Instruction Manual

Automatic
Upper Arm Blood Pressure Monitor

HL868AU

REF **HHBPA-100BT**

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Medical Disclaimer

This manual and product are not meant as a substitute for advice provided by your doctor.

You are not to use the information contained herein, or this product for diagnosing or treating a health problem or prescribing any medication. If you have or suspect that you have a medical problem, promptly consult your healthcare provider.

Intended Use

This device uses the oscillometric method to automatically measure systolic and diastolic blood pressure as well as heart rate.
The measurement position is at human being's arm. All values can be read out on LCD panel.

The device is designed for home use and recommended for use by adults aged 18 years and older with upper arm circumference ranging from 9 inches to 17 inches (approx.23 cm to 43 cm) or 17 inches to 22 inches (approx.43 cm to 56 cm) (optional) and for home use.

The device can accurately measure blood pressure in pregnant patients including those with known or suspected in pre-eclampsia condition.

Besides, the device features a built-in "Data Transferring" function, which enables the device automatically transmits measuring results to paired Bluetooth-enabled device. Also, users could simply synchronize the current date and time of blood pressure monitor by means of application software with the paired Bluetooth-enabled device.

About Blood Pressure

1. What is blood pressure?

Blood pressure is the measurement of the force of blood pushing against the walls of the arteries. Arterial blood pressure is constantly fluctuating during the course of the cardiac cycle. The highest pressure in the cycle is called the systolic blood pressure, and represents the pressure in the artery when the heart is beating. The lowest pressure is the diastolic blood pressure, and represents the pressure in the artery when the heart is at rest. Both the systolic and the diastolic pressure are necessary for a physician to evaluate the status of a patient's blood pressure.

Many factors such as physical activity, anxiety or the time of day, can influence your blood pressure. Blood pressure is typically low in the mornings and increases from the afternoon to the evening. It is on average lower in the summer and higher in the winter.

2. Why is it useful to measure blood pressure at home?

Having one's blood pressure measured by a doctor in a hospital or a clinic is often associated with a phenomenon called "White Coat Hypertension" where the patient becomes nervous or anxious, thus raising his blood pressure. There are also numerous other factors that might cause your blood pressure to be raised at a specific time of day. This is why medical practitioners recommend home monitoring as it is important to get readings of blood pressure during different times of the day to really get an idea of your real blood pressure.

Medical practitioners generally recommend the "Rule of 3", where you are encouraged to take your blood pressure three times in a row (at 3 ~ 5 minute interval), three times a day for three days. After three days you can average all the results and this will give you an accurate idea of what your blood pressure really is.

About Blood Pressure

A. AHA blood pressure classifications:

Standards for assessment of high or low blood pressure without regard to age, have been established by the American Heart Association (AHA 2017), as shown in the chart**.**

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mmHg (lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120-129	and	LESS THAN 80
HIGH BLOOD PRESSURE (HYPERTENSION)STAGE 1	130-139	or	80-89
HIGH BLOOD PRESSURE (HYPERTENSION)STAGE 2	140 OR HIGHER	or	90 OR HIGHER
HYPERTENSIVE CRISIS (consult your doctor immediately)	HIGNER THAN 180	And/or	HIGHER THAN 120

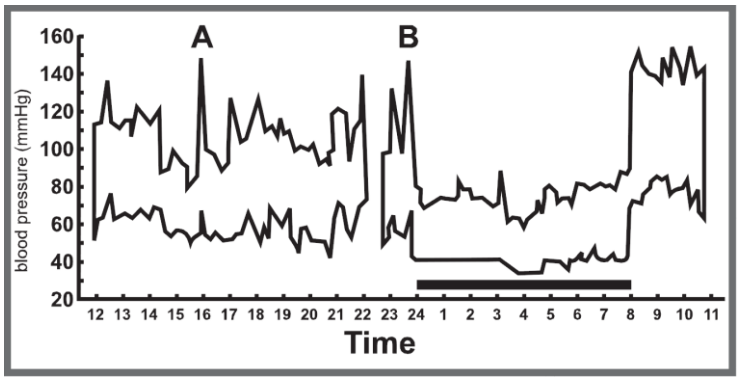
However, this chart is not exact for classification of blood pressure and it's intended to be used as a guide in understanding non-invasive blood pressure measurements. Please consult with your physician for proper diagnosis.

B. Variations in blood pressure:

Individual blood pressures vary greatly both on a daily and a seasonal basis. These variations are even more pronounced in hypertensive patients. Normally the blood pressure rises while at work and is at its lowest during sleeping period.

(hypertensive: means a person who has high blood pressure symptom.)

The graph below illustrates the variations in blood pressure over a whole day with measurement taken every five minutes. The thick line represents sleep. The rise in blood pressure at 4 PM (A in the graph) and 12 AM (B in the graph) correspond to an attack of pain.



(Direct arterial pressure recording in unrestricted man.

Beven, Honour & Stott: Clin. Sci. 36:329. 1969)

[1] : National Institutes of Health, U.S. Department of Health and Human Services.

Measurement Method

HL868AU Automatic Upper Arm Blood Pressure Monitor measures blood pressure and heart rate by oscillometric method, meaning the fluctuations in pressure are measured. Once the cuff is wrapped around your upper arm, just turn on the monitor and inflation automatically starts. The inflation of the cuff creates pressure around the arteries inside upper arm.

