# Model RBP-7000 Series

# Automatic Pulsewave Blood Pressure Monitor

# INSTRUCTION MANUAL


**Shenzhen Raycome Health Technology Co., Ltd**

Dear Customer,

Thank you for purchasing the Raycome Health RBP-7000 Automatic Pulsewave Blood Pressure Monitor. Your new blood pressure monitor is used to measure blood pressure and pulse rate quickly and easily, and stores the results and displays the readings automatically; it adopts the pulse wave method of blood pressure measurement, which is a new generation blood pressure measurement method with reliable result and high accuracy with features as follows:

- *Supports accurate measurement and can easily be used by a single person.*
- *Measurement is possible over a wide range of arm circumferences (17 to 42 cm).*
- *Left or right arm can be used for measurement.*
- *PulseWave blood pressure measurement theory and method.*
- *Measurement results can be announced.*
- *The unit and cuff cover are antibacterial.*
- *The cuff cover can be replaced when necessary.*

In order to use the device correctly and efficiently, please read this Instruction Manual before use. Also you should take good care of the instruction manual so that you can use it expediently and timely when need.

Intended user:The Automatic PulseWave Blood Pressure Monitor is suitable for people who are older than 12 years of age in hospital, clinic and social medical organizations etc.

**Intended use:This product is used to measure adult diastolic blood pressure, systolic blood pressure and pulse rate.**

**Contraindications:**
None.

Version No.:V2.0 Revised date:2023.03.18

Note: The series of RBP-7000 Series includes models RBP-7000, RBP-7000B, RBP-7000W, this is a general instructions.

**NOTE:**

1.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.

2.This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

—Reorient or relocate the receiving antenna.

—Increase the separation between the equipment and receiver.

—Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

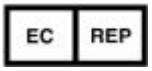
—Consult the dealer or an experienced radio/TV technician for help.

The device has been evaluated to meet general RF exposure requirement. The device can be used in portable exposure condition without restriction.

3.The manufacturer is not responsiblefor any radio or TV interference caused by unauthorized modifications to this equipment. Such modifications could void the user’s authority to operate theequipment.

# CONTENTS

SYMBOLS AND ABBREVIATIONS

| Identifiers | Indications | |
|---|---|---|
| CE 0482 | This product complies with the European Council Directive 93/42/EEC(Medical Device Directive) | |
|  | BF TYPE | |
|  | Class II equipment | |
|  | Lot number | |
|  | Serial number | |
|  | Date of manufacturer | |
|  | Manufacturer | |
|  | Authorized representative in the European Community | |
|  | Consult accompanying documents | |
|  | Dispose of this product and used batteries in accordance with the applicable local regulations for disposal of electrical product | |
| IP20 | Degrees of protection provided by enclosures: Protect against solid foreign objects of 12.5mm diameter | |
|  | Caution | |
|  | RF transmitter device is included | |
| SYS | SYSTOLIC PRESSURE | |
| DIA | DIASTOLIC PRESSURE | |
| Bluetooth Module (Apply to RBP-7000B) | Frequency | 2402MHz—2480MHz |
| | Modulation type | GFSK, π/4 PSK, 8DPSK |
| | Effective radiant power | -6dBm—+4dBm |
| WIFI Module (Apply to RBP-7000W) | Frequency | 2400 MHz—2483.5 MHz |
| | Standard | 802. 11 b/g/n/e/i |
| | Transmission power | 802. 11 b: +20 dBm,<br>802. 11 g: + 17 dBm,<br>802. 11 n: + 14 dBm |

## SAFETY INFORMATION

To assure the correct use of the product, basic safety measures should always be followed including the warnings and cautions listed in this instruction manual.

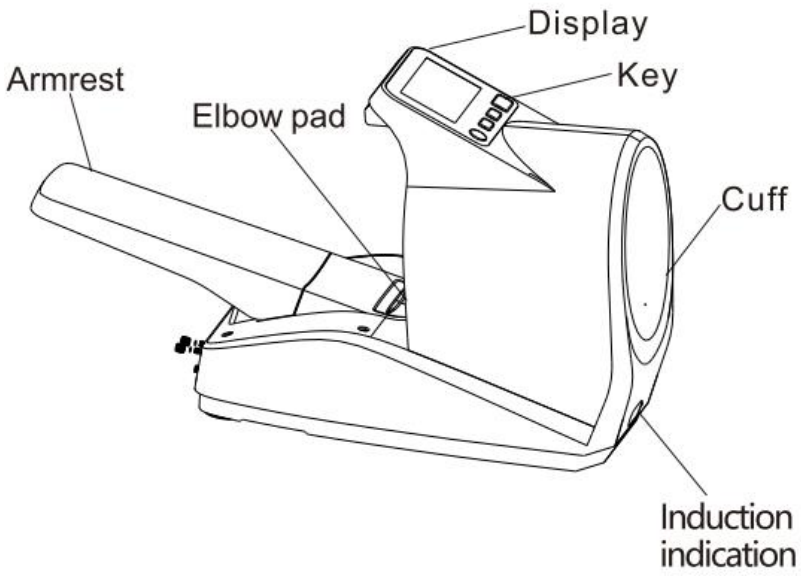
| Identifiers | Indications |
|---|---|
|  | Do not measure blood pressure if the arm has a wound. Blood may come in contact with the cuff cover, allowing infectious diseases to spread.<br>Do not use the monitor in a place where it may get wet, such as by pool. This may result in fire or electrical shock.<br>Do not install any component or equipment that is not specified by Raycome Health on this monitor. This may cause fire or electrical shock. |
|  | If a problem with the monitor is encountered, immediately turn off the power and remove the plug from the electric outlet. Attach an "Out of Service" notice and do not use the monitor. Otherwise fire or electrical shock may result. |

| | |
|---|---|
| Persons under 12 years' old, pregnant women, pre-eclamptic, mental disorder or arrhythmia patients should use this device under Practitioner's guidance. |  |
| Operate the device only as intended. Do not use the device for any other purpose. |  |
| Read all of the information in the instruction manual before operating the unit. |  |
| Do not plug or unplug the power cord into the electrical outlet with wet hands. |  |
| Do not overload power outlets. Plug the device into the appropriate voltage outlet. |  |
| Do not use the cuff on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, please follow Practitioner's guidance. |  |
| Do not use a cellular phone near the device, or it may result in an operational failure. |  |
| Use only Raycome Health authorized parts and accessories. Parts and accessories not approved for use with the device may damage the unit. |  |
| Repeat measuring the same person with an interval of at least 2 minutes because too frequent measurements can cause injury to you due to blood flow interference. |  |

