inflatable cuff is wrapped around the upper arm for a circumference range from 22 to 52cm.
The device is suitable for use by adults, including adults with conditions of diabetes, pregnancy, or preeclampsia.
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 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 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. 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.
- 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.

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.

Device Preparations before Using

Selecting the correct cuff size

Check if the cuff size is suitable for the circumference of your upper arms. The upper arm circumference can be measured using a tape measure around the mid-point of the upper arm.

⚠Caution: Using an undersized or oversized cuff for measurement results inaccurate blood pressure values. Use the correctly sized cuff for measurement to ensure the readings are reliable.

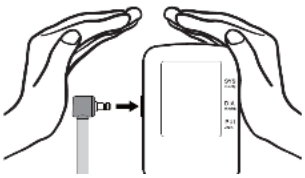
Cuff size	**for circumference of upper arm**
M - L	22 - 42 cm
L - XL	32 - 52 cm

Contact your local Microlife Service if the enclosed cuff does not fit.

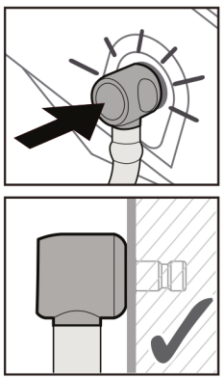
⚠Caution: Only use compatible Microlife cuffs and connectors with this device.

Connecting the cuff to the device

Tube connection: Push the cuff connector into the cuff socket by palm as far as it will go.



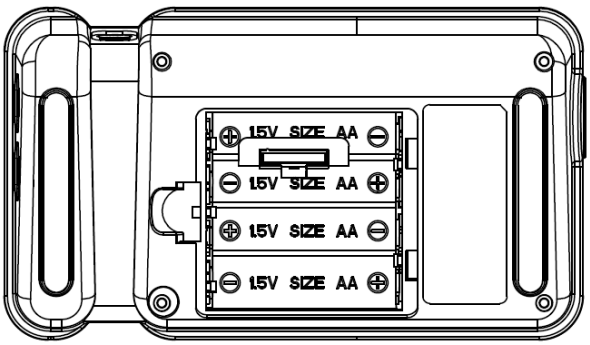
Make sure the cuff connector is securely inserted into the cuff socket of your blood pressure monitor (a soft “click” may be heard when fully inserted).



⚠Caution**:** A loose connection will result in inaccurate readings, and an error message (Err 3).

Inserting the batteries

After you have unpacked your device, first insert the batteries. The battery compartment is on the bottom of the device. Insert the batteries (4 x 1.5 V, size AA) 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!

Setting the date and time

1. After the new batteries are fitted, the year number flashes in the display. You can set the year by pressing the MAM/NEXT -button. To confirm and then set the month, press the BT/CONFIRM button.
2. Press the MAM/NEXT -button to set the month. Press the BT/CONFIRM button to confirm and then set the day.
3. Follow the instructions above to set the day, hour and minutes.
4. Once you have set the minutes and pressed the BT/CONFIRM button, the date and time are set and the time is displayed.
5. If you want to change the date and time, press and hold the SET/USER button for approx. 7-8 seconds until the year number starts to blink. Now you can adjust date and time settings as described above.

⚠**Caution:** Make sure date & time settings is correct on the device. Incorrect settings results misleading data & time records of the measurements.

Setting Alarm

This device is equipped with an alarm function that allows you to set two time slots, making it convenient for measuring blood pressure at fixed times each day, enabling better monitoring of blood pressure changes.

- After completing the date and time setting, now you can start to set the first alarm time.
- “AL OFF” and alarm icon display on the screen. You can turn ON or turn OFF alarm by pressing the MAM/NEXT button and pressing BT button to confirm.
- After turning on the first alarm time, set the hour and minutes using the MAM/NEXT button. To confirm, press BT/CONFIRM button.
- After completing the first alarm time setting, now you can follow the instructions above to set the second alarm time.
- Once you turn on alarm function, alarm icon displays on the screen in standby mode.
- If you want to turn off or change the alarm time, press, and hold the SET/USER button down for approximately 7-8 seconds until the year number starts to flash. To bypass setting time and date, press BT/CONFIRM button and then follow the instructions above to set alarm time.

