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Date: 2023-04-13



MODEL: PG-800A36-1



C E 2862

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The **1** icon indicates something that is compulsory (what must always Matters involving actual compulsory actions are indicated by text or pictures in or near • .The left icon refers to "general compulsion". The Si icon 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 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.

avoid any injury to patient.

otherwise will cause extravasated blood

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

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** \* The warning signs and sample icons shown here are listed for your safe and

diastolic, systolic blood pressure and pulse rate on adult.

in the "ATTACHING THE WRIST CUFF."

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

correct use of the unit, so as to prevent injuries or damages to the device.

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

∠ Caution

6

8

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.

Patient must follow doctor's instruction and should not perform

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 around the magnetic field.

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.

the maintenance instructions of manual.

in the morning while one is still at rest and before eating.

2. What is hypertension and how is it controlled?

1. What is blood pressure?

concerned by the results of one

expands.

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

Stop using the equipment immediately, if it is in contact with water.

-The user can maintain the product, the maintenance method is described in

**ABOUT BLOOD PRESSURE** 

Blood pressure is the force exerted by blood against the walls of the arteries. Systolic

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

pressure occurs when the heart contracts. Diastolic pressure occurs when the heart

Do not measure your blood pressure over 6 times each day. Do not apply the cuff over a wound as this can cause further injury. Do not measure on the wrist which is on the side of a mastectomy, otherwise it could cause injury Observe the air pressure value from the LCD display. When measuring, it could not exceed 280 mmHg, otherwise Please press "on/off" button to stop Do not use force to bend the wrist cuff or the air tube. Do not knock or drop the main unit. Always use the specified accessories in the manual, the use of other parts not approved by the manufacturer may cause faults or injuries

Requests from Manufacturer

For any patient, do not measure more than 3 times continuously, it should be

at least above 5 minutes of interval rest between any two measurements,

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

5 Do not smoke Exercise regularly

mmHg

Have regular physical checkups

Reference Material: Journal of Hypertension

Grade 3 hypertension (severe)

Systolic blood pressure

• 00

minute

Grade 1 hypertension (mild)

16

15

High-normal

**"** 00

hour

Voice

For service information, parts list etc., please contact the dealer.

 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.

4. WHO blood pressure classification

Standards for assessment of high blood

Reduce salt and fat intake

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. It may vary by 30 to 50 mmHg due to

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

otherwise it could cause loss of function.

to "Trouble shooting" of the manual.

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 devices or turn them off. 4. Before using, should wash your hands. 5. Do not measure on the arm which simultaneously used monitoring ME Equipment,

can cause many health problems including stroke and heart attack. Hypertension can be controlled by altering lifestyle, avoiding stress and with medication under a doctor's supervision. To prevent hypertension or keep it under control:

Hypertension, an abnormally high arterial blood pressure, if left unattended,

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 ₾ 130 levels during sleep. So, do not be overly

measurement. Take measurements at the same time every day using the procedure described in this manual, and know your normal 06 blood pressure. Many readings give a more comprehensive blood pressure history Be sure to note date and time when recording your blood pressure. Consult your doctor to interpret your blood pressure data. PRECAUTIONS BEFORE USE 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 details). 8. Average measurement. **PARTS IDENTIFICATION** 

SYMBOLS ON DISPLAY

Value of Systolic

■ Value of Diastolic

Unit of pressure Value of pulse per minut

authorized collecting party subject to the regulation of each individual

:-388

12

14

16

18

22

territory.

Body shake indicat

USER VOICE TIME

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.

6. Consult your doctor if the unexpected readings are obtained, also please refer

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.

Accessory

USB charging line

**BATTERY LIFE AND CHARGING PRECAUTIONS** 

The full-charged battery can be used about 120 times under temperature of 23°C

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

\$ 0 288:88 \$ 288:88 CAM/SET Buttor WHO blood pressure classification ON/OFF Button Memory Button 

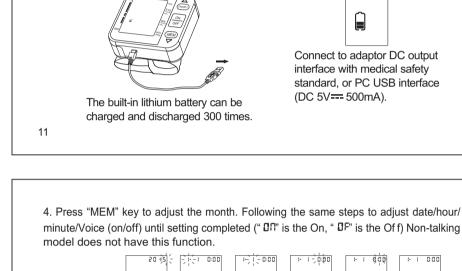
LCD Display: Date and Tim

10

• If battery symbol 🖟 flashes, it means that it is out of power, please charge in time. • Charging method: charge according to the instruction as illustrated in following map, the charging is completed when the screen displays the full charging icon" ii " The screen displays the charging. • Please deal with the discarded electronic products according to Provisions of the City on Environmental Protection. Disposal of empty battery to the

TIME AND VOICE ON/OFF OF SYSTEM SETUP

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



οñ

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

vear

memories or average values.

hypertension 1999. vol 17 No.2

display have inflation icon blinked.

move you hand, wrist or arm.

