Instruction Manual

Automatic Wrist Blood Pressure Monitor



Model No. HL158VA

Table of Contents

Medical Disclaimer	03
Intended Use	03
About Blood Pressure	04
Measurement Method	06
Accuracy	07
Precautions	
Device Overview	10
Symbol Definitions	13
Features	14
Installing Batteries	20
Applying the Cuff	21
Positioning Guide	22
Measurement Procedure	23
Bluetooth Transmitting	27
Memory Function	29
Storage and Maintenance	30
Troubleshooting	31
Warranty & Recalibration	33
Specifications	
Note	35
Appendix	37
Blood Pressure Diary	39

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

HL158VA automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method during inflation. All values can be read out in one LCD panel. Measurement position is at human being's wrist. The intended use of this over-the-counter device is for adults aged 18 years and older with wrist circumference ranging from 5.3 inches to 7.7 inches (approx. 135 mm to 195 mm) and for home use.

HL158VA detects the appearance of irregular heartbeats during measurement; an indicated symbol will appear with measuring reading. And the Risk Category Indicator will show the information with the readings on the screen for the user tracking their blood pressure level.

Besides, the device features a built-in "Bluetooth Data 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

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. 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		DIASTOLIC mmHg
BLOOD PRESSURE CATEGORY	(upper number)		(lower number)
NORMAL	LESS THAN 120	and	LESS THAN 80
ELEVATED	120-129	and	LESS THAN 80
HIGH BLOOD PRESSURE	130-139	0.5	80-89
(HYPERTENSION)STAGE 1	130-139	or	00-09
HIGH BLOOD PRESSURE	140 OR HIGHER	or	90 OR HIGHER
(HYPERTENSION)STAGE 2	140 OK HIGHER	or	90 OK HIGHER
HYPERTENSIVE CRISIS	HIGNER THAN 180	or	HIGHER THAN 120
(consult your doctor immediately)	HIGNER THAN 100	or	HIGHLK 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:

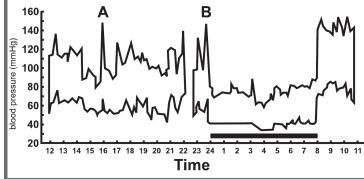
Individual blood pressures vary greatly both on a daily and a seasonal basis. These variations are even more pronounced in hyper tense patients. Normally the blood pressure rises while at work and is at its lowest during sleeping period.

(hyper tense: means a person who has high blood

pressure symptom.)The graph helo

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

HL158VA Automatic Wrist 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 wrist, just turn on the monitor and inflation automatically starts. The inflation of the cuff creates pressure around the arteries inside the wrist.

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 wrist. 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

HL158VA Automatic Wrist Blood Pressure Monitor has been clinically tested against a scientific device called a *mercury sphygmomanometer*, considered the gold standard in blood pressure measurement.

All HL158VA Automatic Wrist Blood Pressure Monitors have performed equivalent to measurements taken with this scientific device and are within the accuracy limits prescribed by the American National Standard for Electronic or Automated Sphygmomanometers.

The SPHYGMOMANOMETER was clinically investigated according to the requirements of ISO 81060-2:2013.

* In case it is needed to have the device checked for calibration, please consult the distributor.

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.
- * This monitor is not intended for use in the MR environment.
- \square Do not take a measurement in a low (less than 41 $^{\circ}F/5$ $^{\circ}C$) and high (more than 104 $^{\circ}\text{F}/40$ $^{\circ}\text{C}$) temperature, nor in a place outside humidity ranges (15 % ~ 93 % R.H.), and atmospheric pressure ranges (700 ~ 1060 hPa), or you may get inaccurate readings. □ Wait 30 ~ 45 minutes before measurement if you've just consumed caffeinated beverages or smoked cigarettes. \square 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 ~ 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 wrist (preferably the left wrist) and measuring around the same time each day. ☐ Perform measurements in a guiet and relaxed environment at room temperature. ☐ Do not move or shake the device during a measurement. Please keep guiet 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 device.
- ☐ If you have one of the circulatory problems as arteriosclerosis, diabetes, liver disease, kidney disease, severe hypertension, peripheral circulation....., please consult your healthcare professional before using the device.
- Blood pressure measurements taken with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultation method and are within the accuracy limits prescribed by the American National Standard for Manual, electronic, or Automated Sphygmomanometers.

