

Owner's Manual

Arm-type Fully Automatic Digital Blood Pressure Monitor

Model **DBP-63D2L**

Arm Type



Document No. : JDBP-D204-105
Version: Z
Date of Issue: XXXX.XX

Contact Information

The lay operator or lay responsible or ganization should contact the manufacturer or the representative of manufacturer.
-for assistance,if needed,in setting up,using or maintaining the product,or
-to report unexpected operation or events.
Manufactured by JOYTECH Healthcare Co.,Ltd.
No.365, Wuzhou Road, 311100 Hangzhou, Zhejiang Province, PEOPLE'S REPUBLIC OF CHINA
Email: info@sejoy.com
Telephone: +86-571-81957767
Fax: +86-571-81957750

Contents

1

Safety Notice	02
Unit Illustration	06
Important Testing Guidelines	08
Quick Start	09
Unit Operation	10
Battery Installation	10
System Settings	11
Applying the Arm Cuff	13
Testing	14
Power Off	17
Memory Check and Last 3 Test Average	18
Memory Deletion	19
Low Battery Indicator	19
Bluetooth requirement and connection	20
Troubleshooting	22
Blood Pressure Information	23
Blood Pressure Q&A	26
Maintenance	27
Specifications	29
Warranty	31
Electromagnetic Compatibility Information	32

Safety Notice

2

Thank you for purchasing the DBP-63D2L Blood Pressure Monitor. The unit has been constructed using reliable circuitry and durable materials. Used properly, this unit will provide years of satisfactory use.

The Arm-type Fully Automatic Digital Blood Pressure Monitors are intended to measure blood pressure (systolic and diastolic) and pulse rate of adults and adolescents over 12 years of age with circumference ranging from 22cm to 42cm.

All functions can be used safely and values can be read out in one LED DISPLAY. Measurement position is on adult upper arm only.

The PATIENT is an intended OPERATOR

Blood pressure measurement determined with this device are equivalent to those obtained by a trained observer using the cuff/ stethoscope auscultation method, within the limits prescribed by the Recognized Consensus Standard (IEC 81060-2-30) for electronic sphygmomanometers.

Target group

It is designed for self-measurement by adults in the home environment and is suitable for users whose upper arm circumference is within the range printed on the cuff. The blood pressure part is for adults and adolescents over 12 years of age .

Precautions to Ensure Safe, Reliable Operation

1. Do not drop the unit. Protect it from sudden jars or shocks.
2. Do not insert foreign objects into any openings.
3. Do not attempt to disassemble the unit.
4. Do not crush the pressure cuff.
5. If the unit has been stored at temperatures below 0 ℃, leave it in a warm place for about 15 minutes before using it. Otherwise, the cuff may not inflate properly.
6. If the unit has been stored at temperatures above 40 ℃, leave it in a cool place for about 15 minutes before using it. Otherwise, the cuff may not inflate properly.
7. Do not store the unit in direct sunlight, high humidity or dust.
8. To avoid any possibility of accidental suffocation, keep children away from the device and do not wrap hose or cable around the neck.
9. Ensure that children do not use the instrument unsupervised; some parts are small enough to be swallowed.
10. Some may get a skin irritation from the cuff taking frequent readings over the course of the day, but this irritation typically goes away on its own after the monitor is removed.

Safety Notice

3

Important Instructions Before Use

- 1. Do not confuse self-monitoring with self-diagnosis. Blood pressure measurements should only be interpreted by a health professional who is familiar with your medical history.
- 2. Contact your physician if test results regularly indicate abnormal readings.
- 3. If you are taking medication, consult with your physician to determine the most appropriate time to measure your blood pressure. NEVER change a prescribed medication without first consulting with your physician.
- 4. Individuals with serious circulation problems may experience discomfort. Consult your physician prior to use.
- 5. For persons with irregular or unstable circulation resulting from diabetes, liver disease, arteriosclerosis or other medical conditions, there may be variations in blood pressure values measured at the wrist versus at the upper arm. Monitoring the trends in your blood pressure taken at either the arm or the wrist is nevertheless useful and important.
- 6. People suffering from vascular constriction, liver disorders or diabetes, people with cardiac pacemakers or a weak pulse, and women who are pregnant should consult their physician before measuring their blood pressure themselves. Different values may be obtained due to their condition.
- 7. People suffering from arrhythmias such as atrial or ventricular premature beats or atrial fibrillation only use this blood pressure monitor in consultation with your doctor. In certain cases oscillometric measurement method can produce incorrect readings.
- 8. Too frequent measurements can cause injury to the patient due to blood flow interference.
- 9. The cuff should not be applied over a wound as this can cause further injury.
- 10. **DO NOT** attach the cuff to a limb being used for IV infusions or any other intravascular access, therapy or an arterio-venous (A-V) shunt. The cuff inflation can temporarily block blood flow, potentially causing harm to the patient.
- 11. The cuff should not be placed on the arm on the side of a mastectomy. In the case of a double mastectomy use the side of the least dominant arm.
- 12. Pressurization of the cuff can temporarily cause loss of function of simultaneously used monitoring equipment on the same limb.
- 13. A compressed or kinked connection hose may cause continuous cuff pressure resulting in blood flow interference and potentially harmful injury to the patient.
- 14. Check that operation of the unit does not result in prolonged impairment of the circulation of the patient.
- 15. Product is designed for its intended use only. Do not misuse in any way.
- 16. Product is not intended for infants or individuals who cannot express their intentions.
- 17. Prolonged over-inflation of the bladder may cause ecchymoma of your arm.
- 18. Do not disassemble the unit or arm cuff. Do not attempt to repair.
- 19. Use only the approved arm cuff for this unit. Use of other arm cuffs may result in incorrect measurement results.
- 20. The system might produce incorrect readings if stored or used outside the manufacturer's specified temperature and humidity ranges. Make sure to store the blood pressure monitor, children, pets and pests are outside of accessible range.
- 21. Do not mix new and old batteries simultaneously.

Safety Notice

4

- 22. Remove batteries from device when not in operation for more than 3 months.
- 23. Dispose batteries properly; observe local laws and regulations.
- 24. Only use a recommended class II AC Medical approved adaptor which comply with 2MOPP, and pass IEC 60601-1, IEC 60601-1-2(or FCC) standard . An unauthorized adapter may cause fire and electric shock.
- 25.  Advising operator that Instruction manual/ Booklet must be consulted.
- 26. Do not use the device during transport vehicles for influencing measurement accuracy such as patient transport in an ambulance or helicopter.
- 27. Contains small parts that may cause a choking hazard if swallowed by infants.
- 28. the blood pressure monitors equipped with bluetooth(BT) module is only transmit historical blood pressure (BP) from the subject device to a user-supplied digital device, and is not intended for active patient monitoring.
- 29.  Please use the power adaptor specified by manufacturer

EMC warning:

- 1. Do not use the device near strong electrical or electromagnetic disturbance sources generated by electrocautery, MRI, electrosurgical units, and diathermy devices, otherwise it may cause incorrect reading.
- 2. 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.
- 3. 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 unit, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.
- 4. Do not use the device near strong electrical or electromagnetic fields generated by cell phones or other devices , they may cause incorrect readings and interference or become interference source to the device.

