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MODEL: PG-800A5D



C E 2862

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The Monitor uses the oscillometric method of blood pressure measurement. 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

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Typical fluctuation within a day

(Measured every five minutes)

SYMBOLS ON DISPLAY

9 R R

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* 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 \otimes icon indicates prohibitions (what you should not do).

Matters involving actual prohibitions are indicated by text or

Patient must follow doctor's instruction and should not perform

Self-diagnosis of measured results and treatment are dangerous,

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

pictures in or near . The left icon refers to "general prohibition".

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

Matters involving actual compulsory actions are indicated by text or pictures in or near \odot . The left icon refers to "general prohibition". ∕!∖ Caution IP Classification: IP20 Type BF Applied part **Consult instruction** The following

The 1 icon indicates something that is compulsory (what must always

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

avoid any injury to patient.

it could cause injury.

"on/off" button to stop

Do not smoke

Reduce salt and fat intake

Maintain proper weight

otherwise will cause extravasated blood.

Do not knock or drop the main unit.

for use MD Indicates medical device

ure more than 3 times continuously, it should

Exercise regularly

90

Have regular physical checkups

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

Requests from Manufacturer

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

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

Do not measure on the wrist which is on the side of a mastectomy, otherwise

When measuring, it could not exceed 280 mmHg, otherwise Please press

Always use the specified accessories in the manual, the use of other parts

Do not measure your blood pressure over 6 times each day.

Observe the air pressure value from the LCD display.

Do not use force to bend the wrist cuff or the air tube.

not approved by the manufacturer may cause faults or injuries

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

Do not apply the cuff over a wound as this can cause further injury



symbol indicates

that the device

is MR-unsafe:

The device should not be used to judge illness, first aid and continuously monitor measuring 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 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. -Not servicing and maintenance while the ME EQUIPMENT is in use. -The user can maintain the product, the maintenance method is described in the maintenance instructions of manual. -Stop using the equipment immediately, if it is in contact with water. **ABOUT BLOOD PRESSURE**

1. What is blood pressure?

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

2. What is hypertension and how is it controlled?

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

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:

mmHo

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 mmHg Grade 3 hypertension (severe) chart below. 110 105 Grade 2 hypertension (moderate) 5. Blood pressure variations e 100 95 Grade 1 hypertension (mild

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

4. Before using, should wash your hands.

devices or turn them off.

High-norma 85 Norma 80 Optimal 120 130 140 150 160 170 180 Systolic blood pressure mn 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 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.

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**

3. WHO blood pressure classification display.

LCD Display: Date and Time Systolic Blood pressure Diastolic Blood pressure

· Battery short circuit must be prevented.

The batteries may leak and cause a malfunction.

Battery Cover

temperatures.

Measurement No.2

Measurement No.1

SET Button

Take measurements at the same time every

day using the procedure described in this

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

concerned by the results of one

even more pronounced.

measurement.

medication without first consulting with your doctor.

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

WHO blood pressure

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

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

steady mood at home. 8.Cuff pressure range 0-299mmHg **FEATURES OF THE PRODUCT** 1. Memory can store 60/60 measurements. 2. Large and clear LCD display.

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

INSERT OR REPLACE BATTERIES 1. Remove the battery cover.

polarities(+) and (-)are correct.

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1.Fastening the wrist cuff

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3. Close the battery cover, Use only LR03, AAA batteries. Disposal of empty battery to • Batteries, which have fluid on surface or be modified, can not be inserted into the products

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

Accessory

Manual

the authorized collecting party subject to the regulation of each individual territory. CAUTION

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.

Insert the batteries as shown in the battery compartment. If not, the device will not work.

• When 🗓 (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

3. Following the same steps to chose year, month, day, hour, minutes, unit conversion

(mmHg/kPa), voice ON/OFF set (" In " On, " IF" is Off), press " (I) " to change the

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07

4-00

* on

• 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, UNIT AND VOICE SYSTEM SETUP Time set, such as year, month, day, hour, minute; unit conversion; voice ON/OFF set

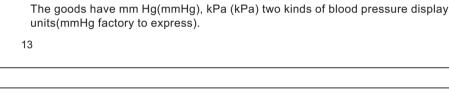
(no voice monitor without this set up function). 1.under Power Off. Press "SET" button, automatically power off in 3 seconds. 2. Press and hold "SET" button until the year number displays and flashes on LCD to enter setting mode. And press " in " button to adjust the year. 12

Boots continued to press the di button exceeding five seconds. The units will be chosen by the above shows mmHg/kPa after decontrol, After the

nomal boot unit values are shown as blood Also select memory unit value changes.

