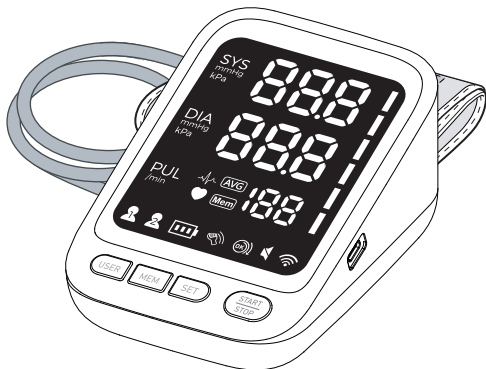


Instruction Manual

Upper Arm Electronic
Blood Pressure Monitor
Model No.: FC-BP113



Manual Ver.: 1.2

Software Ver.: FC-BP113-V1.0

Issuing Date: 2023/06/09



- Please read this instruction manual carefully before using your unit.
- Please keep this instruction manual well for future use.
- Thanks for choosing the Digital Blood Pressure Monitor.
- The PATIENT is an intended OPERATOR.

Revision Record

[illegible]




















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1. Before Using the Unit

1.1 Introduction

- Thank you for purchasing Upper Arm Electronic Blood Pressure Monitor.
- The unit uses the oscillometric method of blood pressure measurement. It means the unit detects the movement of your blood through your brachial artery, and converts your blood pressure into a digital reading. The unit is simple to use because a stethoscope is not needed while using an oscillometric monitor.
- The unit stores automatically 2*120 sets of measurement values. You can read the stored data conveniently by pressing the memory button.
- The unit comes with the following components:
 - Main Unit
 - Arm Cuff
 - Instruction Manual printed in English

SYMBOLS USED IN THIS INSTRUCTION MANUAL			
	Indicates a potentially hazardous situation which, if not avoided, could result in death or serious injury.		
	Indicates a potentially hazardous situation which, if not avoided, may result in minor or moderate injury to the user or patient or damage to the equipment or other property.		
	<p>Please read this instruction manual thoroughly before using the unit. Please keep for future reference. For specific information about your own blood pressure, CONSULT YOUR DOCTOR.</p>		
	Transport package shall be kept away from rain.		Keep away from sunlight
			Fragile, handle with care
<div> <div>EC REP</div> <div>AUTHORISED REPRESENTATIVE IN THE EUROPEAN COMMUNITY</div> </div>			
	Refer to instruction manual/booklet		Unique device identifier
	MANUFACTURER		Date of manufacture
			Made in China
	SERIAL NUMBER		Model number
			Medical device
	Type BF applied part		Importer
			CE mark
	<p>The marking of electrical and electronics devices according to Directive 2002/96/EC. The device accessories and the packaging have to be disposed of waste correctly at the end of the usage. Please follow Local Ordinances or Regulations for disposal.</p>		
	Device used within the Magnetic Resonance (MR) environment is prohibited.		

1.2 Important safety notices

To assure the correct use of the product basic safety measures should always be followed including the precautions listed as below:

- Please read all information in the instruction manual and any other literature included in the box before using the unit.
- Please contact your physician for specific information about your blood pressure. Self-diagnosis and treatment by measure results may be dangerous. Follow the instructions of your health care provider.
- Operate the unit only as intended. Don't use for any other purpose. The unit is intended to use in measuring blood pressure and pulse rate for adult only, not recommended using for neonatal baby at home or medical centre.
- Do not use a cellular phone near the unit. It may result in operational failure.
- Please avoid using in high radiant area in order to make your measuring data correctly.
- Do not disassemble or attempt to repair the unit or components. Do not use the equipment in places where there are flammable gas (such as anesthetic gas, oxygen or hydrogen) or flammable liquid (such as alcohol) .
- Do not use a mobile phone or other devices that emit electromagnetic fields near the unit. This may result in incorrect operation of the unit.
- Indicating that too frequent measurements can cause injury to the PATIENT due to blood flow interference;
- Please remove the batteries if the unit will not be used for Three months or More.
- Please do not put CUFF over a wound, as this can cause further injury;
- Regarding the effect of blood flow interference and resulting harmful injury to the PATIENT caused by continuous CUFF pressure due to connection tubing kinking;
- Statement: Regarding the requirements of the adapter, it should meet the following conditions, output voltage: DC 5V, Current: 1000mA, and comply with IEC 60601-1 and IEC 60601-1-11, provide two MOPP insulation between ac input and dc output.
- Do not install the wrong battery polarity.
- After the battery is exhausted, please replace four new batteries.
- If over three months do not use the device, please remove the battery as it may cause leakage, overhear, rupture and damage the blood pressure monitor body.

