Instruction Manual

Automatic
Upper Arm Blood Pressure Monitor

Model No. HL858DM

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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 the LCD panel. Measurement position is at human being's upper arm. The intended user of this over-the-counter device is adults aged 18 years and older with arm circumference ranging from 9 inches to 17 inches (approx.23 cm to 43 cm) for home use.

HL858DM features BP Category Indicator that will show the information with the readings on the screen for the user tracking their blood pressure level.

HL858DM is equipped with an Advanced IHB (Irregular heartbeat) detection feature to collect and analyze pulses. If the specific irregular heartbeats are detected and it may affect blood pressure reading with deviation, the device will give the user a warning signal. The feature can inform the user that the measured blood pressure reading may be inaccurate once the specific irregular heartbeats are detected.

Besides, the device features a built-in "Bluetooth Transmission" function, which enables the device automatically transmit measuring results to paired Bluetooth-enabled device. Also, users could simply synchronize the current date and time, and check the battery status of blood pressure monitor by means of DailyChek® application software with the paired Bluetooth-enabled device.

About Blood Pressure

A. 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.

B. 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 below 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	or	HIGHER THAN 120

However the above 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.

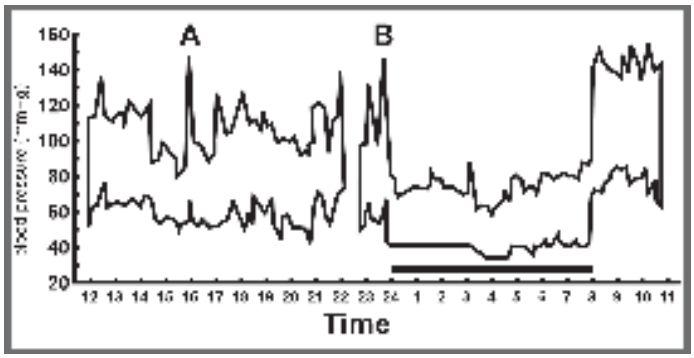
B. Variations in blood pressure:

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)

Measurement Method

HL858DM 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 heart beat, 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 complete, the cuff will automatically deflate.

Note!

*** The patient is an intended operator.**

*** The applied part is the cuff.**

Accuracy

HL858DM 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 HL858DM 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 Sphygmomano-meters.

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

Precautions

* Do not use this manual and product as a substitute for advice, diagnosing or treating a health problem or prescribing any medication by your doctor. If you have a medical problem, promptly consult your healthcare provider.
* Read the Instruction Manual thoroughly before measuring and keep it at hand for your reference at any time.
* This device uses the oscillometric method to measure systolic and diastolic blood pressure as well as your heart rate. It's recommended for use by people over the age of 18 and not to be used on infant or children.
* 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.

- ❑ Do not take a measurement in a low (less than 41 ℉/5 ℃) and high (more than 104 ℉/40 ℃) temperature, nor in a place outside humidity range (15 ~ 93 %RH) and altitude range (-700 ~ 10600 m).
- ❑ Wait 30 minutes before measurement if you have just consumed caffeinated beverages or smoked cigarettes.
- ❑ Rest at least 5 ~ 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 ~ 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.
- ❑ Sit down comfortably and place your elbow on the table with your feet flat on the floor. Please do not cross your legs during measurements.
- ❑ Keep the cuff at heart level. Relax your hand with the palm facing up.
- ❑ 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.
- Keep in mind that blood pressure naturally varies from time to time throughout the day and is affected by lots of different factors such as stress, eating, smoking, alcohol consumption, medication, and physical activity, etc.
- Normally the blood pressure rises while at work and is at its lowest during sleeping period.
- 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 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 EN 1060-4.
- If the cuff is worn incorrectly, or the shape of the upper arm is special (for example, the circumference of the upper arm differs largely from the circumference of the forearm), excessive gap might occur between the arm cuff and the arm, and it might lead to measurement errors or inaccuracies. If you have any question about the condition of cuff wearing and/or measurement result, please consult your healthcare professional.
- The applied part is cuff.

