Arm Blood Pressure Monitor
(Electronic Sphygmomanometer)
User Manual

- Thank your for purchasing our product.
- Please read this manual carefully before using the product.
- Please keep the manual appropriately for future reference.
- This User Manual is suitable to the following models: FT-C21Y, FT-C22Y, FT-C23Y, FT-C24Y, FT-C11B, FT-C12B, FT-C21Y-V, FT-C22Y-V, FTC23Y-V, FT-C24Y-V, FT-C11B-V, FT-C12B-V, FT-C11B-UR and FT-C11B-BT.

Table of Contents

I. General Information

■ Intended Use and Indications For Use

Fudakang Arm Blood Pressure Monitor are non-invasive blood measurement system intended to measure the diastolic, systolic blood pressures and pulse rate of an adult individual in hospitals, hospital-type facilities and home environments.
The BT series Blood Pressure Monitor is with the wireless communication function that is connected to the PC or a mobile phone for record archiving and printing purpose.

■ Specification

Product Name	Arm Blood Pressure
Applied Models	FT-C21Y, FT-C22Y, FT-C23Y, FT-C24Y, FT-C11B, FT-C12B, FT-C21Y-V, FT-C22Y-V, FTC23Y-V, FT-C24Y-V, FT-C11B-V, FT-C12B-V, FT-C11B-UR （for UART port connection） FT-C11B-BT (for Bluetooth connection)
Measurement Principle	Oscillography
Bluetooth Version	Bluetooth 4.1 BLE
Bluetooth Modulation Type	GFSK
Cuff	Soft cuff, Cuff size 470mm×130mm (+/- 5mm) 18.5 × 5.1 inch (+/- 0.2 inch)
Measurable Arm Circumference Range	About 220~300mm (8.7 ~ 11.8 inch)
Measurement Range	Pressure: 0~300mmHg Pulse: 30~180 times/minute
Accuracy	Pressure: ±3mmHg Pulse: ±5%
Power Supply	4 x 1.5V AA Alkaline batteries 6V
Battery Life	Approx. 250 times (180mmHg, 1 time/day, 22℃) ; Each measurement takes around 60 seconds, and each memory checking takes about 1 second
Protection against electric shock	Type BF  Cuff
IP classification	IP21
Working Environment	Temperature: 5~40℃ Humidity: ＜90%RH Pressure: 86~106 kPa

Transport and storage Environment	Temperature: -20~55℃ Humidity: ＜95% RH Pressure: 86~106 kPa
Electric Shock Protection	Internal power unit
Memory Capacity	2 Memory sets ; each 90 reading of data including date and time
Inflation	Automatic Inflation by internal pump
Deflation	Automatic speed deflation system controlled by internal electromagnetic valve.
Display	LCD digital display ; It can show Pressure, Pulse, Date, Time
Color Backlight display on LCD (Optional)	White backlight display when power on Green backlight display when result is normal Red backlight display when result is abnormal
Switch	3(ON/OFF, Memory, SET)
Life Time	Machine : 5 years or 10000 times Cuff : 10000 times AC Adapter: 50000 hours
Contents	-Cuff -4 x1.5V AA alkaline batteries 6V (Optional) -Carrying bag(Optional) -Instruction Manual

Note:

These specification may be changed without prior notice.

- **Contraindications:**

1. Heart disease
2. High blood pressure or other circulatory disease
3. Arm injury

- **Patient Populations:**

The device is intended to use for adults. DO NOT use this device on infants or small children..

- **Cleaning Information:**

1. If the device is very dirty, wipe it clean with a cloth moistened with sterilizing alcohol or a neutral detergent. Then wipe it with a dry cloth.
2. NEVER clean the blood pressure monitor with thinners or benzene, as they may damage it.

3. To clean the cuff, wipe it with a moist cloth. Avoid hard rubbing as this will cause air leakages. Take care also not to get water into the air hose.

- **Maintenance:**

This product is designed for use over an extended period of time; however, it is generally recommended that it be inspected every five years to ensure proper function and performance. The device doesn't need to be calibrated in five years of reliable service. Modification of this equipment is allowed except change the batteries.

- **Protect the Nature Environment:**

Please help to protect natural environment by respecting national and/or local recycling regulations when disposing of the battery and the product at the end of their useful live.

II. PRECAUTION FOR USE AND MAINTENANCE

- **Precautions for Use:**

1. If you suffer from heart disease, high blood pressure or other circulatory disease, consult your physician before using the device. It is intended for adult indoor use only. The device is not suitable for public use.
2. The patient is an intended operator. The patient can measure, transmit data and charge battery under normal circumstances and maintain the device and its accessories according to the user manual.
3. If the cuff pressure feels abnormal or you experience any other irregularity while using the cuff, reduce the pressure immediately by pressing the "ON/OFF" switch and then consult the sales outlet where you purchased the device.
4. If you think the measurement is abnormal or if measurement makes you feel unwell, discontinue use and consult your physician.
5. Blood pressure measurement may not be possible for anyone with a weak pulse or arrhythmia.
6. Repeated blood pressure measurement may cause problems such as congestion or swelling in some people.
7. Frequently repeated blood pressure measurements will not give accurate results. Allow an interval of about 3 minutes between measurements.