WARNING SIGNS AND SYMBOLS USED	
	Keep Dry
	Keep off Sunlight
	Type BF Equipment
	Instructions For Use MUST be Consulted
	Discard the used product to the recycling collection point according to local regulations
	The Bluetooth® Smart word mark and logos are registered trademarks owned by Bluetooth SIG, Inc. and any use of such marks by JOYTECH Healthcare Co., Ltd.
IP22	IP22 indicate dustproof and waterproof grade. Number 2 indicate that Protected against solid foreign objects of 12.5 mm and greater; Number 1 indicate that Protection against vertically falling water drops .
	Magnetic Resonance unsafe

Safety Notice

5

Federla Commulcation Commission (FCC) Interference Statement

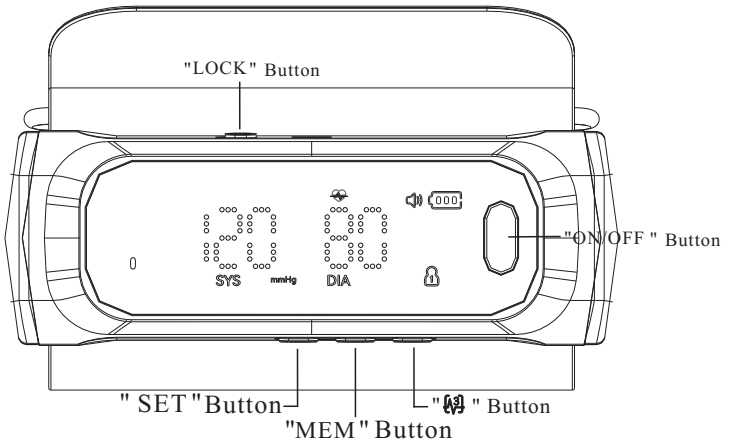
- 1. This device complies with part 15 of the FCC Rules. Operation is subject to the condition that this device does not cause harmful interference.
- 2. This device is verified to comply with part 15 of the FCC Rules for use with cable television service.
- 3. This device complies with part 15 of the 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. Please note that changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate the equipment.
- 4. 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. This equipment complies with radio frequency exposure limits set forth by the FCC for an uncontrolled environment.
- 6. This device must not be co-located or operating in conjunction with any other antenna or transmitter.
- 7. Any changes or modifications not expressly approved by the party responsible for compliance could void the user's authority to operate this equipment.
- 8. Essential performance:

Electrosurgery interference recovery	Refer 202.6.2.101	IEC 80601-2-30
Limits of the error of the manometer	Refer 202.12.1.102	IEC 80601-2-30
Reproducibility of the BLOOD PRESSURE DETERMINATION	Refer 201.12.1.107	IEC 80601-2-30

Unit Illustration

6

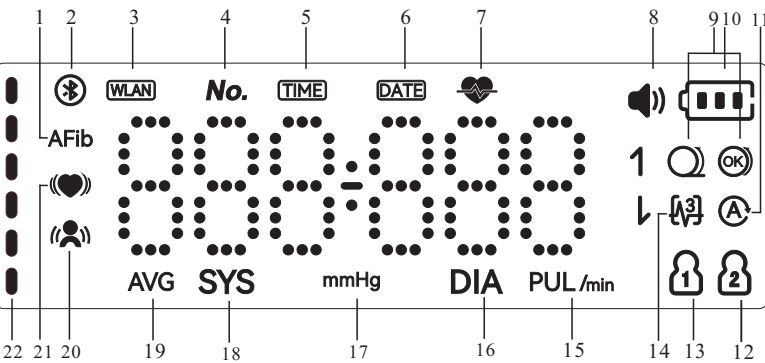
Monitor Unit



Unit Illustration

7

Display

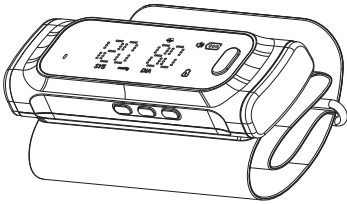


1	Atrial Fibrillation	2	Bluetooth
3	WIFI	4	Memory Number
5	Time display	6	Date display
7	Heartbeat Symbol	8	Voice
9	Cuff Loose Indicator	10	Battery Level
11	Night Measurement	12	Group2
13	Group1	14	Three Measurements
15	Pulse Rate	16	Diastolic Blood Pressure
17	mmHg	18	Systolic Blood Pressure
19	Last 3 Tests Average	20	Arm Shake Indicator
21	Irregular Heartbeat Indicator		
22	WHO Blood Pressure Classification Indicator		

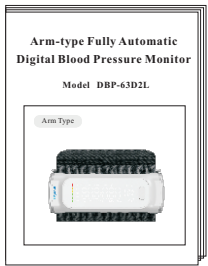
Unit Illustration

8

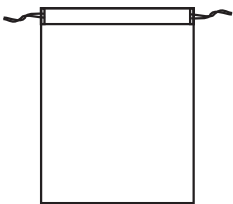
Contents



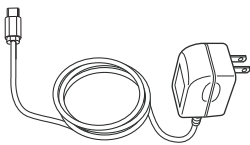
1. Monitor Unit



2. Owner's Manual



3. Storage Bag



4. 2MOPPMedical AC Adapter (DC5.0 V, 1000mA)

Important Testing Guidelines

9

1. Avoid eating, exercising, and bathing for 30 minutes prior to testing.
2. Sit in a calm environment for at least 5 minutes prior to testing.
3. Do not stand while testing. Sit in a relaxed position while keeping your arm level with your heart.
4. Avoid speaking or moving body parts while testing.
5. While testing, avoid strong electromagnetic interference such as microwave ovens and cell phones.
6. Wait 3 minutes or longer before re-testing.
7. Try to measure your blood pressure at the same time each day for consistency.
8. Test comparisons should only be made when monitor is used on the same arm, in the same position, and at the same time of day.
9. This blood pressure monitor is not recommended for people with severe arrhythmia.
10. Do not use this blood pressure monitor if the device is damaged.