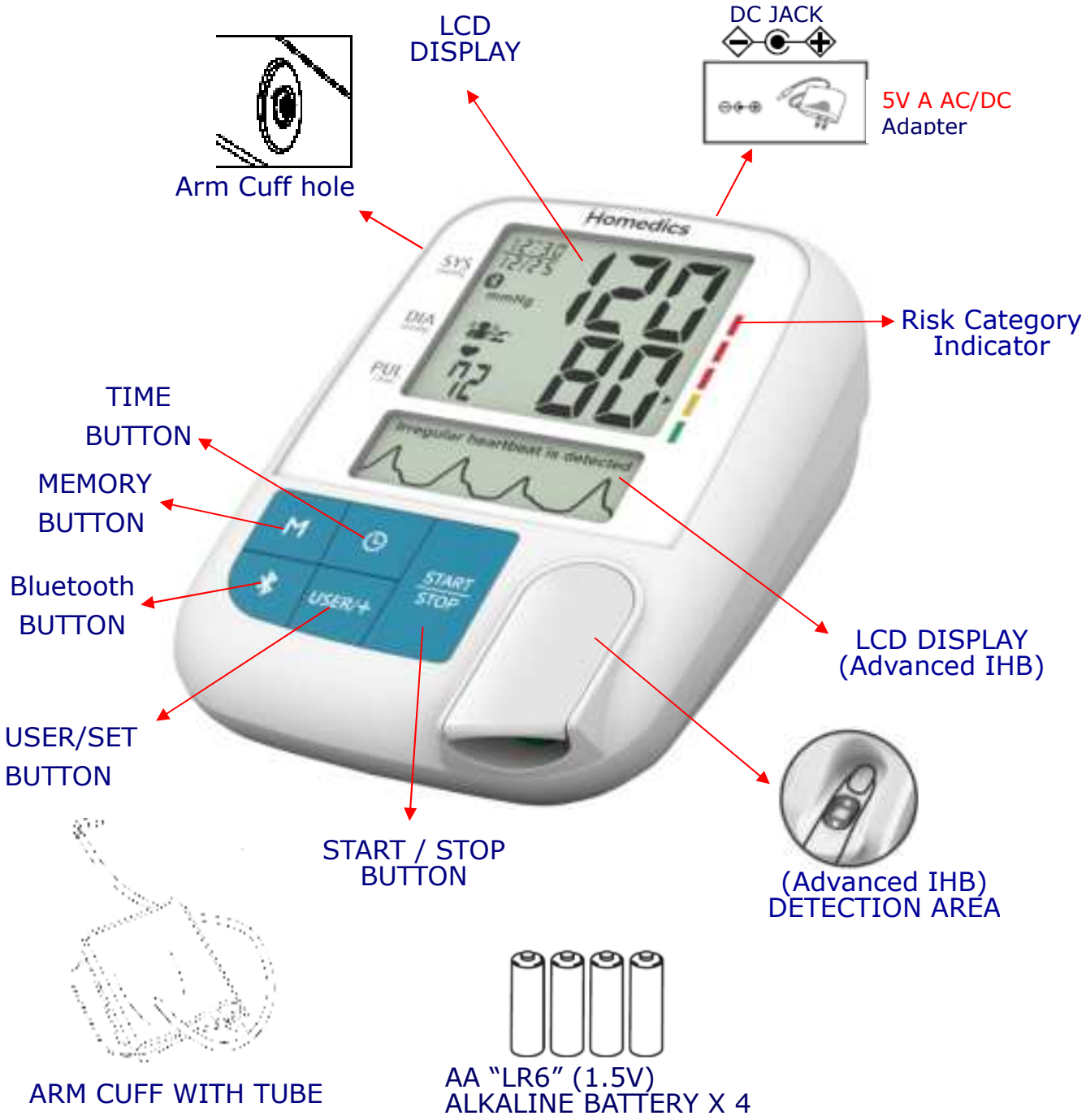
Precautions

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 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 Overview

