AVRO

Electronic Sphygmomanometers

Product Specification

Model:X5

CE 0197

Revision: A/0
Issue Date: 2020-06-10
Jiangxi AICARE Medical Technology Co., Ltd.

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I.Preface

Dear users,
We appreciate for your purchase of our Digital arm blood pressure monitor. 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 EN 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 measures the diastolic pressure and systolic pressure and pulse rate of people over 12 years old in home environments by using a non-invasive oscillometric technique with a single upper arm cuff.
The measurement position is at human being' s upper arm.
All values can be read out in one LCD panel.
This device is specially designed for family use. It is recommended for people over 12 years old with upper arm circumference between 22cm~42cm.
Scope of application of product
This product is used for measurement of blood pressure of people over 12 years old and not for newborns, not for pregnant, including pre-eclamptic patients;
Intended Users
Adult, except contraindications
Patient populations
People over 12 years, 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.

2.Contraindications

1)The product shall not be used for measuring for under 12 years old;
2)Those who suffer from severe arrhythmia shall not use the this product;
3)Do not use this monitor on the injured arm or the arm under medical treatment;
4)Do not apply the arm cuff on the arm while being on an intravenous drip or blood transfusion.

III.Important Safety Information

1.Warnings

⚠To measure the blood pressure accurately and reliably, followings shall be noted when measuring!
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)Note: It would be dangerous by making self-judgment and self-treatment according to the measurement results. Please follow the doctor's advice.
22)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 this monitor.
23)Avoid compression or restriction of the connection tubing.

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 mHg, 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.	Part Name	Model	Quantity
1)	Main unit	X5	1 set
2)	Cuff	URN-2242	1 set
3)	Instructions Manual	/	1 copy

2.Technical specification

Device Name	Electronic Sphygmomanometer
Model	X5
Display Digital LCD	Digital LCD
Method of measurement	Oscillometry
Weight	About 245 g
Dimensions	Appr. 135 (L) X 100 (W) X 68 mm (H)
Cuff	Appr. 150 mm (W) x 450 mm (L)
Cuff Measurement perimeter of the upper arm	220mm~420mm
Material of cuff	Nylon polyester
Measuring pressure range	Blood pressure: 0~295 mmHg, 0~40 kPa
Measuring pressure accuracy	Pressure: within ±3 mmHg (±0.4 kPa), or 2% of the reading , whichever is greater
Pulse range	(40~160) 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 x 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 5V 500 mA
Operating condition	· Temperature: (+5 ~ +40)℃. · Relative Humidity: (15% ~ 90%)RH · Atmospheric pressure: 70 kpa ~ 106 kpa · Power: DC 5V (4 AAA batteries)
Storage and transportation environment	· Environment temperature: -25℃~ +55℃. · Relative humidity: 10% ~ 95% (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	IP 21
Applied parts	Type BF
Electromagnetic compatibility	Group 1 and Class B device
Accessories	Cuff (for arm circumference of 22 cm ~ 42cm) IFU
Software release version	V1.0

V.Structure and descriptions of product

1.Product Picture

Figure 1. Main Unit

Figure 2. Cuff

2.Product structure

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

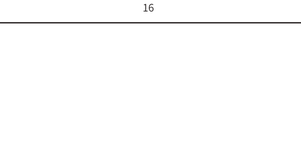


Figure 3. Product Structure

3.Description of LCD Screen

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

Figure 4. Sketch of LCD Screen

VI.Settings

1.Memory clear
Press and hold the " MEM " key for 3 seconds in the reading memory mode to clear the memory value stored in the product.
2.Set the date/time
"Year"
When the monitor is turned on but not measured, press and hold the "SET "key for about 3 seconds, the Year on screen starts to flash, and press the "MEM " key to set the year.
"Month"
After the year is adjusted, press the "SET "key again, the Month starts to flash at this time, and press the "MEM" key to make adjustment.
"Day"
After the month is adjusted, press the "SET "key again, the Date starts to flash at this time, and press the "MEM" key to make adjustment.
"Hours"/"Minutes"
Upon date adjustment, press the "SET " key again and the Hour starts to flash, press the "MEM " key to adjust. Set the "Minutes" by following the above-mentioned steps.
3.Unit conversion
The unit is defaulted as "mmHg". After setting "Date/-Time", press "SET "key and "0" is displayed. If you want to switch unit to "kPa", press ".MEM " key and "0.0" will appear, which means unit conversion is successful. Pressing "MEM" key again to convert from "kPa" to "mmHg".
4."User"
The monitor stores the memory of 2 people x 99 groups, with each group of users enjoying 99 groups of memory. Upon measurement each time, the monitor automatically stores the measurement data. Once the memory capacity is full, the old measurement data will be overwritten by the new one.

