Blood Pressure Monitor

Instruction Manual

Automatic Upper Arm Style
Model: BP820A

Need for the user to follow this instruction manual thoroughly for your safety. Please keep for future reference. For specific information about your own blood pressure, CONSULT YOUR PHYSICIAN.

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1 Introduction

Thank you for purchasing the Combei Blood Pressure Monitor. This blood pressure monitor uses the oscillometric method of blood pressure measurement. This means this monitor detects your blood movement through your brachial artery and converts the movements into a digital reading.

1.1 Safety Instructions

This instruction manual provides you with important information about the Combei Blood Pressure Monitor. To ensure the safe and proper use of this monitor, READ and UNDERSTAND all of the safety and operating instructions. If you do not understand these instructions or have any questions, contact your Combei distributor before attempting to use this monitor. For specific information about your own blood pressure, consult with your physician

1.2 Intended Use

The blood pressure monitor is for use by medical professionals、operator or at home and is a non-invasive blood pressure measurement system intended to measure the diastolic and systolic blood pressures and pulse rate of an adult individual by using a non-invasive technique in which an inflatable CUFF is wrapped around the arm

1.3 Intended users：

Medical staffs or patients who can use the product according to the User Manual.

1.4 Intended Population

This device is suitable for measuring blood pressure and pulse in adults. For special populations, please consult your doctor before using this device.
The use of this device by a special patient population may affect measurement readings, such as， arrhythmias such as atrial or ventricular premature beats or atrial fibrillation;arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease.

1.5 Intended Use Environment:

The blood pressure monitor is for use by medical professionals、operator or at home，Operation conditions 5~40℃ 15%~85%RH(non-condensing) 700 hPa~1060 hPa

1.6 Indications:

Monitor adult blood pressure and pulse

1.7 Contraindications:

- Do not use this device with a defibrillator.
- Do not use this device during an MRI examination.
- Do not use the device in a flammable environment (ie, an oxygen-enriched environment).
- Do not immerse the device in water or other liquids. Do not use acetone or other volatile solutions to clean the device

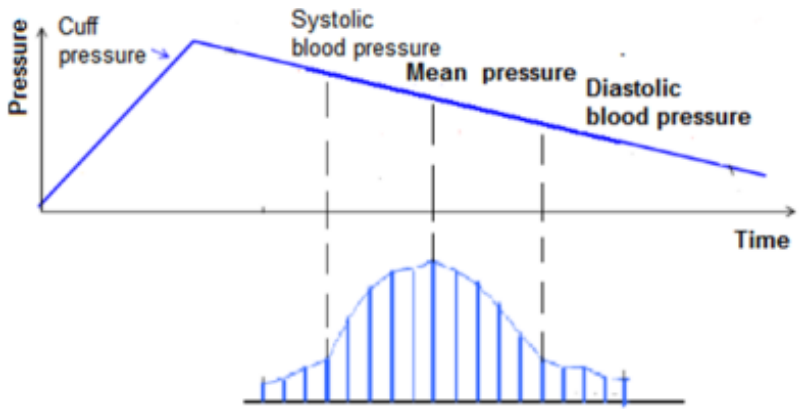
- If you have had a mastectomy, please consult your doctor before using this monitor
- Do not use the monitor in a moving vehicle, such as a car or an airplane
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising, and eating at least 30 minutes before the measurement

1.8 Clinical benefits to be expected:

High blood pressure can be detected 99% effectively before the expected service life of the product, reducing the number of visits to the hospital.

1.9 Introduction to the working principle:

It is mainly composed of the host (air pump, pressure sensor, valve, power supply circuit, button control circuit, display module, CPU control module, embedded software, etc.), cuff, power supply and other parts. The blood pressure is measured by the oscillation ascending phase measurement algorithm. The functional implementation principle is described as follows: The sphygmomanometer uses an air pump to inflate the cuff, which compresses the artery so that it is completely blocked. Then open the air valve to reduce the pressure in the cuff. As the pressure in the cuff decreases, the arteries become completely blocked - gradually opened - the process of opening completely. During hypotension, the variation trend of arterial pressure amplitude is shown in the figure below.



2 Important Safety Information

Read the Important Safety Information in this instruction manual before using this monitor. Follow this instruction manual horoughly for your safety. Keep for future reference. For specific information about your own blood pressure, CONSULT WITH YOUR PHYSICIAN.

2.1 Warning

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

- Before using the device, please ensure that you have read this manual thoroughly and fully understand corresponding precautions and risks.

- Do not use this device with a defibrillator.
- Do not use this device during MRI examination.
- Do not use the device in a combustible environment (i.e., oxygen-enriched environment).
- Never submerge the device in water or other liquids. Do not clean the device with acetone or other volatile solutions.
- Do not drop this device or subject it to strong impact.
- Do not place this device in pressure vessels or gas sterilization device.
- Do not dismantle the device, as this could cause damage or malfunctions or impede the operation of the device.
- Consult with your physician before using this monitor if you have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation; arterial sclerosis; poor perfusion; diabetes; pregnancy; pre-eclampsia or renal disease. NOTE that any of these conditions in addition to patient motion, trembling, or shivering may affect the measurement reading.
- 

