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Measurement Automatic Electronic Blood Pressure Monitor is intended for use by medical professionals or at home to monitor and display diastolic, systolic blood pressure and pulse rate, with an 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.

INTRODUCTION The Monitor uses the oscillometric method of blood pressure measurement.

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".

used in household or fixed places only.

monitor measuring.

C E 2862

This device can not be used for Patient transport and surgical care .It can be

Please press "on/off" button to stop work when you feel uncomfortable with the

Patient must follow doctor's instruction and should not perform

Self-diagnosis of measured results and treatment are dangerous. The device should not be used to judge illness, first aid and continuously

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

wrist, or if the air is inflating abnormally without stop.

-The PATIENT is an intended OPERATOR.

the maintenance instructions of manual.

in the morning while one is still at rest and before eating.

Take measurements at the same time every

manual, and know your normal blood pressure.

day using the procedure described in this

Many readings give a more comprehensive

doctor to interpret your blood pressure data.

3. WHO blood pressure classification display.

5. Automatically turns off (within 1 minute) to save power.

values and measurement time.

Manual

· Battery short circuit must be prevented.

1. Press "SET" key to Time display.

Diastolic blood pressure

Reference material: journal of

the products.

blood pressure history.

2. What is hypertension and how is it controlled?

be observed). Matters involving actual compulsory actions are indicated by text or

3

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

medical device

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

Type BF Applied part

∠! Caution **IP Classification: IP20** Consult instruction The following Please refer to the for use instructions for use MD Indicates Indicates a medical

device that needs to be protected from moisture.

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

Requests from Manufacturer

symbol indicates that the device is MR-unsafe:

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

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.

6

8

10

⚠ Caution

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.

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

**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 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

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

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

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

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:

Hypertension, an abnormally high arterial blood pressure, if left unattended,

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

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 Reference Material: Journal of Hypertension

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

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

been established by the World Health

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.

4. Before using, should wash your hands.

otherwise it could cause loss of function.

to "Trouble shooting" of the manual.

devices or turn them off.

steady mood at home.

device to malfunction.

Diastolic blood 80 120 130 140 150 160 170 180 Systolic blood pressure 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

Grade 3 hypertension (severe)

Grade 2 hypertension (moderate)

Grade 1 hypertension (mild)

1999, Vol 17 No.2

High-normal

105

95 90

85

Typical fluctuation within a day hypertensive individuals, variations are (Measured every five minutes) even more pronounced. 150 Normally, the blood pressure rises while **2** 130 at work or play and falls to its lowest levels during sleep. So, do not be overly concerned by the results of one measurement.

**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.

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

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

PARTS IDENTIFICATION

18

Systolic Blood pressure Diastolic Blood pressu SYMBOLS ON DISPLAY ON/OFF Buttor SET Button WHO blood pr **Battery Cove** 

8.Cuff pressure range 0-299mmHg **FEATURES OF THE PRODUCT** 1. Memory can store 90 measurements. 2. Large and clear LCD display

**INSERT OR REPLACE BATTERIES** 1. Remove the battery cover. Insert new batteries into the battery compartment as shown, taking care that the

polarities(+) and (-)are correct. 3. Close the battery cover, Use only LR03, AAA batteries.

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

• Insert the batteries as shown in the battery compartment. If not, the device will not work.

• When \(\bigsigma\) (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

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

when replacing batteries.

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

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

model does not have this function. **\*** <u>oñ</u> 

date

hour

minute

Voice

month

year

in the figure at the right.

measure on a bare wrist. 2. How to take proper measurements

level as your heart.

displayed regardless of period).

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

E1:can't normally

Increase pressure

E3 inflate pressure

E2E4:have shaking

while measurement

Battery icon on

Value or diastolic

Pressure value

too high

too low

Immunity test

21

27

29

The systolic pressure

The systolic pressure

Value or diastolic

Pressure value

too high

every day.

15

17

13

temperatures. The batteries may leak and cause a malfunction. • Use the specified batteries only. The batteries provided with the device are for testing monitor performance and may have a shorter life.

\* If you are not going to use the unit for a long period of time (approximately three months or more), remove the batteries. \* Replace worn batteries with their polarities in the correct direction.

TIME AND VOICE ON/OFF OF SYSTEM SETUP

• Used batteries may leak and damage the main unit. Pleases observe the following

• Batteries, which have fluid on surface or be modified, can not be inserted into

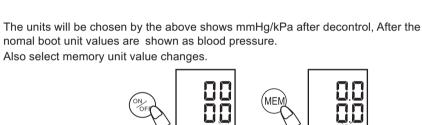
Battery life varies with the ambient temperature and may be shorten at low

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.

