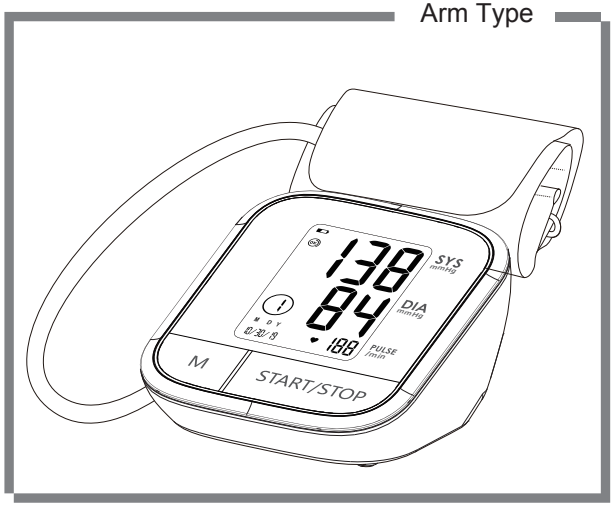
version:1.0

LIFEHOOD

User Manual

Blood Pressure Monitor

Arm Type



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- If any quality questions or confusion, feel free to contact us via E-mail: service.usuk@lifehoodglobal.com.
- 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.

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♥ General Description

Thank you for selecting LIFEHOOD arm type blood pressure monitor (TMB-1775). 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 TMB-1775 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:

- 65×50mm LCD Display
- Maximum 60 records
- 3rd technonoly: Measuring during inflation

♥ Indications for Use

The LIFEHOOD Blood Pressure Monitor is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from 22cm to 42cm(about 8¾ -16½).
It is intended for adult indoor use only.

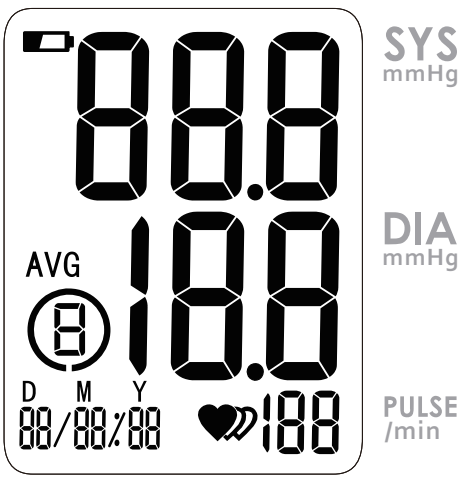
♥ Contraindications

1.The device should not be used by any person who may be suspected of,or is pregnant .
2.The device is not suitable for use on patients with implanted, electrical devices, such as cardiac pacemakers, defibrillators. Contraindications

♥ Measurement Principle

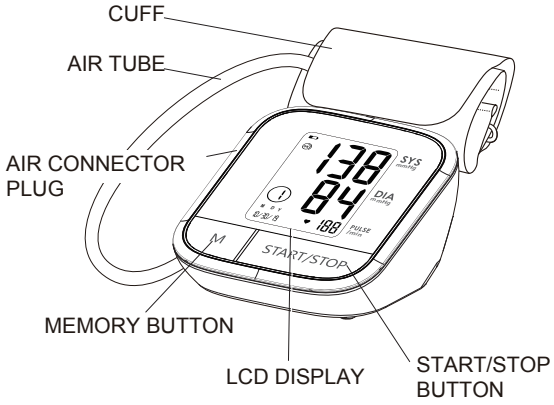
This product uses the Oscillometric Measuring method to detect blood pressure. Before every measurement, the unit establishes a “zero pressure” equivalent to the air pressure.Then it starts inflating the arm cuff, meanwhile, the unit detects pressure oscillations generated by beat-to-beat pulsatile,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

