Blood Pressure Monitor

Model:DB66-1

User Manual

Rev.00

2019/03/14

Thank you for purchasing TRULY Blood Pressure Monitor. Please read through this "User's Manual" before using the product.

Contents

1. Identification For use

Truly Automatic Arm Blood Pressure Monitor intended to measure the systolic and diastolic blood pressure and pulse rate of an adult individual by using a non-invasive technique in which an inflatable cuff is wrapped around the upper arm.
The devices' features include irregular pulse rhythm detection during measurement, and will display a alert signal with the reading when irregular heartbeat is detected.
The devices' feature include Bluetooth function to transmit data to an external Bluetooth device with wireless communication .
The devices are intended to use of Over-The-Counter

2. Safety Precautions

Caution

The monitor uses the oscillometric method to measure systolic and diastolic blood pressure, as well as heart rate 。

- This device is intended for use in measuring blood pressure and pulse rate in the adult population, do not use this device on infants or persons who cannot express their intentions: The monitor is not intended to be a diagnostic device, It is a home healthcare product only and it is not intended to serve as a substitute for the advice of a physician or medical professional。
- Don't not use this device for diagnosis or treatment of any health problem or disease, Measurement results are for reference only, consult a healthcare professional for interpretation of pressure measurements, Contact your physician if you have or suspect any medical problem. Do not change your medications without the advice of your physician or healthcare professional。
- Use only Truly authorized parts and accessories Parts and accessories not approved for use with the device may damage the unit and get a error of measurement。There are no replaceable parts (such as sensors, electrode pads, etc.). Do not disassemble or repair or modify the ME EQUIPMENT, it will get a error of measurement If you need to repair, please contact the dealer and repair it.
- Proper cuff size is critical for accurate measurements ， Follow the instructions in this manual and printed on the arm cuff to ensure the appropriate size of cuff is being used。
- Blood pressure measurement can be affected by the other factors; Position of the user such as bending over the body or cross-legged sitting will produce abdominal pressure or make the position of the arm below the heart, that will increase the blood pressure。
  - ■ This product is not suitable for people with arrhythmias or serious arteriosclerosis. It may have difficulty determining the proper blood pressure for pregnant women and for users with irregular heartbeat, diabetes, pre-eclampsia, poor circulation of blood, measurement on the arm on the side of a mastectomy,kidney problems or for users who have suffered from a stroke；
- When measurement, The pressurization of the cuff to arm where intravascular access or the rapy,or an arterio-venous(A-V) shunt,is present because of temporary

interference to blood flow and could result in injury to the patient；

- When measurement, The pressurization of the cuff can temporarily cause function of simultaneously used monitoring other device on the same limb；
- The pulse display is not suitable for checking the frequency of heart pacemakers；
- Do not use a cellular phone near the device, It may result In an operational failure；
- Do not use the monitor in the driving or flying vehicles；
- Frequenly measuring will make the blood not flow, cause the arm-numbness and abnormal reaction of body。

When you are using the monitor to measure especially frequently used, the arm is compressed by the cuff, and then the fingertip will be caused congestion. During the congestion, please loosen the cuff and lift the hands over your head, and make your right and left hand squeese and stretch 15 times, them will unclog the congestion；
Do not applying the CUFF over a wound, as this can cause further injury；