Any blood pressure recording can be affected by the following factors:

1. The position of the subject, his or her physiologic condition;
2. The performance and accuracy of the device;
3. Cuff size: too small cuff (bladder) will produce a higher blood pressure value than usual, too big cuff (bladder) will produce a lower blood pressure value;
4. Measuring position does not keep level with your heart;
5. Speaking or moving body parts while testing;
6. Not relaxing for about 5 minutes before taking the measurement.

Quick Start

10

1. Install batteries. (See Figure A)
2. Insert cuff air plug into the behind side of monitor unit. (See Figure B)

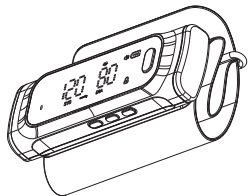


Figure A

3. Remove thick clothing from the arm area.
4. Rest for several minutes prior to testing. Sit down in a quiet place, preferably at a desk or table, with your arm resting on a firm surface and your feet flat on the floor. (See Figure C)

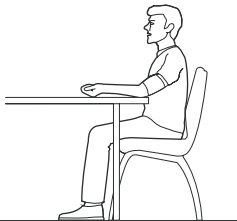


Figure B

5. Apply cuff to your left arm and keep level with your heart. Bottom of cuff should be placed approximately 1-2cm (0.4-0.8") above elbow joint. (See Figures D&E)

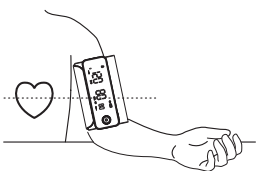


Figure C

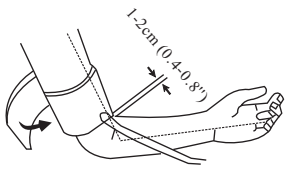


Figure D

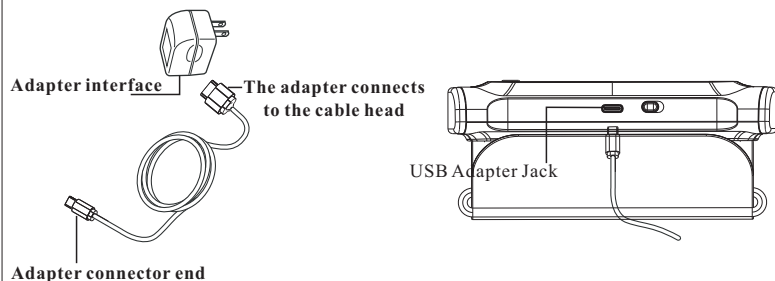
6. Press " ON/OFF " Button to start testing.

Unit Operation

11

Lithium Battery Charging

The device has a built-in lithium battery that must be recharged using a specific power adapter. When low battery indicator icon " " appears on the screen Please connect the power adapter to charge. When charging, the screen will be displayed in a cycle from " " to " ". Insert the adapter connector into the adapter interface, then insert the adapter into the socket, and then connect the adapter to the cable end. Insert the adapter interface on the device and press the on/off button to measure normally. (if this model has been packed) When you plug in the adapter, the screen power display changes, indicating that you are using the adapter for power. When a device is connected to an adapter, the power adapter is part of the entire device.



Note: Power supply is specified as part of ME EQUIPMENT. Do not use other non-standard adapters.

The above adapter parameters are as follows:

Input range: 100V-240V to 50/60Hz, 0.2A

Output range: 5.0V DC 1.0A, 5.0W

The interface at the adapter is USB-A port, and the interface at the device is USB-C port.

Unit Operation

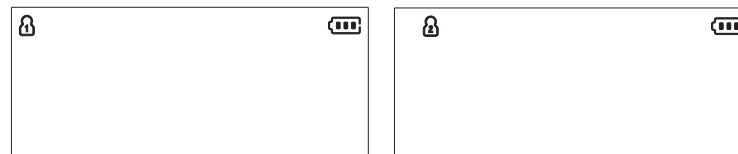
12

System Settings

With power off, Press "SET" button to activate System Settings. The Memory Group icon flashes.

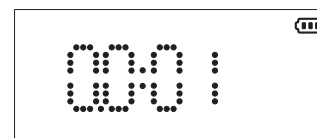
1. Select Memory Group

While in the System Setting mode, you may accumulate test results into 2 different groups. This allows multiple users to save individual test results (up to 150 memories per group.) Press "MEM" button to choose a group setting. Test results will automatically store in each selected group.



2. Time/Date setting

Press "SET" button again to set the Time/Date mode. Set the year first by adjusting the "MEM" button. Press "SET" button again to confirm current month. Continue setting the day, hour and minute in the same way. Every time the "SET" button is pressed, it will lock in your selection and continue in succession (month, day, hour, minute, 12/24 hours)

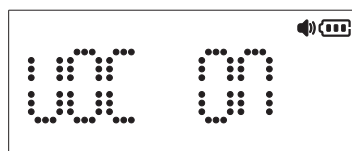
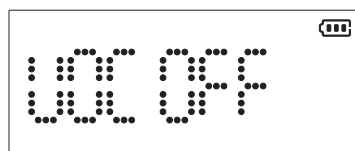


Unit Operation

13

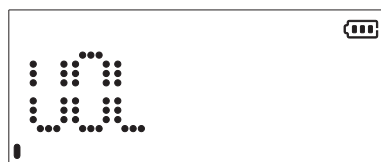
3. Voice Setting

Press "ON/OFF" button to enter voice setting mode. Set voice format ON or OFF by pressing the "MEM" button.



4. Volume Setting

Press "SET" button to enter volume setting mode. Set the voice volume by adjusting the "MEM" button. There are six volume levels.



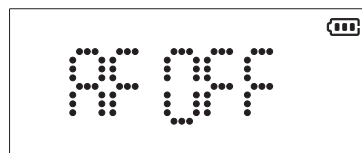
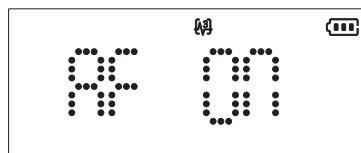
5. Saved Settings

While in any setting mode, press "ON/OFF" button to turn the unit off. All information will be saved.

Note: If unit is left on and not in use for 3 minutes, it will automatically save all information and shut off.

Triple measurement function

Short press the " " key to enter the three measurement setting. In this mode, short press the " " key again to turn on or off the three measurement function.

