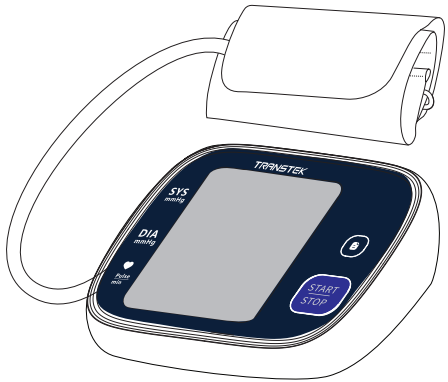
Version:A/0

TRANSTEK

User Manual

Blood Pressure Monitor Model: BBZ32-DB01

Arm Type



Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No.105, Dongli Road, Torch Development District, 528437 Zhongshan, Guangdong, China

- Thank you very much for selecting TRANSTEK Blood Pressure Monitor BBZ32-DB01.
- Please do read the user manual carefully and thoroughtly so as to ensure the safe usage of this product, and keep the manual well for further reference in case you have problems.

Table of Contents

♥ General Description

Thank you for selecting TRANSTEK blood pressure monitor (BBZ32-DB01). The monitor features blood pressure measurement, pulse rate measurement and the result storage.

Readings taken by the BBZ32-DB01 are equivalent to those obtained by a trained observer using the cuff and stethoscope auscultation method.

This manual contains important safety and care information, and provides step by step instructions for using the product.

Read the manual thoroughly before using the product.

Features:

- 74.5mm×54.7 mm Digital LCD display with white backlight
- Maximum 99 records

♥ Indications for Use

This Blood Pressure Monitor is a digital monitor intended for use in measuring blood pressure and pulse rate with arm circumference ranging from 22cm to 32cm (about 8¾″-12½″) or 22cm to 42cm (about 8¾″-16½″)

It is intended for adult indoor use only.

♥ Measurement Principle

This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the atmospheric pressure. Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile, which is used to determine the systolic and diastolic pressure, and also pulse rate.

♥ Receiving and Inspecting your Monitor

Check that the device packaging has not been tampered with and make sure that all contents are present. Before use, ensure that there is no visible damage to the device or accessories and that all packaging material has been removed. If you have any doubts, do not use the device and contact your retailer or the specified Customer Services address.

♥ Safety Information

The signs below might be in the user manual, labeling or other component. They are the requirement of standard and using.

	Recyclable		Type BF applied part
	Direct Current	SN	Serial Number
	Date of manufacture		Manufacturer
	Class II Equipment		For indoor use only
	Refer to instruction manual/booklet To signify that the instruction manual/ booklet must be read. Note: The background color of the symbol is blue.		
MR	MR Unsafe To identify an item which poses unacceptable risks to the patient, medical staff or other persons within the MR environment.		
	Caution Indicates that caution is necessary when operating the device or control close to where the symbol is placed, or that the current situation needs operator awareness or operator action in order to avoid undesirable consequences.		
	The symbol indicates that the product should not be discarded as unsorted waste but must be sent to separate collection facilities for recovery and recycling.		

Precaution

* This device is intended for indoor, home use and is not intended for self-use in public areas.
* This device is portable, but it is not intended for use during patient transport.
* This device is not suitable for continuous monitoring during medical emergencies or operations.
* This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than the arm, or for any purpose other than obtaining a blood pressure measurement.
* This device is for adults. Do not use this device on neonates or infants.
* Consult with your physician before using this monitor if you suffer from the following conditions: common arrhythmias such as premature ventricular beats or atrial fibrillation; peripheral arterial disease; pregnancy; preeclampsia; implantation with electrical devices; undergoing intravascular therapy; arteriovenous shunt or mastectomy. Please note that any of these conditions may affect measurement readings, in addition to patient motion, trembling or shivering.
* Do not use this device for diagnosis or treatment of any health problems or diseases. Please consult with your physician first whether the blood pressure or pulse rate readings can be used as an input in determining clinical actions. Please note that clinical actions can only be determined by the physician, otherwise it may lead to delayed treatment or other dangerous situations.
* If you are taking medication, consult your physician to determine the proper time to measure your blood pressure.
* This device may be used only for the intended use described in this manual, the manufacturer shall have no liability for any incidental, consequential, or special damages caused by misuse or abuse.
* Please use the device under the environment which is provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
* The device may require up to 30 minutes to warm up / cool down from the minimum/ maximum storage temperature before it is ready for use.
* The blood pressure monitor, and the cuff are suitable for use within the patient environment.
* Do not wash the cuff in a washing machine or dishwasher !
* The device contains sensitive electronic components. To avoid measurement errors, avoid taking blood pressure measurements near a strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* Wireless communication equipment, such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies may cause interference that may affect the accuracy of measurements. A minimum distance of 1 foot (30 cm) should be kept from such devices during a measurement.
* Blood Pressure Monitor is intended for use by medical staffs and lay persons, and patient is also an intended user or operater.