By pressing the "SET"key when the monitor is powered on but no measurement is performed, the screen will display the current user group, and then press the "SET" key again to switch the user ("SET" or "MEM" optional). If no set is made, the User 1 SET is defaulted.
5.Reading of main memory value
Press the "MEM " key 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" key again to display the last measurement result. View the measured values of 2, 3... continuously by repeating this step.
6.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' re error codes prompts or display abnormality, please contact the after-sales service center to eliminate the abnormality as per the prompts.

Er1	No pulse detected.
Er2	Too much interference
Er3	The measurement result is wrong
Er6	Airway blocked
Er7	Sensor error
ErP	The inflation cannot reach 25mmHg within 9 seconds
Hi	When the pressure exceeds 295mmHg, it will automatically exhaust.

VII.Preparation

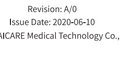
Open the Electronic Sphygmomanometers. The device case should be uniformly colored with no obvious defects such as scars and scratches.
Please keep it properly when carrying and storing.
1.To load the batteries
1)Open the Battery Case cover on the side of the unit and put the 4 batteries (AAA) correctly.
2)Put the Battery Case cover back properly.

Notes:
· When the depleted battery symbol ( ) appears on the display, turn the monitor off and remove all the batteries. Replace with 4 new batteries at the same time. Long life alkaline batteries are recommended.
· The measurement values continue to be stored in memory even after the batteries are replaced.
· 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.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.)

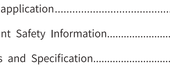
3)Wrap the arm Cuff firmly in place around your left upper arm.
It is advisable to tie the Cuff properly that the arm will not feel physical tension.

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.

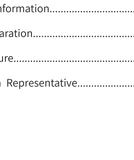
4)Secure closed with the fabric fastener.



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 a properly sized Cuff is used.
6)Do not place the arm Cuff over thick clothes.
3.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.



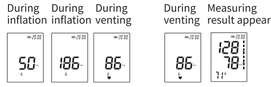
1)Sit in a comfortable chair with your back and arms supported, and maintain the right posture; do not force with your fingers, and keep them stretched.
2)Keep your feet flat and your legs uncrossed.
3)Both arms should be resting comfortably on a table.
4)Place your monitor close enough to touch with your bent elbows.
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 ~ 5 minutes 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.
4.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 5 minutes prior to measurement;
3)Generally, the blood pressure is measured in a sitting position. If a prone position 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" key. After that, 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.

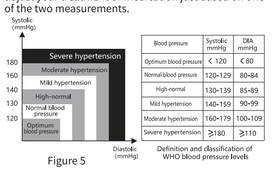


Reading of measured values and make repeated measurements After the automatic measurement is finished, the display screen will automatically display the systolic pressure and diastolic pressure of the person under measurement in mmHg, and simultaneously display the measured pulse rate (in times/minute).

Press the "Start" key again to make another measurement.
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.
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.

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 5 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.

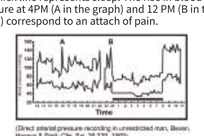


Blood pressure	Systolic mmHg	DIA mmHg
Optimum blood pressure	< 120	< 80
Normal blood pressure	120~129	80~84
High-normal	130~139	85~89
Mild hypertension	140~159	90~99
Moderate hypertension	160~179	100~109
Severe hypertension	≥180	≥110

Definition and classification of WHO blood pressure levels

Figure 5

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 attach of pain.



