



Fully Automatic Upper Arm Blood Pressure Monitor

Model Number: B06T

USER'S MANUAL



A Special Thank You...

Thank you for choosing a cigii blood pressure instrument. We're proud of the care and quality that goes into the manufacture of each and every item that bears our name. Only the finest materials are used to assure you of a timeless instrument designed for optimum performance. You'll quickly appreciate the results, for you now own one of the finest blood pressure instruments that money can buy. With proper care and maintenance, your cigii automatic blood pressure monitor is sure to provide you with many years of dependable service. Please read the following instructions and general information which will prove helpful in allowing you to enjoy your measurement in hospitals and physician's offices throughout the world, where accuracy and dependability are critical, cigii professional diagnostic products are the instruments of choice.

Now you also can enjoy the benefits of cigii engineering and quality in the home. This feature rich instrument was designed to simplify the measurement of blood pressure and pulse rate at home and deliver consistent, dependable results. Your cigii blood pressure monitor is a fully automatic digital blood pressure measuring device for use on the upper arm. It enables very fast and reliable measurement of the systolic and diastolic blood pressure as well as the pulse by way of the oscillometric method. This device offers clinically proven accuracy and has been designed to be user friendly. Read this booklet thoroughly before attempting to use your new cigii Digital Blood Pressure Monitor.

Thank you for your patronage. It is indeed our pleasure to serve you.

Sincerely,

Shenzhen Jmar Medical Technology Co., Ltd..

Introduction and Intended Use

This manual is for cigii B06T models. It is a fully automatic digital blood pressure measuring device for use by adults on the upper arm at home or in your doctor's/nurse's office. It enables very

fast and reliable measurement of systolic and diastolic blood pressure as well as pulse through the oscillometric method. This device offers clinically proven accuracy and has been designed to be user friendly. Before using, please read this instruction manual carefully and then keep it in a safe place. Please contact your doctor for further questions on the subject of blood pressure and its measurement.

Warning: Not suitable for neonatal and infants.

Warning: Not suitable for pregnant patient.

This device can not be used together with hf surgical equipment.

Remember...

- Only a healthcare professional is qualified to interpret blood pressure measurements.
- This device is NOT intended to replace regular medical checkups.
- It is recommended that your physician review your procedure for using this device.
- Blood pressure readings obtained by this device should be verified before prescribing or making adjustments to any medications used to control hypertension. Under no circumstances should YOU alter the dosages of any drugs prescribed by your doctor.
- This monitor is intended for use by adults only. Consult with a physician before using this instrument on a child.
- In cases of irregular heartbeat (Arrhythmia), measurements made with this instrument should only be evaluated after consultation with your doctor.
- Familiarize yourself with the section titled "Important Information on Blood Pressure and its Measurement". It contains important information on the dynamics of blood pressure readings and will help you to obtain the best results.

NOTE!

- This device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens) during use. These can lead to erratic results.
- Do not attempt to service or repair this device yourself. Should a malfunction occur, refer to local distributor or the manufacturer.

Warning:

1. Too frequent measurements can cause injury to the PATIENT due to blood flow interference
2. Don't place the cuff over wound part
3. Pressurization of the CUFF can temporarily cause loss of function of simultaneously used monitoring ME EQUIPMENT on the same limb

Contraindication

Use of this instrument on patients under dialysis therapy or on anticoagulant, antiplatelets, or steroids could cause internal bleeding.

Warnings and Precautions

- Warning: The device contains sensitive electronic components. Avoid strong electrical or electromagnetic fields in the direct vicinity of the device (e.g. mobile telephones, microwave ovens). These can lead to

temporary impairment of the measuring accuracy.

•Warning: Do not use cuffs, AC adapters or batteries other than those included with this product or replacement parts supplied by the manufacturer.

•Warning: This system may fail to yield specified measurement accuracy if operated or stored in temperature or humidity conditions outside the limits stated in the specifications section of this manual.

•Warning:

The separate ac adapter which is intended to connect USB interface of Blood Pressure Monitor has not been evaluated according to IEC 60950-1. The safety of the product shall be reappraised when it power supply by a separate ac adapter.

•Warning:

Turn off the power if the EQUIPMENT is not likely to be used for some time.

•Warning:

The user must check that the equipment functions safely and see that it is in proper working condition before being used.

•Warning:

No modification of this equipment is allowed.

•Warning:

The device is not suitable for use in the presence of flammable anesthetic mixtures with air or with oxygen or nitrous oxide.

•Warning:

This equipment shall not be serviced or maintained while in use with the patient

•Warning:

The patient is an intended operator, the functions of monitoring blood pressure and pulse rate can be safely used by patient. The routine clean and changing batteries can be performed by the patient.

•Caution: To avoid any possibility of accidental strangulation, keep this unit away from children and do not drape tubing around your neck.

•Caution: To avoid damaging the device, keep this unit away from children and pets.

•Caution: The standard material used for the bladder and tubing is latex-free.

•Caution: Use only rechargeable Lithium batteries.

Risk of explosion if battery is replaced by an incorrect type.

Dispose of used batteries according to the instructions.

