

**Shenzhen Pango Medical Electronics Co., Ltd**  
Main Site: Building 2, No. 25 Fenghuang Road, Industrial Zone, Xixiang First Village, Henggang Street, Longgang District, Shenzhen, 518115 Guangdong, P.R. China.  
Additional Site: 2-4 Floor, No. 5 Shanzhuang Rd., Xixiang Village, Xixiang First Village, Henggang Street, Longgang District, Shenzhen, 518115 Guangdong, P.R. China.  
Tel: +86-755-33825989 Fax: +86-755-33825989 Date: 2023-04-13 Rev: A/2

**Lotus N.L.B.V**  
Address: Konijnslaan 10, 16 Land, 2055AA, The Hague, Netherlands.  
Tel: +31 (0)44 1661999

**ELECTRONIC BLOOD PRESSURE MONITOR** **pango**  
Instruction Manual  
MODEL: PG-800A51

**TABLE OF CONTENTS**

INTRODUCTION..... 2  
NOTES ON SAFETY..... 2  
ABOUT BLOOD PRESSURE..... 6  
PRECAUTIONS BEFORE USE..... 8  
FEATURES OF THE PRODUCT..... 9  
PARTS IDENTIFICATION..... 10  
BATTERY LIFE AND CHARGING PRECAUTIONS..... 11  
TIME AND VOICE ON/OFF OF SYSTEM SETUP..... 12  
SELECT USER..... 13  
AVERAGE VALUE INQUIRY..... 14  
UNIT CONVERSION mmHg/kPa DISPLAY..... 14  
WHO BLOOD PRESSURE CLASSIFICATION DISPLAY..... 15  
ATTACHING THE WRIST CUFF..... 15  
HOW TO MEASURE BLOOD PRESSURE..... 16  
OPERATING METHOD OF AVERAGE MEASUREMENT MODULES..... 18  
CLEAN AND MAINTENANCE..... 21  
SPECIFICATIONS..... 23  
TROUBLESHOOTING..... 24  
CALIBRATION METHOD..... 24

**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 linked 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 follows:

**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'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

**Please refer to the instructions for use**

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

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

**Consult instruction for use**

**Medical device**

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

**Caution**

**MR Unsafe**

Patent must follow doctor's instruction and should not perform self-judgment and self-treatment by the measuring result.

Self-judgment 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 two measurements, otherwise will cause exhausted 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
- Exercise regularly
- Reduce salt and fat intake
- 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 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**

- 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.
- 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.

- 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.
- Before using, should wash your hands.
- Do not measure on the arm which simultaneously used monitoring ME Equipment, otherwise it could cause loss of function.
- Consult your doctor if the unexpected readings are obtained, also please refer to "Trouble shooting" of the manual.
- The reading is probably a little lower than measured in the hospital due to the steady mood at home.
- Cuff pressure range 0-299mmHg

**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.

**FEATURES OF THE PRODUCT**

- Memory can store 50 measurements.
- Large and clear LCD display.
- WHO blood pressure classification display.
- Easy to use. Press a button to automatically measure, record the measurement values and measurement time.
- Automatically turns off (within 1 minute) to save power.

**PARTS IDENTIFICATION**

**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.

Connect to adaptor DC output interface with medical safety standard, or PC USB interface (DC 5V≧500mA).

• 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 charged 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**

- Press "SET" key to Time display.
- In the off state, Press and hold "SET" key until the year number displays and flashes on LCD to enter setting mode.
- Press "MEM" key to adjust the year, then press "SET" key again to save your setting and enter the month setting mode.

**AVERAGE VALUE INQUIRY**

Press "A/\*/\*" 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.

**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 user or , please first press button "CAM/SET" to select the user or, then press button "MEM" to inquire memories or average values.

**UNIT CONVERSION mmHg/kPa DISPLAY**

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

**HOW TO MEASURE BLOOD PRESSURE**

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

**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**

- Wrap the wrist cuff around your wrist about (1-2)cm above your hand as shown in the figure at the right.

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 you pressure when do inflation, please don't move you hand, wrist or arm.

**ERROR PHYSICAL MOVEMENT ICON**

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

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

**OPERATING METHOD OF AVERAGE MEASUREMENT MODULES**

- 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 enter Average measurement Modules, and LCD screens "CAM".
- After 1st measurement, LCD will show 20s countdown then start 2nd measurement.

**"C" "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.

3. After the second measurement, the 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.

\* If pulse rare ≤ 60 or ≥ 110 or irregular heartbeats, 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.

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 measurement interference. Please press ON/OFF button to turn off power on stop inflating. The air in arm cuff can be automatically discharged.

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

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

**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).

**CLEAN AND MAINTENANCE**

- Keep this device in the case provided with the device when you do not use it.
- Do not fold the arm cuff too tightly.
- Clean the monitor with a soft dry cloth. Do not use any cleaning solution.
- Do not submerge the device or any components in water
- Store the device and the components in a clean and safe location.

**CAUTION**

- Do not submerge the device or any 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)Beats/min
Accuracy:	Static Pressure: ±3mmHg Pulse: ±5%	
Memory:	90 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	

**Appendix 1 Guidance and Manufacturer Declaration Tables**

**Guidance and manufacturer's declaration - electromagnetic emissions**

The Model PG-800A51 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A51 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-800A51 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.
CISPR 11 Harmonic emissions IEC 61000-3-2	Class B	The Model PG-800A51 Series Electronic Blood Pressure Monitor is used in home and it's powered by DC 3V
Voltage emissions IEC 61000-3-3	N. A.	

**Guidance and manufacturer's declaration - electromagnetic immunity**

The Model PG-800A51 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A51 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 level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±4 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 commercial or hospital environment.

**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 RF 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-800A51 Series Electronic Blood Pressure Monitor**

Rated maximum output power 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	$d = \frac{3.5}{E_1} \sqrt{P}$	$d = \frac{3.5}{E_2} \sqrt{P}$	$d = \frac{3.5}{E_3} \sqrt{P}$
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

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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-800A51 Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Model PG-800A51 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-800A51 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-800A51 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-800A51 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-800A51 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 meters (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.

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

**CALIBRATION METHOD**

- 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.
- Press ON/OFF to close the internal air valve.
- 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**

- ME devices can be used in exposed environments, including electromagnetic interference environment to ensure basic safety and basic performance unchanged.
- 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.

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