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ELECTRONIC BLOOD PRESSURE MONITOR

pangao

Instruction Manual

MODEL: PG-800A5-1

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INTRODUCTION

The Monitor uses the oscillometric method of blood pressure 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 arm wrist cuff bucked around the upper arm. Please read carefully 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. Please read carefully and pay attention to.

Examples of signs

The ⊘ icon indicates prohibitions (what you should not do).
The ❗ icon indicates instructions (what you should do). The pictures in or nearby. The left icon refers to "general prohibition".

The ❗ icon indicates something that is compulsory (what must always be observed).
Failure to observing actual compulsory actions are indicated by text or pictures in or nearby. The 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** — **The following symbol indicates that the device is MR unsafe**

Indicates a medical device that must be protected from moisture — **Indicates medical device**

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

Patient must follow doctor's instruction and should not perform self-judgment and self-treatment by the measuring result.
Do not measure blood pressure on a moving vehicle or in an emergency.
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 bed places only.
Do not use the device on infants or young children when you feel uncomfortable with the wrist, or if the ar is inflating abnormally without stop.
This device should not be used by children under 18 years old or people who cannot express their wishes it will cause harm.
Do not use the unit for purpose other than measuring blood pressure.
Do not drop or throw the device.
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 modify the main unit or the wrist cuff of the blood pressure monitor.
Will cease the unit to function erroneously.

Requests from Manufacturer

Make sure there is no connection tubing kinking before start measuring to avoid injury to patients.
For any particular, the cuff 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 measure blood pressure on the arm which is on the side of a mastectomy.
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 twist or pull the air tube forcibly.
Please keep the wrist cuff and 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 section 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 relaxes.

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?

Blood pressure is the force exerted by blood against the walls of the left ventricle, can cause many health problems including heart and kidney failure. 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:

hypertensive individuals, variations are even more pronounced. Blood pressure tends to decrease rises while at work or play and tends to lowest levels during sleep. So, do not be overly concerned by the results of one measurement.

Blood 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 accurate picture of blood pressure history.

Be sure to note pulse and time when recording your blood pressure. Consult your doctor to interpret your results.

PRECAUTIONS BEFORE USE

1. If you are taking medication, consult with your doctor to determine the most appropriate time to measure blood pressure. NEVER change a prescribed medication without first consulting with your doctor.

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

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 and allows one to become familiar with one's readings and provides a more accurate, complete blood pressure history.

4. WHO blood pressure classification

Standard for "JNC7 JET" classification purposes, without regard to age, have been established by the World Health Organization (WHO) as shown in chart below.

5. Blood pressure variations

An individual's blood pressure varies from time to time and from moment to moment. It may vary by 30 to 50 mmHg during various conditions during the day. In

2. For people with irregular or unstable peripheral circulation problems due to hypertension, diabetes, or the elderly, it may be difficult to obtain a stable fluctuation in blood pressure values measured at the upper arm cuffs or the arm.
3. Measurements may be impaired if this device is used near televisions, microwave ovens, X-ray medical 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. Do not use the device if the blood pressure 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:0-280mmHg

FEATURES OF THE PRODUCT

1. Memory can store 90 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 batteries is 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 shorter the battery life, or cause the device to malfunction.
- The "LOW BATTERY mark) does not appear when the batteries run out.
- Please ensure to distinguish positive pole "+" and negative pole "-" 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.
- Do not remove any 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 must be taken out of the main unit. Please 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 batteries with fresh polarities in the correct direction.

TIME AND VOICE ON/OFF OF SYSTEM SETUP

1. Press "SET" for 3 seconds to enter the setup mode.
2. In the off state, Press and hold "SET" key until the year number flashes, release the "SET" key to enter the year setup.
3. Press "MEM" key to adjust the year, then press "SET" key again to save year setting and enter the month setting mode.

4. Press "MEM" key to adjust the month. Following the same steps to adjust date/hour/ minute/voice (on/off) until setting completed ("-8" is the On, "-9" is the Off) Non-talking 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 units(mmHg factory to express).

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.

WHO BLOOD PRESSURE CLASSIFICATION DISPLAY

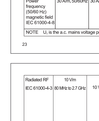
Diastolic blood pressure
Reference material journal of hypertension 1999. vol 17 No.2

- 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) Place 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.
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.
- Sit quietly and ensure 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.
- Measure your blood pressure at about the same time every day.

HOW TO MEASURE BLOOD PRESSURE

1. Fasten the wrist cuff according to the instructions in "ATTACHING THE WRIST CUFF."
2. Press "ON/OFF" button to turn on the power, the unit will display all LCD display, then switch to measurement, and display "0"or last measurement result.

3. Start measurement, the cuff in the strap will automatically inflate.
The mark will flash on LCD. When measurement is complete, the results will be displayed.

READ MEMORY

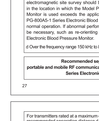
Press " MEM " button to inquire memory average values ("Σ/2"Average Value Display: the latest 3 groups of memory average values (Memory values are displayed regardless of period).