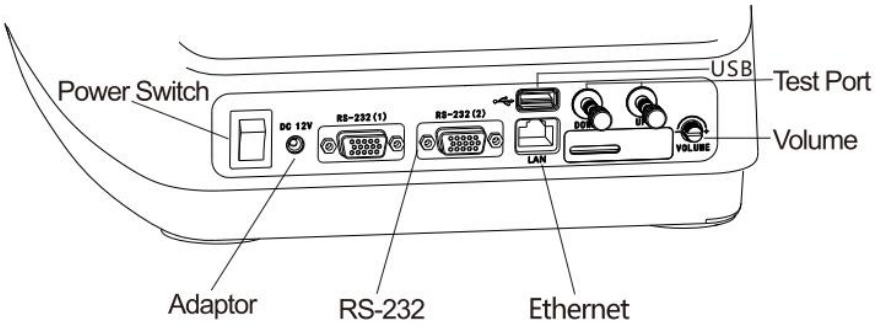
| | |
|---|---|
| Do not subject the monitor to strong shocks, such as dropping on the floor. |  |
| Do not overload power outlets. Plug the device into the appropriate voltage outlet. |  |
| Dispose of the device and components according to applicable local regulations. Unlawful disposal may cause environmental pollution. |  |
| Any measurement can be influenced by the position and the body condition, so please do not measure in the following situations:<br>( 1) Improper posture, cause you can't measure or inaccurate status.<br>(2)After intense exercise or under nervous motion, the data will be higher than the actually measured one.<br>(3)A muscle spasm or trembling, disenables you to measure correctly.<br>(4) Due to wearing thick clothes, blood pressure can't be measured or the data is higher than the actual one.<br>(5)The arm set could be dirty when the arm is wet. |  |
| Do not adjust medication based on measurement results from this blood pressure monitor. Take medication as prescribed by your physician. Only a physician is qualified to diagnose and treat High Blood Pressure. |  |
| Instructions for warning increase - to avoid the risk of electric shock, the equipment must be connected to the power supply network with protective earthing only |  |
| Do not use the device around a strong electric field, an electromagnetic field (such as an MRI scan room) or mobile wireless communication devices. Using the device in an improper environment may result in malfunction or damage |  |
| Before boot, press and hold the buttons "MEM" and "SET" simultaneously, then press the button "START/ STOP" to turn on the sphygmomanometer. This will make the device enter the test mode.<br>Please don't apply these steps unless they are necessary. | Suggestion |
| Changes or modifications not approved by Raycome Health will void the user warranty. Do not disassemble or attempt to repair the unit or components. | Suggestion |
| This product should be calibrated by a qualified institution each year or it may result in an operational failure. | Suggestion |
| Attention should be added: do not use mobile phone or interphone and other wireless communication equipment near this product, and do not use the product under the environment of strong electric magnetic field; otherwise it may affect the normal work of this product. | Suggestion |

| | |
|---|---|
| The operator should be a physician or a medical staff supervised by a physician, both of whom have received sufficient training in clinical pressure monitor technology. | |
| Only the personnel authorized or trained by the manufacturer can maintain the device. Any unauthorized personnel should not assemble or disassemble the device. | |
| Do not store or use this product outside the range of temperature and humidity specified in the manual.<br>Working temperature and humidity: 5 C to 40 C, 15% RH to 85% RH.<br>Suitable temperature and humidity: - 20 C ~ + 55 C, 93% RH or less)<br>Otherwise the claimed performance may not be achieved, and the lifespan of the sphygmomanometer may be reduced | |
| Do not service or maintain the device while it is in use with a patient. | |
| Do not twist the test port, or it will cause equipment failure .<br>(see figure MAIN UNIT (Back Side)) | |
| Accessory equipment connected to analog and digital interfaces must becert ified according to the respective EN/IEC standards (for example, EN/IEC 60950 for dataprocessing equipment and EN/IEC 60601- 1 for med ical equipment). Furthermore, all configurations shall comply with EN/IEC 60601- 1. | |

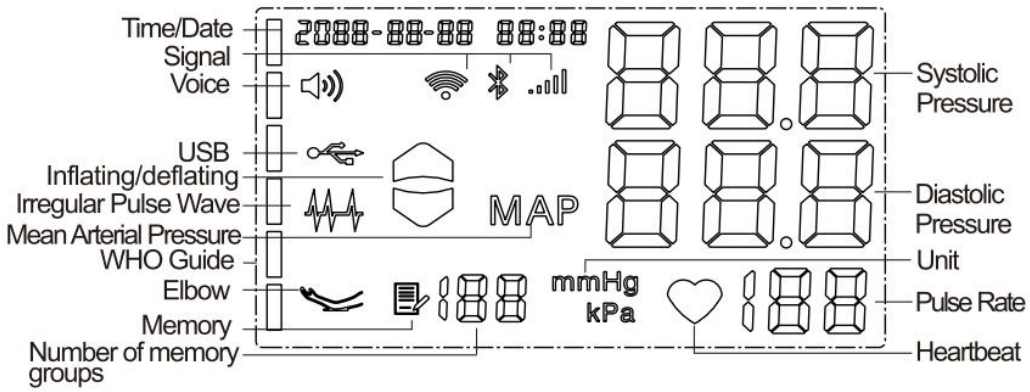
## COMPONENTS OF THE PRODUCTS




MAIN UNIT(Front Side)




**MAIN UNIT (Back Side)**




MAIN UNIT (Display)