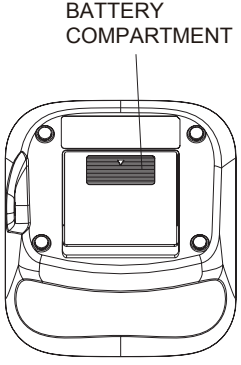
♥ Screen Elements



SYMBOL	DESCRIPTION	EXPLANATION
SYS	Systolic pressure	High blood pressure
DIA	Diastolic pressure	Low blood pressure
PUL/min	Pulse display	Pulse in beats per minute
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
	Blood pressure level indicator	Indicate the blood pressure level
Lo +	Low battery	Batteries are low and need to be replaced
	Irregular heartbeat	Blood pressure monitor is detecting an irregular heartbeat during measurement.
D M Y	Current Time	Year/Month/Day, Hour : Minute
	Heartbeat	Blood pressure monitor is detecting a heartbeat during measurement.
AVG	Average value	The average value of lastest tree grops blood pressure

♥ Monitor Components





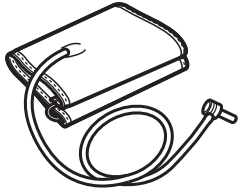
Component list of pressure measuring system

1 Cuff
2 Air pipe
3 PCBA
4 Pump
5 Valve

♥ List

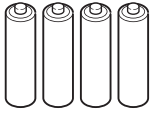
1.Blood Pressure Monitor (TMB-1775)

2.Cuff(Type BF applied part): 8.75"- 16.5"(22cm~42cm)



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

3. 4×AAA batteries



4.User manual

♥ The Choice of Power Supply

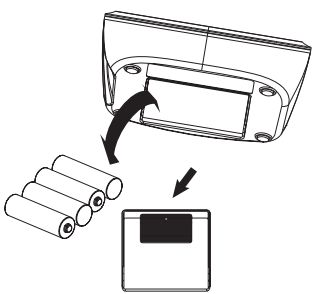
1.Battery powered mode:
6VDC 4×AAA batteries

⚠ CAUTION

In order to get the optimal performance and protect your monitor, please use the correct batteries.

♥ Installing and Replacing the Batteries

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



Replace the batteries whenever the below happens

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

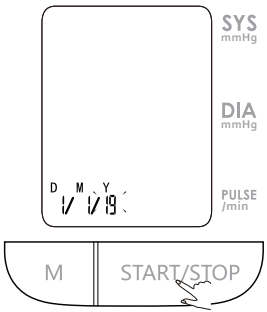
⚠ CAUTION

- 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.

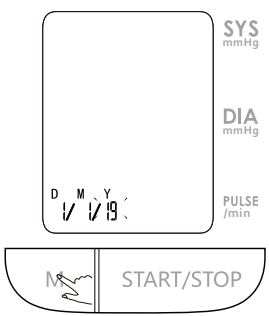
♥ Setting Date and Time.

It is important to set the date and time 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 :2019—2059; Time format:24H)

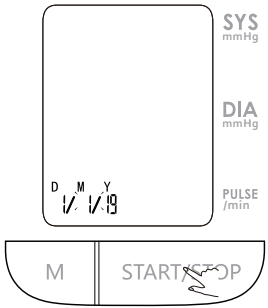
1. When the monitor is off, hold pressing " START/STOP " for 3 seconds to enter the mode for year setting.



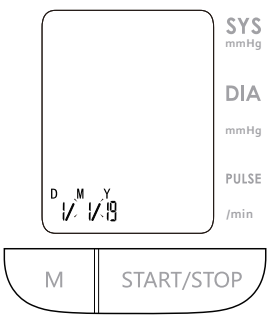
2. Press " M " button to change the [YEAR]. Each press will increase the number by one in a cycling manner.