*Attention !

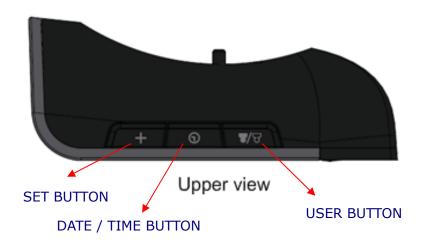
- 1. Do not use the device on infants, children, or those who cannot express their own intention.
- The medical device should not used adjacent to or stacked with other equipment. In case adjacent or stacked use is necessary. The medical device should be observed to verify normal operation in the configuration 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

♦ Product components



Device Overview



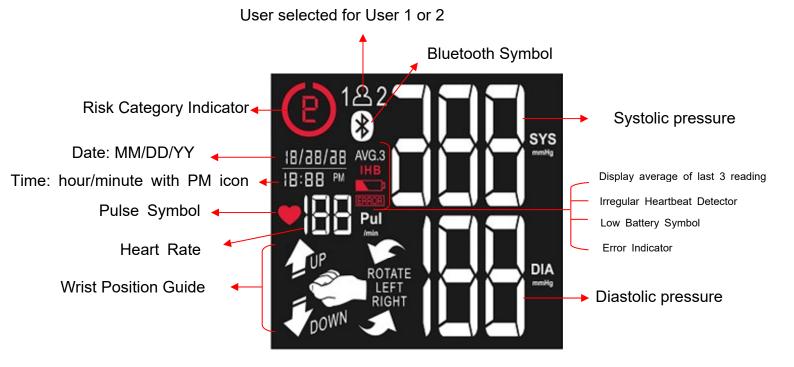


*Caution !

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

Device Overview

◆ Unit display



Symbol Definitions

SYMBOLS	Definitions
	This symbol appears when the battery power is excessively low or the polarity reverses.
Low Pathomy Cymhal	→ We suggest you replace all batteries with new ones, and
Low Battery Symbol	make sure the +/- polarities are properly positioned.
ERROR	Error Symbol: Error display.
	Once pulse is detected, the symbol flashes with each
	pulse beat.
Pulse Symbol	→ Our suggestion:
Tuise Symbol	Please do not talk or move during measurements.
	This symbol appears for 1 minute 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.
Wrist Position Guide	The Wrist Position Guide is used as an aid in determining if the device is at the appropriate angle and height.
1음	User 1: Appears when the monitor is operated by User 1.
2 凸	User 2: Appears when the monitor is operated by User 2.
AVG. 3 Average of Last 3 Measurements	Memory Average: Display average of last 3 readings
Risk Category Indicator	Compares readings against blood pressure guidelines. See next page for more information.
Bluetooth Symbol	Under Bluetooth Data Transmission / Link Mode, LCD displays this symbol.

♦ WRIST POSITION Guide

HL158VA has a built-in the Wrist Position Guide will be used as an aid to help user determining if the device is at appropriate angle and height. After you press START STOP button, the display will illuminate with different icons that are designed to guide you move your wrist. Once the appropriate angle and height is found, the Pulse () Symbol will flash with beep sound for 3 times and measurement will begin. This feature is optional and users can turn this feature OFF by holding START STOP button for 3 seconds.

SYMBOL	ACTION
PUP	Move your wrist up.
DOWN	Move your wrist down.
ROTATE	Rotate your wrist to your left.
ROTATE	Rotate your wrist to your right.

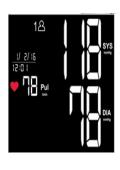
*Note!

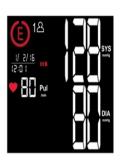
This Wrist Position Guide is only for reference on blood pressure measurement. Due to difference in individual size, physique, and being dependent on the height of the table and desk, in addition to the position of the hand in comparison to the horizontal plane of reference and the heart, this feature may not helpful in all cases. If you feel the position of the wrist according to Wrist Position Guide does NOT match your heart level, you can select to turn this feature off and consult your healthcare provider.

