ePA-46B

sphygmomanometer

user manual

shenzhen belter health measurement and analysis technology co.,ltd

Thank you for purchasing the BELTER electronic sphygmomanometer

This product is a sphygmomanometer which uses noninvasive method to measure human blood pressure.Please be sure to read the instructions before use.After reading, please safekeeping for inspection at any time, reference.

Scope of application: used for blood pressure and pulse measurement of human body.

The sphygmomanometer is able to store up to 100 measurements per user (maximum 2 users) and equipped with the Bluetooth Smart technology to achieve reliable transmission linkage with a mobile device or tablet PC that is with the logo and corresponding application. From now on, you can easily track your health on a daily basis.

Referent Standards and Documents

No	Standard Name	Reference No.
1	Standard Name	Reference No.
2	Medical Device Quality System for the regulation requirement	EN ISO13485: 2012
3	Medical device risk management to medical devices application	EN ISO14971: 2012
4	Symbol for the label of medical devices	EN 980: 2008
5	Term, symbol and information of medical device—information of medical device manufacturer offering	EN 1041: 2008
6	Medical electrical equipment – Part 1: General requirements for safety	EN60601-1: 2006/AC:2010
7	Medical electrical equipment – Part 1-2: General requirements for safety – Collateral standard: Electromagnetic compatibility – Requirements and tests	EN 60601-1-2: 2007
8	Clinical investigation of medical devices for human subjects. General requirements	EN ISO 14155-1:2009
9	Clinical investigation of medical devices for human subjects. Clinical investigation plans	EN ISO 14155-2:2009
10	Medical device software – Software life-cycle processes	EN 62304: 2006/AC: 2008
11	Medical electrical equipment – Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability	EN 60601-1-6: 2010
12	Medical electrical equipment. Part 1-11:General requirements for basic safety and essential performance. Collateral standard:Requirements for medical electrical equipment and medical electrical	EN 60601-1-11

	systems used in the home healthcare environment	
13	Medical devices – Application of usability engineering to medical devices	EN62366: 2008
14	Council Directive 93/42/EECof 14 June 1993 concerning medical devices OJ L 169 of 12 July 1993 (including Directive 2007/47/EC)	MDD 93/42/EEC
15	Non-invasive sphygmomanometers —Part 1: General requirements	EN 1060-1
16	Non-invasive sphygmomanometers.Part 3:Supplementary requirements for electro-mechanical blood pressure measuring systems	EN 1060-3
17	Manual, electronic, or automated sphygmomanometers	SP10
18	User Manual	Version:1.0

Important safety notes

SIGNS AND SYMBOLS

The following signs appear in this manual. READ THE SAFETY SECTION AND ALL INSTRUCTIONS AND WARNINGS COMPLETELY AND CAREFULLY BEFORE USING THIS PRODUCT. FOLLOW ALL SAFETY INSTRUCTIONS AND WARNINGS TO AVOID HAZARDOUS SITUATIONS AND TO MAKE CORRECT USE OF THIS PRODUCT.

symbol	Description
⚠ WARNING	WARNING indicates a hazardous situation which, if not avoided, could Result in death or serious injury
⚠ **CAUTION**	CAUTION indicates a hazardous situation which, if not avoided, may result in minor or moderate injury
⚠ **NOTICE**	NOTICE addresses practices not related to personal injury, such as product and/or property damage
	Type BF
Bluetooth SMART	**Bluetooth function**
DISPOSAL	Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is

	necessary
CE 0123	This item is compliant with Medical Device Directive 93/42/EEC of June 14,1993, a directive of the European Economic community
	Refer to instruction manual / booklet
IP22	Degree of protection against harmful ingress of particulate matter and water
	Manufacturer
EC REP Company Address	Authorized representative in the European Community
	Date of manufacture
SN	Serial number
SYS	systolic
DIA	diastolic
PUL	pulse

warning

Do not use this product in the mixed gas of flammable gas with air or wih oxygen or with nitrous oxide conditions.

