SALTER®

SINCE 1760

AUTOMATIC ARM BLOOD PRESSURE MONITOR

Instructions and Guarantee

Register your product today at
www.salterhousewares.com.au

INTRODUCTION

General Description

Thank you for selecting Salter arm type blood pressure monitor. The monitor features blood pressure measurement, pulse rate measurement and the result storage. The design provides you with two years of reliable service. Readings taken by the blood pressure monitor 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:

- 73 mm × 49 mm Blue LCD display with white backlight
- Technology 60 records per each user, except user Guest
- 3rd technonoly: Measuring during inflation

Indications for Use

The Salter Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22 cm to 42 cm (about 8 ¾″-16 ½″).

It is intended for adult indoor use only.

Contraindications

1. The device is not suitable for use on may be pregnant women or pregnant women.
2. The device is not suitable for use on patients with implanted, electronical devices, such as cardiac pacemakers, defibrillators.

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 air 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.

Safety Information

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

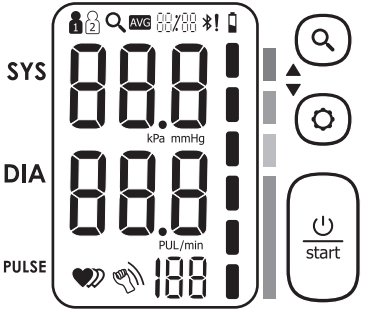
	Symbol for "THE OPERATION GUIDE MUST BE READ"		Symbol for "TYPE BF APPLIED PARTS
CE 0123	Symbol for "COMPLIES WITH MDD 93/42/EEC REQUIREMENTS"		Symbol for "ENVIRONMENT PROTECTION – Waste electrical products should not be disposed of with household waste. Please follow local guidelines.
	Symbol for "MANUFACTURER"		
SN	Symbol for "SERIAL NUMBER"	EC REP	Authorized Representative in the European Community
	Symbol for "DIRECT CURRENT"		
	Symbol for "MANUFACTURE DATE"		
	Caution: These notes must be observed to prevent any damage to the device		

⚠ CAUTION

* This device is intended for adult use only. It is not intended for use with neonatal patients, pregnant or pre-eclamptic patients.
* The device is not intended for patient transport outside a healthcare facility.
* The device is not intended for public use.
* This device is intended for no-invasive measuring and monitoring of arterial blood pressure.
It is not intended for use on extremities other than the arm or for functions other than obtaining a blood pressure measurement.
* Do not confuse self-monitoring with self-diagnosis. This unit allows you to monitor your blood pressure. Do not begin or end medical treatment without asking a physician for treatment advice.
* If you are taking medication,consult your physician to determine the most appropriate time to measure your blood pressure. Never change a prescribed medication without consulting your Physician.
* When the device was used to measure patients who have common arrhythmias such as atrial or ventricular premature beats or atrial fibrillation, the best result may occur with deviation. Please consult your physician about the result.
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressure reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
* The equipment is not AP/APG equipment and not suitable for use in the presence of a flammable anesthetic mixture with air of with oxygen or nitrous oxide.
* The operator shall not touch output of batteries /adapter and the patient simultaneously.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/ burst signal.
* The user must check that the equipment functions safely and see that it is in proper working condition before being used.
* This device is contraindicated for any female who may be suspected of, or is pregnant. Besides providing inaccurate readings, the effects of this device on the fetus are unknown.
* Manufacturer will make available on request circuit diagrams, component parts list etc.
* This unit is not suitable for continuous monitoring during medical emergencies or operations. Otherwise, the patient's arm and fingers will become anaesthetic, swollen and even purple due to a lack of blood.
* Please use the device under the environment which was provided in the user manual. Otherwise, the performance and lifetime of the device will be impacted and reduced.
* During use, the patient will be in contact with the cuff. The materials of the cuff have been tested and found to comply with requirements of ISO 10993-5:2009 and ISO 10993-10:2010. It will not cause any potential sensization or irritation reaction.
* Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE. Otherwise, it may cause damage to the unit or danger to the user/patients.
* The device doesn't need to be calibrated within two years of reliable service.
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Salter. Don't open or repair the device by yourself.
* Please report to Salter if any unexpected operation or events occur.
* Please use the soft cloth to clean the whole unit. Don't use any abrasive or volatile cleaners.
* **Warning:** No servicing/maintenance while the ME equipment is in use.
* The patient is an intended operator. The patient can measure,transmit data and change battery under normal circumstances and maintain the device and its accessories according to the user manual.
* Adaptor is specified as a part of ME EQUIPMENT.
* The plug/adapter plug pins insulates the device from the main supply. Do not position the device in a position where it is difficult to disconnect from

