

# Electronic Sphygmomanometers Model:X11 Instructions for Use

◆ In order for you to use this product safely, please be sure to read the instruction manual before use.  
◆ A warranty card is included, please do not lose it.  
◆ The illustrations in this manual are effects.

Jiangxi AICARE Medical Technology Co., Ltd.

TV, mobile phone, microwave oven, X-ray, etc.  
9. Do not use this product on newborn babies.  
10. Do not use this product for purposes other than blood pressure measurement.  
11. If not used for a long time, the battery should be removed to prevent battery leakage.  
12. When the air bag is excessively pressurized for a long time, it may cause pain, numbness, and even congestion in the arm. Please do not pressurize more than 300mmHg, and do not maintain armband pressure greater than 15mmHg for more than 3 minutes.  
13. Arrhythmias such as premature ventricular bleeding, premature ventricular bleeding, and atrial fibrillation during measurement may lead to the detection of irregular pulse rates. The electronic sphygmomanometer can still work normally, but the measured blood pressure value may be inaccurate. When irregularities occur frequently, it is recommended that you consult your doctor.  
14. If the electronic sphygmomanometer is used or stored outside the temperature and humidity range specified in this manual, the safety and performance of the electronic sphygmomanometer may fail, or the electronic sphygmomanometer may even be damaged.  
15. When replacing the armband, please use the armband provided by the manufacturer. Replacing the original parts

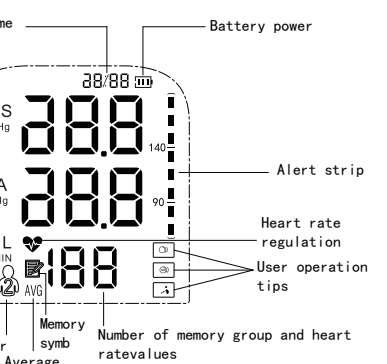
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with an armband not provided by the manufacturer may cause measurement errors.  
16. Please contact the manufacturer for static pressure testing.  
17. Please avoid sharing armbands with others to avoid cross infection.  
18. If you need to provide circuit diagrams, component lists, etc., please contact the manufacturer.

### Chapter 7 Product SETS

1. Display interface symbol meaning diagram



## Preface

Dear user:  
We appreciate for your purchase of our Arm-type electronic sphygmomanometer. 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.

### Product 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 reduced is comfort caused by incorrect pressurization, shorten measurement time, and extend the life of the Cuff.

## Chapter 1 Symbols and meanings related to safety requirements in this product

Symbol figure	Meaning	Symbol figure	Meaning
	Serial number		General warning sign
	"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		WEEE information for the disposal or recycling of waste WEEECheek with your local Authority or retailer for recycling advice
	Date of manufacture		Authorized representative in the European community
	Keep away from sunlight		Keep dry
	TYPE BF APPLIED PART		Fragile, handle with care
	CE marking of conformity, and Notified Body Code		Manufacturer
	Once pulse is detected, the symbol flashes with each pulse beat. Our suggestion: Please do not talk or move during measurements		This Way UP

	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.
	Solids: Protected against touch by fingers (>12.5mm)Liquids: Protected against vertically falling water drops

## Chapter 2 Scope of application and Precaution

2.1.Scope of application  
This product is used to measure human blood pressure. It is only suitable for adults over 12 years old and cannot be used for newborns!  
2.2.Precautions for use

⚠ Note: To ensure accurate and reliable blood pressure measurements, please be sure to pay attention to the following points when measuring!  
⚠ Please sit quietly for 5 minutes before measuring, and then use the correct posture to measure your blood pressure.

- ⊘ Please do not measure while standing, walking, or when the body part is under pressure.
- ⊘ Please do not measure after smoking, drinking alcohol, or drinking coffee (black tea).
- ⊘ Please do not measure after exercising or bathing.
- ⊘ Please do not talk or move your body during the measurement process.

- ⊘ Please do not move, shake your arms or bend your fingers during measurement.
- ⊘ Please do not measure when it is too cold, too hot or when the environment changes drastically.
- ⊘ Please do not measure in moving vehicles.
- ⊘ Please do not perform continuous measurements for a long time (it is recommended that the interval between two consecutive measurements should not be less than 3 minutes).
- ⊘ Please do not move the blood pressure monitor during measurement.
- ⊘ Please do not take measurements within 1 hour after a meal.
- ⚠ Note: It is dangerous to judge and treat yourself based on the measurement results . Please follow your doctor's advice.

