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Date: 2023-04-13





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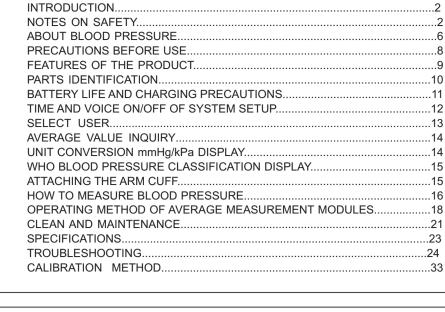


TABLE OF CONTENTS

The • icon indicates something that is compulsory (what must always be observed) Matters involving actual compulsory actions are indicated by text or pictures in or near • .The left icon refers to "general compulsion". The Sicon indicates something can't be disassembled or "Don' disassemble" Matters involving actual compulsory actions are indicated by text or pictures in or near \sqrt{s}. The left icon refers to "general prohibition". Type BF Applied part **IP Classification: IP22**

Requests from Manufacturer

Make sure there is no connection tubing kinking before start measuring to

Consult instruction Please refer to the for use instructions for use MD Indicates Indicates a medical medical device device that needs to be protected from moisture.

Contact its local authorities to determine the proper method of disposal of potentially bio hazardous parts and accessories.

5

∠!\ Caution The following symbol indicates that the device is MR-unsafe:

in the "ATTACHING THE WRIST CUFF." The expected life of the product is 5 years. The product complies with the electromagnetic compatibility requirement of IEC 60601-1-2 and safety standards of IEC 60601-1 and performance of IEC 80601-2-30 as specified in Regulation (EU)2017/745. **NOTES ON SAFETY**

diastolic, systolic blood pressure and pulse rate on adult.

* The icons and meanings are as follow. Examples of signs

* The warning signs and sample icons shown here are listed for your safe and correct use of the unit, so as to prevent injuries or damages to the device.

INTRODUCTION The Monitor uses the oscillometric method of blood pressure measurement.

Intended for use by medical professionals or at home to monitor and display

With an air wrist cuff buckled around one's wrist according to the instructions

The \otimes icon indicates prohibitions (what you should not do). Matters involving actual prohibitions are indicated by text or pictures in or near . The left icon refers to "general prohibition".

Patient must follow doctor's instruction and should not perform self-judgment and self-treatment by the measuring result, Self-diagnosis of measured results and treatment are dangerous. The device should not be used to judge illness, first aid and continuously This device can not be used for Patient transport and surgical care .It can be used in household or fixed places only. Please press "on/off" button to stop work when you feel uncomfortable with the wrist, or if the air is inflating abnormally without stop.

This device should not be used by children under 18 years old or people who cannot express their will, otherwise it will cause harm. Do not use the unit for purpose other than measuring blood pressure. May cause accident or trouble. Please do not use mobile phone around the device. Please do not use The device is prohibited from being used during movement. Do not use the equipment in outdoor or shower rooms.

Do not disassemble, repair, or remodel the main unit or the wrist cuff of the blood pressure monitor. Will cause the unit to function erroneously

-The PATIENT is an intended OPERATOR.

concerned by the results of one

Take measurements at the same time

in this manual, and know your normal

every day using the procedure described

doctor to interpret your blood pressure data.

Many readings give a more comprehensive blood pressure history

measurement.

blood pressure.

8. Average measurement.

1. Press "SET" key to Time display.

-The user can maintain the product, the maintenance method is described in avoid any injury to patient. the maintenance instructions of manual. For any patient, do not measure more than 3 times continuously, it should be Stop using the equipment immediately, if it is in contact with water. at least above 5 minutes of interval rest between any two measurements, otherwise will cause extravasated blood **ABOUT BLOOD PRESSURE** Do not measure your blood pressure over 6 times each day. 1. What is blood pressure? Do not apply the cuff over a wound as this can cause further injury. Blood pressure is the force exerted by blood against the walls of the arteries. Systolic Do not measure on the wrist which is on the side of a mastectomy, otherwise it could cause injury expands. Observe the air pressure value from the LCD display. When measuring, it could not exceed 280 mmHg, otherwise Please press in the morning while one is still at rest and before eating. Do not use force to bend the wrist cuff or the air tube.