## HOW TO INSTALL THE MONITOR

### Attach the cuff cover

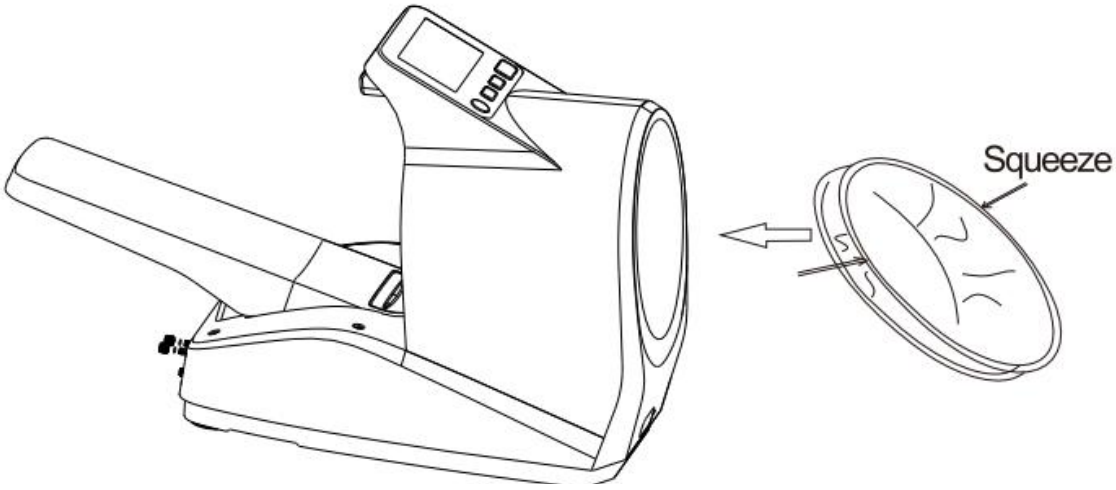
Elastic armset rings on both sides of the cuff cover can withstand a squeezed range. Press the rings as a suitable oval and insert the cuff cover into the armtube. As shown, the protuberant part of elastic ring aligns with card slot, and elastic ring seams aligns with card slot, when the arm set all in then let go, elastic recovery into round shape, adjust the elastic ring and smooth out arm set.

NOTE:

- The cuff cover was attached to the unit at the factory. Replace a new cuff cover as above mentioned steps when necessary.
- This cuff is of uniform size, suitable for 17~42CM arm girth, and supports one person with high accuracy measurements. The cuff is the applied part of this product.
- Regarding the cuff applied over a wound, this can cause further injury
- Regarding applying the cuff and its pressurization on any limb where intravascular access or therapy, or an arterio-venous (A-V) shunt, because temporary interference to blood flow could result in injury to the patient
- Regarding applying the cuff by A side and its pressurization on the arm and mastectomy.
- Regarding the information that, the function of Monitor medical electrical equipments which

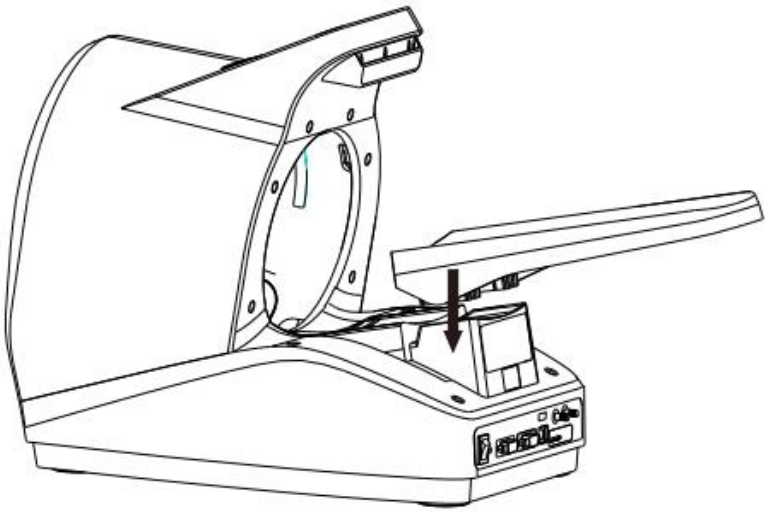
simultaneously apply on the same limb will temporarily loss by cuffpressurization. Recommend an interval 2 minutes before the first reading is taken.

- Measurement Range: Pressure: 0 to 300mmHg



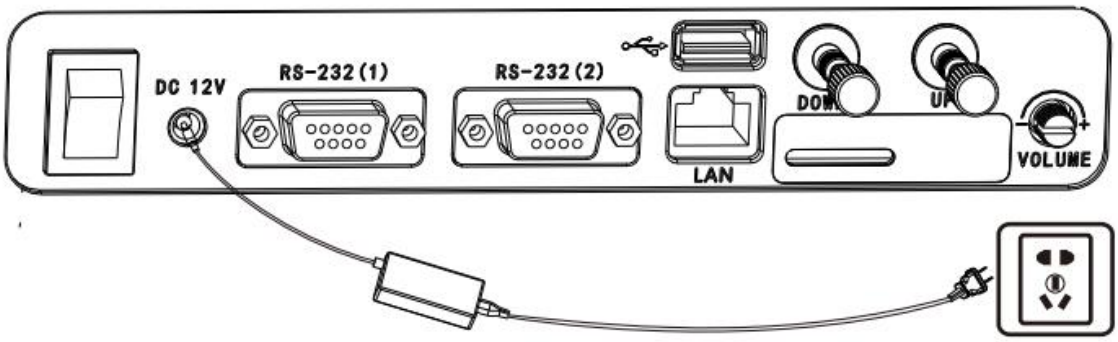

**Attach the cuff cover**

Put hand slid snaps, and the host fastened in the direction of the arrow shown below.



**Power connection**

Firstly, the special adapter is plugged into the network, then the adapter and the host are connected, then the power switch of the sphygmomanometer is turned on, and the sphygmomanometer starts normally.




Note: Do not unplug the power plug when your hands are wet, or you may get an electric shock.

## HOW TO CONNECT TO THE POWER SOURCE

1. This product using the AC power supply, for the consideration of safety, before you connect the power cord, make sure the power switch on the back side is OFF.

2. Insert the output plug side of the power adapter into the DC connector on the back of the monitor.

3.Insert the other plug of the power adapter into the network outlet.

**Caution**: Do not plug or unplug the power cord into the electrical outlet with wet hands, or this may result in electric shock.

## CHECKING THE UNIT BEFORE USAGE

Before turning on the power, please check the followings:

External appearance:

- The monitor is not deformed due to falling or other impact.
- The monitor is not dirty or wet.
- The power cord is not damaged and there is no loose connection.
- The cuff or cuff cover is not deformed or damaged.
- The cuff cover is installed properly.