•Attention: Self-measurement means control, not diagnosis or treatment. Unusual values must always be discussed with your doctor. Under no circumstances should you alter the dosages of any drugs prescribed by your doctor.

•Attention: The pulse display is not suitable for checking the frequency of heart pacemakers!

•Attention: In cases of irregular heartbeat, measurements made with this instrument should only be evaluated after consultation with your doctor.

Note: To obtain the greatest accuracy from your blood pressure instrument, it is recommended that the instrument be used within the specified temperature and the relative humidity, please see the Technical Specifications

Note: The cuff is treated as the applied part.

The user should contact the manufacturer for assistance, if needed, in setting up, using or maintaining the device.

2. Important Information on Blood Pressure and its Measurement

Version Number: 1.0

2.1. How does high or low blood pressure arise?

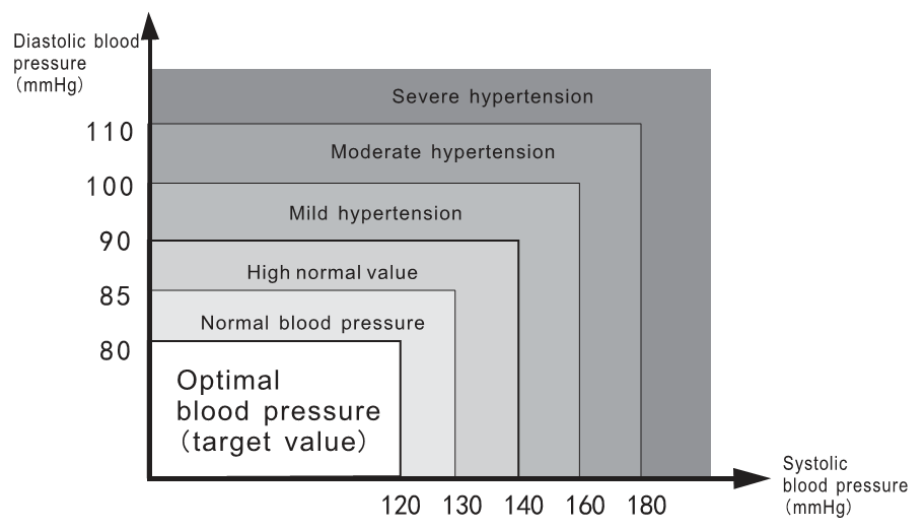
Your level of blood pressure is determined in the circulatory center of the brain and adjusts to a variety of situations through feedback from the nervous system. To adjust blood pressure, the strength and speed of the heart (Pulse), as well as the width of circulatory blood vessels is altered. Blood vessel width is controlled by fine muscles in the blood vessel walls.

Your level of arterial blood pressure changes periodically during heart activity: During the “blood ejection” (Systole) the value is highest (systolic blood pressure value). At the end of the heart’s “rest period” (Diastole) pressure is lowest (diastolic blood pressure value).

Blood pressure values must lie within certain normal ranges in order to prevent particular diseases.

2.2. Which values are normal?

Please refer to the diagram below(Picture-01)



Picture-01

Blood pressure is very high if your diastolic pressure is above 90 mmHg and/or your systolic blood pressure is over 160 mmHg, while at rest. In this case, please consult your physician immediately.

Long-term values at this level endanger your health due to continual damage to the blood vessels in your body. If your systolic blood pressure values are between 140 mmHg and 159 mmHg and/or the diastolic blood pressure values between 90 mmHg and 99 mmHg, consult your physician. Regular self-checks are necessary. If you have blood pressure values that are too low, (i.e., systolic values under 105 mmHg and/or diastolic values under 60 mmHg), consult your physician. Even with normal blood pressure values, a regular self-check with your blood pressure monitor is recommended. You can detect possible changes in your values early and react appropriately. If you are undergoing medical treatment to control your blood pressure, keep a record of values along with time of day and date. Show these values to your physician. Never use the results of your measurements to independently alter the drug doses prescribed by your physician.