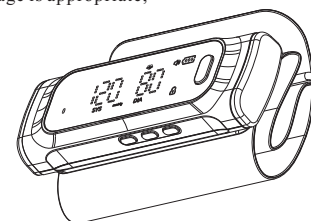


Unit Operation

14

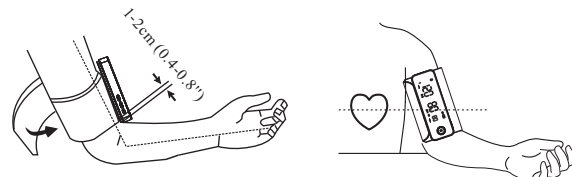
Applying the Arm Cuff

1. Pick up the sphygmomanometer, open the arm band, put the sphygmomanometer and arm band on the arm, to firm air leakage is appropriate;



2. With sticky nylon section facing outward, insert end of cuff underneath metal ring of cuff.

3. Fasten cuff about 1-2cm (0.4-0.8") above the elbow joint. For best results apply cuff to bare arm and keep level with heart while testing.

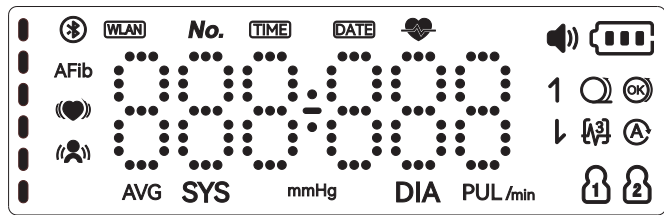


Note: Do not insert air plug into opening located on right side of monitor unit. This opening is designed for an optional power supply only.

Testing

1. Power On

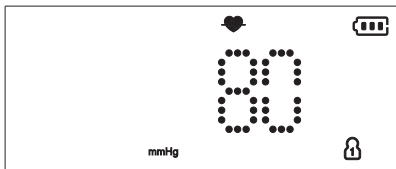
Press and hold " ON/OFF " button to turn the unit on. The LED screen will appear for one second as unit performs a quick diagnosis. A voice tone will indicate when unit is ready for testing.



Note: Unit will not function if residual air from previous testing is present in cuff.
The LED will flash " " until pressure is stabilized.

2. Testing

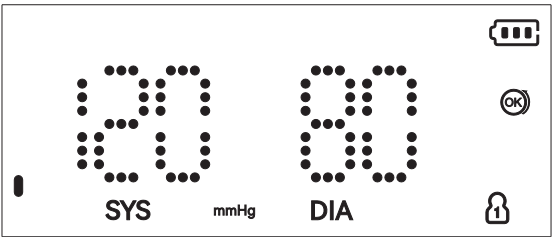
After cuff inflation, air will slowly rise as indicated by the corresponding cuff pressure value. A flashing " " will appear simultaneously on screen signaling heart beat detection.



Note: Keep relaxed during testing. Avoid speaking or moving body parts.

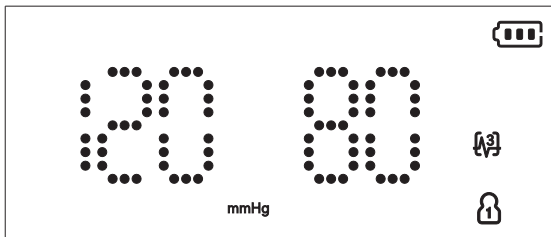
3. Result Display

The screen will display measurements for systolic and diastolic blood pressure with voice broadcast. An indicator representing the current measurement will appear next to the corresponding WHO Classification.



4. Continuous measurement mode is enabled(MAM Function)

Start the continuous measurement mode. Before the end of the third measurement, the corresponding data will be displayed at the end of each measurement, and a 30 seconds countdown will be performed on the screen. At the end of the third measurement, if there is a significant deviation in one of the three data sets, the next set of tests will be performed and the third measurement results will be displayed. Before that, if the difference between the three sets of data was too large, the error was reported directly, while the screen ran 30 seconds countdown to the next measurement. If three consecutive measurements are wrong, the sphygmomanometer will automatically shut down. If three sets of normal data are measured under correct operation, the third correct data is not displayed on the screen, and the average value of the three times is displayed directly. Indicators representing the current measure will appear next to the corresponding WHO classification.



Note: Refer to Page 23~24 for detail WHO Blood Pressure Classification Information.

Irregular Heartbeat Indicator

If the monitor detects an irregular heart rhythm two or more times during the measuring process, the Irregular Heartbeat Symbol " " appears on screen along with measurement results. Irregular heartbeat rhythm is defined as rhythm that is either 25% slower or faster than the average rhythm detected while measuring systolic blood pressure and diastolic blood pressure. Consult your physician if the Irregular Heartbeat Symbol " " frequently appears with your test results.

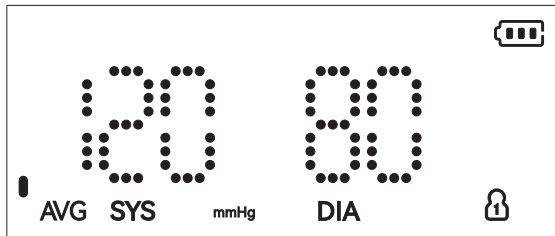
Power Off

The " ON/OFF " button can be pressed to turn off the unit in any mode. The unit can turn off the power itself about 3 minutes no operation in any mode.

Safety Precaution: If pressure in arm cuff becomes too extreme while testing, press the " ON/OFF " button to turn power off. The cuff pressure will rapidly dissipate once the unit is off.

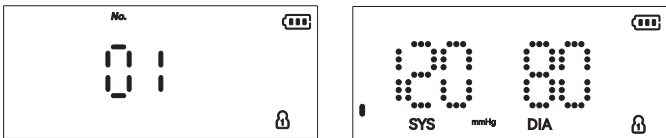
Last 3 Tests Average

With power off, press the "MEM" button to activate screen display. After the unit performs a self-diagnosis ,the screen will display the average test results from the last 3 readings of the last group used. The "AVG" symbol will appear along with the corresponding WHO Blood Pressure Indicator. The Memory Check mode can be accessed by pressing "MEM" button. To check the average results from other groups, select the desired group first prior to activating "SET" button in the off position.(See "Select Memory Group" on Page 12)



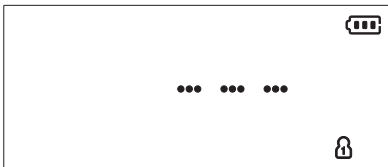
Memory Check

You may check past test results by using the "MEM" button. The most recent test result and oldest test result in memory can be viewed by pressing and holding the "MEM" button. Upon activating test results, you can press the "MEM" button to scroll through all test results stored in memory.