After turning on the power, check the followings:

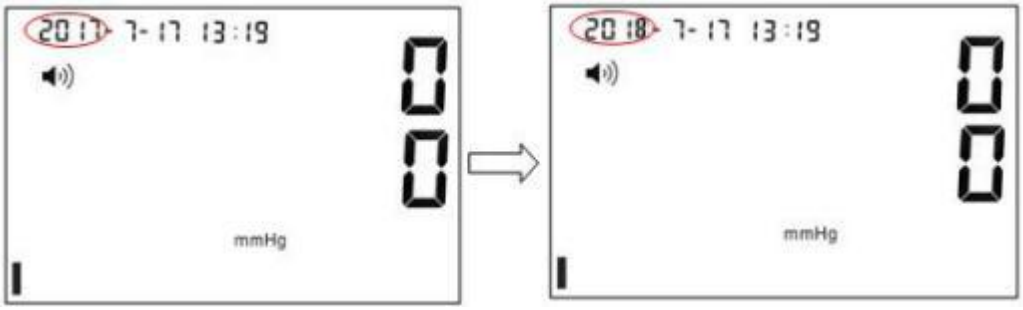
- The volume for audio voice is OK.
- There are no strange noises during measurement.
- There is no indication of IP leakage.
- The date and time are set correctly.

## ⚠HOW TO SET THE TIME/VOICE/UNIT /MAP

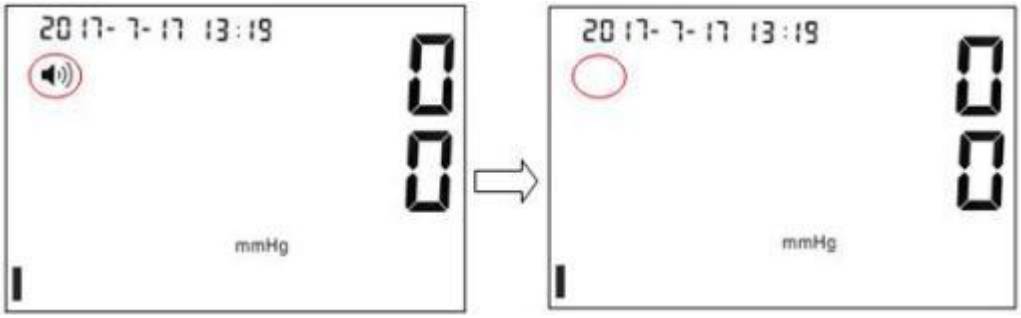
In standby mode, press the button "SET" to switch to the setting mode. Press the button "SET" to switch to the next setting item. Setting items appears successively: year, month, day, hour, minute, voice, unit and MAP. At this point, the corresponding settings flicker. Press the button "START/STOP" to exit the setup.

1. Time Settings: When in the time setting section (year, month, day, hour, minute), change the value by pressing button “MEM” . Every time the button is pressed, the current value of the flicker item

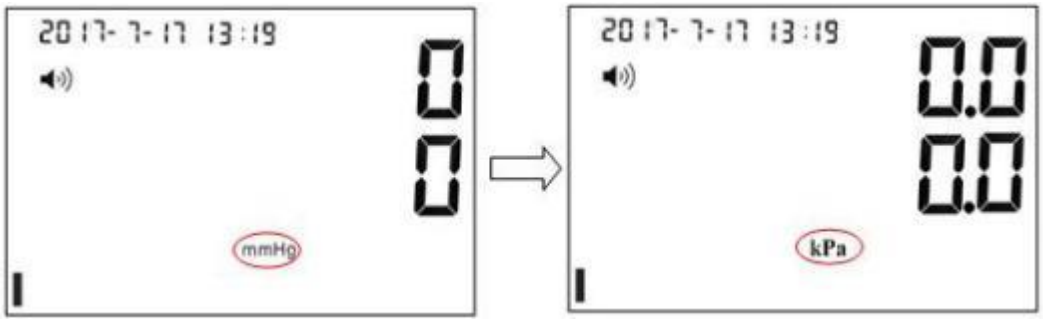
increases by 1. Long press the "MEM" button to continuously adjust the current value of the flicker item (the setting range of the year is 2017-2050). The following figure is the year adjustment interface chart:



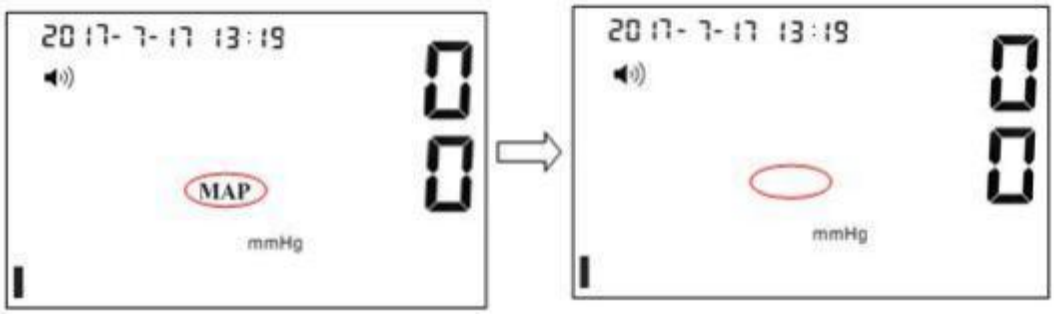

2. Voice settings: When in the voice setting section, voice symbol blinking displays, press the "MEM" button to open or close the voice function. The voice symbol lighting indicates the opening of the voice function and the voice symbol extinction indicates the closing of the voice function, as shown in the following figure:




3. Unit settings: When in the unit settings section, the unit symbol blinking and press the "MEM" key to switch unit. The "mmHg" symbol lighting indicates the unit selection as mmHg, and the "kPa" symbol lighting indicates the unit selection as kPa, as shown in the following figure:




4. Mean Arterial Pressure Setting: When in the Mean Arterial Pressure Setting section, the MAP symbol lighting and press the "MEM" button to open or close the Mean Arterial Pressure. The MAP symbol lighting indicates the Mean Arterial Pressure Function is on, and the MAP symbol extinction indicates the Mean Arterial Pressure Function is off, as shown in the following figure:



## INTELLIGENT INDUCTION/ AUTOMATIC SLEEP MODE

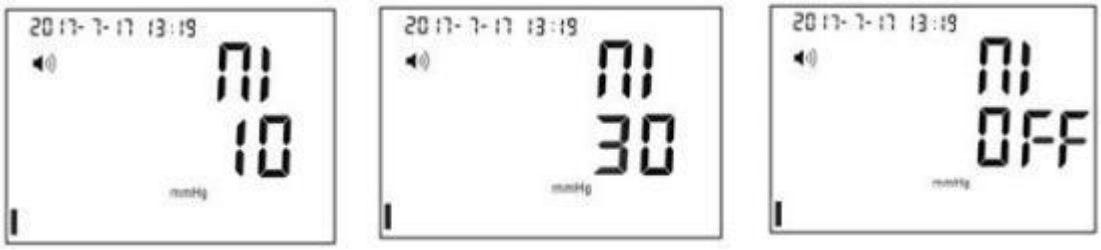
**Intelligent induction**

1) When the machine is in a dormant state (black screen state), the machine automatically wakes up, the display screen lights up and intelligent induction indicates if someone is close to the front of the sleeve.

