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ELECTRONIC BLOOD PRESSURE MONITOR

pangao

Instruction Manual

MODEL: PG-800A4D

CE 2862

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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.

The product complies with the electromagnetic compatibility requirement of IEC 60601-1-2 and safety standards of IEC 60601-1 and performance of IEC 80601-2-30 as specified in Regulation (EU)2017/745.

NOTES ON SAFETY

* The warning signs and sample icons shown here are listed for your safe and correct use of the unit, so as to prevent injuries or damages to the device.
* The icons and meanings are as follow.

Examples of signs

⊘ The ⊘ icon indicates prohibitions (what you should not do). Matters involving actual prohibitions are indicated by text or pictures in or near ⊘. The left icon refers to "general prohibition".

❗ The ❗ icon indicates something that is compulsory (what must always be observed). Matters involving actual compulsory actions are indicated by text or pictures in or near ❗. The left icon refers to "general compulsion".

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

Type BF Applied part

IP Classification: IP20

⚠ **Caution**

Please refer to the instructions for use

Consult instruction for use

Indicates a medical device that needs to be protected from moisture.

MD Indicates medical device

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

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

MR Unsafe
Do not use this equipment in the MRI scan room

⚠ *Caution* Patient must follow doctor's instruction and should not perform 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.	⊘

Requests from Manufacturer
Make sure there is no connection tubing kinking before start measuring to avoid any injury to patient.
For any patient, do not measure more than 3 times continuously, it should be at least above 5 minutes of interval rest between any two measurements, otherwise will cause extravasated blood.
Do not measure your blood pressure over 6 times each day.
Do not apply the cuff over a wound as this can cause further injury.
Do not measure on the wrist which is on the side of a mastectomy, otherwise it could cause injury.
Observe the air pressure value from the LCD display.
When measuring, it could not exceed 280 mmHg, otherwise Please press "on/off " button to stop
Do not use force to bend the wrist cuff or the air tube.
Do not knock or drop the main unit.
Always use the specified accessories in the manual, the use of other parts not approved by the manufacturer may cause faults or injuries.
For service information, parts list etc., please contact the dealer.

-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?

Blood pressure is the force exerted by blood against the walls of the arteries. Systolic pressure occurs when the heart contracts. Diastolic pressure occurs when the heart expands.

Blood pressure is measured in millimeters of mercury (mmHg). One's natural blood pressure is represented by the fundamental pressure, which is measured first thing in the morning while one is still at rest and before eating.

2. What is hypertension and how is it controlled?

Hypertension, an abnormally high arterial blood pressure, if left unattended, can cause many health problems including stroke and heart attack. Hypertension can be controlled by altering lifestyle, avoiding stress and with medication under a doctor's supervision.
To prevent hypertension or keep it under control:

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

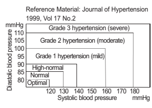
3. Why measure blood pressure at home?

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 been established by the World Health Organization (WHO), and shown in chart below.

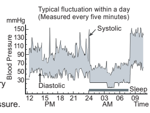
Reference Material: Journal of Hypertension 1999, Vol 17 No.2



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 hypertensive individuals, variations are even more pronounced.

Typical fluctuation within a day (Measured every five minutes)



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 measurement.
Take measurements at the same time every 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 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.

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

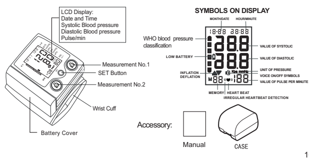
8.Cuff pressure range 0-299mmHg

FEATURES OF THE PRODUCT

1. Memory can store 60/60 measurements.
2. Large and clear LCD display.

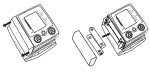
3. WHO blood pressure classification display.
4. Easy to use, Press a button to automatically measure, record the measurement values and measurement time.
5. Automatically turns off (within 1 minute) to save power.

PARTS IDENTIFICATION



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 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 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.

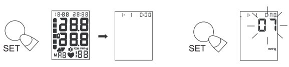
- Batteries, which have fluid on surface or be modified, can not be inserted into the products.
- Battery short circuit must be prevented.
- Battery life varies with the ambient temperature and may be shorten at low temperatures.
- The batteries may leak and cause a malfunction.
- Use the specified batteries only. The batteries provided with the device are for testing monitor performance and may have a shorter life.
- Used batteries may leak and damage the main unit. Pleases observe the following points.
  * 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

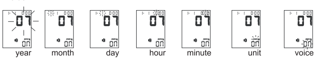
Time set, such as year, month, day, hour, minute; unit conversion; voice ON/OFF set (no voice monitor without this set up function).

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 " ① " button to adjust the year.



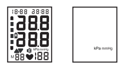
3.Following the same steps to chose year, month, day, hour, minutes, unit conversion (mmHg/kPa), voice ON/OFF set (" On " On, " OF " is Off), press " ② " to change the value.



UNIT CONVERSION mmHg/kPa DISPLAY

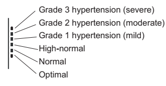
The goods have mm Hg(mmHg), kPa (kPa) two kinds of blood pressure display units(mmHg factory to express).

Boots continued to press the ① 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 pressure.
Also select memory unit value changes.



