Instruction Manual

Automatic Upper Arm Blood Pressure Monitor





Model No. HL858DC

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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 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 13 inches (approx.23 cm to 33 cm) and for home use.

HL858DC 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.

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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?

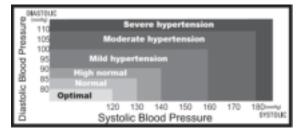
Having one's blood pressure measured by a doctor in a hospital or a clinic, is often associated with a phenomenon called "White Coat Hypertension" where the patient becomes nervous or anxious, thus raising his blood pressure. There are also numerous other factors that might cause your blood pressure 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 $3 \sim 5$ 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. 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.

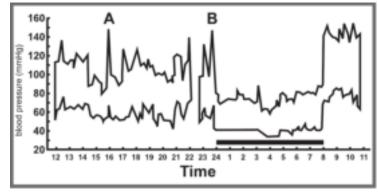
B. Variations in blood pressure:

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

(hyper tense: 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.



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

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 low (less than 41 \Box /5 \Box) and high (more than 104 \Box /40 \Box) temperature, nor in a place outside humidity ranges (15 % \sim 93 % R.H.), and atmospheric pressure ranges (700 \sim
	1060 hPa), or you may get inaccurate readings. Wait 30 \sim 45 minutes before measurement if you've just consumed caffeinated beverages or smoked cigarettes.
	Rest at least $5 \sim 10$ minutes before taking a measurement.
_	To allow your blood vessels to return to the condition prior to taking the measurement, please wait at least $3 \sim 5$ minutes in 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.
	This product is not suitable for:

- Pregnant women
- People with arrhythmias
- Undergoing intravenous injection on any limb
- Currently in a dialysis treatment
- In pre-eclampsia condition

Precautions

- ☐ 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 determined with this device are quivalent to those obtained by a trained observer using the cuff/stethoscope auscultation method and are within the accuracy limits prescribed by the American National Standard for Manual, electronic, or Automated Sphygmomanometers.
- ☐ The applied part is cuff.

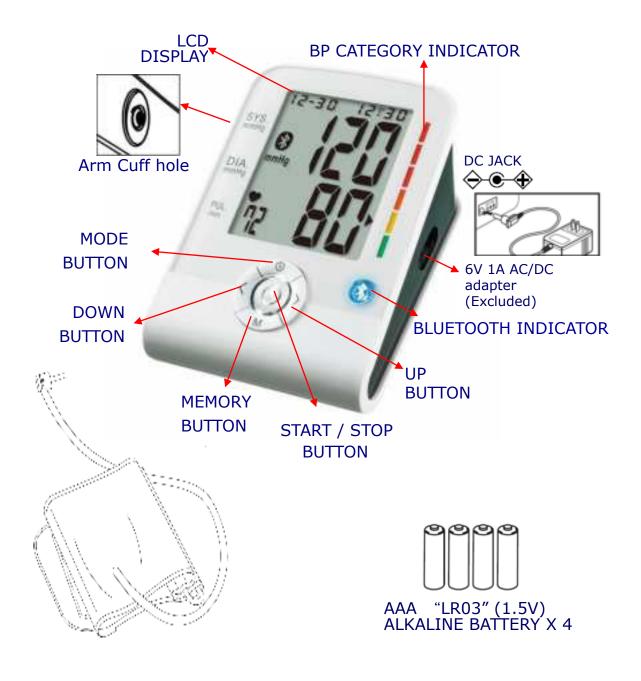
*Attention !

- 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 use 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.

