size:320*297mm

Owner's Manual

Wrist-type Fully Automatic

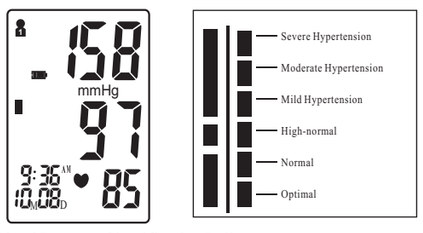
Digital Blood Pressure Monitor

DBP-2141

Document No.: JDBP-C004-003 Version: Z

WHO Blood Pressure Classification Indicator

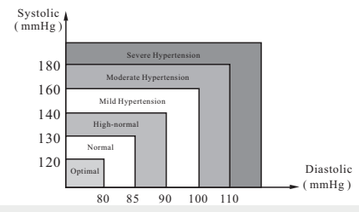
The DBP-2141 is equipped with a classification indicator based on established guidelines from the World Health Organization. The chart below (color coded on monitor unit) indicates test results.



▮: Blood Pressure Classification Indicator

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.

Matters Needing Attention

Thank you for purchasing the DBP-2141 Blood Pressure Monitor.The unit has been constructed using reliable circuitry and durable materials. Used properly, this unit will provide yeas of satisfactory use.

The digital blood pressure monitor is intended for measurement the systolic and diastolic blood pressureand pulse rate from wrist of adults and adolescents over the age of 12 by using a non-invasive technique. The device can be reusable for clinical use and home use.

Please read this manual thoroughly before using the unit. Please retain this manual forfuture reference. For specific information about your blood pressure, please consult your doctor.The patient is an intended operator.

To avoid risk and damage follow all warning precautions. Operate unit only as intended.Read all instructions prior to use.

WARNING SIGNS AND SYMBOLS USED	
⚠	Caution
❗	Mandatory
⃠	Prohibited
	Type BF Equipment
	Instructions For Use MUST be Consulted
SN	Serial Number

	Discard the used product to the recycling Collection point according to local regulations
CE 0123	The product conforms to the requirements of the Regulation (EU) 2017/745 MDR on medical devices
	Manufacturer
EC REP	Authorised Representative in the European Community
	Keep Dry
	Keep off Sunlight
	Manufacturing Date
MD	Medical Device

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 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.
22. Do not mix new and old batteries simultaneously
23. Replace batteries when Low Battery Indicator "▭" appears on screen. Replace both batteries at the same time.
24. Do not mix battery types. Long-life alkaline batteries are recommended.
25. Remove batteries from device when not in operation for more than 3 months.
26. Do not insert the batteries with their polarities incorrectly aligned.
27. Dispose batteries properly; observe local laws and regulations.
28. Advising operator that Instruction manual/ Booklet must be consulted .
29. Do not use the device during transport vehicles for influencing measurement accuracy,such as patient transport in an ambulance or helicopter.
30. Contains small parts that may cause a chocking hazard if swallowed by infants.
31. Please align the polarities of each battery with the +ve and -ve signs imprinted on the battery housing when you replace the batteries .
32. The time required for the device to warm from the minimum storage temperature(-25°C)between use until the device is ready for use at Ambient Temperature 20°C: about 2 hours.
33. The time required for the device to cool from the maximum storage temperature (70°C) between use until the device is ready for use at ambient temperature (20 °C) : about 2 hours.

Contraindications

Not suitable for severe arrhythmia;
Not applicable to children aged 12 and under (including newborns and infants).

Important Testing Guidelines

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.

Scope Of Application

This product is intended for adults to measure and display blood pressure and pulse rate at home or in healthcare Settings.

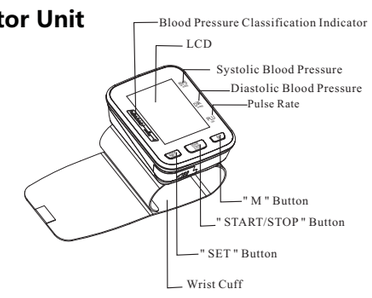
Product Structure And Composition

Product composition: Arm type sphygmomanometer is composed of host, battery and arm band.

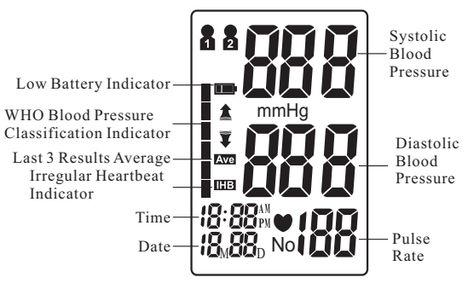
Package Contents

- Monitor Unit
- Owner's Manual
- Plastic Storage Case
- 2 AAA batteries

Monitor Unit



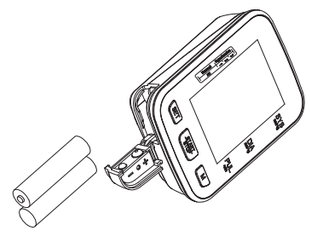
Display



Power Operation

Battery Installation

Slide battery cover off as indicated by arrow.Install 2 new AAA alkaline batteries according to polarity.Close battery cover.



