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ELECTRONIC BLOOD PRESSURE MONITOR **pango**
Instruction Manual
 MODEL: PG-800A37-1

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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 **!** icon indicates something that is compulsory (what must always be observed). Matters involving actual compulsory actions are indicated by text or pictures 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 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.

NOTES ON SAFETY

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

Examples of signs

The **⊘** icon indicates prohibition (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".

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

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 50 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.

6. WHO blood pressure classification display.

7. AVG: Average value in the morning, average value at night (see User Manual for details).

8. Average measurement.

PARTS IDENTIFICATION

SYMBOLS ON DISPLAY

USER VOICE TIME

Average value in the morning: 116
 Average value at night: 128
 Average value: 128
 Memory average: 128
 Heart beat: 72

1. Memory can store 50 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.

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.

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 display is off, press button "CAM/SET" to select the user (1) or (2), then press button "ON/OFF" to measure blood pressure.

If need to inquire memories (1) or (2) average values of user (1) or (2), please firstly press button "SET" to select the user or , then press button "MEM" to inquire memories or average values.

AVERAGE VALUE INQUIRY

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

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

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

• **NIGHT** "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.

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.

HOW TO MEASURE BLOOD PRESSURE

1. Fasten the wrist cuff according to the instructions in "ATTACHING THE WRIST CUFF".

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.

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 "CAM/SET" button to turn on the monitor for measurement, when the blood pressure value on LCD screen increases, press [CAM/SET] button to enter 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 analyzes the 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 and displayed on the 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 cuff is loose during measurement, please wrap 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 an stop 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 "MEM" 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 (MEMORY) button five seconds, the LCD display "00" has been to delete all memory.

CLEAN AND MAINTENANCE

1. Keep this device in the case provided with the device when not in use.
 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 in the monitor 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)Beats/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)X21(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.

1. Type of protection against electric shock: INTERNALLY POWERED EQUIPMENT.
 2. Degree of protection against electric shock: TYPE BF APPLIED PART.
 3. Mode of operation: CONTINUOUS OPERATION.
 4. Equipment not suitable for category AP/AGP equipment in presence.

STATEMENT

The system might not meet its performance specifications if stored or used outside the temperature and humidity as mentioned below:
 Operating conditions: +5°C~+40°C, 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.

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

Guidance and manufacturer's declaration - electromagnetic immunity

The Model PG-800A37-1 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A37-1 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, ±4 kV, ±8 kV, ±15 kV 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_i is the a.c. mains voltage prior to application of the test level.

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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-800A37-1 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 $d = \frac{3.5}{\sqrt{f}} \sqrt{P_t}$

For transmitters rated at a maximum output power not listed above the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P_t 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 standard 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.

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.

Recommended separation distances between portable and mobile RF communications equipment and the Model PG-800A37-1 Series Electronic Blood Pressure Monitor

Rated maximum output of transmitter	Separation distance according to frequency of transmitter			
	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz	
W	$d = \frac{3.5}{\sqrt{f}} \sqrt{P_t}$	$d = \frac{3.5}{\sqrt{f}} \sqrt{P_t}$	$d = \frac{3.5}{\sqrt{f}} \sqrt{P_t}$	
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	

The Model PG-800A37-1 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-800A37-1 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-800A37-1 Series Electronic Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment.

For transmitters rated at a maximum output power not listed above the recommended separation distance in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P_t is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

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