

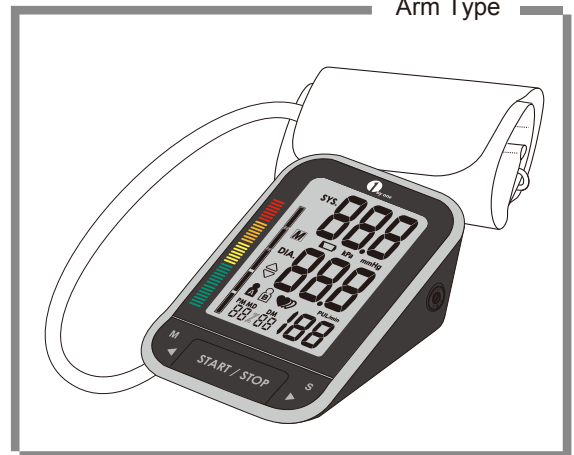


User Manual

Arm Blood Pressure Meter

Model : TMB-1585

Arm Type



Distributed by:
1byone Products Inc.
2313 E PHILADELPHIA ST STE M, CA, US, , 917618048
www.1byone.com

- Thank you very much for selecting 1byone Arm Blood Pressure Meter.
- Please do read the user manual carefully and thoroughly 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

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:








- 100mm×68 mm Digital LCD display
- Maximum 60 records per each user
- 3rd technology: Measuring during inflation (The updated technology in the world)

♥ Indications for Use

The 1by one Arm Blood Pressure Meter is digital monitors intended for use in measuring blood pressure and heartbeat rate with arm circumference ranging from about 22 cm to 42 cm (about 8¾"-16½").
It is intended for adult indoor use only.

♥ 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 "TYPE BF APPLIED PARTS"
	Symbol for "SERIAL NUMBER"		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 "DIRECT CURRENT"		
	Symbol for "MANUFACTURE DATE"		Caution: These notes must be observed to prevent any damage to the device.

CAUTION

The device is not suitable for measuring the blood pressure of children. Ask your doctor before using it on older children.
The device is not suitable for use on pregnant women, patients with implanted, electrocical 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
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.
Please keep the unit out of reach of infants, children or pets, since inhalation or swallowing of small parts is dangerous or even fatal.
The device has been evaluated clinically using manual cuff/stethoscope auscultation as the reference.
Blood pressure measurements determined with this device are equivalent to those obtained by a trained observer using the cuff/stethoscope auscultatory method, within the limits prescribed by the American National Standard, Manual, electronic, or automated sphygmomanometers."

