Instruction Manual

Automatic
Wrist Blood Pressure Monitor

Model No. HL158B1-BD

BPW-800BT-WT

VER:A001 20220325U

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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 automatically measures human's Systolic, Diastolic blood pressure and heart rate by using the oscillometric method during deflation. 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.

HL158B1-BD 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.

Additionally, the Wrist Position Guide is used as an aid in determining if the device is at correct position in relationship to the heart.

About Blood Pressure

1. What is Blood Pressure?

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

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

2. Why Is It Useful to Measure Blood Pressure at Home?

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

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

About Blood Pressure

A. AHA Blood Pressure Classifications:

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

BLOOD PRESSURE CATEGORY	SYSTOLIC mmHg (Upper Number)		DIASTOLIC mmHg (Lower Number)
HYPERTENSIVE CRISIS (consult your doctor immediately)	HIGHER THAN 180	AND/OR	HIGHER THAN 120
HIGH BLOOD PRESSURE (HPERTENSION STAGE 2)	140 or HIGHER	OR	90 or HIGHER
HIGH BLOOD PRESSURE (HYPERTENSION STAGE 1)	130 ~ 139	OR	80 ~ 89
ELEVATED	120 ~ 129	AND	LESS THAN 80
NORMAL	LESS THAN 120	AND	LESS THAN 80

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

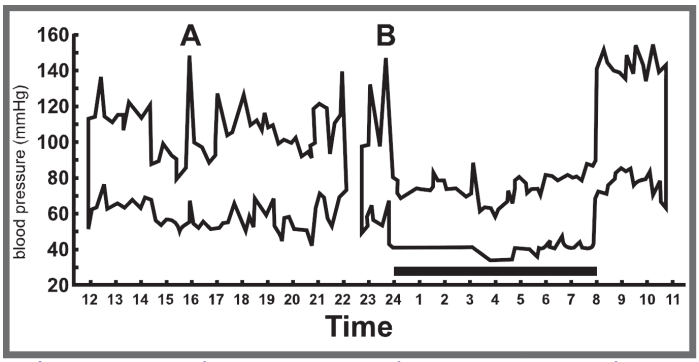
B. Variations in Blood Pressure:

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

(Hyper-tense means a person who has high blood pressure symptom.)

The graph below illustrated the variations in blood pressure over a whole day with measurement taken every five minutes.

The thick line represents sleep. The rise in blood pressure at 4 PM (A in the graph) and 12 AM (B in the graph) correspond to an attack of pain.



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

Measurement Method

HL158B1-BD 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 heartbeat, 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.**

Accuracy

HL158B1-BD 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 HL158B1-BD 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 81060-2:2018.

*** 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.
* The patient is an intended operator, who can operate the device by himself or herself, not necessarily by a physician or operator.
* This monitor is not intended for use in the MR environment.

- ❑ The device should not be used to either self-diagnose Hypertension or exclude the diagnosis of Hypertension. If your blood pressure reading is out of normal range, please consult your physician. Even your blood pressure reading is within the "normal" range, the device cannot exclude the diagnosis of Hypertension.
- ❑ Do not take a measurement in a low (less than 41°F / 5°C) and high (more than 104°F/ 40°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.
- ❑ 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 wrist (preferably the left wrist) and measuring around the same time each day.
- ❑ Perform measurements in a quiet and relaxed environment at room temperature.
- ❑ Do not move or shake the device during a measurement. Please keep quiet and do not talk during measurements.
- ❑ The device has no any interface to provide updates/upgrades and therefore device is no security vulnerabilities.

Precautions

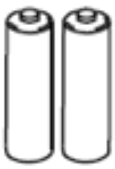
- This product is not suitable for:
  - Pregnant women
  - People with arrhythmias
  - Undergoing intravenous injection on any limb
  - Currently in a dialysis treatment
  - In pre-eclampsia condition
- For those who have had a mastectomy or lymph node clearance, it is recommended to take a measurement on the unaffected side.
- When used among medical electronic equipment on the same limb, pressurization of the cuff may cause temporarily malfunction to other devices.
- If you have one of the circulatory problems as arteriosclerosis, diabetes, liver disease, kidney disease, severe hypertension, peripheral circulation……, please consult your healthcare professional before using the device.
- Blood pressure measurements taken with this device are equivalent to those obtained by a trained observer using the cuff / stethoscope auscultation method and are within the accuracy limits prescribed by the Standard of EN 1060-4.
- The applied part is cuff.