8. If you suffer from a severe problem with blood circulation in your arms, consult your physician before using the device. Failure to do so could be hazardous to your health.
9. Measurement may not be possible for anyone with insufficient blood flow to the area where measurements will be taken or who suffers from a frequent irregular heartbeat. Consult your physician for advice on whether to use the device.
10. DO NOT wrap the cuff around an elbow. DO NOT wrap over a wound.
11. DO NOT wrap the arm cuff around an elbow in which a drip (intravenous infusion) is inserted or which is being used for blood transfusion as part of medical treatment. Doing so could result in an injury or a serious accident.
12. DO NOT wrap the cuff on the arm on the side of a mastectomy.
13. DO NOT use the device in the vicinity of flammable gases such as those used for anesthesia. Doing so could ignite the gases and cause an explosion.
14. DO NOT use the device in enriched oxygen environments such as a hospital's hyperbaric chamber or oxygen tent. Doing so could ignite the oxygen and cause a fire.
15. DO NOT use mobile phones near the device as this could result in a malfunction. DO NOT use the device with hf surgical equipment.
16. If you use a cardiac pacemaker, consult your physician before using the device.
17. Be sure to use this device only for measuring blood pressure. DO NOT use it for any other purpose.
18. DO NOT use this device on infants, pregnant women or pre-eclamptic patients.
19. DO NOT use this device for patients that transport outside a healthcare facility.
20. Blood pressure measurement may not be possible for anyone with common arrhythmias such as arterial or ventricular premature beats or arterial fibrillation.
21. Be careful to strangulation due to cables and hoses, particularly due to excessive length. It will not cause any potential alergic reaction or contact injury. If you are allergic to dacron or plastic, please don't use this device

■ **Precautions for Maintenance:**

1. DO NOT store the blood pressure monitor in locations exposed to direct sunlight, high temperatures (over 60℃), low temperatures (below -20℃), high relative humidity (over 85%) or excessive amounts of dust.
2. DO NOT drop the blood pressure monitor or subject it to other shocks or vibration.
3. Remove the batteries if the device will be left unused for a long period.

4. DO NOT attempt to disassemble the device. User can open battery cover for new battery installation.
   DO NOT bend the cuff or air hose excessively.
5. NEVER clean the blood pressure monitor with thinners or benzene, as they may damage it.
6. DO NOT hard rub when clean the cuff. Take care not to get water into the air hose.
7. DO keep the device out of reach of children, pets and insects.

III. Name of Each Part

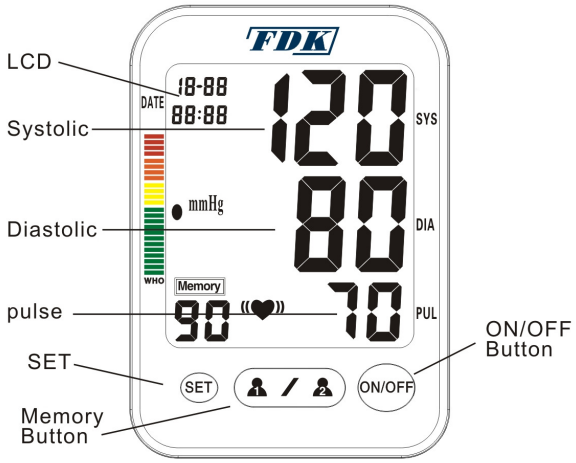


Figure 1 - Appearance

- ❖ MEMORY" Button /Clock Setting
- ❖ Memory Button /Measured Result recall/ Clock Number Adjusting
- ❖ "ON/OFF" Button
- ❖ LCD Display
- ❖ Systolic Indicator
- ❖ Diastolic Indicator
- ❖ Pulse Indicator

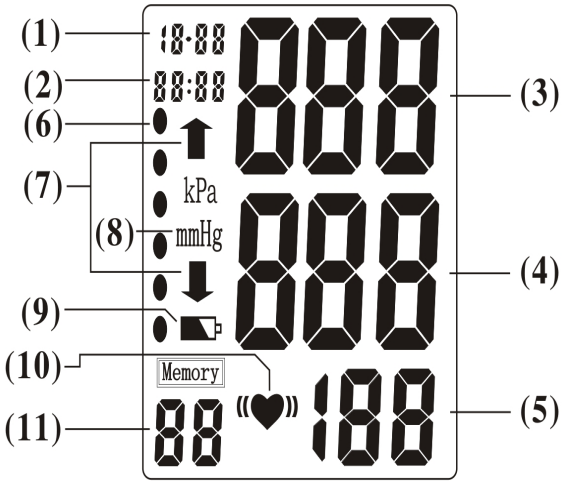


Figure 2 – Display of LCD

Note for LCD display:

(1) Date: Month - Day

(2) Time: Hour – Minute

(3) Systolic Blood Pressure (unit: mmHg)

(4) Diastolic Blood Pressure (unit: mmHg)

(5) Pulse Rate(unit: beat/minute)

(6) WHO Blood Pressure Classification Indicator

(7) Inflation / Deflation Indicator

(8) Blood Pressure Measurement Unit

(9) Battery Symbol

(10) Irregular heartbeat Indicator

(11) Memory Record Number

*** Back light display function is optional.**

IV. Measure Procedure

■ Battery Loading

Remove the battery compartment cover by gently pushing down on arrow and sliding cover forward.

Place batteries with positive “+” and negative “-“ terminals into compartment and make sure they match the indicated terminals in the compartment.

Close the battery cover by gently sliding it into the compartment and pressing it into place.. ***See Figure 3.***

Note：

When the LCD display shows “Low Battery” signal ,the batteries must be replaced for accurate readings. ***See Figure 4***

Do not use rechargeable batteries (voltage 1.2V). They are not suitable for this product, can damage the monitor and will cause inaccurate readings to be obtained.

Remove the batteries if the monitor will not be used for six month or longer to avoid damage from the possibility of leaking batteries.

All the measurements will remain in the memory should the batteries become drained, removed, or replaced.

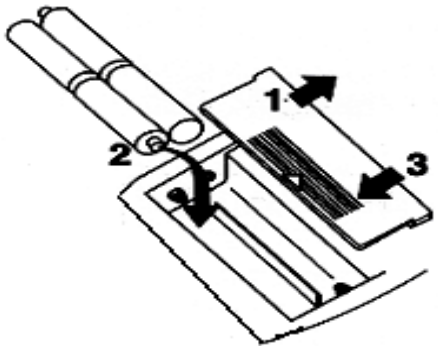


Figure 3

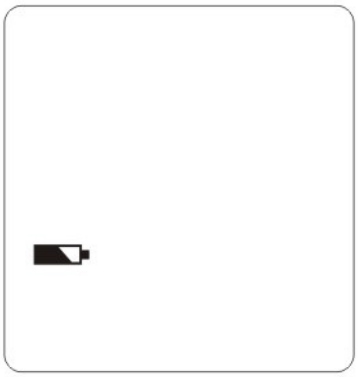


Figure 4

NOTE: AC adapter is optional for power supply. Only use the adapter provided by manufacturer, that is complying with EC60601-1 standard requirements. Do not touch the AC adapter with wet hand while it is working. Do not tangle the power cords of the adapter during measuring process. The adapter is part of the blood pressure monitor. Unplug the AC adapter from power outlet to isolate the device from supply mains

- **Clock Adjusting and Unit Change**

Press the “SET” button for 5 seconds during the device is turned off, the number of the YEAR will begin to blink on the LCD display. Press the “ ” button to advance the YEAR displayed. When you have reached the correct date, press the “SET” button and release. (Don't keep on clicking on the 'SET' button without being released during programming.) When the “SET” button is

pressed and released, the YEAR will stop blinking and the MONTH will begin to blink. Press and release the " 1 2 " button until the desired month is reached. ***See Figure 5.***

Repeat this process to set the DAY, HOUR, MINUTES.

After you change the batteries, you have to readjust the date and time. Time is maintained using a 24 HOUR clock. AM/PM is not displayed.

NOTE: When the number that you wish to set – i.e. YEAR, MONTH, DAY, HOUR, MINUTE - is blinking, each time you press and release the " 1 " button, the number will increase by one. ***Time is displayed using a 24 hour clock. AM/PM are not displayed.

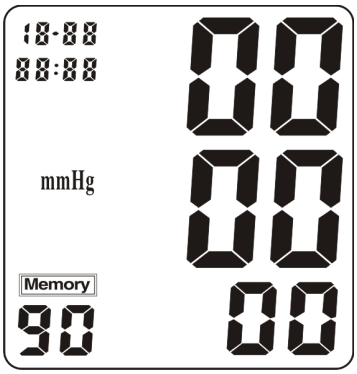


Figure 5

For the unit change, you can select the mmHg or Kpa; and the mmHg is the definition unit. When the machine is turned off, press the button "ON/OFF" more than about 10 seconds till LCD blinks ,then press Memory button to switch between mmHg and Kpa .

■ Arm Cuff Connecting

★ The cuff should be snug but not too tight. You should be able to insert two fingers between the cuff and your arm.

★ Place the cuff around the left bare arm ½" to ¾"' above the elbow joint. The air tube should be oriented to run down the center of the inside of your arm. (Refer to diagram on cuff for proper placement.)