WHO BLOOD PRESSURE CLASSIFICATION DISPLAY

HOW TO MEASURE BLOOD PRESSURE



ATTACHING THE WRIST CUFF

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

2)Fasten the wrist cuff tightly by using the Velcro Strip.

Measure your blood pressure at about the same time every day.

1. under power off. hold (1) or (2) for 3 seconds, get into relative

memory mode, it reads average of latest 3 measurements,

*If you forget to turn it off, will automatically power off in one minute.

3. Delete memory (all the memory will be deleted) Showing memory, hold

"SET" for 5 seconds, display " П□" means all the memories have

*More than 60 measurements, it will deletes the earliest one automatically.

CLEAN AND MAINTENANCE

SPECIFICATIONS

Digital LCD display

90 Memories

Oscillometric Measurement

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

2x1.5V Batteries(LR3 or AAA)

+5°C~+40°C. 30%RH~80%RH

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

Atmospheric pressure: 86kPa~106kPa

use alkaline battery, measure above 200 times.

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

press for the buttons (UP). "SET" button for the

*The stored memory will not lose after replacing battery.

voice report (monitor with talking system only)

* After measurement, press "SET"

2.Do not fold the arm cuff too tightly.

Measuring Method

Measuring Range:

Indication

Accuracy:

Memory:

Power supply:

Operating condition:

2. Press (1) or (2), to cut off the power.

memory (DOWN)

been deleted.

17

your hand as shown in the figure at the right.

UNIT CONVERSION mmHg/kPa DISPLAY

For proper measurements, fasten the wrist cuff tightly and 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.

MEMORY STORAGE

High-normal Normal Optimal

Set up the wrist cuff to your wrist as previous

1.Press (1) or (2) button, the display shows "0",

Inflation icon flashes on display when it begins

2. Automatic deflation after measurement and display

the blood pressure, heart rate, and blood pressure

indicator, voice report (monitor with talking system only)

Mistake, display "E", please refer to the instruction about

section of "ATTACHING THE WRIST CUFF"

• During the inflation, please do not move

troubleshooting.

Diastolic blood pressure

Reference material: journal of

hypertension 1999. vol 17 No.2

Grade 3 hypertension (severe)

Grade 1 hypertension (mild)

Grade 2 hypertension (moderate)

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16

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 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 right after physical exercise or a bath. Rest twenty or thirty minutes before taking measurement.

• If cuff remove during the measurement, please fix the cuff and test again. • Stop the measurement in emergency, please press [1] or [2], to cut off the Automatic deflation at the same time. 3. Power off. Press $\bigcap_{[1]}$ or $\bigcap_{[2]}$, to cut off the power.

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.

3. Clean the monitor with a soft dry cloth. Do not use any cleaning solution.

* Then air dry the cuff. **CAUTION** * Do not submerge the device or any of the components in water. Do not subject the monitor to extreme hot or cold temperatures, humidity or direct

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

the temperature and humidity as mentioned below:

When you push the

POWER button or

Emissions

RF emissions

RF emissions

CISPR 11

CISPR 11

Harmonic

emissions IEC 61000-3-2

emissions IEC 61000-3-3

fluctuations/flicker

Voltage

Battery icon flash

that it is used in such an environment

Compliance

Group 1

Class B

N. A.

N. A.

* Store the device and the components in a clean, safe location. * Do not subject the monitor to strong shocks, such as dropping the unit on the floor. * 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

1. Type of protection against electric shock: INTERNALLY POWERED EQUIPMENT. 2.Degree or protection against electric shock: TYPE BF APPLIED PART. 3. Mode of operation: CONTINUOUS OPERATION. 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

Operating conditions: +5°C~+40°C. 30%RH~80%RH 86kPa~106kPa Storage conditions: -20°C~+55°C. 10%RH~93%RH **TROUBLESHOOTING** If you have trouble in using the unit please check the following points first. **ERROR DISPLAY** POSSIBLE CAUSE HOW TO CORRECT No battery installation Insert batteries Nothing is displayed

Replace new batteries

Electromagnetic environment-guidance

The Model PG-800A5D Series Electronic Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions

The Model PG-800A5D Series Electronic Blood

are very low and are not likely to cause any

Pressure Monitor is used in home and it's

interference in nearby electronic equipment.