This device is not intended for use by people (including children) with restricted physical, sensory or mental skills or a lack of experience and/or a lack of knowledge, unless they are supervised by a person who has responsibility for their safety or they receive instructions from this person on how to use the device. Children should be supervised around the device to ensure they do not play with it.
- Do not store the device in the following locations: locations in which the device is exposed to direct sunlight, high temperatures or levels of moisture, or heavy contamination; locations near to sources of water or fire; or locations that are subject to strong electromagnetic influences.
- BP measurements, such as those taken with this device, cannot identify all diseases. Regardless of the measurement taken using this device, you should consult your doctor immediately if you experience symptoms that could indicate acute disease.
- Do not self-diagnose or self-medicate on the basis of this device without consulting your doctor. In particular, do not start taking any new medication or change the type and/or dosage of any existing medication without prior approval.
- It is not possible to use this device to diagnose illness or diseases. This is exclusively the responsibility of your doctor.
- Clean the device and cuff with a dry, soft cloth or a cloth dampened with water and a neutral detergent. Never use alcohol, benzene, thinner or other harsh chemicals to clean the device or cuff.
- To measure blood pressure, the arm must be squeezed by the cuff hard enough to temporarily stop blood flow through the artery. This may cause pain, numbness or a temporary red mark to the arm. This condition will appear especially when measurement is repeated successively. Any pain, numbness, or red marks will disappear with time.
- People who have a severe circulatory deficit in the arm must consult a doctor before using the device, to avoid medical problems.
- As this medical device uses an alternative small-bore connector design differ

ent from those specified in the ISO 80369 series, there is a possibility that a misconnection can occur between this medical device and a medical device using a different alternative small-bore connector, which can result in a HAZ ARDOUS SITUATION causing HARM to the patient. Special measures need be taken by the user to mitigate these reasonable foreseeable RISKS

- Do not repair or maintain the equipment during use to avoid incorrect operation of the equipment and deviation or error of the measured value.
- The measurement procedure checks the CUFF tube. Do not twist the CUFF tube to avoid the pressure of the CUFF causing pain, numbness, or temporary red marks on the user's arm.
- Do not measure too frequently, which may cause pain and numbness to the user's arm due to obstructed blood flow.
- Do not use a cuff on an arm with a wound as it may cause further injury.
- When CUFF is applied to any limb and pressure is applied, the measurement can be stopped if the pressure temporarily interferes with the flow of blood and may cause numbness in the arm.
- By observing that there are no obvious symptoms of discomfort in the limb, the operation of the sphygmomanometer will not cause long-term damage to the patient's blood circulation.

AC Adapter (optional accessory) Handling and Usage

- DO NOT use the AC adapter if this monitor or the AC adapter cable is damaged. If this monitor or the cable is damaged, turn off the power and unplug the AC adapter immediately.
- Plug the AC adapter into the appropriate voltage outlet. DO NOT use in a multi-outlet plug.
- NEVER plug in or unplug the AC adapter from the electric outlet with wet hands.
- DO NOT disassemble or attempt to repair the AC adapter.

Battery Handling and Usage

Keep batteries out of the reach of infants, toddlers and children

2.2 Caution

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

- Stop using this monitor and consult with your physician if you experience skin irritation or discomfort.
- If you have had a mastectomy or lymph node removal, talk to your doctor before using this monitoring device.
- ONLY inflate the arm cuff when it is applied on your upper arm.
- Remove the arm cuff if it does not start deflating during a measurement.
- DO NOT use this monitor for any purpose other than measuring blood pressure.
- During measurement, make sure that no mobile device or any other electrical device that emit electromagnetic fields is within 30 cm of this monitor. This may result in incorrect operation of the monitor and/or cause an inaccurate

reading.

- DO NOT use this monitor in a moving vehicle such as in a car or on an aircraft.
- DO NOT use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation and/or cause an inaccurate reading.
- Avoid bathing, drinking alcohol or caffeine, smoking, exercising and eating for at least 30 minutes before taking a measurement.
- Rest for at least 5 minutes before taking a measurement.
- Remove tight-fitting or thick clothing from your arm while taking a measurement.
- Remain still and DO NOT talk while taking a measurement.
- ONLY use the arm cuff on persons whose arm circumference is within the specified range of the cuff.
- Ensure that this monitor has acclimated to room temperature before taking a measurement. Taking a measurement after an extreme temperature change could lead to an inaccurate reading. recommends waiting for approximately 2 hours for the monitor to warm up or cool down when the monitor is used in an environment within the temperature specified as operating conditions after it is stored either at the maximum or at the minimum storage temperature. For additional information on operating and storage/transport temperature, refer to section 10.
- DO NOT use this monitor after the durable period has ended. Refer to section 10.
- During measurement, the cuff should be avoided from being interfered with by extrusion or other external forces, and it should only be used on people whose arm circumference is within the specified range of the cuff.
- and batteries may damage and/or may be hazardous to this monitor. ONLY use the approved arm cuff for this monitor. Use of other arm cuffs may result in incorrect readings.
- Read and follow the “Correct Disposal of This Product”in section 6 when disposing of the device and any used accessories or optional parts.