Memory Deletion

Memory for a selected group may be deleted while in Memory Check mode. Press and hold the " SET " button for approximately 3 seconds to delete all memory records from the selected groupwith voice broadcast "Memory Clear" and then transfer into testing mode. Press the " ON/OFF " button to turn the unit off.



Note: Memory cannot be recovered once it has been deleted.

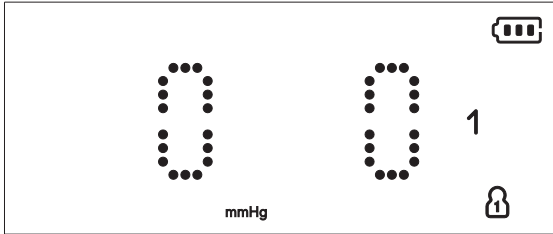
Low Battery Indicator

The unit will broadcast "Low Battery" when battery life is depleting and unable to inflate cuff for testing. The " " appears simultaneously for approximately 5 seconds prior to shutting off. Replace batteries at this time. No memory loss will occur throughout this process.



Static Pressure Measurement

In the power down state, press and hold the " ON/OFF " button, and then install the batteries. Until the LED screen is full, release the " ON/OFF " button. When the LED screen displays the double zero, the blood pressure meter is in static state. Software version is displayed: 10 is a software version in the figure.



Note: Only Service personnel permitted to access to this mode, the mode unavailable in normal use.

Arm Shake Indicator

If there is arm movement during the measurement, " (person with shake icon) " may be shown. Indicates that this may lead to abnormal measurement results, and the LED screen will display " (person with shake icon) " after the measurement is finished.

Cuff loose Indicator

When starting the measurement, " (OK icon) " will be displayed when the cuff is properly wound. When the cuff is too loose, " (cuff loose icon) " will be displayed. At this time, please wear the cuff correctly and start measuring again.

Bluetooth requirements

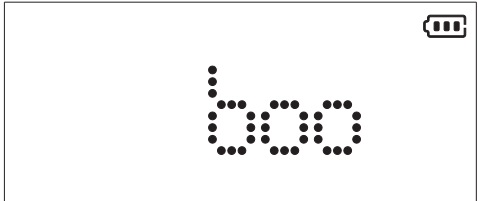
- The monitor requires a device with:
- . 2.4G WIFI
 - . Bluetooth 4.0 or later
 - . Android 5.0 or later
 - . IOS 9.0 or later
- And works with:
- . iphone , iPod, iPad
 - . Android Phones and Tablets

WIFI Distribution Network

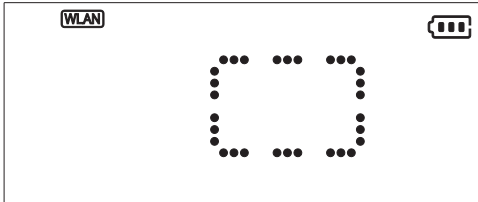
- Using for the first time
1. Download the free "JoyTech" App: On your mobile phone or tablet go to www.sejoy.com.
 2. Open the App on your phone or tablet. If requested, you should enable Bluetooth on your device. You can enable Bluetooth And WIFI under the Settings menu on your smart phone or tablet.
 3. Create a new user login, or login with your existing user name and password.
 4. Selection device "Blood pressure monitor". At this point, you will be prompted to enter the WIFI password. Once entered, the device will automatically connect to WiFi. When the connection is successful, it indicates that the device has been connected to the router.

-Pairing your monitor with a Smart Device

1. Open the "blood pressure monitor" and follow the pairing instructions shown on your smart phone.
- The date and time on your monitor will automatically be set when you pair it with your smart device.



2. Confirm that your monitor is connected successfully.
- When your monitor is connected successfully to your smart phone, it will be display like below.



Troubleshooting

Abnormal phenomenon	Cause analysis	Processing method
Abnormal sphygmomanometer	The armband is tied too tight or too loose, Or the arm strap is tied incorrectly;	Roll the armband correctly
	Move the arm during measurement or Electronic sphygmomanometer	Stay quiet, keep your arm steady, and do not move the monitor
	Speaking, nervous or emotional during measurement	Instead of talking, take deep breaths to calm your mood and relax your body
	Incorrect measurement posture	Adjust posture, see "Blood pressure gauge Wearing"
	There is interference in charging process or improper operation in measuring process	See operation Instructions.
	If the operator is in a strong electromagnetic interference environment, resulting in the loss or reduction of function/performance	It is recommended that the operator, away from the environment, choose an environment with asingle electromagnetic field, and then re-measure after the product is recovered.

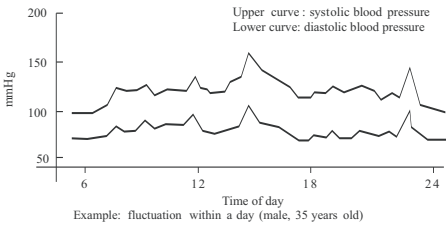
The following table shows the error signs that may occur during measurement, possible causes and handling methods. Please measure again using the correct method

Error display	The cause of the problem	The solution
Er1	Can't detect high and low pressure	Please fasten the cuff before measuring
Er2	Cuff too loose or loose	Please fasten the cuff before measuring
Er3	Severe arm or body movement leads to abnormal reporting errors	Hold the arm or body still and measure again
Er4	The pressure exceeds 300mmHg	Please fasten the cuff before measuring
Er5	The pressure exceeds 15mmHg for 3 minutes	Check whether the cuff is knotted or the vent valve is blocked. If the problem persists, contact the manufacturer
Er6	Blood pressure measurements were out of range	Please tighten and measure again. If you cannot solve the problem, please contact the manufacturer
(Battery icon)	Low Battery	Replace the battery or connect the power adapter (if any).

Note: If you cannot solve the abnormal situation by yourself, you can consult the manufacturer or the manufacturer's designated unit by phone. It is forbidden to disassemble and repair without permission. If necessary, professional maintenance personnel can ask the manufacturer for the list of components and circuit schematic diagram.

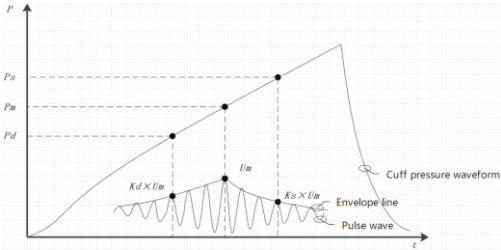
Blood Pressure

Blood pressure is the force of blood pushing against the walls of arteries. It is typically measured in millimeters of mercury (mmHg.) Systolic blood pressure is the maximum force exerted against blood vessel walls each time the heart beats. Diastolic blood pressure is the force exerted on blood vessels when the heart is resting between beats. An individual's blood pressure frequently changes throughout the course of a day. Excitement and tension can cause blood pressure to rise, while drinking alcohol and bathing can lower blood pressure. Certain hormones like adrenaline (which your body releases under stress) can cause blood vessels to constrict, leading to a rise in blood pressure. If these measuring numbers become too high, it means the heart is working harder than it should.