2) When the machine is in the standby state, the machine automatically lights up the intelligent induction indication if someone is close to the front of the sleeve.

**Automatic sleep mode**

1) In standby state, press the "SET" button for more than 3 seconds to enter the automatic sleep mode setting, as shown below. In this mode, press the "MEM" button to set the automatic sleep mode into 10s, 30s, 60s and turn off the automatic sleep mode. Press the "START/STOP" button to save and exit the setting mode.




2) When the time of setting the automatic sleep mode is 10s, 30s and 60s respectively, the machine automatically enters the sleep state in 10s, 30s and 60s without any operation, and the LCD display is turned off.

3) When the automatic sleep mode is closed, the machine does not automatically enter the sleep mode.

## PROPER POSTURE

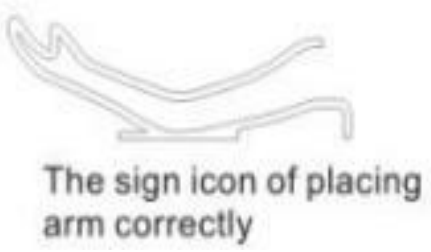
1. Sit straight in a chair with your feet flat on the floor.

2. If a thick garment such as a jacket or sweater is worn, it should be removed. Measurement is possible on bare skin or over thin clothing.

3. Insert the arm into the arm cuff, place the forearm and palm on the Armrest naturally with palm facing up, and arm elbow over arm cuff about 1 cm. Your body should be slightly close to the arm cuff and into 120° with blood pressure monitor. Don't be oppression abdomen or chest, keep relaxed and natural state.

4. Repeatedly measure same person at interval of at least 2 minutes, as too frequent measurements can result in injury due to interference of blood flow and incorrect measurements are obtained.

5.Tubes will arm in arm, forearm and palm natural placed on the shelf hand, palms up, arm elbow tube of about 1 cm over arm, elbow and be placed on the elbow buttons, slightly towards the arm cylinder body, the body and blood pressure at 120。don't oppression abdomen or chest, relaxed and natural condition



The sign icon of placing arm correctly

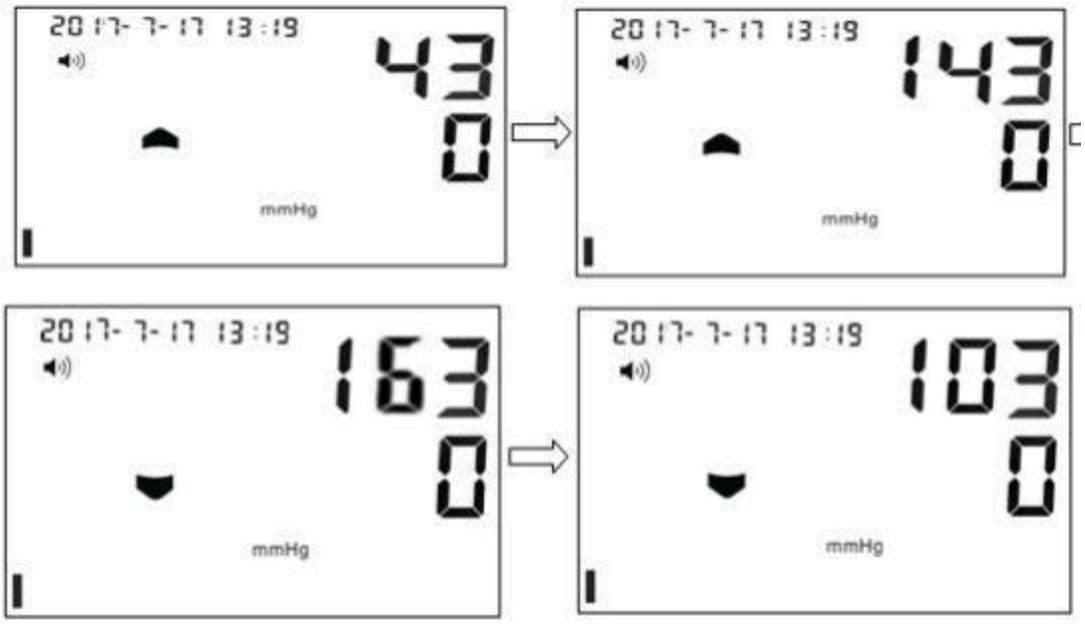
**Caution:**

- It will not be measured correctly when your arm press the edge of arm cuff.
- It will not be measured correctly when your elbow did not reach across the arm cuff.
- It will not be measured correctly when your elbow is not placed in the location specified.
- When your elbow is placed in the correct position, screen will display as shown in the above icon (The sign icon of placing arm correctly).
- If there are unexpected readings, consult your doctor. Do not judge yourself or treat yourself.
- Readings may be affected by the location of the measurement, patient's location, exercise, or patient's medical condition, resulting in errors or cannot be measured, please consult your doctor for guidance.
- The sleeves are consumable and still meet the safety and performance requirements after 10,000 cycles.
- Any blood pressure measurement will be affected by the person's posture and physical condition. Therefore, please do not make the measurement below:
  (1) If the measurement posture is not correct, the measurement cannot be measured or the measurement is not accurate.
  (2) High blood pressure can be measured after strenuous exercise or when nervous.
  (3) The muscle spasm or quiver will fail to be measured correctly.
  (4) When wearing thick clothes, the blood pressure cannot be measured or result is too high.
  (5) When the arm is wet, the arm sleeve will be dirty.