Press "MEM" button to continue reading out the latest measurements , "MEM" for the bottom(SF) "SET" button for the memory (OOMM)

Power Measurement closure or after the end of the state .can press the "MEM" button read out the latest measurement of memory

DELETE MEMORY

The state read out the memory (memory) button five seconds, the LCD display "Dd" then begin to delete all memory.



CLEAN AND MAINTENANCE

1.Keep this device in the case provided with the device when you do not use it.
2.Do not twist 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.Do not place the device in direct sunlight or near a heat source or in a damp location.
6.The clean steps for the arm cuff is provided as follows:
- Completely wipe the inner side (the side that contacts skin) of the cuff with a soft cloth lightly moistened with 75% Ethyl alcohol 2 times. Replace the soft cloth after wipe each.
- Then air dry the cuff.

CAUTION

- Do not submerge the device or any of the components in water.
- Do not place the device in direct sunlight or near a heat source, humidity or direct sunlight.
- Store the device and the components in a clean, safe location.
- Do not bend the air tube and do not place any thing on the tube and 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 that it functions properly.
- See the Calibration Method for more details.

SPECIFICATIONS

Measuring Method	Oscillometric
Indication	Digital LCD display
Measuring Range	Pressure:0~280mmHg Pulse:40~199 beats/min
Accuracy:	Static Pressure : ±3mmHg Pulse : ± 5%
Memory:	90 Memories
Power supply:	2A1.5V Batteries(LR03 or AAA) use alkaline battery, measure above 200 times.
Operating condition:	+5℃~40℃, 15%RH~93%RH Atmospheric pressure: 70kPa~106kPa
Storage condition:	-20℃~+55℃, 0%RH~93%RH Atmospheric pressure:50kPa~106kPa
Dimensions:	Approx: 76(W)X68(H)X32(D)mm
Weight:	Approx: 120g excluding batteries
Classification	Type BF
Wrist circumference	(13.5~21)cm

- Specifications may be changed without notice in the event of improvement being made.

TROUBLE SHOOTING

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 pressing POWER button	No battery installation	Insert batteries
	Battery worn out	Replace new batteries
❗Battery out has	The polarities of batteries placed wrongly	Insert battery in the correct polarities

E1:can't normally increase pressure	Check your cuff and air leakage	Replace wrist cuff with new one	
E3:Inflate pressure too high	Pressure value of more than 280mmHg	Re-measurement or send back dealer for re-calibrate pressure	
E2Error:when while measurement	Hand or body shaking while measurement	keeping static and correct gesture to measure again	
E4 Battery low or	Battery low power	Replace battery and measure again	
The systolic pressure Value or diastolic Pressure value too high	1.The wrist cuff was held by hand or other objects. 2.The wrist cuff was not attached properly.	keeping correct position and gesture to measure again	
	3.You moved your body or spoke during measurement.		
The systolic pressure Value or diastolic Pressure value too low	1.Your blood pressure 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-800A5-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A5-1 Series Electronic Blood Pressure Monitor should assure that it is used in such an environment.

Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The Model PG-800A5-1 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-800A5-1 Series Electronic Blood Pressure Monitor is suitable for use in home and Its 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-800A5-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A5-1 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, ±4kV, ±8 kV, ±15kV air	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Model PG-800A5-1 Series Electronic Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Power frequency (50/60Hz) magnetic field IEC 61000-4-8	30A/m, 50/60Hz	30A/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 is the a.c. mains voltage prior to application of the test level			

Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	N/A

$$d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$$ 80MHz to 800MHz

$$d=\left[\frac{7}{V_1}\right]\sqrt{P}$$ 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 1.800 MHz to 2.000 MHz; 3.500 MHz to 4.000 MHz; 5.300 MHz to 5.405 MHz; 7.100 MHz to 10.150 MHz; 14.000 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. In addition, 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.

Conducted RF IEC 61000-4-6	10 Vrms 150 kHz to 80 MHz outside ISM bands	N/A
	10 Vrms 150 kHz to 80 MHz inside ISM bands	

$$d=\left[\frac{3.5}{V_2}\right]\sqrt{P}$$

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 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 1.800 MHz to 2.000 MHz; 3.500 MHz to 4.000 MHz; 5.300 MHz to 5.405 MHz; 7.100 MHz to 10.150 MHz; 14.000 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. In addition, 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-800A5-1 Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Model PG-800A5-1 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-800A5-1 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-800A5-1 Series Electronic Blood Pressure Monitor

The Model PG-800A5-1 Series Electronic Blood Pressure Monitor is intended for use in electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Model PG-800A5-1 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-800A5-1 Series Electronic Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output power of transmitter W	150 kHz to 80 MHz $d=\left[\frac{3.5}{V_1}\right]\sqrt{P}$	80 MHz to 800 MHz $d=\left[\frac{3.5}{E_1}\right]\sqrt{P}$	800 MHz to 2.7 GHz $d=\left[\frac{7}{E_1}\right]\sqrt{P}$
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

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. Connect the air tube to 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.