Intended purpose: The Upper Arm Electronic Blood Pressure Monitor is intended used to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.

Indication: Intermittent measurement of human body blood pressure from upper arm.

Contraindications:

- The product can not be used for patients with arrhythmia.
- This product can not be used for infants, neonates or pregnancy.
- People who can not express himself can not use this product.

Intended users: Professional medical staff, lay persons.

Patient population: Adults.

Clinical benefits: Measuring body blood pressure so as to help to diagnose human body conditions.

1.3 Warning and safety notices

■ Regarding the application of the CUFF and its pressurization on any limb where vascular access or therapy, or an arteriole-venous (A-V) shunt, is present because of temporary interference to blood flow and could result in injury to the PATIENT;

■ Regarding the application of the CUFF and its pressurization on the arm on the side of a mastectomy;

■ Pressurization of the CUFF can temporarily cause loss of function simultaneously used monitoring ME EQUIPMENT on the same limb;

■ Regarding the need to check (for example, by observation of the limb concerned) that operation of the AUTOMATED Blood Pressure Monitor does not result in prolonged impairment of the circulation of the blood of the PATIENT.

■ When the arm is oppressed by air pressure, please loosen CUFF or remove batteries.

■ Please do not touch the patient and battery output simultaneously when measurement.

■ Warning: Do not allow to use the lure connectors. If lure lock connectors be used in the construction of tubing, there is a risk that they might be inadvertently connected to vascular fluid systems and allowing air to be pumped into a blood vessel.

■ 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 Blood Pressure Monitor, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Warning: The Blood Pressure Monitor is placed in the position not touched by pets, pests or children.

Warning: The neck of a child or animal is strangled due to the too long air hose, which is a threat to life, etc.;

Warning: The hazard of accidental ingestion due to the small parts that can be disassembled (such as batteries, etc.) after being touched by a child;

Place the product out of the reach of children, etc.; use it under the supervision of an adult, etc.;

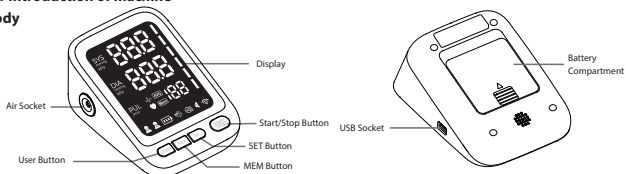
Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the local competent authority of the user's place.

The Upper Arm Electronic Blood Pressure Monitor was clinically investigated according to the requirements of ISO 81060-2:2018+A1:2020.