- When measurement, please check that operation of the device does not result in prolonged impairment of the circulation of the blood of the patient；
- Do not compress the cuff tube during the measurement, or it will cause fail inflation or affect the result of measurement；
- Please use the product in the approved operate environment, the time required for the ME EQUIPMENT to warm from the minimum storage temperature is two hours；the time required for the ME EQUIPMENT to cool from the maximum storage temperature is two hours；or will cause the inaccurate result of Handling batteries properly: measurement；
- Handling batteries properly: measurement
  - As soon as old batteries run out, replace with newbatteries,
  - Do not use old and new batteries together
  - Align the polarities of batteries correctly;
  - When the unit will not be used for more than 3 months,remove the batteries,Ohterwise, batteries may leak and cause damage to the unit。
- Dispose of the device,components and optional ,accessories according to applicable local regulation,Unlawful disposal may cause environmental pollution。
- Don’t calling around the Blood pressure monitor when it is using ,Don’t move and avokd electromagnetic interference and noise interference when measuring that to avoid to measure error。
- When the screen display the battery for one degree,it means that low Voltage and must change the new one to void to measure error。
- Babies, young children or individuals who cannot express their consent are not suitable to take blood pressure measurement.
- Keep the equipment away from children and pets.
- Blood pressure readings may change in case of pregnancy. Pregnant women can consult their doctor before taking measurement。
- Individuals with serious arteriosclerosis are not suitable to take blood pressure measurement。
- Self-measurement is not medical treatment If there are unusual values, please consult your doctor。

3. Quick Start Guide

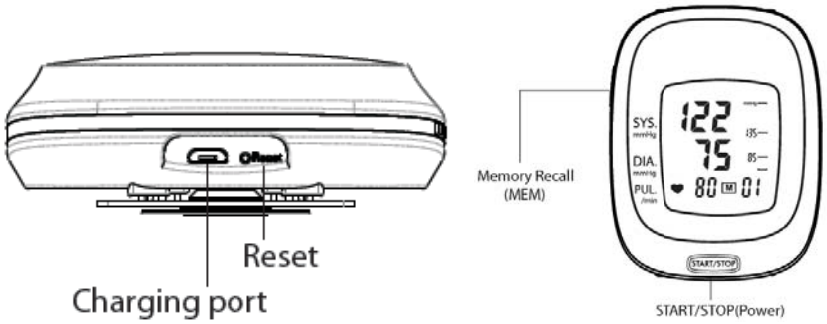
3.1 Charging

- Charging with the power adapter when the battery indicator "▭" show low voltage.
- There will be twenkle "▭" when charging.
- When the battery is fully charge.battery indicator "▭" will disappear.

Adapter: Input:100-240Va.c. 0.2A;;Output: 5.0Vd.c. 1.0A

Note :During charging the blood pressure monitor will not be tested.

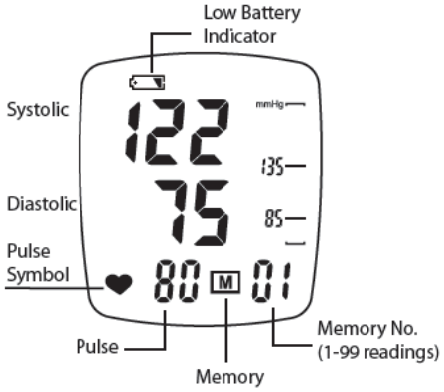
3.2 Monitor



Features

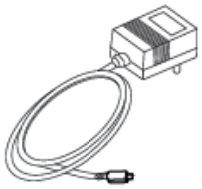
- One touch operation
- 99 Total Memory
- Bluetooth 4.0
- Averaging mode-the average value of the last 3 measurements stored in the memory will display
- Auto –off power saving feature
- Polymer battery

Display



Package Contents

Main Unit


power supply adapter

4 Taking measurement

Note:

- **Avoid smoking,eating or exercising for 30 minutes before taking measurement.**
- **Do not move or talk during measurement.**
- **Measurement can be taken on either arm.**

4.1 Sitting Correctly

1 Relax

2 Sit upright in a chair with your both feet on the floor.

3 Remove tight fitting clothing from you upper arm and thick clothing .Do not roll up your sleeve if it is too tight。

4 Place your arm on a table so that the cuff will be at the same level as your heart.

4.2 Applying the Arm Cuff

1 Place your elbow on a table and palm facing upward,and wrap the arm cuff around the upper left arm.

2 Pull on the end of the cuff until it wraps securely around your upper arm.Do not over tighten the cuff .Allow 1~2 cm or ½ inch between the bottom of the cuff and your elbow joint.

