AILE

Electronic Sphygmomanometers Instructions for Use Model: X5

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Jiangxi AICARE Medical Technology Co., Ltd.

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I.Preface

Dear users,

We appreciate for your purchase of our Electronic Sphygmomanometers. Before using this monitor, read the Manual carefully and use it correctly. Please keep the Manual properly after reading for easy check and reference at any time. This monitor is for adults use, but not for newborns.

Introduction:

It is an Electronic Sphygmomanometers consisting of the Main Unit and Cuff. It is suitable for measurement of systolic blood pressure, diastolic blood pressure and pulse of the human body. The blood pressure measured by it is equivalent to that measured by auscultation method, and the error is controlled within the range specified in IEC 80601-2-30 Non-invasive automated monitor.

This Electronic Sphygmomanometers employs the intelligent pressurization to automatically pressurize to a suitable pressure value based on your blood pressure. It is designed to effectively reduce discomfort caused by incorrect pressurization, shorten measurement time, and extend the life of the Cuff.

II.Range of application

1.Intended Use

Electronic Sphygmomanometers is intended to measure the systolic and diastolic blood pressure as well as the pulse rate of adult person and adolescents age 18 through 21 years of age. It can be used at medical facilities or at home.

2.Application of product

Intended Users

Adult, and adolescents age 18 through 21 years of age, except contraindications.

Parts of the body/tissues, duration

This device is a non-invasive Electronic Sphygmomanometers, the cuff will be wore in upper arm by user during measuring.

Single Use/Reusable

This product is an active and reusable device.

3.Contraindications

1)The product shall not be used for measuring for under 18 years old, including newborns;

2)Those who suffer from severe arrhythmia shall not use the this product;

3)The pregnant women, including pre-eclamptic patients, shall not use this product.

III.Important Safety Information

1.Warnings

⚠To measure the blood pressure accurately and reliably, following shall be noted when using:

1)Don’ t disassemble the monitor or arm cuff. This may cause an inaccurate reading.

2)Do not apply the arm cuff on the arm while being on an intravenous drip or blood transfusion.

3)Consult your physician before using this monitor on the arm with an arterio-venous (A-V) shunt.

4)Don’ t use the Cuff on the arm on the side of a mastectomy or lymph node clearance.

5)Do not use this monitor with other medical electrical (ME) equipment simultaneously. This may result in incorrect operation of the monitor and/or cause an inaccurate reading.

6)Measurements may be impaired if the device is used close to televisions, microwave ovens, cellular telephones, X-ray or other device with strong electrical fields.

7)Don’ t use this monitor on the injured arm or the arm under medical treatment, as this can cause further injury.

8)Do not use in a location with moisture, or a location where water may splash on this monitor. This may damage this monitor.

9)Use only the approved arm cuff for this monitor. Use of other arm cuffs may result in incorrect measurement results.

10)Do not fold or kink the air tube while taking a measurement. This may cause harmful injury by interrupting blood flow.

11)Do not measure while standing, walking, or your body is under pressure.

12)Do not measure after smoking, drinking alcohol, or coffee (black tea).

13)Do not measure after exercise or bathing.

14)Do not speak or move your body during measurement.

15)Do not move, shake your arms or bend your fingers during measurement.

16)Do not measure under the excessively cold or hot condition, or the environment suffering drastic changes.

17)Do not measure in a moving vehicle (car, airplane).

18)Measure too frequently can cause injury to the patient due to blood flow interference, (It is recommended that the interval between two adjacent measurements be no less than 3 minutes)

19)Do not move the monitor during the measurement.

20)Do not measure within 1 hour after meal.

21)Do not use this monitor on the injured arm or the arm under medical treatment.

22)Do not apply the arm cuff on the arm while being on an intravenous drip or blood transfusion.

23)Note: It would be dangerous by making self-judgment and self-treatment according to the measurement results. Please follow the doctor’s advice.