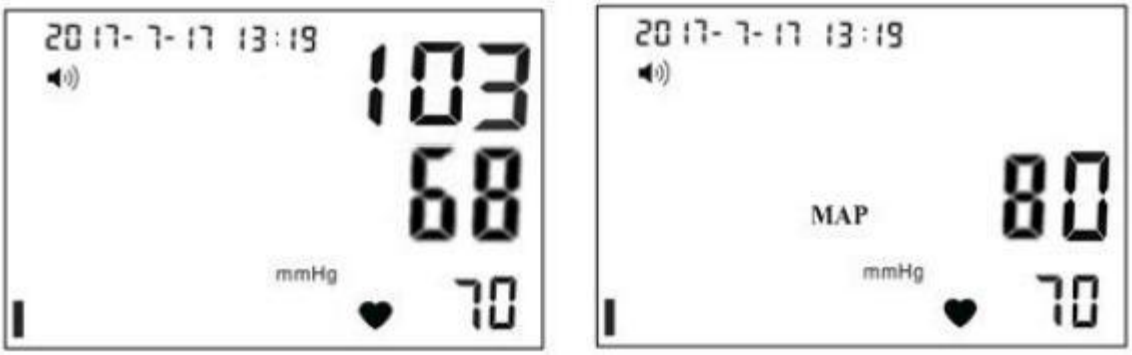
## HOW TO MEASURE BLOOD PRESSURE

Before measurement, the user should try to relax, calm down, sit quietly about 2-3 minutes and you are advised to be measured at the same time every day.

1. Press the button “START/STOP” to start measurement.




2. When the measurement is finished, the result will be displayed and saved automatically. When the MAP is opened, the mean arterial pressure and pulse value measured at that time will be displayed after displaying the systolic pressure, diastolic pressure and pulse value for about 3 seconds. Systolic blood pressure, diastolic blood pressure and mean arterial blood pressure were measured and displayed in turn.




Systolic/diastolic/pulse value display interface

Mean arterial pressure/ pulse value display interface

⚠ CAUTION:

- During the inflation process, it will automatically inflate to a higher pressure if the user's blood pressure is high.
- If you feel pain or discomfort during the measurement, please press the button "START/STOP" to stop the operation; if the button fails to work, please press the button "EMERGENCY STOP" immediately.
- Do not move the body or talk when measuring
- Wait at least 2 minutes between measurements. The wait time allows the arteries to return to the condition prior to taking the blood pressure measurement. You may need to increase the wait time depending on your individual physiological characteristics.
- The temperature of the cuff may exceed 41 degrees at 40 degrees Celsius.Patients should not repeat measurements for more than three minutes at a time

## USING THE MEMORY FUNCTION

**1. Check the data**

This machine can store 100 sets of memory measurements. If more than 100 sets of measurements are stored, the earliest memory measurements will be automatically covered to save the latest measurements.

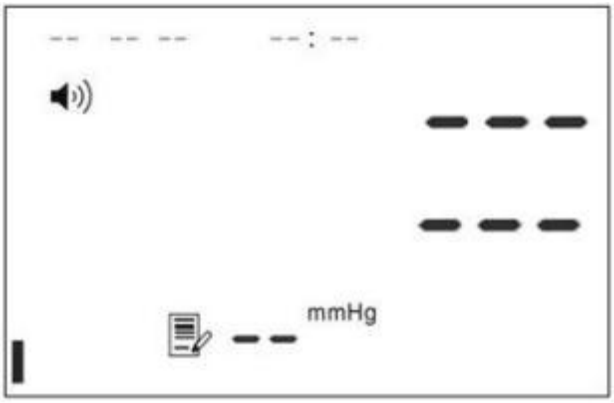
In standby state, press the "MEM" button and enter the state of viewing measured values. Each time the "MEM" button is pressed repeatedly, the number of memory groups is reduced by one, and the corresponding memory measurement values will be displayed in the order from new to old. Until the first set of memory measurements are displayed, press the "MEM" button and the last set will be returned to the display, so that the loop is as shown in the following figure. Press the "START/STOP" button to exit the memory function. When the MAP is opened, the mean arterial pressure and pulse number of the memory value are displayed about 3 seconds after the display of systolic pressure, diastolic pressure and pulse value. The values of systolic pressure, diastolic pressure and average arterial pressure are repeated in turn.


Systolic/diastolic/pulse value display interface


Average arterial pressure/pulse value display interface

**2. To delete all values stored in the memory**

In the memory value checking state, press and hold the "MEM" button for at least 3 seconds to delete all values stored in the memory.



**NOTE:**

The deletion function is to delete all memory values at one time. It is not possible to delete specific memory measurements one by one.

## DATA TRANSMISSION AND RECEPTION

1. Model RBP-7000 can transmit and receive data through serial port and USB interface.
2. Model RBP-7000B can transmit and receive data through Bluetooth, serial port and USB interface.
3. Model RBP-7000W can transmit and receive data through WIFI, serial port and USB interface.
4. All models of RBP-7000 series can transmit data through Ethernet interface.

**Note:**

1. For specific data communication protocols, please contact the manufacturer.
2. Through Bluetooth, serial port and USB interface, commands can be sent to control the host to start measurement and stop measurement.

## CARE AND MAINTENANCE

1. If the monitor is dirty, use a soft cloth moistened with diluted neutral detergent or diluted disinfecting alcohol (well wrung) to wipe off the dirt. Note, however that the power connector should not be wiped or moistened in any way.
2. Do not crash or fall down blood pressure monitor.
3. Do not submerge the device or any of the components in water.
4. Do not subject the monitor to extreme hot or cold temperatures, humidity or direct sunlight.
5. Changes or modification not approved by Raycome Health will void the user warranty. Do not disassemble or attempt to repair the unit or components.
6. Unplug the unit from the AC outlet if it will not be used long time.
7. Use only Raycome Health authorized parts and accessories. Parts and accessories not approved for use with the device may damage the unit.
8. Replacement of the arm sleeve: the elastic ring on both sides of the arm sleeve is elastic material, taking the old arm sleeve down, extruding the new arm into the ellipse within the range of elastic energy, placing it in the arms, aligning the projecting part on the elastic clasp with the slot, and the elastic ring stitching at the bottom of the groove, when all the arms enter the rear hand and elastic ring. Restore the circle, adjust the elastic ring and trim the arm sleeve.
9. Rack replacement and installation: follow the arrow's reverse direction, remove the handle plate, slide the new hand plate into the button according to the arrow direction, and fasten it to the main engine.
10. Operation guide change installation: follow the arrow's reverse direction, remove the old operation guide, and then insert the new operation guide into the main card slot according to the arrow direction.
11. Fuse: open the cover with cross screwdriver counter clockwise, put the same specification fuse into the safe seat, and tighten the cover with the cross screw clockwise.
12. It can be used to measure blood pressure in adults and pregnant women.