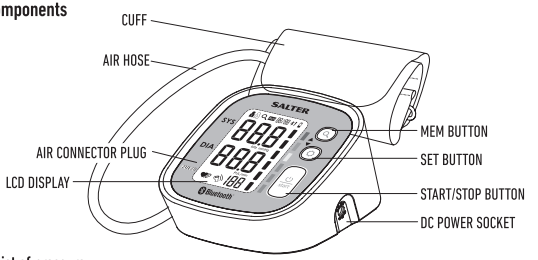
the supply mains to safely terminate operation of ME EQUIPMENT.
* Before every use, check the device, do not use the device or an electrode if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
* Be careful to strangulation due to cables and hoses, particularly due to excessive length.
* Keep unit out of the reach of young children / pets to avoid inhalation or swallowing of small parts. The cord/tube can cause strangulation.
* At least 30 min required for ME equipment to warm from the minimum storage temperature between uses until it is ready for intended use. At least 30 min required for ME equipment to cool from the maximum storage temperature between uses until it is ready for intended use.
* When not in use, store the device with the adapter in a dry room and protect it against extreme moisture, heat, lint, dust and direct sunlight. Never place any heavy objects on the storage case.
* Warning: Be careful to regarding the effect of blood flow interference and resulting harmful injury to the patient caused by continuous cuff pressure due to connection tubing.
* When using this device, please pay attention to the following situation which may interrupt blood flow and influence blood circulation of the patient, thus cause harmful injury to the patient: connection tubing kinking too frequent and consecutive multiple measurements; the application of the cuff and its pressurization on any arm where intravascular access or therapy, or an arterio-venous (A-V) shunt, is present; inflating the cuff on the side of a mastectomy.
* **Warning:** Do not apply the cuff over a wound;otherwise it can cause further injury.
* Do not inflate the cuff on the samb limb which other monitoring ME equipment is applied around simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME equipment.
* Please check that operation of the device does not result in prolonged impairment of patient blood circulation.
* When measurement, please avoid compression or restriction of the connection tubing.
* The device cannot be used with HF surgical equipment at the same time.
* The ACCOMPANYING DOCUMENT shall disclose that the SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.
* To verify the calibration of the AUTOMATED SPHYGMOMANOMETER, please contact the manufacturer.
* This device may be used only for the purpose described in this booklet. The manufacturer cannot be held liable for damage caused by incorrect application.
* This device comprises sensitive components and must be treated with caution. Observe the storage and operating conditions described in this booklet.
* Do not wash the cuff in a washing machine or dishwasher!
* It is recommended that the performance should be checked every 2 years and after maintenance and repair, by retesting at least the requirements in limits of the error of the cuff pressure indication and air leakage (testing at least at 50 mmHg and 200 mmHg).
* There is no luer lock connectors are used in the construction of tubing, there is a possibility that they might be inadvertently connected to intravascular fluid systems, allowing air to be pumped into a blood vessel.
* This equipment needs to be installed and put into service in accordance with the information provided in the ACCOMPANYING DOCUMENTS;
* Wireless communications equipment such as wireless home network devices, mobile phones, cordless telephones and their base stations, walkie-talkies can affect this equipment and should be kept at least a distance d away from the equipment. The distance d is calculated by the MANUFACTURER from the 80 MHz to 5.8 GHz column of Table 4 and Table 9 of IEC 60601-1-2:2014, as appropriate.