2. What is hypertension and how is it controlled? Do not knock or drop the main unit. Hypertension, an abnormally high arterial blood pressure, if left unattended, Always use the specified accessories in the manual, the use of other parts can cause many health problems including stroke and heart attack. not approved by the manufacturer may cause faults or injuries Hypertension can be controlled by altering lifestyle, avoiding stress and with For service information, parts list etc., please contact the dealer. medication under a doctor's supervision. To prevent hypertension or keep it under control:

Do not smoke Exercise regularly Reduce salt and fat intake Have regular physical checkups Maintain proper weight 3. Why measure blood pressure at home? Blood pressure measured at a clinic or doctor's office may cause apprehension

and produce an elevated reading, 25 to 30 mmHg higher than that measured at

home, Home measurement reduces the effects of outside influences on blood

pressure readings, supplements the doctor's readings and provides a more

accurate, complete blood pressure history

devices or turn them off.

Accessory

The built-in lithium battery can be

charged and discharged 300 times.

4. Before using, should wash your hands.

Reference Material: Journal of Hypertension 4. WHO blood pressure classification Standards for assessment of high blood mmHg Grade 3 hypertension (severe) 2 110 2 105 pressure, without regard to age, have been established by the World Health Grade 2 hypertension (moderate) 100 Organization (WHO), and shown in 95 90 Grade 1 hypertension (mild) chart below. High-normal 85 5. Blood pressure variations 80 Optimal An individual's blood pressure varies greatly on a daily and seasonal basis. Systolic blood pressure It may vary by 30 to 50 mmHg due to

various conditions during the day. In hypertensive individuals, variations are even

3. Measurements may be impaired if this device is used near televisions, microwave

ovens. X-ray, mobile phone equipment or other devices with strong electrical fields.

To prevent such interference, use the monitor at a sufficient distance from such

5. Do not measure on the arm which simultaneously used monitoring ME Equipment,

pressure occurs when the heart contracts. Diastolic pressure occurs when the heart Blood pressure is measured in millimeters of mercury (mmHg). One's natural blood pressure is represented by the fundamental pressure, which is measured first thing

-Not servicing and maintenance while the ME EQUIPMENT is in use.

6 more pronounced. Typical fluctuation within a day (Measured every five minutes) Normally, the blood pressure rises while at work or play and falls to its lowest 150 levels during sleep. So, do not be overly **2** 130

1. If you are taking medication, consult with your doctor to determine the most appropriate time to measure your blood pressure. NEVER change a prescribed medication without first consulting with your doctor. 2. For people with irregular or unstable peripheral circulation problems due to diabetes, liver disease, hardening of the arteries, etc., there may be fluctuation in blood pressure values measured at the upper arm versus at the wrist. 6. WHO blood pressure classification display.

7. AVG: average value in the morning, average value at night (see User Manual for

PARTS IDENTIFICATION

Be sure to note date and time when recording your blood pressure. Consult your

PRECAUTIONS BEFORE USE

otherwise it could cause loss of function. 6. Consult your doctor if the unexpected readings are obtained, also please refer to "Trouble shooting" of the manual. 7. The reading is probably a little lower than measured in the hospital due to the steady mood at home. 8.Cuff pressure range 0-299mmHg

FEATURES OF THE PRODUC 1. Memory can store 90 measurements. 2. Large and clear LCD display. 3. WHO blood pressure classification display. 4. Easy to use, Press a button to automatically measure, record the measurement

values and measurement time. 5. Automatically turns off (within 1 minute) to save power.

USB charging line

BATTERY LIFE AND CHARGING PRECAUTIONS

The full-charged battery can be used about 120 times under temperature of $23^{\circ}\!\text{C}$

Connect to adaptor DC output

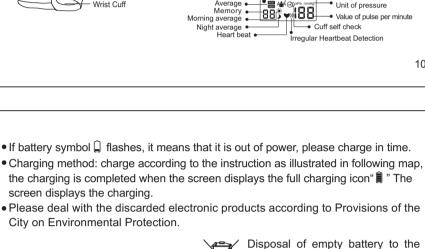
standard, or PC USB interface

interface with medical safety

(DC 5V== 500mA).

inside room, inflating to 180 mmHg (22.6 kPa) every time and twice a day.