24)The Mains supply adaptor is not provided by this product. DC 5V input port only can be powered by approved(IEC/EN 60601-1) DC adaptor (DC 5V/500 mA).Use of other DC adaptor may damage of this monitor.

25)Avoid compression or restriction of the connection tubing.

26)Adapter with Micro-USB cable (not provided) :

- Do not use the Micro-USB cable and Adapter if the device or the cable is damaged. Turn off the power and unplug the power plug immediately.
- Plug the Adapter with Micro-USB cable into the appropriate voltage outlet. Do not use in a multi-outlet plug.
- Never plug in or unplug the device form the electric outlet with wet hands.
- Fully insert the power plug into the outlet.
- When disconnecting the power plug from the outlet, do not pull the power cord. Be sure to pull from the power plug safely.
- Unplug the adapter when not in use.
- Disconnect the power plug before cleaning.

27)Battery(not provided):

- Do not insert the batteries with their polarities incorrectly aligned.

Our company does not provide the batteries; all the models are powered by 4 AAA dry batteries (DC 6V). Do not use other types of batteries. Do not use new and used batteries together.

This device does not support the battery charging function. Do not use the rechargeable battery to charge in this device.

2.Notes

1)Avoid eating, smoking and strenuous exercise for 30 minutes prior to blood pressure measurement.

2)Sitting is the correct measurement posture for measurement of blood pressure, and the Cuff and the heart should be on the same level. Therefore, the blood pressure value measured at the front of the counter may be slightly different from value that is measured correctly.

3)Any blood pressure measurement is affected by the posture and physical condition of the subject. Please be quiet while measuring, and do not move your arms or body.

4)Maintain the same state and same posture for each time of measurement.

5)The monitor of this model should be tied on the left arm.

6)When continuous measurement is made on the same person, loosen the Cuff to have the arm rested for at least 3 minutes before next measurement.

7)The Cuff provided by this product is suitable for arms of people over 12 years old.

8)Avoid electromagnetic interference above 10V/m during measurement. The possible sources of interference may be from TV, mobile phone, microwave oven, X-ray, etc.

9)Do not measure the blood pressure of newborn babies using this product.

10)Do not have this product used for purposes other than blood pressure measurement.

11)Remove the batteries when the product is not in use for a long time to prevent the battery from leakage.

12)When the bladder of cuff is over-pressurized constantly, the pain, numbness and even congestion may occur to the arm. Do not pressurize when it exceeds 300 mmHg, and do not maintain the cuff pressure higher than 15mmHg for more than 3 minutes.

13)Arrhythmia such as PAC, PVC, and atrial fibrillation during the measurement process may lead to the detection of irregular pulse

rate. The electronic monitor can still work normally, but the measured blood pressure value may be inaccurate. When irregularities occur frequently, please consult a doctor.

14)If the monitor is used and stored beyond the temperature and humidity range specified in this Manual, its safety or performance may be affected or become invalid, or even be totally damaged.

15)When replacing the Cuff, use the Cuff supplied by the manufacturer. If the original part is replaced with a Cuff not supplied by the manufacturer, measurement errors may occur.

16)Contact the manufacturer for static pressure test.

17)Do not share the Cuff with others to avoid cross-contamination.

18)Don’ t use the device in the environment with higher than 40℃ or lower than 5℃, and over RH 15%~90%.

19)The protective glass outside the LCD frame is very important and also the fragile part of the instrument, so it must be used carefully.

20)Please do not charge the non-rechargeable battery and do not throw the battery into the fire.

21)Please do not expose the product to the sun or touch water.

22)To help avoid strangulation, keep the air tube away from infants, toddlers or children.

23)Keep components out of the reach of infants, toddlers or children. This product contains small parts that may cause a choking hazard if swallowed by infants, toddlers or children.

24)Keep batteries out of the reach of infants, toddlers or children.

25)Do not store your monitor and other components:

- If the monitor and other components are wet.
- In locations exposed to extreme temperatures, humidity, direct sunlight, dust or corrosive vapors such as bleach.
- In locations exposed to vibrations or shocks.