LCD display signal



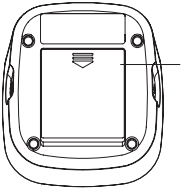
SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic pressure	High blood pressure
DIA	Diastolic pressure	Low blood pressure
PUL/min	Pulse display	Pulse in beats per minute
	Memory	Indicate it is in the memory mode and which group of memory it is.
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
Lo+	Low battery	Batteries are low and need to be replaced
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
	Blood pressure level indicator	Indicate the blood pressure level
88:88	Time	Year/Month/Day, Hour:Minute
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
1	User 1	Start measurement,save and transmit the measuring results for User 1
2	User 2	Start measurement, save and transmit the measuring results for User 2
	Motion indicator	Motion may result in an inaccurate measurement
AVG	Average value	The average value of blood pressure
	Bluetooth icon	Indicate the Bluetooth is working
!	Data storage	Indicate the data is waiting to be transmitted

Monitor Components



Component list of pressure measuring system

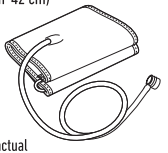
1 Cuff
2 Air pipe
3 PCBA
4 Pump
5 Valve



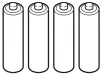
List

1. Blood pressure monitor

2. Cuff (Type BF applied part) 22 cm-42 cm)



3. 4 × AA alkaline batteries

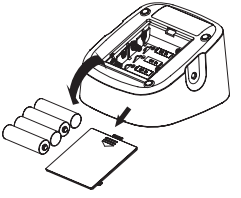


4. User manual

(Please use Salter Authorized cuff. The size of the actual cuff please refer to the label on the attached cuff.)

Installing and Replacing the Batteries

- Open the battery cover.
- Install the batteries as indicated in the battery compartment. (Always select the authorized / specified battery: Four AA-size alkaline batteries).
- Replace the battery cover.



Replace the batteries under the following circumstances:

- Lo + displays on the LCD
- The LCD display is dim
- When powering on the monitor, the LCD doesn't light up.

CAUTION

- Do not use new and used batteries together.
- Do not use different types of batteries together.
- Do not dispose the batteries in fire. Batteries may explode or leak.
- Remove batteries if the device is not likely to be used for some time.
- Worn batteries are harmful to the environment. Do not dispose with daily garbage.
- Remove the old batteries from the device following your local recycling guidelines.

MIBODY APP

Before using your device for the first time:

1. Download and install the Salter MiBody App from the App store. Use keyword search terms "Salter" or "MiBody"
2. Turn Bluetooth "On" in the "Settings" menu of your iPhone/iPad.
3. Open the MiBody App and follow the on screen instructions to set up your user account.

PAIRING DEVICES

1. Turn Bluetooth "On" in the "Settings" menu of your mobile device.
2. Open the MiBody App.
3. Press the ⋮ button.
4. Press "Add Device".
5. When the blood pressure monitor is off press and hold the START STOP button until "⧉" is displayed on the screen.
6. The App should automatically find the blood pressure monitor. If not, just press the ↻ to find the blood pressure monitor.
7. Once found, Select the user number you wish to pair. Touch the OK button to finish.
8. If pairing is successful ᛒ will be displayed.
9. If pairing is unsuccessful E12 will be displayed.
10. The blood pressure monitor will automatically switch off.
11. Repeat procedure for each user and each mobile device.

Note: Each user number can only be paired with one mobile device. Results will be sent to the paired device only.

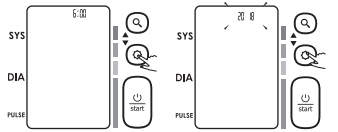
SETTING DATE, TIME AND MEASUREMENT UNIT

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: 2018—2058 time format: 24H)

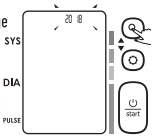
1. When the monitor is off, press "☼"button,it will display the time. Then press and hold "☼" button to enter the mode for year setting.

Notes:

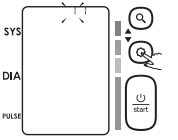
1. During the process of setting, you can press "⏻ start" button to stop setting at any time.
2. If there is no operation during the process of setting, it will turn off within 1 minute).



