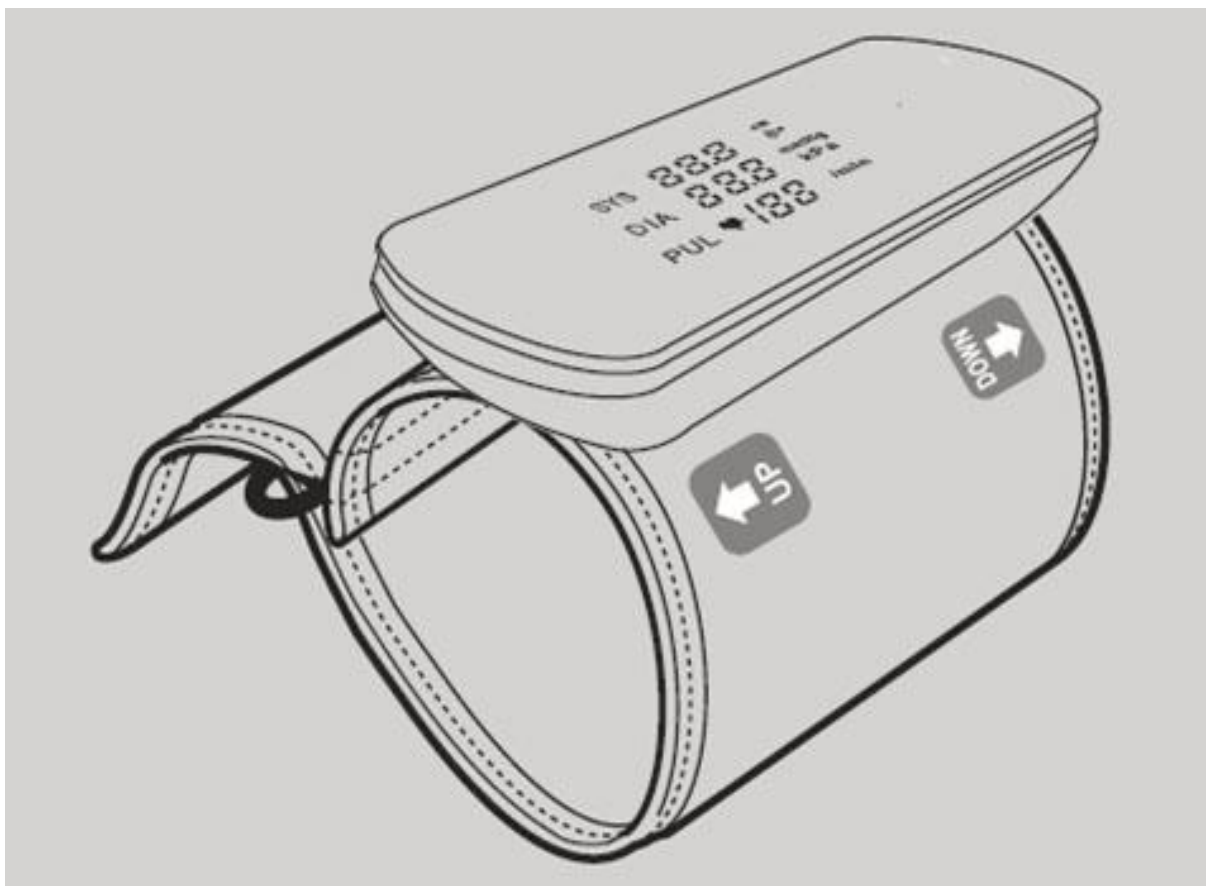


VBPA

Blood Pressure Meter



user manual

shenzhen belter health measurement and analysis technology co.,ltd

Thank you for purchasing the BELTER electronic Blood Pressure Meter

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.

Referent Standards and Documents

Edition: AO

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: 2005/AC:2012
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 systems used in the home healthcare environment	EN 60601-1-11: 2010
13	Medical devices – Application of usability engineering to medical devices	EN62366: 2008
14	<u>Council Directive 93/42/EEC</u> of 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	Secondary cells and batteries containing alkaline	IEC62133:2012







Edition: AO






	or other non-acid electrolytes – Safety requirements for portable sealed secondary cells, and for batteries made from them, for use in portable applications	
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
 DISPOSAL	Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary
CE	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
	Authorized representative in the European Community
	Date of manufacture
	Serial number
SYS	systolic
DIA	diastolic
PUL	pulse
	Bluetooth connection symbol

 **warning**

Do not use this product in the mixed gas of flammable gas with air or with 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 special arm band, otherwise may not be able to measure correctly.

