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Date: 2023-04-13 Rev:A/2 **MODEL: PG-800A11** 

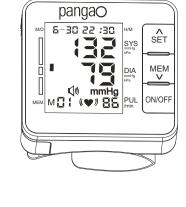


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The • icon indicates something that is compulsory (what must always

Matters involving actual compulsory actions are indicated by text or

CE<sub>2862</sub>



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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 The Monitor uses the oscillometric method of blood pressure measurement.

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.

Patient must follow doctor's instruction and should not perform self-iudgment 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

\* 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".

May cause accident or trouble.

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 \sample . The left icon refers to "general prohibition". Type BF Applied part **IP Classification: IP20** 

Consult instruction 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.

The following symbol indicates that the device is MR-unsafe:

**∕!** Caution

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.

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 maintenance instructions of manual.

-The PATIENT is an intended OPERATOR. -Not servicing and maintenance while the ME EQUIPMENT is in use.

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

can cause many health problems including stroke and heart attack.

-The user can maintain the product, the maintenance method is described in

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

Requests from Manufacturer

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

**ABOUT BLOOD PRESSURE** 1. What is blood pressure? Blood pressure is the force exerted by blood against the walls of the arteries. Systolic

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

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

pressure occurs when the heart contracts. Diastolic pressure occurs when the heart Blood pressure is measured in millimeters of mercury (mmHg). One's natural blood pressure is represented by the fundamental pressure, which is measured first thing in the morning while one is still at rest and before eating. 2. What is hypertension and how is it controlled? Hypertension, an abnormally high arterial blood pressure, if left unattended,

Grade 1 hypertension (mild) 95 An individual's blood pressure varies poold 90 greatly on a daily and seasonal basis. High-norma 85 It may vary by 30 to 50 mmHg due to 80 Optimal various conditions during the day. In 120 130 140 150 160 170 180

3. Why measure blood pressure at home?

accurate, complete blood pressure history.

4. WHO blood pressure classification

Standards for assessment of high blood

pressure, without regard to age, have

been established by the World Health

Organization (WHO), and shown in

5. Blood pressure variations

devices or turn them off.

2. Large and clear LCD display.

1. Remove the battery cover.

**CAUTION** 

polarities(+) and (-)are correct.

units(mmHg factory to express).

1. Fastening the wrist cuff

every day.

15

in the figure at the right

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

4. Before using, should wash your hands.

otherwise it could cause loss of function.

chart below

Systolic blood pressure 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.

each individual territory.

Reference Material: Journal of Hypertension

Grade 3 hypertension (severe)

Grade 2 hypertension (moderate)

1999. Vol 17 No.2

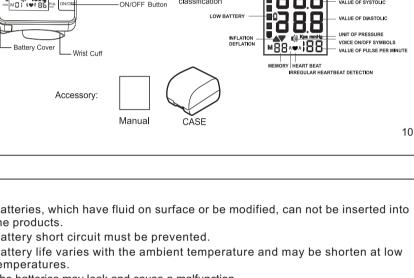
2 110

100 100

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. 8.Cuff pressure range 0-299mmHg **FEATURES OF THE PRODUCT** 1. Memory can store 90 measurements.

**INSERT OR REPLACE BATTERIES** 

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



• 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.  $\ensuremath{\square}$  (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.

model does not have this function.

UNIT CONVERSION mmHg/kPa DISPLAY

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

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

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

\* 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.

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. ON/OFF **"** 07 **"**-000 ŌΠ hour minute Voice

Diastolic blood pressure

Reference material: journal of

hypertension 1999. vol 17 No.2

MEM WHO BLOOD PRESSURE CLASSIFICATION DISPLAY Grade 3 hypertension (severe)

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. 13

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 For best accuracy in blood pressure measurement:

• 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 left after physical exercise or a bath.

**READ MEMORY** Press " MEM " button to inquire memory average values " RUS "Average Value Display: the latest 3 groups of memory average values (Memory values are displayed regardless of period). Press "MEM" button, a memory reading out the latest measurements, "MEM" for the buttons(UP). "SET" button for the memory (DOWN)

**DELETE MEMORY** 

button read out the latest measurement of memory.

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

2.Do not fold the arm cuff too tightly.

