2

6

8

Typical fluctuation within a day

SYMBOLS ON DISPLAY

UNIT OF PRESSURE

VALUE OF PULSE PER MINUTE

10

12

14

16

BLOOD PRESSURE MONITOR Procare Instruction Manual

WRIST ELECTRONIC

**C** € 0413

**FDA Approved** 

MODEL: 240389



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NOTES ON SAFETY......2 ABOUT BLOOD PRESSURE......6 PRECAUTIONS BEFORE USE......8 FEATURES OF THE PRODUCT.......9 PARTS IDENTIFICATION......10 INSERT OR REPLACE BATTERIES......11 TIME AND OF SYSTEM SETUP......12 UNIT CONVERSION mmHg/kPa DISPLAY......13 WHO BLOOD PRESSURE CLASSIFICATION DISPLAY......14 ATTACHING THE ARM CUFF......15 HOW TO MEASURE BLOOD PRESSURE......16 The **1** icon indicates something that is compulsory (what must always

Matters involving actual compulsory actions are indicated by text or

The S icon indicates something can't be disassembled or "Don' disassemble"

Matters involving actual compulsory actions are indicated by text or pictures

pictures in or near • .The left icon refers to "general compulsion".

be observed).

3

5

Do not smoke

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.

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

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

4. Press "MEM" key to adjust the month. Following the same steps to adjust date/hour/

and enter the month setting mode.

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.

READ MEMOR Y

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

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"

2x1.5V Batteries(LR03 or 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

Type BF

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

Atmospheric pressure: 70kPa~106kPa

Atmospheric pressure:50kPa~106kPa

Check your wrist cuff if any Replace wrist cuff with new one

use alkaline battery, measure above 200 times.

every day.

Power supply:

Operating condition:

Storage condition:

Dimensions:

Classification

Wrist circumference

Weight:

E1:can't normally

15

minute.

Reduce salt and fat intake

Maintain proper weight

TABLE OF CONTENTS

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 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 SAFTEY

\* 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".

Patient must follow doctor's instruction and should not perform self-judgment and self-treatment by the measuring result, Self-diagnosis of measured results and treatment are dangerous. The device should not be used to judge illness, first aid and continuously monitor measuring. This device can not be used for Patient transport and surgical care .It can be used in household or fixed places only.

Please press "on/off" button to stop work when you feel uncomfortable with the wrist, or if the air is inflating abnormally without stop. Do not let a child below 12 years old and the people who can't express one's intention. When it is used by the people of 12~18 years old, it should accompanied

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

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

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

ABOUT BLOOD PRESSURE

Blood pressure is the force exerted by blood against the walls of the arteries. Systolic

mmHg

-The PATIENT is an intended OPERATOR.

the maintenance instructions of manual.

1. What is blood pressure?

hypertensive individuals, variations are

Normally, the blood pressure rises while

LCD Display: Date and Time Systolic Blood pressure Diastolic Blood pressur

SET Button

WHO blood pressu

The units will be chosen by the above shows mmHg/kPa after decontrol, After the

nomal boot unit values are shown as blood pressure.

Also select memory unit value changes

Clean the monitor and cuff with a soft dry cloth.

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

**ERROR DISPLAY** 

Nothing is displayed

When you push the

Battery icon flash

POWER button or

TROUBLESHOOTING

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

HOW TO CORRECT

Replace new batteries

Insert battery in the correct

20

Insert batteries

POSSIBLE CAUSE

Battery worn out

placed wrongly

Appendix 1 Guidance and Manufacturer Declaration Tables

3 \/rmc150 kHz

NI/A

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

in an electromagnetic environment in which radiated RF disturbances are controlled.

240389 Series Electronic Blood Pressure Monitor is intended for use

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28

Guidance and manufacturer's declaration – electromagnetic emissions

No battery installation

The polarities of batteries

Do not use any abrasive or volatile cleaners.

even more pronounced.

in or near \strace{\infty}. The left icon refers to "general prohibition". Type BF Applied part The following symbol indicates that by the Adult. May cause accident or trouble. the device is MR-unsafe: Do not use the unit for purpose other than measuring blood pressure. Please refer to the instructions for use May cause accident or trouble. Please do not use mobile phone around the device. Please do not use Indicates a medical device that needs to the device around the magnetic field. be protected from moisture. The device is prohibited from being used during movement. Do not use the equipment in outdoor or shower rooms. Marking of electrical and electronic equipment in accordance with Article Do not disassemble, repair, or remodel the main unit or the wrist cuff of the 11(2) of Directive 2002/96/EC (WEEE) blood pressure monitor. Will cause the unit to function erroneously.