## Chapter 3 Product Features and Product Technical Specification

- Product list
  - 1)Main unit 1 set
  - 2)Cuff 1 set
  - 3)Manuals 1 copy

## Specifications

Device Name	Electronic Sphygmomanometers
Models	X 11
Display Digital LCD	Digital LCD
Method of measurement	Oscillometry
Cuff	Appr. 150 mm (W) × 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, 0~40kPa
Measuring pressure accuracy	Pressure: within ±3 mmHg (±0.4 kPa), or 2% of the reading
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 × 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 *Do not provide, please buy it by yourself
Operating condition	Temperature: (+5 ~ +40)℃
	Relative Humidity: (15% ~ 90%)RH
	Atmospheric pressure: 70 kpa ~ 106 kpa
Storage and transportation environment	Power: AAA batteries (4pc) or DC 5V 500 mA
	Environment temperature: -25℃~ +55℃;
	Relative humidity: 10% ~ 95% (non-condensing);
	No corrosive gas, well ventilated room.
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) Instructions for Use

## Chapter 4 Product Structure and Description

- Product structure  
The product consists of a main unit (including air pump, pressure sensor, deflation valve, power supply circuit, button control circuit, display module, CPU control module, embedded software, etc.) and a cuff. see picture 1.



Main Unit



Cuff

- Intended use: This product uses the oscillometric method to measure diastolic blood pressure, systolic blood pressure, and pulse in adults over 12 years old. The values are for diagnostic reference. Statement:  
1. The blood pressure value measured by this device is equivalent to the value measured by the auscultation method, and its error complies with the requirements of EN IEC 80601-2-30.  
2. Please store or use the blood pressure monitor within the following temperature and humidity range specified by the manufacturer. If the blood pressure monitor is stored or used beyond the specified temperature and humidity, it may cause abnormal performance or functionality of the product.

### Set "Year"/"Minute"

After the date adjustment is completed, press the " Set " button :



Then the date starts flashing :



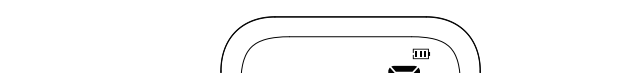
And press the "MEM" key to adjust . The system default device time is, for example, 13 o'clock. Each short press of the "MEM" key will increase the time by 1 until 0 o'clock (24-hour clock) and press the "MEM" key again to return to 1 o'clock. Cycle in turn. After SET the hour, press the " Set " button again to set the minute, and follow the same method as before to set the "minute".

After SET the hour, press the " Set " button again to set the minute, and follow the same method as before to set the "minute".

And press the "MEM" key to adjust, the system default date of the device, for example, 28, every short press "MEM" key month +1, until December and then press the "MEM" key back to 1, and so on.

### Set "Hour"/"Minute"

After the date adjustment is completed, press the " Set " button :



Then the date starts flashing :



And press the "MEM" key to adjust, the system default device month for example, February, every short press "MEM" key month +1, until December and then press the "MEM" key back to January, and so on.

And press the "MEM" key to adjust, the system default date of the device, for example, 28, every short press "MEM" key date +1, until 31 and then press the "MEM" key back to 1, and so on.

And press the "MEM" key to adjust, the system default date of the device, for example, 28, every short press "MEM" key date +1, until 31 and then press the "MEM" key back to 1, and so on.

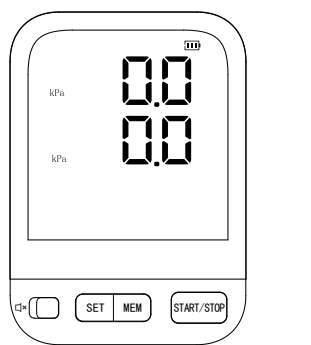
Operating temperature and humidity: ( +5℃ ~ +40℃ ) ; ( 15% ~ 80% ) RH;  
Transportation and storage temperature and humidity: ( -20 ~ +55 ) C ; ( 10% ~ 93% ) RH.  
3. This machine can be connected to an external 5V/500mA DC power supply. Please use a power adapter that complies with medical device standards (IEC 60601-1-2:2005+AMD1:2012/IEC 60601-1-2:2015).