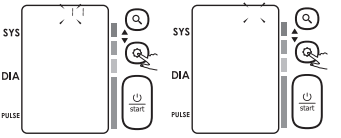
2. Press "☼" button to change the [YEAR]. Each press will increase the digit by one in a cycling manner. If you hold pressing "☼" button, the digit will increase quickly.



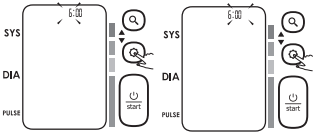
3. When you get the right year, press "☼" button to set down and turn to next step.



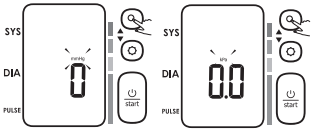
4. Repeat steps 2 and 3 to set the [MONTH] and [DAY].



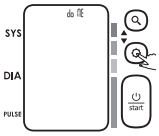
5. Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].



6. Repeat steps 2 and 3 to set the [UNIT].



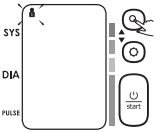
7. After the unit is set, the LCD will display "done" first, then display all the settings you have done and then turn off.



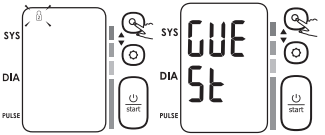
BEFORE YOU START

Select the User

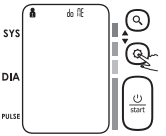
1. When the monitor is off, press and hold "🔍" button to enter user setting mode. The user ID will blink.



2. Then press "🔍" button again, select the user ID among user 1, user 2 and guest.

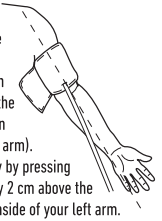


3. When the suitable user ID blinks, press "☼" button to confirm. It will display User ID+ donE" and then turn off.



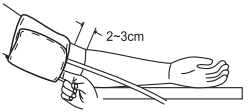
MEASUREMENT

Tie the Cuff



1. Tie the cuff on your upper arm, then position the tube off-center toward the inner side of arm in line with the little finger. Or position the artery mark ϕ over 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. This is your main artery.

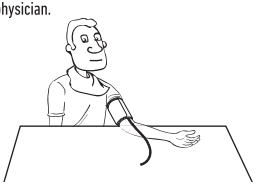
2. The cuff should be snug but not too tight. You should be able to insert one finger between the cuff and your arm.



3. Sit comfortably with your tested arm resting on a flat surface.

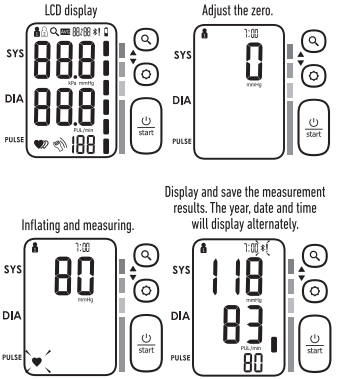
4. Patients with Hypertension:
The middle of the cuff should be at the level of the right atrium of the heart; Before starting measurement, please sit comfortably with legs uncrossed, feet flat on the floor, back and arm supported.

- Rest for 5 minutes before measuring.
- Wait at least 3 minutes between measurements. This allows your blood circulation to recover.
- For a meaningful comparison, try to measure under similar conditions. For example, take daily measurements at approximately the same time, position of upper arm, or as directed by a physician.

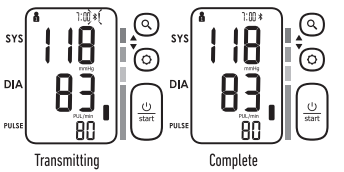


Start the Measurement

1. When the monitor is off, press " start " button to turn on the monitor, and it will finish the whole measurement. (Take user 1 for example.)



2. This device will proceed to data transmission after measurement. The Bluetooth symbol blinks on the LCD indicates data is transmitting.



3. With the blood pressure monitor successfully paired-up with your mobile device, the measurement data will be automatically transmitted to your mobile device via Bluetooth.

(1). The symbol ! will disappear after successful data transmission, and you may check your personal health data stored in your mobile device.

(2). If the data transmission fails, the symbol ! will remain The pending measurement data will be transmitted to your mobile device when next measurement is complete.

