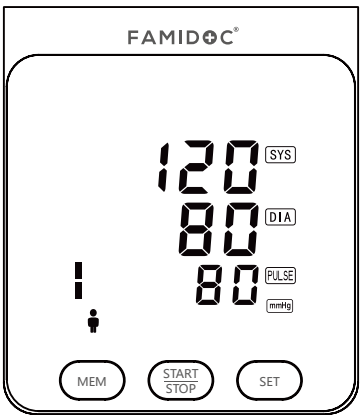
Upper Arm Blood Pressure Monitor

Model： FDBP-A4



USER MANUAL

Subject to our actual product

- Thanks for using our product.
- Take care of this instruction manual.
- Please read this manual carefully before using.

Precaution:
Please read the instruction manual carefully before use it. If you have any questions, please consult the salesperson in the purchasing center or ask your doctor.

CONTENT

1. Warnings and precautions

1.1 Warning

- This product is not suitable for newborns.
- When the measurement is complete, consult your doctor if you have any doubts about the measurement results.Do not self-diagnosis and treatment according to measurement results.
- When common arrhythmia (such as atria premature beats, premature ventricular and atrial fibrillation) occurs, it will affect the measurement accuracy of blood pressure. If it is only sporadic, please take a rest for two hours before measuring. If it is a frequent nature, please go to the hospital for confirmation and treatment immediately.
- If the airbag is inflated for a long time, immediately press the [START/STOP] button to stop the measurement. Continued inflation presses the hand arm, which can cause limb numbness.
- Do not allow children to use the instrument without authorization: Some small parts may cause ingestion.
- It is forbidden to measure blood pressure on the side where the breast is removed.
- Do not allow children to use instruments without permission:Small parts can cause the risk of ingestion.Hose may cause choking hazar.

1.2 Precautions

- Avoid high temperature, humidity, dust and direct sunlight.
- Avoid damage to the arm band and rubber tube due to folding
- Do not disassemble this unit yourself! Otherwise it will cause the manufacturer's school pressure calibration to fail!
- Avoid falling or violently vibrating the body.
- The normal measurement period is about 1 minute. If the measurement is not stopped for a long time, please press the "START/STOP" button to stop the measurement. Avoid numbness of the limbs due to prolonged compression of the arm.
- Original or medically compliant power adapters (eg iec 60601-1 certified) must be used, and non-original accessories may present

unpredictable risks.

- For better reading of the display, please note the following visible conditions:
  - Ambient brightness: 100lx~1500lx
  - Line of sight: less than 30cm
  - Viewing angle: normal display ± 30 °
- Extreme temperature, humidity, and altitude conditions can affect the performance of the measurement, and the sphygmomanometer may not meet the stated performance specifications.
- Do not put the cuff on the wound, which will cause further damage.
- Do not measure blood pressure if there is intravascular access or treatment, or arteriovenous (A-V) shunt.
- This equipment shall not be shared with high-frequency surgical equipment.

1.3 Purpose/intended use of device

Arm Blood Pressure Monitor is intended to measure the blood pressure and pulse rate of adults and children at least 12 years of age, at household or medical center. with the cuff around the left upper arm according to the instruction in the user's guide manual.

The patient is an intended operator

Intended operator should receive at least 8 years of education so that can read and understand the user manual.

2. Instruction

2.1 Product Features

The FDBP-A4 is an Upper Arm Blood Pressure Monitor that simultaneously measure systolic, diastolic blood pressure and pulse rate through the principle of pressure oscillation.Not only its accuracy reaches the medical grade, but also suitable for home health care. In addition, the humanized design provides users with the greatest convenience.

2.2 Self -Measurement

- Please keep in mind :self-measurement is equal to self-control, not diagnosis or treatment. If you have abnormal blood pressure, should consult physician immediately and follow physician' s instructions to take medicine.
- The pulse displayed by this unit is not suitable to be a fixed frequency detector that identify heart rate!
- Those who have a history of heavier arrhythmia, should consult a professional physician about measured blood pressure value and confirm.

2.3 Electromagnetic Interference

Due to the unit has sensitive electronic components, avoid using it directly in strong electromagnetic environment (such as:mobile phone, microwave oven etc.), as it may lead to inaccurate results.