(Direct arterial pressure recording in unrestricted man, Bevan, Honour & Stott: Clin. Sci. 36:329. 1969)

IX.Requirements of Storage and maintenance

1)Avoid falling or strong collisions.
2)Avoid high temperatures 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 for disinfection.
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 for disinfection.

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 figure	Meaning	Symbol figure	Meaning
	General warning sign		TYPE BF APPLIED PART
	Low voltage prompt	SN	Serial number
	WEEE information for the disposal or recycling of waste WEEE Check with your local Authority or retailer for recycling advice	CE 0197	CE marking of conformity, and Notified Body Code
	Date of manufacture	EC REP	Authorized representative in the European community
	Manufacturer	Pulse Symbol	Once pulse is detected, the symbol flashes with each pulse beat. Our suggestion: Please do not talk or move during measurements.
	Keep away from sunlight		Keep dry
	This Way UP		Fragile, handle with care
	This symbols appears when the battery power is excessively low or the polarity reverses. We suggestion you replace all batteries with new ones, and make sure the +/- polarities are properly positioned.		
	"Consult accompanying documents " is intended to alert the user to refer to the operator manual or other instructions when complete information cannot be provided on the label		
IP21	Solids: Protected against touch by fingers (>12.5mm) Liquids: Protected against vertically falling water drops		

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, Qianping Industrial Park, Le'an County, Fuzhou City, 344300 Jiangxi，P.R.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 IEC 60601-1-2 standard for class A 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: 0~295 mmHg, 0~40 kPa
Measuring pressure accuracy	Pressure: within ±3 mmHg (±0.4 kPa)or 2% of the reading , whichever is greater
Pulse measurement range	(40~160) beats/min
Pulse rate accuracy	Within ±5% of the reading
Reproducibility of the BLOOD PRESSURE DETERMINATION	≤ 3.0mmHg

Guidance and manufacture's declaration – electromagnetic emissions	
The RF Generators is suitable for use in the specified electromagnetic environment (s) and it has meets the following standard' s emission requirements.	
Phenomenon	Profession healthcare facility environment
Conducted and radiated RF emissions	CISPR 11, Group 1, Class B
Harmonic distortion	IEC 61000-3-2, not applicable
Voltage fluctuations and flicker	IEC 61000-3-3 not applicable

Guidance and manufacture's declaration – electromagnetic immunity		
The RF Generators is suitable for use in the specified electromagnetic environment and it has meets the following immunity test levels. Higher immunity levels may cause the RF Generator' s essential performance lost or degraded.		
Phenomenon	Basic EMC standard or test method	Professional healthcare facility environment
Electrostatic discharge	IEC 61000-4-2	+/- 8 kV contact +/- 2 kV, +/- 4 kV, +/- 8 kV, +/- 15 kV air
Radiated RF EM fields	IEC 61000-4-3	10V/m 80MHz-2.7GHz 80%AM at 2 Hz

Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See the RF wireless communication equipment table in "Recommended minimum separation distances"
Rated power frequency magnetic fields	IEC 61000-4-8	30A/m; 50Hz or 60Hz
Electric fast transients bursts	IEC 61000-4-4	±2kV 100kHz repetition frequency
Surges	IEC 61000-4-5	Line to line: ±0.5kV, ±1kV
Conducted disturbances induced by RF fields	IEC 61000-4-6	3 V in 0.15 MHz ~ 80 MHz 5 V in ISM and/or amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 2 Hz
Voltage dips	IEC 61000-4-11	0% UT: 0.5 cycle at 0°, 45°, 90°, 135°, 180°, 225°, 270°, and 315°
		0% UT: 1 cycle and 70% UT: 25/30 cycles sine phase at 0°
Voltage interruptions	IEC 61000-4-11	0% UT: 250/300 cycle
UT: rated voltage(s); E.g. 25/30 cycles means 25 cycles at 50Hz or 30 cycles at 60Hz		

Recommended minimum separation distances						
Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. This RF Generators has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this RF Generators as recommended below.						
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
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 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, IDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9

XV.Manufacture

【MANUFACTURER】
Jiangxi AICARE Medical Technology Co., Ltd.
No. 6, South Side of Nanhuan Road, Qianping Industrial Park, Le'an County, Fuzhou City, 344300 Jiangxi，P.R.China

XVI.European Representative

【EUROPEAN REPRESENTATIVE】
Caretechion GmbH
Niederrheinstr. 71, 40474 Duesseldorf, Germany.