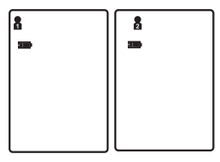
Note:
1) Replace batteries when Low Battery Indicator " ▭ " appears on screen.
2) Batteries should be removed from device when not in operation for an extended period of time.

System Settings

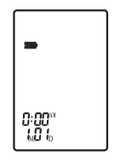
System Settings

With power off, press " SET " button to actuate system setting, the Memory Group icon flashes.

1. Select memory Group
   Wile 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 " M " button to choose a group setting: The test results will automatically store in each selected group.



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



Quick Start

1. Install batteries. (See Figure A)
2. Remove clothing from the wrist area. (See Figure B)

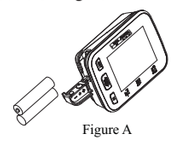


Figure A

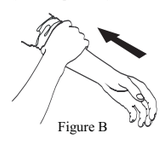


Figure B

3. Remove thick clothing from the arm area.
4. Sit in a comfortable position and place wrist level with heart. (See Figure D)

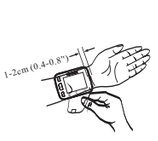


Figure C


Figure D

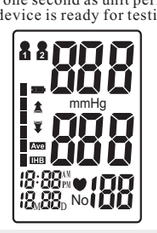
5. Press " START/STOP " button to start testing. (See Figure E)


Figure E

Unit Operation

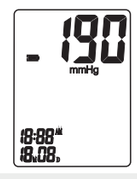
Testing

1. Power On
   Press and hold "START/STOP" button until a beep sounds.The LCD screen will appear for one second as unit performs a quick diagnosis. A long tone indicates device is ready for testing.



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

2. Pressurization
   The unit will automatically inflate to the proper pressure value and stop inflating. During this time, please keep quiet.

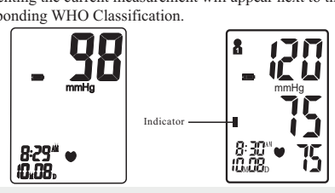


Note: Pressurization will gradually subside and ultimately stop when cuff is not properly applied to the arm.If this occurs, press "START/ STOP"button to turn the unit off.

3. Testing
   After cuff inflation, air will slowly subside 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.

4. Result Display
   Four short beeps sound when testing is complete. The screen will display measurements for systolic and diastolic blood pressure. An indicator representing the current measurement will appear next to the corresponding WHO Classification.



Note: Refer to detaile d 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 " IHB "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 " IHB " frequently appears with your test results.

Note: Be sure the appropriate Memory Group selection is made prior to testing.If the number of tests surpasses the allotted 60 memories per group, the most recent tests will appear first, thus eliminating the oldest readings.

Power Off

The "START/ STOP" 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.

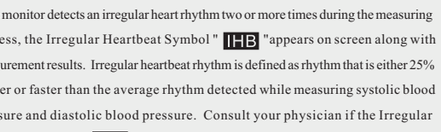
⚠ Safety Precaution: If pressure in arm cuff becomes too extreme while testing, press the "START/ STOP" button to turn power off. The cuff pressure will rapidly dissipate once the unit is off.

Last 3 Tests Average and Memory Check

With power off, press the " M " button to activatescreen 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, you must firstly select the desired group and then turn monitor off. (See "Select Memory Group")

While in last 3 tests average mode, press "MEM"button again, you may check the last test results. 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.



If the memory is less than 3 groups, press the "MODE" button to memory check mode.

Note: Previous test will only be displayed from the most recently used memory group.To check previous test results in other memory groups, you must first select the desired group and then turn monitor off. (See "Select Memory Group")

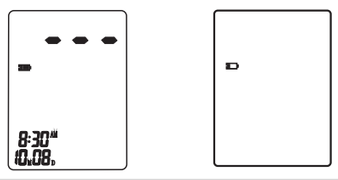
Memory Deletion

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 group. Press the " START/STOP " button to turn the unit off.

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

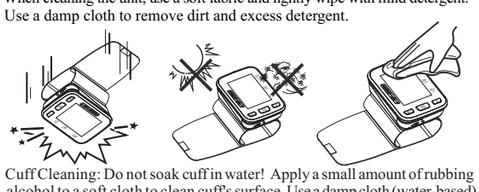
Low Battery Indicator

Four short warning beeps sound 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.

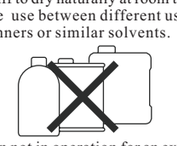


Maintenance

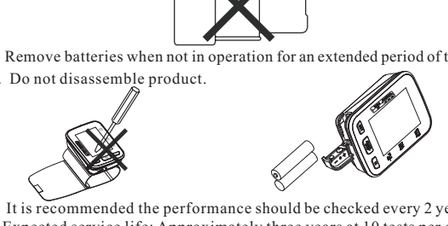
1. Avoid dropping, slamming, or throwing the unit.
2. Avoid extreme temperatures. Do not expose unit directly under sunshine.
3. When cleaning the unit, use a soft fabric and lightly wipe with mild detergent. Use a damp cloth to remove dirt and excess detergent.



