V01: 20220818

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Questions or comments?
Please call toll-free:
1-855-822-6999 M-F 9 a.m.- 5 p.m. CST
E-mail: service@healthcare-manager.com
Manufactured for
Easy Healthcare Corporation
360 Shore Dr. Burr Ridge, IL US 60527
Made in China

—

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Veuillez appeler le numéro gratuit
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du lundi au vendredi, de 9h à 17h, CST
service@healthcare-manager.com
fabriqué pour
Easy Healthcare Corporation
360 Shore Dr. Burr Ridge, IL US 60527
Fabriqué en Chine

EBP-095

Blood Pressure Monitor

Arm Type

User Manual

Table of Contents

♥ General Description

Thank you for selecting easy@Home® arm type blood pressure Monitor (EBP-095). The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service.

Readings taken by the EBP-095 are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step by step instructions for using the product.

Read the manual thoroughly before using the product.

Features:

- 60mm*80mm Digital LCD display
- Maximum 60 records
- Measuring during inflation technology

♥ Indications for Use

The Blood Pressure Monitor is digital monitors intended for use, in measuring blood pressure and heartbeat rate in adult patient population with arm circumference ranging from 22 cm to 42 cm (about 9 - 17 inches).

♥ Safety Information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

CN	Date and Country of manufacture		Type BF applied part	SN	Serial number
⎓	Direct current		General symbol for recovery		Class II equipment
	Refer to instruction manual To signify that the instruction manual must be read.	IP21	It means the device could be protected against solid foreign objects of 12,5mm Φ and greater, and against vertically falling water drops.		For indoor use only
	Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences				
MR	This device has not been tested for use in an MR environment and should not be used exposed to MR environments while patients are wearing the device. Keep it outside the MPI scanner room.				
	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.				

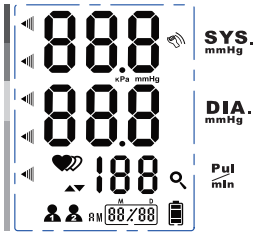
CAUTION

* This device is intended for indoor, home use.
* This device is not intended for public use.
* This device is portable, but it is not intended for use during patient transport.
* This device is not suitable for continuous monitoring during medical emergencies or operations.
* This device is intended for no-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm, or for any purpose other than obtaining a blood pressure measurement.
* This device is for adults. Do not use this device on neonates or infants. Do not use it on children unless otherwise instructed by a medical professional.
* Do not use on the women in pregnant, including pre-eclamptic, patients.
* The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.
* The effectiveness of this device has not been established for use:
  -on users with common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation,
  -on users with peripheral arterial disease,
  -on users undergoing intravascular therapy, or with arteriovenous (AV) shunt.
  Consult a medical professional before use.
* Do not use this device for diagnosis or treatment of any health problem or disease. Contact your physician if you have or suspect any medical problem. Do not change your medications without the advice of your physician or health care professional.
* If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.
* This device may be used only for the intended use described in this manual, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.
* Report any unexpected operation or events to the manufacturer.
* Do not apply the cuff on an arm that has an intravenous drip or a blood transfusion attached.
* Warning: Do not kink, fold, stretch, compress, or otherwise deform the tube during measuring, as the cuff pressure might continuously increase, which could prevent blood flow and result injury.
* Warning: Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
* Warning: Do not apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.
* Warning: Do not place the cuff on the arm of a person whose arteries or veins are undergoing medical treatment, i.e. intra-vascular access or intra-vascular therapy or an arteriovenous (A-V) shunt, which could disrupt blood circulation and cause injuries.
* Do not place the cuff on the arm on the same side of a mastectomy (especially when lymph nodes have been removed). it is recommended to take measurements on the unaffected side.
* Do not wrap the cuff on the same arm to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.
* Please check that the operation of the device do not result in prolonged impairment of patient blood circulation.
* Warning: On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the arm (cuff pressure >300 mmHg or constant pressure >15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.
* Warning: Do not use this device with high-frequency (HF) surgical equipment at the same time.