Attention !

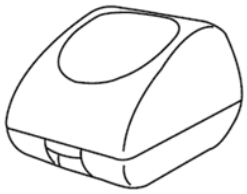
1) Do not use the device on infants, children, or those who cannot express their own intention.
2) The medical device should not be used adjacent to or stacked with other equipment. When the blood pressure monitor are used in a high level radio frequency electromagnetic fields (e.g. close to the wireless communication equipment), it may lose or degrade essential performance, such as device giving the error code, deviated readings, or malfunction.
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 wrist. 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



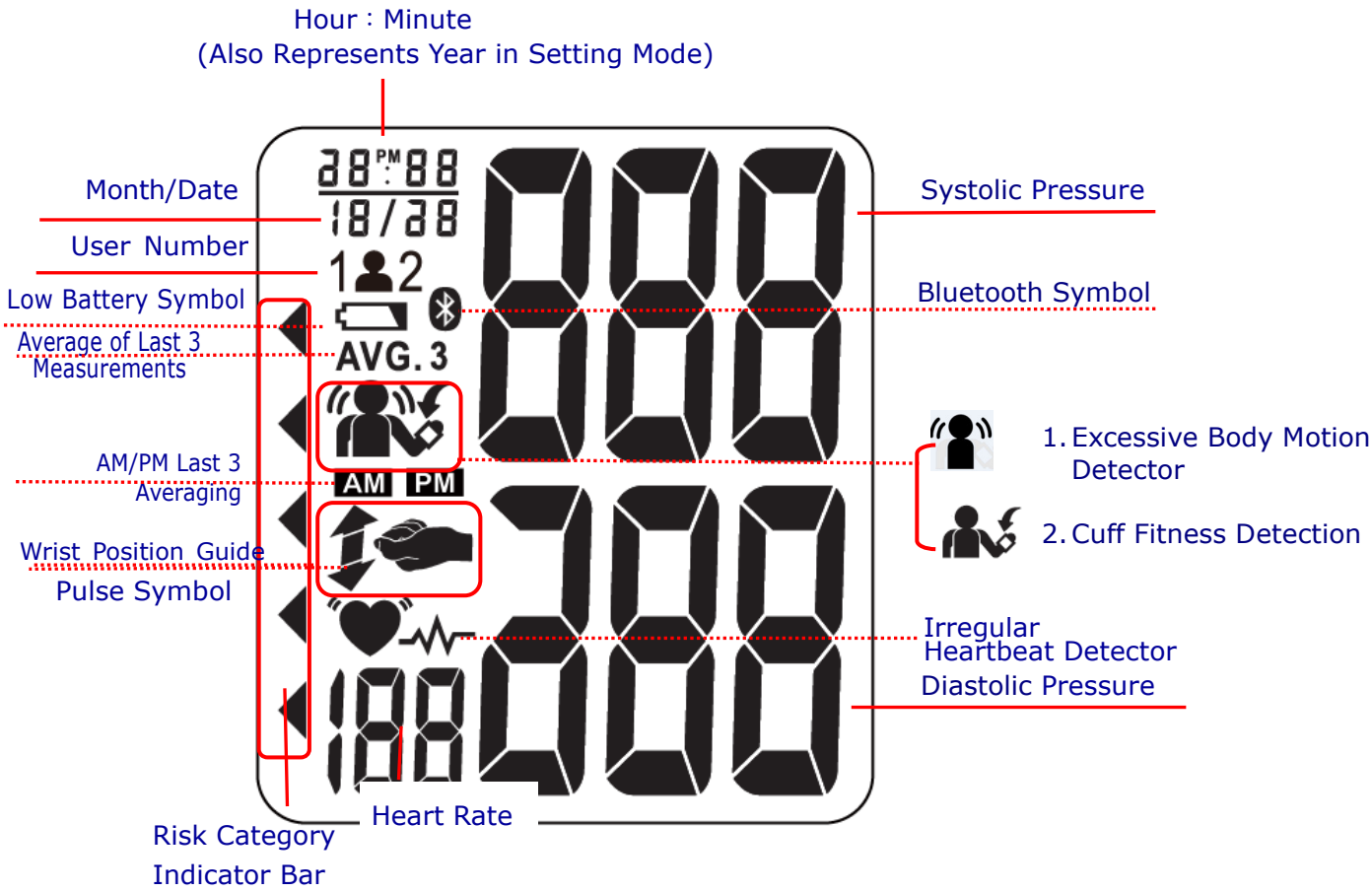
AAA "LR03" (1.5V)
Alkaline Battery X 2



Storage Case

Device Overview

◆ Unit Display



Symbol Definitions

SYMBOLS	Definitions
 Low Battery Symbol	This symbol appears when the battery power is excessively low or the polarity reverses. ➔ We suggest you replace all batteries with new ones, and make sure the +/- polarities are properly positioned.
 Pulse Symbol	Once pulse is detected, the symbol flashes with each pulse beat. ➔ Our suggestion: Please do not talk or move during measurements.
 Irregular Heartbeat Detector	This symbol appears when an irregular heart beat was detected. ➔ Our suggestion: Repeat the measurement after resting for at least 5 minutes, and restart your measurement while sitting down comfortably and quietly. If symbols appear frequently, please contact your physician.
 Excessive Body Motion Detector	Displayed if body movement is detected during measurement, especially, the movement on the wrist the blood pressure monitor is worn on. Besides, if cuff is worn improperly, or the shape of the wrist is unusual, excessive gap might exist between the wrist cuff and the wrist. 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.
 Wrist Position Guide	The Wrist Position Guide is used as an aid in determining if the device is at the appropriate angle and height.
 Bluetooth Symbol	LCD displays this symbol when Bluetooth is active.
	**AM/ PM Averaging:** Indicates the reading being displayed is an average from the last 3 morning or last 3 evening measurements.
 Risk Category Indicator Bar	The arrowhead points out the specific Risk Category that your measurement reading fits in.