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Device Overview

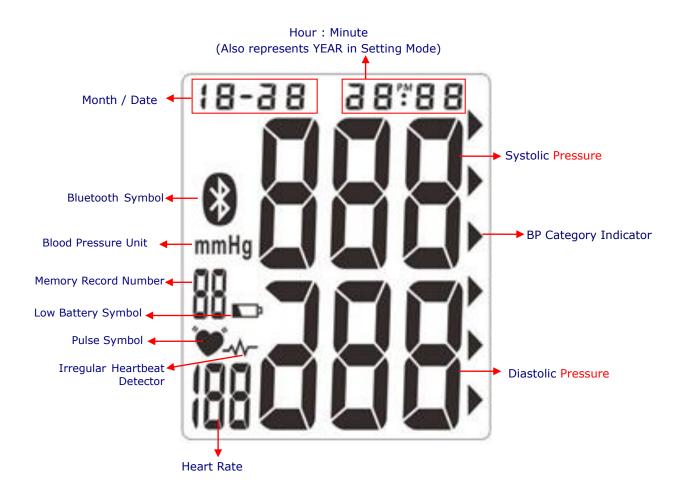
Part names and product components



ARM CUFF WITH TUBE

Symbol Definitions

Unit display



Symbol Definitions

SYMBOLS	Definitions
_	This symbol appears when the battery power is excessively low or the polarity reverses.
Low Battery Symbol	→ We suggest you replace all batteries with new ones, and make sure the +/- polarities are properly positioned.
•	Once pulse is detected, the symbol flashes with each pulse beat.
Pulse Symbol	→ Our suggestion: Please do not talk or move during measurements.
* * ***	This symbol appears when the user was talking, moving, shaking, or an irregular heart beat was detected during measurements.
Irregular Heartbeat Detector	→ 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.
Bluetooth Symbol	LCD displays this symbol when Bluetooth is active.
BP Category Indicator	The arrowhead points out the specific BP Category that your measurement reading fits in.

Features

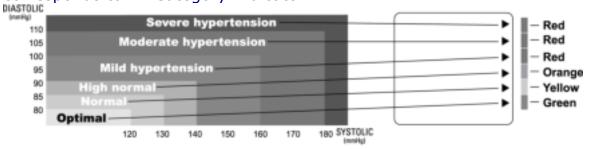
♦ BP Category Indicator

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:

_	s of Blood ire 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.

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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.
- As a safeguard, we recommend that if you have arrhythmias such as atrial or ventricular premature beats and atrial fibrillation or any other special conditions you should check with your physician before using your device.
- The IHB function is not 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 heart beat intervals of subject device is calculated with the three proper heart beat 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 at least 25% difference from the average heart beat interval will generate the IHB icon on the screen.

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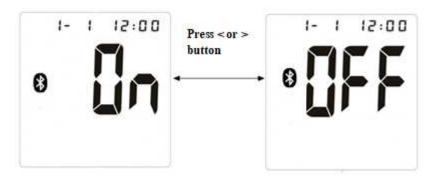
Bluetooth Transmission

HL858DC features a Bluetooth transmission function, which enables the device automatically transmit measured results to paired Bluetooth-enabled device after measurement. When connection established, the device would transmit, systolic pressure, diastolic pressure, and pulse with time to the Bluetooth enabled device.

Before attempting to sync the device with your smart device, make sure Bluetooth function is turned ON in both your smart device and the monitor, and make sure your Bluetooth-enabled device have downloaded the App. See the "App for Bluetooth" section for details.

◆ Turn the Bluetooth function ON/OFF

1.This function default setting is on. Under standby mode, user can switch the function ON or OFF. By pressing "O" button the device will enter to setting year, date & time first. When these setting are done, press the "O" button again, press or button to turn Bluetooth function ON or OFF.



Bluetooth function is On

Bluetooth function is OFF

Transmit Readings

1. There are 2 ways to activate Bluetooth function.

a. Automatically activate:

When measurement completed, the device activates Bluetooth function automatically, and Bluetooth symbol will flash on the screen.

b. **Manually activate:**

Under standby mode, user can press the "**M**" button for 3 seconds to activate Bluetooth function, and Bluetooth symbol will flash on the screen.

Bluetooth Transmission

- 2.If HL858DC is connected successfully to your smart device, Bluetooth symbol will appear on the screen.
- 3. If the monitor cannot be connected to paired Bluetooth-enabled device over 45 seconds, LCD will display Error message "E4" and Bluetooth will be turned off.

◆ App for Bluetooth

Download and install "**DailyChek**®" app on your smart device from Google Play or App store.

System requirement of the Bluetooth-enabled device

☐ Bluetooth 4.2 for	Android 6.0 or above
☐ Bluetooth 4.2 for	r iOS 7.0 or above

:NOTE:

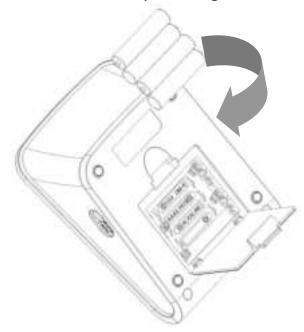
- HL858DC is subject to and complies with electromagnetic compatibility (EMC) standard of IEC 60601-1-2, EN 301 489-1, EN 301 489-17, EN 300 328 and U.S. federal guidelines, Part 15 of the FCC (Federal Communications Commission) rules for devices with RF capability. These guidelines help ensure that your device will not affect the operation of other nearby devices. Additionally, other devices should not affect the use of your device.
- Make sure HL858DC and paired Bluetooth-enabled device are within acceptable distance (no more than 10 meters) with each other. If not, put them closer.
- Be sure to select the correct User on the monitor before your blood pressure measurement begins.

Installing Batteries

When LOW BATTERY SYMBOL appears on the display, or no reaction toward operation, please change batteries.

