

Instruction Manual

Automatic Upper Arm Blood Pressure Monitor

Model No. HL858A1



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 in one 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) and for home use.

HL858A1 detects the appearance of irregular heartbeats during measurement; an indicated symbol will appear with measuring reading. And the BP Category Indicator will show the information with the readings on the screen for the user tracking their blood pressure level.

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.

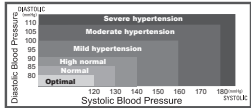
2. Why is it useful to measure blood pressure at home?

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.

A. WHO blood pressure classifications:

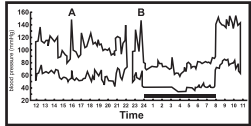
Standards for assessment of high or low blood pressure without regard to age, have been established by the World Health Organization (WHO), as shown in the chart.



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.



(Direct arterial pressure recording in unrestricted man, Bevan, Honour & Sleight: Clin. Sci. 36:329, 1969)

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

The graph below illustrated 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

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 temperatures lower than 41°F (5°C) or higher than 104°F (40°C), 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 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.
- Consult with your physician before measuring blood pressure when you are under these conditions:
 - Currently pregnant
 - Diagnosed with pre-eclampsia
 - 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.
- If you have one of the circulatory problems as arteriosclerosis, diabetes, liver disease, kidney disease, severe hypertension, peripheral circulation, please consult your healthcare professional before using the device.
- 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.
- The applied part is the cuff.

* Attention!

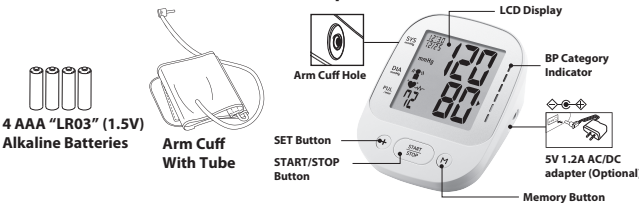
1. Do not use the device on infants, children, or those who cannot express their own intention. To avoid accidental strangulation, keep this product away from children and do not drape tube around neck.
2. The medical device should not be used adjacent to or stacked with other equipment. In case adjacent 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:

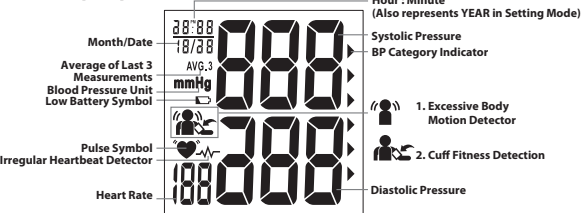
- Not suitable for use in presence of flammable anesthetic mixture with air or with Oxygen or nitrous oxide
- Continuous operation with short-time loading

Device Overview

Part Names and Product Components



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	Displayed 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.
Cuff Fitness Detection Symbol	Displayed if the cuff was wrapped incorrectly, which is too tight or too loose. This function aids in detecting if the cuff is wrapped properly.
BP Category Indicator	The arrowhead points out the specific BP Category that your measurement reading fits in.
AVG. 3 Average of Last 3 Measurements	This symbol appears when LCD displays average value of last 3 readings.

Features

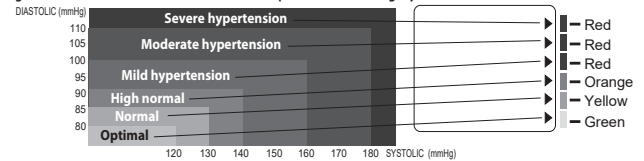
BP Category Indicator

This device is equipped with BP Category Indicator which classifies your blood pressure measurements into six stages (Optimal to Severe hypertension) as shown in below chart:

Stages of Blood Pressure Levels	Systolic (mmHg)	Diastolic (mmHg)	Color	Recommendations by SIGN 49: Hypertension in older people
Grade 3 Severe Hypertension	≥180	≥110	Red	Confirm immediately and repeat BP in one day and again within one week depending on clinical situation
Grade 2 Moderate Hypertension	160~179	100~109	Red	Serial blood pressures repeated within one month.
Grade 1 Mild Hypertension	140~159	90~99	Red	Provide advice about lifestyle modification and confirm within two months.
High-Normal	130~139	85~89	Orange	Provide advice about lifestyle modification and recheck in one year.
Normal	120~129	80~84	Yellow	Recheck in 2 - 5 years.
Optimal	<120	<80	Green	(patients aged > 75 years offered annual health check)

* Source: WHO, 2003

After each measurement is completed, LCD display will show your position automatically on the six segments of the bar indicator which corresponds to BP Category Indicator.