3.Potential adverse reaction

1)Patients with severe blood circulation disorders and Blood diseases, Inflate the arm cuff than necessary may cause blood stasis or paralysis of the arm;

2)Patients with severe blood circulation disorders and Blood diseases may cause acute internal bleeding due to the compression of the arm.

4.Waste disposal

1)Direct disposal of electronic products and batteries in garbage cans will cause harm to the environment. Please dispose them according to the local laws.

2)Don’t throw the Electronic Sphygmomanometers in the garbage can at the end of use; please dispose it according to the local laws or contact with the manufacturer for recycling.

IV.Features and Specification

1.List of product

No.	Plot Name	Model	Quantity
1)	Main unit	X5	1 set
2)	Cuff	/	1 set
3)	Instructions for Use	/	1 copy

2.Technical specification

2.Technical specification

Device Name	Electronic Sphygmomanometers
Models	X5
Display Digital LCD	Digital LCD
Method of measurement	Oscillometry
Cuff	Applr: 150 mm (W) × 400 mm (L)
Cuff Measurement perimeter of the upper arm	22cm~42cm
Material of cuff	Nylon polyester
Measuring pressure range	Blood pressure: 0~299 mmHg, 0~40kPa
Measuring pressure accuracy	Pressure within ±3 mmHg (±0.4 kPa), or 2% of the reading
Pulse range	40~180 times per minute
Pulse accuracy	Within ±5% of the reading
Pressure measurement	Resistance type pressure sensor
Working mode	Continuous operation
Number of memory	2 people × 99 groups
Air-blow device	Blow-off valve
Inflation	Auto pressurization by air pump
Venting	Uniform-speed decompression by solenoid valve
Auto power-off	Two minutes
Power supply	AAA batteries (4pc) or DC 6V 500 mA *Do not provide, please buy it by yourself
Operating condition	Temperature: (+5 ~ +40)℃ Relative Humidity: (15% ~ 85%)RH Atmospheric pressure: 70 kpa ~ 106 kpa
Storage and transportation environment	Power: AAA batteries (4pc) or DC 6V 500 mA Environment temperature: -20℃ ~ +60℃; Relative humidity: 10% ~ 85% (non-condensing) No corrosive gas, well ventilated room. Transportation requirements must conform to regulations of the order contract, but severe impact, vibration and rain and snow splash during transportation must be prevented.
IP class	IP21
Applied parts	Type BF
Electromagnetic compatibility	Group 1 and Class B device
Accessories	Cuff (for arm circumference of 22 cm ~ 42cm) Instructions for Use

V.Structure and descriptions of product

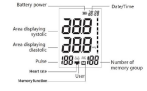
1.Product structure

The product consists of a main unit and a cuff. See below Figures.

Figure 1. Product Structure of X5

Figure 4. Cuff for all models

2.Description of LCD Screen



VI.Settings

1.Memory clear

Press and hold the MEM button for 3 seconds in the reading memory mode to clear the memory value stored in the product.

2.To enter Static Mode

Press the SET button when the product is not powered on, and the time will be displayed on the screen, and then press SET+ MEM button at the same time to enter the static pressure mode.

3.Set the date/time

"Year"

When the monitor is turned on but not measured, press and hold the SET button for about 3 seconds, the Year on screen starts to flash, and press the MEM button to set the year.

"Month"

After the year is adjusted, press the SET button again, the Month starts to flash at this time, and press the MEM button to make adjustment.

"Day"

After the month is adjusted, press the SET button again, the Date starts to flash at this time, and press the MEM button to make adjustment.

"Hours"/"Minutes"

Upon date adjustment, press the SET button again and the Hour starts to flash, press the MEM button to adjust. Set the "Minutes" by following the above-mentioned steps.

4.Unit conversion

The unit is defaulted as "mmHg" . After setting "Date/Time" , press SET button and "D" is displayed. If you want to switch unit to "kPa" ,press MEM button and "D.0" will appear, which means unit conversion is successful.