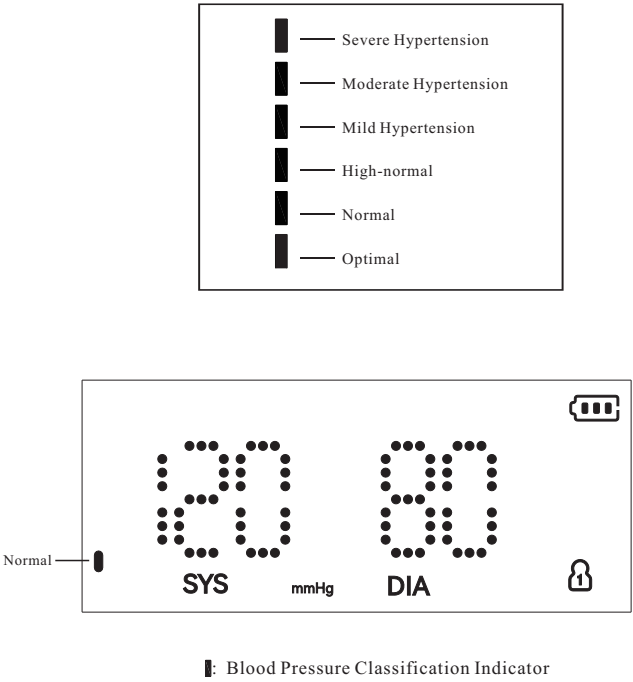
OPERATING PRINCIPLES

Oscillogram method: Also known as pressure oscillation method, this process is to inflate the cuff to block arterial blood flow, and then detect the gas pressure in the cuff during the process of deflating and extract weak pulse waves. The sphygmomanometer is used to measure blood pressure in the process of pressor, so the control algorithm and structure are needed to make the pressure process stable and uniform. The measurement principle is also oscillographic method, which is consistent with the antihypertensive sphygmomanometer. When the measurement results, then open the valve to quickly deflate. The corresponding relationship between the oscillatory wave amplitude and the pressure waveform in the oscillogram method of the booster electronic sphygmomanometer is shown in the figure below.



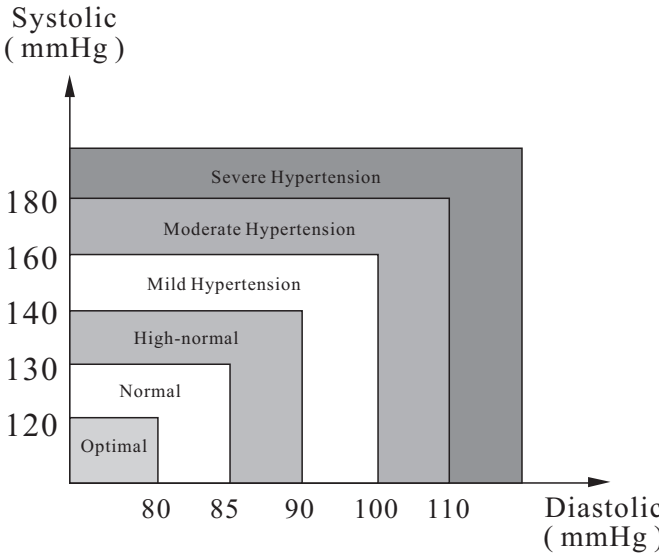
WHO Blood Pressure Classification Indicator

The DBP-63D2L is equipped with a classification indicator based on established guidelines from the World Health Organization. The chart below (color coded on monitor unit) indicates test results.



Health Reminder

Hypertension is a dangerous disease that can affect the quality of life. It can lead to a lot of problems including heart failure, kidney failure, and cerebral hemorrhaging. By maintaining a healthy lifestyle and visiting your physician on a regular basis, hypertension and relative diseases are much easier to control when diagnosed in their early stages.



Note: Do not be alarmed if an abnormal reading occurs. A better indication of an individual's blood pressure occurs after 2-3 readings are taken at the same time each day over an extended period of time. Consult your physician if test results remain abnormal.

- Q: What is the difference between measuring blood pressure at home or at a professional healthcare clinic?
- A: Blood pressure readings taken at home are now seen to give a more accurate account as they better reflect your daily life. Readings can be elevated when taken in a clinical or medical environment. This is known as White Coat Hypertension and may be caused by feeling anxious or nervous.

Note: Abnormal test results may be caused by:

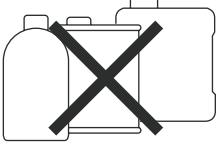
1. Improper cuff placement
Make sure cuff is snug-not too tight or too loose.
Make sure bottom of the cuff is approximately 1-2cm (1/2") above the elbow joint.
2. Improper body position
Make sure to keep your body in an upright position.
3. Feeling anxious or nervous
Take 2-3 deep breaths, wait a few minutes and resume testing.

- Q: What causes different readings?
- A: Blood pressure varies throughout the course of a day. Many factors including diet, stress, cuff placement, etc. may affect an individual's blood pressure.
- Q: Should I apply the cuff to the left or right arm? What is the difference?
- A: Either arm can be used when testing, however, when comparing results, the same arm should be used. Testing on your left arm may provide more accurate results as it is located closer to your heart.
- Q: What is the best time of day for testing?
- A: Morning time or any time you feel relaxed and stress free.

1. Avoid dropping, slamming, or throwing the unit.
2. Avoid extreme temperatures. Do not expose unit directly under sunshine.

3. When cleaning the unit, use a soft fabric and lightly wipe with mild detergent.
Use a damp cloth to remove dirt and excess detergent.

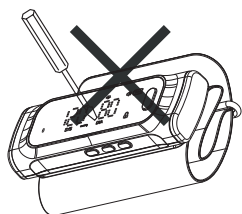
4. Cuff Cleaning: Do not soak cuff in water! Apply a small amount of rubbing alcohol to a soft cloth to clean cuff's surface. Use a damp cloth (water-based) to wipe clean. Allow cuff to dry naturally at room temperature. The cuff must be cleaned and disinfected before use between different users.
5. Do not use petrol, thinners or similar solvents.



