Shenzhen Pango Medical Electronics Co., Ltd. Main Site: Building 2, No. 25 Fenghuang Road, Industrial Zone, Xikeng First Village, Henggang Street, Longgang District, Shenzhen, 518115 Guangdong, P. R. China. Additional site I: 2-4 Floor ,No.5 Shanzhuang Rd., Xikeng Village, Henggang Town, Longgang District, Shenzhen, 518115 Guangdong, P. R. China. Tel:+86-755-33825988 Fax:+86-755-33825989

EC REP Lotus NL B.V. Address: Koningin Julianaplein 10, 1e Verd, 2595AA, The Hague, Netherlands.

Date: 2023-04-13



Instruction Manual MODEL: PG-800A52



Rev:A/2



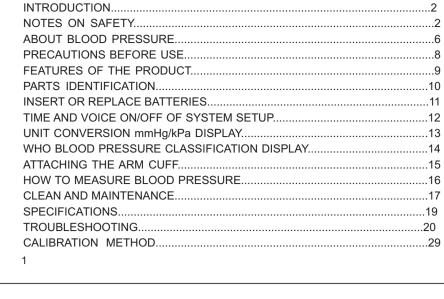


TABLE OF CONTENTS

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."

INTRODUCTION

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".

Patient must follow doctor's instruction and should not perform

Self-diagnosis of measured results and treatment are dangerous.

self-judgment and self-treatment by the measuring result,

Matters involving actual compulsory actions are indicated by text or

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

The • icon indicates something that is compulsory (what must always

in or near \(\mathbb{O} \) . The left icon refers to "general prohibition". $\angle ! \setminus$ Caution Type BF Applied part **IP Classification: IP22** Consult instruction for use The following

Please refer to the instructions for use Indicates a medical device that needs to be

MD Indicates medical device

protected from moisture.

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

symbol indicates

that the device

is MR-unsafe:

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 .lt 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.

-Not servicing and maintenance while the ME EQUIPMENT is in use.

-Stop using the equipment immediately, if it is in contact with water.

-The PATIENT is an intended OPERATOR.

the maintenance instructions of manual.

6

Typical fluctuation within a day

⚠ Caution

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,

Requests from Manufacturer

Make sure there is no connection tubing kinking before start measuring to

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.

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

Observe the air pressure value from the LCD display.

For service information, parts list etc., please contact the dealer.

 Do not smoke Exercise regularly

Maintain proper weight

3. Why measure blood pressure at home?

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

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

5. Blood pressure variations

devices or turn them off.

steady mood at home.

4. Before using, should wash your hands.

otherwise it could cause loss of function.

to "Trouble shooting" of the manual.

8.Cuff pressure range 0-299mmHg

1. Remove the battery cover.

11

13

chart below.

 Reduce salt and fat intake Have regular physical checkups

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

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

5. Do not measure on the arm which simultaneously used monitoring ME Equipment,

6. Consult your doctor if the unexpected readings are obtained, also please refer

7. The reading is probably a little lower than measured in the hospital due to the

FEATURES OF THE PRODUCT

90 85

Normal 80 Optimal

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

-The user can maintain the product, the maintenance method is described in

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

To prevent hypertension or keep it under control:

hypertensive individuals, variations are

Many readings give a more comprehensive

doctor to interpret your blood pressure data.

blood pressure history.

medication under a doctor's supervision.

(Measured every five minutes) mmHq 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 90 70 50 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.

Be sure to note date and time when recording your blood pressure. Consult your

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

Reference Material: Journal of Hypertension

Grade 3 hypertension (severe)

120 130 140 150 160 170 180 Systolic blood pressure mm

Grade 2 hypertension (moderate)

1999, Vol 17 No.2

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

3. WHO blood pressure classification display.

• Battery short circuit must be prevented.

• The batteries may leak and cause a malfunction.

medication without first consulting with your doctor.

values and measurement time. 5. Automatically turns off (within 1 minute) to save power. PARTS IDENTIFICATION

4. Easy to use, Press a button to automatically measure, record the measurement

SYMBOLS ON DISPLAY 388 SET Button (b) **Battery Cover** Accessory Manua 10 • Batteries, which have fluid on surface or be modified, can not be inserted into

1. Memory can store 90 measurements. 2. Large and clear LCD display

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.

INSERT OR REPLACE BATTERIES

Disposal of empty battery to the authorized collecting party subject to the regulation of

each individual territory.

CAUTION • Insert the batteries as shown in the battery compartment. If not, the device will not work. • When 🗓 (LOW BATTERY mark) blinks in the display, replace all batteries with new ones. Do not mix old and new batteries. It may shorten the battery life, or cause the device to malfunction.

model does not have this function.

units(mmHg factory to express).

1. Fastening the wrist cuff

level as your heart.

displayed regardless of period).

every day.

15

in the figure at the right.