*Note!

When a person's systolic and diastolic pressures fall into different categories, the higher category should apply.
e.g. systolic pressure 181 & diastolic pressure 99 → Red category (Severe Hypertension)
e.g. systolic pressure 110 & diastolic pressure 95 → Red category (Mild Hypertension)

*Note!

The above table 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. Usually this is not a cause for concern; however we recommend you consult with your physician for proper diagnosis or seek medical advice according to our recommendation mentioned above. Please note that the device does not appropriate to diagnose hypertension, and it is only for user reference on blood pressure monitoring.

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!

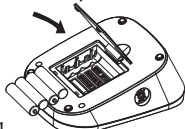
- The pulse display is not suitable for checking the frequency of heart pacemakers. If a certain pulse irregularity is detected during measurement often, we recommend you seek medical advice.
- The IHB function is neither designed for use by people with arrhythmias nor for diagnosing or treating an arrhythmic 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.

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!

- 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.
- Memories (if any) will not be deleted during battery replacement.
- Date and time will be reset if AC/DC adapter is unplugged and unit is without batteries. Even when batteries are in the monitor, plugged in or unplugged the AC adapter may cause the time and date to reset.
- After replacing the batteries, the date and time will be reset.
- Install battery to the correct polarity, incorrect installation may cause short circuit or explosion.

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.

Using the AC/DC Adapter

This monitor is designed for operation with batteries or an AC/DC adapter. Please use only a compatible AC/DC adapter with required voltage and current as indicated in this manual.

*Note!

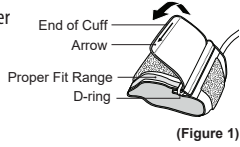
- No batteries are needed when operating with an AC/DC adapter.
- Please unload the batteries when operating with an AC/DC adapter for an extended period of time.
- Leaving the batteries in the compartment for a long time may cause leakage, which may lead to damage of the unit.
- Recommend Adapter specification, do not use otherwise:
Model: FranMar International, FRM06-S05-EU
- Rating:
Input: 100~240V, 50/60 Hz, 0.3A Output: 5V, DC, 1.2A,

*Note!

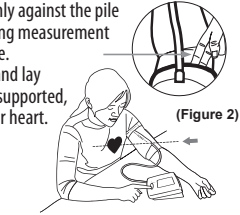
When you use the blood pressure monitor with AC/DC adapter, do not position the device to make it difficult to disconnect the adapter plug.

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)
- If the cuff is located correctly, the velcro will be on the outside of the cuff and 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 2 ~ 3 cm (approx. 1 inch) above the inner elbow.
- Pull the end of the cuff so that it tightens evenly around your arm, allowing 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 on the cuff falls within the Proper Fit Range.
- Sit on a chair comfortably, put your feet flat on the floor and lay your forearm on the table, make sure your back and arm supported, legs uncrossed, 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.



(Figure 1)



(Figure 2)

*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 2 ~ 3 cm (1 inch) between the inner elbow and the lower edge of the cuff, or the measurement may not be accurate.
- In case the cuff kept pumping up non-stop, unwrap the cuff at once.
- Do not wrap the cuff around any body part other than your arm.
- 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.

Measurement Procedure

Switching on the Monitor

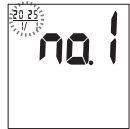
- A. Put in 4 AAA "LR03" (1.5V) alkaline batteries or plug in the AC/DC adapter, all segments appear on the screen for 3 seconds.
- B. The monitor will automatically turn to standby mode.



STANDBY MODE

Setting Year, Date and Time

- A. To enter setting mode, press **+** button for 3 seconds under standby mode. The YEAR digit flashes.
- B. Use **M** button to set current year. Press **+** button to confirm the year and switch to MONTH setting. Press **M** button to set the current MONTH.
- C. Continue to set current DATE (varies from 1 to 31), HOUR (12, 1, 12^{PM}, 1^{PM}, 11^{PM}) and MINUTE (00,01, 59) by following Step B.
- D. Users can adjust YEAR-MONTH-DATE-HOUR-MINUTE in an orderly manner.
- E. Press **+** button to save the settings and switches to Standby Mode.



