

ELECTRONIC BLOOD PRESSURE MONITOR **Instruction Manual**

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The • icon indicates something that is compulsory (what must always

The Monitor uses the oscillometric method of blood pressure measurement.

C E 2862

Measurement Automatic Electronic Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate, with an air wrist cuff buckled around one's wrist according to the instructions 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

INTRODUCTION

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 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 ⊘ 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-diagnosis of measured results and treatment are dangerous. The device should not be used to judge illness, first aid and continuously

self-judgment and self-treatment by the measuring result,

wrist, or if the air is inflating abnormally without stop.

the maintenance instructions of manual.

hypertensive individuals, variations are

Normally, the blood pressure rises while at work or play and falls to its lowest

levels during sleep. So, do not be overly

Take measurements at the same time every

manual, and know your normal blood pressure.

3. WHO blood pressure classification display.

5. Automatically turns off (within 1 minute) to save power.

values and measurement time.

the products.

temperatures.

Battery short circuit must be prevented.

• The batteries may leak and cause a malfunction.

day using the procedure described in this

Many readings give a more comprehensive

concerned by the results of one

even more pronounced.

measurement.

monitor measuring.

used in household or fixed places only.

2

6

Typical fluctuation within a day

(Measured every five minutes)

06

8

1 Caution

Matters involving actual compulsory actions are indicated by text or pictures in or near • .The left icon refers to "general compulsion". The \odot icon indicates something can't be disassembled or "Don' disassemble"

Matters involving actual compulsory actions are indicated by text or pictures in or near \(\mathbb{O} \) . The left icon refers to "general prohibition". <u>∕!</u> Caution **IP Classification: IP20** Type BF Applied part Consult instruction for use The following

Please refer to the instructions for use Indicates a medical device that needs to be

be observed).

1

5

MD Indicates

medical device protected from moisture. Contact its local authorities to determine the proper method of disposal of potentially bio

hazardous parts and accessories.

symbol indicates that the device is MR-unsafe:

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

This device can not be used for Patient transport and surgical care .It can be

Please press "on/off" button to stop work when you feel uncomfortable with the

blood pressure monitor. Will cause the unit to function erroneously.

-The PATIENT is an intended OPERATOR. -Not servicing and maintenance while the ME EQUIPMENT is in use. -The user can maintain the product, the maintenance method is described in

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

Make sure there is no connection tubing kinking before start measuring to avoid any injury to patient. 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, otherwise will cause extravasated blood. 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 For service information, parts list etc., please contact the dealer.

Requests from Manufacturer

ABOUT BLOOD PRESSURE 1. What is blood pressure? Blood pressure is the force exerted by blood against the walls of the arteries. Systolic 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 in the morning while one is still at rest and before eating 2. What is hypertension and how is it controlled? Hypertension, an abnormally high arterial blood pressure, if left unattended, 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:

mmHg

150

90 70

Blood

 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 pressure, without regard to age, have Reference Material: Journal of Hypertension been established by the World Health 1999, Vol 17 No.2

mmHa

95

Exercise regularly

Have regular physical checkups

5. Blood pressure variations 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

Organization (WHO), and shown in

chart below.

Do not smoke

Reduce salt and fat intake

100 pool 95 90 90 85 High-normal 120 130 140 150 160 170 180 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.

Grade 3 hypertension (severe)

Grade 2 hypertension (moderate)

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.

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, 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.

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

8.Cuff pressure range 0-299mmHg FEATURES OF THE PRODUCT 1. Memory can store 90 measurements. 2. Large and clear LCD display 9

INSERT OR REPLACE BATTERIES

1. Remove the battery cover.

polarities(+) and (-)are correct.

model does not have this function.

units(mmHg factory to express).

1. Fastening the wrist cuff

level as your heart.

measure on a bare wrist. 2. How to take proper measurements

For best accuracy in blood pressure measurement: • 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

• Remain still and keep quiet during measurement.

13

15

17

Accuracy:

Power supply:

Operating condition:

Storage condition:

Dimensions:

Classification

Wrist circumference

Weight:

Memory

SYMBOLS ON DISPLAY LCD Display systolic Blood press Diastolic Blood press 18-88 88-88 WHO blood pressu

PARTS IDENTIFICATION

4. Easy to use, Press a button to automatically measure, record the measurement

988 SET Buttor Accessory: Wrist Cuf Manual 10

Disposal of empty battery to the authorized collecting party subject to the regulation of

3. Close the battery cover, Use only LR03, AAA batteries.

each individual territory. **CAUTION** • Insert the batteries as shown in the battery compartment. If not, the device will not work.