Measuring Method

Power supply:

Operating condition:

Storage condition:

Dimensions:

Classification

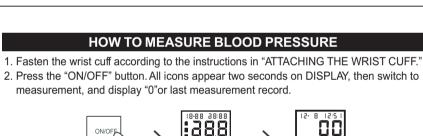
Wrist circumference

Weight:

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

• Measure your blood pressure at about the same time

Optimal 14



Grade 2 hypertension (moderate)

16

18

20

Grade 1 hypertension (mild)

High-normal

3. Clean the monitor with a soft dry cloth. Do not use any cleaning solution. 4.Do not submerge the device or any components in water 5. Store the device and the components in a clean and safe location. 6. The clean steps for the cuff is provided as following. \* Completely wipe the inner side (the side that contacts skin) of the cuff with a soft cloth lightly moistened with 75% Ethyl alcohol 3 times. Replace the soft cloth after each wipe \* 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,

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

• 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

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

to ensure proper function and performance.

See the Calibration Method for more details

\* 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

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

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

Digital LCD display Indication Pressure:(30~280)mmHg Measuring Range: Pulse:(40~199)Beat/min Static Pressure:  $\pm 3$ mmHg Pulse:  $\pm 5\%$ Accuracy: Memory 90 Memories

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 the temperature and humidity as mentioned below: Operating conditions: +5°C~+40°C. 15%RH~93%RH 70kPa~106kPa Storage conditions: -20°C~+55°C. 0%RH~93%RH TROUBLE SHOOTING If you have trouble in using the unit please check the following points first.

Battery worn out

placed wrongly

**Appendix 1 Guidance and Manufacturer Declaration Tables** 

Guidance and manufacturer's declaration – electromagnetic emissions

The Model PG-800A11 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A11 Series Electronic Blood Pressure Monitor should

The polarities of batteries

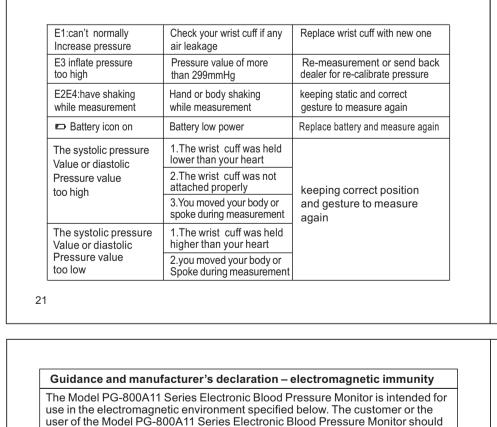
**HOW TO CORRECT** 

Replace new batteries

Insert battery in the correct

Insert batteries

polarities



Compliance

level

±8 kV contact

±2 kV, ±4 kV,

±8 kV, ±15 KV

NOTE U<sub>T</sub> is the a.c. mains voltage prior to application of the test level

30 A/m, 50/60Hz 30 A/m, 50/60Hz Power frequency magnetic

Electromagnetic environmentguidance

Floors should be wood, concrete

or ceramic tile. If floors are covered

with synthetic material, the relative

humidity should be at least 30 %.

location in a typical commercial

fields should be at levels

characteristic of a typical

or hospital environment.

assure that it is used in such an environment.

IEC 60601

test level

±8 kV contact

±2 kV. ±4 kV

±8 kV, ±15KV

Immunity test

Electrostatic

discharge

(ESD)IEC

61000-4-2

frequency

(50/60 Hz)

magnetic field

IEC 61000-4-8

Power

-20°C~+55°C, 0%RH~93%RH

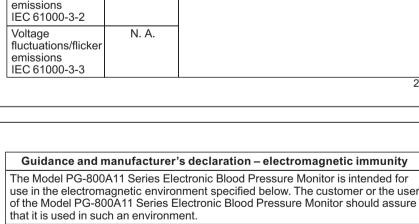
Approx: 72(W)X67(H)X33(D)mm

Approx: 130g, excluding batteries

Type BF

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

Atmospheric pressure:50kPa~106kPa



level

N/A

Compliance Electromagnetic environment - guidance

the transmitter.