Taking a Measurement

A. Under standby mode, press **+** button to select User 1 or User 2.

B. With the cuff wrapped around your arm, press **START/STOP** button to confirm the chosen user and start measurement.

C. All display symbols appear on the screen for 1.5 seconds. After all symbols disappear, the display will show “00”. The monitor is “Ready to Measure” and will automatically inflate to the level that is right for you.

D. 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. The device will detect your pulse and determine the blood pressure.

***Note!**

- If the cuff does not stop inflating, remove the cuff at once.
- To stop measurement, press **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 1 minute.

E. After the monitor has determined your blood pressure and heart rate, the cuff automatically deflates. Your systolic rate, diastolic rate, heart rate and corresponding BP Category Indicator, Irregular Heartbeat Detector and Excessive body motion detector (if any) are displayed with date and time for 1 minute and save results to memory automatically.

F. Device automatically shuts off if no operation over 1 minute.

Memory Function

Storing Data

After each measurement, the systolic and diastolic pressure, heart rate and BP Category Indicator, Irregular Heartbeat Detector and Excessive body motion detector (if any) with the time and date will be automatically stored.

The monitor features 2 user memory capabilities. Each user holds the last 120 measurements, and automatically replacing the oldest data with new one.

Recalling Data

A. Press **+** button to select User 1 or User 2.

B. Press **M** button to enter Memory Mode. If there is no data stored before, nothing (except month, date, and time) will appear on the display. If yes, the first reading will be the average of last 3 measurements.

C. Press **M** button to read the following measurements in sequence.

D. To stop reading the memories, press **START/STOP** button to switch to standby mode.

Erasing Data

A. Press **+** button to select User 1 or User 2.

B. Press **M** button to enter Memory Mode.

C. Press and hold **M** and **+** buttons at the same time, all the data for the selected user will be erased automatically.

D. To confirm the data in the selected user has been erased, press **M** button and no data should appear.

***Note!** The data CANNOT be restored once deleted.

Storage and Maintenance

General Use

- Do not twist the cuff in any way.
- Does not press **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 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 the cuff with a soft dry cloth, or
- Use a dry cloth with water to clean the device (do not flush directly, do not soak 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 / disinfection/ before use, 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

- 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 storage case 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 temperatures below –13°F/–25°C or above 158°F/70°C, nor in a place where the humidity level exceeds 93% R.H.

Troubleshooting

SYMBOLS/ SYMPTOMS	CONDITIONS/CAUSES	INDICATION/CORRECTION
Unit does not turn on when START/STOP button is pushed.	Worn-out batteries. Battery polarities have been positioned incorrectly.	Replace them with 4 new AAA “LR03” alkaline batteries. Re-insert the batteries in the correct positions.
EE Measuring Error Symbol appears when blood pressure value displayed is excessively low or high.	Cuff has been placed incorrectly.	Wrap the cuff properly so that it is positioned correctly.
E1 Measuring Error Symbol	Air circuit abnormality. Cuff tube may not be plugged into monitor correctly.	Check cuff connection. Measure again.
E2 Measuring Error Symbol	Inflation pressure exceeding 300 mmHg.	Switch the unit off, then measure again.
E3 Measuring Error Symbol	Can't determine blood pressure measurement data. Cuff is worn improperly, or the shape of the upper arm is unusual (for example, the circumferences of the upper part of the upper arm is noticeably larger than the lower part of the upper arm; or the middle part of the upper arm is noticeably larger than the upper part and lower part of the upper arm), excessive gap might exist between the arm cuff and the arm.	Wrap the cuff properly and keep steady. Measure again. Wrap the cuff snugly so that it is positioned correctly.
Excessive Body Motion Detector	Body movement during measurement, especially, the movement on the arm the blood pressure monitor is worn on, e.g. Talking, moving or shaking of the arm with the cuff on while measurement. Cuff is worn improperly, or the shape of the upper arm is unusual (for example, the circumferences of the upper part of the upper arm is noticeably larger than the lower part of the upper arm; or the middle part of the upper arm is noticeably larger than the upper part and lower part of the upper arm), excessive gap might be exist between the arm cuff and the arm.	Measure again. Keep arm steady during measurement. Wrap the cuff properly and keep steady. Measure again.
Notice: The measured blood pressure reading may not be accurate if the icon is displayed.		If you have any question about the cuff wearing and/or measurement result, please consult your healthcare professional.
Cuff Fitness Detection Symbol	The cuff was wrapped incorrectly (for example too loosely or too tightly).	Please reference “Applying the Cuff” section to wrap the cuff correctly.
Note: If “EP” 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.