CAUTION

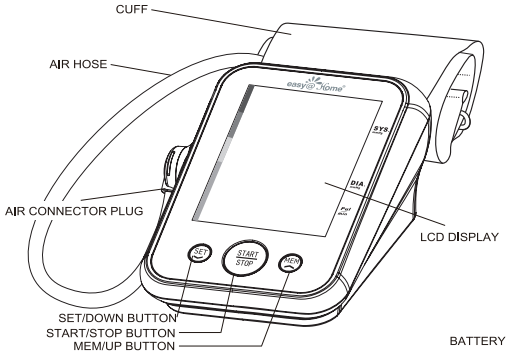
* Warning: This device is not AP/APG equipment. Do not use the device where flammable anesthetic are present, or in environments mixture with air of with oxygen or nitrous oxide.
* The device contains sensitive electronic components.To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.
* You can use this device to take your own measurement, no third-party operator is required.
* Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
* The device may require up to 30 minutes to warm up / cool down from the minimum / maximum storage temperature before it is ready for use.
* Warning: Excessive cuff tube lengths could cause strangulation if you don't manage them properly.
* Warning: Do not touch output of the batteries/adapter and the user simultaneously.
* Adapter is specified as a part of ME EQUIPMENT.
* Warning: The power cord is considered the disconnect device for isolating this equipment from supply mains. Do not position the equipment so that it is difficult to reach or disconnect.
* The blood pressure monitor, its adapter, and the cuff are suitable for use within the patient environment.
* Warning: Do not use this device if you are allergic to polyester, nylon, or plastic.
* Warning: Only use accessories approved by manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
* Warning: If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the Power button immediately to release the air from the cuff.
* No calibration is required within two years of reliable service.
* Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out by authorized service centers.
* At the request of authorized service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by the manufacturer or distributor.
* It is recommended that the performance should be checked after repair, maintenance, and every two years of use, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg).
* Warning: Do not use the device while under maintenance, or being serviced.
* Store your device, cuff and adapter in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.
* Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during storage.
* Warning: Keep the device, cuff, and batteries away from children as they may pose a risk of choking or strangulation if used improperly.
* Clean both device and cuff with a soft, dry cloth. If necessary use a dampened cloth and natural detergent. Do not use alcohol, benzene, or other harsh chemicals.
* Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* Dispose of accessories, detachable parts, and the device according to the local guidelines.

♥ LCD Display Signal

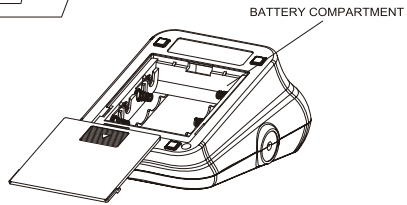


SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pul/min	Pulse	Pulse/minute
▼	Deflating	CUFF air is exhausting of deflating
RM 88/88	Current Time	Time(year:month:day:hour:minute)
M 88/88	Memory	If "MEM" shows, the displayed measurement values is from the memory.
kPa mmHg	Measurement unit	Measurement Unit of the blood pressure (1mmHg=0.133kPa) (1kPa=7.5mmHg)
Lo +	Low battery	Batteries are low and need to be replaced
♥	Irregular heartbeat	Irregular heartbeat detection
	Grade	The grade of the blood pressure
♥	Heartbeat	Heartbeat detection during measurement
	Shocking reminder	Shocking will result in inaccurate
1	User 1	Start measurement for user 1 and save the measuring result automatically
2	User 2	Start measurement for user 2 and save the measuring result automatically
🔍	Data Enquiry Mode	Recall the records

♥ Monitor Components



Component list of pressure measuring system
1 Cuff
2 Air pipe
3 PCBA
4 Pump
5 Valve



♥ List

1. Blood Pressure Monitor (EBP-095)

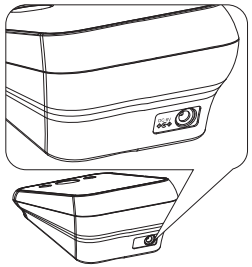
2.Cuff (Type BF applied part)

(Please use easy@Home® authorized cuff 22cm~32cm (8¾"-12½") or 22cm~42cm (8¾"-16½"). The size of the actual cuff please refer to the label on the attached cuff.)