⚠ CAUTION

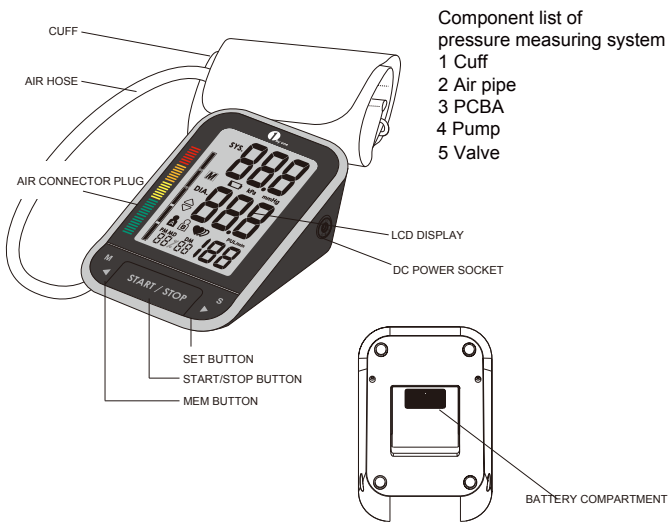
This device is intended only for adult use in homes.
 This device is intended for non-invasive measuring and monitoring of arterial blood pressure. It is not intended for use on extremities other than arm or for functions other than obtaining a blood pressure measurement.
 If you experience discomfort 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.
 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.
 Too frequent and consecutive measurements could cause disturbances in blood circulation and injuries.
 Do not wrap the cuff on the same arm which other monitoring ME EQUIPMENT is applied simultaneously, because this could cause temporary loss of function of those simultaneously-used monitoring ME EQUIPMENT.
 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.
 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.
 This unit is not suitable for continuous monitoring during medical emergencies or operations.
 This device cannot be used with HF surgical equipment at the same time.
 This device is not intended for patient transports outside a healthcare facility.
 To avoid measurement errors, please avoid the condition of strong electromagnetic field radiated interference signal or electrical fast transient/burst signal.
 The operator shall not touch output of batteries/adaptor and the patient simultaneously. Manufacturer will make available on request circuit diagrams, component parts list etc.
 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 sensitization or irritation reaction. Never apply the cuff over hurt skin.
 Do not use the unit in case of existing polyester resp. synthetic allergies.
 Be careful to strangulation due to cables and hoses, particularly due to excessive length.
 Do not connect the air hose to other medical equipment, as this could cause air to be pumped into intravascular systems or high pressure, what could lead to dangerous injuries.
 Before use, make sure the device functions safely and is in proper working condition.
 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.
 Please use ACCESSORIES and detachable partes specified/ authorised by MANUFACTURE.
 Otherwise, it may cause damage to the unit or danger to the user/patients.
 Please dispose of ACCESSORIES, detachable parts, and the ME EQUIPMENT according to the local guidelines.
 Please do not attempt to repair the unit yourself in the event of malfunctions. Only have repairs carried out by authorized service centers.
 Please report to Manufacturer if any unexpected operation or events occur.
 The device doesn't need to be calibrated in two years of reliable service.
 Please use the soft cloth to clean the whole unit. Don't use any abrasive or volatile cleaners.

♥ LCD display signal



SYMBOL	DESCRIPTION	EXPLANATION
SYS.	Systolic blood pressure	High pressure result
DIA.	Diastolic blood pressure	Low pressure result
PUL/min	Pulse per minute	Beats per minute, BPM
▽	Deflating	CUFF air is exhausting of deflating
M	Memory	The displayed measurement values is from the memory.
kPa	kPa	Measurement Unit of the blood pressure (1kPa=7.5mmHg)
mmHg	mmHg	Measurement Unit of the blood pressure (1mmHg=0.133kPa)
! + 🔋	Low battery	Batteries are low and need to be replaced
♥	Irregular heartbeat	Irregular heartbeat Detection
I	Grade	The grade of the blood pressure
PM MD DM 88:88	Current Time	Year/Month/Day, Hour/Minute
♥	Heartbeat	Heartbeat detection during the measurement
A	User A	Start measurement and save the measuring results for User A
B	User B	Start measurement and save the measuring results for User B
△	Inflation	The air is inflating into the cuff.

♥ Monitor Components



Component list of pressure measuring system
 1 Cuff
 2 Air pipe
 3 PCBA
 4 Pump
 5 Valve

♥ List

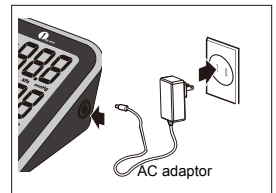
- 1. Arm Blood Pressure Meter
- 2. Cuff (Type BF applied part) (about 22cm~42cm)
 (Please use 1byone authorized cuff. The size of the actual cuff please refer to the label on the attached cuff.)
- 3. Storage bag
- 4. User manual

♥ The Choice of Power Supply

1. Battery powered mode:
 6VDC 4×AAA batteries(Not Included)

2. AC adaptor powered mode:
 6V 1A
 (Please only use the recommended AC adaptor model).(Not Included)

Please unplug the adaptor to depart from the using utility power.