AC Adapter (optional accessory) Handling and Usage

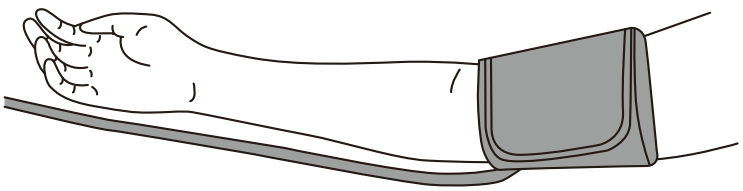
- Fully insert the AC adapter into the outlet.
- When unplugging the AC adapter from the outlet, be sure to safely
- pull from the AC adapter. DO NOT pull from the AC adapter cable.
- When handling the AC adapter cable:
  Do not damage it. / Do not break it. / Do not tamper with it.
  DO NOT pinch it. / Do not forcibly bend or pull it. / Do not twist it.
  DO NOT use it if it is gathered in a bundle.
  DO NOT place it under heavy objects.
- Wipe any dust off of the AC adapter.
- Unplug the AC adapter when not in use.
- Unplug the AC adapter before cleaning this monitor.

Battery Handling and Usage

- DO NOT insert batteries with their polarities incorrectly aligned.
- ONLY use 4 “AA” alkaline or manganese batteries with this monitor.
- DO NOT use other types of batteries. DO NOT use new and used batteries together. DO NOT use different brands of batteries together.
- Remove batteries if this monitor will not be used for a long period of time.
- If battery fluid should get in your eyes, immediately rinse with plenty of clean water. Consult with your physician immediately.
- If battery fluid should get on your skin, wash your skin immediately with plenty of clean, lukewarm water. If irritation, injury or pain persists, consult with your physician.
- DO NOT use batteries after their expiration date.
- Periodically check batteries to ensure they are in good working condition.

2.3 General Precautions

- To stop a measurement, press the [START/STOP] button while taking a measurement.
- When you take a measurement on the right arm, the air tube should be at the side of your elbow. Be careful not to rest your arm on the air tube.



- Blood pressure may differ between the right and left arm, and may result in a different measurement value. Always use the same arm for measurements. If the values between both arms differ substantially, check with your physician on which arm to use for your measurements.
- When using an optional AC adapter, make sure not to place your monitor in a location where it is difficult to plug and unplug the AC adapter.

Battery Handling and Usage

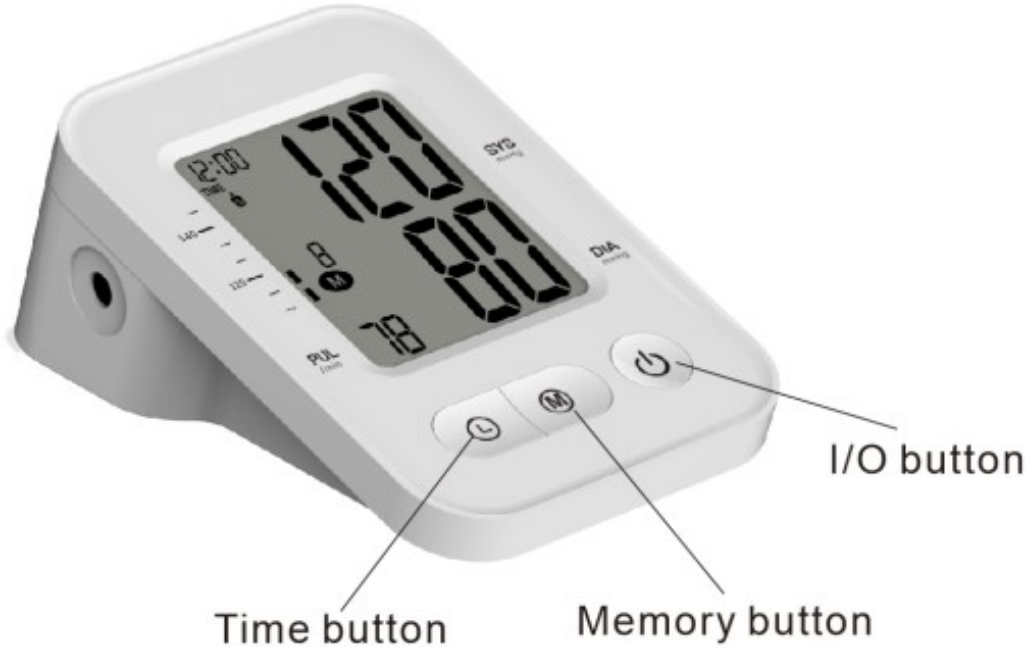
- Disposal of used batteries should be carried out in accordance with local regulations.
- The supplied batteries may have a shorter life span than new batteries

Remember to have a record of your blood pressure and pulse readings for your physician. A single measurement does not provide an accurate indication of your true blood pressure.