Within the cuff is a gauge which senses the fluctuations (oscillations) in pressure. The fluctuation measured represents the degree of intensity that your arteries contracting with each heartbeat, and also a result of the pressure that the cuff has placed on the upper arm. The monitor measures these contractions and converts the information to a digital value. This is the result displayed on the monitor screen.

Once the measurement is completed, the cuff will automatically deflate.

Accuracy

HL868AU Automatic Upper Arm Blood Pressure Monitor has been clinically tested against a scientific device called *mercury sphygmomanometer*, considered the gold standard in blood pressure measurement.

All HL868AU Automatic Upper Arm Blood Pressure Monitors have performed equivalent to measurements taken with this scientific device and are within the accuracy limits prescribed by the American National Standard for Electronic or Automated Sphygmomanometers.

The SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2018.

In case it is needed to have the device checked for calibration, please consult the distributor. This is recommended to be considered every two years.

Precautions

* Read the Instruction Manual thoroughly before measuring and keep it at hand for your reference at any time.
* The device is designed for home use and not suitable for clinical use.
* The patient is an intended operator, who can operate the device by himself or herself, not necessarily by a physician or operator.
* This monitor is not intended for use in the MR environment.

- ❑ The device should not be used to either self-diagnose Hypertension or exclude the diagnosis of Hypertension. If your blood pressure reading is out of normal range, please consult your physician. Even your blood pressure reading is within the "normal" range, the device cannot exclude the diagnosis of Hypertension.
- ❑ Do not take a measurement in a too low (less than 41 ℉/5 ℃) or too high (more than 104 ℉/40 ℃) temperature, nor in a place outside humidity ranges (15 % ~ 93 % R.H.) and atmospheric pressure ranges (700 ~ 1060 hPa), or you may get inaccurate readings.
- ❑ Wait for 30 ~ 45 minutes before measurement if you've just consumed caffeinated beverages or smoked cigarettes.
- ❑ Please rest for at least 5~10 minutes before taking the measurement.
- ❑ To allow your blood vessels to return to the condition prior to taking the measurement, please wait at least 3 ~ 5 minutes between measurements. You may need to adjust the wait time according to your personal physiological situation.
- ❑ We recommend you using the same arm (preferably the left arm) and measuring around the same time each day.
- ❑ Perform measurements in a quiet and relaxed environment at room temperature.
- ❑ Do not move or shake the device during a measurement. Please keep quiet and do not talk during measurements.
- ❑ If you are pregnant, you should pay more attention to your blood pressure changes, because during this time, it may change drastically.
- ❑ This monitor is clinically validated for use in pregnancy and pre-eclampsia. When you detect unusual readings in pregnancy, you should measure again after taking some rest. If the reading is still abnormal, consult your doctor or gynecologist.

Precautions

- Consult with your physician before measuring blood pressure when you are under these conditions:
  - Diagnosed with arrhythmias
  - Undergoing intravenous injection on any limb
  - Currently in a dialysis treatment
- For those who have had a mastectomy or lymph node clearance, it is recommended to take a measurement on the unaffected side.
- When used among medical electronic equipment on the same limb, pressurization of the cuff may cause temporarily malfunction to other devices.
- Blood pressure measurements should be interpreted by a physician or a trained health professional who is familiar with your medical history. Using the unit and recording the results regularly for your physician to interpret, you will keep your physician informed of the continuing changes in your blood pressure.
- If you have one of the circulatory problems such as arteriosclerosis, diabetes, liver disease, kidney disease, severe hypertension, peripheral circulation……, please consult your healthcare professional before using the device.
- Results are not intended for direct diagnosis. Please consult with a physician if you have any questions or concerns about your results.
- Blood pressure measurements taken with this device are equivalent to those obtained by a trained observer using the cuff/ stethoscope auscultation method and are within the accuracy limits prescribed by the Standard of ISO 81060-2-30.
- The applied part is the cuff.

Attention !

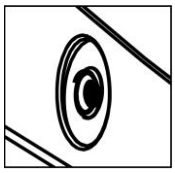
1. Do not use the device on infants, children, or those who cannot express their own intention. To avoid accidental strangulation, keep this product away from children and do not drape tube around neck.
2. The medical device should not be used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary. The medical device should be observed to verify normal operation in the configuration in which it will be used.
3. Consider the electromagnetic compatibility of the device (ex. power disturbance, radio frequency interference etc.) Please use it indoor only.
4. Over high frequency measurements may result in blood flow interference, which is likely to cause uncomfortable sensations, such as partial subcutaneous hemorrhage, or temporary numbness to your arm. In general, these symptoms should not last long. However, if you do not recover in time, please seek your medical practitioners for help.