3. About Blood Pressure

3.1 What is Blood Pressure?

Blood pressure (BP) is regulated by brain circulation center.Through the regulation of nervous system,the body can adapt to or change blood pressure , so that make different body parts corresponding reflected in different states.Human body changes the blood vessel diameter and pulse via the changes of smooth muscle of microvessels, thereby changing blood pressure. When heart contracts to apex , blood pressure shows the highest state , called systolic (SYS); when heart relaxes to nadir , blood pressure shows the lowest state, called diastolic (DIA).

3.2 What is normal blood pressure?

If blood pressure value is too high during rest: diastolic pressure (DIA) exceeds 90 mmHg, and either systolic pressure (SYS) is higher than 140 mmHg. In this case, please consult your physician immediately. Prolonged hypertension will damage blood vessels and important organs such as kidneys and even the heart. Consult your physician if systolic blood pressure (SYS) is between 140mmHg and 160mmHg

and diastolic pressure (DIA) is between 90mmHg and 100mmHg. In addition, regularly self-measurement is also very necessary. Please consult your physician when blood pressure value is too low, that is, systolic blood pressure (SYS) is lower than 100 mmHg, and diastolic blood pressure (DIA) is lower than 60 mmHg.

It is necessary to use this sphygmomanometer for regular blood pressure self-measurement even though your blood pressure is in the normal scope. Through this method, you can find changes in blood pressure earlier and take appropriate measures. If you are in the period of medication to control your blood pressure, please self-measurement and record your blood pressure every day. And take the records to your physician. Please do not privately change the prescription and dosage prescribed by the physician according to your measurement .

The following is a standard taxonomy established by the World Health Organization (WHO) for blood pressure, showed in the below table: Unit (mmHg)

Scope	Systolic(SYS)	Diastolic (DIA)	Corresponding measures
Hypotension	<100	<60	Ask doctor for measurement
Desirable	100~120	60~80	Self-measurement
Normal	120~130	80~85	Self-measurement
Pre hypertension	130~139	85~89	Self-measurement
Stage 1 Hypertension	140~159	90~99	Consult the doctor
Stage 2 Hypertension	160~179	100~109	Consult the doctor ASAP
Hypertensive Crisis	≥ 180	≥ 110	Danger! Please consult the doctor immediately

At the same time, the United Nations Committee on the Investigation, Evaluation and Treatment of Hypertension in 1988 recommended that whether it is systolic (SYS) or diastolic (DIA), average person must undergo at least three measurements ,further diagnosis is needed when blood pressure is found to be higher than the normal level.

3.3 What measure should be taken when blood pressure is too high or low?

a) Please consult physician.

b) Prolonged ascending blood pressure (different types of SYS) will endanger human health. Deposits on the walls of the blood vessels limit the flow of blood (that can result in arteriosclerosis), which is very dangerous. Because it will cause insufficient blood supply to body' s important part (heart, brain, muscles and etc.), even severely destroy the structure of heart.

c) There are many factors that cause high blood pressure. We could divide them into common hypertension and secondary hypertension. Secondary hypertension will lead to organ disorders. If your blood pressure value continues to rise, ask physician about possible causes.

d) Changing your lifestyle also can prevent or lower hypertension, but this habit must be a part of healthy life, including:

1) Dietary Habit
Maintain normal weight as guided by doctor. Do not eat too much salt, as many "packaged foods" contain more salt. Avoid eating greasy food. (Packaged foods usually contain large amounts of fat).

2) Preventing Diseases
Adhere to medical guidelines for preventing certain diseases, such as diabetes, fat metabolic disorders and gout .

3) Living Habit
Don't smoke, avoid drinking too much or high concentration drinking; limit the intake of caffeine (coffee, tea, chocolate and etc.)

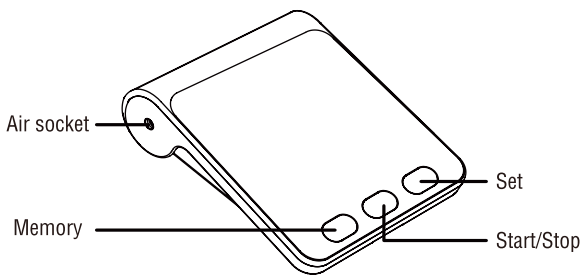
4) Physical Exercise
After medical examination, carry out regularly physical exercise; choose the sports program that requires endurance rather than strength. Please note that do not exercise reaching your physical

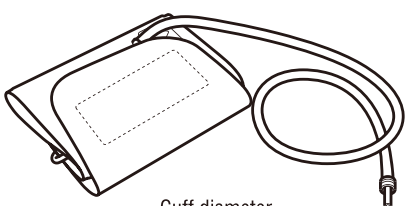
limit. Patients over 40 years old who is with medical history, consult physician before you start to exercise.