⚠ Caution

* Do not attempt to repair the unit yourself if it malfunctions. Only have repairs carried out byauthorized service centers.
* It is recommended that the performance should be checked after repair, maintenance, and every two years of use, by retesting the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg). Please contact manufacturer or distributor for authorized service personnel.
* Store your device, cuff in a clean and dry place, protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on it.
* Make sure the rubber tube of the cuff is not squeezed, stretched, or kinked during storage.
* Dispose of accessories, detachable parts, and the device according to the local guidelines.

Warning

* Do not apply the cuff on an arm that has an intravenous drip or a blood transfusion attached.
* Do not kink, fold, stretch, compress, or otherwise deform the tube during measuring, as the cuff pressure might continuously increase, which could prevent blood flow and result injury.
* Taking blood pressure measurements too frequently could disrupt blood circulation and cause injuries.
* Do not apply cuff to areas on patient where skin is delicate or damaged. Check cuff site frequently for irritation.
* Do not place the cuff on the arm of a person whose arteries or veins are undergoing medical treatment, i.e. intra-vascular access or intra-vascular therapy or an arteriovenous (A-V) shunt, which could disrupt blood circulation and cause injuries.
* Do not place the cuff on the arm on the same side of a mastectomy (especially when lymph nodes have been removed). it is recommended to take measurements on the unaffected side.
* Do not wrap the cuff on the same arm to which another monitoring device is applied. One or both devices could temporarily stop functioning if you try to use them at the same time.
* Please check (for example, by observation of the limb concerned) that the operation of the device does not result in prolonged impairment of patient blood circulation.
* On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, loosen and remove the cuff immediately. Prolonged high pressure applied to the arm (cuff pressure >300 mmHg or constant pressure >15 mmHg for more than 3 minutes) might lead to bruising and discolored skin.
* Do not use this device with high-frequency (HF) surgical equipment at the same time.
* This device is not used in conjunction with oxygen rich environments, not intended for use with flammable anaesthetics, not intended for use in conjunction with flammable agents.
* Do not touch output of the batteries and the user simultaneously.
* The power cord is considered the disconnect device for isolating this equipment from supply mains. Do not position the equipment so that it is difficult to reach or disconnect.
* Do not use this device if you are allergic to polyester, nylon, or plastic.
* Only use accessories approved by manufacturer. Using unapproved accessories might cause damage to the unit and injure users.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the Power button immediately to release the air from the cuff.
* Do not use the device while under maintenance, or being serviced.
* The air tube poses a risk of strangulation. Furthermore, the small parts of product and batteries present a choking hazard if swallowed. They should therefore always be kept away from infants/children.
* Sensor degradation or looseness may reduce performance of device or cause other problems.

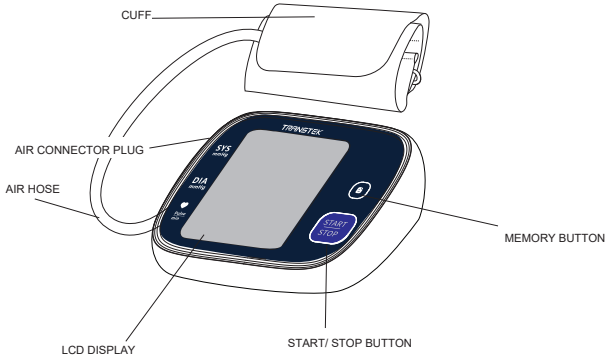
Notice

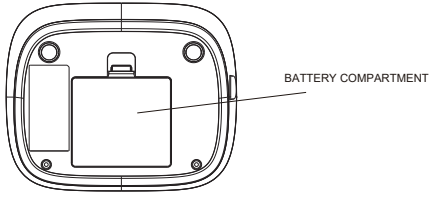
* You can use this device to take your own measurement, no third-party operator is required.
* At the request of authorized service personnel, circuit diagrams, component part lists, descriptions, and calibration procedures will be made available by the manufacturer or distributor.
* The expected lifetime of the cuff may vary by the frequency of washing, skin condition, and storage state.
* Please report to the manufacturer and the competent authority of the Member State / the FDA in which you are established about any serious incident that has occurred in relation to this device.

