

Date: 2023-04-13 Rev:A/2 PRESSURE MONITOR **Instruction Manual** MODEL: PG-800A4



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CE2862



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INTRODUCTION The Monitor uses the oscillometric method of blood pressure measurement. Measurement Automatic Electronic Blood Pressure Monitor is intended for CUFF." The expected life of the product is 5 years.

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 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 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".

monitor measuring.

used in household or fixed places only.

May cause accident or trouble.

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

cannot express their will, otherwise it will cause harm.

-The PATIENT is an intended OPERATOR

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

even more pronounced.

Patient must follow doctor's instruction and should not perform 1 Caution self-judgment and self-treatment by the measuring result, Self-diagnosis of measured results and treatment are dangerous.

This device should not be used by children under 18 years old or people who

Do not use the unit for purpose other than measuring blood pressure.

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

2

6

8

10

Typical fluctuation within a day

(Measured every five minutes)

be observed)

pictures in or near • .The left icon refers to "general compulsion". The \odot icon indicates something can't be disassembled or "Don' disassemble" in or near \(\mathbb{O} \) . The left icon refers to "general prohibition".

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

Matters involving actual compulsory actions are indicated by text or

Matters involving actual compulsory actions are indicated by text or pictures <u>∕!</u> Caution **IP Classification: IP20** Type BF Applied part The following

Please refer to the instructions for use Indicates a medical

Consult instruction for use MD Indicates 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. that the device is MR-unsafe:

symbol indicates

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

-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

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

Do not smoke Exercise regularly Reduce salt and fat intake Have regular physical checkups Maintain proper weight

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 expands.

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:

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 Organization (WHO), and shown in mmHa

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,

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

7. The reading is probably a little lower than measured in the hospital due to the

FEATURES OF THE PRODUCT

greatly on a daily and seasonal basis. It may vary by 30 to 50 mmHg due to various conditions during the day. In

An individual's blood pressure varies

5. Blood pressure variations

chart below.

blood pressure values measured at the upper arm versus at the wrist.

4. Before using, should wash your hands.

otherwise it could cause loss of function.

to "Trouble shooting" of the manual.

8.Cuff pressure range 0-299mmHg

1. Remove the battery cover.

device to malfunction.

when replacing batteries.

model does not have this function.

devices or turn them off.

steady mood at home.

100 pool 95 90 95 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

Grade 3 hypertension (severe)

Grade 2 hypertension (moderate)

concerned by the results of one measurement. Take measurements at the same time every day using the procedure described in this 06 manual, and know your normal 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

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

mmHg

values and measurement time. 5. Automatically turns off (within 1 minute) to save power. **PARTS IDENTIFICATION** SYMBOLS ON DISPLAY LCD Display:
Date and Time
Systolic Blood pressure
Diastolic Blood pressure

medication without first consulting with your doctor.

3. WHO blood pressure classification display.

WHO blood pressur :88 Accessory: Battery Cover Manua CASE • Batteries, which have fluid on surface or be modified, can not be inserted into the products. Battery short circuit must be prevented. • Battery life varies with the ambient temperature and may be shorten at low

1. Memory can store 90 measurements 2. Large and clear LCD display 9

polarities(+) and (-)are correct. 3. Close the battery cover, Use only LR03, AAA batteries. Disposal of empty battery to

INSERT OR REPLACE BATTERIES

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

the authorized collecting party subject to the regulation of each individual territory. CAUTION • Insert the batteries as shown in the battery compartment. If not, the device will not work.

• 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 (LOW BATTERY mark) does not appear when the batteries run out.

I- I 0:00

* 00

"-`on

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

• Please ensure to distinguish positive polar "+" and negative polar "-" of batteries

• The batteries may leak and cause a malfunction. • Use the specified batteries only. The batteries provided with the device are for 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 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.

WHO BLOOD PRESSURE CLASSIFICATION DISPLAY

The units will be chosen by the above shows mmHg/kPa after decontrol, After the nomal boot unit values are shown as blood pressure. Also select memory unit value changes.