Maintenance

27

6. Do not disassemble product.



7. It is recommended the performance should be checked every 2 years.
8. Expected service life: Approximately three years at 10 tests per day.
- 9.No service and maintenance while it is in use and maintenance only be performed by service personnel. Service and maintenance require parts, repair, technical support will be provided.
10. If it is not used for a long time, it is recommended to charge the lithium battery within 3-4 months to ensure that it does not lose power. Users can not replace the lithium battery by themselvesIf it is confirmed that the lithium battery is faulty, please do not repair it by yourself. Please contact the manufacturer or dealer in time.
- 11.If the lithium battery is not charged in time, or the lithium battery is placed for a long time, there may be the situation that the lithium battery is about to run out. In this case, the device cannot be turned on. In this case, the lithium battery should be charged immediately.

The following rules must be observed during use:

1. Prevent lithium batteries from entering water. Do not heat lithium batteries, do not throw lithium batteries into fire.
2. Lithium batteries should not be used for a long time in an environment of more than 60°C.
3. The device can only use lithium batteries specified by the manufacturer.
4. Use the specified AC adapter to charge the device.
5. In order to avoid the normal use of lithium batteries due to self-discharge in the storage process, please charge the lithium batteries every 3-4 months to ensure the normal operation of lithium batteries.

Specifications

28

Product Description	Arm-type Fully Automatic Digital Blood Pressure Monitor	
Model	DBP-63D2L	
Display	LED Digital Display Size:78mm×24. 8mm (3.07" x 0.976")	
Measurement Method	Oscillometric Method	
Measurement Range	Systolic Pressure	60mmHg~260mmHg
	Diastolic Pressure	40mmHg~200mmHg
	Pressure	0mmHg~299mmHg
	Pressure Deviation	±3mmHg
	Pulse	30 ~ 180 Beats/Minute
	Pulse Deviation	±5%
Pressurization	Automatic Pressurization	
Memory	2x150 Memories in Two Groups with Date and Time	
Function	Irregular Heartbeat Detection	
	WHO Classification Indicator	
	Last 3 Tests Average	
	Low Battery Detection	
	Automatic Power-Off	
	Voice	
	2.4G WIFI And Bluetooth(Only for distribution network use)	
Power Source	Lithium battery 3.7 V or DC5.0v 1000mA medical external power supply (DC5.0V, 1000mA)(recommended, not provided)	
Battery Life	Approximately 2 months at 3 tests per day	
Unit Weight	Approx.xxxg (x.xx oz.) (excluding battery)	
Unit Dimensions	Approx.140 x 49 x25.2mm (5.51" x 1.93" x 0.992")(L x W x H)	
Cuff Circumference	Approx.135 (W) x 485(L) mm (Medium cuff: Fits arm circumference 22-42 cm)	

Specifications

29

Operating Environment	Temperature	10℃ ~ 40℃ (50°F~104°F)
	Humidity	15% ~ 93%RH
	Pressure	80kPa~106kPa
Storage Environment	Temperature	-25℃~55℃ (-13°F~131°F)
	Humidity	≤93% RH
Transport Environment	Temperature	-25℃~55℃ (-13°F~131°F)
	Humidity	≤93% RH
Bluetooth	Modulation Type	GFSK
	Version	5.2 BT Signal mode
	Operation frequency	2. 4GHz (2400~2483. 5MHz)
	Operation distance	≤ 5m
	Transmission power	< 20 dBm
	Bandwidth	1.0MHz
	Effective radiated power	-2.8 dBm
Classification	Internal Powered Equipment, Type BF  , Cuff is the Applied Part	
Ingress Protection Rating	IP22, Indoor Use Only	

Specifications are subject to change without notice.

Safety Standard (included but not limited) :

1. IEC 80601-2-30, medical electrical equipment – part 2-30: particular requirements for the basic safety and essential performance of automated noninvasive sphygmomanometers. (Cardiovascular)
2. ISO 81060-2, non-invasive sphygmomanometers – part 2: clinical validation of automated measurement type. (Cardiovascular)
3. AAMI / ANSI ES 60601-1:2005/(R) 2012 and C1:2009/(R) 2012 and, a2:2010/(r) 2012 (consolidated text) medical electrical equipment -- part 1: general requirements for basic safety and essential performance
4. AAMI/ANSI/IEC 60601-1-2, Medical Electrical Equipment -- Part 1-2: General Requirements For Basic Safety And Essential Performance -- Collateral Standard: Electromagnetic Disturbances -- Requirements And Tests (General II (ES/EMC)).
5. IEC 60601-1-11, medical electrical equipment – part 1-11: general requirements for basic safety and essential performance – collateral standard: requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment.

Warranty

30

The Blood Pressure Monitor is guaranteed for 2-year from the date of purchase. If the Blood Pressure Monitor does not function properly due to defective components or poor workmanship, we will repair or replace it freely. The warranty does not cover damages to your Blood Pressue Monitor due to improper handling. Please contact local retailer for details.

Electromagnetic Compatibility Information 31

The device satisfies the EMC requirements of the international standard IEC 60601-1-2. The requirements are satisfied under the conditions described in the table below. The device is an electrical medical product and is subject to special precautionary measures with regard to EMC which must be published in the instructions for use. Portable and mobile HF communications equipment can affect the device. Use of the unit in conjunction with non-approved accessories can affect the device negatively and alter the electromagnetic compatibility. The device should not be used directly adjacent to or between other electrical equipment.

Environments of Intended use : Home healthcare environment and Professional healthcare facility environment.

Table 1

Guidance and declaration of manufacturer-electromagnetic emissions	
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.	
Emissions test	Compliance
Radiated emission CISPR 11	Group 1, class B.
Conducted emission CISPR 11	Group 1, class B.
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Electromagnetic Compatibility Information 32

Table 2

Guidance and declaration of manufacturer-electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
IMMUNITY test	IEC 60601 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
Electrostatic transient/burst IEC 61000-4-4	± 2 kV, 100kHz, for AC power port	± 2 kV, 100kHz, for AC power port
Surge IEC 61000-4-5	±0.5kV, ±1kV (differential mode)	±0.5kV, ±1kV (differential mode)
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle	0 % UT; 0,5 cycle At 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle and 70 % UT; 25/30 cycles Single phase: at 0° 0 % UT; 250/300 cycle
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz

Electromagnetic Compatibility Information 33

Table 2(continued)