SYMBOLS ON DISPLAY USER VOICE TIME CAM/SET Butto 1.388 ON/OFF Button Body shake indication Value of Diastolic



TIME AND VOICE ON/OFF OF SYSTEM SETUP

AVERAGE VALUE INQUIRY

Press " A/*/▶" button to inquire various memory average values of user 1 or user 2.

" AVG "Average Value Display: the latest 3 groups of memory average values (Memory

" 💥 " Display of average value in the morning: the latest 3 groups of memory average

" Display of average value at night: the latest 3 groups of memory average values

2. In the off state, Press and hold "SET" key until the year number

3. Press "MEM" key to adjust the year, then press "SET" key

again to save your setting and enter the month setting mode.

measured during 17:00~2:00 (the next day morning) every day.

displays and flashes on LCD to enter setting mode.

values are displayed regardless of period).

values measured during 4:00~9:59 every day.

10

12

authorized collecting party subject

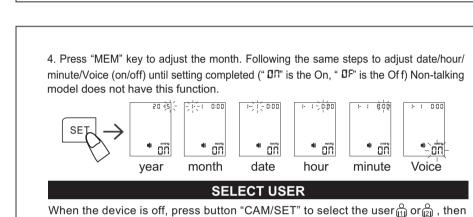
to the regulation of each individual

:388

82

18

territory.



press button "ON/OFF" to measure blood pressure.

13

15

1. Fastening the wrist cuff

in the figure at the right.

display have inflation icon blinked.

move you hand, wrist or arm.

and displayed on LCD screen.

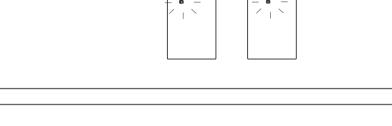
and show it on the LCD screen.

show it on the LCD screen.

19

press button "CAM/SET" to select the user or , then press button "MEM" to inquire memories or average values.

*If need to inquire memories in or in average values of user in or in or in please firstly

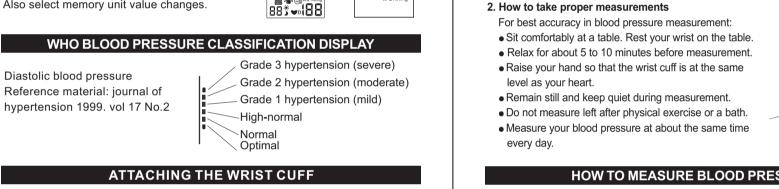


mmHg/kPa after decontrol, After the nomal boot unit values are shown as blood Also select memory unit value changes.

The units will be chosen by the above shows

The goods have mm Hg(mmHg), kPa (kPa) two kinds of blood pressure display units(mmHg factory to express). Boots continued to press the ON/OFF button exceeding five seconds. 14 2) Fasten the wrist cuff tightly by using the Velcro Strip. For proper measurements, fasten the wrist cuff tightly and measure on a bare wrist.

UNIT CONVERSION mmHg/kPa DISPLAY



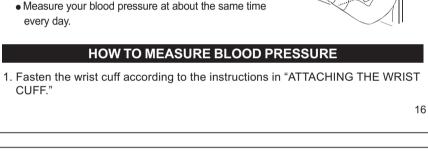
ON/OFF • Now the user can press button CAM/SET to begin Average measurement.

2. Press ON/OFF to Power on, display show all then reset to "0", then start

measurement, will have voice indication(If have voice feature) Start to Inflate,

Device already start to measure your pressure when do inflation, please don't

1) Wrap the wrist cuff around your wrist about (1-2)cm above your hand as shown



When cuff is worn correctly, it shows ③ . If loosely, it shows ③ in this case, please

press [On/Off] button to turn off the power, and then re-wear the cuff correctly before

Physical movement during measurement may lead to incorrect measurement result.