 Average of Last 3 Measurements	This symbol appears when LCD displays average value of last 3 readings.
	User 1: Appears when the monitor is operated by User 1.
	User 2: Appears when the monitor is operated by User 2.

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 mmHg (Upper Number)		DIASTOLIC mmHg (Lower Number)	INDICATOR COLOR	
HYPERTENSIVE CRISIS (consult your doctor immediately)	>180	AND/OR	>120		Red
HIGH BLOOD PRESSURE (HPERTENSION STAGE 2)	140 ~ 180	OR	90 ~ 120		
HIGH BLOOD PRESSURE (HYPERTENSION STAGE 1)	130 ~ 139	OR	80 ~ 89		
ELEVATED	120 ~ 129	AND	< 80		Yellow
NORMAL	< 120	AND	< 80		Green

*Source: AHA, 2017

After measurement, LCD displays the systolic and diastolic pressure, heart rate, date and time along with Risk Category Indicator bar. The higher the blood pressure, the higher the bar. Compare the bar with the three colors at the right 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 (Hypertensive crisis)
e.g. systolic Pressure 110 & diastolic Pressure 95 ⇨ Red category (Hypertension stage 2)

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

◆ Irregular Heartbeat Detector

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

Note !

- The pulse display is not suitable for checking the frequency of heart pacemakers. If a certain pulse irregularity is detected during measurement often, we recommend you seek medical advice
- As a safeguard, we recommend that if you have arrhythmias such as atrial or ventricular premature beats and atrial fibrillation or any other special conditions you should check with your physician before using your device.
- The IHB function is not designed for use by people with arrhythmias nor for diagnosing or treating an arrhythmic problem. In order to filter the unstable status of user and avoid affecting the detection of heart rate from any movement, shaking or talking in the beginning of measurement, the method of averaging heart beat intervals of subject device is calculated with the three proper heart beat pulses detected in the beginning of measurement and that is different from a strict mathematical averaging of all recorded intervals.
- At least 3 beats with at least 25 % difference from the average heart beat interval will generate the IHB icon on the screen.