Risk Category Indicator(AHA 2017)

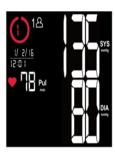
This device is equipped with Risk Category Indicator which classifies your blood pressure measurements into five stages (Normal, Elevated, Hypertension stage 1, Hypertension stage 2 and Hypertensive crisis) based on the blood pressure standards established by the American Heart Association (AHA). Besides, 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 four symbols to represent your measuring result. Refer to below comparison chart for details:

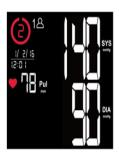
BLOOD PRESSURE CATEGOR	SYSTOLIC mm Hg (upper number)		DIASTOLIC mm Hg (lower number)	Symbol
NORMAL	<120	and	< 80	
ELEVATED	120-129	and	< 80	(E)
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 1	130-139	or	80-89	<u>C</u>
HIGH BLOOD PRESSURE (HYPERTENSION) STAGE 2	140-180	or	90-120	©
HYPERTENSIVE CRISIS (consult your doctor immediately)	>180	or	>120	





Note: Systolic or diastolic over define value, then display the symbol.







NORMAL

ELEVATED

HYPERTENSION STAGE 1 HYPERTENSION STAGE 2 HYPERTENSIVE CRISIS

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 rate 181 & diastolic rate 99

⇒ Hypertensive crisis

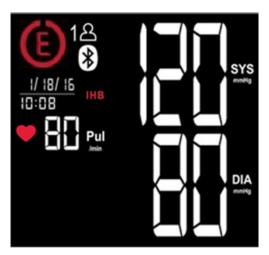
◆ Irregular Heartbeat Detector

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.



- 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.

Bluetooth Data Transmission

HL158VA 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 "b" button for 3 seconds to resend the measurement data.

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 7.0 or above

- HL158VA 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 HL158VA 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.

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 4.3 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. Open the APP. New user please register your profile.
- 4. Confirm your profile is correct and Click OK to next step.
- 5. User must login again. After login, please turn ON Bluetooth feature of the BPM.
- 6. 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.

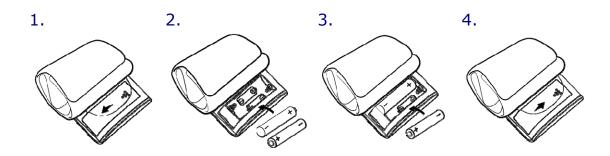
- 1. **DailyChek**® Software Manual contains explanations of functions and instructions of how to activate them.
- 2. Access **DailyChek**® Software Manual via **DailyChek**® Application Software to completely utilize this feature.

Installing Batteries

When LOW BATTERY SYMBOL appears on the display, or nothing appears on the display when the power is switched on, please change the 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.

Remove the battery cover and insert 2 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 take the used batteries to the recycling collection point according to your local regulations.
- Keep the battery away from small children in case they swallow it.
- If the device is not to be used for over 2 months, please remove the batteries from its compartment for power-saving.
- Please replace all worn-out batteries with new ones when you are operating the Bluetooth transmission function, and the LOW BATTERY SYMBOL appears on the display.
- Memories (if any) will not be deleted during battery replacement.
- After replacing the batteries, reset the date and time.

Applying the Cuff

■ Do not place the pressure cuff over a jacket or sweater sleeve. Wrap the pressure cuff around the bare wrist with the monitor facing you.

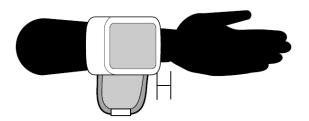


- ☐ Wrap the cuff snugly. Do not make it too tight.
- □ Fold the remaining part of the cuff back out of the way.



□ Leave approximately 0.4 inch (10 mm) between the cuff and the bottom of your hand palm.

0.4 inch (10 mm)



5.3 ~ 7.7 inch (approx.135 ~ 195 mm)

- Do not use this device if your wrist has any wound or injury.
- Do not wrap the cuff around any body part other than your wrist.
- In case the cuff kept pumping up no-stop, open the cuff at once

Positioning Guide

It is extremely important that the cuff be at the same height as the heart.

Having the cuff higher or lower may cause inaccurate results.

- 1. 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.
- 2. Position the blood pressure monitor on your wrist.
- 3. Place your elbow on the table and rest the back of your hand on the device storage case or other object.
- 4. Rest your wrist on the armrest until it's at the same height as your heart.
- 5. Relax your hand and turn your palm upwards.