★ Keep the cuff at approximately the same level as your heart.

★ Unless your physician recommends otherwise, always use the left arm to measure your blood pressure. ***See Figure 6***

★ Arm cuff connecting should make arm feel no much tension. Don't connect too tense (otherwise the measurement will be not precise).

★ Keep up right position on the same height of heart.

★ Do not bend with the cuff or the air tube. Do not inflate before fitting the cuff.

★ When the cuff is dirty, detach it from the equipment, wash the cuff by hand with proper detergent and rinse it in the enough cold water, dry in air. Never iron it.

★ Only use the manufacturer cuff with the main unit to ensure accurate measurement.

NOTE:

★REFER TO THE DIAGRAM PRINTED ON THE CUFF FOR PROPER PLACEMENT.

★FOR ACCURATE READINGS, THE CUFF/PRESSURE MUST BE ORIENTED CORRECTLY AND ALIGNED WITH THE ARTERY.

★CONTINUOUS CUFF PRESSURE MAY EFFECT BLOOD FLOW AND CAUSE HARMFUL INJURY

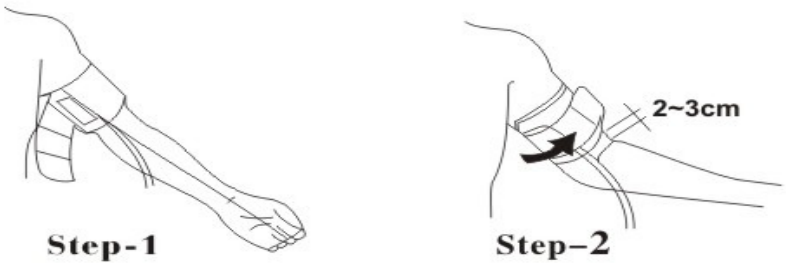


Figure 6

Note: The cuff is " TYPE BF APPLIED PART"

■ Measuring Process

POSTURE FOR TAKING BLOOD PRESSURE MONITOR

★ Make yourself comfortable and sit-up straight, legs uncrossed, feet flat on the floor

★ Place your arm with cuff in front of you on the table with your palm facing up.

★ Cuff should be at the same height as your heart.

TIPS FOR BLOOD PRESSURE MONITORING

★ Relax for about 5 minutes before measurement.

★ Do not smoke or ingest caffeine at least 30 minutes prior to measurement.

★ Remove any constricting clothing and place the cuff on a bare arm.

★ Keep still and do not talk until the measurement is complete.

★ The cuff must be neither too tight nor too loose. Using a little force, you should be able to place two fingers between the cuff and your arm.

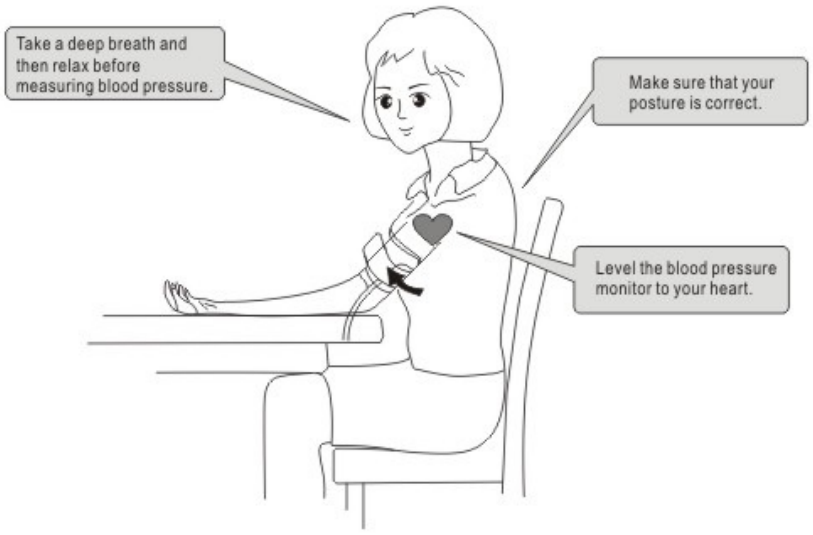


Figure 7

After you are in a comfortable position, press the "ON/OFF" button. The device will perform a self verification/check. During this verification/check the LCD will display all "8's". At the conclusion of the verification/check the LCD will display "00". ***See Figure 8.*** If the device has voice function, it will speak out the displayed blood pressure, heart rate. If an irregular heartbeat is detected, the IRREGULAR HEARTBEAT symbol will appear and blink in the display screen. ***See Figure9.***

NOTE:

★ Do not self-diagnosis according to measured result. Consult with your physician for further diagnosis.

★ If the device cause any discomfort during measuring process or fail to perform as indicated ,please turn off the power or discontinue use.

★ If cuff inflates up to 300 mmHg (40kPa) doesn't stop, please remove the cuff or turn off the device immediately.