Features

HL158B1-BD has a built-in Wrist Position Guide function used as an aid to help user determining if the device is at appropriate height.

◆ Turning Wrist Position Guide ON/OFF

This function default setting is on. User can switch the function ON and OFF. Under standby mode, users can press button, the device will enter to set year, date, month, hour, minute and Bluetooth function first. When these setting are done, press the button again, use button to switch the Wrist Position Guide function ON and OFF.

Wrist Position Guide ON

Wrist Position Guide OFF

◆ Wrist Position Guide

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 height is detected, the Pulse (♥) Symbol will flash with beep sound for 3 times and measurement will begin.

SYMBOL		ACTION
	**UP**	Move your wrist up.
	**DOWN**	Move your wrist down.

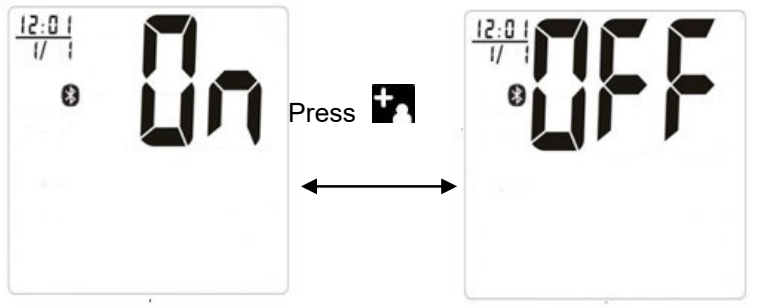
Note!
This Wrist Position Guide is only for reference on blood pressure measurement. Due to difference in individual size, physique, and being dependent on the height of the table and desk, in addition to the position of the hand in comparison to the horizontal plane of reference and the heart, this 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.

Bluetooth Transmission

HL158B1-BD features a Bluetooth transmission function, which enables the device automatically transmit measured results to paired Bluetooth-enabled device after measurement. When connection established, the device would transmit, systolic pressure, diastolic pressure, and pulse with time to the Bluetooth enabled device.
Before attempting to sync the device with your smart device, make sure Bluetooth function is turned ON in both your smart device and the monitor, and make sure your Bluetooth-enabled device have downloaded the App. See the "App for Bluetooth" section for details.

◆ Turn the Bluetooth Function ON/OFF

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



Bluetooth function is ON　　Bluetooth function is OFF

◆ Transmit Readings

1. There are 2 ways to activate Bluetooth function.
   - **a. <u>Automatically Activate:</u>**
     When measurement completed, the device activates Bluetooth function automatically, and Bluetooth symbol will flash on the screen.
   - **b. <u>Manually Activate:</u>**
     Under standby mode, user can press and hold the button for 3 seconds to activate Bluetooth function, and Bluetooth symbol will flash on the screen.

Bluetooth Transmission

2. If HL158B1-BD is connected successfully to your smart device, Bluetooth symbol will appear on the screen.
3. If the monitor cannot be connected to paired Bluetooth-enabled device over 45 seconds, LCD will display Error message "E4" and Bluetooth will be turned off.

◆ App for Bluetooth

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

System requirement of the Bluetooth-enabled device

- □ Bluetooth 4.2 for Android 6.0 or above
- □ Bluetooth 4.2 for iOS 7.0 or above

NOTE:

- HL158B1-BD is subject to and complies with electromagnetic compatibility (EMC) standard of EN 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 device. Moving away from the source of the interference or turning off these devices to resolve the problem.
- Make sure HL158B1-BD and paired Bluetooth 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.