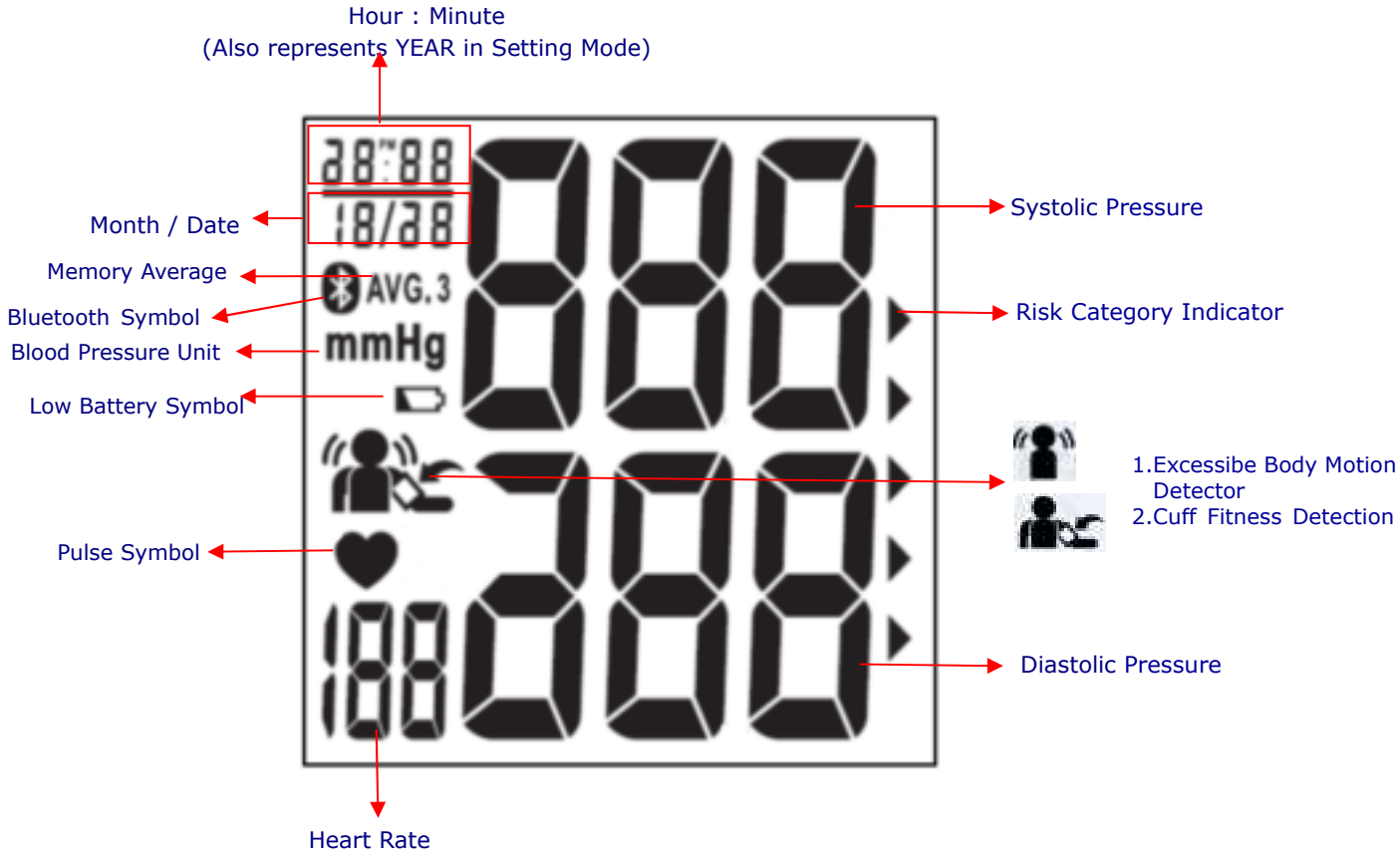
- Part names and product components



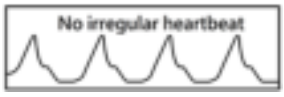
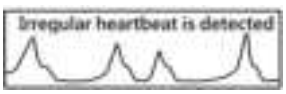
Caution !
Substitution of a component different from that supplied might result in measurement error.