Setting Notification Sound

After completing the Alarm setting, “BEP OFF” display on the screen. You can turn ON or turn OFF alarm by pressing the MAM/NEXT button and pressing BT/CONFIRM button to confirm.

Setting the user

This blood pressure monitor is designed to store 200 measurements for each of two users. Memories are not stored in guest mode.

- Select the intended user (user 1 or user 2 or guest) by pressing the SET/USER button.
- Before each measurement, ensure that the correct user is selected.

Set up Bluetooth® auto-transfer mode

Once the Bluetooth auto-transfer mode is enabled, Bluetooth will automatically turn on after each measurement to transfer the data to the app.

- To turn on Bluetooth® auto-transfer mode, press and hold the SET/USER button down for approximately 3-4 seconds until “SET” displaying in the left-hand side screen and then release the button.
- “bt OFF” and BT icon display on the screen. You can turn ON or turn OFF the mode by pressing the MAM/NEXT button and pressing BT/CONFIRM button to confirm.

⚠ **Caution:** The setting of Bluetooth auto-transfer mode is adjustable for each individual user. Every time switching users, please check the status of the Bluetooth auto-transfer mode

Note: Bluetooth function is unavailable in guest mode.

Setting Count Down

This device features a countdown function to ensure that measurements are taken after a designated rest period. The countdown can be set to 1, 3, or 5 minutes before starting the measurement.

- Press and hold the SET/USER button down for approximately 3-4 seconds until “SET” displaying in the left-hand side screen and then release the button.
- “bt OFF” and BT icon display on the screen. You can bypass the setting of Bluetooth auto-transfer mode by pressing BT/CONFIRM button.
- “cdt OFF” and count down icon display on the screen. You can set 1, 3, or 5 minutes or OFF the mode by pressing the MAM/NEXT button and pressing BT/CONFIRM button to confirm.

Selecting Standard mode or MAM mode for measurement

Before each measurement, select standard (single measurement) or MAM mode (automatic triple measurement). In MAM mode, 3 measurements are automatically taken in succession, and the result is then automatically analyzed and displayed.

Because the blood pressure constantly fluctuates, an average blood pressure based on consecutive measurements is more reliable than based on a single measurement.

- To select MAM mode, Press the MAM/NEXT button, the MAM mode-symbol appears in the display. Press the MAM/NEXT button again back to Standard mode.
- The bottom, right hand section of the display shows a 1, 2 or 3 to indicate which of the 3 measurements is currently being taken.
- There is a break of 15 seconds between the measurements. A countdown indicates the remaining time.
- The individual results are not displayed. Your blood pressure will only be displayed after all 3

measurements are taken.

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

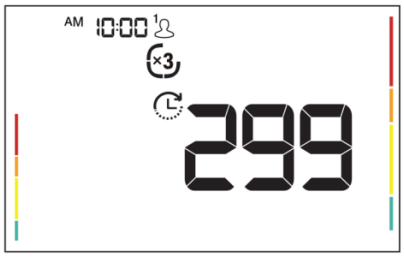
- Make sure to use the correct cuff size suitable for patient's arm circumference. Always measure on the same arm (normally left).
- Remove thick clothing and close-fitting garments from the upper arm. To avoid constriction, shirt sleeves should not be rolled up - they do not interfere with the cuff if they are laid flat.
- Fit the cuff snugly around the upper arm, with the lower edge positioned 1-2 cm above the elbow, and the artery mark aligned with the (brachial) artery in the inner side of the arm. The gaps between the cuff and the arm on both top and bottom edges of the cuff should be no wider than two fingers width.
- Support your arm on a desktop so it is relaxed. Make sure the middle of the cuff is at the same height as your heart (right atrium).