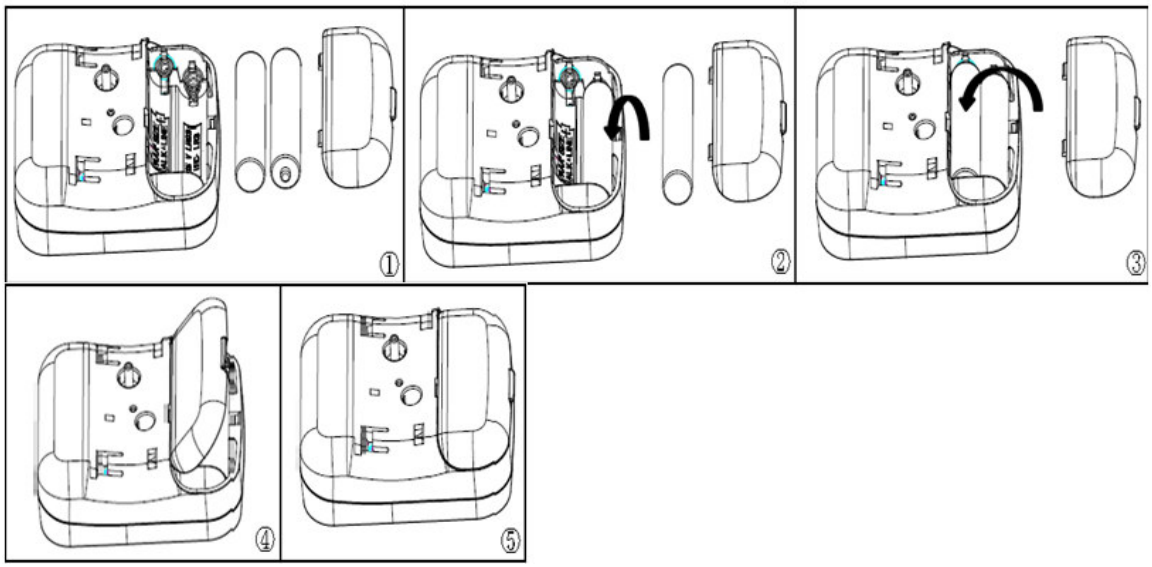
About Bluetooth Data Transmission Function

The Bluetooth data transmission function might not be workable to some Bluetooth-enabled devices because of the compatibility of Android system. Some issues that the Bluetooth implementations on these devices have unresolved errors. It is not because of the Bluetooth module in monitor is not supported.

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.
All batteries used must be the same type.
Slide the battery cover, prepare 2 AAA (1.5V, LR03) alkaline batteries.
Insert one battery on the outside first, and then insert another inside as shown on the figure below. Please make sure the polarities "+" and "–" ends are coinciding with similar markings engraved on the battery housing.

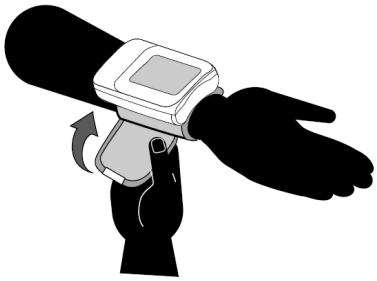


Attention !

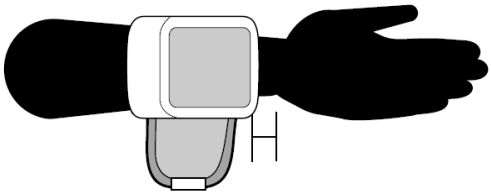
- Batteries are hazardous waste. Do not dispose of them together with the household garbage. Please discard worn-out batteries to the recycling site according to local regulations.
- Keep the battery away from children in case they choke on it.
- To prolong the battery life and prevent damage caused by leakage, remove the batteries from the device if the device is not to be used for a long period.
- Replacing batteries clear all stored memory.
- After replacing the batteries, reset 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 (135 ~ 195 mm)

Note !

- 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 non-stop, unwrap the cuff at once.
- 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 has any wound or injury, especially after surgery on the wrist. Otherwise, it may cause infection at the surgical site. Please use the device after the wound has healed.

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.

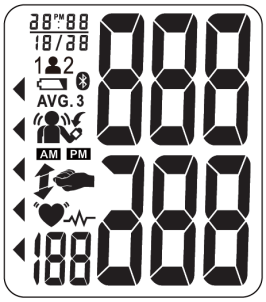
5. Relax your hand and turn your palm upwards.

6. 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.