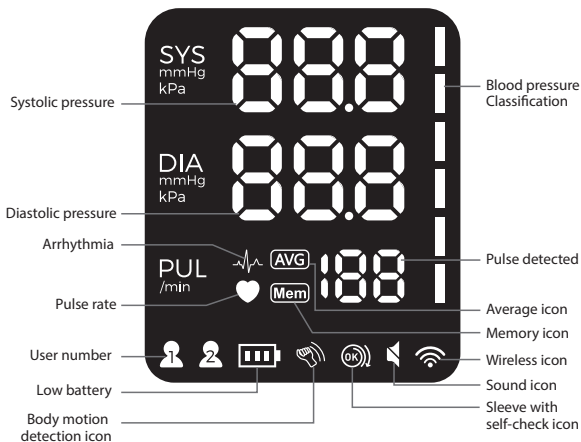
2. Operating Instruction

2.1 Introduction of machine

Body

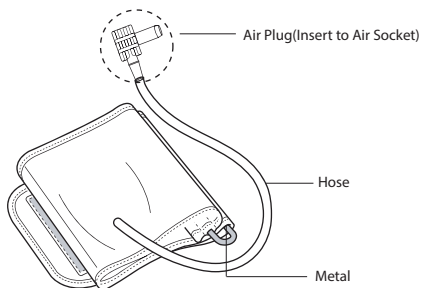


Display



Arm Cuff

- Fit for 9-17 inches (22cm~42cm) range of upper arm perimeter

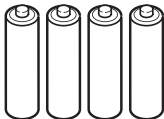


⚠ If your arm cuff is broken or not functional, please use a new cuff.

⚠ A new arm cuff does not include an air plug. Please continue to use the old air plug on the new arm cuff.

Power

4 AA Alkaline Batteries



⚠ Do not use rechargeable batteries.

Instruction Manual

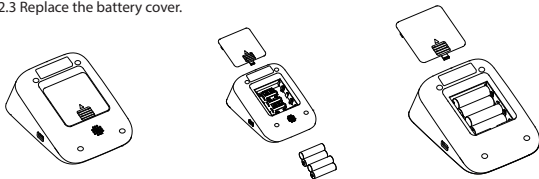
- Please keep the instruction manual well after using.

2.2 Battery Installation / Replacement

2.2.1 Remove the battery covers from the battery compartment.

2.2.2 Install 4 "AA" size batteries to match the + (positive) and - (negative) polarities with the polarities of the battery compartment as indicated.

2.2.3 Replace the battery cover.



⚠ Caution!

- Replace batteries if the symbol of low battery appears on the display.
- Never leave any low battery in the battery compartment since they may leak and cause damage to the unit.

2.3 Settings

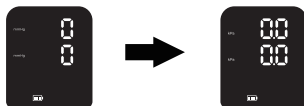
2.3.1 To set voice

Long press the "SET" button when power off, you can see the "SP_{ON}" icon appears and flashes, then press the "MEM" button to adjust the sound on or off. When the screen shows "SP_{ON}", Blood Pressure Monitor sound is on; when the screen shows "SP_{OFF}", Blood Pressure Monitor sound is off. Press "START/STOP" button to save the current setting and turn off.



2.3.2 To set unit

Based on the first step and press the "SET" button to change the previous unit(kPa or mmHg), the mark " $\frac{0}{0}$ " appears and flashes, now the BPM is in mmHg status, and then press the "MEM" button, to change it into " $\frac{00}{00}$ ", now the BPM is in kPa status. Press the "START/STOP" button to confirm the current setting.



2.3.3 To set user

Press the "USER" button when power off, and then press then "USER" button again to switch User 1 or User 2.



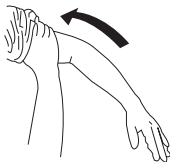
The operation of setting can be stopped at any time by pressing "START/STOP" button.

2.4 Proper Use of the Arm Cuff

2.4.1 Make sure the air plug is inserted properly in the main unit.



2.4.2 Remove all clothes from your upper arm allowing the cuff to fit directly on the skin.



2.4.3 Sit in a chair with your feet flat on the floor. Place your arm on a table so as to level the cuff to your heart.



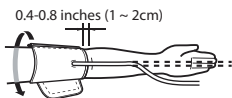
2.4.4 Pass the end of the cuff through the metal, and keep the hose outward.



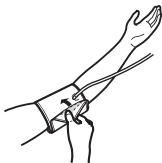
2.4.5 Put your arm through the loop, then pull it up to the position of your upper arm.