3. 4*AA Batteries

4. User manual

♥ The Choice of Power Supply



1.Battery powered mode:
6VDC 4*AA batteries

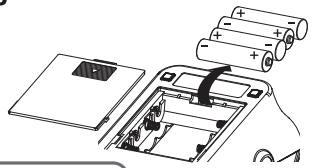
2.This unit has an optional AC Power adaptor which is available as an accessory.Only use AC adaptor with below specification (not included).
Input: 100-240VAC 50/60Hz 0.2A Max
Output: 6V ⎓ 1000mA
(Conforms to UL certificate)
Right picture is the hole in for power adaptor.

⚠CAUTION

In order to get the best effect and protect your monitor,please use the right battery and special power adaptor.

♥ Installing and Replacing the Batteries

1. Slide off the battery cover.
2. Install the batteries by matching the correct polarity, as shown.
3. Replace the cover.



Replace the batteries whenever the below happen

- The LO+ shows
- The display dims
- The display does not light up

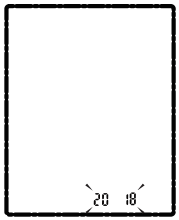
⚠CAUTION

- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose the batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.
- Remove the old batteries from the device following your local recycling guidelines.

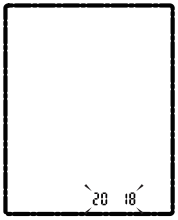
♥ Setting Date, Time and Measurement Unit

It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (year :2018—2058 time format:12 H)

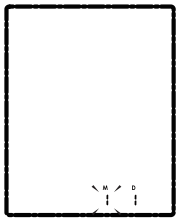
1.When the unit is off, hold “SET” for 3 seconds to enter the mode for year setting.



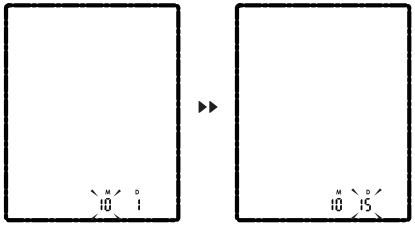
2.Press the “MEM” to change the [YEAR]. Each press will increase the numeral by one in a cycling manner.



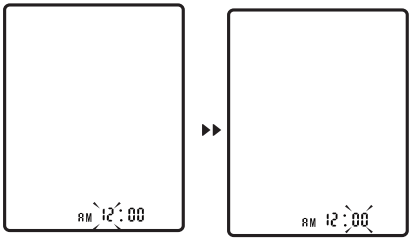
3.When you get the right year, press “SET” to confirm, and it will divert to the [MONTH] setting.



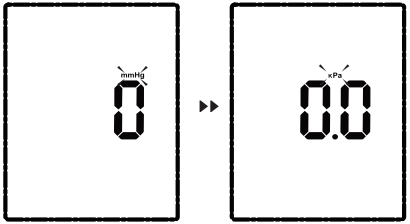
4.Repeat steps 2 and 3 to set the [MONTH] and [DAY].



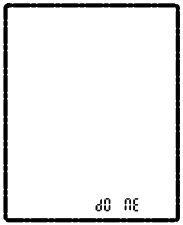
5.Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].



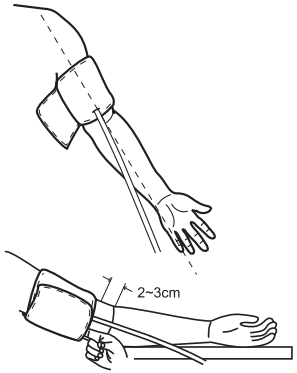
6.Repeat steps 2 and 3 to set the [MEASUREMENT UNIT].



7.After the [MEASUREMENT UNIT] is set,the LCD will display “dOnE”, and then turn off.



♥ Tie the Cuff



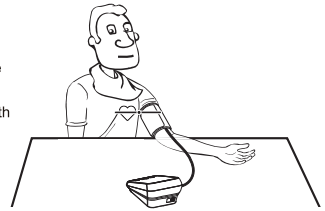
1. Remove all jewelry, such as watches and bracelets from your left arm.
Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.

2. Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.

3. Hold your arm with your palm facing up and tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger. Or position the artery mark Φ over the main artery (on the inside of your arm). Note: Locate the main artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest. This is your main artery.

4. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.

5. Sit comfortably with your tested arm resting on a flat surface. Place your elbow on a table so that the cuff is at the same level as your heart. Turn your palm upwards. Sit upright in a chair, and take 5-6 deep breaths.



6. Helpful tips for Patients, especially for Patients with Hypertension:

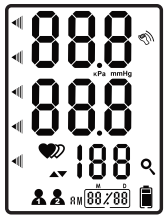
- Rest for 5 minutes before first measurement.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- Take the measurement in a silent room.
- The patient must relax as much as possible and do not move and talk during the measurement procedure.
- The cuff should maintain at the same level as the right atrium of the heart.
- Please sit comfortably. Do not cross your legs and keep your feet flat on the ground.
- Keep your back against the backrest of the chair.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

♥ Start the Measurement

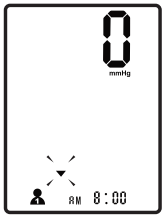
Before you start the measurement, please press the SET button to choose either User 1 or User 2 as the User ID. When the desired User ID is shown, press START/STOP button to confirm the User ID.

1.After selecting the user, press the “START/STOP” to start measurement, and it will finish the whole measurement for the selected user.
Take User 1 for example·

LCD display

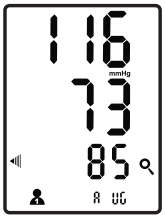


Automatically adjust to zero



Inflating and measuring

Display and save the results. The corresponding backlight shows according to the grade of blood pressure.



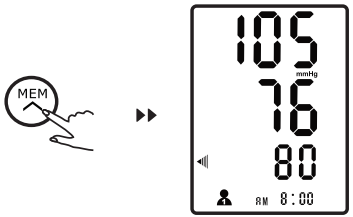
2. Press “START/STOP” button to power off, otherwise it will turn off within 1 minute.

Tips:

A. You can press “START/STOP” button at any time to stop measuring.
B. Maximum 60 records are recorded for both for USER 1 and USER 2.
C. If the measurement result is out of the measurement range (SYS: 60mmHg -230mmHg; or DIA:40mmHg - 130mmHg; or Pulse: 40-199 pulse/minute), the LCD will display “out”. Consult the Error code on page 18 for more information and further instructions.

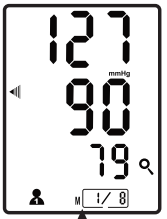
♥ Recall the Records

1. When the monitor is off, please press the “MEM” to show the average value of the latest three resords. If there are less than 3 record entries, it will display the latest record instead and the icon will not appear. Device displays different colors at different levels when the monitor is under the memory mode. Consult the standard blood pressure classification on pages 16 for more information and further instructions.

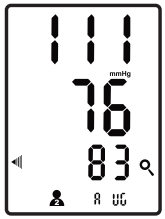


2. Press MEM button or SET button to rotate the records. Up to 60 records will be stored under each user ID.

Date,time will be shown under the Pulse by turns.



3. If you want to check another user's records,press STAR/SOP button to turn off the monitor when it is in the memory recall mode. Then press SET button, the user icon will be shown, press "SET" button to select the desired user ID, press "MEM" button to review the selected user's records.



4. Press the START/STOP button to turn off the monltor.Otherwise, the monior will shut off within 1 minute after last operation.

⚠CAUTION

The most recent record (1) is shown first. Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (60) is dropped from the list.

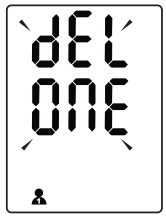
♥ Delete the Records

If you did not get the correct measurement, you can delete all results or the latest result for the selected user by the following steps below.