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.
AVG. 3 Memory Average		This symbol appears when LCD displays average value of last 3 readings.
 Excessive Body Motion Detector		Displayed if body movement is detected during measurement, especially, the movement on the arm the blood pressure monitor is worn on. Besides, if cuff is worn improperly, or the shape of the upper arm is unusual (for example, the circumference of the upper arm differs largely from the circumference of the forearm), excessive gap might exist between the arm cuff and the arm. 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 is the function aid in detecting if the cuff is wrapped properly.
 Risk Category Indicator		The arrowhead points out the specific Risk Category that your measurement reading fits in
Advanced IHB Detection feature-related Symbol *These two symbols are only generic symbols to indicate the detection (or non-detection) of IHB, not actual heartbeat waveforms detected as a function of time.*		This symbol appears when there is **Advanced IHB** negative.
		This symbol appears when there is **Advanced IHB** positive.
		➔ 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 **Advanced IHB** positive symbol appears frequently, we recommend the patient to seek professional medical advice.

 Bluetooth Symbol	LCD displays this symbol when Bluetooth is active.

Features

◆ Risk Category Indicator (AHA 2017)

This device is equipped with Risk Category Indicator which classifies your blood pressure measurements into five stages (Normal, Elevated, Hypertension stage 1, Hypertension stage 2 and Hypertensive crisis) based on the blood pressure standards established by the American Heart Association (AHA). Besides, for yours and your loved ones health, we further classify the five stages into numeral ranges, which sorts out hypertension symptoms more clearly. Moreover, to your convenience and readability, we use three corresponding colors to represent your measuring result. Refer to below comparison chart for details:

BLOOD PRESSURE CATEGORY	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)	INDICATOR COLOR	
[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
[illegible]	[illegible]	[illegible]	[illegible]		
[illegible]	[illegible]	[illegible]	[illegible]		[illegible]
[illegible]	[illegible]	[illegible]	[illegible]		

* Source : ATIA 2017

After measurement, LCD displays the systolic and diastolic pressure, heart rate, date and time along with Risk Category Indicator symbols. Compare the symbol of LCD display, to know the classification of your blood pressure based on American Heart Association standard (AHA 2017).

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.

Features

For adults 18 and older who are not on medicine for high blood pressure, are not having a short-term serious illness, and do not have other conditions, such as diabetes and kidney disease. To determine category of risk when systolic and diastolic readings fall into two areas, use the higher of the two numbers for classification. There is an exception to the above definition of high blood pressure for people with diabetes and chronic kidney disease.

***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.

Features

◆ Bluetooth Data Transmission

HL858DM features a built-in "Bluetooth Data Transmission" function, which enables the device automatically transmit measuring results to paired Bluetooth-enabled device after measurement. When connection established, BPM would transmit memory data such as Measure Date, Systolic, Diastolic and Pulse to the Bluetooth enabled device.

If paired Bluetooth-enabled device is not working or is not within RF range of this device, the measuring results will be stored in the blood pressure monitor's memory. Besides, user can press "  " button for one time to open the Bluetooth function.

Bluetooth compatibility with blood pressure monitor for Bluetooth-enabled device is:

- Bluetooth 4.2 for Android 6.0 or above,
- Bluetooth 4.2 for iOS 9.0 or above

Note !

- HL858DM 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 HL858DM 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.
- Bluetooth date transmission is not available under measurement.