Switch on the monitor

- A. Put in 2 AAA 1.5V (LR03) alkaline batteries.
- B. All segments appear on the screen for 3 seconds.
- C. The monitor will automatically turn to sleeping mode (all LCD segment cleared).



Setting time, date, and year

- A. Press **O** button ("MONTH" flashes). Press **+** button to adjust MONTH value (1, 2, 3,..., 12).
- B. Press button ("DATE" flashes). Use button to adjust DATE value (1, 2, 3,..., 31).
- C. Adjust YEAR, HOUR (1, 2, 3,.....12_{PM},1_{PM},..., 12) and MINUTE (00,01,02,03,.....59) as described in Step A above. When settings are done, press button to confirm the entries. The device is ready to measure.

◆ Turning Wrist Position Guide ON/OFF

The Wrist Position Guide is set "on" as default. User can press and hold $\frac{START}{STOP}$ button for 3 seconds to turn the Wrist Position Guide ON/OFF in Sleeping Mode.



Wrist Position Guide ON



Wrist Position Guide OFF

◆ Turning Bluetooth Feature ON/OFF

User can press and hold button 3 seconds to turn the Bluetooth feature ON/OFF in Sleeping Mode.





Bluetooth icon ON

Bluetooth icon OFF

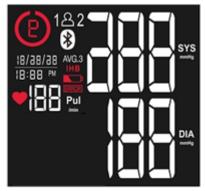
Note: The Bluetooth icon switch default setting is ON

Taking a Measurement

A. Press button to select User 1 or 2.

B-1. **Start a Measurement:** (with Wrist Position Guide off)

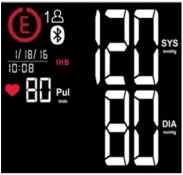
1. With the cuff wrapped around your wrist, press STOP button to start measurement. All display units appear on the screen for 3 seconds.



2. As the cuff inflates, the monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation. The Heartbeat Symbol () flashes at every heartbeat. Remain still and do not move until the entire measurement process is completed. The device will detect your pulse and determine the blood pressure.

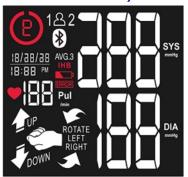
*Note /

- \bullet If the cuff does not stop inflating, remove the cuff at once. $\underline{\text{START}}$
- To stop measurement, press **STOP** button. The cuff will deflate immediately after the button is pressed.
- 3. After the monitor has determined your blood pressure and heart rate, the cuff automatically deflates. Your systolic rate, diastolic rate, heart rate and corresponding Risk Category Indicator and Irregular Heartbeat Detector (if any) are displayed with date and time for 1 minute and save results to memory automatically.

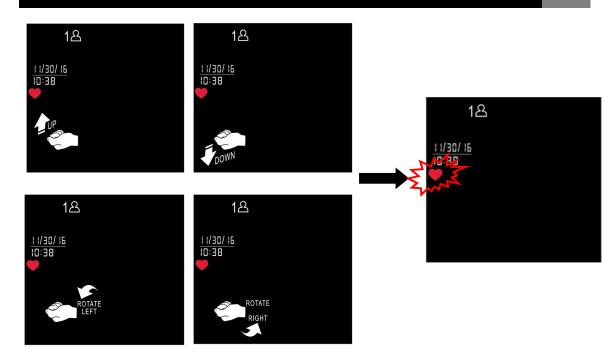


- B-2. Start a Measurement: (with Wrist Position Guide on)
 - 1. With the cuff wrapped around your

wrist, press START STOP button to start measurement. All display units appear on the screen for 3 seconds.



 Adjust the position of your wrist according to the Wrist Position Guide symbol appears on the display. When the device senses that your wrist is in the appropriate angle and height, the Pulse Symbol (♥) will flash with beep sound for 3 times and measurement will begin.



3. As the cuff inflates, the monitor automatically determines your ideal inflation level. This monitor detects your blood pressure and pulse rate during inflation. The Pulse () Symbol flashes at every pulse beat. Remain still and do not move until the entire measurement process is completed. The device will detect your pulse and determine the blood pressure.

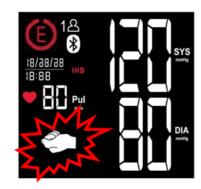
*Note !