Do not dispose of electrical appliances as unsorted municipal waste, use separate collection facilities. Contact you local government for information regarding the collection systems available. If electrical appliances are disposed of in landfills or dumps, hazardous substances can leak into the groundwater and get into the food chain, damaging your health and well-being.

The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.

The device requires no calibration.

The device is not repairable and contains no user serviceable parts.

No modification of this equipment is allowed.

Remove batteries if equipment is not likely to be used for some time.

The user must check that the equipment functions safely and see that it is in proper working condition before being used.

The manufacturer does not require such preventive inspections by other persons.

. It is dangerous to carry on self judgment and self treatment by the sufferer himself,so please follow doctor's instruction. Self judgment may lead to exacerbation of disease

. Get a serious blood circulation obstacle, blood paroxysm sufferer, please use under the doctor's instruction, while measuring because the arm is squeezed may cause impatient internal bleeding

. Infant and person not be able to express himself,please do not use

. Please control the add pressue to the armband in the range of 300 mmHgs(40 kpas) , otherwise the arm may appear blood clot, benumbed symptom

. This product is only used for human body blood pressure measurement and used outside the purpose of measuring human body blood pressure, may take place accident

. Please don't use a cell phone in the neighborhood of this product and have the danger to make product mistake action

. Please don't dismantle to unload or fix by yourself, reformation of the blood pressure account of essence or armband, otherwise can not measure correctly

. Please use AA alkaline battery, don't use other batteries, otherwise may arouse breakdown

. If the electrolyte in the battery gets into your eye, please immediately flush with a great deal of clear water, will result into to blindness or other harmful danger, need to immediately arrive hospital nearby to cure

. If the electrolyte in the battery glues on the skin or the clothes, please immediately flush with a great deal of clear water, otherwise may hurt skin

Please use special arm band, otherwise may not be able to measure correctly.

If the abnormal situation of adding pressure cannot stop or abnormal air exhaustion occurs while measuring,please remove the arm band or pull out the air pipe,otherwise may suffer peripheral nerve disorder.

⚠ **CAUTION**

.Please be sure to use the appropriate cuffs band, otherwise you can't get correct measurement

.Please don't pack a plus or minus pole of battery to pack anti-. After the battery is used up, please replace it with new battery at the same time, long time no need to use ,please take out the battery

. The method to abandon the battery after use please deal with it according to city environmental protection regulations.

Please do not mix use new and old batteries,otherwise may cause leakage, fever, fracture of the battery to damage the product.

Please use according to the storage temperature and humidity standard recored in the user manual.

When arrhythmia situation occurs,the measurement value may be incorrect or can not be measured.

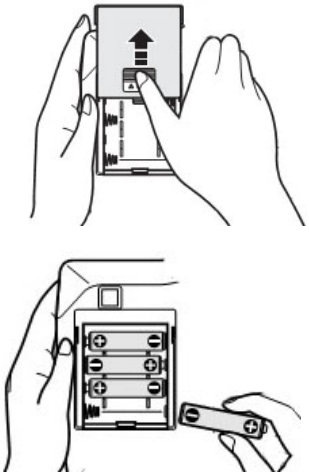
⚠ **NOTICE**

.Please don't make an effort to curve armband and armband windpipe
.While dismantling an air tube, please take the forepart of the air tube plug to pull out
.Please don't bump shot or drop the product, this may lead to the measurement value of the product incorrect.
Please do not add pressue before the arm band wraps around the upper arm,or you can not get correct measurement value.
When the plug or wire of the power adapter is damaged,please immediately drawn it out of the socket,otherwise may cause the danger of fire or electric shock.
Please do not use wet hand to pull the power adapter from the socket,otherwise may cause electric shock or fire burn.

Operating instructions:

How to install and replace the battery

1. Downward push the battery cover, remove the battery cover from ontology



2. Install or replace the 4 AA batteries,Make the battery positive (+) and negative (-) extremely consistent with the marks in the battery box,and then close the battery cover.