Features

◆ Application Software for Bluetooth

To fully utilize this feature, users need to ensure Bluetooth support of Wireless (usually under settings menu) on their Android or iOS device for contactless data exchange. Then, download and install "**DailyChek®**" application software from Google Play on the Bluetooth-enabled device which is compatible with Android 4.2 or iOS 7.0 or above. Please follow the following steps for installing:

1. To install **DailyChek®** FREE APP, go to the Google Play ™ APP store, and search for **DailyChek®**.
2. Click the **INSTALL** button. Once installed, click on **DailyChek®** APP icon.
3. Now you can start using your Android version or iOS version of **DailyChek®** APP with Bluetooth feature, it's a simple tool to log, track and trend your test results from your Bluetooth-enabled Device.

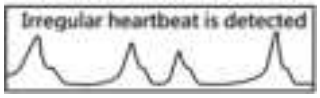
Note !

1. **DailyChek®** Software Manual contains explanations of functions and instructions of how to activate them.
2. Access **DailyChek®** Software Manual via **DailyChek®** Application Software to completely utilize this feature.

Features

◆ Advanced Irregular Heartbeat Detector

This device equipped an Advanced IHB detection feature. The symbol Advanced IHB appears on screen indicates the specific heartbeat irregularity was detected during measurement. The Advanced IHB is designed to enhance the detectability on irregular heartbeats that arise from the internal causes of human body and tend to affect the blood pressure reading during the measurement. The algorithm of Advanced IHB can identify the specific irregular heartbeats that may cause deviated blood pressure reading. The principle of Advanced IHB is to collect and analyze pulse signal frequency from the user's finger. If the specific irregular heartbeats are detected and it may affect blood pressure reading with deviation, the device will give the user a warning signal to indicate the measured blood pressure reading may be inaccurate. The specific type of heart arrhythmia or irregular heartbeat that may affects the accuracy of blood pressure measurement. The feature can inform the user that the measured blood pressure reading may be inaccurate once the specific irregular heartbeats are detected. The detection of Advanced IHB is determined by collecting a period of pulse signals from the Advanced IHB detection area.

If Advanced IHB is detected during measurement, the Advanced IHB positive symbol 

is displayed. If Advanced IHB positive symbol appears frequently, we recommend the patient to seek professional medical advice. And please note that the device does not replace a cardiac examination, but serves to detect specific pulse irregularity at an early stage.

Note !

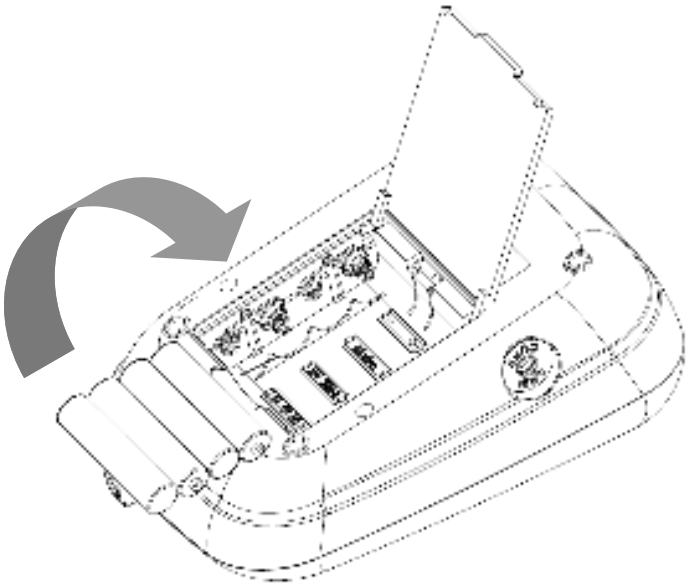
- Sometimes the device will determine Advanced IHB positive even when it is not there. This could happen if the hand and finger move during the measuring or another rhythm problem is present. Keep the hand and finger still during the measuring.
- This device may not detect Advanced IHB correctly in people with pacemakers or defibrillators.
- We recommend you consult with your physician for proper diagnosis or seek medical advice, if Advanced IHB positive symbol appears frequently.