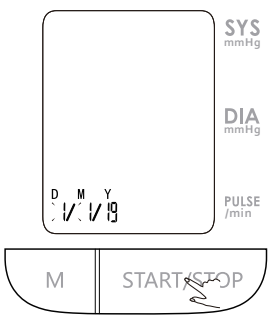


3. Press " START/STOP " button to confirm [YEAR].
   Then the monitor diverts to [MONTH] and [DAY] setting.

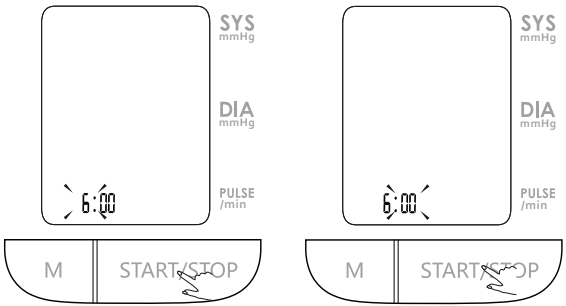


4. Repeat step 2 and 3 to set the [MONTH] and [DAY].

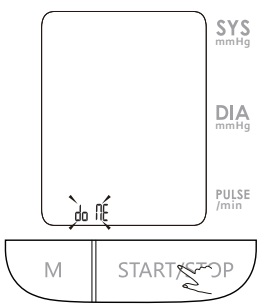




5. Repeat step 2 and 3 to set the [HOUR] and [MINUTE].



6. After hour and minute is set,the LCD will display “donE” first, then display all the settings you have done and then turn off.



♥ Applying the Arm Cuff

To achieve an accurate blood pressure reading, follow these steps to position the blood pressure cuff properly.

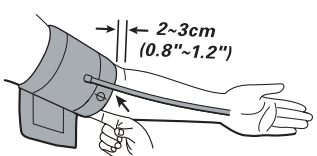
1. Remove tight-fitting clothing or tight rolled up sleeve from your left upper arm. Do not place the arm cuff over thick clothes.

2. Insert the air plug into the air jack securely.

3. Wrap the arm cuff firmly in place around your left upper arm. The bottom edge of the cuff should be 2 to 3 centimeters (0.8 to 1.2inches) above the bend in your arm, and the tube and artery marker should appear on your arm as shown.

Note: If your doctor has diagnosed you with poor circulation in your left arm, please use your right arm.

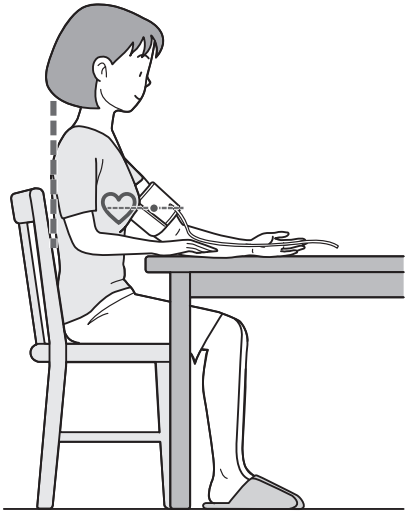
4. Keeping the artery marker and the tube in place, wrap the cuff snugly around your arm, but not too tight. If you can insert just two fingers between the cuff and your arm, the tightness is acceptable.



♥ How to Sit Correctly

To take a measurement, you need to be relaxed and comfortably seated,under comfortable room temperature. Avoid bathing, drinking alcohol or caffeine, smoking, exercising or eating 30 minutes before taking a measurement.

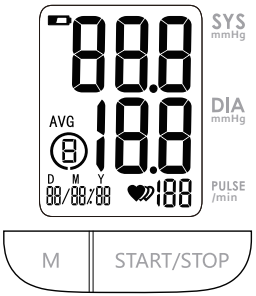
- Sit comfortably in a chair that supports your back.
- Keep legs uncrossed.
- Place feet flat on the floor.
- Support your arm on the flat surface.
- The arm cuff should be placed on your arm at the same level as your heart.