Also select memory unit value changes.

nomal boot unit values are shown as blood pressure.

2. In the off state, Press and hold "SET" key until the year number



14

16

18

20

Grade 3 hypertension (severe)

Grade 1 hypertension (mild)

Grade 2 hypertension (moderate)

The goods have mm Hg(mmHg), kPa (kPa) two kinds of blood pressure display units(mmHg factory to express). Press "ON / OFF" button for 10 seconds to display unit switching interface, then press "MEM" key to select mmHg / KPa, press "ON / OFF" button to exit.

UNIT CONVERSION mmHg/kPa DISPLAY

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

**READ MEMORY** 

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

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"

**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

Check your wrist cuff if any

Pressure value of more

Hand or body shaking

1. The wrist cuff was held

lower than your heart

The wrist cuff was not

3. You moved your body or

spoke during measurement

1. The wrist cuff was held

2.you moved your body or

Spoke during measurement

Guidance and manufacturer's declaration - electromagnetic immunity

The Model PG-800A12 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the

user of the Model PG-800A12 Series Electronic Blood Pressure Monitor should

Compliance

level

assure that it is used in such an environment.

IEC 60601

test level

higher than your heart

while measurement

Battery low power

attached properly

air leakage

than 299mmHg

Oscillometric Measurement

Pressure:(30~280)mmHg Pulse:(40~199)Beat/min

2x1.5V Batteries(LR03or AAA)

+5°C~+40°C. 15%RH~93%RH

-20°C~+55°C.0%RH~93%RH

Approx: 62(W)X78(H)X31(D)mm

Approx: 130g, excluding batteries

Static Pressure: ±3mmHg Pulse: ±5%

Atmospheric pressure: 70kPa~106kPa

Atmospheric pressure:50kPa~106kPa

use alkaline battery, measure above 200 times.

Replace wrist cuff with new one

dealer for re-calibrate pressure

keeping static and correct

gesture to measure again

Re-measurement or send back

Replace battery and measure again

keeping correct position

and gesture to measure

Electromagnetic environment-

guidance

again

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

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

2) Fasten the wrist cuff tightly by using the Velcro Strip. For proper measurements, fasten the wrist cuff tightly and

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.

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

button read out the latest measurement of memory.

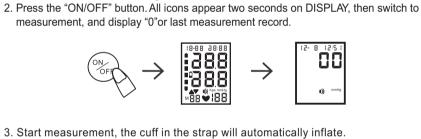
display "∏□" has been to delete all memory.

Raise your hand so that the wrist cuff is at the same

• 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 hypertension 1999. vol 17 No.2 High-normal Normal Optimal

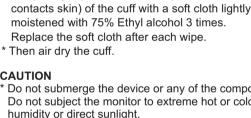
**HOW TO MEASURE BLOOD PRESSURE** 1. Fasten the wrist cuff according to the instructions in "ATTACHING THE WRIST CUFF."

WHO BLOOD PRESSURE CLASSIFICATION DISPLAY



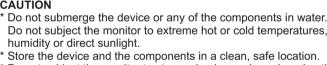
The mark(♥)will flash on LCD. When complete, the results will be displayed.

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



See the Calibration Method for more details.

**CAUTION** 



\* 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.

2.Degree or protection against electric shock: TYPE BF APPLIED PART.

1. Type of protection against electric shock: INTERNALLY POWERED EQUIPMENT.

TROUBLE SHOOTING

**HOW TO CORRECT** 

Replace new batteries

Insert battery in the correct

Insert batteries

Electromagnetic environment-guidance

The Model PG-800A12 Series Electronic Blood

The Model PG-800A12 Series Electronic Blood

equipment should be used no closer to

Electronic Blood Pressure Monitor,

the transmitter.

any part of the Model PG-800A12 Series

including cables, than the recommended

separation distance calculated from the

equation applicable to the frequency of

24

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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.

Pressure Monitor is used in home and it's

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

POSSIBLE CAUSE

Battery worn out

placed wrongly

assure that it is used in such an environment.

Compliance

Group 1

Class B

N. A.

N. A.

to 80 MHz

6 Vrms

150 kHz to

ISM bandsa

30 MHZ outside

No battery installation

The polarities of batteries

4. Equipment not suitable for category AP&APG equipment use 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

**ERROR DISPLAY** 

Nothing is displayed When you push the

POWER button or

**Emissions** 

CISPR 11

CISPR 11

Harmonic

emissions

Voltage

emissions IE(

Conducted RF

IEC 61000-4-6

frequency ranges.