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.

Exercise regularly

Have regular physical checkups

Requests from Manufacturer

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

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 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:

₾ 130 at work or play and falls to its lowest 3. Why measure blood pressure at home? Blood Pressul 90 70 50 30 Blood pressure measured at a clinic or doctor's office may cause apprehension levels during sleep. So, do not be overly concerned by the results of one 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 measurement. pressure readings, supplements the doctor's readings and provides a more Take measurements at the same time every accurate, complete blood pressure history. day using the procedure described in this 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 Organization (WHO), and shown in doctor to interpret your blood pressure data. mmHo Grade 3 hypertension (severe) 110 105 100 chart below. Grade 2 hypertension (moderate) PRECAUTIONS BEFORE USE 5. Blood pressure variations Grade 1 hypertension (mild) An individual's blood pressure varies 90 85 1. If you are taking medication, consult with your doctor to determine the most greatly on a daily and seasonal basis. High-normal appropriate time to measure your blood pressure. NEVER change a prescribed Norma It may vary by 30 to 50 mmHg due to various conditions during the day. In medication without first consulting with your doctor. 120 130 140 150 160 170 180 Systolic blood pressure 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

8.Cuff pressure range 0-299mmHg Wrist Cuff FEATURES OF THE PRODUCT Accessory 1. Memory can store 90 measurements. 2. Large and clear LCD display. Manual 9 • Batteries, which have fluid on surface or be modified, can not be inserted into INSERT OR REPLACE BATTERIES the products. 1. Remove the battery cover. Battery short circuit must be prevented. 2. Insert new batteries into the battery compartment as shown, taking care that the • Battery life varies with the ambient temperature and may be shorten at low polarities(+) and (-)are correct. temperatures. 3. Close the battery cover, Use only LR03, AAA batteries. 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. Disposal of empty battery to Used batteries may leak and damage the main unit. Pleases observe the following the authorized collecting party subject to the regulation of \* If you are not going to use the unit for a long period of time (approximately three each individual territory. months or more), remove the batteries. \* Replace worn batteries with their polarities in the correct direction. • Insert the batteries as shown in the battery compartment. If not, the device will not work. SETUP TIME OF SYSTEM • When \(\hat{\mathbb{L}}\) (LOW BATTERY mark) blinks in the display, replace all batteries with new 1. Press "SET" key to turn on. ones. Do not mix old and new batteries. It may shorten the battery life, or cause the device to malfunction 2. Press and hold "SET" key until the year number displays and (LOW BATTERY mark) does not appear when the batteries run out. flashes on LCD to enter setting mode. • Please ensure to distinguish positive polar "+" and negative polar "-" of batteries when replacing batteries.

month date hour minute WHO BLOOD PRESSURE CLASSIFICATION DISPLAY Grade 3 hypertension (severe) UNIT CONVERSION mmHg/kPa DISPLAY Diastolic blood pressure Grade 2 hypertension (moderate) Reference material: journal of The goods have mm Hg(mmHg), kPa (kPa) two kinds of blood pressure display Grade 1 hypertension (mild) hypertension 1999. vol 17 No.2 units(mmHg factory to express). High-normal Press "ON / OFF" button for 10 seconds to display unit switching interface, then Normal press "MEM" key to select mmHg / KPa, press "ON / OFF" button to exit. Optimal 13

ATTACHING THE ARM CUFF HOW TO TAKE PROPER MEASUREMENTS 1. Fasten the wrist cuff according to the instructions in "ATTACHING THE WRIST CUFF." 1. Fastening the wrist cuff 2. Press the "ON/OFF" button. All icons appear two seconds on DISPLAY, then switch to 1) Wrap the wrist cuff around your wrist about (1-2)cm above your hand as shown measurement, and display "0" or last measurement record. in the figure at the right. 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. 3. Start measurement, the cuff in the strap will automatically inflate. Relax for about 5 to 10 minutes before measurement. The mark will flash on LCD. When complete, the results will be displayed. Raise your hand so that the wrist cuff is at the same level as your heart. Remain still and keep quiet during measurement. 58 Do not measure right after physical exercise or a bath.