⚠ **NOTICE**

Please replace the battery in the state of the body cut off power.
If you remove the battery in the boot state, then count time to stop.
When the low battery icon () appears on the screen please replace 4 batteries. Recommend alkaline battery with longer service life.
When 3 month or longer time without the use of the blood pressure please take out the battery.
After replacing the battery, you may need to reset the date / time.
The method to abandon the battery after use please deal with it according to city

environmental protection regulations.

How to select the adapter and use

Please choose the output voltage is DC6V, output current is 1A dedicated to medical treatment power supply adapter.

Please insert the plug of the power adapter into the power adapter interface of the product.

Please insert the power adapter into the socket.

⚠ **NOTICE**

Please do not use nondedicated power adapter.

Even if you use the power adapter, please stall batteries into the product.

The installation of batteries is to protect the time settings.

If you do not install batteries, unplug the power adapter from the socket,the machine will automatically stop counting time, the history data will be deleted.

Set customer, date and time

Please carry on enactment according to the sequence of customer, age, month and date, hour and minute

Shut down status bottom, double-click 【SET 】button to get into a customer to choose mode.

Show a customer at this time 1, press 【MEM 】button to chose customer 2:

Press 【 SET 】 button, set【age value 】

Press one time[memory]button, promote 1.

It can quickly change data while continuously pressing down a button

⚠ **NOTICE**

The enactment scope of year is 2000-2040.If the year attains 2040, it will return 2000

Press 【 SET 】button, set 【the month be worth 】

Press one time[MEM]button, promote 1.

It can quickly change data while continuously pressing down a button

Press 【SET】button, set 【date 】

Press one time[MEM]button, promote 1.

It can quickly change data while continuously pressing down a button

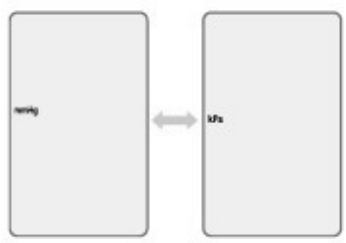
Press 【SET 】button, set【hour& minute 】

Press one time[MEM]button, promote 1.

It can quickly change data while continuously pressing down a button

Set unit

At shut down status, press 【SET 】button, then press 【MEM 】button to carry on the conversion of the blood pressure unit"mmHg" and"kPa".



The use of memory function

Press 【MEM 】button, the device shows user's group.Press 【SET】button again, it shows the latest diagraph result.(Press 【SET】button up to change user)

During the process of reading measuring memory,

When long press 【MEM 】button, all the memory value will be deleted.
If show "---", means delete finished.

⚠ **NOTICE**

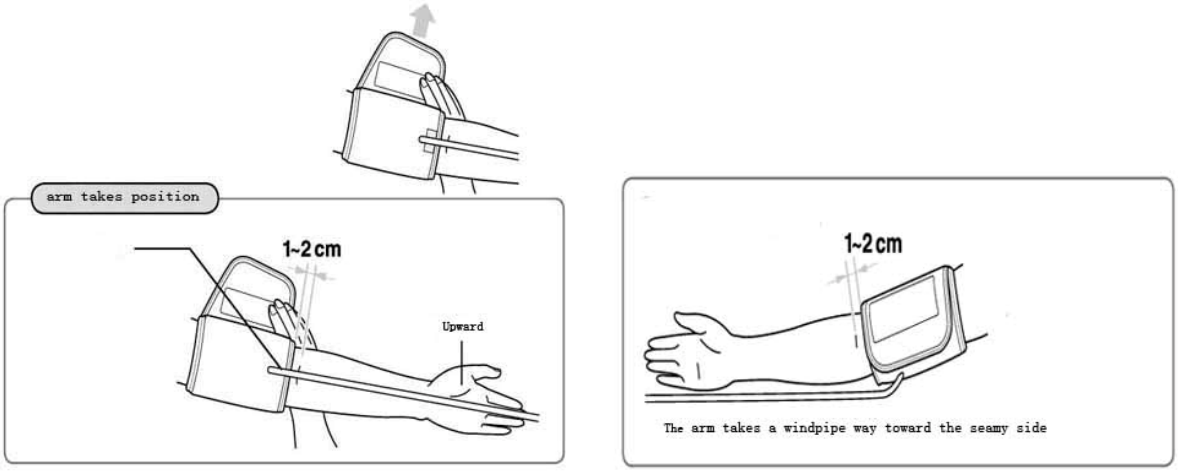
This blood pressure is automatically save test value and pulse with measurement date and time, 60 sets of diagraphs are kept. If saved data is over than 60 sets, the oldest diagraph result will be deleted, newest one will be saved.