Pressing MEM button again to convert from "kPa" to "mmHg".

6.Reading of main memory value

Press the MEM button after the measurement is finished or in the power-off mode, and the LCD will display and broadcast the averaged result of the last three measurements.

Press the MEM button again to display and broadcast the last measurement result. View the measured values of 2, 3 , . continuously by repeating this step.

7.Error code description

Before using the arm-type electronic monitor, check to see if the monitor has an error code prompt or be unable to display the number (or symbol)after power on. If there’ ns error codes prompts or display abnormality, please contact the after-sales service center to eliminate the abnormality asper the prompts.

Er 1	This may be caused due 1 o f the aneroidally fast air leak rate, or the pulse mark o f the pul ean under detection is too wide. Plea se check the cuff, r e-tie it and mea sure a gain.
Er2	The blood pressure signal cannot be measured due to noise. Please measure again.
Er3	The measurement result is incorrect, and re-measurement is required.
Er4	Inflation fails, please check the cuff. Measure again after you have tied it properly
Hi	Inflation pressure is gr eater than 30T o 15mmHg (4T kPa o 1kPa). Please measure a gain.
LOW BATTERY	Please check or replace the batter y, and test again.

Note: A re-measurement is required if the above symbol appears

VII.Preparation

1)Open the Electronic Sphygmomanometers. The device case should be uniformly colored with no obvious defects such as scars and scratches.

1.To load the batteries

1)Open the Battery Case cover on the side of the unit and put the4 batteries (AAA) correctly.

2)Put the Battery Case cover back properly.

Notes:

•Load the batteries as shown in the picture. If not, the monitor will not work.

•When the Low Battery Symbol appears on the display, turn the monitor off and remove all the batteries. Replace with 4 new batteries at the same time. Do not mix old and new batteries. It may shorten the battery life, or cause the monitor to malfunction.Long life alkaline batteries are recommended.

•The measurement values continue to be stored in memory even after the batteries are replaced.

•Remove the batteries if the monitor is not to be used for a long period of time (more than 3 months). Otherwise, the batteries may leak and cause a malfunction.

•Our company does not provide the batteries; the users are required to buy batteries which meet safety standards. All models are powered by 4 AAA dry batteries (DC 6V). Do not use other types of batteries.

•This monitor does not support the battery charging function. Do not use the rechargeable battery to charge in this monitor.

•The supplied batteries may have a shorter life.

⚠Disposal of used batteries should be carried out in accordance with the national/local regulations for the disposal of batteries.

2.Using the Adapter with Micro-USB cable

1) Insert the Adapter with Micro-USB cable Into the AC adapter jack of the monitor.

2) Plus the Adapter into an electrical outlet.

To disconnect the Adapter, unplug the Adapter from the electrical outlet first, and then remove the Adapter with Micro-USB cable form the monitor.

3) Our company does not provide the adapter and Micro-USB cable; the users are required to buy the adapter (DC 5V/500mA) and Micro-USB cable which meet safety requirements of IEC 60601-1. Use of an adapter or Micro-USB cable which does not meet the requirements may damage and/or may be hazardous to the monitor and users.

3.To tie the Cuff

1)The standard accessory is the cuff (M), which is suitable for the subject with arm circumference of 22cm ~ 42cm.

2)Insert the hose top plug into the opening located on the side of the Main Unit. (Only the original standard Cuff can be used for this Main Unit.)

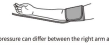
3)Wrap the arm Cuff firmly in place around your left upper arm. It is advisable to tie the Cuff properly that the arm will not feel physical tension.

The bottom edge of the arm cuff should be 2 to 3 cm above the elbow. Air tube is on the inside of your arm and aligned with your middle finger.

4)Secure closed with the fabric fastener.

Notes:

•When you take a measurement on the right arm, the air tube will be at the side of your elbow. Be careful not to rest your arm on the air tube.



