PG-JS-800A-15-03-A

WRIST ELECTRONIC BLOOD PRESSURE MONITOR

procare

Instruction Manual

MODEL: 240389

CE 0413
FDA Approved

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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 an wrist cuff buckled around one's wrist according to the instructions in the " ATTACHING THE WRIST CUFF" section of this manual. Features of the monitor:

The product complies with the electromagnetic compatibility requirement of EN60601-1-2 and safety standards of EN60601-1 and performance of IEC 80601-2-30 as specified in EEC directive 93/42/EEC.

NOTES ON SAFETY

- The warning signs and sample icons shown here are listed for your safe and correct use of the product, 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).
The ! icon indicates what you must pay attention to (follow the pictures in or near⊘. The left icon refers to "general prohibition".

The ⊘ icon indicates something 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 disassemble" is indicated by text or pictures. Any actions are indicated by text or pictures in or near⊘.. The left icon refers to"general prohibition".

Type BF Applied part

The following symbol indicates that the device is WEEE-compliant.

Please refer to the instructions for use

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

Marking of electrical and electronic equipment in accordance with Article 11(2) of Directive 2002/96/EC (WEEE).

Patient must follow doctor's instruction and should not perform self-judgment and self-treatment by the measured values. Self-diagnosis of measured results and treatment are dangerous, which may delay the time for a patient to receive a continuously monitor measures.

Caution

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

Do not let a child below 12 years old and the people who can't express one's intention. When it used by the people of 12~18 years old, it should accompanied by the Adult. May cause wrong or failure result.

Do not use the cell for purpose other than measuring blood pressure.

Do not disassemble the cell.

Please do not take 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 device without authorization.

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.

Do not measure blood pressure more than 3 times continuously; it should be at least above 5 minutes of interval 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 blood pressure 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 299 mmHg, otherwise Please press "on/off" button to stop.

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

3. Why measure blood press ure at home?

Blood pressure can change a lot. Your doctor's office may cause apprehension and produce an elevated reading. 20 to 30 reading higher than 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 (HBP) and low blood (LBP) been established by the World Health Organization (WHO), and shown in chart below.

5. Blood pressure variations

Blood pressure measurement varies greatly on a daily and seasonal basis. It may vary by 30 to 50 mmHg due to various conditions during the day to

2. For people with irregular or unstable peripheral circulation problems due to diabetes, liver disease, hardening of the arteries, etc., there may be fluctuation in blood pressure values measured at the upper arm versus at the wrist.

3. Measurements may be impaired if this device is used near televisions, microwave ovens, or in areas with strong electromagnetic fields or strong electrical fields. To prevent such interference, use the monitor at a sufficient distance from such devices. or turn them off.

4. Before using, should wash your hands.

5. Do not measure on the arm which simultaneously used monitoring ME Equipment, otherwise it could causing injury.

6.Consult your doctor if the unexpected readings are obtained, also please refer to "Trouble shooting" of the manual.

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

8.Cuff pressure range 0-299mmHg

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.

FEATURES OF THE PRODUCT

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

PARTS IDENTIFICATION

SYMBOLS ON DISPLAY

SYS	systolic	DIA	diastolic
PUL	pulse	MEM	memory
	low battery		irregular heartbeat
	cuff pressure		pulse rate
	blood pressure		mmHg/kPa

INSERT OR REPLACE BATTERIES

1. Remove the battery cover.
2. Insert 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 2 LOW BATTERY mark) blinks in the display, replace ALL batteries with new ones, Do not mix old and new batteries, or different types, such as alkaline, or the cause a device to malfunction.
- If LOW BATTERY mark) does not appear when the batteries run out.
- Please ensure to distinguish positive pole "+" and negative pole "-" of batteries when replacing batteries.

- Batteries, which have fluid on surface or be modified, can not be inserted into the products.
- Battery short circuit must be prevented.
- Battery life varies with the ambient temperature and may be shorten at low temperatures.
- Do not throw away 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. Please 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 new batteries in the correct direction.

SETUP TIME OF SYSTEM

1. Press "SET" key to turn on.
2. Press and hold "SET" key until the pair number displays and flashes on LCD to enter setting mode.

3. Press "SEM" key to adjust the year, then press "SET" key again to save your setting and enter the next setting mode.
4. Press "MEM" key to adjust the month. Following the same steps to adjust date/hour/minute.

UNIT CONVERSION mmHg/kPa DISPLAY

The goods have mm Hg(mmHg), kPa (kPa) two kinds of blood pressure display unit(mmHg factory is express).

Press "ON / OFF" button for 5 seconds to display unit switching interface, then press "MEM" key to select mmHg / kPa, press "ON / OFF" button to exit.