WHO BLOOD PRESSURE CLASSIFICATION DISPLAY

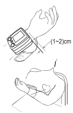
Diastolic blood pressure
Reference material: journal of hypertension 1999. vol 17 No.2


Grade 3 hypertension (severe)
Grade 2 hypertension (moderate)
Grade 1 hypertension (mild)
High-normal
Normal
Optimal

ATTACHING THE WRIST CUFF

1.Fastening the wrist cuff

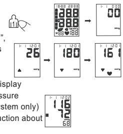
1)Wrap the wrist cuff around your wrist about (1-2)cm above your hand as shown in the figure at the right.
2)Fasten the wrist cuff tightly by using the Velcro Strip. Note).
For proper measurements, fasten the wrist cuff tightly and measure on a bare wrist.



2. How to take proper measurements

For best accuracy in blood pressure measurement:
- Sit comfortably at a table. Rest your wrist on the table.
- 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.

HOW TO MEASURE BLOOD PRESSURE



- Set up the wrist cuff to your wrist as previous section of **"ATTACHING THE WRIST CUFF"**

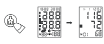
1.Press ① or ② button, the display shows " 0 ", Inflation icon flashes on display when it begins to inflate.
- During the inflation, please do not move

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 troubleshooting.
- 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 power.

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

MEMORY STORAGE

1. under power off. hold ① or ② for 3 seconds, get into relative memory mode, it reads average of latest 3 measurements, press ① for the buttons (UP). "SET" button for the memory (DOWN)
   * voice report (monitor with talking system only)
   * After measurement, press "SET"

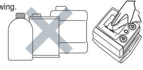


2. Press ① or ②, to cut off the power.
   *If you forget to turn it off, will automatically power off in one minute.
   *More than 60 measurements, it will deletes the earliest one automatically.
   *The stored memory will not lose after replacing battery.
3. Delete memory (all the memory will be deleted) Showing memory, hold "SET" for 5 seconds, display " no " means all the memories have been deleted.

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.

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.



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

SPECIFICATIONS

Measuring Method	Oscillometric Measurement
Indication	Digital LCD display
Measuring Range:	Pressure:(30~280)mmHg Pulse:(40~199)Beat/min
Accuracy:	Static Pressure: ±3mmHg Pulse: ±5%
Memory:	90 Memories
Power supply:	2x1.5V Batteries(LR3 or AAA) use alkaline battery, measure above 200 times.
Operating condition:	+5℃~+40℃. 30%RH~80%RH Atmospheric pressure: 86kPa~106kPa
Storage condition:	-20℃~+55℃. 10%RH~93%RH Atmospheric pressure:50kPa~106kPa
Dimensions:	Approx: 66(W)X73(H)X28(D)mm
Weight:	Approx: 105g, 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.

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 categoryAP&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℃~+40℃. 30%RH~80%RH 86kPa~106kPa
Storage conditions: -20℃~+55℃. 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
Nothing is displayed When you push the POWER button or ▭ Battery icon flash	No battery installation	Insert batteries
	Battery worn out	Replace new batteries
	The polarities of batteries placed wrongly	Insert battery in the correct polarities
E1:can't normally Increase pressure	Check your wrist cuff if any air leakage	Replace wrist cuff with new one
E3 inflate pressure too high		Re-measurement or send back dealer for re-calibrate pressure
E2E4:have shaking while measurement	Hand or body shaking while measurement	keeping static and correct gesture to measure again
▭ Battery icon on	Battery low power	Replace battery and measure again
The systolic pressure Value or diastolic Pressure value too high	1.The wrist cuff was held lower than your heart	keeping correct position and gesture to measure again
	2.The wrist cuff was not attached properly	
	3.You moved your body or spoke during measurement	
The systolic pressure Value or diastolic Pressure value too low	1.The wrist cuff was held higher than your heart	
	2.you moved your body or Spoke during measurement	

Appendix 1 Guidance and Manufacturer Declaration Tables

Guidance and manufacturer's declaration – electromagnetic emissions

The Model PG-800A4D Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A4D Series Electronic Blood Pressure Monitor should assure that it is used in such an environment.

Emissions	**Compliance**	**Electromagnetic environment-guidance**
RF emissions CISPR 11	Group 1	The Model PG-800A4D 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.
RF emissions CISPR 11	Class B	The Model PG-800A4D Series Electronic Blood Pressure Monitor is used in home and it's powered by DC 3V
Harmonic emissions IEC 61000-3-2	N. A.	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N. A.	

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model PG-800A4D Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A4D 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**
Electrostatic discharge (ESD)IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15KV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m, 50/60Hz	30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level			

Guidance and manufacturer's declaration – electromagnetic immunity			
The Model PG-800A4D Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A4D 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-800A4D 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** $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$ 80MHz to 800MHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$ 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 survey, [a] should be less than the compliance level in each frequency range [b] Interference may occur in the vicinity of equipment marked with the following symbol:

NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a The ISM (industrial, scientific and medical) bands between 0,15 MHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHZ, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 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.

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-800A4D Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Model PG-800A4D 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-800A4D 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-800A4D Series Electronic Blood Pressure Monitor

The Model PG-800A4D 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-800A4D 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-800A4D Series Electronic Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	**Separation distance according to frequency of transmitter m**		
	150 kHz to 80 MHz $d=[\frac{3.5}{V_1}]\sqrt{P}$	**80 MHz to 800 MHz** $d=[\frac{3.5}{E_1}]\sqrt{P}$	**800 MHz to 2.7 GHz** $d=[\frac{7}{E_1}]\sqrt{P}$
0.01	0.12	0.12	0.23
0.1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
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 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.

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.

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.

⚠ **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., 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 of the blood pressure determination, ±3mmHg.

Clinical benefits: Accurate measurement of SBP and DBP, clinical performance meets the requirements of ISO 81060-2:2018.