Name:KINGSMEAD SERVICE LIMITED
Address:19 MEZZANINE FLOOR 19-21 CRAWFORD STREET LONDON ENGLAND W1H 1PJ

DE

Rahmen
1.Speicher klar
Halten Sie im Lesespeichermodus die Taste "MEM" 3 Sekunden lang gedrückt, um den im Produkt gespeicherten Speicherwert zu löschen.
2.Stellen Sie Datum und Uhrzeit ein
"Year"
Wenn der Monitor eingeschaltet, aber nicht gemessen ist, halten Sie die Taste "SET"etwa 3 Sekunden lang gedrückt. Der Bildschirm "Year" beginnt zu blinken, und drücken Sie die Taste "MEM", um das Jahr einzustellen.
"Month"
Nachdem das Jahr angepasst wurde, drücken Sie erneut die Taste "SET". Der Monat beginnt zu diesem Zeitpunkt zu blinken, und drücken Sie die Taste "MEM", um die Einstellung vorzunehmen.
"Day" ：
Nachdem der Monat angepasst wurde, drücken Sie erneut die Taste "SET". Zu diesem Zeitpunkt beginnt das Datum zu blinken, und drücken Sie die Taste "MEM", um die Einstellung vorzunehmen.
"Hours"/"Minutes"
Drücken Sie nach der Datumseinstellung erneut die Taste "SET" und die Stunde beginnt zu blinken. Drücken Sie zum Einstellen die Taste "MEM". Stellen Sie die "Minutes" ein, indem Sie die oben genannten Schritte ausführen.
3.Einheitenumrechnung
Das Gerät ist standardmäßig auf „mmHg“ eingestellt. Drücken Sie nach dem Einstellen von "Date/Time"die Taste "SET" und "0" wird angezeigt. Wenn Sie das Gerät auf „kPa“ schalten möchten, drücken Sie die Taste "MEM". Daraufhin wird "0.0" angezeigt. Dies bedeutet, dass die Gerätekonvertierung erfolgreich ist.Pressing "MEM" key again to convert from "kPa" to "mmHg".
4.""Benutzer"
Der Monitor speichert den Speicher von 2 Personen x 99 Gruppen, wobei jede Benutzergruppe über 99 Speichergruppen verfügt. Bei jeder Messung speichert der Monitor die Messdaten automatisch. Sobald die Speicherkapazität voll ist, werden die alten Messdaten durch die neuen überschrieben. Durch Drücken der Taste "SET", wenn der Monitor eingeschaltet ist, aber keine Messung durchgeführt wird, wird auf dem Bildschirm die aktuelle Benutzergruppe angezeigt. Drücken Sie dann erneut die Taste "SET", um den Benutzer umzuschalten (optional "SET" oder "MEM")). Wenn keine Einstellung vorgenommen wird, ist die Einstellung Benutzer 1 voreingestellt.
5.Lesen des Hauptspeicherwerts
Drücken Sie die Taste "MEM", nachdem die Messung beendet wurde oder sich im Ausschaltmodus befindet. Das LCD zeigt das gemittelte letzten drei Messungen an und sendet es.
Drücken Sie die Taste "MEM" erneut, um das letzte Messergebnis anzuzeigen. Zeigen Sie die gemessenen Werte von 2, 3 ... kontinuierlich an, indem Sie diesen Schritt wiederholen.
6.Fehlercode-Beschreibung
Überprüfen Sie vor der Verwendung des elektronischen Monitors vom Armtyp, ob auf dem Monitor eine Fehlercode-Eingabeaufforderung angezeigt wird oder ob die Nummer (oder das Symbol) nach dem Einschalten nicht angezeigt werden kann. Wenn Fehlercodes angezeigt werden oder Anomalien angezeigt werden, wenden Sie sich an das Kundendienstzentrum, um die Anomalien gemäß den Eingabeaufforderungen zu beseitigen.

