2

6

Typical fluctuation within a day

06

(Measured every five minutes)

SYMBOLS ON DISPLAY

12

14

16

18

20

22

24

26

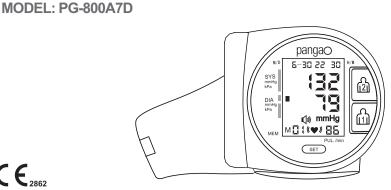
28

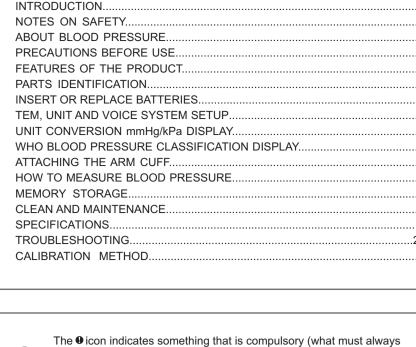
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C E 2862 Rev:A/2





INTRODUCTION 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.

ABOUT BLOOD PRESSURE......6 PRECAUTIONS BEFORE USE.....8 FEATURES OF THE PRODUCT.....9 INSERT OR REPLACE BATTERIES......11 TEM, UNIT AND VOICE SYSTEM SETUP......12 UNIT CONVERSION mmHg/kPa DISPLAY......13 WHO BLOOD PRESSURE CLASSIFICATION DISPLAY......14 ATTACHING THE ARM CUFF......15 HOW TO MEASURE BLOOD PRESSURE......16 MEMORY STORAGE......17 CLEAN AND MAINTENANCE......17 SPECIFICATIONS......19 CALIBRATION METHOD......29

TABLE OF CONTENTS

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 \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

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

be observed).

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

Matters involving actual compulsory actions are indicated by text or

in or near \(\mathbb{O} \) . The left icon refers to "general prohibition". ∠!\ Caution Type BF Applied part IP Classification: IP20 **Consult instruction** The following

for use

Please refer to the instructions for use

MD Indicates Indicates a medical medical device

device that needs to be protected from moisture. Contact its local authorities to determine the proper method

of disposal of potentially bio hazardous parts and accessories.

avoid any injury to patient.

Requests from Manufacturer

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

symbol indicates

that the device

is MR-unsafe:

self-judgment and self-treatment by the measuring result, Self-diagnosis of measured results and treatment are dangerous, The device should not be used to judge illness, first aid and continuously 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.

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.

5

Do not smoke Exercise regularly Have regular physical checkups Reduce salt and fat intake 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 Blood pressure is measured in millimeters of mercury (mmHg). One's natural blood

-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

-The PATIENT is an intended OPERATOR.

the maintenance instructions of manual.

hypertensive individuals, variations are

Normally, the blood pressure rises while

levels during sleep. So, do not be overly

Take measurements at the same time every

Many readings give a more comprehensive

doctor to interpret your blood pressure data.

3. WHO blood pressure classification display.

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

values and measurement time.

LCD Display

• Battery short circuit must be prevented.

(no voice monitor without this set up function).

Diastolic blood pressure

to inflate.

troubleshooting.

* Then air dry the cuff.

POWER button or

Emissions

RF emissions

RF emissions

CISPR 11

CISPR 11

Harmonic

emissions

emissions IEC 61000-3-3

Voltage

IEC 61000-3-2

fluctuations/flicker

Battery icon flash

that it is used in such an environment.

Compliance

Group 1

Class B

N. A.

N. A.

CAUTION

Reference material: journal of

hypertension 1999. vol 17 No.2

Inflation icon flashes on display when it begins

2. Automatic deflation after measurement and display

the blood pressure, heart rate, and blood pressure

Automatic deflation at the same time. 3. Power off. Press (1) or (2), to cut off the power.

indicator, voice report (monitor with talking system only)

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

• If cuff remove during the measurement, please fix the cuff and test again.

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.

* 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.

6.The clean steps for the cuff is provided as following.

• Stop the measurement in emergency, please press (1) or (2), to cut off the

• During the inflation, please do not move

• The batteries may leak and cause a malfunction.

temperatures

manual, and know your normal blood pressure.

day using the procedure described in this

at work or play and falls to its lowest

concerned by the results of one

even more pronounced.

blood pressure history

measurement.

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:

mmHa

150

110

90 70 50

₾ 130

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

chart below.

pressure readings, supplements the doctor's readings and provides a more accurate, complete blood pressure history.

3. Why measure blood pressure at home?

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 Grade 3 hypertension (severe)

110 105 100

95 90

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

High-norma 85 Normal Optimal 1 140 150 160 170 180 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 2 hypertension (moderate)

Grade 1 hypertension (mild)

appropriate time to measure your blood pressure. NEVER change a prescribed medication without first consulting with your doctor.

Be sure to note date and time when recording your blood pressure. Consult your

PRECAUTIONS BEFORE USE

1. If you are taking medication, consult with your doctor to determine the most

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

PARTS IDENTIFICATION

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

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

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. 8.Cuff pressure range 0-299mmHg

FEATURES OF THE PRODUCT 1. Memory can store 60/60 measurements. 2. Large and clear LCD display.

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.

Date and Time Systolic Blood pressure Diastolic Blood pressure WHO blood pre 136 <u>₽</u> ۵, Accessory Manual 10 • Batteries, which have fluid on surface or be modified, can not be inserted into the products.

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

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

each individual territory. CAUTION

• 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

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

• 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

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

* 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

2. Press and hold "SET" button until the year number displays and flashes on LCD to enter setting mode. And press " button to adjust the year.

1.under Power Off. Press "SET" button, automatically power off in 3 seconds.