OPERATING METHOD OF AVERAGE MEASUREMENT MODULES

2. After 1st measurent, LCD will show 20s countdown then start 2nd measurement.

1. Press "On/Off" button to turn on the monitor for measurement, when the

blood pressure value on LCD screen increases, press [CAM/SET] button to entre Average measurement Modules, and LCD screens "CAM".

26 16 "® "CUFF WEARING ICON The cuff wearing icon can help remind the user whether the cuff is worn correctly or not.

scope, the average blood pressure value will be calculated out

* If SYS BP1-SYS Bp2≥12mmHg ,DIA BP1-DIA BP2 ≥6mmHg , it will enter into "20" seconds countdown, and automatically re-start to the third measurement. After finishing measurement, the device will calculate the blood pressure average value,

* If pulse rare \leq 60 or \geq 110 or irregular heartbeat , blood pressure monitor

will automatically take measurements for three times continuously. After finishing

measurements, the device will calculate the blood pressure average value and

After finishing measurements, the air in arm cuff will automatically discharge .There

Press "MEM" button, a memory reading out the latest measurements, "MEM" for

Power Measurement closure or after the end of the state .can press the "MEM"

DELETE MEMORY The state read out the memory press the (memory) button five seconds, the LCD

the buttons(UP). "SET" button for the memory (DOWN)

button read out the latest measurement of memory.

display "П□" has been to delete all memory.

Measuring Method

Measuring Range:

Indication

Accuracy:

Memory:

Power supply:

Classification

E1:can't normally

Increase pressure

E3 inflate pressure

E2E4:have shaking

too high

Immunity test

Electrostatic

discharge

(ESD)IEC

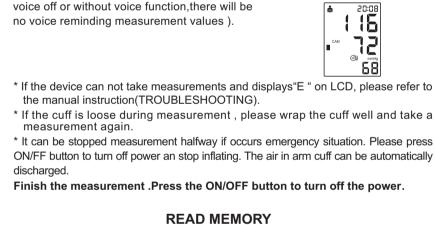
Wrist circumference

will display the blood pressure value, pulse rate, and blood pressure indication on 3. After the second measurement, the blood pressure monitor 15 LCD.And there will be voice reminding measurement values (If the product with analyzesthe values measured during the first measurement and the second measurement, if these values are within standard

measurement.

" ** " ERROR PHYSICAL MOVEMENT ICON

Please re-measure if any physical movement occurs.



Press " MEM " button to inquire memory average values " AUS "Average Value Display: the latest 3 groups of memory average values (Memory values are

displayed regardless of period).

CAUTION

humidity or direct sunlight.

ΠO **CLEAN AND MAINTENANCE** 1. Keep this device in the case provided with the device when you do not use it. 2.Do not fold the arm cuff too tightly. 3.Clean the monitor with a soft dry cloth. Do not use any cleaning solution. 4.Do not submerge the device or any components in water.

5. Store the device and the components in a clean and safe location;

SPECIFICATIONS

Oscillometric Measurement

Pressure:(30~280)mmHg Pulse:(40~199)Beat/min

Digital LCD display

90 Memories

Type BF

(13.5~19.5)cm

Check your wrist cuff if any

Pressure value of more

Hand or body shaking

air leakage

than 299mmHg

Specifications may be changed without notice in the event of improvement being made

Replace wrist cuff with new one

keeping static and correct

Electromagnetic environment-

quidance

Floors should be wood, concrete

or ceramic tile. If floors are covered

with synthetic material, the relative

compliance level in each frequency range

Interference may occur in the vicinity

of equipment marked with the following

Re-measurement or send back dealer for re-calibrate pressure

DC 3.7V 400mAh

Operating condition: +5°C~+40°C. 15%RH~93%RH Atmospheric pressure: 70kPa~106kPa Storage condition: -20°C~+55°C. 0%RH~93%RH Atmospheric pressure:50kPa~106kPa Approx: 72(W)X67(H)X22(D)mm Dimensions: Weight: Approx: 120g, excluding batteries

measure above 120 times.