■ Reading Memory Results

READING AN AVERAGE OF THE LATEST THREE MEASUREMENTS (AVg)

★ When the monitor is turned off, press and release the " 1 or 2 " button. LCD will display "**AVg**" in the upper corner of the LCD Display. The result that is first displayed and the result that is first announced – if in "TALKING" mode – is the average of your latest three measurements.

★ To review the results that are in memory – PRESS the " 1 or 2 " button to scroll through previous measurements. Each time you press and release the " 1 or 2 " button the next oldest result will be displayed. If the "TALKING" function is turned "ON" each result will be verbally announced,

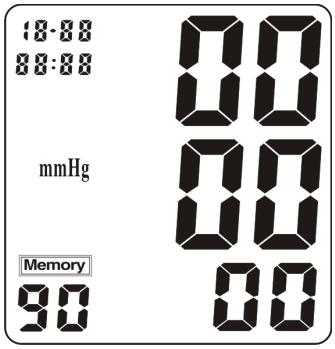


Figure 8

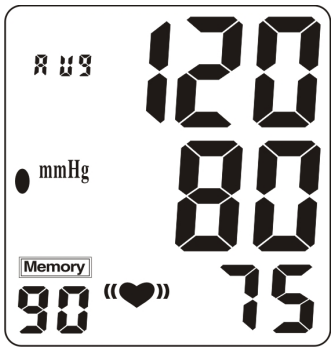


Figure 9

2-PERSON MEASUREMENT SETTING FUNCTION

This model has 2-Person memory banks and 90 memories storage for each. Press and release 'SET' button can prompt to P1 (Person 1) or P2 (Person 2) as your ID to access the measurement for the first time operation when the device is turned off. Each time, before taking measurement or check memory from the storage, please be sure you have advanced to the correct ID (P1 or P2) which you already set forth prior to turning on the device.

- **Assessing High Blood Pressure for Adults**

The follow standards for assessing high blood pressure (without regard to age or gender) have been established as a guide line according to WHO (World Health Organization) standard. ***See Figure 10.*** Please note that other risk factors (e.g. diabetes, obesity, smoking, etc.) need to be taken into consideration and may affect these figures. Consult with your physician for accurate assessment.

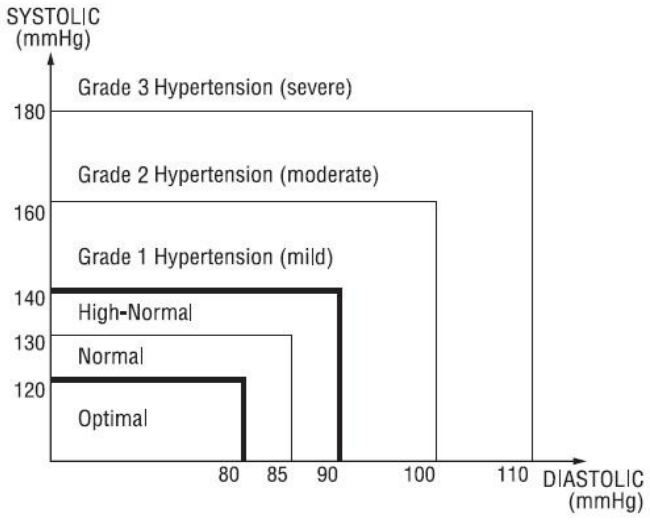


Figure 10

From the above figure, we can see the classification of blood pressure for adults is as below. The WHO BP Classification Indicating Bar would show out the blood pressure level by the color indicator .

Blood Pressure Classification	SBP (mmHg)	DBP (mmHg)	COLOR INDICATOR
Optimal	<120	<80	GREEN
Normal	120-129	80-84	
High-Normal	130-139	85-89	
Stage 1 Hypertension	140-159	90-99	YELLOW
Stage 2 Hypertension	160-179	100-109	ORANGE
Stage 3 Hypertension	≧180	≧110	RED

Note:

The graph is not exact, but may be used as a guide in understanding non-invasive blood pressure measurements. The device is only intended for use with adults.

■ **Delete for all Memories**

★ Press and hold the 1 or 2 ” BUTTON until all numbers change to “ZERO”.. All results in memory are now deleted. LCD will show the ***Figure 11*** for two seconds.

Note: Date and time settings are not changed by using the memory delete function.

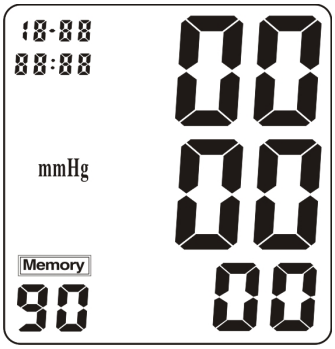


Figure 11

- **Shut Down**

After measurement, press button “ON/OFF” to turn off the device. The device will be automatically power off after 1 minute of none use.