Taking a Blood Pressure Measurement

Starting measurement

1.. Press the START/STOP button to start the measurement. Device will display current date and time, then inflate the cuff automatically.

Note: If the count down function is turned ON, after pressing the START/STOP button, the count down will start and the remaining second will display on the screen. Device will inflate the cuff after count down finishes. Press START/STOP button to skip count down and move to start measurement.

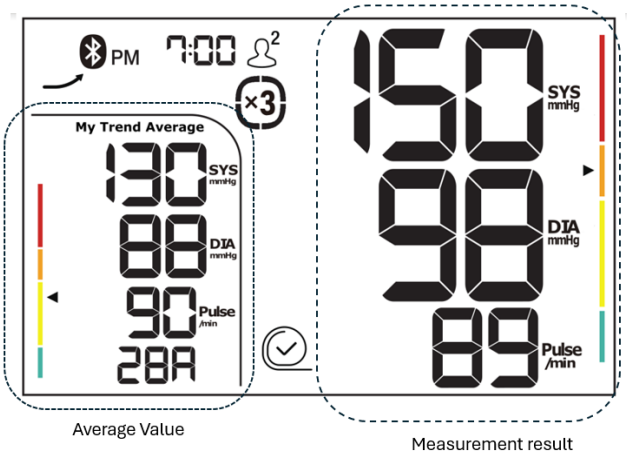


2. The measurement is performed during the inflation. The inflation speed may vary, this is a normal occurrence.

4. During the measurement, the pulse indicator flashes in the display. Relax, breathe normally and do not tense your arm muscles until the measurement result is displayed.

⚠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!

5. The result, comprising the systolic and the diastolic blood pressure and the pulse rate is displayed on the right hand side screen, and the average of all-stored values in the last 28 days for the current user will appear on the left hand side screen. You can press MAM/NEXT button to move to the average of all-stored values. The cuff can now be removed. The device returns to stand-by after approx. 1 min.



Aborting measurement (Emergency Stop)

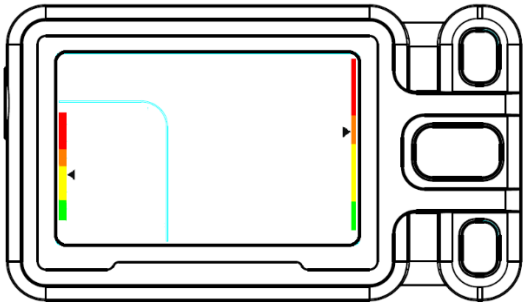
Caution: You can stop the measurement at any time by pressing the START/STOP button, disconnecting the cuff, and by opening the cuff. (E.g. if you feel uneasy or an unpleasant pressure sensation).

How not to store a reading

As soon as the reading is displayed press and hold the M button until «M» is flashing. Confirm to delete the reading by pressing the SET/USER button.
«CL» is displayed when the reading is deleted from the memory successfully.

How do I evaluate my blood pressure?

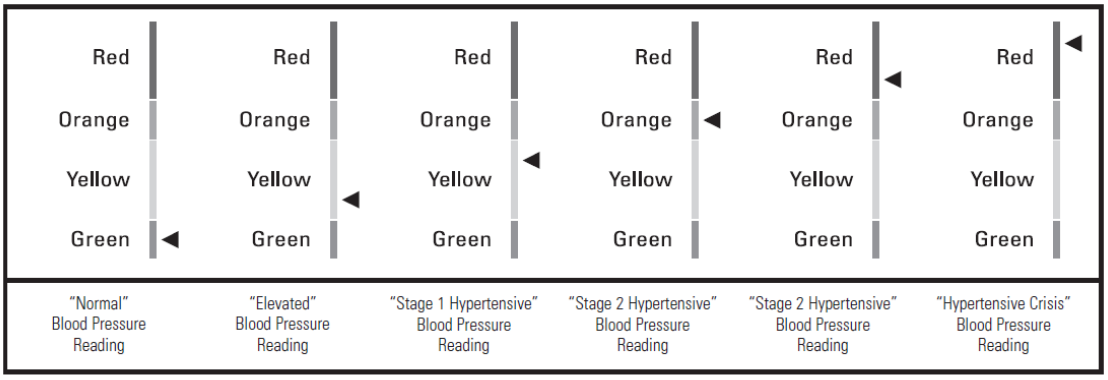
The triangle on the left-hand edge and the right hand edge of the display points at the range within which the measured blood pressure value lies.