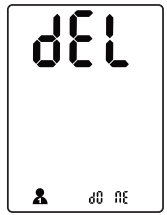
1.If you want to delete all the results, hold "MEM" for 3 seconds when the monitor is in the memory mode ,then "dEL ALL" will show.

OR

If you want to delete the latest result, hold "SET" for 3 seconds when the monitor is in the memory mode ,then "dEL OnE" will show.

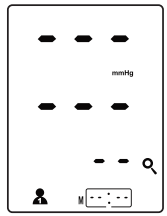


2.Press "MEM" to confirm deleting and the monitor will turn off.



3.If you don't want to delete the records, press "STRAT/STOP" button or "SET" button to escape.

4. If there is no record. the right display will show when recalling the record.



♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.

wait at least 1 hour after dinner or drinking

Immediate measurement after tea, coffee, smoking

Wait at least 20 minutes after taking a bath

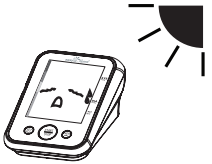
When talking or moving your fingers

In a very cold environment

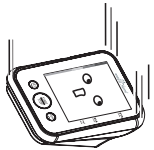
When you want to discharge urine

♥ Maintenance

In order to get the best performance, please follow the instructions below.



Put in a dry place and avoid the sunshine



Avoid intense shaking and collisions

Use wet cloths to remove dirt

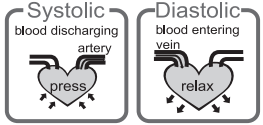
Avoid touching water, clean it with a dry cloth in case.

Avoid dusty and unstable temperature environment

Avoid washing the cuff

♥ What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



♥ What is the standard blood pressure classification?

The chart on the right is the standard blood pressure classification published by American Heart Association (AHA).

AHA Home Guideline for Upper Limit of Normal BP

SYS	135 mm Hg
DIA	85 mm Hg

This chart reflects blood pressure categories defined by American Heart Association.

Backlight on BPM	AHA Color guide line	Blood Pressure Category	Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Blue	Green	Normal	less than 120	and	less than 80
Blue	Green	Prehypertension	120-129	and	less than 80
Orange	Yellow	High Blood Pressure (Hypertension) Stage 1	130-139	or	80-89
Red	Orange	High Blood Pressure (Hypertension) Stage 2	140 or higher	or	90 or higher
Red	Red	Hypertensive Crisis (Emergency care needed)	Higher than 180	and/or	Higher than 120

⚠ CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

♥ Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the device is measuring systolic pressure and diastolic pressure. During each measurement, blood pressure monitor will keep a record of all the pulse intervals and calculate the average value of them. If there are two or more pulse intervals, the difference between each interval and the average is more than the average value of ±25%， or there are four or more pulse intervals, the difference between each interval and the average is more than the average value of ±15%, then the irregular heartbeat symbol will appear on the display with the measurement result to indicate this abnormality.

⚠ CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

♥ Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.

2.If the person takes medicine, the pressure will vary more.

3.Wait at least 3 minutes for another measurement.

♥ Why do I get a different blood pressure at home compared to the hospital?

The blood pressure is different even throughout the day due to weather, emotion, exercise etc, Also, there is the “white coat” effect, which means blood pressure usually increases in clinical settings.

What you need to pay attention to when you measure your blood pressure at home:

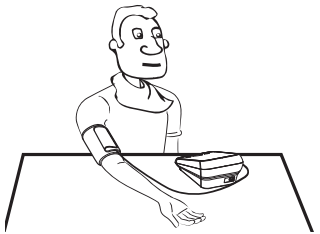
If the cuff is tied properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
If you feel anxious.

Taking 2-3 deep breaths before beginning will be better for measuring.

Advice: Relax yourself for 4-5 minutes until you calm down.

♥ Is the result the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different people. We suggest you measure the same arm every time.



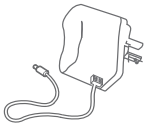
This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products not operating as you think it should, check here before arranging for servicing.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display is dim or will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Lo +  Show on the display	Batteries are low.	Replace with new batteries
Error message	E 3 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 10 or E11 shows	The monitor detected motion while measuring.	Movement can affect the measurement.Relax for a moment and then measure again.
	E20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again
	E21 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EExx,shows on the display.	A calibration error occurred.	Retake the measurement.If the problem persists,contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.
Warning message	“out ” shows	Out of measurement range	Relax for a moment. Refasten the cuff and then measure again. If the problem persists, contact your physician.