♥ LCD display signal

SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic blood pressure	High pressure result
DIA	Diastolic blood pressure	Low pressure result
Pulse min	Pulse display	Pulse in beats per minute
mmHg	mmHg	Measurement unit of blood pressure
	Blood pressure level	Indicate blood pressure level
M D Yr	Current Time	Time(year:month:day:hour:minute)
	Pulse rate	Pulse rate dectetion during measurement
	Hand shaking	Hand shaking makes results inaccurate
	Battery Indicator	Indicate the current battery
	Irregular pulse rate	Irregular pulse rate
M	Memory Query	Indicate it is in the memory mode and which group of memory it is.
AVG	Average sign	The average of the last 3 measurements (within 30 minutes)
OK	Cuff wearing	The cuff is secured
	Bluetooth icon	Indicate the bluetooth is working
	Data transmitting	Data is transmitting

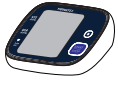
♥ Monitor Components





♥ List

1.Blood Pressure Monitor (BBZ32-BB01)



2.Cuff (Type BF applied part)

Upper arm cuff:22-32cm or
Upper arm cuff:22-42cm

3. 4×AAA batteries

4. User manual

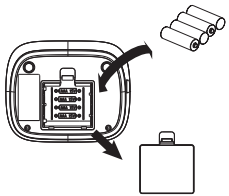
♥ Choice of Power Supply

1.Battery powered mode:
6VDC 4×AAA batteries

> ⚠ CAUTION
> In order to get the best effect and protect your monitor,please use the right battery which complies with local safety standard.

♥ Installing and Replacing the Batteries

- Open the battery cover.
- Install the batteries by matching the correct polarity, as shown.
- Replace the battery cover.



Replace the batteries whenever the below happen

- The bAt Lo + shows
- The display is dim.
- The display does not light up

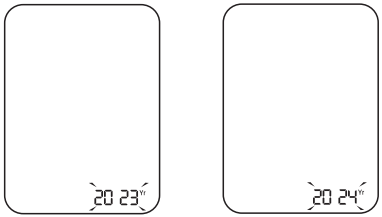
> ⚠ CAUTION
> - New and used batteries, or different types of batteries shall not be used together.
> - Remove batteries if the device is not likely to be used for some time.
> - Do not heat or deform the batteries, or dispose of them in fire.
> - Batteries should not be disposed of with household waste.
> - Please check with your local authority for battery recycling advice.

♥ Setting Date and Time

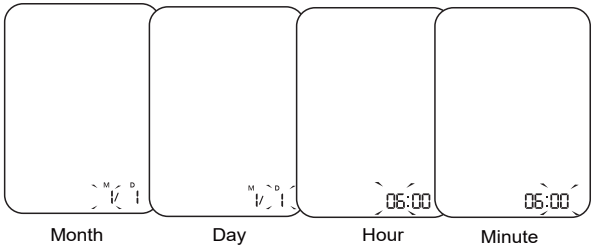
It is important to set the clock before using your blood pressure monitor, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year :2023—2053 time format: 12H/24H)

1 When the device is powered on for the first time, short press the "Power" button to automatically enter the setting mode.
(Or when the power is turned off, long press the "MEMORY" button and "START/STOP" button to enter the setting mode)

First set the year, [Year] will flash,
Press and hold the “Memory” button to quickly advance the years.



2. Press the “START/STOP” button to confirm the year, then the [month] will flash. Repeat the same steps to change the month, day, hour and minute.



3. After the [Minute] is set,the LCD will display “ OK”, and then it will turn off automatically.

Note:
If you want to interrupt the setting at any step during the setting process, short press the “START/STOP” button or do not press any button and it will automatically shut down after 30 seconds.
The set data will be automatically saved and the machine will shut down.

♥ Pair a smart device with the monitor

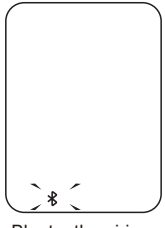
You are the intended operator of this blood pressure monitor. You can measure your blood pressure and then save and send measurement data to a smart device (such as smartphone or tablet) with Bluetooth wireless connectivity and application.

1. **Turn on the Bluetooth and the app on your smart device.**
   Make sure both are ON when pair-up is proceeding.

2. **When the monitor is off, press and hold the “START/STOP” button to start pair-up**, **the bluetooth symbol will flash.**

3. **If successful**, the bluetooth symbol will not flash any more the LCD will display “ OK”, and the monitor will automatically shut off after several seconds.