display "Пa" has been to delete all memory. CAUTION \* Do not submerge the device or any of the components in water. Do not subject the monitor to extreme hot or cold temperatures, Пο 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. CARE AND MAINTENANCE \* Remove the batteries if the unit will not be used for three months or To keep your digital blood pressure monitor in the best condition and protect the unit longer. Always replace all the batteries with new ones at the same time. from damage, follow the directions listed below: This product is designed for use over an extended period of time; however, it Keep the monitor in the storage case when not in use. is generally recommended that it be inspected and calibrated every two years Do not fold the arm cuff too tightly. to ensure proper function and performance. The fabric fastener could touch the inner surface of the arm cuf and damage it. (\* Pressure calibration is done by EU representatives) 18 **SPECIFICATIONS** 1. Type of protection against electric shock: INTERNALLY POWERED EQUIPMENT. 2. Degree or protection against electric shock: TYPE BF APPLIED PART. Oscillometric Measurement Measuring Method 3. Mode of operation: CONTINUOUS OPERATION. Indication Digital LCD display 4. Equipment not suitable for category AP& APG equipment use in presence. Measuring Range: Pressure:(30~280)mmHg Pulse:(40~199)Beat/min the system might not meet its performance specifications if stored or used outside Static Pressure: ±3mmHg Pulse: ±5% Accuracy: the temperature and humidity as mentioned below: 90 Memories Memory: Operating conditions: +5°C~+40°C. 15%RH~93%RH 70kPa~106kPa

Increase pressu	'	/000	The Model 240389 Series Electronic Blood Pressure Monitor is intende								
E3 inflate pressu too high	ure Pressui	re value of more 99mmHg	Re-measurement or send back dealer for re-calibrate pressure			nagnetic enviro 240389 Se	vironment specified below. The customer or the Series Electronic Blood Pressure Monitor should				
E2E4:have shak while measurem	٠ ١	r body shaking neasurement	keeping static and correct gesture to measure again		Emissions	Compliance	Electromagnetic environment-guidance				
■ Battery icon		low power	Replace battery and measure again		RF emissions CISPR 11	Group 1	The Model 240389 Series Electronic Blood Pressure Monitor uses RF energy only for its				
The systolic pre	1	wrist cuff was held han your heart				ı	internal function. Therefore, its ŘF emissions are very low and are not likely to cause any interference in nearby electronic equipment.				
Pressure value too high	2.The	wrist cuff was not ed properly	keeping correct position		RF emissions CISPR 11	Class B	The Model 240389 Series Electronic Bloc Pressure Monitor is used in home and it's				
too mgm	3.You r spoke o	moved your body or during measurement	and gesture to measure		Harmonic emissions	N. A.	powered by DC 3V				
The systolic pre		wrist cuff was held than your heart		IEC (	IEC 61000-3-2 Voltage	N. A.					
Pressure value too low		moved your body or during measuremer	nt		fluctuations/flicker emissions	N. A.					
21					IEC 61000-3-3		22				
Guidance and	d manufacture	r's declaration -	- electromagnetic immunity	7	Guidance and n	nanufacturer	's declaration – electromagnetic immunity				
use in the electi	romagnetic env del 240389	rironment specific Series Electronic	Pressure Monitor is intended for ad below. The customer or the Blood Pressure Monitor should		use in the electroma	agnetic enviror 389 Series E	ectronic Blood Pressure Monitor is intended for nment specified below. The customer or the user Electronic Blood Pressure Monitor should assure ent.				
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment- guidance			C 60601 Co	ompliance Electromagnetic environment - guidance level				