Power supply	Battery powered mode: 6VDC 4*AA batteries AC adaptor powered mode: (INPUT: 100-240VAC 50/60Hz 0.2A Max OUTPUT: 6V⎓ 1000mA)(Not Included)
Display mode	Digital LCD V.A.60mm*80mm（2.36”*3.15”）
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg(0kPa ~ 39.9kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Accuracy	Pressure: 5℃-40℃(41℉-104℉)within±3mmHg(0.4kPa) pulse value:±5%
Normal working condition	A temperature range of :+5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but not requiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of : 700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50hPa
Measurement perimeter of the upper arm	About 22cm~42cm(8¾”-16½”) 22-32cm, 22-45cm
Net Weight	Approx.262g(9.24oz)(Excluding the batteries)
External dimensions	Approx.102mm*143mm*73mm(4.02”*5.63”*2.87”)
Attachment	4*AA batteries, one storage bag, user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21: This device is protected against solid foreign objects of 12.5mm and greater, and protected against vertically falling water drops.
Software Version	A01

♥ Authorized Components

1. please use the easy@Home® authorized adapter. (Not Included)



2.Storage bag.

Adapter
Input: 100-240VAC 50/60Hz 0.2A Max
Output: 6V ⎓ 1000mA
(BLJ06L060100P-U)

♥ Contact Information

For more information about our products, please visit Healthcare-Manager.com , or call toll-free at 1-855-822-6999 M-F 9 a.m.-5 p.m. CST. We attend to all questions, concerns, and guidance about our resources.

♥ Contraindications

1.The device should not be used by any person who can possible be or is pregnant.
2.The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators.

♥ Adverse Reactions

None

♥ Measurement Principle

This product uses the Oscillometric Measuring Method to detect blood pressure. Before every measurement, the unit establishes a “zero point” equivalent to the atmospheric pressure. Then it starts inflating the cuff. Meanwhile, the unit detects pressure oscillation generated by beat-to-beat pulsation, which is used to determine the systolic pressure and diastolic pressure as well as pulse rate. Systolic pressure is the maximum pressure your heart exerts while beating (the top number), and diastolic pressure is the amount of pressure in your arteries between beats (the bottom number). Pulse rate (also known as heart rate) is the number of times your heart beats per minute.

♥ Complied Standards List

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
Labeling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements
User manual	EN 1041:2008 +A1:2013 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/ IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems IEC 80601-2-30:2009+A1:2013 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

FCC Statement

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.

EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic
resonance imaging, where the intensity of EM disturbances is high.

Warning: Use of this equipment adjacent to or stacked with other equipment should be avoided because it
could result in improper operation. If such use is necessary, this equipment and the other equipment should be
observed to verify that they are operating normally.

Warning: Use of accessories, transducers and cables other than those specified or provided by the
manufacturer of this equipment could result in increased electromagnetic emissions or decreased
electromagnetic immunity of this equipment and result in improper operation."

Warning: Portable RF communications equipment (including peripherals such as antenna cables and external
antennas) should be used no closer than 30 cm (12 inches) to any part of the equipment EBP-095L, including
cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could
result.

Technical description:

1, all necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to
electromagnetic disturbances for the excepted service life.
2, Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Comply

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity		
Immunity Test	**IEC 60601-1-2 Test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency
Surge IEC61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode

Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°.0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles; Single phase: at 0°.0 % U_T; 250/300 cycle	0 % U_T; 0,5 cycle. At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315°. 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles; Single phase: at 0°. 0 % U_T; 250/300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conduced RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
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							
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communica-tions equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Modulation (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380-390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	430-470	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704-787	LTE Band 13, 17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18Hz	2	0.3	28
	870						
	930						
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217Hz	2	0.3	28
	1845						
	1970						
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						