   Note
   The date and time on your monitor will automatically be set after paired with your smart device successfully.



Bluetooth pairing

Bluetooth pairing successful

If unsuccessful within 60 seconds, it is judged timeout and the monitor will shut off.

Specifications for Bluetooth Transmission		
Bluetooth	Throughput	2.5K-5K
	Latency	50ms
	PER	＜10%
	Operating Frequency	2402-2480MHz
	Transmission Power	0±2dBm
	Transmission Distance	10m

Note:
1. The necessary Quality of Service (QoS) is fully considered here for wirelessly enabled functions.
2. Interference may occur in the vicinity of equipment marked with the following symbol . And BBZ32-DB01 may interfere the vicinal electrical equipment.
3. Keep the monitor at least 20 centimeters away from the human body (especially the head) when data transmission is proceeding after measurement.
4. To enable the data transmission function, this device shall be paired to an appropriate BT mobile terminal.

Warning

About a wireless communication interference

The monitor operates in the unlicensed ISM band at 2.4 GHz. In case it is used around the other wireless devices including microwave and wireless LAN, which operate at the same frequency band as the monitor, there is a possibility that interference occurs between the monitor and such other devices. If such interference occurs, please stop the operation of other devices or relocate the monitor before using it or do not use it around the other wireless devices.

List of compatible devices:

For iOS devices:
The operating system must be iOS 13.0 or more.

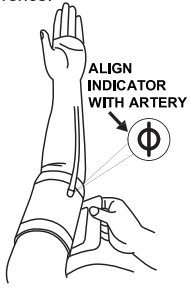
For Android devices:

The operating system must be Android 5.0 or more.

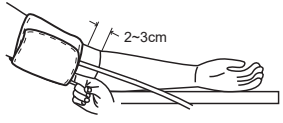
♥ Applying the cuff

Only use a cuff that has been approved by the manufacturer for this device model. Before use, please confirm if it fits your arm circumference.

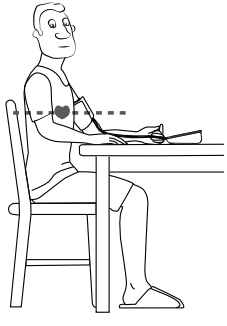
1. **Remove all jewelry, such as watches and bracelets from your left arm.**
   Note: If your doctor has diagnosed you with poor circulation in your left arm, use your right arm.
2. **Roll or push up your sleeve to expose the skin. Make sure your sleeve is not too tight.**
3. **Hold your arm with your palm facing up and tie the cuff on your upper arm, align the Artery indicator ϕ with the main Artery (on the inside of your arm).**
   Note: Locate the main Artery by pressing with 2 fingers approximately 2 cm above the bend of your elbow on the inside of your left arm. Identify where the pulse can be felt the strongest, that is your main Artery!



4. **Make sure the bottom edge of the arm cuff 2 to 3 cm above the inside elbow. Then wrap the cuff securely.**
   Note: The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.



5. **Sit upright in a comfortable chair with your back against the backrest of the chair. Keep your feet flat and your legs uncrossed.**
   Place your arm resting comfortably on a flat table. The cuff worn on your arm should be placed at the same level as your right atrium of the heart.



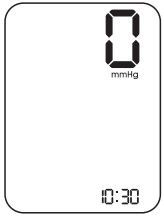
6. **Take 5-6 deep breaths and let's start measuring!**

Helpful tips:

- Take the measurement in a silent room.
- Rest for 5 minutes before a measurement.
- Wait at least 3 minutes before another measurement. This allows your blood circulation to recover.
- Be relaxed and do not move and talk during the measurement procedure.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, on the same arm, or as directed by a physician.

♥ Start the Measurement

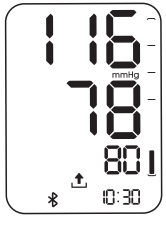
1. When the monitor is OFF, press the “START/STOP” button, it will finish the whole measurement automatically, save and transmit the measurement data.