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

 Do not measure left after physical exercise or a bath. • Measure your blood pressure at about the same time

the buttons(UP). "SET" button for the memory (DOWN)

button read out the latest measurement of memory

display "∏□" has been to delete all memory.

2.Do not fold the arm cuff too tightly.

Measuring Method

Measuring Range

Indication

Accuracy

Memory

Power supply

Operating condition

Storage condition

Dimensions

Classification

Wrist circumference

Weight

Remain still and keep quiet during measurement.

4. Press "MEM" key to adjust the month. Following the same steps to adjust date/hour/ minute/Voice (on/off) until setting completed (" In" is the On, " IF" is the Off) Non-talking

1- 1-0:00

date

UNIT CONVERSION mmHg/kPa DISPLAY

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

ATTACHING THE WRIST CUFF

READ MEMORY

Press " MEM " button to inquire memory average values " RUS "Average Value

Press "MEM" button, a memory reading out the latest measurements, "MEM" for

Power Measurement closure or after the end of the state .can press the "MEM"

DELETE MEMORY The state read out the memory press the (memory) button five seconds, the LCD

CLEAN AND MAINTENANCE

SPECIFICATIONS

Digital LCD display

90 Memories

Type BF

(13.5~19.5)cm Specifications may be changed without notice in the event of improvement being made.

Oscillometric Measurement

Pressure:(30~280)mmHg

Pulse:(40~199)Beat/min

2x1.5V Batteries(LR03 or AAA)

+5°C~+40°C. 15%RH~93%RH

-20°C~+55°C. 0%RH~93%RH

Approx: 72(W)X67(H)X30(D)mm

Approx: 130g, excluding batteries

Static Pressure: ± 3 mmHg Pulse: $\pm 5\%$

Atmospheric pressure: 70kPa~106kPa

Atmospheric pressure:50kPa~106kPa

use alkaline battery, measure above 200 times.

1. Keep this device in the case provided with the device when you do not use it.

3. Clean the monitor with a soft dry cloth. Do not use any cleaning solution.

75

ПΟ

Display: the latest 3 groups of memory average values (Memory values are

1) Wrap the wrist cuff around your wrist about (1-2)cm above your hand as shown

hour

month

• Please ensure to distinguish positive polar "+" and negative polar "-" of batteries

(LOW BATTERY mark) does not appear when the batteries run out.

testing monitor performance and may have a shorter life. Used batteries may leak and damage the main unit. Pleases observe the following * If you are not going to use the unit for a long period of time (approximately three months or more), remove the batteries.

• Battery life varies with the ambient temperature and may be shorten at low

• Use the specified batteries only. The batteries provided with the device are for

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.

* Replace worn batteries with their polarities in the correct direction.

3. Press "MEM" key to adjust the year, then press "SET" key again to save your setting and enter the month setting mode.

WHO BLOOD PRESSURE CLASSIFICATION DISPLAY

nomal boot unit values are shown as blood pressure.

The units will be chosen by the above shows mmHg/kPa after decontrol, After the Also select memory unit value changes.

mem

Grade 3 hypertension (severe)

Grade 1 hypertension (mild)

High-normal

Normal

Optimal

Grade 2 hypertension (moderate)

14

16

18

20

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.

"-\"\"\"

Voice

minute

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:

Then air dry the cuff.

CAUTION

STATEMENT

ERROR DISPLAY

Nothing is displayed When you push the

POWER button or

Emissions

CISPR 11

RF emissions

Battery icon flash

that it is used in such an environment

that it is used in such an environment

Immunity test

Conducted RF

IEC 61000-4-6

IEC 60601

test level

3 Vrms150 kHz

to 80 MHz

6 Vrms

150 kHz to

80 MHZ outside

ISM bandsa

Compliance

Group 1

Diastolic blood pressure

Reference material: journal of

hypertension 1999. vol 17 No.2

HOW TO MEASURE BLOOD PRESSURE 1. Fasten the wrist cuff according to the instructions in "ATTACHING THE WRIST CUFF." 2. Press the "ON/OFF" button. All icons appear two seconds on DISPLAY, then switch to measurement, and display "0" or last measurement record.

4.Do not submerge the device or any components in water

5. Store the device and the components in a clean and safe location.

68

3. Start measurement, the cuff in the strap will automatically inflate.

The mark will flash on LCD. When complete, the results will be displayed.

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.

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.

the temperature and humidity as mentioned below:

Storage conditions: -20°C~+55°C. 0%RH~93%RH

Operating conditions: +5°C~+40°C. 15%RH~93%RH 70kPa~106kPa

POSSIBLE CAUSE

Battery worn out

placed wrongly

Appendix 1 Guidance and Manufacturer Declaration Tables

No battery installation

The polarities of batteries

TROUBLE SHOOTING

If you have trouble in using the unit please check the following points first.

* Do not submerge the device or any of the components in water.