Diastolic blood pressure

Reference material: iournal of

hypertension 1999. vol 17 No.2

temperatures.

14

16

18

20

month year date hour minute Voice UNIT CONVERSION mmHg/kPa DISPLAY

ΩÑ

• 00

" 00

The goods have mm Hg(mmHg), kPa (kPa) two kinds of blood pressure display units(mmHg factory to express). Press "ON / OFF" button for 10 seconds to display unit switching interface, then press "MEM" key to select mmHg / KPa, press "ON / OFF" button to exit.

ATTACHING THE WRIST CUFF

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

High-normal Normal Optimal

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 measurement, and display "0" or last measurement record

Grade 3 hypertension (severe)

Grade 1 hypertension (mild)

Grade 2 hypertension (moderate)

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

every day.

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1. Fastening the wrist cuff

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• 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.

READ MEMORY Press " MEM " button to inquire memory average values " RU9 "Average Value displayed regardless of period).

For best accuracy in blood pressure measurement:

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

Display: the latest 3 groups of memory average values (Memory values are the buttons(UP). "SET" button for the memory (DOWN) button read out the latest measurement of memory. DELETE MEMORY

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

2.Do not fold the arm cuff too tightly.

Accuracy

Memory

Power supply

Operating condition

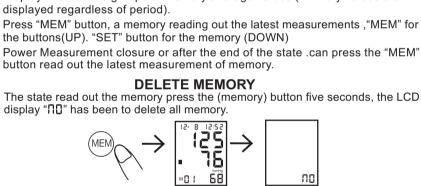
Storage condition

Dimensions

Classification

Wrist circumference

Weight



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

Atmospheric pressure: 70kPa~106kPa

Atmospheric pressure:50kPa~106kPa

use alkaline battery, measure above 200 times.

2x1.5V Batteries(LR03or AAA)

+5°C~+40°C. 15%RH~93%RH

-20°C~+55°C. 0%RH~93%RH

Approx: 66(W)X73(H)X28(D)mm

Approx: 105g, excluding batteries

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

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

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

CAUTION

STATEMENT

ERROR DISPLAY

Nothing is displayed

When you push the

POWER button or

Battery icon flash

used in such an environment.

Emissions

RF emissions

CISPR 11

Conducted RF

50.0 MHz to 54.0 MHz.

humidity or direct sunlight.

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

25

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

lightly moistened with 75% Ethyl alcohol 3 times. Replace the soft cloth after each wipe. * Then air dry the cuff. * Do not submerge the device or any of the components in water. Do not subject the monitor to extreme hot or cold temperatures,

SPECIFICATIONS Measuring Method Oscillometric Measurement Digital LCD display Indication Pressure:(30~280)mmHg Measuring Range 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

CLEAN AND MAINTENANCE

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

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.

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

Battery worn out

placed wrongly

Appendix 1 Guidance and Manufacturer Declaration Tables

Compliance

Group 1

3 Vrms150 kHz

to 80 MHz

6 Vrms

Guidance and manufacturer's declaration – electromagnetic emissions The Model PG-800A4 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A4 Series Electronic Blood Pressure Monitor should assure that it is

No battery installation

The polarities of batteries

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

HOW TO CORRECT

Replace new batteries

Insert battery in the correct

Insert batteries

Electromagnetic environment-guidance

The Model PG-800A4 Series Electronic Blood

Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions

Portable and mobile RF communications

equipment should be used no closer to

any part of the Model PG-800A4 Series

are very low and are not likely to cause any interference in nearby electronic equipment

polarities

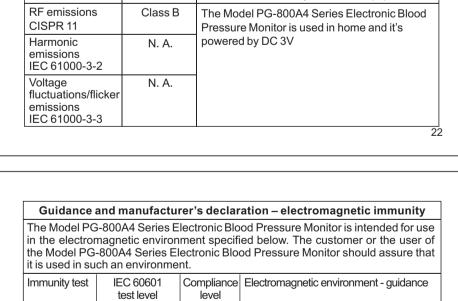
If you have trouble in using the unit please check the following points first.