## ERROR INDICATORS

| Error Code | Reasons | Measures |
|---|---|---|
| EE 1 | Airbag pressure exceeds the maximum allowed (300mHg) | Tur off the power switch or press the emergency stop switch |
| EE 2 | Incorrect arm position or air leaking during measurement | Put the arm in correct posture as stated in this manual. |
| | Incorrect arm position or air leaking during measurement | Replace the arm cuff with a new one. |
| EE 5 | The arm is put with incorrect posture | Put the arm in correct posture as stated in this manual. |
| | Air is leaking from the lower bladder of the arm cuff | Replace the cuff with the new one. |
| EE 6 | The arm is put with incorrect posture | Put the arm in correct posture as stated in this manual. |
| EE 9 | Deflated time of the arm cuff is too long | Repeat measurement. |
| Others | Unknown errors | Contact Raycome Health. |

## TROUBLESHOOTING TIPS

The following chart lists common faults you may come across when you use blood pressure monitor. Please contact our after-sales service department for help in case problems still cannot be solved.

| Number | Phenomenon of fault | Possible reason | solution |
|---|---|---|---|
| 1 | Nothing is displayed after pressing the "Start / Stop"key | The power switch is not turned on | Start the blood pressure monitor after turming on the power switch |
| | | The power adapter is not connected properly | Please reconnect the power adapter |
| 2 | Unable to measure or measurement value is too high. | Arm cuffmay not be at the same level as the heart. | Please sit and put the arm in the cuff correctly. |

| | | | |
|---|---|---|---|
| 3 | Measurement values appear too high or too low. | Blood pressure varies constantly. Many factors including stress, time of day, and how you wrap the cuff, may affect your blood pressure. | Take a deep breath to relax and keep quiet. |

## PRODUCT SPECIFICATION

Name: Automatic Pulsewave Blood Pressure Monitor
Model: RBP-7000, RBP-7000B, RBP-7000W
Measurement Range: Pressure: 0 to 300mmHg (0 to 40kPa)
Pulse rate: 30 to 200/min
Pressure measuring range:
Systolic : 60-265mmHg Diastolic:30-200mmHg
Accuracy: Pressure: ± 2mmHg (±0.267kPa)
Pulse rate: ±2%
Storage Capacity: 100 sets
Power Supply: AC 100-240V, 50-60Hz; d.c. 12V, 3.5A
Operating Temperature/Relative Humidity/Air Pressure: 41°F to 104 °F (5℃ to 40℃) / 15% to 85% RH/80kPa to106kPa
Storage and Transportation Temperature/ Relative Humidity/Air Pressure: -4 °F to 131 °F (-20 ℃ to 55 ℃) / ≤93%RH/ 50kPa to106kPa
Main Unit Weight: 6.0kg
Main Unit Dimension: 387.7mm (L) × 244. 1mm (W) × 340.2mm (H) ( 15.26"(L) ×9.61" (W) ×13.39" (H))
Shock Protection: Class I, Type BF applied part.

## Appendix A: PACKING LIST

When the user opens the packing of this product, please check the following packing list.
If objects are not found or have any other questions, please contact us.

| No. | Name | Quantity |
|---|---|---|
| 1 | Main Unit | 1 |
| 2 | Armrest | 1 |
| 3 | Instruction Panel | 1 |

| | | |
|---|---|---|
| 4 | Cuff Cover ( Attached to the unit at factory) | 1 |
| 5 | Adaptor | 1 |
| 6 | Instruction Manual | 1 |

## APPENDIX B: EMC

⚠Please install and use this instrument according to the EMC information provided in this Instruction Manual.

⚠The portable and mobile RF communications equipment can affect this instrument‘s normal operation.

⚠Please use the accessories sold by our company, the inappropriate one may result in increased emission or decreased immunity of this instrument.

⚠The instrument should not be used adjacent or stacked with other equipment and if adjacent or stacked use is necessary, please verify its normal operation in the configuration in which it will be used.

**Table 1:**

| | | | |
|---|---|---|---|
| 1 | **Guidance and manufacturer’s declaration – electromagnetic emission** | | |
| 2 | The Automatic Pulsewave Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of Pulsewave Blood Pressure Monitor should assure that it is used in such an environment. | | |
| 3 | **Emissions test** | **Compliance** | **Electromagnetic environment - guidance** |
| 4 | RF emissions CISPR11 | Group 1 | The Automatic Pulsewave Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment |
| 5 | RF emissions CISPR11 | Class A | The Automatic Pulsewave Blood Pressure |

| | | | |
|---|---|---|---|
| 6 | Harmonic emissions IEC 61000-3-2 | Not applicable | monitor is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes. |
| 7 | Voltage fluctuations / flicker emissions IEC 61000-3-3 | Not applicable | |

**Table 2:**

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The Automatic Pulsewave Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Automatic Pulsewave Blood Pressure Monitor should assure that it is used in such an environment. | | | |
| **Immunity test** | **EN 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| Electrostatic discharge (ESD)<br><br>IEC 61000-4-2 | ± 8 kV contact<br><br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | ±8 kV contact<br><br>±2 kV, ±4 kV, ±8 kV, ±15 kV air | Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %. |
| Electrostatic transient / burst<br><br>IEC 61000-4-4 | ± 2 kV for power supply lines<br>100 kHz repetition frequency<br>± 1 kV for input/output lines | ± 2 kV for power supply lines<br>100 kHz repetition frequency<br>± 1 kV for input/output lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge<br><br>IEC 61000-4-5 | ± 0.5 kV, ± 1 kV differential mode<br>line-line | ± 0.5 kV, ± 1 kV differential mode<br>line-line | Mains power quality should be that of a typical commercial or hospital environment. |

