ELECTRONIC BLOOD panga **PRESSURE MONITOR** Instruction Manual MODEL: PG-800A35 pangaO 06:55 06-3 Shenzhen Pango Medical Electronics Co., Ltd MC: (•)85 EC REP Lotus NL B.V. Main Site: Building 2, No. 25 Fenghuang Road, Industrial Address: Koningin Julianaplein 10, 1e Verd, Zone, Xikeng First Village, Henggang Street, Longgang 2595AA, The Hague, Netherlands. District, Shenzhen, 518115 Guangdong, P. R. China. MEM (SET) ON/OFF Tel: +31644168999 Additional site I: 2-4 Floor ,No.5 Shanzhuang Rd., Xikeng Village, Henggang Town, Longgang District, Shenzhen, **CE**₂₈₆₂ 518115 Guangdong, P. R. China. Tel:+86-755-33825988 Fax:+86-755-33825989 Date: 2023-04-13 Rev:A/2

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INTRODUCTION

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

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

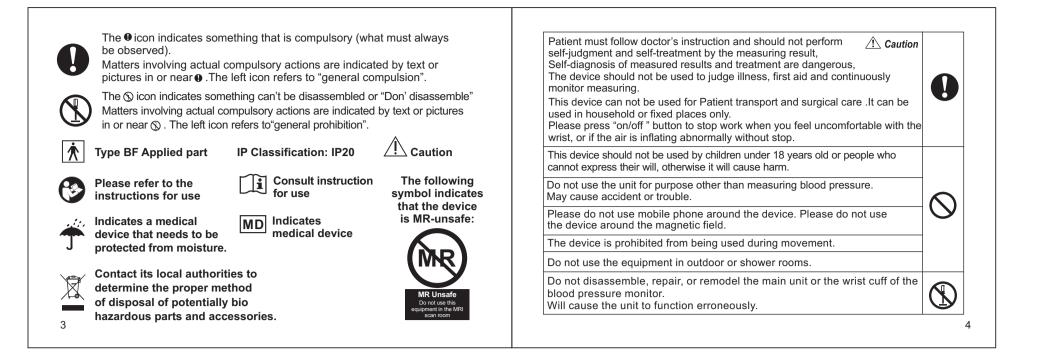
* The warning signs and sample icons shown here are listed for your safe and correct use of the unit, so as to prevent injuries or damages to the device. * The icons and meanings are as follow.

Examples of signs



The \otimes 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".



Requests from Manufacturer

Requests non 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:

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- Do not smoke Exercise regularly Typical fluctuation within a day hypertensive individuals, variations are • Reduce salt and fat intake Have regular physical checkups (Measured every five minutes) even more pronounced. mmHa Maintain proper weight 150 Systolic Normally, the blood pressure rises while 130 at work or play and falls to its lowest 3. Why measure blood pressure at home? levels during sleep. So, do not be overly Blood pressure measured at a clinic or doctor's office may cause apprehension Pre 90 concerned by the results of one and produce an elevated reading, 25 to 30 mmHg higher than that measured at 70 Blood 50 home, Home measurement reduces the effects of outside influences on blood measurement. pressure readings, supplements the doctor's readings and provides a more 30 Take measurements at the same time every Diastolic Sleep accurate, complete blood pressure history. day using the procedure described in this 09 Time 18 21 06 12 15 PM 24 03 AM manual, and know your normal blood pressure. 4. WHO blood pressure classification Many readings give a more comprehensive Standards for assessment of high blood blood pressure history. pressure, without regard to age, have Reference Material: Journal of Hypertension Be sure to note date and time when recording your blood pressure. Consult your been established by the World Health 1999, Vol 17 No.2 doctor to interpret your blood pressure data. Organization (WHO), and shown in mmHg Grade 3 hypertension (severe) ≌ 110 chart below 105 Grade 2 hypertension (moderate) PRECAUTIONS BEFORE USE 5. Blood pressure variations <u> 음</u> 100 Grade 1 hypertension (mild) An individual's blood pressure varies 95 astolic blood 90 1. If you are taking medication, consult with your doctor to determine the most greatly on a daily and seasonal basis. High-norma 85 appropriate time to measure your blood pressure. NEVER change a prescribed It may vary by 30 to 50 mmHg due to Norma 80 Optimal medication without first consulting with your doctor. various conditions during the day. In Di 120 130 140 150 160 170 180 Systolic blood pressure mr mmHg 8 7 2. For people with irregular or unstable peripheral circulation problems due to 3. WHO blood pressure classification display. diabetes, liver disease, hardening of the arteries, etc., there may be fluctuation in 4. Easy to use, Press a button to automatically measure, record the measurement blood pressure values measured at the upper arm versus at the wrist. values and measurement time. 5. Automatically turns off (within 1 minute) to save power. 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. PARTS IDENTIFICATION To prevent such interference, use the monitor at a sufficient distance from such devices or turn them off. LCD Display: Date and Time 4. Before using, should wash your hands. Systolic Blood pressu Diastolic Blood pressu 5. Do not measure on the arm which simultaneously used monitoring ME Equipment, otherwise it could cause loss of function. SYMBOLS ON DISPLAY 6.Consult your doctor if the unexpected readings are obtained, also please refer Memory Button ONTH/DATE HOUR Ē, to "Trouble shooting" of the manual. **ON/OFF** Button 18-88 38-81 SET Button WHO blood press 7. The reading is probably a little lower than measured in the hospital due to the <u>388</u> classification steady mood at home. 8 8 VALUE OF DIASTOLI 8.Cuff pressure range 0-299mmHg Wrist Cuff JNIT OF PRESSURE OICE ON/OFF SYMI **FEATURES OF THE PRODUCT** VALUE OF PULSE PER HEART BEAT 1. Memory can store 90 measurements. Accessory 2. Large and clear LCD display. Manual CASE 10 9 • Batteries, which have fluid on surface or be modified, can not be inserted into **INSERT OR REPLACE BATTERIES**
 - 1. Remove the battery cover.

