MODEL: PG-800A6D

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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

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

2

6

Typical fluctuation within a day

(Measured every five minutes)

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".

The Oicon indicates something that is compulsory (what must always Patient must follow doctor's instruction and should not perform self-judgment and self-treatment by the measuring result, Matters involving actual compulsory actions are indicated by text or Self-diagnosis of measured results and treatment are dangerous, pictures in or near • .The left icon refers to "general compulsion".

The Solicon indicates something can't be disassembled or "Don' disassemble" Matters involving actual compulsory actions are indicated by text or pictures in or near \strace{3} . The left icon refers to "general prohibition". ∠! Caution Type BF Applied part IP Classification: IP20

Consult instruction Please refer to the for use instructions for use MD Indicates Indicates a medical

device that needs to be protected from moisture. Contact its local authorities to

medical device determine the proper method

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

ure more than 3 times continuously, it should

Exercise regularly

Have regular physical checkups

hazardous parts and accessories.

otherwise will cause extravasated blood.

Do not knock or drop the main unit.

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

of disposal of potentially bio

is MR-unsafe:

The following

symbol indicates

that the device

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

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

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

the maintenance instructions of manual.

1. What is blood pressure?

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.

ABOUT BLOOD PRESSURE

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

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.

2. Large and clear LCD display.

when replacing batteries.

0.

° on

1.Fastening the wrist cuff

measure on a bare wrist.

memory (DOWN)

been deleted.

Measuring Method

Measuring Range:

Indication

Accuracy:

Memory:

Power supply:

Operating condition:

Storage condition:

Dimensions:

Classification

Wrist circumference

Weight:

21

15

2. How to take proper measurements

" 0Ñ

* 00

90 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

Grade 1 hypertension (mild

day using the procedure described in this 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

hypertensive individuals, variations are

Normally, the blood pressure rises while

Take measurements at the same time every

doctor to interpret your blood pressure data.

3. WHO blood pressure classification display.

values and measurement time.

Battery Cover

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.

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

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

Measurement No.1

SET Button

WHO blood press

9 R R

10

12

14

16

18

20

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

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.

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,

8.Cuff pressure range 0-299mmHg **FEATURES OF THE PRODUCT** 1. Memory can store 60/60 measurements.

9

INSERT OR REPLACE BATTERIES 1. Remove the battery cover. 2. Insert new batteries into the battery compartment as shown, taking care that the polarities(+) and (-)are correct.

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

Disposal of empty battery to

the authorized collecting party subject to the regulation of

07

4-00

* on

• 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 temperatures. The batteries may leak and cause a malfunction.

Accessory

Manual

each individual territory. CAUTION

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

 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 device to malfunction

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

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

" oñ

רם

° oñ

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.

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

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 " $\widehat{\mathbb{H}}$ " button to adjust the year.

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

WHO BLOOD PRESSURE CLASSIFICATION DISPLAY

UNIT CONVERSION mmHg/kPa DISPLAY The goods have mm Hg(mmHg), kPa (kPa) two kinds of blood pressure display units(mmHg factory to express). 13

ATTACHING THE WRIST CUFF

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

For proper measurements, fasten the wrist cuff tightly and

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

Sit comfortably at a table. Rest your wrist on the table.

your hand as shown in the figure at the right.

For best accuracy in blood pressure measurement:

* voice report (monitor with talking system only)

*The stored memory will not lose after replacing battery. 3. Delete memory (all the memory will be deleted) Showing memory,

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

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

hold "SET" for 5 seconds, display " ∏ " means all the memories have

CLEAN AND MAINTENANCE

SPECIFICATIONS

Digital LCD display

90 Memories

Type BF

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

Oscillometric Measurement

Pressure:(30~280)mmHg

2x1.5V Batteries(LR3 or AAA)

+5°C~+40°C. 30%RH~80%RH

-20°C~+55°C. 10%RH~93%RH

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

Approx: 105g, excluding batteries

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

Atmospheric pressure: 86kPa~106kPa

Atmospheric pressure:50kPa~106kPa

use alkaline battery, measure above 200 times.