Device information:

- Not suitable for use in presence of flammable anesthetic mixture with air or with oxygen or nitrous oxide
- Continuous operation with short-time loading

Device Overview

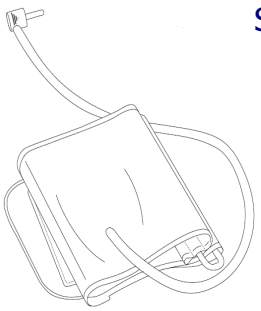
◆ Part names and product components



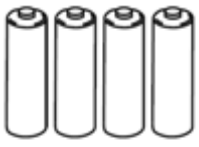
Arm Cuff hole

LCD Display

START / STOP Button



Arm Cuff with Tube



AAA "LR03" (1.5V) Alkaline Battery X 4

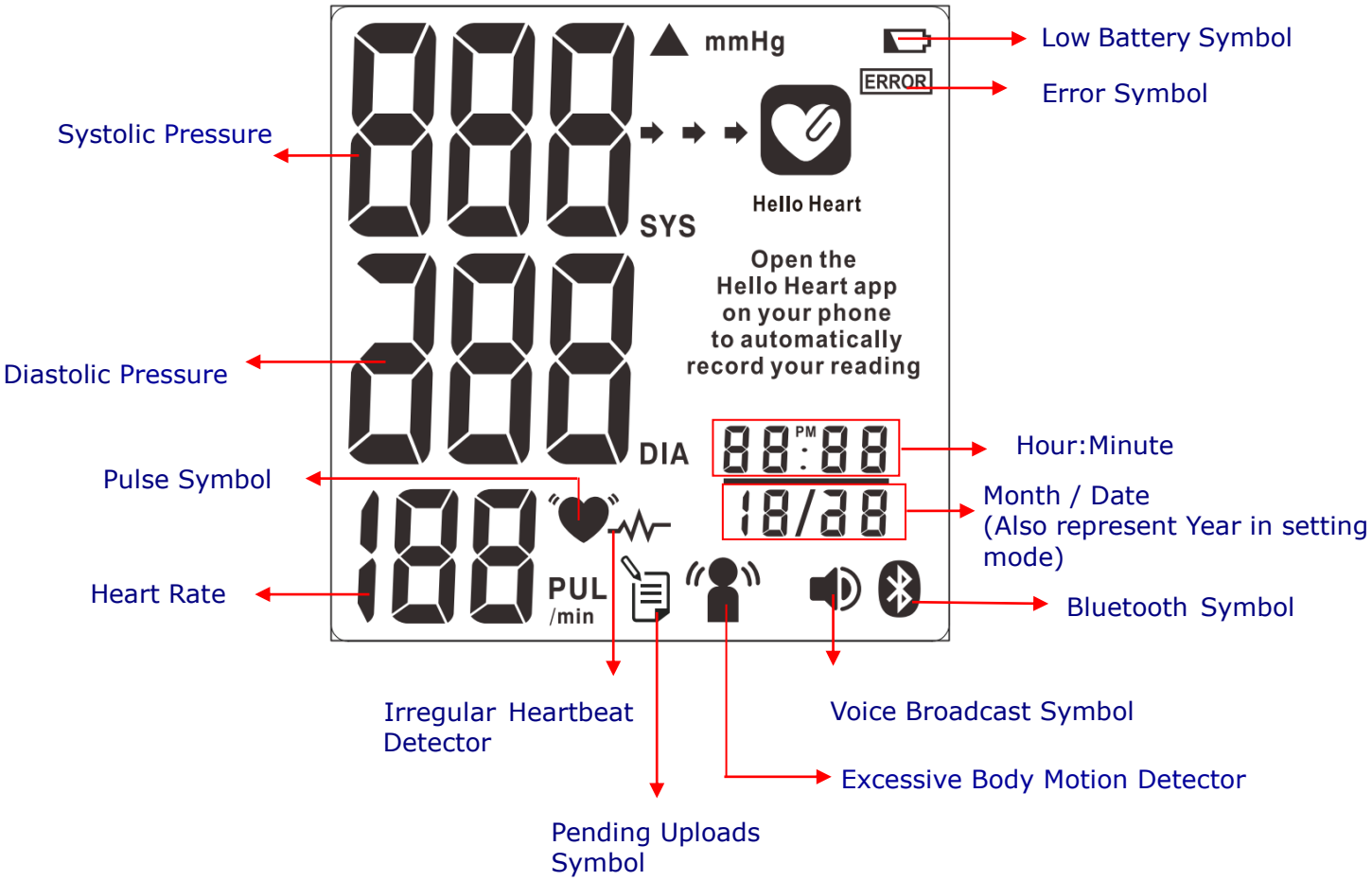
Travel Bag

Caution !

Substitution of a component different from that supplied might result in measurement error.

Device Overview

◆ Unit display



Symbol Definitions

SYMBOLS	Definitions
 Low Battery Symbol	This symbol appears when the battery power is excessively low or the polarity reverses. ➔ We suggest you replace all batteries with new ones, and make sure the +/- polarities are properly positioned.
 Pulse Symbol	Once pulse is detected, the symbol flashes with each pulse beat. ➔ Our suggestion: Please do not talk or move during measurements.
 Irregular Heartbeat Detector	This symbol appears when an irregular heartbeat was detected. ➔ Our suggestion: Please do not talk or move during measurements. Repeat the measurement after resting for at least 5 minutes, and restart your measurement while sitting down comfortably and quietly. If symbols appear frequently, please contact your physician.
 Excessive Body Motion Detector	This symbol appears if body movement is detected during measurement, especially on the arm that the cuff is worn on. Notice: The measured blood pressure reading may not be accurate if the icon is displayed.
 Bluetooth Symbol	LCD displays this symbol when Bluetooth is active.
 Error Symbol	Error Display.
 Pending Uploads Symbol	This symbol appears if a specific number of memory values have not been uploaded.