Guidance and declaration of manufacturer-electromagnetic immunity		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
IMMUNITY test	IEC 60601 test level	Compliance level
Radiated RF EM fields IEC 61000-4-3	3V/m and 10 V/m 80MHz-2.7 Ghz 80%AM at 1kHz	3V/m and 10 V/m 80MHz-2.7 Ghz 80%AM at 1kHz
Proximity fields from RF wireless communications equipment	IEC 61000-4-3	See table 3
Conducted disturbances Induced by RF fields IEC 61000-4-6	3 V in 0.15 MHz- 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1kHz	3 V in 0.15 MHz- 80 MHz 6 V in ISM and amateur radio bands between 0.15 MHz and 80 MHz 80 % AM at 1kHz
Proximity magnetic fields IEC 61000-4-39	See table 4	See table 4

Electromagnetic Compatibility Information 34

Table 3

Guidance and declaration of manufacturer-electromagnetic immunity						
Nowadays, many RF wireless equipments have being used in various healthcare locations where medical equipment and/or systems are used. When they are used in close proximity to medical equipment and/or systems, the medical equipment and/or systems' basic safety and essential performance may be affected. Arm-type Fully Automatic Digital Blood Pressure Monitor has been tested with the immunity test level in the below table and meet the related requirements of IEC 60601-1-2:2014. The customer and/or user should help keep a minimum distance between RF wireless communications equipment and this medical equipment and/or systems as recommended below.						
Test frequency (MHz)	Band (MHz)	Service	Modulation	Maximum power (W)	Distance (m)	Immunity test level (V/m)
385	380-390	TETRA 400	Pulse modulation 18Hz	1.8	0.3	27
450	430-470	GMR5 460 FRS 460	PM ± 5 kHz deviation 1 kHz sine	2	0.3	28
710	704-787	LTE Band 13, 17	Pulse modulation 217Hz	0.2	0.3	9
745						
780						
810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18Hz	2	0.3	28
870						
930						
1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4, 25; UMTS	Pulse modulation 217Hz	2	0.3	28
1845						
1970						
2450	2400-2570	Bluetooth,WLAN, 802.11 b/g/n,RFID 2450,LTE Band 7	Pulse modulation 217Hz	2	0.3	28
5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217Hz	0.2	0.3	9
5500						
5785						

Table 4

Test specifications for ENCLOSURE PORT IMMUNITY to proximity magnetic fields		
Test frequency	Modulation	IMMUNITY TEST LEVEL(A/m)
30 kHz a)	CW	8
134,2kHz	Pulse Modulation _{u)} 2,1kHz	65 _{c)}
13,56MHz	Pulse Modulation _{u)} 50kHz	7,5 _{c)}
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME and professional healthcare ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) r.m.s.,before modulation is applied.		

Important Instructions Before Use

1. 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.

2.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 Arm-type Fully Automatic Digital Blood Pressure Monitor, including cables specified by the MANUFACTURER. Otherwise, degradation of the performance of this equipment could result.

3.The software identifier refer to the software evaluation report.

4.verify manometer pressure accuracy:

In the power down state, press and hold the " ON/OFF" button, and theninstall the batteries. Until the LED screen is full, release the " ON/OFF" button. When the LED screen displays the double zero, the bloodpressure meter is in static state. At this point, 500ml gas capacity, calibrated standard pressure gauge and manual pressure device can be connected to the sphygmomanometer through the sleeve interface of the sphygmomanometer, and manual pressure can be applied to the effective display range of the sphygmomanometer, and then the difference between the reading of the sphygmomanometer and that of the standard pressure gauge can be compared.This mode can be used to verify manometer pressure accuracy.

5.Contraindications:

Product is not intended for infants or individuals who cannot express their intentions.

6.Intended Use

The digital blood pressure monitor are reusable for clinical and home use and are non-invasive blood pressure measurement systems designed to measure the systolic and diastolic blood pressure and pulse rate of adolescents and adults individual by using a non-invasive technique, which is a well-known technique in the market called the “oscillometric method”. it can measure the systolic blood pressure, diastolic blood pressure and pulse rated on up-arm,and the device is reusable for clinical or home use.

7.The patient is the operator:
the PATIENT is an intended OPERATOR.
the PATIENT Do not carry out other maintenance operations except to replace the battery.

8.WARNING:

Do not modify this equipment without authorization of the manufacturer.

9. ESSENTIAL PERFORMANCE Maintenance advice:

Pressure calibration will be carried out when this product leaves the factory. Patients can use the method described in the section "Verify Manometer Pressure Accuracy" to verify the accuracy. If the accuracy deviation is large, please contact the manufacturer to recalibration.

10.Mechanical strength and resistance to heatThe resistance to heat will be retained by device during the EXPECTED SERVICE LIFE of the ME EQUIPMENT.

11.Do not place the blood pressure monitor and cuff at will. It will cause asphyxiation if the child swallows or twine around his neck.

12.The cuff and the case of the blood pressure monitor have been tested for biocompatibility and do not contain allergenic or harmful materials.Please stop using it if allergy occurs during use.

13. Warning:

Non-professionals do not modify the equipment, otherwise it will make the equipment measurement is not accurate.

14. Warning:

Do not expose the equipment for a long time, otherwise it will reduce the performance of the equipment.

15. Warning:

This device is not used for children and pets

16. Clean:

The equipment can be cleaned by lay operator according to the cleaning procedures in the instructions

17. Warning:

Do not use a damaged cuff for blood pressure measurement.

18. Warning:

When measuring with the cuff, if the tester feels seriously uncomfortable, press the button of the blood pressure monitor to deflate the cuff, or remove the cuff directly from the arm.

19. Warning:

If an unexpected reading occurs, the operator can take several more measurements and consult a doctor.

20. Warning:

This equipment is used outside the specified environment, may damage the equipment, and may be inaccurate measurement.

21.ME equipment not intended for use in conjunction with flammable agents “ME equipment not intended for use in oxygen rich environment”.

22. Warning:

The storage device can be used normally two hours after the storage device changes from the highest temperature or lowest temperature to normal temperature.

23. Warning:

Isnstructions provided indicating not to position ME EQUIPMENT to make it difficult to operate the disconnection device.

24. Warning:

To avoid any possibility of accidental suffocation, keep children away from the device and do not wrap hose or cable around the neck.

25. Warning:

Do not use other non-standard adapters. Use UE05LV4-050100SPA or UE05LU4-050100SPA adapters.

Correct Disposal of This Product
(Waste Electrical & Electronic Equipment)

This marking shown on the product indicates that it should not be disposed with other household waste at the end of its life. To prevent potential harm to the environment or to human health, please separate this product from other types of wastes and recycle it responsibly. When disposing this type of product, contact the retailer where product was purchased or contact your local government office for details regarding how this item can be disposed in an environmentally safe recycling center. Business users should contact their supplier and check the terms and conditions of the purchasing agreement. This product should not be mixed with other commercial wastes for disposal. This product is free of hazardous materials.