The colored indicator on the left-hand edge and the right 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 black triangle will display onscreen next to the colored hypertension indicator. The height of the black triangle will show if the measurement is within the normal (green), borderline (yellow/orange) or danger (red) 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:

- green zone, your measurement is "Normal."
- lower yellow zone, it is "Elevated."

- upper yellow zone, it is "Stage 1 Hypertensive."
- orange zone, it is "Stage 2 Hypertensive."
- lower red zone, it is "Stage 2 Hypertensive."
- upper red 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.

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.

Average Indicator (My Check)

This symbol  indicates after each measurement, if the most recent measured value lies below, above or on the same level as your stored averages value

1. If the measured Systole or Diastole is more than 5mmHg higher than the stored average, the arrow shows upwards.
2. If the measure d Systole or Diastole is more than 5mmHg lower than the stored average, the arrow shows downwards
3. If the measured Systole and Diastole's difference between the stored average are within 5mmHg, the arrow shows straight on.
4. If the measured Systole and Diastole values are trending in different directions from the stored average, the Systole value flashes first with the up or down arrow for two seconds. Then, the diastole value flashes with the up or down arrow for two seconds.

Review Measurement in Memory

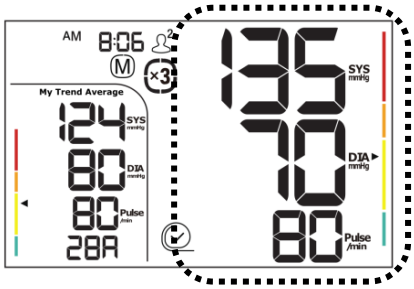
Measurement memory function

This device automatically stores the last 200 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 SET/USER button.

Viewing the stored values in memory

Pressing the M-button , allows you to see the last performed measurement. The right hand side of the display first shows «M» and a value, e.g.«M17». This means that there are 17 single values in the memory. Pressing the M-button again displays the previous value. Pressing the M-button repeatedly enables you to move from one stored value to another.



Memory full

Pay attention that the maximum memory capacity of 200 memories is not exceeded. When the 200 memory is full, the oldest value is automatically overwritten with the 201st value.

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

Clearing all values in memory

If you are sure that you want to permanently remove all stored values, hold down the M-button when device is in stand-by until «CL ALL» appears and then release the button. To permanently clear the memory, press the SET/USER button while «CL ALL» is flashing. Individual values cannot be cleared.

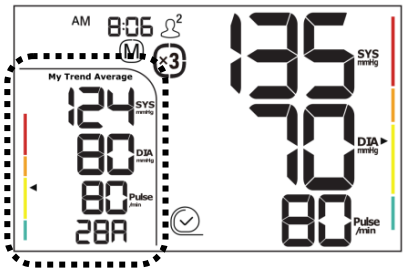
Cancel deletion: press START/STOP button while «CL ALL» is flashing.

Viewing the average of measurement value

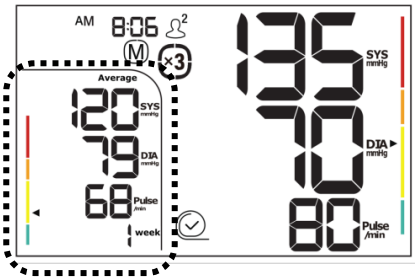
Doctors recommend that you compare blood pressure measurements taken at the same time each day to help ensure consistent conditions during measurements. To assist you, this blood pressure

monitor is equipped with three types of measurement value averaging capabilities: 28 days, weekly and all stored measurement value.