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 AA (LR6) 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.
- The device will keep the last measuring results after changing batteries, please reset date and time.
- Please replace all worn-out batteries with new ones when you are operating the Advanced IHB Detection feature, and the LOW BATTERY SYMBOL  appears on the display.

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:

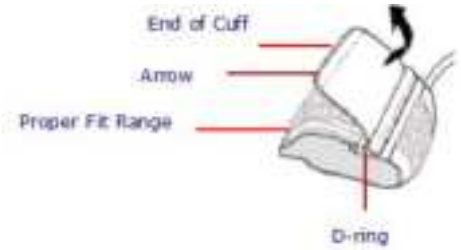
Model: FranMar International, FRM06-S05-UU
Rating:
Input: 100 ~ 240V, AC, 47 ~ 63 Hz, 0.4 ~ 0.2 A
Output: 5 V, DC, 1A, 

Note !

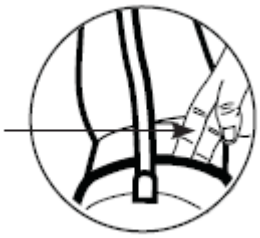
When you use the blood pressure monitor with AC/DC adapter, do no posit the device to make it difficult to disconnect the adapter plug.

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.
- ❑ 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 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 !

- 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 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

STANDBY MODE

◆ Switch on the Monitor

A. Put in 4 AA "LR6" (1.5V) alkaline batteries.

B. Press START/STOP button to switch on the monitor. The monitor will automatically turn to standby mode.

◆ Setting Year, Date and Time

A. Press button ("YEAR" flashes). Press / and button to adjust YEAR value.

B. Press button ("MONTH" flashes). Use / and button to adjust MONTH (1, 2, 3,……, 12).

C. Adjust DATE (1, 2, 3,…, 31), HOUR (1, 2, 3,……., 23, 0) and MINUTE (00,01,02,03,.....59) as described in Step A above.

D. Turning Bluetooth Feature Toggle ON/OFF

User can press / and button to turn the Bluetooth feature ON/OFF in Setup Mode.

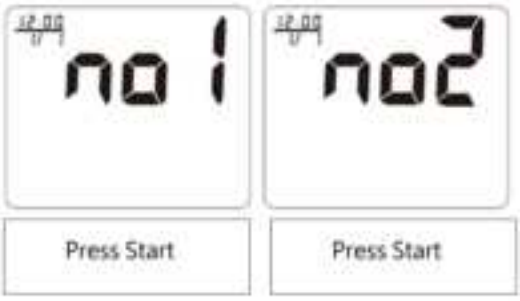
Bluetooth feature ON

Bluetooth feature OFF

E. When settings are done, press button to confirm the settings. The device turns to standby mode.

◆ Taking a Measurement

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

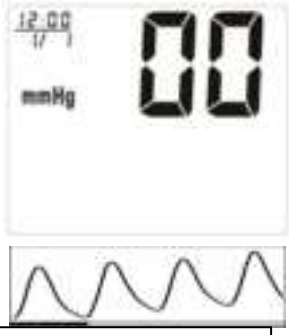


Measurement Procedure

B. With the cuff wrapped around your upper arm, and place the finger of the opposite hand (index finger recommended) gently on the Advanced IHB detection area, then make sure the finger place at the correct position, press START/STOP button to start measurement. All display units appear on the screen for 1.5 seconds.

Note !
- Do not inflate the cuff until it is wrapped around your upper arm.
- Please clean the finger before taking the Advanced IHB Detection measurement.
- Advanced IHB detection will have error result if blood pressure measurement is applied on the same arm as the finger detected.

C. 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.



Note!

When press the START/STOP key, the measurement of blood pressure and Advanced IHB detection will be both activated, if only Advanced IHB detection feature will be measured, please press the START/STOP key again to stop the measurement of blood pressure.