- **Voice Function**

The device with voice function can speak out in the following state:

- The device will speak out the prompt that “keep silence to take a cuff at the same height with your heart ” when the measure begin.
- The device will speak out the displayed blood pressure (systolic and diastolic pressure), heart rate after each measurement finish.
- The device will speak out the last time displayed memory blood pressure (systolic and diastolic pressure), and heart rate when reading memory result.

Note: The voice function is ONLY for models FT-C21Y-V, FT-C22Y-V, FT-C23Y-V, FT-C24Y-V, FT-C11B-V, FT-C12B-V.

- **UART connection and Blue Tooth Function**

- The UART connection model is FT-C11B-UR

Operation Method:

★ Install the APK by the receiving device manufacture accordance with the communication protocol into the signal receiving device such as mobile phone.

★ Use cable to connect receiving device with the blood pressure monitor which with UART port.

★ Activate the receiving device and let it be in stand-by status for blood pressure measuring.

★ Activate the blood pressure monitor which with UART port and start testing according to the normal blood pressure monitor operation method.

★ After testing the result including systolic pressure, diastolic pressure and pulse will display on LCD, press the SEND button to send these data to the receiving device such as mobile phone.

- The UART port connector & Cable specification:

1. Any type of USB (micro USB, mini USB, standard USB) or serial connector is defined by the customer.
2. Cable : OD 3.5 +/- 0.1 mm , # 28 x 4 Color wires
3. Contact resistance >2 ohm
4. Insulation resistance: DC 300V 20 Mohm /10 ms

➢ The Blue Tooth function model is FT-C11B-BT.

Operation Method:

★ Install the APK accordance with the communication protocol into the blue tooth signal receiving device such as mobile phone.

★ Activate the blue tooth signal receiving device such as mobile phone to match with the blue tooth of NIBP.

★ Start to measure according to the normal blood pressure monitor operation method.

★ After measuring the result will be displayed on LCD including systolic pressure, diastolic pressure and pulse will be automatically sent to the blue tooth receiving device such as mobile phone.

The additional function of this model blood pressure monitor is that transmit the testing result to the APK in the receiving device via blue tooth technology.

- Example for the Blue Tooth operating connection :

Bluetooth 4.1 work with IOS System

Firstly search in the "APP Store" for "Light Blue" application software 

（as this image）and install properly。

Ⅰ.Open the installed "Light Blue" application software (see Figure 1) and activate Bluetooth 4.1 blood pressure monitor.

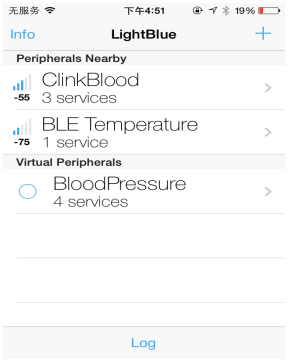


Figure 1

After mobile phone Bluetooth module searched to find the Bluetooth blood pressure monitor, it display “ClinkBlood”.

Ⅱ.Press the “ClinkBlood” till “Connected” display on mobile phone screen which means successfully connected with blood pressure monitor.

Ⅲ.Slide mobile phone screen to "Slave - > Host" and switch its NOTIFIED VALUES status from "Listen for notifications" to "Stop listening", which means it will be status of "Listening" once open. As shown in Figure 2 and Figure 3

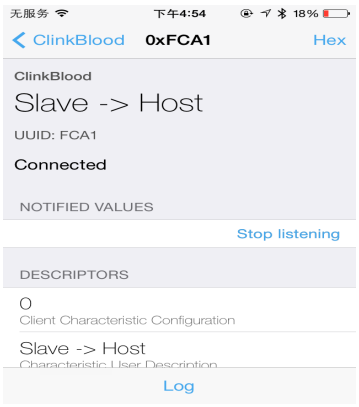


Figure 2

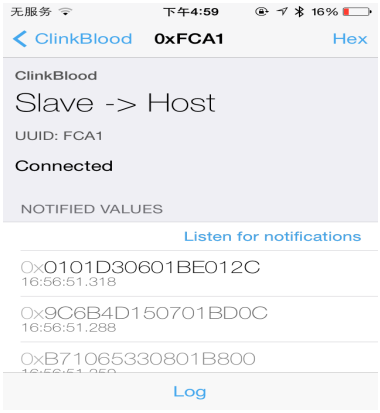


Figure 3

Ⅳ.Then go to “Host->Slave”, in“Write new value”, input below commands respectively