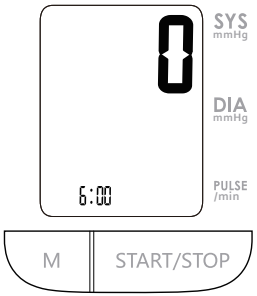
♥ Start the Measurement

1. Press the “START/STOP” button to power up the monitor and begin the blood pressure measurement.

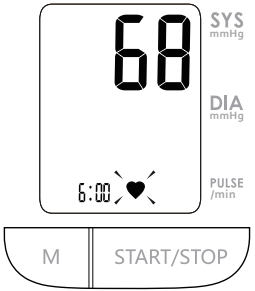
LCD display



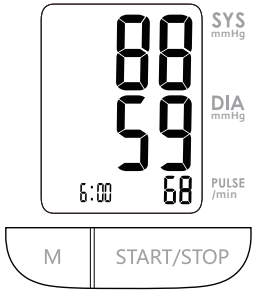
START



Inflating and measuring.



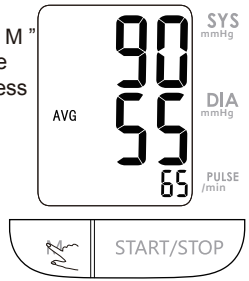
Display and save the measurement



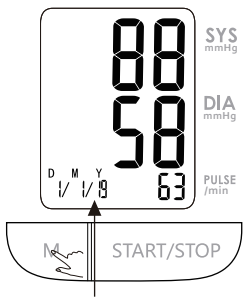
2. Press the “START/STOP” button to turn the monitor off. It will automatically turn off within 1 minute.

♥ Recall the Records

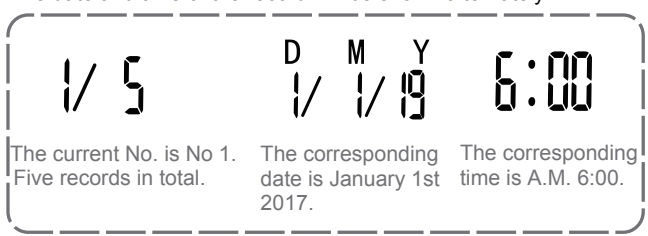
1. When the monitor is off, please press “ M ” button to show the average value of the latest three records.If the records are less than 3 groups, it will display the latest record instead.



2. Press the “M” to get the record you want.



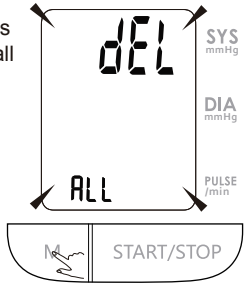
The date and time of the record will be shown alternately.



♥ Delete the Records

If you did not get the correct measurement, you can delete all results for the selected user by following steps below .

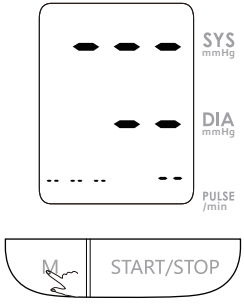
1. Hold pressing " M " button for 3 seconds when the monitor is in the memory recall mode ,the flash display "dEL ALL" will show.



2. Hold Press " START/STOP " button to confirm deleting and the monitor will turn off.
   Note: To exit out of delete mode without deleting any records, press "START/STOP" button.

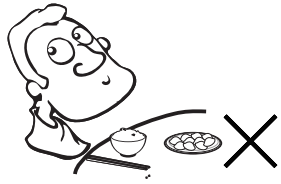
3. If there is no record, press "M" button, the right display will be show.

   Note: You cannot partially delete the values stored in the memory. All values for the user will be deleted.



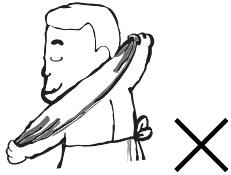
♥ Tips for Measurement

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

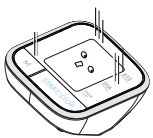
When you want to discharge urine

♥ 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, clean it with a dry cloth in case.



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.

♥ 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 chart on the right is the standard blood pressure classification published by American Heart Association (AHA).

AHA Home Guideline for Upper Limit of Normal BP

SYS	135 mm Hg
DIA	85 mm Hg

This chart reflects blood pressure categories defined by American Heart Association.