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 each pulse beat. Remain still and do not move until the entire

Measurement Procedure

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.
- If there is any error during the measurement, such as movement or hard pressure from the finger, the error message will be displayed as below:

E4 Try Again or E5 Try Again or E6 Try Again

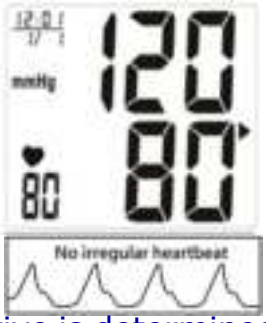
* For details, please refer to Troubleshooting

E. After the monitor has determined your blood pressure and heart rate, the cuff automatically deflates. Your systolic rate, diastolic rate, pulse, BP Category Indicator Bar and Advanced IHB Detection feature-related symbol are displayed with date and time for 1 minute.

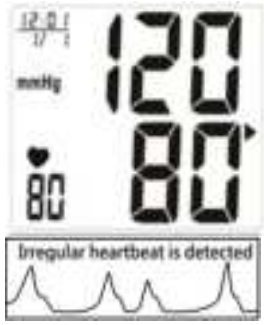
Note !

During the measurement for both blood pressure and Advanced IHB detection at the same time, users may see the result from any one measurement from the other one. Please do not move and wait for both measurement results displayed.

E-1. If Advanced IHB negative is determined during the measurement as normal result, the LCD display will be as below:



E-2. If Advanced IHB positive is determined during the measurement, the Advanced IHB positive symbol will be displayed on the LCD as below:



F. The blood pressure measurment is completed and without any operation for 1 minutes, device automatically shuts off.

Memory Function

◆ Storing data

After each measurement, the systolic and diastolic pressure, heart rate, pulse, Risk Category Indicator Bar, **Advanced IHB** Detection feature-related symbol with date and time will be automatically stored.

The monitor can store up to 240 memories for 2 users, and automatically replace the oldest data with new one.

Note !
If only do the Advanced IHB Detection measurement, your data can Not be stored.

◆ Recalling data

A. Press [illegible]/+ button to select User 1, or 2.
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 **M** or button to scroll through all stored measuring results.

D. To stop reading memories, press START/STOP button, and switch to Standby Mode.

◆ Erasing data

A. Press [illegible]/+ button to select User 1 or 2.
B. Press M button to enter Memory Mode.
C. Press and hold [illegible]/+ 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.

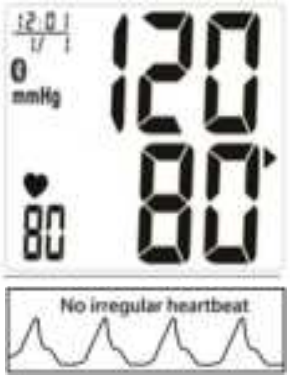
Bluetooth Transmission

To activate Bluetooth function, please make sure your Bluetooth-enabled device have downloaded APP, and follow pairing instruction.

There are 2 ways to process Bluetooth Transmission if Bluetooth function is ON:

Measurement Completed:

1. After measurement completed, the device activates Bluetooth function automatically and the Bluetooth symbol will begin flashing on the screen.
2. HL858DM can pair up with Bluetooth-enabled device. To transmit measuring results to other Bluetooth-enabled.



Press button for one time:

Under Standby Mode,

1. Press button into the Bluetooth mode, the Bluetooth Symbol will begin flashing on the screen.
2. While transmitting the reading to your Bluetooth-enabled Device, HL858DMetooth Symbol will remain steady on the screen.
3. HL858DM can pair up with Bluetooth-enabled device.
   To transmit measuring results to other Bluetooth-enabled device, please retry as mention above.

Fail connection:

If HL858DMannot be connected to paired Bluetooth-enabled device over 45 seconds, LCD will display Error message “Et” and Bluetooth will be turned off.

Bluetooth Transmission

A. Date/Time Synchronization

1. The BPM's Date/Time Setting can be synchronized by Bluetooth-enabled device (e.g. smart phone) which has downloaded and installed DailyChek® application software.