Further information

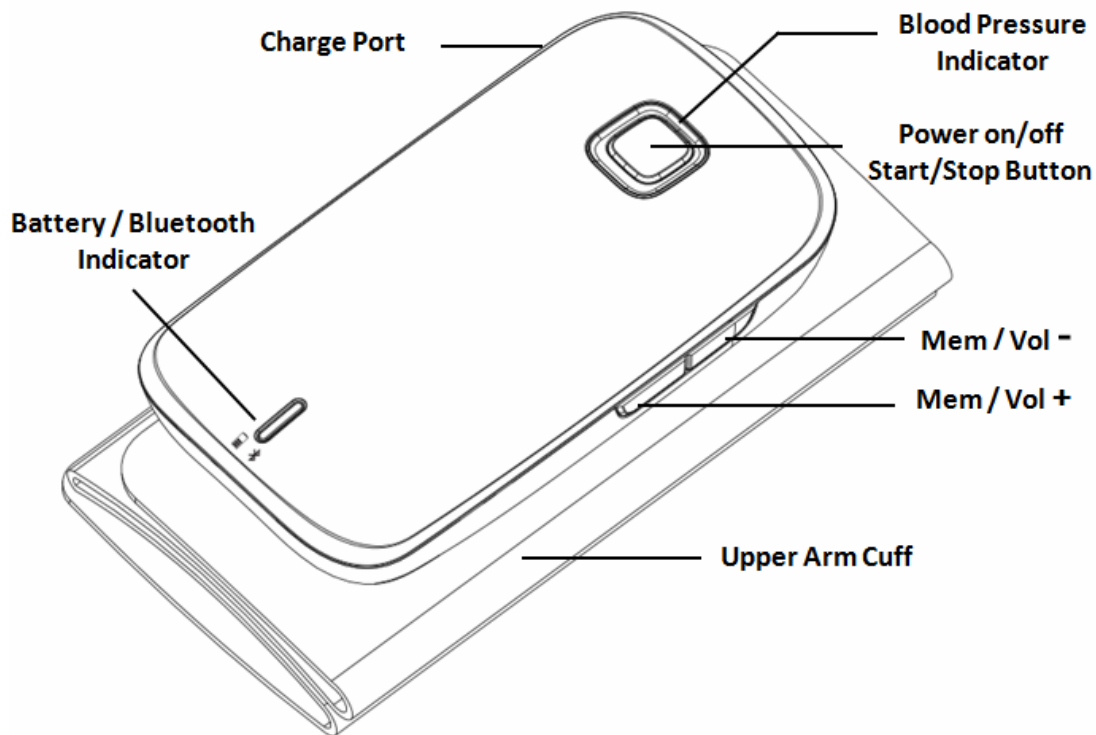
- If your values are mostly normal under resting conditions but exceptionally high under conditions of physical or psychological stress, it is possible that you are suffering from so-called “labile hypertension.” Consult your doctor.
- Correctly measured diastolic blood pressure values above 120 mmHg require immediate medical treatment.

2.3. What can be done if regular high or low values are obtained?

- 1) Consult your doctor.
- 2) Increased blood pressure values (various forms of hypertension) are associated with considerable health risks over time. Arterial blood vessels in your body are endangered due to constriction caused by deposits in the vessel walls (Arteriosclerosis). A deficient supply of blood to important organs (heart, brain, muscles) can result from arteriosclerosis. Furthermore, the heart will become structurally damaged with increased blood pressure values.
- 3) There are many different causes of high blood pressure. We differentiate between the common primary (essential) hypertension, and secondary hypertension. The latter group can be ascribed to specific organ malfunctions. Please consult your doctor for information about the possible origins of your own increased blood pressure values.
- 4) There are measures which you can take to reduce and even prevent high blood pressure.

3. Components of your blood pressure monitor

a) Measuring unit



Features of Model B06T:

- 1- Voice broadcast function;
- 2- Bluetooth wireless connection with Smart phone;
- 3- Remoted by Applications on IOS or Android smart phones
- 4- Operated on device with one button;
- 5- With 99 groups memories;

- 6- Support the average measurement results;
- 7- Built-in rechargeable lithium battery;
- 8- Cuff and main unit are integrated as one part;
- 9- With charging indicator;
- 10- With Blood Pressure result indicator

Note: Arm circumference should be measured with a measuring tape in the middle of the relaxed upper arm. Do not force the cuff connection into the opening.

4. Using your Monitor for the First Time

4.1 Battery Power checking

Battery Power checking

The battery is built-in rechargeable Lithium battery

Press the "Power on/off" button, if the "Battery Indicator" keep in "Red", it means the battery power is low, and the unit need to be re-charged, the power supply should be DC5V/1A. Please recharge it and when the "Battery Indicator" keeps in "Green", it means the battery is full recharged. It can be used normally. If battery is not full re-charged, the indicator flashes in Red

Assessment indicator

The indicator is set around the stop/start button. After measurement, the indicator will turn into different colors according to the assessment. Blue means normal; Yellow means mild high blood pressure; Red means high blood pressure.

4.2 System Settings

After the battery is full recharged, some functions can be set before use this monitor:

a. Start/Stop

Press the Start/Stop button one time. The indicator around the button turns blue, the bluetooth is waiting for connection. Press the button again can start the measurement directly, or connect device with smart phone, it can be remote controlled by App which is installed beforehand in the smart phone. The voice "Bluetooth is connected" if the device connect with smart phone by bluetooth successfully

b. Setting the Volume

Press and hold the Vol+ / Vol- button, you will hear the voice guide of Volume up / Volume down to set your favorite voice volume.

c. Assessment memory record

Press Vol+ / Vol- button once will seek for the assessment record of next/previous

Press the Vol+ and hold and press Vol- and hold, keep pressing both buttons simultaneously will clear all the assessment records.

5. Measurement Procedure

Note: You should always be seated and calm before and during measurement.

5.1. Before measurement:

- Avoid eating and smoking as well as all forms of exertion directly before measurement. These factors influence the measurement result. Find time to relax by sitting in an armchair in a quiet atmosphere for about ten minutes before taking a measurement.
- Remove any garment that fits closely to your upper arm.
- Always measure on the same arm (normally left).
- Always compare measurements taken at the same time of day, since blood pressure changes during the course of the day, as much as 20-40 mmHg.