Precaution: Consult your physician before using the device for any of the following conditions: common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, arterial sclerosis, poor perfusion, diabetes, old age, pregnancy, pre-eclampsia, renal diseases. Note that PATIENT motion, trembling, shivering may affect the reading.

The physiological status of the patients described above affects the blood pressure measurement. The measurement site and measurement posture of the patient can also affect the value of blood pressure, please see section 6 for the correct method.

4. Description of Product structure



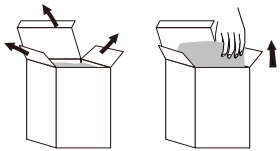


Cuff diameter
(22-42cm)

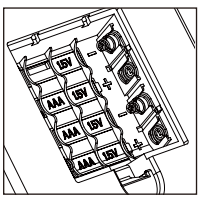
5. Operation manual

5.1 Unpacking

Unpack the box and lay the product flat on the table.



5.2 Install the battery



After opening the package, firstly install the battery. The battery case is located on the base of sphygmomanometer.Process of battery installation is as follow:

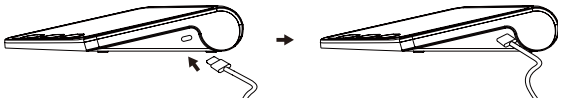
1) Remove battery cover
2) Insert battery, and make sure the positive, negative pole of battery are same as battery case 's positive,negative pole.
3) If LED displayed low battery signal ,please replace new battery.

Precaution

- Once the low battery signal is displayed, the unit will not be available unless you replace new battery.
- Please use 4 standard"AAA" ,long-lasting alkaline batteries.
- Remove battery if the unit is to remain unused for an extended period.

5.3 Use adapter

Except the battery, this unit can also use a USB 5V adapter.Must use the original or medical power supplies that meet medical standards. (example: IEC 60601-1 certification). Transformer connects to power socket is shown on the following. Adaptor connects to the power socket of the product and press the [START/STOP][MEM][SET] button to test if it is power.



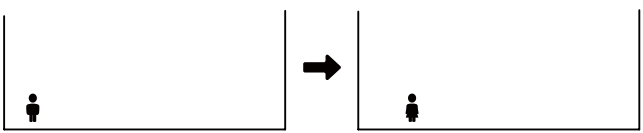
- Power source is adapter instead of a battery when using adapter.
- If power failure suddenly during measurement (for example, adapter plug is disconnected to power outlet), adapter single-pin plug should be unplugged and reinsert into the unit again.
- Any problems about adapter, please consult purchased dealer locally.

5.3 Connect to Cuff

After removing the cuff, connect the trachea of the cuff to the tracheal connection hole on the left side of the unit (the hole marked with the cuff mark). The air pipe should be properly connected when connecting to prevent the air path from being bent or blocked.

5.4 User switch

The system defaults to user 1. In shutdown mode, press the [SET] button to switch to user 2, which can be switched cyclically.

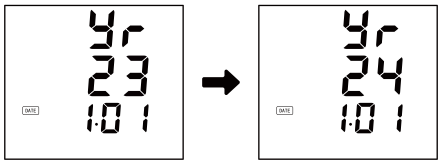


5.5 Setting time, date and kPa/mmHg unit selection

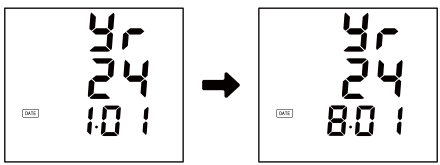
The unit automatically records the date and time of each measurement, which is very important.Because the blood pressure of the human body is constantly changing on the same day, it is recommended that you set the correct date and time immediately after installing the battery.Please set the correct date and time as following,(Example: enter time and day -12:01 pm. on Aug. 28th)

1. In the shutdown mode, press the [SET] key for 3 seconds, the product enters the function setting mode (if not selected, the system defaults to the manufacturing time).The last two digits

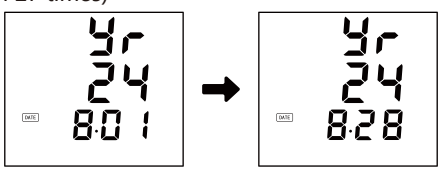
of the year will flash on the screen. You can enter the year by pressing the [MEM] button (for example, you can increase the year from 23 to 24 by pressing it one time).