## Chapter 5 Working and Storage Conditions

- Working conditions
  - Working environment
    - Temperature: 5 C ~ 40 C ;
    - Relative humidity: (15% ~ 80%) RH;
    - Atmospheric pressure: 80 kPa ~ 105 kPa.
  - Working power supply voltage: DC 5V 500mA or AAA batteries(4pc)

### 2. Storage conditions

The packaged electronic sphygmomanometer should be stored in a room with a temperature of -20℃ to +55℃ , a relative humidity of 10 % to 93% , no corrosive gases, and a well-ventilated room.



Once the memory capacity is full, the old measurement data will be overwritten by the new data. When the sphygmomanometer is powered on but not measuring, short press the " Set " button , the screen will display the current user group icon , press the " Set " button again to switch users (you can select " " or " "). If no SET is made, the system defaults to user " " .

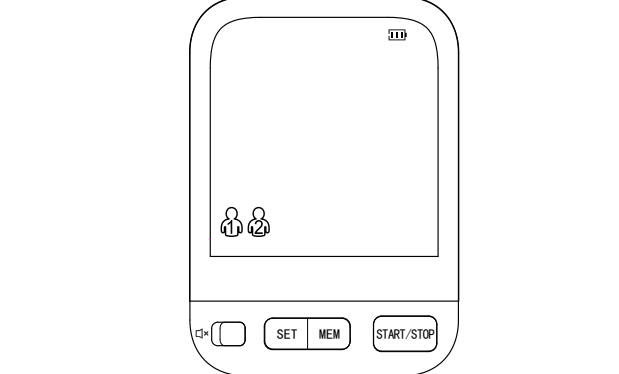
5. 【Voice switch 】  
Turn the voice button " " on the left side of the device to turn on/off the sound.

6. 【Set User】  
This blood pressure monitor stores 2 people × 99 sets of memories, and each group of users has 99 sets of memories. After each measurement, the blood pressure monitor automatically stores the measurement data.

## Chapter 6Contraindications and Precautions

- Contraindications: People with severe arrhythmias are not suitable for using electronic blood pressure monitors.
- Precautions:
  - Avoid eating, smoking and strenuous exercise within 30 minutes before measuring blood pressure.
  - The correct measurement posture is sitting, and the armband and the heart should be on the same level. Therefore, the blood pressure value measured while standing at the counter may be slightly different from the correct blood pressure measurement value.
  - Any blood pressure measurement is affected by the posture and physical condition of the person being measured. Please remain quiet and do not move your arms or body while measuring.
  - Each measurement should be in the same state and posture.
  - This model of electronic blood pressure monitor should be used on the left arm.
  - When the same person performs continuous measurements, the armband should be loosened and the arm should rest for at least 3 minutes before testing again.
  - This armband is suitable for the arms of adults over 12 years old.
  - Electromagnetic interference above 3V/m should be avoided during measurement. Possible interference sources include:

Once the memory capacity is full, the old measurement data will be overwritten by the new data. When the sphygmomanometer is powered on but not measuring, short press the " Set " button , the screen will display the current user group icon , press the " Set " button again to switch users (you can select " " or " "). If no SET is made, the system defaults to user " " .





7. 【Read memory value】  
After the measurement is completed or in shutdown mode, press the " MEM " button, and the screen display will display and broadcast the average measurement results of the last three times.



Press the "MEM" key again to display and broadcast the last measurement result. Repeat this action to continuously view the 2nd, 3rd... measurement values.

## 8. 【Error code description】

Before using the arm-type electronic sphygmomanometer, please check whether an error code prompt appears or the numbers (or symbols) cannot be displayed after the sphygmomanometer is turned on. If a relevant error code prompt or abnormal display occurs, please follow the relevant prompts and contact the after-sales service center to eliminate the abnormality in time.