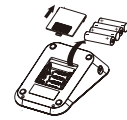


⚠ CAUTION

In order to get the best effect and protect your Arm Blood Pressure Meter, please use the right battery and special power adaptor which complies with U.S. safety standard.

♥ Installing and Replacing the Batteries

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



Replace the batteries whenever the below happen

- The shows
- The display dims
- The display does not light up

⚠ CAUTION

- Remove batteries if the device is not likely to be used for some time.
- The old batteries are harmful to the environment, do not dispose with other daily trash.
- Remove the old batteries from the device and follow your local recycling guidelines.
- Do not dispose of batteries in fire. Batteries may explode or leak.

♥ 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.

The device also compares the longest and the shortest time intervals of detected pulse waves to mean time interval then calculates standard deviation. The device will display a warning signal with the reading to indicate the detection of irregular heartbeat when the difference of the time intervals is over 25%.

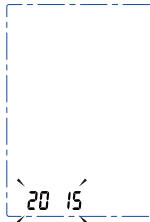
♥ Setting Date, Time and Measurement Unit

It is important to set the clock before using your Arm Blood Pressure Meter, so that a time stamp can be assigned to each record that is stored in the memory. (The setting range of the year :2014—2054 time format:12H/24H)

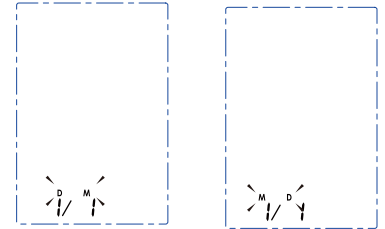
1. When the Arm Blood Pressure Meter is off, hold pressing "S" button about 3 seconds to enter the mode for year setting.



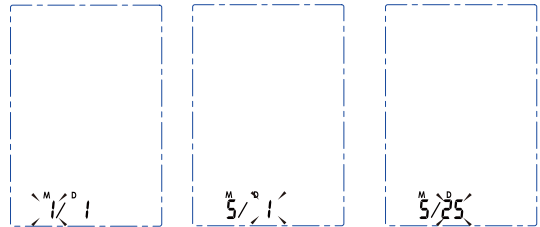
2. Press "M" button to change the [YEAR]. Each press will increase the numeral by one in a cycling manner.



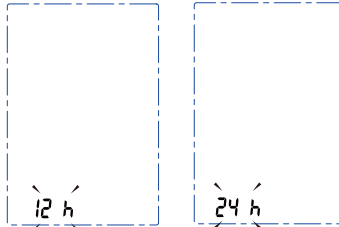
3. When you get the right year, press "S" button to set down and turn to next step. You can set the [DATE FORMAT] between D/M and M/D by pressing 'M' button



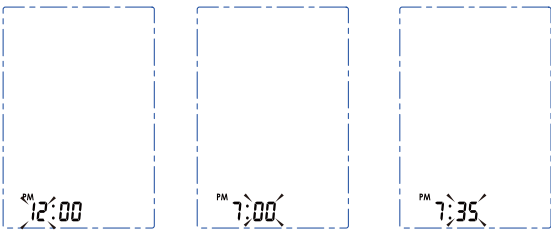
4. Repeat steps 2 and 3 to set the [MONTH] and [DAY].



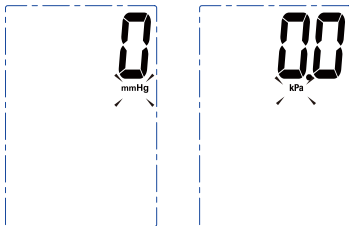
5. Repeat steps 2 and 3 to set the [TIME FORMAT] between 12H and 24H.



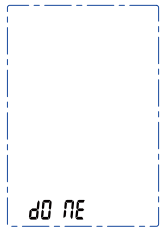
6.Repeat steps 2 and 3 to set the [HOUR] and [MINUTE].



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

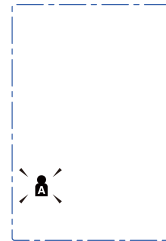


8.After the unit is set,the LCD will display "done" first, then display all the settings you have done and then turn off.