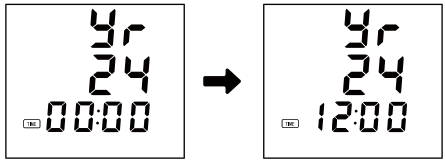
2. Press the [SET] button, and there will be a jump of the month in the left corner of the screen. At this time, the first digit of the month starts to flash. You can enter the month by pressing the [MEM] button (for example, you can increase the month from January to 8 months by pressing 7 times).



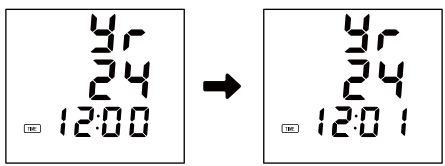
3. Press the [SET] button again, the screen will switch to the date setting, at this time, the last two digits of the date will start to flash. You can enter the date by pressing the [MEM] button (for example, you can change the date from 1st to 28th by pressing the button 27 times)



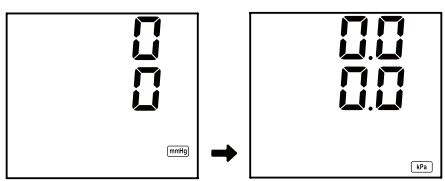
4. Press the [SET] button again, the screen will switch to the time setting. At this time, the first digit (indicating hour) starts to flash. Please input the time by pressing the [MEM] button (for example, you can change the time from 0:00 to 12:00 by pressing the [MEM] button 12 times).



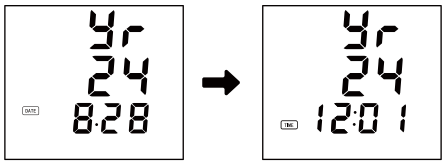
5. Press the [SET] button again, and the last two digits (in minutes) will start to flash. You can enter the minute by pressing the [MEM] button (for example, pressing the button 1 times will increase the time from 0 minutes to 1 minutes).



6. Press the [SET] button again to enter the kPa/mmHg unit selection. You can select kPa or mmHg by pressing the [MEM] button, "0.0" will display on the screen when kPa is selected, and "0" will display when mmHg is selected.

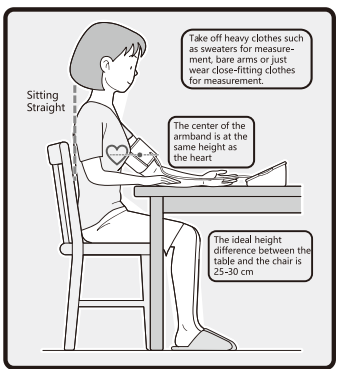


7. In the last step, press the [SET] button, and the date will be displayed after the setting is completed (the date will be displayed first, and it will automatically jump to the time after 3 seconds). When there is no operation, it will automatically shut down after 30 seconds.



6. Measurement of blood pressure

6.1 Preparation before measurement



- Avoid eating, smoking or any form of activity before measuring, all of which will affect the measurement. Try to relax in a quiet environment, rest for 10 minutes, and then take measurements.
- If you have heavy clothing, please detach from the upper arm.
- Select the arm for blood pressure measurement (usually the left arm) and take blood pressure measurements on the same arm and in the same area.
- Regularly take blood pressure measurements at the same time every day, because blood pressure will change differently over time.

6.2 Common factors that lead to erroneous measurements

Note: Comparative blood pressure measurements should be performed in the same condition (usually referred to quiet conditions)!

- If the arm artery is low (high) relative to the heart , it will result in a

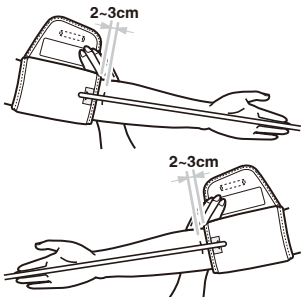
high (low) blood pressure value. (Each 15cm height difference will produce 1.3kPa/10mmHg error value)!

- This unit is not suitable for newborns.
- Note: Please use the original arm cuff that meets the clinical test requirement!
- The loose or air bag exposed cuff will lead to false blood pressure.
- The arm will compress the blood vessels due to repeated measurements. This condition will also cause a biased blood pressure value. Therefore, when making repeated measurements, be sure to rest for 3-5 minutes or raise your arm for 3 minutes to reduce the congestion.