If and when measuring pressure cannot stop or abnormal exhaust abnormal situation, please press the "START/STOP", otherwise you may suffer from peripheral nerve disorder.

If and when measuring pressure cannot stop or abnormal abnormal gas exhaust, press the "START/STOP" no action, please manually release the arm belt.

 **CAUTION**

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

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 bump shot or drop the product, this may lead to the measurement value of the product incorrect.

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.

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 the FCC rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses, and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.

If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

To assure continued compliance, any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.

Radiation Exposure Statement

This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment and it also complies with Part 15 of FCC RF Rules.

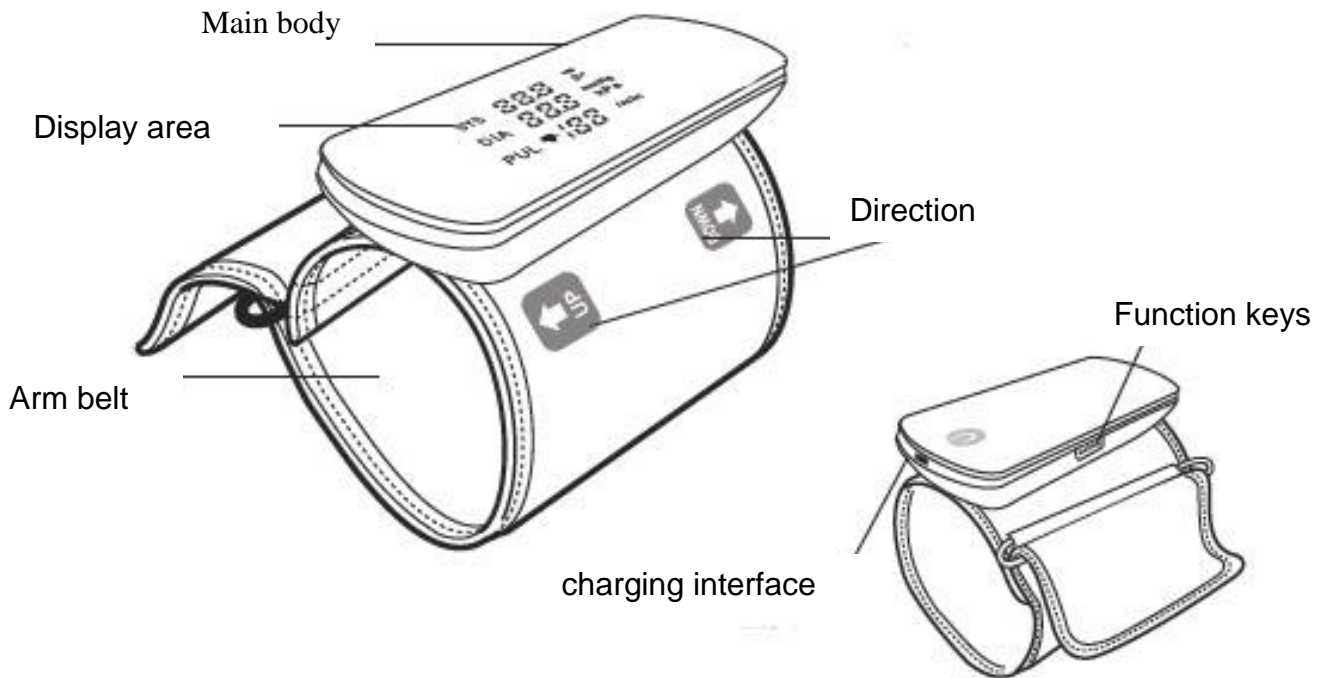
CAUTION

To comply with the limits of the Class B digital device, pursuant to Part 15 of the FCC Rules, this device is comply with Class B limits. All peripherals must be shielded and grounded. Operation with non-certified peripherals or non-shielded cables may results in interference to radio or reception.