5.2. Common sources of error:

Note: Comparable blood pressure measurements always require the same conditions! •Conditions should always be quiet.

- All efforts by the user to support the arm can increase blood pressure. Make sure you are in a comfortable, relaxed position and do not flex any of the muscles in the measurement arm during the measurement. Use a cushion for support if necessary.
- If the arm artery lies considerably lower or higher than the heart, an erroneously high or low blood pressure will be measured! Each 25-30cm difference in height between your heart and the cuff results in a measurement error of 10 mmHg!
- Cuffs that are too narrow or too short result in false measurement values. Selecting the correct cuff is extremely important. Cuff size is dependent upon the circumference of the arm (measured in the center). The permissible range is printed on the cuff.

Cuff works under the pressure range 0-300mmHg.

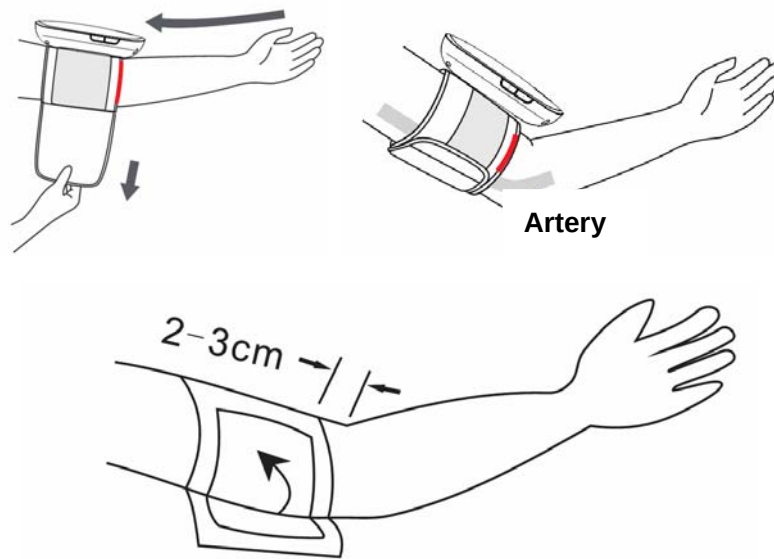
The wide range rigid cuff is : 8.7" – 14.2" (22 - 36 cm).

- A loose cuff or a sideways protruding air pocket causes false measurement values.
- With repeated measurements, blood accumulates in the arm, which can lead to false results. Consecutive blood pressure measurements should be repeated after a 1 minute pause or after your arm has been held up in order to allow the accumulated blood to flow away.

5.3. Fitting the Cuff

Please refer to picture-06

- a) The cuff is pre-formed for easier use. Remove tight or bulky clothing from your upper arm.
- b) Wrap the cuff around your upper left arm. The rubber tube should be on the inside of your arm extending downward to your hand. Make certain the cuff lies approximately 1/2" to 3/4" (1 to 2 cm) above the elbow. Important! The red mark on the edge of the cuff (Artery Mark) must lie over the artery which runs down the inner side of the arm.
- c) To secure the cuff, wrap it around your arm and press the hook and loop closure together.
- d) There should be little free space between your arm and the cuff. You should be able to fit 2 fingers between your arm and the cuff. Cuffs that don't fit properly result in false measurement values. Measure your arm circumference if you are not sure of proper fit.
- e) Lay your arm on a table (palm upward) so the cuff is at the same height as your heart. Make sure the tube is not kinked.
- f) Remaining seated quietly for at least two minutes before you begin the measurement.



Picture-06

5.4 Measure Procedure

Refer to picture 07

1. Sit comfortably in a chair with your feet flat on the floor.
2. Stretch your arm forward on the desk and keep relaxing, make sure the palm of hand is upturned. Make sure arm is in correct position, to avoid body movement. Sit still and do not talk or move during the measurement.

After the cuff has been appropriately positioned on the arm and connected to the blood pressure monitor, the measurement can begin:

a) Operate on the device

Press the Stop/Start button as the power on (blue indicator is turned on). The pump begins to inflate the cuff.

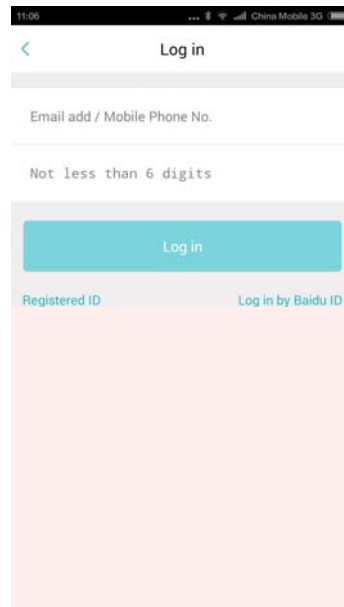
After automatically reaching an individual pressure, the pump stops and the pressure slowly falls, until the measurement finish, the assessment result will be voice out, and the assessment indicator will turn to different colors accordingly.

b) Operate via the App on smart phone. Please refer the below pictures describe how to remote control on the App.