Er1	Kein Puls erkannt.
Er2	Zu viele Störungen
Er3	Das Messergebnis ist falsch
Er6	Atemwege blockiert
Er7	Sensorfehler
ErP	Das Aufpumpen kann nicht innerhalb von 9 Sekunden 25 mmHg erreichen
H!	Wenn der Druck 295 mmHg überschreitet, wird er automatisch entlüftet.

FR

Réglages
1.Mémoire claire
Appuyez sur la touche «MEM» et maintenez-la enfoncée pendant 3 secondes en mode mémoire de lecture pour effacer la valeur de la mémoire stockée dans le produit.
2.Réglez la date / l'heure
"An"
Lorsque le moniteur est allumé mais pas mesuré, appuyez sur la touche «SET» et maintenez-la enfoncée pendant environ 3 secondes, l'année à l'écran se met à clignoter et appuyez sur la touche «MEM» pour régler l'année.
"Mois"
Une fois l'année ajustée, appuyez à nouveau sur la touche «SET», le mois commence à clignoter à ce moment, et appuyez sur la touche «MEM» pour effectuer le réglage.
"Jour"
Une fois le mois ajusté, appuyez à nouveau sur la touche «SET», la date commence à clignoter à ce moment, et appuyez sur la touche «MEM» pour effectuer le réglage..
"Heures"/"Minutes"
Lors du réglage de la date, appuyez à nouveau sur la touche «SET» et l'heure commence à clignoter, appuyez sur la touche «MEM» pour régler. Réglez les «minutes» en suivant les étapes mentionnées ci-dessus.
3.conversion d'unité
L'unité est par défaut «mmHg». Après avoir réglé «Date / Heure», appuyez sur la touche «SET» et «0» s'affiche. Si vous voulez changer l'unité sur "kPa", appuyez sur la touche "MEM" et "0.0" apparaîtra, ce qui signifie que la conversion d'unité est réussie..
Appuyez à nouveau sur la touche "MEM" pour convertir de "kPa" en "mmHg".
4."utilisateur"
Le moniteur stocke la mémoire de 2 personnes x 99 groupes, chaque groupe d'utilisateurs bénéficiant de 99 groupes de mémoire. Lors de l'utilisation à chaque fois, le moniteur stocke automatiquement les données de mesure. Une fois la capacité de la mémoire pleine, les anciennes données de mesure seront écrasées par les nouvelles.
En appuyant sur la touche «SET» lorsque le moniteur est allumé mais qu'aucune mesure n'est effectuée, l'écran affichera le groupe d'utilisateurs actuel, puis appuyez à nouveau sur la touche «SET» pour changer d'utilisateur («SET» ou «MEM» en option). Si aucun réglage n'est effectué, l'utilisateur 1 SET est défini par défaut.
5.Lecture de la valeur de la mémoire principale
Appuyez sur la touche «MEM» une fois la mesure terminée ou en mode hors tension, et l'écran LCD affichera et résultat moyen des trois dernières mesures.
Appuyez à nouveau sur la touche «MEM» pour afficher le dernier résultat de mesure. Visualisez les valeurs mesurées de 2, 3 ... en continu en répétant cette étape.
6.Description du code d'erreur
Avant d'utiliser le moniteur électronique de type bras, vérifiez si le moniteur a une invite de code d'erreur ou s'il est incapable d'afficher le numéro (ou le symbole) après la mise sous tension. S'il y a des invites de codes d'erreur ou une anomalie d'affichage, veuillez contacter le centre de service après-vente pour éliminer l'anomalie conformément aux invites.

Er1	Aucune impulsion détectée.
Er2	Trop d'interférences
Er3	Le résultat de la mesure est faux
Er6	Voies respiratoires bloquées
Er7	Erreur de capteur
ErP	Le gonflage ne peut pas atteindre 25 mmHg en 9 secondes
H!	Lorsque la pression dépasse 295 mmHg, il s'épuise automatiquement.