Adjust the zero.
(Bluetooth not paired)

Cuff wrap detection.
symbol “ ” flash
(Bluetooth not paired)

Cuff wrap ok.
Inflating and measuring.
(Bluetooth is paired)

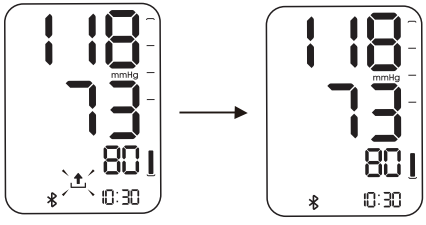


Display and save the measurement result
(Bluetooth is paired)

2. After the measurement was finished, the bluetooth symbol “ ” blinks and data transmission starts. (Please connect the app during the transmission)

If data transmission successful, the symbol “ ” will not blink and “ ” will disappear, after sevral seconds, “ ” will also disappear, and then the monitor will turn off automatically after about 1 minute.

If unsuccessful within 60 seconds, it is judged timeout and the monitor will shut off.



Transmission successful.

3. Press “START/ STOP” button to turn off, otherwise it will turn off automatically.

Note

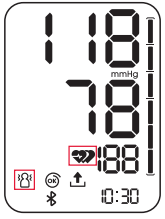
1. Any time if you want to stop the measurement, you can press the “START/ STOP” button manually.
2. When the selected user has history memory record, the monitor will display its last measurement record first before starting measurement.

3. About the irregular pulse rate and excessive body motion during the measurement.

- During a measurement, If an irregular pulse rate is detected, the symbol will display in the measurement result. See page 23 for more information.
- During a measurement, when the excessive body motion, especially of the arm the cuff is worn is detected, the symbol will flash about 5 seconds and detect again. If it is no longer detected, the symbol will disappear; If still detected, the symbol will final display in the measurement result.

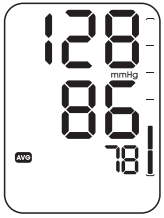
Note

The measured blood pressure reading may not be accurate if this symbol is displayed.



♥ Recall the Records

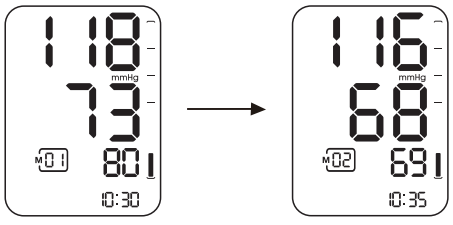
1. When the monitor is off, press the “MEMORY” button ,it displays the average of the three measurements within the last 30 minutes, with the average symbol.



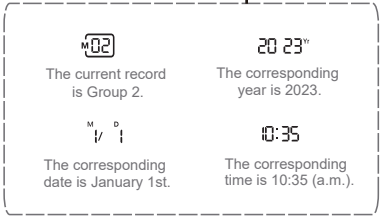
Note

- If there are not enough 3 records within 30 minutes, after entering the memory mode, the most recent measurement record will be directly displayed.

2. Press the “MEMORY” button to display the next record.



Date,Time and Year will display alternately.



Note

- Each new measurement is assigned to the first (1) record. All other records are pushed back one digit (e.g., 2 becomes 3, and so on), and the last record (99) is dropped from the list.

♥ Delete the Records

you can delete all results by following steps below.

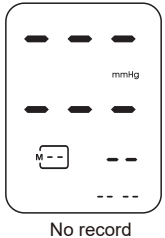
1. Enter the memory recall mode as described in section [Recall the Records].
2. Press and hold “SETTINGS” button and “START/STOP” button for 3 seconds, and the display will show a blinking “dEL ALL” along .
3. Use the “UP” or “DOWN” button to switch between “dEL ALL” and “dEL no”, Press “START/STOP” to confirm the selection.

If “dEL ALL” is selected, will delete all the record of the current user. Several seconds later, it will display “---”.

If “dEL no” is selected, it will stop the deletion.

“dEL ALL” blinks

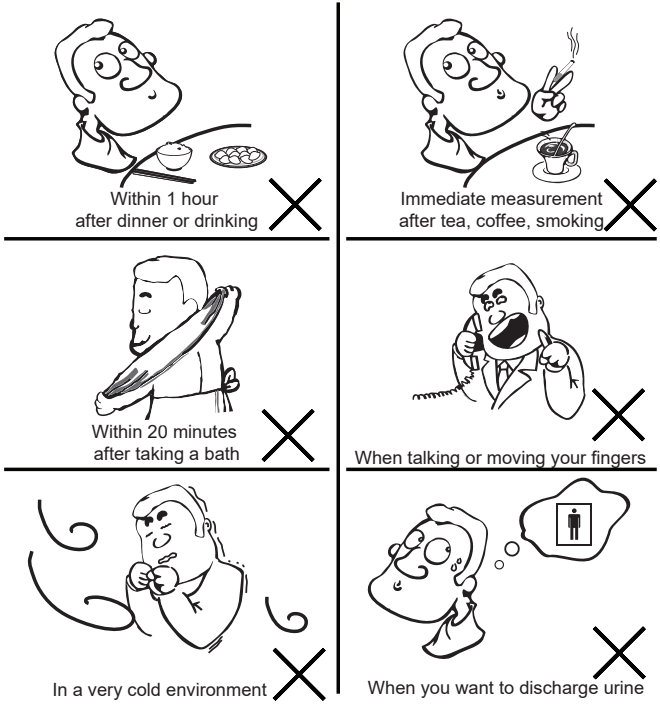
“dEL no” blinks



No record

♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.