- i. Install the App from google play store or Apple app store.
- ii. Turn on the App, the main display interface of the cigii health care will show up picture (App 01)
- iii. Log in :After a few seconds, it enters the log in step, for the first time to use, please register a new ID, and follow the steps of guidance, picture (App 02), after log in, it come to the first page of app, picture (App 03)



App 01

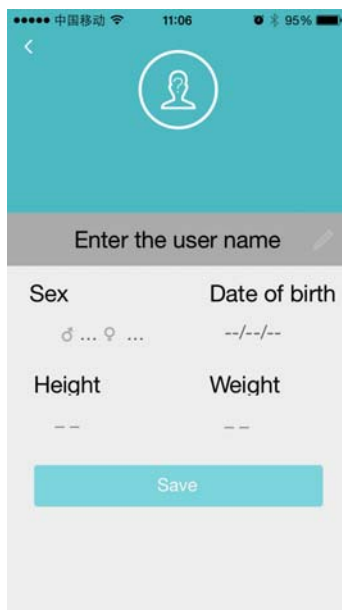


App 02

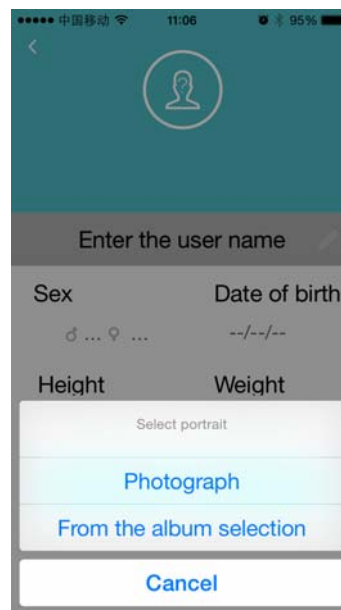


App 03

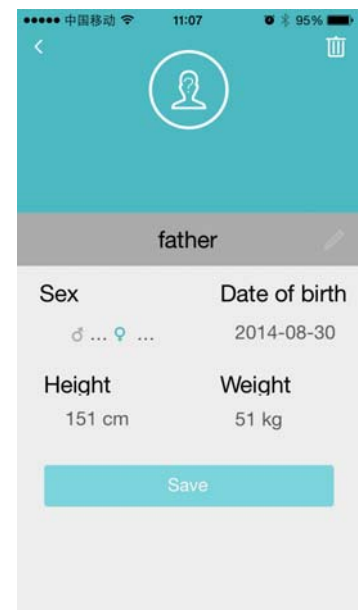
- iv. Add a new member: please see pictures (App 04,05,06), and finish the setting of member, in step of App 05, user can add a photo of the member into the app.



App 04



App 05

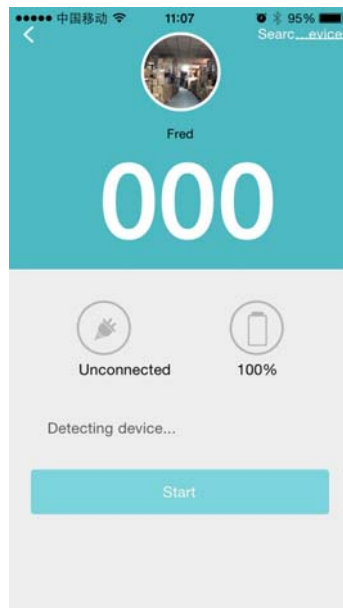


App 06

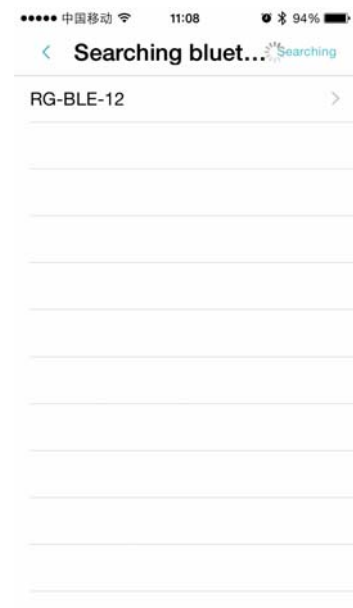
- v. Connect Bluetooth: Turn on the bluetooth on smart phone, and connect the bluetooth with smart phone, see the pictures (App 07,08,09), in picture App 07. Click the button "Detecting on the left top of screen" will come to next step of App 08. In picture App 08, click the Search....device on the right top of the window, the next step of App 09 will show up.