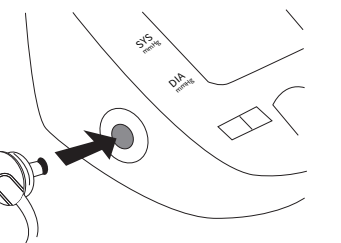
code	illustrate
Er1	This may be caused due to the excessively fast air leak rate, or the pulse mark of the person under detection is too weak. Please check the cuff, re-tie it and measure again.
Er2	The blood pressure signal cannot be measured due to noise. Please measure again.
Er3	The measurement result is incorrect, and re-measurement is required.
ErP	Inflation fails, please check the cuff. Measure again after you have tied it properly.
h1	Inflation pressure is greater than 307 ± 8 mmHg (41 kPa ± 1kPa). Please measure it again.
	Please check or replace the battery, and test again.
	Or no indication on screen

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

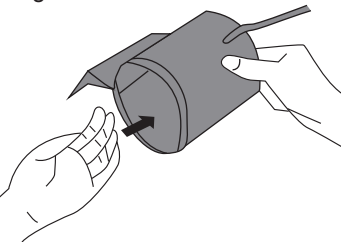
## Chapter 8 Measurement

### 1. Cuff roll-up

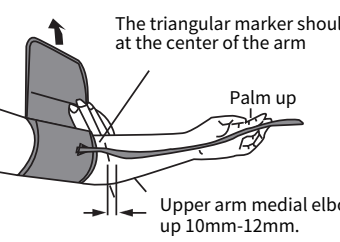
a. Insert the top plug of the air tube into the cuff opening on the side of the blood pressure monitor and confirm that there is no looseness.



b. Put your left arm into the cuff. The palm of your hand should be oriented in line with the air tube of the cuff, and the triangle mark should be on the extension of your middle finger.



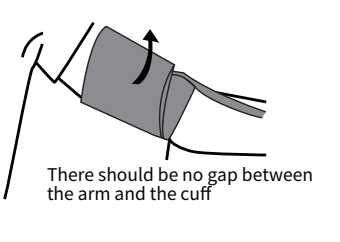
c. Pull the end of the cuff outward to adjust the position of the cuff.



d. Secure with cloth buckles.

There should be no gap between the arm and the cuff, and wrap along the arm. It is advisable to roll up the cuff so that your arms do not feel tight.

Even if the cuff is tilted, it will not affect the structure as long as it is fixed above the triangle mark.



There should be no gap between the arm and the cuff. Notice:

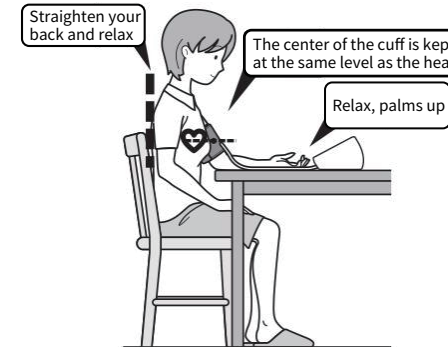
- Please refer to the arm circumference range marked on the cuff to determine whether you are using the appropriate size cuff.
- Do not roll and tie too tightly, otherwise it will cause inaccurate measurement.

### 2. Correct measurement posture

Correct measuring posture is very important for Chapter Measurement

- Please sit in a room with a suitable temperature to measure your blood pressure, straighten your body, maintain a correct sitting posture, do not use force on your fingers, and maintain a natural stretch.
- This model of electronic blood pressure monitor should be used on the left arm. Take blood pressure measurements at the same time every day, with the same arm and in the same position.
- When measuring, please keep the middle part of the cuff consistent with the height of the heart (position of the nipple).
- Please read the precautions in Chapter 2 of this manual carefully before measuring.
- Please judge the measurement results under the guidance of a doctor to help you manage your health.

## Correctly measure posture



Straighten your back and relax. The center of the cuff is kept at the same level as the heart. Relax, palms up.

### Wrong measurement posture

The cuff is wrapped too loosely



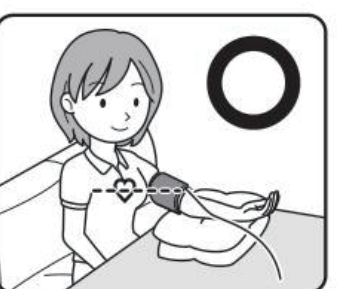
Moving or talking during measurement



leaning forward posture



If the cuff is below your heart, place a cushion or towel underneath it.