•The blood pressure can differ between the right arm and the left arm, also the measured blood pressure values can be different. AICARE recommends to always use the same arm for measurement. If the values between both arms differ substantially, please check with your physician which arm to use for your measurements.

•Do not tie the Cuff too tight, otherwise the measurement will be inaccurate.

5)Refer to the range of arms indicated on the Cuff to determine if aproperly sized Cuff is used.

6)Do not place the arm Cuff over thick clothes.

4.How to Sit Correctly

The correct posture is also extremely important to measurement. To take a measurement, you need to be relaxed and comfortably seated at comfortable room temperature.

1)Sit in a comfortable chair with your back and arms supported, and maintain the right posture; do not force with your fingers, and keep them stretched.

2)Keep your feet flat and your legs uncrossed.

3)Both arms should be resting comfortably on a table.

4)Place your monitor close enough to touch with your bent elbow.

5)The arm cuff should be placed on your arm at the same level as your heart for a blood pressure measurement.

6)Please measure while the body is relaxed, and keep it in peace for 4 ~ 5minutes before measurement. Otherwise, the measurement results will be affected. At the same time, make blood pressure measurement with the same arm and the same posture every day.

7)Judge the measurement results under the guidance of a doctor to help you manage your health.

8)When the person being measured suffers from arrhythmia (i.e. PAC, PVC, and atrial fibrillation), the measurement results may be inaccurate.

5.For the accuracy of the measurement, we recommend

1)Do not have intense activities 30 minutes before the measurement, do not smoke or drink coffee or alcohol;

2)Have rest and sit in a comfortable and quiet atmosphere for at least 5minutes prior to measurement;

3)Generally, the blood pressure is measured in a sitting position. If a pronposition is required, remember to tell the doctor;

4)Measure the blood pressure at least twice each time, with the interval of not less than 5 minutes. A longer interval may be required depending on your physical condition.

5)Patients suffering from arrhythmia and arteriosclerosis should be measured by medical workers so as to make professional diagnosis.

6)Avoid any electromagnetic interference or noise interference during measurement.

VIII.Method to measure the blood pressure

1)Start measuring after you have worn the cuff by pressing the "START/STOP" button. After that, the monitor begins voice broadcasting to start the measurement.

2)Since the monitor also checks the pulse during the inflation process, do not move any part of your body during measurement.

3)When the monitor is slowly vented, the value on the display keeps decreasing and the heartbeat icon (heart shaped) keeps flashing until the measurement results appear.

Reading of measured values and make repeated measurements After the automatic measurement is finished, the display screen will automatically display the systolic pressure and diastolic pressure of the person under measurement in mmHg, and simultaneously display the measured pulse rate (in times/minute).The voice will simultaneously broadcast the measurement results .

Press the "START/STOP" button to turn off the device.

Notes 1: Due to the fluctuation of blood pressure, each measurement result may vary. If the user’s blood pressure fluctuates greatly, it is best to measure 3 times and take the average value as the measured value.

Compared with the casual blood pressure as measured, the blood pressure measured using the above method will be the true value of the human blood pressure

Note 2: The effectiveness of the device in measuring blood pressure is verified by auscultation. To obtain information about the verification method, please contact the after-sales service center.

Note 3: If your left arm is not available for measurement, use the right arm. However, in any case, each measurement must be performed on the arm of the same side for an effective comparison of measurements.

4)Voice broadcast list

The device has voice broadcast function, below is the description of voice broadcast:

No.	Triggers	Operation	Voice broadcast content
1	START/STOP button	Press the START/STOP button once in the state of shutdown (standby state)	Attention please. Please keep silent and relax. Keep the cuff at heart level.
		After measurement.	Systolic pressure: "XXX" mmHg Systolic pressure: "XXX" millimeter of mercury pillar (or kilopascal); diastolic pressure: "XXX" millimeter of mercury pillar (or kilopascal) Your pulse is "XXX" beats per minute. Measurement result is "XXXXX". Thank you, wish you a good health.
2	MEM button	Press the MEM button in the state of shutdown (View measurement).	Measurement result is "XXXXX". Systolic pressure: "XXX" millimeter of mercury pillar (or kilopascal); diastolic pressure: "XXX" millimeter of mercury pillar (or kilopascal). Your pulse is "XXX" beats per minute.
		After broadcasting the measurement result, press the "MEM" button again.	Last time your blood pressure was. Systolic pressure: XXX millimeter of mercury pillar (or kilopascal); diastolic pressure: XXX millimeter of mercury pillar (or kilopascal). Your pulse is XXX beats per minute.
3	Low battery	When the battery voltage is lower than 4.8V.	Low battery. Please replace the battery.

Note 1: "XXX" in the table indicates the measured blood pressure and pulse value.
Note 2: Voice broadcast of "Attention please", "Ok normal", "slow down a bit", "your blood is low", "Good not measure your Pulse at this time".

Guidance for assessment of adult hypertension

Blood pressure is the pressure that blood is transmitted to the arteries through the heart-throb (contraction and relaxation).

The pressure at which the blood is delivered to the artery during systole is called systolic pressure, also as the higher pressure; and the pressure the time of diastole after the blood that circulates throughout the body is returned to the heart is called diastolic pressure, also as the lower pressure.

Figure 6 offers the standard blood pressure values of WHO. Hypotension is not defined. A blood pressure reading lower than 100 mmHg for the top number (systolic) is generally considered as hypotension. Guidelines for the classification of hypertension (regardless of age and gender) is provided. Please note that factors such as diabetes, obesity, and smoking would affect blood pressure measurements. If you have any questions, please consult your doctor, and do not adjust your treatment or medication just based on one of the two measurements.

Figure 6

	Blood pressure	Systolic (mmHg)	Diastolic (mmHg)
	Common blood pressure	100~139	60~89
	Normal blood pressure	100~139	60~84
	Mild hypertension	140~159	90~99
	Moderate hypertension	160~179	100~109
	Severe hypertension	≥180	≥110

Definition and classification of WHO blood pressure level

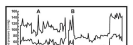
Variation in blood pressure:

Individual blood pressures vary greatly both on a daily and a seasonal basis. These variations are even more pronounced in hyper tense patients. Normally the blood pressure rises while at work and is at its lowest during sleeping period.

(hypertense: means a person who has high blood pressure symptom.)

The graph below illustrated the variations in blood pressure over a whole day with measurement taken every five minutes.

The thick line represents sleep. The rise in blood pressure at 4PM (A in the graph) and 12 PM (B in the graph) correspond to an attack of pain.



(Direct arterial pressure recording in unrestricted man. Steven, Hanavi & Blodi: Clin. Sci. 30:326; 1966)

IX.Requirements of Storage and maintenance

1)Avoid falling or strong collisions.

2)Avoid high temperature or exposure to direct sunlight.

3)Don’ t in any twist the cuff.

4)Do not press "START/STOP" button if the cuff is not wrapped around your upper arm.

5)Avoid immersing the unit and the Cuff into water.

6)Please leave the product indoors for one hour before using if it is brought into a warm room from a cold environment.

7)Remove the battery when the product will not be used for 3 months or more.

8)Use only four "AAA" batteries with this Main Unit. Don’ t use new and used batteries together.

9)Do not implement the maintenance procedure for equipment during measurement.

10)Put in a dry place and avoid sunshine, avoid immersing it in the water.

11)Make sure the cuff is completely dry before using.

12)Do not attempt to disassemble or change any parts of the monitor, including arm cuff, due to substitution of a component different from that supplied might result in measurement error.

13)After each use, wipe the cuff with a thoroughly wrung-out cloth that is dampened with water or a mild detergent, then dry with a dry cloth. If necessary, gently wipe it with absorbent cotton soaked with 75% alcohol.

14)If the product is not used for a long period of time, it is recommended to start the product once every two months. After the monitor is running, clean it with a soft and dry cloth.