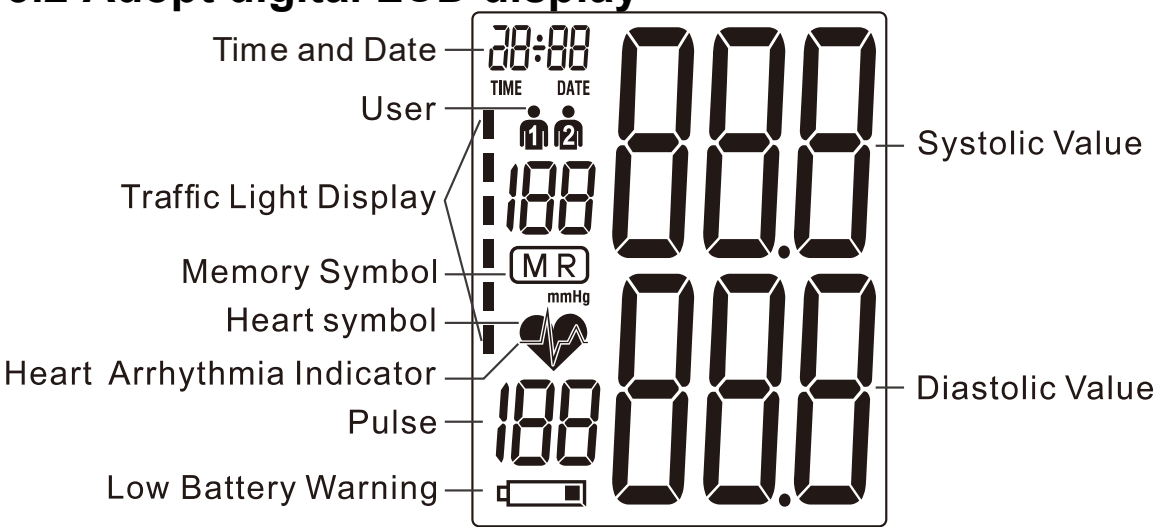
3 Know your device

3.1 Operating key：

- TIME Button: set date and time
- MEMORY Button: check memory and clear measurement values
- I/O Button: Power on and measure start



3.2 Adopt digital LCD display



3.3 Common Functions:

1) Blood pressure and heart rate are measured
2) Memory storage and clearing functions
3) Date and time Settings

Note: The above basic normal functions can be safely used by the operator.

3.4 Functional Description

Low Battery Warning:

If the battery warning icon appears in the display, the batteries remain 20% power to warn user the batteries will be run out.

If the battery warning icon appears in the display, the batteries are empty and must be replaced by new ones

Attention! After the battery warning icon appears, the device is blocked until the batteries have been replaced.

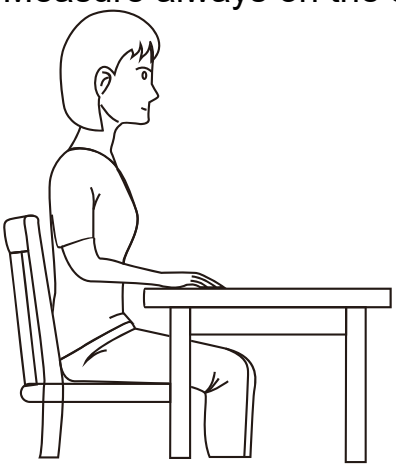
3.5 Preparing for a Measurement

30 minutes before

Avoid eating, smoking as well as all forms of exertion directly before the measurement. All these factors influence the measurement result. Try and find time to relax by sitting in an armchair in a quite atmosphere for about ten minutes before the measurement.

5 minutes before: Relax and rest

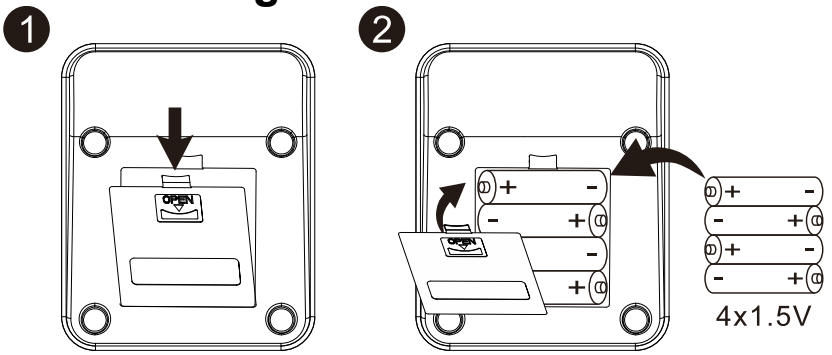
Measure always on the same arm (normally left). .



4 Preparation before use

Please check the complete accessories before using this product.
Final assembly includes this battery installed (see section 4.1) and cuff wearing (see section 5.1)

4.1 Installing Batteries



1) Insert the batteries (4 x size AA 1.5V), thereby observing the indicated polarity.
2) If the battery warning icon appears in the display, the batteries remain 20% power to warn user the batteries will be run out .
3) If the battery warning icon appears in the display, the batteries are empty and

must be replaced by new ones

1) Attention! •After the battery warning icon appears, the device is blocked until the batteries have been replaced.
2) Please use «AA» Long-Life or Alkaline 1.5V Batteries. The use of 1.2V Accumulators is not recommended.
3) If the blood pressure monitor is left unused for long periods, please remove the batteries from the device.

4.2 Setting Date and Time

Please press the TIME button and the date will be shown in the display. Set user > year > month > day > hour > minute

- **Set user**

Press the TIME button for at least 3 seconds. The display now indicates the set user, during which the set user blink, To confirm, press ON/OFF button Click the MEMORY button to select User

- **Setting the time date**

1) Press the TIME button for at least 3 seconds firstly , user icon will blink. Then press TIME button again the display now indicates the set year, during which the four characters blink. The correct year can be entered by pressing the MEMORY button
2) Press the TIME button again. The display now switches to the current date, during which the first character (month) blinks. The corresponding month can now be entered by pressing the MEMORY button.
3) Press the TIME button again. The last two characters (day) are now blinking The corresponding day can now be entered by pressing the MEMORY button.
4) Press the TIME button again. The display now switches to the current time, during which the first character (Hour) blinks The corresponding hour can now be entered by pressing the MEMORY button.
5) Press the TIME button again. The last two characters (Minutes) now blink. The exact time can now be entered by pressing the MEMORY button
6) Once you have made your settings, press the TIME button (TIME / DATE). The setting is confirmed and the clock starts running..