Using steps

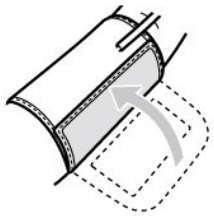
1、 Tie up arm to take

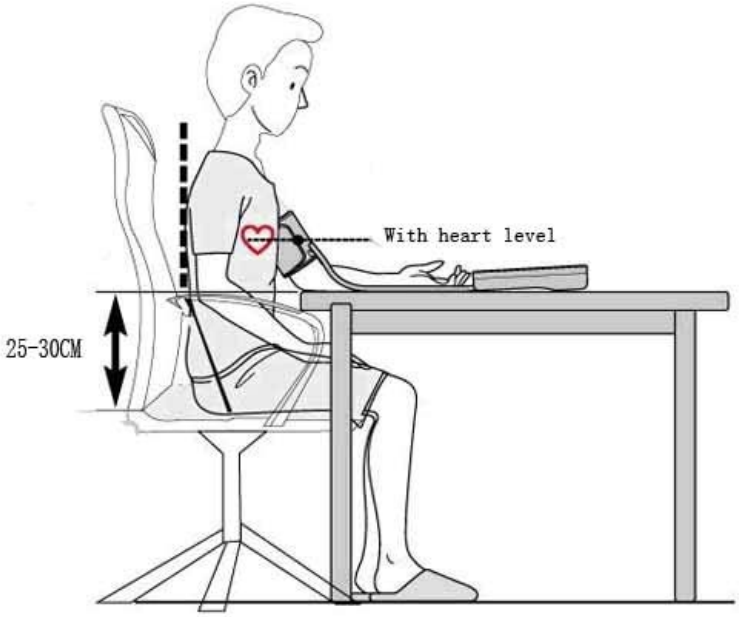
A、plug the air tube of the armband into the joint of the product.
B、open the armband,put armband air tube toward the palm inside.(as below pictures)

C, fix the armband in position, as position shown in below pictures .



C、fix the armband tightly.





（Correct diagraph posture）

⚠ **NOTICE**

If you use it out of the indicated temperature and humidity range,it may not be able to achieve claimed performance requirement.
While measuring you must ensure the correct posture to obtain accurate results.

Even forget to turn off the power ,after about 2 minutes it will shutdown automatically .

Please measure and control blood pressure at the same time every day.

Measurement should be taken in quiet places ,the measured person should be in a relaxed sitting position.

You'd better have a rest of 15 minutes before measurement.

data transfer

The data uploads to cellular phone or computer via blue tooth.

Key of symbols

signal	Warning-see user manual	Treatment
E-1	The armband fix too loose	Check whether armband is loose to move, re-fasten tight again for measuring.
E-2	Speaking during measurement or move the arm	Keep body and arm stable and measure again
E-5	There's interference or work not correctly during measurement.	Shut down, re-measure once.
E-3	The product leaks air or arm's taking don't put good enough.	Please check arm to take whether already put like.
	Battery energy shortage	Please replace battery