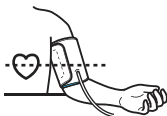
2.4.6 The hose runs down the inside of your arm. The bottom of the cuff should be approximately 0.4-0.8 inches (1~2cm) above your elbow.



2.4.7 Wrap the cuff tightly around your upper arm by using the velcro strip. Make sure at least there should be 1-2 fingers space between arm and cuff.



2.4.8 Relax your arm, keep the palm upward and the fingers curving naturally, then turn on the unit and start to measure.



2.5 Considerations for measuring

2.5.1 The correct using method

- (1) Elbow on the table; comfortably seated; legs uncrossed; back and arm supported;
- (2) Keep the center of the cuff and the heart or nipples at the same height.
- (3) Do not put the clothes into the cuff.
- (4) Palms up, body keep relaxed.
- (5) Sitting in a chair keep your foot flat on the ground.

A recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE; a recommendation that 5 min elapses before the first reading is taken; need to avoid compression or restriction of the connection tubing.

2.5.2 Ideal environment for measuring blood pressure

- (1) Get up in the morning, when the mood is relaxed.
- (2) No consciousness to the toilet.
- (3) Room temperature is about 20 °C.
- (4) A quiet place and there was no noise around.

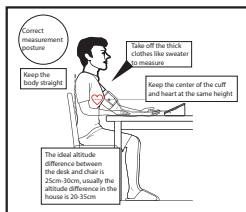
2.5.3 Measure blood pressure at the same time every day: Blood pressure is constantly changing and cannot judge the situation only by the result of once blood pressure measurement, according to a period of time, repeated measurements to determine blood pressure condition is more reliable. So please stick to measure blood pressure every day, select the mood in a day can keep the most stable state period such as early in the morning after getting up. Ideal method is to measure as far as possible at the same time every day.

Note: Be sure to have more than 2-3-minute interval between two measurements.

Depending on your individual physiological characteristics, between the two measurements may need to rest for a longer time.

Please keep the wristband around the wrist before you start measuring.

Do not measure your blood pressure on bus.



2.6 Function

2.6.1. The device has the WHO warning strip “■” symbol display function, with the blood pressure value change, the higher blood pressure value “■” symbol will appear relatively in the higher position (refer to WHO definition of high blood pressure levels-reference table).

2.6.2. The device has the average of the last three display function (press the memory key for the first time to display the value that is the average of the last three measurements).

2.6.3. The device has a large screen display and digital legible.

2.6.4. The device has kPa and mmHg display switching and measurement functions.

2.6.5. The device has double memory lookup function and can store 120 set of measurements for each person to remember the normal status of your blood pressure.

2.6.6. Clock function: year, month, day, hour, minute setting.

2.6.7. Low power detection: detecting low power under any working state, LED displays “■” symbol indicates low power.

2.6.8. Overpressure protection function: when the pressure is more than 300mmHg, the device will exhaust fast automatically.

2.6.9. Automatic shutdown function: no operation for 2 minute the device will be shut down automatically.

2.6.10. Heartbeat prompting voice.

2.6.11. Measurement completed prompting voice.

2.6.12. Incorrect prompting function.

RATED ranges of the DETERMINATION :

Cuff pressure: 0-299 mmHg

SYS: 45-255 mmHg

DIA: 24-216 mmHg

2.7 Take a Measurement

2.7.1 Press the “START/ STOP” button.

All display symbols appear on the screen. The cuff starts to inflate automatically.



2.7.2 Measurement start. When pressurized to stop blood flow, the Blood Pressure Monitor stops pressure before automatically leaking air and automatically measuring blood pressure. The heartbeat symbol flashes once a pulse is detected.

When the heart beat symbol appears and flashes, the Blood Pressure Monitor detects the pulse and begins to calculate the pulse automatically.