Replace all worn-out batteries with new ones and do not mix new and used batteries. 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 (1.5V,LR03) 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.
- Memories (if any) will not be deleted during battery replacement.
- After replacing the batteries, reset the date and time.

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: SINPRO, HPU15-102

Rating:

Input: 100 ~ 240V, AC, 47 ~ 63 Hz, 0.4 ~ 0.2 A

*Note !

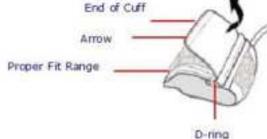
When you use the blood pressure monitor with AC/DC adapter, do position the device to make it difficult to disconnect the adapter plug.

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.
- □ 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.
- ☐ 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, allow room for 2 fingers to fit between the cuff and your arm.
- please make sure the cuff do not slip during measurement, and the arrow falls within the Proper Fit Range.
- When the cuff is positioned properly, press the velcro firmly against the pile side of the cuff.
- ☐ 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.

Note !

- Fit the cuff snugly, leaving enough space for $2 \sim 3$ 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.
- The device is not supposed to be used when your arm is wounded or injured.
- 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.
- Do not use this device if your wrist (Arm) has any wound or injury, especially after surgery on the wrist (Arm). Otherwise, it may cause infection at the surgical site. Please use the device after the wound has healed.







Measurement Procedure

Switch on the Monitor

A. When the power is turned on, The monitor will automatically turn to standby mode.



Setting Year, Date and Time

- A. Press button ("YEAR" flashes). Press or > STANDBY MODE button to adjust YEAR value.
- B. Press **⑤** button ("MONTH" flashes). Use **⋖** or **>** button to adjust MONTH (1, 2, 3,....., 12).
- C. Adjust DATE (1, 2, 3,..., 31), HOUR (1, 2, 3,......12_{PM},1_{PM},..., 12) and MINUTE (00,01,02,03,.....59) as described in Step A above.
- D. When settings are done, press button to confirm the settings. The device turns to standby mode.

Using your Bluetooth smart device.

The date and time on your monitor can be automatically updated, when you connect it with your smart device.

Once the date and time have been successfully synced, future readings will automatically have the correct date and time.

*Note !

• The Bluetooth Feature Switch default setting is ON

Taking a Measurement

A. Before measurement, press or button to select User 1, 2, or 3.







Measurement Procedure

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

All display units appear on the screen.



*Note !

Do not inflate the cuff until it is wrapped around your upper arm.

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.



C. After inflation of the cuff, the pressure will slowly decrease. When pulse is detected, PULSE SYMBOL flashes.



*Note !

- If the cuff does not stop inflating, remove the cuff at once.
- To stop measurement, press $\begin{tabular}{c} \begin{tabular}{c} \b$
- D. LCD screen displays your systolic rate, diastolic rate, pulse, BP Category Indicator, and Irregular Heartbeat Detector symbol (if any) with date and time for 1 minute.

 (Year and Date / Time display alternate automatically)





E. Without any operation for 1 minute, device automatically shuts off.

Memory Function

Storing data

After each measurement, the systolic and diastolic pressure, heart rate, pulse, BP Category Indicator, and Irregular Heartbeat Detector symbol (if any) with date and time will be automatically stored. The monitor can store up to 120 memories for 3 users, and automatically replace the oldest data with new one.

◆ Recalling data

- A. Press
 or
 button to select User 1, 2, or 3.
- B. Press M button to enter Memory Mode.
 LCD displays average of last 3 measuring results first.
- C. Press **M** button again, LCD displays the latest measuring result. Use **S** or **D** button to scroll through all stored measuring results. (Year and Date / Time display alternate automatically)
- D. To stop reading memories, press $\begin{tabular}{c} \begin{tabular}{c} \begin{tabular}$

Erasing data

- A. Press
 or
 button to select User 1, 2, or 3.
- B. Press M button to enter Memory Mode.
- C. Press and hold and buttons at the same time, the data 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: Once deleted, your data can NOT be restored.









Storage and Maintenance

	storage arra marricoriarios
♦	General Use
	Do not in any way twist the cuff.
	Do not press \circ button if the cuff is not wrapped around your upper arm.
	Do not drop the product and avoid any strong impacts.
♦	Maintenance
То	ensure that your device is in optimal use and to avoid damage,
ŗ	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 (not directly flush, 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
rec	commended 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.