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.

Specifications

Model Number	HL858A1
Measurement Method	Oscillometric
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	240 Memory Total for 2 Users
Unit Dimensions	5.51 x 4.33 x 2.22 inch (L x W x H) 140 x 110 x 56.5 mm (L x W x H)
Unit Weight	255 g ± 5 g (8.99 oz ± 0.18 oz) (Cuff and batteries excluded)
Cuff Size	NC-01: Normal size cuff 9 ~ 13 inch (23 ~ 33 cm) UC-01(Optional): Universal size cuff 9~17 inch (23 ~ 43 cm)
Storage/ Transportation Environment	Temperature: -25°C ~ 70°C (-13°F ~ 158°F) Humidity: ≤ 93 % R.H.
Operation Environment	Temperature: 5°C ~ 40°C (41°F ~ 104°F) Humidity: 15% ~ 93% R.H. Atmospheric pressure: 700 hPa ~ 1060 hPa
Power Supply	1.DC 6V, AAA “LR03” (1.5V) alkaline battery x 4 2.DC 5V 1.2A AC/DC adapter (Optional)
Battery Life	Approx. 300 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 1 minute, device automatically shuts off.
Accessories	4 AAA “LR03” Alkaline Batteries, Arm Cuff with Tube, Instruction Manual, Pouch

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

Note

This blood pressure monitor complies with the EC Directive (93/42/EEC) and bears the CE mark. This blood pressure monitor also complies with mainly following standards (included but not limited):

Safety standard:
EN 60601-1 Medical electrical equipment part 1: General requirements for safety
And essential performance.

EMC standard:
EN 60601-1-2 Medical electrical equipment part 1-2: General requirements for safety
- Collateral standard: Electromagnetic compatibility- Requirements and tests

Performance standards:
EN ISO 81060-2 Non-invasive sphygmomanometers - Part 2: Clinical investigation of intermittent automated measurement type IEC 80601-2-30 Medical electrical equipment - Part 2-30: Particular requirements for the basic safety and essential performance of automated non-invasive sphygmomanometers

Explanation of symbols :

Symbol	Explanation	Health & Life Information
CE	CE conformity marking	-
0197	Notified Body (NB) number	-
	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 electrical and electronic equipment (WEEE)	Discard the used product to the recycling collection point according to local regulations.
	Battery for disposal	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
EC REP	Authorized representative in the European Community	EMERGO EUROPE B.V. Westervoortsedijk 60, 6827 AT Arnhem, The Netherlands
SN	Serial number	YYMMXXXXXX
LOT	Batch code	LOT 2YYMOXX
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°)
	Importer –if applicable with Name and address	-
	Distributor–if applicable with Name and address	-
	Humidity limitation	-
	Temperature limit	-
	Atmospheric pressure limitation	-
	Non-ionizing electromagnetic radiation	-
	Keep away from sunlight	-
MCN	Country of origin	-
MD	Medical Device	-

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



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	Class A	
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	

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 °C~35°C, Relative Humidity:30 %~60 %.
Power frequency (50 or 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.
Electrical fast transient/burst IEC 61000-4-4	± 2 kV for power supply lines ± 1 kV for input/output lines	± 2 kV for power supply lines ± 1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-4-5	AC Power port ±1 kV Line to Line	AC Power port ±1 kV Line to Line	Mains power quality should be that of a typical commercial or hospital environment.
interruptions and voltage variations on power supply input lines	0% UT; 0.5 cycle At 0°:45°,90°, 135°,180°,225°, 270°and 315°. 0 % UT; 1 cycles 70 % UT; 25/30 cycles 0 % UT; 250/300 cycle	0% UT; 0.5 cycle At 0°:45°,90°, 135°,180°,225°, 270°and 315°. 0 % UT; 1 cycles 70 % UT; 25 cycles 0 % UT; 250 cycle	Mains power quality should be that of a typical commercial or hospital environment. If the user of the device requires continued operation during power mains interruptions, it is recommended that the device be powered from an uninterruptible power supply or a battery.

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	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq.	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	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: $E=6\sqrt{d \cdot P}$ 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.			

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.		