Blood Pressure Category		Systolic mmHg (upper#)		Diastolic mmHg (lower#)
Normal		less than 120	and	less than 80
Elevated	P	120-129	and	less than 80
High Blood Pressure (Hypertension) Stage 1	1	130-139	or	80-89
High Blood Pressure (Hypertension) Stage 2	2	140 or higher	or	90 or higher
Hypertensive Crisis (Emergency care needed)	3	Higher than 180	and /or	Higher than 120

⚠ 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.

♥ Irregular Heartbeat Detector

An irregular heartbeat is detected when a heartbeat rhythm varies while the device is measuring systolic pressure and diastolic pressure. During each measurement, blood pressure monitor will keep a record of all the pulse intervals and calculate the average value of them. 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%, then the irregular heartbeat symbol will appear on the display with the measurement result.

⚠ CAUTION

The appearance of the IHB icon indicates that a pulse irregularity consistent with an irregular heart-beat 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 through out the day?

1. Individual blood pressure varies multiple times everyday. It is also affected by the way you tie yourcuff and your measurement position, so please takethe 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.

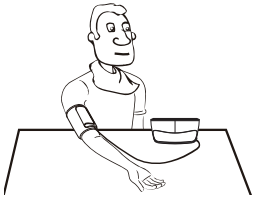
♥ Is the result the same if measuring on the right arm?

The blood pressure is differenteven 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 yourself 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.



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 not operating as you think it should, check here before arranging for servicing.

PRO -BLEM	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.	Refasten the cuff and then measure again.
	E 02 shows	The monitor detected motion while measuring.	Movement can affect the measurement. 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 treatment of the measurement failed.	Relax for a moment and then measure again.
	EExx,shows on the display	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. Refasten the cuff and then measure again. If the problem persists, contact your physician.

Power supply	Battery powered mode: 6VDC 4×AAA batteries
Display mode	V.A.65×50mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~299mmHg Measurement pressure: SYS: 60mmHg~230mmHg DIA: 40mmHg~130mmHg Pulse value: (40-199)beat/minute
Accuracy	Pressure: 5°C-40°Cwithin± 3mmHg(0.4kPa) 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 50hPa
Measurement perimeter	22cm~42cm
Weight	Approx.225g(Excluding the dry cells and cuff)

External dimensions	Approx.120.2mm×108.2mm×68.5mm
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 protected against solid foreign objects of 12.5mm 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.

♥ Safety Information

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

	Symbol for “THE OPERATION GUIDE MUST BE READ”
	Symbol for “MANUFACTURER”
SN	Symbol for “SERIAL NUMBER”
	Symbol for “DIRECT CURRENT”
	Symbol for “MANUFACTURE DATE”
	Caution: These notes must be observed to prevent any damage to the device.
	Symbol for “TYPE BF APPLIED PARTS”
	Symbol for “ENVIRONMENT PROTECTION - Electrical waste products should not be disposed of with household waste. Please recycle where facilities exist. Check with your local authority or retailer for recycling advice”
	Symbol for “RECYCLE”
	The Green Dot is the license symbol of a European network of industry-funded systems for recycling the packaging materials of consumer goods.

⚠ CAUTION

* Be careful to strangulation due to cables and hoses, particularly due to excessive length.
* 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.
* 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 distanced is caculated 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.
* Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE.
  Otherwise, it may cause damage to the unit or danger to the user/patients.
* 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.
* 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.
* This device is intended for adult use in homes only.
* The device is not suitable for use on neonatal patients, pregnant women,patients with implanted, electronical devices, patients with pre-eclampsia, premature ventricular beats, atrial fibrillation, peripheral, arterial disease and patients undergoing intravascular therapy or arterio-venous shunt or people who received a mastectomy.
  Please consult your doctor prior to using the unit if you suffer from illnesses.
* The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.