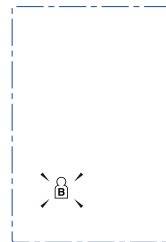


♥ Select the User

1.When the Arm Blood Pressure Meter is off , Press and hold 'M' button for 2 seconds to enter user setting mode. The user ID will blink.



2.Then press "M" button again, select the user ID between user A and user B.



3. After selecting the suitable user ID, press "S" button to confirm. Then the LCD will turn off.

♥ 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.

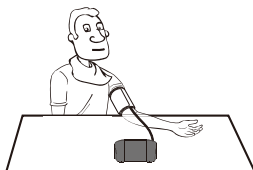
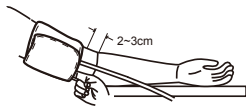
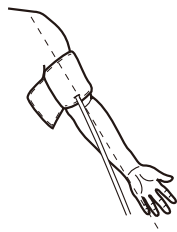
3. Sit comfortably with your tested arm resting on a flat surface.

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.



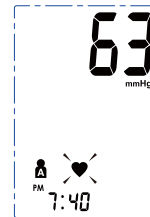
♥ Start the Measurement

1. When the Arm Blood Pressure Meter is off, press the "START/STOP" button to turn on it, and it will finish the whole measurement. (Take user A for example.)

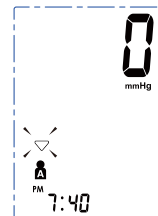
LCD display



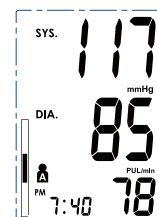
Inflating and measuring.



Adjust to zero.



Display and save the measurement results.

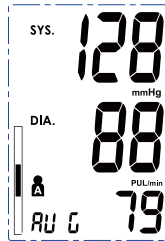


2. Press the "START/STOP" button to power off, otherwise it will turn off within 1 minute.

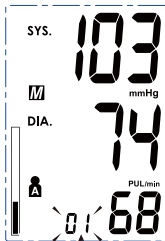
Tips: Maximum 60 records are both for User A and User B.

♥ Recall the Records

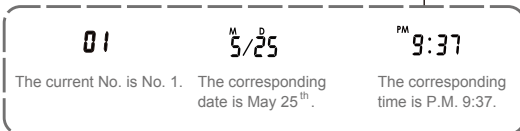
1. When the Arm Blood Pressure Meter is off, please press "M" button to show the average value of the latest three records.
(Note: If the records are less than 3 groups, the LCD will display the recent record instead. Take user A for example.)



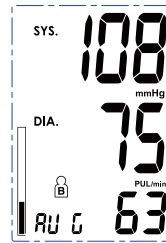
2. Press "M" button or "S" button to get the record you want.



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



3. If you want to check another user's records, press "START/STOP" button to turn off the Arm Blood Pressure Meter when it is in the memory inquiry mode. Press and hold 'M' button for 2 seconds to enter into the selecting user ID mode, press "M" again to select the user ID between user A and user B, press "S" button to confirm the user ID, then press "M" button to check the selected user's measurement records.



⚠ 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.

♥ Delete the Records

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

1. Hold pressing "M" button for 3 seconds when the Arm Blood Pressure Meter is in the memory recall mode, the flash display "User ID+ dEL ALL" will show.

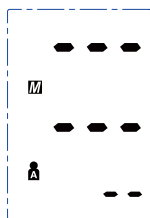


Note: To exit out of delete mode without deleting any records, press START/STOP button before pressing "S" button to confirm any delete commands.