Measurement Procedure

◆ Switch on the Monitor

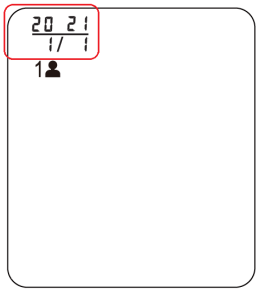
A) Put in 2 AAA 1.5V (LR03) alkaline batteries.
B) All segments appear on the screen for 3 seconds.
C) The monitor will automatically turn to sleeping mode (all LCD segment cleared).

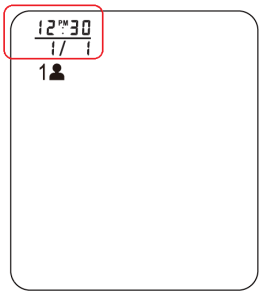


◆ Setting Year, Date and Time

Year, date and time can be set by two methods, either set manually using the + and ◷ buttons or sync automatically using your Bluetooth smart device.

1. Set Manually





A) Under standby mode, press ◷ button to enter setting mode, then YEAR digit flashes. Use + button to select current year.
B) Press ◷ button ("MONTH" flashes). Press + button to adjust MONTH value (1, 2, 3,..., 12).
C) Press ◷ button ("DATE" flashes). Use + button to adjust DATE value (1, 2, 3,..., 31).
D) Adjust HOUR (1, 2, 3,……12PM,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.

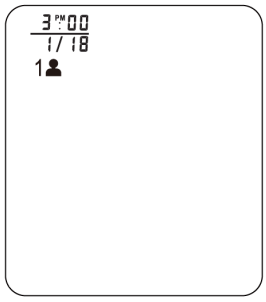
2. Using Your Bluetooth Smart Device

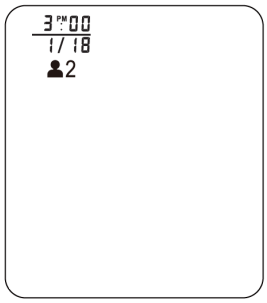
The date and time on your monitor can be automatically updated, when you connect it with your smart device.
Once the date and time have been successfully synced, future readings will automatically have the correct date and time.

Measurement Procedure

◆ Taking a Measurement

A. Press button to select User 1 (1) or User 2 (2).

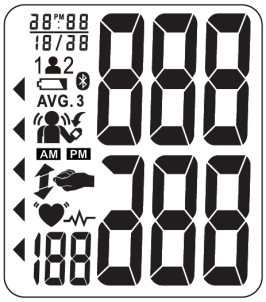




B. Start a Measurement:

B-1. Measurement with Wrist Position Guide Off

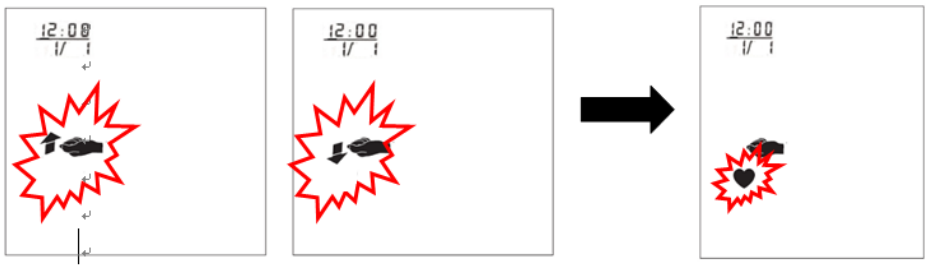
With the cuff wrapped around your wrist, press **START/STOP** button to start measurement. All display units appear on the screen for 3 seconds.



B-2. Measurement with Wrist Position Guide On

B-2-1. With the cuff wrapped around your wrist, press **START/STOP** button to start measurement. All display units appear on the screen for 3 seconds.

B-2-2. 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 height, the Pulse Symbol (♥) will flash with beep sound for 3 times and measurement will begin.

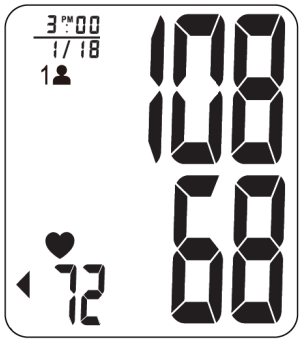


Measurement Procedure

B-2-3. 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.

C. As the cuff inflates, the monitor automatically determines your ideal 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.