| | | | |
|---|---|---|---|
| Voltage dips, short interruptions and voltage variations on power supply input lines<br><br>IEC 61000-4- 11 | 0 % UT<br>(100 % dip in UT )<br>for 0.5 cycle at 0° , 45° , 90° , 135° ,180° , 225° , 270° , and 315°<br><br>0 % UT<br>(100 % dip in UT )<br>for 1 cycle at 0°<br><br>70 % UT<br>(30 % dip in UT )<br>for 25/30 cycles at 0°<br><br>0 % UT<br>(100 % dip in UT )<br>for 250/300 cycle at 0° | 0 % UT<br>(100 % dip in UT )<br>for 0.5 cycle at 0° , 45° , 90° , 135° ,180° , 225° , 270° , and 315°<br><br>0 % UT<br>(100 % dip in UT )<br>for 1 cycle at 0°<br><br>70 % UT<br>(30 % dip in UT )<br>for 25/30 cycles at 0°<br><br>0 % UT<br>(100 % dip in UT )<br>for 250/300 cycle at 0° | Mains power quality should be that of a typical commercial or hospital environment. If the user of the Automatic Pulsewave Blood Pressure Monitor requires continued operation during power mains interruptions, it is recommended that the Automatic Pulsewave Blood Pressure Monitor be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field<br><br>IEC 61000-4-8 | 30 A/m, 50/60Hz | 30 A/m, 50/60Hz | Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment. |
| NOTE | $U_T$ is the a. c. mains voltage prior to application of the test level. | | |

**Table 3:**

| **Guidance and manufacturer's declaration – electromagnetic immunity** | | | |
|---|---|---|---|
| The Automatic Pulsewave Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Automatic Pulsewave Blood Pressure Monitor should assure that it is used in such an environment. | | | |
| **Immunity test** | **EN 60601 test level** | **Compliance level** | **Electromagnetic environment - guidance** |
| | | | Portable and mobile RF communications equipment should be used no closer to any part of the Automatic Pulsewave Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br><br>**Recommended separation distance**<br>$d = [\frac{3.5}{V_1}]\sqrt{P}$ |

| | | | |
|---|---|---|---|
| Conducted RF<br><br>IEC 61000-4-6 | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms 150 kHz to 80 MHz in ISM bands | 3 Vrms<br>150 kHz to 80 MHz<br>6 Vrms 150 kHz to 80 MHz in ISM bands | $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz<br><br>$d=[\frac{7}{E_1}]\sqrt{P}$ 800 MHz to 2.7 GHz<br><br>Where $P$ is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m).[b] |
| Radiated RF<br><br>IEC 61000-4-3 | 3 V/m<br><br>80 MHz to 2.7 GHz | 3 V/m | Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey.[a] should be less than the compliance level in each frequency range[b]<br><br>Interference may occur in the vicinity of equipment marked with the following symbol:<br><br>  |

**NOTE 1** At 80 MHz and 800 MHz, the higher frequency range applies.

**NOTE 2** These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the EVS100 is used exceeds the

applicable RF compliance level above, the EVS100 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the EVS100.

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

**Table 4:**

| **Recommended separation distances between portable and mobile RF communications equipment and the Pulsewave Blood Pressure Monitor** | | | |
|---|---|---|---|
| The Automatic Pulsewave Blood Pressure Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Automatic Pulsewave Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Automatic Pulsewave Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment. | | | |
| Rated maximum output of transmitter W | **Separation distance according to frequency of transmitter m** | | |
| | 150 kHz to 80 MHz $d = [\frac{3.5}{V_1}]\sqrt{P}$ | 80 MHz to 800 MHz $d = [\frac{3.5}{E_1}]\sqrt{P}$ | 800 MHz to 2.7 GHz $d = [\frac{7}{E_1}]\sqrt{P}$ |
| 0.01 | 0.12 | 0.04 | 0.07 |
| 0.1 | 0.37 | 0.12 | 0.23 |
| 1 | 1.17 | 0.35 | 0.7 |
| 10 | 3.7 | 1.11 | 2.22 |
| 100 | 11.7 | 3.5 | 7.0 |
| For transmitters rated at a maximum output power not listed above the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.<br><br>**NOTE 1** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br><br>**NOTE 2** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people. | | | |

| **Recommended separation distances between RF wireless communications equipment** | | | | | |
|---|---|---|---|---|---|
| The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between RF wireless communications equipment and the device as recommended below, according to the maximum output power of the communications equipment. | | | | | |
| **Frequency MHz** | **Maximum Power** | **Distance** | **IEC 60601 Test Level** | **Compliance Level** | **Electromagnetic Environment -** |

<table>
<tr><td></td><td>W</td><td></td><td></td><td></td><td rowspan="17">Guidance<br>RF wireless communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.<br>Recommended separation distance<br>$E = \frac{6}{d}\sqrt{P}$<br>Where P is the maximum output power rating of the ransmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitter, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:<br>  </td></tr>
<tr><td>385</td><td>1.8</td><td>0.3</td><td>27</td><td>27</td></tr>
<tr><td>450</td><td>2</td><td>0.3</td><td>28</td><td>28</td></tr>
<tr><td>710</td><td rowspan="3">0.2</td><td rowspan="3">0.3</td><td rowspan="3">9</td><td rowspan="3">9</td></tr>
<tr><td>745</td></tr>
<tr><td>780</td></tr>
<tr><td>810</td><td rowspan="3">2</td><td rowspan="3">0.3</td><td rowspan="3">28</td><td rowspan="3">28</td></tr>
<tr><td>870</td></tr>
<tr><td>930</td></tr>
<tr><td>1720</td><td rowspan="3">2</td><td rowspan="3">0.3</td><td rowspan="3">28</td><td rowspan="3">28</td></tr>
<tr><td>1845</td></tr>
<tr><td>1970</td></tr>
<tr><td>2450</td><td>2</td><td>0.3</td><td>28</td><td>28</td></tr>
<tr><td>5240</td><td rowspan="3">0.2</td><td rowspan="3">0.3</td><td rowspan="3">9</td><td rowspan="3">9</td></tr>
<tr><td>5500</td></tr>
<tr><td>5785</td></tr>
<tr><td colspan="6">Note 1: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.</td></tr>
</table>

WARNINGS!

• This device should not be used in the vicinity or on the top of other electronic equipment such as cell phone, transceiver or radio control products. If you have to do so, the device should be observed to verify normal operation.

• The use of accessories and power cord other than those specified, with the exception of cables sold by the manufacturer of the equipment or system as replacement parts for internal components, may result in increased emissions or decreased immunity of the equipment or system.

**Product Name**: Automatic Pulsewave Blood Pressure Monitor

**Model**: RBP-7000, RBP-7000B, RBP-7000W

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