Troubleshooting

SYMBOLS/SYMPTOMS	CONDITIONS/CAUSES	INDICATION/ CORRECTION	
Unit does not turn on when button is	Worn-out batteries.	Replace them with 4 new AAA (1.5V, LR03) alkaline batteries.	
pushed.	Battery polarities have been positioned incorrectly.	Re-insert the batteries in the correct positions.	
Measuring Error Symbol appears when blood	Cuff has been placed incorrectly.	Wrap the cuff properly so that it is positioned correctly.	
pressure value displayed is excessively low or high.		Measure again. Keep arm steady during	
	Shaking of the arm with the cuff on.	measurement.	
Measuring Error Symbol	Air circuit abnormality. Cuff tube may not be plugged into monitor correctly.	Check cuff connection. Measure again.	
Measuring Error Symbol	Inflation pressure exceeding 300 mmHg.	Switch the unit off, then measure again.	
Measuring Error Symbol	Can't determine blood pressure measurement data.	Wrap the cuff properly and keep steady. Measure again.	
Measuring Error Symbol	If the device cannot be connected to paired Bluetooth-enabled device over 45 seconds, LCD will display Error message "E4" and Bluetooth will be turned off.	Please press M button for 3 seconds to start Bluetooth function.	
	Paring has not been completed.	Please re-pairing the BPM and Bluetooth device with each other.	
BPM cannot communicate with Bluetooth device	Bluetooth function is not turn on.	See the "the Bluetooth Transmission" section to turn on Bluetooth function.	
	The distance between BPM and Bluetooth device is out of transmitting range.	Please make sure the acceptable distance (≤ 10 meters) with each other.	
	Use an incompatible Bluetooth device. Use non-Bluetooth-enabled	Please refer to "the Bluetooth Transmission" section	
	device. Unexpected loss of	Re-insert the batteries and try again.	
	electrical/mechanical integrity.	Return the device to your local distributor or importer.	
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 also note that this service 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 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	HL858DC
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.
Inflation	Automatic Inflation (Air Pump)
Deflation	Automatic Air Release Control Valve
Display	Liquid Crystal Display
Memory	120 Memory Total for 3 Users
Unit Dimensions	97.92 X 139.95 X 56.75 mm (L X W X H) 3.86 X 5.51 X 2.23 inch (L X W X H)
Unit Weight	291 g \pm 10 g (10.26 oz \pm 0.35 oz) (Cuff & Batteries Excluded)
Cuff Size	NC01: Normal size cuff 23 ~ 33 cm (approx. 9 ~ 13 inch)
Storage/ Transportation Environment	Temperature: -25 °C \sim 70 °C (-13 °F \sim 158 °F) Humidity: \leq 93 % R.H.
Operation Environment	Temperature: 5 °C ~ 40 °C (41 °F ~ 104 °F) Humidity: 15 % ~ 93 % R.H. Atmospheric pressure: 700hPa ~ 1060hPa
Power Supply	1. DC 6V AAA "LR03" (1.5V) alkaline battery x 4 2. DC 6V 1A AC/DC adapter (Excluded)
Battery Life	Approx. 200 Measurements (Bluetooth ON)
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, Storage Pouch
RF Type	Bluetooth 4.2 BLE
System requirement of the Bluetooth device	Bluetooth 4.2 for Android 4.3 or above Bluetooth 4.2 for iOS 7.0 or above

^{*}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
③	Refer to instruction manual/booklet	-
†	TYPE BF Applied Part	-
Ø	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.
R	Waste of electrical and electronic equipment (WEEE)	Discard the used product to the recycling collection point according to local regulations
SN	Serial number	SN
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°)
((<u>*</u>))	Non-ionizing electromagnetic radiation	-

Device information:

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

Manufacturer: HEALTH & LIFE CO., LTD.

9F, No. 186, Jian Yi Road, Zhonghe District23553, New Taipei City, Taiwan

www.healthandlife.com.tw

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:

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 the 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.

CAUTION:

To assure continued FCC compliance:

Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.

RF exposure warning

- The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.
 The equipment must not be co-located or operation in conjunction with any other antenna or transmitter. FCC Label Compliance 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.

*Note!

"Changes or modifications not expressly approved by the manufacturer could void the user's authority to operate the equipment"

HL858DC 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 \pm 3 mmHg (\pm 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
Harmonic emissions IEC 61000-3-2	Class A	establishments, and those directly connected to the public low-voltage power supply network
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Complies	that supplies buildings used for domestic purposes.

♦ 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: $15\% \sim 35\%$, Relative Humidity: $30\% \sim 60\%$.
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; 0.5 cycle At 0°,45°,90°,135°,180 °,225°,270°and 315°.	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
11000-4-11	70 % UT; 25/30 cycles 0 % UT; 250/300 cycle	70 % UT; 25 cycles 0 % UT; 250 cycle	powered from an uninterruptible power supply or a battery.

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.	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 (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: $E = 6/d$ where P is the maximum power in W , d is the minimum separation distance in W , and W is the infimum separation distance in W , and W is the IMMUNITY TEST LEVELS in W . 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.

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

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.

Appendix

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

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