 - 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.



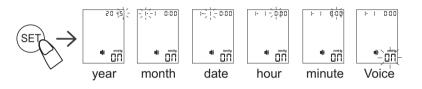


Disposal of empty battery to the authorized collecting party subject to the regulation of each individual territory.

CAUTION

- Insert the batteries as shown in the battery compartment. If not, the device will not work. • When 1 (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.
- (LOW BATTERY mark) does not appear when the batteries run out.
- Please ensure to distinguish positive polar "+" and negative polar "-" of batteries when replacing batteries.
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4. Press "MEM" key to adjust the month. Following the same steps to adjust date/hour/ minute/Voice (on/off) until setting completed (" III" is the On, " IF" is the Of f) Non-talking model does not have this function.



UNIT CONVERSION mmHg/kPa DISPLAY

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.

- the products
- Battery short circuit must be prevented.
- Battery life varies with the ambient temperature and may be shorten at low 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.
- Used batteries may leak and damage the main unit. Pleases observe the following points.
- * 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.

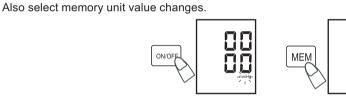
TIME AND VOICE ON/OFF OF SYSTEM SETUP

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.



The units will be chosen by the above shows mmHg/kPa after decontrol, After the nomal boot unit values are shown as blood pressure.

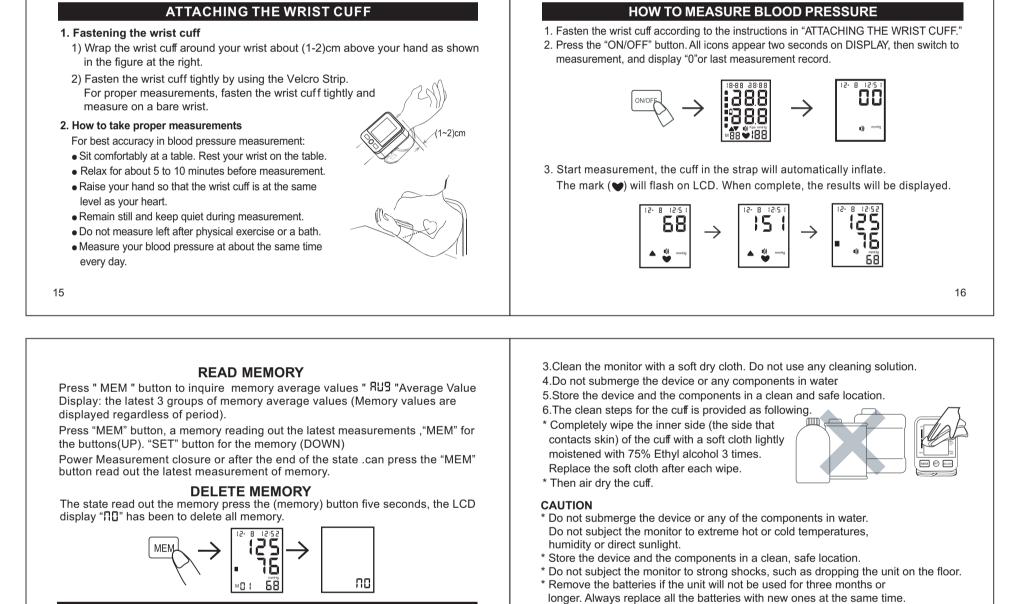


Normal

Optimal

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



- **CLEAN AND MAINTENANCE**
- 1.Keep this device in the case provided with the device when you do not use it. 2.Do not fold the arm cuff too tightly.