Features

◆ Irregular Heartbeat Detector

The symbol  will appear on screen indicating a certain heartbeat irregularity was detected during measurement.
The heartbeat rhythm that is more than or less than 25% from the average rhythm is usually defined as an irregular heartbeat rhythm.
Talking, moving, shaking or an irregular pulse during the measurement can result in the appearance of this symbol.
Usually this is not a cause for concern, however if the symbol appears often, we recommend you seek medical advice.
And please note that the device does not replace a cardiac examination, but serves to detect pulse irregularities at an early stage.

Note !

- The pulse display is not suitable for checking the frequency of heart pacemakers. If a certain pulse irregularity is detected during measurement often, we recommend you seek medical advice
- The IHB function is designed neither for use by people with arrhythmias nor for diagnosing or treating an arrhythmic problem. In order to filter the unstable status of user and avoid affecting the detection of heart rate from any movement, shaking or talking in the beginning of measurement, the method of averaging heartbeat intervals of subject device is calculated with the three proper heartbeat pulses detected in the beginning of measurement and that is different from a strict mathematical averaging of all recorded intervals.
- At least 3 beats with 25% or greater difference from the average heartbeat interval will generate the IHB icon on the screen.

◆ Talking Function

The device features a talking function for you to hear your measurement results.

Features

◆ Data Transferring

This product is an arm type blood pressure monitor. Design without entering personal information. The device has a transmission function. During the transmission process, the measurement data is designed to be encrypted, and will not be tampered with unauthorized access nor retrieve user-related information. The firmware and software of the product have been pre-programmed in the production stage. Both the burned in microcontroller programmer and the software were designed encrypted; there is no concern about the software safety.

Bluetooth function requirement:

☐ An Android device with Android version 6.0 or above and hardware support for Bluetooth 4.2.

☐ An iOS device with iOS version 7.0 or above and hardware support for Bluetooth 4.2.

Note:

Please refer to the instruction manual of your smart phone for how to activate the Bluetooth function.

Note !

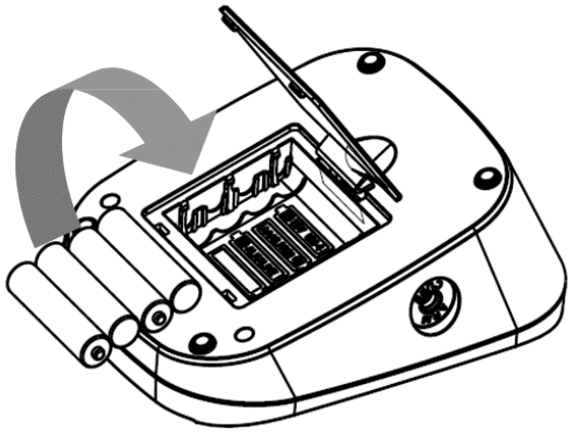
- HL868AU is subject to and complies with electromagnetic compatibility (EMC) standard of IEC 60601-1-2, EN 301 489-1, EN 301 489-17, EN 300 328 and U.S. federal guidelines, Part 15 of the FCC (Federal Communications Commission) rules for devices with RF capability. These guidelines help ensure that your device will not affect the operation of other nearby devices. Additionally, other devices should not affect the use of your device.
- Other wireless devices that are in use nearby, such as a cell or mobile phone, or a wireless network, may prevent or delay the transmission of data from your device to paired Bluetooth-enabled device. Moving away from the source of the interference or turning off these devices to resolve the problem.
- Make sure HL868AU and paired Bluetooth-enabled device are within acceptable distance (no more than 10 meters) with each other. If not, put them closer.
- Bluetooth data transmission is not available under measurement

Installing Batteries

When low battery symbol appears on the display, or there is no reaction toward operation, please change batteries.

Replace all worn-out batteries with new ones and do not mix new and used batteries. All batteries used must be the same type. Do not mix alkaline, standard (carbon-zinc) or rechargeable (cadmium) batteries either. Such action may shorten the battery life or cause the device to malfunction.

Slide the battery cover and insert 4 AAA "LR03"(1.5V) alkaline batteries into the battery compartment as shown on the figure below. Make sure the polarities "+" and "–" ends are coinciding with similar markings engraved on the battery housing.



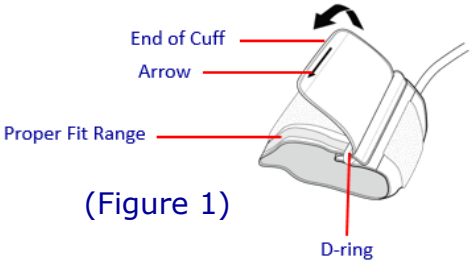
Attention !

- Batteries are hazardous waste. Do not dispose of them together with the household garbage. Please discard worn-out batteries to the recycling site according to local regulations.
- Keep the battery away from children in case they choke on it.
- To prolong the battery life and prevent damage caused by leakage, remove the batteries from the device if the device is not to be used for a long period.
- After replacing the batteries, the date and time will be reset.

Batteries are hazardous waste. Do not dispose of them together with the household garbage. Please discard worn-out batteries to the recycling site according to local regulations.