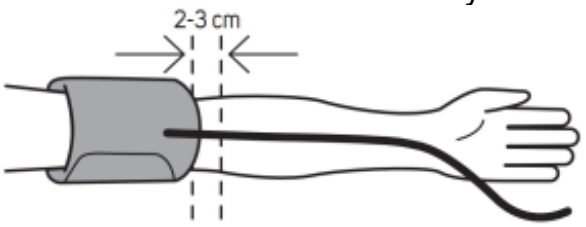
5 Use equipment

5.1 Applying the Arm Cuff

Attempt to carry out the measurements regularly at the same time of day, since the blood-pressure changes during the course of the day

1) Remove tight-fitting clothing or tight rolled up sleeve from your left upper arm. Do not place the arm cuff over thick clothes.
2) Insert the air plug into the air connector securely

3) Tube side of the cuff should be 2 - 3 cm above the inside elbow.Make sure that air tube is on the inside of your arm and wrap the cuff

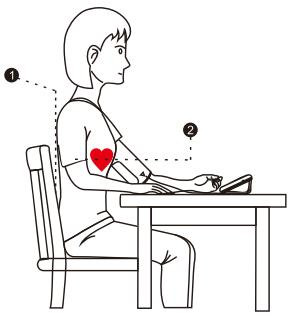


Notes:

- When you take a measurement on the right arm, the air tube will be at the side of your elbow. Be careful not to rest your arm on the air tube.
- The blood pressure can differ between the right arm and the left arm, and the measured blood pressure values can be different, and recommends to always use the same arm for measurement. If the values between both arms differ substantially, please check with your physician which arm to use for your measurements.

5.2 Sitting Correctly

1) Sit comfortably with your back and arm supported
2) Place the arm cuff at the same level as your heart.
3) Keep feet flat, legs uncrossed, remain still and do not talk.
4) The sphygmomanometer is placed in a position that the user can normally operate, and the blood pressure reading displayed after the measurement is completed is not affected in any way..

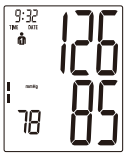


5.3 Taking a Measurement

1) Press the ON/OFF button, the pump begins to inflate the cuff. In the display, the increasing cuff-pressure is continually displayed.
2) After reaching the inflation pressure, the pump stops and the pressure slowly falls away. The cuff-pressure is displayed during the measurement. When the device has detected the pulse, the heart symbol in the display

begins to blink

3) When the measurement has been concluded, The measured systolic and diastolic blood-pressure values as well as the pulse frequency are now displayed. Example (Fig.): Systole 126, Diastole 85, Pulse 78



6)

4) The measurement results are displayed, until you switch the device off or the device switches automatically off, to save the batteries.

5) When the measurement results are as follows:

- Measurement results display error provided, please follow the instructions in section 3 to exclude.
- If the measurement results are significantly off, please re-measure or consult your doctor.

5.4 Discontinuing a measurement

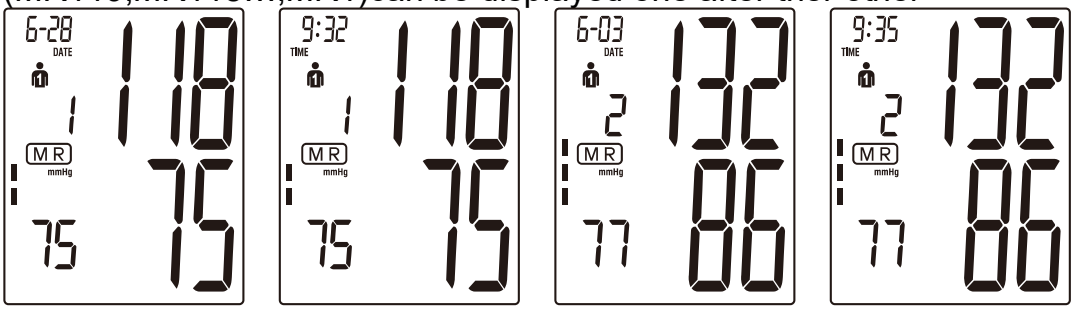
If it is necessary to interrupt a blood pressure measurement for any reason (e.g. the patient feels unwell), the “ON/OFF” power button can be pressed at any time. The device then immediately lowers the cuff-pressure automatically.

5.5 Using Memory Functions

1) Test volume query:

Before using memory functions, select your user ID

The blood-pressure monitor automatically stores each of the last 120 measurement values. By pressing the MEMORY button, an average value of Average of the Latest 3 Readings and the further last 120 measurements (MR119,MR118…,MR1)can be displayed one after ther other



2) Deleting All Readings

Before you delete all readings stored in the memory, make sure you will not need refer to the readings at a later date. Keeping a written record is prudent and may provide additional information for your doctor’s visit. In order to delete all stored readings, depress the MEMORY button for at least 5 seconds, the display will show the symbol «CL» and then release the button. To permanently clear the memory, Press the MEMORY button while «CL» deletes stored readings.