2. Insert new batteries into the battery compartment as shown, taking care that the

• When \(\hat{\partial}\) (LOW BATTERY mark) blinks in the display, replace all batteries with new ones. Do not mix old and new batteries. It may shorten the battery life, or cause the device to malfunction. (LOW BATTERY mark) does not appear when the batteries run out. • Please ensure to distinguish positive polar "+" and negative polar "-" of batteries when replacing batteries.

11 4. Press "MEM" key to adjust the month. Following the same steps to adjust date/hour/

minute/Voice (on/off) until setting completed (" In" is the On, " IF" is the Off) Non-talking

testing monitor performance and may have a shorter life. Used batteries may leak and damage the main unit. Pleases observe the following * If you are not going to use the unit for a long period of time (approximately three

• Batteries, which have fluid on surface or be modified, can not be inserted into

• Battery life varies with the ambient temperature and may be shorten at low

• Use the specified batteries only. The batteries provided with the device are for

months or more), remove the batteries. * Replace worn batteries with their polarities in the correct direction. TIME AND VOICE ON/OFF OF SYSTEM SETUP 1. Press "SET" key to Time display. 2. In the off state, Press and hold "SET" key until the year number

displays and flashes on LCD to enter setting mode. 3. Press "MEM" key to adjust the year, then press "SET" key again to save your setting and enter the month setting mode.

The units will be chosen by the above shows mmHg/kPa after decontrol, After the

• 00 **"**-\on ***** 00 month date minute Voice **UNIT CONVERSION mmHg/kPa DISPLAY**

WHO BLOOD PRESSURE CLASSIFICATION DISPLAY Diastolic blood pressure

Reference material: journal of

hypertension 1999. vol 17 No.2

OFF

Also select memory unit value changes.

nomal boot unit values are shown as blood pressure.

Grade 3 hypertension (severe) Grade 2 hypertension (moderate) Grade 1 hypertension (mild) High-normal

14

16

18

20

28

 $d = \left[\frac{7}{E_1}\right]\sqrt{P}$

0.23

0.73

2.3

7.3

23

press "MEM" key to select mmHg / KPa, press "ON / OFF" button to exit.

ATTACHING THE WRIST CUFF

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

Press "ON / OFF" button for 10 seconds to display unit switching interface, then

1) Wrap the wrist cuff around your wrist about (1-2)cm above your hand as shown in the figure at the right. 2) Fasten the wrist cuff tightly by using the Velcro Strip. For proper measurements, fasten the wrist cuff tightly and

Optimal

3. Start measurement, the cuff in the strap will automatically inflate.

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The mark(♥)will flash on LCD. When complete, the results will be displayed.



* Then air dry the cuff.

humidity or direct sunlight.

CAUTION

STATEMENT

ERROR DISPLAY

Nothing is displayed

When you push the

POWER button or

Battery icon flash

in such an environment

HOW TO MEASURE BLOOD PRESSURE 1. Fasten the wrist cuff according to the instructions in "ATTACHING THE WRIST CUFF." 2. Press the "ON/OFF" button. All icons appear two seconds on DISPLAY, then switch to

• Do not measure left after physical exercise or a bath. • Measure your blood pressure at about the same time every day.

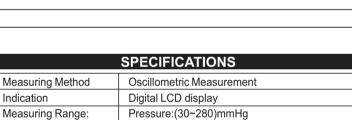
displayed regardless of period). button read out the latest measurement of memory. **DELETE MEMORY**

READ MEMORY Press " MEM " button to inquire memory average values " RUB "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"

×0: 68

CLEAN AND MAINTENANCE

The state read out the memory press the (memory) button five seconds, the LCD display "∏□" has been to delete all memory



2x1.5V Batteries(LR03or AAA)

+5°C~+40°C. 15%RH~93%RH Atmospheric pressure: 70kPa~106kPa

-20°C~+55°C. 0%RH~93%RH

Approx: 66(W)X72(H)X28(D)mm

Approx: 105g, excluding batteries

Atmospheric pressure:50kPa~106kPa

Static Pressure: ± 3 mmHg Pulse: $\pm 5\%$

use alkaline battery, measure above 200 times.

Pulse:(40~199)Beat/min

90 Memories

Type BF

(13.5~19.5)cm * Specifications may be changed without notice in the event of improvement being made. 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. 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.

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

ПО

* 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. • 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 to ensure proper function and performance. * See the Calibration Method for more details. 1. Type of protection against electric shock: INTERNALLY POWERED EQUIPMENT.