3 Make sure the cuff is at the same level as your heart.

4.3 Taking Measurement

1 Press the “START/STOP”button.the cuff will automatically inflate and the measurement will start.

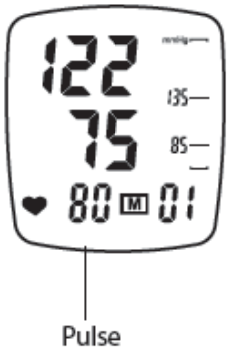
2 When the measurement is complete,the cuff will automatically deflate and your systolic and diastolic pressure values and pulse rate will display.

3 Remove the arm cuff and take note of your measurement results.

Note:

You can press the“START/STOP”button to stop measurement at any time.

4.4 Heartbeat Readings



Besides Systolic and Diastolic values, Pulse will also be displayed after a measurement

Irregular Heartbeat

This unit has a unique feature that alerts user of irregular heartbeat detection during measurement.

Note： An irregular heartbeat is defined as a heartbeat rhythm that has a variation of more than25% from the average rhythm detected during measurement.

If such irregular rhythm occurs twice or more during the same measurement, the display screen will show the pulse value and "IH" symbol alternately. Example: (90 / IH)

Note： Please consult your doctor if irregular heartbeat occurs often.

Regular but Below Normal Heartbeat

If the monitor detects a pulse rate below 60 beats per minute during measurement, the monitor will display the pulse value and "LO" symbol alternately.Example: (58 / LO)

Regular but Above Normal Heartbeat

If the monitor detects a pulse rate above 100 beats per minute during measurement, the monitor will display the pulse value and "HI" symbol alternately.Example: (102 / HI)

5 . Memory Functions

After measurement,the last set of measured values will be saved automatically after measurement when the unit is turned off by pressing ““START/STOP””button or by automatic power off after 3 minutes.

5.1 View Past Readings

1 Press the “MEM”button to enter memory function,

2 First press the “MEM”button to display the “ AVG“ of last 3 values.second press to the “MEM”button will display first sets of value and so on.

3 This can stored up to 99 sets of past readings.

5.2 Delete Past Readings

When the monitor’s power is off,press and hold the memory button”MEM”for 5 seconds until the memory icon “ⓜ”appears in the display .Without releasing the memory button,press the power button“START/STOP” and “EE EE” will appear.Release the power button “START/STOP” and the memory button.”MEM” to erase all stored readings from the monitor.

6.Troubleshooting

Problem	Cause	Solution
No display when you press the Power /Start button	Have the batteries run out?	Charging with power adapter
	“Reset “button close	Press reset button
“Er P” displayed	Fail to inflate	Check if the cuff is properly connected.Replace the air tube if it is broken.
“Er 1” displayed	Deflate too rapidly	Return for servicing.
“Er 2” displayed	Movement during measurement	Do not move during measurement
	Signal interference	Remove interfering source e,g. mobile phones,magnets.
“Er 3” displayed	Incorrect results	Measure again

Note: If your problem cannot be solved by the above,consult your store of purchase.Do not disassemble the unit.

7. Storage & Maintenance

✧ Keep away the unit from direct sunlight,extreme temperatures,humidity or moisture.

✧ Use a dry,soft cloth to clean the unit,or if desired,use a cloth lightly dampened with water.

- ✧ Do not use alcohol,benzene,thinner or other volatile liquids to clean the unit.
- ✧ Do not wash or expose the arm cuff to liquid.
- ✧ The user must check that the equipment functions safely and see that it is in proper working condition before being used.

WARNING: long power cable and air hose.To avoid strangulation and entanglement,keep cable and hoses out of reach of young children.

