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ELECTRONIC BLOOD PRESSURE MONITOR

Instruction Manual

MODEL: PG-800A11-1

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INTRODUCTION

The Monitor uses the oscillometric method of blood pressure measurement. Intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate on adult. 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".

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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't 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: IP22

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 needs to be protected from moisture.

MD Indicates medical device

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

MR Unsafe
Equivalent to a Class IIb device

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.

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

Typical fluctuation within a day (Measured every five minutes)

more pronounced. 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 80 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

SYMBOLS ON DISPLAY

Accessory:

BATTERY LIFE AND CHARGING PRECAUTIONS

The full-charged battery can be used about 120 times under temperature of 23°C inside room, inflating to 180 mmHg (22.6 kPa) every time and twice a day.

The built-in lithium battery can be charged and discharged 300 times.

- If battery symbol flashes, it means that it is out of power, please charge in time.
- Charging method: charge according to the instructions as illustrated in following map, the charging is completed when the screen displays the full charging icon .
- Please deal with the discarded electronic products according to Provisions of the City on Environmental Protection.

Disposal of empty battery to the authorized collecting party subject to the regulation of each individual territory.

TIME AND VOICE ON/OFF OF SYSTEM SETUP

1. Press "SET" key to Time display.
2. In the 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.

4. Press "MEM" key to adjust the month. Following the same steps to adjust date/hour/minute/Voice (on/off) until setting completed ("DP" is the On, "DP" is the Off) Non-talking mode does not have this function.

SELECT USER

When the device is off, press button "CAM/SET" to select the user or , then press button "ON/OFF" to measure blood pressure.

* If need to inquire memories or average values of use or , please firstly press button "CAM/SET" to select the user or, then press button "MEM" to inquire memories or average values.

AVERAGE VALUE INQUIRY

Press "A / K / P" button to inquire various memory average values of user 1 or user 2.

"Average Value Display: the latest 3 groups of memory average values (Memory values are displayed regardless of period).

* "Display of average value in the morning: the latest 3 groups of memory average values measured during 4:00~9:59 every day.

* "Display of average value at night: the latest 3 groups of memory average values measured during 17:00~2:00 (the next day morning) every day.

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 ON/OFF button exceeding five seconds.

The units will be chosen by the above shows mmHg/kPa after decontrol. After the normal 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.

For proper measurements, fasten the wrist cuff tightly and measure on a bare wrist.

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 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 to Power on, display show all then reset to "0", then start measurement, will have voice indication(If have voice feature) Start to inflate, display have inflation icon blink.

* Device already start to measure your pressure when do inflation, please don't move you hand, wrist or arm.

* Now the user can press button CAM/SET to begin Average measurement.

* "CUFF WEARING ICON

The cuff wearing icon can help remind the user whether the cuff is worn correctly or not.

When cuff is worn correctly, it shows . If loosely, it shows in this case, please press [On/Off] button to turn off the power, and then re-wear the cuff correctly before measurement.

* "ERROR PHYSICAL MOVEMENT ICON

Physical movement during measurement may lead to incorrect measurement result. Please re-measure if any physical movement occurs.

OPERATING METHOD OF AVERAGE MEASUREMENT MODULES

1. Press "On/Off" button to turn on the monitor for measurement, when the blood pressure value on LCD screen increases, press [CAM/SET] button to entre Average measurement Modules, and LCD screens "CAM".
2. After 1st measurement, LCD will show 20s countdown then start 2nd measurement.

3. After the second measurement, the blood pressure monitor analyzeths values measured during the first measurement and the second measurement, if these values are within standard scope, the average blood pressure value will be calculated out and displayed on LCD screen.

* If SYS BP1-SYS BP2 ≥ 12mmHg, DIA BP1-DIA BP2 ≥ 6mmHg, it will enter into "20" seconds countdown, and automatically re-start to the third measurement. After finishing measurement,the device will calculate the blood pressure average value, and show it on the LCD screen.

* If pulse rare ≤ 60 or ≥ 110 or irregular heartbeat, blood pressure monitor will automatically take measurements for three times continuously. After finishing measurements,the device will calculate the blood pressure average value and show it on the LCD screen.

After finishing measurements, the air in cuff will automatically discharge. Then

will display the blood pressure value, pulse rate and blood pressure indication on LCD. And there will be voice reminding measurement values (If the product with voice off or without voice function, there will be no voice reminding measurement values).

* If the device can not take measurements and displays "E" on LCD, please refer to the manual instruction.(TROUBLESHOOTING).

* If the cuff is loosed during measurement, please wear the cuff well and take a measurement again.

* It can be stopped measurement halfway if occurs emergency situation. Please press ON/OFF button to turn off power on soft inflating. The air in arm cuff can be automatically discharged.

Finish the measurement. Press the ON/OFF button to turn off the power.

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)

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 press (the memory) button five seconds, the LCD display "n0" will be 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 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:	80 Memories		
Power supply:	DC 3.7V 400mAh measure above 120 times.		
Operating condition:	+5°C~+40°C, 15%RH~93%RH Atmospheric pressure: 70kPa~106kPa		
Storage condition:	-20°C~+55°C, 0%RH~93%RH Atmospheric pressure:50kPa~106kPa		
Dimensions:	Approx: 72(W)X67(H)X22(D)mm		
Weight:	Approx: 120g, 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.

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	No battery installation	Insert batteries	
When you push the POWER button or Battery icon flash	Battery worn out	please charge in time	
	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	Pressure value of more than 299mmHg	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 2. The wrist cuff was not attached properly 3. You moved your body or spoke during measurement	keeping correct position and gesture to measure again
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-800A11-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A11-1 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-800A11-1 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 Harmonic emissions IEC 61000-3-2 Voltage fluctuations/flicker emissions IEC 61000-3-3	Class B N. A.	The Model PG-800A11-1 Series Electronic Blood Pressure Monitor is used in home and it's powered by DC 3V	

Guidance and manufacturer's declaration –electromagnetic immunity			
The Model PG-800A11-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A11-1 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 IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, (ESD)IEC 61000-4-2	±8 kV contact ±2 kV, ±5 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_i is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer's declaration –electromagnetic immunity			
The Model PG-800A11-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A11-1 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
Conducted RF IEC 61000-4-6	3 Vrms/150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHz outside ISM bands	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Model PG-800A11-1 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 $d = \frac{3.5}{\sqrt{f}} \sqrt{P_t}$

Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	$d = \frac{3.5}{\sqrt{f}} \sqrt{P_t}$ $d = \frac{7}{\sqrt{f}} \sqrt{P_t}$ 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, should be less than the compliance level in each frequency range. Interference may occur in the vicinity of equipment marked with the following symbol:
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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.			

Recommended separation distances between portable and mobile RF communications equipment and the Model PG-800A11-1 Series Electronic Blood Pressure Monitor			
Rated maximum output power of transmitter W	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
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

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-800A11-1 Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Model PG-800A11-1 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-800A11-1 Series Electronic Blood Pressure Monitor.			
d) Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.			

The Model PG-800A11-1 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-800A11-1 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-800A11-1 Series Electronic Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.			
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manufacturer.

NOTE 1: At 800 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 adjust the internal air value