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

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

POSSIBLE CAUSE

Battery worn out

placed wrongly

Appendix 1 Guidance and Manufacturer Declaration Tables

No battery installation

The polarities of batteries

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

TROUBLE SHOOTING

HOW TO CORRECT

Replace new batteries

Insert battery in the correct

Insert batteries

polarities

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

Do not subject the monitor to strong snocks, such as dropping the unit on the floor

Do not submerge the device or any of the components in water. Do not subject the monitor to extreme hot or cold temperatures,

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

3. Mode of operation: CONTINUOUS OPERATION

the temperature and humidity as mentioned below:

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

E1:can't normally Increase pressure	Check your wrist cuff if any air leakage	Replace wrist cuff with new one	
E3 inflate pressure too high	Pressure value of more than 299mmHg	Re-measurement or send back dealer for re-calibrate pressure	
E2E4:have shaking while measurement	Hand or body shaking while measurement	keeping static and correct gesture to measure again	
➡ Battery icon on	Battery low power	Replace battery and measure agair	
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	1.The wrist cuff was held higher than your heart		
Pressure value too low	2.you moved your body or Spoke during measurement		

the PG-800A6 Series Electronic Blood Pressure Monitor should assure that it is used in such an environment. **Emissions** Compliance Electromagnetic environment-guidance The PG-800A6 Series Electronic Blood RF emissions Group 1 Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions CISPR 11 are very low and are not likely to cause any interference in nearby electronic equipment. RF emissions Class B The PG-800A6 Series Electronic Blood CISPR 11 Pressure Monitor is used in home and it's Harmonic powered by DC 3V N. A. emissions IEC 61000-3-2 Voltage N. A. fluctuations/flicker emissions IEC 61000-3-3

Guidance and manufacturer's declaration – electromagnetic immunity

The PG-800A6 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the PG-800A6 Series Electronic Blood Pressure Monitor should assure that it is used

Guidance and manufacturer's declaration – electromagnetic emissions The PG-800A6 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of

Guidance and manufacturer's declaration – electromagnetic immunity						
the electromag	6 Series Electronic Blood Pressure Monitor is intended for use in gnetic environment specified below. The customer or the user of the ries Electronic Blood Pressure Monitor should assure that it is used vironment.					
Immunity test	Immunity test IEC 60601 test level		Electromagnetic environment- guidance			
Electrostatic discharge (ESD)IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15KV air	kV, ±2 kV, ±4 kV, or ceramic tile. If floors are co				
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60	Hz Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.			
NOTE U_T is the a.c. mains voltage prior to application of the test level						
23						
Radiated RF	10 V/m		(3.5)			
IEC 61000-4-3	80 MHz to 2.7 GHz	10 V/m	$V = \left[\frac{3.5}{E_1}\right] \sqrt{P}$ 80MHz to 800MHz			

 $d = \left[\frac{7}{E}\right] \sqrt{P} \quad 800 \text{MHz to } 2.7 \text{GHz}$

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance		
Conducted RF IEC 61000-4-6	3 Vrms150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHZ outside ISM bandsa	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Models PG-800A6 Series Electronic Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. $d = \left[\frac{3.5}{V_{\rm I}}\right]\sqrt{P}$		
			2		
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.					

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

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz

is affected by absorption and reflection from structures, objects and people.

used exceeds the applicable RF compliance level above, the PG-800A6 Series Electronic Blood Pressure Monitor should be observed to verify normal operation.		Rated maximum Separation distance according to frequency of transmitter output of m
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 PG-800A6 Series Electronic Blood Pressure Monitor is		The PG-800A6 Series Electronic Blood Pressure Monitor is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the PG-800A6 Series Electronic Blood Pressure Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the PG-800A6 Series Electronic Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.
 		26
as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range Interference may occur in the vicinity of equipment marked with the following symbol: (((*)))		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 additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.
where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m). Field strengths from fixed RF transmitters,	MHz; and 40,66 and 80 MHz are MHz to 7,3 MHz, MHZ, 21,0 MHz	are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 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, 7 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 50,0 MHz to 54,0 MHz.

Recommended separation distances between portable and mobile RF communications equipment and the PG-800A6 Series **Electronic Blood Pressure Monitor** 27 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

If abnormal performance is observed, additional measures may be necessary,

such as re-orienting or relocating the PG-800A6 Series Electronic Blood Pressure

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

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. output power rating of the transmitter in watts (W) according to the transmitter NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

propagation is affected by absorption and reflection from structures, objects and people. **CALIBRATION METHOD**

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

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

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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

the member states where the patient is located. Essential performance: Limits of the error of the manometer, ±3mmHg.Reproducibility

Clinical benefits: Accurate measurement of SBP and DBP, clinical performance meets the requirements of ISO 81060-2:2018. 30

transmitter 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.7 GHz W 0.12 0.01 0.12 0.38 0.38 0.1 1 1.2 1.2 10 3.8 3.8

12

100

1. ME devices can be used in exposed environments, including electromagnetic interference environment to ensure basic safety and basic performance unchanged.

12

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1. Press and hold the "ON/OFF, MEM" button at the same time, load the battery, enter

interface to the cuff interface.

of the blood pressure determination, ±3mmHg.