Boots continued to press the in 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

Grade 3 hypertension (severe)

Grade 1 hypertension (mild)

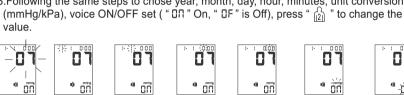
High-normal

Normal

Grade 2 hypertension (moderate)

month year

device to malfunction.



day



07



on

07

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.Fastening the wrist cuff 1)Wrap the wrist cuff around your wrist about (1-2)cm above your hand as shown in the figure at the right.

Optimal **HOW TO MEASURE BLOOD PRESSURE** • Set up the wrist cuff to your wrist as previous section of "ATTACHING THE WRIST CUFF" 1.Press or button, the display shows "0",

 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.

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

Relax for about 5 to 10 minutes before measurement.

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

measure on a bare wrist.

15

2. How to take proper measurements

For best accuracy in blood pressure measurement:

For proper measurements, fasten the wrist cuff tightly and

Measure your blood pressure at about the same time every day

memory (DOWN) * voice report (monitor with talking system only) * After measurement, press "SET 2. Press [1] or [2], to cut off the power.

Indication

Accuracy:

Memory:

Power supply:

Operating condition:

Storage condition:

Dimensions:

Classification

Wrist circumference

Weight:

21

25

27

Immunity test

Measuring Range:

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

MEMORY STORAGE 1. under power off. hold fin or fi2 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. *More than 60 measurements, it will deletes the earliest one automatically. *The stored memory will not lose after replacing battery. 3. Delete memory (all the memory will be deleted) Showing memory, hold "SET" for 5 seconds, display " □□" means all the memories have

SPECIFICATIONS Oscillometric Measurement Measuring Method

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.

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

2x1.5V Batteries(LR3 or AAA)

+5°C~+40°C. 30%RH~80%RH

-20°C~+55°C. 10%RH~93%RH

Approx: 75(W)X68(H)X31(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.

CLEAN AND MAINTENANCE 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.

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.

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

* Do not submerge the device or any of the components in water.

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

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

* Do not subject the monitor to strong shocks, such as dropping the unit on the floor.

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

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 dealer for re-calibrate pressure too high keeping static and correct E2E4:have shaking Hand or body shaking while measurement while measurement gesture to measure again Battery icon on Battery low power Replace battery and measure again 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 Value or diastolic higher than your heart Pressure value 2.you moved your body or too low Spoke during measurement

Guidance and manufacturer's declaration – electromagnetic immunity The Model PG-800A7D Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A7D Series Electronic Blood Pressure Monitor should

Compliance

assure that it is used in such an environment. IEC 60601

test level guidance Electrostatic ±8 kV contact ±8 kV contact Floors should be wood, concrete ±2 kV, ±4 kV, discharge ±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 frequency magnetic Power 30 A/m, 50/60Hz fields should be at levels frequency characteristic of a typical (50/60 Hz) magnetic field location in a typical commercial or hospital environment. IEC 61000-4-8 NOTE U_T is the a.c. mains voltage prior to application of the test level 23 10 V/m \overline{P} 80MHz to 800MHz 10 V/m

3. Mode of operation: CONTINUOUS OPERATION. 4. Equipment not suitable for category AP&APG equipment use in presence. **STATEMENT** 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. **ERROR DISPLAY** POSSIBLE CAUSE **HOW TO CORRECT** No battery installation Insert batteries Nothing is displayed When you push the Battery worn out Replace new batteries

The polarities of batteries

placed wrongly

Appendix 1 Guidance and Manufacturer Declaration Tables

Guidance and manufacturer's declaration – electromagnetic emissions

The Model PG-800A7D Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A7D Series Electronic Blood Pressure Monitor should assure

powered by DC 3V

Insert battery in the correct

polarities

Electromagnetic environment-guidance

The Model PG-800A7D Series Electronic Blood

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

are very low and are not likely to cause any

interference in nearby electronic equipment.

Pressure Monitor is used in home and it's

The Model PG-800A7D Series Electronic Blood

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model PG-800A7D Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A7D Series Electronic Blood Pressure Monitor should assure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance
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 Model PG-800A7D Series Electronic Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
			Recommended separation distance

Radiated RF IEC 61000-4-3 80 MHz to 2.7 GHz \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 survey, a should be less than the 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

Electromagnetic environment-

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

The Model PG-800A7D 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-800A7D 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-800A7D 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 m transmitter 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.7 GHz

Recommended separation distances between portable and mobile RF communications equipment and the Model PG-800A7D **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

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic

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.

3. Connect the external standard barometric interface and the digital barometer

2. Press ON/OFF to close the internal air valve.

interface to the cuff interface.

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

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

it will be reported to the manufacturer and the competent authorities of the user and/or the member states where the patient is located. Notes: Essential performance: Limits of the error of the manometer, ±3mmHg.Reproducibility

30 102

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

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 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

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

electromagnetic site survey should be considered. If the measured field strength in the location in which the Model PG-800A7D Series Electronic Blood Pressure

Monitor is used exceeds the applicable RF compliance level above, the Model

PG-800A7D 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-800A7D Series

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

Electronic Blood Pressure Monitor.

additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

 $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ 0.01 0.23 0.12 0.38 0.38 0.73 0.1 1.2 1.2 2.3 10 7.3 3.8 3.8 100 12 12 23

the value of the digital pressure gauge should be in the range of +/-3mmHg.

event, significant alteration of the product resulting in change of intended use, etc.,

of the blood pressure determination, ±3mmHg. the requirements of ISO 81060-2:2018.

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

output power rating of the transmitter in watts (W) according to the transmitter manufacturer. propagation is affected by absorption and reflection from structures, objects and