- If the cuff does not stop inflating, remove the cuff at once.
- To stop measurement, press STOP button. The cuff will deflate immediately after the button is pressed.
- 4. After the monitor has determined your blood pressure and heart rate, the cuff automatically deflates. Your systolic rate, diastolic rate, heart rate and corresponding Risk Category Indicator and

Irregular Heartbeat Detector (if any) are displayed with date and time for 1 minute and save results to memory automatically.

*Note /

 Even if the monitor is not in the ideal position after 10 seconds, the measurement will still begin. If this occurs, the wrist symbol will appear and be stored in the memory with the measurement.



Bluetooth Transmitting

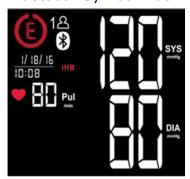
To activate Bluetooth function, please make sure your Bluetooth-enabled device have downloaded APP, and follow pairing instruction.

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. While transmitting the reading to your Bluetooth-enabled Device, HL158VA Bluetooth Symbol will remain steady on the screen.
- HL158VA can only pair up with one Bluetooth-enabled device at a time.
 To transmit measuring results to other Bluetooth-enabled device, please retry Steps 1 ~ 2.

Bluetooth Symbol Flash



Press and hold button for 3 seconds:

Under Sleeping Mode and Standby Mode,

- 1. Press and hold button for 3 seconds to wake up the device and starting Bluetooth function (Bluetooth Symbol flashing)
- 2. While connecting to your Bluetooth-enabled Device, HL158VA Bluetooth Symbol will remain steady on the screen.
- 3. HL158VA can only pair up with one Bluetooth-enabled device at a time.

To transmit measuring results to other Bluetooth-enabled device, please retry as mention above.

Fail connection:

If HL158VA cannot be connected to paired Bluetooth-enabled device over 45 seconds, LCD will display Error message "E4" and Bluetooth will be turned off.



Bluetooth Transmitting

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 when Bluetooth is connecting, the BPM will transmit the current battery status for user's reference.

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

Memory Function

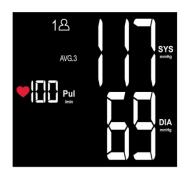
Storing data

After each measurement, the systolic and diastolic pressure, heart rate, Risk Category Indicator and Irregular heartbeat detector (if any) with date and time will be automatically stored. The monitor can store up to 120 memory sets for per user, and automatically replace the oldest data with new one.

Recalling data

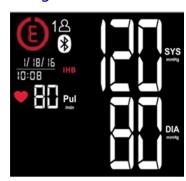
- A. Press button to select User 1 or 2.
- B. Press M button to enter Memory Mode.

 LCD displays average of last 3 records.



Average of last 3 records

- C. Press M button again, LCD displays the second last measuring result. Use
 - M button to scroll through all stored measuring results.
- D. To stop reading memories, press START STOP button, and switch to sleep mode.



120th Memory

Erasing data

- A. button to select User 1 or 2.
- B. Press M button to enter Memory Mode.
- C. Press and hold + and \bullet buttons at the same time, the data will be erased automatically.
- D. To confirm deletion, press M button and no data should appear.



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

Storage and Maintenance

◆ General Use

- Do not in any way twist the cuff. START
- Do not press STOP button if the cuff is not wrapped around the wrist.
- Do not drop the product and avoid any strong impacts.

Maintenance

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

- ☐ 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 START when STOP button is	Worn-out batteries.	Replace them with 2 new AAA (1.5V) (LR03) alkaline batteries.
pushed.	Battery polarities have been positioned incorrectly.	Re-insert the batteries in the correct positions.
ERROR & EE Measuring Error Symbol	Cuff has been placed incorrectly.	Wrap the cuff properly so that it is positioned correctly.
appears when blood pressure value displayed is excessively low or high	Did you talk or move during measurement? Shaking of the wrist with the cuff on.	Measure again. Keep wrist steady during measurement.
ERROR & E1 Measuring Error Symbol	Air circuit abnormality. Cuff tube may not be plugged into monitor correctly.	Check cuff connection. Measure again.
ERROR & E2 Measuring Error Symbol	Inflation pressure exceeding 300 mmHg.	Switch the unit off, then measure again.
ERROR & E3 Measuring Error Symbol	Can't determine blood pressure measurement data.	Wrap the cuff properly and keep steady. Measure again.
ERROR & E4 Measuring Error Symbol	If HL158VA 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 and hold button for 3 seconds to start Bluetooth function.