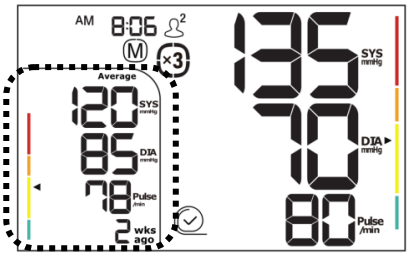
• Press “M” (Memory) button. The average of all-stored values in the last 28 days for the current user will appear. “28A” will be displayed on the bottom of the left-hand side of the screen.



• Press MAM/BT button again. The average of the latest one-week ago stored values for the current user will appear. “1 week” will be displayed on the bottom of the left-hand side of the screen.



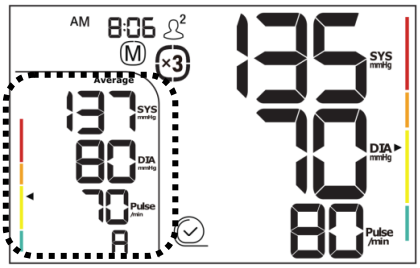
• Press MAM/BT button again. The average of the second to last week value, from the fourteenth day ago to the eighth day ago, will appear. “2 wks” will be displayed on the bottom of the left hand side of the screen.



• Press MAM/BT button again. The average of the third to last week value, from the twenty-first day ago to the fifteenth day ago , will appear. “3 wks” will be displayed on the bottom of the left-hand side of the screen.

• Press MAM/BT button again. The average of the fourth to last week value, from the twenty-eighth day ago to the twenty-second day ago, will appear. “4 wks” will be displayed on the bottom of the left-hand side of the screen.

• Press MAM/BT button again. The average of the all stored measurement value, will appear. “A” will be displayed on the bottom of the left-hand side of the screen.



- Press MAM/BT button again to go back to 28 days average value

Bluetooth® Function

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

Download the Microlife Connected Health+ US app and check mobile application OS Compatibility with Apps here:

Android: IOS:

Note: The App will not be able to receive readings and the alert on the App will display unless the date & time have been properly set on your blood pressure monitor. To solve this problem, please follow the instructions in FAQ on the App.

Note: Please be sure to refer to the FAQ on the app regarding the process for first-time app usage when using Bluetooth for the first time.

Before using Bluetooth data transmission function for the first time, Bluetooth pairing between the device and the mobile phone needs to be completed.

Caution: It is recommended to conduct Bluetooth pairing in private to reduce the device exposure to cybersecurity vulnerability.

Bluetooth® pairing & app setup

1. Open «Microlife Connected Health+» App on the smartphone (Make sure the app is running in the foreground, not in the background.)
2. Press BT/CONFIRM button to turn on Bluetooth® manually to connect device to smartphone.
3. When smartphone finds the device, the smartphone will show a message to pair with the device. Confirm on smartphone to complete pairing. Cancel to abort pairing.
4. After pairing, the app will show a message to setup the device user selection (1 or 2) to the app user profile. Confirm to proceed with setup. Cancel to abort setup (if user selection is incorrect).
5. After setup, when Bluetooth® auto-transfer mode is set “ON”, the device will automatically exchange measurement data and date/time settings with the app. Bluetooth® turns off automatically after data exchange

Bluetooth® operations when Bluetooth® auto-transfer mode is set "ON"

- Automatically turn on Bluetooth®: Bluetooth® will activate automatically after a measurement. Bluetooth® symbol on display will blink.
- Automatically turn off Bluetooth®: Bluetooth® will turn off automatically after 2 minutes if a smartphone does not connect to the device.
- Manually turn on Bluetooth®: Press BT/CONFIRM button to activate Bluetooth®, Bluetooth® symbol on display will blink.
- Manually turn off Bluetooth®: Press START/STOP button to turn off Bluetooth®.