IT

Impostazioni
1.Memoria chiara
Tenere premuto il tasto "MEM" per 3 secondi in modalità memoria di lettura per cancellare il valore della memoria memorizzato nel prodotto.
2.Imposta data / ora
"Year"
Quando il monitor è acceso ma non misurato, premere e tenere premuto il tasto "SET" per circa 3 secondi, l '"Year" sullo schermo inizia a lampeggiare e premere il tasto "MEM" per impostare l'anno.
"Month"
Dopo che l'anno è stato regolato, premere di nuovo il tasto "SET", il "mese" inizia a lampeggiare in questo momento e premere il tasto "MEM" per effettuare la regolazione.
"Day"
Dopo che il mese è stato regolato, premere di nuovo il tasto "SET", la data inizia a lampeggiare in questo momento e premere il tasto "MEM" per effettuare la regolazione..
"Hours "/"Minutes"
Dopo la regolazione della data, premere nuovamente il tasto "SET" e l'ora inizia a lampeggiare, premere il tasto "MEM" per regolare. Impostare i "Minuti" seguendo i passaggi sopra indicati.
3.Conversione di unità
L'impostazione predefinita dell'unità è "mmHg".
Dopo aver impostato "Data / Time", premere il tasto "SET" e viene visualizzato "0". Se si desidera impostare l'unità su "kPa", premere il tasto "MEM" e apparirà "0.0", il che significa che la conversione dell'unità è riuscita..
Pressing "MEM" key again to convert from "kPa" to "mmHg".
4."User
Il monitor memorizza la memoria di 2 persone x 99 gruppi, con ogni gruppo di utenti che gode di 99 gruppi di memoria. Ad ogni misurazione, il monitor memorizza automaticamente i dati di misurazione. Quando la capacità di memoria è piena, i vecchi dati di misurazione verranno sovrascritti da quelli nuovi. Premendo il tasto "SET" quando il monitor è acceso ma non viene eseguita alcuna misurazione, lo schermo visualizzerà il gruppo di utenti corrente, quindi premere nuovamente il tasto "SET" per cambiare utente ("SET" o "MEM" opzionale). Se non viene eseguita alcuna impostazione, viene impostato come predefinito l'User 1 SET.
5.Lettura del valore della memoria principale
Premere il tasto "MEM" dopo che la misurazione è terminata o in modalità di spegnimento, e il display LCD visualizzerà e risultato medio delle ultime tre misurazioni.
Premere nuovamente il tasto "MEM" per visualizzare l'ultimo risultato della misurazione. Visualizza i valori misurati di 2, 3 ... continuamente ripetendo questo passaggio.
6.Descrizione del codice di errore
Prima di utilizzare il monitor elettronico a braccio, controllare se il monitor presenta un messaggio di errore o se non è possibile visualizzare il numero (o il simbolo) dopo l'accensione. Se vengono visualizzati messaggi di codici di errore o anomalie del display, contattare il centro di assistenza post-vendita per eliminare l'anomalia secondo le istruzioni.

Er1	Nessun impulso rilevato.
Er2	Troppe interferenze
Er3	Il risultato della misurazione è sbagliato
Er6	Vie aeree bloccate
Er7	Errore del sensore
ErP	Il gonfiaggio non può raggiungere i 25 mmHg entro 9 secondi
H!	Quando la pressione supera i 295 mmHg, si esaurirà automaticamente.