4. Press the " start " button to power off, otherwise it will turn off within 1 minute.

Tips:

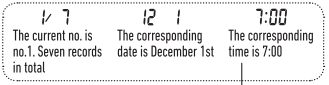
1. There are 3 users in total. Each user has 60 records,except user Guest.
2. You can press "start" button at any time to stop measuring during the process of measurement.
3. If the measurement result is out of the measurement range (SYS: 60mmHg to 230mmHg; or DIA: 40mmHg to 130mmHg;or Pulse: 40-199 pulse/minute), the LCD will display "out".
4. If an irregular heartbeat was detected during the reading, the irregular heartbeat detector indicator will appear on the display. See page 22 for more information on the irregular heartbeat detector feature.
5. If a motion was detected during the reading, the motion indicator will appear on the display. It can affect the accuracy of the measurement.
6. There isn't any user icon shown on the display during the process of measurement when you select user "Guest". After each measurement, the device will turn off automatically if there is no operation. However, the measurement result won't be stored and transmitted.

DATA MANAGEMENT

Recall the Records

1. When the monitor is off, please press "🔍" button to show the average value of the latest three records. (Note: If the records are less than 3 groups, the LCD will display the recent record instead. Take user 1 for example.)

2. Press "🔍" button or "☼" button to get the records you want.



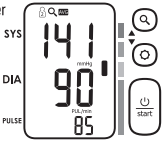
The current no. is no.1. Seven records in total

The corresponding date is December 1st

The corresponding time is 7:00

The record number, date and time of the measurement records will display alternately.

3. If you want to check another user's records, press "start" button to turn off the monitor when the blood pressure monitor is in the memory mode. Press and hold "🔍" button to enter into the electing user ID mode, press "🔍" button again to select the user ID among user 1, user 2 and Guest., press "☼" button to confirm the user ID , then press "🔍" button to check the selected user's measurement records.



4. Press the "start" button to power off, otherwise it will turn off within 1 minute.

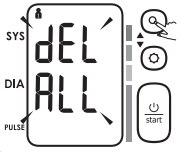
⚠ CAUTION

The most recent record (1) is shown first. 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 (60) is dropped from the list. The measurement results of user Guest won't be stored in the blood pressure monitor, so you can't review any data of user Guest.

Delete the records

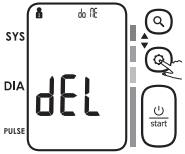
If you did not get the correct measurement, you can delete all results for the selected user by following steps. (Take User 1 for example.)

1. Hold pressing " " button about 3 seconds when the monitor is in the memory mode, the flash display " dEL ALL"+ User ID will show.

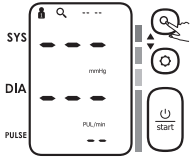


Note: To exit out of delete mode without deleting any records, press "start" button before pressing " " button to confirm any delete commands.

2. Press " " button to confirm deleting and the monitor will display "User ID+dEL dOnE" and then turn off.



3. If there is no record, when you press " " button to check the record, the following display will show.



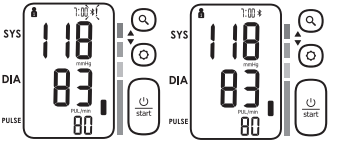
Bluetooth Module No.: AW51822
RF Frequency Range: 2402 MHz to 2480 MHz
Output Power Range: ≤4 dBm
Transmitting Distance: 10 meter

LIST OF COMPATIBLE DEVICES:
For iOS devices:
The operating system must be iOS 8 or more, such as iPhone 4S, iPhone 5/5C/5S, iPhone 6/6 Plus and so on.
For Android devices:
The operating system must be 4.3 or more.

Data Transmission

With the advanced Bluetooth 4.0 technology applied, the mobile or portable equipments, which are equipped with Bluetooth function in line with BLE Technical Specifications as well as BLP Protocol established by global organization Bluetooth SIG, are capable to receive your personal health data.

1. After each measurement, this device will proceed to data transmission after measurement. The Bluetooth symbol blinks on the LCD indicates data is transmitting.