## Chapter 9 Installation and Use Instruction

Open the arm-type electronic sphygmomanometer. The outer shell of the sphygmomanometer should be uniform in color and have no obvious flaws, scratches or other defects. Please take care of it when carrying and storing it.

### 1. Install the battery

1). Built-in lithium-ion polymer battery.

### 2. Armband roll-up

- The standard accessory is an armband (M): suitable for people measuring arm circumference 22 to 32cm.
- Insert the top plug of the hose into the opening on the side of the blood pressure monitor. (This blood pressure monitor can only be used with the original standard armband, and other brands of armbands cannot be replaced.)

- Generally, blood pressure is measured in a sitting position. If a lying position is used, this should be noted when notifying the doctor;
- Measure blood pressure at least twice each time, with an interval of no less than 3 minutes. Depending on your physical condition, a longer interval may be required.

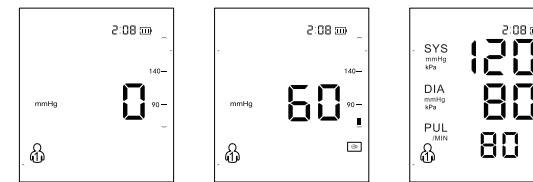
5. Patients with arrhythmia and arteriosclerosis should be measured by medical staff for professional diagnosis.

6. Try to avoid any electromagnetic interference or noise interference in the environment when measuring.

### 4. How to measure blood pressure

- After you put on the cuff, you can start measuring. Press the "switch" button, and the sphygmomanometer will start measuring blood pressure after playing a voice.
- During the inflation process, the blood pressure monitor is also checking the pulse, so please do not move any part of the body during the entire measurement process.

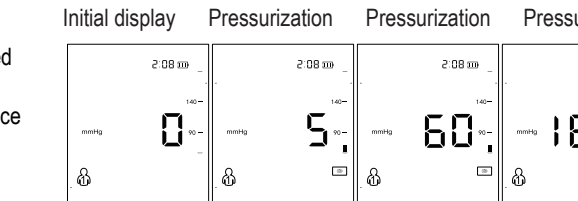
Initial display During pressurization/decompression Measurement results



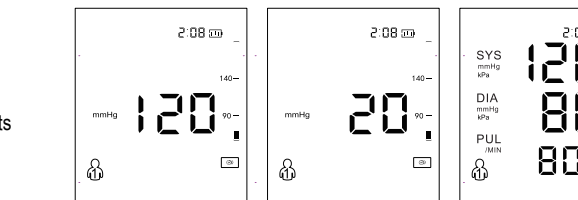
### Guarantee/warranty card

- product quality assurance
- The company will provide a two-year free warranty for this product from the date of purchase.
- Our company does not provide free warranty service for the following failures caused by the user's personal reasons:
  - Failure caused by unauthorized disassembly, assembly, or modification of the product;
  - Internal failure of the fuselage caused by accidentally falling during handling or use;
  - Failure caused by improper use or lack of reasonable maintenance;
  - Failure caused by failure to operate according to the correct knowledge in the instruction manual;
  - Failures caused by natural disasters, such as flooding, fire, etc.;
  - Failure caused by the armband being injured by a sharp object, causing the internal air bag to rupture and become unable to be pressurized;
  - Failures caused by improper repairs by repair shops not authorized by our company, etc.
- When requesting free services, you must present a valid warranty card and purchase voucher.
- When requesting warranty service, please bring this product to the point of sale for repair.
- Repair services outside the warranty scope will be charged according to regulations.

3. When the sphygmomanometer slowly deflates, the value on the display screen continues to decrease until the measurement result appears.



Decompression Decompression Measurement results



## Reading measured values and repeating measurements

After the automatic measurement is completed, the display screen will automatically display the high and low pressure of the user's blood pressure in mmHg units, and at the same time display the measured pulse (beats/minute).

When you take another measurement, just press the "switch" key again.

Note 1. Due to the fluctuation of blood pressure, the results of each measurement will be different. If the user's blood pressure fluctuates greatly, it is best to measure three times and take the average value as the blood pressure measurement value. Compared with even blood pressure measurement, the blood pressure measured by the above method can better represent the true value of human blood pressure.