6.3 The correct method of using the cuff:

a. Make sure the arm strap connector is fully inserted into the sphygmomanometer vent.

b. Please take off your coat, sweater and other thicker clothes, do not have any accessories, bare upper arm or wear a thin shirt for measurement.



c. Wrap the cuff around the left arm.

d. Do not wrap the cuff too tightly (It is the best to easily insert a finger) and the lower edge of the cuff should be 2~3 cm from the hand bend (as shown).

e. After wrapping the cuff around the upper arm, place the air tube on the inside of the arm and on the same line as the middle finger (as shown).

f. When measuring, please sit in the chair, place your feet flat on the floor, place your arms on the table, and put the arms and the heart on the same level to relax and measure in a relaxed and natural posture.

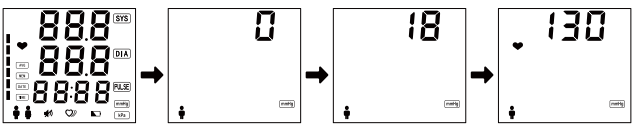
Suggestion:

If the arm strap cannot be worn on the left arm, the arm sleeve is worn on the right arm and it is recommended to use the same arm measurement later.

6.4 Measurement step

After the arm band is set, the blood pressure measurement can be performed as follows:

1) Tap the [START/STOP] button, the screen will be cleared after 1 second, then the arm band will begin to inflate. The LED display shows the change of the air pressure in the arm band.As following:
2) When the sphygmomanometer detects heartbeat, a flashing "♥" symbol will appear on the LED display.
3) When the sphygmomanometer completes the measurement display will show SYS, DIA and pulse frequency.



4) If you forget to turn off the power, the unit will automatically turn off the power in 30 second.

Note: This product is available in millimeters of mercury or kPa depending on the region. Use the product according to the user manual base on the selected display mode.

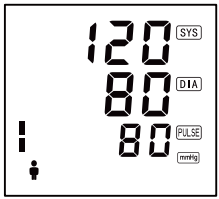
6.5 Arrhythmia prompt and WHO blood pressure definition function

1) Arrhythmia prompt function:

♡)) The unit can detect the arrhythmia. When this symbol appears after the measurement is completed, it may differ from your normal blood pressure. Please measure it a few more times. If this symbol is displayed frequently, it is recommended that you tell the doctor about this situation, and ask the doctor for frequent information on the irregular heartbeat indicator.

2) WHO blood pressure definition function

This unit comes with a SYS warning and a warning bar reminder function. As shown on the right, we can read from the height of the



World Health Organization blood pressure indicators, blood pressure is distributed in DIA (no WHO voice prompts) and ideal blood pressure, normal blood pressure (green), normal partial hypertension (orange), mild hypertension, moderate hypertension, and severe hypertension (red). After the measurement is completed, the black zebra crossing appears at the corresponding position according to the SYS and DIA.

The correspondence between color and blood pressure values is shown in the following table:

Scope	Systolic (SYS)	Diastolic (DIA)	Indicator Color
Desirable	<120	<80	Green*1
Normal	120~130	80~85	Green*2
Pre hypertension	130~139	85~89	orange
Stage 1 Hypertension	140~159	90~99	Red*1
Stage 2 Hypertension	160~179	100~109	Red*2
Hypertensive Crisis	≥ 180	≥ 110	Red*3

The meaning of the indicator color:
Green, it represents normal blood pressure.
Red,please consult physician.

6.6 Memory—displays the last memory value

This sphygmomanometer automatically stores the last measurement of 99 groups of two users.
In the shutdown and wait state, press the [Mem] button displays the average value of the last three measurements for the current user. Press [Mem] or [Set] again to read the previously measured value. First

display the 1 second memory group and test date, then display the 1 second memory group and test time, and finally display the test data.

6.7 Stop measurement

If there is any discomfort or for some reason, such as when the airbag is in a persistent over-inflated state, there may be a risk. At this time, the blood pressure measurement must be stopped. You can press the [START/STOP] button and the sphygmomanometer will immediately release the air pressure in the cuff to suit your need.

6.8 Memory-erases all memory

Please note !

- Before you delete the memory, please confirm carefully stored data will not be used in the future.The best way is to keep good records so that you can provide your doctor with the necessary information.
- If decided to permanently delete all stored value, (note: choose the user groups need to delete the memory, pressing [Mem] until the display memory after the "---" then release the button.
- To delete all user data and factory: press and hold the [Mem] and [Set] buttons in the query mode until the display position of SYS and DIA and heart rate shows horizontal bar, then the memory will be deleted.
- The machine can't get rid of individual numeric values.