Connect blood pressure monitor：04 00 A0 A4

Blood pressure monitor start measuring：04 00 A1 A5

Blood pressure monitor stop：04 00 A2 A6 As shown in Figure 4 and Figure 5

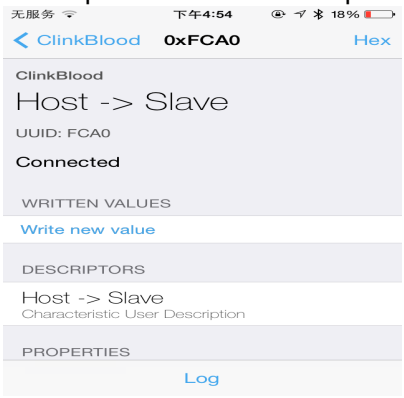


Figure 4

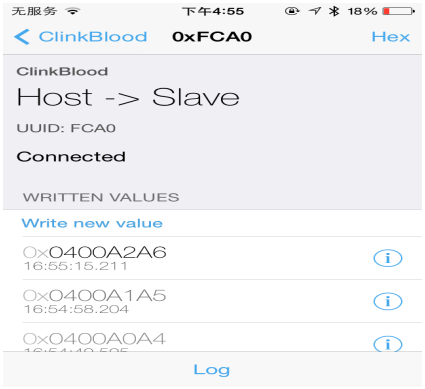
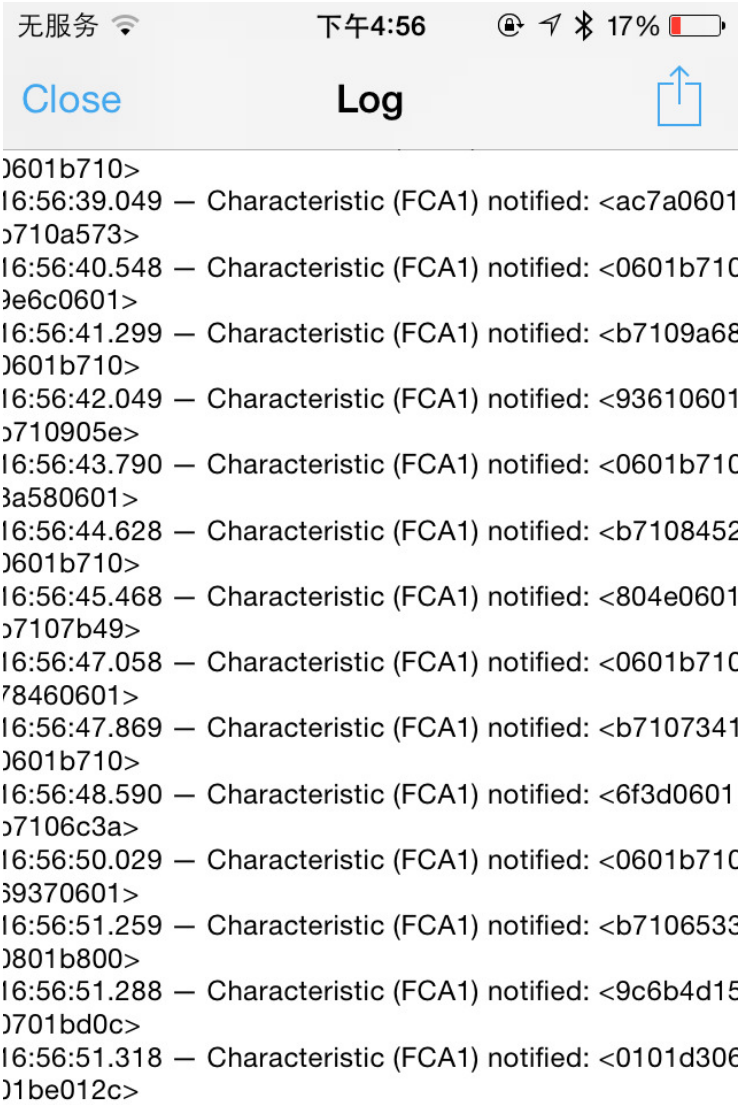


Figure5

Ⅴ. Press command of “Connect”，then press “Start measuring” command，blood pressure monitor start to measure, open “Log” to see the blood pressure monitor dynamic measurement process. It
is hexadecimal.



The above two models have all function as same normal NIBP, only have different “result output “method.