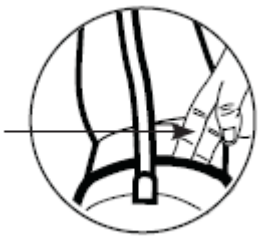
Applying the Cuff

- ❑ Wrap the cuff on a bare arm or over thin clothing. Thick clothing or a rolled up sleeve will cause inaccurate blood pressure measurements.
- ❑ Use only the approved arm cuff for this device. Use of other arm cuffs may result in incorrect measurement result.
- ❑ Press your brachial artery approximately 1 inch (2 ~ 3 cm) above the elbow on the inside of your left arm to determine where your strongest pulse is.
- ❑ Slide the end of arm cuff furthest from the tube through the metal ring to a loop. The smooth cloth should be on the inside of the cuff. (Figure 1)

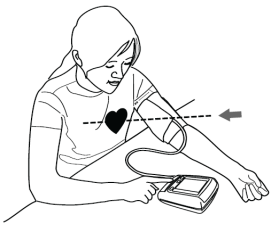


(Figure 1)

- ❑ If the cuff is located correctly, the velcro will be on the outside of the cuff, metal ring will not touch your skin.
- ❑ Put left arm through the cuff loop. The tube should lie over the brachial artery on the inner part of the arm.
  The bottom edge of the cuff should be 1 inch (2 ~ 3 cm) above the inner elbow.


(Figure 2)

- ❑ Pull the end of the cuff so that it tightens evenly around your arm, allow room for 2 fingers to fit between the cuff and your arm. (Figure 2)
- ❑ When the cuff is positioned properly, press the velcro firmly against the pile side of the cuff. Please make sure the cuff do not slip during measurement, and the arrow falls within the Proper Fit Range.



- ❑ Sit on a chair and lay your forearm on the table so that the cuff is at the same level as your heart.
- ❑ Relax your arm and turn your arm upward.
- ❑ Make sure there are no kinks in the air tube.

Note !

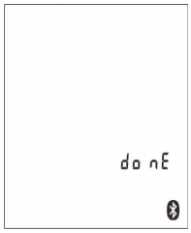
- If you have any infectious skin disease or the device is used by users with infectious skin disease, please do not continue using the device.
- Before using the device, user should check the appearance of cuff. If you notice blood or other soil on cuff, please do not use this device.
- If there is one of above situations, please dispose the device without reuse.
- Fit the cuff snugly, leaving enough space for 1 inch (2 ~ 3 cm) between the inner elbow and the lower edge of the cuff, or the measurement may not be accurate.
- This monitor comes with one size of arm cuff: 9" ~ 17" (23 ~ 43 cm).
- In case the cuff kept pumping up non-stop, unwrap the cuff at once.
- Do not use this device if your arm has any wound or injury, especially after surgery on the arm. Otherwise, it may cause infection at the surgical site. Please use the device after the wound has healed.

Monitor Pairing Procedure

A. Put in 4 AAA “LR03” (1.5V) alkaline batteries, all segments appear on the screen.

B. The LCD will display as shown in the figure on the right, please pairing your monitor with the app first. Measurement or system settings on the blood pressure monitor are only available after a successful pairing.

C. If the monitor has successfully paired with your smart device, the Bluetooth symbol will appear on the screen with the segment “donE”.



D. If HL868AU fails to pair with your smart device, the Bluetooth symbol will appear on the screen with the segment “FAIL”.

E. The date and time on your monitor will be automatically updated when the monitor is pair with the smart device.

NOTE:

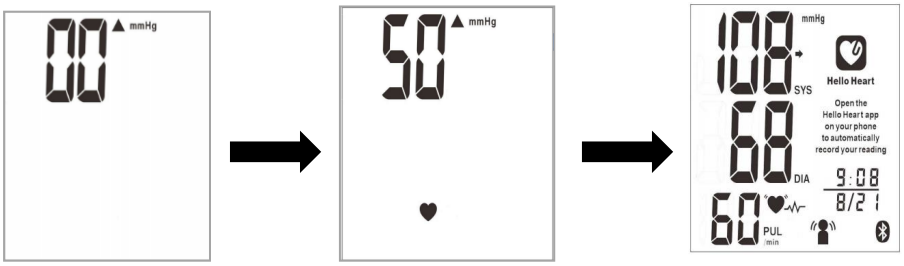
The monitor will enforce a mandatory pause when a specific number of data that have not been uploaded. It will automatically prompt users to open the app until all data is uploaded.

Measurement Procedure

◆ Talking a Measurement

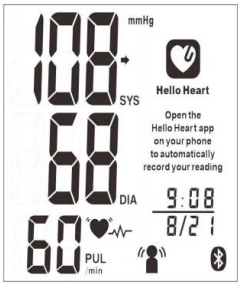
A. With the cuff wrapped around your upper arm, press the START button to start measurement.

B. As the cuff inflates, the monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation. The Pulse Symbol ♥ flashes at every heartbeat. Remain still and do not move until the entire measurement process is completed.



C. After the monitor has detected your blood pressure and pulse rate, the cuff automatically deflates. Your systolic rate, diastolic rate, pulse rate, irregular heartbeat detector and excessive body motion detector (if any) are displayed with date and time for 40 seconds.

Meanwhile, the monitor activates Bluetooth function automatically to transmit the measurement to the paired-device, the Bluetooth symbol will flash on the screen. If the monitor failed to transmit the measurement, LCD will be displayed Error message "E12".



D. Without any operation for 40 seconds, device automatically shuts off.

Note !

- Do not inflate the cuff until it is wrapped around your upper arm.
- If the cuff does not stop inflating, remove the cuff at once.
- To stop measurement, you may press the **START/STOP** button. The cuff will deflate immediately after the button is pressed.
- The monitor will automatically switch to sleeping mode if no operation in 40 seconds.