⚠ CAUTION

* 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.
* Do not take any therapeutic measures on the basis of a self measurement. Never alter the dose of a medicine prescribed by a doctor. Consult your doctor if you have any question about your blood pressure.
* 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.
* Don't kink the connection tube during use, otherwise, the cuff pressure may continuously increase which can prevent blood flow and result in harmful injury to the PATIENT.
* 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 same 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.

⚠ CAUTION

* On the rare occasion of a fault causing the cuff to remain fully inflated during measurement, open the cuff immediately. Prolonged high pressure (cuff pressure > 300mmHg or constant pressure > 15mmHg for more than 3 minutes) applied to the arm may lead to an ecchymosis.
* 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 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.
* Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
* 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.
* When not in use, store the device 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.
* 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.
* 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.

⚠ CAUTION

* Warning: No servicing/maintenance while the ME equipment is in use.
* The patient can measure data and change batteries under normal circumstances and maintain the device and its accessories according to the user manual.
* To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
* The blood pressure monitor and the cuff are suitable for use within the patient environment. If you are allergic to polyester, nylon or plastic, please don't use this device.
* 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.
* If you experience discomfort during a measurement, such as pain in the arm or other complaints, press the START/STOP button to release the air immediately from the cuff. Loosen the cuff and remove it from your arm.
* If the cuff pressure reaches 40 kPa (300 mmHg), the unit will automatically deflate. Should the cuff not deflate when pressures reaches 40 kPa (300 mmHg), detach the cuff from the arm and press the START/STOP button to stop inflation.
* Before use, make sure the device functions safely and is in proper working condition. Check the device, do not use the device if it is damaged in any way. The continuous use of a damaged unit may cause injury, improper results, or serious danger.
* Do not wash the cuff in a washing machine or dishwasher!
* The service life of the cuff may vary by the frequency of washing, skin condition, and storage state. The typical service life is 10000 times.
* 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 50mmHg and 200mmHg).
* Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.

⚠ CAUTION

* Manufacturer will make available on request circuit diagrams, component part lists, descriptions, calibration instructions,etc., to assist to service personnel in parts repair.
* The operator shall not touch output of batteries and the patient simultaneously.
* Cleaning :Dust environment may affect the performance of the unit. Please use the soft cloth to clean the whole unit before and after use. Don’t use any abrasive or volatile cleaners.
* The device doesn’t need to be calibrated within two years of reliable service.
* If you have any problems with this device, such as setting up, maintaining or using, please contact the SERVICE PERSONNEL of Transtek. Don’t open or repair the device by yourself in the event of malfunctions. The device must only be serviced, repaired and opened by individuals at authorized sales/service centers.
* Please report to Transtek if any unexpected operation or events occur.
* Keep the unit out of reach of infants, young children or pets to avoid inhalation or swallowing of small parts. It is dangerous or even fatal.

♥ Contact Information

For more information about our products, please contact us by mail,you can get customer service, usual problems and customer download, Lifehood will serve you anytime.

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

Company:
Guangdong Transtek Medical Electronics Co., Ltd.

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

If any quality questions or confusion, feel free to contact us :

HONGKONG XUHUA INDUSTRIAL CO., LTD.

RM 605, 6/F DAVID HSE 8-20 NANKING ST JORDAN KL, HONGKONG
E-mail: service.usuk@lifehoodglobal.com

♥ FCC Statement

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.

♥ Complied Standards List

Risk management	EN ISO 14971:2012 / ISO 14971:2007 Medical devices - Application of risk management to medical devices
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/ IEC 60601-1:2005+A1:2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance EN 60601-1-11:2010/ 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 compatibility - 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 80601-2-30:2013 Medical electrical equipment -Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

♥ Complied Standards List

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/IEC 60601-1-6:2010+A1:2013 Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability EN 62366:2008/ IEC 62366-1:2015 Medical devices -Application of usability engineering to medical devices
processes	EN 62304:2006/AC: 2008 / IEC 62304:2006 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 emissions		
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The device 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 device is suitable for use in all establishments, other than domestic 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	