1

RF emissions

RF emissions

IEC 61000-3-2

fluctuations/flicker

Battery icon flash

3. Mode of operation: CONTINUOUS OPERATION

**Appendix 1 Guidance and Manufacturer Declaration Tables** Guidance and manufacturer's declaration – electromagnetic emissions The Model PG-800A12 Series Electronic Blood Pressure Monitor is intended for

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

user of the Model PG-800A12 Series Electronic Blood Pressure Monitor should

	IEC 61000-3-	3					
				22			
Guidance and manufacturer's declaration – electromagnetic immunity							
	use in the election of the Model F	ctromagnetic env PG-800A12 Serie	0A12 Series Electronic Blood Pressure Monitor is intended for magnetic environment specified below. The customer or the user 800A12 Series Electronic Blood Pressure Monitor should assure uch an environment.				
	Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment - guidance			
		3 Vrms150 kHz	N/A	Portable and mobile RF communications			

powered by DC 3V

Floors should be wood, concrete Electrostatic ±8 kV contact ±8 kV contact ±2 kV, ±4 kV, ±2 kV, ±4 kV, or ceramic tile. If floors are covered discharge (ESD)IEC ±8 kV, ±15KV ±8 kV, ±15 KV with synthetic material, the relative 61000-4-2 humidity should be at least 30 %. Power 30 A/m, 50/60Hz 30 A/m, 50/60Hz Power frequency magnetic frequency fields should be at levels characteristic of a typical (50/60 Hz) location in a typical commercial magnetic field or hospital environment. IEC 61000-4-8 NOTE  $U_{\tau}$  is the a.c. mains voltage prior to application of the test level 23 Radiated RF 10 V/m  $d = \frac{3.5}{E_1} \sqrt{P} \quad 80 \text{MHz to } 800 \text{MHz}$ 10 V/m IEC 61000-4-3 80 MHz to 2.7 GHz  $d = \left| \frac{7}{E_1} \right| \sqrt{P}$  800MHz to 2.7GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres(m).

Recommended separation distance 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

The Model PG-800A12 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-800A12 Series Electronic Blood Pressure

				symbol: (((•)))					
2	25								
	(cellular/cord and FM radio with accuracy transmitters, measured fix Electronic Ecompliance Pressure Moperformance re-orienting Pressure Mo	eld strengths from fixed transmitters, such as base stations for radio plar/cordless) telephones and land mobile radios, amateur radio, AM FM radio broadcast and TV broadcast cannot be predicted theoretically accuracy. To assess the electromagnetic environment due to fixed RF smitters, an electromagnetic site survey should be considered. If the sured field strength in the location in which the Model PG-800A12 Series tronic Blood Pressure Monitor is used exceeds the applicable RF pliance level above, the Model PG-800A12 Series Electronic Blood sure Monitor should be observed to verify normal operation. If abnormal primance is observed, additional measures may be necessary, such as inenting or relocating the Model PG-800A12 Series Electronic Blood sure Monitor.							
	Recommended separation distances between portable and mobile RF communications equipment and the Model PG-800A1 Series Electronic Blood Pressure Monitor								

Monitor can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model PG-800A12 Series Electronic Blood Pressure Monitor as recommended below, according to the maximum output power of the communications equipment. Separation distance according to frequency of transmitter Rated maximum output of transmitter 150 kHz to 80 MHz | 80 MHz to 800 MHz | 800 MHz to 2.7 GHz  $d = \left[\frac{7}{E_1}\right]\sqrt{P}$ W 0.12 0.23 0.01 0.12 0.1 0.38 0.38 0.73

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 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

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

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

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

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 interface

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 it will be reported to the manufacturer and the competent authorities of the user and/or

the requirements of ISO 81060-2:2018.

1.2

Notes:

Essential performance: Limits of the error of the manometer, ±3mmHg.Reproducibility Clinical benefits: Accurate measurement of SBP and DBP, clinical performance meets

survey, a should be less than the compliance level in each frequency range Interference may occur in the vicinity

Field strengths from fixed RF transmitters,

as determined by an electromagnetic site

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 NOTE 2 These guidelines may not apply in all situations. Electromagnetic

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event, significant alteration of the product resulting in change of intended use, etc., the member states where the patient is located. of the blood pressure determination, ±3mmHg.