Memory Function

◆ Storing Data

After each measurement, your systolic pressure, diastolic pressure, pulse rate, irregular heartbeat detector and excessive body motion detector (if any) with date and time will be automatically stored. The monitor can store up to 120 memory sets.

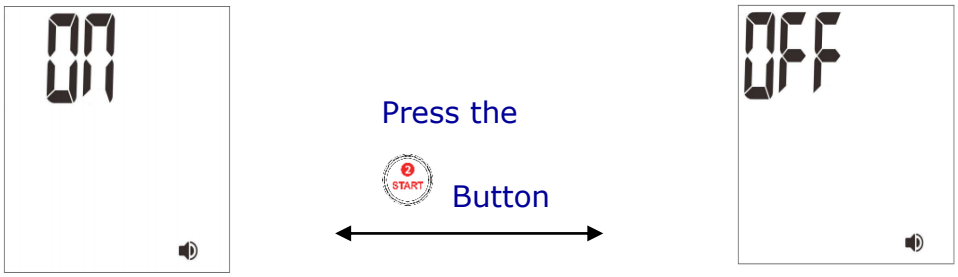
System Settings

◆ Turn the Talking Function ON/OFF

A. After pairing your monitor with the app, press the START button for 3 seconds under sleeping mode to enter talking function setting, the default setting of talking function is OFF.

B. Press the START button to turn ON or OFF talking function.

C. Press the START button for 3 seconds to enter memory erasing mode.



Talking Function is ON

Talking Function is OFF

D. To confirm the setting, wait for 10 seconds and the monitor will automatically shut down.

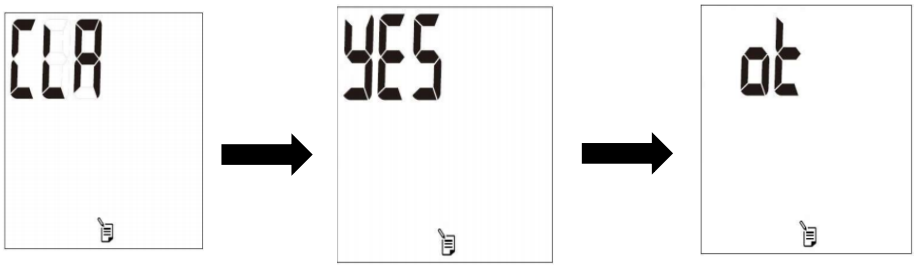
System Settings

◆ Erasing Data

A. Press the START button for 3 seconds under talking function setting to enter the erasing data mode, the LCD displays "CLA".

B. Press the START button, the LCD will display "YES" to confirm that the memory will be erased. To skip data erasing mode, press the START button for 3 seconds to enter time setting mode.

C. Press the START button to erase the memory. Once the memory is erased, the LCD display "ot".

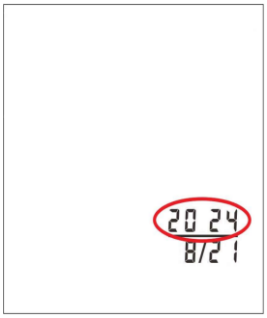


E. To confirm the setting, wait for 10 seconds and the monitor will automatically shut down.

Note: Once deleted, your data can NOT be restored.

◆ Setting Year, Date and Time

A. To enter setting mode, press the START button for 3 seconds under memory erasing mode ("year" flashes). Press the START button to adjust year (2024, 2025, 2026,....., 2039).



B. Press the START button for 3 seconds ("month" flashes). Press the START button to adjust month (1, 2, 3,....., 12).

C. Press the START button for 3 seconds ("date" flashes). Press the START button to adjust date (1, 2, 3,....., 31).

D. Adjust hour (12, 1,.....12^{PM},1 ^{PM},....., 11^{PM}) and minute (00,01,02,03,……59) as described in Step B above.

E. To confirm the setting, wait for 10 seconds and the monitor will automatically shut down.

Storage and Maintenance

◆ General Use

- ❑ Do not twist the cuff in any way.
- ❑ Do not press the **START/STOP** button if the cuff is not wrapped around your upper arm.
- ❑ Do not drop the product and avoid any strong impacts.

◆ Maintenance

- ❑ Do not attempt to disassemble or change any parts of the monitor, only trained technicians are allowed to repair and disassemble the device, including software upgrades, cuff, patches and maintenance, because a substitution of a component different from that supplied might result in measurement error.
- ❑ If any suggestion or service is requested, please consult your service station.
- ❑ Do not implement the maintenance procedures for equipment during measurement.

To ensure that your device is in optimal use and to avoid damage, please refer to the following instructions:

- ❑ Clean the device and cuff with a soft dry cloth, or
- ❑ Use a dry cloth with water to clean the device (do not flush it directly, do not soak it in water, and hold the device dry), or
- ❑ Do not use detergent or any strong chemicals to clean the device.
- ❑ Make sure the cuff is completely dry before using.