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 before use between different users.
5. Do not use petrol, thinners or similar solvents.



6. Remove batteries when not in operation for an extended period of time.
7. Do not disassemble product.



8. It is recommended the performance should be checked every 2 years.
9. Expected service life: Approximately three years at 10 tests per day.
10. No service and maintenance while it is in use and maintenance only be performed by servicepersonnel. Service and maintenance require parts, repair, technical support will be provided.

Troubleshooting

Problem	Possible Cause	Solution
Blood pressure results are not within typical range	Cuff is too tight or not properly positioned on the arm	Firmly reposition cuff approximately 1-2cm (1/2") above the elbow joint (See Page 11)
	Inaccurate test results due to body movement or monitor movement	Sit in a relaxed position with arm placed near heart.Avoid speaking or moving body parts while testing. Make sure the monitor unit is placed in a stationary position throughout the testing period.(See Page 8)
" Err "displayed	Cuff fails to inflate properly	Make sure hose is properly fastened to cuff and monitor unit
	Improper operation	Read user manual carefully and re-test properly.
	Pressurization is over cuff rated pressure 300mmHg	Read user manual carefully and re-test properly.
	Values of blood pressure outside the rated range for blood pressure	Please re-test properly.

Specifications

Model	DBP-2141	
Display	LCD Display	
Measurement Range	Systolic Pressure	60mmHg～260mmHg
	Diastolic Pressure	30mmHg～200mmHg
	Pressure	0mmHg～300mmHg
	Pressure error range	±3mmHg
	Pulse	30～180 Beats/Minute
	Pulse error range	±5%
Pressurization	Automatic Pressurization	
Memory	2x150 Memories with Date and Time	
Function	Irregular Heartbeat Detection	
	WHO Classification Indicator	
	Last 3 Results Average	
	Low Battery Detection	
	Automatic Power-Off	

Power Source	2 Alkaline Batteries Size AAA	
Battery Life	Approximately 2 months at 3 tests per day	
Unit Weight	Approx.114g (4.02 oz.) (excluding battery)	
Unit Dimensions	Approx.84 x 64 x 29mm (3.31"x2.52"x1.14") (LxWxH)	
Cuff Circumference	Fits wrist circumference 13.5-21.5 cm(5.3"-8.5")	
Operating Environment	Temperature	10℃～40℃ (50℉~104℉)
	Humidity	15%～93% RH
	Pressure	700hPa~1060hPa
Storage Environment	Temperature:	-25℃~70℃ (-13℉~158℉)
	Humidity	≤93% RH
	Pressure	700hPa~1060hPa
Classification	Internal Powered Equipment,Type BF ,	
Ingress Protection Rating	IP22	

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.

Electromagnetic Compatibility Information

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	N/A
Harmonic emissions IEC 61000-3-2	N/A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	N/A

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**
Radiated RF EM fields IEC 61000-4-3	3V/m or 10 V/m 80MHz-2.7 Ghz 80%AM at 1kHz (See table 3)	3V/m or 10 V/m 80MHz-2.7 Ghz 80%AM at 1kHz (See table 3)
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m; 50Hz or 60Hz	30 A/m; 50Hz or 60Hz
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
Proximity magnetic field IEC 61000-4-39	See Table 5	See Table 5

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	GMRS 460 FRS 460	FM ± 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 frquency	Modulation	IMMUNITY TEST LEVEL(A/m)
30 kHz a)	CW	8
134,2kHz	Pulse Modulation b) 2.1kHz	65 c)
13,56MHz	Pulse Modulation b) 50kHz	7.5 c)
a) This test is applicable only to ME EQUIPMENT and ME SYSTEMS intended for use in the HOME HEALTHCARE ENVIRONMENT. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) r.m.s.,before modulation is applied.		

Warranty Commitment

The Blood Pressure Monitor is guaranteed for 2-year from the date of purchase. If theBlood 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 Pressure Monitor due to improper handling. Please contact local retailer for details.

Contact Information
JOYTECH Healthcare Co.,Ltd.
No.365, Wuzhou Road, Yuhang Economic Development Zone, Hangzhou City,311100 Zhejiang, China
Please contact us on:
Email: info@sejoy.com
Telephone: +86-571-81957767
Fax: +86-571-81957750

Additional Notes

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 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 , and the file code is **JYRJ230321001.**
4. **verify manometer pressure accuracy:**
In the power down state, press and hold the " START/STOP" button, and then install the batteries. Until the LCD screen is full, release the "START/STOP" button. When the LCD 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. Indications for use:The digital blood pressure monitor is used to measure blood pressure and pulse rate from upper-arm.
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. Warning: The Operator should not use the system and should inform the customer service, if the ESSENTIAL PERFORMANCE is lost or degraded due to EM DISTURBANCES.
22. Warning: Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.
23. Warning: Failure to use this equipment in the specified type of shielded location could result in degradation of the performance of this equipment, interference with other equipment or interference with radio services
24. ME equipment not intended for use in conjunction with flammable agents "ME equipment not intended for use in oxygen rich environment"