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	SPECIFICATIONS
Measuring Method	Oscillometric Measurement
Indication	Digital LCD display
Measuring Range:	Pressure:(30~280)mmHg Pulse:(40~199)Beat/min
Accuracy:	Static Pressure: \pm 3mmHg Pulse: \pm 5%
Memory:	90 Memories
Power supply:	2x1.5V Batteries(LR03or AAA) use alkaline battery, measure above 200 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: 62(W)X78(H)X31(D)mm
Weight:	Approx: 130g, 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. 19
- 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. 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

to ensure proper function and performance.

See the Calibration Method for more details.

TROUBLE SHOOTING
have trouble in using the unit please check the following points first.

 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

lf you have trouble in u	sing 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	Battery worn out	Replace new batteries
POWER button or Battery icon flash	The polarities of batteries placed wrongly	Insert battery in the correct polarities

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

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Guidance and manufacturer's declaration - electromagnetic immunity The Model PG-800A35 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A35 Series Electronic Blood Pressure Monitor should assure that it is used in such an environment.

Appendix 1 Guidance and Manufacturer Declaration Tables

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Guidance and manufacturer's declaration – electromagnetic emissions					
The Model PG-800A35 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A35 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-800A35 Series Electronic Bloo Pressure Monitor uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.			
RF emissions CISPR 11	Class B	The Model PG-800A35 Series Electronic Blood Pressure Monitor is used in home and it's			
Harmonic emissions IEC 61000-3-2	N. A.	powered by DC 3V			
Voltage fluctuations/flicker emissions IEC 61000-3-3	N. A.				
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Guidance and manufacturer's declaration – electromagnetic immunity The Model PG-800A35 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model PG-800A35 Series Electronic Blood Pressure Monitor should assure that it is used in such an environment.

Immunity test	IEC 60601	Compliance	Electromagnetic environment- guidance		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, ±15KV air		Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.			Conducted RF IEC 61000-4-6	3 Vrms150 kHz to 80 MHz 6 Vrms 150 kHz to 80 MHZ outside ISM bandsa		Portable and mobile RF communications equipment should be used no closer to any part of the Model PG-800A35 Series Electronic Blood Pressure Monitor, including cables, than the recommended
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8			Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.					separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d = \left[\frac{3.5}{V_{c}}\right]\sqrt{P}$	
NOTE U _T is th	ne a.c. mains voita	age prior to applic	ation of the test level					2	

Radiated RF 10 V/m		$d = \left[\frac{3.5}{E}\right] \sqrt{P}$ 80MHz to 800MHz	NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies.
IEC 61000-4-3 80 MHz to 2.7 GH	łz 10 V/m		NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.
		$d = \left[\frac{7}{E_1}\right]\sqrt{P} 800 \text{MHz to } 2.7 \text{GHz}$ 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,	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.
		as determined by an electromagnetic site survey, ^a should be less than the compliance level in each frequency range ^b Interference may occur in the vicinity of equipment marked with the following symbol: $((\bullet))$	b The compliance levels in the ISM frequency bands between 150 kHz and 80 MHz and in the frequency range 80 MHz to 2,7 GHz are intended to decrease the likelihood that mobile/portable communications equipment could cause interference if it is inadvertently brought into patient areas. For this reason, an additional factor of 10/3 has been incorporated into the formulae used in calculating the recommended separation distance for transmitters in these frequency ranges.

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-800A35 Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Model PG-800A35 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-800A35 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-800A35 Series Electronic **Blood Pressure Monitor**

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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 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 interface.

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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.

The Model PG-800A35 Series Electronic Blood Pressure Monitor is intended for

use in an electromagnetic environment in which radiated RF disturbances are

Blood Pressure Monitor can help prevent electromagnetic interference by

 $d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$

0.12

0.38

1.2

3.8

12

of the communications equipment.

Rated maximum

output of

transmitter

W

0.01

0.1

1

10

100

controlled. The customer or the user of the Model PG-800A35 Series Electronic

maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the Model PG-800A35 Series Electronic Blood

Pressure Monitor as recommended below, according to the maximum output power

Separation distance according to frequency of transmitter

m

150 kHz to 80 MHz 80 MHz to 800 MHz 800 MHz to 2.7 GHz

 $d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$

0.12

0.38

1.2

3.8

12

 $d = \left[\frac{7}{E_1}\right] \sqrt{P}$

0.23

0.73

2.3

7.3

23

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A 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.

Notes:

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.

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