2.7.3 The blood pressure and pulse rate are displayed when the measurement completed. The cuff is deflated automatically, and all of the measurement results be stored in the memory.

The “” symbol will be displayed if irregular heartbeat is detected.



2.7.4 Press the “START/ STOP” button to turn off the unit.

The unit will automatically turn off after two minutes if no more operation.

NOTE: The inflation or measurement can be stopped by pressing the “START/ STOP” button at any time.

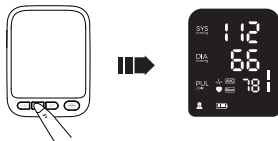
2.8 Use the Memory function

The unit stores the blood pressure and pulse rate in the memory after completing a measurement each time. 2x120 sets of measurement values can be stored automatically. The earliest record will be deleted automatically to save the latest measurement value when more than 2x120 sets.

The unit also calculates an average reading based on the values of the latest 3 times measurement .

2.8.1 To enter the memory mode & to read the average value

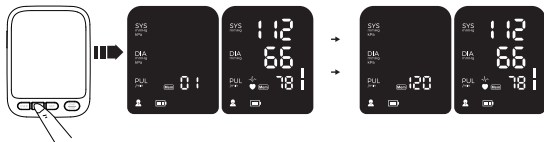
Press the "MEM" button while the unit is off, the unit enters the memory mode and the average value of the latest 3 times measurement values of the current user will be displayed.



2.8.2 To read the measurement value

Press the "MEM" button when power off, the latest measurement values will be displayed.

Press the "MEM" button once more, the measurement values before the latest will be displayed, and so on.

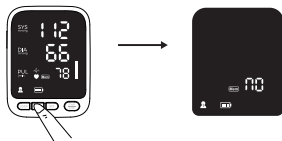


2.8.3 To delete the memory value

■ In the memory mode, long press the "MEM" button, the unit displays the following symbol to cancel all the memory records of the current user.

■ Press the "START/STOP" to cancel the memory records of the current user if you are sure all the data of corresponding user can be deleted, the unit will turn off after deleting.

■ Please operate the delete memory function cautiously.



2.9 About Blood Pressure

2.9.1 Irregular Heartbeat Symbol IHB

When the unit detects an irregular rhythm two or more times during the measurement, the irregular heartbeat Symbol will appear on the display with the measurement values.

An irregular heartbeat rhythm is defined as a rhythm that is more than 25% slower or 25% faster from the average rhythm which detected while the monitor is measuring the systolic blood pressure and the diastolic blood pressure.

If the Irregular Heartbeat Symbol (\sim) displays with your measurement results, we recommend you consult your physician, and follow the doctor's directions.



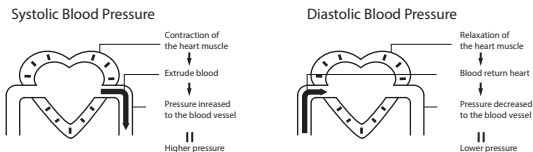
2.9.2 Blood Circulation

The blood circulation is responsible for supplying the body with oxygen.

Blood pressure is the pressure exerted on the arteries.

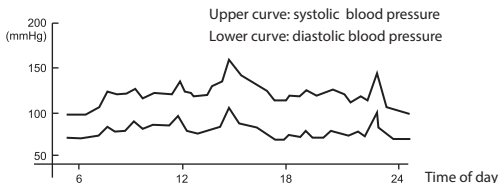
The systolic blood pressure value (higher pressure or top value) represents the blood pressure produced by contraction of the heart muscle.

The diastolic blood pressure value (lower pressure or lower value) represents the blood pressure produced by relaxation of the heart muscle.