♥ Maintenance

In order to get the best performance, please follow the instructions below.

1. Cleaning Process:

Step 1: Make sure to switch off and unplug the device prior to cleaning.
Step 2: Use a soft cloth wetted with soapy water to clean the cuff first, and then use a soft cloth wetted with clear water to remove residual soap until there is no visible residual contaminants. Attention shall be paid to avoid liquid invasion into the cuff.
Step 3: Use a dry soft cloth to wipe the cuff, in order to remove residual moisture.
Step 4: Dry the cuff at a well-ventilated place after cleaning.

2. Disinfection Process:

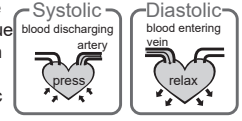
Step 1: Make sure to switch off and unplug the device prior to disinfection.
Step 2: Use a soft cloth wetted with 70% isopropanol to disinfect the cuff for about 10 minutes. Attention shall be paid to avoid liquid invasion into the cuff.
Step 3: Use a clean dry cloth or towel to wipe off the disinfectant until there is no visible residue.
Step 4: Dry the cuff at a well-ventilated place after disinfection.

- **Suggestion:**

Frequency of Cleaning and Disinfection:
For single patient multiple use, it's recommended to clean the device surface once a month or whenever it's necessary.
For multiple patient multiple use, it's recommended to clean the device every time before and after usage. Maintenance procedures shall be taken as per instruction.

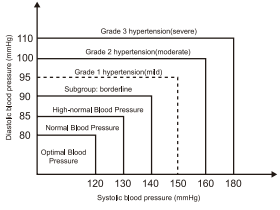
♥What are systolic pressure and diastolic pressure?

When ventricles contract and pump blood out of the heart, the blood pressure reaches its maximum value in the cycle, which is called systolic pressure. When the ventricles relax, the blood pressure reaches its minimum value in the cycle, which is called diastolic pressure.



♥What is the standard blood pressure classification?

The blood pressure classification published by World Health Organization (WHO) and International Society of Hypertension (ISH) in 1999 is as follows:



⚠ CAUTION

Only a physician can tell your normal BP range. Please contact a physician if your measuring result falls out of the range. Please note that only a physician can tell whether your blood pressure value has reached a dangerous point.

Blood Pressure (mm Hg) \ Level	Optimal	Normal	High-normal	Mild	Moderate	Severe
SYS	<120	120-129	130-139	140-159	160-179	≥180
DIA	<80	80-84	85-89	90-99	100-109	≥110

♥Irregular Pulse Rate Detector

An irregular pulse rate will be detected if there is an irregular pulse rhythm while measuring systolic and diastolic blood pressure. When measurements were performed, the monitor will record all pulse intervals and calculate the average. If two or more pulse intervals were recorded, and the difference between each interval and the average is larger than ±25% of the average; or if four or more pulse intervals were recorded, and the difference between each interval and the average is larger than ±15% of the average value, the irregular pulse symbol will be displayed along with measurement results.

⚠ CAUTION

The appearance of the IPR icon indicates that a pulse irregularity consistent with an irregular pulse rate was detected during measurement. Usually this is NOT a cause for concern. However, if the symbol appears often, we recommend you seek medical advice. Please note that the irregular pulse rate detector results cannot be used directly for clinical judgement. Please seek medical advice from professionals before making any medical decisions.

♥Why does my blood pressure fluctuate throughout the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.

2.If the person takes medicine, the pressure will vary more.

3.Wait at least 3 minutes for another measurement.

♥Why do I get a different blood pressure at home compared to the hospital?

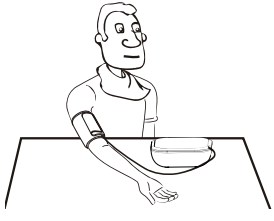
The blood pressure is different even throughout the day due to weather, emotion, exercise etc. Also, there is the “white coat” effect, which means blood pressure usually increases in clinical settings.