2. With the blood pressure monitor successfully connected with your mobile device, the measurement data will be automatically transmitted to your mobile device via Bluetooth.

(1). The symbol **!** will disappear after successful data transmission, and you may check your personal health data stored in your mobile device.

(2). If the data transmission fails, the symbol **!** will remain. The pending measurement data will be transmitted to your mobile device when next measurement is complete.

3. The monitor will shut off after data transmission process is complete.

CAUTION

Interference may occur in the vicinity of equipment marked with the following symbol And blood pressure monitor may interfering vicinity electrical equipment.
Sensitive people, including pregnant women pre-eclamptic and those who implanted medical electronic instruments, should avoid using the unit whenever possible.
Keep the monitor at least 20 centimeters away from the human body (especially the head) when the data transmission is proceeding after measurement.
To enable the data transmission function, this product should be paired to Bluetooth end at 2.4 GHz.

How to mitigate possible interference?

The range between the device and BT end should be reasonably close, from 1 meter to 10 meters. Please ensure no obstacles between the device and BT end so as to obtain quality connection and to lower the RF output range.
To avoid interference, other electronic devices (particularly those with wireless transmission / Transmitter) should be kept at least 1 meter away from the monitor.

INFORMATION FOR USER

Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.

Within 1 hour after dinner or drinking

Immediate measurement after tea, coffee, smoking

Within 20 minutes after taking a bath

When talking or moving your fingers

In a very cold environment

When you want to discharge urine

Maintenance

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

Put in a dry place and avoid the sunshine

Avoid touching water,

Avoid intense shaking and collisions

Avoid dusty and unstable temperature environment

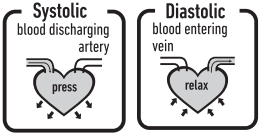
Using wet cloths to remove dirt

Do not attempt to clean the reusable cuff with water and never immerse the cuff in water.

ABOUT BLOOD PRESSURE

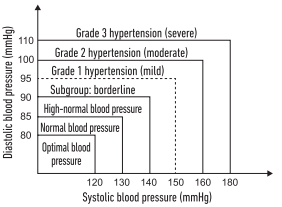
What are systolic pressure and diastolic pressure?

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. Kindly note that only a physician could 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 Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, the monitor records all the pulse intervals and calculate the average; if there are two or more pulse intervals,the difference between each interval and the average is more than the average value of ±25 % , or there are four or more pulse intervals, the difference between each interval and the average is more than the average value of ±15 %,the irregular heartbeat symbol appears on the display when the measurement results are appear.

CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heartbeat 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 device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

Why does my blood pressure fluctuate throughout the day?

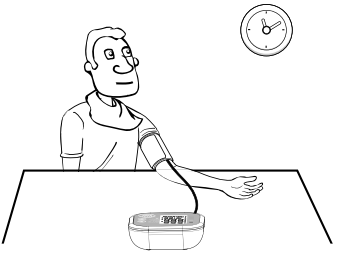
1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie your cuff and your measurement position, so please take the measurement under the same conditions.
2. If the person takes medicine, the pressure will vary more.
3. Wait at least 3 minutes for another measurement.

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.

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

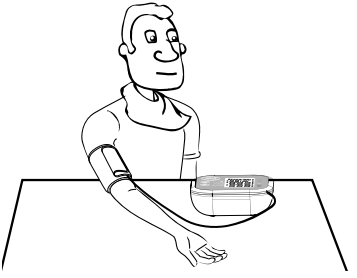
It is ok for both arms, but there will be some different results for different people.
We suggest you measure the same arm every time.



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 yourself for 4-5 minutes until you calm down.



TROUBLESHOOTING

This section includes a list of error messages and frequently asked questions for problems you may encounter with your blood pressure monitor. If the products is not operating as you think it should, check here before arranging for servicing.

PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
Low batteries	Display is dim or show +Lo	Batteries are low.	Replace with new batteries
Error message	E 01 shows	The cuff is too tight or too loose.	Readjust the cuff ,not too loose or too tight and then measure again.
	E 02 shows	The monitor detected motion, talking or the pluse is too poor while measuring.	Relax for a moment and then measure again.
	E 03 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again
	E 04 shows	The monitor detected motion, talking or the pluse is too poor while measuring.	The treatment of the measurement failed.
	EEX, shows on the display.	A calibration error occurred.	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 message measure again. If the problem persists, contact your physician.