2.9.3 Health and Blood Pressure

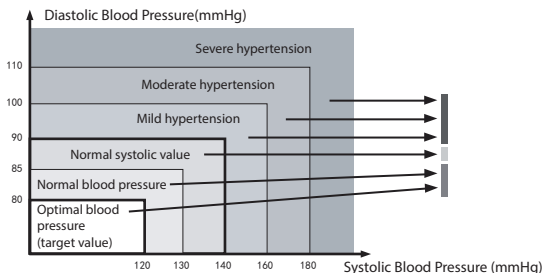
The incidence of hypertension increases with age. In addition, if lack of exercise, excess body fat and high levels of cholesterol(LDL), would sticks to the inside of blood vessels, which reduces elasticity of these vessels. Hypertension accelerated arteriosclerosis which can lead to serious conditions such as stroke and myocardial infarction. For these reasons it is very important to know whether the blood pressure is within a healthy range. Blood pressure fluctuates from minute to minute, throughout the day. Therefore it is essential to take regular measurements to help you identify an average blood pressure.



2.9.4 Classification of Blood Pressure

After each measurement is completed, the LED display will show your position automatically on the six segments of the bar indicator which corresponds to World Health Organization (WHO) Blood Pressure Indicator.

Reference Material: Journal of Hypertension 1999, Vol 17 No.2



***Note!**

When a person's systolic and diastolic pressures fall into different categories, the higher category should apply.

2.9.5 Symptoms of High Blood Pressure

High blood pressure can go unnoticed for a long time, since it doesn't cause noticeable symptoms. The following are possible causes of abnormally high blood pressure:

- Overweight;
- High cholesterol level;
- Smoking;
- Excessive alcohol consumption;
- Stress and emotional upset;
- Excessive consumption of salt;
- Lack of physical exercise;
- Genetic / hereditary predisposition;
- Underlying illnesses, such as kidney disorders or endocrine disturbance.

2.9.6 Treatment of High Blood Pressure

If your blood pressure reaches upper values of 140~160 mmHg and lower values of 90~95 mmHg in repeated measurements over several days, you should consult doctor for detailed medical examination. You can assist the treatment prescribed by your doctor in the following ways:

- Loose weight and lower your cholesterol level;
- Reduce the consumption of alcohol;
- Reduce the intake of salt;
- Stop smoking;
- Take regular exercise;
- Monitor your blood pressure.

3. Care and Maintenance

3.1 Cleaning/Disinfecting and Maintenance

To keep your blood pressure monitor in the best condition and protect the unit from damage, please follow the directions listed below:

- 3.1.1 Clean the blood pressure monitor frequently after use by a user. Do not use any abrasive or volatile cleaners. Never immerse the unit or any components in water.
- 3.1.2 Use a soft dry cloth towel to clean this blood pressure monitor, if it is very filthy you can wet the towel with water or neutral detergent, wring out it and wipe the monitor.
- 3.1.3 Disinfection the cuff with moistened 75% alcohol cotton wool.
- 3.1.4 Store the unit in a safe and dry location. Do not fold the cuff too tight. Do not subject the unit to extreme hot or cold temperatures/humidity and do not subject the unit under the direct sunlight.
- 3.1.5 Avoid subjecting the unit to strong shocks, such as dropping the unit on the floor.
- 3.1.6 Remove the batteries if the unit will not be used for three months or longer. Always replace all the batteries with new ones at the same time.
- 3.1.7 Use the unit consistent with the instruction provided in this manual. Use only authorized parts and accessories.

3.1.8 Do not repair or open the machine by yourself. If a defect occurs, Please contact the local distributor.18



3.1.9 We will provide circuit diagrams, component part lists, descriptions, calibration instructions, or other information to assist service personnel who is trained by the manufacturer and has got the relevant qualification certificate.

3.2 Calibration and Service

The accuracy of this blood pressure monitor has been carefully tested and is designed for a long service life. It is generally recommended to have the unit inspected every two years to ensure correct functioning and accuracy. Please consult local authorized distributor or dealer.

3.3 Error Indicators

The following symbols will appear on the display when measuring abnormally.