If the main unit gets dirty, clean it with a soft and dry cloth. If the main unit is extremely dirty, wipe its body thoroughly with a wrung-out cloth that is dampened with water or a mild detergent, and dry with a dry cloth. If necessary, gently wipe it with absorbent cotton soaked with alcohol.

X.Calibration and Service

1)The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life.

2)It is generally recommended to have the device inspected every 2 years to ensure correct functioning and accuracy. Please consult your local AICARE representative.

3)Service life information:

Main unit: 5 years (6 times/day);

Cuff: The Cuff is a consumable. The life of the Cuff is about 1 year when measured 6 times a day (3 times in the morning and 3 times in the evening), (under the test conditions of manufacturer);

In order to measure blood pressure correctly, it is recommended to replace it in time.

In case of air leakage, replace the cuff with a new one.

XI.Instructions for Waste Disposal

⚠Disposal of used batteries should be carried out in accordance with the national/local regulations for the disposal of batteries.

⚠Dispose of this Main Unit, components and optional accessories according to applicable local regulations. Unlawful disposal may cause environmental pollution.

⚠Don’t throw the Electronic Sphygmomanometers in the garbage can at the end of use; please dispose it according to the local laws or contact with the manufacturer for recycling.

Correct Disposal of This Product (Waste Electrical & Electronic Equipment)

This marking shown on the product or its literature, indicates that it should not be disposed of, with other household wastes at the end of its working life. To prevent possible harm to the environment or human health from uncontrolled waste disposal, please separate this product from other types of wastes and recycle it responsibly to promote the sustainable reuse of material resources. Household users should contact either the retailer where they purchased this product, or their local government office, for details of where and how they can return this item for environmentally safe recycling.

Business users should contact their supplier and check the terms and conditions of the purchase contract. This product should not be mixed with other commercial waste for disposal.

XII.Symbol Description

Symbol Name	Meaning	Symbol Name	Meaning	Symbol Name	Meaning
SN	Serial number		Caution! Consult accompanying documents! or Consult the instructions for use to see the operating instructions carefully before use. Important safety information cannot be placed on the device		Cuff marking of Applied Part: Type Heather Body Code
	Manufacturer	EC REP	Authorized representative in the European Community		NEBS information: Non-invasive blood pressure monitor
	Date of manufacture		Fragile, handle with care		Check with your local Authority or recycler for recycling advice
	Keep away from sunlight		Keep dry		Temperature limitation
	FORE SIP APPLIED PART		Fragile, handle with care	Pulse Output	Pulse Output: Pulse Output
1 kg Battery Operated					Stress pulse to operate the alarm system/ function with the patient
					Our suggestion: Please do not take measurements.
IP21	Solid: Protected against hand intrusion (≥ 12.5mm) Liquids: Protected against vertically falling water drops				

⚠ This symbols appears when the battery power is necessarily low or the polarity reversed.

⚠ This symbols appears when attachment with nose clamp, and make sure the ‘ ‘ - ‘ polarities are showing correctly.

XIII.Service information

Name of after-sales service unit: Jiangxi AICARE Medical Technology Co., Ltd.

Contact Information: +86-794-6577516

Address: No.6, South Side of Nanhuan Road Qianjing Industrial Park, Le’ an County, Fuzhou City, 344300 ,Jiangxi Province, China

XIV.EMC Declaration

[EMC DECLARATION]

All types of electronic equipment may cause electromagnetic interference to other equipment through the air or the cable connected with it. The term EMC (electromagnetic compatibility) refers to the ability of a device to be unaffected by electromagnetic interference from other devices and not to affect other devices through similar electromagnetic radiation.

To fully achieve the specified EMC performance, users should follow the detailed described in the service manual to properly install the product.

⚠ **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. If such use is necessary, this equipment and the other equipment should be observed to verify that they are operating normally.