SPECIFICATIONS

Power supply	Battery powered mode: 6V DC 4 × AA alkaline batteries AC adaptor powered mode:6 V ⎓ 1A (not included) (Please only use the recommended AC adaptor model)
Display mode	Blue LCD display with white backlight V.A.73 mm × 49 mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0 mmHg~299 mmHg (0 kPa ~ 39.9 kPa) Measurement pressure: SYS: 60 mmHg ~230 mmHg (8.0 kPa~30.7 kPa) DIA: 40 mmHg ~ 130 mmHg (5.3 kPa~17.3 kPa) Pulse value: (40–199) beat/minute
Accuracy	Pressure: 5 °C~40 °c within±0.4kpa(3mmHg) pulse value:±5 %
Normal working condition	A temperature range of :+5 °C to + 40 °C A relative humidity range of 15% to 90%, non-condensing, but not requiring 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
Measurement perimeter of the upper arm	About 22 cm~42 cm
Net Weight	Approx.270 g (Excluding the dry cells and cuff)
External dimensions	Approx.118 mm ×126 mm × 72 mm
Attachment	4×AA alkaline 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 protected against solid foreign objects of 12.5 mm and greater, and protect against vertically falling water drops.
Device Classification	Battery Powered Mode: Internally Powered ME Equipment
Software version	A01

WARNING: No modification of this equipment is allowed.

CONTACT INFORMATION

For more information about our products, please visit www.salterhousewares.com.au
Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No.105,Dongli Road, Torch Development District, 528437 Zhongshan, Guangdong, China （注： 528437 后无逗号）

Model: TMB-1597-BN

Imported into AUS by Brand Merchant
Brand Merchant Pty Ltd
Suite 8, 8A St Andrews Street,
Brighton Victoria 3186, Australia

COMPLIED STANDARDS LIST

Risk management	Zone A, No.105,Dongli Road, Torch Development District, 528437 Zhongshan, Guangdong, China （注： 528437 后无逗号）
Labeling	EN ISO 15223-1:2016 / ISO 15223-1:2016 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. Part 1 : General requirements
User manual	EN 1041:2008 Information supplied by the manufacturer of medical devices
General Requirements for Safety	EN 60601-1:2006+A1:2013/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2015/ IEC 60601-1-11:2015 Medical electrical equipment - Part 1-11: General requirements for basic safety and essential performance - Collateral standard: Requirements for medical electrical equipment and medical electrical systems used in the home healthcare environment
Electromagnetic compatibility	EN 60601-1-2:2015/ IEC 60601-1-2:2014 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic disturbances - Requirements and tests
Performance requirements	EN ISO 81060-1:2012 Non-invasive sphygmomanometers - Part 1: Requirements and test methods for non-automated measurement type EN 1060-3:1997+A2:2009 Non-invasive sphygmomanometers - Part 3: Supplementary requirements for electro-mechanical blood pressure measuring systems IEC 80601-2-30:2009+A1:2013 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers
Clinical investigation	EN 1060-4:2004 Non-invasive sphygmomanometers - Part 4: Test procedures to determine the overall system accuracy of automated non-invasive sphygmomanometers ISO 81060-2:2013 Non-invasive sphygmomanometers - Part 2: Clinical validation of automated measurement type
Usability	EN 60601-1-6:2010+A1:2015/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability IEC 62366-1:2015 Medical devices - Part 1: Application of usability engineering to medical devices
Software life-cycle processes	EN 62304:2006/AC: 2008 / IEC 62304: 2006+A1:2015 Medical device software - Software life-cycle processes
Bio-compatibility	ISO 10993-1:2009 Biological evaluation of medical devices- Part 1: Evaluation and testing within a risk management process ISO 10993-5:2009 Biological evaluation of medical devices - Part 5: Tests for in vitro cytotoxicity ISO 10993-10:2010 Biological evaluation of medical devices - Part 10: Tests for irritation and skin sensitization