Troubleshooting

SYMBOLS/SYMPTOMS	CONDITIONS/CAUSES	INDICATION/ CORRECTION	
BPM cannot communicate with Bluetooth-enabled	Paring has not been completed.	Please re-pairing the BPM and Bluetooth-enabled device with each other.	
	Bluetooth function is not turn on.	Please press and hold START STOP button for 3 seconds under sleep mode.	
	The distance between BPM and Bluetooth-enabled device is out of transmitting range.	Please make sure the acceptable distance (≤10 meters) with each other.	
device	Use an incompatible Bluetooth-enabled device.	Please refer to Page 18 "Bluetooth	
	Use non-Bluetooth-enabled device.	compatibility" & Page 35 "RF Specification"	
		Re-insert the batteries and try again.	
	Unexpected loss of 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.			

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 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	HL158VA	
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	
Accuracy	Pulse: ± 5 % Max.	
Inflation	Automatic Inflation (Air Pump)	
Deflation	Automatic (Passive Exhaust Valve)	
Display	Transmissive TN LCD (with backlight)	
Memory	2 x 120 Memory Sets	
Unit Dimensions	90.0 X 70.0 X 35.3 mm (L X W X H) 3.54 X 2.76 X 1.39 inch (L X W X H)	
Unit Weight (Batteries Excluded)	128 g ± 10 g (4.48 oz ± 0.35 oz)	
Cuff Size	135 ~ 195 mm (5.3 ~ 7.7 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	DC 3V AAA (LR03) (1.5V) Alkaline Battery x 2	
Battery Life	Approx. 200 Measurements	
Shelf life (battery)	3 years (Temperature: $20 \pm 2^{\circ}$ C; Relative humidity: $65 \pm 20\%$ RH)	
Product Life	5 Years (4 times per day)	
Sleeping Mode	Without any operation for 1 minute, device automatically shuts off.	
Accessories	Instruction manual, 2 AAA (LR03) (1.5V) alkaline batteries, Storage pouch	

Specifications

RF Type	Bluetooth 4.2 BLE
System requirement of the	Bluetooth 4.2 for Android 6.0 or above,
Bluetooth-enabled device	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
	Follow instruction for use	-
*	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.
Z	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°)
$((\overset{\bullet}{\bullet}))$	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".

HL158VA 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	Not Applicable	establishments, and those directly connected to the public low-voltage
Voltage fluctuations/ flicker emissions IEC 61000-3-3	Not Applicable	power supply network 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° C \sim 35 $^{\circ}$ C Relative Humidity: 30% \sim 60%.
Power frequency magnetic field IEC 61000-4-8	30 A/m 50 or 60 Hz	30 A/m 50 or 60 Hz	Power frequency magnetic fields should be at levels characteristic of a typical location in a typical commercial or hospital environment.

Appendix

◆ Guidance and manufacturer's declaration – electromagnetic immunity

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

Immunity test	IEC 60601 test level	Compliance level	Electromagnetic environment – guidance
Conducted RF IEC 61000-4-6	3V rms At 0.15-80 MHz 6V rms At ISM & Radio Amateur Freq	Not Applicable	Portable and mobile RF communications equipment should be used no closer to any part of the device, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter.
Radiated RF IEC 61000-4-3 Proximity fields from RF wireless communications equipment IEC 61000-4-3	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz,Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	10 V/m at 80-2700 MHz AM Modulation And 9-28V/m at 385-6000MHz,Pulse Mode and other Modulation. The system shall be tested as specified in IEC60601-1-2 Table 9 for proximity fields from RF wireless communications equipment using the test methods specified in IEC 61000-4-3	Recommended separation distance Considering to reduce the minimum separation distance, based on RISK MANAGEMENT, and using higher IMMUNITY TEST LEVELS that are appropriate for the reduced minimum separation distance. Minimum separation distances for higher IMMUNITY TEST LEVELS shall be calculated using the following equation: $E = 6/d \sqrt{P}$ where P is the maximum power in W, d is the minimum separation distance in m, and E is the IMMUNITY TEST LEVELS in V/m. Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, a should be less than the compliance level in each frequency range.b Interference may occur in the vicinity of equipment marked with the following symbol: $(((2)))$

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	Modulation	IMMUNITY TEST LEVEL	
(MHz)			
		(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 :	