2. Press "S" button to confirm deleting and the Arm Blood Pressure Meter will display "dEL dOnE" and then turn off.

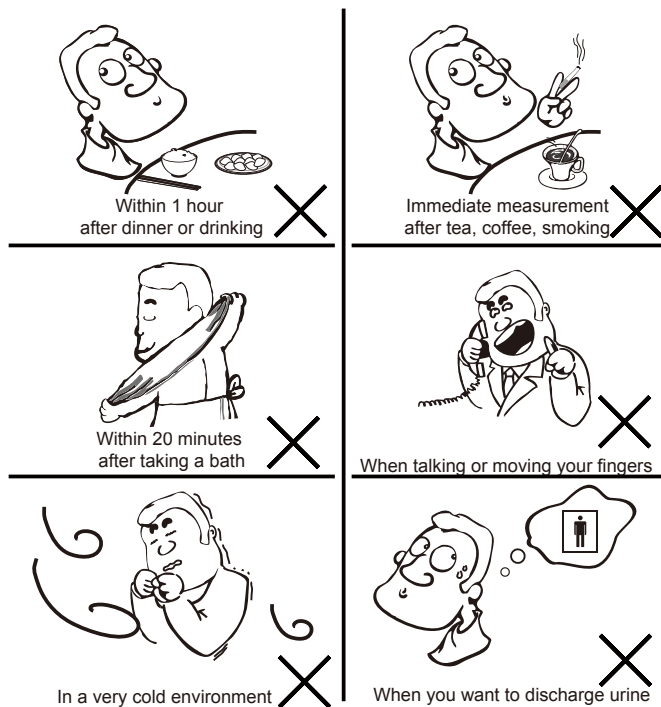


3. If there is no record, the following display will show.



♥ Tips for Measurement

Measurements may be inaccurate if taken in the following circumstances.

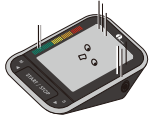


♥ Maintenance

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



Put in a dry place and avoid the sunshine



Avoid intense shaking and collisions



Using wet cloths to remove dirt



Avoid touching water, clean it with a dry cloth in case.



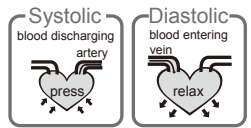
Avoid dusty and unstable temperature environment



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#)	and	Diastolic mmHg (lower#)
Normal	less than 120	and	less than 80
Prehypertension	120-139	or	80-89
High Blood Pressure (Hypertension) Stage 1	140-159	or	90-99
High Blood Pressure (Hypertension) Stage 2	160 or higher	or	100 or higher
Hypertensive Crisis (Emergency care needed)	Higher than 180	or	Higher than 110

⚠ 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

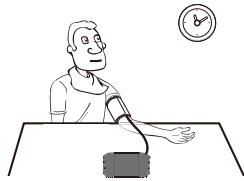
An irregular heartbeat is detected when a heartbeat rhythm varies while the unit is measuring the systolic and diastolic blood pressure. During each measurement, this equipment records the heartbeat intervals and works out the standard deviation. If the calculated value is larger than or equal to 15, the irregular heartbeat symbol appears on the symbol when the measurement results are displayed.

⚠ 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 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?

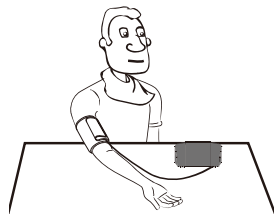
The blood pressure is different even throughout the day due to weather, emotion, exercise etc. Also, there is the “white coat” effect, which means blood pressure usually increases in clinical settings.

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 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 Arm Blood Pressure Meter . If the products not operating as you think it should, check here before arranging for servicing.