7. Error warning/Troubleshooting

7.1 False Alarm

The LED will display an error warning If any of the following occurs,as shown in figure marked:

Error code after leaving the factory	Description	Reason of error	Solutions
Er01	Error of measurement	Too much noise to detect an effective pulse signal	Please rest for 2 minutes, adjust the cuff, keep quiet during measurement, do not move or talk.
		No pulse was detected	
		The results deviated from the normal range	
	Static pressure exceeds the set protection point	Set upper limit protection when the pressure over 295mmHg	Measure blood pressure again
	Zero overtime	1. During the process of returning to zero, the air pressure in the cuff continues to fluctuate; 2. The sensor part of the circuit is abnormal; 3. Sensor damage.	1. Keep the cuff intact when returning to zero; 2. Detecting the power supply of the sensor; 3. Replace the sensor.
Er02	Abnormal cuff wearing	1. The cuff is not worn; 2. Wearing too loose; 3. Wearing too tight; 4.Cuff pressure is abnormal;	Adjust the cuff. It is advisable to insert two fingers just after the tightness is tied. The cuff mouth of the cuff is kept 2cm on the elbow socket.

Lo	Power is not enough	The power is lower than the minimum operating voltage.	Replace the battery

Other Information

Even a healthy individual, the blood pressure is constantly changing (presenting a jagged line), so when you make comparative measurements, you must be in a fixed state (quiet environment)! If the difference is greater than 2.0 kPa / 15 mmHg if the above conditions are met, or in some cases, in case of irregular hearbeat, please consult your doctor.

7.2 Troubleshooting

If any faults (or abnormal conditions) occur during use, you can check and exclude according to the items listed in the following table:

Malfunction	Exclude
When the battery is installed and the switch is turned on, the LED shows nothing.	1.Check whether the positive and negative poles of the battery are placed correctly. 2.If the fault persists, please reposition or replace the battery.
The air pump has begun to inflate, but there is no rise in arm pressure.	Check the hose connection for air leakage or whether it is fully inserted into the socket.
Sphygmomanometers fail to measure blood pressure frequently, or the blood pressure is abnormally high or low.	1. Re-set the correct cuff. 2. If the left upper arm of the belt is covered with sleeves or other clothing, please take off. Re-measure blood pressure.
Each measurement was different, although the sphygmomanometer was functional or showed normal blood pressure.	Please study the following points: "further consultation" or "6.2 common factors leading to wrong measurement". Remeasure!

self-measured value is different from the measured value of the doctor.	*Record daily measurements and consult your doctor.
After the sphygmomanometer is pressurized, the air pressure of the cuff is released. And the rate is slow even not released at all.	*The air hole connection of the hose in the arm belt has the phenomenon of "plastic ring" falling off. Please put the plastic ring on and measure again.

Any technical problems related to blood pressure monitor, should consult experts or medical personnel, do not disassemble repair without permission!Unauthorized disassembly, will lose the warranty right!

8. Daily use and maintenance

8.1 Clean

- When the product is dirty due to prolonged use, it is necessary to follow the requirements for cleaning:
- When the outer shell is dirty, gently wipe it with a wet soft cotton cloth. If the outer shell is seriously soiled, wipe it with a soft dry cloth dipped in 75% medical alcohol. It is recommended to clean at least once a month.
- Please pay attention to keeping the cuffs clean. After repeated use for a long time, 95% concentration of medical alcohol can be sprayed on the inside of the measuring contact of the cuff for disinfection. If it is heavily soiled, it is recommended to replace the cuff. You can contact the dealer or manufacturer for disposal.
- This product is intended for home use and is a personal product. Please use medical alcohol to clean it before use it to others.
- Note: This product is not waterproof. Please be careful not to be too moist when cleaning. Also it is not suitable for splashing with water.
- Please do not use any other solutions to clean this unit except those method recommended by manufacturer.Because it may damage your sphygmomanometer.

- Avoid washing the cuff!

8.2 Maintenance

Our company does not authorize any organization and individuals to carry out maintenance.Therefore, please do not disassemble or adjust this unit if you feel the product has functional problems. Electronic sphygmomanometer is a very precise product, any improper maintenance, disassembly and adjustment will lead to inaccurate measurement.

- Avoid the damage of cuff and rubber tube caused by folding
- Avoid falling or shaking this unit violently.
- Within warranty period,please contact the distributor or manufacturer if you have any questions about the product.