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

Also select memory unit value changes.

WHO BLOOD PRESSURE CLASSIFICATION DISPLAY

ATTACHING THE ARM CUFF

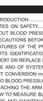
1.Fastening the wrist cuff.

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

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
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 level as your heart.
Remain still and keep quiet during measurement.
Do not measure right after physical exercise or a bath.
Measure your blood pressure at about the same time every day.



HOW TO TAKE PROPER MEASUREMENTS

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" for measurement.

3. Start measurement, the cuff in the strap will automatically inflate.
The mark will flash on LCD. When complete, the results will be displayed.

READ MEMOR Y

Press "MEM" button, a memory reading out the latest measurements ; "MEM" for each additional press, the next set of readings (AVG).

Power Measurement Ensure or after the end of the state ,can press the "MEM" button read out the latest measurement of memory.

DELETE MEMOR Y

The state read out the memory press the (memory) button five seconds, the LCD display "Ea" has been to delete all memory.

CARE AND MAINTENANCE

To keep your digital blood pressure monitor in the best condition and protect the unit from damage, follow the directions listed below:
Keep the monitor and cuff dry. Wipe with soft cloth if necessary to use.
Do not fold the arm cuff too tightly.
The fabric fastener could touch the inner surface of the arm cuff and damage it.

Clean the monitor and cuff with a soft dry cloth.
Do not use any abrasive or volatile cleaners.

CAUTION

- Do not submerge the device or any of the components in water.
- Do not subject the monitor to extreme hot or cold temperatures.
- Do not attempt to repair.
- 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.

The monitor is designed to provide accurate measurement period of time; however, it is generally recommended that it be inspected and calibrated every two years to ensure proper function and performance.
(* Pressure calibration is done by EU representatives)

SPECIFICATIONS

Measuring Method	Oscillometric Measurement
Indication	Digital LCD display
Measuring Range:	Pressure:0~299mmHg Pulse:(40~199)Beat/min
Accuracy:	Static Pressure : 3 mmHg Pulse : ± 5%
Memory:	90 Memories
Power supply:	2x1.5V Batteries(LR03 or AAA) use alkaline battery measure above 200 times
Operating condition:	+5°C~+40°C (41°F~104°F) Atmospheric pressure: 70kPa~106kPa
Storage condition:	-20°C~+55°C (-5°F~131°F) 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.

TROUBLESHOOTING

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

ERROR DISPLAY	POSSIBLE CAUSE	HOW TO CORRECT
Nothing is displayed When you push the POWER button or # Battery icon flash	No battery installation	Insert batteries
	Batteries are exhausted	Replace new batteries
	The polarities of batteries placed wrongly	Insert battery in the correct polarities

Appendix I Guidance and Manufacturer Declaration Tables

Guidance and manufacturer's declaration – electromagnetic emissions

The Model 240389 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 240389 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 240389 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.
RF emissions CISPR 11	Class B	The Model 240389 Series Electronic Blood Pressure Monitor is used in home and it's powered by DC 3V
Harmonic emissions IEC 61000-3-2	N. A.	
Voltage fluctuations/flicker emissions IEC 61000-3-3	N. A.	

Guidance and manufacturer's declaration – electromagnetic immunity

The Model 240389 Series Electronic Blood Pressure Monitor is intended for use in the electromagnetic environment specified below. The customer or the user of the Model 240389 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
Conducted RF IEC 61000-4-6	3 Vrms (150 kHz to 80 MHz) and 6 Vrms in ISM and amateur radio bands between 150 kHz and 80 MHz	N/A	Portable and mobile RF communications equipment should be used no closer to any part of the Model 240389 Series Electronic Blood Pressure Monitor, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=\frac{3.5}{V_1}\sqrt{P}$ $d=\frac{3.5}{E_1}\sqrt{P}$ 80MHz to 2.7GHz

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Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz	10 V/m	$d=\frac{3.5}{E_1}\sqrt{P}$ 80MHz to 800MHz $d=\frac{7}{E_1}\sqrt{P}$ 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 meters(m).

Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, should be less than the compliance level in each frequency range.

Interference may occur in the vicinity of equipment marked with the following symbol

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 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 240389 Series Electronic Blood Pressure Monitor is used exceeds the applicable RF compliance level above, the Model 240389 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 240389 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 240389 Series Electronic Blood Pressure Monitor

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.

Rated maximum output of transmitter	Separation distance according to frequency of trans mitter		
W	150 kHz to 80 MHz $d=\frac{3.5}{V_1}\sqrt{P}$	80 MHz to 800 MHz $d=\frac{3.5}{E_1}\sqrt{P}$	800 MHz to 2.7 GHz $d=\frac{7}{E_1}\sqrt{P}$
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

cos