MODIFICATION

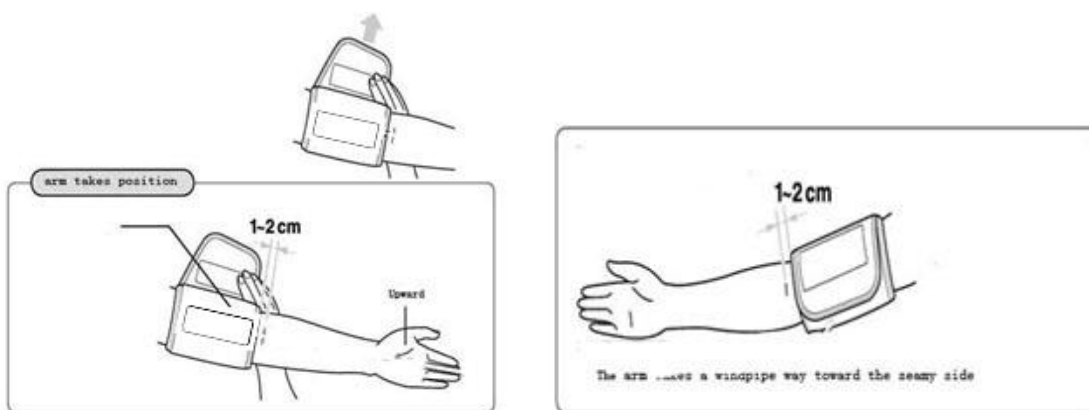
Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the device.

Operating instructions:

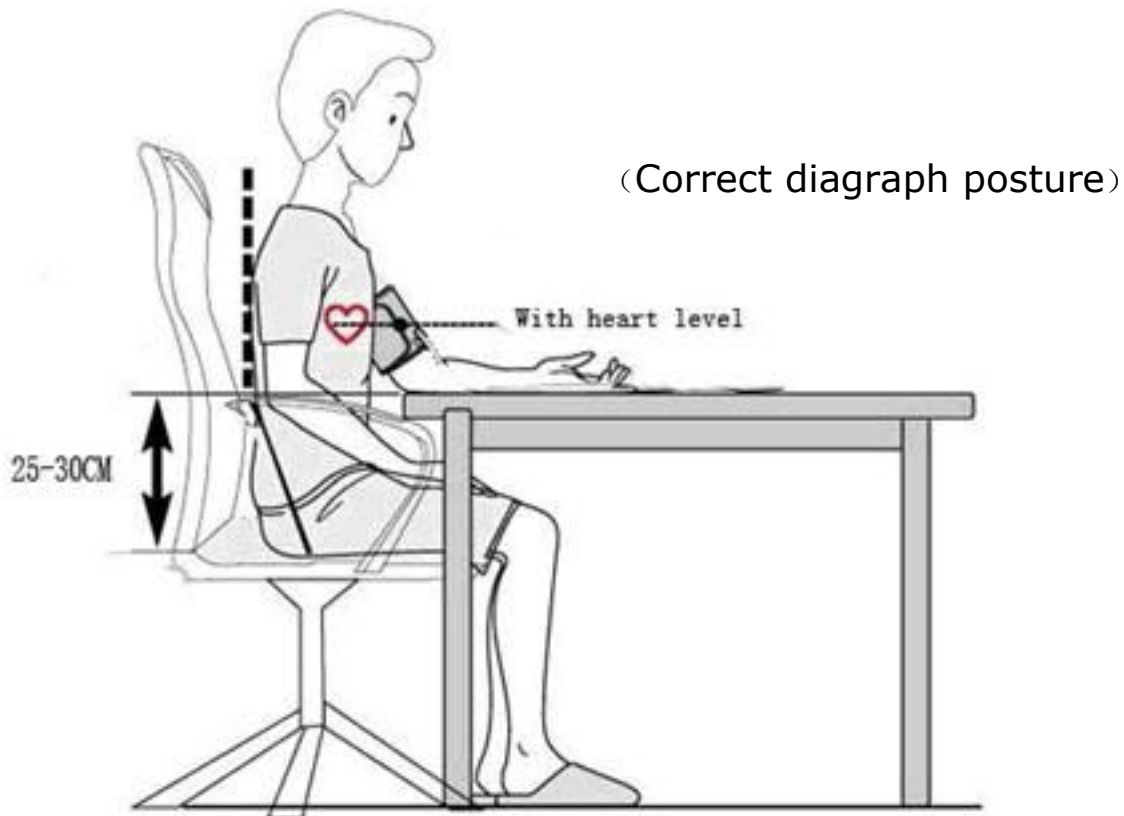


Using steps

- 1、 Please charge the product performed before use
- 2、 Please take off your coat
- 3、 According to the product label "UP\DOWN", will be inserted in the arm cuff