ES

Configuraciones
1.Memoria clara
Mantenga presionada la tecla "MEM" durante 3 segundos en el modo de memoria de lectura para borrar el valor de la memoria almacenado en el producto.
2.Configure la fecha / hora
"Año"
Cuando el monitor está encendido pero no se mide, presione y mantenga presionada la tecla "SET" durante unos 3 segundos, el año en la pantalla comienza a parpadear y presione la tecla "MEM" para configurar el año.
"Mes"
Después de ajustar el año, presione la tecla "SET" nuevamente, el mes comienza a parpadear en este momento, y presione la tecla "MEM" para realizar el ajuste.
"Día"
Después de ajustar el mes, presione la tecla "SET" nuevamente, la fecha comienza a parpadear en este momento, y presione la tecla "MEM" para hacer el ajuste.
"Horas" / "Minutos"
Luego del ajuste de la fecha, presione la tecla "SET" nuevamente y la Hora comenzará a destellar, presione la tecla "MEM" para ajustar. Configure los "Minutos" siguiendo los pasos mencionados anteriormente.
3.Conversión de unidades
La unidad está predeterminada como "mmHg".
Después de configurar "Fecha / Hora", presione la tecla "SET" y se mostrará "0". Si desea cambiar la unidad a "kPa", presione la tecla "MEM" y aparecerá "0.0", lo que significa que la conversión de la unidad se realizó correctamente.
Presionando la tecla "MEM" nuevamente para convertir de "kPa" a "mmHg".
4."Usuario"
El monitor almacena la memoria de 2 personas x 99 grupos, y cada grupo de usuarios disfruta de 99 grupos de memoria. Al medir cada vez, el monitor almacena automáticamente los datos de medición. Una vez que la capacidad de la memoria esté llena, los datos de medición antiguos serán sobrescritos por los nuevos.
Al presionar la tecla "SET" cuando el monitor está encendido pero no se realiza ninguna medición, la pantalla mostrará el grupo de usuarios actual, y luego presione la tecla "SET" nuevamente para cambiar el usuario ("SET" o "MEM" opcional). Si no se realiza ningún ajuste, el usuario 1 SET está predeterminado.
5.Lectura del valor de la memoria principal
Presione la tecla "MEM" después de que finalice la medición o en el modo de apagado, y la pantalla LCD mostrará y resultado promedio de las últimas tres mediciones.
Presione la tecla "MEM" nuevamente para mostrar el último resultado de la medición. Ver los valores medidos de 2, 3 ... continuamente repitiendo este paso.
6.Descripción del código de error
Antes de usar el monitor electrónico tipo brazo, verifique si el monitor tiene un mensaje de código de error o no puede mostrar el número (o símbolo) después de encenderlo. Si hay indicaciones de códigos de error o se muestra una anomalía, comuníquese con el centro de servicio posventa para eliminar la anomalía según las indicaciones.

Er1	No se detectó pulso.
Er2	Demasiada interferencia
Er3	El resultado de la medición es incorrecto
Er6	Vía respiratoria bloqueada
Er7	Error de sensor
ErP	La inflación no puede alcanzar los 25 mmHg en 9 segundos.
H!	Cuando la presión supera los 295 mmHg, se agotará automáticamente.

português

quadro
1. Armazenamento claro
No modo de leitura de memória, pressione e segure o botão "MEM" por 3 segundos para limpar o valor da memória armazenado no produto.
2. Defina a data e hora
"Ano"
Se o monitor estiver ligado, mas não for medido, pressione e segure o botão "SET" por cerca de 3 segundos. A tela "Ano" começará a piscar e pressione o botão "MEM" para definir o ano.
"Mês"
Após o ajuste do ano, pressione o botão "SET" novamente. O mês começará a piscar neste ponto e, em seguida, pressione o botão "MEM" para definir.
"Dia"
Após o mês ter sido ajustado, pressione o botão "SET" novamente. Neste ponto, a data começará a piscar e pressione o botão "MEM" para definir.
"Horas" / "Minutos"
Após definir a data, pressione o botão "SET" novamente e a hora começará a piscar. Pressione o botão "MEM" para definir. Defina os "Minutos" seguindo os passos acima.
3. Conversão de unidades
O dispositivo é definido como "mmHg" por padrão. Após definir "Data / Hora", pressione o botão "SET" e "0" será exibido. Se você quiser mudar o dispositivo para "kPa", pressione o botão "MEM". "0.0" será exibido. Isto significa que a conversão do dispositivo foi bem sucedida, pressionando a tecla "MEM" novamente para converter de "kPa" para "mmHg".
4. "Usuário"
O monitor armazena a memória de 2 pessoas x 99 grupos, com cada grupo de usuários tendo 99 grupos de memória. O monitor salva automaticamente os dados de medição para cada medição. Assim que a capacidade da memória estiver cheia, os dados de medição antigos serão substituídos pelos novos.
Ao pressionar a tecla "SET" quando o monitor está ligado, mas nenhuma medição está sendo realizada, o grupo de usuários atual é exibido na tela. Em seguida, pressione o botão "SET" novamente para alternar o usuário (opcionalmente "SET" ou "MEM")). Se nenhuma configuração for feita, a configuração do Usuário 1 é predefinida.
5. Leia o valor da memória principal
Pressione a tecla "MEM" após o término da medição ou no modo de desligamento. O LCD mostra a média das últimas três medições e as envia.
Pressione o botão "MEM" novamente para exibir o último resultado da medição. Exiba os valores medidos de 2, 3 ... continuamente, repetindo esta etapa.
6. Descrição do código de erro
Antes de usar o monitor eletrônico tipo braço, verifique se o monitor exibe um prompt de código de erro ou se o número (ou ícone) não pode ser exibido após ser ligado. Se algum código de erro for exibido ou anomalias, entre em contato com o centro de atendimento ao cliente para corrigir as anormalidades de acordo com as instruções.