6 Useful Information

What is Blood Pressure?

Blood pressure is a measure of the force of blood flowing against the walls of the arteries. Arterial blood pressure is constantly changing during the course of the heart’s cycle.

The highest pressure in the cycle is called the Systolic Blood Pressure; the lowest is the Diastolic Blood Pressure. Both pressures, the Systolic and Diastolic, are necessary to enable a physician to evaluate the status of a patient's blood pressure.

What is Arrhythmia?

Arrhythmia is a condition where the heartbeat rhythm is abnormal due to flaws in the bio-electrical system that drives the heartbeat. Typical symptoms are skipped heartbeats, premature contraction, an abnormally rapid (tachycardia) or slow (bradycardia) pulse.

How do I evaluate my blood pressure?

The triangle on the left-hand edge of the display points at the range within which the measured blood pressure value lies. The value is either within the optimum, elevated or high range. The classification corresponds to the following ranges defined by international guidelines (ESH, ESC, JSH). Data in mmHg

Classification of hypertension:

These values are provided by the 2023 ESH Guidelines for the management
The BP category is defined by the highest level of BP, whether systolic or diastolic.
Isolated systolic or diastolic hypertension is graded 1, 2 or 3 according to SBP and DBP values in the ranges indicated. The same classification is used for adolescents ≧16 years old.

Category	Systolic (mmHg)	Diastolic (mmHg)
Optimal	<120	<80
Normal	120-129	80–84
High- Normal	130-139	85–89
Grade 1 hypertension	140–159	90–99
Grade 2 hypertension	160–179	100–109
Grade 3 hypertension	≧180	≧110
Isolated systolic hypertension	≧140	≦90
Isolated diastolic hypertension	≦140	≧90

7 Error Messages and Troubleshooting

If any of the below problems occur during measurement, check to make sure that no other electrical device is within 30 cm. If the problem persists,please refer to the table below.

Error No.	Possible cause(s)
ERR 1	No pulse has been detected.
ERR 2	Unnatural pressure impulses influence the measurement result. Reason: The arm was moved during the Measurement (Artefact).
ERR 3	The inflation of the cuff takes too long. The cuff is not correctly

	seated.
ERR 5	The measured readings indicated an unacceptable difference between systolic and diastolic pressures. Take another reading following directions carefully. Contact you doctor if you continue to get unusual readings.
Hi ERR8	CUFF pressure >290 mmHg

Other possible malfunctions and their elimination

If problems occur when using the device, the following points should be checked and if necessary, the corresponding measures are to be taken:

Malfunction	Remedy
The display remains empty when the instrument is switched on although the batteries are in place.	1.Check batteries for correct polarity and if necessary insert correctly. 2.If the display is unusual, re-insert batteries or exchange them.
The device frequently fails to measure the blood pressure values, or the values measured are too low (too high).	Check the positioning of the cuff. Measure the blood-pressure again in peace and quiet under observance of the details made under point 5.
Every measurement produces a different value although the instrument functions normally and the values displayed are normal	Please read the following information and the points listed under «Common sources of error». Repeat the measurement. Please note: Blood pressure fluctuates continually so successive measurements will show some variability.
Blood pressure measured differs from those values measured by the doctor.	Record the daily development of the values and consult your doctor. Please note: Individuals visiting their doctor frequently experience anxiety which can result in a higher reading at the doctor than obtained at home under resting conditions.

8 Maintenance

Users can perform the following maintenance operations on the device, but pay attention to the precautions mentioned in each maintenance item.

8.1 Maintenance

To protect your monitor from damage, follow the directions below:
Changes or modifications not approved by the manufacturer will void the user warranty.

Caution

DO NOT disassemble or attempt to repair this monitor or other components. This may cause an inaccurate reading.

8.2 Storage

Keep your monitor in the storage case when not in use.

1) Remove the arm cuff from the monitor.

Caution To unplug the air plug, pull on the plastic air plug at the base of the tube, not the tube itself.

2) Gently fold the air tube into the arm cuff. Note: Do not bend or crease the air tube excessively.
3) Place your monitor and other components in the storage case.

- Store your monitor and other components in a clean, safe location.
- Do not store your monitor and other components:
  - ✧ If your monitor and other components are wet.
  - ✧ In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
  - ✧ In locations exposed to vibrations or shocks.

8.3 Cleaning

Use a soft dry cloth or a soft cloth moistened with mild (neutral) detergent to clean your monitor and arm cuff, and then wipe them with a drycloth.

The following operations are prohibited:

- Do not use any abrasive or volatile cleaners.
- Do not wash or immerse your monitor and arm cuff or other components in water.
- Do not use gasoline, thinners or similar solvents to clean your monitor and arm cuff or other components.

8.4 Battery replacement and maintenance：

1) When the device shows that the battery is low, please replace the battery in time.
2) When the battery is installed on the product and is not used for a long time (about 1 week), it should be taken out in time for separate storage.

Note: The installation of the battery is detailed in section 4.1 of this manual.

8.5 Calibration and Service

- The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life.
- It is generally recommended to have the unit inspected every two years to ensure correct functioning and accuracy. Please consult your authorised dealer or the Customer Service at the address given on the packaging or attached literature.