8.3 Calibration

The electronic sphygmomanometer has been calibrated at the time of manufacture. We recommend a static pressure test for this sphygmomanometer every 2 years, with the option of an authorized dealer to calibrate your device. At any time, if you question the accuracy of the measurement, please feel free to contact your dealer or manufacturer for disposal.

9. Reference standard

We Famidoc Technology Co., Ltd. solemnly declares that the FDBP-A4 Upper Arm Blood Pressure Monitor we produced and sold meets the following standards:

Performance safety standard:YY 0670/ IEC 80601-2-30
Electromagnetic compatibility:IEC60601-1-2
Safety standard:GB 9706.1/ IEC60601-1

Claim: The blood pressure value tested by this device is equivalent to that measured by auscultation, and the error is in accordance with the requirements of the code IEC/EN 80601-2-30.

Please read this instruction carefully before use.The product is part of BF application equipment of internal power supply.

10. Place in

If this unit is damaged and need to be discarded,please dispose of the discarded electronic waste in accordance with the relevant national laws and regulations , dispose of the battery or product should not be directly placed in the garbage can.
Please consult the licensor who responsible for local waste disposal if you have any questions.

11. Technical specifications

Mode	FDBP-A4
Displayer	LED displayer
Measuring method	Oscillometric method
Measuring scope	Pressure： 0kPa~39.3kPa(0mmHg~295mmHg) Pulse: (40~199) times / minute
Memory	Automatically store each 99 sets of measured values for two users
Resolution	0.1kPa(1mmHg)
Accuracy	Static pressure: ±0.4 kPa (±3 mmHg) Pulse: within ±5% of the reading
Power	4x1.5V AAA Batteries
Special accessory	Cuff, instruction manual, and 4pcs AAA/LR03 alkaline batteries
Size	(L) 145mm* (W) 123 mm* (H) 41 mm
Weight	About 370g (including battery)
Withstand pressure for the cuff	360mmHg

Upper arm circumference	220~420mm
Electric shock protection type	Class II device
Shock protection procedure	BF application part
Expected use lifetime	Body in 5 years
Application component	Cuff
Operating condition	Temperature: 5° C~40° C Humidity: 15% RH~90% RH, No condensation Atmospheric pressure: 70kPa~106kPa
Transportation and storage condition	Temperature: -25° C~55° C Humidity: 15% RH~95% RH, No condensation Atmospheric pressure: 70kPa~106kPa Please strictly observe the environmental conditions of transportation and storage, otherwise it will affect the accuracy of the equipment.

The FDBP-A4 was clinically investigated according to the requirements of ISO 81060-2: 2013.

12. Package list

Component	Quantity
Body	1 set
Cuff	1 pc (with trachea)
AAA battery	4pcs
Instruction manual	1 PC

13. Standardized symbolic description

	General warning sign
	Follow instructions for use
	Type BF applied parts
UDI	Unique device identifier
	Electric shock protection type :Class II equipment
	Disposal in accordance with Directive 2002/96/EC (WEEE)
CE 1639	Complies with the European Medical Device Regulation (EU) 2017/745, Notified Body is SGS Belgium NV.
	Manufacturer
EC REP	Authorized representative in the European Community
SN	Serial number
LOT	Batch code
	Date of manufacture
SYS	The value of SYSTOLIC BLOOD PRESSURE
DIA	The value of DIASTOLIC BLOOD PRESSURE
MD	Medical Device
IP21	Level of protection for ingress of water or particulate matter into ME EQUIPMENT

14. Electromagnetic compatibility information

Note:

- The Upper Arm Blood Pressure Monitor FDBP-A4 meets the electromagnetic compatibility requirements of YY0505, YY0670, IEC60601-1-2;
- Users should install and use the electromagnetic compatibility information provided by the random files. Portable and mobile RF communication devices may affect the performance of the Upper Arm Blood Pressure Monitor FDBP-A4. Avoiding strong electromagnetic interference when used, such as Close to mobile phones, microwave ovens, etc.
- The instructions for the guide and the manufacturer are detailed in the attachment.

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.

·Use of accessories, transducers and cables other than those specified or provided by the manufacturer of this the FDBP-A4 could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation

·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 FDBP-A4, including cables specified by the manufacturer. Otherwise, degradation of the performance of this equipment could result.