Bluetooth® status

- Bluetooth® symbol blinking slowly: Bluetooth® is activated and waiting for connection.
- Bluetooth® symbol not blinking: Bluetooth® connection established.
- Bluetooth® symbol blinking rapidly: Bluetooth® connection error.
- In case of Bluetooth® connection error, turn off device Bluetooth®, wait for a minute, then re-try Bluetooth® connection. Refer to chapter «10. Error messages» for details.

 **Caution:**

To ensure the data security while using Bluetooth® function, please refer to the following recommendations:

Ensure the built-in security and privacy measures of your mobile phone (e.g., user authentication) is setup and activated.

Employ best practices of password strengthening when creating an account on the App.

Beware of the status of device Bluetooth functionality: Bluetooth® is only functioning when activated manually or set to automatically active after a measurement.

Turn off device in case of abnormal Bluetooth connection, such as device Bluetooth status being connected but app status showing disconnected, to reduce data security vulnerability.

Keep the App updated to ensure its mobile phone compatibility and data security.

Battery Indicator and Battery Replacement

Low battery

When the batteries are approximately 25% left, the battery symbol will flash as soon as the device is switched on (partly filled battery displayed). Although the device will continue to measure reliably, it's recommended to replace the batteries as soon as possible.

Flat battery and replacement

When the batteries are flat, the battery symbol 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 at the back of the device.
2. Replace the batteries – ensure correct polarity as shown by the symbols in the compartment.
3. To set date and time, follow the procedure described in «Section 2.».

- The memory retains all values although date and time must be reset – the year number therefore flashes automatically after the batteries are replaced.

Accessories

Blood Pressure Cuffs

Accessories: Standard Cuff: Wide range soft cuff for arm circumference 22-42cm

Optional cuff : L XL size soft cuff: 32 52cm)

Spare Parts

Batteries

- Use 4 new 1.5 V, size AA 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.

Error Messages & Troubleshooting

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. Please follow the procedure described in “Tube connection” to ensure the cuff is properly connected.
«Err 5»	Abnormal result	The measuring signals are inaccurate and no result can therefore be displayed. Or This is low priority technical alarm. The measurement value is out of measuring range . 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. *
	Bluetooth® symbol (13) blinks rapidly	Bluetooth® connection error. Turn off the device and close the app on the smartphone. Wait for 1 minute, open the app on the smartphone and manually activate Bluetooth® on the device to retry Bluetooth connection and data transfer.
«Err bt»	Bluetooth® self check error	Bluetooth® is malfunctioning. Contact your local Microlife distributor.

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

For incidents to data security of device use, please contact Microlife support at:

productsecurity@microlife.com

Maintenance, Service, and Disposal

Maintenance

When not in use:

- Disconnect the cuff and parts from the device.
- 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

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.

Technical Specification

Product Category: Non-invasive oscillometric blood pressure gauge

Product Description: Upper arm automatic blood pressure monitor

Model Number: BPHJE2-D

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

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

Weight: 451g (including batteries)

Dimensions: L: 165.6mm, W: 95mm, H: 61mm

Measurement Method: Oscillometric method, corresponds to Korotkoff method:

Phase I systolic / Phase V diastolic

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

Power Source – Internal: 4 x 1.5V LR3(AA) batteries

IP Rating: IP21: Protected against solid objects with a diameter of ≧12.5mm. ; Protected against vertically falling drops of water, e.g. condensation.

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 81060-2:2018 was conducted on blood pressure device using

For information about the embedded software of the device (e.g., software version and BOM), please contact Microlife at: productsecurity@microlife.com

For information about device security and vulnerability, please visit Microlife official website at: https://security.microlifecloud.com

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

MICROLIFE CORP.

Microlife Corporation

9F, No. 431, RuiGuang Road, NeiHu,

Taipei, 114, Taiwan, China

Distributed by:

MICROLIFE U.S.A., INC.

1617 Gulf To Bay Blvd Floor 2

Clearwater,FL 33755

Toll Free Help Line: 1-800-568-4147

Email: custserv@microlifeusa.com

www.microlifeusa.com

Made in China

IFU BPHJE2-D- EN V1-2451