8. Product Specifications

Model No.	DB66-1
Measurement method	Oscillometric
Measurement range	Pressure:20~280 mmHg Pulse Rate:40~195 beats/min
Accuracy	Pressure: ±3 mmHg Pulse Rate: ±5%
Inflation	Pump driven
Pressure Detection	Semi-conductor
Power Supply	Polymer battery
Auto power off	3 minute after not being used
The pressure of the running	70KPa~106KPa
Storage Environment.	-20℃~60℃,10%~95%RH
Operating Environment.	10℃~40℃,30%~85%RH
Dimensions	110×85×24mm
Net Weight	250g (batteries excluded)
Used Life Span of Battery	1000 times
Software version	
Use Period	5 year
Application part	Out of contact the body,:onnect tub、shell contact the body :cuff
Cuff Dimensions	For arm circumference of 22~34cm(Special size to be ordered separately)
Package Content	Instruction Manual, Set ,Warrant Card,power supply adapter

Note:Subject to modification without prior notice.

9. EMC Declaration

Guidance and manufacturer's declaration – electromagnetic immunity			
The XXX" is intended for use in the electromagnetic environment specified below. The customer or the user of the "XXX" should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	±6 kV contact ±8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30 %.
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	±1 kV differential mode ±2 kV common mode	±1 kV differential mode ±2 kV common mode	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	<5 % *U*T (>95 % dip in *U*T) for 0,5 cycle 40 % *U*T (60 % dip in *U*T) for 5 cycles 70 % *U*T (30 % dip in *U*T) for 25 cycles <5 % *U*T (>95 % dip in *U*T) for 5 sec	Mains power quality should be that of a typical commercial or hospital environment. If the user of the "XXX" requires continued operation during power mains interruptions, it is recommended that the "XXX" be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE *U*T is the a.c. mains voltage prior to application of the test level.			

EMC Declaration (Continued)

Guidance and manufacturer's declaration – electromagnetic immunity			
The "XXX" is intended for use in the electromagnetic environment specified below. The customer or the user of the "XXX" should ensure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 V	Portable and mobile RF communications equipment should be used no closer to any part of the "XXX", including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. **Recommended separation distance** **d=1.2 √ P** d=1.2 **√ P** **80MHz to 800MHz** **d=2.3 √ P** **800MHz to 2.5 GHz**
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2,5 GHz	3 V/m	where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in metres (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,[a] should be less than the compliance level in each frequency range.[b] Interference may occur in the vicinity of equipment marked with the following symbol: 
NOTE 1 At 80 MHz and 800 MHz, the higher frequency range applies. NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.			

a Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the "XXX" is used exceeds the applicable RF compliance level above, the Medical XXX should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the "XXX".

b Over the frequency range 150 kHz to 80 MHz, field strengths should be less than [*V*1] V/m.

EMC Declaration

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

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

11. Disposal

At the end of its use don't dispose the appliance, including removable parts and Accessories, together with the other urban waste, but conformably to 2002/96/EC. Since to be treated apart from home waste, you must take it to a differential collection centre specific for electric and electronic equipment. Otherwise you can give it back to the retailer as you buy an equivalent apparatus. There will be Server sanctions in case of transgression。

The batteries used in this device must be disposed of in the special bins at the end of their life。

12. FCC Statement

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to part 15 of FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user Is encouraged to try to correct the interference by one or more of the following measures:

Reorient or relocate the receiving antenna Increase the separation between the equipment and receiver.

Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.

Consult the dealer or an experienced radio/TV technician for help.

This device complies with Part 15 of FCC Rules. Operation is subject 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.

Information to user：

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

Note: The manufacturer is not responsible for any radio or TV interference caused by unauthorized modifications to this equipment such modifications could void the user's authority, to operate this equipment.

Manufactured in accordance with International Standards

 Manufacturer

 Rerfer to the instructions

 Equipment of BF

 Recycling and Processing

CE 0123 The european Union flag

EC REP The represent of European Union

IP22 IP is short for Ingress Protection which means that Protection's level.

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