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



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

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.

Memory Function

◆ Storing Data

After each measurement, your systolic, diastolic, heart rate and corresponding Risk Category Indicator, Irregular Heartbeat Detector, Excessive body motion detector and wrist position guide (if any) with the time and date will be automatically stored.
The monitor features 2 user memory capabilities. Each user holds the last 120 measurements, and automatically replacing the oldest data with new one.

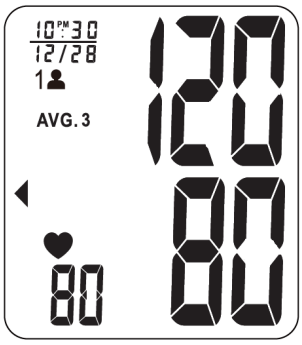
◆ Memory Function

Press M button to see previous measuring results, including average of last 3 measurements and an average of 3 AM or PM measurements. Reviewing your morning (AM) and nighttime (PM) blood pressure can provide important information about your health condition.

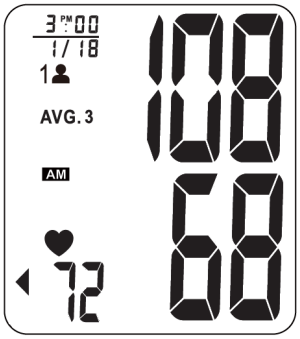
SYMBOL	Status
AVG.3	An average of Last 3 Measurements
AM	An average of Last 3 Morning Measurements (4:00 AM – 12:00 PM)
PM	An average of Last 3 Nighttime Measurements (6:00 PM – 2:00 AM)

Memory Function

◆ Recalling Data



A. Press button to select User 1 or User 2.
B. Press button to enter Memory Mode. If there is no data stored before, nothing (except month, date, and time) will appear on the display. If yes, the first reading will be the average of last 3 measurements.
C. Press button again, LCD displays average of latest 3 AM measurements, and then is average of latest 3 PM measurements. If fewer than three measurements will not be displayed.



D. Every new press of the button will recall a previous reading. The latest reading will be recalled first. Use button to scroll through all stored measuring results from the earliest to the latest one.
E. To stop reading the memories, press **START/STOP** button to switch to Sleeping Mode.

◆ Erasing Data

A. Press button to select User 1, User 2.
B. Press button to enter Memory Mode.
C. Press and hold and buttons at the same time, all the data for the selected user will be erased automatically.
D. To confirm deletion, press button and no data should appear.

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

Storage and Maintenance

◆ General Use

- ❑ Do not twist the cuff in any way.
- ❑ Do not press START/STOP button if the cuff is not wrapped around your wrist.
- ❑ 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 the cuff and patches, because a substitution of a component different from supplied might result in measurement error.
- ❑ If any suggestion or service is requested, please consult your service station.
- ❑ Do not implement the maintenance procedures for equipment during measurement.

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

- ❑ Clean the device and 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.

Storage and Maintenance

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 when **START/STOP** button is pushed.	Worn-out batteries.	Replace them with 2 new AAA (LR03) 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.
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.
	Cuff is worn improperly	Wrap the cuff snugly so that it is positioned correctly. If you have any question about the cuff wearing and/or measurement result, please consult your healthcare professional.
E4 Measuring Error Symbol	If the device cannot be connected to paired Bluetooth-enabled device over 45 seconds, LCD will display Error message "E4" and Bluetooth will be turned off.	Please press M button for 3 seconds to start Bluetooth function.
 Excessive Body Motion Detector **Notice:** The measured blood pressure reading may not be accurate if the icon is displayed.	Body movement during measurement, especially, the movement on the wrist the blood pressure monitor is worn on. e.g. Talking, moving or shaking of the arm with the cuff on while measurement.	Measure again. Keep steady during measurement.
	Cuff is worn improperly, or the shape of the wrist is unusual, excessive gap might be exist between the cuff and the wrist.	Wrap the cuff properly and keep steady. Measure again. If you have any question about the cuff wearing and/or measurement result, please consult your healthcare professional.