⚠ **WARNING:** Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

⚠ **WARNING:** Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30 cm (12 inches) to any part of the RF Generators, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

⚠ **CAUTION:** Please do not modify the equipment by yourself or any other unauthoritative organization. Unauthorized changes or modifications could void the user’s authority to operate the device.

⚠ **CAUTION:** Unless the device provided by our company, Devices which intrinsically transmit radio waves such as cellular phones, radio transceivers, mobile radio transmitters, radio-controlled toys, and so on, should preferably not be operated near the unit.

⚠ **CAUTION:** This device that is used may emit some radio frequency energy. This device may cause radio frequency interference to other medical, non-medical and radio communications’ devices. To effectively prevent such interference, this product conforms to the radio frequency emission limit specified in IEC60601-1-2 standard for class B of group 1. However, the company does not guarantee that there will be no interference in individual installation environments.

ESSENTIAL PERFORMANCE:

Description	Testing and verification
Measuring pressure range	Blood pressure: 0~299 mmHg 0~40kPa
Measuring pressure accuracy	within ±3 mmHg (±0.4 kPa)
Pulse measurement range	40~180 beats/min
Pulse rate accuracy	Within ±5% of the reading
Repeatability of the BLOOD PRESSURE DETERMINATION	≤ 3.0mmHg

Guidance and manufacturer’s declaration – electromagnetic emissions	
The RF Generators is suitable for use in the specified electromagnetic environment (s) and it has meets the following emissions requirements.	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic distortion IEC 61000-3-2	not applicable
Voltage fluctuations / Flicker IEC 61000-3-3	not applicable

Guidance and manufacturer’s declaration – electromagnetic immunity			
The RF Generators is suitable for use in the specified electromagnetic environment(s) and it has meets the following immunity test levels. Higher immunity levels may cause the RF Generator’s essential performance lost or degrade.			
Immunity Test	IEC 60601-1-2 Test level	Compliance level	
Electrostatic discharge (ESD) IEC 61000-4-2	±2, ±4 kV contact ±2 kV, +4 kV, +8 kV, +15 kV air	±2, ±4 kV, +4 kV, +8 kV, +15 kV air	
Radiated RF EM fields IEC 61000-4-3	10V/m 80MHz-2500MHz	10V/m 80MHz-2500MHz	
Rated power frequency magnetic fields IEC 61000-4-8	30A/m, 50 Hz	30A/m, 50Hz	
Electric fast transients burst IEC 61000-4-4	±2kV 100kHz, for mains port	±2kV 100kHz, for mains port	
Surges IEC 61000-4-5	±0.5kV, ±1.0kV,(Common mode) ±0.5kV, ±1.0kV(Differential mode)	±0.5kV, ±1.0kV,(Common mode) ±0.5kV, ±1.0kV(Differential mode)	
Conducted disturbances induced by RF fields IEC 61000-4-6	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz, 80 % AM, 1KHz	3 V 0.15 MHz – 80 MHz 6 V in ISM bands between 0.15 MHz and 80 MHz, 80 % AM, 1KHz	
Voltage dips and short interruptions IEC 61000-4-11	0% U T(0.5 cycle), 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°; 0% U T(1 cycle); 70% U T(25/30 cycle); 0% U T(250/300 cycle)	0% U T(0.5 cycle), 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°; 0% U T(1 cycle); 70% U T(25/30 cycle); 0% U T(250/300 cycle)	

NOTE U T is the a.c. mains voltage prior to application of the test level.

Guidance and manufacturer’s declaration – electromagnetic immunity					
Radiated RF IEC61000-4-3	Test frequency (MHz)	Band (MHz)	Service	Modulation	Max power (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
Close communication	385	380 ~ 390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27
RF wireless communication equipment	450	430 ~ 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0.3	28
	710	704 ~ 787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9
	745						
	780						
	810	800 ~ 960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28
	870						
	930						
	1720	1700 ~ 1990	GSM 1800; CDMA 1900; UMTS; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217 Hz	0.2	0.3	28
	1845						
	1970						
	2450	2400 ~ 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2