According to the use environment of the sphygmomanometer, the recommended disinfection method and frequency are as follows:

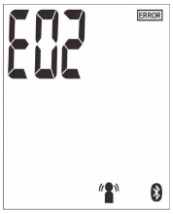
- ❑ Only use it yourself (home use), it can be cleaned at ordinary times, and wipe it once a month with a commercially available 75% alcohol cotton sheet (for the cuff) for more than 30 seconds each time.
- ❑ If it is used for more than one person (home use), it can be cleaned at ordinary times. It is disinfected once a week (for the cuff belt) with a commercially available 75% alcohol cotton sheet, for more than 30 seconds each time.
- ❑ After cleaning / disinfecting/ before using, please make sure that there are no blood stains or soil on the LCD, the device and cuff. If there is any blood stains or soil, please dispose the device without reuse.
- ❑ If it is used in a complex environment (such as a hospital) or after multiple people (non-family), please discard the old cuff and replace it with a new one.

Storage and Maintenance

◆ Storage

- ❑ If the device is not to be used for a long time, please remove the batteries from the device (leaking of battery acid can cause the device to malfunction).
- ❑ Always store the unit in the travel bag after use. It is intended to be transported or stored in a carrying case between uses.
- ❑ Do not place the device directly under sunlight, in high temperature, or in humid or dusty places.
- ❑ Do not store the device in extremely low (less than –13℉/–25℃) and high (more than 158℉/70℃) temperature, nor in a place its humidity exceeds 93% R.H.

Troubleshooting

SYMBOLS/SYMPTOMS	CONDITIONS/CAUSES	INDICATION/ CORRECTION
Unit does not turn on when the **START/STOP** button is pushed.	Worn-out batteries	Replace them with 4 new AAA (LR03) alkaline batteries.
	Battery polarities have been positioned incorrectly.	Re-insert the batteries in the correct positions.
 Measuring Error Symbol	The cuff is too tight or too loose.	Wrap the cuff properly. Check cuff connection. Measure again.
	The cuff has been placed incorrectly	
	Cuff tube may not be plugged into monitor correctly.	
 Measuring Error Symbol	Body movement is detected during measurement, especially on the arm that the cuff is worn on. e.g. Talking, moving or shaking of the arm with the cuff on while measurement. **Notice:** The measured blood pressure reading may not be accurate if the icon is displayed.	Measure again. Keep arm steady during measurement.
 Measuring Error Symbol	Can’t determine blood pressure measurement data.	Loosen clothing around the arm, wrap the cuff properly and keep steady. Measure again.
 Measuring Error Symbol	Unable to complete the measurement	Rest for a moment and measure again.

Troubleshooting

SYMBOLS/SYMPTOMS	CONDITIONS/CAUSES	INDICATION/ CORRECTION
 Measuring Error Symbol	Paring has not been completed.	Please re-pairing the BPM and Bluetooth -enabled device with each other.
	The distance between BPM and Bluetooth-enabled device is out of transmitting range.	Please make sure the acceptable distance (≦10 meters) with each other.
	Use an incompatible Bluetooth-enabled device.	Please refer to "Data Transferring"
	Use non-Bluetooth-enabled device.	
	Unexpected loss of electrical/mechanical integrity.	Re-insert the batteries and try again.
 Measuring Error Symbol	Reading results are outside the measurement range	Rest for a moment. Refasten the cuff and measure again. If the problem persists, contact your physician
Note: If "E06" appears on the display, just return the device to your local distributor or importer.		

Limited Warranty

◆ **Warranty For Two Years from the manufacturing date**

Please note that this warranty does not cover damage caused by misuse or abuse; accident; the attachment of any unauthorized accessory; alteration to the product; improper installation; unauthorized repairs or modifications; improper use of electrical/power supply; loss of power; dropped product; malfunction or damage of an operating part from failure to provide manufacturer's recommended maintenance; transportation damage; theft; neglect; vandalism; or environmental conditions; loss of use during the period the product is at a repair facility or otherwise awaiting parts or repair; or any other conditions whatsoever that are beyond the control of importers or distributors.

Specifications

Model Number	HL868AU
Measurement Method	Oscillometric (Inflation)
Rated Range of Cuff Pressure	0 ~ 300 mmHg
Rated Range of Determination	40 ~ 280 mmHg
Measurement Range of Heart Rate	40~199 Beats/Minute
Accuracy	Pressure: ± 3 mmHg Pulse: ± 5 % Max.
Display	Liquid Crystal Display
Memory	120 memory Set
RF Type	Bluetooth 5.0 BLE
Unit Dimensions	5.07 x 3.96 x 1.89 inch (Lx W x H) 128.7 x 100.5 x 48 mm(Lx W x H)
Unit Weight	254 g ± 5 g (8.95 oz ± 0.18 oz) (Cuff and batteries excluded)
Cuff Size	UC-01: Universal size cuff 9~17 inch (23 ~ 43 cm) ELC-01(Optional): Extra Large size cuff 17~22 inch (43 ~56 cm)
Storage/ Transportation Environment	Temperature: -25 °C ~70 °C (-13 °F ~ 158 °F) Humidity: ≤ 93 % R.H. Atmospheric pressure: 700hPa ~ 1060hPa
Operation Environment	Temperature: 5 °C ~ 40 °C (41 °F ~ 104 °F) Humidity: 15 % ~ 93 % R.H. Atmospheric pressure: 700hPa ~ 1060hPa
Power Supply	DC 6V, AAA "LR03" (1.5V) alkaline battery x 4
Battery Life	Approx. 250 Measurements
Shelf Life (battery)	2 years (Temperature: 20 ± 2°C; Relative humidity: 65 ± 20%RH)
Product Life	5 Years (4 times per day)
Sleeping Mode	Without any operation for 40 seconds, device automatically switch off.
Accessories	4 AAA "LR03" (1.5V) Alkaline Batteries, Arm Cuff with Tube, Instruction Manual, Travel Bag, Readme, Instruction Card, Measure Tape