"® "CUFF WEARING ICON

and displayed on LCD screen.

and show it on the LCD screen.

show it on the LCD screen.

Measuring Method

Measuring Range:

Indication

Dimensions:

The systolic pressure

Value or diastolic

(50/60 Hz)

29

33

Pressure value

too low

25

Weight:

19

13

οñ

date

**SELECT USER** When the device is off, press button "CAM/SET" to select the user  $\stackrel{\circ}{\mathbb{N}}$  or  $\stackrel{\circ}{\mathbb{N}}$ , then

\*If need to inquire memories in or in average values of user in or in or in please firstly press button "CAM/SET" to select the user or , then press button "MEM" to inquire

month

3. Press "MEM" key to adjust the year, then press "SET" key again to save your setting and enter the month setting mode. **AVERAGE VALUE INQUIRY** 

values are displayed regardless of period).

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

every day.

displays and flashes on LCD to enter setting mode.

1. Press "SET" key to Time display.

measured during 17:00~2:00 (the next day morning) every day. 82 UNIT CONVERSION mmHg/kPa DISPLAY

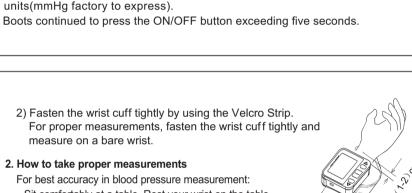
The goods have mm Hg(mmHg), kPa (kPa) two kinds of blood pressure display

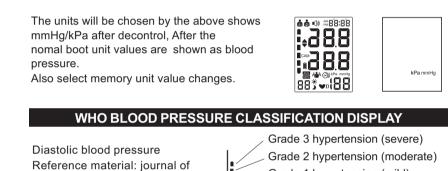
Press " A/\*/▶" button to inquire various memory average values of user 1 or user 2.

" 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





Normal ATTACHING THE WRIST CUFF 1. Fastening the wrist cuff 1) Wrap the wrist cuff around your wrist about (1-2)cm above your hand as shown in the figure at the right. 15

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

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

The cuff wearing icon can help remind the user whether the cuff is worn correctly or not.

\* 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

26

3. After the second measurement, the blood pressure monitor

analyzesthe values measured during the first measurement and the second measurement, if these values are within standard

scope, the average blood pressure value will be calculated out

• Sit comfortably at a table. Rest your wrist on the table. Relax for about 5 to 10 minutes before measurement. • Raise your hand so that the wrist cuff is at the same level as your heart. • Remain still and keep quiet during measurement. Do not measure left after physical exercise or a bath. • Measure your blood pressure at about the same time

**HOW TO MEASURE BLOOD PRESSURE** 

1. Fasten the wrist cuff according to the instructions in "ATTACHING THE WRIST

When cuff is worn correctly, it shows  $\circledcirc$  . If loosely, it shows  $\circledcirc$  in this case, please

press [On/Off] button to turn off the power, and then re-wear the cuff correctly before measurement. " \*\* " ERROR PHYSICAL MOVEMENT ICON Physical movement during measurement may lead to incorrect measurement result. Please re-measure if any physical movement occurs. **OPERATING METHOD OF AVERAGE MEASUREMENT MODULES** 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".

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

0 1 will display the blood pressure value, pulse rate, and blood pressure indication on LCD.And there will be voice reminding measurement values (If the product with

voice off or without voice function, there will be

no voice reminding measurement values ).

displayed regardless of period).

humidity or direct sunlight.