2. When Bluetooth connection is established, the Bluetooth-enabled device can send commend with the date/time information to BPM and the BPM's date/time will be updated.

B. Battery Status Check

The feature provides users as a simple/convenient tool to check the battery status before measurement. Upon receiving the request from Bluetooth-enabled device either on Standby Mode or after measurement, the BPM will transmit the current battery status for user's reference.

Note !

- Without any operation in 1 minute, the device shuts off automatically and Bluetooth Transmission OFF.
- Standby Mode: Segments appeared but not under BPM measuring or data transmitting.
- Sleeping Mode: Clear all LCD segments.

Storage and Maintenance

◆ General Use

- ❑ Do not in any way twist the cuff.
- ❑ Do 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 cuff and patches, due to 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 (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 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 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 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 extremely low (less than –13℉/–25℃) and high (more than 122℉/50℃) temperature, nor in a place its humidity 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.	Replace them with 4 new AA (LR6) alkaline batteries.
	Battery polarities have been positioned incorrectly.	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.
	Did you talk or move during measurement?	Measure again. Keep arm steady during measurement.
	Shaking of the arm with the cuff on.	
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.	Wrap the cuff properly and keep steady. Measure again.
Et Measuring Error Symbol	If HL858DM 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 button for one time to start Bluetooth function.
E4 Try Again	Finger hasn't be placed on Advanced IHB detection area.	Keep finger gently place and well-covered on Advanced IHB detection area and measure again.
Measuring Error Symbol	Finger moved away from the detection area when the measurement has not been completed yet.	Measure again and don't move away your finger before measurement completed.
E5 Try Again	Finger press too hard on Advanced IHB detection area.	Measure again. Gently place finger on Advanced IHB detection area.
Measuring Error Symbol	Cold Finger and weak pulse signals Can't determine Advanced IHB measurement data.	Measure again. Keep finger warm and gently place on Advanced IHB detection area.
E6 Try Again Measuring Error Symbol	Pulse signals could not be detected continuously by the Advanced IHB detection area for a period.	Place the finger on Advanced IHB detection area and keep steady. Measure again.
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	HL858DM
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.
Inflation	Automatic Inflation (Air Pump)
Deflation	Automatic Air Release Control Valve
Display	Liquid Crystal Display
Memory	240 Memory Total for 2 Users
Unit Dimensions	6.08 x 4.24 x 2.37 inch (L x W x H) 154.5 x 107.8 x 60.4 mm (L x W x H)
Unit Weight	295.8 g ± 5 g (10.43 oz ± 0.17 oz) (Cuff and batteries excluded)
Cuff Size	UC-01: Universal cuff size: 9"~17" / 23~43 cm
Storage/ Transportation Environment	Temperature: -25 °C ~50 °C (-13 °F ~ 122 °F) Humidity: ≤ 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,AA "LR6" (1.5V) alkaline battery x 4 2. DC 5V 1A AC/DC Adapter (Optional)
Battery Life	Approx. 200 Measurements
Shelf life (battery)	3 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 AA (LR6) Alkaline Batteries, Arm Cuff with Tube, Instruction Manual, Storage Pouch
RF Type	Bluetooth 5.0 BLE
System requirement of the Bluetooth-enabled device	Bluetooth 4.2 for Android 6.0 or above Bluetooth 4.2 for iOS 9.0 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
	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.-
	Serial number	 YYMMXXXXXX
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	-
	MRI unsafe	An item that is known to pose hazards in all MRI environments.

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 for: HEALTH & LIFE CO., LTD.
9F, No. 186, Jian Yi Road, Zhonghe District23553, New Taipei City, Taiwan
www.healthandlife.com.tw

Note

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
1. The equipment complies with FCC RF exposure limits set forth for an uncontrolled environment.
2. 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"

HL858DM 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	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℃~35℃, 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 IEC 61000-4-11	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.

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: $E = 6/d \sqrt{P}$ 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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