Portable and mobile RF communications

any part of the Model PG-800A11 Series

including cables, than the recommended separation distance calculated from the

equation applicable to the frequency of

Recommended separation distance

26

equipment should be used no closer to

Electronic Blood Pressure Monitor,

Radiated RF  $d = \left| \frac{3.5}{E_1} \right| \sqrt{P} \quad 80 \text{MHz to } 800 \text{MHz}$ 10 V/m IEC 61000-4-3 80 MHz to 2.7 GHz  $d = \left| \frac{7}{E_1} \right| \sqrt{P} \quad 800 \text{MHz to } 2.7 \text{GHz}$ 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 Interference may occur in the vicinity of equipment marked with the following symbol: (((•)))

c Field strengths from fixed transmitters, such as base stations for radio (cellular/

electromagnetic site survey should be considered. If the measured field strength

PG-800A11 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-800A11 Series

Electronic Blood Pressure Monitor.

27

29

in the location in which the Model PG-800A11 Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Model

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

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

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

The Model PG-800A11 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-800A11 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-800A11 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 output of 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.7 GHz transmitter  $d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$ 

d Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m. 0.01 0.12 0.12 0.23 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-800A11 10 3.8 3.8 7.3 Series Electronic Blood Pressure Monitor 100 12 12 23 28 4. External input 50mmHg and 200mmHg standard static air pressure, and observe the For transmitters rated at a maximum output power not listed above the air pressure value displayed at the position of the LCD systolic pressure (SYS) and recommended separation distance d in metres (m) can be estimated using the the value of the digital pressure gauge should be in the range of +/-3mmHg. 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 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and

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

Essential performance: Limits of the error of the manometer, ±3mmHg.Reproducibility of the blood pressure determination, ±3mmHg. Clinical benefits: Accurate measurement of SBP and DBP, clinical performance meets the requirements of ISO 81060-2:2018. 30

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: 6 Typical fluctuation within a day hypertensive individuals, variations are (Measured every five minutes) even more pronounced. mmHa 150 Normally, the blood pressure rises while ₾ 130 at work or play and falls to its lowest levels during sleep. So, do not be overly concerned by the results of one 50 measurement. Take measurements at the same time every Diastolic day using the procedure described in this 18 21 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 medication without first consulting with your doctor. 8 3. WHO blood pressure classification display. 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 To prevent such interference, use the monitor at a sufficient distance from such LCD Display: Date and Time Systolic Blood pressure Diastolic Blood pressure SYMBOLS ON DISPLAY 5. Do not measure on the arm which simultaneously used monitoring ME Equipment, Pulse/min SET Button 18-88 38:88 Memory Button WHO blood press classification • 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. • Use the specified batteries only. The batteries provided with the device are for testing monitor performance and may have a shorter life. Disposal of empty battery to Used batteries may leak and damage the main unit. Pleases observe the following the authorized collecting party subject to the regulation of

> month date vear

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

Power Measurement closure or after the end of the state .can press the "MEM" The state read out the memory press the (memory) button five seconds, the LCD ПΟ

**CLEAN AND MAINTENANCE** 

1. Keep this device in the case provided with the device when you do not use it. **SPECIFICATIONS** Oscillometric Measurement 2x1.5V Batteries(LR03 or AAA) use alkaline battery, measure above 200 times.

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

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 **ERROR DISPLAY** POSSIBLE CAUSE No battery installation

Nothing is displayed When you push the

POWER button or

Battery icon flash

CAUTION

humidity or direct sunlight.

assure that it is used in such an environment. **Emissions** Compliance Electromagnetic environment-guidance The Model PG-800A11 Series Electronic Blood RF emissions Group 1 Pressure Monitor uses RF energy only for its CISPR 11 internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment RF emissions Class B The Model PG-800A11 Series Electronic Blood CISPR 11 Pressure Monitor is used in home and it's powered by DC 3V Harmonic N. A. emissions

IEC 60601

test level

3 Vrms150 kHz

to 80 MHz

6 Vrms

150 kHz to

80 MHZ outside

ISM bandsa

Immunity test

Conducted RF

IEC 61000-4-6

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

Rated maximum

frequency ranges

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.,

the member states where the patient is located. **CALIBRATION METHOD** 

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

it will be reported to the manufacturer and the competent authorities of the user and/or