App 07

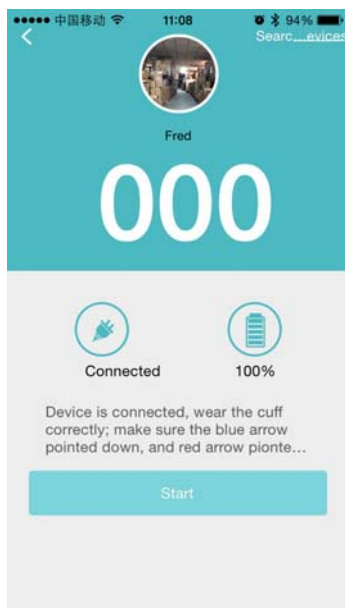


App 08

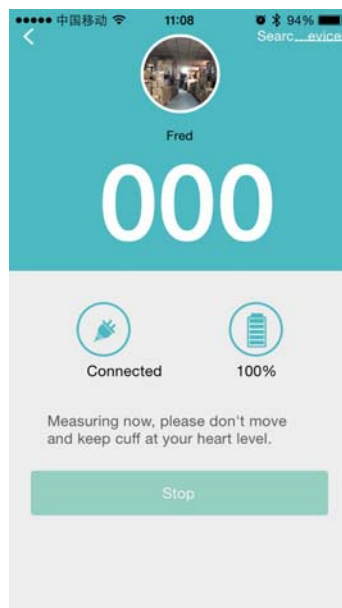


App 09

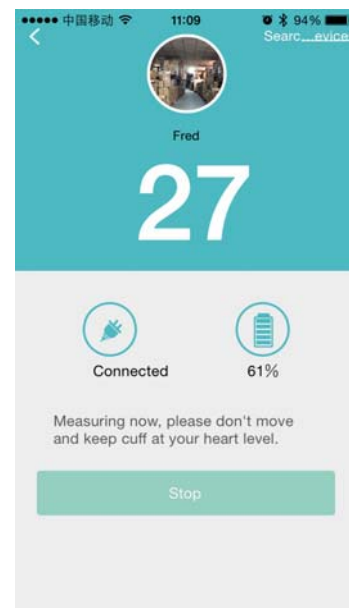
- vi. Start the measurement: Once the device is connect with smart phone with bluetooth, user can start measurement by remote controlling on the App. Please see picture (App 10, 11, 12) Press the “start” button on the app, and the start measurement, during the measurement, user can see the battery capacity and the pressure of the cuff rise and decline value showing on the screen of smart phone, at the same time the indicator keep in blue color.



App 10



App 11



App 12

- vii. After the measurement: When the measurement is finished, the assessment will be voiced out and show on the App. Please see the pictures (App 13), and the result can be shared on internet. Please see picture App 14

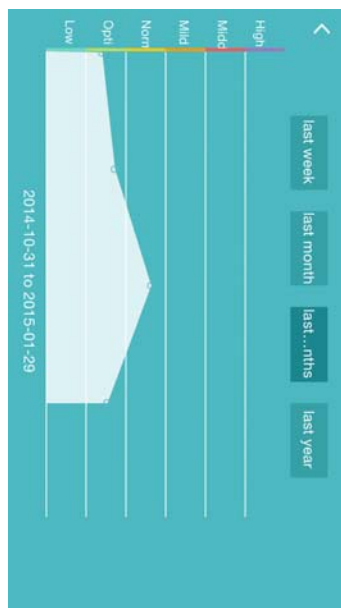


App 13



App 14

- viii. Keep the record of assessment and share on internet. After each measurement, this assessment will be kept in the App, and can be read as different ways in chart and digits. And user can know the blood pressure trend in a certain period. Please see pictures (App 15, 16, and 17)



NOTE:

Patient Position:

- 1) comfortably seated
- 2) legs uncrossed
- 3) feet flat on the floor
- 4) back and arm supported
- 5) middle of the CUFF at the level of the right atrium of the heart

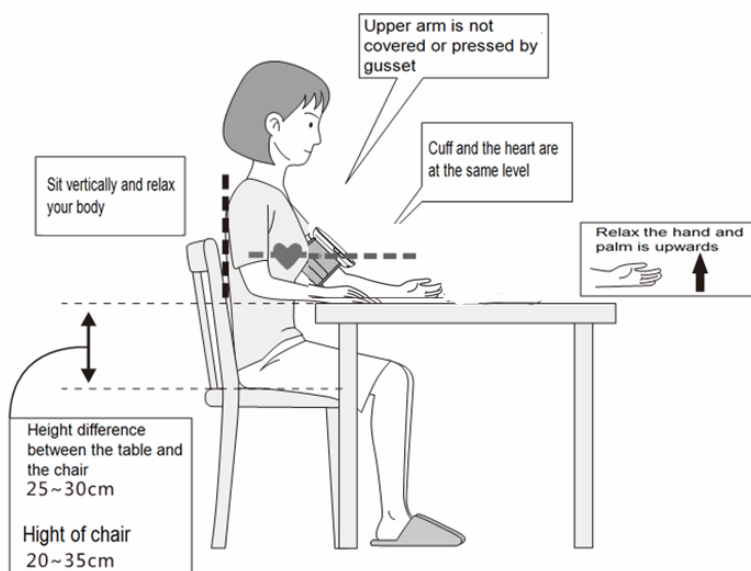
Recommended Use Methods

1. recommendation that the PATIENT relax as much as possible and not talk during the measurement PROCEDURE
2. recommendation that 5 min should elapse before the first reading is taken
3. any reading can be affected by the measurement site, the position of the PATIENT, exercise, or the PATIENT'S physiologic condition
4. performance of the AUTOMATED SPHYGMOMANOMETER can be affected by extremes of temperature, humidity and altitude

1.To stop the inflation or measurement, push the START/STOP button. The monitor will stop inflating, start deflating, and will turn off. If the monitor is remote operated by App on smart phone, it also can be stop on App

2.After the monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your blood pressure will be voiced out or shown on the app on smart phone if operated by App.