- 4、 Adjustment arm, make the product center position and heart at the same level



5、 Press start / stop button to start the measurement (SART/STOP)

6、 The compression process is complete, the product will gradually reduce the pressure cuff, relax and keep still and not to talk

7、 After the measurement is completed, the air arm belt will be automatically discharged, the measurement results will be displayed on the surface of the corresponding column

 **NOTICE**

The initial use, please charge the battery, because the internal product factory charged amount and the storage time of products can lead to battery power consumed.

If wear a thick coat, please take it off, in order to better measure

Pay attention to dress more thick coat will cause a weak pulse, the measurement results of error

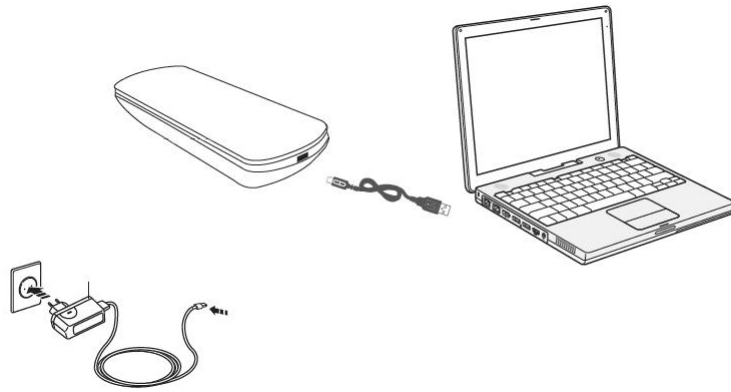
Any time to terminate the measurement, but just need to press the start / stop button (START/STOP), quick exhaust valve will quickly decrease with pressure in the arm

Such as the continuous measurement, the interval time should exceed 10 minutes

How to select the adapter and use

Please choose the output voltage is DC5V, output current is 1A dedicated to medical treatment power supply adapter.

Please read the wiring in the annex to the insertion product and then connected to the power supply.



⚠ 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
Err-1	Sensor abnormal	Check whether there is no airbag gas discharged

Edition: AO

Err-2	Blood pressure was not detected in heart or can't figure out	Check if the dress is too thick
Err-3	Abnormal measurement results	Keep body and arm stable and measure again
Err-4	Cuff too loose or leakage (10 seconds pressure less than 30mmHg)	Shut down, re-measure once.
Err-5	trachea is blocked	To test whether a hard object
Err-6	High pressure fluctuation measurement	Keep body and arm stable and measure again
Err-7	Pressure exceeds the upper limit	Please check arm to take whether already put like.
Err-H	pressure is too high	
	Battery energy shortage	Please charge

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
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

Edition: AO

Add to ran over distance in suddenly the power failure reset clock	Battery energy exhaustion	Please charge
After pressing button, don't show	Battery energy exhaustion	Give product charge
Other phenomena	Show the appearance trembles Can not measure	Please press 【START/STOP】 button, re-operate 1 time. Please charge the battery 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	IVBPA
Display mode	LED
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	DC5v/
Weight	265g
Shape size	W70 mm*L155 mm*H74mm
Arm band size:	Arm belt500mm×130mm (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

Edition: AO

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 $\leq \pm 5 \text{mmHg} / \pm 0.67 \text{kPa}$
Battery service life	An electric charge can be used about 2 weeks
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 required 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.

Edition: AO

3) problem caused by incorrect maintenance

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

Product Composition

A piece of the product

A copy of instruction for use

A charging connection wire

Adverse events :non



ShenZhen Belter Health Measurement and Analysis Technology Co.,ltd

702/704, Block C, Tsinghua Unis Science Park, No.13 Langshan Rd, Hi-Tech Industrial Park(north), Nanshan District, 518057 Shenzhen, People's Republic of China



Wellkang Ltd
Suite B, 29 Harley Street
LONDON, W1G 9QR, U.K.
www.CE-Marking.EU



2015-03