polarities

Insert battery in the correct

Battery worn out

placed wrongly

Appendix 1 Guidance and Manufacturer Declaration Tables

Guidance and manufacturer's declaration – electromagnetic emissions

The Model PG-800A5D Series Electronic Blood Pressure Monitor is intended for

use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A5D Series Electronic Blood Pressure Monitor should assure

powered by DC 3V

The polarities of batteries

Guidance and manufacturer's declaration - electromagnetic immunity The Model PG-800A5D Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A5D Series Electronic Blood Pressure Monitor should assure that it is used in such an environment. IEC 60601 Compliance | Electromagnetic environment - guidance test level level 3 Vrms150 kHz Portable and mobile RF communications to 80 MHz equipment should be used no closer to Conducted RF any part of the Model PG-800A5D Series 6 Vrms 150 kHz to Electronic Blood Pressure Monitor, IEC 61000-4-6 80 MHZ outside including cables, than the recommended ISM bandsa separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left| \frac{3.5}{V_1} \right| \sqrt{P}$

magnetic field IEC 61000-4-8 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 $d = \left[\frac{3.5}{E_1}\right] \sqrt{P} \quad 80 \text{MHz to } 800 \text{MHz}$ IEC 61000-4-3 80 MHz to 2.7 GHz $d = \left| \frac{7}{E_{\bullet}} \right| \sqrt{P}$ 800MHz to 2.7GHz 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, as determined by an electromagnetic site

±8 kV, ±15 KV

30 A/m, 50/60Hz

with synthetic material, the relative

humidity should be at least 30 %.

location in a typical commercial

Power frequency magnetic

fields should be at levels

characteristic of a typical

survey, a should be less than the

symbol: (((•)))

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

compliance level in each frequency range

Interference may occur in the vicinity

of equipment marked with the following

±8 kV, ±15KV

30 A/m, 50/60Hz

(ESD)IEC

61000-4-2

frequency

(50/60 Hz)

Power

25

27

29

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. 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.

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

The Model PG-800A6D 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-800A5D 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-800A5D Series Electronic Blood Pressure Monitor as recommended

electromagnetic site survey should be considered. If the measured field strength in the location in which the Model PG-800A5D Series Electronic Blood Pressure below, according to the maximum output power of the communications equipment. Monitor is used exceeds the applicable RF compliance level above, the Model Rated maximum Separation distance according to frequency of transmitter PG-800A5D Series Electronic Blood Pressure Monitor should be observed to verify output of transmitter normal operation. If abnormal performance is observed, additional measures may 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-800A5D Series $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$ $d = \left[\frac{7}{E_1}\right] \sqrt{P}$ Electronic Blood Pressure Monitor. d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. 0.12 0.12 0.23 0.01 0.1 0.38 0.38 0.73 Recommended separation distances between 1.2 1.2 2.3 portable and mobile RF communications equipment and the Model PG-800A5D 10 3.8 3.8 7.3 Series Electronic Blood Pressure Monitor 100 12 12 23

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 manufacturer.

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

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

CALIBRATION METHOD 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.

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

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.

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

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-20°C~+55°C. 10%RH~93%RH Storage condition: Atmospheric pressure:50kPa~106kPa Dimensions: Approx: 67(W)X66(H)X28(D)mm Weight: Approx: 100g, excluding batteries Classification Type BF Wrist circumference (13.5~19.5)cm * Specifications may be changed without notice in the event of improvement being made. E1:can't normally Check your wrist cuff if any Replace wrist cuff with new one Increase pressure air leakage E3 inflate pressure Re-measurement or send back too high dealer for re-calibrate pressure E2E4:have shaking Hand or body shaking keeping static and correct while measurement while measurement gesture to measure again Replace battery and measure again Battery icon on Battery low power 1.The wrist cuff was held The systolic pressure lower than your heart Value or diastolic 2. The wrist cuff was not Pressure value attached properly keeping correct position too high 3. You moved your body or and gesture to measure spoke during measurement again The systolic pressure 1.The wrist cuff was held higher than your heart Value or diastolic Pressure value 2.you moved your body or too low Spoke during measurement 21 Guidance and manufacturer's declaration – electromagnetic immunity The Model PG-800A5D Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A5D 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 guidance Electrostatic ±8 kV contact ±8 kV contact Floors should be wood, concrete discharge ±2 kV, ±4 kV ±2 kV, ±4 kV, or ceramic tile. If floors are covered

Immunity test

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

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

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the requirements of ISO 81060-2:2018.