3.The monitor will automatically turn off after two minutes no operation



Picture-07

5.6 Error Indicates

The following symbol will appear on the display when measuring abnormal

Trouble removal

Problem	Check	Cause and solution
Power low	The battery indicator turns in red	Charge the device under DC 5V/1A
No power after charging	After charging, the battery indicator never turns into green	Send the device to after sales center
No Inflation	Whether the cuff is broken or leak	Send to after sales center
Err and stop working	Whether move the arm when the cuff is inflating	Keep no moving and peaceful

	Check if chatting when measuring	Keep quiet when measuring
Cuff leak	Whether the cuff wrap too loose	Wrap the cuff tightly
	Whether the cuff borken	Send the device back to after sales center
Please contact the distributor if you can not solve the problems. Do not disassemble the unit by yourself		

SYMBOL DESCRIPTIONS

The following symbols may appear in this manual, on the Digital Blood Pressure Monitor B06T, or on it's accessories. Some of the symbols represent standards and compliances associated with the Digital Blood Pressure Monitor B06T and its use.



Authorized Representative in the European Community



CE Mark: conforms to essential requirements of the Medical Device Directive 93/42/EEC.



Date of manufacture.



Manufacturer

SN

Specifies serial number



Type BF applied part



Direct current



DISPOSAL: Do not dispose this product as unsorted municipal waste. Collection of such waste separately for special treatment is necessary.



Follow instructions for use

IP21

The degree of avoid ingress of water or particulate matter into ME equipment

5.7. Memory

At the end of a measurement, this monitor automatically stores each result with date and time. Each unit stores 99 sets measurements

Viewing the stored values

Press Vol+ / Vol- button once will seek for the assessment record of next/previous

Press the Vol+ and hold and press Vol- and hold, keep pressing both button simultaneously will clear all the assessment records.

5.8. Discontinuing a Measurement

If it is necessary to interrupt a blood pressure measurement for any reason (e.g the patient feels unwell), the Start/Stop button can be pressed at any time. The device then immediately lowers the cuff pressure automatically.

5.10. Using the AC Adapter

Press the "Power on/off" button, if the "Battery Indicator" keep in "Red", it means the battery power is low, and the unit need to be re-charged, the power supply should be DC 5V/1A.

Use only the approved brand AC adapter to avoid damaging the unit. **The charging adaptor shall comply with insulation requirement of IEC 60950-1 at least.**

- a) Ensure that the AC adapter and cable are not damaged.
- b) Plug the adapter cable into the AC adapter port on the right side of the blood pressure monitor.
- c) Plug the adapter into your electrical outlet. When the AC adapter is connected, no battery current is consumed.

Care and Maintenance

Wash hands after each time measurement.

If one device is used by different patients, wash hands before and after each use.

- a) Do not expose the device to extreme temperatures, humidity, dust or direct sunlight.
- b) The cuff contains a sensitive air-tight bubble. Handle this cuff carefully and avoid all types of stress through twisting or buckling.
- c) Clean the device with a soft, dry cloth. Do not use gas, thinners or similar solvents. Spots on the cuff can be removed carefully with a damp cloth and soapsuds. The cuff with bladder must not be washed in a dishwasher, clothes washer, or submerged in water.
- d) Handle the tube carefully. Do not pull on it. Do not allow the tubing to kink and keep it away from sharp edges.
- e) Do not drop the monitor or treat it roughly in any way. Avoid strong vibrations.
- f) Never open the monitor! This invalidates the manufacturer's warranty.
- g) Batteries and electronic instruments must be disposed of in accordance with the locally applicable regulations, not with domestic waste.

6.1. Accuracy test

Sensitive measuring devices must be checked for accuracy from time to time. We recommend a periodical inspection of your unit by an authorized dealer every 1 year. Please turn to local distributor or the manufacturer.

7. Warranty

Your cigii blood pressure monitor is guaranteed for 2 years against manufacturers' defects for the original purchaser only, from date of purchase. The warranty does not apply to damage caused by improper handling, accidents, professional use, not following the operating instructions or alterations made to the instrument by third parties.

Warranty only applies to the instrument. All accessories including the cuff are guaranteed for one year, USB charging cable is included.

Note: According to international standards, your monitor should be checked for accuracy every year.