1. Type of protection against electric shock: INTERNALLY POWERED EQUIPMENT. 2.Degree or protection against electric shock: TYPE BF APPLIED PART. 3. Mode of operation: CONTINUOUS OPERATION 4. Equipment not suitable for category AP&APG equipment use in presence. the system might not meet its performance specifications if stored or used outside

HOW TO CORRECT

Replace new batteries

Insert battery in the correct

Insert batteries

Electromagnetic environment-guidance

The Model PG-800A52 Series Electronic Blood

Pressure Monitor uses RF energy only for its

internal function. Therefore, its RF emissions

Compliance Electromagnetic environment - guidance

Portable and mobile RF communications

equipment should be used no closer to

any part of the Model PG-800A52

polarities

E1:can't normally Check your wrist cuff if any Replace wrist cuff with new one Increase pressure air leakage E3 inflate pressure Re-measurement or send back Pressure value of more dealer for re-calibrate pressure too high than 299mmHg E2E4:have shaking Hand or body shaking keeping static and correct gesture to measure again while measurement while measurement Battery icon on Battery low power Replace battery and measure again 1.The wrist cuff was held The systolic pressure lower than your heart Value or diastolic 2. The wrist cuff was not Pressure value attached properly keeping correct position too high 3. You moved your body or and gesture to measure spoke during measurement The systolic pressure 1. The wrist cuff was held Value or diastolic higher than your heart 2.you moved your body or too low Spoke during measurement 21

Guidance and manufacturer's declaration - electromagnetic immunity

use in the electromagnetic environment specified below. The customer or the

assure that it is used in such an environment.

Immunity test

Electrostatic

discharge

(ESD)IEC

61000-4-2

25

IEC 60601

test level

±8 kV contact

±2 kV, ±4 kV,

±8 kV, ±15KV

The Model PG-800A52 Series Electronic Blood Pressure Monitor is intended for

user of the Model PG-800A52 Series Electronic Blood Pressure Monitor should

Compliance

level

±8 kV contact

±2 kV, ±4 kV,

±8 kV, ±15 KV

Electromagnetic environment-

guidance

Floors should be wood, concrete

or ceramic tile. If floors are covered

with synthetic material, the relative

humidity should be at least 30 %.

are very low and are not likely to cause any interference in nearby electronic equipment RF emissions The Model PG-800A52 Series Electronic Blood Class B CISPR 11 Pressure Monitor is used in home and it's powered by DC 3V Harmonic N. A. emissions IEC 61000-3-2 N. A. Voltage fluctuations/flicker emissions IEC 61000-3-3 22

Guidance and manufacturer's declaration – electromagnetic immunity

The Model PG-800A52 Series Electronic Blood Pressure Monitor is intended for

use in the electromagnetic environment specified below. The customer or the user

of the Model PG-800A52 Series Electronic Blood Pressure Monitor should assure

level

Guidance and manufacturer's declaration - electromagnetic emissions

The Model PG-800A52 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user

of the Model PG-800A52 Series Electronic Blood Pressure Monitor should assure

fields should be at levels frequency (50/60 Hz) characteristic of a typical location in a typical commercial magnetic field or hospital environment. IEC 61000-4-8 NOTE U_{τ} is the a.c. mains voltage prior to application of the test level 23 Radiated RF 10 V/m \sqrt{P} 80MHz to 800MHz 10 V/m IEC 61000-4-3 80 MHz to 2.7 GHz $d = \left| \frac{7}{E_{\cdot}} \right| \sqrt{P}$ 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

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

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-800A52 Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Model PG-800A52 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-800A52 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-800A52 Series Electronic **Blood Pressure Monitor** 27

For transmitters rated at a maximum output power not listed above the

then release the button.

29

interface to the cuff interface.

2. Press ON/OFF to close the internal air valve.

1 1.2 1.2 2.3 10 3.8 3.8 7.3 100 12 12 23 28 4. External input 50mmHg and 200mmHg standard static air pressure, and observe the

0.38

the member states where the patient is located. Essential performance: Limits of the error of the manometer, ±3mmHg.Reproducibility

recommended separation distance d in metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter 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

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

Notes:

of the blood pressure determination, ±3mmHg. Clinical benefits: Accurate measurement of SBP and DBP, clinical performance meets the requirements of ISO 81060-2:2018. 102

30 A/m, 50/60Hz 30 A/m, 50/60Hz Power frequency magnetic Power Interference may occur in the vicinity of equipment marked with the following

symbol:

frequency ranges. c Field strengths from fixed transmitters, such as base stations for radio (cellular/

Rated maximum transmitter

the static air pressure calibration mode after the LCD screen is fully displayed, and 3. Connect the external standard barometric interface and the digital barometer

of the communications equipment.

0.12

0.38

output of

W

0.01

0.1

30

Series Electronic Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of Recommended separation distance 24

26

The Model PG-800A52 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-800A52 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-800A52 Series Electronic Blood Pressure Monitor as recommended below, according to the maximum output power Separation distance according to frequency of transmitter 150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2.7 GHz 0.12

0.73

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