Note 2. Please consult professionals for the measured blood pressure value.

Note 3. The effectiveness of this device in measuring blood pressure is verified by the auscultation method. If you need to obtain relevant information about this verification method, please contact the after-sales service center.

Note 4. There may be risks when the air bag is over-inflated for a long time.

Note: If you are unable to use your left arm to measure, please use your right arm to measure, but in any case, each measurement must be taken on the same side of the arm to facilitate measurement comparison.

## Chapter 10 Guidance on the Assessment of Hypertension in Adults

Blood pressure is the pressure at which blood is carried through the heart's pulsations (contractions and relaxations) into the arteries.

When the heart contracts, the pressure that sends blood out to the arteries is called systolic pressure, which is high pressure; when the blood circulates throughout the body and returns to the heart, the pressure when the heart relaxes is called diastolic pressure, which is low pressure.

The World Health Organization (WHO) standard blood pressure values are shown in Figure 5. There is no definition of hypotension. It is generally considered to be hypotension when the high pressure is less than 90 mmHg and the low pressure is less than 60 mmHg.

Guidance on the classification of hypertension (regardless of age and gender). Please note that factors such as diabetes, obesity, and smoking will affect blood pressure measurements. If you have any questions, please consult your doctor. Please do not adjust your treatment or medication based on the results of one or two measurements.

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

Definition and classification of WHO blood pressure level

Static pressure test: If users need static pressure measurement, please contact customer service staff.

## Chapter 11 Maintenance Requirements

- Avoid falling or strong collision.
- Avoid high temperature or direct sunlight.
- Prevent the machine and armband from being soaked in water.
- If it is brought into a warm room from a cold environment, please leave it indoors for one hour before using it.
- Please do not disassemble or assemble the machine by yourself.
- Battery maintenance requirements
  - When using lithium-ion polymer battery equipment, keep away from heat sources and high voltages, prevent children from playing with the batteries, and do not drop the batteries.
  - Do not disassemble or replace the battery by yourself. Battery replacement must be returned to the manufacturer or after-sales service point for professional technical personnel to handle. Do not leave the battery in a damp place to avoid danger.
  - After each use of the cuff, the cuff should be fully wrung out with a rag soaked in water or neutral detergent, wipe the cuff, and then dry it with a dry cloth. If necessary, wipe gently with absorbent cotton dipped in disinfectant alcohol for disinfection.
  - If the product is not used for a long time, it is recommended to turn it on and run it for testing once every two months. After running the blood pressure monitor, clean it with a dry soft cloth.
  - If the host is dirty, please clean it with a dry soft cloth. If the main unit is particularly dirty, you can use a rag soaked in water or neutral detergent to fully wring it out, wipe it, and then wipe it dry with a dry cloth. If necessary, wipe gently with absorbent cotton dipped in disinfectant alcohol for disinfection.
- If the host is dirty, please clean it with a dry soft cloth. If the main unit is particularly dirty, you can use a rag soaked in water or neutral detergent to fully wring it out, wipe it, and then wipe it dry with a dry cloth. If necessary, wipe gently with absorbent cotton dipped in disinfectant alcohol for disinfection.

## Chapter 12 Electromagnetic Compatibility Accessories

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. <i>This RF Generators</i> 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 <i>this RF Generators</i> 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	2	0.3	28

			sine			
710						
745	704-787	LTE Band 1, 3, 4, 25;	Pulse modulation 217Hz	0.2	0.3	9
780						
810		GSM 800/900,				
870		TETRA 800,	Pulse modulation 18Hz	2	0.3	28
930	800-960	IDEN 820,				
		CDMA 850,				
		LTE Band 7				
1720		GSM 1800;				
1845		CDMA 1900;	Pulse modulation 217Hz	2	0.3	28
1970	1700-1990	GSM 1900;				

		DECT; LTE Band 1, 3, 4, 25;				
		UMTS				
2450	2400-2570	Bluetooth, WLAN, 802.11b/g/n, RFID 2450,	Pulse modulation 217Hz	2	0.3	28
5240		WLAN				
5500	5100-5800	802.11a/n	Pulse modulation 217Hz	0.2	0.3	9
5785		a/n				