Excrescent check

Excrescent circumstance	Reason	Treatment
Measured result is big deviation from normal	Armband doesn't take correctly	The exactitude ties up good arm to take
	talks or moves arm during the measuring	Keep quiet and measure
	The clothes of curling up oppressed arm	take off the clothes and measure again
Don't add to press	Air plug do not plug in the ontology of air tube correct	Connect the tube correctly
	The arm takes to leak air	Purchase new arm to take.
The arm takes in the in a short time to carry on exhaustion	The arm takes to tie up too loosely	Please tie up tight arm to take
Add to ran over distance in suddenly the power failure reset clock	Battery energy exhaustion	Replace new battery
After pressing button, don't show	Battery energy exhaustion	Replace new battery
	The power gets in touch with bad or pack anti-	The exactitude puts into battery
Other phenomena	Show the appearance trembles Can not measure	Please press 【ON/OFF】 button, re-operate 1 time. Please replace battery to try. In addition still can not measure, please consult room contact with BELTER healthily

⚠ **NOTICE**

This product has carried on check in the factory,please execute strictly in accordance with the instruction manual.

function specification

Name	Sphygmomanometer
Model number	ePA-46B
Display mode	Display mode
Bluetooth	Supported Bluetooth V2.0
Measurement scope	The pressure measurement scope:0-280 mmHg(0-37.3 kPa)
Pulse scope:	40-200 Time/minute
Accuracy	Pressure:±3 mm Hg
Pulse accuracy	:±5%
Power	DC6v/"AA*4"
Weight	196g
Shape size	W74 mm*L152 mm*H33 mm
Arm band size:	W154 mm*L 486 mm,air tube to grow 600 mm（Apply arm the scope22cm-36cm）
operating environment	a) temperature : +5℃-+40℃ a) relative humidity：15%-80% b) atmospheric pressure :700hpa-1060hpa
Transportation and storage environment	a)temperature :-20℃-+50℃ b)relative humidity：15%-90% c)atmospheric pressure :500hpa-1060hpa
Protection against electric shock	internal electric source,.BF application part
clinical allow maximum error margin	This product pass clinical verification, the clinical maximum allowable error is ≤±5mmHg/±0.67kPa
Battery service life	300times(alkaline dry battery can use)
product expects life span	2years

CLASSIFICATION

1. Internally powered equipment;
2. Type BF applied part: cuff;
3. IP22;
4. Not category AP / APG equipment;
5. Mode of operation: continuous operation.

Cleaning, maintenance and Storage

Please always clean sphygmomanometer.

Please use clean soft cloth ,gently wipe the LCD and shell, do not use solvents, and do not be soak it in water or other liquids.

Please do not wash the arm band of the product.

If the product is especially dirty you can use a soft cloth with water or neutral detergent, fully wring dry to wipe the product.

Please do not use gasoline, thinner or similar solvent to clean arm band.

When you do not use, please storage the sphygmomanometer and accessories in the collection bag.

Please do not place the sphygmomanometer and arm band in high temperature, damp, full of water vapor or direct sunlight conditions.

Please do not let the blood pressure cuff suffer strong shock or vibration (e.g., fell on the ground).

Please do not put the blood pressure at easy splashing places.

Please don't put this product where there is chemical or corrosive gas.

Please do not dismantle the blood pressure.

Please storage the product in requied environment.

Calibration and repair

This product has been calibrated and tested when delivered from the factory.

If you have doubt about the measurement result of the product ,

please contact us and give the product to specialized person to repair

- Warranty:

If you use the device according to the manual, replace it within 3 months and guarantee for free a year.

The following situations are not included in warranty time:

1） problem caused by self dismounting

2） problem caused by shocking during use or delivery.

3） problem caused by incorrect maintenance

4） problem caused by incorrect operating, problems caused by unprofessional repair.

Product Composition

A piece of the product

Cuff band and air pipe line（model:BEARM-01）1PCS

Probation dry cell（4 AA batteries）

Collect soft band 1 piece

A copy of instruction for use

Adverse events :non

ShenZhen Belter Health Measurement and Analysis Technology Co.,ltd

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LONDON, W1G 9QR, U.K.
www.CE-Marking.EU

2012-09

CE 0123

FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates 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.

This device complies with Part 15 of FCC Rules.

Operation is subject to the following two conditions:

This device may not cause harmful interference, and This device must accept any interference received, including interference that may cause undesired operation.

Note: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment. such modifications could void the user’s authority to operate this equipment.