What you need to pay attention to when you measure your blood pressure at home:

If the cuff is tied properly.
If the cuff is too tight or too loose.
If the cuff is tied on the upper arm.
If you feel anxious.
Taking 2-3 deep breaths before beginning will be better for measuring.
Advice: Relax for 4-5 minutes until you calm down.

♥Is the result the same if measuring on the right arm?

It is ok for both arms, but there will be some different results for different people. We suggest you measure the same arm every time.



If any abnormality arises during use, please check the following points:

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display can not light up.	Batteries are depleted.	Replace with new batteries.
		Batteries are inserted incorrectly.	Insert the batteries correctly.
High Battery	bAt H shows	The battery is too high.	Replace with the correct DC plug.
Low Battery	bAt Lo& shows	The battery is too low.	Replace with new batteries.
Error message	E 1 shows	The cuff is not wrapped or wrapped incorrectly, or the cuff air plug is loose.	Refasten the cuff and insert air tube plug correctly then measure again.
	E 2 or shows	Excessive body motion (such as shaking of the arm with the cuff on) or weak Pulse is detected.	Relax for 5 minutes. and then keep still, measure again.
	E 3 shows	Pulse is not detected during measuring.	Loosen the clothing on the arm and measure again.
	E 4 shows	The measurement failed.	Relax for 5 minutes and measure again.
	EExx shows	A calibration error occurred (XX can be some digital symbol, such as 01, 02,etc., if this similar situation appear, all belong to calibration error.)	Retake the measurement.If the problem persists, contact the retailer or our customer service department for further assistance. Refer to the warranty for contact information and return instructions.
Warning message	out shows	Out of measurement range	Relax for a moment and then measure again. If the problem persists, contact your physician.

NOTE: If the product still does not work, contact Customer Service. Under no circumstance should you disassemble or attempt to repair the unit by yourself.

Power supply	Battery powered mode: 6VDC 4×AAA batteries
Display mode	Digital LCD V.A.74.5mm × 54.7mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg Measurement pressure: SYS: 55mmHg~255mmHg DIA: 25mmHg~200mmHg Pulse value: (40-199)beat/minute
Accuracy	Static Pressure: 5℃-40℃ within ±3mmHg Pulse value: ±5% Clinical validation: Mean difference within ±5mmHg; Standard deviation ≤8mmHg
Normal working condition	A temperature range of: +5°C to +40°C A relative humidity range of 15% to 90%, non-condensing, but notrequiring a water vapour partial pressure greater than 50 hPa An atmospheric pressure range of 700 hPa to 1060 hPa
Storage & transportation condition	Temperature:-20°C to +60°C A relative humidity range of ≤ 93%, non-condensing, at a water vapour pressure up to 50 hPa An atmospheric pressure range of 500 hPa to 1060 hPa
Measurement perimeter of the upper arm	About 22cm~32cm or 22cm~42cm
Weight	Approx.211g (Excluding the batteries and cuff)
External dimensions	Approx.121.3mm × 98.8mm × 42.3mm
Attachment	4×AAA batteries,User manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21 It means the device could be protected against solid foreign objects of 12,5mm Φ and greater, and against vertically falling water drops.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment
Software Version	A01
Expected Lifetime	Device: 3 years or 30,000 measurements (may vary based on usage conditions) Cuff: 10000 times Alkaline battery: About 200-300 times
Types of use/reuse	Multiple patient multiple use

WARNING: No modification of this equipment is allowed.

♥ Contact Information

For more information about our products, please visit www.transtekcorp.com.

Manufactured by: Guangdong Transtek Medical Electronics Co., Ltd.

Company: Guangdong Transtek Medical Electronics Co., Ltd.

Address: Zone A, No.105, Dongli Road, Torch Development District, 528437 Zhongshan, Guangdong, China

♥ EMC Guidance

The ME EQUIPMENT or ME SYSTEM is suitable for home healthcare environments.

Essential performance:
Accuracy of measuring blood pressure and pulse rate

Measurement Range	Systolic pressure: 55-255 mmHg Diastolic pressure: 25-200 mmHg Pulse: 40-199 beats/minute
Rated Cuff Pressure	0-299 mmHg (0-39.9 kPa)
Accuracy	Pressure: ±3 mmHg / 0.4 kPa Pulse: ±5%

The Basis Safety of the Blood Pressure Monitor (BBZ32-DB01) is as following: Deviation from normal operation that poses an unacceptable risk to the patient or operator.