**STATEMENT** 

**ERROR DISPLAY** 

**Emissions** 

RF emissions

RF emissions

IEC 61000-3-2

fluctuations/flicker

CISPR 11

CISPR 11

Harmonic

Voltage

emissions IEC 61000-3-3

15 \* If the device can not take measurements and displays"E " on LCD, please refer to the manual instruction(TROUBLESHOOTING). \* If the cuff is loose during measurement, please wrap the cuff well and take a measurement again. \* It can be stopped measurement halfway if occurs emergency situation. Please press ON/FF button to turn off power an stop inflating. The air in arm cuff can be automatically discharged. Finish the measurement .Press the ON/OFF button to turn off the power.

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

Press "MEM" button, a memory reading out the latest measurements, "MEM" for the buttons(UP). "SET" button for the memory (DOWN) Power Measurement closure or after the end of the state .can press the "MEM" button read out the latest measurement of memory. **DELETE MEMORY** The state read out the memory press the (memory) button five seconds, the LCD display "\"\" has been to delete all memory.

ПΩ

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 **SPECIFICATIONS** 

Oscillometric Measurement

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

**CLEAN AND MAINTENANCE** 

1.Keep this device in the case provided with the device when you do not use it.

Static Pressure: ±3mmHg Pulse: ±5% Accuracy: 90 Memories Memory: DC 3.7V 400mAh Power supply: measure above 120 times. +5°C~+40°C. 15%RH~93%RH Operating condition: Atmospheric pressure: 70kPa~106kPa Storage condition: -20°C~+55°C. 0%RH~93%RH

Atmospheric pressure:50kPa~106kPa Approx: 72(W)X67(H)X21(D)mm

again

characteristic of a typical

Approx: 120g, excluding batteries

Digital LCD display

5. Store the device and the components in a clean and safe location. 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. **CAUTION** \* Do not submerge the device or any of the components in water.

\* 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.

2.Degree or protection against electric shock: TYPE BF APPLIED PART.

Operating conditions: +5°C~+40°C. 15%RH~93%RH 70kPa~106kPa

POSSIBLE CAUSE

4. Equipment not suitable for category AP&APG equipment use in presence.

the system might not meet its performance specifications if stored or used outside

**TROUBLE SHOOTING** 

If you have trouble in using the unit please check the following points first.

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

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

to ensure proper function and performance. \* See the Calibration Method for more details.

3. Mode of operation: CONTINUOUS OPERATION

the temperature and humidity as mentioned below:

Storage conditions: -20°C~+55°C. 0%RH~93%RH

Group 1

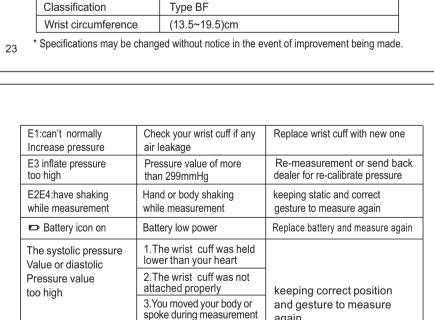
Class B

N. A.

N. A.

\* 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.



1.The wrist cuff was held

2.you moved your body or

Spoke during measurement

higher than your heart

No battery installation Insert batteries Nothing is displayed When you push the Battery worn out please charge in time POWER button or The polarities of batteries Insert battery in the correct Battery icon flash placed wrongly polarities 24 **Appendix 1 Guidance and Manufacturer Declaration Tables** Guidance and manufacturer's declaration – electromagnetic emissions

25								26
Guidance ar	nd manufacture	r's declaration -	- electromagnetic immunity		Guidance	and manufactu	rer's declar	ration – electromagnetic immunity
The Model PG-800A36-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A36-1 Series Electronic Blood Pressure Monitor should assure that it is used in such an environment.					The Model PG-800A36-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below The customer or the user of the Model PG-800A36-1 Series Electronic Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment- guidance		Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
Electrostatic discharge (ESD)IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15KV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.		Conducted RF IEC 61000-4-6	80 MHZ outside		Portable and mobile RF communications equipment should be used no closer to any part of the Model PG-800A36-1 Series Electronic Blood Pressure Monitor, including cables, than the recommended
Power frequency	30 A/m, 50/60Hz		Power frequency magnetic fields should be at levels			ISM bandsa		separation distance calculated from the equation applicable to the frequency of the transmitter