Electrostatic discharge (ESD)IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15KV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 KV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.	Conducted RF IEC 61000-4-6	80 MHZ outside	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
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8		30 A/m, 50/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.		ISM bandsa		separation distance calculated from the equation applicable to the frequency of the transmitter.  Recommended separation distance
NOTE U <sub>⊤</sub> is th	ne a.c. mains volt	age prior to applic	cation of the test level				$d = \frac{\acute{e}3.5}{\acute{e}} \frac{\grave{u}}{V_1} \sqrt{N} $
23							24
Radiated RF IEC 61000-4-3	10 V/m 80 MHz to 2.7 GHz		$= \frac{\acute{e}3.5 \mathring{u}}{\overset{\circ}{e}} \sqrt{P}  80 \text{MHz to } 800 \text{MHz}$	NOTE 2 These	e guidelines may no	ot apply in a	ner frequency range applies.  all situations. Electromagnetic propagation structures, objects and people.
		10 V/m d =	= é3.5 ù /P 80MHz to 800MHz	NOTE 2 These	e guidelines may no	ot apply in a	all situations. Electromagnetic propagation
		whe	$d = \frac{\acute{e}}{\grave{e}} \frac{1}{\acute{u}} \sqrt{P}  800 \text{MHz to } 2.7 \text{GHz}$ where P is the maximum output power	are 6,765 MH	lz to 6,795 MHz; 1	3,553 MH	al) bands between 0,15 MHz and 80 MHz z to 13,567 MHz; 26,957 MHz to 27,283 amateur radio bands between 0,15 MHz
		acco and dista	ng of the transmitter in watts (W) ording to the transmitter manufacturer d is the recommended separation ance in metres(m).	MHz to 7,3 MI MHZ, 21,0 MI	Hz, 10,1 MHz to 10 Hz to 21,4 MHz, 24	,15 MHz,	MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 o 24,99 MHz, 28,0 MHz to 29,7 MHz and
		as d	d strengths from fixed RF transmitters, letermined by an electromagnetic site	50,0 MHz to 5		ISM from	uency bands between 150 kHz and 80
		com	survey, <sup>a</sup> should be less than the compliance level in each frequency range <sup>b</sup>	MHz and in t	he frequency rang	ge 80 MH:	z to 2,7 GHz are intended to decrease nmunications equipment could cause

frequency ranges.

The customer of the Monitor can help distance between and the Model 24	e user of the Model prevent electromagne portable and mobile F 40389 Series Electro	240389 Series Electic interference by m RF communications ec nic Blood Pressure Mo	ctronic Blood Pressure naintaining a minimum quipment (transmitters) onitor as recommended
Rated maximum output of	uency of trans mitter		
trans mitter	150 kHz to 80 MHz	80 MHz to 800 MHz	800 MHz to 2.7 GHz
W	$d = \left[\frac{3.5}{V_1}\right] \sqrt{P}$	$d = \left[\frac{3.5}{E_1}\right] \sqrt{P}$	$d = \left[\frac{7}{E_1}\right] \sqrt{P}$
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	Rectromagnetic interference by maintaining a and mobile RF communications equipment (tra eries Electronic Blood Pressure Monitor as recommunication output power of the communications equipment ation distance according to frequency of trameto 80 MHz   80 MHz to 800 MHz   800 MHz to $\frac{3.5}{V_{\perp}}\sqrt{P}$   $d = [\frac{3.5}{E_{\perp}}]\sqrt{P}$   $d = [\frac{7}{E}]\sqrt{P}$   $d = [\frac{7}{E}]\sqrt{P}$   $d = [\frac{3.5}{E_{\perp}}]\sqrt{P}$   $d = [\frac{3.5}{E_{\perp$	7.3
100	12	12	23
			2
	The customer or the Monitor can help distance between pand the Model 20 below, according to Rated maximum output of transmitter  W  0.01 0.1 1 10	The customer or the user of the Model Monitor can help prevent electromagned distance between portable and mobile F and the Model 240389 Series Electrobelow, according to the maximum output of trans mitter  W  Separation distance to the maximum output of trans mitter $d = [\frac{3.5}{V_1}]\sqrt{P}$ 0.01  0.12  0.1  0.38  1  1.2  10  3.8	$\begin{array}{c ccccccccccccccccccccccccccccccccccc$

Interference may occur in the vicinity

symbol: (((•)))

c Field strengths from fixed transmitters, such as base stations for radio

of equipment marked with the following

people.

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

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and