***The contents of this manual and the specifications of the device covered by this manual are subject to change for improvement without notice.**

Note

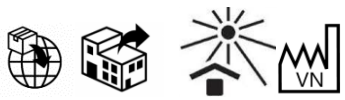
Explanation of symbols :

Symbol	Explanation	Health & Life Information
	Refer to instruction manual/booklet	-
	TYPE BF Applied Part	-
	To avoid inaccurate results caused by electromagnetic interference	Warning: Portable RF communications equipment (including peripherals such as antenna cables and external antennas) should be used no closer than 30cm (12 inches) to any part of the device, Otherwise, degradation of the performance of this equipment could result.
	Waste of batteries	Discard the used batteries to the recycling collection point according to local regulations.
	Manufacturer	 HEALTH & LIFE Co., Ltd. 9F, No. 186, Jian Yi Road,Zhonghe District, New Taipei City 23553, Taiwan www.healthandlife.com.tw
	Date of manufacture	 YYYY-MM
	Importer –if applicable with Name and address	
	Distributor–if applicable with Name and address	
	Serial number	 YYMMXXXXXX
	Batch code	 3YYM0XX
	Model number	
	Catalogue number	
	Humidity limitation	
	Temperature limit	
	Atmospheric pressure limitation	

Note

IP22	Ingress Protection Rating	First characteristic numeral- Degree of protection against access to hazardous parts and against solid foreign objects N1=2 (Protected against solid foreign objects of 12.5 mm Ø and greater) Second characteristic numeral- Degree of protection against ingress of water N2=2 (Protected against vertically falling water drops when ENCLOSURE tilted up to 15°)
	Non-ionizing electromagnetic radiation	-
	Medical Device	-
	Keep away from sunlight	-
	Country of manufacture	-

Manufacturer: HEALTH & LIFE CO., LTD.
9F, No. 186, Jian Yi Road, Zhonghe District 23553, New Taipei City, Taiwan
www.healthandlife.com.tw



Note

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

"This product meets applicable national SAR limits of 1.6W/kg.

This specific maximum SAR values can be found in the section of this user guide. When carrying the product or using it while worn on your body, maintain a distance of 0 mm from the body to ensure compliance with RF exposure requirements. Note that the product may be transmitting even if you are not Surfing Internet. Body SAR: 0.00 W/kg

*Note ！
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.

HL868AU essential performance per IEC 80601-2-30 additional essential performance requirements:

- 201.12.1.102 Limits of the error of the manometer from environmental conditions
  Over the temperature range of 5 °C to 40 °C (41 °F ~ 104 °F) and the relative humidity range of 15 % to 93 %(non-condensing), the maximum error for the measurement of the CUFF pressure at any point of the NOMINAL measurement range shall be less than or equal to ± 3 mmHg (± 0.4 kPa) or 2 % of the reading, whichever is greater.
- 201.12.1.107 Reproducibility of the blood pressure determination
  The laboratory Reproducibility of the BLOOD PRESSURE DETERMINATION of the AUTOMATED SPHYGMOMANOMETER shall be less than 3 mmHg (0.4 kPa).

Appendix

◆ **Guidance and manufacturer's declaration – electromagnetic emissions**

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Emissions test	**Compliance**	**Electromagnetic environment – guidance**
RF emissions CISPR 11	Group 1	RF energy is used only to maintain device's operation. Therefore, its RF emissions are so low that it's 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, including domestic establishments, and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Not Applicable	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	

◆ **Guidance and manufacturer's declaration – electromagnetic immunity**

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment – guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	± 8 kV contact discharge ± 15 kV air discharge	± 8 kV contact discharge ± 15 kV air discharge	In the case of air discharge testing, the climatic conditions shall be within the following ranges: Ambient Temperature:15℃~35℃ Relative Humidity: 30%~60%.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Appendix

◆ Guidance and manufacturer's declaration – electromagnetic immunity

The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq	Not Applicable	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 applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3 Proximity fields from RF wireless communications equipment IEC 61000-4-3	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz,Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz,Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	Recommended separation distance Considering to reduce 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: $E = 6/d \sqrt{P}$ where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVELS in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey,a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: 

Note 1) At 80 MHz and 800 MHz, the higher frequency range applies.

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

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the 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 reorienting or relocating the device.

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

Appendix

Test specifications for enclosure port immunity to RF wireless communications equipment.

Test frequency (MHz)	Modulation	IMMUNITY TEST LEVEL (V/m)
385	Pulse modulation 18 Hz a)	27
450	FM ± 5 kHz deviation 1kHz sine b)	28
710	Pulse modulation 217 Hz a)	9
745		
780		
810	Pulse modulation 18 Hz a)	28
870		
930		
1720	Pulse modulation 217 Hz a)	28
1845		
1970		
2450	Pulse modulation 217 Hz a)	28
5240	Pulse modulation 217 Hz a)	9
5500		
5785		

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). The carrier shall be modulated using a 50% duty cycle square wave signal.
b). 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.

Blood Pressure Diary

Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	

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