Er1	Nenhum pulso detectado.
Er2	Muita interferência
Er3	O resultado da medição está incorreto
Er6	Obstrução das vias aéreas
Er7	Erro de sensor
ErP	A inflação não pode atingir 25 mmHg em 9 segundos.
H!	Quando a pressão excede 295 mmHg, ela se esgota automaticamente.

русский

VI. Настройки
1. память ясна
Нажмите и удерживайте кнопку "MEM" в течение 3 секунд в режиме чтения памяти, чтобы очистить значение памяти, сохраненное в продукте.
2. установить дату / время
"Год"
Когда монитор включен, но измерения не ведутся, нажмите и удерживайте кнопку "SET" около 3 секунд, год на экране начнет мигать, и нажмите кнопку "MEM", чтобы установить год.
"Месяц"
После настройки года снова нажмите кнопку "SET», месяц начнет мигать в это время, и нажмите кнопку "MEM", чтобы выполнить настройку.
"День"
После настройки месяца снова нажмите кнопку "SET" , дата начнет мигать в это время, и нажмите кнопку "MEM", чтобы выполнить настройку.
"Часы" / "Минуты"
После настройки даты нажмите кнопку "SET" еще раз, и часы начнут мигать, нажмите кнопку "MEM" для настройки.Установите "Минуты" , выполнив вышеупомянутые шаги.
3. преобразование единиц измерения
Единицей измерения по умолчанию является " mmHg". появляется, что означает успешное преобразование единиц измерения.
Повторное нажатие кнопки "MEM" для преобразования из" kPa" в" mmHg" . .
4. "Пользователь"
Монитор хранит память 2 человек x 99 групп, при этом каждая группа пользователей использует 99 групп памяти. При каждом измерении монитор автоматически сохраняет данные измерений. Как только объем памяти заполнится, старые данные измерений будут перезаписаны. по новой.
При нажатии кнопки "SET", когда монитор включен, но измерения не выполняются, на экране отобразится текущая группа пользователей, а затем снова нажмите кнопку "SET", чтобы переключить пользователя ("SET" или " MEM" необязательно. Если ничего не задано, по умолчанию используется User 1 SET.
5.Чтение значения основной памяти
Нажмите кнопку " MEM" после завершения измерения или в режиме отключения питания, и на ЖК-дисплее отобразится и транслируется усредненный результат трех последних измерений.
Нажмите кнопку " MEM" еще раз, чтобы отобразить результат последнего измерения.Посмотрите измеренные значения 2, 3 ... непрерывно, повторяя этот шаг.
6. описание кода ошибки
Перед использованием электронного монитора ручного типа проверьте, отображается ли на мониторе подсказка с кодом ошибки или не отображается ли номер (или символ) после включения питания. Если появляются подсказки с кодами ошибок или ненормальное отображение, обратитесь в службу поддержки. -сервисный центр продаж для устранения неисправности согласно подсказкам.

Er1	Нет обнаружения пульса.
Er2	Демасиада интерференция
Er3	El resultado de la medición es неверно
Er6	Obstrucción de la vía aerea
Er7	Ошибка датчика
ErP	La inflación no puede alcanzar los 25 mmHg en 9 segundos.
H!	Cuando la presión supera los 295 mmHg, se agotará automáticamente.