Warning: Don't be near the active HF surgical equipment and the RF shielded room of an ME system for magnetic resonance imaging, where the intensity of EM disturbances is high.

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.

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.

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

Technical description:

1. All necessary instructions for maintaining BASIC SAFETY and ESSENTIAL PERFORMANCE with regard to electromagnetic disturbances for the expected lifetime.

2. Guidance and manufacturer's declaration-electromagnetic emissions and Immunity.

Table 1

Guidance and manufacturer's declaration - electromagnetic emissions	
Emissions test	**Compliance**
RF emissions CISPR 11	Group 1
RF emissions CISPR 11	Class [B]
Harmonic emissions IEC 61000-3-2	Not applicable
Voltage fluctuations / flicker emissions IEC 61000-3-3	Not applicable

Table 2

Guidance and manufacturer's declaration – electromagnetic Immunity		
Immunity Test	IEC 60601-1-2 Test level	Compliance level
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV air
Electrical fast transient/burst IEC 61000-4-4	Not applicable	Not applicable
Surge IEC61000-4-5	Not applicable	Not applicable
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	Not applicable	Not applicable
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz / 60 Hz	30 A/m 50 Hz / 60 Hz
Conduced RF IEC61000-4-6	Not applicable	Not applicable
Radiated RF IEC61000-4-3	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz	10 V/m 80 MHz – 2,7 GHz 80% AM at 1 kHz
NOTE U_T is the a.c. mains voltage prior to application of the test level.		

Table 3

Guidance and manufacturer's declaration - electromagnetic Immunity								
Radiated RF IEC61000-4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communicati-ons equipment)	Test Frequency (MHz)	Band (MHz)	Service	Modulation	Maximum Power (W)	Distance (m)	IEC 60601-1-2 Test Level (V/m)	Compliance level (V/m)
	385	380-390	TETRA 400	Pulse modulation 18 Hz	1.8	0.3	27	27
	450	430-470	GMRS 460, FRS 460	FM ± 5k Hz deviation 1 kHz sine	2	0.3	28	28
	710	704-787	LTE Band 13, 17	Pulse modulation 217 Hz	0.2	0.3	9	9
	745							
	780							
	810	800-960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation 18 Hz	2	0.3	28	28
	870							
	930							
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation 217 Hz	2	0.3	28	28
	1845							
	1970							
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7	Pulse modulation 217 Hz	2	0.3	28	28
	5240	5100-5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9	9
	5500							
	5785							

♥ FCC Statement

FCC ID: OU9BBZ32-AA01

This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions:
(1) This device may not cause harmful interference, and
(2) this device must accept any interference received, including interference that may cause undesired operation.

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

This equipment has been tested and found to comply with the limits for a Class B digital device, pursuant to Part 15 of the FCC Rules. These limits are designed to provide reasonable protection against harmful interference in a residential installation. This equipment generates, uses and can radiate radio frequency energy and, if not installed and used in accordance with the instructions, may cause harmful interference to radio communications. However, there is no guarantee that interference will not occur in a particular installation.
If this equipment does cause harmful interference to radio or television reception, which can be determined by turning the equipment off and on, the user is encouraged to try to correct the interference by one or more of the following measures:
-- Reorient or relocate the receiving antenna.
-- Increase the separation between the equipment and receiver.
-- Connect the equipment into an outlet on a circuit different from that to which the receiver is connected.
-- Consult the dealer or an experienced radio/TV technician for help.

RF Exposure Compliance
This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment. This transmitter must not be co-located or operating in conjunction with any other antenna or transmitter.

ISED ID (IC ID)

IC: 12725A-BBZ32-AA01

This device contains licence-exempt transmitter(s)/receiver(s) that comply with Innovation, Science and Economic Development Canada's licence-exempt RSS(s). Operation is subject to the following two conditions:

(1) This device may not cause interference.

(2) This device must accept any interference, including interference that may cause undesired operation of the device.

L'émetteur/récepteur exempt de licence contenu dans le présent appareil est conforme aux CNR d'Innovation, Sciences et Développement économique Canada applicables aux appareils radio exempts de licence. L'exploitation est autorisée aux deux conditions suivantes :

1) L'appareil ne doit pas produire de brouillage;

2) L'appareil doit accepter tout brouillage radioélectrique subi, même si le brouillage est susceptible d'en compromettre le fonctionnement.

ISED Radiation Exposure statement

This equipment complies with IC RSS-102 radiation exposure limits set forth for an uncontrolled environment. This equipment should be installed and operated with minimum distance 5 mm between the radiator and your body.