Attachment:

Guidance and manufacturer´s declaration – electromagnetic emission – for all EQUIPMENT AND SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic emission		
The FDBP-A4 is intended for use in the electromagnetic environment specified below. The customer or the user of FDBP-A4 should assure that it is used in such an environment.		
Emissions test	Compliance	Electromagnetic environment-guidance
RF emissions CISPR 11	Group 1	The FDBP-A4 uses RF energy only for its internal function. There for, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class B	The FDBP-A4 suitable for use in all establishments, including domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration – electromagnetic immunity – for all EQUIPMENT and SYSTEMS

Guidance and manufacturer´s declaration – electromagnetic immunity			
The FDBP-A4 is intended for use in the electromagnetic environment specified below. The customer or the user of the FDBP-A4 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	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	± 8 kV contact ± 2 kV, ± 4 kV, ± 8 kV, ± 15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.

Electrostatic transient / burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/ output lines	± 2 kV for power supply lines	Mains power quality should be that of a typical commercial or hospital environment.
surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	± 1 kV differential mode	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	0 % U_T; 0,5 cycle U_T At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle	0 % U_T; 0,5 cycle U_T At 0° , 45° , 90° , 135° , 180° , 225° , 270° and 315° 0 % U_T; 1 cycle and 70 % U_T; 25/30 cycles Single phase: at 0° 0 % U_T; 250/300 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the FDBP-A4 requires continued operation during power mains interruptions, it is recommended that the FDBP-A4 be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30A/m	30A/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 manufacturer´s declaration – electromagnetic immunity – for EQUIPMENT and SYSTEM

Guidance and manufacturer´s declaration – electromagnetic immunity
The FDBP-A4 is intended for use in the electromagnetic environment specified below. The customer or the user of the FDBP-A4 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 Vrms 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	3V 150 kHz to 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz	Portable and mobile RF communications equipment should be used no closer to any part of the FDBP-A4, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=[\frac{3.5}{V_2}]\sqrt{P}$ $d=[\frac{3.5}{V_2}]\sqrt{P}$ $d=[\frac{3.5}{E_1}]\sqrt{P}$ 80 MHz to 800 MHz $d=[\frac{7}{E_2}]\sqrt{P}$ 800 MHz to 2.7 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).[b] 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: 
	10 V/m 80 MHz to 2.7 GHz	10 V/m 80 MHz to 2.7 GHz	
Radiated RF IEC 61000-4-3	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	385MHz-5785MHz Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communication equipment (Refer to table 9 of IEC 60601-1-2:2014)	

Note 1: At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2: These guidelines may not apply in all situations. Electromagnetic is affected by absorption and reflection from structures, objects and people.

[a] The ISM (industrial, scientific and medical) bands between 150 kHz and 80 MHz are 6,765 MHz to 6,795 MHz; 13,553 MHz to 13,567 MHz; 26,957 MHz to 27,283 MHz; and 40,66 MHz to 40,70 MHz. The amateur radio bands between 0,15 MHz and 80 MHz are 1,8 MHz to 2,0 MHz, 3,5 MHz to 4,0 MHz, 5,3 MHz to 5,4 MHz, 7 MHz to 7,3 MHz, 10,1 MHz to 10,15 MHz, 14 MHz to 14,2 MHz, 18,07 MHz to 18,17 MHz, 21,0 MHz to 21,4 MHz, 24,89 MHz to 24,99 MHz, 28,0 MHz to 29,7 MHz and 50,0 MHz to 54,0 MHz.

[b] 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 FDBP-A4 is used exceeds the applicable RF compliance level above, the FDBP-A4 should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re¬orienting or relocating the FDBP-A4.

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

Recommended separation distances between portable and mobile RF communications equipment and the EQUIPMENT or SYSTEM - for EQUIPMENT and SYSTEMS

Recommended separation distances between portable and mobile RF communications equipment and the FDBP-A4.

The FDBP-A4 is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the FDBP-A4 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the FDBP-A4 as recommended below, according to the maximum output power of the communications equipment.

Rated maximum output of transmitter W	Separation distance according to frequency of transmitter			
	150 kHz to 80 MHz outside ISM and amateur radio bands $d=[\frac{3.5}{V_1}]\sqrt{P}$	150 kHz to 80 MHz in ISM and amateur radio bands $d=[\frac{12}{V_2}]\sqrt{P}$	80 MHz to 800 MHz $d=[\frac{3.5}{E_1}]\sqrt{P}$	800 MHz to 2.7 GHz $d=[\frac{7}{E_2}]\sqrt{P}$
0.01	0.12	0.20	0.035	0.07
0.1	0.38	0.63	0.11	0.22
1	1.2	2.00	0.35	0.70
10	3.8	6.32	1.10	2.21
100	12	20.00	35	70

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.

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