Pulse:(40~199)Beat/min

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

* After measurement, press "SET"

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

troubleshooting.

Diastolic blood pressure

Reference material: journal of

hypertension 1999. vol 17 No.2

Also select memory unit value changes.

Optimal

Grade 3 hypertension (severe)

Grade 1 hypertension (mild)

High-normal

Normal

Grade 2 hypertension (moderate)

 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.

Measure your blood pressure at about the same time every day

MEMORY STORAGE 1. under power off. hold fin or fight for 3 seconds, get into relative memory mode, it reads average of latest 3 measurements, press fin for the buttons (UP). "SET" button for the

HOW TO MEASURE BLOOD PRESSURE • Set up the wrist cuff to your wrist as previous section of "ATTACHING THE WRIST CUFF" 1.Press (1) or (2) button, the display shows "0", Inflation icon flashes on display when it begins

• 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.

• During the inflation, please do not move

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

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.

Remove the batteries if the unit will not be used for three months or longer. Always

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

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

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

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

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 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.

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

3. Mode of operation: CONTINUOUS OPERATION.

ERROR DISPLAY

Nothing is displayed When you push the

POWER button or

Emissions

RF emissions

RF emissions

CISPR 11

CISPR 11

Harmonic

emissions

Battery icon flash

that it is used in such an environment

Compliance

Group 1

Class B

N. A.

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

the system might not meet its performance specifications if stored or used outside the temperature and humidity as mentioned below: 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.

HOW TO CORRECT

Replace new batteries

Insert battery in the correct

Insert batteries

Electromagnetic environment-guidance

The Model PG-800A6D Series Electronic Blood Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions

The Model PG-800A6D 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

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

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

POSSIBLE CAUSE

Battery worn out

placed wrongly

Appendix 1 Guidance and Manufacturer Declaration Tables

Guidance and manufacturer's declaration – electromagnetic emissions

The Model PG-800A6D Series Electronic Blood Pressure Monitor is intended for

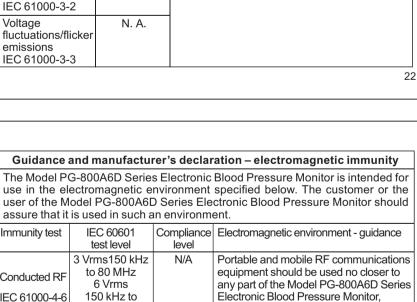
use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A6D Series Electronic Blood Pressure Monitor should assure

No battery installation

The polarities of batteries

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

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 keeping static and correct Hand or body shaking while measurement while measurement gesture to measure again Battery low power Replace battery and measure again Battery icon on 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



powered by DC 3V

Guidance and manufacturer's declaration – electromagnetic immunity The Model PG-800A6D Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A6D 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 ±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 Power 30 A/m, 50/60Hz Power frequency magnetic frequency fields should be at levels characteristic of a typical (50/60 Hz) location in a typical commercial magnetic field IEC 61000-4-8 or hospital environment. NOTE U_{τ} 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

Conducted RF 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 $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$ 24 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.

distance in metres(m). Field strengths from fixed RF transmitters, 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: (((•))) 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-800A6D Series Electronic Blood Pressure

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

where P is the maximum output power

and d is the recommended separation

according to the transmitter manufacturer

rating of the transmitter in watts (W)

Monitor is used exceeds the applicable RF compliance level above, the Model PG-800A6D 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-800A6D 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-800A6D

Series Electronic Blood Pressure Monitor

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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

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.

1.2 1.2 2.3 10 3.8 3.8 7.3 100 12 12 23

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

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 the member states where the patient is located. of the blood pressure determination, ±3mmHg.

frequency ranges.

0.01 0.1

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

 $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$

0.12

0.38

Clinical benefits: Accurate measurement of SBP and DBP, clinical performance meets

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

the requirements of ISO 81060-2:2018.

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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 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

26

28

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

0.23

0.73

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-800A6D 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-800A6D Series Electronic Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment. Rated maximum Separation distance according to frequency of transmitter output of transmitter

150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.7 GHz

0.12

0.38