How to enter to test mode :

This function is mainly for professionals to enter the pressure calibration mode of the electronic sphygmomanometer and check the pressure value of the

electronic sphygmomanometer through a standard pressure meter Test methods :

- Press and hold “on/off button” while battery was installed , then “CA” and “0” will be displayed

8.6 Optional Medical Accessories

Arm cuff：22~32cm(M-size cuff) or 22~42cm (M-L size cuff)

AC Adapter：(Input：AC 100 - 240V50 - 60Hz，Output：USB 5V/1A)

9 Limited Warranty

Thank you for buying an Combei product. This product is constructed of high quality materials and great care has been taken in its manufacturing.
It is designed to give you every satisfaction, provided that it is properly operated and maintained as described in the instruction manual.
This product is warranted by Combei for a period of 3 years after the date of purchase. The proper construction, workmanship and materials of this product is warranted by Combei. During this period of warranty Combei will, without charge for labour or parts, repair or replace the defect product or any defective parts.
The warranty does not cover any of the following:

a) Transport costs and risks of transport.
b) Costs for repairs and / or defects resulting from repairs done by unauthorised persons.
c) Periodic check-ups and maintenance.
d) Failure or wear of optional parts or other attachments other than the main device itself, unless explicitly warranted above.
e) Costs arising due to non-acceptance of a claim (those will be charged for).
f) Damages of any kind including personal caused accidentally or from misuse.
g) Calibration service is not included within the warranty.
h) Optional parts have a one (1) year warranty from date of purchase. Optional parts include, but are not limited to the following items: cuff and cuff tube.

Should warranty service be required please apply to the dealer whom the product was purchased from or an authorised Combei distributor. For the address refer to the product packaging / literature or to your specialised retailer. If you have difficulties in finding Combei customer services, contact us for information: http://www.combei.cn/eindex.asp
Repair or replacement under the warranty does not give rise to any extension or renewal of the warranty period.
The warranty will be granted only if the complete product is returned together with the original invoice / cash ticket issued to the consumer by the retailer.

10 Correct Disposal of This Product

(Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of, with other household wastes at the end of its working life.
To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources.
Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.
Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

11 Manufacturer Information

Contact information

Shenzhen Combei Technology Co., Ltd.
11-5B, No.105, Huanguan South Road, Dahe Community,
Guanhu Street, Longhua District,Shenzhen,
518110 Guangdong
P.R. China
manufacturer contact : Mr. Kevin Fong
E-mail : kevin.fong@combei.cn
TEL:+86-755-29588956 EXT:818,809

EU representative information

EC REP

MedNet EC-REP GmbH,
Borkstrasse 10, 48163 Münster, Germany

12 Reference To Standards

Device standard:	Device corresponds to the requirements of the European standard for non-invasive blood- pressure monitor EN IEC 80601-2-30 EN ISO 81060-2 EN 60601-1 EN 60601-1-6 EN 62366-1 EN 62304 EN ISO 10993-1 EN ISO 10993-5 EN ISO 10993-23 ISO 14971
Electrical compatibility:	Device fulfils the stipulations of the REGULATION (EU) 2017/745 for Medical Products Class IIa.

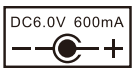
EN 60601-1-2
EN 60601-1-11

13 Technical specifications

Product description	Blood Pressure Monitor		
Product category	Electronic Sphygmomanometers		
Model	BP820A		
Display	LCD digital display		
Cuff pressure range	0 to 290mmHg		
Blood pressure measurement range	SYS: 60 to 255 mmHg DIA : 30 to 199mmHg		
Static accuracy	Pressure: ±3 mmHg		
Pulse	Pulse measurement range ： 40 to 199 beats / min ±5% of display reading		
Measurement method	Oscillometric , corresponding to Korotkoff method: Phase I : systolic , Phase V : diastolic		
IP classification	IP20		
Inflation	Automatic by electric pump	Deflation	Automatic pressure release valve
Power supply interface	⎓ 5V/1A	Applied part	 Type BF (arm cuff)
Mode of operation	Continuous operation		
Power source:	Battery：4x1.5V "AA" alkaline Batteries or Optional Adapter：(Input：AC 100 - 240 V/50- 60 Hz, Output：DC 5V/1A)		
Battery life	Approximately 1000 measurements (using new alkaline batteries)		
Durable period (Service life)	Monitor: 5 years Cuff:1 years		
Operation conditions	5~40°C 15%~85%RH(non-condensing) 700 hPa~1060 hPa		
Storage/transport conditions	-10~55°C 10%~95%RH(non-condensing) 500 hPa ~1060 hPa		
Protection against electric shock	CLASS II and INTERNALLY POWERED		

Dimensions :	Monitor:154× 100× 62 ±1.0 mm(TBD)
Weight :	Monitor: approximately 250 g (not including batteries) Arm cuff: approximately 170 g
Accessories:	**Cuff**: circumference 22~32cm(M-size cuff) or 22~42cm (M-L size cuff) , **Battery**: 4x1.5V "AA" alkaline Batteries **Optional AC adapter:** (Input: AC 100 - 240 V/50- 60 Hz, Output: DC 5V/1A)
Contents	**device, cuff, battery, user manual**
Memory	2 x 120 memories for 2 users (SYS, DIA, Pulse)