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 again
The systolic pressure Value or diastolic Pressure value too high	1.The wrist cuff was held lower than your heart	keeping correct position and gesture to measure again
	2.The wrist cuff was not attached properly	
	3. You moved your body or spoke during measurement	
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 Model PG-800A4 Series Electronic Blood Pressure Monitor should assure that it is used in such an environment IEC 60601 Compliance Electromagnetic environment-Immunity test test level level ±8 kV contact ±8 kV contact Electrostatic Floors should be wood, concrete discharge ±2 kV, ±4 kV, ±2 kV, ±4 kV, or ceramic tile. If floors are covered ±8 kV, ±15KV ±8 kV, ±15 KV (ESD)IEC with synthetic material, the relative 61000-4-2 humidity should be at least 30 %. 30 A/m, 50/60Hz 30 A/m, 50/60Hz Power Power frequency magnetic fields should be at levels frequency (50/60 Hz) characteristic of a typical location in a typical commercial magnetic field or hospital environment. IEC 61000-4-8 NOTE U_T is the a.c. mains voltage prior to application of the test level 23 Radiated RF 10 V/m $d = \frac{3.5}{E_1} \sqrt{P} \quad 80 \text{MHz to } 800 \text{MHz}$ IEC 61000-4-3 80 MHz to 2.7 GHz 10 V/m

Guidance and manufacturer's declaration – electromagnetic immunity

The Model PG-800A4 Series Electronic Blood Pressure Monitor is intended for use

in the electromagnetic environment specified below. The customer or the user of

IEC 61000-4-6 150 kHz to Electronic Blood Pressure Monitor, including cables, than the recommended 30 MHZ outside ISM bandsa separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance 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 is affected by absorption and reflection from structures, objects and people

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

N/A

as determined by an electromagnetic site b The compliance levels in the ISM frequency bands between 150 kHz and 80 survey, a should be less than the MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease compliance level in each frequency range the likelihood that mobile/portable communications equipment could cause Interference may occur in the vicinity interference if it is inadvertently brought into patient areas. For this reason, an of equipment marked with the following additional factor of 10/3 has been incorporated into the formulae used in symbol: (((•))) calculating the recommended separation distance for transmitters in these frequency ranges. 25 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-800A4 Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Model Rated maximum PG-800A4 Series Electronic Blood Pressure Monitor should be observed to verify output of normal operation. If abnormal performance is observed, additional measures may transmitter 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.7 GHz be necessary, such as re-orienting or relocating the Model PG-800A4 Series W Electronic Blood Pressure Monitor. d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. 0.01 0.12 0.38 0.1

 $d = \left| \frac{7}{E_1} \right| \sqrt{P}$ 800MHz to 2.7GHz

where P is the maximum output power

and d is the recommended separation

according to the transmitter manufacturer

Field strengths from fixed RF transmitters,

rating of the transmitter in watts (W)

distance in metres(m).

The Model PG-800A4 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 Model PG-800A4 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 Model PG-800A4 Series Electronic Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment. Separation distance according to frequency of transmitter

0.12

0.38

2.3 1 1.2 1.2 10 3.8 3.8 7.3 100 12 12 23 28 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.

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**

Recommended separation distances between

portable and mobile RF communications equipment and the Model PG-800A4

Series Electronic Blood Pressure Monitor

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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency

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manufacturer.

range applies.

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. 29

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

⚠ Caution 1. ME devices can be used in exposed environments, including electromagnetic

of the blood pressure determination, ±3mmHg. Clinical benefits: Accurate measurement of SBP and DBP, clinical performance meets

30

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

0.23

0.73

26

interference environment to ensure basic safety and basic performance unchanged.

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

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 requirements of ISO 81060-2:2018.

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