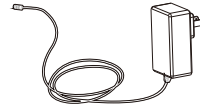
PROBLEM	SYMPTOM	CHECK THIS	REMEDY
No power	Display will not light up.	Batteries are exhausted.	Replace with new batteries
		Batteries are inserted incorrectly.	Insert the batteries correctly
		AC adaptor is inserted incorrectly.	Insert the AC adaptor tightly
Low batteries	Display is dim or shows 	Batteries are low.	Replace with new batteries
Error message	E 1 shows	The cuff is not secure.	Refasten the cuff and then measure again.
	E 2 shows	The cuff is very tight	Readjust the cuff ,not too loose or too tight and then measure again.
	E 3 shows	The pressure of the cuff is excess.	Relax for a moment and then measure again.
	E10 or E11 shows	The Arm Blood Pressure Meter detected motion, talking or the pulse is too poor while measuring.	Relax for a moment and then measure again.
	E20 shows	The measurement process does not detect the pulse signal.	Loosen the clothing on the arm and then measure again
	E21 shows	The treatment of the measurement failed.	Relax for a moment and then measure again.
	EExx,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.

Power supply	Battery powered mode: 6VDC 4×AAA batteries (Not Included) AC adaptor powered mode: 6V $\overline{\text{---}}$ 1A (Please only use the recommended AC adaptor model),(Not Included)
Display mode	Digital LCD V.A.100mm×68mm
Measurement mode	Oscillographic testing mode
Measurement range	Rated cuff pressure: 0mmHg~300mmHg(0kPa ~ 40kPa) Measurement pressure: SYS: 60mmHg~230mmHg (8.0kPa~30.7kPa) DIA: 40mmHg~130mmHg (5.3kPa~17.3kPa) Pulse value: (40-199)beat/minute
Accuracy	Pressure: 5°C-40°C within±3mmHg(0.4kPa) pulse value:±5%
Normal working condition	Temperature:5°C to 40°C Relative humidity: ≤85%RH Atmospheric pressure: 86kPa to 106kPa
Storage & transportation condition	Temperature:-20°C -60°C Relative Humidity: 10%RH-93%RH Atmospheric Pressure: 50kPa-106 kPa
Measurement perimeter of the upper arm	About 22cm~42cm
Net Weight	Approx.282g(Excluding the dry cells and cuff)
External dimensions	Approx.154mm×106mm×57.1mm
Attachment	1×storage bag,user manual
Mode of operation	Continuous operation
Degree of protection	Type BF applied part
Protection against ingress of water	IP21
Software Version	V01

WARNING: No modification of this equipment is allowed.

♥ Authorized Component

1. please use the 1byone authorized adapter. (Not Included)



Adapter
SKU 703US-0003 (MODEL: KH0601000UW)
Input: 100~240V~
50/60Hz, 0.3A Max
Output: 6V $\overline{\text{---}}$ 1000mA

♥ Complied Standards List

Risk management	ISO/EN 14971:2012 Medical devices — Application of risk management to medical devices
Labeling	ISO/EN 15223-1:2012 Medical devices. Symbols to be used with medical device labels, labelling and information to be supplied. General requirements
User manual	EN 1041: 2008 Medical equipment manufacturers to provide information
General Requirements for Safety	IEC 60601-1: 2005+A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance IEC 60601-1-11 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	IEC/EN 60601-1-2:2007 Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral standard: Electromagnetic compatibility - Requirements and tests
Performance requirements and Clinical investigation	IEC 80601-2-30:2009 Medical electrical equipment- Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers ANSI/AAMI SP10:2002/A2: 2008 Manual, electronic, or automated sphygmomanometers
Software life-cycle processes	IEC/EN 62304:2006+AC: 2008 Medical device software - Software life cycle processes
Usability	IEC 62366 Medical devices - Application of usability engineering to medical devices (IEC 62366:2007) IEC 60601-1-6 Medical electrical equipment - Part 1-6 : General requirements for basic safety and essential performance - collateral standard : Usability

♥ 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.

♥ EMC Guidance

- 1) This equipment needs to be installed and put into service in accordance with the information provided in the user manual;
- 2) 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 $d=3,3m$ away from the equipment.

(Note: As indicated in Table 6 of IEC 60601-1-2:2007 for ME EQUIPMENT, a typical cell phone with a maximum output power of 2 W yields $d=3, 3m$ at an IMMUNITY LEVEL of 3V/m)