V. Troubleshooting

Abnormality	Reason	Checkout
LCD shows Low Battery icon 	Batteries are low.	Change new batteries.
Shows abnormal result	Cuff is not tightened properly or its position is incorrect.	Tighten cuff correctly and refer to “Arm Cuff Connecting”.
	The arm is moved during measuring.	Stay calm, arm remains steady. Do not move during measuring.
	Irregular heartbeat	You can test again for light irregular heartbeat patients. It is inappropriate for serious irregular heartbeat patients to use this device.
Shows abnormal result	Speaking, frightened nervous or excited measurement	Do not speak, take deep breath 2~3 times to relax yourself.
	Wrong position	Adjust position; refer to “Arm Cuff Swathing”.
	Some interference in inflation or wrong operation during measuring	Refer to the inflation step in “Measuring process”.
After power on ,no display on LCD	Battery problem or wrong battery polarity	Install battery correctly or replace new battery; If the device is still not activated, then stop using it.
Cuff inflation rate is too low or does not inflate	Air tube not connected with main device properly; Cuff or bladder inside the cuff leakage air	Reconnect the air tube; Purchase a new cuff
Cuff deflates too quickly	Cuff has been applied too loose.	Make sure cuff is wrapped up correctly
Measure result is different from the hospital or value is inconsistent	This is normal	Blood pressure value is varying during the day and will also be affected by emotional and physical condition
LCD shows “Er U”	Insufficient inflation	Measure again.
LCD shows “Er H”	Inflation over 305 mmHg	Measure again
LCD shows “Er 1”	Undetectable the pulse	Measure again
LCD shows “Er 2”	Radiation interference	Away the radiation source
LCD shows “Er 3”	Measured result wrong	Measure again

Note: If you cannot resolve the problem, you can contact manufacturer or its service agent for replacement policy.

STATEMENTS AND DECLARATIONS:

1. MEDICAL ELECTRICAL EQUIPMENT needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided in the ACCOMPANYING DOCUMENTS

2. Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d = 3,3 m away from the equipment. (Note. As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields d = 3,3 m at an IMMUNITY LEVEL of 3 V/m)

3. The manufacturer are available for request of circuit diagrams, component part lists, descriptions ,calibration instructions ,or other information that will assist service personnel to repair those parts of the device

4. 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.

5. Guidance and manufacturer's delclaration

Guidance and manufacture's declaration – electromagnetic emission		
The [EQUIPMENT or SYSTEM] i*s* intended for use in the electromagnetic environment specified below. The customer of the user of the [EQUIPMENT or SYSTEM] should assure that it is used in such an environment.		
Emission test	**Compliance**	**Electromagnetic environment –**

		guidance
RF emissions CISPR 11	Group 1	The [EQUIPMENT or SYSTEM] use 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.
RF emission CISPR 11	Class B	
Harmonic emissions IEC 61000-3-2	Not applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not applicable	

Guidance and manufacture's declaration – electromagnetic immunity			
The [EQUIPMENT or SYSTEM] is intended for use in the electromagnetic environment specified below. The customer or the user of [EQUIPMENT or SYSTEM] should assure 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 floor are covered with synthetic material, the relative humidity should be at least 30%. If ESD interfere with the operation of equipment ,counter measurements such as wrist strap, grounding shall be considered.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	Not applicable	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	Not applicable	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)	Not applicable	Mains power quality should be that of a typical commercial or hospital environment. If the user of the TL-100Drequires continued operation during power mains interruptions, it is recommended that the TL-100Dbe powered from an uninterruptible power supply

	for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec		or a battery.
Power frequency (50Hz) magnetic field IEC 61000-4-8	3A/m	3A/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.			

Guidance and manufacture's declaration – electromagnetic immunity			
The [EQUIPMENT or SYSTEM] i*s* intended for use in the electromagnetic environment specified below. The customer or the user of [EQUIPMENT or SYSTEM] should assure 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	3 V_{rms} 150 kHz to 80 MHz	Not applicable	Portable and mobile RF communications equipment should be used no closer to any part of the [EQUIPMENT or SYSTEM], including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** $d = 1.167\sqrt{P}$
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	$d = 1.167\sqrt{P}$ 80 MHz to 800 MHz $d = 2.333\sqrt{P}$ 800 MHz 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 [EQUIPMENT or SYSTEM] is used exceeds the applicable RF compliance level above, the [EQUIPMENT or SYSTEM] should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the [EQUIPMENT or SYSTEM].

[b] Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the [EQUIPMENT or SYSTEM]**.**

The [EQUIPMENT or SYSTEM] i*s* intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the [EQUIPMENT or SYSTEM] can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the [EQUIPMENT or SYSTEM] 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 $d = 1.167\sqrt{P}$	**80 MHz to 800 MHz** $d = 1.167\sqrt{P}$	**800 MHz to 2.5 GHz** $d = 2.333\sqrt{P}$
0.01	**0.117**	**0.117**	**0.233**
0.1	**0.369**	**0.369**	**0.738**
1	**1.167**	**1.167**	**2.333**
10	**3.689**	**3.689**	**7.379**
100	**11.667**	**11.667**	**23.333**

For transmitters rated at a maximum output power not listed above, the recommended separation distance d in metres (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.

FCC ID: 2ADNQFTC11BBT

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.

Explanation of Symbols:

LOT Symbol for batch code  Symbol for manufacturer

 Symbol for ‘CE”

 Symbol for “electrical and electronic equipment”

 Symbol for “TYPE BF APPLIED PART”

 Symbol for “Follow operating instructions”

IP21 Symbol for “the IP classification”

 Symbol for “ RF transmitters”

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Software Version1.3

Manual Version:V2.0