Symbol	Cause	Correction
	The course of inflating appears error	Wrap the cuff correctly and tightly
		Inflate over again after ensuring
	When measurement fails	Do not move your arm and body and keep quiet
		Measure over again according to correct way
	When the batteries power is too low	Replace all of the worn batteries with new ones

3.4 Troubleshooting

Problem	Causes and Solutions
No power	Replace all of the worn batteries with new ones
No display appears on the display screen	Check the battery installation for proper placement of the batteries polarities
Measurement values appear too high or too low	Blood pressure varies constantly. Many factors may effect your blood pressure, including stress, time of day, how you wrap the cuff. Review the sections "Proper Way of Measurement" and "Take a Measurement"

3.5 Technical Data

3.5.1 Specifications

1	Model	FC-BP113
2	Measurement Method	Oscillographic measurement method
3	Display	LED Digital Display
4	Measurement Range	Blood Pressure range: 0~299mmHg (0 kPa - 39.9 kPa) Pulse: 40 to 180 beats/min
5	Accuracy of the cuff pressure	Static Pressure: ± 3 mmHg(± 0.4 kPa) Pulse rate: Within $\pm 5\%$ of reading
6	Inflation	Automatic inflation by pump
7	Deflation	Automatic rapid deflation
8	Pressure Detection	Semiconductor pressure sensor
9	Memory	2 Users * 120 memories
10	Power supply	4 AA alkaline batteries (not included), DC6V
		USB Type C (DC5V1A)
11	Battery life	Approximately 300 measurements when using alkaline batteries at the room temperature of 22°C and by using three times a day and inflating to 170 mmHg
12	Storage Condition	Temperature: -4°F to 140°F (-20°C to 55°C) Humidity: 0 to 95% RH Atmospheric pressure: 70 - 106kPa
13	Operating Condition	Temperature: 50°F to 104°F (10°C to 40°C) Humidity: 15 to 85% RH
14	Automatic Power-OFF	Within 2 Minutes
15	Weight of Main Unit	338.6g
16	External Dimensions	112*155*79mm
17	Cuff	9-17 inches (22-42cm)
18	Electric Shock Protection	Internal power supply appliance type B
19	Accessorial Components	Cuff, Instruction Manual
20	Device Life	5 Years

To improve performance, these specifications are subject to change without notice.

The device, accessories and the packaging have to be disposed of correctly after the end of the usage, so that the risk of patient or user can be lowered to acceptable level.

3.5.2 Statement

- The unit is intended to be used to measure blood pressure (systolic and diastolic) and heart rate from the upper arm by using the oscillometric method.
- The unit is intended for using in only adult population, not applied to the other populations such as neonatal baby
- It can't be used while the wrist (arm) has bleeding or wound to avoid the blood flowing from the wound when pressurizing.
- The device's accessories and batteries have to be disposed of waste correctly at the end of the usage, please follow Local Ordinances or Regulations for disposal.
- Applied part: CUFF.

Protection Class: Internally powered equipment.

• Applied Part Type: Type BF.

Moisture Protection: IP21, continue operation.

Altitude<2000m;

Overvoltage:II;

Pollution degree:2

- The risk of patient and user can be lowered to acceptable level.
- The unit might not meet its performance specification if stored or used outside the following specified temperature, humidity and altitude ranges.
- The unit satisfies the requirements of IEC60601-1 Medical electrical equipment, IEC 60601-1-2: Electromagnetic compatibility –Requirements and tests IEC 80601-2-30: Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type EN1060-3: Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems.

3.5.3 IEC 60601-1-2 : 2014 ME EQUIPMENT and ME SYSTEMS identification, marking and documents for Class B product

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments and so on.

Warning: Don't near active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

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 Upper Arm Electronic Blood Pressure Monitor, including cables specified by the manufacturer.

Otherwise, degradation of the performance of this equipment could result.