8. Certifications

Device standard:

This device is manufactured to meet the European blood pressure monitors:

EN1060-1 / 1995 • EN1060-3 / 1997 • EN1060-4 / 2004

Electromagnetic compatibility:

Device fulfills the stipulations of the International standard

IEC60950-1-2

9. Technical Specifications

Model: B06T

Wight: 250g (unit net weight)

Size: 118 (W) x 110 (L) x 52(H) mm

Accessories: 1× Main Device, 1× Users manual, 1× Warranty card, 1× charge cable

Operating Conditions: Temperature: 5°C to 40°C; Humidity: 15% to 93% RH;

Pressure altitude: 70KPa~ 106Kpa

Storage And Shipping Conditions: Temperature: -25°C to 70°C; Humidity: 10% to 93% RH; Pressure altitude: 70KPa~ 106Kpa

Measuring method: Oscillometric

Pressure sensor: Capacitive

Measuring range: DIA: 40-130mmHg; SYS: 60-230mmHg

Pulse: 40 to 199 per minute

Cuff pressure display range: 0–299 mmHg

Memory: Automatically stores the last 99 measurements

Measuring resolution: 1 mmHg

Accuracy: Pressure within ± 3 mmHg / pulse ± 5 % of the reading

Power source: Built-in Lithium Ion Polymer Battery

Accessories: Wide range rigid cuff 8.7" – 14.2" (22 - 36 cm)

Automatically power off :120 seconds

Users: Adult

Expected service life of the device and accessories: 7 years

Technical alterations reserved!

ENVIRONMENTAL REQUIREMENTS

OPERATING CONDITIONS

Temperature: 5°C to 40°C

Humidity: 15% to 93% RH

Pressure altitude: 70KPa~ 106Kpa

STORAGE AND SHIPPING CONDITIONS

Temperature: -25°C to 70°C

Humidity: 10% to 93% RH

Pressure altitude: 70KPa~ 106Kpa

CLASSIFICATION

1. Internally powered equipment; (supplied by Built-in Lithium Ion Polymer Battery)
2. Type BF applied part;
3. IP21;
4. No Sterilize requirement;
5. Not category AP / APG equipment
6. Mode of operation: continuous

EMC Declaration

Guidance and manufacturer's declaration – electromagnetic immunity			
The "Digital Blood Pressure Monitor B06T" is intended for use in the electromagnetic environment specified below. The customer or the user of the "Digital Blood Pressure Monitor B06T" should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	<5 % U_T (>95 % dip in U_T) for 0,5 cycle 40 % U_T (60 % dip in U_T) for 5 cycles 70 % U_T (30 % dip in U_T) for 25 cycles <5 % U_T (>95 % dip in U_T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the "Digital Blood Pressure Monitor B06T" requires continued operation during power mains interruptions, it is recommended that the "Digital Blood Pressure Monitor B06T" be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE U_T is the a.c. mains voltage prior to application of the test level.			

4. EMC Declaration (Continued)

Guidance and manufacturer's declaration – electromagnetic immunity			
The "Digital Blood Pressure Monitor B06T" is intended for use in the electromagnetic environment specified below. The customer or the user of the "Digital Blood Pressure Monitor B06T" should ensure that it is used in such an environment.			
Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6 Radiated RF IEC 61000-4-3	3 Vrms 150 kHz to 80 MHz 3 V/m 80 MHz to 2,5 GHz	3 V 3 V/m	Portable and mobile RF communications equipment should be used no closer to any part of the "Digital Blood Pressure Monitor B06T", including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.2 \sqrt{P}$ $d=1.2 \sqrt{P}$ 80MHz to 800MHz $d=2.3 \sqrt{P}$ 800MHz to 2.5 GHz where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,^a should be less than the compliance level in each frequency range.^b Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			
^a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the "Digital Blood Pressure Monitor B06T" is used exceeds the applicable RF compliance level above, the Medical Digital Blood Pressure Monitor B06T should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the "Digital Blood Pressure Monitor B06T". ^b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than $[V_1]$ V/m.			

4. EMC Declaration (Continued)

Guidance and manufacturer's declaration – electromagnetic emissions		
The "Digital Blood Pressure Monitor B06T" is intended for use in the electromagnetic environment specified below. The customer or the user of the "Digital Blood Pressure Monitor B06T" should ensure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment – guidance
RF emissions CISPR 11	Group 1	The "Digital Blood Pressure Monitor B06T" uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. The "Digital Blood Pressure Monitor B06T" is suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
RF emissions CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

Recommended separation distances between portable and mobile RF communications equipment and the Medical Digital Blood Pressure Monitor B06T			
The "Digital Blood Pressure Monitor B06T" is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the Medical Digital Blood Pressure Monitor B06T can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the "Digital Blood Pressure Monitor B06T" as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	Separation distance according to frequency of transmitter m		
	150 kHz to 80 MHz $d = [\frac{3,5}{V_1}] \sqrt{P}$	80 MHz to 800 MHz $d = [\frac{3,5}{E_1}] \sqrt{P}$	800 MHz to 2,5 GHz $d = [\frac{7}{E_1}] \sqrt{P}$
0,01	0.12	0.12	0.23
0,1	0.38	0.38	0.73
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23
For transmitters rated at a maximum output power not listed above, the recommended separation distance d in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

10. Warranty Card

	Faults	Reasons	What is repaired
The First Repair			
	Date: _____ Repaired By: _____		
The Second Repair			
	Date: _____ Repaired By: _____		

FCC Statement:

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

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

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.

CONTACT INFORMATION

Digital Blood Pressure Monitor B06T is manufactured by:

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