Troubleshooting

SYMBOLS/SYMPTOMS	CONDITIONS/CAUSES	INDICATION/CORRECTION
 Cuff Fitness Detection Symbol	The cuff was wrapped incorrectly (for example too loosely or too tightly).	Please reference “applying the Cuff” section to wrap the cuff correctly.
BPM cannot communicate with Bluetooth-enabled device	Paring has not been completed.	Please re-pairing the BPM and Bluetooth -enabled device with each other.
	Bluetooth function is not turn on.	See the “the Bluetooth Transmission” section to turn on Bluetooth function.
	The distance between BPM and Bluetooth-enabled device is out of transmitting range.	Please make sure the acceptable distance (≦10 meters) with each other.
	Use an incompatible Bluetooth-enabled device.	Please refer to Page15 “Bluetooth compatibility” & Page 35 "RF Specification”
	Use non-Bluetooth-enabled device.	
	Unexpected loss of electrical/mechanical integrity.	Re-insert the batteries and try again.
Note: If "EP" appears on the display, just return the device to your local distributor or importer.		

Warranty & Recalibration

- **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	HL158B1-BD
Measurement Method	Oscillometric
Rated Range of Cuff Pressure	0~300 mmHg
Rated Range of Determination	40~280 mmHg
Measurement Range of Heart Rate	Pulse : 40 ~ 199 Beats / Minute
Accuracy	Pressure: ± 3 mmHg Pulse: ± 5 % Max.
Inflation	Automatic Inflation (Air Pump)
Deflation	Automatic (Passive Exhaust Valve)
Display	Liquid Crystal Display
Memory	240 Memory Total for 2 Users
Unit Dimensions	73.79mmx 60.15mmx 22.94mm (L x W x H) 2.91 x 2.37 x 0.90 inch (L x W x H)
Unit Weight	69 g ± 3 g (Without Cuff & Batteries)
Cuff Size	5.3 ~ 7.7 inch (approx.135 ~ 195 mm)
Storage/Transportation Environment	Temperature: -25 °C ~ 70 °C (-13 °F ~ 158 °F) Humidity: ≤ 93 % R.H.
Operation Environment	Temperature: 5 °C ~ 40 °C (41 °F ~ 104 °F) Humidity: 15 % ~ 93 % R.H. Atmospheric pressure: 700 hPa ~ 1060 hPa
Power Supply	DC 3V AAA "LR03" (1.5V) Alkaline Battery x 2
Battery Life	Approx. 250 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	Instruction Manual, 2 AAA (LR03) Alkaline Batteries, Storage Pouch
RF Type	Bluetooth 4.2 BLE
System requirement of the Bluetooth-enabled device	Bluetooth 4.2 for Android 6.0 or above Bluetooth 4.2 for iOS 7.0 or above

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

Note

Explanation of Symbols:

Symbol	Explanation	Health & Life Information
	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.
SN	Serial number	SN 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	-

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 District 23553, 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:

1. Any changes or modifications not expressly approved by the grantee of this device could void the user's authority to operate the equipment.
2. This equipment complies with FCC radiation exposure limits set forth for an uncontrolled environment.

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".

HL158B1-BD 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 Limits of the change in error of the blood pressure determination
  The laboratory limits of the change in error of the BLOOD PRESSURE DETERMINATION of the AUTOMATED SPHYGMOMANOMETER shall be less than 3 mmHg (0.4 kPa).

Appendix

- **Guidance and manufacturer's declaration – electromagnetic emissions**
  The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

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

- **Guidance and manufacturer's declaration – electromagnetic immunity**
  The device is intended for use in the electromagnetic environments listed below, and should only be used in such environments:

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

Appendix

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

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

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

Note 1) At 80 MHz and 800 MHz, the higher frequency range applies.
Note 2) These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

a) Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the device is used exceeds the applicable RF compliance level above, the device should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the device.

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

Appendix

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

Test frequency (MHz)	Modulation	IMMUNITY TEST LEVEL (V/m)
385	Pulse modulation 18 Hz	27
450	FM ± 5 kHz deviation 1kHz sine	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 :	
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Systolic / Diastolic :				Pulse :	
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Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	
Date :		Time :		☐Before ☐After	Meal
Systolic / Diastolic :				Pulse :	