If any: a list of all cables and maximum lengths of cables (if applicable), transducers and other ACCESSORIES that are replaceable by the RESPONSIBLE ORGANIZATION and that are likely to affect compliance of the ME EQUIPMENT or ME SYSTEM with the requirements of Clause 7 (EMISSIONS) and Clause 8 (IMMUNITY). ACCESSORIES may be specified either generically (e.g. shielded cable, load impedance) or specifically (e.g. by MANUFACTURER and EQUIPMENT OR TYPE REFERENCE).

If any: the performance of the ME EQUIPMENT or ME SYSTEM that was determined to be ESSENTIAL PERFORMANCE and a description of what the OPERATOR can expect if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES (the defined term "ESSENTIAL PERFORMANCE" need not be used).

3.6 Technical description

3.6.1 All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected service life.

3.6.2 Guidance and manufacturer's declaration -electromagnetic emissions and Immunity

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	Compliance
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Compliance

Table 2

Guidance and manufacturer's declaration - electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air
Electrical fast transient/burst IEC 61000-4-4	Power supply lines: ± 2 kV 100 kHz repetition frequency	Power supply lines: ± 2 kV 100 kHz repetition frequency
Surge IEC 61000-4-5	line(s) to line(s): ± 1 kV.	line(s) to line(s): ± 1 kV.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0% 1 cycle And 70% 25/30 cycles Single phase: at 0 0% 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz
Conducted RF IEC61000-4-6	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands)80% Am at 1kHz	150KHz to 80MHz: 3Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz

Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80 % AM at 1 kHz
NOTE UT is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communications equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power(W)	Distance (m)	IEC 60601-1-2 Test level (V/m)	Compliance level (V/m)
	385	380 – 390	TETRA 400	Pulse modulation 18 Hz	1,8	0,3	27	27
	450	430– 470	GMRS 460, FRS 460	FM ± 5 kHz deviation 1 kHz sine	2	0,3	28	28
	710	704 – 787	LTE Band 13,17	Pulse modulation 217 Hz	0,2	0,3	9	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	28
	870							
	930							

	1720	1700 – 1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3,4, 25; UMTS	Pulse modulation 217 Hz	2	0,3	28	28
	1845							
	1970							
	2450	2400 – 2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0,3	28	28
	5240	5100 – 5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0,2	0,3	9	9
	5500							
	5785							

This device complies with part 15 of the FCC Rules.

Operation is subject to the following two conditions:

- (1) This device may not cause harmful interference, and
- (2) this device must accept any interference received, including interference that may cause undesired operation.

NOTE: This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of the FCC Rules.

These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation. If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:

- Reorient or relocate the receiving antenna.
- Increase the separation between the equipment and receiver.
- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
- Consult the dealer or an experienced radio/TV technician for help.

Changes or modifications to the product not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.

4. Warranty Information

■ The unit, excluding the unit cuff, is guaranteed to be free of defects in workmanship and materials for a period of two years from the date listed on the purchase record, when used in accordance with the instructions provided with the unit. The unit cuff is warranted to be free from defects in materials and workmanship appearing within one year from the date listed on the purchase record when the unit is used in accordance with the instructions provided with the unit.

■ This guarantee does not cover damage incurred by using without following in accordance with the instructions, accidental damage, or being tampered/serviced by unauthorized service agents.

■ For repair under this warranty. Our authorized service agent must be advised of the fault within the period of the warranty. This warranty covers parts and labor only under normal operations.

A transportation fee or freight fee that may be incurred will be the owner's responsibility. Any defect resulting from natural causes, e.g., flood, hurricane etc., is not within this guarantee.

■ Unit subjected to misuse, abuse, and neglect of these manual contents, non-instructional purposes, and unauthorized repair or modifications will be excluded from this warranty. This guarantee specifically excludes expendables and consumables, for example batteries.

All warranty claims must be directed to the distributor responsible for the sale of the device. The content of this warranty is subject to change without further notice.

■ **WARNING:** No modification of this equipment is allowed.



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