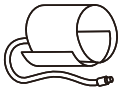
Note

1) These specifications are subject to change without notice.
2) This monitor is clinically investigated according to the requirements of EN ISO 81060-2. In the clinical validation study, BP820A was used on 85 subjects for determination of diastolic blood pressure.
3) IP classification is degrees of protection provided by enclosures in accordance with IEC 60529. This monitor and optional AC adapter are protected against solid foreign objects of 12.5 mm diameter and greater such as a finger.
4) Please be noticed the power adapter is not supplied from the origin ,users can buy the adapter in the market which must comply to EN60601-1,EN60601-1-2 

or USB socket 5V DC 1A

14 Symbols Description

Symbols	Description	Symbols	Description
EC REP	Indicates the authorized representative in the European Community/ European Union		Applied part - Type BF Degree of protection against electric shock (leakage current)
LOT	Batch code Indicates the manufacturer's batch code so that the batch or lot can be identified		Electrical and electronic equipment marks Reduce electronic and electrical waste as unsorted waste and collect it separately
	Indication of connector polarity		Refer to instruction manual/ booklet Follow instructions for use
CE 019	CE Marking of Conformity Announcement number institutions		Consult instructions for use or consult electronic instructions for use Indicates the need for the

Symbols	Description	Symbols	Description
			user to consult the instructions for use
IP20	Ingress protection degree provided by IEC 60529		General warning sign
	Class II equipment. Protection against electric shock		Caution
	Date of manufacture		Keep dry
	Serial number		Manufacturer Indicates the medical device manufacturer
	Indicates the item is a medical device		Unique device identifier
	General prohibition sign		Cuff Connector
	Mobile Tips(option)		CUFF Tips(option)
	MAX Tips(option)		This is the correct upright position of the distribution packages for transport and/or storage.
	Maximum number of identical transport packages/items which may be stacked on the bottom package, where “6” is the limiting number.		Fragile, handle with care
	Warning! Not suitable for children under 3 years old		Direct current

15 Guidance and Manufacturer’ s Declaration

Important Information Regarding (EMC)

Important information regarding Electro Magnetic Compatibility (EMC)

With the increased number of electronic devices such as PC’s and mobile (cellular) telephones, medical devices in use may be susceptible to electromagnetic interference from other devices. Electromagnetic interference may result in incorrect operation of the medical device and create a potentially unsafe situation. Medical devices should also not interfere with other devices.

In order to regulate the requirements for EMC (Electro Magnetic Compatibility) with the aim to prevent unsafe product situations, the IEC60601-1-2 standard has been implemented. This standard defines the levels of immunity to electromagnetic interferences as well as maximum levels of electromagnetic emissions for medical devices.

Our medical devices comply with IEC60601-1-2 in terms of immunity and emissions.

Guidance and manufacturer’s declaration - electromagnetic emissions		
This product is suitable for electromagnetic environment as described below. Users should ensure that they are used in such an environment.		
Emission Test	Compliance	Electromagnetic Environment
RF emission CISPR 11	Group 1	BP820A use RF energy only for their internal function. Therefore, their RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	BP820A are suitable for used in all establishments other than domestic and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Compliance	
Voltage fluctuations / flicker emissions IEC 61000-3-3	Compliance	

Guidance & Declaration — electromagnetic immunity			
This product is suitable for the following electromagnetic environment. Users should ensure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±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 %.
Electrical fast	±2kV for power	±2kV for power	Mains power quality

transient/burst IEC 61000-4-4	supply lines ±1 kV for Input/output lines	supply lines	should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±0.5 kV, ±1 kV line to line ±0.5 kV, ±1 kV, ±2 kV line to ground	±0.5 kV, ±1 kV line to 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 IEC 61000-4-11.	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 5/6 sec	<5 % UT (>95% dip in UT.) for 0.5 cycle <5 % UT (>95% dip in UT) for 1 cycle 70% UT (30% dip in UT) for 25/30 cycles <5% UT (>95 % dip in UT) for 250/300 cycles	Mains power quality should be that of a typical commercial or hospital environment. If the user of the all models require continued operation during power mains interruptions, it is recommended that the all models be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m	N/A	N/A
NOTE UT is the a.c. mains voltage prior to application of the test level.			

Guidance & Declaration - Electromagnetic immunity			
This product is suitable for use in the electromagnetic environment specified below. Users should ensure that they are used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of all models, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance

Radiated RF IEC 61000-4-3	6 Vrms in ISM and amateur radio bands 10 V/m, 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	N/A 10 V/m, 80 MHz to 2.7 GHz 385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	d=[3,5/V1]×P1/2 d=1.2×P1/2 80 MHz to 800 MHz d=2.3×P1/2 800 MHz to 2.7 GHz where P is the maximum output power rating of the transmitter In watts (W) according to the transmitter manufacturer and d Is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur In the vicinity of equipment marked with the following symbol: 

NOTE 1 At 80 MHz and 800 MHz. the higher frequency range applies.
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a] Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the models are used exceeds the applicable RF compliance level above, the model AirMi 1 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the models.

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

Recommended separation distances between portable and mobile RF communications equipment and all models
This product is suitable for controlling the electromagnetic environment of

radiofrequency interference. Users can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communication devices (transmitters)

Rated maximum output power of transmitter (W)	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz d = 1.2×p1/2	80 MHz to 800 MHz d = 1.2×p1/2	800 MHz to 2.7 GHz d = 2.3×p1/2
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (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) accordable to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz. the separation distance for the higher frequency range applies.

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