6. The clean steps for the cuff is provided as following. * Completely wipe the inner side (the side that contacts skin) of the cuff with a soft cloth lightly moistened with 75% Ethyl alcohol 3 times. Replace the soft cloth after each wipe. * Then air dry the cuff.

* Do not subject the monitor to strong shocks, such as dropping the unit on the floor.

• This product is designed for use over an extended period of time; however, it

is generally recommended that it be inspected and calibrated every two years

1. Type of protection against electric shock: INTERNALLY POWERED EQUIPMENT.

Do not submerge the device or any of the components in water.

Do not subject the monitor to extreme hot or cold temperatures,

* Remove the batteries if the unit will not be used for three months or

longer. Always replace all the batteries with new ones at the same time

The polarities of batteries

placed wrongly

Appendix 1 Guidance and Manufacturer Declaration Tables

assure that it is used in such an environment.

Compliance

Group 1

Class B

N. A.

N. A.

ISM bandsa

50,0 MHz to 54,0 MHz.

0.01

0.1

1

0.38

1.2

Guidance and manufacturer's declaration – electromagnetic emissions

The Model PG-800A11-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A11 Series Electronic Blood Pressure Monitor should

Insert battery in the correct

polarities

Electromagnetic environment-guidance The Model PG-800A11-1 Series Electronic Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions

are very low and are not likely to cause any interferénce in nearby electronic équipment.

separation distance calculated from the

equation applicable to the frequency of

Recommended separation distance

the transmitter.

The Model PG-800A11-1 Series Electronic

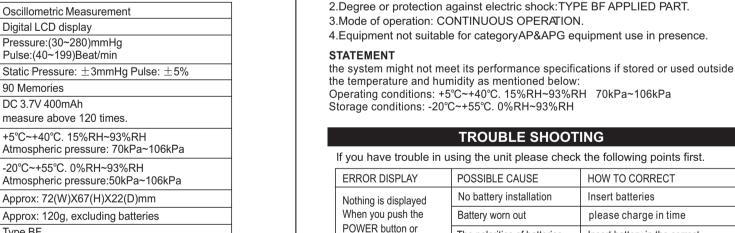
Blood Pressure Monitor is used in home and

it's powered by DC 3V

* Store the device and the components in a clean, safe location.

to ensure proper function and performance.

* See the Calibration Method for more details.



Battery icon flash

Emissions

RF emissions

RF emissions

IEC 61000-3-2 Voltage

fluctuations/flicker

CISPR 11

CISPR 11

Harmonic

	while measurement	while measurement	gesture to measure again			
	Battery icon on	Battery low power	Replace battery and measure again			
	The systolic pressure Value or diastolic Pressure value too high	1.The wrist cuff was held lower than your heart				
		2.The wrist cuff was not attached properly	keeping correct position			
		3. You moved your body or spoke during measurement	and gesture to measure again			
	The systolic pressure Value or diastolic Pressure value too low	1.The wrist cuff was held higher than your heart				
		2.you moved your body or Spoke during measurement				
2	5					
	Guidance and manufacturer's declaration – electromagnetic immunity					
	The Model PG-800A11-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A11-1 Series Electronic Blood Pressure Monitor should assure that it is used in such an environment.					