Table 2

Guidance and manufacturer's declaration – electromagnetic immunity			
The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000 -4-2	±8 kV contact ±15 kV air	±8 kV contact ±15 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%
Electrical fast transient/ burst IEC 61000 -4-4	power supply lines:±2 kV input/output lines:±1 kV	power supply lines:±2 kV	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC61000 -4-5	line(s) to line(s): ±1 kV line(s) to earth: ±2 kV 100 kHz repetition frequency	line(s) to line(s): ±1 kV 100 kHz repetition frequency	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000 -4-11	0% 0.5 cycle At 0°,45°,90°,135° 180°,225°,270°and 315° 0% 1 cycle and 70% 25/30 cycles Single phase: at 0 0% 300 cycle	0% 0.5 cycle At 0°,45°,90°,135° 180°,225°,270°and 315° 0% 1 cycle and 70% 25/30 cycles Single phase: at 0 0% 300 cycle	Mains power quality should be that of a typical commercial or hospital environment.
Power frequency (50Hz/60Hz) magnetic field IEC 61000 -4-8	30 A/m 50Hz/60Hz	30 A/m 50Hz/60Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.
NOTE UT is the a.c. mains voltage prior to application of the test level			

Table 3

Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.				
Immunity test	IEC 60601 Test level	Compliance level	Electromagnetic environment - guidance	
IEC 61000 -4-6	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	150 kHz to 80 MHz: 3 Vrms 6Vrms (in ISM and amateur radio bands) 80% Am at 1kHz	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation appropriate for the frequency of the transmitter. Recommended separation distances:d=0.35;d=1.2	
Radiated RF IEC 61000 -4-3	10V/m, 80% Am at 1kHz	10V/m, 80% Am at 1kHz	80 MHz to 800 MHz: d=1.2 800 MHz to 2.7 GHz: d=2.3	where,***P*** is the maximum output power rating of the transmitter in watts (W)according to the transmitter manufacturer, ***d*** is the recommended separation distance in meters (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:

Table 3

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

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

Table 4

Recommended separation distances between portable and mobile RF communications equipment and the device.

The device is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the device can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmittters) and the device 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 = 3.5	80 MHz to 800 MHz d = 1.2	800 MHz to 2.7 GHz d = 2.3
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 metres (m) can be estimated using the equation applicable to the frequency of the transmitter, where ***P*** is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1 At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2 These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

EMC GUIDANCE

Guidance and manufacturer's declaration - electromagnetic immunity

The device is intended for use in the electromagnetic environment specified below. The customer or the user of the device should assure that it is used in such an environment.

Radiated RF IEC61000 -4-3 (Test specifications for ENCLOSURE PORT IMMUNITY to RF wireless communic -ations 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) 18Hz	2	0.3	28
	870							
	930							
	1720	1700-1990	GSM 1800; CDMA 1900; GSM 1900; DECT; LTE Band 1, 3, 4,25; UMTS		Pulse modulation b) 217Hz	2	0.3	28
	1845							
	1970							
	2450	2400-2570	Bluetooth, WLAN, 802.11 b/g/n, RFID 2450, LTE Band 7		Pulse modulation b) 217Hz	2	0.3	28
	5240	5100-5800	WLAN 802.11 a/n		Pulse modulation b) 217Hz	0.2	0.3	9
	5500							
	5785							

Table 5

NOTE If necessary to achieve the IMMUNITY TEST LEVEL, the distance between the transmitting antenna and the ME EQUIPMENT or ME SYSTEM may be reduced to 1 m. The 1 m test distance is permitted by IEC 61000-4-3.
a) For some services, only the uplink frequencies are included. b) The carrier shall be modulated using a 50% duty cycle square wave signal. c) As an alternative to FM modulation, 50% pulse modulation at 18 Hz may be used because while it does not represent actual modulation, it would be worst case.
The MANUFACTURER should consider reducing the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = \frac{6}{d}\sqrt{P}$ Where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVEL in V/m.