EMC GUIDANCE

1. This product needs special precautions regarding EMC and needs to be installed and put into service according to the EMC information provided, and this unit can be affected by portable and mobile RF communications equipment.
2.* Do not use a mobile phone or other devices that emit electromagnetic fields, near the unit. This may result in incorrect operation of the unit.
3. **CAUTION:** This unit has been thoroughly tested and inspected to assure proper performance and operation!
4.* **CAUTION:** This machine should not be used adjacent to or stacked with other equipment and that if adjacent or stacked use is necessary, this machine should be observed to verify normal operation in the configuration in which it will be used.

Table 1

Guidance and manufacturer's declaration – electromagnetic emission	
Emission test	**Compliance**
RF emissions CISPR 11	Group 1
RF emission CISPR 11	Class B
Harmonic emissions IEC 61000-3-2	Class A
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies

Table 2

Guidance and manufacturer's declaration – electromagnetic emission		
Immunity test	**IEC 60601 test level**	**Compliance level**
Electrostatic discharge (ESD) IEC 61000-4-2	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV, air	±8 kV contact ±2 kV, ±4 kV, ±8 kV, ±15 kV, air
Electrical fast transient/burst IEC 61000-4-4	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency	±2 kV for power supply lines ±1 kV signal input/output 100 kHz repetition frequency
Surge IEC 61000-4-5	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode	±0.5 kV, ±1 kV differential mode ±0.5 kV, ±1 kV,±2 kV common mode
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	0%UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°,225°,270° and 315°. 0%UT ; 1 cycle and 70 %UT ; 25/30 cycles. Single phase: at 0°. 0 % UT ; 300 cycle	0%UT; 0.5 cycle. At 0°, 45°, 90°, 135°, 180°,225°,270° and 315°. 0%UT ; 1 cycle and 70%UT ; 25/30 cycles. Single phase: at 0°. 0% UT ; 300 cycle
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 Hz/60 Hz	30 A/m 50 Hz/60 Hz
Conducted RF IEC61000-4-6	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz	3 V 0,15 MHz – 80 MHz 6 V in ISM and amateur radio bands between 0,15 MHz and 80 MHz 80 % AM at 1 kHz
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 communications equipment)	Test frequency (Mhz)	Band a) (MHz)	Service a)	Modulation b)	Modulation b) (W)	Distance (m)	IMMUNITY TEST LEVEL (V/m)
	385	380–390	TETRA 400	Pulse modulation b) 18Hz	1.8	0.3	27
	450	430–470	GMRS 460, FRS 460	FM c) ± 5kHz deviation 1kHz sine	2	0.3	28
	710	704–787	LTE Band 13,17	Pulse modulation b) 217Hz	0.2	0.3	9
	745						
	780						
	810	800–960	GSM 800/900, TETRA 800, iDEN 820, CDMA 850, LTE Band 5	Pulse modulation b) 18 Hz	2	0.3	28
	870						
	930						
	1720	1700–1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS	Pulse modulation b) 217 Hz	2	0.3	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
	5240	5100–5800	WLAN 802.11 a/n	Pulse modulation 217 Hz	0.2	0.3	9
	5500						
	5785						

If this product does not reach you in an acceptable condition please contact our Customer Services Department by **www.salterhousewares.com.au**.

Please have your delivery note to hand as details from it will be required.

If you wish to return this product please return it to the retailer from where it was purchased with your receipt (subject to their terms and conditions).

DECLARATION OF CONFORMITY

Hereby, Transtek, declares that this audio device is in compliance with the essential requirements and other relevant provisions of Radio Equipment Directive 2014/53/EU. A full version of the Declaration of Conformity can be obtained from www.transtek.cn/DoC

Guangdong Transtek Medical Electronics Co., Ltd.
Zone A, No.105,Dongli Road, Torch Development District,
528437 Zhongshan, Guangdong,
China （注：528437后无逗号）

Imported into AUS by Brand Merchant
Brand Merchant Pty Ltd
Suite 8, 8A St Andrews Street,
Brighton Victoria 3186, Australia