magnetic field IEC 61000-4-8 location in a typ or hospital environment of the test location in the tes		$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$
Radiated RF IEC 61000-4-3 80 MHz to 2.7 GHz $d = \left[\frac{3.5}{E_{\scriptscriptstyle \parallel}}\right] \sqrt{P}  80 \text{MHz}$ $d = \left[\frac{7}{E_{\scriptscriptstyle \parallel}}\right] \sqrt{P}  800 \text{MHz}$	Hz to 800MHz  NOTE 2 The is affected by a The ISM (i	30 MHz and 800 MHz, the higher frequency range applies. ese guidelines may not apply in all situations. Electromagnetic propagation y absorption and reflection from structures, objects and people. industrial, scientific and medical) bands between 0,15 MHz and 80 MHz
where P is the maximum rating of the transmitted according to the transmitted according to the transmitted and d is the recommend distance in metres(m).  Field strengths from fix	num output power er in watts (W) smitter manufacturer ended separation ).  MHz; and 4 and 80 MHz MHz to 7,3 M MHz, 21,0 M xed RF transmitters,  50,0 MHz to	MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 k0,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz z are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 554,0 MHz.
as determined by an e survey, a should be less compliance level in eac Interference may occu of equipment marked w	ss than the ach frequency range bur in the vicinity with the following	pliance levels in the ISM frequency bands between 150 kHz and 80 in the frequency range 80 MHz to 2,7 GHz are intended to decrease and that mobile/portable communications equipment could cause the if it is inadvertently brought into patient areas. For this reason, an factor of 10/3 has been incorporated into the formulae used in

c Field strengths from fixed transmitters, such as base stations for radio (cellular/ in an electromagnetic environment in which radiated RF disturbances are controlled. cordless) telephones and land mobile radios, amateur radio, AM and FM radio The customer or the user of the Model PG-800A36-1 Series Electronic Blood Pressure broadcast and TV broadcast cannot be predicted theoretically with accuracy Monitor can help prevent electromagnetic interference by maintaining a minimum distance To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength Model PG-800A36-1 Series Electronic Blood Pressure Monitor as recommended below, in the location in which the Model PG-800A36-1 Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Model PG-800A36-1 Series Electronic Blood Pressure Monitor should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the Model PG-800A36-1 Series Electronic Blood Pressure Monitor. d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. Recommended separation distances between portable and mobile RF communications equipment and the Model PG-800A36-1 **Series Electronic Blood Pressure Monitor** 

symbol:  $((\bullet))$ 

output of 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.7 GHz transmitter W 0.01 0.23 0.38 0.38 0.73 0.1 1.2 1.2 2.3 1 10 3.8 3.8 7.3 100 12 12 23 32

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

interference environment to ensure basic safety and basic performance unchanged. 2.In the event of any serious event related to this product, such as serious adverse 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

Essential performance: Limits of the error of the manometer, ±3mmHg.Reproducibility of the blood pressure determination, ±3mmHg.

Clinical benefits: Accurate measurement of SBP and DBP, clinical performance meets the requirements of ISO 81060-2:2018. 102 34

according to the maximum output power of the communications equipment. Rated maximum Separation distance according to frequency of transmitter

additional factor of 10/3 has been incorporated into the formulae used in

calculating the recommended separation distance for transmitters in these

The Model PG-800A36-1 Series Electronic Blood Pressure Monitor is intended for use

between portable and mobile RF communications equipment (transmitters) and the

The Model PG-800A36-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A36-1 Series Electronic Blood Pressure Monitor should assure that it is used in such an environment. Compliance Electromagnetic environment-guidance The Model PG-800A36-1 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 interference in nearby electronic equipment The Model PG-800A36-1 Series Electronic Blood Pressure Monitor is used in home and it's powered by DC 3V

HOW TO CORRECT

Recommended separation distance

28

30

31 For transmitters rated at a maximum output power not listed above the recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter

1. Press and hold the "ON/OFF, MEM" button at the same time, load the battery, enter the static air pressure calibration mode after the LCD screen is fully displayed, and then release the button. 2. Press ON/OFF to close the internal air valve. 3. Connect the external standard barometric interface and the digital barometer interface to the cuff interface.

Notes:

frequency ranges.

4. External input 50mmHg and 200mmHg standard static air pressure, and observe the air pressure value displayed at the position of the LCD systolic pressure (SYS) and

the value of the digital pressure gauge should be in the range of +/-3mmHg. ⚠ Caution 1. ME devices can be used in exposed environments, including electromagnetic the member states where the patient is located.