Compliance

level

±8 kV contact

±2 kV, ±4 kV,

±8 kV, ±15 KV

IEC 60601

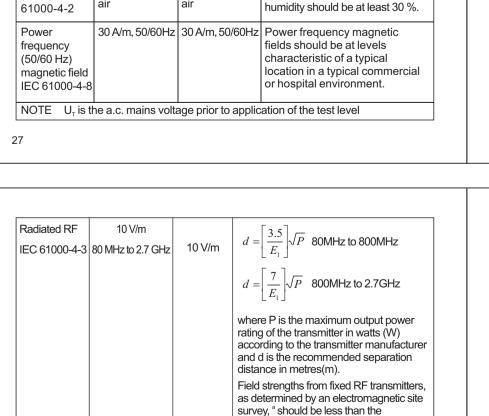
test level

±8 kV contact

±2 kV, ±4 kV,

±8 kV, ±15KV

emissions IEC 61000-3-						
			26			
Guidance and manufacturer's declaration – electromagnetic immunity						
The Model PG-800A11-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A11-1 Series Electronic Blood Pressure Monitor should assure that it is used in such an environment.						
Immunity test IEC 60601 Compliance Electromagnetic environm		Electromagnetic environment - guidance				
Conducted RF	3 Vrms150 kHz to 80 MHz 6 Vrms	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Model PG-800A11-1			
IEC 61000-4-6			Series Electronic Blood Pressure Monitor, including cables, than the recommended			



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

Recommended separation distances between

NOTE 2 These guidelines may not apply in all situations. Electromagnetic

		$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	•		
			28		
NOTE 1 At 80 MHz a	and 800 MHz, the hi	gher frequency ran	ge applies.		
NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.					
- The IOM (in december)	l:	1\	0 45 MHz === 1 00 MHz		
,		,	0,15 MHz and 80 MHz		
'			26,957 MHz to 27,283		
MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz					
and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz,					

MHz to 7.3 MHz. 10.1 MHz to 10.15 MHz. 14 MHz to 14.2 MHz. 18.07 MHz to 18.17

MHZ, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and

b The compliance levels in the ISM frequency bands between 150 kHz and 80

MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease

the likelihood that mobile/portable communications equipment could cause

interference if it is inadvertently brought into patient areas. For this reason, an

0.38

1.2

interference environment to ensure basic safety and basic performance unchanged.

0.73

2.3

32

symbol: (((•)))	calcu		ecommended separ	incorporated into the ration distance for tr	
c Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the Model PG-800A11-1 Series Electronic Blood Pressure	in an The c Monite distan and th below	electromagne customer or the or can help p nce between p ne Model PG-8	etic environment in whe user of the Model Poprevent electromagne portable and mobile 1800A11-1 Series Electro	nich radiated RF distur G-800A11-1 Series Ele	ctronic Blood Pressure laintaining a minimum quipment (transmitters) onitor as recommended
Monitor is used exceeds the applicable RF compliance level above, the Model PG-800A11-1 Series Electronic Blood Pressure Monitor should be observed to		Rated maximum Separation distance according to frequency of transmitter output of m			
verify normal operation. If abnormal performance is observed, additional		ansmitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
measures may be necessary, such as re-orienting or relocating the Model PG-800A11-1 Series Electronic Blood Pressure Monitor.		w	$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$	$d = \left[\frac{7}{E_1}\right]\sqrt{P}$

portable and mobile RF communications equipment and the Model PG-800A11-1 10 7.3 3.8 3.8 **Series Electronic Blood Pressure Monitor** 100 23 12 12 31 4. External input 50mmHg and 200mmHg standard static air pressure, and observe the For transmitters rated at a maximum output power not listed above the air pressure value displayed at the position of the LCD systolic pressure (SYS) and recommended separation distance d in metres (m) can be estimated using the the value of the digital pressure gauge should be in the range of +/-3mmHg. equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter **⚠** Caution NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency 1. ME devices can be used in exposed environments, including electromagnetic range applies.

2.In the event of any serious event related to this product, such as serious adverse propagation is affected by absorption and reflection from structures, objects and event, significant alteration of the product resulting in change of intended use, etc., it will be reported to the manufacturer and the competent authorities of the user and/or the member states where the patient is located. **CALIBRATION METHOD** 1. Press and hold the "ON/OFF, MEM" button at the same time, load the battery, enter Essential performance: Limits of the error of the manometer, ±3mmHg.Reproducibility the static air pressure calibration mode after the LCD screen is fully displayed, and of the blood pressure determination, ±3mmHg. then release the button.

Clinical benefits: Accurate measurement of SBP and DBP, clinical performance meets 2. Press ON/OFF to close the internal air valve. the requirements of ISO 81060-2:2018. 3. Connect the external standard barometric interface and the digital barometer interface to the cuff interface. 102 34